Gynecological consequences of female genital mutilation/cutting (FGM/C)

Report from Kunnskapssenteret (Norwegian Knowledge Centre for the Health Services)
No 11–2014

Systematic review



The traditional practice of female genital mutilation or cutting (FGM/C) covers a range of procedures (clitoridectomy, excision, infibulation, and other) performed on the genitals of females of different ages. This systematic review aimed to summarize empirical quantitative research describing the gynecological consequences of FGM/C on girls and women. We included 136 primary studies, 42 of which compared groups of women who had been subjected to FGM/C with women who had no or different types of genital alterations. The main finding is that FGM/C has harmful consequences for a woman's gynecological health. We found that: • Women with FGM/C seem to be more likely than women without FGM/C to experience urinary tract infection, bacterial vaginosis, and pain during intercourse. • There seems to be a trend for women with FGM/C to be more likely than women without FGM/C to experience: burning/painful urination, problems with menstruation, vaginal discharge and vaginal itching. • There seems to be no clear trend for either a greater or lower risk of HIV and sexually transmitted infections among women who have undergone FGM/C. • (continued)

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There were insufficient data for us to conclude whether the risk of other gynecological complications (tissue damage, vaginal adhesions and obstructions, cysts, infertility) is different among women with FGM/C compared to women without FGM/C, and whether various FGM/C types differentially affect the risk of other gynecological complications (except regarding urinary tract infection). This systematic review found that sufficient evidence exist to conclude that women who have undergone FGM/C suffer a greater risk of gynecological complications than women who have not undergone the procedure. There were no indications of gynecological benefits of FGM/C. Rather, there is a real chance of under-reporting of many of the health issues covered in this systematic review.

Title Gynecological consequences of female genital mutilation/cut-

ting (FGM/C)

Norwegian Gynekologiske konsekvenser av kvinnelig kjønnslemlestelse

title

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We would like to thank Tove Ringerike, Ingeborg B. Lidal, Owolabi Bjälkander and Marleen Temmerman for their expertise in this project. Norwegian Knowledge Centre for the Health Services assumes final responsibility for the content of this report.

Norwegian Knowledge Centre for the Health Services Oslo, May 2014

Key messages

The traditional practice of female genital mutilation or cutting (FGM/C) covers a range of procedures (clitoridectomy, excision, infibulation, and other) performed on the genitals of females of different ages. This systematic review aimed to summarize empirical quantitative research describing the gynecological consequences of FGM/C on girls and women.

We included 136 primary studies, 42 of which compared groups of women who had been subjected to FGM/C with women who had no or different types of genital alterations. The main finding is that FGM/C has harmful consequences for a woman's gynecological health. We found that:

- Women with FGM/C seem to be more likely than women without FGM/C to experience urinary tract infection, bacterial vaginosis, and pain during intercourse.
- There seems to be a trend for women with FGM/C to be more likely than women without FGM/C to experience: burning/painful urination, problems with menstruation, vaginal discharge and vaginal itching.
- There seems to be no clear trend for either a greater or lower risk of HIV and sexually transmitted infections among women who have undergone FGM/C.
- There were insufficient data for us to conclude whether the risk of other gynecological complications (tissue damage, vaginal adhesions and obstructions, cysts, infertility) is different among women with FGM/C compared to women without FGM/C, and whether various FGM/C types differentially affect the risk of other gynecological complications (except regarding urinary tract infection).

This systematic review found that sufficient evidence exist to conclude that women who have undergone FGM/C suffer a greater risk of gynecological complications than women who have not undergone the procedure. There were no indications of gynecological benefits of FGM/C. Rather, there is a real chance of under-reporting of many of the health issues covered in this systematic review.

Title:

Gynecological consequences of female genital mutilation/cutting (FGM/C)

Type of publication:

Systematic review

A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (metanalysis) may or may not be used to analyse and summarise the results of the included studies.

Doesn't answer everything:

- -Excluded studies that fall outside of the inclusion criteria
- No health economic evaluation
- -No recommendations

Publisher:

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Executive summary

Background

The traditional practice of female genital mutilation or cutting (FGM/C) covers a range of procedures performed on the genitals of females of different ages. It is defined by the World Health Organization (WHO) as "all procedures involving partial or total removal of the female external genitalia or other injury to the female genital organs for non-medical reasons." According to the WHO typology, there are three main types of FGM/C: type I (clitoridectomy), type II (excision), type III (infibulation or pharaonic circumcision), and type IV which is used to describe all other harmful procedures to the female genitalia for non-medical purposes. According to a recent UNICEF report, there are over 125 million girls and women alive today who have undergone FGM/C in the 29 countries where the practice is concentrated. These are a swathe of 27 African countries stretching from the Atlantic Coast to the Horn of Africa, and Iraq and Yemen in the Middle East. In most countries for which reliable data are available, clitoridectomy and excision are most commonly practiced. Since FGM/C involves the cutting, or other alteration, of sensitive genital tissue, it is reasonable to assume that it is an act that is prejudicial to girls' and women's health in the short-term and long-term. Thus, the question addressed in the present systematic review is whether women who have been subjected to FGM/C are more likely than women who have not been subjected to FGM/C to experience long-term gynecological health complications.

Objective

This systematic review summarizes empirical quantitative research describing the gynecological consequences of FGM/C on girls and women (excluding obstetric consequences and sexual functioning, which are covered in separate reports). The overall aim of this systematic review is to support well-informed decisions in health promotion and health care that improve quality of services related to the consequences of FGM/C. The key research question was: What are the gynecological consequences of FGM/C?

Method

This systematic review was conducted in accordance with the guidelines in the NOKC Handbook for Summarizing Evidence and the Cochrane Handbook for Systematic Reviews of Interventions. The main literature search strategy was systematic searches for literature in 15 international electronic literature databases. Studies eligible for inclusion were systematic reviews, cohort studies, case-control studies, cross-sectional studies, case series, and case reports. The population of interest was girls and women who have been subjected to any type of FGM/C. In this report, we summarized the gynecological consequences of FGM/C, including outcomes such as infections, infertility, and problems with urination. We also included psychological health outcomes of FGM/C on girls (15 years or younger). Two reviewers screened literature, considered the methodological quality of the studies, and extracted data. Because results from studies with a comparison group are most valid for evaluating risk of experiencing complications, we prioritized presenting results from comparative studies. We summarized the study level results in texts and tables and calculated effect estimates. When an outcome was sufficiently similar across studies, we pooled those that could be grouped together using the statistical technique of meta-analysis. We applied the instrument Grading of Recommendations Assessment, Development and Evaluation (GRADE) to assess the extent to which we have confidence in the effect estimates.

Results

We included 136 primary (observational) studies reporting on gynecological outcomes among girls and women who had undergone FGM/C. There were 42 comparative studies (i.e., they compared groups of women with FGM/C to women with noor a different type of genital alteration), including three case-control studies and one retrospective cohort study. We arrived upon a final decision of high methodological study quality for 19% of the comparative studies while 45% had moderate study quality. In our assessment, using the GRADE instrument, the quality of the evidence was very low with regards to documenting a conclusive relationship between FGM/C and gynecological consequences.

In total, the 136 studies included 130,558 women. The most frequently measured outcomes were cysts, various vaginal obstructions, and tissue damage. However, many of the sequels were relatively rare events. Therefore, there were often few events that could be entered into analyses, which in turn meant that the analyses were often unable to establish whether there are statistically significant differences between groups being compared. Consequently, there was in many cases insufficient information available from the included studies to inform the question of difference in risk. There was only one study concerning psychological health outcomes among girls. The main finding is that FGM/C has harmful consequences for a woman's gynecological health. We found that:

- Women with FGM/C seem to be more likely than women without FGM/C to experience urinary tract infection, bacterial vaginosis, and pain during intercourse.
- There seems to be a trend for women with FGM/C to be more likely than women without FGM/C to experience: burning/painful urination, problems with menstruation, vaginal discharge and vaginal itching.
- There seems to be no clear trend for either a greater or lower risk of HIV and sexually transmitted infections among women who have undergone FGM/C.
- There were insufficient data for us to conclude whether the risk of other gynecological complications (tissue damage, vaginal adhesions and obstructions, cysts, infertility) is different among women with FGM/C compared to women without FGM/C, and whether various FGM/C types differentially affect the risk of other gynecological complications (except regarding urinary tract infection).

Discussion

The findings show that women who have been subjected to FGM/C seem to be at greater risk for urinary tract infections and bacterial vaginosis, and possibly also at greater risk for pain during intercourse, burning/painful urination, problems with menstruation, and vaginal discharge and itching when compared to women who have not been subjected to FGM/C. Whatever the mechanisms for the higher prevalences of these gynecological problems and symptoms among women who have undergone FGM/C are - even years and decades after the procedure - these results thus strengthen arguments that FGM/C is injurious for women's health. There is a real chance of under-reporting of many of the health issues covered in this systematic review, due to women's reluctance to report complications in contexts where FGM/C is discouraged, or even illegal, and failure to attribute the complication to FGM/C. Some studies had few participants and/or a low number of events, which decreased studies' power to detect potential differences and produced wide confidence intervals, which in turn lowered the quality of the evidence. However, from a women's health perspective, irrespective of the range of complications or exact size of the greater risk from FGM/C, even the lowest rates of complications are undesirable. We believe sufficient evidence exist to conclude that women who have undergone FGM/C suffer a greater risk of physical complications, thus, future research should attend to appropriate care and treatment for girls and women who suffer complications.

Conclusion

This systematic review found that sufficient evidence exist to conclude that women who have undergone FGM/C suffer a greater risk of gynecological complications than women who have not undergone the procedure. There were no indications of gynecological benefits of FGM/C.

Hovedfunn (norsk)

Kvinnelig kjønnslemlestelse er blitt utført i ulike former i årtusener og innebærer at hele eller deler av de ytre kvinnelige kjønnsorganene fjernes eller skades uten at det er en medisinsk begrunnelse for det. Denne systematiske oversikten hadde som mål å oppsummere empirisk kvantitativ forskning om gynekologiske konsekvenser av kjønnslemlestelse. Vi inkluderte 136 primærstudier, hvorav det var 42 studier som sammenlignet kvinner som var kjønnslemlestet med kvinner som ikke var kjønnslemlestet, eller som sammenlignet ulike typer kjønnslemlestelse. Hovedfunnet er at kjønnslemlestelse er skadelig for kvinners gynekologiske helse. Vi fant:

- Det ser ut til at kvinner som er kjønnslemlestet har større risiko for å oppleve urinveisinfeksjon, bakteriell vaginose og smerter under samleie sammenlignet med kvinner som ikke er kjønnslemlestet.
- Det ser ut til at kvinner som er kjønnslemlestet har større risiko for sviende/smertefull vannlating, problemer med menstruasjon, vaginal utflod og kløe enn kvinner som ikke er kjønnslemlestet, men dataene er ikke tilstrekkelige til å trekke sikre konklusjoner.
- Det er usikkert om det er forskjell i risiko for hiv og seksuelt overførbare infeksjoner mellom kvinner som er kjønnslemlestet og kvinner som ikke er kjønnslemlestet, men det ser ikke ut til å finnes en klar trend for verken større eller mindre risiko blant kvinner som er kjønnslemlestet.
- Det er ikke grunnlag for å konkludere om risikoen for andre gynekologiske komplikasjoner (vevskader, vaginale obstruksjoner, cyster, infertilitet) er annerledes for kvinner som er kjønnslemlestet enn for de som ikke er det, og om risikoen for andre gynekologiske komplikasjoner varierer mellom ulike typer kjønnslemlestelse (med unntak av urinveisinfeksjon).

Denne systematiske oversikten fant at kvinner som er kjønnslemlestet i større grad opplever gynekologiske problemer og symptomer enn kvinner som ikke er blitt utsatt for kjønnslemlestet. Vi fant ingen indikasjoner på at kjønnslemlestelse har helsemessige gevinster. I stedet fins det en reell mulighet for underrapportering av mange av helseproblemene som vi inkluderte i denne systematiske oversikten.

Tittel:

Gynekologiske konsekvenser av kvinnelig kjønnslemlestelse

Publikasjonstype:

Systematisk oversikt

En systematisk oversikt er resultatet av å

- innhente
- kritisk vurdere og
- sammenfatte relevante forskningsresultater ved hjelp av forhåndsdefinerte og eksplisitte metoder.

Svarer ikke på alt:

- Ingen studier utenfor de eksplisitte inklusjonskriteriene
- Ingen helseøkonomisk evaluering
- Ingen anbefalinger

Hvem står bak denne rapporten?

Kunnskapssenteret har skrevet rapporten på oppdrag fra Verdens Helseorganisasjon og NORAD.

Når ble litteratursøket utført?

Søk etter studier ble avsluttet Januar, 2012.

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Sammendrag (norsk)

Gynekologiske konsekvenser av kvinnelig kjønnslemlestelse

Bakgrunn

Kvinnelig kjønnslemlestelse består av ulike inngrep utført på kjønnsorganene til jenter og kvinner i ulike aldre. Praksisen er definert av Verdens helseorganisasjon (WHO) som "alle inngrep som innebærer delvis- eller fullstendig fjerning av de eksterne kvinnelige kjønnsorganer eller andre skader av de kvinnelige kjønnsorganer for ikke-medisinske årsaker." WHO klassifiserer tre hovedtyper kjønnslemlestelse: type I (klitoridektomi), type II (eksisjon), type III (infibulasjon) og en fjerde uklassifisert type. Ifølge en ny rapport fra UNICEF er det mer enn 125 millioner jenter og kvinner som i dag lever med kjønnslemlestelse i de 29 landene hvor praksisen er konsentrert. Dette er et belte av 27 afrikanske land som strekker seg fra Atlanterhavskysten til Afrikas horn, pluss Irak og Yemen i Midtøsten. I de fleste land hvor pålitelige data er tilgjengelig er klitoridektomi og eksisjon de typene av kjønnslemlestelse som forekommer oftest. Siden kjønnslemlestelse innebærer kutting, eller annen modifisering, av sensitivt genitalvev er det rimelig å anta at det er et inngrep som har helseskadelige følger. Spørsmålet vi tok for oss i denne systematiske oversikten var derfor hvorvidt kvinner som har vært utsatt for kjønnslemlestelse har større risiko for å oppleve gynekologiske komplikasjoner enn kvinner som ikke har vært utsatt for kjønnslemlestelse.

Problemstilling

Denne systematiske oversikten oppsummerer kvantitativ forskning som beskriver de gynekologiske konsekvensene av kvinnelig kjønnslemlestelse (med unntak av obstetriske konsekvenser og seksuell funksjonalitet, som er beskrevet i separate rapporter). Det overordnede målet er å bidra til gode beslutninger i forebyggende helsearbeid og omsorg som kan forbedre kvaliteten på tjenester knyttet til konsekvensene av kjønnslemlestelse. Hovedspørsmålet var: Hva er de gynekologiske konsekvenser av kvinnelig kjønnslemlestelse?

Metode

Denne systematiske oversikten ble utført i henhold til Kunnskapssenteret metodehåndbok og Cochrane Handbook for Systematic Reviews of Interventions. Den viktigste strategien for identifisering av litteratur var litteratursøk i 15 internasjonale databaser. Vi kunne inkludere følgende studiedesign: systematiske oversikter, kohortestudier, kasuskontrollstudier, tverrsnittstudier, kasus-serier og kasuistikker. Populasjonen av interesse var jenter/kvinner som var blitt utsatt for en type kjønnslemlestelse. I denne rapporten oppsummerte vi gynekologiske konsekvenser av kjønnslemlestelse, slik som infeksjoner, sterilitet og problemer med vannlating. Vi inkluderte også psykisk helse på jenter (15 år eller yngre). To forskere valgte ut litteratur, vurderte den metodiske kvaliteten på studiene og trakk ut data fra studiene. Resultater fra studier som sammenligner grupper gir de mest gyldige svarene på risiko for å oppleve komplikasjoner. Derfor prioriterte vi å presentere resultater fra komparative studier. Vi oppsummerte resultater på studienivå i tekst og tabeller og beregnet effektestimat. For studier som var tilstrekkelig like summerte vi resultatene i meta-analyser for å beregne risiko. Vi benyttet instrumentet Grading of Recommendations, Assessment, Development and Evaluation (GRADE) for å vurdere i hvilken grad vi har tillit til effektestimatene.

Resultat

Vi inkluderte 136 primære observasjonsstudier som presenterte resultater angående gynekologiske- og andre langtidskonsekvenser av kjønnslemlestelse. Vi inkluderte 42 komparative studier (dvs. de sammenlignet kvinner utsatt for kjønnslemlestelse med kvinner uten kjønnslemlestelse, eller de sammenlignet kvinner som hadde ulike typer kjønnslemlestelse), inkludert tre kasuskontrollstudier og én retrospektiv kohortestudie. Blant de komparative studiene ble 19 prosent vurdert til å ha høy metodologiske studiekvalitet og 45 prosent hadde moderat studiekvalitet. Vi vurderte kvaliteten på den samlede dokumentasjonen for endepunktene ved hjelp av GRADE til å være av svært lav kvalitet. Det betyr at dokumentasjonen ikke er solid nok til at vi kan ha tiltro til effektestimatene om en sikker sammenheng mellom kjønnslemlestelse og gynekologiske konsekvenser. Totalt sett inkluderte de 136 studiene 130 558 jenter/kvinner. De mest hyppig undersøkte utfallsmålene var cyster, vaginal obstruksjon og andre vevskader. Mange av helseproblemene var rapportert relativt sjeldent. I slike tilfeller inngikk kun et lite antall hendelser i analysene, noe som igjen gjorde at disse analysene ikke kunne fastslå om det var statistisk signifikante forskjeller mellom gruppene som ble sammenlignet. Dette førte til at det i mange tilfeller ikke fantes tilstrekkelig informasjon fra de inkluderte studiene til å besvare spørsmålet om forskjeller i risiko. Vi inkluderte én studie som omhandlet psykisk helse blant jenter. Hovedfunnet er at kjønnslemlestelse er skadelig for kvinners gynekologiske helse. Vi fant:

- Det ser ut til at kvinner som er kjønnslemlestet har større risiko for å oppleve urinveisinfeksjon, bakteriell vaginose og smerter under samleie sammenlignet med kvinner som ikke er kjønnslemlestet.
- Det ser ut til at kvinner som er kjønnslemlestet har større risiko for sviende/smertefull vannlating, problemer med menstruasjon, vaginal utflod og kløe enn kvinner som ikke er kjønnslemlestet, men dataene er ikke tilstrekkelige til å trekke sikre konklusjoner.
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- Det er ikke grunnlag for å konkludere om risikoen for andre gynekologiske komplikasjoner (vevskader, vaginale obstruksjoner, cyster, infertilitet) er annerledes for kvinner som er kjønnslemlestet enn for de som ikke er det, og om risikoen for andre gynekologiske komplikasjoner varierer mellom ulike typer kjønnslemlestelse (med unntak av urinveisinfeksjon).

Diskusjon

Funnene viser at sammenlignet med kvinner som ikke har blitt kjønnslemlestet, ser det ut til kvinner med kjønnslemlestelse har større risiko for urinveisinfeksjon og bakteriell vaginose, og muligens også større risiko for smerter under samleie, sviende/smertefull vannlating, problemer med menstruasjon, samt vaginal utflod og kløe. Uansett hva mekanismene måtte være for den tilsynelatende høyere forekomsten av disse problemene og symptomene blant kvinner som er kjønnslemlestet - ofte flere år og tiår etter inngrepet – så styrker disse resultatene argumentet om at kjønnslemlestelse er skadelig for kvinners helse. Det fins en reell mulighet for underrapportering av mange av helseproblemene vi inkluderte i denne systematiske oversikten, på grunn av motvilje mot å rapportere komplikasjoner i samfunn hvor det er sterk motstand mot kjønnslemlestelse, eller til og med ulovlig, og manglende evne til å knytte komplikasjoner til kjønnslemlestelsen. Noen studier hadde få deltakere og eller et lavt antall hendelser. Dette reduserte studienes mulighet til å påvise potensielle forskjeller og ga brede konfidensintervaller, hvilket reduserte vår tillit til estimatene. Vi mener det likevel foreligger tilstrekkelig data til å konkludere med at kvinner som har blitt kjønnslemlestet har en større risiko for fysiske helsekomplikasjoner. Fremtidig forskning bør undersøke hensiktsmessig omsorg og behandling til jenter og kvinner som lider av komplikasjoner.

Konklusjon

Denne systematiske oversikten fant at kvinner som er kjønnslemlestet i større grad opplever skadelige gynekologiske konsekvenser enn kvinner som ikke er kjønnslemlestet. Vi fant ingen indikasjoner på at kjønnslemlestelse har helsemessige gevinster.

Nasjonalt kunnskapssenter for helsetjenesten fremskaffer og formidler kunnskap om effekt av metoder, virkemidler og tiltak og om kvalitet innen alle deler av helsetjenesten. Målet er å bidra til gode beslutninger slik at brukerne får best mulig helsetjenester. Kunnskapssenteret er formelt et forvaltningsorgan under Helsedirektoratet, men har ikke myndighetsfunksjoner og kan ikke instrueres i faglige spørsmål.

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Preface

The World Health Organization (WHO) and the Norwegian Agency for Development Cooperation (NORAD) commissioned a summary of available research on the physical health consequences following female genital mutilation/cutting (FGM/C) from the Norwegian Knowledge Centre for the Health Services (NOKC). This evidence review will supplement the background documentation for supporting organizations like the WHO and NORAD's work concerning FGM/C among girls/women subjected to and at risk for the practice in countries where FGM/C may occur.

Given the enormous scope of the documentation identified we prepared three reports. The present report concerns the gynecological consequences of FGM/C. We also include psychological health outcomes on girls. Two reports have been completed. One examines the obstetric consequences following FGM/C (1). The second report covers the immediate (acute) consequences following FGM/C (2).

The project group consisted of:

- Project coordinator: researcher, Rigmor C Berg, NOKC
- Researcher: Vigdis Underland, NOKC

We are indebted to search specialist Sari Ormstad for conducting the literature search and Jan Odgaard-Jensen for providing statistical support. Both are with the NOKC. We are grateful for peer review by two internal and two external reviewers:

- Tove Ringerike, researcher, NOKC, Norway
- Ingeborg B. Lidal, researcher, NOKC, Norway
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The aim of this report is to support well-informed decisions in health care that lead to improved quality of services. The evidence should be considered together with other relevant issues, such as clinical experience and patient preference.

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Objective

This systematic review summarizes empirical quantitative research describing the gynecological consequences of FGM/C on girls and women (excluding obstetric and immediate consequences, which have been reviewed in separate reports). We also summarize quantitative research describing the psychological health consequences of FGM/C on girls 14 years or younger. The overall aim of the systematic review is to support well-informed decisions in health promotion and health care that improve quality of services related to the consequences of FGM/C.

The main research question for this systematic review was:

• What are the gynecological consequences of FGM/C?

Background

FGM/C

Description and history

The traditional practice of female genital mutilation or cutting, also known as female circumcision, covers a range of procedures performed on the genitals of females of different ages. It is defined by the World Health Organization (WHO) as "all procedures involving partial or total removal of the female external genitalia or other injury to the female genital organs for non-medical reasons" ((3)p1). The term female genital mutilation/cutting (FGM/C) is currently the official terminology preferred by UNICEF and UNFPA, and the one we adopt in this report (a glossary of terms is listed in appendix 1). The hybrid term FGM/C is meant to signal that the practice is a violation of the rights of girls and women while at the same time to acknowledge the importance of using value-neutral terminology when working with practicing communities (4).

In 1995, WHO provided the first typology of FGM/C that offered a more precise anatomical description of the varied practices falling under the FGM/C term (3) (the external female genital anatomy is depicted in figure 1).

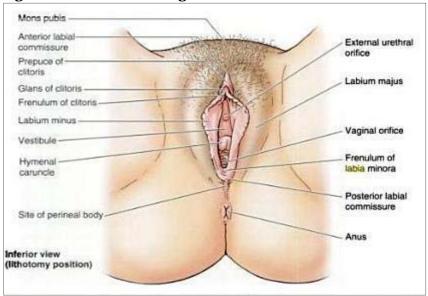


Figure 1: Female external genitalia

Source: Google images. Not subject to copyright.

According to WHO's updated 2007 typology, there are three main types of FGM/C: type I (clitoridectomy) is the removal of the clitoral hood, with or without removal of all or part of the clitoris. Type II (excision) involves the removal of the clitoris, together with part of the labia minora. Type III (infibulation or pharaonic circumcision) is the removal of part or all of the external genitalia (clitoris, labia minora and majora), and stitching or narrowing of the vaginal opening, leaving a very small opening to allow the flow of urine and menstrual blood. There is also a fourth category that is described as introcision. This type IV may involve nicking, pricking, piercing or incision of the clitoris and or labia; stretching the clitoris and or labia, cauterization by burning of the clitoris and surrounding tissues, scraping of the vaginal orifice or cutting of the vagina and introduction of corrosive substances into the vagina to tighten or narrow it (3).

Throughout history, human beings have modified, and sometimes harmed, their bodies in the name of culture, tradition, religion, beauty, health or social status. In fact, one of the most persistent forms of body modification involves alteration of the genitalia (5). There is no definitive evidence about the origin of FGM/C or when it first appeared, but the earliest documented and known cases are from ancient Egyptian mummies, thus it is believed that various forms of FGM/C have been performed for some 4000 years (6;7). Today, alteration of the female genitalia is still being practiced, though with varying magnitude, primarily on girls and women in the African continent, despite global campaigns to eliminate the practice.

Prevalence and reasons

According to a recent UNICEF report (8), there are over 125 million girls and women alive today who have undergone FGM/C in the 29 countries where the practice is concentrated. These are a swath of 27 African countries stretching from the Atlantic Coast to the Horn of Africa, and Iraq and Yemen in the Middle East. Prevalence is particularly high in Somalia (98%), Guinea (96%), Djibouti (93%), Egypt (91%), Eritrea (89%), Mali (89%), Sierra Leone (88%), and Sudan (88%). The practice is largely ethnically dependent, thus, when practicing ethnic groups migrate beyond their geographical borders, they carry the FGM/C custom with them. It follows that prevalence of FGM/C varies greatly both between and within the 29 countries where the practice is concentrated (8). It is also found in some countries in Asia and Western countries that host immigrants (9). Recent analyses have revealed an overall decline in the prevalence of FGM/C over the past two decades. However, while a downward trend is noticeable in countries such as Benin, the Central African Republic, Kenya, and Iraq, prevalence is virtually unchanged in a few other countries, such as Gambia, Mali, and Somalia (8).

Practicing communities differ in the types of FGM/C they practice. Infibulation is largely confined to Eritrea, Djibouti, Niger, Senegal, and Somalia, where over 20% of girls and women with FGM/C have type III. 'Nicking', which is a cut in the external

female genitalia with no flesh removed, is commonly practiced in some countries, such as the Central African Republic, Eritrea, Mali, and Nigeria. However, in most countries with reliable data, clitoridectomy and excision (types I and II) are most commonly practiced (8).

With 3 million girls at risk for the practice every year (8), FGM/C is a widespread and highly valued ritual practiced for various reasons. UNICEF (8) has found that social acceptance is the most frequently cited reason for supporting the continuation of the practice. In most practicing communities, FGM/C is regarded as a customary rule of behavior that continues due to social expectations: the practice is normative, unquestioned, and what everyone in the community does to belong. At the same time, data suggest the practice is intertwined with ethnic identity (4;8) and rooted in religio-social beliefs within a frame of psycho-sexual and personal reasons that vary across practicing groups (10;11).

Efforts to eliminate FGM/C

Efforts to end FGM/C dates back to at least the 1920s, when British Protestant missionaries started campaigning against the practice in Kenya, and the Egyptian Society of Physicians, with support from the Ministry of Health and religious scholars, issued a public statement delineating the negative health effects of the practice (8). Historically, national and global efforts to end FGM/C focused on the adverse health consequences of the practice. For example, in 1959 the Egyptian Ministry of Health stipulated that FGM/C should not be performed in any government-run health units or hospitals (8). Similarly, a number of medical associations have opposed the performance of FGM/C by medical professionals ('medicalization'), including the International Federation of Gynecology and Obstetrics (12). Partially as a result of concern that the health focus inadvertently may have promoted medicalization of FGM/C, in the early 1990s, the practice was reconceptualized as a human rights issue (13). This shift in focus from health to human rights drew strength from the rise in international support and landmark meetings such as the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW) in 1979, the International Conference on Population and Development (ICPD) in 1994 and the fourth World Conference on Women (1995) (8). Notably, African activists through the Inter-African Committee on Traditional Practices Affecting the Health of Women and Children (14) as well as the African Union through the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (commonly referred to as the Maputo Protocol) (15) have consistently called for the prohibition of all forms of FGM/C, highlighting the violation of the right to health, physical integrity, and life as reasons for doing so.

Gynecological health and FGM/C

Since FGM/C involves the cutting, or other alteration, of sensitive genital tissue, typically with crude instruments and without anaesthetics (8), it is reasonable to assume that it is a traumatic act that is prejudicial to girls' and women's health in the short-term and the long-term. In fact, in previous systematic reviews we established that FGM/C is associated with attenuation of a woman's sexual functioning (16), and possibly linked with psychological disturbances (17). We also concluded that women who have undergone FGM/C are at greater risk of experiencing obstetric complications compared to women without FGM/C (18), and that girls and women who undergo FGM/C suffer a range of, and typically several, complications during the FGM/C procedure and the short-term postoperative period (2). Missing in our efforts to determine the scope of adverse health consequences of FGM/C over the short- and long-term is a systematic review on the gynecological and related health sequela of FGM/C.

Gynaecology or gynecology is the medical practice dealing with the health of the female reproductive system (uterus, vagina, and ovaries). A broad variety of empirical examinations exist on the gynecological consequences of FGM/C, including two literature reviews. The first included eight studies that assessed FGM/C complications, such as scars, cysts, infections, and infertility (19). Regrettably, only frequencies were presented. In the updated 2005 review, however, additional studies were included and estimates of increased risks provided from six comparative studies. In this review, gynecological risk such as HIV infection, reproductive tract infections, urinary problems, and infertility from the included studies were described, although not analyzed. In summarizing the findings, the author stated "statistically higher risks are documented for some but not all types of infections; the evidence regarding urinary symptoms is inconclusive; the evidence on obstetric and gynecological complications is mixed" ((20) p443).

To fill the gap in systematic review evidence of the range of gynecological and related health consequences of FGM/C, this systematic review aims to provide a clearer picture of whether women with FGM/C are more likely than women without FGM/C to experience gynecological health complications.

Method

The systematic review of the gynecological health consequences of FGM/C was conducted in accordance with the guidelines in the NOKC Handbook for Summarizing Evidence (21) and the Cochrane Handbook for Systematic Reviews of Interventions (22). As the last in a series of three reports mapping the physical health consequences of FGM/C, we followed the same, standard approach for conducting systematic reviews (there was one literature search for all three reports).

Literature search

We systematically searched for literature in the following 15 international electronic literature databases:

- African Index Medicus
- British Nursing Index and Archive
- CINAHL
- The Cochrane Library:
 - Cochrane Central Register of Controlled Trials
 - o Cochrane Database of Systematic Reviews
 - o Database of Abstracts of Reviews of Effects
 - o Health Technology Assessment Database
- EMBASE
- MEDLINE
- PILOTS
- POPLINE
- PsycINFO
- Social Services Abstracts
- Sociological Abstracts
- WHOLIS

The database search strategy was designed by Sari Ormstad, information retrieval specialist at the NOKC, in cooperation with the project group and commissioners. As shown in appendix 2, the search strategy incorporated both subject headings (e.g. MeSH terms in MEDLINE) and text words, in title and abstract, relating to FGM/C. Because we prioritized sensitivity over specificity we neither applied method filters nor restricted the searches to any specific languages or publication dates. The last database search for studies was carried out in January 2012. The planned search in

Anthropology Plus was not carried out because NOKC did not have access to this database after 2011.

We supplemented the electronic database searches with four additional search strategies. One, we searched in reference lists of relevant reviews and all included studies. Two, we searched in sources for grey literature, including OpenGrey, OpenSigle, and OAIster. Three, we communicated with experts engaged in FGM/C related work. And lastly, we browsed the websites of the following six international organizations that are engaged in projects regarding FGM/C:

- Population Council: http://www.popcouncil.org/
- Population Reference Bureau (PRB): http://www.prb.org/
- The Centre for Development and Population Activities (CEDPA): http://www.cedpa.org/
- The United Nations Children's Fund (UNICEF): http://www.unicef.org/
- The United Nations Population Fund (UNFPA): http://www.unfpa.org/public/
- The World Health Organization (WHO): http://www.who.int/en/

Inclusion criteria

We accepted a range of study designs, including non-randomized studies because we aimed to synthesize evidence of the effect of an exposure that ethically cannot be randomized:

- systematic reviews
- cohort studies
- case-control studies
- cross-sectional studies
- · case series
- case reports

In accordance with recommendations set forth in the Cochrane Handbook (22), we used study design features, applying the Cochrane glossary definitions (http://www.cochrane.org/glossary), to designate the studies.

Population: Girls and women who have been subjected to any type of FGM/C (type I-IV as classified by WHO). There were no limitations with respect to age, race/ethnicity, nationality or other participant characteristics.

Event: FGM/C classified as type I-IV according to the WHO modified typology.

Comparison: No FGM/C or a different type of FGM/C. We accepted studies with and without a comparison group. The studies that reported a comparison group had to compare either 1) a type of FGM/C vs no FGM/C, or 2) one type of FGM/C vs another type, e.g., type I vs type III, as defined by WHO.

Outcome: We included the range of physical consequences or complications following FGM/C experienced by girls and women in the short-term and the long term. In the present report, we summarize the gynecological health consequences of FGM/C (excluding obstetric complications, which are detailed in a separate systematic review). The gynecological health consequences included but were not limited to: tissue damage, infections, infertility, as well as problems with urination and menstruation. In this report we also included psychological health outcomes on children aged 15 or younger. Psychological outcomes on adult women have been described in an earlier systematic review (17). We note that all physical outcomes were included, but obstetric and immediate outcomes are presented in separate reports published by the NOKC (1;2).

With regards to other inclusion criteria, we accepted all publication languages. When considered likely to meet the inclusion criteria, studies in languages not mastered by the review team were translated to English by Google translator or multilingual colleagues at the NOKC. Professional translation was not necessary for any of the studies included in this report. Further, unpublished reports, abstracts, brief and preliminary reports were considered for inclusion on the same basis as published reports. Methodological study quality was not a basis for inclusion/exclusion. Lastly, although the outcomes had to be documented by health personnel/study investigators or self-reported by the girls/women having experienced the outcomes, when physical outcomes pertained to children, we accepted reports also by the girl's parents.

Exclusion criteria

We excluded all studies not meeting our pre-specified inclusion criteria. Specifically, we excluded qualitative studies and all studies without a quantitative measure of a physical consequence of FGM/C (we included psychological health outcomes on girls). We also excluded consequences of a woman's FGM/C on other individuals (e.g. her sexual partner) and studies about FGM/C on populations where alterations of genital tissue were performed for medically indicated or purely cosmetic reasons.

Selection of studies

Screening of literature was a two-stage process whereby each level consisted of increasing scrutiny of the studies based on the inclusion criteria of the systematic review. First, the two authors (Berg and Underland) independently read all titles and, when available, abstracts resulting from the search process. We compared our judgments regarding relevance, proceeding to eliminate clearly non-relevant studies and obtain full text copies of the remaining potentially relevant studies. Second, the same pair of authors independently, and next jointly, classified the studies as clearly

relevant, that is, met all inclusion criteria and therefore to be included, or not relevant and therefore to be excluded. The list of excluded studies formally considered in full text is shown in appendix 3, with reasons for exclusion indicated.

For each of the two screening levels, the reviewers used pre-designed inclusion forms to guide their assessment. These forms contained questions regarding type of study, types of participants, type of FGM/C, and outcomes measured. There were few differences in opinion in the screening process. These differences were resolved by re-examining the record and discussing the study's relevance. If consensus had not been reached, we would have contacted the author(s) of the studies in question to aid the selection process and/or consulted a third person.

Data extraction and analysis

Data extraction

Similarly to the process for selection of studies, the two reviewers independently and systematically extracted data from the included studies using a pre-designed data recording form. The two reviewers then compared and agreed upon the data extracted. The few differences in opinion in the data extraction process were resolved through re-examination of the publication and consensus.

The following core data were extracted from all included studies:

- Title, authors, and other publication details
- Study design
- Sample characteristics (current age, country of residency)
- FGM/C characteristics (type of cutting, age of cutting, type of practitioner, method of 'measurement' of FGM/C)
- Methods of outcome measurement (clinical, self-report, report by parent)
- Health consequences

Concerning the extraction of health consequences, we extracted dichotomous and continuous data for all outcomes, i.e. health consequence/complications, meeting the inclusion criteria. We extracted crude data and, when such data were available, adjusted outcome data (adjusted comparison (effect) estimates and their standard errors or confidence intervals). When sample sizes and/or the number of events for eligible outcomes were missing in the publication, we contacted the corresponding author(s) via e-mail and requested that they send us the data.

Assessment of methodological study quality

For the assessment of methodological study quality the two review authors first independently appraised the studies. A final decision of high, moderate or low methodological study quality was agreed upon by the authors after discussing whether there was a discrepancy between the two reviewers with respect to the assessments.

We used appropriate checklists for each included study design. For case series, cross-sectional descriptive studies, case-control, and cohort studies, we used the respective NOKC checklists (21). Given our focus on consequences of exposure to FGM/C, the NOKC assessment tool for cross-sectional studies was used for analytic cross-sectional comparative studies (where two or more groups of women were compared with respect to consequences of FGM/C) but modified by the addition of five questions from the NOKC quality assessment tool for cohort studies in order to capture whether 1) the compared groups (women with FGM/C and women without FGM/C or women with different types of FGM/C) were selected from the same population; 2) the groups were comparable with respect to important background factors; 3) exposure and outcome were measured in the same way in the two groups; 4) the person who assessed the outcome was blind to whether participants were exposed or not; and 5) known, potentially important confounders had been considered in the study design and/or analyses, resulting in an adapted checklist with 12 questions. Lastly, we note that we did not assess the methodological quality of case reports. Case reports are descriptive studies that report observations on a single or a few individuals and are considered among the study designs with lowest validity for effect questions. Thus, a methodological quality assessment would not have added valuable information. Appendix 4 shows the paired reviewers' assessment of each checklist question of each study.

Data analysis

We grouped the data according to outcomes across the studies, keeping the outcome categories or labels reported in each individual study, and we present the results of these in text and tables. In line with Cochrane Handbook (22) recommendations, results from those studies with highest internal validity (studies which compared groups of girls/women) were given preference. Consequently, results from studies with the lowest internal validity were placed in appendix 5. For these descriptive cross-sectional studies, case series, and case reports — which express the number of women with FGM/C who experienced one or more gynecological complications — the reported proportion of women experiencing an eligible outcome is presented in tables (appendix 5).

For the case-control studies presenting dichotomous variables, we estimated effect by the odds ratio (OR) and 95%CI, because a case-control design involves the selection of research subjects on the basis of the outcome measurement rather than on the basis of the exposure. We estimated effect on dichotomous variables in other comparative studies by the relative risk (RR) and 95% confidence interval (95%CI). We estimated effect on continuous variables by mean difference (MD, or standardized mean difference when there were differences in measurement) and 95%CI.

As described in the Cochrane Handbook (22), combing outcome data across studies is appropriate when the same outcome is assessed in similar populations across similar studies in a similar manner, and when the outcome is reasonable resistant to biases and relatively homogeneous in this respect. Moreover, for non-randomized studies it is in most cases appropriate to analyze adjusted rather than unadjusted effect estimates. In the present systematic review, when an outcome was sufficiently similar across studies, we pooled those that could be grouped together. When available, we pooled adjusted effect estimates, otherwise we pooled the unadjusted effect estimates based on crude data from the individual studies. As far as possible, we pooled outcomes that were clinically assessed. We used the statistical technique of meta-analysis to estimate risk, with RevMan v5.2. (tech.cochrane.org/revman), which is the Cochrane Collaboration meta-analysis software. As is standard, we conducted Mantel-Haenszel random effects meta-analysis for dichotomous outcomes. If continuous outcomes had been eligible for meta-analyses, we would have used inverse-variance random effects meta-analyses. For outcomes that were not eligible for meta-analyses we show the forest plots with no pooled effect estimate, in order to illustrate a potential direction of effect across studies. We examined between-study heterogeneity, with the Chi-square test (Chi²) and I-square statistic (I²). A high I² value shows that most of the variability across studies is due to heterogeneity rather than to chance.

When possible (i.e. there was a sufficient number of similar studies), we planned to perform sub-group analyses for:

- performer (health care provider and traditional excisor/circumciser)
- age (at which FGM/C was done, at onset of complications, or time between procedure and onset)
- type of FGM/C (according to WHO modified typology)
- other pertinent factors, such as type of study and measurement.

We had sufficient data to perform sub-group analyses for type of measurement (self-report and clinical assessment). For clarity of presentation, when such tests showed no significant differences we present the final meta-analysis result as well as note the result of the sub-group analysis.

In the last step of the analysis, we applied the instrument Grading of Recommendations Assessment, Development and Evaluation (GRADE) to assess the extent to which we could have confidence in the effect estimates (23). GRADE is a transparent and systematic approach to grading the strength of evidence that can minimize bias and aid interpretation. Using GRADE-Profiler version 3.6, we applied the following eight criteria:

- · methodological quality of study
- consistency (were results consistent across studies?
- directness (did the evidence directly answer the health care question?)
- precision (were the results precise enough?)
- publication bias

- strength of evidence of association
- evidence of a dose-response gradient
- all plausible confounders would have reduced the effect.

For further details about the GRADE system we refer to publications by the GRADE Working Group (gradeworkinggroup.org). However, we note that the standard definitions in grading the quality of the evidence were applied (24):

- High: We are very confident that the true effect lies close to that of the estimate of effect.
- Moderate: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- Low: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
- Very low: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

When it comes to establishing a causal relationship between exposure to an intervention, or procedure such as FGM/C, and an outcome, evidence based on observational studies will usually be appreciably weaker than evidence from experimental studies. In the present systematic review, since all included studies were non-randomized, observational studies, the evaluation of evidence started from a position of low quality, as per GRADE instructions. For resource reasons we assessed the quality of the evidence only for outcomes which were eligible for meta-analysis.

Results

Description of included literature

Results of the search

The literature search yielded 5,109 records (figure 2). After exclusion of duplicates and non-eligible records, we screened 431 in full text (12 potentially relevant records could not be located in full text: (25-36)). Excluded publications are listed with reasons for exclusion in appendix 3. After sorting eligible studies according to outcomes, we included 135 primary studies reporting on gynecological outcomes and one study reporting on psychological health outcomes among girls.

5,109 identified references from
literature search

4,666 references excluded
on the basis of title and abstract
12 records not obtained in full text

246 full texts excluded
on the basis of non-matching PICO

185 studies sorted thematically

49 studies presented in our separate
reports regarding obstetric- and
immediate consequences

Description of included studies

The 136 included studies, presented in 133 publications, were of various publication types: articles (n=118, 89%), reports (n=7), conference abstracts (n=3), meeting papers (n=2), book chapters (n=2), and there was one book included. The majority of the studies were published after 2000 (n=72). The other studies were published in the 1990s (n=29), 1980s (n=15), 1970s (n=11), 1960s (n=5), and the earliest publication included was a case report from 1950. In total, the studies included 130,558

women (range=1 - 12,477). The most frequently measured outcomes were cysts, various adhesions or obstructions, and tissue damage. The great majority of studies (78%) had clinically measured outcomes.

We included 42 comparative studies (two or more groups were compared). Most were cross-sectional studies but there were three case-control studies (37-39) and one retrospective cohort study (40). The 42 comparative studies are summarized in table 1, while table 2 shows the 94 non-comparative studies. With regards to the comparative studies, we arrived upon a final decision of high study quality for the three case-control studies and moderate for the retrospective cohort study. Across the 38 comparative cross-sectional studies, five (13.2%) had high methodological study quality, 18 (47.3%) had moderate quality, and 15 (39.5%) were judged to have low methodological study quality.

Table 1: Included comparative studies (n=42)

| Author, year (Ref) | Study quality | Population, Country | Outcomes (self report or clinical verification) |
|--------------------------------------|------------------|------------------------|--|
| Almroth 2005a a (37) | High | N=279, Sudan | Infertility (clinical) |
| Almroth 2005b (41) | High | N=255, Sudan | Infections of the reproductive/urinary tracts (clinical) |
| Alsibiani 2010 (42) | Moderate | N=260, Saudi Arabia | Problems with sexual intercourse (self-report) |
| Balk 2000 b (43) | Moderate | N=5856, Sudan | Infertility (self-report) |
| Brewer 2007 ° (44) | High | N=539, Kenya | HIV/STIs (clinical) |
| Browning 2010 ^d (40) | Moderate | N=492, Ethiopia | Problems with urination (clinical) |
| De Silva 1989 (45) | Low | N=2157, Saudi Arabia | Problems with urination, infections of the reproductive/ urinary tracts (clinical) |
| Diop 1998 (46) | Low | N=5390, Mali | Tissue damage, vaginal obstruction, problems with urination, other (clinical/self-report) |
| El Dareer 1983 (47) | Low | N=3210, Sudan | Tissue damage, cysts, problems with urination, problems with menstruation, infections of the reproductive/urinary tracts (self-report) |
| El-defrawi 2001 (48) | Moderate | N=250, Egypt | Problems with sexual intercourse, problems with menstruation (self-report) |
| Elmusharaf 2006 ^a (38) | High | N=222, Sudan | HIV/STIs (clinical) |
| Elnashar 2007 (49) | Low | N=264, Egypt | Problems with urination, problems with menstruation, problems with sexual intercourse, vaginal discharge (self-report) |
| Eritrea DHS 2002 (50) | Low | N=7765, Eritrea | Problems with sexual intercourse (self-report) |
| Eritrea DHS 1995 (51) | Low | N=4775, Eritrea | Problems with sexual intercourse (self-report) |
| Fillo 2007 ° (52) | Moderate | N=12477,Burkina Faso | Infections of the reproductive/urinary tracts (not stated) |
| Holmgren 2003 (53) | Moderate | N=857, Guinea-Bissau | HIV/STIs (clinical) |
| Ibrahim 2011 (54) | Moderate | N=100, Sudan | Cervical cancer (clinical) |
| Inhorn 1993 a (39) | High | N=190, Egypt | Infertility (clinical) |

| Jackson 2005 (55) | Low | N=?, Ghana | Infertility (self-report) |
|------------------------------------|----------|----------------------|--|
| Jones 1999-I (56) | Low | N=1920, Burkina Faso | Infections of the reproductive/urinary tracts, other (clinical) |
| Jones 1999-II (56) | Moderate | N=5337, Mali | Other gynecological complications (clinical) |
| Kanki 1992 (57) | Moderate | N=1710, Senegal | HIV/STIs (clinical) |
| Kaplan 2011 (58) | Moderate | N=871, Gambia | Tissue damage, other gynecological complications (clinical) |
| Kizilhan 2011 (59) | Moderate | N=140, Iraq | Psychological health, somatic disturbances (clinical) |
| Klouman 2005 (60) | Moderate | N=396, Tanzania | HIV/STIs, infertility, other complications (clinical) |
| Larsen 2002 b (61) | Moderate | N=5849, Sudan | Infertility (self-report) |
| Larsen 2000-l f (62) | Moderate | N=4388, CAR | Infertility (self-report) |
| Larsen 2000-II g (62) | Moderate | N=5930, Ivory Coast | Infertility (self-report) |
| Larsen 2000-III h (62) | Moderate | N=6043, Tanzania | Infertility (self-report) |
| Larsen 1989 (63) | Low | N=2183, Sudan | Infertility (self-report) |
| Maslovskaya 2009 ^c (64) | High | N=3114, Kenya | HIV/STIs (clinical) |
| Morison 2001 (65) | High | N=1157, Gambia | Tissue damage, cysts, problems with urination, problems with menstruation, problems with sexual intercourse, HIV/STIs, infertility, other (clinical) |
| Msuya 2002 (66) | High | N=379, Tanzania | HIV/STIs, vaginal complication (clinical) |
| Nwajei 2003 (67) | Low | N=400, Nigeria | Vaginal complication (self-report) |
| Odoi 1997 (68) | Low | N=195, Ghana | Problems with sexual intercourse (self-report) |
| Okonofua 2002 (69) | Moderate | N=1836, Nigeria | Tissue damage, vaginal obstruction, cysts, problems with urination, problems with sexual intercourse, other vaginal complication (clinical/self-report) |
| Pépin 2006 (70) | Moderate | N=1026,Guinea-Bissau | HIV (clinical) |
| Pépin 1991 (71) | Low | N=345, Gambia | HIV (clinical) |
| Rushwan 1983 (72) | Low | N=2502, Sudan | Tissue damage, cysts, problems with menstruation, problems with sexual intercourse, infections of the reproductive/urinary tracts, infertility, other vaginal complication (self-report) |
| Shandall 1967 (73) | Low | N=4487, Sudan | Tissue damage, cysts, infections of the reproductive/urinary tracts, other complication (clinical) |
| Yount 2007 c (74) | Moderate | N=3167, Kenya | HIV/STIs (clinical) |
| Yount 2006 (75) | Low | N=1700, Egypt | Infertility (self-report) |
| | | | |

Legend: a= case-control study; b= study based on Sudan DHS 1989/1990; c= study based on Kenya DHS 2003; d=retrospective cohort study; e= study based on Burkina Faso DHS 2003; f= study based on Central African Republic (CAR) DHS 1995; g= study based on Ivory Coast DHS 1995; h= study based on Tanzania DHS 1997. Jones 1999 included one study sample from Burkina Faso and one from Mali (denoted here as Jones 1999-I and Jones 1999-II); N=? numbers not reported/unclear.

There were 94 non-comparative studies: 43 case reports, 29 case series, and 22 cross-sectional studies (table 2). More than half (60.8%) of the non-comparative studies were rated to have low methodological study quality.

 ${\bf Table~2: Included~non-comparative~studies~(cross-sectional,~case~series~and~}$

case report studies) (n=94)

| Author, year | Study design | Study quality | Population, Country | Outcomes (self report or clinical verification) |
|----------------------------|-----------------|------------------|------------------------|--|
| Abor 2006 (76) | Cross-sectional | Low | N=34, Ghana | Tissue damage, problems with voiding, problems with menstruation, problems with sexual intercourse, infections of the reproductive/urinary tracts, other (self-report) |
| Aboyejin 2003 (77) | Case series | Moderate | N=93, Nigeria | Vaginal adhesions/obstruction, cysts, other (clinical) |
| Adekunle 1999 (78) | Case series | Low | N=39, Nigeria | Vaginal adhesions/obstruction, cysts (clinical) |
| Adelusi 1976 (79) | Case series | Low | N=28, Nigeria | Vaginal adhesions/obstruction (clinical) |
| Adinma 1997 (80) | Cross-sectional | Low | N=256, Nigeria | Tissue damage (clinical) |
| Agugua 1982 (81) | Case series | Low | N=73, Nigeria | Tissue damage, vaginal adhesions/obstruction, cysts, infections of the reproductive/urinary tracts (clinical) |
| Akotionga 2001 (82) | Case series | High | N=49, Burkina Faso | Problems with voiding, problems with menstruation, problems with sexual intercourse (clinical) |
| Akpuaka 1998 (83) | Case report | NA | N=5, Nigeria | Vaginal adhesions/obstruction, cysts (clinical) |
| Ali 1998 (84) | Case series | High | N=1912, Sudan | Infertility (unclear) |
| Al-Hussaini 2003 (85) | Cross-sectional | Moderate | N=254, Egypt | Other complications (clinical) |
| Al-Maghrabi 2005 (86) | Case report | NA | N=1, Saudi-Arabia | Cysts (clinical) |
| Arbesman 1993 (87) | Cross-sectional | Low | N=12, USA | Problems with voiding, problems with menstruation, problems with sexual intercourse, vaginal problems (self-report) |
| Asante 2010 (88) | Case report | NA | N=1, USA | Cysts (clinical) |
| Asuen 1977 (89) | Case report | NA | N=2, Nigeria | Vaginal adhesions/obstruction (clinical) |
| Awang 2004 (90) | Case report | NA | N=1, Malaysia | Vaginal adhesions/obstruction (clinical) |
| Aziz 1980 (91) | Cross-sectional | Low | N=7505, Sudan | Problems with voiding, infertility (clinical) |
| Baaij 1999 (92) | Case report | NA | N=3, Netherlands | Vaginal adhesions/obstruction, cysts, problems with sexual intercourse (clinical) |
| Badejo 1983 (93) | Case series | High | N=12, Nigeria | Vaginal adhesions/obstruction, cysts (clinical) |
| Bankolé Sanni 1997 (94) | Case series | Moderate | N=6, Ivory Coast | Tissue damage, vaginal adhesions/obstruction (clinical) |
| Bitho 1975 (95) | Case report | NA | N=3, Senegal | Vaginal adhesions/obstruction, problems with voiding (clinical) |
| Bonessio 2001 (96) | Case series | Low | N=9, Italy | Tissue damage, vaginal adhesions/obstruction, problems with menstruation, problems with sexual intercourse, infertility, other (clinical) |
| Drices 2004 (07) | Case report | NA | N=1, USA | Vaginal adhesions/obstruction (clinical) |
| Brisson 2001 (97) | | | | |
| Brown 1989 (98) | Cross-sectional | Low | N=105, Somalia | Problems with menstruation (self-report) |

| Chalmers 2000 (100) | Cross-sectional | Low | N=432, Canada | Tissue damage, cysts, problems with voiding, problems with menstruation, problems with sexual intercourse, infections of the reproductive/urinary tracts (self-report) |
|---------------------------------|-----------------|----------|--------------------|--|
| Chen 2004 (101) | Case report | NA | N=1, USA | Vaginal adhesions/obstruction (clinical) |
| Dare 2004 (102) | Cross-sectional | Low | N=522, Nigeria | Tissue damage, vaginal adhesions/obstruction, cysts, problems with voiding, infertility (self-report) |
| Dewhurst 1964 (103) | Case report | NA | N=1, England | Vaginal adhesions/obstruction (clinical) |
| Diejomaoh 1981 (104) | Case series | Low | N=12, Nigeria | Vaginal adhesions/obstruction, problems with voiding (clinical) |
| Dirie 1992 (105) | Cross-sectional | Low | N=290, Somalia | Tissue damage, cysts, problems with voiding, problems with menstruation (self-report) |
| Dirie 1991 (106) | Case series | Moderate | N=118, Somalia | Vaginal adhesions/obstruction, cysts (clinical) |
| Dörflinger 2000 (107) | Case series | Low | N=10, Sudan | Problems with voiding, problems with menstruation, problems with sexual intercourse, infections of the reproductive/urinary tracts, other (clinical) |
| Duvie 1980 (108) | Case series | Low | N=31, Nigeria | Cyst (clinical) |
| Eguwatu 1981 (109) | Case series | Low | N=58, Nigeria | Tissue damage, vaginal adhesions/obstruction, cysts, problems with voiding, problems with sexual intercourse, infertility, other (clinical/self-report) |
| Ekenze 2009 (110) | Case series | Low | N=18, Nigeria | Vaginal adhesions/obstruction, cysts (clinical) |
| Ekenze 2007 (111) | Case series | High | N=21, Nigeria | Other vaginal complication (clinical) |
| Elgaali 2005 (112) | Cross-sectional | Moderate | N=220,Scandinavia | Other complications (self-report) |
| Epstein 2001 (113) | Case report | NA | N=1, USA | Vaginal adhesions/obstruction (clinical) |
| Erian 1995 (114) | Case report | NA | N=3, multiple | Vaginal adhesions/obstruction (clinical) |
| Etokidem 2007 (115) | Case report | NA | N=1, Nigeria | HIV (clinical) |
| Ezem 2007 (116) | Case report | NA | N=1, Nigeria | Cysts (clinical) |
| Fahal 1998 (117) | Case report | NA | N=1, Sudan | Infections of the reproductive/urinary tracts (clinical) |
| Fernández-Aguilar 2003 (118) | Case report | NA | N=1, Belgium | Other (clinical) |
| Fox 1997 (119) | Cross-sectional | Low | N=22, England | Tissue damage, cysts, problems with sexual intercourse, infections of the reproductive/urinary tracts (clinical/self-report) |
| Franco 2006 (120) | Case report | NA | N=1, Italy | Tissue damage (clinical) |
| Frith 1960 (121) | Case series | Moderate | N=4, Qatar | Vaginal adhesions/obstruction (clinical) |
| Gadallah 1996 (122) | Cross-sectional | Moderate | N=?, Egypt | Unclear (because pages missing) |
| German 1968 (123) | Case series | Low | N=187, Bahrain | Vaginal adhesions/obstruction (clinical) |
| Giama 1979 (124) | Case series | Low | N=14, Italy | Tissue damage, problems with menstruation, other (clinical) |
| Hanly 1995 (125) | Case series | Low | N=10, Saudi Arabia | Cysts (clinical) |
| Hamoudi 2010 (126) | Case report | NA | N=1, Canada | Cysts (clinical) |
| | | | | |

| Hathout 1963 (127) | Case report | NA | N=1, Egypt | Cysts (clinical) |
|-------------------------------------|-----------------|----------|-------------------------|--|
| lbekwe 2004 (128) | Case report | NA | N=1, Nigeria | Vaginal adhesions/obstruction (clinical) |
| Iregbulem 1980 (129) | Case series | Low | N=10, Nigeria | Vaginal adhesions/obstruction, cysts (clinical) |
| Ismail 1982 (130) | Cross-sectional | Low | N=290, Somalia | Tissue damage, vaginal adhesions/obstruction, cysts (clinical/self-report) |
| Jaleel 2002 (131) | Case report | NA | N=1, England | Problems with sexual intercourse (clinical) |
| Knight 1999 (132) | Cross-sectional | Moderate | N=51, Australia | Problems with menstruation, problems with sexual intercourse, infections of the reproductive/urinary tracts (self-report) |
| Kothe 1973 (133) | Case report | NA | N=1, Germany | Infections of the reproductive/urinary tracts (clinical) |
| Kristensen 2008 (134) | Case report | NA | N=2, Denmark | Cysts (clinical) |
| Kroll 2000 (135) | Case report | NA | N=1, USA | Cysts (clinical) |
| Lashley 2009 (136) | Case report | NA | N=1, Netherlands | Cysts (clinical) |
| Laycock 1950 (137) | Case report | NA | N=10, Somalia | Tissue damage, vaginal adhesions/obstruction, cysts, other (clinical) |
| Lenzi 1970 (138) | Case report | NA | N=4, Somalia | Infertility (clinical) |
| Lenzi 1969 (139) | Case report | NA | N=2, Italy | Infertility (clinical) |
| Litorp 2008 (140) | Cross-sectional | Low | N=40, Sweden | Problems with voiding, problems with menstruation, problems with sexual intercourse, other (self-report) |
| MacLeod 1995 (141) | Case report | NA | N=1, Canada | Cysts (clinical) |
| Mandara 2004 (142) | Cross-sectional | Low | N=170, Nigeria | Tissue damage (clinical) |
| Mawad 1994 (143) | Case series | Moderate | N=934, Sudan | Tissue damage, problems with sexual intercourse, vaginal complications, other (clinical) |
| McCleary 1994 (144) | Case report | NA | N=1, Canada | Tissue damage (clinical) |
| Millogo-Traore 2002 (145) | Case report | NA | N=3, Burkina Faso | Vaginal adhesions/obstruction (clinical) |
| Ministere de la Sante 1998 (146) | Cross-sectional | Low | N=1786, Burkina Faso | Tissue damage, vaginal adhesions/obstruction, infections of the reproductive/urinary tracts (clinical) |
| Modawi 1974 (147) | Cross-sectional | Low | N=3000, Sudan | Tissue damage, problems with sexual intercourse, other (not stated) |
| Möller 2003 (148) | Case report | NA | N=1, Denmark | Cysts (clinical) |
| Momoh 2001 (149) | Cross-sectional | Low | N=86, England | Tissue damage, cysts, problems with voiding, problems with menstruation, problems with sexual intercourse, infections of the reproductive/urinary tracts, infertility (clinical/self-report) |
| Moreira 2002 (150) | Case report | NA | N=3, Senegal | Cysts (clinical) |
| Morris 2005 (151) | Case report | NA | N=3, USA | Other (clinical) |
| Mühlbach 1985 (152) | Case report | NA | N=1, Germany | Vaginal adhesions/obstruction (clinical) |
| Nour 2006 (153) | Case report | NA | N=1, USA | Vaginal adhesions/obstruction (clinical) |
| | | | | |

| Ofodile 1979 (154) | Case series | Low | N=19, Nigeria | Cysts (clinical) |
|--------------------|-----------------|----------|--------------------|---|
| Onuigbo 1974 (155) | Case report | NA | N=1, Nigeria | Other (clinical) |
| Orji 2006 (156) | Cross-sectional | Moderate | N=423, Nigeria | Tissue damage, vaginal adhesions/obstruction (clinical) |
| Osifo 2010 (157) | Case series | High | N=37, Nigeria | Cysts (clinical) |
| Osifo 2009 (158) | Case series | High | N=51, Nigeria | Tissue damage, vaginal adhesions/obstruction, problems with sexual intercourse, vaginal complication (clinical) |
| Oye 1976 (159) | Case report | NA | N=1, Nigeria | Vaginal adhesions/obstruction (clinical) |
| Ozumba 1992 (160) | Case series | High | N=78, Nigeria | Vaginal adhesions/obstruction (clinical) |
| Pieters 1972 (161) | Case report | NA | N=2, Somalia | Tissue damage, vaginal adhesions/obstruction (clinical) |
| Rizk 2007 (162) | Case report | NA | N=2, UAE | Cysts (clinical) |
| Rouzi 2010 (42) | Case series | High | N=29, Saudi Arabia | Cysts (clinical) |
| Rouzi 2001 (163) | Case series | Low | N=21, Saudi Arabia | Cysts (clinical) |
| Saad 1998 (164) | Cross-sectional | Low | N=9006, Sudan | Tissue damage, cysts, problems with voiding, problems with sexual intercourse, infertility (not stated) |
| Saber 2009 (165) | Case report | NA | N=1, Egypt | Cysts (clinical) |
| Tahzib 1983 (166) | Case series | Moderate | N=1443, Nigeria | Tissue damage (clinical) |
| Walker 1995 (167) | Case report | NA | N=4, USA | Vaginal adhesions/obstruction (clinical) |
| Yoong 2004 (168) | Case report | NA | N=1, England | Cysts (clinical) |

Legend: UAE= United Arab Emirates; N?= numbers not reported/unclear; NA= not applicable (we did not assess the methodological quality of case reports).

Study design and sample recruitment

According to the study features, three of the included studies were case-control studies, one was a retrospective cohort study, and 38 employed a cross-sectional study design in which two or more groups of women with different types of FGM/C, or no FGM/C, were compared (we refer to these as comparative studies). For some outcomes, a few of the comparative studies reported results only for the women with FGM/C– these outcome results are placed in appendix 5. There were also 22 single-group cross-sectional studies, 29 case series, and 43 case reports. All included studies are briefly presented in tables 1-2 above.

Most of the 136 included studies were based on a non-random sample. However, we included eight Demographic and Health Surveys (DHS), presented in 11 studies. DHS are nationally-representative household surveys that provide results for a range of population and health data. Additionally, the study by Yount and Carrera (75) was based on a representative survey of 3,125 households in Minya, Egypt. Lastly, El Dareer's study (47) used a multistage random sampling technique, with the Northern Sudan household as the unit of sampling, to recruit 3,210 women.

Population in the comparative studies

The 42 included comparative studies involved 90,911 women (table 3). Of these women, 56% had some form of FGM/C and 44% had not been subjected to FGM/C. The majority (n=32, 84%) of the comparative studies examined differences between women with FGM/C and women without FGM/C. Six studies compared women with various types of FGM/C (37;50;51;58;63;75). Four studies presented a mix of comparisons (47;69;72;73). Almost all of the comparative studies took place in a country in Africa: Burkina Faso, Central African Republic, Egypt, Eritrea, Ethiopia, Gambia, Ghana, Guinea-Bissau, Ivory Coast, Kenya, Mali, Nigeria, Senegal, Sudan, and Tanzania. Three studies took place in the Middle East: two studies were from Saudi Arabia (42;45) and one was from Iraq (59). With the exception of two studies that examined outcomes among young girls (41;59), across the studies, the women's ages at the time of the study ranged from adolescence to around 50. The mean age of the women in the comparative studies was 30 years.

With respect to FGM/C characteristics of the women with this procedure, 15 of the 42 comparative studies did not describe the type or extent of genital alteration (table 3). Across the studies that offered information about women's FGM/C characteristics, about 24% of the women were described as having FGM/C type I, 34% had type II, and 42% had type III. In 56% of the studies, FGM/C status was self-reported, in 37% of the studies women were examined gynaecologically, and in three studies (7%) it was not explained how women's FGM/C status was ascertained. Information regarding the girls' age at the time of the FGM/C procedure was scarce. Most of the studies (n=27), did not state the women's age at the time of the FGM/C procedure. However, according to the studies that offered descriptions of the participants' FGM/C characteristics, the women had been subjected to FGM/C in early childhood, typically before the age of 10 (mean age approximately 7 years), and typically by a traditional circumciser.

Table 3: Description of the population in included comparative studies (n=42)

| Author, year | N | Country | Age (yrs) | FGM/C characteristics |
|----------------------------|-------------------------------------|--------------|--------------|--|
| Almroth 2005a ^a | N=279 (19 TI, 9 TII, 243 TIII) | Sudan | 17-35 | Type: 87% TIII (gyn exam) Age cut/by: median 7 yrs / not stated |
| Almroth 2005b | N=255 (52 cut, 203 non-cut) | Sudan | 4-9 | Type: 67% TIII (gyn exam) Age cut/by: not stated / 100% tc |
| Alsibiani 2010 | N=260 (130 cut, 130 non-cut) | Saudi Arabia | 16-39 | Type: 41% TI-II, 42% TIII (self-report) Age cut/by: not stated |
| Balk 2000 | N= 5856 (4602 cut, 1254 non-cut) | Sudan | 15-49 | Type: 76% TIII (self-report) Age cut/by: not stated |
| Brewer 2007 | N=539 (95 cut, 444 non-cut) | Kenya | 15-24 | Type: 'circumcised' (self-report) Age cut/by: not stated |
| Browning 2010 b | N=492 (255 cut, 237 non-cut) | Ethiopa | Mean 28.5 | Type: 100% TI-II (gyn exam) Age cut/by: not stated |

| De Silva 1989 | N=2157 (167 cut, 1990 non-cut) | Saudi Arabia/ Sudan | ≥15 | Type: 9% TI, 34%TII, 32% TIII (gyn exam) Age cut/by: not stated |
|--------------------------|---|------------------------|---------------|---|
| Diop 1998 | N=5390 (4959 cut, 431 non-cut) | Mali | Mean 27.0 | Type: 21% TI, 73% TII, 6% TIII (gyn exam) Age cut/by: not stated |
| El Dareer 1983 | N=3210 (3171 cut, 39 non-cut) | Sudan | 70% 15-34 | Type: 95% TIII (self-report) Age cut/by: mean 7 yrs (2-11) / 81% tc |
| El-Defrawi 2001 | N=250 (200 cut, 50 non-cut) | Egypt | not stated | Type: 87% TI, 13% TII (not stated) Age cut/by: not stated |
| Elmusharaf 2006 a | N=222 (219 cut, 3 non-cut) | Sudan | 17-38 | Type: 93% TII-III (gyn exam) Age cut/by: not stated |
| Elnashar 2007 | N=264 (200 cut, 64 non-cut) | Egypt | 15-49 | Type: 'circumcised' (self-report) Age cut/by: not stated |
| Eritrea DHS 2002 | N=7765 (310TI-II,2028TIII,3572TIV) | Eritrea | 15-49 | Type: 4% TI-II, 39% TIII, 46% TIV= nicked (self-report) Age cut/by: 62% ≤1 yrs / 84% tc |
| Eritrea DHS 1995 | N=4775 (2960 TI, 191 TII, 1624 TIII) | Eritrea | 15-49 | Type: 62% TI, 4% TII, 34% TIII (self-report) Age cut/by: 60% ≤5 yrs / 91% tc |
| Fillo 2007 | N=12477 (not stated) | Burkina Faso | not stated | Type: 'female genital cutting' (self-report) Age cut/by: not stated |
| Holmgren 2003 | N=857 (799 cut, 58 non-cut) | Guinea- Bissau | Mean 56.8 | Type: 'circumcised' (self-report) Age cut/by: not stated |
| Ibrahim 2011 | N=100 (90 cut, 10 non-cut) | Sudan | Mean 35.0 | Type: not stated (unclear) Age cut/by: not stated |
| Inhorn 1993 ^a | N=190 (184 cut, 6 non-cut) | Egypt | 15-45 | Type: 42% TI, 53% TII (self-report) Age cut/by: not stated / 87% tc |
| Jackson 2005 | N=not stated (not stated) | Ghana | 20-49 | Type: 'cut' (self-report) Age cut/by: not stated / 100% tc |
| Jones 1999-I | N=1920 (1787 cut, 133 non-cut) | Burkina Faso | Mean 26.6 | Type: 56% TI, 39% TII, 5%TIII (gyn exam) Age cut/by: median 9.5 yrs / not stated |
| Jones 1999-II | N=5337 (5017 cut, 320 non-cut) | Mali | Mean 25.0 | Type: 21% TI, 74% TII, 5%TIII (gyn exam) Age cut/by: not stated |
| Kanki 1992 | N=1710 (276 cut, 1434 non-cut) | Senegal | 20-69 | Type: 'clitoridectomy' (self-report) Age cut/by: not stated |
| Kaplan 2011 | N=871 (577 TI, 229 TII, 65 TIII) | Gambia | not stated | Type: 66% TI, 26% TII (gyn exam) Age cut/by: not stated |
| Kizilhan 2011 | N=140 (79 cut, 61 non-cut) | Iraq | Mean 12.3 | Type: 'circumcised' (not stated) Age cut/by: 2-10 yrs / not stated |
| Klouman 2005 | N=396 (287 cut, 109 non-cut) | Tanzania | 15-44 | Type: 45% TI, 55% TII (gyn exam) Age cut/by: mean 9.6 yrs / not stated |
| Larsen 2002 | N=5849 (5217 cut, 632 non-cut) | Sudan | 25-49 | Type: 15% TI, 85% TII-III (self-report) Age cut/by: not stated / 64% tc, 36% hcp |
| Larsen 2000-l | N=4388 (2061 cut, 2327 non-cut) | CAR | 15-49 | Type: 'circumcised' (self-report) Age cut/by: 32% 1-9 yrs, 59% 10-14 yrs / not stated |
| Larsen 2000-II | N=5930 (2884 cut, 3046 non-cut) | Ivory Coast | 15-49 | Type: 'circumcised' (self-report) Age cut/by: 51% 1-9 yrs, 29% 10-14 / not stated |
| Larsen 2000-III | N=6043 | Tanzania | 15-49 | Type: 57% TI, 42% TII-III (self-report) |
| | | | | |

| | (1179 cut, 4864 non-cut) | | | Age cut/by:20% 0-9yrs, 30% 10-14yrs / 81% to |
|------------------|---------------------------------------|-------------------|---------------|--|
| Larsen 1989 | N=2183 (1749 TIII, 434 other) | Sudan | 20-44 | Type: 'circumcised' (self-report) Age cut/by: not stated |
| Maslovskaya 2009 | N=3114 (962 cut, 2152 non-cut) | Kenya | 15-49 | Type: 'female genital cutting' (self-report) Age cut/by: not stated |
| Morison 2001 | N=1157 (668 cut, 489 non-cut) | Gambia | 15-54 | Type: 98% TII (gyn exam) Age cut/by: mean 6.1 yrs / not stated |
| Msuya 2002 | N=379 (63 cut, 316 non-cut) | Tanzania | not stated | Type: 97% TI (gyn exam) Age cut/by: median 10 yrs / not stated |
| Nwajei 2003 | N=400 (120 cut, 280 non-cut) | Nigeria | not stated | Type: 100% TI (self-report) Age cut/by: not stated |
| Odoi 1997 | N=195 (76 cut, 119 non-cut) | Ghana | not stated | Type: 100% TI-II (gyn exam) Age cut/by: early childhood to 18yrs / 100% tc |
| Okonofua 2002 | N=1836 (827 cut, 1009 non-cut) | Nigeria | not stated | Type: 71% TI, 24% TII, 3% TIII, 1% TIV (gyn exam) Age cut/by: not stated |
| Pépin 2006 | N=1026 (488 cut, 538 non-cut) | Guniea- Bissau | ≥50 yrs | Type: 'excision' (self-report) Age cut/by: not stated |
| Pépin 1991 | N=345 (90 cut, 255 non-cut) | Gambia | Mean 29 | Type: 'circumcised' (self-report) Age cut/by: not stated |
| Rushwan 1983 | N=2502 (2291 cut, 211 non-cut) | Sudan | not stated | Type: 96% TIII (self-report) Age cut/by: not stated / 53% hcp |
| Shandall 1967 | N=4487 (4246 cut, 241 non-cut) | Sudan | not stated | Type: 77% TIII (gyn exam) Age cut/by: 5-10 yrs / not stated |
| Yount 2007 | N=3167 (1071 cut, 2096 non-cut) | Kenya | 15-49 | Type: 'female genital cutting' (self-report) Age cut/by: not stated |
| Yount 2006 | N=1700 (72 TI, 1232 TII, 396 TIII) | Egypt | 17-55 | Type: 4% TI, 73% TII, 16% TIV (self-report) Age cut/by: modal 9-10 yrs / 93% tc |

Legend: a= case-control study; b= retrospective cohort study; TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III; TIV= FGM/C type IV; gyn exam= gynecological exam; hcp= health care practitioner; tc= traditional circumciser.

Population in the non-comparative studies

With respect to the 94 non-comparative studies, almost half of the studies (n=43) were case reports with one or a few women's FGM/C complications described (table 4). All in all, there were 39,647 women included in the 94 studies (range=1 – 9006). Fifty-six percent (n=52) of the non-comparative studies took place in a country in Africa. Most were from Nigeria (n=26), but there were also studies from Burkina Faso, Central African Republic, Egypt, Ghana, Ivory Coast, Senegal, Somalia, and Sudan. There were 41 non-comparative studies included that were carried out outside of Africa: four were from Saudi Arabia, and there was one study each from Bahrain, Malaysia, the United Arab Emirates, and Qatar, nine studies took place in the USA, four in Canada, 20 in a country in Europe, and one in Australia. The participants in the studies from North America and Europe were largely from northern Africa, in particular Somalia and Sudan. Across the 94 non-comparative studies, there was a range of ages, from infants to 75-year-olds. There was also a mix of FGM/C types, ascertained by gynecological examination in 78 of them and self-reported in eight studies. Two studies, from Bahrain and Qatar, described complications follow-

ing insertion of rock salt into the vagina, and one Nigerian study explained the nature and number of women who experienced vesicovaginal fistula after gishiri cut (a gishiri cut is a backward cut from the vagina into the perineum). Less than half of the studies reported on the women's age when undergoing the FGM/C procedure and who performed the procedure, but in general, the women self-reported that they had been subjected to FGM/C in early childhood, in most cases by a traditional circumciser.

Table 4: Description of the population in included non-comparative studies (n=94)

| Author, year | N | Country (Origin) | Age | FGM/C characteristics |
|------------------|--------|--------------------------|-----------------|---|
| Abor 2006 | N=34 | Ghana | 21-50 | Type: 'have undergone FGM' (self-report) Age cut/by: 47% 0-10 yrs, 29% 11-15 yrs / 100% tc |
| Aboyejin 2003 | N=93 | Nigeria | 8mo - 16yrs | Type: 'female circumcision' (gyn exam) Age cut/by: not stated |
| Adekunle 1999 | N=39 | Nigeria | 90% 0-14 yrs | Type: 100% TI (gyn exam) Age cut/by: not stated |
| Adelusi 1976 | N=28 | Nigeria | 61% 21-40 | Type: 'circumcision' (not stated) Age cut/by: not stated |
| Adinma | N=124 | Nigeria | 16-40 | Type: 22% TI, 78% TII (gyn exam) Age cut/by: 97% in childhood / not stated |
| Agugua 1982 | N=73 | Nigeria | 75% ≤ 12 yrs | Type: 'female circumcision' (gyn exam) Age cut/by: 72 of 73 cut within 21 days of birth |
| Akotionga 2001 | N=49 | Burkina Faso | 5-32 | Type: 'excision' (gyn exam) Age cut/by: 67% 3-7 yrs, up to age 19 / 100% tc |
| Akupuaka 1998 | N=5 | Nigeria | 2-24 | Type: 'female circumcision' (gyn exam) Age cut/by: not stated |
| Ali 1998 | N=1912 | Sudan | not stated | Type: 'female circumcision' (gyn exam) Age cut/by: not stated |
| Al-Hussaini 2003 | N=254 | Egypt | 16-37 | Type: 51% TI, 49% TII (gyn exam) Age cut/by: 47% 0-10 yrs, 29% 11-15 yrs / 100% tc |
| Al-Maghrabi 2005 | N=1 | Saudi Arabia | 31 | Type: TIII (gyn exam) Age cut/by: not stated |
| Arbesman 1993 | N=12 | USA (Somalia) | Mean 32 | Type: 33% TI-II, 58% TIII (self-report) Age cut/by: mean 7.4 yrs / 74% hcp |
| Asante 2010 | N=1 | USA (Guinea) | 37 | Type: 'female circumcision' (gyn exam) Age cut/by: not stated |
| Asuen 1977 | N=2 | Nigeria | 8 mo, 23 yrs | Type: TII and TIII (gyn exam) Age cut/by: 1 day before hospital admission, 8 days old |
| Awang 2004 | N=1 | Malaysia | 16 | Type: TII or III (gyn exam) Age cut/by: 3 months |
| Aziz 1980 | N=7505 | Sudan | not stated | Type: 100% TIII (not stated) Age cut/by:100% trained midwife |
| Baaij 1999 | N=3 | Netherlands (Somalia) | 21-28 | Type: 100% TIII (gyn exam) Age cut/by: "as girls" / not stated |

| Badejo 1983 | N=12 | Nigeria | 0-18 mo | Type: 'circumcised' (gyn exam) Age cut/by: not stated |
|-----------------------|--------|------------------------------------|-----------------|--|
| Bankolé-Sanni 1997 | N=6 | Ivory Coast | Mean 3 | Type: 'circumcised' (gyn exam) Age cut/by: not stated |
| Bitho 1975 | N=3 | Senegal | Mean 32 | Type: 100% TI-II (gyn exam) Age cut/by: mean 9.6 yrs / not stated |
| Bonessio 2001 | N=9 | Italy (Somalia, Ethiopia) | 21-45 | Type: 100%TIII (gyn exam) Age cut/by: not stated |
| Brisson 2001 | N=1 | USA ('Africa') | 16 | Type: TIII (gyn exam) Age cut/by: not stated / tc |
| Brown 1989 | N=105 | Somalia | adults | Type: 'circumcised' (not stated) Age cut/by: 5-7 yrs / not stated |
| CAR DHS 1995 | N=2555 | Central African Republic | 15-49 | Type: 'circumcision' (self-report) Age cut/by: 55% 0-10 yrs / not stated |
| Chalmers 2000 | N=432 | Canada (Somalia) | Mean 34.0 | Type: 0.2% TI, 0.5% TII, 96%TIII (self-report) Age cut/by: mean 5.7 yrs / 58% tc, 10% hcp |
| Chen 2004 | N=1 | USA (Sudan) | 31 | Type: TIII (gyn exam) Age cut/by: 8 yrs / not stated |
| Dare 2004 | N=522 | Nigeria | Mean 26 | Type: 69% TI, 31% TII (gyn exam) Age cut/by: mean 6.9 yrs / 89% tc, 11% hcp |
| Dewhurst 1964 | N=1 | England (Sudan) | 22 | Type: TII (gyn exam) Age cut/by: 11 yrs / not stated |
| Diejomaoh 1981 | N=12 | Nigeria | 2mo – 15 yrs | Type: 'female circumcision' (gyn exam) Age cut/by: 1-3 weeks, 100% tc |
| Dirie 1992 | N=290 | Somalia | Mean 22 | Type: 88%TIII (self-report) Age cut/by: mean 7 yrs / 48% hcp, 52% tc |
| Dirie 1991 | N=118 | Somalia | ≥6 yrs | Type: 'female circumcision' (gyn exam) Age cut/by: not stated |
| Dörflinger 2000 | N=10 | Sudan | 8-41 | Type: 3% TII, 97%TIII (gyn exam) Age cut/by: median 8 yrs (0-12) / not stated |
| Duvie 1980 | N=31 | Nigeria | 3-75 | Type: 'female circumcision' (gyn exam) Age cut/by: not stated |
| Eguwatu 1981 | N=58 | Nigeria | ≤12- 24 | Type: 'simple excision' (gyn exam) Age cut/by: 57 of 58 cut within 21 days of birth / 100% tc |
| Ekenze 2009 | N=18 | Nigeria | Med 1yr | Type: 'circumcision' (gyn exam) Age cut/by: not stated / 100% tc |
| Ekenze 2007 | N=21 | Nigeria | Mean 3.5 | Type: 57% TI, 43% TII (gyn exam) Age cut/by: 8-90 days after birth / 33% hcp, 67% tc |
| Elgaali 2005 | N=220 | 'Scandinavia' (northern Africa) | Med 20.5 | Type: 57% TI, 32% TII, 11% TIII (self-report) Age cut/by: mean 7 yrs / not stated |
| Epstein 2001 | N=1 | USA (Somalia) | 23 | Type: TI (gyn exam) Age cut/by: 5 yrs / not stated |
| Erian 1995 | N=3 | Australia, UK (Somalia, Sudan) | Mean 24 | Type: 100% TIII (gyn exam) Age cut/by: 4-14 yrs / not stated |
| Etokidem 2007 | N=1 | Nigeria | 6 | Type: 'female genital cutting' (gyn exam) Age cut/by: 3.5 yrs / not stated |
| Ezem 2007 | N=1 | Nigeria | 65 | Type: 'female genital mutilation' (gyn exam) Age cut/by: not stated |
| | | <u>-</u> | | |

| Fahal 1998 | N=1 | Sudan | 20 | Type: TIII (gyn exam) Age cut/by: < 10 yrs / not stated |
|---------------------------|---------------|------------------------------|---------------|---|
| Fernández-Aguilar 2003 | N=1 | Belgium (Guinea) | 27 | Type: TIII (gyn exam) Age cut/by: 17 yrs / not stated |
| Fox 1997 | N=22 | England (multiple) | not stated | Type: 46% TIII, 54% 'other FGM' (gyn exam) Age cut/by: not stated |
| Franco 2006 | N=1 | Italy | 25 | Type: TIII (gyn exam) Age cut/by: childhood / not stated |
| Frith 1960 | N=4 | Qatar | Mean 23 | Type: 100% TIV= insertion of rock salt (gyn exam) Age cut/by: first few weeks after childbirth / not stated a |
| Gadallah 1996 | N= unclear | Egypt | unclear | Type: unclear because pages missing Age cut/by: unclear because pages missing |
| German 1968 | N=187 | Bahrain | not stated | Type: 100% TIV (insertion of rock salt) (gyn exam) Age cut/by: after first childbirth / not stated |
| Giama 1979 | N=14 | Italy (not stated) | 20-28 | Type: 100%TIII (gyn exam) Age cut/by: not stated |
| Hamoudi 2010 | N=1 | Canada (Sudan) | 36 | Type: TIII (gyn exam) Age cut/by: 4 yrs / not stated |
| Hanly 1995 | N=10 | Saudi Arabia | Mean 18 | Type: 100% TIII (gyn exam) Age cut/by: not stated |
| Hathout 1963 | N=1 | Egypt | 23 | Type: 'circumcised' (gyn exam) Age cut/by: 8 yrs / not stated |
| Ibekwe 2004 | N=1 | Nigeria | 17 | Type: 'circumcised' (gyn exam) Age cut/by:early childhood / not stated |
| Iregbulem 1980 | N=10 | Nigeria | 3-20 | Type: 100% TII (gyn exam) Age cut/by: not stated |
| Ismail 1982 | N=290 | Somalia | ≥18 | Type: 9% TI, 6 % TII, 85% TIII (self-report) Age cut/by: 1-5 yrs/ 48% hcp, 52% tc |
| Jaleel 2002 | N=1 | England (Somalia) | 24 | Type:TIII (gyn exam) Age cut/by: 10 yrs / not stated |
| Knight 1999 | N=51 | Australia (multiple) | Mean 25 | Type: 6% TI, 14% TII, 78% TIII (gyn exam) Age cut/by: mean 6 yrs / 39% hcp, 61% tc |
| Kothe 1973 | N=1 | Germany (Sudan) | 28 | Type: TIII (gyn exam) Age cut/by: 7 yrs / not stated |
| Kristensen 2008 | N=2 | Denmark (not stated) | 27 and 39 | Type: 'female circumcision' (gyn exam) Age cut/by: childhood / not stated |
| Kroll 2000 | N=1 | USA (Eritrea) | 19 | Type: TI (gyn exam) Age cut/by: 8 weeks / not stated |
| Lashley 2009 | N=1 | Netherlands (Somalia) | 25 | Type: TIII (gyn exam) Age cut/by: not stated |
| Laycock 1950 | N=10 | Somalia | Mean 20 | Type: 100% TIII (gyn exam) Age cut/by: ca 13-15 yrs / not stated |
| Lenzi 1970 | N=4 | Somalia | Mean 23 | Type: 100% TIII (gyn exam) Age cut/by: 7-8 yrs / not stated |
| Lenzi 1969 | N=2 | Italy (not stated) | 20 and 25 | Type: TIII (gyn exam) Age cut/by: infancy / not stated |
| Litorp 2008 | N=40 | Sweden (Somalia, Eritrea) | Mean 31.8 | Type: most type I or II (self-report) Age cut/by: mean 6.1 yrs (0-12) / 38% tc |
| | | | | |

| MacLeod 1995 | N=1 | Canada ('African') | 23 | Type: 'female circumcison' (gyn exam) Age cut/by: 7 yrs / not stated |
|-------------------------------|--------|--------------------------------------|-------------------|--|
| Mandara 2004 | N=170 | Nigeria | not stated | Type: 31% TI, 57% TII, 5% TIII (gyn exam) Age cut/by: in childhood and puberty / 5% hcp, 18% tc |
| Mawad 1994 | N=934 | Sudan | not stated | Type: 'female circumcison' (gyn exam) Age cut/by: not stated |
| McCleary 1994 | N=1 | Canada (Somalia) | 25 | Type: TIII (gyn exam) Age cut/by: not stated |
| Millogo-Traore 2002 | N=3 | Burkina Faso | Mean 19 | Type: 100% TIII (gyn exam) Age cut/by: 6-14 yrs / not stated |
| Ministere de la Sante 1998 | N=1786 | Burkina Faso | Mean 27 | Type: 56% TI, 39% TII, 5% TIII (gyn exam) Age cut/by: mean 8 / 31% tc, 1% hcp |
| Modawi 1974 | N=3000 | Sudan | not stated | Type: 85% TIII (not stated) Age cut/by: not stated |
| Möller 2003 | N=1 | Denmark (Somalia) | 29 | Type: TIII (gyn exam) Age cut/by: 5 yrs / tc |
| Momoh 2001 | N=81 | England ('Africa') | Mean 27 | Type: 22% TI, 3% TII, 75% TIII (gyn exam) Age cut/by: median 7 yrs / 28% hcp |
| Moreira 2002 | N=3 | Senegal | Mean 24 | Type: 'excision' (gyn exam) Age cut/by: childhood / not stated |
| Morris 2005 | N=3 | USA (Somalia) | Mean 29 | Type: 100% TIII (gyn exam) Age cut/by: childhood / not stated |
| Mühlbach 1985 | N=1 | Germany (Sudan) | 28 | Type: TIII (gyn exam) Age cut/by: 6 yrs / hcp |
| Nour 2006 | N=1 | USA (Somalia) | 32 | Type: TIII (gyn exam) Age cut/by: not stated |
| Ofodile 1979 | N=19 | Nigeria | 15 mo – 30 yrs | Type: not stated (gyn exam) Age cut/by: not stated |
| Onuigbo 1974 | N=1 | Nigeria | 33 | Type: 'ritual circumcision' (gyn exam) Age cut/by: childhood / not stated |
| Orji 2006 | N=423 | Nigeria | Mean 33.7 | Type: 87% TI, 13% TII (gyn exam) Age cut/by:95% cut in childhood, 80% tc, 14% hcp |
| Osifo 2010 | N=37 | Nigeria | ≤ 21 | Type: 'traditional female genital mutilation' (gyn exam) Age cut/by: neonatal period / not stated |
| Osifo 2009 | N=51 | Nigeria | Mean 5.0 | Type: 41% TI, 59% TII (gyn exam) Age cut/by: not stated / 94% tc, 6% hcp |
| Oye 1976 | N=1 | Nigeria | 8 mo | Type: 'had circumcision' (gyn exam) Age cut/by: 8 days after birth / tc |
| Ozumba 1992 | N=78 | Nigeria | Mean 17 | Type: seems like TI-II (gyn exam) Age cut/by: mostly done in neonatal period / not stated |
| Pieters 1972 | N=2 | Somalia | 25 and 35 | Type: 100% TIII (gyn exam) Age cut/by: childhood / not stated |
| Rizk 2007 | N=2 | UAE ^b (Eritrea, Egypt) | 30 and 47 | Type: TI and TIII (gyn exam) Age cut/by: childhood / not stated |
| Rouzi 2010 | N=29 | Saudi Arabia | Mean 28 | Type: 'female genital mutilation' (unclear) Age cut/by: not stated |
| | | | | |

| Saad 1998 | N=9006 | Sudan | not stated | Type: 63% TIII (not stated) Age cut/by: not stated | |
|-------------|--------|----------------------|---------------|--|--|
| Saber 2009 | N=1 | Egypt | 21 | Type: TI (gyn exam) Age cut/by: 11 yrs / not stated | |
| Tahzib 1983 | N=1443 | Nigeria | Most 14-30 | Type: 100% TIV=gishiri cut ^c (gyn exam) Age cut/by: not stated | |
| Walker 1995 | N=4 | USA (Somalia) | 14-18 | Type: TII-III (gyn exam) Age cut/by: early childhood / not stated | |
| Yoong 2004 | N=1 | England (Somalia) | 29 | Type: TI (gyn exam) Age cut/by: 5 yrs / not stated | |

Legend: a= "balls of rock salt the size of a hen's egg are placed in the vagina by the patient's female relatives or the local handy woman" (Frith 1969 p82); b= UAE, United Arab Emirates; c= "cutting of the anterior and, rarely, the posterior aspect of the vagina with a razor blade" (Tahzib 1983 p388).

Outcomes

There were ten frequently reported outcomes regarding gynecological consequences in the 136 included studies (there was one study about psychological health outcomes among girls). Across the 42 comparative studies, the most frequently measured outcomes were infertility, HIV/STIs, problems with sexual intercourse, tissue damage, and vaginal discharge and itching. In this chapter, we present the data for the ten outcomes in the following order:

- Tissue damage (reported in 36 studies; 7 comparative, 29 non-comparative)
- Vaginal adhesions and obstruction (reported in 43 studies; 2 comparative, 41 non-comparative)
- Cysts (reported in 44 studies; 5 comparative, 39 non-comparative)
- Problems with urination and voiding (reported in 24 studies; 7 comparative, 17 non-comparative)
- Problems with menstruation (reported in 18 studies; 4 comparative, 14 non-comparative)
- Problems with sexual intercourse (reported in 27 studies; 9 comparative, 18 non-comparative)
- Infections of the reproductive and urinary tracts (reported in 18 studies; 7 comparative, 11 non-comparative)
- HIV and STIs (reported in 12 studies; 11 comparative, 1 non-comparative)
- Infertility (reported in 23 studies; 13 comparative, 10 non-comparative)
- Vaginal discharge, itching, and related vaginal complications (reported in 12 studies; 8 comparative, 4 non-comparative)
- Other (reported in 25 studies; 8 comparative, 17 non-comparative)

From the above list, it is clear that a great number of studies and a range of important outcomes for women's health met the inclusion criteria for this systematic review. Nonetheless, we preface the results of the rest of the chapter by underscoring that many of these sequels are relatively rare events. Therefore, there are also relatively few events that can be entered into analyses. In turn, the analyses are often

unable to establish whether there are statistically significant differences between groups being compared and the confidence intervals are wide. The accurate interpretation in these cases is that there is insufficient information available from these included studies to inform the question of difference in risk between groups.

In the following sections, the outcomes reported are focused on results from the 42 comparative studies. Results from the 94 non-comparative studies are located in appendix 5.

Outcome: Genital tissue damage

As delineated in the introduction, FGM/C comprises a range of procedures that involve removal or alteration of the female genital organs. The procedure has the potential to cause injury to healthy female genital tissue. We included 37 studies, seven of which were comparative studies, that reported on long-term damage to genital tissue, including scarring, keloid, abscess, fistula, and other genital tissue injury.

Scarring in female genital tissue

FGM/C vs no FGM/C

One comparative study reported on genital scarring in women with FGM/C and women with no FGM/C (69). As shown in table 5, 9% of women with FGM/C type II had genital scarring, compared to 1% of women with type I. There was no scarring observed in women without FGM/C. This study documented that there was a significantly greater risk of scar formation in women with FGM/C type I and in women with FGM/C type II compared to women with no FGM/C.

Table 5: Study outcomes and effect estimates for scarring (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted results RR (95%CI) |
|---------------|----------------|-------------------|-------------|---------------------------------|
| Okonofua 2002 | Scar formation | 6/590 (1.0%) TI | 0/1003 (0%) | 22.32 (1.26, 396.9) TI vs No |
| | | 19/202 (9.4%) TII | | 213.3 (12.82, 3547.9) TII vs No |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type II.

Comparison of types of FGM/C

Three studies reported scarring in women with various types of FGM/C (58;69;73). As the data in table 6 show, the frequency of scarring ranged from 0.4% among women with FGM/C type I, to 27.5% among women with FGM/C type II.

We note that Okonufua (69) stated that the unadjusted odds ratio for scarring in women with FGM/C type I vs type II was 0.10 (CI= 0.04, 0.25), and the adjusted odds ratio was 0.08 (CI= 0.03, 0.23). Both the unadjusted and adjusted result showed that there was a statistically lower risk of scarring in women with FGM/C type I than type II.

Table 6: Study outcomes and effect estimates for scarring (in types of FGM/C)

| Author, year Outcome FGM/C Type I | | | FGM/C Type II | FGM/C Type III | Unadjusted and adjusted results (95%CI) | |
|--------------------------------------|-------------------|----------------|------------------|-------------------|--|--|
| Kaplan 2011 | Abnormal scarring | 87/577 (15.1%) | 63/229 (27.5%) | 11/65 (16.9%) | RR= 0.55 (0.41, 0.73) TI vs TII RR= 0.89 (0.50, 1.58) TI vs TIII RR= 1.63 (0.91, 2.90) TII vs TIII | |
| Okonofua 2002 | Scar formation | 6/590 (1.0%) | 19/202 (9.4%) | | OR= 0.10 (0.04, 0.25) TI vs TII ^a Adjusted OR=0.08 (CI= 0.03, 0.23) ^b | |
| Shandall 1967 | Scarring | 3/807 (0.4%) | | 29/3013 (1.0%) | RR= 0.39 (0.12, 1.26) TI vs TIII | |

Legend: RR/OR= unadjusted relative risk/odds ratio with 95% confidence interval (CI), calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III. a= reported in publication. b= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first pregnancy, whether woman was married at first pregnancy, times pregnant at survey.

We carried out meta-analyses, pooling available data from two studies reporting on scarring in women who had either FGM/C type I or II (figure 3).

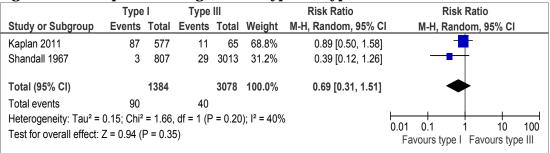
Figure 3: Forest plot, scarring (FGM/C type I vs type II)

| | Type | 1 | Type | II | | Risk Ratio | Risk F | Ratio |
|-----------------------------------|------------------------|----------|-------------|---------|--------------------------|---------------------|------------------------------|------------------------|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Random, 95% CI | M-H, Rando | om, 95% CI |
| Kaplan 2011 | 87 | 577 | 63 | 229 | 53.6% | 0.55 [0.41, 0.73] | - | |
| Okonofua 2002 | 6 | 590 | 19 | 202 | 46.4% | 0.11 [0.04, 0.27] | - | |
| Total (95% CI) | | 1167 | | 431 | 100.0% | 0.26 [0.05, 1.28] | | |
| Total events | 93 | | 82 | | | | | |
| Heterogeneity: Tau ² = | 1.23; Chi ² | = 11.48 | 3, df = 1 (| P = 0.0 | 007); I ² = 9 | 91% | | 10 100 |
| Test for overall effect: | Z = 1.66 (I | P = 0.10 | 0) | | | , | 0.01 0.1 1 Favours type I | 10 100 Favours type II |

The pooled result could not establish a statistically significant difference between women with FGM/C type I and II regarding scarring (RR= 0.26, CI= 0.05, 1.28). In these two studies, the absolute risk difference was 14 more cases of scarring among women with FGM/C type II per 100 woman (CI= 18 fewer to 5 more) compared to women with FGM/C type I. Considerable heterogeneity indicated by I² and Chi² (I²= 91%, Chi²= 11.5, p< 0.0007) showed inconsistency across the two studies, but both studies showed a significant difference. Using GRADE, we judged the quality of the evidence for this outcome as very low (table 36). The Summary of Findings (GRADE) tables are presented at the end of the results chapter and the GRADE Evidence profile tables are in appendix 6.

We conducted a second meta-analysis of scarring, in this analysis comparing women with FGM/C type I to women with FGM/C type III (figure 4).

Figure 4: Forest plot, scarring (FGM/C type I vs type III)



The pooled estimate could not establish a statistically significant difference between women with FGM/C type I and III regarding scarring (RR= 0.69, CI= 0.31, 1.51). In these two studies, the absolute risk difference was 0 more cases of scarring among women with FGM/C type III per 100 woman compared to women with FGM/C type I (CI= 1 fewer to 1 more). The quality of the evidence for this outcome is very low (table 37).

Keloids in female genital tissue

One type of tissue damage frequently reported in the FGM/C literature is the formation of keloids, which are thick scars resulting from excessive growth of fibrous tissue after tissue damage (figure 5).

Figure 5: Keloid



Source: Google images. Not subject to copyright.

FGM/C vs no FGM/C

One comparative study reported on keloid formation in women with FGM/C and women with no FGM/C (table 7). In this representative study from Sudan, 11 of 3102 women (0.4%) with FGM/C self-reported keloid, while no women who had not undergone FGM/C (n=39) reported that they had a keloid (47). A statistically significant difference could not be established between the two groups of women with respect to keloid.

Table 7: Study outcome and effect estimates for keloid (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted result RR (95%CI) | |
|-----------------------|---------|---------------------|-----------|------------------------------|--|
| El Dareer 1983 Keloid | | 0/80 (0%) TI | 0/39 (0%) | Not estimable TI vs No | |
| | | 11/3022 (0.4%) TIII | | 0.30 (0.02, 5.08) TIII vs No | |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TIII= FGM/C type III.

Comparison of types of FGM/C

Four studies collected data on keloids in women with various types of FGM/C (46;47;72;73). There was one publication from which data on keloids were not possible to extract and we did not succeed in obtaining data from the authors (46). In the representative study from Sudan, 0.4% of women with FGM/C self-reported keloids (47) (table 8). Across the studies, few women with FGM/C reported keloids (range=0-3.6%). In all of the studies, fewer women with FGM/C type I-II had keloids compared to women with FGM/C type III, although none of the studies could establish a statistically significant difference between the groups (table 8).

Table 8: Study outcomes and effect estimates for keloid (in types of FGM/C)

| Author, year Outcome | | FGM/C Type I-II | FGM/C Type III | Unadjusted results RR (95%CI) |
|----------------------|----------------------------------|-----------------|-----------------|-------------------------------|
| Diop 1989 | Keloid | No data | | |
| El Dareer 1983 | Keloid | 0/80 (0%) | 11/3022 (0.36%) | 0.34 (0.00, 171.20) ° |
| Rushwan 1983 | Painful scar/keloid ^a | 0/88 (0%) TI-II | 25/2203 (1.1%) | 0.49 (0.03, 7.91) |
| Shandall 1967 | Keloid formation ^b | 3/807(0.37%) | 107/3013 (3.6%) | 0.10 (0.03, 0.33) |
| Shandall 1967 | Keloid formation ^a | 0/227(0%) | 8/236 (3.4%) | 0.06 (0.00, 1.05) |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI-II= FGM/C type I-II. a= daughters. b= adult women. c= manually computed due to 0 events in one group and exceptionally different group sizes (cannot be accurately computed by RevMan).

In figure 6, we show the three studies that reported on keloid formation in women with either FGM/C type I-II or III. Across the two studies with estimable data on keloids, the difference between women with FGM/C type I-II and those with type III in frequency of developing keloids favored type I-II.

Figure 6: Forest plot, keloid (FGM/C type I-II vs type III)

| | type l | I-II | type | III | | Risk Ratio | Risk Ratio |
|-------------------|--------|-------|--------|-------|--------|---------------------|------------------------------------|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El Dareer 1983 | 0 | 0 | 0 | 0 | | Not estimable | |
| Rushwan 1983 | 0 | 88 | 25 | 2203 | | 0.49 [0.03, 7.91] | |
| Shandall 1967 | 3 | 1034 | 115 | 3249 | | 0.08 [0.03, 0.26] | |
| | | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | | Favours type I-II Favours type III |

Note: El Dareer 1983 not accurately estimable in RevMan due to 0 events in one group and exceptionally different group sizes.

Abscess in female genital tissue

The medical dictionary (169) describes abscess as a localized collection of pus surrounded by inflamed tissue. An abscess is often caused by breaks or cuts in the skin, such as cuts made in the FGM/C procedure. This allows germs to get into glands, which cause an inflammatory response. The response can occur shortly after injury to tissue, but also long after. Abscess is reported as a long-term complication in this systematic review because it was described as a "delayed" and "later complication" in the included studies reporting this outcome. The condition is depicted in figure 7.

Figure 7: Abscess



Source: Google images. Not subject to copyright.

FGM/C vs no FGM/C

We included three comparative studies that reported on abscess in women with FGM/C and women with no FGM/C (47;72;73). Abscess was a rare event. Across the studies, the frequency of abscess ranged from o-4.7% (table 9). In the representative study from Sudan, 4.6% of women with FGM/C and 0% of women without FGM/C self-reported abscess. None of the three included studies could establish a statistically significant difference in risk regarding abscess between women with and without FGM/C.

Table 9: Study outcomes and effect estimates for abscess (FGM/C vs no)

| Author, year Outcome | | FGM/C | No FGM/C | Unadjusted results RR (95%CI) | | |
|----------------------|---------------------|--|--------------|---|--|--|
| El Dareer 1983 | Abscess | 0/80 (0%) TI 143/3022 (4.7%) TIII | 0/39 (0%) | 1.00 TI vs No 3.80 (0.24, 59.94) TIII vs No | | |
| Rushwan 1983 | Abscess | 2/88 (2.3%) TI-II 52/2203 (2.3%) TIII | 1/211 (0.5%) | 4.80 (0.44, 52.21) TI-II vs No 4.98 (0.69, 35.84) TIII vs No | | |
| Shandall 1967 | Abscess of scar | 0/807 (0%) TI 12/3013 (0.4%) TIII | 0/204 (0%) | 1.00 TI vs No 1.70 (0.10, 28.62) TIII vs No | | |
| Shandall 1967 | Bartholin's abscess | 1/807 (0.1%) TI 3/3013 (0.1%) TIII | 1/204 (0.5%) | 0.25 (0.02, 4.02) TI vs No 0.20 (0.02, 1.94) TIII vs No | | |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type III.

The forest plot in figure 8 shows that across three studies with data on abscess, the risk in developing abscess varied between women with FGM/C and women who had not undergone FGM/C.

Figure 8: Forest plot, abscess (FGM/C vs no)

| | | | | | - | |
|-------------------|--------|-------|---------------|-------|---------------------|-------------------------------|
| | FGM/ | С | non-c | ut | Risk Ratio | Risk Ratio |
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El Dareer 1983 | 143 | 3102 | 0 | 39 | 3.70 [0.23, 58.40] | - 1 |
| Rushwan 1983 | 54 | 2291 | 1 | 211 | 4.97 [0.69, 35.77] | +++ |
| Shandall 1967 | 16 | 3820 | 1 | 204 | 0.85 [0.11, 6.41] | |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours FGM/C Favours non-cut |
| | | | | | | |

Comparison of types of FGM/C

Three studies provided data on abscess in women with various types of FGM/C (47;72;73). As shown in table 10, 0-4.7% of the women in the samples reported having abscess.

Table 10: Study outcomes and effect estimates for abscess (in types of FGM/C)

| Author, year | Outcome | FGM/C Type I | FGM/C Type III | Unadjusted results RR (95%CI) |
|----------------|--------------------------------|-------------------|-----------------|-------------------------------|
| El Dareer 1983 | Abscess | 0/80 (0%) | 143/3022 (4.7%) | 0.13 (0.01, 2.07) |
| Rushwan 1983 | Abscess | 2/88 (2.3%) TI-II | 52/2203 (2.4%) | 0.96 (0.24, 3.89) |
| Shandall 1967 | Abscess formation ^a | 0/227 (0%) | 3/236 (1.3%) | 0.15 (0.01, 2.86) |
| Shandall 1967 | Abscess formation ^b | 1/807(0.1%) | 34/3013 (1.1%) | 0.11 (0.02, 0.80) |
| Shandall 1967 | Abscess of scar ^b | 0/807(0%) | 12/3013 (0.4%) | 0.15 (0.01, 2.52) |
| Shandall 1967 | Bartholin's abscess b | 1/807 (0.1%) | 3/3013 (0.01%) | 1.24 (0.13, 11.95) |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI-II= FGM/C type I-II. a= daughters. b= adult women.

Figure 9 shows that across three studies with data on abscess, the difference between women with FGM/C type I-II and those with type III in frequency of developing abscess varied.

Figure 9: Forest plot, abscess (FGM/C type I-II vs type III)

| | type I | -II | type | III | Risk Ratio | Risk Ratio |
|-------------------|--------|-------|---------------|-------|---------------------|-----------------------------------|
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El Dareer 1983 | 0 | 80 | 143 | 3022 | 0.13 [0.01, 2.07] | ← |
| Rushwan 1983 | 2 | 88 | 52 | 2203 | 0.96 [0.24, 3.89] | |
| Shandall 1967 | 2 | 1034 | 52 | 3249 | 0.12 [0.03, 0.50] | |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours typel-II Favours type III |

Fistula in female genital tissue

A fistula is an abnormal passage that leads from an abscess or hollow organ or part to the body surface or from one hollow organ or part to another. An example is vesicovaginal fistula, in which there is an opening or passage between the urinary bladder and the vagina.

We included one comparative study that reported on fistula in women with and without FGM/C (65). Table 11 shows that the study was unable to establish a statistically significant difference between the two groups of women with respect to vesicovaginal fistula.

Table 11: Study outcomes and effect estimates for fistula (FGM/C vs no)

| Author, year | Outcome | FGM/C TI-III | No FGM/C | Unadjusted result RR (95%CI) |
|--------------|-----------------------|--------------|--------------|------------------------------|
| Morison 2001 | Vesicovaginal fistula | 0/589 (0%) | 1/452 (0.2%) | 0.26 (0.01, 6.27) |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type III.

Damaged female genital tissue

There were two comparative studies that reported on damaged tissue in relation to FGM/C, such as disfigurement and damaged perineum. As evident in table 13, one study compared women who had undergone FGM/C type I with women who had undergone no FGM/C (65), while the other study included both women with various types of FGM/C and women with no FGM/C (69). The frequency of damaged tissue in women varied across type of tissue damage and genital alteration.

None of these studies could establish a statistically significant difference, neither in unadjusted analyses nor adjusted analyses, between women with FGM/C type I and women with no FGM/C, with regards to damaged perineum and insufficient anal sphincter (table 12). However, one study found that women with FGM/C had a significantly higher risk of disfigurement: Unadjusted results showed that women with FGM/C type I and type II had a significantly higher risk of disfigurement than women with rown of FGM/C. Both the unadjusted and adjusted results showed that women with FGM/C type I had a significantly higher risk of disfigurement than women with type II.

Table 12: Study outcomes and effect estimates for damaged tissue (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted and adjusted results (95%CI) |
|---------------|-----------------------------|--------------------|-----------------|---|
| Morison 2001 | Damaged perineum | 336/546 (61.5%) TI | 240/427 (56.2%) | RR= 1.09 (0.98, 1.22) TI vs No OR=1.25 (0.96, 1.61) TI vs No Adjusted OR= 1.24 (0.95, 1.63) TI vs No ^a |
| Morison 2001 | Insufficient anal sphincter | 17/526 (3.2%) TI | 16/421 (3.8%) | RR= 0.85 (0.43, 1.66) TI vs No OR=0.85 (0.42, 1.69) TI vs No Adjusted OR= 0.81 (0.40, 1.64) TI vs No b |
| Okonofua 2002 | Disfigurement | 25/590 (4.2%) TI | 0/1003 (0%) | OR=90.5 (5.50, 1489.4) TI vs No RR= 86.64 (5.28, 1420.5) TI vs No |
| Okonofua 2002 | Disfigurement | 7/202 (3.5%) TII | 0/1003 (0%) | RR= 74.19 (4.25, 1293.8) TII vs No OR= 76.99 (5.50, 1489.4) TII vs No |

OR= 0.51 (0.30, 0.87) TI vs TII $^{\circ}$ OR= 0.38 (0.20, 0.74) TI vs TII d

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI). All RR/OR are unadjusted and calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II. a= adjusted for age, marital status, parity; b= adjusted for age, parity. c= reported in publication. d (Okonofua 2002)= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first pregnancy, whether woman was married at first pregnancy, times pregnant at survey.

What we know about tissue damage

- It is uncertain whether there is a difference in the risk of scarring between women with FGM/C and women with no FGM/C. It is also uncertain whether there is a difference in the risk of scarring between women with FGM/C type I and women with FGM/C type II or type III.
- It is uncertain whether there is a difference in the risk of developing keloids between women with FGM/C type I-II and women with FGM/C type III.
- It is uncertain whether there is a difference in the risk of developing abscess between women with FGM/C and women without FGM/C. It is also uncertain whether there is a difference in the risk of developing abscess between women with FGM/C type I-II and women with FGM/C type III.
- It is uncertain whether there is a difference in the risk of fistula between women with FGM/C and women with no FGM/C.
- It is uncertain whether there is a difference in the risk of having damaged tissue (damaged perineum, insufficient anal sphincter, disfigurement), between women with FGM/C type I and women with no FGM/C. It is also uncertain whether there is a difference in the risk of having disfigurement between women with FGM/C type I and women with FGM/C type II.

Outcome: Vaginal obstruction

FGM/C related literature sometimes explains that one gynecological consequence of the genital alteration procedure is urinary- and genital tract obstruction, for example because the vaginal lips (labia minora and labia majora) become fused together thus covering the vaginal vestibule. We included two comparative studies that reported obstruction (table 13). In the publication by Diop and colleagues (46), data on stenosis and vaginal occlusion were not possible to extract and we did not succeed in obtaining data from the authors.

It was possible to extract data from the study by Okonofua and colleagues (69). As seen in table 13, this study showed that the risk of a narrowed introitus was statistically higher (in unadjusted analyses) for women with FGM/C type II compared to women with no FGM/C, and (in both unadjusted and adjusted analyses) for women with FGM/C type II compared to women with type I.

Table 13: Study outcomes and effect estimates for vaginal obstruction

| Author, year | Outcome | FGM/C Type I | FGM/C Type II | No FGM/C | Unadjusted and adjusted results (95%CI) |
|---------------|--------------------|-----------------|------------------|-------------|--|
| Diop 1998 | Stenosis | No data | _ | | |
| Diop 1989 | Vaginal occlusion | No data | | | |
| Okonofua 2002 | Narrowed introitus | 4/590 (0.7%) | | 0/1003 (0%) | RR=15.29 (0.82, 283.5) |
| Okonofua 2002 | Narrowed introitus | | 7/202 (3.5%) | 0/1003 (0%) | RR=74.2 (4.25, 1293.8) |
| Okonofua 2002 | Narrowed introitus | 4/590 (0.7%) | 7/202 (3.5%) | | RR= 0.20 (0.06, 0.66) OR= 0.19 (0.06, 0.66) ^a Adjusted OR= 0.19 (0.04, 0.83) ^b |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI). All RR/OR are unadjusted and calculated by the SR authors unless otherwise noted. a= OR reported in publication. b= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first pregnancy, whether woman was married at first pregnancy, times pregnant at survey.

What we know about vaginal obstruction

• It is uncertain whether there is a difference in the risk of experiencing vaginal obstruction between women with FGM/C (type I or II) compared to women with no FGM/C. It is also uncertain whether there is a difference in the risk of experiencing vaginal obstruction and occlusion between women with FGM/C type I and type II.

Outcome: Cysts

We identified numerous studies that documented cysts in women with FGM/C. A cyst is a closed sac that has a distinct membrane and develops abnormally in a body structure (figure 10).

Figure 10: Cyst on genital area of a woman



Source: Google images. Not subject to copyright.

FGM/C vs no FGM/C

Four comparative studies provided data on cysts in women with FGM/C and women with no FGM/C (47;65;69;73) (table 14). One of the studies was a representative

household study from Sudan (47). It showed that 0.6% of women with FGM/C self-reported having an inclusion cyst and 0% of women without FGM/C reported having a cyst. In the individual studies, there were generally no statistically significant differences in the frequency of cysts in women with FGM/C compared to women who had not undergone FGM/C. One study reported an adjusted result: Morison and colleagues (65) were unable to establish a statistically significant difference between women with FGM/C and women without FGM/C with regards to having cysts (OR=1.75, CI=0.77, 3.99, adjusting for age and parity).

Table 14: Study outcomes and effect estimates for cyst (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted results RR (95%CI) |
|----------------|---------------------------|---------------------|--------------|-----------------------------------|
| El Dareer 1983 | Inclusion cyst | 0/80 (0%) TI | 0/39 (0%) | 1.00 |
| El Dareer 1983 | Inclusion cyst | 19/3022 (0.6%) TIII | 0/39 (0%) | 2.47 (0.00, 1222.51) ^a |
| Morison 2001 | Cyst | 18/654 (2.7%) Tns | 9/481 (1.9%) | 1.47 (0.67, 3.25) |
| Okonofua 2002 | Cyst | 15/590 (2.5%) TI | 0/1003 (0%) | 52.66 (3.16, 878.52) |
| Okonofua 2002 | Cyst | 9/202 (4.5%) TII | 0/1003 (0%) | 93.97 (5.49, 1608.1) |
| Shandall 1967 | Bartholin's cyst | 1/807 (0.1%) TI | 1/204 (0.5%) | 0.25 (0.02, 4.02) |
| Shandall 1967 | Bartholin's cyst | 4/3013 (0.1%) TIII | 1/204 (0.5%) | 0.27 (0.03, 2.41) |
| Shandall 1967 | Implantation dermoid cyst | 2/807 (0.3%) TI | 0/204 (0%) | 1.27 (0.06, 26.32) |
| Shandall 1967 | Implantation dermoid cyst | 51/3013 (1.7%) TIII | 0/204 (0%) | 7.01 (0.43, 113.11) |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III; Tns= FGM/C type not specified. a= manually computed due to zero number of events in one group and exceptionally different group sizes (cannot be accurately computed by RevMan).

We conducted meta-analysis of the outcome cyst, pooling results from three studies comparing women with FGM/C to women with no FGM/C (figure 11). Data on cysts were based on clinical assessment in these three studies (in the study by El-Dareer (47), measurement of cyst was based on self-report and it was therefore not included in the meta-analysis).

Figure 11: Forest plot, cysts (FGM/C vs no)

| | FGM. | C | non-c | ut | | Risk Ratio | Risk Ratio | |
|--|--------|-------|--------|----------|--------------------------------------|-----------------------|--------------------|---------------|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Random, 95% CI | M-H, Random, 95% C | <u> </u> |
| Morison 2001 | 18 | 654 | 9 | 481 | 41.7% | 1.47 [0.67, 3.25] | + | |
| Okonofua 2002 | 24 | 792 | 0 | 1003 | 22.3% | 62.04 [3.78, 1018.56] | | - |
| Shandall 1967 | 58 | 3820 | 2 | 204 | 35.9% | 1.55 [0.38, 6.30] | - | |
| Total (95% CI) | | 5266 | | 1688 | 100.0% | 3.45 [0.54, 22.17] | | - |
| Total events | 100 | | 11 | | | | | |
| Heterogeneity: Tau ² = Test for overall effect: 2 | | | • | 9 = 0.00 | 9); I ² = 79 ⁰ | % I | 0.01 | 100 on-cut |

Figure 11 shows that the pooled relative risk of cyst was 3.45 (CI=0.54, 22.17) in women with FGM/C. The pooled result could not establish a statistically significant difference in risk between the two groups of women. The absolute risk difference

was 2 more cases of cysts among women with FGM/C per 100 woman (CI= o fewer to 14 more) compared to women without FGM/C. There was considerable heterogeneity, indicated by I^2 and Chi^2 ($I^2=79\%$, $Chi^2=9.41$, p=0.009). The quality of the evidence for this outcome is very low (table 34). The meta-analytic result was based on unadjusted results from three studies. We note that the pooled result, which could not establish a statistically significant difference in risk between women with and without FGM/C with regards to cysts, is similar to the adjusted result reported by Morison and colleagues (65), shown above.

Comparison of types of FGM/C

There were four comparative studies that provided data on cysts in women with various types of FGM/C (table 15). Across the five individual outcomes there was one statistically significant difference: in the largest study, the risk of cysts was lower in women with FGM/C type I than type III. There was one adjusted result reported. Okonofua and colleagues (69) were unable to establish a statistically significant difference between women with FGM/C type I and those with type II with respect to cysts (OR=0.52, CI=0.18, 1.51, adjusting for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first pregnancy, whether woman was married at first pregnancy, times pregnant at survey. The unadjusted result for this outcome was reported OR= 0.56, CI=0.24, 1.30).

Table 15: Study outcomes and effect estimates for cyst (in types of FGM/C)

| Author, year | Outcome | FGM/C Type I-II | FGM/C Type III | Unadjusted results RR (95%CI) |
|----------------|---------------------------|--------------------------------------|----------------|-------------------------------|
| El Dareer 1983 | Inclusion cyst | 0/80 (0%) TI | 19/3022 (0.6%) | RR= 0.96 (0.06, 15.71) |
| Okonofua 2002 | Cyst | 15/590 (2.5%) TI 9/202 (4.5%) TII | | RR= 0.57 (0.25, 1.28) |
| Rushwan 1983 | Inclusion cyst | 3/88 (3.4%) TI-II | 41/2203 (1.9%) | RR= 1.83 (0.58, 5.80) |
| Shandall 1967 | Bartholin's cyst | 1/807 (0.1%) TI | 4/3013 (0.1%) | RR= 0.93 (0.10, 8.34) |
| Shandall 1967 | Implantation dermoid cyst | 2/807 (0.2%) TI | 51/3013 (1.7%) | RR= 0.15 (0.04, 0.60) |

Legend: RR= relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III.

As shown in figure 12, the risk of cyst development in women with FGM/C type I versus type III varied across the three studies that reported on this outcome.

Figure 12: Forest plot, cysts (FGM/C type I-II vs type III)

| | type | I | type | III | Risk Ratio | Risk Ratio |
|-------------------|--------|-------|---------------|-------|---------------------|---------------------------------|
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El Dareer 1983 | 0 | 80 | 19 | 3022 | 0.96 [0.06, 15.71] | |
| Rushwan 1983 | 3 | 88 | 41 | 2203 | 1.83 [0.58, 5.80] | ++- |
| Shandall 1967 | 3 | 807 | 55 | 3013 | 0.20 [0.06, 0.65] | |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours type I Favours type III |

What we know about cysts

- It is uncertain whether there is a difference in the risk of developing cysts between women with FGM/C and women without FGM/C.
- It is uncertain whether there is a difference in the risk of developing cysts between women with FGM/C type I-II and women with FGM/C type III, and between women with FGM/C type I and women with FGM/C type II.

Outcome: Problems with urination

Urological complications have been reported to occur following FGM/C. We included five comparative studies that had measured complications related to urination in women with FGM/C and women without FGM/C (40;46;49;65;69). In one publication, extractable data were not available and we did not succeed in obtaining data from the authors (46). As seen in table 16, across the four studies with extractable data, 4-26% of women with FGM/C and 2-20% of women without FGM/C experienced problems with urination. None of these four studies could establish a statistically significant difference, neither in unadjusted analyses nor in adjusted analyses, between the groups of women with respect to problems with urination.

Table 16: Study outcomes and effect estimates for problems with urination (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted and adjusted results (95%CI) |
|---------------|------------------------------|----------------------|----------------|---|
| Browning 2010 | Persistent incontinence | 61/236 (25.8%) TI-II | 46/228 (20.2%) | RR= 1.28 (0.91, 1.79) |
| Browning 2010 | Urinary retention | 15/236 (6.4%) TI-II | 17/228 (7.5%) | RR= 0.85 (0.44, 1.67) |
| Diop 1998 | Urinary retention | No data | | |
| Diop 1998 | Incontinence | No data | | |
| Elnashar 2007 | Burning micturation | 24/200 (12.0%) Tns | 3/64 (4.7%) | RR= 2.56 (0.80, 8.22) |
| Elnashar 2007 | Involuntary micturation | 39/200 (19.5%) Tns | 7/64 (10.9%) | RR= 1.78 (0.84, 3.79) |
| Morison 2001 | Difficulty controlling urine | 41/597 (6.9%) TI-III | 36/458 (7.9%) | RR= 0.87 (0.57, 1.34) OR= 0.86 (0.54, 1.38) Adjusted OR= 0.80 (0.48, 1.33) ^a |
| Okonofua 2002 | Painful/burning urination | 30/825 (3.6%) TI-IV | 22/1003 (2.2%) | RR= 1.66 (0.96, 2.85) OR= 1.68 (0.96, 2.94) b Adjusted OR= 1.29 (0.65, 2.57) c |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI). All RR/OR are unadjusted and calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III; TIV= FGM/C type IV; Tns= FGM/C type not specified. a= adjusted for age, marital status, parity. b= reported in publication. c= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first sex, whether woman was married at first sex, frequency of sex in last month, times pregnant at survey. In Okonofua (2002) FGM/C type IV was described as unclassified type of FGM/C that included any or other procedures or manipulations of the genitalia (not type I-III).

Figure 13 shows that the risk of incontinence in women with FGM/C versus women with no FGM/C varied across the three studies that reported on this outcome.

Figure 13: Forest plot, incontinence (FGM/C vs no)

| | | | | - | | |
|-------------------|--------|-------|---------------|-------|---------------------|-------------------------------|
| | FGM/ | С | non-c | ut | Risk Ratio | Risk Ratio |
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| Browning 2010 | 61 | 236 | 46 | 228 | 1.28 [0.91, 1.79] | 1- |
| Elnashar 2007 | 39 | 200 | 7 | 64 | 1.78 [0.84, 3.79] | ++ |
| Morison 2001 | 41 | 597 | 36 | 458 | 0.87 [0.57, 1.34] | + |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours FGM/C Favours non-cut |
| | | | | | | |

As shown in figure 14, two comparative studies reported on the outcome burning/painful urination. In both studies, there was a non-statistically significant trend for a greater risk of burning/painful urination among women who had undergone FGM/C.

Figure 14: Forest plot, burning/painful urination (FGM/C vs no)

| | FGM/ | C | non-c | ut | Risk Ratio | Risk Ratio |
|-------------------|--------|-------|---------------|-------|---------------------|-------------------------------|
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| Elnashar 2007 | 24 | 200 | 3 | 64 | 2.56 [0.80, 8.22] | ++- |
| Okonofua 2002 | 30 | 825 | 22 | 1003 | 1.66 [0.96, 2.85] | |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours FGM/C Favours non-cut |
| | | | | | | |

What we know about problems with urination

- It is uncertain whether there is a difference in the risk of suffering from incontinence between women with FGM/C and women without FGM/C.
- It is uncertain whether there is a difference in the risk of suffering burning/painful urination between women with FGM/C and women without FGM/C, but there seems to be a trend for the risk to be greater among women with FGM/C.

Outcome: Problems with menstruation

Some women experience problems with their menstrual cycle. Dysmenorrhea refers to painful menstruation.

FGM/C vs no FGM/C

We included five comparative studies that provided data on outcomes related to menstruation in women with and without FGM/C (47-49;65;72). These studies' results are shown in table 17. There was one representative study from Sudan (47), showing that 1.3% of women with FGM/C self-reported a menstruation-related problem, and 0% of women without FGM/C reported such a problem. Across the

studies, o-81% of women with FGM/C and o-56% of women without FGM/C had menstruation-related problems. The studies reported several significant differences between the women with respect to menstruation problems. The studies by El-Defrawi (48) and Elnashar (49) showed that women with FGM/C had a greater risk of experiencing dysmenorrhea and irregular menses compared to women without FGM/C. In contrast, Morison and colleagues (65) found that women with FGM/C had a lower risk of menstrual problems than women who had not undergone FGM/C. This study also provided adjusted results: Morison and colleagues (65) found that menstrual problems in women with FGM/C – when adjusting for age, marital status, and parity – showed an OR= 0.74 (CI=0.50, 1.11). That is, in adjusted analyses, contrary to unadjusted analyses, the study was unable to establish a statistically significant difference between women with and without FGM/C with regards to menstrual problems.

Table 17: Study outcomes and effect estimates for problems with menstruation (FGM/C vs no)

| (FGM/C VS II | 10) | | | |
|-----------------|-----------------------------------|------------------------|----------------|----------------------------------|
| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted results RR (95%CI) |
| El Dareer 1983 | Difficulty in menstruation | 0/80 (0%) TI | 0/39 (0%) | 1.00 |
| El Dareer 1983 | Difficulty in menstruation | 39/3022 (1.3%) TIII | 0/39 (0%) | 1.05 (0.07, 16.71) |
| El-Defrawi 2001 | Dysmenorrhea | 161/200 (80.5%) TI-II | 28/50 (56%) | 1.44 (1.11, 1.86) |
| Elnashar 2007 | Irregular menses | 40/200 (20.0%) Tns | 5/64 (7.8%) | 2.56 (1.06, 6.21) |
| Elnashar 2007 | Moderate-severe dysmenorrhea | 80/200 (40.0%) Tns | 12/64 (18.8%) | 2.13 (1.25, 3.65) |
| Morison 2001 | Menstrual problems | 100/305 (32.8%) TI-III | 78/182 (42.9%) | 0.77 (0.61, 0.97) |
| Rushwan 1983 | Difficult passing menstrual blood | 0/8 (0%) TI-II | 6/211 (2.8%) | 0.43 (0.00, 212.47) a |
| Rushwan 1983 | Difficult passing menstrual blood | 110/2203 (5.0%) TIII | 6/211 (2.8%) | 1.76 (0.78, 3.95) |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III; Tns= FGM/C type not specified. a= manually computed due to 0 events in one group and exceptionally different group sizes (cannot be accurately computed by RevMan).

In figure 15, we show the five studies that reported on a menstruation problem in women who had FGM/C or no FGM/C. And in figure 16 we show the two studies that compared women with FGM/C type III and women with no FGM/C. Both figures suggest that the risk of menstruation-related problems between women with FGM/C and women with no FGM/C may be greater among women with FGM/C.

Figure 15: Forest plot, problems with menstruation (FGM/C vs no)

| | FGM/C | | non-cut | | Risk Ratio | Risk Ratio |
|-------------------|--------|-------|---------------|-------|---------------------|-------------------------------|
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El Dareer 1983 | 39 | 3102 | 0 | 39 | 1.02 [0.06, 16.28] | |
| El-defrawi 2001 | 161 | 200 | 28 | 50 | 1.44 [1.11, 1.86] | + |
| Elnashar 2007 | 120 | 200 | 17 | 64 | 2.26 [1.48, 3.45] | + |
| Morison 2001 | 100 | 305 | 78 | 182 | 0.77 [0.61, 0.97] | + |
| Rushwan 1983 | 110 | 2211 | 6 | 211 | 1.75 [0.78, 3.93] | ++- |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours FGM/C Favours non-cut |

Figure 16: Forest plot, problems with menstruation (FGM/C type III vs no)

| | type | III | non-c | ut | Risk Ratio | Risk Ratio |
|-------------------|--------|-------|---------------|-------|---------------------|----------------------------------|
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El Dareer 1983 | 39 | 3022 | 0 | 39 | 1.05 [0.07, 16.71] | |
| Rushwan 1983 | 110 | 2203 | 6 | 211 | 1.76 [0.78, 3.95] | ++- |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours type III Favours non-cut |

Comparison of types of FGM/C

Two studies included data concerning problems with menstruation in women with various types of FGM/C (47;72). As seen in table 18, neither study was able to establish a significant difference between women with various types of FGM/C. However, we note that there were no participants in the group of women who had undergone FGM/C type I-II who reported difficulty in menstruation while 1-5% of women with type III did.

Table 18: Study outcomes and effect estimates for problems with menstruation (in types of FGM/C)

| Author, year | Outcome | FGM/C Type I-II | FGM/C Type III | Unadjusted results RR (95%CI) |
|----------------|-----------------------------------|--------------------|----------------------|----------------------------------|
| El Dareer 1983 | Difficulty in menstruation | 0/80 (0%) TI | 39/3022 (1.3%) TIII | 0.10 (0.00, 47.64) a |
| Rushwan 1983 | Difficult passing menstrual blood | 0/8 (0%) TI-II | 110/2203 (5.0%) TIII | 0.25 (0.00, 117.28) a |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type III. a= manually computed due to 0 events in one group and exceptionally different group sizes (cannot be accurately computed by RevMan).

What we know about problems with menstruation

- It is uncertain whether there is a difference in the risk of experiencing problems with menstruation between women with FGM/C and women without FGM/C, but there seems to be a trend for the risk to be greater among women with FGM/C.
- It is uncertain whether there is a difference in the risk of experiencing problems with menstruation between women with FGM/C type I-II and women with FGM/C type III.

Outcome: Pain during intercourse

In a previous systematic review we examined the consequences of FGM/C on women's sexual functioning, such as desire, satisfaction, and orgasm (16). Such sexual functioning outcomes are therefore not covered here, but we included the complication pain and similar physical problems during intercourse (e.g. bleeding and difficulty with penetration).

FGM/C vs no FGM/C

Six comparative studies presented data regarding pain and bleeding during sexual intercourse in women with and without FGM/C (48;49;65;68;69;72). These are presented in table 19. While the frequency of reported pain during intercourse varied across the studies, it was generally higher in women with FGM/C (1-46%) relative to women without FGM/C (0-32%). There was one statistically significant difference at study level: in the study by Elnashar (49), women with FGM/C had a greater risk of dyspareunia (pain during intercourse) than women without FGM/C. However, the two adjusted results by Morison and colleagues (65) and Okonofua and colleagues (69) found no statistically significant difference between the two groups of women.

Table 19: Study outcomes and effect estimates for pain and bleeding during sexual intercourse (FGM/C vs no)

| | 150 (1 41111 0 15 110 | • • | | |
|-----------------|-------------------------|-----------------------|----------------|---|
| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted and adjusted results (95%CI) |
| El-Defrawi 2001 | Dyspareunia | 92/200 (46.0%) TI-II | 16/50 (32.0%) | RR= 1.44 (0.93, 2.21) |
| Elnashar 2007 | Dyspareunia | 81/200 (40.5%) Tns | 12/64 (18.7%) | RR= 2.16 (1.26, 3.70) |
| Morison 2001 | Painful sex | 62/394 (15.7%) TI-III | 47/329 (14.3%) | RR= 1.10 (0.78, 1.56) OR=1.12 (0.74, 1.69) Adjusted OR=1.09 (0.71, 1.66) ^a |
| Odoi 1997 | Persistent dyspareunia | 10/76 (13.2%) TI-II | 6/119 (5.0%) | RR= 2.61 (0.99, 6.89) |
| Odoi 1997 | Post-coital bleeding | 4/76 (5.3%) TI-II | 0/119 (0%) | RR=14.03 (0.77, 256.9) |
| Okonofua 2002 | Pain during intercourse | 30/825 (3.6%) TI-IV | 23/1003 (2.3%) | RR= 1.59 (0.93, 2.71) OR=1.61(0.93,2.79) ^b Adjusted OR= 1.48 (0.76, 2.87) ^c |
| Rushwan 1983 | Pain during intercourse | 1/88 (1.1%) TI-II | 6/211 (2.8%) | RR= 0.40 (0.05, 3.27) |
| Rushwan 1983 | Pain during intercourse | 125/2203 (5.7%) TIII | 6/211 (2.8%) | RR= 2.00 (0.89, 4.47) |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI). All RR/OR are unadjusted and calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III; TIV= FGM/C type IV. a= adjusted for age, marital status, parity. b= reported in publication. c= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first sex, whether woman was married at first sex, frequency of sex in last month, times pregnant at survey. In Okonofua (2002) FGM/C type IV was described as unclassified type of FGM/C that included any or other procedures or manipulations of the genitalia (not type I-III).

As shown in figure 17, in the six included studies, the estimated risk of pain during intercourse was consistently higher among women with FGM/C compared to women who had not undergone the procedure.

Figure 17: Forest plot, dyspareunia/pain during intercourse (FGM/C vs no)

| U | | ~ . | | - | U | |
|-------------------|--------|-------|--------|-------|---------------------|--|
| | FGM | C | non-c | ut | Risk Ratio | Risk Ratio |
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El-defrawi 2001 | 92 | 200 | 16 | 50 | 1.44 [0.93, 2.21] | - |
| Elnashar 2007 | 81 | 200 | 12 | 64 | 2.16 [1.26, 3.70] | + |
| Morison 2001 | 62 | 394 | 47 | 329 | 1.10 [0.78, 1.56] | + |
| Odoi 1997 | 10 | 76 | 6 | 119 | 2.61 [0.99, 6.89] | |
| Okonofua 2002 | 30 | 825 | 23 | 1003 | 1.59 [0.93, 2.71] | +- |
| Rushwan 1983 | 126 | 2291 | 6 | 211 | 1.93 [0.86, 4.33] | +- |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours FGM/C Favours non-cut |
| | | | | | | |

One study measured pain during sex as a continuous outcome (42). The pain score in the FGM/C group was 3.5 (SD=1.0) and in the non-FGM/C group it was 3.8 (SD=1.1). The authors stated that there was no statistically significant difference between the groups in their average pain score, but no statistical results were provided in the publication.

Comparison of types of FGM/C

Three comparative studies provided data concerning problems with sexual intercourse in women with various types of FGM/C (50;51;72). The two included DHS reports were representative household studies from Eritrea (table 20). They showed that the average frequency of women self-reporting problems during sexual relations was 1% in women with FGM/C type IV, 5% in women with type I-II, and 18% in women with type III. As table 20 shows, for almost all the outcomes there was a statistically significant difference between the groups. In all of these cases, the more invasive type of FGM/C was associated with greater risk of problems with sexual intercourse. All results were unadjusted.

Table 20: Study outcomes and effect estimates for pain and problems during sexual intercourse (in types of FGM/C)

| Author, year | Outcome | FGM/C Type I-II | FGM/C Type II and IV | FGM/C Type III | Unadjusted results RR (95%CI) |
|------------------|----------------------------------|---------------------|-------------------------|-------------------|--|
| Eritrea DHS 2002 | Problems during sexual relations | 15/234 (6.4%) TI-II | 25/2779 (1.0%) TIV | 373/2556 (14.6%) | 0.44 (0.27, 0.72) TI-II vs TIII 7.13 (3.81, 13.33) TI-II vs TIV 16.22 (10.86, 24.23) TIII vs TIV |
| Eritrea DHS 1995 | Problems during sexual relations | 60/2240 (2.7%) TI | 58/190 (30.5%) TII | 360/1444 (24.9%) | 0.08 (0.06, 0.11) TI vs TII 0.10 (0.08, 0.13) TI vs TIII 1.22 (0.97, 1.54) TII vs TIII |
| Rushwan 1983 | Pain during intercourse | 1/88 (1.1%) TI-II | | 125/2203 (5.7%) | 0.20 (0.03, 1.42) TI-II vs TIII |
| Rushwan 1983 | Difficult/no penetration | 2/88 (2.3%) TI-II | | 213/2203 (9.7%) | 0.24 (0.06, 0.93) TI-II vs TIII |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III; TIV= FGM/C type IV.

Figure 18 shows that in the two studies that reported on problems during sexual relations, the risk of problems was consistently lower among women with FGM/C type I-II compared to type III. The result was statistically significant in both studies.

Figure 18: Forest plot, problems with sexual intercourse (FGM/C type I-II vs type III)

| | type I | -II | type | III | Risk Ratio | Risk | Ratio |
|-------------------|---------------|-------|---------------|-------|---------------------|-------------------|-----------------|
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Rand | om, 95% CI |
| Eritrea DHS 1995 | 118 | 2430 | 360 | 1444 | 0.19 [0.16, 0.24] | + | |
| Eritrea DHS 2002 | 15 | 234 | 373 | 2556 | 0.44 [0.27, 0.72] | + | |
| | | | | | | 0.01 0.1 | 1 10 100 |
| | | | | | | Favours type I-II | |
| | | | | | | r avouro typo r n | r avouro typo m |

What we know about problems with sexual intercourse

- The risk of suffering pain during intercourse between women with FGM/C and women without FGM/C seems to favor not having FGM/C.
- The risk of suffering problems during intercourse between women with FGM/C type I-II and women with FGM/C type III seems to favor FGM/C type I-II.

Outcome: Infections of the reproductive and urinary tracts

FGM/C vs no FGM/C

In table 21, we present the ten included studies that reported on infection of the reproductive and urinary tracts in women with and without FGM/C (41;45;47;52;56;60;65;66;72;73). There were three publications from which unadjusted data on infections were not possible to extract and we did not succeed in obtaining data from the authors (52;56;60). Two results (47;52) were based on representative studies, from Sudan and Burkina Faso, respectively. In these studies, the frequency of self-reporting chronic pelvic infection (pelvic inflammatory disease) was 7.8% in women with FGM/C and 7.7% in women without FGM/C. The frequency of self-reporting recurrent urinary tract infection was 9.1% in women with FGM/C and 10.3% in women without FGM/C. Across all studies, the frequency of infections varied, from 1-56% among women with FGM/C and 1-30% among those without the procedure. In general, the study level results showed that a higher proportion of women with FGM/C had infections than women without FGM/C, and the difference was more pronounced when women had FGM/C type III than a type of lesser anatomical extent.

There were four adjusted results. Fillo and Leone (52) found a statistically higher risk of reproductive tract infections in women with FGM/C compared to women without FGM/C (OR=1.54). Jones and colleagues (56) explained that the adjusted result for FGM/C vs non-FGM/C with regards to genital infection showed that women with FGM/C in Burkina Faso were at greater risk of genital infection

(OR=1.72). There were two adjusted results with regards to bacterial vaginosis. The effect estimate in Klouman (60) failed to establish statistical significance in adjusted analyses. In contrast, Morison (65) found that women with FGM/C were at greater risk of bacterial vaginosis (OR=1.66). We also note that Almroth and colleagues (41) stated that "girls who were found by inspection to have a form of FGM that narrowed the vulva had significantly more urinary tract infections, according to the criteria, than others (57% and 30%, respectively) (OR= 3.0, 95%CI= 1.2, 8.0)." It is unclear which groups are compared (FGM/C vs no, or different types of FGM/C).

Table 21: Study outcomes and effect estimates for infections of the reproductive

and urinary tracts (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted and adjusted results (95%CI) |
|----------------|--|--|-----------------|---|
| Almroth 2005b | Urinary tract infection (UTI) | 5/16 (31.3%) TI-II 18/32 (56.3%) TIII | 61/203 (30.0%) | RR= 1.04 (0.49, 2.22) TI-II vs No RR= 1.87 (1.29, 2.71) TIII vs No |
| De Silva 1989 | Urinary tract infection (UTI) | 47/153 (30.7%) TI-III | 101/1691 (6.0%) | RR= 5.14 (3.80, 6.97) |
| De Silva 1989 | Reproductive tract infection/vaginitis | 53/108 (49.0%) TI-III | 84/398 (21.1%) | RR= 2.33 (1.77, 3.05) |
| El Dareer 1983 | Chronic pelvic infection | 5/80 (6.3%) TI 236/3022 (7.8%) TIII | 3/39 (7.7%) | RR= 0.81 (0.20, 3.23) TI vs No RR= 1.02 (0.34, 3.03) TIII vs No |
| El Dareer 1983 | Recurrent UTI | 7/80 (8.8%) TI 276/3022 (9.1%) TIII | 4/39 (10.3%) | RR= 0.85 (0.27, 2.74) TI vs No RR= 0.89 (0.35, 2.27) TIII vs No |
| Fillo 2007 | Reproductive tract infec. | No data | | Adjusted OR=1.54 (1.08, 2.21) a |
| Jones 1999-l | Genital infection | No data | - | Adjusted OR= 1.72 (1.02, 2.92) b |
| Klouman 2005 | Candida albicans vaginitis | No data | | OR= 1.7 (0.5, 6.1) ° |
| Klouman 2005 | Trichomonas vaginalis vaginitis | No data | - | OR= 1.0 (0.6, 1.7) ° |
| Klouman 2005 | Pelvic inflammatory disease | No data | | OR= 1.1 (0.5, 2.2) ° |
| Klouman 2005 | Bacterial vaginosis | No data | - | OR= 4.6 (0.6, 35.5) ° Adjusted OR= 3.7 (0.5, 31.7) d |
| Morison 2001 | Bacterial vaginosis | 240/571 (42.0%) TI-III | 132/437 (30.2%) | RR= 1.39 (1.17, 1.65) OR= 1.68 (1.29, 2.18) Adjusted OR=1.66 (1.25, 2.18) ° |
| Msuya 2002 | Bacterial vaginosis | 17/63 (27.0%) TI-II | 111/316 (35.1%) | RR= 0.77 (0.50, 1.18) |
| Rushwan 1983 | Recurrent UTI | 2/88 (2.3%) TI-II 375/2203 (17.0%) TIII | 3/211 (1.4%) | RR= 1.60 (0.27, 9.40) TI-II vs No RR= 11.97 (3.88, 36.96) TIII vs No |
| Rushwan 1983 | Chronic pelvic infection | 1/88 (1.1%) TI-II 401/2203 (18.2%) TIII | 3/211 (1.4%) | RR= 0.80 (0.08, 7.58) TI-II vs No RR= 12.8 (4.15, 39.51) TIII vs No |
| Shandall 1967 | Urinary infection | 30/807 (3.7%) TI 482/3013 (16.0%) TIII | 8/204 (3.9%) | RR= 0.95 (0.44, 2.04) TI vs No RR= 4.08 (2.06, 8.09) TIII vs No |
| Shandall 1967 | Recurrent urinary infection | 9/807 (1.1%) TI 120/3013 (4.0%) TIII | 2/204 (1.0%) | RR= 1.14 (0.25, 5.22) TI vs No RR= 4.06 (1.01, 16.31) TIII vs No |
| Shandall 1967 | Chronic pelvic infection | 31/807 (3.8%) TI 393/3013 (13.0%) TIII | 12/204 (5.9%) | RR= 0.65 (0.34, 1.25) TI vs No RR= 2.22 (1.27, 3.87) TIII vs No |
| | | | | |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI), calculated by the SR authors. All RR/OR are unadjusted and calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III; TIV= FGM/C type IV. a=controlling for age, parity, BMI, education, economic status, place of residence, marital status, ethnicity, and sexual partners in the past 12 months. b= controlling for age, number of deliveries, education, religion, marital status, type of consultation. c= unadjusted OR reported in the publication. d= controlling for age (and possibly for marital status, religion, ethnic group, education, sexual partners).e (Morison 2001)= controlling for age, marital status, and parity.

We could carry out meta-analyses for three outcomes regarding infections of the reproductive and urinary tracts: urinary tract infections, bacterial vaginosis, and chronic pelvic infection. These meta-analyses are presented below.

We pooled available data from five studies that reported data on urinary tract infection. These data were unadjusted. In three studies, urinary tract infection was clinically measured and in two studies the outcome was self-reported. The sub-group analysis for type of reporting was not significant (Chi²=0.00, P=0.98), therefore we show the forest plot without these subgroups. Figure 19 presents the result for urinary tract infection, comparing women with FGM/C and women without FGM/C.

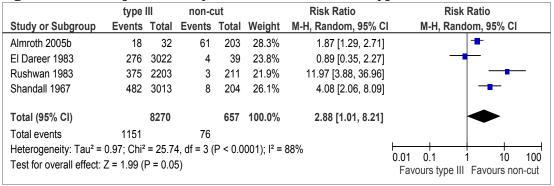
Figure 19: Forest plot, urinary tract infection (FGM/C vs no)

| 0 | | | | | | • | |
|-----------------------------------|------------------------|----------|-------------|---------|-------------------------|---------------------|---|
| | FGM | C | non-c | ut | | Risk Ratio | Risk Ratio |
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Random, 95% CI | M-H, Random, 95% CI |
| Almroth 2005b | 23 | 48 | 61 | 203 | 23.0% | 1.59 [1.11, 2.29] | - - - |
| De Silva 1989 | 47 | 153 | 101 | 1691 | 23.4% | 5.14 [3.80, 6.97] | - |
| El Dareer 1983 | 283 | 3102 | 4 | 39 | 17.6% | 0.89 [0.35, 2.27] | |
| Rushwan 1983 | 377 | 2291 | 3 | 211 | 15.7% | 11.57 [3.75, 35.73] | |
| Shandall 1967 | 513 | 3820 | 8 | 204 | 20.2% | 3.42 [1.73, 6.79] | - |
| Total (95% CI) | | 9414 | | 2348 | 100.0% | 3.01 [1.42, 6.38] | • |
| Total events | 1243 | | 177 | | | | |
| Heterogeneity: Tau ² = | 0.60; Chi ² | = 37.35 | 5, df = 4 (| P < 0.0 | 0001); l ² = | = 89% | |
| Test for overall effect: | Z = 2.89 (I | P = 0.00 | 04) | | | | 0.01 0.1 1 10 100 Favours FGM/C Favours non-cut |

As evident from the forest plot, we found a statistically significant difference between women with FGM/C and non-cut women with respect to urinary tract infection (RR=3.01, CI=1.42, 6.38). Women with any type of FGM/C were 3 times at greater risk of urinary tract infection compared to women without FGM/C. The absolute risk difference was 15 more cases of urinary tract infections among women with FGM/C per 100 woman (CI= 3 more to 40 more) compared to women without FGM/C. There was considerable, unexplained heterogeneity across the studies ($I^2=89\%$, $Chi^2=37.4$, p<0.00001). Using GRADE, we judged the quality of this outcome as very low (table 34).

We also carried out meta-analyses for urinary tract infection comparing women with FGM/C type III and women without FGM/C. In two studies, urinary tract infection was clinically measured and in another two studies the outcome was self-reported. The sub-group analysis for type of reporting was not significant (Chi²=0.01, P=0.91), therefore we show the forest plot without these subgroups. Figure 20 presents the result for urinary tract infection, comparing women with FGM/C type III and women without FGM/C.

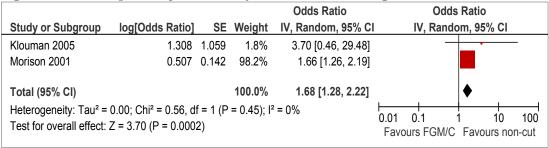
Figure 20: Forest plot, urinary tract infection (FGM/C type III vs no)



The pooled estimate showed that with regards to urinary tract infection, there was a statistically significant difference between women with FGM/C type III and women who had not undergone FGM/C (RR=2.88, CI= 1.01, 8.21). Women with FGM/C type III were 2.9 times at greater risk of urinary tract infection compared to women without FGM/C. We found that based on these four studies, the absolute risk difference was 22 more cases of urinary tract infections among women with FGM/C type III per 100 woman (CI= 0 more to 83 more) compared to women without FGM/C. Considerable, unexplained heterogeneity indicated by I^2 and Chi^2 (I^2 = 88%, Chi^2 = 25.7, p<0.0001) showed inconsistency across studies. We judged the quality of this outcome as very low (table 35).

We also carried out meta-analyses for bacterial vaginosis, pooling available adjusted data from two studies. Figure 21 presents the result for bacterial vaginosis, comparing women with FGM/C and women without FGM/C.

Figure 21: Forest plot, adjusted analyses for bacterial vaginosis (FGM/C vs no)



The pooled estimate shows that there was a statistically significant difference between women with FGM/C and women without FGM/C with respect to bacterial vaginosis (OR=1.68, CI= 1.28, 2.22). Using GRADE, we judged the quality of this outcome as very low (table 34).

Further, the forest plots in figures 22-23 show that across three comparative studies with data on chronic pelvic infection, the difference between women with various types of FGM/C and women who had not undergone FGM/C in frequency of developing chronic pelvic infection varied.

Figure 22: Forest plot, chronic pelvic infection (FGM/C vs no)

| | _ | | | | | |
|-------------------|--------|-------|---------------|-------|---------------------|-------------------------------|
| | FGM/ | С | non-c | ut | Risk Ratio | Risk Ratio |
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El Dareer 1983 | 241 | 3102 | 3 | 39 | 1.01 [0.34, 3.02] | |
| Rushwan 1983 | 402 | 2291 | 3 | 211 | 12.34 [4.00, 38.09] | |
| Shandall 1967 | 424 | 3820 | 12 | 204 | 1.89 [1.08, 3.29] | |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours FGM/C Favours non-cut |
| | | | | | | |

Figure 23: Forest plot, chronic pelvic infection (FGM/C type III vs no)

| | | | | | · · · · · · · · · · · · · · · · · · · | <u> </u> |
|-------------------|---------------|-------|---------------|-------|---------------------------------------|--|
| | type I | II | non-c | ut | Risk Ratio | Risk Ratio |
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| El Dareer 1983 | 236 | 3022 | 3 | 39 | 1.02 [0.34, 3.03] | |
| Rushwan 1983 | 401 | 2203 | 3 | 211 | 12.80 [4.15, 39.51] | |
| Shandall 1967 | 393 | 3013 | 12 | 204 | 2.22 [1.27, 3.87] | - |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours type III Favours non-cut |
| | | | | | | . a. |

Comparison of types of FGM/C

Table 22 presents the study outcomes and unadjusted effect estimates of the four studies that reported on infections of the reproductive and urinary tracts in women with various types of FGM/C (41;47;72;73). The results show that for every outcome, a higher proportion of women with FGM/C type III than type I-II had infections, but the difference was not always statistically significant.

Table 22: Study outcomes and effect estimates for infections of the reproductive

and urinary tracts (in types of FGM/C)

| Author, year | Outcome | FGM/C Type I-II | FGM/C Type III | Unadjusted results RR (95%CI) |
|----------------|---|--------------------|------------------|----------------------------------|
| Almroth 2005b | Urinary tract infection (UTI) | 5/16 (31.3%) TI-II | 18/32 (56.3%) | 0.56 (0.25, 1.22) |
| El Dareer 1983 | Chronic pelvic infection | 5/80 (6.3%) TI | 236/3022 (7.8%) | 0.80 (0.34, 1.89) |
| El Dareer 1983 | Recurrent UTI | 7/80 (8.8%) TI | 276/3022 (9.1%) | 0.96 (0.47, 1.96) |
| Rushwan 1983 | Recurrent UTI | 2/88 (2.3%) TI-II | 375/2203 (17.0%) | 0.13 (0.03, 0.53) |
| Rushwan 1983 | Chronic pelvic infection | 1/88 (1.1%) TI-II | 401/2203 (18.2%) | 0.06 (0.01, 0.44) |
| Shandall 1967 | Urinary infection | 30/807 (3.7%) TI | 482/3013 (16.0%) | 0.23 (0.16, 0.33) |
| Shandall 1967 | andall 1967 Recurrent urinary infection | | 120/3013 (4.0%) | 0.28 (0.14, 0.55) |
| Shandall 1967 | Chronic pelvic infection | 31/807 (3.8%) TI | 393/3013 (13.0%) | 0.29 (0.21, 0.42) |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors. TI= FGM/C type I; TII= FGM/C type II.

We carried out meta-analyses for urinary tract infection comparing women with FGM/C type I-II and type III. In two studies, urinary tract infection was clinically measured and in two studies the outcome was self-reported. The sub-group analysis

for type of reporting was not significant (Chi²=0.01, P=0.92), therefore we show the forest plot without these subgroups. Figure 24 presents the result for urinary tract infection, comparing women with FGM/C type I-II and type III.

Figure 24: Forest plot, urinary tract infection (FGM/C type I-II vs type III)

| | type I | -II | type | III | | Risk Ratio | Risk Ratio |
|-----------------------------------|------------------------|----------|-------------|---------|------------------------|---------------------|--|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Random, 95% CI | M-H, Random, 95% CI |
| Almroth 2005b | 5 | 16 | 18 | 32 | 25.4% | 0.56 [0.25, 1.22] | - |
| El Dareer 1983 | 7 | 80 | 276 | 3022 | 26.4% | 0.96 [0.47, 1.96] | - |
| Rushwan 1983 | 2 | 88 | 375 | 2203 | 17.5% | 0.13 [0.03, 0.53] | |
| Shandall 1967 | 30 | 807 | 482 | 3013 | 30.7% | 0.23 [0.16, 0.33] | - |
| Total (95% CI) | | 991 | | 8270 | 100.0% | 0.38 [0.16, 0.89] | • |
| Total events | 44 | | 1151 | | | | |
| Heterogeneity: Tau ² = | 0.57; Chi ² | = 16.55 | 5, df = 3 (| P = 0.0 | 009); I ² = | 82% | |
| Test for overall effect: | Z = 2.23 (I | P = 0.03 | 3) | | | | 0.01 0.1 1 10 10 Favours type I-II Favours type II |

The pooled estimate showed that there was a statistically significant difference between women with FGM/C type I-II and type III (RR=0.38, CI= 0.16, 0.89). Women with FGM/C type I-II had a 60% lower risk of urinary tract infection compared to women with FGM/C type III. The absolute risk difference was 9 fewer cases of urinary tract infections among women with FGM/C type I-II per 100 woman (CI= 2 fewer to 12 fewer) compared to women with FGM/C type III. Considerable, unexplained heterogeneity indicated by I^2 and Chi^2 (I^2 = 82%, Chi^2 = 16.6, p<0.001) showed inconsistency across studies. We judged the quality of this outcome as very low (table 38).

Additionally, as shown in figure 25, across three studies with data on chronic pelvic infection, the risk was generally lower among women with FGM/C type I-II compared to women with type III, but the difference in frequency of developing chronic pelvic infection varied.

Figure 25: Forest plot, chronic pelvic infection (FGM/C type I-II vs type III)

| | | | | | ~ - | | | <i>-</i> | |
|--------|-------------|---------------|---|---|---|--|--|---|---|
| type I | -II | type | III | Risk Ratio | | | Risk | Ratio | |
| Events | Total | Events | Total | M-H, Random, 95% CI | | M-I | H, Rand | om, 95% | CI |
| 5 | 80 | 236 | 3022 | 0.80 [0.34, 1.89] | | | -+ | _ | |
| 1 | 88 | 401 | 2203 | 0.06 [0.01, 0.44] | | + | | | |
| 31 | 807 | 393 | 3013 | 0.29 [0.21, 0.42] | | | + | | |
| | | | | | 0.01 Favo | ٠. | • | | |
| | Events 5 | 5 80 1 88 | Events Total Events 5 80 236 1 88 401 | Events Total Events Total 5 80 236 3022 1 88 401 2203 | Events Total Events Total M-H, Random, 95% CI 5 80 236 3022 0.80 [0.34, 1.89] 1 88 401 2203 0.06 [0.01, 0.44] | type I-II Risk Ratio Events Total Events Total M-H, Random, 95% CI 5 80 236 3022 0.80 [0.34, 1.89] | type I-II type III Risk Ratio Events Total Events Total M-H, Random, 95% CI M-I 5 80 236 3022 0.80 [0.34, 1.89] I 1 88 401 2203 0.06 [0.01, 0.44] I 31 807 393 3013 0.29 [0.21, 0.42] I 0.01 0.01 0.01 0.01 0.01 | type I-II type III Risk Ratio Risk Events Total Events Total M-H, Random, 95% CI M-H, Random, 95% CI 5 80 236 3022 0.80 [0.34, 1.89] ———————————————————————————————————— | type I-II type III Risk Ratio Risk Ratio Events Total Events Total M-H, Random, 95% CI M-H, Random, 95% CI 5 80 236 3022 0.80 [0.34, 1.89] ———————————————————————————————————— |

What we know about infections of the reproductive and urinary tracts

- Women with FGM/C type I-III seem to be more likely than women with no FGM/C to experience urinary tract infections.
- Women with FGM/C type III seem to be more likely than women with no FGM/C to experience urinary tract infections.

- Women with FGM/C type III seem to be more likely than women with FGM/C type I-II to experience urinary tract infections.
- Women with FGM/C seem to be more likely than women with no FGM/C to experience bacterial vaginosis.
- It is uncertain whether there is a difference in the risk of developing chronic pelvic infections between women with FGM/C and women without FGM/C.
- It is uncertain whether there is a difference in the risk of developing chronic pelvic infections between women with FGM/C type I-II and women with FGM/C type III.

Outcome: HIV and STIs

One included case-control study reported on sexually transmitted infections (STIs) (table 23). Elmusharaf and colleagues (38) found there was no significant difference between cases positive for any STI and controls with respect to FGM/C.

Table 23: Study outcome and effect estimate for STIs in case-control study

| Author, year | Outcome | Cases n= | Cases n=16 | | Unadjusted and adjusted results OR (95%CI) |
|-----------------|-------------------|-------------------|------------|-----|--|
| Elmusharaf 2006 | STIs ^a | FGM/C Type I | 3 | 11 | OR= 1.55 (0.49, 6.49) |
| | | FGM/C Type II-III | 13 | 182 | Adjusted OR= 1.13 (0.73, 1.77) b |
| | | No FGM/C | 0 | 3 | |

Legend: OR= odds ratio with 95% confidence interval (CI). a= Chlamydia trachomatic, neisseria gonorrhea, treponema pallidum. b= adjusted for age, infertility, education, socio-economic level, duration of marriage.

In addition to the case-control study presented above, ten cross-sectional studies provided data on HIV/STIs in women with and without FGM/C. The studies' outcome results are presented in table 24. There was one publications from which unadjusted data on syphilis and Chlamydial infection were not possible to extract and we did not succeed in obtaining data from the authors (60). We note that three of these cross-sectional studies (44;64;74) were based on a representative study. They were analyses of the 2003 DHS from Kenya. The researchers restricted their analyses in various ways, thus the sample sizes varied in each analysis. However, across these three analyses, the frequency of HIV in women with FGM/C was 3.2-6.3% and in women without FGM/C it was 1.4-10.2%.

In table 24, we also show the unadjusted and adjusted effect estimates from the ten studies that included data on HIV/STIs in women with FGM/C and women with no FGM/C. The majority of the analyses showed no statistically significant differences between women with and without FGM/C concerning HIV/STIs. However, we note results of the adjusted analyses. First, in adjusted analyses, Brewer and colleagues (44) found that FGM/C was an independent correlate of HIV infection in Kenyan adolescent females (partial correlation = 0.07). Maslovskaya and colleagues (64) found that FGM/C significantly increased the risk of HIV in women who had a

younger or same-age first-union partner, but lowered it for women who had an older first-union partner. Also Yount and Abraham (74) found that FGM/C was not directly associated with HIV, but, in contrast to Maslovskaya and colleagues (64), indirectly through pathways such as through older partners.

Table 24: Study outcomes for HIV and STIs (FGM/C vs no)

| Brewer 2007 HIV 3/95 (3.2%) This 6/444 (1.4%) RR= 2.34 (0.59, 9.18) or, Re= 2.38 (0.59, 9.98) * Holmgren 2003 HIV-1 20799 (2.5%) This 1/58 (1.7%) RR= 1.45 (0.20, 10.63) Holmgren 2003 HIV-2 124/799 (15.5%) This 9/58 (15.5%) RR= 1.00 (0.54, 1.86) Holmgren 2003 HTLV-1 74/749 (9.9%) This 8/15 (14.5%) RR= 0.84 (0.11, 1.06) Kanki 1992 HIV-1 3/179 (1.5%) This 49/1078 (4.6%) RR= 0.76 (0.54, 1.05) Ore 0.68 (0.30, 0.99) Dakar *, 0.37 (0.17, 0.78) Zinguinchor *a Adjusted ORE 0.47 (0.27, 0.85) or 0.27 (0.27, 0.85) or 0.27 (0.17, 0.78) Zinguinchor *a Adjusted ORE 0.47 (0.27, 0.85) or 0.47 (0.27, 0.28) or 0.42 (0.27, 0.28 | Author, year | Outcome | FGM/C | No FGM/C | Unadjusted and adjusted results (95%CI) |
|---|------------------|------------------------|------------------------|------------------|---|
| Holmgren 2003 HIV-2 124/799 (15.5%) This 9/58 (15.5%) RR= 1.00 (0.54, 1.86) | Brewer 2007 | HIV | 3/95 (3.2%) Tns | 6/444 (1.4%) | OR= 2.38 (0.59, 9.69) a |
| Holingren 2003 HTLV-I 74/749 (9.9%) This 8/55 (14.5%) RR= 0.68 (0.35, 1.34) Kanki 1992 HIV-1 3/197 (1.5%) This 49/1078 (4.6%) RR= 0.75 (0.54, 1.05) Kanki 1992 HIV-2 35/276 (12.7%) This 242/1434 (16.9%) RR= 0.75 (0.54, 1.05) CR= 0.68 (0.30, 0.99) Dakar #, 0.37 (0.17, 0.78) Zinguinchor * Adjusted OR= 0.47 (0.27, 0.85) * Klouman 2005 HIV 5.6% TI-II 4.7% OR= 1.2 (0.4, 3.4) * Adjusted OR= 1.4 (0.6, 3.0) * Klouman 2005 Syphilis No data OR= 0.7 (0.3, 2.2) * Klouman 2005 Chlamydial infection No data OR= 0.9 (0.4, 2.2) * Maslovskaya 2009 HIV 61/962 (6.3%) This 213/2152 (9.9%) RR= 0.64 (0.49, 0.84) OR= 0.62 (0.46, 0.83) Adjusted OR= 2.20 (1.12, 4.31) * Morison 2001 Candida 71/604 (11.8%) TI-III 62/456 (13.6%) RR= 0.86 (0.63, 1.19) OR= 0.85 (0.59, 1.22) Adjusted OR= 2.00 (1.12, 4.31) * Morison 2001 Syphilis 14/643 (2.2%) TI-III 25/474 (5.3%) RR= 0.41 (0.22, 0.79) OR= 0.40 (0.21, 0.78) Adjusted OR= 4.71 (0.24, 0.94) * Morison 2001 Herpes simplex virus 2 286/637 (44.9%) TI-III 9/443 (0.%) RR | Holmgren 2003 | HIV-1 | 20/799 (2.5%) Tns | 1/58 (1.7%) | RR= 1.45 (0.20, 10.63) |
| Kanki 1992 HIV-1 3/197 (1.5%) Tns 49/1076 (4.6%) RR= 0.34 (0.11, 1.06) Kanki 1992 HIV-2 35/276 (12.7%) Tns 242/1434 (16.9%) RR= 0.75 (0.54, 1.05) OR= 0.68 (0.30, 0.99) Dakar*, 0.37 (0.17, 0.78) Zinguinchor* adjusted OR= 0.47 (0.27, 0.85) c Klouman 2005 HIV 5.6% TI-II 4.7% OR= 1.2 (0.4, 3.4) * adjusted OR= 0.47 (0.27, 0.85) c Klouman 2005 Syphilis No data OR= 0.7 (0.3, 2.2) * adjusted OR= 1.4 (0.6, 3.0) d Masiovskaya 2009 HIV 61/962 (6.3%) Tns 213/2152 (9.9%) RR= 0.64 (0.49, 0.84) OR= 0.62 (0.46, 0.83) Adjusted OR= 2.20 (1.12, 4.31) * adjusted OR= 0.85 (0.59, 1.22) Adjusted OR= 0.85 (0.58, 1.24) I Morison 2001 Herpes simplex virus 2 286/637 (44.9%) TI-III 86/471 (18.3%) RR= 0.41 (0.22, 0.79) OR= 0.40 (0.21, 0.78) Adjusted OR= 0.47 (0.24, 0.94) s Morison 2001 Herpes simplex virus 2 286/637 (44.9%) TI-III 86/471 (18.3%) RR= 2.46 (1.99, 3.03) OR= 3.65 (2.5, 4.83) Adjusted OR= 0.47 (0.24, 0.94) s Morison 2001 Chlamydia 3/573 (0.5%) TI-III 9/443 (2.0%) RR= Not estimable Morison 2001 Chlamydia | Holmgren 2003 | HIV-2 | 124/799 (15.5%) Tns | 9/58 (15.5%) | RR= 1.00 (0.54, 1.86) |
| Kanki 1992 HIV-2 35/276 (12.7%) Tns 242/1434 (16.9%) RR= 0.75 (0.54, 1.05) OR= 0.68 (0.30, 0.99) Dakar *, 0.37 (0.17, 0.78) Zinguinctor * Adjusted OR= 0.47 (0.27, 0.85) ** Klouman 2005 HIV 5.6% TI-II 4.7% OR= 1.2 (0.4, 3.4) * Adjusted OR= 1.4 (0.6, 3.0) * Adjusted OR= 1.4 (0.6, 3.0) ** Klouman 2005 Syphilis No data OR= 0.9 (0.4, 2.2) * Maslovskaya 2009 HIV 61/962 (6.3%) Tns 213/2152 (9.9%) RR= 0.64 (0.49, 0.84) OR= 0.62 (0.46, 0.83) Adjusted OR= 0.82 (0.46, 0.83) Adjusted OR= 0.22 (0.11,2,4.31) ** Morison 2001 Candida 71/604 (11.8%) TI-III 62/456 (13.6%) RR= 0.86 (0.63, 1.19) OR= 0.85 (0.58, 1.22) Adjusted OR= 0.85 (0.58, 1.24) IN OR= 0.85 (0.58, 1.24) | Holmgren 2003 | HTLV-I | 74/749 (9.9%) Tns | 8/55 (14.5%) | RR= 0.68 (0.35, 1.34) |
| No continue | Kanki 1992 | HIV-1 | 3/197 (1.5%) Tns | 49/1078 (4.6%) | RR= 0.34 (0.11, 1.06) |
| Klouman 2005 Syphilis No data OR= 0.7 (0.3, 2.2) a Klouman 2005 Chlarmydial infection No data OR= 0.9 (0.4, 2.2) a Maslovskaya 2009 HIV 61/962 (6.3%) Tns 213/2152 (9.9%) RR= 0.64 (0.49, 0.84) OR= 0.62 (0.46, 0.83) Adjusted OR= 2.20 (1.12, 4.31) a Morison 2001 Candida 71/604 (11.8%) TI-III 62/456 (13.6%) RR= 0.86 (0.63, 1.19) OR= 0.85 (0.59, 1.22) Adjusted OR= 0.85 (0.58, 1.24) f Morison 2001 Syphilis 14/643 (2.2%) TI-III 25/474 (5.3%) RR= 0.41 (0.20, 0.79) OR= 0.40 (0.21, 0.78) Adjusted OR= 0.47 (0.24, 0.94) g Morison 2001 Herpes simplex virus 2 286/637 (44.9%) TI-III 86/471 (18.3%) RR= 2.46 (1.99, 3.03) OR= 3.65 (2.75, 4.83) Adjusted OR= 4.71 (3.46, 6.44) f Morison 2001 Gonorrhoea 0/573 (0%) TI-III 0/443 (0%) RR= Not estimable Morison 2001 Chlamydia 3/573 (0.5%) TI-III 9/443 (2.0%) RR= 0.26 (0.07, 0.95) Morison 2001 Gonococcal/ chlamydia 1/63 (1.6%) TI-III 24/450 (5.3%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) Adjusted OR= 1.31 (0.77, 2.22) a Msuya 2002 Gonococcal/ chlamydia 1/63 (1.6%) TI-III 65/316 (20.6%) <td>Kanki 1992</td> <td>HIV-2</td> <td>35/276 (12.7%) Tns</td> <td>242/1434 (16.9%)</td> <td>OR= 0.68 (0.30, 0.99) Dakar ^a, 0.37 (0.17, 0.78) Zinguinchor ^a</td> | Kanki 1992 | HIV-2 | 35/276 (12.7%) Tns | 242/1434 (16.9%) | OR= 0.68 (0.30, 0.99) Dakar ^a , 0.37 (0.17, 0.78) Zinguinchor ^a |
| Klouman 2005 Chlamydial infection No data OR= 0.9 (0.4, 2.2) ° Maslovskaya 2009 HIV 61/962 (6.3%) Tns 213/2152 (9.9%) RR= 0.64 (0.49, 0.84) OR= 0.62 (0.46, 0.83) Adjusted OR= 2.20 (1.12, 4.31) ° Morison 2001 Candida 71/604 (11.8%) TI-III 62/456 (13.6%) RR= 0.86 (0.63, 1.19) OR= 0.85 (0.59, 1.22) Adjusted OR= 0.85 (0.58, 1.24) ¹ Morison 2001 Syphilis 14/643 (2.2%) TI-III 25/474 (5.3%) RR= 0.41 (0.22, 0.79) OR= 0.40 (0.21, 0.78) Adjusted OR= 0.47 (0.24, 0.94) ° Morison 2001 Herpes simplex virus 2 286/637 (44.9%) TI-III 86/471 (18.3%) RR= 2.46 (1.99, 3.03) OR= 3.65 (2.75, 4.83) Adjusted OR= 4.71 (3.46, 6.44) ¹ Morison 2001 Gonorrhoea 0/573 (0%) TI-III 9/443 (2.0%) RR= Not estimable Morison 2001 Chlamydia 3/573 (0.5%) TI-III 9/443 (2.0%) RR= 0.26 (0.07, 0.95) Morison 2001 Trichomoniasis 41/586 (7.0%) TI-III 24/450 (5.3%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) Adjusted OR= 1.31 (0.77, 2.22) ° Msuya 2002 Gonococcal/ chlamydia cervicitis 15/63 (23.8%) TI-II 65/316 (20.6%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) | Klouman 2005 | HIV | 5.6% TI-II | 4.7% | , |
| Maslovskaya 2009 HIV 61/962 (6.3%) Tns 213/2152 (9.9%) RR= 0.64 (0.49, 0.84) OR= 0.62 (0.46, 0.83) Adjusted OR= 2.20 (1.12, 4.31) oR= 0.62 (0.46, 0.83) Adjusted OR= 2.20 (1.12, 4.31) oR= 0.85 (0.59, 1.22) Adjusted OR= 2.20 (1.12, 4.31) oR= 0.85 (0.59, 1.22) Adjusted OR= 0.85 (0.59, 1.22) Adjusted OR= 0.85 (0.58, 1.24) oR= 0.85 (0.58, 1.24) oR= 0.40 (0.21, 0.78) Adjusted OR= 0.85 (0.58, 1.24) oR= 0.40 (0.21, 0.78) Adjusted OR= 0.47 (0.24, 0.94) oR= 0.40 (0.21, 0.78) Adjusted OR= 0.47 (0.24, 0.94) oR= 0.40 (0.21, 0.78) Adjusted OR= 0.47 (0.24, 0.94) oR= 0.65 (0.58, 1.24) oR= 0.65 (0.68, | Klouman 2005 | Syphilis | No data | | OR= 0.7 (0.3, 2.2) ^a |
| Morison 2001 Candida T1/604 (11.8%) TI-III 62/456 (13.6%) RR= 0.86 (0.63, 1.19) OR= 0.85 (0.59, 1.22) Adjusted OR= 0.85 (0.58, 1.24) † | Klouman 2005 | Chlamydial infection | No data | | OR= 0.9 (0.4, 2.2) a |
| Morison 2001 Syphilis 14/643 (2.2%) TI-III 25/474 (5.3%) RR= 0.41 (0.22, 0.79) OR= 0.85 (0.58, 1.24) Property | Maslovskaya 2009 | HIV | 61/962 (6.3%) Tns | 213/2152 (9.9%) | OR= 0.62 (0.46, 0.83) |
| Morison 2001 Herpes simplex virus 2 286/637 (44.9%) TI-III 86/471 (18.3%) RR = 2.46 (1.99, 3.03) OR = 3.65 (2.75, 4.83) Adjusted OR = 4.71 (3.46, 6.44) f | Morison 2001 | Candida | 71/604 (11.8%) TI-III | 62/456 (13.6%) | OR= 0.85 (0.59, 1.22) |
| Morison 2001 Gonorrhoea 0/573 (0%) TI-III 0/443 (0%) RR= Not estimable Morison 2001 Chlamydia 3/573 (0.5%) TI-III 9/443 (2.0%) RR= 0.26 (0.07, 0.95) Morison 2001 Trichomoniasis 41/586 (7.0%) TI-III 24/450 (5.3%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) Adjusted OR= 1.31 (0.77, 2.22) g Msuya 2002 Gonococcal/ chlamydia cervicitis 1/63 (1.6%) TI-II 11/316 (3.5%) RR= 0.46 (0.06, 3.47) Msuya 2002 Trichomoniasis 15/63 (23.8%) TI-II 65/316 (20.6%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) | Morison 2001 | Syphilis | 14/643 (2.2%) TI-III | 25/474 (5.3%) | OR= 0.40 (0.21, 0.78) |
| Morison 2001 Chlamydia 3/573 (0.5%) TI-III 9/443 (2.0%) RR= 0.26 (0.07, 0.95) Morison 2001 Trichomoniasis 41/586 (7.0%) TI-III 24/450 (5.3%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) Adjusted OR= 1.31 (0.77, 2.22) g Msuya 2002 Gonococcal/ chlamydia cervicitis 1/63 (1.6%) TI-II 11/316 (3.5%) RR= 0.46 (0.06, 3.47) Msuya 2002 Trichomoniasis 15/63 (23.8%) TI-II 65/316 (20.6%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) | Morison 2001 | Herpes simplex virus 2 | 286/637 (44.9%) TI-III | 86/471 (18.3%) | OR= 3.65 (2.75, 4.83) |
| Morison 2001 Trichomoniasis 41/586 (7.0%) TI-III 24/450 (5.3%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) Adjusted OR= 1.31 (0.77, 2.22) g Msuya 2002 Gonococcal/ chlamydia cervicitis 1/63 (1.6%) TI-II 11/316 (3.5%) RR= 0.46 (0.06, 3.47) Msuya 2002 Trichomoniasis 15/63 (23.8%) TI-II 65/316 (20.6%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) | Morison 2001 | Gonorrhoea | 0/573 (0%) TI-III | 0/443 (0%) | RR= Not estimable |
| Msuya 2002 Gonococcal/ chlamydia cervicitis Msuya 2002 Gonococcal/ chlamydia cervicitis 11/316 (3.5%) RR = 0.46 (0.06, 3.47) | Morison 2001 | Chlamydia | 3/573 (0.5%) TI-III | 9/443 (2.0%) | RR= 0.26 (0.07, 0.95) |
| cervicitis Msuya 2002 Trichomoniasis 15/63 (23.8%) TI-II 65/316 (20.6%) RR= 1.31 (0.80, 2.14) OR= 1.34 (0.79, 2.24) | Morison 2001 | Trichomoniasis | 41/586 (7.0%) TI-III | 24/450 (5.3%) | OR= 1.34 (0.79, 2.24) |
| OR= 1.34 (0.79, 2.24) | Msuya 2002 | | 1/63 (1.6%) TI-II | 11/316 (3.5%) | RR= 0.46 (0.06, 3.47) |
| Msuya 2002 Candidiasis 16/63 (25.4%) TI-II 86/316 (27.2%) RR= 0.93 (0.59, 1.48) | Msuya 2002 | Trichomoniasis | 15/63 (23.8%) TI-II | 65/316 (20.6%) | , |
| | Msuya 2002 | Candidiasis | 16/63 (25.4%) TI-II | 86/316 (27.2%) | RR= 0.93 (0.59, 1.48) |

| Msuya 2002 | Syphilis | 2/63 (3.2%) TI-II | 14/316 (4.4%) | RR= 0.72 (0.17, 3.08) |
|------------|------------------------|---------------------|------------------|--|
| Msuya 2002 | HepB (HbsAg) | 1/63 (1.6%) TI-II | 15/316 (4.7%) | RR= 0.33 (0.04, 2.49) |
| Msuya 2002 | HIV-1 | 5/63 (7.9%) TI-II | 39/316 (12.3%) | RR= 0.64 (0.26, 1.57) |
| Msuya 2002 | Herpes simplex virus 2 | 27/63 (42.9%) TI-II | 121/316 (38.3%) | RR= 1.12 (0.81, 1.54) |
| Pépin 2006 | HIV-2 | 90/488 (18.4%) Tns | 70/538 (13.0%) | RR= 1.42 (1.06, 1.89) OR= 1.51 (1.08, 2.12) ^a Adjusted OR= 1.54 (1.08, 2.18) ^h |
| Pépin 1991 | HIV-2 | 18/90 (20.0%) Tns | 69/255 (27.1%) | RR= 0.74 (0.47, 1.17) |
| Yount 2007 | HIV-1 | 63/1071 (5.9%) Tns | 214/2096 (10.2%) | RR= 0.58 (0.44, 0.76) OR= 0.55 (0.39, 0.77) a Adjusted OR= 0.88 (0.55, 1.41) i Adjusted OR= 0.80 (0.49, 1.30) j Adjusted OR= 0.81 (0.50, 1.33) k |
| Yount 2007 | STI/Ulcer | 20/1071 (1.9%) Tns | 63/2096 (3.0%) | RR= 0.62 (0.38, 1.02) |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI). All RR/OR are unadjusted and calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type I; TIS= FGM/C type II; TIS= FGM/C

We carried out meta-analyses for HIV, pooling available adjusted data from four primary studies (the data in (64;74) were based on the same sample and we used the analysis with the least restricted sample, which was (74)). In two studies, the outcome was restricted to HIV-2. The sub-group analysis for type of HIV was not significant (Chi²=1.78, P=0.18), therefore we show the forest plot without subgroups. Figure 26 presents the meta-analysis result for HIV, comparing women with FGM/C and women without FGM/C.

Figure 26: Forest plot, adjusted analyses of HIV (FGM/C vs no)

| | | | | Odds Ratio | Odds Ratio | |
|-----------------------------------|---------------------|-----------|------------|------------------------|----------------------------|-----|
| Study or Subgroup | log[Odds Ratio] | SE | Weight | IV, Random, 95% CI | IV, Random, 95% CI | |
| Kanki 1992 | -0.755 | 0.293 | 24.6% | 0.47 [0.26, 0.83] | - | |
| Klouman 2005 | 0.336 | 0.411 | 19.7% | 1.40 [0.63, 3.13] | | |
| Pépin 2006 | 0.432 | 0.179 | 29.3% | 1.54 [1.08, 2.19] | - | |
| Yount 2007 | -0.211 | 0.25 | 26.4% | 0.81 [0.50, 1.32] | + | |
| Total (95% CI) | | | 100.0% | 0.95 [0.54, 1.67] | • | |
| Heterogeneity: Tau ² = | 0.25; Chi² = 13.68, | df = 3 (F | o = 0.003) | ; I ² = 78% | 0.01 0.1 1 10 | 100 |
| Test for overall effect: 2 | Z = 0.17 (P = 0.87) | | | | Favours FGM/C Favours non- | |

The meta-analysis could not establish a statistically significant difference between women with FGM/C and women without FGM/C with regards to HIV (RR=0.95, CI= 0.54, 1.67). Considerable, unexplained heterogeneity indicated by I² and Chi²

(I^2 = 78%, Chi²= 13.7, p<0.003) showed inconsistency across studies. Using GRADE, we judged the quality of this outcome as very low (table 34).

We also carried out meta-analyses for STIs, pooling available unadjusted data from three studies. Figure 27 shows the result for STIs, comparing women with FGM/C and women without FGM/C.

Figure 27: Forest plot, unadjusted analysis of STIs (FGM/C vs no)

| | FGM/ | C | non-c | ut | | Risk Ratio | Risk Ratio |
|-----------------------------------|-----------|--------------|---------------|---------|-------------------------|---------------------|--|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Random, 95% CI | M-H, Random, 95% CI |
| Morison 2001 | 415 | 668 | 206 | 489 | 39.5% | 1.47 [1.31, 1.66] | • |
| Msuya 2002 | 45 | 63 | 211 | 316 | 37.6% | 1.07 [0.90, 1.27] | • |
| Yount 2007 | 20 | 1071 | 63 | 2096 | 22.9% | 0.62 [0.38, 1.02] | - |
| Total (95% CI) | | 1802 | | 2901 | 100.0% | 1.07 [0.75, 1.53] | • |
| Total events | 480 | | 480 | | | | |
| Heterogeneity: Tau ² = | 0.08; Chi | $i^2 = 17.9$ | 52, df = 2 | (P = 0. | 0002); l ^z : | = 89% | 1004 014 100 100 |
| Test for overall effect: | | | | | | | 0.01 0.1 1 10 100 Favours cut Favours non-cut |

As evident from the forest plot, the pooled analysis could not establish a statistically significant difference between women with FGM/C and women without FGM/C with respect to STIs (RR= 1.07, CI= 0.75, 1.53). We found that the absolute risk difference was 1 more case of STIs among women with FGM/C per 100 woman (CI= 4 fewer to 9 more) compared to women without FGM/C. There was considerable, unexplained heterogeneity across studies (I^2 = 89%, Chi²= 17.5, p<0.0002). We judged the quality of this outcome as very low (table 42).

What we know about HIV and STIs

- It is uncertain whether there is a difference in the risk of HIV infection among women with FGM/C compared to women with no FGM/C, but there seems to be no clear trend for either a greater or lower risk among women who have undergone FGM/C.
- It is uncertain whether there is a difference in the risk of STIs among women with FGM/C compared to women without FGM/C, but there seems to be no clear trend for either a greater or lower risk among women who have undergone FGM/C.

Outcome: Infertility

Infertile individuals are physiologically incapable of, or unsuccessful in, achieving pregnancy over a considerable period of time in spite of attempts. We included a number of studies that reported on infertility in relation to FGM/C.

FGM/C vs no FGM/C

Two included case-control studies of high methodological quality examined whether FGM/C was a predictor for infertility (37;39). The data from these studies are shown

in table 25. Almroth and colleagues (37) investigated whether women with primary infertility had a higher risk of having undergone FGM/C than controls. In Almroth and colleagues' statistical model in which determination of FGM/C was based the WHO classification of FGM/C (type III vs milder forms or no FGM/C), there was no significant association between infertility and FGM/C (univariate model OR=1.71 [0.66, 4.86] p=0.331; multivariate model OR= 1.77 [0.52, 7.10] p=0.472). The multivariate model adjusted for extent of FGM/C, socioeconomic status, years in school, seropositivity for at least one of N gonorrhoeae and C trachomatis versus negative for both.

In the case-control study by Inhorn and Buss (39), unadjusted and adjusted odds ratios for risk factors associated with infertility were reported. In this study, infertile cases were more likely to have FGM/C type II than type I (unadjusted OR= 1.9 [0.9, 4.2], adjusted OR= 1.9 [0.8, 4.2]), and were more likely to have been cut by a traditional than a medical circumciser (OR=2.2 [0.8, 5.9], adjusted OR= 2.1 [0.8, 5.7]). These associations were not statistically significant. However, when type of FGM/C and circumciser were considered together, the association was significant. Women who either had FGM/C type II or were cut by a traditional circumciser were at greater risk of infertility than women who had experienced neither (unadjusted OR= 2.0 [1.1, 3.6], adjusted OR= 2.0 [1.1, 3.7]). Analyses were adjusted for marital duration and woman's age. Data were not shown, but Inhorn and Buss explained that "women who had had both an excision and a traditional practitioner are at four times greater risk of TFI [tubal-factor infertility] than are women who had had neither."

Table 25: Study outcomes for infertility in case-control studies

| Author, year | Outcome | · | Cases | Controls |
|---------------|--------------------------------|---|-------------------------------|-------------------------------------|
| Almroth 2005a | Infertility | FGM/C Type I FGM/C Type II FGM/C Type III No FGM/C | 5/99 1/99 91/99 2/99 | 14/179 8/179 152/179 5/179 |
| Inhorn 1993 | Tubal-factor infertility (TFI) | FGM/C Type I FGM/C Type II | 13/100 26/100 | 42/90 44/90 |

There were also 11 comparative cross-sectional studies that reported on infertility in women with and without FGM/C. The outcome data from these studies are shown in table 26. Data were not possible to extract from four publications and we did not succeed in obtaining the data from the authors (55;60;61;63). Four of these cross-sectional studies were representative (43;62). They were analyses of DHS from Sudan, Central African Republic, Ivory Coast, and Tanzania. Across these four representative studies, the average frequency of infertility in women with FGM/C was 22.4%, and in women without FGM/C it was 22.0%.

In table 26, we also show the unadjusted and adjusted effect estimates from the studies that included data on infertility in women with FGM/C and women without

FGM/C. We note that two of these cross-sectional studies were based on the same sample (43;61). They were analyses of the 1989-90 DHS from Sudan. The researchers restricted their analyses in various ways, thus the sample sizes varied in each analysis.

Table 26: Study outcomes for infertility (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted and adjusted results (95%CI) |
|-----------------|----------------------------|--|--------------------|---|
| Balk 2000 | Low fertility a | 1/206 (0.5%) TI-II | 11/1254 (0.9%) | RR= 0.55 (0.07, 4.26) TI-II vs No |
| Balk 2000 | Low fertility ^a | 7/221 (3.3%) TIII | 11/1254 (0.9%) | RR= 3.61 (1.42, 9.21) TIII vs No OR= 3.67 (1.43, 9.44) TIII vs No Adjusted OR= 2.06 p<0.01 TIII vs other/no ^c Adjusted OR= 1.49 p=0.167 TIII vs other/no ^d |
| Jackson 2005 | Live birth | No data | | RR= 1.43 (1.05, 1.93) ^e |
| Klouman 2005 | Infertile | 13.1% | 10.2% | OR= 1.3 (0.7, 2.7) e |
| Larsen 2002 | Primary infertility | 7/516 (1.4%) TI | 8/471 (1.7%) | RR= 0.80 (0.29, 2.19) TI vs No OR= 0.71 TI vs No ° Adjusted OR= 1.0 TI vs No ^f |
| Larsen 2002 | Primary infertility | 107/3231 (3.3%) TII-III | 8/471 (1.7%) | RR= 1.95 (0.96, 3.97) TII-III vs No OR=1.91 TII-III vs No ^e Adjusted OR= 2.76 p< 0.001 TII-III vs No ^f |
| Larsen 2002 | Secondary infertility | No data | | OR= 0.92 TI vs No ° OR=1.04 TII-III vs No f Adjusted OR= 1.0 TI vs No Adjusted OR= 0.99 TII-III vs No f |
| Larsen 2000-l | Childless | 111/1626 (6.8%) Tns | 98/1754 (5.6%) | RR= 1.22 (0.94, 1.59) |
| Larsen 2000-l | Infertile | 5192/15593 (33.3%) Tns | 4216/15645 (26.7%) | RR= 1.24 (1.19, 1.28) |
| Larsen 2000-II | Childless | 48/2085 (2.3%) Tns | 63/2096 (3.0%) | RR= 0.77 (0.53, 1.11) |
| Larsen 2000-ll | Infertile | 2910/18076 (16.1%) Tns | 4634/19891 (23.3%) | RR= 0.69 (0.66, 0.72) |
| Larsen 2000-III | Childless | 18/817 (2.2%) TI-III | 81/3367 (2.4%) | RR= 0.92 (0.55, 1.52) |
| Larsen 2000-III | Infertile | 1285/8033 (16.0%) TI-III | 6592/33463 (19.7%) | RR= 0.81 (0.77, 0.86) TI-III vs No OR= 0.91 TI vs No ° OR= 0.84 TII-III vs No, p<0.05 ° |
| Larsen 2000-III | Have a child | No data | | OR= 1.08 p<0.01 TI vs No ° OR= 1.03 TII-III vs No ° |
| Larsen 1989 | Sterility ^b | No data | | Adjusted OR= 1.77 ^g |
| Larsen 1989 | Childless b | No data | | - |
| Morison 2001 | Infertility | 43/420 (10.2%) TI-III | 35/356 (9.8%) | RR= 1.04 (0.68, 1.59) OR=1.05 (0.65, 1.67) Adjusted OR= 1.20 (0.70, 2.07) ^h |
| Rushwan 1983 | Infertility | 0/88 (0%) TI-II 58/2203 (2.6%) TIII | 3/211 (1.4%) | RR= 0.34 (0.02, 6.52) TI-II vs No RR= 1.85 (0.59, 5.86) TIII vs No |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI). All RR/OR are unadjusted and calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III; Tns= FGM/C type not specified. a= defined as 0 children ever born, data provided by author. b= Larsen 1989 compared women with FGM/C type III to women with no or other type of FGM/C. c= seems to control for factors that affect the likelihood of infibulation (age, number of unions, number of children ever born, level of education, religion, location of current residence, region of childhood residence, socioeconomic status). d= seems to control for factors that affect the likelihood of infibulation (age, number of unions, number of children ever born, level of education, religion, location of current residence, region of childhood residence, socioeconomic status) and whether the respondent is currently divorced. e= unadjusted estimate reported in publication. f= adjusted for age, residence, region, times married, ever use of contraception. g= data from Sudan only, seemingly adjusted for age, region, religion, residence, education, husband's education, husband's work status, time married, marital status, ever used contraception. h= adjusted for age, marital status, parity.

The forest plots in figures 28-29 show that across several studies with data on infertility, the difference between women with FGM/C and women who had not undergone FGM/C in frequency of infertility varied (the data in (43;61) were based on the same sample and we used the analysis with the least restricted sample, which was (61)).

Figure 28: Forest plot, infertility (FGM/C vs no)

| | | | | • | • | |
|-------------------|--------|-------|---------|-------|---------------------|-------------------------------|
| | FGM/C | | non-cut | | Risk Ratio | Risk Ratio |
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| Klouman 2005 | 0 | 0 | 0 | 0 | Not estimable | |
| Larsen 2000-l | 5192 | 15593 | 4216 | 15645 | 1.24 [1.19, 1.28] | l l |
| Larsen 2000-II | 2910 | 18076 | 4634 | 19891 | 0.69 [0.66, 0.72] | 1 |
| Larsen 2000-III | 1285 | 8033 | 6592 | 33463 | 0.81 [0.77, 0.86] | t l |
| Larsen 2002 | 114 | 3747 | 8 | 471 | 1.79 [0.88, 3.64] | - |
| Morison 2001 | 43 | 420 | 35 | 356 | 1.04 [0.68, 1.59] | + |
| Rushwan 1983 | 58 | 2291 | 3 | 211 | 1.78 [0.56, 5.63] | ++- |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours FGM/C Favours non-cut |

Figure 29: Forest plot, childless (FGM/C vs no)

| | FGM/C | | non-cut | | Risk Ratio | Risk Ratio |
|-------------------|---------------|-------|---------------|-------|---------------------|-------------------------------|
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| Larsen 2000-l | 111 | 1626 | 98 | 1754 | 1.22 [0.94, 1.59] | + |
| Larsen 2000-II | 48 | 2085 | 63 | 2096 | 0.77 [0.53, 1.11] | + † |
| Larsen 2000-III | 18 | 817 | 81 | 3367 | 0.92 [0.55, 1.52] | , - |
| | | | | | | 0.01 0.1 1 10 100 |
| | | | | | | Favours FGM/C Favours non-cut |

Comparison of types of FGM/C

There were four studies that presented data on infertility in women with various types of FGM/C (43;61;72;75). The results of these studies are shown in table 27. The effect estimates for infertility in women with various types of FGM/C show that there were few significant differences between groups of women with regards to this reproductive issue.

Table 27: Study outcomes for infertility (in types of FGM/C)

| Author, year | Outcome | FGM/C Type I-II | FGM/C Type II-III | FGM/C Type IV | Unadjusted and adjusted results (95%CI) |
|--------------|----------------------------|-----------------------|----------------------------|-----------------------------------|--|
| Balk 2000 | Low fertility ^a | 1/206 (0.5%) TI-II | 7/221 (19.0%) TIII | | RR= 0.15 (0.02, 1.23) TI-II vs TIII |
| Larsen 2002 | Primary infertility | 7/516 (1.4%) TI | 107/3231 (3.3%) TII-III | | RR= 0.41 (0.19, 0.88) TI vs TII-III |
| Rushwan 1983 | Infertility | 0/88 (0%) TI-II | 58/2203 (2.6%) TIII | | RR= 0.21 (0.01, 3.40) TI-II vs TIII |
| Yount 2006 | Never pregnant (infertile) | 1/72 (1.4%) TI | 30/1232 (2.4%) TII | 12/396 (3.0%) TIV ^b | RR= 0.57 (0.08, 4.12) TI vs TIII RR= 0.46 (0.06, 3.47) TI vs TIV RR= 0.80 (0.42, 1.55) TII vs TIV |
| Yount 2006 | No live births | 1/72 (1.4%) TI | 49/1232 (4.0%) TII | 13/396 (3.3%) TIV ^b | RR= 0.35 (0.05, 2.49) TI vs TII OR= 0.34 (0.05, 2.50) TI vs TII Adjusted OR= 1.02 TI vs TII ° RR= 0.42 (0.06, 3.18) TI vs TIV RR= 1.21 (0.66, 2.21) TII vs TIV OR= 0.36 (0.05, 2.60) TI vs other Adjusted OR= 1.14 TI vs other ° |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI). All RR/OR are unadjusted and calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type III. a= data provided by author. b= In Yount (2006) FGM/C type IV was "other, unspecified, labia minora only". c= unclear factors adjusted for in multivariate logistic regression.

The forest plot in figure 30 shows that the difference between women with FGM/C type I-II and type III seem to favor FGM/C type I-II, but the result is statistically uncertain.

Figure 30: Forest plot, infertility (FGM/C type I-II vs type III)

| type I- | -II | type | III | Risk Ratio | Risk Ratio |
|---------|-------|---------------|------------------------|---|---|
| Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| 1 | 206 | 7 | 221 | 0.15 [0.02, 1.23] | |
| 0 | 88 | 58 | 2203 | 0.21 [0.01, 3.40] | |
| | | | | | 0.01 0.1 1 10 100 |
| | | | | | Favours type I-II Favours type III |
| | .71. | 1 206 | EventsTotalEvents12067 | Events Total Events Total 1 206 7 221 | Events Total Events Total M-H, Random, 95% CI 1 206 7 221 0.15 [0.02, 1.23] |

What we know about infertility

- It is uncertain whether there is a difference in the risk of infertility between women with FGM/C and women with no FGM/C.
- It is uncertain whether there is a difference in the risk of infertility between women with FGM/C type I-II and women with FGM/C type III.

Outcome: Vaginal discharge, itching, and related vaginal complications

Included studies that reported on various vaginal complications have been sub-divided into three groups based on outcome classification: vaginal discharge, vaginal itching, and other. These are presented below.

Vaginal discharge

Four comparative studies reported on vaginal discharge (49;65;67;69) (table 28). The frequency of vaginal discharge varied across studies, from 6-80% among women with FGM/C to 2-73% among women who had not been subjected to FGM/C. In general, both the unadjusted and adjusted results show that there was a trend for women with FGM/C to be at greater risk of vaginal discharge compared to women with no FGM/C.

Table 28: Study outcomes for vaginal discharge (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted and adjusted results (95% CI) |
|---------------|--------------------------------|------------------------|-----------------|--|
| Elnashar 2007 | Vaginal discharge | 161/200 (80.5%) Tns | 44/64 (68.8%) | RR=1.17 (0.98, 1.40) |
| Morison 2001 | Abnormal vaginal discharge | 269/645 (41.7%) TI-III | 205/481 (73.2%) | RR=0.98 (0.85, 1.12) OR=1.14 (0.90, 1.45) Adjusted OR= 0.94 (0.74, 1.21) ^a |
| Nwajei 2003 | Offensive discharge | 17/120 (14.2%) TI | 20/280 (7.1%) | RR= 1.98 (1.08, 3.65) |
| Okonofua 2002 | Yellow, bad-smelling discharge | 52/825 (6.3%) TI-IV | 24/1003 (2.4%) | RR= 2.63 (1.64, 4.23) OR= 2.74 (1.68, 4.49) ^b Adjusted OR= 2.81 (1.54, 5.09) ^c |
| Okonofua 2002 | White vaginal discharge | 96/825 (11.6%) TI-IV | 54/1003 (5.4%) | RR= 2.16 (1.57, 2.98) OR= 2.31 (1.64, 3.27) ^b Adjusted OR= 1.65 (1.09, 2.49) ^c |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI) calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TIII= FGM/C type III; TIV= FGM/C type IV; Tns= FGM/C type not specified. a= adjusted for age, marital status, parity. b= unadjusted OR provided in publication. c= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first sex, whether woman was married at first sex, frequency of sex in last month, times pregnant at survey. In Okonofua (2002) FGM/C type IV was described as unclassified type of FGM/C that included any or other procedures or manipulations of the genitalia (not type I-III).

Figure 31 shows that there was a trend for the risk of vaginal discharge generally to be greater among women who had undergone FGM/C, compared to women who had not undergone FGM/C.

Figure 31: Forest plot, vaginal discharge (FGM/C vs no)

| | FGM/ | C non-cut Risk Ratio | | Risk Ratio | Risk Ratio | |
|-------------------|--------|----------------------|--------|------------|---------------------|--|
| Study or Subgroup | Events | Total | Events | Total | M-H, Random, 95% CI | M-H, Random, 95% CI |
| Elnashar 2007 | 161 | 200 | 44 | 64 | 1.17 [0.98, 1.40] | † |
| Morison 2001 | 269 | 645 | 205 | 481 | 0.98 [0.85, 1.12] | † |
| Nwajei 2003 | 17 | 120 | 20 | 280 | 1.98 [1.08, 3.65] | - - - - - - - - - |
| Okonofua 2002 | 148 | 825 | 78 | 1003 | 2.31 [1.78, 2.99] | + |
| | | | | | | 0.01 0.1 1 10 100 Favours FGM/C Favours non-cut |

Vaginal itching

Two included studies, Nwajei and colleagues (67) and Okonofua and colleagues (69), provided data on vaginal itching in women with and without FGM/C. The outcomes

and effect estimates of vaginal itching are presented in table 29. Nwajei and colleagues (67) could not establish a statistically significant difference between the two groups of women with respect to itching. Okonofua and colleagues (69) found a statistically significant difference in the univariate analysis, which disappeared in the multivariate analysis.

Table 29: Study outcomes and effect estimates for vaginal itching (FGM/C vs no)

| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted and adjusted results (95%CI) |
|---------------|---------|-----------------------|-----------------|--|
| Nwajei 2003 | Itching | 58/120 (48.3%) TI | 134/280 (47.9%) | RR= 1.01 (0.81, 1.26) |
| Okonofua 2002 | Itching | 111/825 (13.5%) TI-IV | 80/1003 (8.0%) | RR= 1.69 (1.28, 2.21) OR= 1.79 (1.32, 2.43) ^a Adjusted OR= 1.30 (0.90, 1.88) ^b |

Legend: RR/OR= unadjusted relative risk/odds ratio with 95% confidence interval (CI) calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TIV= FGM/C type IV. a=unadjusted OR provided in publication. b= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first sex, whether woman was married at first sex, frequency of sex in last month, times pregnant at survey. In Okonofua (2002) FGM/C type IV was described as unclassified type of FGM/C that included any or other procedures or manipulations of the genitalia (not type I-III).

Other vaginal complications

Five studies reported on a vaginal complication that was not reported in any of the other included comparative studies (54;65;67;69;72). As seen in table 30, these were labeled: cervical cancer, squamous cell intraepithelial lesions, offensive odor, genital ulcer, and vaginal deposits. There were two statistically significant differences at study level: compared to women with no FGM/C, women with FGM/C had a higher risk of genital ulcer and a lower risk of offensive odor.

Table 30: Study outcomes and effect estimates for other vaginal complications

| Author, year | Outcome | FGM//C | No FGM/C | Unadjusted and adjusted results (95%CI) |
|---------------|---------------------------------------|--|----------------|---|
| Ibrahim 2011 | Cervical cancer | 14/90 (15.6%) Tns | 2/10 (20.0%) | RR= 0.78 (0.21, 2.94) ^a OR= 4.78 (1.13, 20.1) ^b |
| Morison 2001 | Squamous cell intraepithelial lesions | 39/586 (6.7%) TI-III | 22/453 (4.9%) | RR= 1.37 (0.82, 2.28) ^a Adjusted OR= 1.42 (0.81, 2.46) ^c |
| Nwajei 2003 | Offensive odor | 6/120 (5.0%) TI | 39/280 (13.9%) | RR= 0.36 (0.16, 0.83) a |
| Okonofua 2002 | Genital ulcer | 17/825 (2.1%) TI-IV | 5/1003 (0.5%) | RR= 4.13 (1.53, 11.16) ^a Adjusted OR= 4.38 (1.13, 17.0) ^d |
| Rushwan 1983 | Vaginal deposits/stones | 0/88 (0%) TI-II 3/2203 (0.14%) TIII | | TI-II vs TIII RR= 0.81 (0.00, 436.49) ° |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI) calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type II; TIV= FGM/C type IV. a= unadjusted RR calculated by the SR authors. b= unadjusted OR reported in publication. c= adjusted for age, marital status. d= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first sex, whether woman was married at first sex, frequency of sex in last month, times pregnant at survey. In Okonofua (2002) FGM/C type IV was described as unclassified type of FGM/C that included any or other procedures or manipulations of the genitalia (not type I-III). e= manually computed due to 0 number of events in one group and exceptionally different group sizes (cannot be accurately computed by RevMan).

What we know about vaginal discharge, itching, and related vaginal problems

• It is uncertain whether there is a difference in the risk of vaginal discharge and vaginal itching between women with FGM/C and women without FGM/C, but there seems to be a trend for the risk to be greater among women who have undergone FGM/C.

Outcome: Other gynecological complications

Eight comparative studies reported various gynecological complications not described earlier in this report (46;56;58;59;65;69;73). Each outcome was only reported in one study, thus no firm conclusions can be drawn regarding these outcomes. There were two publications from which data were not possible to extract and we did not succeed in obtaining data from the authors (46;56). The outcomes are presented in table 31.

The unadjusted and adjusted effect estimates for 'other' gynecological complications show that no statistically significant differences could be established between women with FGM/C and no FGM/C with regards to somatic disturbance. Conversely, there was a significant difference between these groups concerning anaemia, prolapse, repeated lower abdominal pain, and bacteriuria (when women had FGM/C type III). Concerning the result for prolapse, we note that Morison and colleagues (65) explain that further analyses showed that "the observed difference in the prevalence of prolapse between cut and non-cut women was the result of the high prevalence of prolapse in Wollofs rather than being consistent with an effect of cutting" (p 647). Lastly, women with a more invasive type of FGM/C were of statistically greater risk for 'gynecological problems', late complications, and bacteriuria, in both unadjusted and adjusted analyses.

Table 31: Study outcomes for other complications

| Author, year | Outcome | FGM//C | No FGM/C | Unadjusted and adjusted results (95% CI) |
|---------------|------------------------------------|--|-----------------|--|
| Diop 1998 | Abnormal bleeding | 61% | | |
| Jones 1999-I | Gynecological problem ^a | | | Adjusted OR=0.61 (0.46, 0.82) TI vs TII ° Adjusted OR=2.45 (1.47, 4.09) TIII vs TII |
| Jones 1999-II | Gynecological problem ^a | | | Adjusted OR=0.71 (0.41, 1.24) TI vs TII ° Adjusted OR= 2.43 (1.40, 4.24) TIII vs TII |
| Kaplan 2011 | Late complications | 101/577 (17.5%) TI 71/229 (31.0%) TII 17/65 (26.2%) TIII | | RR= 0.56 (0.43, 0.73) TI vs TII RR= 0.67 (0.43, 1.04) TI vs TIII RR= 1.19 (0.75, 1.86) TII vs TIII |
| Kizilhan 2011 | Somatic disturbance b | 29/79 (36.7%) Tns | 8/30 (26.7%) | RR= 1.38 (0.71, 2.66) |
| Morison 2001 | Prolapse | 253/548 (46.2%) TI-III | 223/426 (52.3%) | RR= 0.84 (0.74, 0.96) |

| | | | | OR= 0.78 (0.61, 1.01) Adjusted OR=0.72 (0.55, 0.95) ^d |
|---------------|-------------------------------|---|---------------------|--|
| Morison 2001 | Anaemia | 351/642 (54.7%) TI-III | 226/463 (48.8%) | RR= 1.12 (1.00, 1.26) OR= 1.26 (1.00, 1.61) Adjusted OR=1.31 (1.02, 1.68) ^d |
| Okonofua 2002 | Repeated lower abdominal pain | 136/825 (16.5%) TI-IV | 110/1003 (11.0%) | RR= 1.50 (1.19, 1.90) OR= 1.60 (1.22, 2.10) ^e Adjusted OR= 1.54 (1.11, 2.14) ^f |
| Shandall 1967 | Bacteriuria | 64/807 (7.9%) TI 843/3013 (28.0%) TIII | 16/204 (7.8%) | RR= 0.28 (0.22, 0.36) TI vs TIII RR= 1.01 (0.60, 1.71) TI vs No RR= 3.57 (2.22, 5.73) TIII vs No |

Legend: RR/OR= relative risk/odds ratio with 95% confidence interval (CI) calculated by the SR authors unless otherwise noted. TI= FGM/C type I; TII= FGM/C type II; TIII= FGM/C type II; TIV= FGM/C type IV; Tns= FGM/C type not specified. a= keloid, hemorrhage, stenosis, vaginal synechia, vaginal obstruction, vesicovaginal fistula, rectovaginal fistula, urinary incontinence, other. Number of events not extractable from the publication. b=stomach ache, regurgitation, headache, circulatory disturbance, etc. c= adjusted for age, number of deliveries, education, religion, marital status, residence, type of consultation. d= adjusted for age, marital status, parity. e= unadjusted OR reported in publication. f= controlling for woman's age at survey, religion, ethnic group, education, husband's education, marital status, number of co-wives, age at first sex, whether woman was married at first sex, frequency of sex in last month, times pregnant at survey. In Okonofua (2002) FGM/C type IV was described as unclassified type of FGM/C that included any or other procedures or manipulations of the genitalia (not type I-III).

Psychological health

In a previous systematic review we examined the psychological consequences of FGM/C on adult women (17). Such outcomes are therefore not included here. However, we identified and included one study that examined psychological health related to FGM/C among children (59). The author did not specify the type of FGM/C the girls had been subjected to. The author explained that statistically significant differences were determined with the Mann-Whitney U-test, and p-values were provided. The dichotomous outcome data from the study are presented in table 32 and the continuous results in table 33.

Our analyses of the dichotomous and continuous outcomes from this study showed that girls with FGM/C displayed statistically higher scores on anxiety, Post-Traumatic Stress Disorder (PTSD), depression, and self-esteem compared to girls from the same area who had not been subjected to FGM/C.

Table 32: Study outcomes (dichotomous) and effect estimates for psychological health

| iicaitii | | | | |
|---------------|-----------------------|---------------|-------------|----------------------------------|
| Author, year | Outcome | FGM/C | No FGM/C | Unadjusted results RR (95%CI) |
| Kizilhan 2011 | Anxiety disorder | 36/79 (45.6%) | 2/30 (6.7%) | 6.84 (1.75, 26.64) |
| Kizilhan 2011 | Somatoform disorders | 17/79 (21.5%) | 1/30 (3.3%) | 6.46 (0.90, 46.41) |
| Kizilhan 2011 | Personality disorders | 11/79 (13.9%) | 0/30 (0%) | 4.56 (0.62, 33.54) |

Legend: RR= unadjusted relative risk with 95% confidence interval (CI), calculated by the SR authors.

Table 33: Study outcomes (continuous) and effect estimates for psychological health

| Author, year | Outcome ^a | FGM/C group Mean (SD) | No FGM/C group Mean (SD) | Unadjusted results Mean diff (95%CI) | Result in publication |
|---------------|----------------------|--------------------------|-----------------------------|---|-----------------------|
| Kizilhan 2011 | PTSD (0-80) | 44.3 (13.7) | 14.5 (11.5) | 29.8 (24.7, 34.9) | P<0.001 |
| Kizilhan 2011 | Depression (0-54) | 33.6 (4.6) | 11.1 (5.5) | 22.5 (20.3, 24.7) | P<0.001 |
| Kizilhan 2011 | Self-esteem (0-25) | 21.6 (3.2) | 7.1 (2.7) | 14.5 (13.3, 15.7) | P<0.001 |

Legend: Mean diff=mean difference calculated by the SR authors. SD= standard deviation. a= the numbers in parentheses are theoretical scale score ranges.

In sum, data from one cross-sectional study, conducted in Iraq, indicate that girls with FGM/C run a greater risk of experiencing anxiety, PTSD, depression, and low self-esteem compared to girls with no exposure to FGM/C.

Other gynecological complications reported in non-comparative studies

In the results chapter we have presented results from the 42 included comparative studies. We also included 94 non-comparative studies. Such descriptive cross-sectional studies, case series and case reports can give a sense of possible complications following FGM/C – case reports remain the cornerstone of the initial detection of new adverse effects – and the range of frequency of complications. Thus, mapping such links is important for directing potential future investigations. However, descriptive cross-sectional studies, case series and case reports do not provide answers concerning the strength of association between FGM/C and the proposed complications.

Gynecological consequences of FGM/C reported in the 94 non-comparative studies were the same as those reported in the comparative studies, except for ten additional outcomes. Additional gynecological outcomes reported in the descriptive cross-sectional studies were: pelvic inflammatory disease (reported in 5.9% of women) and tight circumcision (reported in 1.0% of women in the study). Further, six case series documented the following complications in women with FGM/C: urethral mucosal prolapse, vaginal hypoplasia, urosepsis, vulval lump, Suppurative Bartolinitis, and too tight circumcision. Finally, in four case reports, neuroma, prolapse, benign vaginal villi, and primary vaginal stone were reported in women with FGM/C. These outcomes are presented in appendix 5.

Summary of Findings tables

The following five tables (tables 34-38) present our assessment of the quality of the evidence, organized according to comparison. As explained in the methods chapter,

GRADE is a system for assessing the extent to which we can have confidence in the effect estimates, and it ranges from a judgment of high to very low confidence (23;170). The definitions of the four classifications are provided in the Summary of Findings tables.

Table 34 shows our confidence in the effect estimates for cysts, urinary tract infection, HIV, STIs, and bacterial vaginosis comparing women who have undergone a type of FGM/C to women who have not undergone the practice. We judged the quality of all of these outcomes as very low.

Table 34: Summary of Findings table for the comparison FGM/C vs no FGM/C

FGM/C compared to non-FGM/C for girls/women - Gynecological outcomes

Patient or population: Girls/women

Settings: Community Intervention: FGM/C Comparison: non-FGM/C

| Outcomes | Illustrative comparative risks* | | Relative | No of | Quality of the |
|-----------------------------|---------------------------------|--------------------|----------------|--------------|----------------------------|
| | (95% CI) | | effect | Participants | |
| | Assumed risk | Corresponding risk | (95% CI) | (studies) | (GRADE) |
| | non-FGM/C | FGM/C | | | |
| Cysts | | | RR 3.45 | 6954 | ⊕⊝⊝⊝ |
| • | 1 per 100 | 2 per 100 | (0.54 to | (3 studies) | very low ^{1,2} |
| | i per 100 | (0 to 16) | 22.17) | , | • |
| Urinary tract | | (| RR 3.01 | 11762 | # 000 |
| infection | | | (1.42 to 6.38) | | very low ^{3,4} |
| mection | 8 per 100 | 23 per 100 | (1.42 (0 0.36) | (5 studies) | very low |
| | | (11 to 48) | | | |
| HIV | | | OR 0.95 | unclear | $\oplus\Theta\Theta\Theta$ |
| (adjusted analyses) | See | See | (0.54 to 1.67) | (4 studies) | very low ^{5,6} |
| | comment | comment | | | See comment ¹⁰ |
| STIs | | | RR 1.07 | 4703 | 0000 |
| | 17 per 100 | 18 per 100 | (0.75 to 1.53) | (3 studies) | very low ^{7,8} |
| | | (12 to 25) | | | |
| Bacterial vaginosis (adjus- | | | OR 1.68 | unclear | 0000 |
| ted analyses) | See | See | (1.28 to 2.22) | (2 studies) | very low 9,10 |
| | comment | comment | | | See comment ¹⁰ |

^{*}The basis for the assumed risk (e.g. the median control group risk across studies) is based on risk in control group in included studies. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio; **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** We are very uncertain about the estimate.

¹ I-square= 79%.

² CI is wide, crosses limitations of precision (CI=0.54, 22.17).

³ 3 of 5 studies had low methodological study quality.

⁴ I-square= 89%.

⁵ I-square= 78%, non-overlapping CIs.
⁶ CI is wide, crosses limitations of precision (CI=0.54, 1.67).

⁷ I-square= 89%, non-overlapping CIs.

⁸ CI crosses limitations of precision (CI= 0.75, 1.53)

⁹ We were unable to include a third study in the pooled analysis, which in contrast to the two included studies showed benefit, not harm.

10 Adjusted analyses. Number of participants not specified.

As shown in table 35, we judged the quality of the outcome urinary tract infection, when women who have undergone FGM/C type III were compared to women who have not undergone the practice, as very low.

Table 35: Summary of Findings table for the comparison FGM/C type III vs no FGM/C $\,$

FGM/C type III compared to non-FGM/C for girls/women - Gynecological outcomes

Patient or population: Girls/women

Settings: Community Intervention: FGM/C type III Comparison: non-FGM/C

| Outcomes | Illustrative comparative risks* (95% CI) Assumed risk Corresponding risk | | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence (GRADE) |
|---------------|--|----------------|--------------------------------|------------------------------|---------------------------------|
| | non-FGM/C | FGM/C type III | | | |
| Urinary tract | | | RR 2.88 | 8927 | ⊕⊖⊝⊝ |
| infection | 12 per 100 | 33 per 100 | (1.01 to 8.21) | (4 studies) | very low ^{1,2,3} |
| | | (12 to 95) | | | |

^{*}The basis for the assumed risk (e.g. the median control group risk across studies) is based on risk in control group in included studies. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio; **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** We are very uncertain about the estimate.

¹ 3 of 4 studies had low methodological study quality.

² I-square= 89% and non-overlapping CIs.

³ Wide CI (1.05, 7.91)

Table 36 shows the risk of scarring in girls with FGM/C type I vs FGM/C type II. We judged the quality of the outcome, scarring, as very low.

Table 36: Summary of Findings table for the comparison FGM/C type I vs FGM/C type II

FGM/C type I compared to FGM/C type II for girls/women – Gynecological outcomes

Patient or population: Girls/women

Settings: Community Intervention: FGM/C type I Comparison: FGM/C type II

| Outcomes | Illustrative compa | arative risks* (95% CI) Corresponding risk | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence |
|----------|--------------------|--|--------------------------------|------------------------------------|-------------------------|
| | FGM/C type II | FGM/C type I | | | |
| Scarring | | | RR 0.26 | 1598 | 0000 |
| | 19 per 100 | 5 per 100 | (0.05 to 1.28) | (2 studies) | very low ^{1,2} |
| | | (1 to 24) | | | |

^{*}The basis for the assumed risk (e.g. the median control group risk across studies) is based on risk in control group in included studies. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio; **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** We are very uncertain about the estimate.

¹ We did not downgrade but note the non-overlapping CIs (and thus 91% I-square).

² CI is wide, crosses limitations of precision (CI=0.05, 1.28).

Table 37 shows the comparison FGM/C type I vs FGM/C type III. We judged the quality of the outcome, scarring, as very low.

Table 37: Summary of Findings table for the comparison FGM/C type I vs FGM/C type III

FGM/C type I compared to FGM/C type III for girls/women - Gynecological outcomes

Patient or population: Girls/women

Settings: Community Intervention: FGM/C type I Comparison: FGM/C type III

| Outcomes | Assumed risk | Corresponding risk | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence (GRADE) |
|----------|----------------|-----------------------|--------------------------------|------------------------------------|---------------------------------|
| Scarring | FGM/C type III | FGM/C type I | RR 0.69 | 4462 | 0 000 |
| | 1 per 100 | 1 per 100 (0 to 2) | (0.31 to 1.51) | (2 studies) | very low ¹ |

^{*}The basis for the assumed risk (e.g. the median control group risk across studies) is based on risk in control group in included studies. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio; **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** We are very uncertain about the estimate.

¹ CI is wide, crosses limitations of precision (CI=0.31, 1.51).

Table 38 shows the comparison FGM/C type I-II vs FGM/C type III. We judged the quality of the outcome, urinary tract infection, as very low.

Table 38: Summary of Findings table for the comparison FGM/C type I-II vs FGM/C type III

FGM/C type I-II compared to FGM/C type III for girls/women - Gynecological outcomes

Patient or population: Girls/women

Settings: Community Intervention: FGM/C type I-II Comparison: FGM/C type III

| Outcomes | Illustrative comparative risks* (95% CI) Assumed risk Corresponding risk | | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence (GRADE) |
|---------------|--|-----------------|--------------------------------|------------------------------|---------------------------------|
| | FGM/C type III | FGM/C type I-II | | | |
| urinary tract | | | RR 0.38 | 9261 | ⊕⊖⊝⊝ |
| infection | 14 per 100 | 5 per 100 | (0.16 to 0.89) | (4 studies) | very low ^{1,2} |
| | | (2 to 12) | | | |

^{*}The basis for the assumed risk (e.g. the median control group risk across studies) is based on risk in control group in included studies. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio; **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** We are very uncertain about the estimate.

¹ 3 of 4 studies had low methodological study quality.

² I-square= 82%

Discussion

In this systematic review we aimed to summarize empirical data assessing the gynecological consequences of FGM/C. We included 136 studies with a total of 130,558 girls and women. We prioritized evidence from the 42 comparative studies, including three case-control studies, in which 56% of the women had some form of FGM/C and were compared to women who had not undergone FGM/C. The majority of these studies were of either high (19%) or moderate (45%) methodological quality. It was possible to compare the risk of ten gynecological outcomes in women with FGM/C versus women with no FGM/C: Tissue damage, vaginal obstruction, cysts, problems with urination and voiding, problems with menstruation, pain during sexual intercourse, infections of the reproductive and urinary tracts, HIV and sexually transmitted infections (STIs), infertility, and various vaginal complications such as discharge and itching. In brief, the findings suggest that compared to women with no FGM/C, women who have been subjected to FGM/C are at an increased risk of urinary tract infection, bacterial vaginosis, and possibly also to burning/painful urination, vaginal discharge and itching, problems with menstruation, and pain during intercourse. For a number of other outcomes, the data either failed to establish a significant difference in risk or were insufficient to show whether or not FGM/C contributes to gynecological problems.

Discussion of main results

Observed associations with FGM/C

The meta-analytic findings show that women with FGM/C seem to be three times more likely to have urinary tract infections and 1.7 times more likely to suffer from bacterial vaginosis compared to women without FGM/C. Additionally, women with the most extensive type of FGM/C, type III, seem to be about 2.5 times more likely than women with FGM/C types I-II to have urinary tract infections, suggesting that the risk of experiencing such infections is a function of the anatomical extent of the FGM/C procedure. This dose-response finding strengthens the argument for the existence of a causal relationship between FGM/C and urinary tract infection, but should not be used as an argument to 'medicalize' the practice towards less extensive genital cutting. On the contrary, as explained by physician Almroth (41), any alteration of the natural anatomy of the vulva could lead to changes, structural and physiological, which in turn have negative effects on a woman's gynecological health. In

fact, clinical evidence summarized in the present systematic review indicates that women who have been cut seem to experience a heightened risk of bacterial vaginosis. As explained also by Morison and colleagues (65), the seemingly higher risk of bacterial vaginosis in women with FGM/C may be because of the removal of the protective labia minora. This genital tissue likely helps to maintain a healthy vaginal environment. The fact that women with FGM/C seem to be at a significantly increased risk of urinary tract infections and bacterial vaginosis indicates that FGM/C is a type of iatrogenic trauma predisposing women to infections.

Although the evidence was not conclusive, years and sometimes decades after the traditional genital alteration procedure, it seemed that women with FGM/C not only had a greater risk of urinary tract infections and bacterial vaginosis, but also of experiencing burning/painful urination, vaginal discharge and itching, and problems with menstruation, as compared to women with no FGM/C. Both burning and painful urination as well as vaginal discharge and itching are commonly reported symptoms associated with urinary- and reproductive tract infections and bacterial vaginosis (169), and are thus unsurprising in the context of the findings of the present systematic review. Burning and painful urination may also be due to scar tissue around the urinary outlet. We located few comparative studies examining scarring, but found that there seemed to be a greater risk of scar formation in women with FGM/C — particularly those with more extensive types — compared to women with no FGM/C, and no significant difference in risk between women with FGM/C type I and women with FGM/C type II or type III. Across the nine studies reporting on scarring, 0.4% to 54.2% of women with FGM/C had scarring from the genital cutting. Keloids and damaged tissue were also frequently reported. Similarly, with regards to problems with menstruation, the mechanism(s) for the seemingly higher prevalences of dysmenorrhea and difficulty passing menstrual blood in women with FGM/C is unclear, but may be related to pelvic congestion and, in women with FGM/C type III, a very small vaginal opening may explain restricted menstrual flow.

In a previous systematic review, we examined the sexual consequences of FGM/C, concluding that "women with FGM/C are more likely to experience pain during intercourse" compared to women without FGM/C (16). With an additional study included in the present systematic review, we strengthen this earlier finding. Furthermore, while in our previous systematic review we did not assess differences between types of FGM/C, in the present review, we identified a likely greater risk of problems during sexual intercourse for women with FGM/C type III compared to those with type I and II. In fact, two representative household studies from Eritrea showed that prevalence of problems during sexual relations was 1% in women with nicking, 5% in women with type I-II, and 18% in women who were infibulated (50;51). A plausible mechanism of pain during sexual intercourse for females with FGM/C, similar to problems with menstruation, is a tiny vaginal opening among infibulated women. There was only one comparative study with data on labial fusion, but 26 clinical re-

ports document that many girls and women who have been subjected to FGM/C suffer from labial fusion, vulval adhesions and synechia, and gynetresia. More than a dozen case reports also describe various vaginal obstructions, such as partial vulval stenosis and atresia that require medical assistance. Several of the clinical reports detail the resulting difficulties — including inabilities — passing menstrual blood and penetrating for coitus (e.g. (97;101;103;113;114;145)).

Whatever the mechanisms for the seemingly higher prevalences of urinary tract infections, bacterial vaginosis, burning/painful urination, vaginal discharge and itching, problems with menstruation, and pain during sexual intercourse in women with FGM/C, the abandonment of this practice is thus advisable from a women's health perspective. Additionally, according to United Nations agencies, particularly WHO (3;171), abolishment is desirable from a human rights standpoint. Interestingly, experts (65) state that in most practicing communities, anti-FGM/C approaches based on its harmful health consequences is less controversial than those based on human rights. Potentially, such approaches are considered a more legitimate argument against the practice. In a series of systematic reviews we have documented that FGM/C is indeed implicated in sexual problems (16), obstetric complications (1), immediate harms such as urine retention, excessive bleeding, swelling, problems with healing, and pain (2), and in the present systematic review we show that women with FGM/C seem to be at an increased risk of urinary tract infections, bacterial vaginosis, and at a likely greater risk of burning/painful urination, vaginal discharge and itching, pain during intercourse, and experiencing problems with menstruation. Rather than arguing that abandonment strategies narrowly focus on the damaging health effects, we believe approaches should be appropriate to its target audience, which in most cases would include health arguments. Further, such information must be based on sound data because they make claims more credible to practicing communities and, in turn, more effective. It must be noted that there are health outcomes for which there is no convincing evidence of a relationship with FGM/C and others for which there is insufficient evidence to conclude whether there is a difference in risk between women with FGM/C and women without FGM/C. We turn our attention to such gynecological outcomes below.

No significant associations with FGM/C

For many outcomes, while a number of studies were identified, there were often few events, which meant that studies' power to detect potential differences between groups of women was low and the confidence intervals were wide. The quality of the evidence was thus downgraded. Despite the fact that the low quality of the data preclude firm conclusions about effect sizes, our findings suggest that there is no statistically significant difference in risk of HIV and STIs. That is, there seems to be no clear trend for either a greater or lower risk of HIV and STIs among women who have undergone FGM/C. This is not to say that such infections cannot occur as a consequence of the procedure. They certainly can. For example, a few years ago, Etokidem (115) presented a case report of a 6-year-old girl who contacted HIV

through ritual FGM/C in Nigeria, presumably through the use of a non-sterilized ceremonial cutting instrument. Similarly, researchers such as Pépin and colleagues (70) support the possibility of HIV transmission during mass FGM/C rituals in which the same knife is used on multiple girls. Nonetheless, the fact that HIV and STIs appear not to be significantly associated with FGM/C at the meta-analytic level implies that ritual genital cutting is not a key factor in their occurrence.

It must be noted that our results suggest that FGM/C neither increased nor decreased the risk of HIV and STIs. From a public health perspective it is an important finding that, unlike male circumcision, having undergone FGM/C is not protective against acquiring STIs and HIV. Systematic reviews have confirmed that male circumcision reduces the risk of heterosexual HIV acquisition in men (172) and likely also homosexual acquisition in men (173).

Unknown association with FGM/C for some outcomes

For a range of outcomes, there was limited evidence as well as limited quality of the available evidence. The ability to draw conclusions is therefore limited. For example, we found and included only one quantitative study that described the psychological health consequences of FGM/C on girls 15 years or younger. In a previous systematic review (17), researchers from the NOKC examined the psychological consequences of FGM/C on adult women, including only four controlled studies. Together, the previous and the present systematic reviews reveal a gap in the research literature regarding the psychological sequela of FGM/C. Further, the data were insufficient to determine whether or not genital cutting contributes to scarring, keloid, fistula, cysts, vaginal obstructions, abscess, incontinence, chronic pelvic infections, and infertility. It was also uncertain whether women with different types of FGM/C were at differential risks of experiencing such gynecological outcomes. Most of these health issues were relatively rare among all groups of women, as seen in a representative study from Sudan: El Dareer (47) delineates that neither women without FGM/C nor women with type I self-reported keloids, abscess, or cysts. Among women with FGM/C type III, 0.4% had a keloid, 0.6% a cyst, and 4.6% had an abscess. The above health problems are often cited in activist FGM/C literature as common long term problems of FGM/C (e.g. (174-180)), and may occur as a consequence of FGM/C, but the data are insufficient to conclude that FGM/C significantly contributes to their occurrence.

When considering that the included data are insufficient to show whether or not genital cutting significantly contributes to scarring, keloid, fistula, cysts, vaginal obstructions, abscess, incontinence, chronic pelvic infections, and infertility, it is important to remember that all these gynecological problems are multifactorial and occur among both females subjected to FGM/C and those not. Labial fusion, for example, is a common gynecological problem among prepubertal girls (181-183). It is reported to occur in up to 1.8% of female prepubertal patients (184) and is sometimes accompanied by complications believed to be associated with FGM/C, such as local

inflammation, dysuria, and obstruction (185). With respect to the finding that women with FGM/C were not found to be of a different risk of fistula than women with no FGM/C, we agree with Browning and colleagues (40), who suggest that FGM/C, rather than a cause of fistula, may be a "marker for the presence of other important risk factors that combine to promote obstetric fistulae" (p.582). Such factors include disempowerment of women (low socioeconomic status, restricted personal autonomy, lack of education), limited contraceptive choice, early marriage and childbirth, and high fertility in settings where their timely access to emergency obstetric services, which too often are of low quality, is poor. It is also possible that complications such as labial fusion and blockage are more frequently reported in the medical case literature when they occur among girls or women who have undergone FGM/C than when they occur among women without FGM/C, creating an artificial impression that there is a causal relationship. On the other hand, there is a real chance of under-reporting of many of the health issues covered in this systematic review. Outcomes were often self-reported by primarily adult women who were asked to recall health problems occurring years and sometimes decades in the past. Importantly, as suggested in the literature (e.g. (158)(189)) women may fail to report complications in contexts where FGM/C is discouraged or even illegal and they may not themselves attribute the complication to the procedure of FGM/C, leading to under-reporting of complications from FGM/C.

Quality of the evidence

Of the 136 included studies there were three case-control studies. These were rated as having high study quality. Also five of the 38 comparative cross-sectional studies (13%) had high methodological study quality, 18 (47%) had moderate quality, and 15 (40%) were judged to have low methodological study quality. In contrast, few (18%) of the non-comparative studies were rated to have high methodological study quality. About a fifth of these non-comparative studies (21%) had moderate methodological study quality and 61% were rated to have low methodological study quality. Although we included 42 comparative studies, with an average sample size of 2390 women, some studies had a small sample size and a number of studies had a low number of events, for example for outcomes such as keloid. A low number of events decreases studies' power to detect potential differences and produces wide confidence intervals, which in turn lowers the quality of the evidence. With GRADE we assessed the quality of the evidence for outcomes that were eligible for meta-analysis. The results for the six outcomes scarring, cysts, urinary tract infection, HIV, STIs, and bacterial vaginosis were assessed as 'very low'. This means that any estimate of their effect is very uncertain (24). In sum, using the GRADE instrument, the quality of the evidence was very low with regards to documenting a relationship between FGM/C and gynecological consequences.

As we and others have discussed elsewhere (1;20), a cultural practice like FGM/C does not lend itself to a randomized controlled trial, the gold standard for making

causal inferences. In fact, to date, we have identified only three case-control studies on FGM/C, which point to the methodological difficulties in studying the health sequela of FGM/C. The bulk of credible research on FGM/C derives from comparative cross-sectional studies in which 'exposed' (females with FGM/C) and 'unexposed' (females without FGM/C) groups are compared, or differently exposed females are compared, and the risk between the groups are assessed. The cross-sectional design of all but four of the studies means that a causal effect of FGM/C cannot necessarily be ascribed to any observed differences in prevalence between women with FGM/C and women who have not undergone FGM/C. Cross-sectional studies are marred by a high risk of bias with respect to sampling because the recruitment of sufficiently equivalent and large exposed and unexposed groups of women may be difficult. A strength of the included studies in the present systematic review was that the nonexposed group was selected from the same population as the exposed group. Unfortunately, the groups were rarely comparable with respect to important background factors. Further, thirty comparative studies (79%) included in this systematic review controlled for confounders. Because data on FGM/C are observational, tests for the presence of confounding factors are important. This affords greater certainty about the data and results (186). Thus, we suggest that analyses such as multivariate regression analysis be undertaken in future studies. Whenever adjusted results were available in the included studies, we reported and used these in our systematic review, but because a number of studies failed to report adjusted results, most of our pooled analyses included unadjusted results, which affords less certainty in the results. Lastly, with respect to sampling, we found that 15 of the 61 included cross-sectional studies (25%) could be considered representative. The women with FGM/C in the majority of the samples therefore may not be representative of the general population of women with FGM/C regarding factors such as complications. Data on young girls in particular were scarce: Among the comparative studies, only two examined outcomes among young girls (41;59). All of the cross-sectional studies, except three (41;59;64), failed to explain whether and how the participants who agreed to participate were different from those who refused to participate.

Another methodological challenge in FGM/C research is measurement of 'exposure' to the practice. Measuring exposure to FGM/C means determining whether study participants have undergone FGM/C and extent or type of genital tissue modified. In our systematic reviews, we have applied the WHO classification system of FGM/C (3). We found that a similar classification system was applied also by the majority of the included studies. In about three quarters of the included studies, classification and exposure were based on gynaecological examination, while it was based on self-report in the remaining studies. A range of studies has shown that validity and reliability of self-reported FGM/C status vary, but that most women can correctly say whether or not they have undergone some type of FGM/C (65;80;187;188). Additionally, because some studies simply described the exposed women as "circumcised", "cut", or as having "excision" or "female genital cutting", and combined dif-

ferent types of genital cutting (typically types I and II), the assessment of risk between different types of FGM/C are likely more uncertain than those comparing women with FGM/C and women with no FGM/C.

Continuing with limitations with regards to measurement, outcome measurements of the gynecological outcomes were by clinical- and self-report in 59% and 41% of the comparative studies, respectively. Most of the reported outcomes included in this systematic review are amenable to direct physical measurement. Clinical assessment of outcomes such as infection of the urinary tract is clearly less prone to bias than self-report, thus we encourage researchers to conduct clinical examinations of outcomes whenever possible. According to Bjälkander and colleagues (189), there is an under-reporting of complications from FGM/C, both because of the sensitivities regarding FGM/C in many settings and also because not all women (or parents of girls) would attribute complications to FGM/C. It seems reasonable that in groups where FGM/C prevalence is high, certain consequences that are common may be considered normal and not associated with the practice. For instance, Hanny Lightfoot-Klein (190) interviewed women who reported that it took on average 10-15 minutes to empty their bladder and considered this condition normal. It follows that in a community where everyone is infibulated, this may not be perceived and reported as 'difficult urination'. It bears mentioning however, that all our meta-analyses pooled clinically assessed outcomes, and for meta-analyses which included both clinical and self-reported outcomes we performed sub-group analyses, finding no statistical differences. Thus, for all meta-analyses results in the present systematic review (scarring, cysts, urinary tract infection, HIV, STIs, bacterial vaginosis), outcome measurement is likely no limitation. In contrast, it was a limitation that definitions of outcomes were often uncertain or unstated, meaning that we could not always be sure that similarly labeled outcomes were identically defined and measured in each included study. Only one quarter (26%) of the comparative cross-sectional studies showed that the measures were reliable and valid.

The very low quality of the evidence and methodological shortcomings notwith-standing, the difference in examining effectiveness and harm in a systematic review bears mentioning. As explained in the Cochrane Handbook (22), while the study of beneficial effects typically necessitates randomized studies, adverse effects of treatment or exposure can often be effectively investigated in non-randomized studies. Study designs that are more susceptible to bias, such as comparative cross-sectional studies, may in the absence of better evidence be acceptable for evaluation of harm. Although the evidence is uncertain or very low – due to a lack of randomized studies – the value of knowing that there is the possibility of a potentially serious harm is considerable. Relatedly, when assessing adverse effects and not expected beneficial effects, one must distinguish between quantifying and detecting an effect of an intervention. Thus, according to the Cochrane Handbook, "if a review can establish beyond reasonable doubt that an intervention causes a particular harm, the precision and susceptibility to bias of the estimated effect may not be critical" (22).

Strengths and limitations

As described in the preface, this systematic review is the last in a series of three systematic reviews mapping the range of physical health consequences of FGM/C. The first two delineated the obstetric harms and immediate complications. Each systematic review was conducted according to the same, standard approach for conducting systematic reviews. Therefore, in this section, we summarize strengths and limitations detailed in the first systematic review, on obstetric consequences (1).

First, the results derive from a comprehensive and systematic literature search and a systematic process for identifying relevant studies. Selection of studies was carried out by two independent reviewers and the inclusion selection of studies was based on pre-set inclusion criteria. These are detailed in a published protocol (see http://www.crd.york.ac.uk/PROSPERO/). Second, we included all empirical research while prioritizing the reporting of comparative studies, i.e., study designs which can say something about the likelihood of health consequences from the exposure (FGM/C) on an outcome (e.g. urinary tract infection). Third, the 42 comparative studies that presented data on the differences in outcomes between groups made it possible to statistically estimate the risk of gynecological complications in women who had undergone FGM/C versus women who had not undergone FGM/C, or undergone different types of FGM/C, and in many cases we could perform metanalyses. In sum, we applied a systematic approach at all steps of the systematic review.

Our systematic review has some limitations, including a literature search that is more than one year old. Related, from this and previous systematic reviews we have carried out on the issue of FGM/C, our impression is that the literature on FGM/C includes numerous unpublished and other hard-to-obtain works. Therefore, despite our comprehensive search strategy, it is possible that we have missed some studies and our systematic review may be subject to publication bias. We failed to obtain 12 possibly relevant records in full text (25-36) and primary data from five studies (46;56;60;61;63). We acknowledge the limitation of only including outcomes for the girl or woman having undergone FGM/C and not other individuals, such as her sexual partners.

Some caution is warranted in interpreting the results of this systematic review. Using GRADE, we assessed the quality of the evidence for all outcomes as being too low to warrant conclusions about a causal relationship between FGM/C and gynecological complications. The low quality of the evidence was due to the weaknesses of the observational design of all included studies, inconsistencies in results, and imprecision of effect estimates. Despite the large sample sizes for several of the pooled analyses, events were few, and the confidence intervals for some of the effect estimates,

particularly cysts and urinary tract infection, remained wide. Additional outcome research would likely narrow the confidence intervals, and for some outcomes possibly alter the direction of effect.

Conclusion

In this extensive systematic review of 136 studies we sought to determine the effect of FGM/C on gynecological health outcomes by assessing the risk of having gynecological events among women who had undergone FGM/C and women who had not. We found that genital cutting has harmful consequences for a woman's gynecological health. Specifically, the findings of a statistical relationship between FGM/C and urinary tract infections as well as bacterial vaginosis are not only statistically significant, but also decidedly relevant for preventive work against this cultural practice, such as community campaigns. Moreover, healthcare personnel should be aware of likely gynecological complications experienced by women who have undergone FGM/C and be prepared to provide relevant care. The findings have political implications since two international health organizations, WHO and NORAD, asked for systematic review evidence on the physical consequences of the practice. The findings permit these and other organizations to make informed statements based on the currently best available level of evidence and take further steps. The evidence lends support to arguments backing the political will to prevent the age-old practice of FGM/C though for example education about its harms for gynecological health.

All in all, the results range from suggesting a significantly greater risk of gynecological complications to indicating no significant difference in risk. It must be highlighted that the systematic review findings showed no indication of there being gynecological benefits of FGM/C. At the same time, it qualified some widely held assumptions about the categorically negative impact of FGM/C on women's gynecological health. The results could not establish a significant relationship between FGM/C and HIV and STIs. There were also several uncertain links between FGM/C and gynecological morbidities, including cysts, fistula, abscess, incontinence, chronic pelvic infections, and infertility. From a women's health perspective, irrespective of the range of complications or exact size of the greater risk from FGM/C, the greater likelihood of suffering and morbidity, even years and decades after the procedure, strengthens arguments that FGM/C is injurious for women's health.

Need for further research

Together with two previously published systematic reviews (1;2), this report constitutes today's best available evidence of the physical complications of FGM/C. They

document that there seems to exist a significantly greater risk, but also no significant difference in risk for some outcomes, among women who have been subjected to FGM/C relative to women with no FGM/C. Caution is required in interpreting the exact size of the greater risk of complications, but for many outcomes it is unlikely that further research would alter the conclusions. As we have stated previously (1;2), from a women's health standpoint even the lowest rates of complications are undesirable. We believe sufficient evidence exist to conclude that women who have undergone FGM/C suffer a greater risk of physical complications, thus, further research into this question is unlikely to produce practical value.

On the other hand, there is a dearth of research on the psychological health consequences of FGM/C and consequences on young girls. Thus, there is a need for research into the full range of the psychological health consequences of subjecting girls and young women to the various types of FGM/C. There is a need also for more research on young girls and research into the best and most acceptable care and treatment for girls and women who suffer complications. Studies into the psychological health consequences and the physical complications of FGM/C – in the event that researchers consider further investigations of the association between FGM/C and physical outcomes ethically and financially justified – should base such investigations on the best possible methodological study design, ensure representativeness and equivalency between exposed and unexposed groups of women, and apply standardized definitions and clinical measures for exposure as well as outcomes to the extent that it is possible.

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Appendix

Appendix 1: Glossary

The explanation for medical terms is taken from the MedlinePlus Medical Dictionary (http://www.nlm.nih.gov/medlineplus/mplusdictionary.html). The explanation of methodological and statistical terms is from the glossary of the Cochrane handbook.

TERM EXPLANATION

Abscess A localized collection of pus surrounded by inflamed tissue.

Adhesion Connection of tissues not normally connected.

Anaemia A condition in which the blood is deficient (in red blood cells,

hemoglobin, or total volume).

Anal sphincter The muscle controlling the closing of the anus.

Anuria Absence of or defective urine excretion.

Apareunia Impossibility to have sexual intercourse.

Atresia Absence or closure of a natural passage of the body. E.g., the

vulva.

Bacterial vaginosis A mild infection of the vagina caused by bacteria.

Bacteriuria The presence of bacteria in the urine.

Bartholin's abscess The buildup of pus that forms a lump (swelling) in one of the

Bartholin's glands, which are located on each side of the vaginal opening (the glands and secrete fluid that helps lubricate

the vagina).

Candidiasis An infection caused by the Candida fungus.

Cyst A closed sac. It has a distinct membrane and develops abnor-

mally in a body cavity or structure, anywhere on the body.

Cystitis Inflammation of the urinary bladder.

Dermoid A congenital cystic tumour (cyst) whose walls are lined with

epithelium. Made up of cutaneous elements.

Dysmenorrhea Painful menstruation.

Dyspareunia Difficult or painful sexual intercourse.

DHS Demographic and Health Survey. This is a nationally repre-

sentative household survey that provides data for a wide range of monitoring and impact evaluation indicators in the areas of population, health, and nutrition. It is typically conducted

about every five years.

Dysuria Difficult or painful discharge of urine.

Escherichia coli E. coli. A bacterium that is commonly found in the lower in-

testine, and that can cause infectious disease.

Fistula An abnormal passage that leads from an abscess or hollow or-

gan or part to the body surface or from one hollow organ or part to another. E.g., vesicovaginal fistula (urinary bladder

and vagina).

Gishiri cut A type of FGM/C covered under the WHO typology type IV

(other). It is a posterior (or backward) cut from the vagina

into the perineum.

Gynetresia Absence of a normal opening in the lumen (inner opening) of

the female genital tract (vagina). Can be congenital or ac-

quired, e.g., due to injury.

HbsAg The surface antigen of the hepatitis B virus (HBV) – it indi-

cates current hepatitis B infection.

Hematocolpos An accumulation of blood within the vagina.

Hemorrhage A profuse loss of blood.

Hepatitis B An infectious illness of the liver caused by the hepatitis B vi-

rus.

HIV Human immunodeficiency virus. A retrovirus that infects and

destroys helper T cells of the immune system. HIV-1 is the most common type. HIV-2 is found mainly in West Africa, and is less virulent and has a longer incubation period than

HIV-1.

HTLV-I A retrovirus. It is found in association with adult T-cell leuke-

mia and a progressive paralyzing myelopathy.

Hydronephrosis Cystic distension of the kidney caused by the accumulation of

urine in the renal pelvis as a result of obstruction to outflow and accompanied by atrophy of the kidney structure and cyst

formation.

Hypertrophy The excessive development of an organ or part.

Hypoplasia A condition of arrested development in which an organ or part

remains below the normal size or in an immature state.

Incontinence The inability of the body to control the evacuative functions

(urination/micturation, defecation/voiding the bowels). Typi-

cally: urine leakage.

Infertility Not fertile. Incapable of or unsuccessful in achieving preg-

nancy over a considerable period of time in spite of attempts.

Infection The presence of infective agent in or on a suitable host. E.g.,

urinary infection.

Keloid A thick scar resulting from excessive growth of fibrous tissue.

Labial adhesion The abnormal union (growing together) of the labia.

Lymphangiectases Dilatation of the lymphatic vessels.

Mycetoma A condition characterized by invasion of the deep subcutane-

ous tissues with fungi or actinomycetes.

Necrotizing faciltis A severe soft tissue infection. It is marked by edema, necrosis

of subcutaneous tissues, painful red swollen skin. It usually occurs as a complication of surgery, injury, or infection.

Neuroma A tumor or mass growing from a nerve. This can be in an am-

putation stump resulting from abnormal regrowth of the

stumps of severed nerves.

Occlusion Obstruction (often blocking of a passage, e.g. the vagina).

Oligomenorrhea Abnormally infrequent or scanty menstrual flow.

Perineum The area between the anus and the posterior part of the exter-

nal genitalia.

Pelvic inflamma-

tory disease

An infection of the female reproductive tract (from microorganism like gonorrhea) that is marked especially by lower abdominal pain, abnormal vaginal discharge, fever. It is a lead-

ing cause of infertility in women.

Prolapse The falling down or slipping of a body part from its usual posi-

tion. E.g., urethral mucosal prolapsed.

Also called septicaemia. A systemic inflammatory response Sepsis

> syndrome caused by an infection. It is usually characterized by abnormal body temperature and white blood cell count, rapid

heart rate. Potentially deadly.

SR Systematic review.

Stenosis A narrowing or constriction of the diameter of a bodily pas-

sage or orifice, such as the vagina.

Sterile Failing to produce or incapable of producing offspring.

STI Sexually transmitted infection. The most common bacterial

> types are: Chlamydia (dysmenorrea trachomatis), gonorrhea (neisseria gonorrhoeae), granuloma inguinale, syphilis (treponema pallidum). The most common viral types are: Hepatitis B virus, herpes simplex virus, HIV, Human Papillomavirus.

An adhesion of parts. **Synechia**

An abnormal mass of tissue. It can form in any part of the **Tumor**

body. It can be benign or cancerous (malignant).

Ulcer A break in skin or mucous membrane with loss of surface tis-

sue, disintegration and necrosis of epithelial tissue, and often

pus.

UNFPA United Nations Population Fund

Urinary retention Also called ischuria. It is the inability to urinate. It is charac-

terized by poor urinary stream with intermittent flow, strain-

ing, a sense of incomplete voiding, and hesitancy.

ton

Urinary tract infec- The presence of infective agent in the urinary tract, the system

that makes urine and carries it out of the body.

Vaginitis An inflammation of the vagina (often due to infection). It may

be marked by irritation and vaginal discharge.

An abnormal or diseased condition of the vagina. **Vaginosis**

Villi Microscopic finger-like projections that line walls, such as

vagina. They can be benign (non-cancerous) or cancerous.

Appendix 2: Search for literature

African Index Medicus

Database: African Index Medicus

Date: 22.12.2011

Number of records: 14

Search:

"CIRCUMCISION" [Descriptor] or "CIRCUMCISION, FEMALE" [Descriptor] or

"INFIBULATION" [Descriptor]

British Nursing Index and Archive

Database: Ovid British Nursing Index and Archive 1985 to January 2012

Date: 20.01.2012

Number of records: 177

Search:

1. Circumcision/

- 2. ((female\$ or wom#n or girl\$1) adj3 (mutilation\$ or circumcis\$ or cutting\$)).tw.
- 3. "fgm/c".tw.
- 4. ((removal\$ or alteration\$ or excision\$) adj6 female genital\$).tw.
- 5. pharaonic circumcision\$.tw.
- 6. sunna.tw.
- 7. (clitoridectom\$ or clitorectom\$).tw.
- 8. (infibulat\$ or reinfibulat\$ or deinfibulat\$).tw.

9. or/1-8

CINAHL

Database: EBSCO Host CINAHL 1981-Present

Date: 16.01.2012

Number of records: 443

Search:

| # | Query | Limiters/Expanders | Last Run Via | Re- sults | |
|----|--|----------------------------------|--|--------------|------------|
| S7 | S1 or S2 or S3 or S4 or S5 or S6 | Search modes – Boolean/Phrase | Interface – EBSCOhost Search Screen – Ad- vanced Search Database – CINAHL | 534 | Edit S7 |
| S6 | TI (sunna or clitoridectom* or clitorectom* or infibulat* reinfibulat* or deinfibulat*) OR AB (sunna or clitoridectom* or clitorectom* or inbibulat* reinfibulat* or deinfibulat*) | Search modes – Boolean/Phrase | Interface – EBSCOhost Search Screen – Ad- vanced Search Database – CINAHL | 4 | Edit S6 |
| S5 | TI pharaonic W0 cir- cumcision* OR AB pharaonic W0 cir- cumcision* | Search modes – Boolean/Phrase | Interface – EBSCOhost Search Screen – Ad- vanced Search Database – CINAHL | 2 | Edit S5 |

| \$4 | TI ((removal* or alteration* or excision*) N6 (female W0 genital*)) OR AB ((removal* or alteration* or excision*) N6 (female W0 genital*)) | Search modes – Boolean/Phrase | Interface – EBSCOhost Search Screen – Ad- vanced Search Database – CINAHL | 4 | Edit S4 |
|-----|--|----------------------------------|--|-----|------------|
| S3 | TI "fgm/c" OR AB "fgm/c" | Search modes – Boolean/Phrase | Interface – EBSCOhost Search Screen – Ad- vanced Search Database – CINAHL | 1 | Edit S3 |
| S2 | TI ((female* or wom#n or girl*) N3 (mutilation* or circumcis* or cutting*)) OR AB ((female* or wom#n or girl*) N3 (mutilation* or circumcis* or cutting*)) | Search modes – Boolean/Phrase | Interface – EBSCOhost Search Screen – Ad- vanced Search Database – CINAHL | 345 | Edit S2 |
| S1 | (MH "Circumcision, Female") | Search modes – Boolean/Phrase | Interface – EBSCOhost Search Screen – Ad- vanced Search Database – CINAHL | 443 | Edit S1 |

The Cochrane Library

Databases in The Cochrane Library:

- Cochrane Database of Systematic Reviews (CDSR): Issue 12 of 12, Dec 2011
- Cochrane Central Register of Controlled Trials (CENTRAL),
- Database of Abstracts of Reviews of Effects (DARE)
- Health Technology Assessment Database (HTA): Issue 4 of 4 Oct 2011

Date: 09.01.2012

Number of records: CDSR: 1; CENTRAL: 12; DARE: 0; HTA: 3

Search:

#1 MeSH descriptor Circumcision, Female, this term only

((female* or woman or women or girl or girls) near/3 (mutilation* or circumcis* or cutting*)) or "fgm/c" or ((removal* or alteration* or excision*) near/6 (female next genital*)) or (pharaonic next circumcision*) or sunna or clitoridectom* or clitorectom* or infibu-

#2
lat* or reinfibulat* or deinfibulat*:ti or ((female* or woman or women or girl or girls) near/3 (mutilation* or circumcis* or cutting*)) or "fgm/c" or ((removal* or alteration* or excision*) near/6 (female next genital*)) or (pharaonic next circumcision*) or sunna or clitoridectom* or clitorectom* or infibulat* or reinfibulat* or deinfibulat*:ab

#3 (#1 OR #2)

EMBASE

Database: Ovid Embase 1980 to 2012 Week 02

Date: 20.01.2012

Number of records: 1442

Search:

- 1. female circumcision/ or female genital mutilation/ or female genital cutting/ or infibulation/
- 2. ((female\$ or wom#n or girl\$1) adj3 (mutilation\$ or circumcis\$ or cutting\$)).tw.
- 3. "fgm/c".tw.
- 4. ((removal\$ or alteration\$ or excision\$) adj6 female genital\$).tw.
- 5. pharaonic circumcision\$.tw.
- 6. sunna.tw.
- 7. (clitoridectom\$ or clitorectom\$).tw.
- 8. (infibulat\$ or reinfibulat\$ or deinfibulat\$).tw.
- 9. or/1-8

MEDLINE® In-Process & Other Non-Indexed Citations

Database: Ovid MEDLINE® In-Process & Other Non-Indexed Citations and Ovid MEDLINE® 1946 to Present (1946 to January Week 2 2012; January 19, 2012)

Date: 20.01.2012

Number of records: 1299

Search:

- 1. Circumcision, Female/
- 2. ((female\$ or wom#n or girl\$1) adj3 (mutilation\$ or circumcis\$ or cutting\$)).tw.
- 3. "fgm/c".tw.
- 4. ((removal\$ or alteration\$ or excision\$) adj6 female genital\$).tw.
- 5. pharaonic circumcision\$.tw.
- 6. sunna.tw.
- 7. (clitoridectom\$ or clitorectom\$).tw.
- 8. (infibulat\$ or reinfibulat\$ or deinfibulat\$).tw.
- 9. or/1-8

PILOTS

Database: CSA Illumina: PILOTS database (1871-Current)

Date: 02.03.2011 Number of records: 17

Search:

((DE=("genital mutilation")) or (TI=(((female* or woman or women or girl or girls) within 3 (mutilation* or excision* or cutting*)) or fgm or ((removal* or alteration* or excision*) within 6 female genital*) or pharaonic circumcision* or sunna or clitoridectom* or clitorectom* or excision* or reinfibulat* or deinfibulat*)) or (AB=(((female* or woman or women or girl or girls) within 3 (mutilation* or circumcis* or cutting*)) or fgm or ((removal* or alteration* or excision*) within 6 female genital*)

or pharaonic circumcision* or sunna or clitoridectom* or clitorectom* or dysmenorrh* or reinfibulat* or deinfibulat*)))

POPLINE

Database: POPLINE® (POPulation information onLINE)

Date: 03.03.2011

Number of records: 1331

Search:

KEYWORDS:

FEMALE GENITAL CUTTING

PsycINFO

Database: Ovid PsycINFO 1806 to January Week 3 2012

Date: 20.01.2012

Number of records: 574

Search:

1. Circumcision/

- 2. ((female\$ or wom#n or girl\$1) adj3 (mutilation\$ or circumcis\$ or cutting\$)).tw.
- 3. "fgm/c".tw.
- 4. ((removal\$ or alteration\$ or excision\$) adj6 female genital\$).tw.
- 5. pharaonic circumcision\$.tw.
- 6. sunna.tw.
- 7. (clitoridectom\$ or clitorectom\$).tw.
- 8. (infibulat\$ or reinfibulat\$ or deinfibulat\$).tw.
- 9. or/1-8

Social Services Abstracts

Database: ProQuest: Social Services Abstracts (1979-Current)

Date: 25.01.2012

Number of records: 94

Search:

su.EXACT("Genital Mutilation" OR "Circumcision") OR ti((female* NEAR/3 (mutilation* OR excision* OR cutting*))) OR ab((female* NEAR/3 (mutilation* OR circumcis* OR cutting*)))

Sociological Abstracts

Database: ProQuest: Sociological Abstracts (1952-Current)

Date: 25.01.2012

Number of records: 436

Search:

su.EXACT("Genital Mutilation" OR "Circumcision") OR ti((female* NEAR/3 (mutilation* OR excision* OR cutting*))) OR ab((female* NEAR/3 (mutilation* OR excision* OR cutting*)))

WHOLIS

Database: WHO Library & Information Networks for Knowledge Database

(WHOLIS)

Date: 03.03.2011

Number of records: 72

Search:

words or phrase "((female\$ or wom?n or girl or girls) near3 (mutilation\$ or circumcis\$ or cutting\$))"

OR

words or phrase ""fgm/c""

OR

words or phrase "((removal\$ or alteration\$ or excision\$) near6 (female adj genital\$))"

OR

words or phrase "(pharaonic adj circumcision\$)"

OR

words or phrase "sunna"

OR

words or phrase "(clitoridectom\$ or clitorectom\$)"

OR

words or phrase "(infibulat\$ or reinfibulat\$ or deinfibulat\$)"

Appendix 3: Excluded studies

Table 1.1: Excluded studies read in full text and reason for exclusion

| Study first author (ref no.) | Cause for exclusion of study |
|------------------------------|---|
| NN 1994 (191) | Not empirical study |
| NN 2007 (192) | Not empirical study |
| NN 1996 (193) | Not empirical study |
| NN 1997 (194) | Not empirical study |
| Abariga 2009 (195) | No physical consequences/complications following FGM/C reported |
| Abubakar 2004 (196) | No physical consequences/complications following FGM/C reported |
| Abu-Shamma 1949 (197) | Not empirical study |
| Adanu 2005 (198) | Population not girls/women subjected to FGM/C |
| Adelusi 1975 (199) | No physical consequences/complications following FGM/C reported |
| Adeneye 2006 (200) | No physical consequences/complications following FGM/C reported |
| Adeokun 2006 (201) | No physical consequences/complications following FGM/C reported |
| Adeyinka 2009 (202) | No physical consequences/complications following FGM/C reported |

| Study first author (ref no.) | Cause for exclusion of study |
|------------------------------|--|
| Adinma 1999 (203) | No physical consequences/complications following FGM/C reported |
| Afifi 2007 (204) | No physical consequences/complications following FGM/C reported |
| Ahmed 2000 (205) | Not empirical study |
| Ahmed 2005 (206) | Not empirical study |
| Ahnaimugan 1978 (207) | No physical consequences/complications following FGM/C reported |
| Al-Krenawi 1999 (208) | No physical consequences/complications following FGM/C reported |
| Al-Krenawi 1999 (209) | No physical consequences/complications following FGM/C reported |
| Allag 2001 (210) | No physical consequences/complications following FGM/C reported |
| Ahmed Allam 1999 (211) | Population not girls/women subjected to FGM/C |
| Allam 2001 (212) | Population not girls/women subjected to FGM/C |
| Almroth-Berggren 2001 (213) | No physical consequences/complications following FGM/C reported |
| Amusan 2006 (214) | No physical consequences/complications following FGM/C reported |
| Anderson 1929 (215) | No extractable physical consequences following FGM/C reported |
| Applebaum 2008 (216) | No physical consequences/complications following FGM/C reported |
| Archibong 1987 (217) | No physical consequences/complications following FGM/C reported |
| Arthur 1942 (218) | Not empirical study |
| Asali 1995 (219) | No physical consequences/complications following FGM/C reported (qual) |
| Azadeh 1997 (220) | Not empirical study |
| Baasher 1982 (221) | Not empirical study |
| Badri 1992 (222) | Not empirical study |
| Badri 1984 (223) | Not empirical study (review) |
| Baido 2004 (224) | No physical consequences/complications following FGM/C reported |
| Baido 2007 (225) | No physical consequences/complications following FGM/C reported |
| Baker 1993 (226) | No physical consequences/complications following FGM/C reported |
| Bakr 1985 (227) | Not empirical study |
| Balogun 2001 (228) | Not empirical study |
| Barber 2010 (229) | Not empirical study |
| Beck 2008 (230) | Not empirical study |
| Behrendt 2005 (231) | No physical consequences/complications following FGM/C reported |
| Belmaker 2011 (232) | No physical consequences/complications following FGM/C reported |
| Bender 1999 (233) | Not empirical study |
| Bikoo 2008 (234) | Not empirical study |
| Boddy 1982 (235) | No physical consequences/complications following FGM/C reported (qual) |
| Bonilla 1997 (236) | Not empirical study |
| Brady 1999 (237) | Not empirical study |
| Briggs 2002 (238) | No physical consequences/complications following FGM/C reported |

| Study first author (ref no.) | Cause for exclusion of study |
|------------------------------|--|
| Brotmacher 1955 (239) | Not empirical study |
| Burkina Faso DHS 1999 (240) | No physical consequences/complications following FGM/C reported |
| Caldwell 1983 (241) | No physical consequences/complications following FGM/C reported |
| Campbell 1995 (242) | No physical consequences/complications following FGM/C reported (qual) |
| Cameron DHS 2004 (243) | No physical consequences/complications following FGM/C reported |
| Cannon 1964 (244) | No physical consequences/complications following FGM/C reported |
| Capraro 1972 (245) | No physical consequences/complications following FGM/C reported |
| Carton 2008 (246) | Not empirical study |
| Certinkurşun 2009 (247) | No physical consequences/complications following FGM/C reported |
| Cohen 1992 (248) | Population not girls/women subjected to FGM/C |
| Coker 1998 (249) | No physical consequences/complications following FGM/C reported |
| Cook 1979 (250) | Not empirical study |
| Damas 1972 (251) | No physical consequences/complications following FGM/C reported |
| Dattijo 2010 (252) | No physical consequences/complications following FGM/C reported |
| Davis 1999 (253) | No physical consequences/complications following FGM/C reported |
| Daw 1970 (254) | No physical consequences/complications following FGM/C reported |
| Dekou 2002 (255) | Population not girls/women subjected to FGM/C |
| De Villeneuve 1937 (256) | Not empirical study |
| Dirie 1991 (257) | No physical consequences/complications following FGM/C reported |
| Ebomoyi 1987 (258) | No physical consequences/complications following FGM/C reported |
| Ebong 1997 (259) | No physical consequences/complications following FGM/C reported |
| Egypt DHS 2008 (260) | No physical consequences/complications following FGM/C reported |
| Egypt DHS 2005 (261) | No physical consequences/complications following FGM/C reported |
| Egypt DHS 2003 (262) | No physical consequences/complications following FGM/C reported |
| Egypt DHS 2000 (263) | No physical consequences/complications following FGM/C reported |
| Ehigiegba 1998 (264) | No physical consequences/complications following FGM/C reported |
| Eke 2006 (265) | Not empirical study |
| Ekwueme 2010 (266) | No physical consequences/complications following FGM/C reported |
| Elmusharaf 2009 (267) | No physical consequences/complications following FGM/C reported |
| Elmusharaf 2006 (187) | No physical consequences/complications following FGM/C reported |
| Elnashar 2007 (268) | No physical consequences/complications following FGM/C reported |
| Epelboin 1979 (269) | No physical consequences/complications following FGM/C reported (qual) |
| Ericksen 1995 (270) | No physical consequences/complications following FGM/C reported |
| Essen 2002 (271) | Consequences/complications following FGM/C not reported for women |
| | |
| Ethiopia DHS 2005 (272) | No physical consequences/complications following FGM/C reported |

| Study first author (ref no.) | Cause for exclusion of study |
|------------------------------|--|
| Fahmy 2010 (274) | No physical consequences/complications following FGM/C reported |
| Feyi-Waboso 2006 (275) | No physical consequences/complications following FGM/C reported |
| Fleischer 1975 (276) | No physical consequences/complications following FGM/C reported |
| Gage 2006 (277) | No physical consequences/complications following FGM/C reported |
| Gallo 1985 (278) | No physical consequences/complications following FGM/C reported |
| Gallo 1985 (279) | No physical consequences/complications following FGM/C reported |
| Ghana DHS 2003 (280) | No physical consequences/complications following FGM/C reported |
| Gillian 1929 (281) | Not empirical study |
| Gilson 1995 (282) | Not empirical study |
| Githiora 2011 (283) | No physical consequences/complications following FGM/C reported |
| Gordon 2007 (284) | Not empirical study |
| Grisaru 1997 (285) | No physical consequences/complications following FGM/C reported |
| Gruenbaum 2006 (286) | No physical consequences/complications following FGM/C reported |
| Gurunluoglu 1999 (287) | Population not girls/women subjected to FGM/C |
| Hanselmann 2011 (288) | No physical consequences/complications following FGM/C reported |
| Harris 1951 (289) | No physical consequences/complications following FGM/C reported |
| Harrison 1983 (290) | Not empirical study |
| Hassan 1995 (291) | Not empirical study |
| Hassanin 2008 (292) | No physical consequences/complications following FGM/C reported |
| Henrion 2007 (293) | Not empirical study |
| Herieka 2003 (294) | No physical consequences/complications following FGM/C reported |
| Hezekiah 1989 (295) | Not empirical study |
| Hosken 1978 (296) | Not empirical study |
| Hosken 1993 (297) | Not empirical study (review) |
| Hrdy 1987 (298) | Not empirical study |
| Huber 1966 (299) | Not empirical study |
| Hulverscheidt 2009 (300) | Not empirical study |
| Igwegbe 2000 (301) | No physical consequences/complications following FGM/C reported |
| Isa 1999 (302) | No physical consequences/complications following FGM/C reported |
| Ismail 2009 (303) | No physical consequences/complications following FGM/C reported |
| Ivory Coast DHS 1999 (304) | No physical consequences/complications following FGM/C reported |
| Jackson 2003 (305) | No physical consequences/complications following FGM/C reported |
| Jaffer 2006 (306) | No physical consequences/complications following FGM/C reported |
| Jirovsky 2010 (307) | No physical consequences/complications following FGM/C reported |
| Johansen 2002 (308) | No physical consequences/complications following FGM/C reported (qual) |
| | |

| Study first author (ref no.) | Cause for exclusion of study |
|------------------------------|---|
| Kangoum 2004 (310) | No physical consequences/complications following FGM/C reported |
| Karmaker 2011 (311) | No physical consequences/complications following FGM/C reported |
| Kassegne 2010 (312) | No physical consequences/complications following FGM/C reported |
| Kästner 2005 (313) | Not empirical study |
| Keita 2001 (314) | No physical consequences/complications following FGM/C reported |
| Kenya DHS 2009 (315) | No physical consequences/complications following FGM/C reported |
| Kenya DHS 2003 (316) | No physical consequences/complications following FGM/C reported |
| Kenya DHS 1998 (317) | No physical consequences/complications following FGM/C reported |
| Khadivzadeh 2009 (318) | No physical consequences/complications following FGM/C reported |
| Khan 1997 (319) | No physical consequences/complications following FGM/C reported |
| Khanam 1977 (320) | Population not girls/women subjected to FGM/C |
| Khisa 2011 (321) | No physical consequences/complications following FGM/C reported |
| Kingston 1957 (322) | Not empirical study |
| Kiragu 1995 (323) | Not empirical study |
| Kun 1997 (324) | Not empirical study |
| Lagarde 2003 (325) | No physical consequences/complications following FGM/C reported |
| Lax 2000 (326) | Not empirical study |
| Levin 1980 (327) | Not empirical study |
| Liberia DHS 2007 (328) | No physical consequences/complications following FGM/C reported |
| Lightfoot-Klein 1983 (329) | No physical consequences/complications following FGM/C reported |
| Lightfoot-Klein 1989 (330) | No physical consequences/complications following FGM/C reported |
| Lightfoot-Klein 1989 (331) | No physical consequences/complications following FGM/C reported |
| Lightfoot-Klein 1993 (332) | Not empirical study |
| Lister 1960 (333) | No physical consequences/complications following FGM/C reported |
| Longo 1964 (334) | Not empirical study |
| Lowenstein 1978 (335) | No physical consequences/complications following FGM/C reported |
| Lundberg 2008 (336) | No physical consequences/complications following FGM/C reported |
| Mahran 1981 (337) | Not empirical study |
| Mali DHS 1996 (338) | No physical consequences/complications following FGM/C reported |
| Marin 1980 (339) | Not empirical study |
| Marinho 2009 (340) | Population not girls/women subjected to FGM/C |
| Masho 2009 (341) | No physical consequences/complications following FGM/C reported |
| Mboto 2010 (342) | No physical consequences/complications following FGM/C reported |
| McLintock 1985 (343) | Population not girls/women subjected to FGM/C |
| Melhado 2006 (344) | Not empirical study |
| Menage 2006 (345) | Not empirical study |

| Study first author (ref no.) | Cause for exclusion of study |
|------------------------------|--|
| Meniru 1994 (346) | Not empirical study |
| Missailidis 2000 (347) | No physical consequences/complications following FGM/C reported (qual) |
| Mitike 2009 (348) | No physical consequences/complications following FGM/C reported |
| Mohamud 1991 (349) | Consequences/complications following FGM/C not reported for women |
| Momoh 2004 (350) | No physical consequences/complications following FGM/C reported |
| Momoh 2010 (351) | Not empirical study |
| Momoh 2011 (352) | Not empirical study |
| Monjok 2007 (6) | Not empirical study |
| Morgan 2006 (353) | Not empirical study |
| Morison 2003 (354) | Not empirical study |
| Morris 1996 (355) | No physical consequences/complications following FGM/C reported |
| Morris 1999 (356) | Not empirical study |
| Mseddi 2007 (357) | No physical consequences/complications following FGM/C reported |
| Mustafa 1972 (358) | No physical consequences/complications following FGM/C reported |
| Ncayiyana 2003 (359) | Not empirical study |
| Ng 2000 (360) | Not empirical study |
| Niger DHS 2006 (361) | No physical consequences/complications following FGM/C reported |
| Niger DHS 1998 (362) | No physical consequences/complications following FGM/C reported |
| Nigeria DHS 2008 (363) | No physical consequences/complications following FGM/C reported |
| Nigeria DHS 2003 (364) | No physical consequences/complications following FGM/C reported |
| Nigeria DHS 1999 (365) | No physical consequences/complications following FGM/C reported |
| Nkrumah 1999 (366) | Not empirical study |
| Nnodum 2002 (367) | Only sexual and psychological consequences following FGM/C reported |
| No 2004 (368) | Not empirical study |
| Nour 2004 (369) | Not empirical study |
| Nour 2006 (370) | Reports on effect of defibulation |
| Nour 2008 (371) | Not empirical study |
| Ntiri 1993 (372) | No physical consequences/complications following FGM/C reported |
| Obermeyer 1999 (373) | Not empirical study (review paper) |
| Obermeyer 1999 (374) | Not empirical study (review paper) |
| Obermeyer 2005 (375) | Not empirical study (review paper) |
| Odimegwu 2001 (376) | No physical consequences/complications following FGM/C reported |
| Odimegwu 2000 (377) | No physical consequences/complications following FGM/C reported |
| Odu 2008 (378) | No physical consequences/complications following FGM/C reported |
| | |
| Odujinrin 1989 (379) | No physical consequences/complications following FGM/C reported |

| Study first author (ref no.) | Cause for exclusion of study |
|------------------------------|---|
| Olamijulo 1983 (381) | No physical consequences/complications following FGM/C reported |
| Onuigbo 1976 (382) | No physical consequences/complications following FGM/C reported |
| Osinowo 2003 (383) | No physical consequences/complications following FGM/C reported |
| Oyeledun 1997 (384) | No data for physical consequences following FGM/C reported |
| Paul 1993 (385) | No physical consequences/complications following FGM/C reported |
| Penna 2002 (386) | Reports on effect of defibulation with laser surgery |
| Peterman 2009 (387) | No data for physical consequences following FGM/C reported |
| Philp 1925 (388) | Not empirical study |
| Preston 1942 (389) | Population not girls/women subjected to FGM/C |
| Preston 1951 (390) | No physical consequences/complications following FGM/C reported |
| Preston 1954 (391) | Not empirical study |
| Rasheed 2011 (392) | No physical consequences/complications following FGM/C reported |
| Renaud 1968 (393) | Not empirical study |
| Reyners 2004 (394) | Not empirical study |
| Roberts 1944 (395) | Population seems not to be girls/women subjected to FGM/C |
| Roles 1966 (396) | Not empirical study |
| Ronge 2006 (397) | Not empirical study |
| Rouzi 2001 (398) | Reports on effect of defibulation |
| Satti 2006 (399) | No physical consequences/complications following FGM/C reported |
| Senegal DHS 2011 (400) | No physical consequences/complications following FGM/C reported |
| Sequeira 1931(401) | Not empirical study |
| Shah 2009 (402) | Not empirical study |
| Shay 2010 (403) | No physical consequences/complications following FGM/C reported |
| Sierra Leone DHS 2008 (404) | No physical consequences/complications following FGM/C reported |
| Silberstein 1977 (405) | Not empirical study (review) |
| Snow 2002 (406) | No physical consequences/complications following FGM/C reported |
| Stewart 2002 (407) | No physical consequences/complications following FGM/C reported |
| Suardi 2010 (408) | No physical consequences/complications following FGM/C reported |
| Sudan DHS 1990 (409) | No physical consequences/complications following FGM/C reported |
| Tanganelli 1989 (410) | Not empirical study |
| Tanzania DHS 2010 (411) | No physical consequences/complications following FGM/C reported |
| Tanzania DHS 2004 (412) | No physical consequences/complications following FGM/C reported |
| Tanzania DHS 1996 (413) | No physical consequences/complications following FGM/C reported |
| Tegman 1990 (414) | Not empirical study |
| Thabet 2003 (415) | Only sexual consequences/complications following FGM/C reported |
| Thabet 2009 (416) | No physical consequences/complications following FGM/C reported |
| | |

| Study first author (ref no.) | Cause for exclusion of study |
|------------------------------|---|
| Thomas 2010 (417) | No physical consequences/complications following FGM/C reported |
| Ugboma 2004 (418) | No physical consequences/complications following FGM/C reported |
| Utz-Billing 2008 (419) | Not empirical study |
| Vaizey 1955 (420) | Not empirical study |
| Van Roosmalen 2000 (421) | Not empirical study |
| Van Rossem 2009 (422) | No physical consequences/complications following FGM/C reported |
| Vangen 2006 (423) | Not empirical study |
| Verzin 1975 (424) | Not empirical study |
| Wagner 2000 (425) | Not empirical study |
| WHO 2000 (426) | Not empirical study (review) |
| Williams 1999 (427) | Not empirical study |
| Wilson 1955 (428) | No physical consequences/complications following FGM/C reported |
| Worsley 1938 (429) | Not empirical study |
| Yemen DHS 1992 (430) | No physical consequences/complications following FGM/C reported |
| Yoder 2004 (431) | Not empirical study |
| Yoong 2005 (432) | Population mix of girls/women subjected to FGM/C and not |
| Young 1949 (433) | Not empirical study |
| Yount 2004 (434) | Not empirical study |

Appendix 4: Methodological quality assessment

Description of assessment of study quality for all studies:

- High quality (few limitations): All or almost all of the criteria from the checklist are met. If some of the criteria are not met, it must be unlikely that the study conclusions will change.
- Moderate quality (some limitations): Some of the criteria are not met and/or the study does not adequately address the criteria. It is unlikely that the study conclusions will change.
- Low quality (serious limitations): Few or no criteria are met and/or the study does not adequately address the criteria. It is likely that the study conclusions will change.

Quality assessment of comparative studies

Quality assessment questions for case-control studies. All questions are answered 'yes', 'unclear/somewhat', or 'no':

- 1. Were cases and controls recruited from comparable populations?
- 2. Were the cases and controls comparable with respect to important confounders?
- 3. Was the condition of the cases adequately described and/or the diagnosis validated?
- 4. Was it clear that the controls were free of the condition?
- 5. Have known, potential confounders been considered in the study design and/or analyses?
- 6. Was the exposure to harm/injury/intervention measured in the same way in the two groups?
- **7.** Was the person who assessed the exposure blind to whether participants were cases or controls (and does it matter whether this person was blinded)?
- 8. Is the response rate adequate for both groups?

In the table below, each assessment question is answered 'yes', 'unclear/somewhat', or 'no'. The numbers in the top row refer to the assessment question.

Table 2.1: Results of quality assessment of case-control studies

| Study | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | Assessment |
|-----------------|-----|-----|-----|-----|-----|-----|---------|---------|------------|
| Almroth 2005a | yes | yes | yes | yes | yes | yes | no | unclear | High |
| Elmusharaf 2006 | yes | yes | yes | yes | yes | yes | unclear | unclear | High |
| Inhorn 1993 | yes | yes | yes | yes | yes | yes | unclear | unclear | High |

Quality assessment questions for cohort study.

All questions are answered 'yes', 'unclear/somewhat', or 'no':

- 1. Were the groups (the exposed and non-exposed in the cohort) comparable with respect to important background factors?
- 2. Were the exposed individuals representative of a defined population?
- 3. Was the non-exposed group selected from the same population as the exposed group?
- 4. Was the study propective?
- 5. Was the exposure and the outcome measured in the same way and reliably in the two groups?
- 6. Was an adequate number of individuals in the cohort followed?
- 7. Did the researchers perform a loss-to-follow-up analysis that ascertained whether the ones who were lost differed from the ones who were not lost?
- 8. Was the follow-up time adequate to ascertain positive and/or negative outcomes?
- 9. Have known, potential confounders been considered in the study design and/or analyses?
- 10. Was the person who assessed the outcome blind to whether participants were exposed or not?

In the table below, each assessment question is answered 'yes', 'unclear/somewhat', or 'no'. The numbers in the top row refer to the assessment question.

Table 3.1: Results of quality assessment of cohort study

| Study | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Assessment |
|---------------|-----|---------|-----|----|-----|----|----|----|-----|---------|------------|
| Browning 2010 | yes | unclear | yes | no | yes | na | na | na | yes | unclear | Moderate |

Quality assessment questions for comparative cross-sectional studies. All questions are answered 'yes', 'unclear/somewhat', or 'no' (na= not applicable):

- 1. Was the population from which the sample was drawn clearly defined?
- 2. Was the sample representative of the population?
- 3. Is it explained whether (and how) the participants who agreed to participate are different from those who refused to participate?
- 4. Is the response rate adequate?
- 5. Were standardized data collection methods used?
- 6. Were measures shown to be reliable and valid?
- 7. Were the statistical methods appropriate?
- 8. Was the non-exposed group selected from the same population as the exposed group?
- 9. Were the groups comparable with respect to important background factors?
- 10. Were exposure and outcome measured in the same way and reliably in the two groups?
- 11. Was the person who assessed the outcome blind to whether participants were exposed or not?
- 12. Have known, potential confounders been considered in the study design and/or analyses?

In the table below, each assessment question is answered 'yes', 'unclear/somewhat', or 'no'. The numbers in the top row refer to the assessment question.

Table 4.1: Results of quality assessment of comparative studies

| Study | 1 | 2 | 3 | 4 | 5 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | Assessment |
|------------------|---------|---------|-----|---------|---------|---------|---------|-----|---------|---------|---------|---------|------------|
| Almroth 2005b | yes | unclear | yes | yes | na | yes | yes | yes | yes | yes | yes | unclear | High |
| Alsibiani 2010 | yes | unclear | no | yes | unclear | no | yes | yes | yes | unclear | yes | yes | Moderate |
| Balk 2000 | yes | yes | na | yes | yes | no | yes | yes | yes | unclear | no | yes | Moderate |
| Brewer 2007 | yes | yes | na | yes | yes | yes | yes | yes | unclear | unclear | unclear | yes | High |
| Browning 2010 | yes | unclear | na | na | yes | yes | yes | yes | yes | yes | unclear | yes | High |
| De Silva 1989 | unclear | unclear | no | unclear | yes | unclear | yes | yes | unclear | yes | unclear | unclear | Low |
| Diop 1998 | unclear | unclear | no | unclear | yes | no | yes | yes | unclear | unclear | unclear | unclear | Low |
| El Dareer 1983 | yes | unclear | no | no | yes | no | yes | yes | unclear | unclear | no | unclear | Low |
| El-defrawi 2001 | yes | unclear | no | unclear | yes | yes | unclear | yes | unclear | unclear | unclear | yes | Moderate |
| Elnashar 2007 | yes | yes | no | yes | unclear | no | unclear | yes | unclear | unclear | no | yes | Low |
| Eritrea DHS 2002 | yes | yes | na | yes | yes | no | yes | yes | unclear | unclear | no | unclear | Low |
| Eritrea DHS 1995 | yes | yes | na | yes | yes | no | yes | yes | unclear | unclear | no | unclear | Low |
| Fillo 2007 | yes | yes | na | yes | yes | no | yes | yes | unclear | unclear | no | yes | Moderate |
| Holmgren 2003 | yes | yes | no | yes | yes | unclear | yes | yes | unclear | unclear | unclear | yes | Moderate |
| lbrahim 2011 | yes | unclear | no | yes | yes | yes | yes | yes | unclear | unclear | unclear | unclear | Moderate |
| Jackson 2005 | unclear | unclear | no | unclear | unclear | no | yes | yes | no | unclear | unclear | yes | Low |
| Jones 1999-I | yes | unclear | no | unclear | yes | no | yes | yes | unclear | unclear | unclear | yes | Low |
| Jones 1999-II | yes | unclear | na | yes | yes | no | yes | yes | unclear | unclear | unclear | yes | Moderate |
| Kanki 1992 | yes | unclear | no | unclear | yes | yes | yes | yes | unclear | unclear | unclear | yes | Moderate |

| Study | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | Assessment |
|---------------------|---------|---------|---------|---------|---------|---------|---------|-----|---------|---------|---------|---------|------------|
| Kaplan 2011 | yes | unclear | no | unclear | yes | yes | yes | yes | unclear | yes | unclear | unclear | Moderate |
| Kizilhan 2011 | yes | unclear | yes | yes | yes | unclear | yes | yes | unclear | unclear | unclear | yes | Moderate |
| Klouman 2005 | yes | unclear | unclear | no | yes | yes | yes | yes | yes | yes | no | yes | Moderate |
| Larsen 2002 | yes | yes | na | yes | yes | no | yes | yes | no | unclear | no | yes | Moderate |
| Larsen 2000-l | yes | yes | na | yes | yes | no | yes | yes | unclear | unclear | no | yes | Moderate |
| Larsen 2000-II | yes | yes | na | yes | yes | no | yes | yes | unclear | unclear | no | yes | Moderate |
| Larsen 2000-III | yes | yes | na | yes | yes | no | yes | yes | unclear | unclear | no | yes | Moderate |
| Larsen 1989 | unclear | unclear | no | unclear | unclear | no | yes | yes | unclear | unclear | unclear | yes | Low |
| Maslovskaya 2009 | yes | yes | yes | yes | yes | unclear | yes | yes | unclear | unclear | unclear | yes | High |
| Morison 2001 | yes | yes | unclear | yes | yes | yes | yes | yes | unclear | yes | unclear | yes | High |
| Msuya 2002 | yes | unclear | no | yes | yes | yes | yes | yes | yes | yes | unclear | unclear | High |
| Nwajei 2003 | yes | unclear | no | unclear | unclear | no | unclear | yes | unclear | unclear | unclear | unclear | Low |
| Odoi 1997 | no | unclear | no | unclear | unclear | no | unclear | yes | unclear | unclear | unclear | unclear | Low |
| Okonofua 2002 | yes | unclear | no | yes | yes | no | yes | yes | unclear | yes | yes | yes | Moderate |
| Pépin 2006 | yes | unclear | no | unclear | yes | unclear | yes | yes | unclear | unclear | unclear | yes | Moderate |
| Pépin 1991 | yes | unclear | no | unclear | yes | unclear | yes | yes | unclear | unclear | unclear | unclear | Low |
| Rushwan 1983 | yes | no | no | unclear | yes | no | yes | yes | no | unclear | no | no | Low |
| Shandall 1967 | yes | unclear | no | yes | unclear | unclear | unclear | yes | unclear | yes | unclear | unclear | Low |
| Yount 2007 | yes | yes | na | yes | yes | no | yes | yes | no | unclear | unclear | yes | Moderate |
| Yount 2006 | yes | yes | no | unclear | unclear | no | yes | yes | unclear | unclear | no | yes | Low |

Quality assessment of cross-sectional descriptive studies (one group)

Quality assessment questions for cross-sectional studies. All questions are answered 'yes', 'unclear/somewhat', or 'no' (na= not applicable):

- 1. Was the population from which the sample was drawn clearly defined?
- 2. Was the sample representative of the population?
- 3. Is it explained whether (and how) the participants who agreed to participate are different from those who refused to participate?
- 4. Is the response rate adequate?
- 5. Were standardized data collection methods used?
- 6. Were measures shown to be reliable and valid?
- 7. Were the statistical methods appropriate?

In the table below, each assessment question is answered 'yes', 'unclear/somewhat', or 'no'. The numbers in the top row refer to the assessment question.

Table 5.1: Results of quality assessment of cross-sectional descriptive studies

| Study | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Assessment |
|-------------------------------|---------|---------|---------|---------|---------|---------|---------|------------|
| Abor 2006 | yes | no | no | yes | yes | no | yes | Low |
| Adinma 1997 | yes | unclear | no | yes | unclear | yes | unclear | Low |
| Al-Hussaini 2003 | yes | unclear | unclear | no | yes | yes | yes | Moderate |
| Arbesman 1993 | unclear | unclear | no | unclear | unclear | no | yes | Low |
| Aziz 1980 | no | unclear | no | unclear | unclear | unclear | unclear | Low |
| Brown 1989 | yes | unclear | no | no | yes | no | no | Low |
| CAR DHS 1995 | yes | yes | na | yes | yes | no | yes | Moderate |
| Chalmers 2000 | yes | unclear | no | unclear | yes | no | yes | Low |
| Dare 2004 | yes | unclear | no | unclear | yes | unclear | yes | Low |
| Dirie 1992 | yes | unclear | no | unclear | yes | no | yes | Low |
| Elgaali 2005 | yes | unclear | na | yes | yes | no | yes | Moderate |
| Fox 1997 | no | unclear | na | na | unclear | unclear | yes | Low |
| Gadallah 1996 | yes | yes | no | yes | yes | no | yes | Moderate |
| Ismail 1982 | no | unclear | no | unclear | unclear | no | yes | Low |
| Knight 1999 | yes | unclear | no | yes | yes | unclear | yes | Moderate |
| Litorp 2008 | yes | unclear | no | yes | yes | no | yes | Low |
| Mandara 2004 | unclear | unclear | no | unclear | yes | yes | yes | Low |
| Ministere de la Sante 1998 | yes | unclear | no | unclear | unclear | no | yes | Low |
| Modawi 1974 | no | unclear | na | na | unclear | no | unclear | Low |
| Momoh 2001 | yes | unclear | na | na | unclear | unclear | yes | Low |
| Orji 2006 | yes | unclear | no | unclear | yes | yes | yes | Moderate |
| Saad 1998 | no | unclear | no | na | unclear | no | unclear | Low |

Quality assessment of case series

Quality assessment questions for case series.

All questions are answered 'yes', 'unclear/somewhat', or 'no' (na= not applicable):

- 1. Was the study based on a series of individuals from a suitable group of patients?
- 2. Were measures taken to ensure that the sample was not too selective?
- 3. Were the inclusion criteria for the sample clearly defined?
- 4. Is the response rate adequate?
- 5. Were all included patients at the same stage of disease progression?
- 6. Was the follow-up adequate (type/extent/time) to account for outcomes?
- 7. Were objective criteria used to assess the outcome?
- 8. If case series are compared, were the series adequately described and was the distribution of prognostic factors described?
- 9. Was registration of data prospective?

In the table below, each assessment question is answered 'yes', 'unclear/somewhat', or 'no'. The numbers in the top row refer to the assessment question.

Table 6.1: Results of quality assessment of case series

| Study | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | Assessment |
|-----------------------|---------|---------|---------|---------|---------|---------|-----|----|---------|------------|
| Aboyejin 2003 | yes | yes | yes | na | unclear | unclear | yes | na | no | Moderate |
| Adekunle 1999 | yes | yes | no | na | unclear | na | yes | na | no | Low |
| Adelusi 1976 | yes | unclear | no | na | unclear | na | yes | na | no | Low |
| Agugua 1982 | yes | yes | no | na | unclear | na | yes | na | no | Low |
| Akotionga 2001 | yes | yes | unclear | na | unclear | yes | yes | na | yes | High |
| Ali 1998 | yes | yes | yes | na | yes | yes | yes | na | no | High |
| Badejo 1983 | yes | yes | no | unclear | yes | yes | yes | na | unclear | High |
| Bankolé-Sanni 1997 | yes | unclear | unclear | na | unclear | yes | yes | na | yes | Moderate |
| Bonessio 2001 | unclear | unclear | no | unclear | yes | na | yes | na | unclear | Low |
| Diejomaoh 1981 | yes | unclear | unclear | na | yes | na | yes | na | no | Low |
| Dirie 1991 | yes | unclear | unclear | na | unclear | yes | yes | na | yes | Moderate |
| Dörflinger 2000 | yes | unclear | no | unclear | no | yes | yes | na | unclear | Low |
| Duvie 1980 | yes | unclear | unclear | unclear | unclear | yes | yes | na | unclear | Low |
| Eguwatu 1981 | yes | unclear | no | unclear | unclear | yes | yes | na | no | Low |
| Ekenze 2009 | yes | unclear | unclear | na | unclear | no | yes | na | no | Low |
| Ekenze 2007 | yes | unclear | no | unclear | yes | yes | yes | na | yes | High |
| Frith 1960 | unclear | unclear | yes | unclear | yes | yees | yes | na | unclear | Moderate |
| German 1968 | unclear | unclear | no | na | unclear | yes | yes | na | no | Low |
| Giama 1979 | unclear | unclear | no | na | no | unclear | yes | na | no | Low |
| Hanly 1995 | unclear | unclear | no | unclear | unclear | yes | yes | na | no | Low |

| Study | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | Assessment |
|----------------|-----|---------|---------|---------|---------|---------|-----|----|---------|------------|
| Iregbulem 1980 | yes | unclear | no | unclear | unclear | yes | yes | na | unclear | Low |
| Mawad 1994 | yes | unclear | yes | unclear | no | yes | yes | na | unclear | Moderate |
| Ofodile 1979 | yes | yes | unclear | na | unclear | unclear | yes | na | unclear | Low |
| Osifo 2010 | yes | unclear | yes | unclear | no | yes | yes | na | yes | High |
| Osifo 2009 | yes | unclear | yes | unclear | no | yes | yes | na | yes | High |
| Ozumba 1992 | yes | yes | yes | na | yes | yes | yes | na | no | High |
| Rouzi 2010 | yes | yes | yes | na | unclear | yes | yes | na | no | High |
| Rouzi 2001 | yes | unclear | unclear | unclear | unclear | unclear | yes | na | no | Low |
| Tahzib 1983 | yes | yes | yes | na | unclear | unclear | yes | na | unclear | Moderate |

Appendix 5: Outcome tables

The following outcome tables present results from the non-comparative studies. The tables are organized according to outcomes, in line with the results chapter.

Genital tissue damage

Table 7.1: Non-comparative studies – study outcomes for scarring in female genital tissue

| Author | Study design | Outcome | Result |
|--------------------|-----------------|-----------------------------------|----------------------------------|
| Adinma 1997 | Cross-sectional | Moderate scarring Severe scarring | 47/124 (37.9%) 29/124 (23.4%) |
| Bankolé Sanni 1997 | Case series | Hypertrophic clitoral scar | 1/6 (16.7%) |
| Chalmers 2000 | Cross-sectional | Perineal scarring | 234/432 (54.2%) |
| Fox 1997 | Cross-sectional | Scarred perineum | 4/22 (18.2%) |
| McCleary 1994 | Case report | Severe scarring of vulvar area a | 1 case |

Introital scarring/narrowing

45/423 (10.6%)

Legend: a= pinpoint vaginal opening

Cross-sectional

Orji 2006

Table 8.1: Non-comparative studies – study outcomes for keloid in female genital tissue

| Author | Study design | Outcome | Result |
|-------------------------------|-----------------|-------------|-----------------|
| Dare 2004 | Cross-sectional | Keloid scar | 23/522 (4.4%) |
| Jones 1999-I | Cross-sectional | Keloid | 157/1787 (8.8%) |
| Jones 1999-II | Cross-sectional | Keloid | 16/4826 (0.3%) |
| Ministere de la Sante 1998 | Cross-sectional | Keloid | 157/1786 (8.8%) |
| Momoh 2001 | Cross-sectional | Keloid scar | 17/81 (21.0%) |
| Msuya 2002 | Cross-sectional | Keloid scar | 19/63 (30.2%) |

| Pieters 1972 | Case report | Keloid | 1 case |
|---------------|-------------|--------|--------|
| I ICICIO IOIZ | OddC report | Notola | 1 Gasc |

Table 9.1: Non-comparative studies – study outcomes for abscess in female genital tissue

| Author | Study design | Outcome | Result |
|-------------|-----------------|------------------------------------|-------------------------------|
| Dirie 1991 | Case series | Abscess | 10/10 (100.0%) |
| Ismail 1982 | Cross-sectional | Vulval abscess Clitoral abscess | 7/118 (5.9%) 10/118 (8.5%) |
| Modawi 1974 | Cross-sectional | Vulvar abscess | 8/2526 (0.3%) |
| Saad 1998 | Cross-sectional | Recurrent abscess | 63/9006 (0.7%) |

Table 10.1: Non-comparative studies – study outcomes for damaged genital tis-

| Author | Study design | Outcome | Result |
|---------------|-----------------|---------------------------------------|-----------------|
| Abor 2006 | Cross-sectional | Perineal tears | 6/34 (17.6%) |
| Chalmers 2000 | Cross-sectional | Perineal tears | 269/432 (62.3%) |
| Fox 1997 | Cross-sectional | Sinus (cavity) where clitoris excised | 1/22 (4.5%) |
| Franco 2006 | Case report | Vulvar lymphangiectases | 1 case |
| Laycock 1950 | Case report | Mass of hard tissue | 3 cases |
| Laycock 1950 | Case report | Perineal laceration | 1 case |
| Mawad 1994 | Case series | Perineal tears | 80/934 (8.6%) |
| Modawi 1974 | Cross-sectional | False vagina | 2/2526 (0.1%) |
| Osifo 2009 | Case series | Urethral injury | 1/51 (2.0%) |

Table 11.1: Non-comparative studies – study outcomes for fistula in female genital tissue

| Author | Study design | Outcome | Result |
|---------------|------------------------|-----------------------|-----------------------------------|
| Abor 2006 | Cross-sectional | Genital fistula | 2/34 (5.9%) |
| Agugua 1982 | Case series (children) | Recto-vaginal fistula | 1/55 (1.8%) |
| Bonessio 2001 | Case series | Vaginal fistula | 1/5 (20.0%) |
| Egwuatu 1981 | Case series | Recto-vaginal fistula | 1/43 (2.3%) |
| Giama 1979 | Case series | Recto-vaginal fistula | 1/14 (7.1%) |
| Jones 1999-I | Cross-sectional | Vesicovaginal fistula | 3/1787 (0.2%) |
| Jones 1999-II | Cross-sectional | Vesicovaginal fistula | 2/4826 (0.1%) |
| Jones 1999-II | Cross-sectional | Rectovaginal fistula | 2/4826 (0.1%) |
| Mandara 2004 | Cross-sectional | Vesicovaginal fistula | 3/13 (23.1%) all from Gishiri cut |
| Tahzib 1983 | Case series | Vesicovaginal fistula | 188/1443 (13.0%) |

Labial adhesions and obstructions

Table 12.1: Non-comparative studies – study outcomes for adhesions

| Author | Study design | Outcome | Result |
|-------------------------------|------------------------|---|--------------------------------|
| Aboyejin 2003 | Case series | Labial adhesion | 21/93 (22.6%) |
| Adekunle 1999 | Case series | Labial fusion/adhesion | 20/39 51.3%) |
| Adelusi 1976 | Case series | Acquired gynetresia | 2/28 (7.1%) |
| Agugua 1982 | Case series (children) | Partial labial fusion Complete labial fusion | 16/55 (29.1%) 11/55 (20.0%) |
| Agugua 1982 | Case series (adults) | Complete labial fusion | 1/18 (5.6%) |
| Akupuaka 1998 | Case report | Vulval adhesion | 5 cases |
| Asuen 1977 | Case report | Complete fusion of both labia a | 1 case |
| Awang 2004 | Case report | Almost complete labial fusion b | 1 case |
| Baaij 1999 | Case report | Labial fusion | 1 case |
| Badejo 1983 | Case series | Labial fusion | 2/12 (16.7%) |
| Bitho 1975 | Case report | Labial fusion | 2 cases |
| Brisson 2001 | Case report | Fused labia majora c | 1 case |
| Chen 2004 | Case report | Fused external genitalia d | 1 case |
| Dare 2004 | Cross-sectional | Labial adhesion | 70/522 (13.4%) |
| Dewhurst 1964 | Case report | Labial fusion e | 1 case |
| Diejomaoh 1981 | Case series | Adhesions of the labia minora | 12/12 (100%) |
| Egwuatu 1981 | Case series | Complete labial fusion Partial labial fusion | 9/58 (15.5%) 13/43 (30.2%) |
| Ekenze 2009 | Case series | Labial fusion/ adhesion | 12/18 (66.7%) |
| Ekenze 2007 | Case series | Labial fusion | 8/21 (38.1%) |
| Epstein 2001 | Case report | Labial fusion ^f | 1 case |
| Erian 1995 | Case report | Fused labia / stenosis ^g | 3 cases |
| Iregbulem 1980 | Case series | Vulval adhesion | 10/10 (100%) |
| Jones 1999-l | Cross-sectional | Vaginal synechia | 15/1787 (0.8%) |
| Jones 1999-II | Cross-sectional | Vaginal synechia | 4/4826 (0.1%) |
| Laycock 1950 | Case report | Fused labia | 2 cases |
| Millogo-Traore 2002 | Case report | Labial fusion h | 3 cases |
| Ministere de la Sante 1998 | Cross-sectional | Labial fusion/synechia | 10/1786 (0.6%) |
| Mühlbach 1985 | Case report | Labial minora fusion | 1 case |
| Orji 2006 | Cross-sectional | Labia minora adhesion | 25/423 (5.9%) |
| Osifo 2009 | Case series | Labia adhesion | 10/51 (19.6%) |
| Oye 1976 | Case report | Acquired vulval atresia | 1 case |
| Ozumba 1992 | Case series | Acquired gynetresia | 59/78 (76.0%) |

| Author | Study design | Outcome | Result |
|-------------|--------------|---------------|---------|
| Walker 1995 | Case report | Labial fusion | 4 cases |

Legend: a= child inability to pass urine. b= urinary tract infection, difficulty in voiding. c= Painful menses, inability to pass menstrual blood and to void. d= problems with menstruation, coitus. e= coitus impossible. f= dysmenor-rhea, dysuria, prolonged micturation, dyspareunia, hydronephrosis. g= severe dysmenorrhea, dyspareunia, difficult micturation, inability to penetrate for coitus. h= impossible to have sexual intercourse, two had dysmenor-rhea.

Vaginal blockage

Table 13.1: Non-comparative studies – study outcomes for vaginal blockage

| Author | Study design | Outcome | Result |
|-------------------------------|------------------------|--|------------------------------|
| Agugua 1982 | Case series (children) | Meatal obstruction | 3/55 (5.5%) |
| Agugua 1982 | Case series (children) | Introital stenosis | 2/55 (3.6%) |
| Agugua 1982 | Case series (adults) | Partial vulval stenosis | 11/18 (61.1%) |
| Agugua 1982 | Case series (adults) | Meatal obstruction | 2/18 (11.1%) |
| Bankolé Sanni 1997 | Case series | Partial stenosis of vagina | 4/6 (66.7%) |
| Bankolé Sanni 1997 | Case series | Complete obstruction of vagina and urethral meatus | 1/6 (16.7%) |
| Bonessio 2001 | Case series | Blocked tubes Vaginal stenosis | 1/5 (20.0%) 1/5 (20.0%) |
| Dirie 1991 | Case series | Vaginal stenosis | 43/108 (39.8%) |
| Egwuatu 1981 | Case series | Introital stenosis Partial vulval stenosis | 2/43 (4.7%) 10/15 (66.6%) |
| Frith 1960 | Case series | Vaginal atresia a | 4/4 (100%) |
| German 1968 | Case series | Vaginal stenosis | 187/187 (100%) |
| Ibekwe 2004 | Case report | Stenosed vulva b | 1 case |
| Ismail 1982 | Cross-sectional | Vaginal stenosis | 43/118 (36.4%) |
| Jones 1999-I | Cross-sectional | Stenosis | 51/1787 (2.9%) |
| Jones 1999-I | Cross-sectional | Vaginal obstruction | 15/1787 (0.8%) |
| Jones 1999-II | Cross-sectional | Stenosis | 29/4826 (0.6%) |
| Jones 1999-II | Cross-sectional | Vaginal obstruction | 18/4826 (0.3%) |
| Ministere de la Sante 1998 | Cross-sectional | Stenosis | 51/1786 (2.9%) |
| Ministere de la Sante 1998 | Cross-sectional | Obstruction | 15/1786 (0.8%) |
| Msuya 2002 | Cross-sectional | Vaginal stenosis | 1/63 (1.6%) |
| Nour 2006 | Case report | Urinary calculus ° | 1 case |
| Pieters 1972 | Case report | Stenosis | 1 case |

Legend: a= six years of urinary dribbling, vulval itching, irregular menstruation, one year inability to have coitus. b= impossible to have sexual intercourse, dysmenorrhea; c= infertility, dyspareunia, dysmenorrhea, pain when sitting.

Cysts

Table 14.1: Non-comparative studies – study outcomes for cysts

| 1 able 14.1: Non-co | omparative studies – | study outcomes for cysts | · |
|---------------------|------------------------|--|----------------------------------|
| Author | Study design | Outcome | Result |
| Aboyeji 2003 | Case series | Clitoral cyst | 26/93 (28%) |
| Adekunle 1999 | Case series | Clitoral cyst | 19/39 (48.7%) |
| Agugua 1982 | Case series (children) | Implantation dermoid | 14/55 (25.5%) |
| Agugua 1982 | Case series (adults) | Implantation dermoid | 4/18 (22.2%) |
| Akupuaka 1998 | Case report | Epidermoid cyst | 1 case |
| Al-Maghrabi 2005 | Case report | Epidermal inclusion cyst | 1 case |
| Asante 2010 | Case report | Epidermal inclusion cyst | 1 case |
| Baaij 1999 | Case report | Epidermal cyst | 1 case |
| Badejo 1983 | Case series | Epidermoid inclusion cyst | 4/12 (33.3%) |
| Chalmers 2000 | Cross-sectional | Peineal cysts | 105/432 (24.3%) |
| Dare 2004 | Cross-sectional | Dermoid cyst | 37/522 (7.1%) |
| Dirie 1992 | Cross-sectional | Clitoral cyst | 36/108 (33.3%) |
| Dirie 1991 | Case series | Dermoid cyst | 65/108 (60.2%) |
| Duvie 1980 | Case series | Implantation dermoid of the clitoris | 31/31 (100.0%) |
| Egwuatu 1981 | Case series | Implantation dermoid | 13/58 (22.4%) |
| Ekenze 2009 | Case series | Vulval cyst | 6/18 (33.3%) |
| Ezem 2007 | Case report | Clitoral cyst | 1 case |
| Fox 1997 | Cross-sectional | Dermoid implantation cyst | 2/22 (9.1%) |
| Hanly 1995 | Case series | Implantation dermoid cyst | 10/10 (100%) |
| Hamoudi 2010 | Case report | Epidermal inclusion cyst | 1 case |
| Hathout 1963 | Case report | Implantation dermoid cyst | 1 case |
| Iregbulem 1980 | Case series | Epidermoid cyst | 2/10 (20.0%) |
| Ismail 1982 | Cross-sectional | Vulval cyst Clitoral cyst | 36/118 (30.5%) 22/118 (18.6%) |
| Kristensen 2008 | Case report | Epithelial inclusion cyst | 2 cases |
| Kroll 2000 | Case report | Epithelial inclusion cyst ^a | 1 case |
| Lashley 2009 | Case report | Clitoral/vulvar epidermal cyst | 1 case |
| Laycock 1950 | Case report | Dermoid cyst | 1 case |
| MacLeod 1995 | Case report | Sebaceous cyst | 1 case |
| Möller 2003 | Case report | Cystic structure containing stones b | 1 case |
| Momoh 2001 | Cross-sectional | Dermoid cyst | 10/81 (12.3%) |
| Moreira 2002 | Case report | Epidermal cyst of vulva | 3 cases |
| Ofodile 1979 | Case series | Epidermoid inclusion cyst of clitoris | 19/19 (100%) |
| Osifo 2010 | Case series | Clitoral epidermoid inclusion cyst | 37/37 (100%) |
| Osifo 2009 | Case series | Clitoridal cyst | 22/51 (43.1%) |
| | | | |

| Author | Study design | Outcome | Result 2 cases | |
|------------|-----------------|------------------------------------|-----------------|--|
| Rizk 2007 | Case report | Clitoral epidermoid inclusion cyst | | |
| Rouzi 2010 | Case series | Clitoral cyst | 15/15 (100%) | |
| Rouzi 2001 | Case series | Epidermal clitoral inclusion cyst | 21/21 (100%) | |
| Saad 1998 | Cross-sectional | Vulval inclusion cyst | 338/9006 (3.8%) | |
| Saber 2009 | Case report | Dermoid inclusion cyst 1 ca | | |
| Yoong 2004 | Case report | Epidermal clitoral inclusion cyst | 1 case | |

Legend: a= led to pain, itching, interference with walking. b= coitus impossible.

Problems with urination and voiding

 ${\bf Table~15.1:~Non-comparative~studies-study~outcomes~for~problems~with~urina-study~outcomes~f$

tion and voiding

| uon and voluing | | | | |
|-----------------|------------------------|---|---|--|
| Author | Study design | Outcome | Result | |
| Abor 2006 | Cross-sectional | Urinary retention | 4/34 (11.8%) | |
| Agugua 1982 | Case series (children) | Urethral stricture | 2/55 (3.6%) | |
| Akotionga 2001 | Case series (children) | Urinary retention | 7/9 (77.8%) | |
| Akotionga 2001 | Case series (adults) | Urinary retention | 2/40 (5.0%) | |
| Arbesman 1993 | Cross-sectional | Difficulty urinating Long time to urinate Pain during urination | 1/8 (12.5%) 2/8 (25.0%) 3/8 (37.5%) | |
| Aziz 1980 | Cross-sectional | Urine retention | 900/7505 (12.0%) | |
| Bitho 1975 | Case report | Urine retention | 1 case | |
| Chalmers 2000 | Cross-sectional | Urinary retention | 142/432 (32.9%) | |
| Dare 2004 | Cross-sectional | Urinary disturbance | 22/522 (4.2%) | |
| Diejomaoh 1981 | Case series | Poor urinary stream Difficulty with micturation | 10/12 (83.3%) 8/12 (66.7%) | |
| Dirie 1992 | Cross-sectional | Pain at micturation Poor urinary flow | 57/108 (52.8%) 15/108 (13.9%) | |
| Dörflinger 2000 | Case series | Anuria/ urinary retention | 3/10 (30.0%) | |
| Egwuatu 1981 | Case series (children) | Urinary retention | 12/43 (27.9%) | |
| Egwuatu 1981 | Case series (adults) | Poor urinary stream | 2/15 (13.3%) | |
| Jones 1999-l | Cross-sectional | Urinary incontinence | 20/1787 (1.1%) | |
| Jones 1999-II | Cross-sectional | Urinary incontinence | 11/4826 (0.2%) | |
| Litorp 2008 | Cross-sectional | Urinary problems | 7/37 (18.9%) | |
| Momoh 2001 | Cross-sectional | Poor urinary flow/pain at micturation | 47/81 (58.0%) | |
| Momoh 2001 | Cross-sectional | Urinary incontinence | 5/81 (6.2%) | |
| Saad 1998 | Cross-sectional | Voiding problems | 14/9006 (0.1%) | |
| | | | | |

Problems with menstruation

Table 16.1: Non-comparative studies – study outcomes for problems with menstruation

| Author | Study design | Outcome | Result | |
|-----------------|------------------------|---------------------------------------|-----------------|--|
| Abor 2006 | Cross-sectional | Prolonged bleeding | 2/34 (5.9%) | |
| Akotionga 2001 | Case series (children) | Hematocolpos | 2/9 (18.2%) | |
| Akotionga 2001 | Case series (adults) | Hematocolpus | 3/40 (7.5%) | |
| Arbesman 1993 | Cross-sectional | Menstrual pain | 7/10 (70.0%) | |
| Bonessio 2001 | Case series | Dysmenorrhea | 1/5 (20.0%) | |
| Brown 1989 | Cross-sectional | Severe dysmenorrhea ^a | 68/105 (64.7%) | |
| CAR DHS 1995 | Cross-sectional | Pain during menstruation | 7/2555 (0.3%) | |
| Chalmers 2000 | Cross-sectional | Painful periods | 321/432 (74.3%) | |
| Dirie 1992 | Cross-sectional | Painful menstruation/ hematocolpus | 40/115 (34.8%) | |
| Dörflinger 2000 | Case series | Hematocolpus | 1/10 (10.0%) | |
| Giama 1979 | Case series | Oligomenorrhea | 5/14 (35.7%) | |
| Knight 1999 | Cross-sectional | Dysmenorrhea | 8/51 (15.7%) | |
| Litorp 2008 | Cross-sectional | Menstruation difficulties | 11/37 (29.7%) | |
| Momoh 2001 | Cross-sectional | Dysmenorrhea | 54/81 (66.7%) | |
| Momoh 2001 | Cross-sectional | Hematocolpus | 6/81 (7.4%) | |

Legend: a= most respondents had not experienced intercourse; the most common long term sequelae reported were urinary problems and menstrual difficulties.

Problems with sexual intercourse

Table 17.1: Non-comparative studies – study outcomes for problems with sexual intercourse

| Author | Study design | Outcome | Result |
|-----------------|--|--|----------------------------|
| Abor 2006 | Cross-sectional | Painful sexual intercourse | 18/34 (52.9%) |
| Akotionga 2001 | Case series (adults) | Dyspareunia | 11/40 (27.5%) |
| Akotionga 2001 | Case series (adults) | Impossible penetration/to have sex | 19/40 (47.5%) |
| Arbesman 1993 | Cross-sectional | Dyspareunia 4/9 (44.4% | |
| Baaij 1999 | Case report | Coitus impossible | 1 case |
| Bonessio 2001 | Case series | Dyspareunia | 1/5 (20.0%) |
| Chalmers 2000 | Cross-sectional | Painful sexual intercourse 338/432 (7 | |
| Dörflinger 2000 | Case series | Impossible penetration | 3/10 (30.0%) |
| Egwuatu 1981 | Egwuatu 1981 Case series Dyspare penetra | | 9/15 (60.0%) |
| Fox 1997 | Cross-sectional | Intercourse always painful Too tight for intercourse | 2/22 (9.1%) 2/22 (9.1%) |

| Author | Study design | Outcome | Result |
|-------------|--|-------------------------------|-----------------|
| Jaleel 2002 | Case report Severe dyspareur penetrate a | | 1 case |
| Knight 1999 | Cross-sectional | Dyspareunia | 39/51 (76.5%) |
| Knight 1999 | Cross-sectional | Apareunia | 8/51 (15.7%) |
| Litorp 2008 | Cross-sectional | Sexual difficulties | 14/37 (37.8%) |
| Mawad 1994 | Case series | Defloration hemorrhage trauma | 41/934 (4.4%) |
| Mawad 1994 | Case series | Postcoital injury | 312/934 (33.4%) |
| Modawi 1974 | Cross-sectional | Coital injuries | 4/2526 (0.2%) |
| Momoh 2001 | Cross-sectional | Dyspareunia | 34/81 (42.0%) |
| Osifo 2009 | Case series | Difficulty with penetration | 2/51 (3.9%) |
| Saad 1998 | Cross-sectional | Impossible penetration | 228/9006 (2.5%) |
| Saad 1998 | Cross-sectional | Coital injury/ laceration | 18/9006 (0.2%) |
| Saad 1998 | Cross-sectional | Dyspareunia | 46/9006 (0.5%) |

Legend: a= practiced coitus interfemoral, pelvic pain, recurrent dysuria

Infections of the reproductive and urinary tracts

Table 18.1: Non-comparative studies – study outcomes for infections of the re-

productive and urinary tracts

| Author | Study design | Outcome | Result |
|-------------------------------|---|-------------------------------------|-----------------------------------|
| Abor 2006 | Cross-sectional | Pelvic infections | 4/34 (11.8%) |
| Agugua 1982 | Case series (children) | Urinary infection | 2/55 (3.6%) |
| Chalmers 2000 | Cross-sectional | Pelvic infections Infections | 94/432 (21.7%) 103/432 (23.8%) |
| Dörflinger 2000 | Case series | Infection in genital area | 5/10 (50.0%) |
| Fahal 1998 | Case report | Vulval mycetoma ^a | 1 case |
| Fox 1997 | Cross-sectional | Pelvic inflammatory disease | 3/22 (13.6%) |
| Knight 1999 | Cross-sectional | (Recurrent) urinary tract infection | 15/51 (29.4%) |
| Knight 1999 | Cross-sectional | Vaginal infection | 4/51 (7.8%) |
| Kothe 1973 | Case report | Urinary infection ^b | 1 case |
| Ministere de la Sante 1998 | tere de la Sante Cross-sectional Infection 42 | | 429/1786 (24.0%) |
| Momoh 2001 | Cross-sectional | Recurrent urinary tract infections | 31/81 (38.3%) |

Legend: a= bilateral gross hydronephrosis and hydrourethers with bladder neck obstruction, a pelleterii infection. b= urine retention, chronic recurrent cytopyelonephritis (urethra-cyst-pyelonephritis).

HIV and STIs

Table 19.1: Non-comparative studies – study outcomes for HIV and STIs

| Author | Study design | Outcome | Result |
|---------------|--------------|---------|--------|
| Etokidem 2007 | Case report | HIV | 1 case |

Infertility

Table 20.1: Non-comparative studies – study outcomes for infertility

| Author | Study design | Outcome | Result |
|---------------|-----------------|-------------------------------------|------------------|
| Ali 1998 | Case series | Infertility | 122/1012 (12.1%) |
| Aziz 1980 | Cross-sectional | Infertile for ≥2 years | 165/7505 (2.2%) |
| Bonessio 2001 | Case series | Sterile | 1/5 (20.0%) |
| Dare 2004 | Cross-sectional | Infertility | 22/522 (4.2%) |
| Egwuatu 1981 | Case series | Infertility | 6/15 (40.0%) |
| Lenzi 1970 | Case report | Infertile for ≥5 years a | 4 cases |
| Lenzi 1969 | Case report | Infertile ^b | 2 cases |
| Momoh 2001 | Cross-sectional | Difficulty conceiving | 7/81 (8.6%) |
| Saad 1998 | Cross-sectional | Infertility (due to tubal blockage) | 19/9006 (0.2%) |

Legend: a= chronic phlongosis of the tubes after infection contracted at the time of FGM, pain in lower abdomen, irregular menses, two had obstructed ovarian tubes. b= due to chronic adnexopelvic phlongosis following an ascending infection from FGM.

Vaginal discharge, itching, and related vaginal complications

Table 21.1: Non-comparative studies – study outcomes for vaginal discharge, itching, and related vaginal complications

| Author | Study design | n Outcome Result | | | |
|---------------|--|--|-----------------|--|--|
| Arbesman 1993 | Cross-sectional Bad smelling discharge 1/7 (14.3 | | 1/7 (14.3%) | | |
| Arbesman 1993 | Cross-sectional | Itching in genital area | 2/7 (28.6%) | | |
| Ekenze 2007 | Case series | se series Clitoral swelling 13/21 (61.9% | | | |
| Mawad 1994 | Case series | Vulval swelling ^a | 463/934 (49.6%) | | |
| Osifo 2009 | Case series | eries Vaginal discharge 3/51 (5.9%) | | | |

Legend: a= infected cysts, fibromata, granulations.

Other

Table 22.1: Non-comparative studies – other study outcomes

| Author | Study design | Outcome | Result | |
|---------------------|-----------------|--|----------------|--|
| Abor 2006 | Cross-sectional | Pelvic inflammatory disease | 2/34 (5.9%) | |
| Aboyeji 2003 | Case series | Urethral mucosal prolapse | 20/93 (21.5%) | |
| Al-Hussaini 2003 | Cross-sectional | Secondary complication ^a 6/254 (2.4%) | | |
| Bonessio 2001 | Case series | Pelvic pain | 3/5 (60.0%) | |
| Bonessio 2001 | Case series | Vaginal hypoplasia | 1/5 (20.0%) | |
| CAR DHS 1995 | Cross-sectional | Other complications | 40/2555 (1.6%) | |
| Dörflinger 2000 | Case series | Urosepsis 1/10 (10.0%) | | |
| Egwuatu 1981 | Case series | Vulval lump | 4/15 (26.1%) | |

| Author | Study design | design Outcome | | | |
|------------------------|------------------------------------|--|----------------------------------|--|--|
| Elgaali 2005 | Cross-sectional Late complications | | 28/220 (12.7%) | | |
| Fernández-Aguilar 2003 | Case report | Neuroma /tumor of the clitoris | 1 case | | |
| Giama 1979 | Case series | Chronic cyst-urethritis/urethritis Cystitis | 14/14 (100.0%) 14/14 (100.0%) | | |
| Giama 1979 | Case series | Suppurative Bartolinitis | 4/14 (28.6%) | | |
| Laycock 1950 | Case report | Prolapse ^b | 3 cases | | |
| Litorp 2008 | Cross-sectional | Pain | 8/37 (21.6%) | | |
| Mawad 1994 | Case series | Too tight circumcision 38/934 (4. | | | |
| Modawi 1974 | Cross-sectional | Tight circumcision | 23/2526 (1.0%) | | |
| Morris 2005 | Case report | Benign vaginal villi c | 3 cases | | |
| Onuigbo 1974 | Case report | Primary vaginal stone | 1 case | | |

Legend: a= vaginal discharge, pain. b= prolapsed of rectal mucous membrane, uterine procidentia. c= dyspareunia, dysmenorrheal.

Appendix 6: GRADE Evidence profile tables

The following five GRADE Evidence profile tables (tables 23.1-27.1) present our assessment of the quality of the evidence, organized according to comparison.

Table 23.1: GRADE Evidence profile table for the comparison FGM/C vs no FGM/C

| | | | | | | | | | Summary | of findings | |
|-----------------------|-------------------------------|---------------------------|-----------------------------|----------------------------|---------------------------|-------------------------|----------------------|---------------------|----------------------------|---|------------------|
| | | | Quality as | sessment | | | No of p | articipants | | Effect | |
| No of stu- dies | Design | Limita- tions | Inconsis- tency | In- directness | Impreci- sion | Other considerations | FGM/C | non-FGM/C | Relative (95% CI) | Absolute | Quality |
| Cysts | | | | | | | | | | | |
| 3 | observatio- nal studies | no serious limitations | serious¹ | no serious indirectness | serious² | none | 100/5266 (1.9%) | 11/1688 (0.7%) | RR 3.45 (0.54 to 22.17) | 2 more per 100 (from 0 fewer to 14 more) | ⊕OOO VERY LOW |
| Urinary | y tract infec | tion | | | | | | | | | |
| Ü | observatio- nal studies | serious ³ | serious ⁴ | no serious indirectness | no serious imprecision | none | 1243/9414 (13.2%) | 177/2348 (7.5%) | RR 3.01 (1.42 to 6.38) | 15 more per 100 (from 3 more to 41 more) | ⊕000 |
| | studies | | | | | | (13.270) | | (1.42 to 0.30) | | VERY LOW |
| HIV (ad | djusted anal | yses) | | | | | | | | | |
| | observatio- nal | no serious limitations | serious ⁵ | no serious indirectness | serious ⁶ | none | 0/0 (0%) | 0/0 (0%) | OR 0.95 | cannot be calculated 10 | ⊕000 |
| | studies | | | | | | 0/0 (0%) | | (0.54 to 1.67) | | VERY LOW |
| STIs | | | | | | | | | | | |
| Ü | observatio- nal | no serious limitations | serious ⁷ | no serious indirectness | serious ⁸ | none | 480/1802 (26.6%) | 480/2901 (16.5%) | RR 1.07 (0.75 to 1.53) | 1 more per 100 (from 4 fewer to 9 more) | ⊕000 |
| | studies | | | | | | (20.0%) | | (0./5 to 1.53) | | VERY LOW |
| Bacteri | al vaginosis | (adjusted a | nalyses) | | | | | | | | |
| | observatio- nal | no serious limitations | no serious inconsistency | serious 9 | no serious imprecision | none | 0/0(0%) | 0/0 (0%) | OR 1.68 | cannot be calculated¹º | ⊕000 |
| | studies | | | | | | 0/0 (0%) | | (1.28 to 2.22) | | VERY LOW |

Table 24.1: GRADE Evidence profile table for the comparison FGM/C type III vs no FGM/C

| | 24.1. GKA | D D D TIUC | | | | | J F C | | | | | |
|--------|--------------------------|-------------|----------------|----------------------------|----------------------|----------------|---------------------|--------------------|---------------------------|--|------------------|--|
| | | | | | | | Summary of findings | | | | | |
| | Quality assessment | | | | | | | No of participants | | Effect | | |
| No of | | Limitations | Inconsistency | Indirectness | Imprecision | Other | FGM/C | non-FGM/C | Relative | Absolute | Quality | |
| studie | | | liteonsistency | man cetness | | considerations | type III | non raw, c | (95% CI) | Absorate | | |
| Urina | Urinary tract infection | | | | | | | | | | | |
| 4 | observational studies | serious¹ | | no serious indirectness | serious ³ | none | 1151/8270 (13.9%) | 76/657 (11.6%) | RR 2.88 (1.01 to 8.21) | 22 more per 100 (from 0 more to 83 more) | ⊕OOO VERY LOW | |

¹ 3 of 4 studies had low methodological study quality.

¹ I-square= 79%.

² CI is wide, crosses limitations of precision (CI=0.54, 22.17).

³ 3 of 5 studies had low methodological study quality.

⁴ I-square= 89%.

⁵ I-square= 78%, non-overlapping CIs.

⁶ CI is wide, crosses limitations of precision (CI=0.54, 1.67).

⁷ I-square= 89%, non-overlapping CIs.

⁸ CI crosses limitations of precision (CI= 0.75, 1.53).

⁹ We were unable to include a third study in the pooled analysis, which in contrast to the two included studies showed benefit, not harm.

¹⁰ Adjusted analyses. Number of participants not specified.

² I-square= 88% and non-overlapping CIs.

³ Wide CI (1.01, 8.21)

Table 25.1: GRADE Evidence profile table for the comparison FGM/C type I vs FGM/C type II

| | | | P-0 | | -p | ivi, e type i vs i divi, | | | | | |
|----------|--------------------|---------------------------|---------------|----------------------------|---------------------|--------------------------|--------------|-----------------|---------------------------|---|----------|
| | | | | | Summary of findings | | | | | | |
| | Quality assessment | | | | | | | | No of participants Effect | | |
| No of | Dagign | Limitations | Inconsistency | Indirectness | Immunaisian | Other considerations | FGM/C | FGM/C | Relative | Absolute | Quality |
| studies | Design | Limitations | Inconsistency | muirectiess | imprecision | Other considerations | type I | type II | (95% CI) | Absolute | |
| Scarring | Scarring | | | | | | | | | | |
| 2 | | no serious limitations | | no serious indirectness | serious² | none | 93/1167 (8%) | 82/431 (19%) | RR 0.26 (0.05 to 1.28) | 14 fewer per 100 (from 18 fewer to 5 more) | ⊕000 |
| | | | | | | | | | (0.05 to 1.20) | | VERY LOW |

¹ 91% I-square. Non-overlapping CIs.

Table 26.1: GRADE Evidence profile table for the comparison FGM/C type I vs FGM/C type III

| | | L L'idence | prome table | | | divi/ C type I vs I divi/ v | y pe 111 | | _ | | |
|----------|--------------------------|-------------|---------------|----------------------------|---------------------|-----------------------------|-------------------|-------------------|---------------------------|---|------------------|
| | | | Quality as | sessment | Summary of findings | | | | | | |
| | | | quality as | | No of participants | | Effect | | | | |
| No of | | | | In- | | Other | FGM/C | FGM/C | Relative | Absolute | Quality |
| studies | Design | Limitations | Inconsistency | directness | Imprecision | considerations | type I | type III | (95% CI) | | |
| Scarring | Scarring | | | | | | | | | | |
| 2 | observational studies | | | no serious indirectness | serious¹ | none | 90/1384 (6.5%) | 40/3078 (1.3%) | RR 0.69 (0.31 to 1.51) | o fewer per 100 (from 1 fewer to 1 more) | ⊕OOO VERY LOW |

¹ CI is wide, crosses limitations of precision (CI=0.31, 1.51).

² CI is wide, crosses limitations of precision (CI=0.05, 1.28).

Table 27.1: GRADE Evidence profile table for the comparison FGM/C type I-II vs FGM/C type III

| IUDIC | ~ / · · · · · · · · · · · · · · · · · · | DE Evidei | ice profile t | ubic for the | c compani | on range c | PC I II VS | rami e type n | | | | | |
|-------------------------|---|----------------------|---------------|--------------|---------------------------|----------------|---------------------------|-------------------|----------------|--|----------|--|--|
| | | | | | | | Summary of findings | | | | | | |
| | | | Quality asse | ssment | | | No of participants Effect | | | | | | |
| No of | D | T | | T 10 | T | Other | FGM/C | FGM/C | Relative | A1 1 4 | Quality | | |
| studies | | Limitations | Inconsistency | Indirectness | | considerations | type I-II | type III | (95% CI) | Absolute | | | |
| Urinary tract infection | | | | | | | | | | | | | |
| | observational studies | serious ¹ | | | no serious imprecision | none | 44/991 (4.4%) | 1151/8270 (13.9%) | - 0 - | 9 fewer per 100 (from 2 fewer to 12 fewer) | ⊕000 | | |
| | | | | | | | 11, 22 (111.4) | | (0.16 to 0.89) | | VERY LOW | | |

¹ 3 of 4 studies had low methodological study quality.

² I-square= 82%.