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Original Research Article

## Failed tubectomy procedures: a retrospective study

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### ABSTRACT

**Background:** It is difficult to understand the nature of factors leading to failure of sterilization from single institute. Knowing the factors, we can take preventive measures. Those data were of women who filed claims under Family Planning Indemnity Scheme, 2013 (revised 2016). The scheme was not reached at grassroots; therefore, not enough women got the benefit of this scheme. We gave the list of documents as well, which help medical fraternity working in rural area.

**Methods:** Retrospective study of 32 women of failed tubal ligation over a period of four years (from 2016 to 2019). The variables under consideration of study were, parity and age at the time of tubectomy. Time and method of tubectomy. Interval between tubectomy and subsequent pregnancy. Outcome of subsequent pregnancy and further contraceptive acceptance. Descriptive statistics used for frequency analysis.

**Results:** Median age of women was 26 years during tubal sterilization. Seventy two percent women were accepted sterilization on two children. Sixty nine percent of tubal sterilization were performed in puerperium; concurrent with caesarean section and medical termination of pregnancy, while 31% were during interval period. Thirty four percent of women became pregnant within 24 months(2years) of sterilization and cumulative 75% within 60 months (5 years) after sterilization. Sixty nine percent of women had intrauterine pregnancies and 31% ectopic pregnancies. Fifty six percent women accepted medical termination of pregnancy and 53% chosen repeat tubal sterilization. Four women (12%) gave live births. Two of them accepted repeat sterilization and another two intrauterine contraceptive devices. Thirty one percent women had ectopic pregnancy; nine of them came as ruptured ectopic, therefore, exploratory laparotomy with bilateral total salpingectomy were to be performed.

**Conclusions:** Failed tubal sterilization is common when it was performed at younger age and in puerperium. Missed period after sterilization should have high index of suspicion of ectopic pregnancy, which leads to severe maternal morbidity.

**Keywords:** Failed tubal sterilization, Failed tubectomy, Failed female sterilization, Ectopic pregnancy

### INTRODUCTION

Female sterilization is one of the most common methods of contraception than any other method. Worldwide, 219 million (23%) of women accepted tubectomy as a method of choice of contraception.<sup>1</sup> During the year 2017-2018, of

the 1.78 million of various contraceptive methods used in India, tubectomy as a method of contraception was chosen by 20% of the woman.<sup>2</sup> The field survey in rural area of South India, 81% of women opted for tubectomy as a method of contraception.<sup>3</sup> India is the first country in the world to launch National Family Planning Program in 1952.

Although the tubectomy is highly effective, it has a failure rate of 2 per 200 procedures after any time of procedure.<sup>4</sup> However, it can vary from 0.5% to 3 per/ 1000 procedures within a year of procedure.<sup>5,6</sup> The other authors reported failure rate of 6/495 procedures within 24 months of tubectomy in rural India.<sup>7</sup> The failure rate of tubectomy by laparoscopy found to be 0.54% over a period of four years.<sup>8</sup> The high failure rate of tubectomy was observed, when those procedures were performed in primary health centres in India.<sup>9</sup>

The risk tubectomy failure depends on the age at the time of procedure and method of tubectomy. Younger age ( $\leq 28$  years) at the time of tubectomy has higher risk of failure.<sup>5,10</sup> The risk of ectopic pregnancy varied from 10% to 21% after failed tubectomy. Live births were also reported in subsequent pregnancy after failed tubectomy.<sup>9,11</sup>

Most of the women accept repeat sterilization and few Intrauterine contraceptive devices (IUCD) as a further method of contraception.

Our objectives were to know, whether, time of tubectomy and time since tubectomy has any effect on failure rate. We intended to know obstetric outcome of failed tubectomy and any human errors at the time of procedure as well.

## METHODS

It was a retrospective study of 32 cases of failed tubectomy, over a period of four years from 2016 to 2019. The data were obtained from the Office of the Executive Health Officer (EHO), Public Health, Municipal corporation of Greater Mumbai (MCGM).

### Inclusion criteria

Failed tubectomy cases whose claim files available during those periods only. The cases were from Mumbai District. From any hospital in MCGM area.

### Exclusion criteria

Since we did not have data of failed tubectomies before 2016; therefore, those cases were excluded from the study.

All the relevant information for study purpose was retrieved from, claim files, certificates of tubectomy, tubectomy consent forms, discharge cards of previous tubectomy, obstetric ultrasonography of current pregnancy, and further interventions on subsequent pregnancy.

Data were also obtained from repeat tubectomy consent forms, tubectomy certificates and operative notes (xerox).

To determine the approximate age at the time of tubectomy, we noted year of birth as on Aadhar card. Age and year of tubectomy on sterilization certificates and

consent forms. We applied the rounding technique to simplify determination of age the time of tubectomy. Sixth month was considered as a centre point. Sixth or less than sixth month, we considered lower age and above that the upper age.

The variables used for study purpose were, number of living children, age and gender of last child at the time of tubectomy. Time and method of tubectomy. Interval between tubectomy and subsequent pregnancy. The outcome of failed tubectomy and further acceptance of any contraceptive method.

For every failed case of female or male sterilization procedure, there is a provision of monetary compensation as per the terms and conditions of Family Planning Indemnity Scheme 2013 (revised in 2016) of Ministry of Health and Family Welfare, Government of India. The office of the EHO, does processing of settlement of claims.

### Statistical analysis

The descriptive statistics used to analyse frequency and percent of variables using Statistical Package for Social Sciences (SPSS) software, version 21, (IBM, USA).

## RESULTS

Claims of failed tubectomy procedure of 32 women were available from 2016 to 2019 for study. Seventy two percent women (n=23) had two living children and 28% (=9) were having three or more living children at the time of tubectomy. Fifty nine percent (n=19) and 41% (n=9) women accepted tubectomy when their last child was male and female respectively. Median age of women was 26 years at the time of tubectomy procedure.

**Table 1: Time and method of tubectomy procedure.**

Time and method	Frequency (percentage)
<b>Puerperal</b>	22 (68.75)
Concurrent with caesarean deliver	8 (25.0)
Postpartum (mini laparotomy)	8 (25.0)
Concurrent with MTP*	6 (18.75)
<b>Interval</b>	10 (31.25)
Mini laparotomy	5
Laparoscopy	5
<b>Total</b>	32 (100.0)

\*MTP=Medical termination of pregnancy

Table 1 shows the, time and method of tubectomy procedure. Of the 32 women, 22(69%) accepted tubectomy in puerperium and 31% (n=10) during interval period. About 44% (n=14) women accepted tubectomy concurrent with caesarean delivery and MTP. Five women opted laparoscopic tubectomy and one of those chosen concurrent with medical termination of pregnancy (MTP). Thirteen (46.6%) women preferred mini-laparotomy; eight

of those were in post-partum and other five during interval period.

Table 2 shows that, about 34% (n=11) women became pregnant within 24 months and 41% (n=13) within 25 to 60 months of tubectomy procedure. Twenty five percent (n=8) women reported pregnancy more than 60 months after tubectomy. Cumulative 75% (24 of 32) women reported pregnancy within 60 months of tubectomy procedure.

**Table 2: Interval between tubectomy and subsequent pregnancy.**

Interval	Frequency	Percent
<b>Within 24 months</b>	11	34.4
<b>25 to 60 months</b>	13	40.6
<b>61 months and above</b>	8	25.0
<b>Total</b>	32	100

**Table 3: Outcome of subsequent pregnancies after failed tubectomy.**

Outcome	Frequency	Percentage
<b>Intrauterine pregnancy leading to</b>	22	68.75
Abortion	18 (56.25)	
Live birth	4 (12.50)	
<b>Ectopic pregnancy</b>	10	31.25
<b>Total</b>	32	100

The median interval between tubectomy and subsequent pregnancy was 43 months for intrauterine pregnancy and 61 months for ectopic pregnancy.

Table 3 shows obstetric outcome after failed tubectomy. About 69% (n=22) of subsequent pregnancies were intrauterine and 31% (n=10) were ectopic pregnancies. There were four (12.5%) live births.

Of the 22 (69%) women who had intrauterine pregnancy; 56% (n=18) of them chosen medical termination of pregnancy (MTP). Sixteen women out of 18, accepted MTP with repeat tubectomy as method of further contraception. However, remaining two women, one accepted IUCD and second one interval tubectomy. Of the four women who gave live birth after failed tubectomy; two of them accepted repeat sterilization and the other two intrauterine contraceptive device (IUCD) as further contraceptives. Nine women had ruptured ectopic pregnancies; therefore, exploratory laparotomy with bilateral total salpingectomy was performed. One of the ten women had unruptured ectopic pregnancy, she had laparoscopic bilateral total salpingectomy.

## DISCUSSION

We had 32 women of failed tubectomy in our study. Seventy two percent of them had two living children at the

time of tubectomy; almost same percent of women accepted tubal ligation on two children in other study.<sup>10</sup> However, in another series, 16% of women opted tubectomy on two living children.<sup>12</sup>

The cumulative failure rate of tubal ligation was 7.5/1000 procedures over a period of 10 years<sup>5</sup> and 5.4/1000 procedures of laparoscopy over a period of four years.<sup>8</sup> The under reporting of tubectomy failure is not uncommon in India; even though, the Govt. of India has Family Planning Indemnity Scheme, 2013 (Revised 2016) in place.

The median age of the women was 26 years at the time tubectomy in our study. The other authors also found the younger age i.e., ≤28 years at the time of tubectomy.<sup>5,10</sup> The failure rate was also seen high in age group of 26-30 years at the time of tubectomy.<sup>10</sup>

In other studies, reported failed tubectomy in 78% of women in the age group of 20-30 years.<sup>12-14</sup> In those studies, the age group was large. Therefore, the median age at tubectomy became difficult to determine. Young age at the time of tubectomy was one of the risk factors for failure of tubal ligation.

In our study, about 69% of women chosen to tubal sterilization during puerperium. It seems, most of the women, 53% to 68% preferred tubal ligation in postpartum period.<sup>12,14</sup> However, in other study only 24% women had tubal ligation in postpartum period.<sup>13</sup>

Thirty one percent of women accepted tubectomy during interval period in our study. While other series, 24% of women preferred mini-laparotomy and 23% laparoscopy as a method of tubal ligation.<sup>14</sup> Laparoscopic tubectomy failure was 36.5/1000 procures after clip application.<sup>5</sup> In our study of failed sterilization, about 16% of women chosen laparoscopic band application for tubal ligation.

In current study, about 34% of women became pregnant within 24 months (2 years) of tubectomy procedure. Women could become pregnant even within 12 months of tubal ligation.<sup>14</sup> We observed that, 46% of women reported pregnancy within 24-60 months (2-5 years) of tubal sterilization. In other series, 57% to 71% of women became pregnant within 2-5 years of tubectomy.<sup>12,14</sup> Five women became pregnant after 60 months (5 years) and one woman after 120 months (10 years) of sterilization. In our study, 25% women had pregnancy after 60 months (>5 years) of tubal ligation and one of the women reported pregnancy after 10 years of tubal ligation. The longest interval between of tubal ligation and subsequent pregnancy was 20 years.<sup>14</sup>

In our study, about 69% of subsequent pregnancies were intrauterine, leading to induced abortion in 56% of them. Other reports 29% to 36% of intrauterine pregnancies and 29% had abortive outcome.<sup>8,13</sup> There were 31% ectopic pregnancies in our study. There was a wide variation of

15% to 90% of subsequent pregnancies being ectopic pregnancies.<sup>8,12,13</sup>

The percentage of live births varied from 27% to 40% in subsequent pregnancies<sup>8,9</sup>. Our study 12% of women gave live births. However, other researchers did not make any reference to live births in subsequent intrauterine pregnancies.<sup>8,12,13</sup>

We observed, 15% of women became pregnant due to erroneous technique of tubal ligation, another report too found in 9% of cases.<sup>14</sup>

### Limitations of the study

This study was of cases whose claim files were available. The actual number may be more, since few may not have filed the claims for compensation. Most of the hospitals may not even report due to fear of litigations. Lack of awareness of this scheme in general population and in health care providers as well. Therefore, it would be wise not to generalize the conclusions of this study. However, it does provide the window of opportunity to prevent human errors.

### CONCLUSION

Young age and tubectomy procedure performed during postpartum period either concurrent with cesarean delivery or with MTP are risk factors for failed tubectomy. There was short interval between sterilization and subsequent pregnancy. Whenever, a woman comes with missed period after sterilization, ectopic pregnancy should be ruled out; because, earlier the location of pregnancy (intrauterine or extrauterine) better the maternal outcome. For intrauterine pregnancy, it is the choice of woman either to continue or terminate the pregnancy. Those who choose to terminate the pregnancy, MTP services should be provided.

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