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Evaluation of pregnancy outcome and influencing factors of microsurgical tubal recanalization as a reversal of tubal ligation in a tertiary hospital

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ABSTRACT

Background: Tubal microsurgical recanalization is a procedure which restores the fertility in women who have undergone sterilization voluntarily, thinking that her family is complete. However due to unforeseen circumstances, 1–3% of these women subsequently demand reversal of sterilization. **Aims and Objectives:** This study aims to evaluate the pregnancy rate after reversal surgery and to find out the various factors that influence the success of tubal microsurgical recanalization. **Materials and Methods:** The current study was hospital-based retrospective one involving 48 women undergoing reversal of sterilization at the department of gynecology and obstetrics in tertiary hospital, Kolkata, during the period of 3 years, from July 2015 to June 2018. The women were followed up for a period of 1 year by telephonic contact. Women seeking tubal recanalization was in age group of 20–35 years with normal ovulation and normal semen analysis. Women, >35 years old, anovulation, with obvious pelvic inflammatory disease, endometriosis or fibroid were excluded, women with any contraindications to pregnancy or surgery and any male factor infertility also excluded from the study. **Results:** Out of 48 study subjects, intrauterine pregnancy was achieved in 27 cases (93.1%)), 2 patients (6.9%) had ectopic pregnancy. Out of 27 intrauterine pregnancies, 4 had abortions (13.8%), 3 (10.3%) are ongoing pregnancies, and 20 patients had live birth (69%). **Conclusion:** Tubal microsurgery offers good chances of pregnancy outcome which is favored by the age below 30 years, interval between sterilization and its reversal <4 years, isthmo-isthmic anastomosis, reconstructed tubal length being more than 6 cm, and type of previous sterilization were by Pomeroy's method.

Key words: Microsurgery; Pregnancy; Reversal; Sterilization; Tubal length; Tubal recanalization

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INTRODUCTION

Tubectomy, an integral part of national family planning program of India, is one of the most acceptable methods of female contraception among women of reproductive age. In India, female sterilization is accounted for 36% of all methods of family planning practiced in our country according to NFHS-4 (2015–2016).[1] However, about 10% of them later regret their decision due to unavoidable circumstances, 1–3% of these women subsequently desired for reversal of sterilization due to various reasons such as accidental demise of only child or male child, desirous of more children, loss of child in natural disasters, remarriage, and other socioeconomic influences.[2,3] These women have the option of either opting for artificial reproduction techniques or going for tubal recanalization (either by laparoscopy or tubal microsurgical technique) as a method of reversal but in spite of wide availability of in vitro fertilization, due to

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high cost of it, most women opt for microsurgical tubal recanalization.[3] Although laparoscopic recanalization has taken over conventional open microsurgical technique in west, because of cost and technical expertise involved in this procedure, laparoscopic technique remains available to very few reversal seeking women in India and can be adopted as alternative to tubal microsurgical technique through laparotomy.[4] Popularity in the new microsurgical techniques in reversal of sterilization is mostly due to associated improvement in the success in pregnancy rate in comparison to traditional surgical techniques. Several factors such as the age of the women, type of tubectomy done, duration since tubectomy and remaining length of the tube after reversal operation, and techniques of recanalization have been considered to influence the outcome of recanalization. The present study aimed to find out the conception rate and the factors which can affect the successful pregnancy outcome following tubal recanalization.

Aims and objectives

To find out the pregnancy rate following tubal recanalisation and the factors which can affect the success of microsurgical reversal following tubal ligation.

MATERIALS AND METHODS

This was a hospital-based retrospective study of 48 women, aged 20–35 years, underwent tubal recanalization, in the Department of Obstetrics and Gynaecology of R G Kar Medical College and Hospital, Kolkata, for a period of 3 years, from July 2015 to June 2018. Approval of the Institutional Ethical committee was obtained. All the study women were followed up for a period of 1 year. Inclusion criteria of our study were patient having tubal block due to sterilization (laparoscopic or open method), normal ovulatory function (patient presenting with regular menstrual cycle), and husband's normal semen analysis. Exclusion criteria were pelvic pathology or any congenital uterine anomalies or severe endometriosis or pelvic inflammatory disease, anovulatory infertility, female with bilateral hydrosalpinx or totally distorted bilateral tube as diagnosed by hysterosalpingography or laparoscopy, any male factor for infertility, and remnant length of the fallopian tubes <4 cm as seen in HSG or by laparoscopy.

Sample size

According to study conducted by Jayakrishnan and Beheti, 85.7% conceived following laparoscopic recanalization in cases with sterilization by laparoscopic method of tubal ligation.[5]

Taking this proportion, the sample size was calculated using this formula:

$$n=z^2\ p\ (1-p)/d^2$$

n = sample size
z = 1.96 for 95% confidence limit
p = anticipated proportion = 85.7%
d = Acceptable margin of error = 10% $n = (1.96)^2 \times 85.7 \times (100-85.7)/10^2$
$=47.07 \sim 48$

Overall, it was estimated that 48 women will have to be recruited for the purpose of our study.

Data collection and procedure

Over the period of study, women were enrolled as per the inclusion and exclusion criteria. Data collected by reviewing records and they were followed up over telephonic conversations. Data collection was started from August 2019 and the procedure was continued till February 2020. Topic and objective of the study were clearly explained to each study subjects and informed consent was taken. The participants were assured of the confidentiality. An interview was conducted using a pre-designed pretested semi-structured questionnaire focusing on details of sterilization, including the age at the time of sterilization, parity at the time of sterilization, type of sterilization, interval between sterilization and reversal, and reason for reversal of sterilization.

Obstetrics history including parity and the cause for death of child if any was recorded. Their laboratory investigation details both before and after recanalization taken from hospital records and reports from patients.

Details of recanalization procedure including site of anastomosis, suture material used, adhesion preventing drugs used, post-operative period; post-operative assessment of tubes, ovaries and uterus by both HSG and laparoscopy, any supplementary treatment as example hydrotubation, ovulation induction, metformin needed or not, recorded from records of hospital, and patients records.

Outcome of recanalization in terms of pregnancy and outcome of pregnancy (live birth, abortion, IUFD, ongoing pregnancy, and ectopic pregnancy) was recorded.

Microsurgical technique

Tubal recanalization by microsurgical technique was carried out in the postmenstrual phase. A Pfannenstiel incision was given and the findings such as endometriosis and PID if present were noted. Under magnification with microsurgical instruments and constant irrigation with normal saline, tubectomized sites were freshened. Anastomosis was done by 6-0 Vicryl suture materials for suturing muscularis layer. First bite was taken at 6-O clock position that is mesenteric border and later 3, 9, and 12-O

clock positions. Serosa was approximated similarly. Patency of both ends was established by direct tube testing by injecting methylene blue dye. For fimbriectomy cases, cuff salpingostomy was done. Perfect hemostasis was achieved using bipolar cautery. Tubal length was noted at the end of the surgery. Hydroflotation was done with normal saline.

The parameters studied were condition of the tubes, ovaries, uterus, and type of tubectomy, anatomical site of anastomosis, final length of the reconstructed tube, and the use of adjuvant therapy such as adhesion preventing drugs and irrigation fluids. Prophylactic antibiotics coverage (inj. ciprofloxacin and inj. metronidazole) was used. In all cases, inj. promethazine (Phenergan) 25 mg i.m. 8th hourly was given for 5 days with or without inj. dexamethasone. Any complication, if present, were recorded.

Women were discharged after removal of skin suture and were advised regarding utilization of the fertile period and risk of ectopic pregnancy and to start sexual activity after 2 months. They were followed for a period of 1 year and events such as pregnancy, ectopic pregnancy, and pelvic infection were recorded. If there was no conception within 1 year, hysterosalpingogram was done to check for tubal patency.

Statistical analysis

The data were compiled using Statistical Package for the Social Sciences (SPSS) for Windows (SPSS, Inc., Chicago, IL, USA). Various coding had given to variable and then data recorded for analysis. By proportion and frequency, categorical data were presented. For qualitative data, Chi-square test was used as a test of significance; P<0.05 was considered to be statistically significant.

RESULTS

Out of 48 study subjects, 50% were in the age group of 26–29 years followed by 33.3% were in the age group of 30–35 years and 16.7% were in the age group of below 25 years (Table 1). The mean age of the participants was 28.63±3.22 years with a median of 28 years and range of 23–35 years. Most of the women (54.2%) were having parity 2 or less than that and 56.3% of women underwent sterilization by Pomeroy's method. Most of the study subjects (45.80%) underwent sterilization concurrent with LSCS followed by interval ligation in 25% of patients. Frequency of puerperal ligation and postabortal ligation was same (14.6%). Common reasons seeking recanalization in the study were either death of all children (47.9%) or demise of 1 child (22.9%). In our study, 60.4% of women conceived out of which 69% live birth, 13.8% abortion, and ectopic pregnancy 6.9% and ongoing pregnancy was 10.3% (Table 2). In this study, association between sterilization-recanalization interval <4 years and conception rate after recanalization was statistically significant with P-value 0.05 (Table 3). Remarkable conception (55.2%) was achieved in the age group of 26–29 years, in our study. Association between length of reconstructed tube and conception rate after recanalization was remarkable. The study showed that if the reconstructed tube length is >6 cm, conception rate is highest 68.15% (Table 4). It was seen that isthmo-isthmic anastomosis associated with higher pregnancy rate (70.55%) followed by isthmo-ampullary (57.25%). Most of the tubes (bilaterally) which were found healthy conceived (67.95%). Most of the cases conceived that there was no peritubal adhesion (62.45%). In 69.7% of cases, there was good spillage of dye in HSG, and they conceived. Uterine anomaly was noted in three cases, where pregnancy rate was 66.7%.

Table 1: Distribution of determinants affecting outcome of tubal reversal

Factors affecting outcome of recanalization	Frequency (n=48)	Percentage
Age group		
Up to 25	8	16.7
26–29	24	50.0
30–35	16	33.3
Parity		
2 or less	26	54.2
3 or more	22	45.8
Age of ligation		
Up to 19	14	29.2
20–25	29	60.4
26–30	5	10.4
Method of ligation		
Pomeroy's method	27	56.3
Laparoscopic	17	35.4
Method (Falope ring)		
Fimbriectomy	4	8.3
Site of ligation		
Ampullary	18	37.5
Isthmic	23	47.9
Fimbriectomy	7	14.6
Length of reconstructed tube		
>6 cm	26.5	55.2
4–6 cm	21	43.75
<4 cm	0.5	1.05
Sterilization-recanalization interval		
<4 years	2	4.2
4–6 years	31	64.6
>6 years	15	31.3

Table 2: Pregnancy outcome of tubal microsurgery

Outcome of recanalization	Frequency (No.=48)	Percentage
A. Conceived	29	60.4
Live birth	20	69.0
Abortion	4	13.8
Ongoing pregnancy	3	10.3
Ectopic pregnancy	2	6.9
B. Not conceived	19	39.6

Table 3: Conception rate in relation to various influencing factors

Determinants	Outcome of recanalization		Chi-square value df P value
	Conceived (n=29)	Not conceived (n=19)	
Age group			
Up to 25	5 (17.2)	3 (15.8)	1.132
26–29	16 (55.2)	8 (42.1)	2
30–35	8 (27.6)	8 (42.1)	0.577
Method of ligation			
Pomeroy's method	15 (51.7)	9 (31.0)	0.753
Laparoscopic method (Falope ring)	11 (37.9)	14 (48.3)	2
Fimbriectomy	3 (10.3)	6 (20.7)	0.743
Site of ligation			
Ampullary	9 (31.0)	9 (47.4)	2.692
Isthmic	14 (48.3)	9 (47.4)	2
Fimbriectomy	6 (20.7)	1 (5.3)	0.690
Sterilization-recanalization interval			
<4 years	2 (100.0)	0 (0.0)	10.915
4–6 years	23 (74.2)	8 (25.8)	2
>6 years	4 (26.7)	11 (73.3)	0.004*

*Association between sterilization-recanalization interval < 4 years and conception rate after recanalization was statistically significant with P<0.05.

Table 4: Pregnancy outcome in relation to tubal length after reversal surgery

Length of reconstructed tube	Outcome of recanalization		Chi-square value df P-value
	Conceived, n (%)	Not conceived, n (%)	
Left			
>6	18 (72%)	7 (28%)	2.927 1
4–6	11 (47.8%)	12 (52.2%)	0.087
Right			
>6	18 (64.3%)	10 (35.7%)	1.752
4–6	11 (57.9%)	8 (42.1%)	2
<4	0 (0%)	1 (100%)	0.456

DISCUSSION

There are multiple factors that determine the outcome of tubal recanalization surgery by microsurgical technique. In our study, majority of women (50%) were in the age group of 26–29 years which correspond with the study of Biswas and Mondal where 50.8% was in this age group.[6] Age has a definite effect on pregnancy rate. A higher conception rate (68%) in younger age group (20–30 years) may be attributed to their greater fertility potential as shown in the study by Brar et al.,[7] Jain et al., showed a higher pregnancy rate (75%) when the age of the patient was <25 years.[8] Cohen et al.,[9] performed a multicenter retrospective study and observed pregnancy rates which were significantly lower in women aged 40 compared to younger groups.

In our study, most reversal seekers (54.2%) were para two or less. This high figure of low parity coincides with the study of Maya et al., in which 54.5% of women were para two.[10] The method of previous tubal sterilization used, is an important determining factor for success of sterilization reversal. Biswas and Mondal found that 59.65% of women had previous laparoscopic sterilization.[6] In our study, 35.4% had laparoscopic sterilization and the rest had undergone Pomeroy's type of sterilization. The present study showed a success rate of 56.3% in women who had undergone Pomeroy's method of sterilization as compared to 35.4% in women following reversal of laparoscopic technique. In a prospective study by Maya et al., 90.9% had undergone minilaparotomy using modified Pomeroy technique.[10] Success rate in this study following minilaparotomy was 35%.

In the present study, death of one or all children was the most common reason for couple to seek reversal of sterilization (70.8%). A study by Mukherjee et al.,[11] showed that death of all children was the most common reason (91.8%) for reversal of sterilization, which coincides with the study by Jain et al.,[8] where 70% of women sought reversal for death of all children. This observation is in contrast to Western countries where the most common indication was remarriage or divorce seen in 80–90% of the cases as per Grunert et al.[12] Biswas and Mondal opined that death of a male child (53.5%) in a male dominated society makes the couple to try once more and solicit a sterilization reversal.[6] In the study by Promila et al., death of a male child (64.2%) was the major reason for sterilization reversal.[13]

In the present study, 31.3% of women had undergone sterilization more than 6 years ago, but a higher pregnancy rate (100%) has been reported when the interval between sterilization and reversal operation is <4 years. Biswas and Mondal showed in their study that 50% of women came for sterilization reversal within 3 years of sterilization.[6] In a study by Brar et al., pregnancy rate was 100% when the interval was <2 years.[7] Kalaichelvi et al., found that 87% of women conceived when recanalization was done within

1 year of sterilization while the incidence dropped to 16% when the interval was more than 10 years.[14]

In the present study, the most common site of anastomosis was isthmo-isthmic (42.7%) followed by isthmo-ampullary (27.1%) and the least was cuff salpingostomy (7.3%), which coincides with studies by Brar et al.,[7] and Biswas and Mondal where the most common type of anastomosis was isthmo-isthmic in 48% and 49.1%, respectively.[6]

In the present study, bilateral isthmo-isthmic anastomosis resulted in pregnancies in 70.5% of women, bilateral isthmo-ampullary in 57.25%, and bilateral ampullo-ampullary in 47.2%. Maya et al., in a prospective analysis of 22 women who underwent microsurgical tubal reversal, found that 75% conceived after isthmo-isthmic anastomosis, 33.3% after isthmo-ampullary anastomosis, and none after ampullo-ampullary anastomosis.[10] In a study by Kalaichelvi et al., 76.2% of intrauterine pregnancies were seen in women who had isthmo-isthmic anastomosis while the highest incidence of tubal pregnancies (7.4%) occurred in the isthmo-cornual anastomosis.[14] In a study by Promila et al., 80% of term pregnancies occurred after bilateral isthmo-isthmic anastomosis but only 50% of term pregnancies after bilateral isthmo-ampullary anastomosis.[13]

The most important factor to enhance the effectiveness of recanalization is the length of the reconstructed tubes Silber and Cohen.[15] In the present study, 98.95% had final tubal length of more than 4 cm. The pregnancy was achieved in 68.15% of the women when the tubal length was more than 6 cm in comparison to 47.85% when the length was 4–6 cm.

Jain et al., confirmed the importance of tubal length in terms of live birth rates by their prospective study.[8] When length of tube was more than 8 cm, the pregnancy rate was 83.33% which was markedly reduced to 4%, if length of tube was <4 cm. In a prospective study by Maya et al., with a reconstructed tubal length of more than 8 cm, the pregnancy rate was 100% while with a tubal length ranging from 4 cm to 8 cm, the pregnancy rate was 53.3%. None conceived with tubal length <4 cm.[10]

The current study showed that the overall conception rate was 60.4% (29 cases) out of which 27 cases (93.1%) were intrauterine pregnancies; 2 (6.9%) had ectopic pregnancy, live birth was 69% (20 cases), and abortion rate was 13.8%. In our study, 90.5% conceived within 12 months of reversal of sterilization. In a similar study, Brar et al.,[7] showed 68% intrauterine pregnancy and in a study of Biswas and Mondal showed intrauterine pregnancy rate of 66.27%.[6] In a retrospective study by Yadav et al.,[16] the overall conception rate was 68%, out of which intrauterine pregnancy rate was 62%, ectopic pregnancy rate was 6%, and the abortion rate was 6%. Fifty percent of patients conceived within the first 12 months of reversal of sterilization.

In the present study, out of 48 women, 19 women had not conceived by the end of 1 year, bilateral tubal patency was assessed by hysterosalpingography. Bilateral tubal patency was established in 52.6% (10 cases); unilateral tubal patency was seen in 42.1% (8 cases), and bilateral tubal block in 5.3% (1 case). Out of those women with patent fallopian tube, two women were not staying with their partner, two women were not interested in conception, and five women were having anovulatory cycles following reversal of sterilization. Rest of the women are undergoing ovulation induction and are under regular follow-up.

Limitations of the study

It may be noted that our follow-up period was limited and although pregnancies were spontaneous, some interventions such as hydrotubation and ovulation induction were done to improve the conception rate during the study period. Skill and expertization of the surgeon can influence the outcome which is not included here as well as effectivity of dexamethasone peroperatively has not proven.

CONCLUSION

Although tubal microsurgical reversal offers better pregnancy rate in our study, certain important factors such as age of the patient <30 years, the interval between sterilization and its reversal <4 years, isthmo-isthmic anastomosis, the reconstructed tubal length >6 cm, and previous sterilization by Pomeroy's method played a determining role to achieve successful pregnancy. Since every patient undergoing sterilization is a potential candidate for reversal, we propose that every effort should be made to perform sterilization over isthmus, keeping maximum length of the tube which may bring a ray of hope to hopeless.

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AN- Concept and design of the study, prepared first draft of manuscript, and revision of manuscript; **SG**- Data collection, interpreted the results, review of literature, and manuscript preparation; **AKM-** Coordination and preparation of manuscript; **BCM**- Coordination and support; and **RD**- Concept of study and revision of manuscript.

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