MARIE STOPES INTERNATIONAL

MARIE STOPES LIGATIONS: COMPLICATION RATES AND CLIENT SATISFACTION IN MALAWI

RESEARCH & ANALYSIS: 1

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Acronyms

AV	Adverse event
BLM	Banja La Mtsogolo (MSI's Partner in Malawi)
HIV	Human Immunodeficiency Virus
LA	Local anaesthetic
MSI	Marie Stopes International
MSL	Marie Stopes Ligation

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Executive summary

Tubal ligations are a popular and safe form of permanent contraception for women who choose to limit their family size.

Marie Stopes International (MSI) is a leading provider of tubal ligation services for women across the world. In 2007, MSI provided over 477,000 tubal ligations (brand name Marie Stopes Ligation) in 24 countries. Through more than 30 years of experience, MSI has refined the procedure so it can be carried out in non-medicalised and low resource settings.

In Malawi, MSI performs about 38,000 tubal ligations a year, of which 83% are performed through outreach and 12% performed in static clinics. Despite the popularity of tubal ligations, there are few estimates of the complication rates associated with the procedure in settings outside hospitals. The literature search revealed no studies in Malawi and only one study in the region, which was published over ten years ago. Despite being somewhat out of date, the study is the best benchmark, estimating a 0.7 percent rate for major complications and a rate of 3.4 percent for minor complication rates following tubal ligations.[1]

The rapid assessment described in this report followed 164 MSI tubal ligation clients in Malawi in order to determine the complication rate associated with the procedure, as well as levels of client satisfaction.

The sample was drawn from a total of 20 purposefully-sampled sites. Ten of these were static clinics run by Banja La Mtsogolo (BLM), MSI's Partner in Malawi. The other ten were community outreach clinic initiatives linked to those clinics. These clinics were situated in the Eastern, Southern and Central regions.

After the Marie Stopes Ligation was performed, a research team made follow-up visits to each participant four times at either the outreach site or the static clinic where they were enrolled. In these follow-up visits (conducted three, seven, 14 and 30 days after the operation), each participant was clinically examined for the presence, type and severity of complications with the Marie Stopes Ligation. Data were also gathered on client satisfaction and the client's ability to return to work.

The results show that three percent of all women enrolled in this study had mild complications seven days after the operation. No major complications were identified. All of the minor complications occurred in outreach sites, representing a five percent complication rate at these sites and subsequently a zero percent complication rate at static clinics. This complication rate is consistent with complication rates estimated in Kenya.[1]

Three days after the operation, 59% of women were capable of performing normal work and activities. On average, women stated that it took them 5.5 days (±0.4) before they were able to return to normal activities and work.

Overall, there was a high level of satisfaction with the quality of Marie Stopes Ligation services, particularly amongst clients of outreach sites despite the higher complication rate. On average, 91% of all participants were very satisfied with the medical procedure; the remaining nine percent were somewhat satisfied. Furthermore, by the end of the study, 89% of all participants felt that the counselling and information provided was excellent.

It is not clear from this study why there was a higher complication rate at the BLM outreach clinics rather than at the static clinics. It is possible, since BLM outreach services specifically target poor women, that the clients are not actually comparable due to differences in underlying health and poverty status. However, it cannot be ruled out that there is a difference in the quality of services provided in comparison to static clinics. For example, the underlying causes of these complications hint at poor technique and materials. This is further suggested by the fact that more participants at static clinics were able to perform normal work at the majority of follow up meetings than their counterparts from outreach sites. Unfortunately, it is not possible to determine the cause of the difference in outcomes between outreach and static clinics due to a lack of information on client profiles. A future study is planned in order to investigate this issue further.

Overall, this rapid assessment shows that the Marie Stopes Ligation is a safe procedure with a low risk of complication and high levels of client satisfaction, which can be performed effectively outside traditional clinic or hospital settings.

Background

Female sterilisation is the most widely used contraceptive method in the world today.[2] Approximately 20% of married women worldwide aged 15 to 49 who use contraception have been sterilised. In comparison, just six percent use condoms.[3]

Female sterilisation is achieved through cutting, tying, clipping, attaching rings to or applying an electrical current to the woman's fallopian tubes. Each technique provides a safe and effective method of contraception for women by preventing sperm reaching and fertilising an unfertilised egg. Eggs are still released by the ovaries, but they are broken down and safely absorbed by the body.

Sterilisation is particularly favoured in Latin America and the Caribbean, as well as Northern America and Asia. In Latin America and the Caribbean, for example, the majority (31%) of married women aged 15 to 49 who use contraception have been sterilised.[3] This contrasts sharply with Sub-Saharan Africa, where the figure falls to just two percent.[3] Instead, the majority of women in Sub-Saharan Africa rely upon injections or the contraceptive pill.

This regional disparity is largely because of the relative ease with which injectable contraceptives and the pill are available in Sub-Saharan Africa compared to sterilisation and – to a lesser extent – cultural, socio-economic and religious barriers.[1]

In Malawi, for example, a government drive to train lower-level health workers in providing injectable contraceptives has seen contraceptive use among married women quadruple between 1992 and 2008.[4] Twenty nine percent of married women aged 15 to 49 in Malawi who use contraception now rely upon injectable contraceptives.[3] In comparison, many women are less likely to hear of sterilisation from their peers or have access to it.[5] This is reflected in the fact that less than five percent of married women in Malawi aged 15 to 49 who use contraception have been sterilised. Despite low uptake in Africa, there is growing acceptance and an increasing unmet need.[1 6]

In terms of success and complication rates, studies have typically shown that just one percent of women fall pregnant within the first year of having a tubal ligation and two percent of women fall pregnant over ten years.[7] These pregnancies may result from conception before the procedure, incomplete blockage of the fallopian tubes or the formation of an abnormal connection or passageway (a fistula) which allows the sperm to reach and fertilise an egg. Regardless of how they are caused, however, approximately 75% of pregnancies after tubal ligation are ectopic.[8] The fertilised egg is implanted in any tissue other than the uterus and may cause substantial tissue damage. However, the vast majority of female sterilisations are successful. Furthermore, female sterilisation provides a number of benefits to women many other contraceptives do not. It requires no daily attention like the pill for example. Also, it is cost effective in the long-run, is immediately effective, permanent and allows sexual spontaneity – although additional contraception is necessary to protect against sexually transmitted infections. It also provides some women protection from ovarian cancer.[9]

Furthermore, studies have shown low levels of complications. A review of female sterilisation techniques found no cases of operative mortality or menstrual irregularities.[2] Similarly, most women who undergo sterilisation will not undergo a future hysterectomy unless they have a pre-existing gynaecological disorder.[7] Studies of mini-laparoscopic ligations in developing countries have shown complications in one to four percent of cases, most of which were considered minor. For example, a review of 12 Kenyan studies in 1997 found major complications among 0.7 percent of 12,000 cases and minor complications among 3.4 percent.[1] Almost all women were satisfied at the first follow-up visit, and would recommend the procedure to others. In Nigeria, 1.4 percent of 5,182 cases reviewed across 52 service sites suffered complications and almost 99% were completely satisfied with the procedure.[6] In Thailand, less than one percent of 6,897 cases over 15 years yielded complications (for example uterine perforations and bladder injuries). Similarly, in Senegal, less than one percent of 800 women suffered complications like bladder/bowel injuries and there was only one case of post-operative infection.[10]

This evidence highlights that female sterilisation performed under local anaesthetic can be

a safe and satisfactory out-patient procedure for women in developing countries. However, complications occur even in the most controlled settings like teaching hospitals and clinics, where most studies to date have been set. Few studies have tested outcomes in non-medicalised settings, where there is potential to reach vast numbers of women. This is why this study was an important step to review the complication rates associated with the Marie Stopes Ligation procedure.

Marie Stopes Ligation

Marie Stopes International (MSI) has provided family planning services and products to clients for 30 years, making it one of the most experienced family planning organisations in the world. Operating through its partner Banja La Mtsogolo (BLM), MSI is one of the few providers of female sterilisation in Malawi. BLM opened its first clinic in Malawi in 1987 and currently has 30 static clinics and 250 community outreach clinic initiatives. In 2007, BLM performed 37,907 tubal ligations. Collectively, BLM provides 30% of all family planning services in Malawi, as well as 42% of the country's permanent family planning services.
MSI has developed a comprehensive tubal ligation service (called 'Marie Stopes Ligation'). The Marie Stopes Ligation (MSL) is the brand name for the method of female voluntary surgical contraception, using the 'mini-laparotomy technique', which is performed under local anaesthetic in MSI clinics and outreach sites.
The procedure includes initial confidential consultation, a medical process that takes an average of 15 to 20 minutes, as well as aftercare. The procedure itself is straightforward and is performed by trained clinical team members following MSI clinical principles, which are as follows:

- all procedures are client-focused, aiming to keep the whole experience as simple and excellent as possible
- a non-pharmacological approach to pain management should be offered as far as possible
- the clinical environment should always be client-friendly, informal and demedicalised – overall, the clinic or outreach facility should strive to be as appealing to clients as possible
- the MSI team includes mid-level healthcare providers where possible.

As part of routine procedure, BLM monitors each woman who has undergone a Marie Stopes Ligation on the day of the procedure for complications. However, due to the practical nature of a mobile rural service for women in hard-to-reach communities, the procedure is performed with attention to simplicity and safety. Therefore, women are not normally required to return to the site of the procedure for follow-up unless they have queries or experience complications. Minor complications are dealt with by the local clinical staff at the site and any complications requiring secondary care are referred to a health service, such as a relevant hospital or health clinic; BLM is informed so that further follow up can take place. As follow up is not universal, a rapid assessment was necessary in order to ascertain the quality of Marie Stopes Ligation services offered by BLM and the incidence of adverse events.

Methodology

A rapid assessment was undertaken to follow women who were undergoing tubal ligations at 20 BLM sites.

Following screening and administration of informed consent, each participant was interviewed in advance of having the procedure. A closed question questionnaire was used to assess a limited range of socio-demographic features as well as client satisfaction, feedback and possible minor and major complications. Women were then examined and checked for complications three, seven, 14 and 30 days after the procedure at the original clinic or outreach site.

The designed data collection tools were pre-tested during a four-day pilot. Following the pre-testing, a few changes were made to the study tools in terms of coding of answers and layout.

Sample

The sample included ten static BLM clinics and their associated outreach sites. These clinics were situated in Balaka, Dwangwa, Mangochi, Mchinji, Midima, Mponela, Falls, Mulanje, Ndirande and Zomba. It was estimated that 200 women (100 from outreach sites and 100 from static clinics) would provide a 95% power to detect a five percent rate of complications, accounting for a 20% loss to follow up.

Each static clinic and associated outreach site was asked to recruit ten clients for this study. In total, 164 clients were actually recruited to be part of this study.

Participation in this study depended upon three factors. First, each participant was required to be a Marie Stopes Ligation client within the designated static BLM clinic or associated outreach site. Second, each woman or their legal guardian was informed about the study and those who agreed to participate gave their informed consent (signature or fingerprint). Finally, each participant had to be willing to return to the clinic or outreach site for follow up visits. The clients were given an incentive of MK600 (approximately US$4) on each of the follow-up days.

Fieldwork

Fieldwork was conducted for one month, beginning in mid-August 2008. After the Marie Stopes Ligation was performed, each participant was scheduled for four follow-up visits at either the outreach site or the static clinic where they were enrolled. At these follow-up visits, each participant was clinically examined for the presence, type and severity of complications with the Marie Stopes Ligation. Data were also gathered on client satisfaction. These follow-up visits ensured direct interaction with clients and enabled the researchers to record any adverse events. All participants were followed for the entire month.

The follow-up team included one independent non-clinical person and one BLM clinical person, so that any complications could be treated immediately. Diagnosis of any complications arising during or after the Marie Stopes Ligation was done on every follow-up visit. These complications could have been observed by the client themselves (for example. pain, infection, bleeding) or by the team performing the tubal ligation (for example, intra abdominal bleeding, injury to organs). Complications that did not require referral to a hospital were treated as minor complications, whereas complications serious enough to refer to hospitals were considered as major.

During the course of the study, the BLM operations research manager was responsible for overseeing the recruitment, training, and supervision of the interviewers as well as the management of field logistics and data management. Site coordination was maintained by regular monitoring visits made by BLM team members, the research assistant and the operations research manager. At each site visit, the monitoring ascertained whether:

- the study protocol was properly followed
- participants' records were complete and accurate
- a log was kept with the participants' names, addresses, clinic file numbers and study participant numbers
- the study service inventory log was current and showed the total number of procedures done
- adverse events were being promptly reported to BLM
- the team was carrying out their activities as per agreed terms.

Data analysis

The data were cleaned, edited and entered into Excel. Data analysis included cross tabulations and chi squared tests and used SPSS software.

Key findings

Participant characteristics

In total, 164 women receiving Marie Stopes Ligation within BLM static clinics or their corresponding outreach sites were included in this study. The majority (59%) of these women were enrolled at outreach sites.

The majority of all sites used in this study met the sample target of ten clients per clinic. The Falls outreach site actually exceeded this, recruiting 12 clients in total. In comparison, half of the static clinics failed to meet the sample target because of low client intake.

As Table 1 shows, almost two-thirds of all participants were aged between 25-35 years old. Participants at static clinics were predominantly 31-35 years old whilst most participants at outreach sites were slightly younger (25-30 years old).

Table 1: Distribution of women using BLM clinics and outreach services by age group

Age at sterilisation (years)	BLM (n=67)	Outreach (n=97)	Total
20-24	2.9% (2)	5.2% (5)	7
25-30	23.9% (16)	35.1% (34)	50
31-35	44.8% (30)	26.8% (26)	56
36-40	14.9% (10)	19.6% (19)	29
41-45	4.5% (3)	7.2% (7)	10

*Approximately 7.3% (n=12) of clients did not report their age.

Complications

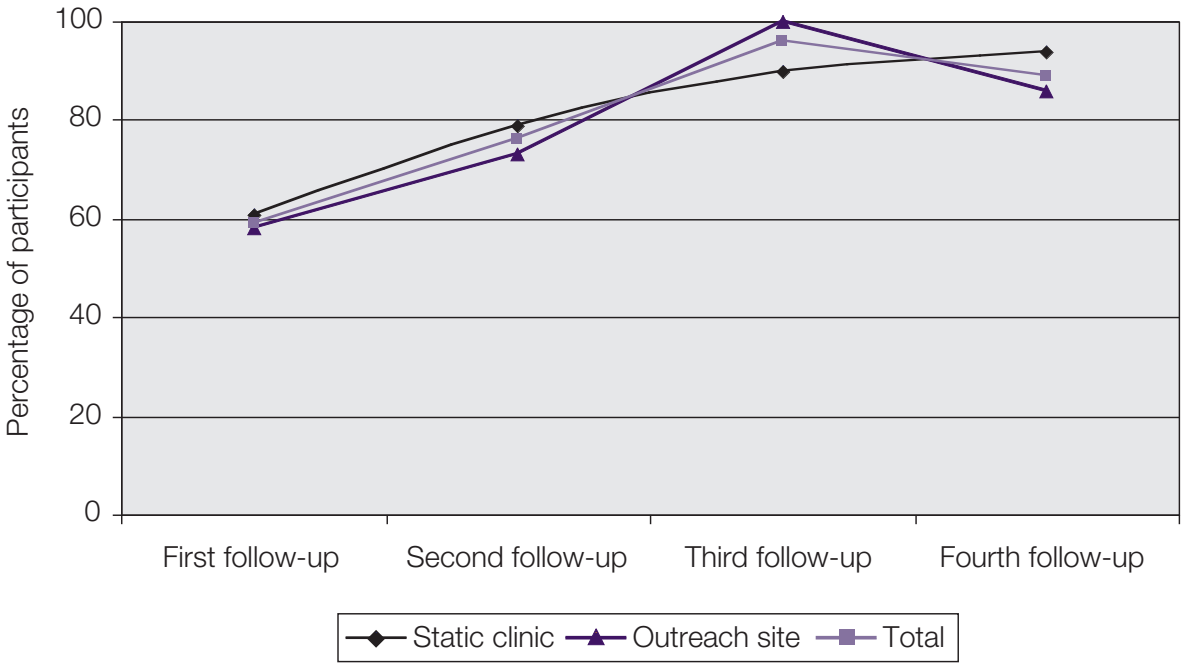
Significantly, there were no complications in any of the 164 Marie Stopes Ligation procedures either during the actual procedure on day one or at the first follow-up on day three. However, some minor complications were identified in five participants by the second follow-up on day seven. These included intra-haemorrhage (2), mild infection (1), mild wound breakdown (1) and burst sutures (1). None of these complications required the client to be referred to a hospital. Instead, all complications were treated with antibiotics by the follow-up team. One complication was identified again at the next follow-up on day 14. However, this woman was assessed as being in very poor health with possible symptoms of HIV-related infections. As a consequence, she was referred to voluntary testing and counselling services where it was confirmed that she was HIV-positive. The follow-up team assessed that the complication was due to a weak immune system rather than the tubal ligation, although this was not confirmed. No further complications were identified

Table 2: Adverse events post-operation and treatment needed

Type of Adverse Events (AV)	Severity	Treatment needed and received	Treatment outcome	Age range (years)	Clinic site	N (164)
Second follow-up						
Haemorrhage	Mild	Yes	PR and CR*	31-35	Outreach: Mangochi± and Ndirande	2 (1.2%)
Infection	Mild	Yes	PR*	41-45	Outreach: Midima	1 (0.6%)
Poor healing / wound breakdown	Mild	Yes	PR*	25-30	Outreach: Balaka	1 (0.6%)
Burst suture / abdomen	Mild	Yes	CR*	25-30	Outreach: Dwangwa	1 (0.6%)
					Total:	**5 (3.0%)**
Third follow-up						
Haemorrhage	Mild	Yes	PR*	31-35	Outreach: Mangochi±	1 (0.6%)
					Total:	**1 (0.6%)**

*No adverse events were detected during the first and fourth follow-up. PR: Partially Resolved; CR: Completely Resolved.

Figure 1: Post procedure survey on the capacity of clients to perform normal work



by the last follow-up visit. Overall, this represents a minor complication rate of three percent. Whilst neither age nor location affected the risk of complication, a difference does exist between static clinics and outreach sites. All of the complications were identified at outreach sites. As a result, five percent of Marie Stopes Ligation procedures performed at outreach sites resulted in a minor complication. The major complication rate for both outreach and static clinics was zero. These complication rates compare favourably to complication rates estimated in Kenya: 0.7 percent for major complications and 3.4 percent for minor complication rates.

The possible underlying reasons for these complications are summarised in the box below.

Returning to normal work and activities

In total, 96% of participants (n = 164) were capable of performing normal work 14 days after the procedure, as illustrated in Figure 1. This increased from 59% (n = 97) three days after the procedure. On average, women stated that it took them 5.5 days (±0.4) before they were able to return to normal activities and work.

Client satisfaction

At the first follow-up visit, 62% of all participants felt that the counselling and information provided by the static clinics and outreach sites was excellent. This increased with each subsequent follow-up to 89% by the end of the study. Participants at outreach sites were significantly more likely to rate the counselling and information as excellent (n = 164, p = 0.01).

In terms of client satisfaction, 91% of the clients were very satisfied with the procedure; the remaining nine percent were somewhat satisfied with the procedure. This shows a high level of perceived satisfaction with the quality of MSI services provided.

POSSIBLE UNDERLYING CAUSES OF COMPLICATIONS

Infection
1. Poor aseptic technique by the surgeon/clinical officer and assistant
2. Poor wound care by client
3. Underlying client health factors e.g. immuno-suppression

Wound breakdown
1. Poor aseptic technique at the time of the procedure resulting in an infection causing the breakdown
2. Underlying client health factors e.g. immuno-suppression
3. Poor wound care by the client

Burst suture
1. Poor quality of suture material
2. Poor aseptic technique causing an infection which in turn leads to a burst suture

Haemorrhage
1. Poor handling of tissues/poor technique resulting in trauma and bleeding

Discussion and recommendations

Overall, this rapid assessment shows that the Marie Stopes Ligation is a safe procedure with a low risk of complication and high levels of client satisfaction, which can be performed quickly and effectively outside traditional clinic or hospital settings, and which allows clients to return to work quickly.

This rapid assessment suggests that three percent of Marie Stopes Ligation procedures result in minor complications. No major complications were identified. These results compare favourably with the Kenya study.[1]

All of the minor complications (n = 5) occurred at the outreach clinics, which suggests that there may be a difference in the quality of service provision in that setting. However, as this study was a simple rapid assessment, not enough data were collected on the process or on the background characteristics of the women to determine the cause of the difference. There are several sources of possible bias:

1) The outreach sites are over-represented; it is therefore more likely that these sites are going to identify complications.

2) It is likely that there are real differences between people who present at a static clinic and those who are reached through outreach sites. This bias is due to the approach taken by MSI to provide outreach services to under-served and poorer women.

3) The study was underpowered to detect rare outcomes, especially when the sample is broken down further to static clinics and outreach sites. The difference in complication rates between outreach sites and static clinics should therefore be read with caution.

Due to various limitations with the study design, it was not possible to determine what was causing the apparent difference in outcomes between outreach and static sites. For example, not enough data on socio-economic and demographic characteristics were collected to determine if women reached through outreach were different to women reached through static clinics. Furthermore, the study only focused on the outcomes and did not examine the processes that were taking place. Process evaluation data would make it possible to see if there were any key differences in how the cases were reported in the sites.

This study has been useful in estimating the complication rates associated with Marie Stopes Ligations in Malawi, as well as in raising a number of questions in need of further research. Clearly, more research is needed to examine the difference in outcomes between static and outreach clinics. The next wave of research will examine background, the process and outcome variables in more detail, as well as employing a stratified sample of clinics (rather than relying on individuals as the sampling unit) in order to assess differences at the clinical level. Finally, this study assessed complication rates but was not able to assess the success rates of Marie Stopes Ligations. Future studies would need to include an additional follow up interview 12 months after the procedure in order to assess how many women became pregnant during that period (as a proxy for success).

Recommendations

- in order to increase access to tubal ligations, outreach programmes and settings outside of the traditional clinic or hospital should be utilised
- all women who are undergoing a tubal ligation should be given information about how to care for the wound and what to do in the case of wound breakdown or burst suture
- women's underlying health conditions should be taken into account before undertaking a tubal ligation. In particular, in cases where women are immuno-suppressed, clinical staff should provide a thorough health screening in order to assess whether or not the operation still has a high chance of success
- organisations such as MSI should routinely collect data on outcomes associated with tubal ligations
- more in-depth research is needed to understand what is causing more minor complications at outreach clinics compared with static clinics as well as to determine the overall success rate associated with tubal ligations.

References

1. Ruminjo JK, F LP. A fifteen year review of female sterilization by minilaparotomy under local anaesthesia in Kenya. Contraception 1997(55):249-60.

2. Nardin JM, Kulier R, Boulvain M. Techniques for the interruption of tubal patency for female sterilisation. Cochrane database of systematic reviews 2002(4).

3. Population Reference Bureau. Family Planning Worldwide, 2008 Data Sheet: Population Reference Bureau, 2008.

4. Gribble J, Haffey J. Reproductive Health in sub-Saharan Africa: Population Reference Bureau, 2008.

5. Ashford L. Ensuring a wide range of family planning choices: Population Reference Bureau, 2008.

6. Jack K, Chao C. Female voluntary surgical contraception via minilaparotomy under local anaesthesia. International Journal of Gynecology and Obstetrics1992;39(2):111-6.

7. Roberts H. Good Practice in Sterilisation. British Medical Journal 2000(320):662-63.

8. Hendrix NW, P CS, C MR. Ectopic pregnancy in sterilized and nonsterilized women: A comparison. Journal of Reproductive Medicine 1998;43:515-20.

9. Rind P. Tubal sterilization may confer some protection against ovarian cancer. Family Planning Perspectives 1992;24(1):44-5.

10. Cisse C, Kerby K, Cisse M, Diallo D, Faye E, Moreira P, et al. Complications of tubal sterilization by minilaparotomy under local anaesthesia. Dakar Medicine 1997;42(2):96-8.

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