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Original Article

Obstetrics and Gynaecology Section

Effect of Bilateral Salpingectomy versus Bilateral Tubal Ligation on Ovarian Reserve for Patients Seeking Permanent Sterilisation: A Prospective Cohort Study

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ABSTRACT

Introduction: Ovarian cancer is a common malignancy in women with a high mortality rate, necessitating effective preventive measures. The American Cancer Society and the American College of Obstetricians and Gynaecologists, in their newer guidelines, suggest that patients undergoing tubectomy have an opportunity for the prevention of ovarian carcinoma by undergoing Prophylactic Bilateral Salpingectomy (PBS) instead of tubectomy in average-risk women. However, salpingectomy is not widely accepted as a method of sterilisation over tubectomy during caesarean section due to concerns about its potentially detrimental effect on ovarian reserve.

Aim: To determine the effect of Bilateral Salpingectomy (BLS) and Bilateral Tubectomy (BLT) on ovarian reserve over a period of six months from surgery and to compare salpingectomy and tubectomy for their intraoperative and postoperative complications.

Materials and Methods: The study is a hospital-based prospective cohort study conducted in the Department of Obstetrics and Gynaecology, Fakhruddin Ali Ahmed Medical College and Hospital (FAAMCH), Barpeta, Assam, India, from Sept 2020 to Aug 2021, over a period of one year, involving women between 32-35 years undergoing sterilisation during caesarean section. Mean Antimullerian Hormone estimation was done preoperatively, at the 3rd month, and at the 6th month to assess changes in ovarian reserve following salpingectomy and tubectomy. Intraoperative blood loss, surgery time, surgical complications, postoperative complications, recovery period, histopathological study of the fallopian tube, etc., were analysed and compared between the two groups. All data were analysed using Statistical Package for Social Sciences (SPSS) version 21.0. A p-value <0.05 was considered statistically significant at a 5% confidence level.

Results: A total of 114 patients were enrolled in the study, of which 9.64% dropped out midway, while the remaining 103 (90.36%) patients were part of the study until its completion. The mean age of the participants was 33 years and six months. There was no significant intergroup variation in preoperative, 3rd month, and 6th month mean Antimullerian Hormone (AMH) values (p>0.05). However, in each group, the preoperative mean AMH was lower than its 3rd month and 6th month values, which were in the normal range. This was attributed to ovarian suppression during pregnancy, which normalised following delivery and showed an increasing trend thereafter. However, on average, salpingectomy required approximately 10 minutes more than tubectomy.

Conclusion: Salpingectomy does not affect ovarian reserve in the short-term of six months. Other than being more time-consuming compared to tubectomy, salpingectomy is on par with traditional tubectomy. Therefore, it may be adopted as a routine sterilisation method considering its role in the prevention of ovarian cancers.

Keywords: Antimullerian hormone, Caesarean section, Complications, Gynaecology, Ovarian cancer, Tubectomy

INTRODUCTION

Ovarian cancer is the eighth most common malignancy among women and continues to have the worst mortality rate of all female cancers, despite considerable progress in its management [1]. GLOBOCAN (Global Cancer Observatory) estimates that by 2040, ovarian cancer cases would increase by 47% to over 434,000, with an increase in mortality each year (up by nearly 59% to over 293,000) [2]. The majority of this burden will be borne by China and India due to a lack of effective cancer control programs and affordable cancer treatments [2]. India must, thus devise and implement ovarian cancer prevention strategies.

Recent research has established that the precursor cells of serous ovarian cancers develop in the fallopian tubes, from where they migrate and adhere to the surface of ovaries and multiply rapidly [3]. This discovery has crucial implications for ovarian cancer prevention, as women concerned about the risk of ovarian cancer may consider having only their fallopian tubes removed initially and ovaries removed later when they are older to prevent early menopausal symptoms. This allows women to keep functioning ovaries along with a greatly minimised risk of ovarian cancer [4]. The American Cancer Society and the American College of Obstetricians and Gynaecologists, in light of the new theory, have issued newer guidelines suggesting PBS as a new preventive strategy for average-risk women who have completed their reproductive desire and do not carry Breast cancer gene (BRCA) mutations [4,5].

Salpingectomy as a sterilisation method during caesarean delivery is equally viable as tubectomy [6,7]. However, it is not widely performed due to the proximity of the tubal and ovarian arteries. There is concern about its potentially detrimental effect on ovarian reserve due to disruption of ovarian blood supply [7]. Preliminary studies on the safety of BLS have shown that ovarian function is preserved for atleast three months following surgery [8-10]. However, extensive research is needed to determine its long-term effect on ovarian function. The medical community needs reassurance that salpingectomy as a preventive strategy is capable of warding-off the risk of premature surgical menopause and all other complications associated with the removal of ovaries, with no alteration in ovarian reserve [11]. While both tubal ligation and complete salpingectomy are considered effective in the prevention of pregnancy, complete salpingectomy is regarded as the most effective method of contraception and offers the greatest benefit in terms of cancer prevention.

The AMH is the most reliable biomarker test for ovarian reserve, as it has a good correlation with the histological count of ovarian follicles [11]. Furthermore, serum AMH has less cycle variability and decline throughout the reproductive lifespan compared to serum Follicle Stimulating Hormone (FSH), Leutinising Hormone (LH), Inhibin B, and Estradiol on day 3 of the cycle, making it a superior and appropriate marker for detecting relatively slight changes in ovarian reserve [12].

The present aims to determine the effect of BLS and BLT on ovarian reserves by evaluating variations in AMH over a six-month period after surgery.

MATERIALS AND METHODS

This hospital-based prospective cohort study was conducted in the Department of Obstetrics and Gynaecology, Fakhruddin Ali Ahmed Medical College (FAAMCH) and Hospital, Barpeta, Assam, India from September 2020 to August 2021, over a period of one year, after obtaining clearance from the FAAMCH Institutional Ethics Committee (IEC_PG/498/2020/10556). All patients were informed about the study, and signed consent was obtained.

Inclusion and Exclusion criteria: Women in the age group of 32-35 years undergoing cesarean section at the institute and eligible for sterilisation were included. Women with a family history of breast and ovarian cancer were excluded.

Purposive sampling was done, and data was collected every Monday. A total of 114 patients were enrolled in the study, of which 9.64% dropped out, while 103 patients were part of the study until its completion.

Study Procedure

The study subjects were categorised into: a) Lower Segment Caesarean Section with BLS (LSCS BLS) group; b) LSCS with BLT (LSCS BLT) group; and c) a control group of patients undergoing LSCS alone without any sterilisation surgery by the treating obstetrician. There was minimal to no risk associated with the participants of the study. A 2 mL fresh venous blood sample was drawn from the participants' arm into a red cap (clot) vacutainer and sent with the necessary form for preoperative AMH estimation [13]. The modified Pomeroy approach of tubectomy and complete salpingectomy was the adopted sterilisation technique. The removed section of the fallopian tube was sent for histopathological analysis. Blood loss was quantified using the visual method [14], which included mop count and suction canister measurements.

Following surgery, patients were monitored for any complications until discharge. The postoperative hospitalisation period was observed. Follow-up visits were held at three months and six months following delivery, during which repeat blood samples were obtained from patients for AMH testing. Serum AMH samples were analysed with the GenII Quantitative Enzyme-linked Immuno Sorbent Assay (ELISA) kit (Beckman Coulter) and read using Rayto RT2100C Microplate Reader. The lowest amount of serum AMH detected with 95% probability was 0.12 ng/mL (calibration 0.01 ng/mL).

For the purpose of the study, AMH was tested preoperatively, at the 3rd month, and at the 6th month postoperative period. The reference range of AMH is given in [Table/Fig-1] [15].

STATISTICAL ANALYSIS

A Chi-square test was done to evaluate the association between categorical variables. An independent t-test was done to compare the mean difference between two groups, and Analysis of Variance (ANOVA) was used for more than two groups of continuous variables that fulfilled normality assumptions. For non normal data, the Kruskal-Wallis test, Friedman test, and Wilcoxon test were used to determine differences in the mean. All data were analysed using SPSS version 21.0. A p-value <0.05 was considered statistically significant at a 5% level of confidence.

Categories	Reference range (mg/mL)
High (often PCOS)	>4.0
Normal	1.5-4.0
Low normal range	1.0-1.5
Low	0.5-1.0

[Table/Fig-1]: The reference range of AMH [15].
PCOS: Polycystic ovarian syndrome

RESULTS

A total of 114 patients (38 each for LSCS BLS, LSCS BLT, and LSCS) were enrolled in the study. Out of these, 11 (9.64%) dropped out midway. The remaining 103 (90.36%) patients were part of the study until completion and were involved in the final analysis. The mean age of the participants was 33 years and six months. The mean preoperative baseline AMH was comparable within the groups (p=0.305). However, the mean AMH for all the groups fell within the 'low range' of reference values [Table/Fig-2].

Group	Total	Mean AMH (Preoperative) (ng/mL)	SD	p-value (Kruskal-Wallis test)
LSCS BLS	35	0.603	0.11505	0.305
LSCS BLT	34	0.637	0.07136	
LSCS	34	0.634	0.09664	
Overall	103	0.625	0.09645	

[Table/Fig-2]: Mean preoperative AMH levels (ng/mL) among the groups.
SD: Standard deviation

The mean AMH at three months postoperative was also comparable within the groups (p=0.321), and the mean AMH for all the groups fell within the 'normal range' of reference values [Table/Fig-3].

Group	Total	Mean AMH (at 3 months) (ng/mL)	SD	p-value (Kruskal-Wallis test)
LSCS BLS	35	2.4	0.42909	0.321
LSCS BLT	34	2.5471	0.41578	
LSCS	34	2.6091	0.55304	
Overall	103	2.5167	0.47242	

[Table/Fig-3]: Mean AMH (ng/mL) among the groups at three months postoperative.

The mean AMH at six months postoperative was also comparable within the groups (p=0.072), and the mean AMH for all the groups fell within the 'normal range' of reference values [Table/Fig-4].

Group	Total	Mean AMH at 6 months) (ng/mL)	SD	p-value (Kruskal-Wallis test)
LSCS BLS	35	2.62	0.45941	0.072
LSCS BLT	34	2.8412	0.4016	
LSCS	34	2.8333	0.58452	
Overall	103	2.7627	0.4927	

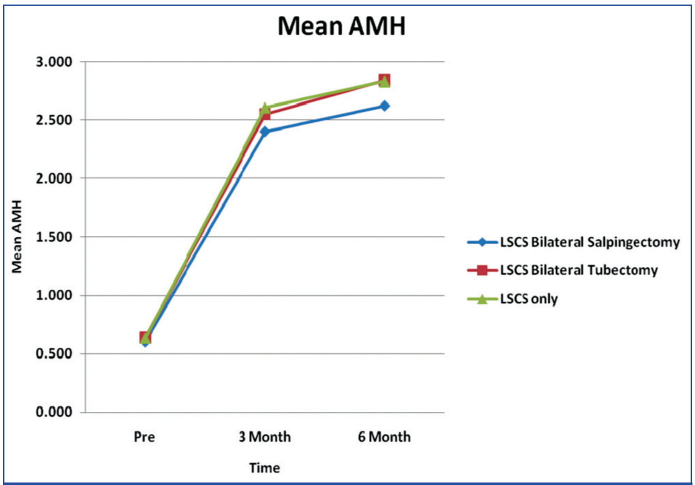
[Table/Fig-4]: Mean AMH (ng/mL) among the groups at six months postoperative.

For each of the groups, a notable rise in AMH level was recorded when comparing the three-month and six-month levels with preoperative levels (p-value <0.001**, statistically highly significant) [Table/Fig-5]. [Table/Fig-6] shows the changing AMH (ng/mL) levels at preoperative, three months, and six months postoperative. The mean time taken was highest for LSCS with BLS (62.57 minutes), followed by LSCS with BLT (52.06 minutes), and for LSCS alone

(47.42 minutes) [Table/Fig-7].The mean intraoperative blood loss was comparable within the three groups and did not show any significant variation (p=0.198) [Table/Fig-8].

LSCS (BLS)	Mean AMH	SD month	p-value Friedman	p-value (Pre vs 3rd) Wilcoxon	p-value (Pre vs 6th) Wilcoxon	p-value (3rd vs 6th) Wilcoxon
Preop	0.603	0.11505	<0.001**	<0.001**	<0.001**	<0.001**
3rd	2.4	0.42909				
6th	2.62	0.45941				
LSCS (BLT)	**Mean AMH**	**SD**	**p-value**	**p-value (Pre vs 3rd)**	**p-value (Pre vs 6th)**	**p-value (3rd vs 6th)**
Preop	0.637	0.07136	<0.001**	<0.001**	<0.001**	<0.001**
3rd	2.5471	0.41578				
6th	2.8412	0.4016				
LSCS	**Mean AMH**	**SD**	**p-value**	**p-value (Pre vs 3rd)**	**p-value (Pre vs 6th)**	**p-value (3rd vs 6th)**
Preoperative	0.634	0.09664	<0.001**	<0.001**	<0.001**	<0.001**
3	2.6091	0.55304				
6	2.8333	0.58452				

[Table/Fig-5]: Intra-group comparison of mean AMH (ng/mL) values for preoperative, 3rd month and 6th month postoperative samples.



[Table/Fig-6]: Line graph showing comparison of changing AMH (ng/mL) levels at preoperative, at three months and at six months postoperative.

Group	Total	Mean surgery length (Mins)	SD	p-value (Kruskal-Wallis test)
LSCS BLS	35	62.57	3.29	<0.001**
LSCS BLT	34	52.06	3.72	
LSCS	34	47.42	5.32	
Overall	103	54.17	7.61	

[Table/Fig-7]: Mean time taken for surgery in minutes.

Group	Total	Mean intraoperative blood loss (mL)	SD	p-value (Kruskal-Wallis test)
LSCS BLS	35	957.14	55.761	0.198
LSCS BLT	34	936.76	61.925	
LSCS	34	934.85	53.743	
Overall	103	943.14	57.609	

[Table/Fig-8]: Mean intraoperative blood loss.

Intraoperative blood transfusion was required in 3 (8.6%) LSCS BLS cases, 3 (8.8%) LSCS BLT cases, and 4 (12.1%) LSCS cases. All cases requiring blood transfusions were due to atonic postpartum haemorrhage, and no surgery-associated complications (like immediate death, bleeding from the tubes, or sepsis) were recorded.

The majority of the patients had an uneventful four-day postoperative hospital stay, with only 6 (5.82%) requiring a hospital stay of more than four days, usually due to complaints of abdominal distension, fever, or postpartum psychosis. None of the postoperative complications were surgery-associated, and none of the cases needed any further surgical intervention or Intensive Care Unit (ICU) care. A total of 103 samples were sent for histopathology, and no cases reported any form of premalignant or malignant pathology of the fallopian tube.

Additionally, the mean postoperative hospital stay was 4.08 (SD=0.359) days for the LSCS BLS group, 4.13 (0.475) days for the LSCS BLT group, and 4.08 (SD=0.359) days for the LSCS group. The p-value was 0.804 (not significant) [Table/Fig-9].

Group	Mean postoperative hospital stay	Standard deviation
LSCS BLS	4.08	0.359
LSCS BLT	4.13	0.475
LSCS	4.08	0.359

[Table/Fig-9]: Mean postoperative hospital stay (in days) for study groups.

There was no case of sterilisation failure or pregnancy reported in any of the groups during the six-month follow-up. However, a longer follow-up period is needed to determine the actual proportion of sterilisation failure among the subjects.

DISCUSSION

Ovarian cancer is often diagnosed late due to its vague symptoms and lack of effective screening. The present aims to replace the age-old tubectomy method of sterilisation with salpingectomy to enhance ovarian cancer prevention, as stated by GLOBACAN [2]. In the present, there was no significant intergroup variation in mean preoperative (baseline) AMH values (p=0.305). Similarly, the p-value for intergroup comparison of the 3rd-month mean AMH was 0.321, and the p-value for intergroup comparison of the 6th-month mean AMH was 0.072, implying no significant variation in the 3rd and 6th-month mean AMH as well. Similar findings were present in previous literature [15]. Herman HG et al., in their study found that the prepartum and postpartum AMH levels between the groups did not show much difference, with an average increase of 0.58±0.98 and 0.39±0.41 ng/mL in the salpingectomy and tubectomy groups, respectively (p=0.45) [16]. Yang M et al., in their meta-analysis on this subject, found that the salpingectomy and tubectomy groups were comparable with regard to short-term changes in ovarian reserve (RR=0.90 and 95% CI: 0.80-1.00) [17].

For each group, the individual as well as the mean AMH was low for preoperative samples compared to their 3rd-month and 6th-month values. However, an increasing trend with time was observed for the mean AMH value in all the groups. For the LSCS BLS group, this mean was 0.603 ng/mL (SD=0.11505) preoperatively, 2.4 ng/mL (SD=0.42909) at the 3rd month, and 2.62 ng/mL (SD=0.45941) at the 6th month, p-value <0.001. For the LSCS BLT group, the mean was 0.637 ng/mL (SD=0.07136) preoperatively, 2.5471 ng/mL (SD=0.41578) at the 3rd month, and 2.8412 ng/mL (SD=0.4016) at the 6th month, p-value <0.001. And for the LSCS group, the mean was 0.634 ng/mL (SD=0.09664) preoperatively, 2.6091 ng/mL (SD=0.55304) at the 3rd month, and 2.8333 ng/mL (SD=0.58452) at the 6th month, p-value <0.001. Low preoperative values may be attributed to ovarian suppression during pregnancy. This finding correlates with another study published in 2013 [17]. The decline in AMH levels during pregnancy indicates ovarian suppression, and AMH levels recover quickly after delivery [6].

In the current study, the mean time taken for LSCS with BLS was 62.57 (SD=3.29) minutes, for LSCS with BLT was 52.06 (SD=3.72) minutes, and for LSCS alone was 47.42 (SD=5.32) minutes. Surgeries that included salpingectomy took an average of

15.15 minutes longer compared to LSCS alone, and surgeries with tubectomy took 4.64 minutes longer than LSCS alone. On average, salpingectomy took 10.51 minutes more than tubectomy in the present. This observation is supported by other literature where an average of 13 minutes and 12.31 minutes longer was taken for salpingectomy [15,18].

In the current study, the average estimated blood loss was 957.14 mL (SD=55.761) for LSCS with BLS, 936.76 mL (SD=61.925) for LSCS with BLT, and 934.85 mL (SD=53.743) for the LSCS group. The p-value was calculated to be 0.198. The present did not find any significant difference in intraoperative blood loss between the groups. A similar study also did not find any significant difference between the salpingectomy and tubectomy groups in terms of estimated blood loss (1.1±1.07 vs. 0.85±1.01 gr/dL, p=0.39) [15].

In the current study, the overall intergroup complication rate was comparable and not significant. The mean postoperative hospitalisation period was comparable within the groups, and there were no postoperative complications that were surgery-associated. None of the cases needed any further surgical intervention or ICU care, etc. A meta-analysis on this subject concluded that the salpingectomy and tubectomy groups were comparable with regard to intraoperative complications (RR=1.42, 95% CI: 0.65-3.11), postoperative complications (RR=1.70, 95% CI: 0.83-3.48), estimated blood loss in total procedures, need for blood transfusion, operative complications, risk of postpartum haemorrhage, surgical site infection, ICU admission, need for presentation to the hospital, short-term ovarian reserve (RR=0.90, 95% CI: 0.80-1.00) [19].

In the present study, not a single case of any form of premalignant or malignant pathology of the fallopian tubes was detected in histopathology reports.

In a study on female sterilisation failure, it was found that 15.71% of failure cases were reported in the first year after surgery, while the majority were reported in the 1-5 year period followed by the 5-10 year period [20]. The Ovarian Research Alliance (OCRA) has advised considering prophylactic removal of fallopian tubes during other pelvic surgeries once the family is completed. The chief scientific officer for the American Cancer Society (ACS) has pointed out that indirect evidence suggests a significant risk reduction associated with opportunistic salpingectomy for the most prevalent serous ovarian cancer and other epithelial cancers. However, salpingectomy is not widely accepted as a routine sterilisation method among obstetricians due to the risk of intraoperative complications, longer procedure time, and potential detrimental effects on ovarian reserve due to suspected disruption of ovarian blood supply [21,22].

The present showed that there was no significant decline in ovarian reserve following salpingectomy compared to tubectomy at the time of caesarean delivery for atleast six months after surgery. A similar study concluded that salpingectomy had no negative impact on ovarian reserve and ovarian response. Additionally, salpingectomy took on average 10.51 minutes longer than tubectomy during caesarean delivery, and the rate of complications, postoperative hospitalisation days, and blood loss were comparable between the two groups [21].

The convenience of untimed sampling, age-specific values, availability of an automated platform, and potential standardisation of AMH assay make it the preferred biomarker for estimating ovarian reserve, which was used in the present to monitor ovarian reserve poststerilisation. However, further studies on a larger population and for a longer duration may be required to consolidate the findings of the present.

Limitation(s)

The study design limited the follow-up of subjects to a short duration of only six months, which may not be sufficient to assess sterilisation failure, if any. Additionally, patients' unawareness and lack of motivation make further follow-up challenging. Moreover, the geographical location of many patients' residences make it nearly impossible to conduct timely check-ups, resulting in increased dropouts.

CONCLUSION(S)

The present suggests that salpingectomy, compared to tubectomy at the time of caesarean delivery, does not have a negative impact on short-term ovarian reserve. Therefore, it may be considered as a routine sterilisation method, given its role in preventing high-grade ovarian cancers. No additional difficulties or specific complications were experienced in performing salpingectomy. Hence, salpingectomy may be considered for implementation in sterilisation surgeries to contribute to a society free from ovarian cancer.

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