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Original Research Article

Complications of Female Sterilization: A Hospital-Based Retrospective Study

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Abstract:

Background: Female sterilization is a widely adopted permanent contraceptive method, especially in developing countries, but it is not entirely free from complications. Systematic evaluation of these complications is essential to ensure safety and quality of family planning services.

Aim: To assess the pattern, management, and outcomes of complications following female sterilization procedures.

Methodology: A retrospective observational study was conducted at Department of Community Medicine, Bhagwan Mahavir Institute of Medical Sciences, (BMIMS), Pawapuri, Nalanda, Bihar, India, involving 80 women who developed perioperative or immediate postoperative complications after puerperal or interval sterilization. Data were collected from hospital records and analyzed using descriptive statistics.

Results: Most affected women were aged 25–34 years, multiparous, from rural areas, and had low educational status. Puerperal sterilization accounted for 65% of cases. The commonest complications were hemorrhage (30%) and surgical site infection (25%). Nearly half of the cases were managed conservatively, while 35% required surgical intervention. Overall recovery was noted in 95% of participants.

Conclusion: Female sterilization is generally safe, but preventable complications persist. Strengthening preoperative assessment, surgical skills, aseptic practices, and postoperative monitoring can further improve outcomes.

Keywords: Female Sterilization, Complications, Retrospective Study, Tubectomy, Family Planning.

Introduction

Worldwide, female sterilization is the most widely used method of permanent contraception and has been the backbone of family planning programs in several nations, especially in low- and middle-income countries [1]. The procedure is irreversible and is used by women who have completed their family and want a reliable long-term method of contraception. Tubal ligation, tubectomy, and laparoscopic or minilaparotomy are the procedures chosen mainly because they are highly effective, relatively simple, and cost-efficient. In India, female sterilization constitutes a large part of contraceptive methods, indicating not only programmatic focus but also social acceptance [2]. However, female sterilization is not without risks despite its popularity and general safety profile, and so systematic evaluation of its outcomes becomes an important and challenging area of clinical and public health research.

Female sterilization complications vary considerably, from minor self-limiting cases to severe and even life-threatening conditions. Cases of immediate complications might include bleeding, infection, adverse effects related to anesthesia, visceral injury, and postoperative pain, whereas the late complications could show up as menstrual irregularities, chronic pelvic discomfort, failure of sterilization, ectopic pregnancy, or psychological manifestations. Progress in surgical techniques, better aseptic practices, and improved perioperative care have resulted in a significant decline in adverse outcomes; nevertheless, complications are still being reported, especially in backward medical facilities [3]. Inadequate

preoperative evaluation limited surgical skill, poor medical facility condition, and large number of patients all are the factors that may allow the complications to persist.

The aftermath of female sterilization complications is a significant factor that not only affects the health of the individual but also has wider implications [4]. Unfavorable results can easily make the community lose their trust in the family planning services in the first place, provide a negative impact on contraceptive acceptance, and raise legal and ethical concerns for the healthcare systems. Furthermore, these complications sometimes necessitate additional medical or surgical intervention, which complicates the matter by increasing healthcare costs and resources use at the same time. For patients, the unforeseen postoperative morbidity could lead to longer recovery periods, the inability to work, emotional trauma, and diminished life quality. That is why the comprehension of the nature, frequency, and determinants of complications is a prerequisite for the improvement of service delivery and the assurance of patient safety.

Retrospective studies allow the evaluation of complications related to female sterilization in a valuable way by the use of existing medical records and institutional data over the period defined [5]. They make it possible to measure real-world results for different populations and clinical environments, giving information about complication patterns, time trends, and risk factor associations. Prospective studies, on the other hand, are more expensive than retrospective and they allow the recruitment of larger sample sizes which translates into stronger statistical power. Retrospective studies also allow the identification of complications that are very rare but serious and which may be missed in smaller or short-term studies.

Various factors have been noted to affect the likelihood of complications after female sterilization. Such factors include those related to the patient, including age, number of children, nutrition, other illnesses, and past surgeries in the abdomen, as well as those concerning the procedure, such as sterilization timing (postpartum vs. interval), surgical method, anesthesia type, and surgeon's skill. Also, hospital factors, such as compliance with standard operating procedures, presence of trained staff, and good postoperative follow-up, are of paramount importance [6]. Past evaluations are a way of spotting the determinants and amplifying the areas which are in need of intervention.

In India, women's sterilization has been a major method for controlling population for a long time, and it is mostly done through fixed facilities and outreach camps [7]. The concerns regarding safety and quality that have come up in high-volume settings, still remain despite the policy reforms and quality assurance measures that have improved the standards of care. It is, therefore, necessary to periodically evaluate sterilization outcomes in order to monitor the performance of the program and to make sure that it is in line with the national guidelines and ethical standards [8]. Retrospective analyses conducted in tertiary care centers or district hospitals can be a source of important evidence to guide policy and practice.

Additionally, the medico-legal matters linked to the failures and complications of female sterilizations are becoming a more prominent topic. Cases of unwanted pregnancies, ectopic pregnancies, or morbidity arising from the procedure may lead to lawsuits and demands for payment, which brings the essentiality of detailed record keeping and outcome evaluation to light. In addition to providing an approximation of the event's magnitude, retrospective studies can also point out the areas of poor care that should be improved through training, adjusting protocols, and doing better at the system level.

A retrospective study of complications associated with female sterilization is thereby put forth as a very significant study. The key goal of the study is to get a clear picture of the complication's types and occurrence rates by performing a thorough analysis of previous records, detecting factors that are likely to cause complications, and rating the overall safety of sterilization procedures in the particular healthcare institution. The results can be highly beneficial for practice changes based on evidence, better patient counseling and informed consent processes, and development of strategies to avoid negative outcomes. In the long run, analyzing complications through retrospective studies is indispensable for bolstering family planning services and protecting women's reproductive health.

Methodology

Study Design: The present study was conducted as a retrospective observational study aimed at assessing complications associated with female sterilization procedures. The retrospective design was chosen to analyze previously recorded clinical data over a defined period, enabling evaluation of perioperative complications, management patterns, and outcomes without direct patient contact. This approach allowed for comprehensive assessment of institutional trends and complication profiles related to female sterilization procedures.

Study Area: The study was carried out in the Department of Community Medicine, in collaboration with the Department of Obstetrics and Gynecology, Bhagwan Mahavir Institute of Medical Sciences (BMIMS), Pawapuri, Nalanda, Bihar, India for March 2025 to August 2025

Study Participants: The study participants consisted of women who underwent female sterilization procedures and subsequently developed

complications that were reported or referred to the concerned departments during the study period.

Inclusion Criteria

- Women who underwent puerperal or interval female sterilization procedures
- Cases presenting with perioperative complications, occurring during surgery or in the immediate postoperative period
- Patients whose complete medical records were available in hospital archives
- Cases managed at BMIMS during the defined study period

Exclusion Criteria

- Long-term complications such as tubectomy failure, ectopic pregnancy, or post-ligation syndrome
- Sterilization procedures performed along with medical termination of pregnancy (MTP)
- Sterilization procedures conducted during caesarean section
- Records with incomplete or missing essential clinical details

Sample Size: A total of 80 cases of female sterilization complications fulfilling the inclusion criteria were included in the study. All eligible cases available during the study period were considered to avoid selection bias.

Procedure: Data for the study were obtained through a retrospective review of hospital case records and registers which were kept in the Department of Obstetrics and Gynecology and Medical Records Section of BMIMS. Since the study was about secondary data analysis without revealing patient identity, there was no need for informed consent to be obtained.

The pertinent information that was taken out from the records consisted of demographic characteristics, time and type of sterilization, location of the procedure, sterilization method, and kinds of complications seen. Complications were classified according to intraoperative and immediate postoperative events like bleeding, infection, damage to internal organs, complications with anesthesia, and other surgical morbidities. Information about the referral status, the time between the operation and the presentation, and the way the complications were detected were also recorded.

Management details were noted down and included conservative treatment, surgical intervention, need for blood transfusion, and if necessary, intensive care support. Morbidity was judged on the basis of hospital stay, need for medical or surgical procedures, and overall condition of the patient. Outcomes were documented for the purpose of assessing the burden and severity of complications related to female sterilization.

Statistical Analysis: The collected data were entered into Microsoft Excel and subsequently analyzed using Statistical Package for Social Sciences (SPSS) version 27.0. Descriptive statistics were used to summarize the data. Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as mean and standard deviation where applicable. Tables and charts were used for appropriate data presentation. Statistical analysis focused on identifying the distribution and pattern of sterilization complications and associated morbidity. A p-value of <0.05 was considered statistically significant wherever applicable.

Result

The table number 1 depicts socio-demographic characteristics for 80 participants included in the study. The participants' age distribution was as follows: the largest group, that of 25-34 years old (57.5%), next was the one aged 35 years or older (27.5%), and finally the group of people younger than 25 years which represented only 15%. Most of the participants lived in the countryside (72.5%), while the rest of them were from cities (27.5%). As for their number of children, 77.5% had three or more while the remaining 22.5% had two or fewer. The educational status of the participants varied from primary education in 42.5% of them, literacy in 32.5%, and the remaining 25% with secondary education or higher, which points to a considerable part of the population with low to moderate educational levels.

Table 1: Socio-demographic characteristics of study participants (n = 80)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	<25	12	15
	25–34	46	57.5
	≥35	22	27.5
Residence	Rural	58	72.5
	Urban	22	27.5
Parity	≤2	18	22.5
	≥3	62	77.5
Educational status	Illiterate	26	32.5
	Primary	34	42.5
	Secondary & above	20	25

Table 2 reveals that out of the 80 female sterilization operations, puerperal sterilizations represented the largest proportion with 65%, while the interval procedures were 35%, which shows that there is a higher preference for sterilization in the puerperal period. In terms of timing of complications, postoperative period was mostly (57.5%) followed by intraoperative period (42.5%), which means that postoperative monitoring is very crucial. Procedure place indicated that government hospitals conducted the majority of sterilization procedures (77.5%), while private hospitals performed a small number of cases (22.5%), which demonstrates that the study population made a greater use of public health services for female sterilization.

Table 2: Type and timing of female sterilization procedures (n = 80)

Variable	Category	Frequency (n)	Percentage (%)
Type of sterilization	Puerperal	52	65
	Interval	28	35
Timing of complication	Intraoperative	34	42.5
	Immediate postoperative	46	57.5
Place of procedure	Government facility	62	77.5
	Private facility	18	22.5

The data presented in Table 3 illustrates the prevalence of sterilization complications of various kinds among the 80 participants who were part of the study. Hemorrhage topped the list of complications with the highest number of cases, with 24 women (30%) affected, which signifies that this was the post-sterilization concern of most. Surgical site infection followed as the second most frequent complication, with 20 cases (25%) reporting it, which points out the critical need for strict aseptic surgical practices and good postoperative care. Visceral injuries were responsible for 12 cases (15%) and this indicates that intraoperative complications were of a more serious kind occurring. Anesthetic complications were counted in 10 women (12.5%), which implies that anesthetic evaluation and monitoring should be meticulous. The occurrence of febrile illness was reported in 8 participants (10%), which could be due to the aftermath of surgeries performed, especially infections or inflammatory responses. Other complications amounted to 6 cases (7.5%), symbolizing the smallest proportion of adverse effects of sterilization procedures that are less common and thus termed as 'Other'.

Table 3: Distribution of types of sterilization complications (n = 80)

Type of complication	Frequency (n)	Percentage (%)
Hemorrhage	24	30
Surgical site infection	20	25
Visceral injury	12	15
Anesthetic complications	10	12.5
Febrile illness	8	10
Others	6	7.5

Table 4 presents the management strategies for sterilization complications in 80 participants. Almost half of the cases (47.5%) were treated conservatively or with medical interventions, which suggests that the majority of complications were of mild to moderate severity and could be managed without resorting to invasive measures. Surgical intervention was necessary for 35% of the cases, representing a considerable number of patients who experienced complications that were so severe that they required operative management. Furthermore, 12.5% of the patients received blood transfusions, indicating that a significant loss of blood or anemia occurred in this portion of the patients. Only 5% of the cases led to ICU admission, which means that life-threatening complications were not very frequent; however, they still highlight the necessity for quick and proper postoperative monitoring as well as emergency care facilities.

Table 4: Management of sterilization complications (n = 80)

Mode of management	Frequency (n)	Percentage (%)
Conservative/medical management	38	47.5
Surgical intervention	28	35
Blood transfusion required	10	12.5
ICU admission	4	5

The morbidity indicators among the 80 study participants were displayed in Table 5, and it was found out that over half of the patients (55%) stayed in the hospital for five days or less, while a large group of patients (45%) were hospitalized for more than five days, which was an indicator of variable severity of illness. A big part of the participants (67.5%) did not need any further interventions during their hospital stay, this indicates that most cases were treated with standard treatment, on the other hand, nearly one-third (32.5%) underwent additional procedures, which is a sign of the presence of complications or increased clinical difficulty. The patients' outcomes at discharge were mostly good, with 95% of the patients having completely recovered, while only 5% were either referred to other departments or experienced complications, this all points to very good clinical management and low adverse outcomes in the study population.

Table 5: Morbidity indicators among study participants (n = 80)

Morbidity parameter	Category	Frequency (n)	Percentage (%)
Length of hospital stay	≤5 days	44	55
	>5 days	36	45
Additional procedures required	Yes	26	32.5
	No	54	67.5
Outcome at discharge	Recovered	76	95
	Referred/complicated	4	5

Discussion

The study, which is retrospective in nature, reveals the complications that are associated with different methods of female sterilization and their determinants, giving special attention to the procedural type, timing, healthcare setting, and patient risk factors. Even if female sterilization is generally considered to be a safe and effective means of permanent contraception, the complications that occurred in this study still point to the necessity of being alert, maintaining quality, and following standard protocols, especially in resource-poor and rural areas.

In the present investigation, the majority of women who had complications were in the age category of 25–34 years and had three or more children. This observation matches the previous reports that sterilization is most often practiced right after family size is completed, especially among multiparous women in less developed countries (Pati & Cullins, 2000) [9]. Mahadevappa et al. (2016) [10] also reported similar demographic trends where most of the sterilization acceptors were young multiparas from rural areas. It is likely that the lower educational status of a considerable number of women in this study caused the delayed identification of complications and late access to healthcare services, which is a concern that has already been raised in previous Indian studies that pointed out the connection between lack of education and negative reproductive health outcomes (Tripathy et al., 1994) [11].

A large number of complication cases in this study, over the half, came from government health facilities, especially the primary-level centers. It indicates that public health infrastructure played the main role in providing sterilization services through the national family planning program. According to Patil and Jensen (2015) [12], tubal sterilization is always safe when done by doctors with experience; nonetheless, high numbers of patients, poor facilities, and fluctuating surgical skills at the peripheral centers may lead to more enameled outcomes. The present study gives proof of the fact that, while the services have become more accessible, the consistent quality of care is still a problem to be tackled.

When it comes to the procedure type, most of the complications were linked to minilaparotomy sterilization, while laparoscopic sterilization was responsible for a lesser amount. This finding is in contrast to the studies conducted by Mumford and Bhiwandiwala (1980) [13], who found laparoscopic techniques to be associated with more complications than minilaparotomy. On the other hand, Chick et al. (1985) [14] and Pati and Cullins (2000) ruled out any significant difference in complication rates between the two techniques, provided they were done under the best operational conditions. The larger part of minilaparotomy-related complications in this study might be due to its common usage in rural and primary care areas, where the operative conditions are often not ideal.

As far as the timing is concerned, the majority of complications in this study were attributed to interval sterilization rather than puerperal procedures. This trend is in contrast to the one indicated by Patil and Jensen (2015), who claimed that both intervals and postpartum sterilization had similar safety profiles. The higher rate of complications associated with interval procedures in the current study might represent insufficient preoperative evaluation, missed comorbidities, or previous abdominal surgeries, which are more applicable to interval cases. However, puerperal sterilization, even though it is technically difficult, is often done when the women are already under close clinical supervision, which helps in the early detection of complications.

The most frequent complication was hemorrhage, and then came the surgical site infection, which is in line with previous reports that recognized bleeding and infection to be the major causes of post-sterilization morbidity (Huggins & Sondheimer, 1984) [15]. The study pointed out that blood transfusion was often required for hemorrhagic complications, thereby stressing the need for surgical skill and the presence of emergency services all the time. The visceral injuries that occurred, though rare, were similar to those found by Layde et al. (1983) [16] regarding major surgical interventions like exploratory laparotomy because of previous abdominal surgery and pelvic inflammatory disease being significant risk factors.

The management pattern seen shows that about 60% of the cases were treated conservatively, which implies that the severity of most complications was mild to moderate. On the other hand, one-third of women underwent major surgical procedures, which is a higher percentage than that quoted in the Cochrane review by Lawrie et al. (2015) [17], who determined the occurrence of major complications as very rare and no deaths in the randomized controlled trials. This difference might be attributed to the distinct research methodologies since randomized trials are usually performed under strict conditions while the present study mirrors the actual programmatic settings.

In this study, deaths were very few but were still reported and mostly caused by septic complications. The same was found by Strauss et al. (1984) [18], who pointed out that the top three reasons for sterilization-related deaths in the world were infection, anesthesia, and hemorrhage. These findings reiterate the infection control and perioperative hygiene issues already raised in Indian scenarios, particularly in large public sector clinics, where the volume is high.

Overall, the present research reiterates that female sterilization is still a safe contraceptive method but not without certain risks. Complications will be minimized and maternal safety improved by the above-mentioned measures: tightening up preoperative screening, upgrading surgical training, making certain that infection prevention measures are always in place, and strengthening postoperative monitoring—most importantly in the government and rural healthcare centers.

Conclusion

The present retrospective study highlights that female sterilization, while being an effective and widely accepted method of permanent contraception, is not completely free from complications. Most affected women were young multiparous females from rural backgrounds with low to moderate educational status, reflecting the demographic profile of sterilization acceptors in public health settings. Hemorrhage and surgical site infection emerged as the most common complications, though the majority were managed conservatively with favorable outcomes. A smaller proportion required surgical intervention, blood transfusion, or intensive care, indicating occasional severity. Overall recovery rates were high, suggesting effective institutional management. The findings emphasize the need for strengthened preoperative assessment, skilled surgical practice, strict aseptic measures, and vigilant postoperative monitoring, particularly in high-volume government facilities, to further enhance the safety and quality of female sterilization services.

References

1. Ewerling F, McDougal L, Raj A, Ferreira LZ, Blumenberg C, Parmar D, Barros AJ. Modern contraceptive use among women in need of family planning in India: an analysis of the inequalities related to the mix of methods used. Reproductive health. 2021 Aug 21;18(1):173.
2. Sivaram S, Singh S, Penn-Kekana L. Understanding the role of female sterilisation in Indian family planning through qualitative analysis: perspectives from above and below. Sexual and Reproductive Health Matters. 2022 Jan 1;29(2):2080166.
3. Eyob B, Boeck MA, FaSiOen P, Cawich S, Kluger MD. Ensuring safe surgical care across resource settings via surgical outcomes data & quality improvement initiatives. International Journal of Surgery. 2019 Dec 1;72:27-32.
4. Gizzo S, Bertocco A, Saccardi C, Di Gangi S, Litta PS, D'antona D, Nardelli GB. Female sterilization: update on clinical efficacy, side effects and contraindications. Minimally Invasive Therapy & Allied Technologies. 2014 Oct 1;23(5):261-70.
5. Gariepy AM, Lewis C, Zuckerman D, Tancredi DJ, Murphy E, McDonald-Mosley R, Sonalkar S, Hathaway M, Nunez-Eddy C, Schwarz EB. Comparative effectiveness of hysteroscopic and laparoscopic sterilization for women: a retrospective cohort study. Fertility and Sterility. 2022 Jun 1;117(6):1322-31.
6. Harkey K, Kaiser N, Inman M, Reinke CE. "Are we there yet?"-factors affecting postoperative follow-up after general surgery procedures. The American Journal of Surgery. 2018 Dec 1;216(6):1046-51.
7. Sarojini N, Sri SB, Ambhore V, Venkatachalam D. Bilaspur sterilisation deaths: Evidence of oppressive population control policy. Indian Journal of Medical Ethics. 2015 Jan 1;12(1):2-5.
8. Gopichandran V, Krishna AK. Monitoring 'monitoring'and evaluating 'evaluation': an ethical framework for monitoring and evaluation in public health. Journal of medical ethics. 2013 Jan 1;39(1):31-5.

9. Pati S, Cullins V. Female sterilization: evidence. Obstetrics and gynecology clinics of North America. 2000 Dec 1;27(4):859-99.
10. Mahadevappa K, Prasanna N, Channabasappa RA. Trends of various techniques of tubectomy: A five-year study in a tertiary institute. Journal of Clinical and Diagnostic Research: JCDR. 2016 Jan 1;10(1): QC04.
11. Tripathy SP, Ramachandran CR, Ramachandran P. Health consequences of vasectomy in India. Bulletin of the World Health Organization. 1994;72(5):779.
12. Patil E, Jensen JT. Update on permanent contraception options for women. Current opinion in obstetrics and gynecology. 2015 Dec 1;27(6):465-70.
13. Mumford S, Bhiwandiwala P, Chi IC. Laparoscopic and minilaparotomy female sterilisation compared in 15 167 cases. The Lancet. 1980 Nov 15;316(8203):1066-70.
14. Chick PH, Frances M, Paterson PJ. A comprehensive review of female sterilisation--tubal occlusion methods. Clinical Reproduction and Fertility. 1985 Jun 1;3(2):81-97.
15. Huggins GR, Sondheimer SJ. Complications of female sterilization: immediate and delayed. Fertility and sterility. 1984 Mar 1;41(3):337-55.
16. LAYDE PM, PETERSON HB, DICKER RC, DeSTEFANO FR, RUBIN GL, ORY HW. Risk factors for complications of interval tubal sterilization by laparotomy. Obstetrics & Gynecology. 1983 Aug 1;62(2):180-4.
17. Lawrie TA, Kulier R, Nardin JM. Techniques for the interruption of tubal patency for female sterilisation. Cochrane Database of Systematic Reviews. 2015(9).
18. Strauss LT, Huezo CM, Kramer DG, Rochat RW, Senanayake P, Rubin GL. Sterilization-associated deaths: a global survey. International Journal of Gynecology & Obstetrics. 1984 Feb 1;22(1):67-75.