



ANALYSIS OF FACTORS FOR FAILURE OF FEMALE STERILIZATION - A RETROSPECTIVE STUDY

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ABSTRACT **OBJECTIVES-** The primary objective of this study is to determine the possible etiological factors and clinicodemographic profile among women with sterilization (ST) failure and secondary objective is to find out the time to failure and outcome of pregnancy following sterilization failure.

MATERIAL AND METHODS- This is a retrospective record-based study which included all women in whom sterilization was carried out and have reported as tubal sterilization failure admitted to Department of Obstetrics and Gynaecology, JIPMER during the period of 6 years (January 2012 to December 2017).

RESULTS- During the above period, 82 women with sterilization failure were admitted. The mean interval after sterilization was 23 months with a range from 2 months to 117 months. Thirty-eight (46.34%) were following puerperal sterilizations (PS), 24 (29.27%) occurred after concurrent sterilization with lower segment Caesarean section (LSCS), 7 (8.54%) were after interval mini laparotomy tubal ligations (minilap TL), 7 (8.54%) were following laparoscopic tubal ligations (Lap TL) and 6 (7.31%) were following postabortal minilaparotomy sterilizations. Sixty-seven (82.71%) women reported failure prior to 12 weeks of gestation and the rest approached beyond 12 weeks. Sixty-five (79.27%) of them were intrauterine pregnancy and 17 (20.73%) were ectopic pregnancy. Among the intrauterine pregnancies, 43 underwent MTP and 22 women continued pregnancy to term. Seventy (85%) underwent re-sterilization the causes of failure were of spontaneous recanalization in 41 (50%), formation of tuboperitoneal fistula in 24 (29.27%) and improper laparoscopic fallope ring placement in 5 (6.1%). Of the 17 women with ectopic pregnancy 16 underwent laparotomy/laparoscopy and spontaneous recanalization was reported in 15 cases (88.23%). The mean duration of sterilization failure was 23 months.

CONCLUSION: The most common etiological factor for sterilization failure was spontaneous recanalization. The pregnancy was intrauterine in 80% and ectopic in 20%. More than 80% reported in first trimester and 61% of them opted for MTP. Twenty-two (26.83%) of women continued pregnancy to term and over-all 70(85.37%) underwent re-sterilization along with MTP, concurrent with LSCS or after delivery and at the time of surgical management for ectopic pregnancy.

KEYWORDS : Female Sterilization failure, spontaneous recanalization, re-sterilization, MTP

INTRODUCTION:

Sterilization (ST) is the most popular method of contraception in India. It is a safe and highly cost-effective procedure that requires a single act of compliance and does not rely on partner behaviour. This feature makes sterilization an ideal method of permanent contraception in developing countries where access to health care providers is limited. Although, tubal sterilization is considered as a permanent method of contraception, pregnancy can occur in 1 in 200 women (0.5%) in the lifetime¹. The causes of failure may be due to faulty technique or due to patient factors.

As there is lack of awareness that pregnancy can occur despite sterilization, some women may present late and decision making to terminate or continue the pregnancy causes dilemma. Pregnancy may be intrauterine or extra uterine (ectopic). It is essential to know the causes of failure so that the data can be used to counsel women undergoing tubectomy regarding the failure rate and the causes for such failure.

MATERIALS AND METHODS-

The present study is a retrospective record based study which included all women in whom sterilization was carried out and have reported as tubal sterilization-failure admitted to Department of Obstetrics and Gynaecology, JIPMER during the period of 6 years from January 2012 to December 2017. The study was approved by the Institutional Ethical committee (NO.JIP/IEC/2018/0259).

The information was collected from the case records of these patients maintained by medical record department (MRD) and entered in data collection proforma. Important aspects of case history included age, Obstetric index, type of sterilization, interval from the time of tubectomy to failure, gestational age at the time of presentation, management of present pregnancy as per the decision of the couple, operation findings in cases of re-sterilization

or during surgical management of ectopic pregnancy. During the re-sterilization, type of previous sterilization procedure that was performed was assessed for correctness, tubal integrity, evidence of

recanalization/ tuboperitoneal fistula. Presence of fallope rings and other associated findings that were recorded was noted. Pregnancy outcomes were recorded in those who continued the pregnancy and who underwent MTP.

RESULTS:

During the selected period of January 2012 – December 2017 total of 13,911 women underwent sterilization and 82 of them reported to the Institution as tubal sterilization-failure. The percentage of failure was 0.58 (Table-1).

Table-1: Failure of sterilization

Year	Total ST performed	Number of ST failure reported	Percentage of ST Failure
2012	2196	9	0.409
2013	2227	16	0.718
2014	2260	8	0.354
2015	2382	14	0.588
2016	2382	18	0.756
2017	2464	17	0.689
Total in 6 years	13,911	82	0.589

The clinicodemographic profile was shown in Table-2. The mean age at failure was 26 years, with a range of 22 to 40 years. Majority (53%) were young women and 70% were of parity 2.

Time to failure ranged from 2 months to 117 months and the mean interval was 23 months. In the majority (38%) failure was reported between 13 months to 24 months and in 23.4 % failure occurred between 25 months to 36 months (2-3 years). In 8.5% failure occurred after a prolonged period of 60 months (5 years)

Methods of previous sterilization: This is depicted in Figure-1 Most of the women 38 (46.34%) underwent puerperal sterilization (PS) and 24 (29.27%) were concurrent with lower segment Caesarean section (LSCS), 7 (8.54%) women underwent laparoscopic tubal ligations (lap TL) and another 7 (8.54%) interval minilaprotomy (minilap TL) and remaining 6 (7.31%) underwent postabortal minilap TL.

Table-2: Clinicodemographic Profile of women with Sterilization Failure

Characteristic	Total No. 82	Percentage (%)
Age: (mean age -26years, range - 22 to 40 years)		
22-25 years	44	53.66
26-30 years	32	39.02
>30 years	6	7.32
Obstetric score (parity)		
Para-2	58	70.73
Para-3	20	24.39
Para-4	3	3.66
Para-5	1	1.22
Time to failure (Interval) failure (mean interval-23 months, range - 2 to 117 months)		
≤ 12 months (1 year)	10	12.2
13-24 months (1-2 years)	31	37.8
25-36 months (2-3 years)	20	24.39
37-48 months (3-4 years)	11	13.41
49-60 months (4-5 years)	3	3.66
More than 60 months (≥ 5 Years)	7	8.54

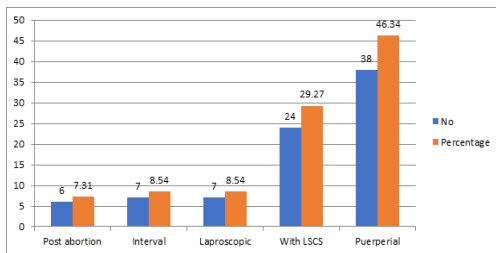


Figure-1. Methods of previous sterilization

Gestational age at diagnosis of sterilization failure: 19 (23.17%) women reported at or prior to 6 weeks, 48 (58.54%) presented between 6-12 weeks, 12 (14.63%) reported at 12-24 weeks and only 3 cases (3.65%) reported after 24 weeks (Figure-2).

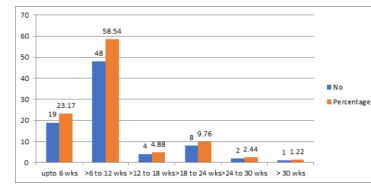


Figure-2: Gestational age at presentation after sterilization

Site of Pregnancy:

Out of 82 women, 65 (79.27%) were intrauterine pregnancy and 17 (20.73%) were ectopic pregnancies. Approximately 82% presented in ruptured state. Out of 17, 11 had right sided ectopic and 6 left sided ectopic (Figure-3)

Management of pregnancy due to failure: This is shown in Table-3 Gestational age ≤12 weeks Sixty-seven women (81.71%) who reported failure up to 12 weeks, 50 (74.63%) were intrauterine pregnancies, in that 41 cases (82%) underwent medical termination of pregnancy (MTP). Out of 41 women who underwent MTP, re sterilization was done with MTP in 33 and, only MTP was done in 7 and remaining one underwent MTP with Cu-T insertion. In remaining 9 women, where pregnancy continued till term, 4 of them delivered vaginally and 5 women underwent LSCS with re sterilization., Those who delivered vaginally in 3 underwent puerperal re sterilization and one was not willing for re sterilization. Of the 17 ectopic pregnancies 16 (94.11%) underwent surgical management (laparotomy/ laparoscopy) and only one woman (5.88%) was managed by medical treatment (Methotrexate).

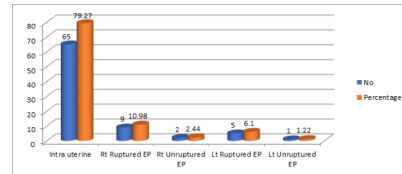


Figure-3: Site of pregnancy

Table-3: Management of pregnancy due to failure

Gestational age	Total number 82 (%)	Site of pregnancy	Outcome of pregnancy	Final management
≤12 Weeks	67 (81.71%)	Intrauterine 50(74.63%)	MTP 41 (82%)	MTP and re sterilization-33(80.49%) MTP only-7 (17.07%) MTP with Cu-T insertion-1(2.44%)
			Continued till term 9(18%)	LSCS with re sterilization-5(55.56%) SVD and re sterilization -3(33.33%) SVD only-1(11.11%)
		Ectopic pregnancy 17(25.37%)	Surgical treatment 16(94.11%)	Laprotomy/Laparoscopy and re sterilization
			Medical treatment 1(5.88%)	Inj. Methotrexate
12+1 to ≤20 Weeks	9 (10.98%)	Intrauterine pregnancy 9 (100%)	MTP 2(22.22%) Continued till term 7(77.78%)	MTP and re sterilization-2(100%) LSCS with re sterilization -4(57.14%) SVD and re sterilization -1(14.29%) SVD only-2(28.57%)
>20 weeks	6 (7.31%)	Intrauterine pregnancy 6(100%)	Continued till term 6 (100%)	LSCS with re sterilization-3(50%) SVD with re sterilization-3(50%)

Gestational age between 12 to 20 weeks: Among 9 women, 2 had second trimester MTP with re sterilization and 7 women continued pregnancy till term and 4 underwent LSCS with re sterilization. Remaining 3 women delivered vaginally and one underwent puerperal re sterilization and 2 were not willing.

In 6 women where pregnancy was more than 20 weeks, all of them pregnancy continued till term and 3 underwent LSCS and re sterilization and the remaining 3 delivered vaginally and underwent re sterilization in the immediate postnatal period

Table-4: Etiology of sterilization-failure

S No.	Etiology of failure	Total number (82)	Percentage
1.	Spontaneous Recanalization	41	50
2.	Tuboperitoneal fistula	24	29.27
3.	Improper ring placement	5	6.1
4.	Etiology could not be ascertained	12	14.63
a.	Not willing for surgery	7	8.54
b.	Unfit for surgery	5	6.09

Spontaneous recanalization was the cause in 41 (50%) women and in 17 recanalization occurred in right tube and in 22 in the left tube. Bilateral recanalization was documented in 2 women. Tuboperitoneal fistula was observed in 24 (29.27%) and improper falope ring placement in 5 (6.1%). Evaluation of cause for failure was not possible in 12 women (14.63%) as either they were unfit for surgery or did not give consent. Out of 17 women with ectopic pregnancy spontaneous recanalization was documented in 15 (88.23%) (Table-4). Methods performed during re sterilization and incidental findings are enumerated in Table-5. Out of 41 women of recanalization recorded, 25 underwent PS, 10 concurrent sterilization with LSCS, 3 interval minilap TL, 2 cases postabortal minilap TL and remaining one Lap TL. While in 24 women with tuboperitoneal fistula 11 underwent concurrent sterilization with LSCS, 7 underwent PS, 4 underwent postabortal minilap TL, one interval minilap TL and remaining one Lap TL. In 5 women, improper procedures were observed due to Lap TL.

Table-5: Methods of re sterilization and intra-operative findings

Methods of sterilization (Total No.-70)	Number of women
Right tubal partial salpingectomy and left side re sterilization	1

Right tubal total salpingectomy and left side resterilization	4
Left tubal total salpingectomy and right side resterilization	10
Laparoscopic bilateral tubal ligation (unruptured ectopic)	1
Postabortal resterilization	35
Postnatal resterilization	7
LSCS with resterilization	12
Improper laparoscopic procedure	
Right side falope ring was found near fimbrial end	1
Left side falope ring not visualised	3
Right side falope ring not visualised	1
Incidental findings	
Left tube adherent to round ligament	1
Adhesion between both tubes and ovaries	1
Left tube kinked and adherent	1
Right tube adherent with right ovary	1
Right tube hydrosalpinx	1

Analysis with respect to time to failure and etiology of failure: Sterilization failure interval ≤12 months: Among 10 women the sterilization failure occurred ≤ 12 months and the possible causes of failure in 3 (30%) of them was recanalization. One woman with ectopic pregnancy and spontaneous recanalization. Initial non-occlusion due to improper falope ring placement was responsible for failure in 2 women (20%). Failure occurred due to formation of tuboperitoneal fistula in two (20%) and in two women the cause could not be evaluated as they did not undergo sterilization.

Sterilization failure interval of 13-24 months:

Among 31 women the possible causes of failure were spontaneous recanalization in 11 (35.48%), formation of tuboperitoneal fistula in 8 (25.81%) and improper falope ring placement in one case (3.23%). Ectopic pregnancy was diagnosed in 5 (16.13%) women and in 4 of them were due to spontaneous recanalization and tuboperitoneal fistula in one. Evaluation was not possible in 6 cases as 3 were unfit for surgery and another three were not willing for reesterilization.

Sterilization failure interval 25-36 months: Among 20 women the possible causes of failure - recanalization in 5 (25%), formation of tuboperitoneal fistula in 6 (30%) and improper falope ring placement in one (5%). Recanalization was detected in 4 out of 5 women with ectopic pregnancy. Four women (20%) could not be evaluated as 3 were not willing for reesterilization and one woman with ectopic underwent medical management

Table 6. Relationship of sterilization failure with Time and site of Pregnancy

Interval of sterilization failure	Recanalization		Tuboperitoneal fistula		Improper falope ring placement		Cause could not be ascertained	
	IUP	EP	IUP	EP	IUP	EP	IUP	EP
≤ 12 months (N=10)	3	1	2	-	2	-	2	-
13-24 months (N=31)	11	4	8	1	1	-	6	-
25-36 months (N=20)	5	4	6	-	1	-	3	1
37- 48 months (N=11)	5	2	3	-	1	-	-	-
49-60 months (N=3)	1	-	2	-	-	-	-	-
≥ 60 months (N=7)	1	4	2	-	-	-	-	-

IUP= Intrauterine Pregnancy; EP= Ectopic Pregnancy

Sterilization-failure interval between 37- 48 months: Among 11 women 5 (45.5%), were due to spontaneous recanalization, 3 (27.27%)

tuboperitoneal fistula and one (9.09%) was due to improper falope ring placement. Recanalization was reported in 2 women ectopic pregnancy.

Sterilization-failure interval between 49 - 60 months: Among 3 women the possible causes of failure - recanalization in one (33.33%) and tuboperitoneal fistula in two (66.67%).

Sterilization-failure interval of more than 60 months: Among 7 women the possible causes of failure were spontaneous recanalization in 1 (14.28%) formation of tuboperitoneal fistula in 2 (28.57%). In four women (57.14%) with ectopic pregnancy recanalization was noted.

The longest documented sterilization-failure interval was 117 months following puerperal sterilization and she presented with left side chronic ectopic pregnancy while the shortest interval was 2 months and it was due to improper laparoscopic falope ring placement and she presented as intrauterine pregnancy.

DISCUSSION:

The overall failure rate in present study is around 0.58 % and 20% were ectopic pregnancies which is similar to the findings of Awonuga AO et al 2 who reported sterilization failure in 0.13-1.3% and ectopic pregnancy in 15-33% of them. Chances of failure is more in younger aged women as younger women are more fertile and have more fertile years remaining in life during which time pregnancy could occur. Almost 92% failures documented in less than 30 years of age in present study correlates with the US multicentric CREST (Collaborative Review of Sterilization) study³. In the present study 70% of women were Para-2 and a high parity of 5.5 was reported by Swende T Z and Hwande T S from Nigeria⁴.

Failure rate ≤ 12 months was 12%, between 1 and 5 years it was 79% and 9% at more than 5 years in the present study and this is similar to Lassner et al in the Brazil study⁵ and also Vessey et al in large UK prospective study⁶.

The longest failure interval was 23 years as documented by Huddleston H T and Dunnihoo DR⁷, while in the present study it was 117 months (around 10 years). Ectopic pregnancy within first year was 10%, between 1-5 years was 18.46% and 57.14% at more than 5 years. The study by Verma R and Gupta JK proposed that initial tubal non-occlusion is more likely to lead to early sterilization failure (within one year), and as it is less likely to damage the tube, the resulting pregnancy is more likely to be intrauterine than ectopic. Conversely, late sterilization failure (after one year) leads to spontaneous tubal recanalization or fistula formation and is more likely to result in an abnormal tubal lumen predisposing to increased risk of ectopic pregnancy⁸. Almost 88% of ectopic pregnancies in the present study were in women who underwent sterilization in conjunction with a pregnancy event such as during immediate postnatal period, concurrent with LSCS and postabortal period. Shah et al also observed high incidence of ectopic pregnancy (92.3%)⁹. The incidence of ectopic pregnancy after sterilization is higher when sterilization is performed during the postpartum period because the tubes are oedematous, friable and congested following pregnancy and this increases the chances of incomplete occlusion of the tubal lumen¹⁰. Chakravarti S and Shardlow J suggested that bilateral salpingectomy should be performed at the time of an exploration for an ectopic pregnancy, which has occurred after a sterilization procedure to avoid recurrent ectopic pregnancy¹¹.

In present study failure with minilap TL was more (62%), concurrent with LSCS 29% and only 9% with lap TL. S V Date et al also found 59% failure were due to minilap TL¹² however, no significant difference between the sterilization methods was found by Kulier et al¹³.

Of the 82% of women who reported pregnancy ≤ 12 weeks gestational age, 61% underwent MTP and 24% underwent laparotomy/ laparoscopy for ectopic and remaining 15% continued pregnancy till term. Those who reported beyond 12 weeks of pregnancy 87% continued pregnancy till term this is in contrast with the study by S V Date et al where 60% underwent 12. The main causes of sterilization failure were spontaneous tubal recanalization and cornual and tuboperitoneal fistula formation 2 In the present study also the most common cause for sterilization failure was spontaneous recanalization in 50% and in 29% it was tuboperitoneal fistula formation. The cause

could not be ascertained in 15% of women as they were not subjected to recanalization.

CONCLUSION:

The most common etiological factor for sterilization failure is spontaneous recanalization. The mean time interval for failure is 23 months. The pregnancy was intrauterine in 80% and ectopic in 20%. More than 80% reported in first trimester and 61% of them opted for MTP. Twenty-two (26.83%) of women continued pregnancy to term and over-all 70(85.37%) underwent resterilization along with MTP, after delivery and at the time of surgical management for ectopic pregnancy. These findings can be utilised for counselling of women prior to sterilization procedure regarding failure rates and regarding the chances of intrauterine and ectopic pregnancy when sterilization failure is suspected.

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