

ORA- Observational Study

A Retrospective Observational Cohort Study on Quality of Life in Anal Fistula Patients Managed with *Ksharasutra*, Complete Fistulectomy and Integrated Treatment

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ABSTRACT:

Background: *Bhagandara* (Fistula-in-ano) is a disease of the anal canal, for the management of which various surgical procedures and *Ksharasutra* ligation (KSL) are the majorly performed routine procedures based on the complexity of Fistula-in-ano (FIA). These treatments have variable outcomes affecting the Quality of Life (QoL), which is seen clinically. As there is a lack of data on QoL of patients who are treated with KSL only, *Ksharasutra* ligation + Partial fistulotomy (KSL+PF), and Complete fistulectomy (CF) so in this study, we aimed to evaluate the effect on QoL in patients who are treated with KSL and KSL+PF and CF. **Study design:** Retrospective observational cohort study. **Objectives:** To evaluate the effect on QoL in Fistula in Ano (FIA) patients treated with KSL, CF and KSL+PF. **Materials and methods:** The study included 95 participants treated by KSL, CF, and KSL+PF for complaints of Fistula in Ano at KLE for the duration of 6 years from January 2018 to August 2024. **Observations:** The participants were categorized in three groups namely KSL (n=44), CF (n=18), KSL+PF (n=33) based on the type of surgeries performed. Amongst all the participants, simple FIA were 18 whereas complex FIA were 77. The analysis of pain via VAS, VDS and postoperative complications, along with quality of life (QoL) was done where KSL demonstrated significantly better outcomes in comparison to CF across all the domains: Domain 1, Domain 3 and Domain 4 (All $p < 0.001$). Similarly, KSL+PF has shown significantly better outcomes in comparison to CF across all the domains (all $p < 0.001$) these findings remained significant after adjustment for baseline clinical variables in multivariable regression analysis. **Conclusion:** KSL & KSL+PF group exhibited better QoL scores compared to CF group. Statistically comparable QoL scores were seen in KSL and KSL+PF but clinically improved QoL was observed in the KSL+PF Group.

KEYWORDS: *Bhagandara*, Fistula in Ano (FIA), *Ksharasutra* ligation (KSL), Quality of Life (QoL)

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1. INTRODUCTION

Fistula in Ano is chronic inflammatory perianal condition defined as abnormal tract between perianal skin and anal canal. Global prevalence of the anal fistula is lacking, due to under reporting with fear of embarrassment and social disgrace. The existing epidemiological data is limited to Europe, with 18.37/lakh individuals and the highest prevalence was reported in Italy 23.20 per lakh. [1] Men are more affected than female with ratio of 12.3:5.6 cases per 100,000 with an average age of 38 years. Obesity, diabetes, smoking, hyperlipidemia and sedentary lifestyle have been found to be risk factors for developing fistula in ano. [2, 3] Quality of life in anal fistula gets affected significantly. [1] In *Ayurveda*, Anal Fistula is considered as one among *Asta Mahagada* (eight major diseases). [4] It occurs as a sequel to Cryptoglandular abscess and may be associated with medical conditions [3] viz. Crohn's Disease, which accounts to 25%. [5] The primary objective of addressing anal fistula is to eliminate the fistulous tract while preserving sphincter function to avoid complications (fecal incontinence) and recurrence often seen within the first year of treatment. [6-8] Medical treatment focuses on pain control, prevention of secondary infection, discharge, and addresses the patient's quality of life, where surgical treatment remains the primary approach. [9-11] However, these treatments pose potentials risks like delayed wound healing, longer hospital stay and varying degrees of functional disability. To address these lacunae, the need of integration of conventional treatments with traditional treatments necessitates improving the clinical outcome. [12] *Ksharasutra* (medicated thread) therapy is well accepted and widely practiced in FIA due to its benefit of preserving anal continence with minimal complications. KSL therapy is practiced either as a standalone or adjunct to Partial fistulotomy (PF) to minimize complications and improve QoL which is seen clinically but the data with postoperative QoL remains limited. So it was hypothesized that the patients undergoing KSL or KSL+PF would demonstrate better

postoperative QoL and fewer complications compared to those undergoing CF. Hence, this observational study was carried out which included 95 patients who were treated with KSL alone, CF and KSL followed by Partial fistulotomy (KSL + PF). Outcomes used to evaluate QoL were postoperative complications, recurrence, sphincter preservation and QoL assessment tool. As FIA is a challenging disease that has various surgical procedures (CF, KSL, KSL+PF) available for its management, but the recent evidence from the systematic reviews and meta-analysis comparing surgical procedures such as fistulotomy & fistulectomy has shown no clear superiority between the two techniques in terms of healing time of fistula, recurrence, and postoperative complications. [13] Furthermore, despite of various advancements in the surgical approaches for the management of FIA, there is no accepted gold standard treatment available for it due to concerns of recurrence, incontinence, and functional impairment. [14] As several studies have reported, the evaluation of various surgical and clinical outcomes by focusing on healing of fistula tracts, recurrence and complications, with minimal emphasis on outcomes centered on the patients' postoperative Quality of Life (QoL). Also, the evidence evaluating the *Ksharasutra*-based interventions with conventional surgical procedures in terms of postoperative QoL remains scarce. Therefore, literature has a significant gap regarding the comparative evaluation of postoperative QoL outcomes in different surgical procedures, particularly including *Ksharasutra*-based procedures. [13] This study highlights the clinical understanding of better postoperative QoL in patients undergoing KS-based interventions in the management of FIA compared to conventional CF, with more patient satisfaction and improved healing results.

Objectives: To evaluate the Quality of Life (QoL) in patients suffering with *Bhagandara* treated with *Ksharasutra* ligation (KSL), Complete Fistulectomy (CF), and *Ksharasutra* ligation followed by Partial fistulotomy (KSL+PF).

2. MATERIAL AND METHODS

Study Setting: This retrospective observational cohort study was carried out on the patients who underwent treatment for Fistula-in-Ano at *Shalyatantra* IPD of KAHER's Shri BMK Ayurveda Mahavidyalaya and Hospital, Belgaum, after obtaining the ethical clearance (reference number: BMK/24/SYM/01)

Study Period: The duration of study extended from January 2018 to August 2024 and the data of performed surgeries during that period was analyzed.

Study Design: This study followed a retrospective observational cohort design in which specially designed case record forms of patients who underwent surgeries for FIA were reviewed to assess postoperative complications, Quality of life (QoL) and other relevant parameters. The exposure was defined as the type of surgical intervention received by the patient KSL, CF, and KSL+PF at the time of treatment. The outcome parameters included VAS (Verbal analogue scale), VDS (Verbal descriptive scale) for evaluating pre- and postoperative pain, RFIS (Revised fecal incontinence score) and flatus score for evaluating postoperative incontinence, WHOQOL-BREF for evaluating QoL and postoperative complications, which were assessed after the surgical procedure in the follow up period. Hence, the temporal sequence was maintained, with exposure being the surgical procedure done before the assessment of outcomes, with a minimum follow-up period of six months, so that sufficient assessment of postoperative QoL and clinical outcomes could be done. Also, the baseline demographic and clinical variables were recorded at the time of admission before the surgery.

Recruitment Flow and Follow-up: The patients were retrospectively identified from hospital medical records of the Department of *Shalyatantra* between January 2018 to August 2024. All the patients who were treated through KSL, CF or KSL+PF for the management of FIA during the study duration were screened for the eligibility. The patients were included if they meet the inclusion criteria, whereas patients falling in the exclusion criteria or with incomplete medical records were

excluded. A total of 95 patients were included after the final analyses. The recruitment flow is shown in Flow diagram 1. A total of 312 medical records were screened of these, the patients excluded were 51 due to incomplete medical records and incomplete postoperative QoL data as part of the complete-case analysis, 33 due to less than six months follow-up, 65 due to Crohn's disease, 28 patients had FIA related to malignancy and 40 patients had not met the inclusion criteria. Follow-up data were obtained from the OPD records, in which variables were assessed for a minimum of 6 months. The median follow-up duration was 15.5 months (IQR: 9-22).

Study Participants: The patients who were operated for the management of *Bhagandara* from January 2018 to August 2024 in the Department of *Shalyatantra* at KLE Shri BMK Ayurveda Mahavidyalaya and Hospital, Belgaum, Karnataka were included in the study. The Surgical intervention (KSL, CF or KSL+PF) was done on the basis of clinical findings and the surgeon's decision for the type of surgical procedure to be done. The characters. Which influenced the type of treatment selected was influenced by the factors like FIA complexity (simple vs complex), length of fistula tract, presence or absence of tract branches, involvement of sphincter muscles and overall patient condition. In general, *Ksharasutra* based procedures (KSL and KSL+PF) were preferred in cases where sphincter preservation was considered important, whereas the CF was more commonly performed in low-lying fistulae. Due to the retrospective observational nature of the study, no randomization was done, and the surgical decisions were based on routine clinical practices. So, a consecutive sampling method was used to select the study participants leading to inclusion of all the participants (n = 95) meeting the inclusion criteria and were operated by KSL, CF or KSL+PF, depending on the type of fistula and its complexity. The variables with missing data, records with incomplete postoperative QoL scores, were excluded. The missing values in demographic or clinical variables were not filled in and were handled by complete-case

analysis. After excluding all the incomplete records, the final dataset had 95 patients with complete data for all the variables to be studied. Hence, no variable-wise missing values were present in the final dataset, and no further imputation was required.

Inclusion Criteria:

The patients of either sex aged between 18 to 75 years operated for crypto glandular FIA by KSL, CF, or KSL + PF during January 2018 and August 2024, with availability of all medical records and with minimum 6 months of follow-up.

Exclusion Criteria:

The patients in which Fistula caused by Crohn's disease, TB, cancer, or who are suffering from HIV, and uncontrolled diabetes.

Missing Data Handling:

All the records that were retrieved were first checked for their completeness before doing any analysis. The complete case analysis was done, which led to the exclusion of 84 records due to their incomplete clinical data and postoperative outcomes. As the incomplete records had missing information on the key study variables which could not be recreated from the retrospective records, so no imputation methods were used. The final dataset for analysis contained complete medical records for all the variables, so no variable-wise missing values were present in final dataset.

Variables & measurement:

In this study, the type of surgical procedure done is an exposure variable which was further categorized into 3 groups namely KSL, CF, KSL+PF. The baseline demographic and clinical variables included sex, age and type of FIA, which was recorded before the surgery (at the time of admission). This data was obtained from the patient's case records filled during the time of admission. The outcome variables included Revised Fecal Incontinence Scale (RFIS) to evaluate control on solid/liquid stool, urgency, soiling, impact on lifestyle [15], Flatus Incontinence score a part of St Marks's Incontinence Score was

used to evaluate involuntary gas leakage and patient discomfort. [16] Postoperative Complications (Wound infection, Bleeding per rectum, Duration of hospital stay, Time to resume normal activity, Recurrence of fistula). The Quality of life (QoL) was evaluated using WHOQOL-BREF which is widely used and validated tool to evaluate the patient's self-reported quality of life across four domains (Domain 1: Physical Health, Domain 2: Psychological Health, Domain 3: Social Relationships, Domain 4: Environment), where each domain was scored and was converted to a scale of 0 to 100 helping in comparison between the patients across various time points. [17] The pain was assessed through Visual Analogue Scale (VAS) and the Verbal Descriptive Scale (VDS) before the treatment during admission and after the treatment in the follow up while other outcomes (RFIS, Flatus score, WHOQOL-BREF and Postoperative complications) were assessed in a postoperative follow-up.

Confounders and their assessment:

Age, sex, FIA complexity (simple vs complex), Hypertension (HTN), Type 2 Diabetes mellitus (DM II) and follow up duration were identified priorly as potential confounders based on the clinical relevance and the existing literature. The confounding variables and potential imbalances were identified by comparing baseline characteristics across the three treatment groups using appropriate statistical tests. Also, the detailed characteristic of FIA like tract length, tract extensions, degree of sphincter involved was reviewed from the records whenever available but as these data was not consistently documented so it could not be included in the statistical analysis. The influence of baseline variables on postoperative QoL has been evaluated using multiple linear regression analysis where WHOQOL-BREF domain scores was dependent variable and treatment group, baseline characteristics were independent variables.

Measurement standardization:

The standardized and validated tools (WHOQOL-BREF for QoL, VAS & VDS for pain, RFIS & flatus score for incontinence) were used to ensure consistency and reliability of data collected for

the assessment of outcomes. Also, the two independent investigators were selected, and oriented about the study protocol, along with definitions of all the variables, to have uniformity in interpretation before starting the data extraction from the records. All the discrepancies were resolved via agreement to minimize the observer bias. The measurements were collected from the routinely maintained case records form and follow-up documents. All the outcome variables were recorded at uniform time points having a minimum follow-up period of six months for all the included participants. For postoperative complications (wound infection, bleeding & recurrence) standard definitions were used.

Bias:

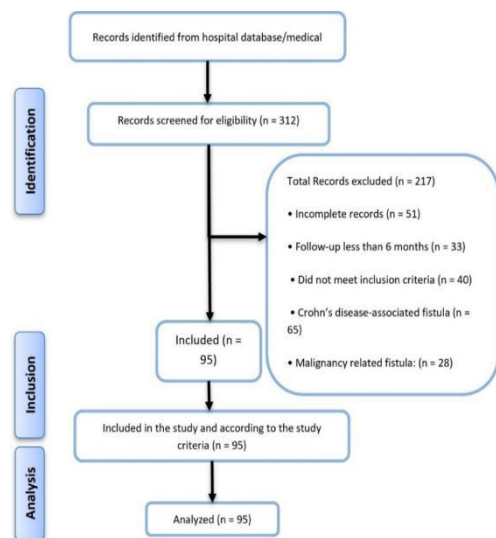
The potential sources of bias were identified, and these biases were addressed in the following manner. To reduce the selection bias, all patients meeting the inclusion criteria were included in the study, whereas patients with incomplete records, having follow-up less than 6 months were excluded from the study but this can introduce some sort of selection bias towards patients with complete records. The use of standardized and validated tools to measure outcome variables helps to address the information bias. As the data was extracted by the two independent investigators from the predefined case record forms this helps to reduce the measurement and observer bias. The baseline characteristics were compared across the treatment groups using appropriate statistical tests also multiple linear regression analysis was done to evaluate their association with postoperative QoL outcomes to minimize confounding bias. Despite of all these measures, the residual confounding cannot be eliminated due to the retrospective observational nature of the study.

Study size:

As this was a retrospective cohort study so no sample size calculation was done, and all eligible patients who underwent surgical intervention for FIA during the study period meeting the inclusion criteria were included in the analysis.

Data Collection and Statistical Analysis:

The data was collected from the case record forms (CRF) which included all the baseline characteristics, follow-up, treatment details along with all the measured outcomes. The data was subjected to both descriptive and inferential statistical analysis by focusing on assessment parameters. The descriptive statistics included Mean $\pm$ Standard Deviation (SD) or Median (minimum, maximum) to summarize demographic, clinical and outcome variables based on their distribution, whereas inferential statistics were used to compare treatment groups and to identify factors associated with postoperative QoL outcomes. Baseline demographic and clinical characteristics were analyzed between the groups using one-way ANOVA for continuous variables and Chi square test for categorical variables. The VAS, VDS, RFIS and Flatus scores were subjected to the Kruskal–Walli’s test because of their ordinal nature or due to non-normal distribution. The significant differences were observed so pairwise comparison was performed using Dunn's post-hoc test with Bonferroni correction for multiple testing. To check the influence of baseline confounding variables on postoperative QoL multiple linear regression analysis was done with WHOQOL-BREF domain score dependent variables where age, sex, HTN, DM II, follow-up and FIA complexity were included as independent variables. The assumption of normality was assessed using Shapiro wilk test whereas the assumption of homogeneity of variances was assessed using Levene’s test. The comparison of all the domains scores from WHOQOL-BREF including total scores for WHOQOL-BREF for between the group analysis was done using one way ANOVA whereas the pairwise comparisons were done using Tukey’s HSD test. Additionally, Welch ANOVA was done to assess sensitivity analysis where homogeneity of variances was not satisfied. All the statistical analysis was done using R software version 4.4.3 where all the tests were two tailed and statistical significance was considered at p value < 0.5.



Flow Diagram 1: (STROBE Flow Diagram)

3. RESULTS

Demographic and Clinical Characteristics of the Study Groups.

The baseline analysis of demographic and clinical characteristics between the groups showed that mean age was similar between the three groups (KSL: 45.09 ± 7.69 , CF: 43.5 ± 7.58 , KSL+PF: 44.76 ± 7.87) and no differences in age was seen between the groups with $p > 0.5$ indicating that the three groups were comparable with respect to the age. The distribution of gender, type of FIA complexity and prevalence of DM II as comorbidity between the groups differed significantly with all $p < 0.5$. The comorbidity of HTN did not differ between the group with $p > 0.05$. ([Table 1](#))

Table 1: Baseline Demographic and Clinical Characteristics of the Study Groups.

Variable		KSL	CF	KSL+PF	Test Statistic	P-Value
Age		45.09 ± 7.69	43.5 ± 7.58	44.76 ± 7.87	0.27	0.7610
Gender	Female	2	5	4	6.75	0.0342
	Male	42	13	29		
Fistula Type	Complex	44	1	32	82.54	< 0.0001
	Simple	0	17	1		
Comorbidities-HTN	Yes	30	14	26	1.29	0.5258
	No	14	4	7		
Comorbidities-DM II	Yes	9	4	15	6.23	0.0443

Surgical Procedure ([Figure 2](#))

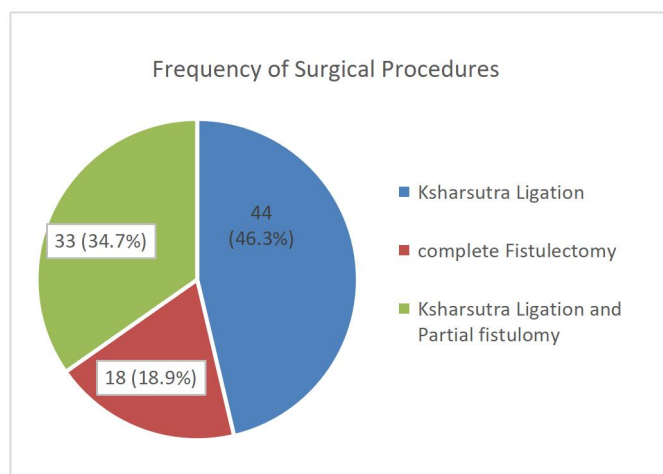


Figure 2: Frequency of different Surgical Procedures Done

Assumption Testing

Normality Assessment: The normality of WHOQOL-BREF domain scores, total score, VAS (B/T, A/T), VDS (B/T, A/T), RFIS and Flatus score was assessed using the Shapiro–Wilk test. Statistically significant deviations from normality were observed for all the domains, total score of the WHOQOL-BREF tool, VAS (B/T, A/T), VDS (B/T, A/T), RFIS and Flatus score with all $p < 0.001$. ([Table 2](#)) As the deviations from normality were seen from the Shapiro Wilk test, but the inspection of groups showed symmetrical distribution of WHOQOL-BREF scores and balanced group sizes, therefore one-way ANOVA was retained due to its established resistance to moderate departures from normality.

Table 2: Shapiro–Wilk Test for Normality of WHOQOL-BREF Domain Scores, Total Score, VAS, VDS, RFIS and Flatus score

Variable	Test Statistic (W)	P-Value
Domain 1 (Physical Health)	0.903	< 0.001
Domain 2 (Psychological Health)	0.859	< 0.001
Domain 3 (Social Relationship)	0.839	< 0.001
Domain 4 (Environmental Health)	0.799	< 0.001
Total Score (TS)	0.742	< 0.001
VAS B/T*	0.908	<0.001
VAS A/T*	0.739	<0.001
VDS B/T*	0.898	<0.001
VDS A/T*	0.747	<0.001
RFIS*	0.535	<0.001
Flatus score	0.497	<0.001

VAS: Visual analogue scale, VDS: verbal descriptive scale, RFIS: Revised fecal incontinence score, B/T: Before treatment, A/T: After treatment

Homogeneity of Variance

Levene's test was done for all the domains and total scores of the WHOQOL-BREF tool to assess the homogeneity of variances assumption required for one-way ANOVA. The test showed a $p > 0.05$ for Domain 1 ($F = 0.807$), Domain 2 ($F = 0.987$), Domain 3 ($F = 0.232$) and Total score ($F = 1.133$) so the assumption of homogeneity of variances was satisfied for these scores. (Table 3) Hence one-way ANOVA was considered for the further analysis, but Domain 4 ($F = 4.188$) broke the homogeneity assumption with $p < 0.05$ therefore, Welch ANOVA was also

done for Domain 4 as a sensitivity analysis which confirmed the findings of standard ANOVA (Welch's $F(2, 49.35) = 826.93$, $p < 0.001$).

Table 3: Levene's Test for Homogeneity of Variance of WHOQOL-BREF Domain Scores & Total Score

Domains	F-value (Levene Statistic)	p-value
Domain 1 (Physical Health)	0.807	0.450
Domain 2 (Psychological Health)	0.987	0.377
Domain 3 (Social Relationship)	0.232	0.793
Domain 4 (Environmental Health)	4.188	0.018
Total Score	1.133	0.326

Quality of life (QOL) assessment (Table 4)

One-way ANOVA demonstrated a highly significant difference in Physical Health, Psychological Health, Social Relationship, Environmental Health, and Total Quality of Life scores among the three surgical procedure groups ($P < 0.001$ for all domains). The Tukey's post hoc analysis showed that the KSL and KSL+PF groups have significantly higher scores compared to CF group across all the domains of WHOQOL-BREF tool along with total score with $p < 0.001$ whereas no statistical significance was observed between the KSL and KSL+PF groups across all the domains and total score with $p > 0.05$. These findings suggest that the *Ksharasutra* based procedures were associated with significantly better postoperative QoL as compared to CF procedure. (Figure 3)

Table 4: Comparison of WHOQOL-BREF Domain Scores and Total Quality of Life Score among Different Surgical Procedures using One-Way ANOVA and Tukey's Post-hoc Test

Domain	Groups	Mean	SD	95% Confidence Interval	F Value	B/W Groups	Comparison Groups	Mean Diff	Pairwise Confidence Interval	95% p-value
Physical Health (Domain 1)	KSL	62.98	6.95	60.86 – 65.09	140.7	<0.001	KSL & CF	30.37	25.78 - 34.95	<0.0001
	CF	32.61	7.25	29.00 – 36.21			KSL+PF & KSL	-0.37	-4.14 - 3.40	0.9701
	KSL + PF	62.61	6.57	60.27 – 64.93			KSL+PF & CF	29.99	25.19-34.79	<0.0001
Psychologic al Health (Domain 2)	KSL	67.64	8.3	65.11 – 70.15	186.7	<0.001	KSL & CF	47.58	41.26 - 53.89	<0.0001
	CF	20.06	7.02	16.56 – 23.54			KSL+PF & KSL	0.81	-4.37 - 6.01	0.9254
	KSL + PF	68.45	11.81	64.26 – 72.64			KSL+PF & CF	48.39	41.78 - 55.01	<0.0001
Social	KSL	71.89	11.09	68.51 – 75.25	220.8	<0.001	KSL & CF	65.49	57.43 - 73.55	<0.0001
	CF	6.39	7.55	2.63 – 10.14			KSL+PF & KSL	2.32	-4.30 - 8.96	0.6823

Relationship (Domain 3)	KSL + PF	74.21	15.01	68.89 – 79.53			KSL+PF & CF	67.82	59.38 - 76.26	<0.0001
Environmen	KSL	75.32	7.15	73.14 – 77.49			KSL & CF	66.42	59.49 - 73.36	<0.0001
tal Health	CF	8.89	5.49	6.15 – 11.62	310.6	<0.001	KSL+PF & KSL	3.23	-2.48 - 8.93	0.3733
(Domain 4)	KSL + PF	78.55	15.06	73.20 – 83.88			KSL+PF & CF	69.65	62.39-76.92	<0.0001
Total	KSL	69.45	5.73	67.71 – 71.19			KSL & CF	52.46	47.45- 57.47	<0.0001
Transformed	CF	16.98	4.16	14.91 – 19.05	364.4	<0.001	KSL & KSL+PF	1.50	-2.62-5.62	0.6628
Score/4	KSL + PF	70.95	10.44	67.24 – 74.65			KSL+PF & CF	53.96	48.71- 59.21	<0.0001

KSL = *Ksharasutra* Ligation, KSL+PF= *Ksharasutra* Ligation + Partial Fistulotomy, CF = Complete Fistulectomy, B/W = Between

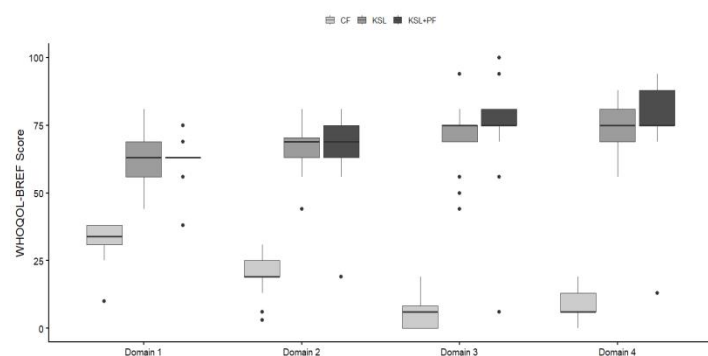


Figure 3: WHOQOL-BREF domains score distribution amongst KSL, CF and KSL+PF groups

Note: Centre line = Median, Boxes = Interquartile range, Whiskers = Range excluding outliers, Points = Outliers

Table 5: Comparison of Preoperative and Postoperative VAS and VDS Scores among Different Surgical Procedures with Post-hoc Pairwise Analysis (Dunn's Test with Bonferroni Correction)

Parameter	Surgical Procedure	Mean	SD	Test Statistic	P-Value	Within Group	Z	P-Value
VAS: B/T	KSL	7.05	1.36	0.97	0.61619	KSL & CF	-0.55	1.0000
	CF	7.28	0.75			KSL & KSL+PF	0.57	1.0000
	KSL + PF	6.91	1.16			CF & KSL+PF	0.97	0.991648
VAS: A/T	KSL	1.41	0.73	42.80	0.00000	KSL & CF	-6.34	0.000000000669
	CF	3.89	1.08			KSL & KSL+PF	0.74	1.0000
	KSL + PF	1.58	0.87			CF & KSL+PF	5.47	0.000000132422
VDS: B/T	KSL	7.32	1.34	2.18	0.33614	KSL & CF	-0.55	1.0000
	CF	7.67	0.69			KSL & KSL+PF	0.56	1.0000
	KSL + PF	7.21	1.05			CF & KSL+PF	0.97	0.9916
VDS: A/T	KSL	1.52	0.9	45.82	0.00000	KSL & CF	-6.17	0.000000002003
	CF	4	0.91			KSL & KSL+PF	0.41	1.0000
	KSL + PF	1.39	0.61			CF & KSL+PF	6.22	0.000000001445

KSL* (*Ksharasutra* Ligation), KSL+PF* (*Ksharasutra* Ligation + Partial fistulotomy), CF* (Complete Fistulectomy), B/T* (Before Treatment), A/T* (After Treatment), VAS* (Visual Analogue Scale), VDS* (Verbal Descriptive Scale)

Revised Fecal Incontinence Scale (RFIS) and Flatus Incontinence Score

The analysis of RFIS and flatus score showed the highly significant differences between the three groups with $p < .05$ and Kruskal Wallis $H = 83.22$ and Kruskal Wallis $H = 10.742$, respectively. Also, the post hoc pair wise analysis was done which showed that the CF group had significantly higher RFIS

and flatus score as compared to KSL group with $Z = -8.58$, $p < 0.05$, $Z = -3.17$, $p < 0.05$ respectively and KSL+PF group with $Z = -8.09$, $p < 0.05$, $Z = 2.76$, $p < 0.05$, respectively whereas, no significant differences were seen between the KSL and KSL+PF groups with $Z = -0.12$, $p > 0.05$ and $Z = -0.35$, $p > 0.05$ for RFIS and flatus scores. (Table 6)

Table 6: RFIS & Flatus Score comparison amongst KSL, CF & KSL+PF using Kruskal-Wallis and Dunn's Post- hoc analysis

Parameters	Group	Mean $\pm$ SD	Kruskal Wallis H	p-value	Pairwise comparison	Z statistic	Bonferroni adjusted p-value
RFIS*	KSL	0.09 $\pm$ 0.60	83.22	<0.0001	KSL & CF	-8.58	<0.0001
	CF	6.06 $\pm$ 1.00			KSL & KSL+PF	-0.12	1.000
	KSL+PF	0.18 $\pm$ 1.04			CF & KSL+PF	8.09	<0.0001
Flatus Score	KSL	0.25 $\pm$ 0.58	10.742	0.0046	KSL & CF	-3.17	0.004
	CF	0.94 $\pm$ 1.00			KSL & KSL+PF	-0.35	1.000
	KSL+PF	0.33 $\pm$ 0.74			CF & KSL+PF	2.76	0.017

RFIS*: Revised fecal incontinence score

Assessment of Potential Confounding Factors

A multiple linear regression analysis was performed using WHOQOL-BREF total score as the dependent variable and treatment group, age, gender, hypertension, diabetes mellitus, fistula type, and follow-up duration as independent variables. The model was statistically significant ($F(8,86) = 121.0$, $p < 0.001$) and explained 91.8% of the variance in WHOQOL-BREF total score (Adjusted $R^2 = 0.911$). Compared with the KSL group, patients treated with conventional fistulectomy (CF) had significantly lower WHOQOL-BREF total scores ($\beta = -103.2$, $p < 0.001$), whereas no significant difference was observed between the KSL and KSL+PF groups ($\beta = 12.7$, $p = 0.066$). Complex fistula type was also independently associated with lower WHOQOL-BREF total scores ($\beta = -109.7$, $p < 0.001$). Age, gender, hypertension, diabetes mellitus, and follow-up duration were not significant predictors of WHOQOL-BREF total score. (Table 7)

Reference categories: KSL for treatment group, female for gender, absence of hypertension and diabetes mellitus for comorbidity variables, and simple fistula for fistula type. Model

statistics: $R^2 = 0.918$, Adjusted $R^2 = 0.911$, $F(8,86) = 121.0$, $p < 0.001$.

Table 7: Multiple Linear Regression Analysis of Factors Associated with WHOQOL-BREF Total Score

Variables	B coefficient	SE	t-value	p-value
Intercept	263.5	22.8	11.56	<0.001
CF & KSL	-103.2	20.9	-4.94	<0.001
KSL+PF & KSL	12.7	6.79	1.87	0.066
Age	0.004	0.366	0.01	0.992
Gender	-13.9	9.05	-1.54	0.127
HTN	3.68	6.54	0.56	0.575
DM II	-2.82	6.49	-0.44	0.665
FIA complexity	-109.7	20.1	-5.45	<0.001
Follow-up	1.98	2.02	0.98	0.330

Postoperative Complications (Figure 4a & 4b)

The duration of hospital stay showed significant differences between the KSL, CF, KSL+PF groups with $p < 0.05$ and large effect size ($\eta^2 H = 0.404$). Also, the post hoc Dunn Bonferroni analysis showed that a CF group patient stayed significantly longer in hospital as compared to KSL (adjusted $p < 0.05$) and KSL+PF (adjusted $p < 0.05$) group patients and no significant

differences in hospital stay was seen between the KSL and KSL+PF groups (adjusted $p > 0.05$). The analysis of time to return to routine activities also have significant differences

between the KSL, CF, KSL+PF groups with $p < 0.05$ and large effect size ($\eta^2H = 0.352$ ([Table 8](#)))

Table 8: Comparison of Postoperative Outcomes among Treatment Groups

Outcome	CF (n=18)	KSL (n=44)	KSL+PF (n=33)	p-value
Bleeding, n (%)	6 (33.3)	3 (6.8)	5 (15.2)	0.029
Secondary infection, n (%)	5 (27.8)	0 (0.0)	2 (6.1)	<0.001
Recurrence, n (%)	3 (16.7)	0 (0.0)	0 (0.0)	0.006
Hospital stay (days), Mean $\pm$ SD	8.50 $\pm$ 1.04	3.02 $\pm$ 1.85	4.36 $\pm$ 2.77	<0.001 ($\eta^2H = 0.404$)
Return to routine activity (days), Mean $\pm$ SD	12.40 $\pm$ 4.18	4.61 $\pm$ 2.68	6.33 $\pm$ 4.75	<0.001 ($\eta^2H = 0.352$)

Note: Data are presented as n (%) or Mean $\pm$ SD. Fisher's Exact Test was used for categorical variables, and Kruskal–Wallis test followed by Dunn–Bonferroni post-hoc comparisons was used for continuous variables. Effect sizes ($\eta^2(H)=0.404$ and 0.352) indicate large treatment-group effects on hospital stay and return to routine activity.

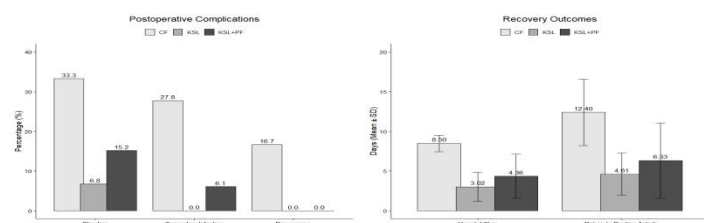


Figure 4a & 4b: Comparison of postoperative outcomes among patients treated with CF, KSL, and KSL+PF.

Note: 4a (Percentage of patients with postoperative bleeding, secondary infection, and recurrence in the CF, KSL, and KSL+PF groups, 4b (Mean hospital stay and time to return to routine activity in the CF, KSL, and KSL+PF groups. Error bars represent standard deviation).

Strengths and Limitations: As the present study evaluated the postoperative outcomes using validated tools like WHOQOL-BREF, VAS, VDS, RFIS, Flatus score while having both complex and simple FIA patients who have a minimum follow-up of 6 months, which provides a clinical relevance are the strengths of this study. Also, the assessment of potential confounders and the use of multiple regression analysis strengthen the interpretation of results. The study has several limitations like

the retrospective observational nature of this study which limits the ability to establish causal relationship between surgical procedure and postoperative outcomes. As the treatment was done based on surgeons' decision, clinical examination and routine clinical practice selection bias may be introduced. Also, the distribution of FIA complexity differed between the groups that may have influenced observed associations. As the study was done from pre-existing case record forms along with patient reported outcomes which can have incomplete documentation or inaccurate data recording which may lead to information bias, but residual bias may still persist despite of every effort. In the study the baseline characteristics, confounders were assessed and regression analysis was done but the variables like fistula tract length, tract branches and degree of sphincter involvement was not analysed so residual confounding cannot be excluded completely. Due to the retrospective design the magnitude of bias cannot be quantified formally, and the generalizability of this study findings may be limited to other healthcare setting as study was conducted at single tertiary Ayurveda hospital.

4. DISCUSSION

The patient-centered outcomes in the management of FIA should not depend only on healing and prevention of recurrence of FIA either they should also include preservation of anal continence, reduced postoperative pain and early restoration of daily day-to-day work which influences the

physical, mental, social and environmental well-being of a patient in a postoperative period. WHOQOL-BREF is a standardized and validated tool which has shown consistency when used in different cultures with both low- and middle-income settings. [17,18] In the present study significant differences in QoL were observed between the patients treated with KSL, CF, and KSL+PF for the management of FIA. The KSL and KSL+PF groups have shown better outcomes as compared to CF across all the domains and total score of WHOQOL-BREF tool and no differences were observed between the KSL and KSL+PF groups. [19] As there are various treatment options available [20,21] they too have their various outcomes and complications of varied degrees associated with them which in specific cases resulted in the uncertainty in the standard treatment protocol for the FIA which further necessitates the present study. The findings of this study show that the procedures which help to preserve sphincter can provide better postoperative QoL which can help in making decision for the patients suffering with FIA as they are difficult to treat. [22] The *Ksharasutra* (medicated thread) therapy is a widely practiced procedure for treating FIA as it helps in preserving the sphincter, but the *Ksharasutra* (medicated thread) therapy requires multiple thread changes which may cause discomfort in positioning, anxiety, interference in daily activities mostly in patients with complex fistula tracts. Also, the duration of treatment and repeated sitting can cause treatment fatigue in patients leading to discontinuation of the therapy. [23-25] On the contrary to this in simple low-lying FIA the CF procedure may provide satisfactory outcomes but it can be associated with the risk factors like impairment of anal continence, wound infection leading to delayed wound healing and prolonged recovery and these concerns are more relevant to complex FIA as they involve more part of anal sphincters where sphincter preservation is more important. As the *Ksharasutra* based procedures have inherent limitations of repeated interventions, but the present findings suggest that these procedures may

offer advantages in maintaining postoperative quality of life and functional outcomes. The patients treated with KSL and KSL+PF showed significantly higher scores in physical health, psychological health, social relationships and environmental domains compared with patients who underwent CF (all Tukey-adjusted $p < 0.0001$). Although KSL+PF has shown higher scores than KSL in most of the domains, these differences were not statistically significant, suggesting a comparable effectiveness of both *Ksharasutra* based procedures ([Table 4](#)). The postoperative pain and continence outcomes (RFIS & Flatus score) also support these observations as both KSL and KSL+PF were associated with lower postoperative VAS and VDS scores compared to CF. ([Table 5](#)) The patients who underwent CF showed significantly higher RFIS and Flatus scores than those who underwent KSL or KSL+PF procedures. ([Table 6](#)) These findings suggest that procedures having greater sphincter preservation may reduce functional impairment and may improve postoperative recovery providing better postoperative QoL. Preservation of anal continence is important as even minor degree of incontinence can affect the social, mental well-being and overall QoL. The integration of KSL with PF (KSL+PF) showed outcomes comparable to KSL therapy alone where the advantages of KSL+PF over KSL include the reduction of fistula tract through partial fistulotomy, and reduced *Ksharasutra* changing while preserving sphincter as per the traditional *Ksharasutra* therapy. The QoL scores were observed to be numerically higher in KSL+PF group which may reflect improved drainage of fistula tract, faster recovery and reduced treatment duration but these differences did not reach statistical significance therefore both *Ksharasutra* based procedures appear to be acceptable clinically for the management of FIA. The present study is aimed at addressing clinical outcomes amongst various surgical interventions and their effect on the patients QoL in postoperative period. However, the interpretation of these findings should consider the baseline differences amongst the treatment groups as significant

differences were observed in gender distribution, FIA complexity, and diabetes mellitus whereas age and HTN were comparable across the groups. As the KSL and KSL+PF groups mainly consisted of complex FIA whereas the CF group mainly consisted of simple FIA ([Table 1](#)). The multiple linear regression analysis was performed ([Table 7](#)), which showed that the type of FIA was independently associated with postoperative QoL outcomes indicating that the disease severity may have influenced the observed results. Regardless of a greater number of patients with complex FIA in the KSL and KSL+PF groups, still these procedures have shown better postoperative QoL outcomes as compared to the CF group which indicates that the benefits were not related to the differences in FIA complexity. In this study the complexity of FIA and allocation of treatment are closely related to each other which is usually seen in the routine clinical practice where all the complex FIA received *Ksharasutra* based treatment, whereas simple FIA were treated with CF hence the regression findings should be interpreted with care. However, the multivariable regression was done, but residual confounding still cannot be excluded completely because allocation of treatment was closely related to the complexity of FIA, also the variables like fistula tract length, tract branches and degree of sphincter involvement were not analysed as they were not consistently available in the records for the adjustment. Clinically significant differences were observed in addition to the statistical significance, as the patients with *Ksharasutra* based procedures had less postoperative pain, shorter stay in the hospital, better control over continence and early return to day-to-day activities than those who underwent CF. Due to non-availability of validated MCID (minimal clinically important difference) for the patients suffering with FIA, the level of differences seen between the groups suggests benefits from the perspectives of patients.

This study was conducted at single hospital which may limit generalizability but is in line with the previous comparative studies which show a trade-off between functional

preservation and prevention of recurrence. [26-28] However, the procedures evaluated (KSL, KSL+PF, & CF) are widely practiced which may enhance its applicability in similar clinical context and inclusion of both simple & complex FIA cases improves the relevance of study to real world practice. This retrospective study may have inherent limitation, several measures like exclusion of incomplete records were excluded during data screening to ensure accuracy of outcome measurement, completeness of key variables and to reduce potential bias which helped minimize bias, standard surgical procedure and consistent follow up within the institution reduced variability in outcome assessment but selection bias due inclusion of patients with complete medical records and follow-up and reliance on medical records along with patients reported outcomes may have led to information bias also residual bias may persist despite of efforts aimed to standardize data extraction, hence the exact magnitude of bias cannot be quantified in this retrospective study.

Future Directions: The prospective randomized controlled multicentric studies can be carried out in future with standardized treatment allocation along with proper characterization of FIA are required along with cost effectiveness of treatment to validate these findings. Also, the establishment of validated disease-specific MCID for the WHOQOL-BREF for patients with FIA would further improve the interpretation of the patient-reported outcomes.

5. CONCLUSION

The comparison of KSL, CF, and KSL+PF procedures in this retrospective observational cohort study, showed that the *Ksharasutra* based interventions, including KSL alone and KSL+PF, were associated with more favourable postoperative quality-of-life scores, lower incontinence scores, fewer postoperative complications, shorter hospital stays, and earlier return to routine activities compared to CF. As the QoL outcomes were seen to be comparable between the KSL and KSL+PF groups but the KSL+PF group was observed to have

lesser *Ksharasutra* changes and better treatment convenience. This study follows a retrospective observational design so the findings of the study should be seen as associations rather than the evidence of treatment superiority. It is not possible to rule out the selection bias and residual confounding but as seen in the study positive results were related to the *Ksharasutra* based procedures which highlights their role clinically for the management of FIA.

Ethical approval: This retrospective study was conducted after obtaining approval from the Institutional Ethical committee for research on Human Subjects of KAHER's Shri BMK Ayurveda Mahavidyalaya (Approval no: BMK/24/SYM/01, Dated: 05/12/2024).

Abbreviations: FIA (Fistula in Ano), KSL (*Ksharasutra* ligation), CF (Complete fistulectomy), KSL + PF (*Ksharasutra* ligation + Partial fistulotomy), WHOQOL-BREF (World Health Organization Quality of life BREF), QoL (Quality of Life), MCID (Minimal clinically important difference), KS (*Ksharasutra*), VAS (Visual analogue scale), VDS (Verbal descriptive scale), RFIS (Revised Fecal Incontinence Score), TB (Tuberculosis), HIV (Human immunodeficiency virus), DM II (Type 2 Diabetes mellitus), SD (Standard deviation), MD (Mean difference), SE (Standard error), IQR (Interquartile range), B/W (Between), A/T (After treatment), B/T (Before treatment), IPD (In-Patient Department)

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