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International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo



CLINICAL ARTICLE

Mortality risk associated with surgical treatment of female genital fistula[☆]Joseph Ruminjo^{a,*}, Evelyn Landry^a, Karen Beattie^a, Adamu Isah^b, Abu Jamil Faisal^c, Sita Millimono^d^a Fistula Care, EngenderHealth, NY, USA^b Fistula Care, EngenderHealth, Sokoto, Nigeria^c Fistula Care, EngenderHealth, Dhaka, Bangladesh^d Fistula Care, EngenderHealth, Conakry, Guinea

ARTICLE INFO

Article history:

Received 20 August 2013

Received in revised form 4 February 2014

Accepted 7 April 2014

Keywords:

Confidential inquiry

Female genital fistula

Mortality risk

Surgical treatment

ABSTRACT

Objective: To describe the mortality risk associated with surgical treatment of female genital fistula and the contributory and contextual factors. **Methods:** In a descriptive study, confidential inquiries and clinical audits were conducted at 14 fistula repair sites in seven resource-poor countries between January 2005 and March 2013. Data collection included interviews with key personnel involved in the clinical management of the deceased, and a review of hospital records and patient files following an audit protocol. **Results:** Overall, 26 060 fistula repairs were performed at 44 sites located in 13 countries; 30 deaths were reported in this period. Twenty-one deaths were attributable to surgery, yielding a case fatality of 0.08 per 100 procedures. The cause of death in nearly half of the cases was various manifestations of sepsis and inflammation. **Conclusion:** The case fatality rate for fistula repair surgery in resource-poor countries was in the same range as that for comparable gynecologic operations in high-resource settings. Clinical and systemic issues to be addressed to reduce the case fatality rate include improvement of perioperative care and follow-up, assuring prudent referral or deferral of difficult cases, and maintaining better records.

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1. Introduction

Intensive efforts at both national and international levels reduced annual maternal mortality globally to approximately 287 000 maternal deaths in 2010, representing a decrease of 47% from the level in 1990. Sub-Saharan Africa (56%) and southern Asia (29%) accounted for 85% of the global burden of maternal deaths in 2010 [1]; obstructed labor is the direct cause of 8% of these deaths [2].

Women who survive obstructed labor may suffer severe and long-term morbidity, and genital fistula being one of the most devastating associated conditions. There are no reliable data on the global burden of fistula [3], but a recent systemic review and meta-analysis estimated that there are more than 1 million cases [4].

Fistula repair carries some risk—as does all major surgery—including that of death. Although evidence for the occurrence of immediate,

medium-term, and longer-term complications from such surgery has been reviewed [5–7], death is rarely mentioned except anecdotally. If death from fistula treatment is infrequent, research will require large caseloads involving multiple sites to compile adequate numbers for analysis. Hancock and Browning [8] and Waaldijk [9] have reported on several actual and potential causes of mortality from fistula treatment. A case fatality rate of 0.7% was reported from a small series of women undergoing repair surgery in Nigeria [10].

By contrast, there are data on mortality for comparable gynecologic surgery, such as hysterectomy, in resource-rich settings. Mortality risk associated with these procedures varies by surgical approach and associated conditions, although crude and attributable rates are often unspecified (Table 1) [11–14]. Mortality rates from diverse surgeries for pelvic organ prolapse are generally lower in these settings, but range from 0.05% to 0.38% [15,16].

The aim of the present study was to describe the mortality risk of surgical treatment for female genital fistula and the contributing and contextual factors.

2. Materials and methods

The data presented in this descriptive study were collected between January 1, 2005, and March 31, 2013, from 44 facilities supported by EngenderHealth that provide services for fistula repair in 13 resource-

[☆] A preliminary version of this work was presented at the 2013 Global Maternal Health Congress in Arusha, Tanzania, co-sponsored by Management and Development for Health, Dar es Salaam, Tanzania, and the Maternal Health Task Force at the Harvard School of Public Health, Boston, USA.

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Table 1
Mortality rates for gynecologic surgical procedures comparable to fistula repair in resource-rich settings.

Surgical procedure	Mortality rate, %	Comments	Reference
Vaginal hysterectomy	0.06	Varies with associated conditions; 119 972 vaginal hysterectomies; United States	Wingo et al. 1985 [11]
Abdominal hysterectomy	0.14	Varies with associated conditions; 317 389 abdominal hysterectomies; United States	Wingo et al. 1985 [11]
“Simple” hysterectomy for benign disease	0.16	Population based; 29 192 women; Denmark	Loft et al. 1991 [12]
Overall hysterectomy mortality for benign disease	0.15	220 vaginal, 1349 abdominal, and 223 laparoscopic hysterectomies; Canada	Kafy et al. 2006 [13]
Hysterectomy for benign disease	0.38	VALUE study: Vaginal Abdominal Laparoscopy Uterine Excision; 37 295 cases	McPherson et al. 2004 [14]
Operations for female stress urinary incontinence	0.05	England, N. Ireland, Wales Literature review, meta-analysis of 282 journal articles on slings, anterior repairs, retropubic, and transvaginal colposuspension	American Urological Association, Clinical Guidelines Panel, 1997 [15]

poor countries with funding from the US Agency for International Development (USAID). Facility administrators consented to the requirements and procedures for the confidential inquiry at the start of EngenderHealth support. Administrators, key service delivery staff, and other interviewees gave voluntary verbal consent if the need arose for confidential inquiry. Institutional review board approval was not required because clinical quality audit for complications and death is part of routine program monitoring and evaluation.

In its Fistula Care project, EngenderHealth developed a death investigation protocol for fistula services as part of routine program monitoring and evaluation in south Asia and Sub-Saharan Africa. Using the protocol and reporting tools, confidential inquiries were conducted for any women who died either during surgery for urinary or fecal fistula of obstetric or traumatic origin or up to 42 days after such surgery (Fistula program stakeholders agreed to the 42-day post-repair mortality timeline, which is consistent with standard reporting for maternal mortality and physiologic recovery after clinical trauma).

Each supported site was asked to notify EngenderHealth within 3 days of the death of a woman who had undergone fistula repair surgery. EngenderHealth clinical staff or consultants collaborated with clinical and administrative staff at the repair facilities to conduct the audits. Interviews were conducted with the surgical team, facility director, and medical and paramedical staff involved in patient screening and other direct clinical care. If a death occurred after discharge, family members, field staff, and providers who might have seen the patient were also interviewed.

The audit team reviewed ward and theater registers, patient records, records of anesthesia and analgesia regimen, and diagnostic investigations, in addition to the chronology of complications and their evolution. The team also reviewed referral records if the patient was treated elsewhere, and autopsy findings if available. The data collection form for the investigation was not designed with pre-coded response options; most questions were open-ended.

Lastly, the audit team conducted on-site observations to identify medical quality issues that might have contributed to death. The audit was designed to be facilitative and constructive, focusing on potential systemic flaws directly or indirectly related to the death, and the approach emphasized diplomacy, sensitivity, and confidentiality. The objectives were to determine the cause of death, identify contributing factors, and ascertain whether death was attributable to the procedure. The findings were also used to determine whether the death was preventable and to design remedial actions. All information gathered during the audits was confidential. The names of the deceased and of service providers were excluded from reports; electronic and hard-copy reports were securely filed.

The denominator for the present analysis was the number of fistula repairs reported over a 9-year study period from the supported sites.

The results are reported as descriptive statistics (total numbers and percentages). There was no statistical analysis.

3. Results

The 44 supported fistula repair sites reported 26 060 repairs over the 9-year period. The supported sites did not report to EngenderHealth the number of women returning for postoperative follow-up. Twenty seven repair facilities were public institutions; the others were private ($n = 5$) or faith-based ($n = 12$). Repair sites were located in both urban and rural settings. The duration of EngenderHealth’s support to these sites ranged from 1 to 8 years.

Thirty deaths were reported across the 44 study sites. After clinical investigation, 21 deaths were deemed likely to be attributable to the procedure. In seven cases, there was no history or examination or laboratory findings indicative of likely attribution (e.g., on the basis of the sequence of clinical events or the time between surgery and death); there was a definitive other cause of death; or there were contrary autopsy findings. There was insufficient information to make a determination in two cases.

The attributable case fatality from fistula surgery was 0.08 per 100 procedures. The gross case fatality rate, inclusive of non-attributable cases, was 0.12 per 100 procedures.

Deaths were reported in 14 repair sites located in seven of the 13 countries. Across the sites reporting death, yearly mortality ranged from 0.00 to 0.36 per 100 procedures (Table 2). The number of reported cases per country ranged from zero to seven, or 0.00–0.29 per 100 procedures (Table 3).

Age, which was reported for 15 of the 21 women, ranged from 17 to 65 years (median 25 years). None of the reported deaths occurred during the postpartum period. The duration of post-procedure survival, noted for 17 women, ranged from 1 to 32 days (median 10 days). No pattern was discernible by country.

The complexity of fistula repair surgery, as assessed by the surgeons, varied. Seven women underwent simple fistula repair via the vaginal route; two women underwent trans-vaginal repairs of medium/intermediate complexity; and six repairs were complex. Among the complex repairs, four women required adjunct or complementary surgery for separate or concurrent rectovaginal fistula and/or colostomy or other procedures: three of these repairs were done via the abdominal route, and one was done via a combined route. For six women, there were insufficient data to determine repair complexity.

Spinal anesthesia was used exclusively in 11 of the 21 cases. General anesthesia was used in three cases, and “other” or combined (i.e., sedation, ketamine, or caudal epidural) was used in three cases. The type of anesthesia was not recorded in the clinical records of four women. No death was reported as directly attributable to anesthesia, but in three

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