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CLINICAL ARTICLE

Safety and acceptability of tubal ligation procedures performed by trained clinical officers in rural Uganda

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ABSTRACT

Objective: To assess safety associated with tubal ligation performed by trained clinical officers (COs) in rural Uganda. *Methods:* Between March and June 2012, 518 women in 4 regions of Uganda were recruited into a prospective cohort study and followed at days 3, 7, and 45 after undergoing tubal ligation performed by a trained CO. Intraoperative and postoperative adverse events (minor, moderate, or major), and acceptability were assessed. *Results:* Mean age was 36 years (range, 20–49 years) and mean number of living children was 6.7 (range, 0–15). The overall rate of major adverse events was 1.5%: 0.4% intraoperatively; 1.9% at day 3; and 0.2% at day 7. The majority of women who underwent tubal ligation reported a good/very good experience at the facility (range, 94%–99%) and would recommend the health services to a friend (range, 93%–98%). *Conclusion:* In the present study, task sharing of tubal ligation to trained COs in private facilities was safe. Women reported high levels of satisfaction with the procedure. Training COs could be an effective strategy for expanding family-planning services to rural Uganda.

1. Introduction

The provision and expansion of family-planning services are a public-health need and a national development priority for many countries across Sub-Saharan Africa. In Uganda, the contraceptive prevalence rate for married women is only 30%. Of the 26% of women using modern contraceptives, 19.6% rely on short-acting methods and 5.7% use long-acting reversible contraception and permanent methods (LARC-PM) [1]. There is a high discontinuation rate (43% at 12 months), resulting in a high total fertility rate: 6.2 overall; 3.8 urban; 6.8 rural [1]. Additionally, 21% of married women have unmet need for spacing and 14% have unmet need for limiting [1]. These levels and dynamics signify the importance of increasing access to quality services for LARC-PM and expanding the role of providers to meet women's contraceptive needs.

Many countries across Sub-Saharan Africa still rely on physicians to perform permanent family-planning services, despite recent WHO guidelines recommending that the performance of these services is within the competency of associate clinicians such as clinical officers (COs) [2]. Uganda is experiencing a shortage of trained health providers in the public sector, with an estimated ratio of 1 physician per 1000 people [3]. There is also an inequitable distribution of health workers between rural and urban areas. Furthermore, Ugandan health workers' duties are skewed toward curative care owing to high disease burden. This has led to a shortage of trained health workers able to provide preventive health services such as permanent family-planning methods in rural settings.

Task sharing—the redistribution of clinical tasks or procedures between health workers—can address the healthcare provider shortages faced by many African countries such as Uganda. Training lower cadres of providers to perform specific medical tasks such as tubal ligation is a means of addressing the demand and unmet need for LARC-PM among women who wish to limit their family size. Many low- and high-income countries already utilize non-physician clinicians (NPCs) to take on diagnostic and clinical functions of physicians [4]. In several countries across Africa, nurses, midwives, and auxiliary nurses insert intrauterine devices and implants, and associate clinicians perform tubal ligation [5,6].

Although task sharing has been advocated for and has gained policy support in Uganda, there is a lack of evidence regarding the safety and acceptability of NPCs performing tubal ligation in rural settings. Previous studies on task shifting of tubal ligation from Bangladesh, Malawi, Mozambique, and Thailand were carried out in hospitals in capital cities [7–11]. In Uganda, Marie Stopes International (MSI) provides short-term and LARC-PM family-planning services in rural areas through its mobile outreach teams in rural clinical settings such as government health clinics.

Clinical officers are allowed to perform tubal ligation in Uganda, as specified by national policy guidelines and family-planning service

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standards; however, the procedure is not included in the national CO training curriculum [12]. Clinical officers undergo 3 years of clinical training at specialist schools, provide diagnosis and treatment in primary healthcare, and are able to conduct minor surgical procedures. The Ugandan Ministry of Health is seeking locally generated evidence on the safety and acceptability of task sharing of tubal ligation to COs. To address this evidence gap, we conducted a study to assess intraoperative and postoperative adverse events, and satisfaction among patients who underwent tubal ligation performed by trained COs in mobile outreach settings in rural Uganda.

2. Materials and methods

From March 1 to June 30, 2012, a single-arm prospective cohort study was conducted. Data were collected at baseline (day of procedure) and at follow-up visits on days 3, 7, and 45 (intervals selected to capture adverse events). The study was approved by The AIDS Support Organization, the Uganda National Council of Science and Technology, and the President's Office for Security Clearance.

Four COs, who were qualified and eligible for minor surgical training, were selected for inclusion in the study. Additional requirements included being interested in receiving tubal ligation training; having the opportunity to practice the procedure regularly post-training; and possessing some minor/major surgical skills, experience, and a dexterous aptitude (measured by observation/assessment from over a year of work on minor surgeries with Marie Stopes Uganda [MSU]).

The Ugandan Ministry of Health curriculum for tubal ligation—comprising 1 week each of theoretical and practical training—was used to train the COs, who had to pass the theoretical element before proceeding to the practical component. The training was led by 2 physicians (more than 13 years of tubal ligation experience) and 2 MSU medical officers (physician trainers with more than 6 years of tubal ligation experience).

The 4 trainers closely supervised the COs during the practical training, which began with pre-procedure counseling, obtaining consent from patients, and observing the trainer. As their competencies increased, the COs became more involved in the procedure until they were able to perform tubal ligation independently (under trainer supervision). The COs were assessed in 3 areas of competency: effective administration of local anesthesia; surgical techniques of the procedure (e.g. opening the layers of the skin, standard incision type [1.5–2 cm], retrieving the tubes, closing the incision); and preparedness to manage adverse events. Trainees also needed to perform tubal ligation within 20 minutes (MSI standard). The COs performed at least 50 tubal ligation procedures under the observation and assessment of the trainers. They were required to be fully competent in all areas before becoming certified to perform tubal ligation alone and participate in the study. It took 6 weeks for the COs to complete this training and achieve competency.

Each of the 4 COs was assigned to an MSU mobile outreach team (medical officer, 2 nurses, and driver) providing family-planning services in 4 regions (central, western × 2, and eastern). The study teams consisted of a research nurse, research assistant, CO, and supervising physician. Women presenting at MSU mobile outreach clinics for family-planning services were screened using an eligibility checklist after undergoing comprehensive family-planning counseling and opting for tubal ligation. Women were assessed for any adverse health conditions such as sexually transmitted infections, coagulation disorders, history of complicated abdominal/pelvic surgery, or previous caesarean scar. The study team had no prior contact with the women to ensure that the women had independently chosen tubal ligation.

To participate in the study, women had to independently opt for tubal ligation; provide informed consent to undergo tubal ligation; be at least 18 years of age; and be more than 3 weeks post-childbirth. Women who provided written informed consent to participate in the study were informed that COs were performing the tubal ligation procedure, although a physician was available for those who preferred that type of provider.

There were 2 study outcomes: safety of tubal ligation provided by a trained CO; and patient acceptability of the tubal ligation procedure. Safety was assessed by capturing the prevalence of adverse effects intraoperatively at baseline and then postoperatively at 3 follow-up visits (days 3, 7, and 45). Postoperative adverse events were categorized as minor, moderate, or major—following MSI definitions for tubal ligation adverse events. Minor adverse events cause minor injury/illness that requires a minimal level of intervention (e.g. taking pain medication) and symptoms are managed at home. Moderate adverse events require clinical intervention from medical personnel. Major adverse events cause long-term incapacity or disability and require hospitalization; this category also includes failed procedures.

Research nurses did not categorize intraoperative adverse events into the 3 levels, but instead recorded whether they occurred. Postoperative adverse events were self-reported by women at follow-up visits and were validated and categorized by the research nurses. Major adverse events were reported to the MSU and MSI Medical Development Teams through the existing internal incident-reporting structures.

Patient acceptability was measured in 3 ways: women's satisfaction with the tubal ligation procedure; women's satisfaction with the overall experience at the facility; and whether women would recommend the procedure to a friend. Satisfaction was measured based on a 5-point Likert scale.

Study data were entered into EpiData (EpiData Association, Odense, Denmark); data management and analysis were performed using Stata version 21 (StataCorp, College Station, TX, USA). Descriptive statistics were used to ascertain the prevalence of adverse events and acceptability.

3. Results

In total, 547 women were screened and 518 women who underwent tubal ligation (minilaparotomy under local anesthesia) were included in the study (Fig. 1). Almost half of the study population were 35–39 years of age (41%) and had 5–7 living children (49%). More than half of the women had used an injectable within the past month, and approximately 20% had not been using any family-planning methods (Table 1).

The most common intraoperative adverse event was pain (53%). A small proportion of women experienced a vasovagal reaction (3%). Additionally, 2 women were unable or refused to have the tubal ligation procedure completed: 1 woman experienced a bowel perforation and 1 woman became uncooperative during the procedure. The supervising physician repaired the bowel perforation, and both women opted to have an implant inserted.

The COs were able to complete 93% (n = 484) of the 518 procedures competently. Of these 484 procedures, nearly 70% were performed independently by the COs, while 29% involved some verbal instructions from the supervisors. The types of intraoperative adverse events that occurred during the procedures in which COs received verbal instructions were pain (38%), vasovagal reaction (43%), failure to mobilize 1 or both tubes (100%), and other adverse events (50%). The supervising physician took over the clinical tools and assisted with only 6 of the 484 procedures.

Postoperative adverse events were categorized by level of severity (mild, moderate, or major; Table 2). At the follow-up visit on day 45, there were no major adverse events. The overall prevalence of postoperative major and moderate adverse events was 1.5% and 10.6%, respectively.

The majority of women gave good or very good ratings for their tubal ligation (range, 92%–99%) and for their overall experience at the facility (range, 94%–99%). Most women (range, 93%–98%) would also recommend the facility to a friend, based on their experience at the time of tubal ligation (Table 3).