

# Female genital mutilation and obstetric outcome: WHO collaborative prospective study in six African countries

WHO study group on female genital mutilation and obstetric outcome\*

## Summary

**Background** Reliable evidence about the effect of female genital mutilation (FGM) on obstetric outcome is scarce. This study examines the effect of different types of FGM on obstetric outcome.

**Methods** 28 393 women attending for singleton delivery between November, 2001, and March, 2003, at 28 obstetric centres in Burkina Faso, Ghana, Kenya, Nigeria, Senegal, and Sudan were examined before delivery to ascertain whether or not they had undergone FGM, and were classified according to the WHO system: FGM I, removal of the prepuce or clitoris, or both; FGM II, removal of clitoris and labia minora; and FGM III, removal of part or all of the external genitalia with stitching or narrowing of the vaginal opening. Prospective information on demographic, health, and reproductive factors was gathered. Participants and their infants were followed up until maternal discharge from hospital.

**Findings** Compared with women without FGM, the adjusted relative risks of certain obstetric complications were, in women with FGM I, II, and III, respectively: caesarean section 1.03 (95% CI 0.88–1.21), 1.29 (1.09–1.52), 1.31 (1.01–1.70); postpartum haemorrhage 1.03 (0.87–1.21), 1.21 (1.01–1.43), 1.69 (1.34–2.12); extended maternal hospital stay 1.15 (0.97–1.35), 1.51 (1.29–1.76), 1.98 (1.54–2.54); infant resuscitation 1.11 (0.95–1.28), 1.28 (1.10–1.49), 1.66 (1.31–2.10), stillbirth or early neonatal death 1.15 (0.94–1.41), 1.32 (1.08–1.62), 1.55 (1.12–2.16), and low birthweight 0.94 (0.82–1.07), 1.03 (0.89–1.18), 0.91 (0.74–1.11). Parity did not significantly affect these relative risks. FGM is estimated to lead to an extra one to two perinatal deaths per 100 deliveries.

**Interpretation** Women with FGM are significantly more likely than those without FGM to have adverse obstetric outcomes. Risks seem to be greater with more extensive FGM.

## Introduction

FGM consists of all procedures that involve partial or total removal of the external female genitalia or other injury to the female genital organs whether for cultural or other non-therapeutic reasons.<sup>1</sup> It is common in several countries, predominantly in Africa, and more than 100 million women and girls are estimated to have had FGM worldwide. Whether obstetric outcomes differ between women who have and those who have not had FGM is unclear, since previous studies have been small and methodologically limited, so have been unable to provide reliable evidence, especially in relation to important outcomes, such as perinatal death.<sup>2–6</sup> The aim of this study was to investigate the effects of different types of FGM on a range of maternal and neonatal outcomes during and immediately after delivery.

## Methods

### Patients and procedures

Women who presented for singleton delivery at 28 obstetric centres in Burkina Faso (five centres), Ghana (three centres), Kenya (three centres), Nigeria (six centres), Senegal (eight centres), and Sudan (three centres) between November, 2001, and March, 2003, and gave consent to participate, were interviewed to obtain information about their personal characteristics and obstetric and medical histories. Those booked for elective caesarean section were not included. Participating women had an antepartum examination of the external genitalia by a trained study

midwife to ascertain whether or not they had had FGM, and if so, which type they had undergone. Women and their infants were then followed up until maternal discharge from hospital for details of delivery and health status. Women were not approached to take part in the study if their labour was too advanced to allow the necessary examination of the genitalia before delivery or if they were not able to give informed consent. The deliveries of women participating in the study were managed according to standard practice at each centre. Study centres varied from fairly isolated rural hospitals to tertiary teaching hospitals in capital cities and were chosen to provide an appropriate diversity of types of FGM, according to the results of a pilot study done in 2000, of 1976 women. WHO research ethics committees and the appropriate national and local research ethics committees at the participating sites approved the study.

Women's FGM status was defined according to the findings at examination of the external genitalia and was

### Panel: WHO classification of female genital mutilation (FGM)

**No FGM:** no evidence of any genital mutilation

**FGM I:** excision of the prepuce, with or without excision of part or all of the clitoris

**FGM II:** excision of the clitoris with partial or total removal of the labia minora

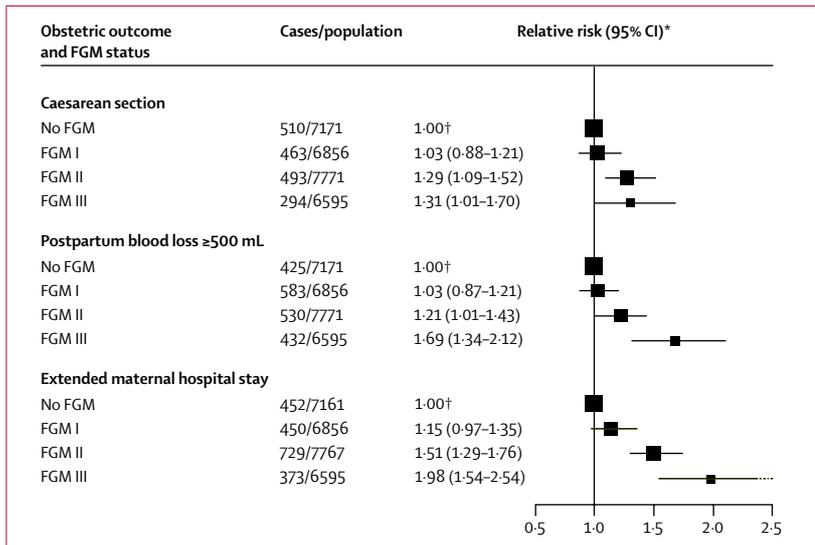
**FGM III:** excision of part or all of the external genitalia and stitching or narrowing of the vaginal opening (infibulation)

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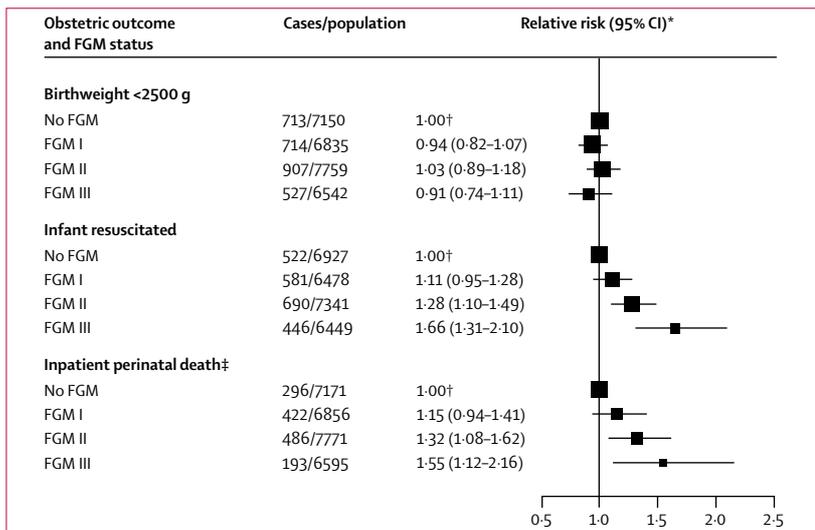
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**Figure 1: Relative risk of adverse maternal outcomes in women with FGM I, II, or III compared with women without FGM**

\*Adjusted for study centre, maternal age, parity, education, socioeconomic status, urban/rural residence, time taken to get to hospital, height, and antenatal care. †Reference group; separate models were used for no FGM versus FGM I, no FGM versus FGM II, and no FGM versus FGM III. In figures 1–3, the areas of the black squares are inversely proportional to the variance of the log relative risk.



**Figure 2: Relative risk of adverse infant outcomes in women with FGM I, II, or III compared with women without FGM**

\*Adjusted for study centre, maternal age, parity, education, socioeconomic status, urban/rural residence, time taken to get to hospital, height, and antenatal care. †Reference group; separate models were used for no FGM versus FGM I, no FGM versus FGM II, and no FGM versus FGM III. ‡Infants who were stillborn or died while the mother was an inpatient.

classified according to the WHO classification system (panel).<sup>1</sup> Weight and height were measured by the study midwife. Large differences between countries in the most appropriate measure of socioeconomic status had been identified during the pilot study (eg, income, number of cattle owned, housing status, occupation). Because of these differences, a single measure of low, medium, and high socioeconomic status was devised with use of locally

relevant criteria and assessment by the study midwife. Other baseline variables were defined according to what the study participant reported at interview.

Follow-up information for the study participant and her infant, including data about operative delivery, episiotomy, perineal tears, birthweight, Apgar score, stillbirth, and neonatal and maternal death, was gathered by the study midwives and investigators, until maternal discharge from hospital (the mean follow-up was 1.8 days). A woman was defined as having had an episiotomy if the study midwife reported a posterolateral, posterior, or lateral episiotomy. Postpartum blood loss was measured according to the protocol for the WHO multicentre randomised trial of misoprostol in management of the third stage of labour.<sup>7</sup> A woman was defined as having an extended hospital stay if the study midwife answered “yes” to the question “Was the length of hospital stay longer than usual for delivery?” For women with vaginal delivery, extended hospital stay was also defined as hospital stay longer than 3 days, as measured by the difference between date of admission and discharge. An infant was defined as having been resuscitated if it had undergone assisted respiration or inflation of the lungs after delivery. The term inpatient perinatal death was used to refer to an infant who was stillborn or died while the mother was an inpatient.

Copies of completed study interview and outcome forms were sent to the central data-processing unit at the department of reproductive health and research at WHO in Geneva, where they were coded and double entered into the study database.

### Statistical analysis

28 509 women joined the study. Data for age, parity, education, urban or rural residence, or height were missing for 126 (0.4%) women and they were excluded from the analyses. Other variables included a category for missing values when that variable was used for adjustment purposes. Response rates were high, with 97% of eligible women in Kenya, 99% in Sudan, and 100% in Burkina Faso, Ghana, and Nigeria joining the study. Response rates in Senegal were not available.

Initial analyses examined the prevalence of various factors according to FGM status, with  $\chi^2$  tests for heterogeneity, to identify potential confounding factors. The main analyses estimated the risk of having a specific adverse maternal or infant outcome versus not having this specific outcome, in women who had had FGM I, II, and III compared separately with women who had not had FGM. Adjusted odds ratios were calculated by unconditional logistic regression, and approximate adjusted relative risks (RR) and their CIs were computed from these from the total number of exposed and non-exposed women and the total number of events.

Study centre, maternal age, parity, education, and socioeconomic status were judged a priori to be confounding factors. Further potential confounding factors were regarded to be those that when added to the model changed

the odds ratio by 5% or more for the main study outcomes (included in figures 1 and 2). The final model adjusted for study centre, maternal age, parity, maternal height, maternal education, socioeconomic status, residence (urban or rural), time taken to reach hospital, and number of antenatal care visits. When these factors had been accounted for, further adjustment for marital status, religion, antepartum weight, and presence of illness at admission did not materially affect the findings. To avoid overadjustment, we did not adjust for previous adverse obstetric outcomes, since these outcomes could have been attributable to complications related to FGM.

Relations were examined for all women combined, then separately for primiparous and multiparous women, apart from those for episiotomy and perineal tear, which are presented separately only for primiparous and multiparous women. Heterogeneity between results according to study centre and parity was examined with Mantel-Haenszel tests on the stratum-specific adjusted RRs. The use of separate models for each type of FGM, compared with the baseline group of women without FGM, was decided a priori and precluded formal tests for trend according to the extent of FGM. We estimated the effect of genital mutilation on the absolute risk of perinatal death by applying the summary RR for all types to background rates of perinatal death typical of the countries where this study was done.<sup>8</sup> Analyses were done with STATA statistical package (version 8).

### Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or the writing of this report. The writing group had full access to all the data in the study and had final responsibility for the decision to submit for publication.

### Results

After exclusions, data from 28 393 women were available for analysis (table 1). As expected, the distribution of the type of FGM varied substantially according to the country from which women joined the study (table 1), as well as by centre within country (data not shown). Although study participants were not representative of or derived directly from the general population, these prevalences are broadly in keeping with the few data for FGM from these

countries.<sup>1,9</sup> The distribution varied significantly according to all the background characteristics shown in table 2.

	No FGM	FGM I	FGM II	FGM III	Total	p*
All women	7171 (25%)	6856 (24%)	7771 (27%)	6595 (23%)	28 393 (100%)†	
<b>Age (years)</b>						
<20	1201 (17%)	974 (14%)	1232 (16%)	633 (10%)	4040 (14%)	<0.0001
20–24	2421 (34%)	1614 (24%)	1989 (26%)	1661 (25%)	7685 (27%)	
25–29	1861 (26%)	2013 (29%)	1990 (26%)	1946 (30%)	7810 (28%)	
30–34	996 (14%)	1360 (20%)	1416 (18%)	1336 (20%)	5108 (18%)	
≥35	692 (10%)	895 (13%)	1144 (15%)	1019 (16%)	3750 (13%)	
Mean age (SD)	25.2 (5.9)	26.6 (6.2)	26.4 (6.6)	27.1 (6.0)	26.3 (6.2)	
<b>Education</b>						
None	2473 (35%)	1872 (27%)	3603 (46%)	1082 (16%)	9030 (32%)	<0.0001
Primary/non-formal	2687 (38%)	2495 (36%)	2636 (34%)	2029 (31%)	9847 (35%)	
Secondary	1662 (23%)	1740 (25%)	1186 (15%)	2537 (39%)	7125 (25%)	
Tertiary	349 (5%)	749 (11%)	346 (5%)	947 (14%)	2391 (8%)	
<b>Socioeconomic status</b>						
Low	2738 (38%)	2699 (39%)	3537 (46%)	1100 (17%)	10 074 (35%)	<0.0001
Medium	4212 (59%)	3894 (57%)	3982 (51%)	5254 (80%)	17 342 (61%)	
High	221 (3%)	263 (4%)	252 (3%)	241 (4%)	977 (3%)	
<b>Religious affiliation</b>						
Christian	4226 (59%)	3419 (50%)	2584 (33%)	383 (6%)	10 612 (37%)	<0.0001
Muslim	2570 (36%)	3142 (46%)	4818 (62%)	6176 (94%)	16 706 (59%)	
Other	375 (5%)	294 (4%)	368 (5%)	368 (6%)	1405 (5%)	
<b>Previous livebirths</b>						
0	3782 (53%)	3274 (48%)	3294 (42%)	2489 (38%)	12 839 (45%)	<0.0001
1	896 (13%)	831 (12%)	1052 (14%)	956 (15%)	3735 (13%)	
2	859 (12%)	754 (11%)	955 (12%)	919 (14%)	3487 (12%)	
3	602 (8%)	628 (9%)	743 (10%)	666 (10%)	2639 (9%)	
4	431 (6%)	498 (7%)	600 (8%)	526 (8%)	2055 (7%)	
≥5	601 (8%)	871 (13%)	1127 (15%)	1039 (16%)	3638 (13%)	
Mean (SD)	1.4 (2.0)	1.8 (2.3)	1.9 (2.3)	2.1 (2.4)	1.8 (2.3)	
<b>Residence</b>						
Rural	2924 (41%)	2487 (36%)	3300 (43%)	1857 (28%)	10 568 (37%)	<0.0001
Urban	4247 (59%)	4369 (64%)	4471 (58%)	4738 (71%)	17 825 (63%)	
<b>Time to travel to hospital</b>						
<30 min	2951 (41%)	3559 (52%)	4327 (56%)	1427 (22%)	12 264 (43%)	<0.0001
30–59 min	2319 (32%)	2206 (32%)	1882 (24%)	2408 (37%)	8815 (31%)	
60–119 min	1320 (18%)	610 (9%)	913 (12%)	2043 (31%)	4886 (17%)	
>119 min	508 (7%)	289 (4%)	466 (6%)	706 (11%)	1969 (7%)	
Mean (SD)	41.5 (53.4)	32.6 (42.0)	36.2 (56.8)	53.5 (61.2)	40.8 (54.4)	
<b>Number of antenatal care visits</b>						
0	372 (5%)	899 (13%)	407 (5%)	205 (3%)	1883 (7%)	<0.0001
1–3	2131 (30%)	1945 (28%)	3479 (45%)	1076 (16%)	8631 (30%)	
≥4	4591 (64%)	3664 (53%)	3627 (47%)	5281 (80%)	17 163 (60%)	
Mean (SD)	4.8 (2.8)	4.6 (3.5)	4.0 (2.6)	6.2 (2.7)	4.9 (3.0)	
<b>Antepartum weight (kg)</b>						
<50	260 (4%)	307 (5%)	369 (5%)	122 (2%)	1058 (4%)	<0.0001
50–59	1988 (28%)	1826 (27%)	2157 (28%)	943 (14%)	6914 (24%)	
60–69	2999 (42%)	2432 (36%)	3029 (39%)	2162 (33%)	10 622 (37%)	
70–79	1322 (18%)	1467 (21%)	1503 (19%)	2029 (31%)	6321 (22%)	
≥80	578 (8%)	806 (12%)	686 (9%)	1332 (20%)	3402 (12%)	
Mean (SD)	64.1 (10.3)	65.4 (11.2)	64.3 (10.4)	68.3 (10.9)	68.3 (11.3)	

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	No FGM	FGM I	FGM II	FGM III	Total
Burkina Faso	938 (19%)	1097 (23%)	2172 (45%)	609 (13%)	4816
Ghana	1841 (60%)	353 (11%)	867 (28%)	33 (1%)	3094
Kenya	1681 (40%)	865 (21%)	1201 (29%)	420 (10%)	4167
Nigeria	646 (12%)	3369 (63%)	1310 (24%)	41 (1%)	5366
Senegal	733 (21%)	837 (24%)	1850 (54%)	29 (1%)	3449
Sudan	1332 (18%)	335 (5%)	371 (5%)	5463 (73%)	7501
Total	7171 (25%)	6856 (24%)	7771 (27%)	6595 (23%)	28 393

Data are number (%).

**Table 1: Distribution of FGM status and total FGM by country**

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Height (cm)						
<150	215 (3%)	188 (3%)	193 (3%)	112 (2%)	708 (2%)	<0.0001
150–159	2523 (35%)	2446 (36%)	2335 (30%)	1777 (27%)	9081 (32%)	
160–169	3268 (46%)	3248 (47%)	4144 (53%)	3235 (49%)	13 895 (49%)	
≥170	1165 (16%)	974 (14%)	1099 (14%)	1471 (22%)	4709 (17%)	
Mean (SD)	161.6 (7.5)	161.3 (7.3)	162.1 (6.8)	162.3 (7.7)	161.8 (7.3)	
Antepartum BMI (kg/m <sup>2</sup> )						
<25	3892 (54%)	3527 (51%)	4270 (55%)	2633 (40%)	14 322 (50%)	<0.0001
25–29	2559 (36%)	2404 (35%)	2713 (35%)	2960 (45%)	10 636 (37%)	
≥30	696 (10%)	907 (13%)	761 (10%)	995 (15%)	3359 (12%)	
Mean (SD)	24.6 (3.8)	25.1 (3.9)	24.5 (3.8)	24.5 (4.1)	25.0 (3.9)	
Existing illness						
No	6642 (93%)	6218 (91%)	6631 (85%)	5973 (91%)	25 464 (90%)	<0.0001
Yes	527 (7%)	637 (9%)	1140 (15%)	622 (9%)	2926 (10%)	

Data are number (%) unless otherwise indicated. BMI=body-mass index. \*From  $\chi^2$  test for heterogeneity. †Row percentage calculated for this row only.

**Table 2: Distribution of FGM status according to background characteristics**

Overall, 1760 (6%) women were delivered by caesarean section, and 1970 (7%) deliveries were complicated by post-partum blood loss of 500 mL or more. Women with FGM II and FGM III were significantly more likely to have a caesarean section and post-partum blood loss of 500 mL or greater than were women who had not had FGM (figure 1). When women with caesarean section were excluded from the analysis of post-partum haemorrhage, the RRs were 1.04 (0.83–1.28) for FGM I, 1.22 (0.96–1.54) for FGM II, and 1.96 (1.45–2.65) for FGM III, compared with women without FGM. Women with FGM were more likely than those without to have an extended hospital stay (figure 1). For women with vaginal deliveries, the RRs of staying in hospital for longer than 3 days were 1.19 (1.01–1.41) for FGM I, 1.55 (1.31–1.83) for FGM II, and 2.34 (1.59–3.45), for FGM III compared with those without FGM; this pattern of risk was similar in nulliparous and parous women.

Among primiparous women, the proportion having episiotomies ranged from 41% in women without FGM to 88% in those with FGM III; in multiparous women, the proportions were 14% and 61%, respectively. The RRs of episiotomy (with or without a perineal tear) in primiparous women were 1.31 (95% CI 1.20–1.44) for FGM I, 1.47 (1.34–1.60) for FGM II, and 1.84 (1.70–1.97), for FGM III compared with women without FGM. In multiparous women, the RRs were 1.75 (1.47–2.09) for FGM I, 2.02 (1.69–2.42) for FGM II, and 2.16 (1.91–2.44) for FGM III compared with those without FGM. In women who had not had an episiotomy, the RRs of a perineal tear for primiparous women were 1.31 (1.03–1.66) for those with FGM I, 1.92 (1.50–2.47) for those with FGM II, and 3.19 (1.91–4.74) for those with FGM III, compared with those without FGM. In multiparous women, the RRs were 1.37 (1.07–1.75) for women with FGM I, 2.17 (1.69–2.82) for those with FGM II, and 1.93 (1.07–3.38) for those with

FGM III compared with women without FGM. There was great heterogeneity in the RR of episiotomy according to study centre.

54 (0.19%) women died before discharge from hospital; nine (0.13%) in those without FGM, 15 (0.22%) in those with FGM I, 23 (0.30%) FGM II, and seven (0.11%) FGM III. The RRs of maternal inpatient death, adjusted for the potential confounding factors outlined before, were 1.39 (0.40–4.84) for women with FGM I, 5.80 (1.77–19.01) for those with FGM II, and 1.57 (0.24–10.22) for those with FGM III, compared with women with no FGM. Additional adjustment for illness at admission resulted in RRs of 1.29 (0.36–4.60) for women with FGM I, 4.18 (1.24–14.08) for those with FGM II, and 1.56 (0.25–9.92) for those with FGM III. The wide CIs around these estimates should be noted.

2861 (10%) infants weighed less than 2500 g at birth, 2239 (8%) were born alive but had resuscitation, and 1400 (5%) were stillborn or died in the immediate postnatal period. The relation between mutilation and the risk of having an infant weighing less than 2500 g was not significant (figure 2). The RR of an infant being resuscitated at delivery was significantly higher for women with FGM II and FGM III than for those without FGM (figure 2). The overall RR of perinatal death was significantly greater in the infants born to women with FGM II and FGM III, than in those of women without FGM (figure 2). Compared with women without FGM, the RR of fresh stillbirth (n=737) was 1.34 (1.00–1.80) for FGM I, 1.48 (1.10–2.01) for FGM II, and 2.15 (1.32–3.51) for FGM III. The RRs of macerated stillbirth (n=448) were 1.06 (0.74–1.51), 1.22 (0.83–1.76), and 1.55 (0.83–2.88), respectively. For infants born alive, there were no significant differences in the proportion with an Apgar score less than 4 according to mother's FGM status, nor were there any significant differences in the proportion who were born alive and died before maternal discharge from hospital.

The overall results were examined for heterogeneity between obstetric centres and according to whether study participants were primiparous or multiparous. There was significant heterogeneity between centres for all types of mutilation for the RR of episiotomy (p<0.0001) and for FGM I (p=0.04) and II (p=0.009) for perineal tear. The centre-specific RRs of episiotomy showed a pattern of higher risk for women with FGM varying in size by centre (data not shown). Of the 18 other comparisons, three RRs showed significant heterogeneity by centre: post-partum blood loss greater than 500 mL for FGM III versus no FGM (p=0.048); extended maternal hospital stay for FGM I versus no mutilation (p=0.001) and infant resuscitation for FGM III versus no FGM (p=0.004).

Overall, the effect of FGM on the obstetric outcomes shown in figure 3 did not differ significantly between primiparous and multiparous women. Of the 18 tests for heterogeneity comparing the effect of type of FGM for every outcome in primiparous versus multiparous women,

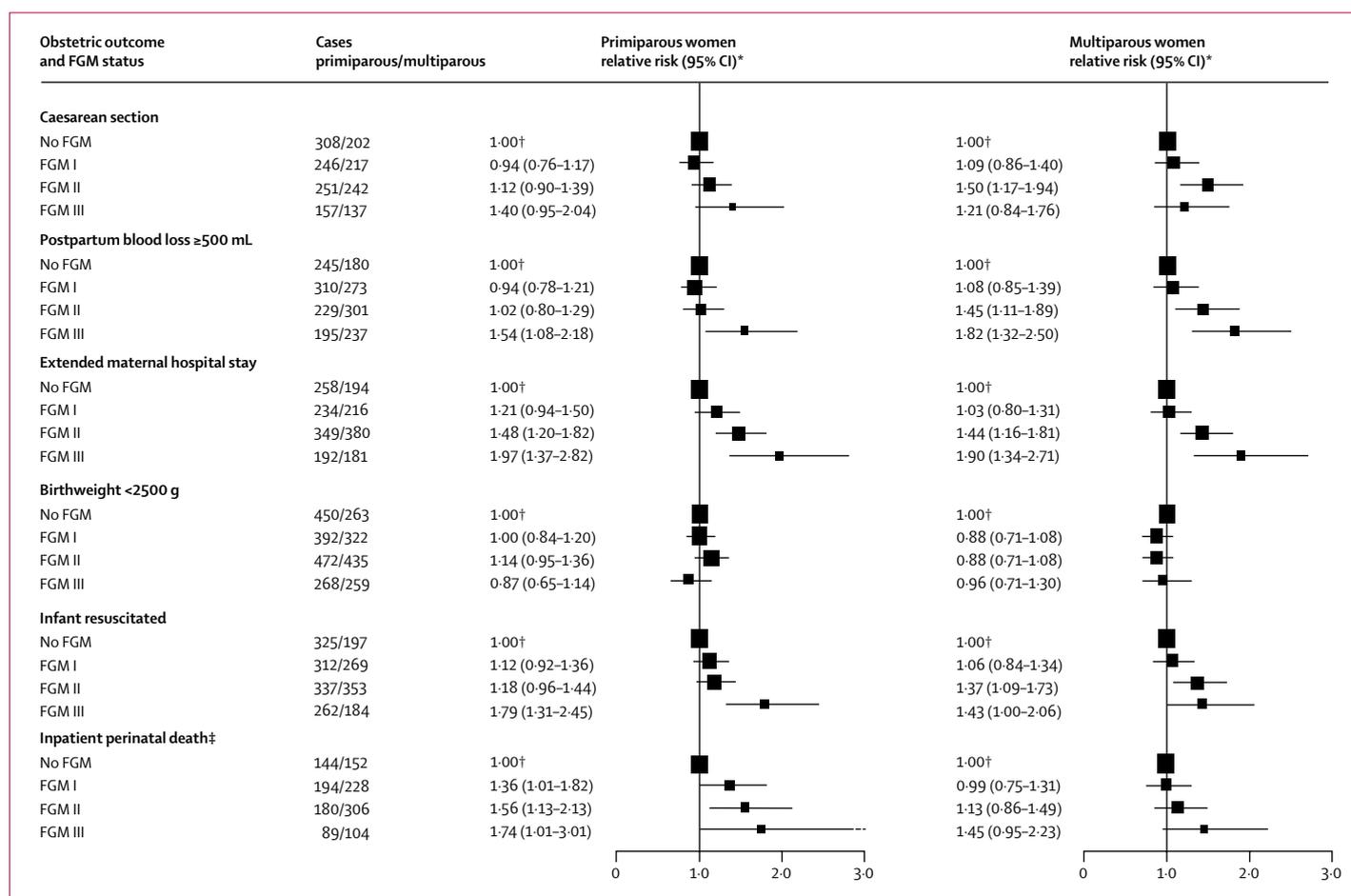


Figure 3: Relative risk of adverse obstetric outcomes in women with FGM I, II, or III compared with women without FGM, according to parity

\*Adjusted for study centre, maternal age, number of children (in multiparous women), education, socioeconomic status, urban/rural residence, time taken to get to hospital, height, and antenatal care. †Reference group; separate models were used for no FGM versus FGM I, no FGM versus FGM II, and no FGM versus FGM III. ‡Infants who were stillborn or died while the mother was an inpatient.

17 were not significant, and for the remaining comparison (the effect of FGM II on post-partum haemorrhage in primiparous versus multiparous women), the p value was 0.045. In view of the absence of any clear pattern of difference between the groups and the number of comparisons made, this finding might be due to chance.

The summary RR of stillbirth or death of the infant while the mother was an inpatient was 1.28 (1.12–1.46) for women with any type of FGM compared with none. Table 3 shows the estimated effect of FGM on the absolute rate of perinatal death, for perinatal mortality rates typical of the region where the study was done. The excess deaths

attributable to FGM ranged from 11 to 17 per 1000 deliveries, in relation to background perinatal mortality rates of 40–60 per 1000 deliveries. On the basis of the summary RR, about 22% (11–32) of perinatal deaths in infants born to women with FGM can be attributed to the FGM.

## Discussion

These results show that deliveries to women who have undergone FGM are significantly more likely to be complicated by caesarean section, postpartum haemorrhage, episiotomy, extended maternal hospital stay, resuscitation of the infant, and inpatient perinatal death, than deliveries to women who have not had FGM. There was no significant association between FGM and the risk of having a low-birthweight infant.

This large prospective study was done at obstetric centres in countries where FGM is common and was designed specifically to examine the relation between different types of FGM and obstetric sequelae. The study has sufficient power to investigate the effect of specific types of FGM on a range of obstetric outcomes, including important but

Rate in women without FGM	Estimated rate in women with FGM	Excess
40	51	11
50	64	14
60	77	17

Table 3: Estimated rates of perinatal death per 1000 births in infants born to women with and without FGM

less common outcomes, such as inpatient perinatal death, that have not previously been reliably examined.

Most women who have undergone FGM live in countries with limited infrastructure for health care or for health research. For practical reasons, this study was done in hospitals, and women with high-risk or complicated deliveries and those able to afford hospital care are likely to be over-represented. As a result, the absolute rates of complications might not be generalisable to women in the broader population in these countries. The overall finding of higher risks of obstetric complications in women with FGM is likely to be more widely applicable; however, the frequency and effect of these complications among women giving birth in hospital might differ from those in women giving birth elsewhere. For example, postpartum haemorrhage and obstructed labour are likely to have more serious results outside the hospital setting. The findings do not apply to women booked for elective caesarean section, as they were excluded from the study. The finding of substantial heterogeneity in the RR of episiotomy (and the related findings on perineal tear) by study centre for all types of mutilation could indicate differences in practice between obstetric centres. Although the summary RRs we present should be interpreted with caution, the centre-specific estimates suggest that the overall finding of greater risk of episiotomy in women with FGM than those without applies broadly within the study population. The absence of a consistent pattern of heterogeneity by centre or parity for any of the other outcomes is reassuring; the absence of such a pattern and the likelihood of some chance findings owing to the large number of comparisons made, suggest that the overall RRs for the main findings can be regarded as an appropriate summary of the results for the study as a whole.

Study outcomes were restricted to those that took place while the study participants were still in hospital, so the effect of FGM on longer-term outcomes such as postpartum infections, fistulae, and later neonatal and infant mortality, could not be investigated. Initial pilot studies showed that longer follow-up would not have been practicable because of high rates of loss to follow-up. Some study centres are obtaining data for later outcomes and will report on these separately. Although study midwives were trained in the classification of the different types of FGM and were experienced in caring for women who have been subjected to such procedures, the ascertainment of FGM status was not independently validated. However, the overall design of the study was prospective, so any misclassification would tend to be towards a null effect. The study midwives might have been aware of the participant's FGM status when certain outcomes were recorded and this awareness could have affected their measurement or interpretation, especially for more subjective outcomes, such as longer than usual maternal stay in hospital and postpartum haemorrhage. However, the direction or form that this potential bias would take is unclear and the findings for outcomes potentially affected

by midwives' attitudes are in keeping with those relating to more objectively measured outcomes, such as caesarean section, perinatal death, and hospital stay longer than 3 days in women with vaginal delivery.

Whether or not a woman undergoes FGM and the type of procedure done are determined culturally and socially. The women participating in the study were from more than 120 different ethnic groups. FGM is closely linked with ethnic group,<sup>9,10</sup> so, in this dataset, adjustment for ethnicity was neither appropriate nor practicable because of the likelihood of overadjustment. For example, 97% of Arab and 96% of Nubian women in the Sudan, 99% of Embu women in Kenya, and 98% of Bini women in Nigeria had undergone FGM, whereas 90% of Ouoloff women in Senegal and 88% of Frafra women in Ghana had not. FGM is also affected by social and demographic factors (table 2). The overall results were adjusted for many of these factors, including those regarded as likely to mediate potential relations between ethnicity and obstetric outcome, which were study centre, age, parity, height, education, socioeconomic status, rural or urban residence, time taken to get to hospital, and antenatal care. Although there is a theoretical possibility that the effects seen here are not directly attributable to FGM, but are a result of bias or residual confounding with ethnicity or some other factor, this adjustment, and the fact that the findings are statistically homogeneous across several study centres, and hence ethnic groups, makes this possibility unlikely. The gradual increase in risk of adverse outcomes associated with increasingly extensive FGM, with the greatest RRs in women with FGM II or III also suggests that the relation is causal. The absence of any association between FGM and birthweight and the strength of the relation between FGM and fresh stillbirth also lend support to this relation, suggesting that the findings are not due to an increased risk of general adverse reproductive outcomes in women with FGM, but rather to risks relating more specifically to difficulties at delivery.

Previous smaller studies have suggested that adverse obstetric outcomes such as episiotomy,<sup>2</sup> tears,<sup>3,5</sup> protracted labour,<sup>2,5</sup> post-partum haemorrhage,<sup>3,5</sup> and low Apgar score<sup>2,5</sup> might be more common in deliveries in women who have had FGM.<sup>3,5</sup> However, reliable data about the effect of different types of FGM on specific obstetric outcomes are scarce, since previous studies have inconsistent findings,<sup>3,4</sup> rarely account for potential confounding factors,<sup>2,5</sup> do not investigate the effects of different types of FGM,<sup>2,3,5</sup> and have been based on self-reported obstetric complications.<sup>3,4</sup> Previous studies also had insufficient power to examine important outcomes such as stillbirth and early neonatal death.

The mechanism by which FGM might cause adverse obstetric outcomes is unclear. Although practices vary from country to country, FGM is generally done in girls younger than 10 years and leads to varying amounts of scar formation. The presence of this scar tissue, which is less elastic than the perineal and vaginal tissue would normally

be, might cause differing degrees of obstruction and tears or episiotomy.<sup>6</sup> A long second stage of labour, along with direct effects on the perineum, could underlie the findings of an increased risk of perineal injury, postpartum haemorrhage, resuscitation of the infant, and fresh stillbirth associated with FGM. The length of the second stage of labour could not be reliably measured in our study settings because good obstetric practice discourages frequent vaginal examinations. Furthermore, the increased risk of caesarean section in women with FGM II or III could theoretically mask an effect on the length of the second stage of labour in women with these types of FGM. There is evidence that FGM is associated with increased rates of genital and urinary-tract infection, which could also have repercussions for obstetric outcomes.<sup>3,5,11</sup>

In keeping with many other countries and regions where the practice of FGM is widespread, the background rates of adverse maternal and infant outcomes in the countries included in this study are high, with the lifetime risk of maternal death ranging from one in 35 in Ghana to one in 12 in Burkina Faso, and estimated perinatal mortality rates ranging from 44 per 1000 births in Sudan to 88 per 1000 births in Nigeria.<sup>8</sup> Thus the increased RR of adverse obstetric outcomes with FGM shown here occurs against high background rates of disease and death. FGM is therefore likely to lead to substantial additional cases of adverse obstetric outcome in many countries, with the estimates presented here suggesting that FGM could cause one to two extra perinatal deaths per 100 deliveries to African women who have had FGM. Adverse obstetric and perinatal outcomes can therefore be added to the known harmful immediate and long-term effects of FGM. This information is important for communities in which FGM is practised, both for women who have undergone such procedures and for future generations of women and girls. FGM remains a pressing human rights issue and reliable evidence about its harmful effects, especially on reproductive outcomes, should contribute to the abandonment of the practice.

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#### Conflict of interest statement

We declare that we have no conflict of interest.

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