

# Breakdown of simple female genital fistula repair after 7 day versus 14 day postoperative bladder catheterisation: a randomised, controlled, open-label, non-inferiority trial



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## Summary

**Background** Duration of bladder catheterisation after female genital fistula repair varies widely. We aimed to establish whether 7 day bladder catheterisation was non-inferior to 14 days in terms of incidence of fistula repair breakdown in women with simple fistula.

**Methods** In this randomised, controlled, open-label, non-inferiority trial, we enrolled patients at eight hospitals in the Democratic Republic of the Congo, Ethiopia, Guinea, Kenya, Niger, Nigeria, Sierra Leone, and Uganda. Consenting patients were eligible if they had a simple fistula that was closed after surgery and remained closed 7 days after surgery, understood study procedures and requirements, and agreed to return for follow-up 3 months after surgery. We excluded women if their fistula was not simple or was radiation-induced, associated with cancer, or due to lymphogranuloma venereum; if they were pregnant; or if they had multiple fistula. A research assistant at each site randomly allocated participants 1:1 (randomly varying block sizes of 4–6; stratified by country) to 7 day or 14 day bladder catheterisation (via a random allocation sequence computer generated centrally by WHO). Outcome assessors were not masked to treatment assignment. The primary outcome was fistula repair breakdown, on the basis of dye test results, any time between 8 days after catheter removal and 3 months after surgery. The non-inferiority margin was 10%, assessed in the per-protocol population. This trial is registered with ClinicalTrials.gov, number NCT01428830.

**Findings** We randomly allocated 524 participants between March 7, 2012, and May 6, 2013; 261 in the 7 day group and 263 in the 14 day group. In the per-protocol analysis, ten (4%) of 250 patients had repair breakdown in the 7 day group (95% CI 2–8) compared with eight (3%) of 251 (2–6) in the 14 day group (risk difference 0·8% [95% CI –2·8 to 4·5]), meeting the criteria for non-inferiority.

**Interpretation** 7 day bladder catheterisation after repair of simple fistula is non-inferior to 14 day catheterisation and could be used for management of women after repair of simple fistula with no evidence of a significantly increased risk of repair breakdown, urinary retention, or residual incontinence up to 3 months after surgery.

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## Introduction

Although rare in most of the world, female genital fistula remains devastating for women in resource-poor settings in Africa and Asia.<sup>1</sup> Most commonly, the fistula is an abnormal opening between the vagina and bladder, resulting in complete urinary incontinence. Prolonged obstructed labour is the main cause; compression of the bladder and vagina against the woman's pelvis by the head of the fetus results in death and sloughing of tissue.

Most female genital fistulas can be repaired surgically.<sup>2</sup> Preoperative, intraoperative, and postoperative practices associated with fistula repair vary widely, including the duration of postoperative bladder catheterisation, which ranges from 5 to 42 days.<sup>3,4</sup> Duration of catheterisation after fistula repair is mainly based on custom rather than on robust scientific evidence.<sup>5</sup> The assumption behind extended catheterisation is that the bladder heals better

at rest than in use. However, no data support this assumption, and findings from one canine study<sup>6</sup> suggest that allowance of filling and emptying is beneficial to bladder healing.

Some indirect supportive evidence exists for short-duration catheterisation after fistula repair. Short-term catheterisation has been used successfully after various other types of urogenital surgery, such as retropubic midurethral sling placement,<sup>7</sup> sigmoidectomy,<sup>8</sup> and repair of intraperitoneal bladder disruptions,<sup>9,10</sup> and, indeed, some expert fistula surgeons leave the catheter for a short duration in most cases.<sup>3</sup> Additionally, in a previous non-inferiority randomised controlled trial,<sup>11</sup> 10 day catheterisation was noted to be not inferior to 14 day catheterisation after fistula repair, although findings are difficult to interpret because most repair breakdowns in both groups occurred before catheter removal in the 10 day group.

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Provision of services in an efficient and cost-effective manner, without compromise of surgical outcomes and overall health and wellbeing of patients, is paramount. Shortening of the duration of bladder catheterisation after fistula repair would improve patients' comfort and potentially lower the risk of catheter-related urinary tract infections and other adverse events. Additional benefits include short hospital stay allowing efficient use of available capacity, reduced workload of nursing staff, and low service costs. We aimed to establish whether 7 day bladder catheterisation was not inferior to 14 days in terms of incidence of fistula repair breakdown in women with simple fistula.

## Methods

### Study design and patients

We did a randomised, controlled, open-label, non-inferiority trial at eight hospitals in the Democratic Republic of the Congo, Ethiopia, Guinea, Kenya, Niger, Nigeria, Sierra Leone, and Uganda. Women were eligible if they met the following inclusion criteria: had a simple fistula, established by the surgeon after repair surgery; had a closed fistula at completion of surgery and up to 7 days after surgery on the basis of negative dye test results; understood study procedures and requirements; agreed to return for one follow-up 3 months after surgery; and provided informed consent for study participation. We excluded women if their fistula was deemed not simple, radiation-induced, associated with cancer, or due to lymphogranuloma venereum, or if they were pregnant. After the trial started, when a question about eligibility of women with more than one fistula arose, we added multiple fistula to the exclusion criteria, implemented from July 31, 2012.

Patients gave written informed consent before initial screening and again before randomisation 7 days after fistula repair surgery. We placed no lower age limit on study participation because genital fistula occurs in young women. We sought proxy consent for minors in accordance with host country legislation, but did not substitute this consent for the minor's own consent. The protocol received approval from 13 technical and ethical review bodies, including the WHO Research Project Review Panel (RP2) and Research Ethics Review Committee, the US Agency for International Development, a national ethical review body in each country, and, where they existed, an institutional ethical body at study sites. The trial protocol has been previously published.<sup>12</sup>

### Randomisation and masking

Random allocation of participants to 7 day or 14 day bladder catheterisation took place 7 days after fistula repair surgery. The allocation sequence was computer generated centrally at WHO and enrolment and randomisation was done by a research assistant based at each study site. Randomisation was in a 1:1 ratio, stratified by country, and restricted with randomly varying

block sizes of 4–6. We concealed allocation through sealed opaque envelopes. Randomisation envelopes were opened by study staff just before random assignment. Because of the nature of fistula repair services and low availability of clinical staff at study sites, we could not mask participants, coinvestigators, those assessing outcomes, or other study staff to treatment allocation.

### Procedures

We screened women scheduled for fistula repair surgery who consented to participate in the study at three time-points before randomisation to ensure that they met the study selection criteria. The initial screening was to ensure that fistula were not radiation-induced, associated with cancer, or due to lymphogranuloma venereum, and that participants understood study procedures, agreed to return for follow-up, and had no contraindications to participation. We gathered details of fistula characteristics and urogenital tract damage during surgery. We placed an indwelling bladder catheter at completion of surgery.

The second screening occurred at the end of surgery; participants with a confirmed simple fistula that was closed on the basis of dye test results continued to be eligible. The final screening occurred 7 days after surgery and included reaffirmation of participants' consent to continue in the trial and confirmation that the fistula was still closed on the basis of dye test results. Women randomly assigned to the 7 day group had their bladder catheter removed on the day of randomisation, whereas those randomly assigned to the 14 day group had their catheter removed after an additional 7 days. We scheduled participants to stay at the facility for 7 days after catheter removal.

Before randomisation, we did not standardise clinical care, although we collected data on procedures and practices used. After randomisation, we did standardise clinical care. Participants received daily perineal and vaginal care, were encouraged to walk and drink water freely, did not receive prophylactic antibiotics or anthelmintics, were monitored carefully for blockage of the bladder catheter and treated as necessary, and did not undergo bladder training. We assessed postvoid residual urine volumes 1, 3, and 7 days after catheter removal by passing a urethral catheter and emptying the bladder immediately after the woman had voided. In the event of excess urine retention, defined as a residual amount of urine in the bladder greater than 50% of the voided volume, we implemented intermittent urethral catheterisation a minimum of three times per day to drain the bladder. We discontinued this catheterisation once the residual volume was less than 50% of the voided volume on two consecutive occasions.

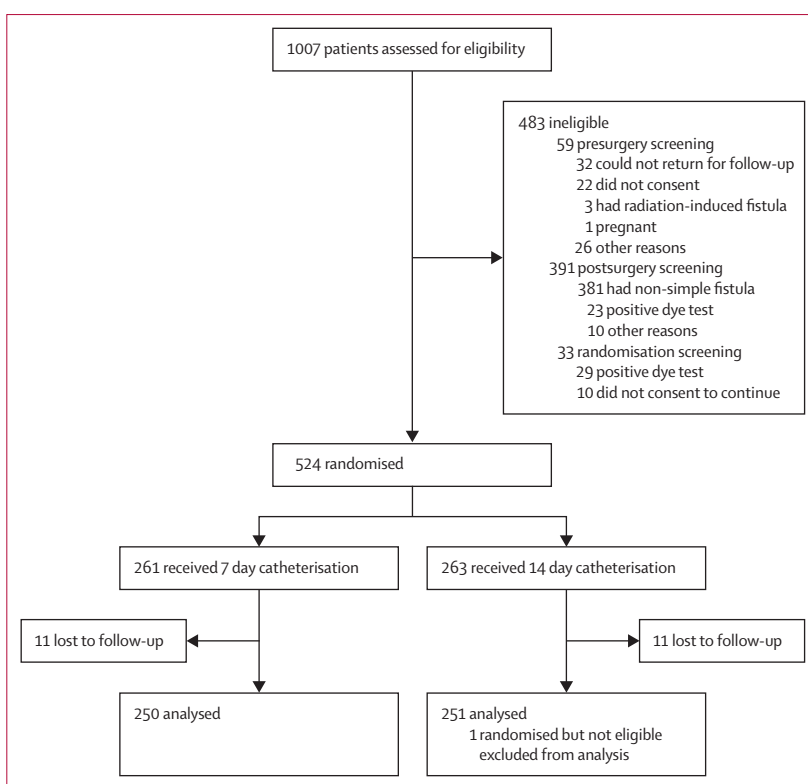
Participants in both groups had a dye test 7 days after catheter removal (ie, 14 days after surgery in the 7 day catheterisation group and 21 days after in the 14 day group). We deemed participants with a positive dye test to

have had a repair breakdown and so their participation in the study ended (further clinical treatment was provided on the basis of standard practices at each study site). We asked participants with a negative dye test to return for follow-up 3 months after repair surgery for an interview, clinical examination, and dye test. We also classified women with a positive dye test at follow-up as a repair breakdown. We provided participants compensation for transportation to and from the clinic for the follow-up visit and gave them a small gift as a token of appreciation for returning.

### Outcomes

The primary outcome was fistula repair breakdown any time between 8 days after catheter removal and 3 months after surgery (established with a dye test at a follow-up visit 3 months after surgery or earlier in women who returned after discharge with a complaint of urine leakage). We defined the primary outcome in this way to limit the potential for bias because it ensured that all participants included in the primary outcome analysis had the same status for the primary outcome (ie, were dye test-negative) at the start of follow-up and that we had the same number of opportunities to measure the primary outcome (ie, an equal number of dye tests) in the two groups. This primary outcome was assessed by a fistula surgeon at each study site. Prespecified secondary outcomes were fistula repair breakdown between catheter removal and 7 days after surgery as established by a dye test 7 days after catheter removal, 3 months after surgery, or earlier in women who returned with complaints (we also separately report repair breakdowns between catheter removal and 7 days after catheter removal as established by the dye test 7 days after catheter removal, although this outcome was not prespecified); urinary retention 1, 3, or 7 days after catheter removal; clinically defined infections and febrile episodes (temperature of more than 38°C) potentially related to treatment; urinary catheter blockage; extended stay in hospital (defined as a stay at the facility beyond 1 week after initial catheter removal for a medical reason that could possibly be related to treatment); and residual incontinence at the 3 month follow-up visit (some incontinence remaining after fistula closure, including overflow, stress, or urge incontinence). Residual incontinence was based on the surgeon's clinical impression—ie, history and symptoms reported by participants, and clinical examination findings; we did no formal urodynamic studies or other diagnostic interventions.

In the protocol, “intermittent catheterisation to manage urinary retention” was a secondary outcome. We intended to assess differences in occurrence of urinary retention between groups. Because intermittent catheterisation is the treatment for urinary retention, we decided to report the data on the disorder itself as the secondary outcome as opposed to the treatment used. This decision was made at an analysis planning meeting several months before completion of data collection by MAB, AS, MW,



**Figure: Trial profile**

At each screening, more than one reason for exclusion was possible.

	7 day group	14 day group
<b>Patient characteristics</b>		
Age (years)	31.9 (11.5 [14.0–75.0]); n=260	30.6 (11.7 [15.0–70.0]); n=261
BMI (kg/m <sup>2</sup> )	22.1 (4.0 [15.6–39.5]); n=259	21.9 (4.3 [13.7–38.9]); n=258
Female genital cutting	133/261 (51%)	136/263 (52%)
Previous repair attempts	57/261 (22%)	58/262 (22%)
Place of residence		
Rural	226/260 (87%)	217/261 (83%)
Urban	25/260 (10%)	40/261 (15%)
Periurban	9/260 (3%)	4/261 (2%)
Highest level of education		
None	154/260 (59%)	155/261 (59%)
Primary	61/260 (23%)	65/261 (25%)
Secondary	44/260 (17%)	40/261 (15%)
Higher	1/260 (<1%)	1/261 (<1%)
Marital status		
Married or cohabiting	179/261 (69%)	192/262 (73%)
Single	24/261 (9%)	24/262 (9%)
Widowed	16/261 (6%)	11/262 (4%)
Divorce or separated	41/261 (16%)	35/262 (13%)
Parity		
Nulliparous	1/256 (<1%)	0/260
Primiparous	67/256 (26%)	82/260 (32%)
Multiparous	188/256 (73%)	178/260 (68%)

(Table 1 continues on next page)

	7 day group	14 day group
(Continued from previous page)		
Leakage started after		
Delivery of a baby	243/261 (93%)	252/262 (96%)
Medical procedure	15/261 (6%)	9/262 (3%)
Female genital cutting	1/261 (<1%)	0/262
Other	2/261 (1%)	1/262 (<1%)
<b>Fistula characteristics</b>		
Location and type of fistula*		
Midvaginal	70/261 (27%)	65/262 (25%)
Juxtaurethral	69/261 (26%)	58/262 (22%)
Juxtacervical	67/261 (26%)	84/262 (32%)
Intracervical	21/261 (8%)	24/262 (9%)
Vault	15/261 (6%)	8/262 (3%)
Urethral	8/261 (3%)	14/262 (5%)
Vesicouterine	8/261 (3%)	6/262 (2%)
Circumferential	7/261 (3%)	10/262 (4%)
Ureteric	3/261 (1%)	2/262 (1%)
Other	3/261 (1%)	2/262 (1%)
Degree of scarring		
None	97/261 (37%)	98/262 (37%)
Mild	128/261 (49%)	131/262 (50%)
Moderate	35/261 (13%)	29/262 (11%)
Severe	1/261 (0.4%)	4/262 (2%)
Status of bladder neck		
Intact	197/261 (75%)	202/262 (77%)
Partial damage	59/261 (23%)	58/262 (22%)
Complete destruction	5/261 (2%)	2/262 (1%)
Status of urethra		
Intact	204/261 (78%)	204/262 (78%)
Partial damage	56/261 (21%)	57/262 (22%)
Complete destruction	1/261 (<1%)	1/262 (<1%)
Duration of continuous leakage (months)	12 (4-84; 1-480); n=257	12 (3-72; 1-480); n=256
Largest diameter of fistula (cm)	1 (0.8-2.0; 0.2-6); n=260	1 (0.5-2.0; 0.1-6); n=261
Bladder capacity (cc)	180 (125-300; 20-850); n=255	200 (129-300; 30-1200); n=258
Data are mean (SD [range]), n/n (%), or median (IQR; range). BMI=body-mass index. *More than one location or type is possible for any given fistula.		

**Table 1: Baseline sociodemographic data and fistula characteristics at enrolment**

JR, and EL. We did not need to seek institutional approval as no change was made in how the women were treated, only in how we classified and reported the data.

**Statistical analysis**

We assessed non-inferiority of 7 day versus 14 day bladder catheterisation in terms of the proportion of patients with fistula repair breakdown with a 10% predefined non-inferiority margin, chosen on the basis of experts' clinical judgment. With the assumption that 13% of patients will have fistula repair breakdown in the control group (based on preliminary data from another study we have completed),<sup>13</sup> non-inferiority would be shown within the margin of 10% at a one-sided significance level of 0.025 and a power of 80% (calculated when the number

of patients with fistula repair breakdown in both arms is the same), with a sample size of 177 per arm (354 women in total). After adjustment by 20% for loss to follow-up, 10% each for protocol violations and withdrawals, and a slight additional increase, our planned total sample size was 507 women.

We planned to do an intention-to-treat analysis of all women randomly assigned who had follow-up data and a per-protocol analysis of this group minus those with protocol violations. Only one relevant protocol violation occurred; a non-eligible patient (her postsurgery dye test was positive) was assigned to the 14 day group and the data and safety monitoring committee recommended that this participant be excluded from all analyses. Therefore we did one analysis on the per-protocol population.

The main outcome was assessed using the 95% CI (Fleiss method with continuity correction) for the difference and the ratio between the proportion of patients with fistula breakdown in the 7 day versus 14 day groups. We did a sensitivity analysis with nine scenarios, all in favour of rejection of the non-inferiority hypothesis; we assumed 100% (two times), 300% (three times), and 500% (four times) increases in the proportion of patients in the 7 day group who had fistula repair breakdown, and 60%, 80%, and 99% reductions in the proportion in the 14 day group, for the missing observations in the corresponding groups. To assess the significance of site variability, we did a multilevel logistic regression, including site as a random effect and treatment as a fixed effect.

We assessed secondary outcomes by comparing the proportion of patients in which they occurred between groups using  $\chi^2$  tests. We recorded secondary outcomes, with the exception of residual incontinence 3 months after surgery (because incontinence data were collected at the 3 month follow-up visit), from randomisation through to the 3 month follow-up visit, and reported them for all participants because some secondary outcomes occurred before participants were discontinued or lost to follow-up.

The data and safety monitoring committee met twice during the trial. The committee reviewed one interim analysis after a third of participants had returned for the 3 month follow-up. They reviewed the proportion of patients with events and the number of patients recruited, and advised that the trial should continue until its planned completion. We used SPSS version 18 for all analyses except for the multilevel logistic regression, for which we used R version 2.14.2.

This trial is registered with ClinicalTrials.gov, number NCT01428830.

**Role of the funding source**

Technical staff employed by the funder of the study participated in design of the study and interpretation of the analysis. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

	7 day group*	14 day group*	Risk difference (95% CI)	Relative risk (95% CI)
<b>Primary outcome</b>				
Breakdown between 8 days after catheter removal and 3 months after surgery	10/250 (4%)	8/251 (3%)	0.8% (-2.8 to 4.5)	1.3 (0.5 to 3.1)
<b>Secondary outcomes</b>				
Breakdown between catheter removal and 3 months after surgery	23/261 (9%)	20/262 (8%)	1.2% (-3.9 to 6.3)	1.2 (0.7 to 2.1)
Breakdown between catheter removal and 7 days after catheter removal	13/261 (5%)	12/262 (5%)	0.4% (-3.6 to 4.4)	1.1 (0.5 to 2.3)
Urinary retention during hospital stay	31/261 (12%)	25/262 (10%)	2.3% (-3.3 to 8.0)	1.3 (0.8 to 2.1)
Infection†	8/261 (3%)	16/262 (6%)	-3.0% (-7.0 to 0.9)	0.5 (0.2 to 1.2)
Febrile episode†	5/261 (2%)	10/262 (4%)	-1.9% (-5.1 to 1.3)	0.5 (0.2 to 1.5)
Extended hospital stay‡	5/261 (2%)	1/262 (<1%)	1.5% (-0.7 to 3.7)	5.0 (0.6 to 42.7)
Catheter blockage	5/261 (2%)	11/262 (4%)	-2.3% (-5.6 to 0.8)	0.5 (0.2 to 1.3)
Residual incontinence at 3 months	9/250 (4%)	6/251 (2%)	1.2% (-2.2 to 4.6)	1.5 (0.5 to 4.2)

\*Data are n/n (%). †Possibly related to study treatment. ‡For a medical reason that could possibly be related to study treatment.

**Table 2: Primary and secondary outcomes**

## Results

Between March 7, 2012, and May 6, 2013, we assessed 1007 patients for eligibility, randomly allocating 524 (52%) patients to 7 day (261 [50%] patients) or 14 day (263 [50%] patients) bladder catheterisation (figure). We originally enrolled 12 women with multiple fistula, randomly allocating three to the 7 day group and nine to the 14 day group, but we excluded these after addition of multiple fistula to the exclusion criteria. We analysed 250 [48%] patients in the 7 day group and 251 [48%] in the 14 day group. The 524 participants were distributed as follows: 90 in the Democratic Republic of the Congo, 23 in Ethiopia, 109 in Guinea, 37 in Kenya, 50 in Niger, 76 in Nigeria, 96 in Sierra Leone, and 43 in Uganda. 11 [4%] patients were lost to follow-up in each group, and one (<1%) patient was excluded from the 14 day group because she was randomly allocated, but was not eligible. The primary outcome was established in seven (1%) of the 501 participants that completed the study (four [2%] of 250 in the 7 day group and three [1%] of 251 in the 14 day group) before the 3 month follow-up because they returned for an unscheduled visit after discharge with complaints of urine leakage.

Baseline sociodemographic and fistula clinical characteristics were similar between participants randomly assigned to the two groups (table 1). Anaesthesia, surgical procedures, and postoperative clinical care did not differ between the two groups. Prophylactic antibiotics were given to 194 (74%) study participants in both treatment groups just before or during surgery. Most participants (7 day group 254 [97%] of 261; 14 day group 257 [98%] of 262) had spinal anaesthesia and were repaired vaginally (7 day group 244 [93%] of 261; 14 day group 245 [94%] of 262). Intraoperative complications were rare, with six haemorrhages (one [<1%] in 7 day group; five [2%] in 14 day group), one transection of the right ureter (in 14 day group; <1%), and one other

complication (in the 7 day group; <1%; data missing). All but one woman in the 14 day group had a vaginal pack after surgery, in place for a mean of 1.4 (SD 0.5) days. Before randomisation, 136 (52%) of 261 in the 7 day group and 145 (55%) of 263 in the 14 day group were given antibiotics empirically during the postoperative period, few women (25 [10%] in both 7 day and 14 day groups) received bladder training, and less than a third (7 day group 82 [31%] of 261; 14 day group 83 [32%] of 263) were counselled to do pelvic floor exercises.

Table 2 shows the primary outcome results. We noted no significant difference in the proportion of patients having fistula repair breakdown between 8 days after catheter removal and 3 months after surgery between the two groups (7 day group 10 [4%] of 250 [95% CI 2–8]; 14 day group 8 [3%] of 251 [2–6]). Because the upper limit of the 95% CI (4.5%) fell below the predefined non-inferiority margin (10%), the results show that 7 day bladder catheterisation after repair of simple fistula is non-inferior to 14 day catheterisation.

Secondary outcomes are shown in table 2. We noted no significant differences between the two treatment groups in any secondary outcomes. These secondary outcomes were rare, occurring in 12% or less of participants. 100 episodes of urinary retention after catheter removal (54 [54%] in the 7 day group and 46 [46%] in the 14 day group) occurred in 56 study participants; most (7 day group 48 [89%] of 54; 14 day group 42 [91%] of 46) were treated successfully with intermittent catheterisation. Ten urinary tract infections (six [2%] of 261 in the 7 day group; four [2%] of 262 in the 14 day group), four (2%) vaginal infections (in the 14 day group), five surgical wound infections (two [1%] in the 7 day group; three [1%] in the 14 day group), and five (2%) other infections (in the 14 day group; data missing) occurred, all mild or moderate in severity, and successfully treated with antibiotics. Catheter blockages were

resolved in roughly equal numbers by either flushing the catheter and drainage tube, or replacing the catheter. On the basis of history and clinical examination findings, clinicians diagnosed the cases of residual incontinence to include stress (11 women), overflow (two), and urge (two) incontinence.

The multilevel logistic regression showed that the site effect was non-significant. We identified no systematic errors in missing data. For the sensitivity analysis, in the worst scenario—ie, four times the proportion of patients who had fistula breakdown in the 11 patients lost to follow-up within the 7 day group and 99% reduction of the proportion in the 11 patients lost within the 14 day group, the combined results give 13% of patients with a breakdown in the 7 day group and 8% in the 14 day group (after rounding; difference 1.9% [95% CI -2.1 to 5.2]), still well below the non-inferiority margin of 10%.

## Discussion

Our results show that 7 day bladder catheterisation is a safe and effective approach for management of women after repair of simple female genital fistula, with no evidence of an increased risk of repair breakdown, urinary retention, or residual incontinence up to 3 months after surgery compared with 14 day catheterisation. Although previously reported practical experience of surgeons<sup>3</sup> and

data from a previous non-inferiority randomised controlled trial<sup>11</sup> provided some basis for short-term catheterisation after fistula repair (panel), the results of our large, multicentre, multicountry trial provide solid empirical evidence that extended catheterisation is unnecessary after repair of simple genital fistula in women. In view of the small number of studies on duration of catheterisation and repair outcomes, and the possibility that the effect of duration of catheterisation differs across strata of fistula complexity, we included only women with simple fistula as the safest, most conservative approach. At the end of surgery, surgeons decided if the fistula was simple using their own criteria and clinical judgment.

We did not use a specific definition of simple, for several reasons. No single, accepted, standardised fistula classification system or common definition of simple exist, and none of the widely used classification systems classify fistula in terms of simplicity. A subjective classification of simple fits with present practice as many ways that fistulas are defined and classified exist. Presumably experience affects classification; however, the degree of experience of participating surgeons varied in this study. During a meeting to review the draft protocol, 17 fistula surgeons with varying skills classified fistula drawings, including important clinical findings, as simple or not simple; inter-rater reliability was moderate or good ( $\kappa=0.55$ ) and no-one classified as simple a fistula that we had defined as complex. Subjective classification of fistula did not affect the study's internal validity because the classification was done before randomisation; differences would be equally distributed between the two groups. Thus, surgeons can classify a fistula as simple on the basis of their experience and skills, and be confident that our results are applicable. Use of a narrow definition of simple or a specific classification system would have limited generalisability of our results.

We noted no evidence of a significant difference between groups in urinary retention after catheter removal. Authors of a review of 11 trials of short-duration versus long-duration bladder catheterisation after various urogenital surgeries<sup>10</sup> noted no clear pattern in occurrence of urinary retention or need for recatheterisation. We also did not see evidence of a significant difference in infections between groups, although others have reported a lower incidence of urinary tract infections with shorter duration catheterisation after urogenital surgery than with longer duration catheterisation.<sup>10,14,15</sup>

The main limitation of our trial is that it was unmasked. In view of the nature of the intervention and of fistula repair services, to mask study or hospital staff, or the women, to treatment group, or to have the outcome assessment done by a surgeon who was unaware of treatment allocation, was not practical. The number of qualified surgeons at each study site was small. Another potential limitation was inclusion of women with multiple

### Panel: Research in context

#### Systematic review

We searched PubMed and the Cochrane Library for articles published before Oct 15, 2013, in English or French, using the following search terms: "female genital fistula repair", "fistula repair", "bladder catheterization", "urinary bladder catheterization", "urethral catheterization", "urinary catheterization", "bladder drainage", "duration of bladder catheterization", "duration of urethral catheterization", "short term bladder catheter", "short term urinary catheterization", and "early catheter removal". We also reviewed the reference lists of appropriate publications that we identified. Publications directly related to duration of urethral catheterisation after repair of female genital fistula were rare, although we found a larger number of publications related to duration of bladder catheterisation after other urogenital surgeries than after repair of female genital fistula. The small number of studies shows that a trend exists towards short-duration catheterisation after urogenital surgery. Findings from the one published randomised controlled trial,<sup>11</sup> a non-inferiority trial, showed that 10 day bladder catheterisation was not inferior to 14 day catheterisation after repair of obstetric fistula. The primary outcome (fistula repair breakdown) was measured at catheter removal, and more than three quarters of repair breakdowns in both groups occurred before catheter removal in the short-term group, making it difficult to assess the role that duration of catheterisation played in repair breakdown.

#### Interpretation

The results from this study provide solid evidence that short-duration bladder catheterisation is a safe and effective approach for management of women after repair of simple genital fistula. No negative effects occurred with 7 day catheterisation and no advantage seems to exist of catheterisation of these women for long periods of time. Implementation of these findings into clinical practice could reduce discomfort for women after fistula repair, reduce costs of services, and allow for more women to have their fistulas repaired than at present.

fistula. When we recognised that we were recruiting women with multiple fistulas early in the study, we stopped recruiting these women, but had already included some. They made up 2% of our participants. Response to treatment and final outcome of each fistula in women with more than one tend to be similar as they are in the same patient. Because our unit of analysis was fistula, inclusion of women with multiple fistula could have artificially increased the precision of our results.

Our results have important implications for clinical practice because advantages of short-duration catheterisation exist. Although no published data exist for the degree of discomfort women have due to indwelling bladder catheterisation after fistula repair surgery, authors of published studies do document that women report substantial discomfort with indwelling urinary catheters after other surgeries, such as surgery for stress urinary incontinence, anterior colporrhaphy, and vaginal prolapse, and abdominal surgeries for digestive tract and gynaecologic conditions.<sup>16–19</sup> We might expect that a short duration of catheterisation after fistula repair would also reduce discomfort for women.

Duration of catheterisation is the main determinant of length of hospital stay after fistula repair surgery,<sup>11</sup> and early catheter removal has been shown to lead to early hospital discharge with other urinary tract surgery, such as ureteral reimplantation surgery.<sup>20</sup> In most resource-poor settings, funds are low, and the need for fistula services exceeds available human and infrastructure capacity. Reduction of duration of postoperative urinary catheterisation will allow for early discharge of women, lowering the cost per repair and increasing capacity for treatment of additional patients with fistulas. A reduction in duration of bladder catheterisation by 4 days has been estimated to allow for a 20% increase in numbers of patients repaired with the same resources.<sup>21</sup> In view of the broad range of durations of postoperative bladder catheterisation that have been documented in Africa and Asia,<sup>3,4</sup> we would expect a great effect on the ability of fistula repair centres to increase their caseloads with a certain amount of resources if 7 day catheterisation was widely adopted after repair of simple fistula.

#### Contributors

SA, MAB, KB, VF, AMG, EL, JR, MW, THB, DD, AL, MM, DN, RO, IS-A, and WKW conceived and designed the trial, and developed the trial protocol. THB, DD, LD, TG-M, IH, AL, MM, DN, RO, IS-A, WKW, AD, and LW acquired data. All authors managed the trial. AD, SL, and LW monitored data. JR and SA monitored clinical quality. AS led data analysis, working with MAB, SL, MW, JR, SA, and AMG. MAB, MW, SA, JR, and AS drafted the report. All authors interpreted the results of the analysis and revised the report.

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#### Declaration of interests

We declare no competing interests.

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