



A Study on the Prevalence and Determinants of Female Sterilisation Failure in A Tertiary Health Care Centre in Thiruvananthapuram, Kerala

Dr.Haseena Hassan

Dept-of Obstetrics and Gynaecology SAT Hospital ; Govt- medical college, Trivandrum ,Kerala

DrThaj M

Dept - of Obstetrics and Gynaecology Travancore medical college,Thattamala ,Kollam, Kerala

ABSTRACT

The study on female sterilisation failure was conducted in SAT Hospital, Medical College, Thiruvananthapuram, Kerala during a period of 16 months from March 2008 to July 2009, as a cross-sectional study. The study population consists of 86 consecutive female sterilisation failure cases admitted in the above period and the data was collected by interview method with a pre-tested questionnaire.

KEYWORDS

INTRODUCTION

Female sterilisation is the most popular method of permanent contraception all over the world.^[1] In India, it is widely implemented in National Family Welfare Programme. Current statistics reveal that in the year 2000-2001, 4.74 million women underwent tubal sterilisation all over India.^[2] It accounts for about 84% of prevalence among married couples using modern methods of contraception.^[3] The advantages of female sterilisation over the other contraceptive methods are that it is a one time method, which does not require sustained motivation of the user for its effectiveness, there by providing the most effective protection against pregnancy. But still an uncertainty prevails regarding the success of female sterilisations because some of these cases may present with pregnancy within a period of few months to several years of sterilisation, either as intrauterine or as ectopic pregnancy. Our hospital being a tertiary level health care referral centre, where a lot of female sterilisation failure cases are being referred from periphery. **Sterilisation failure** may occur due to either technical defect in the surgical procedure or spontaneous recanalisation. Tubal lumen regeneration occurs by two possible mechanisms.^[60]

- [1] **Tuboperitoneal fistula formation**, which may be associated with endosalpingitis, necrosis or tubal atrophy.^[60]
 [2] **Spontaneous tubal reapproximation** associated with tubal reanastomosis and Recanalisation.^[60]
 [3] **Mechanical failure of occlusion device**.^[60] There remains a least theoretical possibility for failure of sterilisation following breakage of ring/ clip, due to poor quality of supply.

MATERIALS AND METHOD

Cross-sectional study was conducted in Department of Obstetrics and Gynaecology, SAT Hospital, Medical College, Thiruvananthapuram. SAT Hospital is a tertiary care referral health centre and a teaching institute situated in Thiruvananthapuram, Kerala during March 2008 to July 2009. The number of cases that were reported during the above period were 86.

Definition

Sterilisation failure case is defined as a case in which pregnancy occurs after an event of sterilisation either intrauterine or ectopic pregnancy.

Study Variables

- [1] Prevalence of female sterilisation failure in SAT Hospital.
 [2] Type of sterilisation failure- intrauterine/ ectopic pregnancy

- [3] Age, parity, residence of the patient
 [4] Sterilisation details regarding age at tubal ligation, place of tubal ligation, person conducting tubal ligation, method of tubal ligation, timing of tubal ligation, missed pregnancy at the time of tubal ligation and post tubal ligation to failure interval.
 [5] Post tubal ligation to failure interval [defined as time interval between tubal ligation and failure event] was assessed. For the study purpose, post tubal ligation failure interval was graded as less than one year, 1-5 years and more than 5 years [Punam et al. study published in Bombay Hospital Journal, 2002].^[25]
 [6] Clinical presentations of sterilisation failure cases identified.
 [7] Details regarding outcome of ectopic pregnancy. Surgical management includes laparotomy for ruptured ectopic and laparoscopy for unruptured and stable ectopic patients.
 [8] Details regarding outcome of intrauterine pregnancy.
 [10] History of abdominal surgeries like LSCS whether done before or with tubal ligation and history of recent or present history of PID and other gynaecological pathologies.
 [11] Details of the surgical procedures including the intraoperative findings were collected. Surgery helped to identify and ligate the source of intraperitoneal bleeding in the case of ruptured ectopic and also to detect other pathologies like reanastomosis, intraperitoneal adhesions, neofimbriae, uteroperitoneal fistula, hydrosalpinx, fibroid and endometriosis which probably had lead to female sterilisation failure.

Exclusion Criteria

- [1] Patients with history of one sided tubal ligation surgeries or the failures due to temporary family planning contraceptive measures were excluded from the study.
 [2] Missed pregnancy at the time of sterilisation were also excluded.

Ethical Considerations

The study was started after getting ethical clearance and informed consent from the patients

Data Analysis

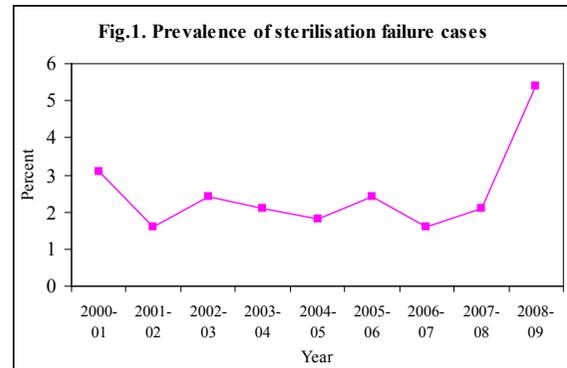
Data were analysed using computer software SPSS version-13.

OBSERVATION AND RESULTS

Table 1 shows the distribution of female sterilisation failure cases and its prevalence in SAT Hospital from 2000 to 2008.

Table 1. Distribution and prevalence of female sterilisation failure cases [2000-2008]

Year	No. of sterilization failure cases	Total number of sterilisations	Prevalence [%]
2000 - 01	68	2228	3.1
2001 - 02	42	2588	1.6
2002 - 03	50	2068	2.4
2003 - 04	42	1967	2.1
2004 - 05	40	2126	1.8
2005 - 06	47	1889	2.4
2006 - 07	28	1662	1.6
2007 - 08	35	1693	2.1
2008 - 09	74	1376	5.4



Source: Hospital statistical records

The prevalence of female sterilisation failure in SAT Hospital in 2008 was 5.4 % compared to 2.1 % in 2007

Table 2. Distribution of female sterilisation failure cases with respect to the site of pregnancy

Category	Frequency	Percent
Intra uterine pregnancy	20	23.3
Extra uterine pregnancy	66	76.7
Total	86	100

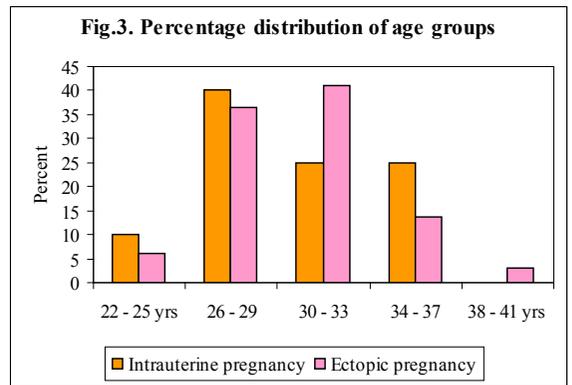
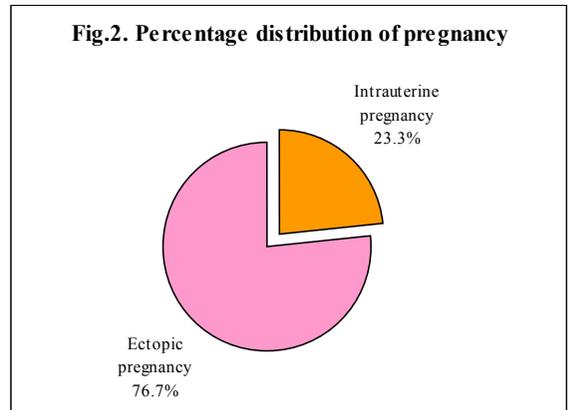


Table 3. Distribution of residence in the study group

Residence	Intrauterine Pregnancy		Ectopic Pregnancy		Total	
	Fre-quency	Percent	Fre-quency	Per-cent	Fre-quency	Per-cent
Rural	16	80.0	47	71.2	63	73.3
Urban	4	20.0	19	28.8	23	26.7
Total	20	100	66	100	86	100

Table 4. Distribution of parity

Parity	Intrauterine pregnancy		Ectopic pregnancy		Total		Signifi-cance
	Fre-quency	Per-cent	Fre-quency	Per-cent	Fre-quency	Per-cent	
2	16	80.0	64	97.0	80	93.0	P >0.05
3+	04	20.0	02	3.0	06	07.0	P >0.05
Total	20	100	66	100	86	100	

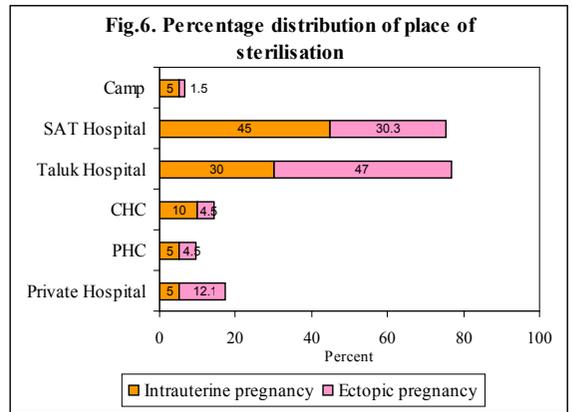
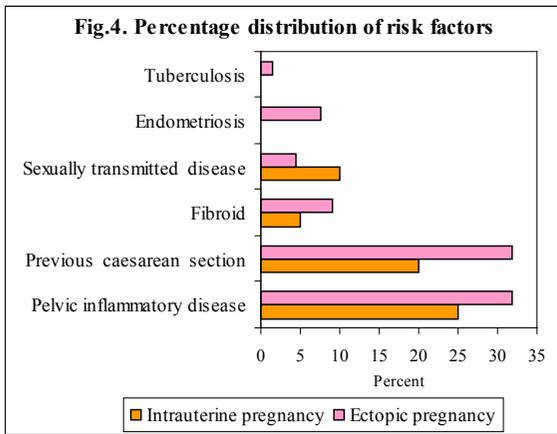


Table 5. Intraoperative findings in the study group

Intraoperative findings	Intrauterine pregnancy n=7		Ectopic pregnancy n=66		Total n=73		Significance
	Frequency	Percent	Frequency	Percent	Frequency	Percent	
Reanastomosis	1	14.3	14	21.2	15	20.5	P >0.05
Adhesions	0	0	6	9.1	6	8.2	P <0.05
Neofimbriae	1	14.3	0	0	1	1.4	P >0.05
Fistula	1	14.3	0	0	1	1.4	P >0.05
Hydro-salpinx	0	0	1	1.5	1	1.4	P >0.05
Altered Anatomy [Ruptured ectopic]	0	0	45	68.2	45	61.6	P <0.05

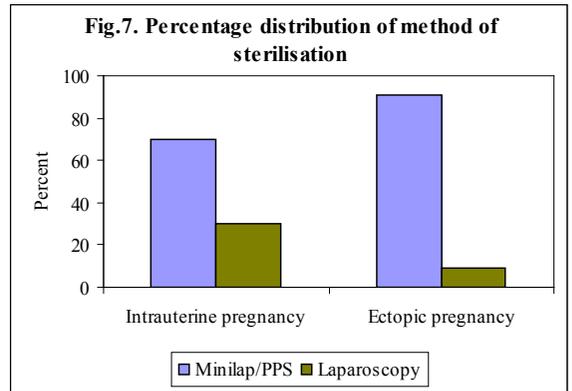
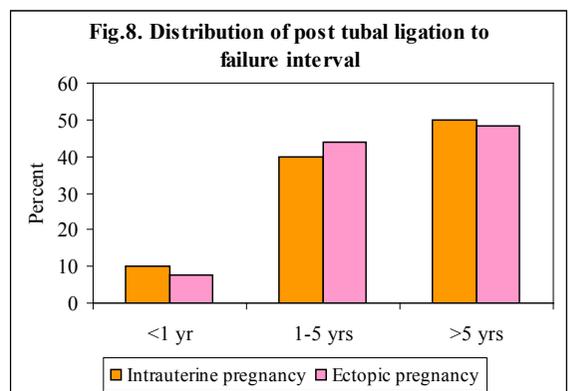
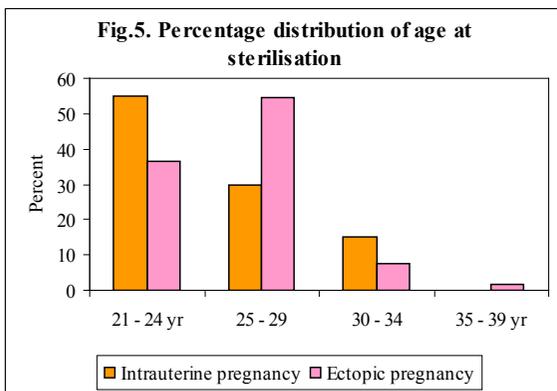


Table 6. Distribution of post tubal ligation to failure interval in the study group

Category	Intrauterine pregnancy		Ectopic pregnancy		Total		Significance
	Frequency	Percent	Frequency	Percent	Frequency	Percent	
<1 yr	2	10.0	5	7.5	7	8.1	P >0.05
1-5 yrs	8	40.0	29	44.0	37	42.9	P >0.05
>5 yrs	10	50.0	32	48.5	42	49.0	P >0.05
Total	20	100	66	100	86	100	



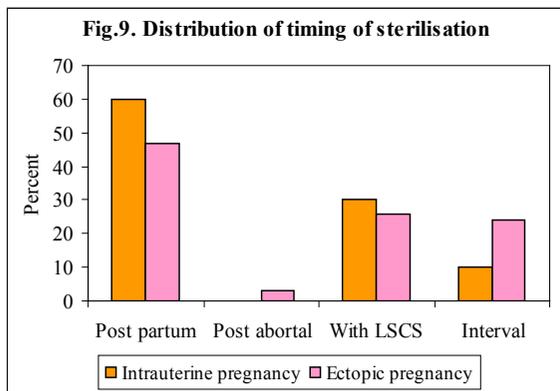


Table 7 .Distribution of clinical features in the study group

Clinical Features	Frequency	Percent
Amenorrhoea	86	100.0
Bleeding p/v	21	24.4
Abdominal pain	76	88.4
Nausea/ Vomiting	41	47.7
Fainting	13	15.1
Pallor	61	70.9

Table 8. Distribution of site of ectopic pregnancy

Category	Right n=46		Left n=20		Total n=66	
	Fre-quency	Per-cent	Fre-quency	Per-cent	Fre-quency	Per-cent
Ampullary	28	60.9	9	45.0	37	56.1
Isthmial	4	8.7	1	5.0	5	7.6
Fimbrial	13	28.2	9	45.0	22	33.3
Cornual	1	2.1	1	5.0	2	3.0

Table 9. Distribution of outcome of intrauterine pregnancy

Category	Frequency n=20	Percent
Continuing pregnancy	9	45.0
MTP + Laparotomicresterilisation	6	30.0
MTP + Laparoscopic resterilisation	1	5.0
Other methods	4	20.0

Table 10. Distribution of cases in which reesterilisation done

Resterilisation	Intrauterine pregnancy		Ectopic pregnancy		Total	
	Fre-quency	Per-cent	Fre-quency	Per-cent	Fre-quency	Per-cent
Yes	7	35.0	66	100	73	84.9
No (Other Methods)	13	65.0	0	0	13	15.1
Total	20	100	66	100	86	100

DISCUSSION AND CONCLUSION

Distribution of Prevalence of Female Sterilisation Failures [2000-2008]

As per the study, during the financial year of 2008-2009, the prevalence was found to be 5.4 %. The year wise trend shows that a sharp rise in the prevalence since 2006. This may be due to the fact that SAT Hospital is a tertiary care referral centre, where many female sterilisation failure cases are referred. It includes both intrauterine and ectopic pregnancies.

Ectopic pregnancies were high (76.7 %) when compared to intrauterine pregnancies (23.3 %). US Collaborative Review of Female Sterilisation Failure Working Group (CREST) study states that the ectopic pregnancies following sterilisation were 33.0 %. There is high morbidity and rare mortality associated with ectopic pregnancies. So early diagnosis and management were absolutely essential, due to which the cases were referred to the higher tertiary level health care centres.

74.4 % of the cases were reported in the age group of 26-33 years. Intrauterine pregnancies were more in the age group of 26-29 years (40.0 %) and ectopic pregnancies were more in the age group of 30-33 years (40.9 %).

Out of the 20 intrauterine pregnancies, 80 % from rural areas and remaining 20 % from urban areas 30.2 % of the cases gave the history of Pelvic inflammatory diseases [PID] and 29.1 % of the cases with previous LSCS. Out of the 20 intrauterine pregnancies there were 5 cases with history of PID and 4 cases with history of prior caesarean sections. Of the 66 ectopic pregnancies, cases with history of PID and previous caesarean section were equally shared (21 cases each). Out of the total sterilisation failures, endometriosis was present in 5 cases of which all were ectopic pregnancies. There was statistically significant association between endometriosis and site of pregnancy in failure [P <0.05].

Laparotomy was done in 73 cases of which 66 cases were ectopic pregnancies and 7 cases of intrauterine pregnancies, where reesterilisation was done following termination of pregnancy. The exact mechanism of failure could not be identified in 45 cases of ectopic pregnancies, as the anatomy was totally distorted. Reanastomosis was identified in 15 cases [20.5 %], of which one case was in intrauterine pregnancy and the remaining 14 were ectopic pregnancies. As per the Punam et al. study,[25] reanastomosis was detected in 49.12 % of the total failures. Adhesions were present in 6.0 % of cases. There was significant association between adhesions and site of pregnancy in failure (P <0.05). Neo-fimbriae, tubop-eritoneal fistula and hydrosalpinx were detected in one case each. There were no cases with slipped band, band on round ligament or missed pregnancy.

In 55 % intrauterine pregnancies, sterilisation was done in the age group of 20-24 year, whereas in ectopic pregnancies

(54.5 %) it was done in the 25-29 years age group.

As per the study, Taluk hospitals had a higher percentage of failures (43.0 %), followed by SAT Hospital (33.7 %).

93 % of tubal ligations were done by Gynaecologists and the remaining 7 % by MBBS doctors This study shows that PPS was done in 86 % of cases and laparoscopy in the remaining 14 %.

In 91.9 % of the failure cases, Tubal-Ligation to Failure Interval was above one year and only 8.1 % in below one year. 49 % of cases were reported after 5 years of sterilization.

50 % of the failure cases reported were following post partum sterilisation, 26.7 % after sterilisation with LSCS, 20.9 % were with interval sterilisations and 2.3 % were following sterilisations with abortions.

100% of the cases gave a history of amenorrhoea. In 24.4 % cases, amenorrhoea was followed by bleeding per vaginum. Abdominal pain was present in 88.4 % of patients.

56.1 % [37 cases] of ectopic pregnancies were in the ampullary portion of the fallopian tube, followed by 22 cases [33.3 %] in the fimbrial portion.

Out of the 20 intrauterine pregnancies, 9 patients opted to continue pregnancy.

Resterilisation was done in 84.9 % of cases [which included all the 66 cases of ectopic pregnancies and 7 cases of intrauterine pregnancies].

This study shows that in spite of failures, tubal sterilisation plays an important role in maternal health and in controlling population explosion world wide.

SUGGESTIONS

1. Adequate counselling regarding the surgery and its complications prior to sterilisation.
2. Documentation has to be done irrespective of the hospitals, where it is done. It should also include intraoperative findings like any difficulty in identifying the fallopian tubes, slipped band, migrated band or occlusion of round ligament.

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