Falope Rings or Modified Pomeroy's Technique for Concurrent Tubal Sterilization

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Abstract

Introduction Sterilization at caesarean section is usually performed by the modified Pomeroy's technique. Application of Falope rings and Filshie clips may also be used for tubal sterilization at caesarean section, and these techniques are also used during laparoscopy or minilaparotomy.

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Objectives The main objective of the study was to evaluate the failure rates, complications, technical difficulties and reversibility of the Falope ring application for tubal sterilization as compared to the traditional modified Pomeroy's technique used during caesarean sections.

Methodology Five hundred multigravid women who underwent caesarean section for various causes and wanted concurrent tubal sterilization were recruited in the study. Two hundred and fifty women underwent tubal sterilization by Falope ring application and the other 250 by modified Pomeroy's technique. Follow-up period ranged from 3 to 42 months. These patients' names were checked against the antenatal booking register, the operating theatre register in case of ectopic pregnancies and a termination of pregnancy register to recognize failed sterilization.

Results Among the 250 women who underwent Falope ring application, no major complications were noted. In the other group, women who underwent tubal sterilization by modified Pomeroy's technique, there was one woman with

serious complication, ectopic pregnancy. Falope ring application was an easy procedure to perform and also less time-consuming than modified Pomeroy's technique.

Conclusion Falope ring sterilization is simple, effective and safe, and the rate of subsequent pregnancy is lower than with conventional modified Pomeroy's technique.

Keywords Ectopic pregnancy · Falope ring · Modified Pomeroy's technique

Introduction

Female sterilization is a popular method of family planning (FP). It is estimated that, worldwide, about 180 million couples opt for this method of contraception [1]. Post-partum sterilization is ideally done within 48 h of vaginal delivery or is performed during caesarean section. In the immediate post-partum period, the fallopian tubes are mostly approached via a minilaparotomy. This approach continues to be widely used in developing countries. It is relatively quick, is relatively free of complications and requires only basic surgical equipment that is readily available in most centres worldwide.

For many years, new methods of sterilizing women have been sought and studied. Ideally, sterilization must be 100 % effective, has no serious complications and must be easily performed in an ambulatory care setting [2]. The most recent techniques of sterilization include cauterization, clamping, cutting and blocking of the fallopian tubes [3].

The modified Pomeroy's technique is currently the most widely used method for post-partum sterilization. Alternative options are application of Filshie clips, Hulka–Clemens clips and Falope rings [4]. In this study, we have compared the failure rates, complications, technical difficulties and reversibility of blocking of the fallopian tube using Falope ring against tubal ligation by modified Pomeroy's technique as method of sterilization.

Materials and Methods

Five hundred multigravid pregnant women who were admitted in the antenatal ward or labour ward of JSS Medical College and Hospital, Mysore, for caesarean section at term and wanted concurrent tubal sterilization were included in the study. Two hundred and fifty patients were randomized in study group (underwent tubal sterilization by Falope rings) and 250 patients in control group (underwent tubal sterilization by modified Pomeroy's technique).

Study Outcome To compare the failure rates, complications, technical difficulties and reversibility of tubal sterilization by the modified Pomeroy's technique and Falope rings when resorted to for post-partum sterilization.

Study Design Randomized controlled trial.

Study Period 1 January 2012 to 30 June 2015.

Informed Consent After explaining the method of tubal sterilization, all the patients and the attenders gave written informed consent.

Inclusion criteria:

- Second gravida or more
- Term gestation

Exclusion criteria:

- Primigravida
- Any maternal or foetal contraindication for tubal sterilization

Patients who were admitted in the antenatal or labour ward and were planned for caesarean delivery and fulfilled the inclusion criteria were recruited for the study.

In all the patients, detailed medical and obstetric history was taken. An informed consent for caesarean section was taken. The patients were randomized into either study group or control group. Block randomization was done with blocks of 2, 4 and 6 with 30, 30 and 40 %, respectively, using RALLOC software. Concealed envelopes were used for randomization.

The procedure was explained to the patients, and a detailed informed consent was obtained fully explaining all the risks and complications.

Caesarean section was performed under spinal anaesthesia in all the cases. After extraction of the baby and delivery of the placenta and membranes, the uterus was closed in one layer using Vicryl No. 1. Active management of third stage of labour (AMTSL) was performed in all the patients.

Women in the study group underwent tubal sterilization by application of Falope rings, whereas modified Pomeroy's technique using plain catgut was performed in women in the control group. After achieving haemostasis, the abdomen was closed in layers.

All the patients were followed up during their post-natal visits (follow-up period ranged from 3 to 42 months). Telephonic conversation was done with most of the patients (40 patients could not be contacted). These patients' names were checked against the antenatal booking register, the operating theatre register in case of ectopic pregnancies and a termination of pregnancy register to recognize failed sterilization.

Statistical Methods

Statistical analysis was carried out using commercial software SPSS (Statistical Package for Social Sciences) version 16. The descriptive measures such as mean, median and standard deviation for continuous variables were obtained. Frequencies and percentages were calculated for all categorical variables.

Results

Five hundred patients were included in the study. Two hundred and fifty patients underwent sterilization by Falope ring application, and the other 250 underwent sterilization by modified Pomeroy's technique.

There was no failure of Falope ring tubal occlusion (0/250). There was one case of failure with modified Pomeroy's technique (1/250). The failure rate of tubal sterilization by modified Pomeroy's technique was 0.4 % (1/250). The failure of modified Pomeroy's technique was a case of ruptured tubal ectopic pregnancy who underwent laparotomy 24 months after the procedure.

Twenty women who underwent tubal sterilization by modified Pomeroy's technique developed tear of the mesosalpinx and had to undergo total salpingectomy. Seven women who underwent application of Falope ring developed tear of the mesosalpinx, and bleeding could be controlled by cauterization in five cases; the other two women had to undergo total salpingectomy. This difference was statistically significant ($p < 0.001$).

There was no significant increase in pain in any of the cases, except for the pain due to the caesarean section on post-operative day 1. None of the patients complained of dyspareunia or any mid-cyclical ovulatory pain.

Falope ring application was much easier to perform than the modified Pomeroy's technique. The mean duration of application of Falope ring on one side was approximately 10 s (20 s for the entire procedure). The mean duration required for tubal sterilization by modified Pomeroy's technique on each side was 2 min (4 min for the entire procedure). The difference in time taken was statistically significant ($p < 0.0001$).

Three patients underwent tubal recanalization in both the groups due to neonatal deaths. One patient from either of the group has conceived. One patient from the Falope ring group had conceived, but underwent missed abortion—D & C was done. Three patients are still trying for conception.

The length of the follow-up period ranged from 3 to 42 months for both the modified Pomeroy's technique and the Falope ring applications.

Discussion

Falope ring sterilization eliminates electrocoagulation and potential burns [5]. It is rapid and effective, and it permits sterilization of an outpatient by means of laparoscopy or minilaparotomy under general or local anaesthesia [6].

There are no studies found after extensive search of the literature comparing the cost aspect, technical difficulties and reversal rates between these two methods of tubal sterilization.

Our prospective study showed no significant difference in failure rates between the current silicon Falope rings and the modified Pomeroy's technique of tubal occlusion when applied at caesarean section. The data were interpreted with caution, and the patients were followed up for a period of 3–42 months (post-procedure) as comparisons of the efficacy of the two different methods of post-partum sterilization vary considerably because of the difference in techniques employed [7, 8].

Falope ring application was found to be an easier technique to perform with lesser complications and time consumption. Operator and technique-related factors such as the expertise of the surgeon, approach to the Fallopian tubes and occlusive methods used for post-partum sterilization have an important role in determining the ease of the procedure. Data from larger sample size are required which would allow identifying reliable differences between the two methods with regard to surgeons' preference for one or the other technique.

We found no studies that compared the cost of the two methods. However, there are expenses for procuring suture material and also histopathological examination of the fragments of tubes excised during a modified Pomeroy's tubal ligation, while there is an initial expenditure for acquiring the Falope ring applicator.

Conclusions

According to the present study, the efficacy of the Falope rings and the modified Pomeroy's technique of post-partum sterilization was similar. However, the Falope rings application was found to be quicker and easier to perform with lesser complication rates than the modified Pomeroy's technique. Application of the Falope rings can be used as an easy alternative to the modified Pomeroy's technique at caesarean section or minilaparotomy [9, 10].

Compliance with Ethical Standards

Conflict of interest There is no conflict of interest involved within the authors of the study.

Informed Consent Written informed consent has been obtained from all the patients before they were enrolled into the study.

References

- Engender Health. Female Sterilization. Contraceptive sterilization: global issues and trends. New York: Engender Health; 2002.
- Lawrie TA, Nardin JM, Kulier R, Boulvain M. Techniques for the interruption of tubal patency for female sterilisation. *Cochrane Database SystRev*. 2011;16(2):CD003034. doi:[10.1002/14651858.CD003034.pub2](https://doi.org/10.1002/14651858.CD003034.pub2).
- Royal College of Obstetricians and Gynaecologists. Male and female sterilisation. London: RCOG Press; 2004.
- Nwagbara PN, Stibbe HM, Browning AJ, et al. Reversal of female sterilisation experience in a district general hospital. *J Obstet Gynaecol*. 1997;17:293–7.
- Peterson HB, Xia Z, Hughes JM. The risk of pregnancy after tubal sterilization: findings from the US collaborative review of sterilization. *Am J Obstet Gynecol*. 1996;174:1161–8.
- Kohaut BA, Musselman BL, Sanchez-Ramos L et al. Randomized trial to compare perioperative outcomes of Filshie clip versus pomeroy technique for postpartum and intraoperative caesarean tubal sterilization: a pilot study. *Contraception*. 2004;69:267–70.
- Peterson HB, Xia Z, Hughes JM. US collaborative review of sterilization working group. the risk of ectopic pregnancy after tubal sterilization. *N Engl J Med*. 1997;336:762–7.
- Filshie GM. Long term experience with the Filshie clip. *Gynaecol Forum*. 2002;7(3):7–10.
- Penfield AJ. The Filshieclip for female sterilization: a review of world experience. *Am J Obstet Gynecol*. 2000;182:485–9.
- Chi IC, Petta CA, McPheeters M. A review of safety, efficacy, pros and cons, and issues of puerperal tubal sterilization—an update. *Adv Contracept*. 1995;11:187–206.