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SPHINCTER CUTTING AND PRESERVING SURGERIES FOR COMPLEX FISTULA IN ANO: A COMPARATIVE STUDY AT A TERTIARY CARE CENTRE IN NORTH INDIA

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ABSTRACT **INTRODUCTION:** Anal fistula represents an important aspect of colorectal practice, being a distressing condition for the patient and sometimes a challenge for the surgeon. Successful surgical management of anal fistulas requires accurate preoperative assessment of the course of the primary fistulous tract and the site of any secondary extension or abscess. Fistula-in-ano has various types of clinical presentations. With time newer techniques have also evolved. Here we comparing the various treating modalities by classifying them as sphincter preserving and sphincter cutting surgeries.

AIMS AND OBJECTIVES : To compare the outcome, duration of wound healing, recurrence rate, and complications after sphincter preserving and sphincter cutting surgeries.

MATERIAL AND METHODS: A total 100 patients were taken up for the study after ethical clearance and proper informed consent. Group A (n=50) patients were selected for sphincter preserving surgeries (VAAFT+FILAC+LIFT, VAAFT+FILAC, LIFT). Group B (n=50) patients were taken up for sphincter cutting procedures (fistulectomy and fistulotomy). Simple fistulas, and those associated with tuberculosis, IBD, carcinomas, or with perianal injury were excluded from the study. Rectovaginal and anovaginal fistulas, patients with history of incontinence, or anal sphincter impairment were also excluded.

RESULTS: 66% patients were males and 34% were females. (1.94:1). Mean age of patients was 41.01$\pm$12.35 between 20-70 years. Transphincteric fistula was the most common type (61%, n=61) and perianal discharge was the most common presentation. (100%, n=100). Primary healing rate at 3 months in sphincter preserving surgeries was 84%, and 66% in cutting surgeries ($p<0.05$). Recurrence ($p<0.05$) was more in cutting surgeries. Incontinence at 1st week ($p<0.05$) and hospital stay ($p<0.05$), were also more after cutting surgeries. However, there was no statistically significant difference in the mean healing time and pain by VAS score at 48 hours.

CONCLUSIONS: Sphincter preserving surgeries for complex fistula in ano are better in terms of less recovery time and better healing rate, less chances of incontinence, recurrence, compared to sphincter cutting surgeries. With the advent of more sphincter sparing techniques the percentage of patients undergoing sphincter cutting techniques should continue to decrease over time.

KEYWORDS : Fistula in-ano, sphincter preserving surgery, sphincter cutting surgery.

INTRODUCTION

An abnormal hollow tract or cavity lined with granulation tissue, connects opening inside the anal canal (primary opening) to opening in the perianal skin (secondary opening) is termed as fistula-in- ano. Anal glands which are located between two layers of anal sphincters and which drains into the anal canal gives origin to anal fistulae. Soiling, pruritis and recurrent suppuration are annoying symptoms associated with chronicity of the disease.

Complex fistulas include those with more muscle involvement (30-50 percent),or anterior fistulas in female patients, as well as recurrent fistulas , and those associated with preexisting fecal incontinence, inflammatory bowel disease, or radiation.

Generally, it is not so harmful but can be very painful and can be very irritating because of the possibility of the formed stools to be passed through the fistulous tract. Treating fistula has always been a complex task for surgeons. Variable results have been produced by all these techniques and are not free for shortcomings. In this study we are combining the LIFT procedures with VAAFT and FILAC for the treatment of complex fistula in ano. The results were compared with the fistulotomy and fistulectomy surgeries for complex fistula in ano to study the outcome between sphincter cutting and sphincter preserving surgeries.

AIMS AND OBJECTIVES

1. To study the clinical profile of complex fistula in ano.
2. To compare duration of wound healing after sphincter preserving and sphincter cutting surgeries.
3. To compare result between sphincter cutting and sphincter preserving surgeries for fistula in ano in terms of healing time and duration of hospital stay.
4. To evaluate recurrence rate after sphincter preserving and sphincter cutting surgeries.
5. To look for complications in operated patients.

MATERIALS AND METHODS

This was an open prospective comparative study done after approval from the Institutional Ethics Committee. A total of 114 patients above 18 years of age with complex fistula in ano were included in the study, out of which 14 patients were lost in follow up period of one year who were excluded from the study.

Patients with simple fistula in ano, pregnant females or females planning for pregnancy in the coming year, fistulas associated with tuberculosis, inflammatory bowel disease, associated with carcinoma, or with perianal injury, rectovaginal and anovaginal fistulas and patients with history of incontinence, or anal sphincter impairment were excluded from the study.

The patients underwent either VAAFT+FILAC+LIFT, VAAFT+FILAC, LIFT, fistulectomy and fistulotomy depending upon their group. Out of the 100 patients, that were operated for complex fistula in ano, 66 were males and 34 females.

Patients were divided into 2 groups- Group A (n=50) patients were selected for sphincter preserving surgeries (VAAFT+FILAC+LIFT, VAAFT+FILAC, LIFT), and Group B (n=50) patients underwent sphincter cutting procedures (fistulectomy and fistulotomy).

PREOPERATIVE PREPARATIONS:

1. Clinical proforma.
2. All the routine investigations were done and imaging techniques adopted where required.
3. The procedure was explained to the patient and informed written consent taken for surgery as well as for participation in study.
4. Bowel preparation was done by proctoclysis enema per rectally.
5. Patient was kept nil per oral for 12 hours before surgery.

Information about the mode of onset, duration of illness, symptoms and previous surgery, any previous treatment for tuberculosis, inflammatory bowel disease, carcinoma, and peri anal injury were

collected. Operative findings were all recorded, intraoperative and postoperative complications were recorded like incontinence, recurrence, pain, discharge, bleeding, and inflammation. Data about number of days lost in work, healing, post of pain score were collected.

Patients were followed up for one year. Patients were observed for healing of fistula, persistence of symptoms, development of any complications, recurrence and quality of life.

STATISTICAL ANALYSIS

The statistical analysis was done using SPSS (statistical package for social sciences) Version 22.0 statistical analysis software.

OBSERVATIONS AND RESULTS:

Table 1: Number of patients and type of procedure:

SPHINCTER PRESERVING PROCEDURES-

Procedure	No. of Patients
VAAFT+FILAC+LIFT	23
VAAFT+FILAC	11
LIFT	15

SPHINCTER CUTTING PROCEDURES-

Procedure	No. of Patients
FISTULOTOMY	23
FISTULECTOMY	27

Table 2: Demographic data:

		Sphincter preserving	Sphincter cutting
Patients average age (years)		40.24+/-12.25	41.78+/-12.28
Sex	Male	30	36
	Female	20	14
Underlying disease		0	0
Preoperative incontinence Wexner's score		0	0
FISTULA TYPE	High trans-sphincteric	24	12
	Horseshoe trans-sphincteric	4	1
	Supra-sphincteric	6	12
	Inter-sphincteric	7	14

Table 3: Age and Sex distribution of patients:

AGE (YEARS)	MALE			FEMALE		
	Sphincter preserving	Sphincter cutting	Total	Sphincter preserving	Sphincter cutting	Total
20-29	6	6	12	4	1	5
30-39	11	8	19	8	5	13
40-49	8	11	19	2	5	7
50-59	6	4	10	3	3	6
60-69	3	1	4	1	0	1
70-79	2	0	2	2	0	2
TOTAL (n=100)	36	30	66	20	14	34

Table 4: Distribution of the patients according to the clinical presentation:

Clinical presentation	**No. of cases**
Discharge	100
Perianal itching	78
Pain	58
External opening	100
Internal opening	82

Table 5: Methods used for localisation of fistulous tract:

Localisation	**No. of cases**
Fistulogram	26
DRE	100
Endorectal usg	23
MRI	40
Dye test	100
Proctoscopy	100

Table 6: Primary Healing (OUTCOME):

	SPHINCTER PSRESERVING	SPHINCTER CUTTING	TOTAL
HEALED	42	33	75
NOT HEALED	8	17	25

Chi square value is 4.32>3.84 which is statistically significant at probability level p value less than .05

Table 7: Healing time:

	SPHINCTER PRESERVING	SPHINCTER CUTTING	p VALUE
HEALING TIME (IN MONTHS)	3.32+/-1.26	3.98+/-2.68	**0.1183** (Statistically not significant)

Table 8: Comparison of recurrence in sphincter preserving and sphincter cutting surgeries:

WOUND	RECURRENCE		NO RECURRENCE	
	Sphincter preserving	Sphincter cutting	Sphincter preserving	Sphincter cutting
HEALED	4	3	38	32
NOT HEALED	1	10	7	5
Percentage	10%	26%		

Chi square value is 4.92>3.84 which is **statistically significant** probability level p value less than .05.

Table 9: POST OP CONTINENCE (WEXNER SCORE) AT FIRST WEEK:

WEXNER SCORE	SPHINCTER PRESERVING	SPHINCTER CUTTING
MORE THAN ZERO	4	12
ZERO	46	38
Percentage of patients with incontinence	8%	24%

Chi square value is 4.76>3.84 is statistically significant at probability level p value less than .05

Table 10: Mean Wexner's Score:

Duration (post op)	**Sphincter preserving**	**Sphincter cutting**	**p value**
1 week	0.16+/-0.57	0.43+/-0.79	<0.001
6 weeks	0.16+/-0.57	0.37+/-0.71	<0.001
3 months	0.12+/-0.43	0.31+/-0.61	<0.001
6 months	0.1+/-0.36	0.31+/-0.61	<0.001
1 year	0.1+/-0.36	0.23+/-0.54	<0.001

Table 11: Length of Hospital Stay (in Days):

HOSPITAL STAY	SPHINCTER PRESERVING	SPHINCTER CUTTING
LESS THAN OR EQUAL TO 2 DAYS	41	32
MORE THAN 2 DAYS	9	18

Mean length of hospital stay for sphincter preserving surgeries is **1.3+/-0.57** days and for sphincter cutting surgeries is **4.6+/-2.4** days. Chi square value is 4.1>3.84 which is statistically significant at probability level p value level less than .05.

Table 12: Return to normal work (in days):

DAYS	SPHINCTER PRESERVING	SPHINCTER CUTTING
WITH IN 25 DAYS	43	34
AFTER 25 DAYS	7	16

Mean no. of days in which patients resumed to normal activity in sphincter preserving surgeries- **21.3+/-6.67** days and sphincter cutting surgeries was **25+/-11.34** days. Chi square value is 4..57>3.84 which is statistically significant at probability level p value level less than 0.05

Table 13: Pain on VAS score (taken at 48 hours):

	SPHINCTER PRESERVING	SPHINCTER CUTTING	P-VALUE
Pain on VAS Score (after 48hrs)	5.10+/-1.37	5.6+/-1.54	0.08

p value is 0.08>0.05 which is insignificant.

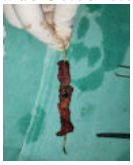

Fig. 1. A FISTULA TRACT

Fig. 2. WOUND AT 4th POST OPERATIVE DAY AFTER FISTULECTOMY

Fig. 3. WOUND AT 20th POST OPERATIVE DAY

Fig. 4. WOUND AT 6TH WEEK

Fig. 5. WOUND AT 3RD MONTH

Fig. 6. INTRA OPERATIVE IMAGE OF HIGH SCROTAL FISTULA.

Fig. 7. WOUND AFTER CLOSURE AT ZERO POST POST OPERATIVE DAY

Fig. 8. WOUND AT 2ND WEEK IN POST OPERATIVE PERIOD

Fig. 9. WOUND AT 6TH WEEK IN POST OPERATIVE PERIOD

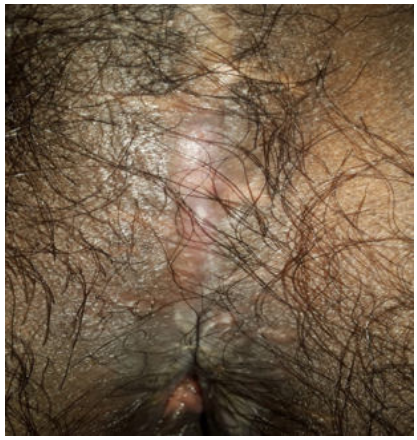

Fig. 10. WOUND AT 3RD MONTH –COMPLETE HEALING

DISCUSSION

Anal fistula represents an important aspect of colorectal practice, being a distressing condition for the patient and sometimes a challenge for the surgeon. Successful surgical management of anal fistulas requires accurate preoperative assessment of the course of the primary fistulous tract and the site of any secondary extension or abscess. Fistula in ano has various types of clinical presentations. Various modalities exist for the management, both traditional, and newer techniques. Our study aimed at comparing various treating modalities by classifying them as sphincter preserving and sphincter cutting surgeries. We followed up patients for a time period of 1 year.

In our study mean age was **41.01+/-12.35** in years and with male preponderance (male : female =**1.94:1**). This was consistent with a study by **Fabiano Roberto Fugita et. al** [1]who stated that there were more patients under 60 years (93.2%; n= 109) than patients over 60 years of age (6.8%; n = 8; binomial test; $p < 0.001$). More male patients (66.7%; n = 78) were treated than female patients (33.3%; n = 39; $p < 0.001$). They concluded that men aged less than 60 years are the most affected by the disease, usually without associated comorbidities. Data from anal fistula operated patients in Helsinki showed an incidence of 8.6 in 100,000; and a ratio of 2:1 between men and women[2-3] similar to what was observed in our study.

Saadeldin Ahmed Idris et al. (2015)[4] stated the rate of intersphincteric fistulae reported in their study was 75.5%. Besides, 19.8% of fistulae are transphincteric, 2.8% are extrasphincteric and 1.9% suprasphincteric. In our study, transsphincteric fistulas accounted for 61%, while suprasphincteric and interasphincteric accounted for 18% and 21%, respectively. This variation could be due to exclusion of patients with comorbidities from our study.

All the 100 patients in our study presented with discharge through external opening, 78 presented with perianal itching, 58 with pain, all 100 with external opening, 82 with internal opening, and none with soiling or incontinence. In support of our study **Shruti Yadu et al(2018)**[5] also stated that 74% patients had perianal discharge while 66% patients presented with perianal pain. Most common mode of presentation was discharge.

VAAFT, is based on the principle of a secure closure of the tract near the internal opening and makes healing rates ranging from 57 to 94.4% possible**.** In our study, healing rate at 3 months with sphincter preserving technique which included (VAAFT, FILAC, LIFT) technique was **84%,** and with sphincter cutting surgeries healing rates was **66%.** This was similar to past studies by **P. Meinero L. Mori et al (2011)**[6] where primary healing was achieved in 72 patients (73.5%) within 2 to 3 months after surgery (VAAFT SPHINCTER PRESERVING MODALITY), in 26 patients (26.5%) no wound healing was observed. **Hall JF et al.(2014)**[7] also stated that, 18% of patients were managed using a LIFT procedure, suggesting atleast a transient interest in adopting the procedure for some fistulas. The LIFT technique was associated with a 79% healing rate at 3 months which is comparable to our study in which 30 percent cases were treated with LIFT Technique part of sphincter preserving surgeries which had 84 percent of healing rate at 3 month.. **Rojanasakul et al**.[8]reported healing in 94.4% of patients after LIFT procedure.

Caroline Sauter Dalbem et al (2014) observed mean healing time for LIFT technique ranged from 4 to 8 weeks. **Ooi et al.** and **Shanwani et al.**[9] reported a mean healing time of 6 and 5 weeks, respectively, but what we observed here is slight different from these studies as mean healing time in sphincter preserving surgeries is 3.32+/-1.26 (in months), in weeks it is 10-12 in weeks which is less than mean healing time for sphincter cutting surgeries 3.98+/-2.68 (in months), in weeks it is 14-16 weeks but this is insignificant. The occurrence of slight variations is probable in accordance with what is considered as "healing". Here, we considered as "complete healing" the interruption of the flow of purulent secretion with coaptation of the edges of the wound. The second reason for longer healing time could be poor hygienic conditions. In the literature, data are lacking for comparison of sphincter preserving and sphincter cutting surgeries in this regard.

As we have observed recurrence in two types of wound; healed wound and non healing wounds in both techniques sphincter preserving as well as sphincter cutting. Recurrence in non healing wound means that post operative site wound has not healed within 3 months after surgery and patient complained of discharge from that wound. In other cases, post operative site wound has healed up but after complete closure of the tract has reported to us with complain of discharge after 6 weeks from that the same site or some other new site.

We observed 10% recurrence after sphincter preserving surgeries out of which 4 cases is in healed wounds and 1 case in non healing wound. On the other side in sphincter cutting surgeries we observed 26% recurrence in which 3 cases were in healed wounds, and 10 cases in non healed wounds. This was consistent with previous studies by **L., Ramachandra; GARG, Mayank (2018)**[10] **who** reported recurrence seen in 5 (25%) cases of fistulectomy followed by 3 (15%) patients in LIFT procedure and 2 (10%) each in fistulotomy and setons respectively. In a study by **Poon Chi-Ming et al** (135 patients), there was recurrence in 13.3% of patients operated by fistulectomy compared to present study where 26 percent case reported with recurrence after fistulectomy (sphincter cutting procedure). **Sameh Hany Emile et al.(2017)**[11] reported with recurrence occurred in 112 (14.2%) patients after a median follow-up of 9 months after Vaaft . Recurrence rates varied according to method of closure of internal opening. Recurrence after VAAFT may be related to previous fistula surgery and the method of closure of the internal opening. In recurrent cases if the anal fistula proved to be a simple intersphincteric fistula, then lay-open of the tract with curettage of its bed was done or if it was the case of more complex anal fistulas, the portion of the tract lying outside the external anal sphincter was laid open or excised whereas the part traversing the anal sphincters treated sphincter-saving procedure.

As quality of life post surgery is an very important aspect to see efficacy of any surgery,here too we measured the quality of life in post op period in terms of hospital stay, convalescence time and continence status of patient. According to our study, mean number of days hospital stay in sphincter preserving surgeries is 1.94+/-1.89 in comparison to sphincter cutting surgeries is 3.1+/-2.9 which is statistically significant with chi square value of 4.1>3.84. **M. L. Ramachandra; GARG, Mayank (2018)** stated that mean hospital stay is maximum in fistulectomy that is 8.5 days followed by 7.6 days in fistulotomy, and 3 days in LIFT (sphincter preserving) procedure. This study favours our observation in aspect of sphincter preserving procedures but not in sphincter cutting procedures (fistulectomy and fistulotomy). Overall it also shows that sphincter preserving procedures has a lesser hospital stay in comparison to sphincter cutting surgeries.

Mean no. of days in which patients resumed to normal activity; sphincter preserving surgeries was 21.3+/ -6.67 days, and in sphincter cutting surgeries was -25+/-11.34 days.

41 cases got discharged within 2 days after sphincter preserving surgeries and 32 got discharged within 2 days after sphincter cutting surgeries, which is statistically significant with chi square value of 4.57>3.84. There was no literature to compare our study for return to normal work days.

For continence status we used Wexner's score, and followed patient in post op period at 1st week, 6th week, 3rd month,6th month and one year. At first week 8 percent patient after sphincter preserving shows incontinence in comparison to 24 percent patient after sphincter cutting surgeries, which is supported by **Bokhari S, Lindsey I. et al.(2009)**[12] who stated stated that patients with complex fistulae undergoing sphincter division demonstrated a significantly higher rate of major incontinence (13%) when compared with those undergoing sphincter conservation (0%) similarly **Kanchwala Q et al.(2020)**[13] also stated that mean Wexner's score at the 1st week and 6 months postoperatively was comparable between fistulotomy and fistulectomy groups. Mean Wexner's score at 6 months follow-up (intra-group comparison) was significantly less as compared to 1st week follow-up in both fistulotomy and fistulectomy groups,there was no statistically significant difference in the severity of Wexner's score at 1st week and 6th month postoperative follow-up between the two groups. In fistulectomy group, at 6th month follow-up, Wexner's score was normal in 49/53 (92.5%) patients, whereas in fistulotomy group, at 6th month follow-up, Wexner's score was normal in 52/57 (91.2%) patients. This study data is not comparable to our study because we classified fistulotomy and fistulectomy as a single group for which we obtained a mean wexner's score collectively as sphincter cutting surgeries at first week and 6th month in post operative period which was compared to sphincter preserving surgeries mean wexner's score at 1st week and 6th month in which it was statistically proven that sphincter preserving surgeries is better than sphincter cutting surgeries in terms of post op incontinence.

We observed our patients at 48 hrs post-operative period for pain according to VAS (VISUAL ANALOGUE SCALE) . Mean score for pain on VAS after sphincter preserving surgeries (including VAAFT) is 5.10+/-1.37 similar to past studies **P. Meinero · L. Mori.et al.(2011)**

stated for VAAFT that pain control was based on the visual analogue scale (VAS) score with a mean value of 4.5 (on a scale of 1–10) during the first 48 h. None of the patients reported pain after the first postoperative week. Twenty-one patients (21.4%) did not require analgesics, whereas 49 patients(50%) needed Ketorolac trimetamine on postoperative day 1, 20 (20.4%) required Ketorolac trimetamine for 3 to 4 days and only 8 (8.2%) needed Ketorolac trimetamine for a week. Ramachandra M. L., Mayank Garg stated that post-operative pain seen in 5 (25%) patients undergoing fistulectomy. No such literature was available for sphincter cutting procedures (fistulectomy and fistulotomy procedures).

CONCLUSION

Anal fistula remains a common and complex disease process. The objectives for treatment this disease remain the successful elimination of current and recurrent disease, and the preservation of sphincter function.

Fistulotomy has been considered as the gold standard for simple fistula in ano, but for complex fistulas, there is no single procedure which is ideal for all the patients, and treatment modality needs to be individualised. Our study focused on characterizing the clinical outcomes associated with sphincter sparing and sphincter cutting procedures for complex fistulas.

Patients undergoing sphincter preserving procedures had a better healing rate and lesser healing time. Quality of life in terms of hospital stay, return to normal work, incontinence rate and post-operative pain was also better with sphincter preserving procedures. Recurrence was also found to be less in this group.

Very few studies have been conducted till date comparing sphincter preserving and sphincter cutting procedures, this could be the reason of the variable results of our study from literature. So, further studies need to be done for a better comparison.

We concluded from our study that sphincter sparing surgeries for complex fistula in ano are better in terms of less recovery time, healing time and better healing rate, lesser chances of incontinence, recurrence in comparison to sphincter cutting surgeries. With the advent of more sphincter sparing techniques, the percentage of patients undergoing sphincter cutting techniques should continue to decrease over time.

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