### Laparoscopic tubal sterilisation reversal and fertility outcomes

### Abstract

#### Purpose

The purpose of the study was two-fold. First was to assess the suitability for tubal recanalisation and factors predicting successful laparoscopic recanalisation. Second was to analyse the fertility outcomes and factors affecting the pregnancy rate following laproscopic tubal recanalisation.

#### Methods

Retrospective chart review of prospectively followed-up 29 women at a tertiary care centre seeking tubal sterilisation reversal between May 2005 to February 2010 were included.

#### Results

In 14 (48.3%) women unilateral tubes were suitable and in only three women (10.3%) bilateral tubes were suitable. All cases with laparoscopic tubal sterilisation were suitable while all cases with fimbriectomy were unsuitable for recanalisation. In six (20.7%) cases salphingostomy was performed as an alternative procedure to tubal reanastomosis. The overall pregnancy rate was 58.8%. In cases with sterilisation by pomeroy's method, four out of 10 (40%) conceived; while for laparoscopic tubal ligation cases six out of seven (85.7%) conceived (p =0.13). None of the patients with final tubal length < 5 cm conceived (p=0.04). Comparing the age at recanalisation, in women  $\leq$ 30 years, 71.4% conceived, as compared to 50% when age of women was more than 30 years (p=0.6).

### Conclusions

The important factors determining the success of recanalisation are technique of sterilisation & the remaining length of the tube after recanalisation. The gynaecologist must use an effective technique of sterilisation to minimise the failure rates, but at the same time, which causes minimal trauma, and aim at preserving the length of the tube so that reversal is more likely to be successful, should the patient's circumstances change.

**Key Words:** Tubal Recanalisation, sterilisation reversal, fimbriectomy, Pregnancy Rate.

#### Introduction

Although wide ranges of contraceptive options are available, tubal sterilisation is currently the most popular form of birth control. It is an important constituent of National Family Planning Programme in India. Tubal sterilisation is being done from primary health centre to the tertiary care centres in government sector and also at private institution and nursing homes. According to NFHS-3 (2005-06), female sterilisation accounted for 37.3 % of all methods of family planning used in the country. <sup>1</sup> This is influenced by the economic compensation being given and according to a survey data, 64% female stated, they would like to go for tubal sterilisation at some time in future. <sup>2</sup>

The method of tubal sterilisation varies according to the expertise available from fimbriectomy to classical pomeroy's to laparoscopic sterilisation. <sup>3</sup> More than 45.5 % of females undergoing sterilisation are between 20-25 years of age. Although it is done as permanent method of sterilisation, due to unforeseen circumstances, 1-3% of these women subsequently demand reversal of sterilisation. <sup>4</sup> There are no studies from the country trying to look at the rate of successful recanalisation procedures based on the type of sterilisation performed.

Conventionally, the gold standard for recanalisation has been microsurgical tubal recanalisation through the laparotomy route. Minimally invasive laparoscopic microsurgery has introduced a new dimension for tubal reconstruction as the magnification obtained is similar to that obtained with an operating microscope. The major advantage is short post-op stay duration with minimal tissue handling, less post-operative adhesions. With the emergence of expertise in advanced laparoscopy techniques, many western centres have demonstrated good success through

laparoscopy and this has been widely regarded as the alternative route to perform microsurgical reversal of a ligated tube. <sup>5</sup> There are no studies from India looking at fertility outcome after laparoscopic tubal recanalisation.

## **Objectives**

The objectives of this study were

- To asses the suitability for reversal and analyse the factors predicting successful laparoscopic recanalisation.
- 2. The safety of laparoscopic tubal sterilisation reversal, and
- To assess the fertility outcome after laparoscopic sterilisation reversal procedure.
- 4. To analyse the factors affecting pregnancy rate after a successful recanalisation.

## **Material and Methods**

### Study setting and design

This study was carried out at a tertiary care centre. Patients are referred to this clinic from the area and also adjoining states. This was retrospective chart review of prospectively followed-up patients from the database of the institute. All patients assessed for tubal sterilisation reversal from May 2005 to February 2010 were included.

Before the operation, patients were thoroughly interrogated, examined and investigated. Detailed counselling of both husband & wife was done regarding the procedure of recanalisation and also that the procedure will be performed only if the tubes are suitable for reanastomosis and if available tubal length is adequate. Also, they were counselled regarding the success rate and the complications after recanalisation and the alternative option of in-vitro fertilisation. Apart from routine investigations for major surgery, a baseline evaluation was done to rule out other factors contributing to infertility including husband's semen analysis. The informed consent was taken from all patients.

#### **Tubal recanalisation procedure**

The tubal sterilisation reversal procedures were performed by laparoscopy under general anaesthesia. First the status of the tubes was evaluated and the suitability of the tubes for recanalisation was decided (by KJK). Depending on the suitability of the tubes for recanalisation, the laparoscopic tubal reanastomosis was performed either unilaterally, bilaterally or not performed at all. End to end tubal anastomosis was performed by two-layer closure using no 7-0 prolene. First four sutures at 6', 3', 9' and 12'-O clock were taken in the muscularis layer and then the serosal stitches were taken. Haemostasis was achieved by precise electrocoagulation by bipolar cautery and injection of diluted vasopressin to mesosalpinx. The patency was assured intraoperatively by methylene blue injection. The patients were discharged on second day of surgery.

#### Post-procedure follow-up

They were asked to come for follow up personally after 2 weeks and then subsequently every 3 months or earlier if needed. Whenever patients failed to come for a review, they were telephonically interviewed. All patients were followed up for a period of 3 years after recanalisation.

After successful recanalisation, the patients were advised to try for conception from the next cycle. The patients in whom recanalisation procedure was not performed due to unsuitability of tubes, the option of IVF and adoption were discussed. All patients after recanalisation were asked to achieve conception naturally or if they failed to conceive after a year they were offered intrauterine insemination.

#### **Outcome Measures**

The outcome measures studied were the suitability of the tubes for the recanalisation procedure analysed for the technique of sterilisation performed previously and the interval between sterilisation and reversal procedures. The procedure of reanastomosis performed and the anatomical site of anastomosis were analysed for the technique of sterilisation performed initially. Also the pregnancy outcome was analysed for the technique of sterilisation initially performed, location of anastomosis, tubal length and age of the patient.

#### **Statistical Analysis**

All statistical analyses were performed using SPSS for Windows version 17.0 (SPSS Inc., Chicago, IL). Data were expressed as means, medians, standard deviations, and percentages. We used student's t -test to compare group means and Fisher Exact test to compare proportions. A P value of < 0.05 was considered significant.

### Results

Twenty-nine women, seeking tubal sterilisation reversal during the study period were included in the analysis. The mean age was 32.9 years (SD 4.8; range 24 – 42). Of the total, eighteen women (62.1%) had all vaginal deliveries, nine patients (31%) had all cesarean deliveries and two (6.9%) had vaginal deliveries with cesarean deliveries. The timing of sterilisation was post-partum in 10 (34.5%), interval sterilisation in nine (31%). In eight (27.6%) sterilisation was performed along with LSCS, and in two (6.9%) sterilisation was done along with MTP. The most common procedure of sterilisation was Pomeroy's sterilisation in 16 (55.2%) women, while Laparoscopic tubal sterilisation was performed in only seven (24.1%) women. Remaining six (20.7%) women had fimbriectomy as the method of sterilisation performed.

#### **Tubal recanalisation**

The mean interval between sterilisation and recanalisation was 6.10 years (SD 4.0; range 1-16). The main reason for seeking sterilisation reversal was death (65.5 %) or disability (6.9 %) of one or more children. In remaining 27.6%, second marriage was the reason for sterilisation reversal. Assessments for suitability showed that in majority of women i.e. 14 (48.3%) unilateral tubes were suitable and in three women (10.3%) bilateral tubes were suitable. All cases with laparoscopic tubal sterilisation had one or both tubes suitable for recanalization. In contrast, all cases with fimbriectomy as method of sterilisation were unsuitable for recanalisation **(figure 1)**. The procedure of recanalisation was done unilaterally in 14 (48.3%) cases **(supplement table 1)**; bilaterally in three (10.3%) cases and procedure could not be

performed in 12 (41.4%) cases. In six (20.7%) cases salphingostomy was performed as an alternative procedure to tubal reanastomosis (supplement table 2). These were five cases with fimbriectomy performed as sterilisation procedure and one case with Pomeroy's sterilisation. In the remaining six patients with unsuitable tubes (five had Pomeroy's sterilisation and one had Fimbriectomy), the procedure was cancelled (figure 2). The status of tubes in all the unsuitable cases is shown in **supplement table 3**. Thus, effectively procedure of tubal reanastomosis was performed in only 58.6% cases. The mean length achieved after recanalization in cases with Pomeroy's sterilisation was 6 cm (SD 1.24), while that for cases with laparoscopic tubal ligation was 7.3 cm (SD 0.9). The type of anastomosis performed was isthumo-ampullary in10 cases (58.82%), isthumo-isthumic in four cases (23.5%), cornuo isthumal in two cases (11.7) and ampullo-ampullary in a single case. In one case with cornuo-isthumal anastomosis, medial end patency was established after hysteroscopic cannulation. In five cases (31.5%) with Pomeroy's sterilisation, anastomosis could not be done. The type of anastomosis as sub classified according to the type of sterilisation is shown in figure 3. None of these patients had any intra-operative, anaesthesia related or post-operative complications. All patients were discharged on second day of surgery.

#### Post procedure fertility outcome

At median follow-up of 28 months, 10 (58.8 %) became pregnant. The mean interval between recanalisation and pregnancy was 6.5 months (SD 4.1). Of these four had underwent isthumo-isthumic anastomosis and six had isthumo –ampullary anastomosis. Out of these 2 had ectopic pregnancies, two are ongoing intrauterine – pregnancy and other delivered at term. In cases with sterilisation by Pomeroy's method four out of 10 (40%) conceived, while for Laparoscopic tubal ligation cases

six out of seven (85.7%) conceived (p =0.13). In cases where recanalisation was done bilaterally, two (67%) conceived, while for unilateral recanalisation eight (57.8%) conceived (p=0.23). None of the patients with final tubal length < 5 cm conceived (p=0.04). Comparing the age at recanalisation, in women  $\leq$  30 years, 71.4% conceived, as compared to 50% when age of women was more than 30 years (p=0.6). None of the patients undergoing neo-salpingostomy conceived. Two of the 12 patients, who were unsuitable for recanalization, opted for in-vitro fertilisation. One patient conceived after IVF and had twin pregnancy and delivered at term.

#### Discussion

Although tubal sterilisation is done as a permanent contraception method, few unfortunate women may seek reversal later. In the current study, the most common reason for seeking reversal was death or disability of child (72%) followed by second marriage (28%). This is similar to previous studies from India. <sup>6, 7</sup> On the contrary, the most common reason for regretting sterilisation in the developed countries was the desire to have children from a new husband. <sup>3</sup>

In India tubal sterilisation is done in private nursing homes as well as government hospitals, from remotest public health centre to the tertiary care centre using different techniques. There are no studies assessing the suitability for reversal, majority of the studies include only the suitable cases and follow their outcome. <sup>6, 8</sup> In this scenario, this study is unique, trying to compare the suitability of reversal across different procedures. In the current study, significant proportion i.e. 42% patients were unsuitable for reversal, in contrast to a study from Belgium, where only 18 % of the cases were unsuitable for surgical reversal. <sup>9</sup> In the current study, 3/4<sup>th</sup> patients had

pomeroy's sterilisation/fimbriectomy as the technique of sterilisation. The technique of fimbriectomy as described by Kroener is considered as the most effective method of sterilisation with minimal failure of sterilisation method. <sup>10</sup> In India tubal ligations are performed as part of the national family planning programme. There are medicolegal and social issues related to the failure of the procedure hence in most centres across the country, gynaecologists perform fimbriectomy, or remove long segments of the tubes during pomeroy's sterilisation making them unsuitable for recanalisation in future. Although laproscopic sterilisation is more conservative and equally effective technique, majority of centres don't have the instruments and expertise to perform the above. Reversal of fimbriectomy by neosalphingostomy has been reported <sup>11</sup> to result in pregnancies, but in our six patients in whom, salphingostomy was performed, none of the patients conceived.

The overall suitability for reversal and final mean length achieved was better for sterilisation performed by laparoscopic fallope ring application (100%) as compared to Pomeroy's method (62.6%). The results are concordant with the current literature. <sup>6, 12</sup> Our study confirmed the importance of tubal length in terms of live birth rates. None conceived when length was < 5 cms. Literature also supports the same, a previous study reported 100% pregnancy rate with >4 cm and 0% with < 3 cm of the tubal length after tubal reversal by microsurgical technique. <sup>13</sup>

The pregnancy rate was better for laparoscopic sterilisation by Falope ring (85.7%), as compared to those with Pomeroy's procedure (40%). The Pomeroy's method of combined ligation and excision usually removes 3 to 4 cm of the isthmic or ampullary portion of the tube and can be even more at times. <sup>13</sup> Such a drastic decrease in post – reversal tube length is bound to manifest as poor pregnancy rate. In studies from other countries, the sterilisation is routinely performed by application of rings or clips

and it is accepted that mechanical occlusion by Filshie clips should be the method of choice for tubal occlusion as it destroys a smaller part of the tube and the reversal, if performed subsequently, is more likely to succeed. <sup>14</sup> The results caution us about the need to adapt appropriate procedure with minimal tissue handling during tubal sterilisation. To the patient contemplating reversal, today one clip or falope ring at the mid-isthmic portion of each fallopian tube offers the best hope because the success of reversal is related, firstly, to the length of tube remaining and, secondly, to the site of the anastomosis. "Cut and tie" surgical methods and unipolar diathermy often destroy a substantial length of the tube. <sup>15</sup>

Several studies of microsurgical reversal reported delivery rates ranging from 50 to 87%. Recent study reported, 40% and 53%, cumulative pregnancy rates at 6 and 12 months for open microsurgery vs. 55% and 71% for laparoscopic microsurgery. Our results compare quite favourably with a pregnancy rate of 53% at median follow-up of 28 months. The fertility outcomes after laparoscopic recanalisation are comparable to other studies from our country in which reversal done by microsurgical methods. <sup>6, 12</sup> The laparoscopic approach potentially involves less manipulation of intraperitoneal organs and causes less bleeding. <sup>16, 17</sup> These advantages may result in fewer adhesions further enhancing the pregnancy rate and is preferred technique in many centres.

The limitations of the study are its retrospective nature, small group to arrive a statistically significant result, and a relatively short follow-up.

# Conclusion

The gynaecologist must use an effective technique of sterilisation to minimise the failure rates, but at the same time, which causes minimal trauma, and aim at preserving the length of the tube so that reversal is more likely to be successful, should the patient's circumstances change.

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### **Legends to Figures**

**Figure 1** - Figure showing suitability for reversal according to the technique of sterilisation.

**Figure 2** – Figure showing status of tubes in unsuitable cases with Pomeroy's sterilisation. (A, B) Status of left tube in a patient. (A) Medial end is 3-4 cm (black arrow), omental adhesions are seen laterally (white arrow); After adhesiolysis (B) only small fimbrial end which could not be anastomosed. (C) Only long medial end seen (black arrow); lateral end and fimbria not seen. (D) Lateral end showing hydrosalphix, fimbria not seen.

**Figure 3** - Figure showing type of anastomosis subclassifed across the technique of sterilisation