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A COMPERATIVE STUDY OF LIGATION OF INTERSPHINCTERIC FISTULA TRACT (LIFT) WITH CONVENTIONAL TREATMENT OF KSHARASUTRA THERAPY IN THE MANAGEMENT OF FISTULA IN ANO: A CLINICAL STUDY

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ABSTRACT

The anal fistula has been a common surgical ailment reported since ancient era. Ksharsutra therapy is an age old, simple and safe minimum invasive surgical technique for treatment of fistula in ano described in ancient classics of Ayurveda is being practiced as a primary method of treatment in all types of fistula in ano including complex and recurrent fistula. LIFT is a new technique for fistula in ano surgery aimed at total sphincter preservation, better primary healing and intact anal function. **Aims and objectives of the study:** The present study is focused on comparative evaluation of surgery of fistula in ano by *ksharsutra* and LIFT technique, regarding post-operative primary healing time, rate of reccurence and normal anal function. **Plan of study:** The present study will be carried out clinically. Forty patient will be selected with fistula in ano diagnosis after detail clinically history and investigatory finding as per designed proforma. **Observations:** we can say that even though in linear tract fistula in ano, *Ksharsutra* is better than new procedure LIFT. **Conclusion:** Complex and recurrent fistula cases should undergo a LIFT technique to reduce the chances of recurrence.

KEYWORDS: Ligation of Intersphincteric Fistula Tract, Digital rectal examination, Ksharasutra.

INTRODUCTION

A fistula is an abnormal communication between any two epithelial-lined surfaces. Fistula in ano however has been explained in detail for the first time by *Sushruta* (1500-1000 BC) under heading of *Bhagandara*, *Acharya Susruta* described surgical and other minimally invasive techniques for the management of *Bhagandara* (fistula in ano). *Sushruta* described *ksharsutra* in treatment of *Nadivrana*, *Bhagandara* and *Arbuda*. The action of *Ksharsutra* is by virtue of the properties of its *Kshara* contents. Which has necrotizing action on tissues. Surgical management of Fistula in ano is widely in practice even though *susruta* also described the excision of fistulous tract (*chhedya bhagandara*) is the first line of treatment; definitely it is beneficial in simple and low anal Fistula in ano, But in complex fistula in ano if we try to eradicate the complete infection there may be fair chances of damage of sphincter, on other hand if we try to preserve sphincter, recurrence is very common phenomenon. So a lots of surgical techniques is invented by surgeons worldwide but none of the technique is ideal for each and every case of Fistula in ano. Now a day *Ksharsutra* therapy is one of the best modalities of treatments for fistula in ano adopted all over the world due its better outcome. If we treat the Fistula in ano by Ksharsutra method even though there may be damage of few fibers of sphincter, patient can maintain his/her continence and simultaneously very low recurrence rate.

LIFT (Ligation of Intersphincteric Fistula Tract) Technique for the management of fistula in ano introduced by Dr. Arun Rojanasakul in Bangkok, Thailand (Division of Colorectal Surgery, Chulalongkorn University) In 2006. Dr. Arun Rojanasakul claimed 94.4% success rate in his first prospective, observational study report. But in Subsequent series have reported a success rate ranges between 57 to 82%. (57% Bleier JI, Moloo H, Goldberg SM 2010.),76.5% CharlesTSANG, Division of Colorectal Surgery, National University Health System 2008, 82.3% Sileri P, Franceschilli L, Angelucci GP, D'Ugo S, Milito G, et al. (2011).

The risk or anal weakness or incontinence is minimized because no sphincter muscle is divided. This technique of the LIFT procedure minimizes complications of infection, recurrence and incontinence. The postoperative recovery is easier as no muscles are divided. Earlier return to work and faster recovery has made this technique a favored initial approach.

MATERIAL AND METHODS

Forty patients, between age group of 16-70 years, registered from OPD/IPD of Department of Shalya Tantra, SCPM Ayuredic Medical college and Hospital, Gonda with the characteristic features of fistula in ano, the patients were randomly divided in to two groups i.e. Group A and Group B. The details of the patients were collected by using a standard proforma.

Grouping of the patient

For present clinical study all 40 patients were randomly divided in two group, Group A and Group B, 20 Patients in each.

Group A 20 Patient treated by Ksharasutra Therapy.

Group B 20 Patient treated by LIFT technique.

Inclusion criteria

Patients diagnosed to have simple fistula is ano of cryptoglandular origin anatomically inter-sphincteric and low trans-sphincteric mostly anterior mid line with straight tract were randomly selected, irrespective of sex, chronicity, *Prakriiti*, length of track etc.

Exclusion criteria

Patients with uncontrolled diabetes mellitus, tuberculosis, malignancy, fistula in ano secondary to other systemic disease like osteomyelitis of coccyx, High anal/Complex fistula in ano, Fistula in ano with abscess cavity, Ulcerative Colitis, Chron's Disease were excluded from the study.

Examination of the patient

Selected Patient were thoroughly examined and investigated. The history and findings were noted in designed proforma specially prepared for the study. The following points were given due importance.

History of the patient

History of the disease with respect to its onset, mode and duration, type of discharge, severity of pain, chronicity of the disease, bowel habits, associated disease like tuberculosis, diabetes, colitis, urinary diseases, cardiac disease, past treatments undertaken for the same disease etc., occupation, *prakriti*, nutritional status, family history and his/her personal habits and addictions were recorded carefully.

1. Systemic examination

Each system was carefully examined before the patient was initiated into treatment. Due importance was given to examine the digestive, cardiovascular, respiratory, nervous and genitourinary systems.

2. Local examination

Inspection

It was one of the most important diagnostic tools required for provisional diagnosis of the type of fistula. The condition of the perianal and scrotal skin, presence of indurations, inflammation, color of skin, quality and quantity of discharge, margins of external openings, numbers of external openings, the O'clock position, were observed.

Palpation

Palpation is done for local temperature, tenderness, area of indurations, consistency etc. The fibrous cord like fistulous track, its extent and direction, presence of pus cavities etc. were also palpated.

Digital rectal examination (DRE)

DRE was done with gloved lubricated index finger to examine the assessment of tone of anal sphincter, infected anal crypt, internal opening and induration for cord like structure presence of fissure bed, pile masses, malignant growths, polyps, blind abscess cavities, hypertrophied anal papillae.

Proctoscopy

Proctoscopy was done routinely to identify the presence of internal opening along with pile masses, ulcerations, polyps, location of internal opening, growth etc.

Probing

This was an important examination which provided accurate knowledge regarding-

i. The track, whether it is complete or not
ii. The extent of the track
iii. The direction of the track
iv. Position of the internal opening.
v. Relation of the internal opening to the anorectal ring
vi. Relation of the fistulous track with the sphincter muscles

vii. Branching of track

viii. Whether the track had extended to the posterior side of midline

ix. Relation, if any, to the neighboring organs.

A soft, malleable probes were carefully passed through the external opening with care, with one finger in the rectum guiding its advancement. Care was necessary in order to have the cooperation of the patient during examination and also to avoid the creation of false track.

Investigations

Routinely the following investigations were carried out

- Blood - Hb, TLC, DLC, ESR, CT, BT, FBS, PPBS, BU, Serum creatinine, HIV, HBsAg
- Urine - Routine and microscopic
- Stool - Ova; cyst, occult blood
- Pus - Culture and sensitivity
- Biopsy - From the floor of fistula if required
- X- Ray - X-ray chest PA view X-ray pelvis to exclude any bony pathology Fistulogram with urograffin
- Anal manometry

Ksharsutra therapy procedure (Pre-operative procedure)

a. The patient should be admitted in the hospital a day before operation.
b. Shave and part preparation done.
c. Patient is kept fasting for at least 8 hours
d. Consent of the patient in written
e. Proctoclysis enema 2-4 hours before the procedure
f. Inj. Xylocaine 2% sensitivity test
g. Inj. Tetanus toxoid 1 Amp. IM stat.

Position: All the patients were given lithotomy position for the procedure.

Kshara sutra therapy procedure (Operative procedure)

In present study most of the cases done under Local anesthesia, but in some cases where patient was very sensitive spinal anesthesia/caudal block was given by anesthetist.

The perianal area is cleaned with Savlon and spirit followed by Betadine painting.
The outer area is covered with sterile cloth, leaving the anal area open.

Digital rectal examination done to locate any induration, internal opening and to exclude other lesions. Probing is done through a malleable probe to locate the internal opening with the index finger of other hand inside the anus. If internal opening is located, the probe is pushed out through the anal verge and the track is threaded loosely by Kshara sutra. Jatyadi oil packing done and sterilized gauze is applied on the anus covering the external opening. Bandage is tied to keep the dressing in proper position. Thereafter the patient is shifted to the ward.

Operative techniques

Ligation of Intersphincteric Fistulous Tract (LIFT) technique Pre-operative Procedure same as Ksharsutra therapy.

Assessment of anal continence was evaluate by using DRE, Anal manometry.

Statistical analysis

Student T test will be used to compare the significant difference among the variables between the groups.

Z test, X^2 (Chi. square) test or fisher's extract probability test will be used to compare the baseline qualitative parameters between the group and to find out the significant changes from baseline to different follow-ups.

OBSERVATIONS AND RESULTS

The present study has been planned to evaluate the efficacy of Ksharsutra Therapy in simple fistula in ano, in comparison to Ligation of Intersphincteric Fistula Tract (LIFT) Technique. For this study, 40 patients of fistula in ano were randomly selected from OPD/IPD of the Department of *Shalya Tantra*, S.S. Hospital, IMS, BHU, Varanasi. They were randomly divided into two groups:

Group A : 20 patients treated by Ksharasutra Therapy.
Group B : 20 patients treated by LIFT Technique.

All 40 patients of Fistula in ano were analysed for age, sex, habitat, socio-economic status, Occupation, Digital Rectal Examination (DRE) etc. This information were observed and recorded.

Table 1: Distribution of patients according to age incidence: (In year).

Age	Group A		Group B	
	No.	%	No.	%
Up to 20	2	10	3	15
21 – 40	8	40	10	50
41 – 60	6	30	5	25
>60	4	20	2	10
Total	20	100	20	100

In present study in group A maximum patients (40%) belongs to age group 21-40 year 30% in 41-60 year of age group 20% in >60years of age group and 10% in up to 20 year of age group. In group B, there were maximum 50% belongs to age group 21-40 year, 25% in 41-60 year of age group, 10% in >60years and 15% patients recorded in age group of up to 20. (Table no.1)

Table 2: Distribution of patients according to sex incidence.

Sex	Group A		Group B	
	No.	%	No.	%
Male	17	85	18	80
Female	3	15	2	20
Total	20	100	20	100

In present study in group A majority of patients (85%) were male and 15% were female and in group B 80% were male and 20% female. (Table no.2)

Table 3: Distribution of patients according to marital status.

Marital status	Group A		Group B	
	No.	%	No.	%
Unmarried	8	40	6	30
Married	12	60	14	70
Total	20	100	20	100

In present study, majority of patients (60%) were married and rest 40% unmarried in group A while in group B 70% were married and 30% unmarried. Overall majority of patients in both, group A (60%) and group B (70%) were married. (Table no.3)

Table 4: Distribution of patients according to habitat.

Habitat	Group A		Group B	
	No.	%	No.	%
Rural	11	55	10	50
Urban	9	45	10	50
Total	20	100	20	100

In present study in group A maximum patients (55%) belongs to rural area and 45% belongs to urban area while in group B 50% belongs to rural area and 50% belongs to urban area. (Table no.4)

Table 5: Distribution of patients according to occupation status.

Occupation	Group A		Group B	
	No.	%	No.	%
Businessman	8	40	8	40
Student	1	5	0	0
Housewife	1	5	2	10
Farmer	4	20	3	15
Teacher	2	10	2	10
Office Job	4	20	5	25
Total	20	100	20	100

In present study In group A 40% patients were from businessman, rest 5%, 5%, 20%, 10% and 20% from students, housewife, farmer, teachers and office job respectively while in group B 40% patients were from businessman rest 10%, 15%, 10%, 25% from housewife, farmer, teachers and office job respectively. In overall maximum patients were from businessman, (40%). (Table no.)

Table 6: Distribution of patients according to Socio-Economic status (SES):

SES	Group A		Group B	
	No.	%	No.	%
Upper	5	25	4	20
Middle	9	45	10	50
Lower	6	30	6	30
total	20	100	20	100

In present study In group A 25% patients belongs to upper socio-economic status 45% middle and 30% belongs to lower socio-economic status, In group B 50% patients belongs to middle socio-economic, 30% belongs to lower socio-economic status ,and 20% from upper socio-economic status. (Table no.6)

Table 7: Distribution of patients according to the dietary habits.

Dietary habit	Group A		Group B	
	No.	%	No.	%
Vegetarian	8	40	9	45
Non-vegetarian	12	60	11	55
Total	20	100	20	100

In present study in group A 40% patients were vegetarian and rest of 60% non-vegetarian 60% and in group B 45% patients were vegetarian and rest of 55% patients non- vegetarian (55%). Most of the patients were non-vegetarian in both the group. (Table no.7)

Table 8: Distribution of patients according to nature of bowel habit.

Bowel habit	Group A		Group B	
	No.	%	No.	%
Normal	5	25	3	15
Constipation	8	40	7	35
Irregular	7	35	10	50
Total	20	100	20	100

In present study in group A maximum 40% patients are constipated, 35% has irregular bowel habit and only 25% has normal bowel habit while in group B 50% has irregular bowel 35% has constipation and only 15% has normal bowel habit. (Table no.8)

Table 9: Distribution of Patients according to nature of discharge from fistulous tract:

Nature of discharge	Group A		Group B	
	No.	%	No.	%
Blood mixed pus	3	15	4	20
Pus	14	70	12	60
Faeces	0	0	0	0
Gas	3	15	4	20
Urine	0	0	0	0
Total	20	100	20	100

In present study in group A majority of patients (70%) has complain of pus discharge from fistulous tract, 15% patients has complain of Blood mixed pus and 15% has complain of gas leak from fistulous tract. In group B majority of patients (60%) has complain of Pus discharge from fistulous tract, 20% patients has complain of Blood mixed pus and 20% has complain of gas leak from fistulous tract, no any patients were taken in this study with complain of urine or faecal discharge from tract. (Table no.9)

Table 10: Distribution of patients with complain of itching in perianal region.

Itching	Group A		Group B	
	No.	%	No.	%
Present	13	65	11	55
Absent	7	35	9	45
total	20	100	20	100

In present study In group A majority 65% patients has itching in perianal region and 35% has no itching complain, in group B 55% patients has itching and 45% have no itching complain. (Table no.10)

Table 11: Distribution of patients according to type of fistula in ano.

Type of simple fistula	Group A		Group B	
	No	%	No	%
Intersphincteric	16	80	17	85
Low transsphincteric	4	20	3	15
Total	20	100	20	100

In present study in group A maximum 80% patients have intersphincteric type of fistula in ano while 20% have low trans-sphincteric type of fistula in ano and in group B 85% patients has intersphincteric type of fistula in ano while only 15% had low transsphincteric fistula in ano. (Table no.11)

Table 12: Distribution of patients on the basis of chronicity of the disease: (in year):

Chronicity (year)	Group A		Group B	
	No.	%	No.	%
< 1 year	10	50	12	60
1-3 year	4	20	4	20
>3-5 year	3	15	2	10
> 5 year	3	15	2	10
Total	20	100	20	100

In present study in Group A (50%) patients were have the disease fistula in ano from less than one year rest 15%, 15%, 20% have more than 5 years, in between >3-5 years, in between 1-3 years respectively and in Group B (60%) patients were have the disease fistula in ano from less than one year rest 10%, 10%, 20% have more than 5 years, in between > 3-5 years, in between 1-3 years respectively. Majority of patients in both group have chronicity of disease less than one year. (Table no.12)

Table 13: Distribution of patients on the basis of local examination of patients.

Local examination	Group A		Group B	
Perianal skin	**No**	**%**	No	%
Perianal Dermatitis	5	25	8	40
Induration				
Induration Present	7	35	9	45
External opening				
9-12 o'clock	5	25	7	35
12-3 o'clock	6	30	8	40
3-6 o'clock	5	25	3	15
6-9 o'clock	4	20	2	10
Position of Internal opening				
Midline Posterior	9	45	5	25
Midline Anterior	10	50	15	75
Lateral	1	5	0	0

In present study in Group A 25% patients have perianal dermatitis and In 35% presence of induration along with tract. In Group B 40% patients have perianal dermatitis and in 45% induration present along with tract**.**

In Group A 30 % patients have external opening in between 12-3 o' clock rest 25%, 25%, 20% have external opening in between9 -12, 3-6, 6-9 o' clock respectivaly. In Group B 40% have external opening in between 12-3 o' clock, rest 35%, 15%, 10% have external opening in between 9-12, 3-6, and 6-9 o' clock respectivaly.

In Group A 50% patients have internal opening of mid line anterior and rest 45%, 5% patients have mid line posterior and lateral respectivaly.

In group B 75% patients have internal opening midline anterior while 25% patients have midline posterior.

Table 14: Result of Pre and Post therapy sphincter tone in Group A based on Digital Rectal Examination.

Sphinctor tone	Pretherapy		Post therapy	
	Case	**%**	**Case**	**%**
Normal	16	80	17	85
Hypertonic	3	15	1	5
Hypotonic	1	5	2	10
Total	20	100	20	100

In present study in group A on digital rectal examination of sphincter tone it is observed that majority of patient were had normal tone (80%) before therapy and also normal tone (85%)

after therapy. Whereas 15% patients were hypertonic before therapy but after treatment (5%) patients were observed as hypertonic anal sphincter, and 10%patients were observed to have hypotonic anal sphincter tone pre and post therapy on digital rectal examination. (Table no.14)

Table 15: Result of Pre and Post therapy sphincter tone in Group B based on Digital Rectal Examination.

Sphinctor tone	Pretherapy		Posttherapy	
	Case	%	Case	%
Normal	17	85	16	80
Hypertonic	3	15	1	5
Hypotonic	0	0	3	15

In present study in group B on digital rectal examination of sphincter tone in it observed that majority of patient were normal tone (85%) before therapy and also normal tone (80%) after therapy. Where as few patients(15%) were hypertonic before therapy and 5% were after therapy. There is no hypotonic patients before treatment but 15% patients was observed hypotonic after completion of treatment. (Table no.15)

Table 16: Persistence of pain after primary threading in Group A and After operation (LIFT) in group B.

Post-operative Duration of pain	Group A		Group B	
	No.	%	No.	%
< 6 Hours	2	10	1	5
7-24 Hours	2	10	1	5
2-3 days	12	60	5	25
4-5 days	4	20	13	65
Total	20	100	20	100

In present study In group A in majority of (60%) patients pain persist for 2-3 days after primary threading and in rest10%, 10%, 20% patients pain persist for <6 hrs,7-24hrs, and 4-5day respectively while in group B in majority of (65%) patients pain persist for 3-5 days and rest 5%, 5%, 25% patients pain persist for in <6 hr,7-24hr, and 2-3day respectively after treatment. (Table no.16)

Table 17: Incidence of Post-operative Complain after three month of treatment in Group A and Group B.

Complain	Group A		Group B	
	No.	%	No.	%
Fibrosis	2	10	2	10
Abscess	1	5	2	10
Pruritus	1	5	1	5
Discharge	2	10	3	15
No complain	14	70	12	60
Total	20	100	20	100

In present study on regular fallow up it is observed in group A 70% patients were has No complain rest 5%, 5%, 10%, 10% has complain of Abscess, Pruritus, Fibrosis and Discharge respectively while in group B 60% patients were has No complain rest 10%, 5%, 10%,15% has complain of Abscess, Pruritus, Fibrosis and Discharge respectively after treatment. Majority of patients in Group A (70%) and in Group B (60%) were have no complain after three month of treatment. (Table no.17)

Table 18: Healing status after three month of treatment in Group A and Group B.

Healing status	Group A		Group B	
	No.	%	No.	%
Healed	19	95	17	85
Unhealed	1	5	3	15
Total	20	100	20	100

In present study In group A after completion of treatment (by ksharasutra) 95% patients were completely healed, were 5% were unhealed while in group B, operated (by LIFT) 85% patients were healed and 15% were unhealed tract. (Table no.18)

Table 19: Incidence of recurrence after three month of treatment in group A and Group B.

Group	Recurrence	
	No.	%
A	1	5
B	3	15

In present study in group A Only 5% patients has recurrence (discharge from external opening) after treatment were in group B 15 % patients has recurrence. (Table no.19)

Table 20: Effect of treatment on perianal dermatitis.

	Pre		Post		Cochrane's Q test p-value
	Number	Percentage	Number	Percentage	
Group A	14	70	7	35	0.008 (HS)
Group B	11	55	6	30	0.014 (S)
Inter group	p=0.327		p=0.490		

In present clinical study out of 40 patients in group A, 14 patients have dermatitis before treatment and after treatment only 7 patients have dermatitis.

In group B, 11 patients have dermatitis before treatment and after treatment only 6 patients have dermatitis.

Regarding statistical analysis, in group A the intragroup statistical analysis were found highly significant.

In group B intragroup statistical analysis were found significant.

In between group comparison there were no statistically significance improvement seen. (Table no.20)

Table 21: Effect of treatment on discharge.

	Pre		Post		Cochrane's Q test p-value
	Number	Percentage	Number	Percentage	
Group A	20	100	2	10	0.000 (HS)
Group B	20	100	5	25	0.000 (HS)
Inter group	p=0.749		p=0.633		

In present study, all 40 patients have some kind of discharges (pus discharge or blood mixed pus discharge or gas discharge) from fistulas tract, after kshar-sutra therapy only 10% patients complain discharge and after LIFT operation 25% patients complain discharge from fistulas tract.

Regarding statistical analysis in intragroup, both group A and B is highly significant though intergroup statistical analysis is not significant. (Table no.21)

Table 22: Effect of treatment on itching.

	Pre		Post		Cochrane's Q test p-value
	Number	Percentage	Number	Percentage	
Group A	13	65	4	20	0.003 (HS)
Group B	11	55	5	25	0.014 (S)
Inter group	p=0.519		p=0.705		

In this study out of 40 patients, 24 patients were had complain of itching in perianal region, In group A, out of 20 patients, 13 patients (65%) has itching complain before therapy, after ksharsutra therapy, only 4 patients (20%) has complain of itching. In group B, out of 20 patients, 11 patients have itching in perianal region and after LIFT operation, 5 patient (25%) has itching complain.

In group A intragroup statistical analysis was found to be highly significant. In group B there was also improvement in perianal itching and intragroup statistical analysis was found to be significant, there were no statistical significance observed in intergroup. (Table no.22)

Table 23: Effect of treatment on Normal anal Sphincter tone.

	Pre		Post		Cochrane's Q test p-value
	Number	Percentage	Number	Percentage	
Group A	16	80	17	85	0.317 (NS)
Group B	17	85	16	80	0.292 (NS)
Inter group	p=0.623		p=0.67		

There was no significant change is observed in normal anal sphincteric tone.

Inter group and intra group statistical analysis was found to be insignificant. (Table no.23)

DISCUSSION

Conventional technique of *Ksharsutra* therapy is best for treatment of simple/low anal fistula and also effective in complex and recurrent fistula although in treatment of complex fistula it takes long duration and it may cause deformed appearance of perianal region.

LIFT (Ligation of Intersphincteric Fistula Tract) Technique for the management of fistula in ano introduced by Dr. Arun Rojanasakul in Bangkok, Thailand (Division of Colorectal Surgery, Chulalongkorn University) in 2006. LIFT is a new technique for fistula in ano surgery aimed at total sphincter preservation, better primary healing and intact anal function. Fistula in ano does not heal spontaneously due to two main reasons. Firstly, fecal particles

can enter the primary opening causing infection. Secondly, the intesphincteric fistula tract is compressed between internal and external anal insphincter thus causing intermittent closed septic foci and persistent sepsis. The authers proposed that ligation and excision of the entrance for fecal particle into the fistula tract and, at the same time, eliminate the intersphincteric septic nidus. This may result in healing of fistula in ano. This procedure does not sever the anal sphincter and postoperative anal function can remain intact. Dr. Arun Rojanasakul claimed 94.4% success rate in his first prospective, observational study report. But in Subsequent series have reported a success rate ranges between 57 to 82%. (57% Bleier JI, Moloo H, Goldberg SM 2010.),76.5% CharlesTSANG, Division of Colorectal Surgery, National University Health System 2008, 82.3% Sileri P, Franceschilli L, Angelucci GP, D'Ugo S, Milito G, et al. (2011).

The anal canal is anatomically peculiar and has a complex physiology, which accounts for its crucial role in continence. An understanding of the anatomy of the anal canal is essential for the appropriate management of anal fistulas.

This present clinical study revealed that, the incidence of fistula in ano more in age group of 21 to 40 years followed by 41 to 60 years age group. In the present study the prevalence of disease was more in middle age group as this is the most active phase of any human and hence overstraining, increased travelling, improper attention to bowel movements, local un-hygiene, long hours of sitting in same posture, usually eating junk and fried food from outside etc. all these factors increase the incidence of the disease in the patients of this age group. This is also supported by the literature that fistula in ano is more common in 3rd, 4th and 5th decades of life (Lunnis P, Nugent K. 2013)

The sex-wise incidence of fistula in ano, it was observed that as compared to females, the males were more likely to suffer from this disease. As out of 40 patients 35 (87.5%) were male and only 5 (12.5%) were females. The Male to female ratio is 7:1 and the cause behind this is long hours of sedentary job, local unhygienic condition, distribution of hairs, increased sweating and unhealthy food habits.

According to Indian demographic distribution most of the population lives in rural areas, in rural areas the lack of Hygiene and lack of awareness and unavailability of healthy food increased incidence in rural people. In our study most of the patients21 (52.5%) were from

the rural background and 19 (47.5%) belongs to urban background. It is owing to these reasons; the disease is more prevalent in rural areas.

In relation to the socio-economic status of the patients, the study revealed that middle class population is more prone for the incidence of fistula in ano. Almost 19 (47.5%) patients belonged to this class followed by lower class12 (30%) and minimum patients were from upper class, only 9 (22.5%). The patients, who are usually involve in sedentary works, like prolonged sitting jobs, were more affected by disease. In occupation wise observation, maximum patients were from business class 16 (40%) followed by office class 9 (22.5%). Minimum patients were students, only 1 (5%).

Majority of the patients of fistula in ano are habituated to a non-vegetarian diet (Kumar H and Sahu M, 1996). From the era of *Sushruta, Charaka, Vagbhatta* and up to the contemporary surgeons, all have emphasized that fish and other bone pieces, egg shell etc., consumed in the food by people, may also be one of the cause of fistula in ano. A similar finding is observed in this study, where greater percentages (57.5%) of patients were of non-vegetarian. The lack of roughage in the food of non- vegetarian diet leads to constipation repeatedly, which is one of the known causes to aggravate the condition.

But In this present study, we observed that majority of the patients 17 (42.5%) have irregular bowel habit. This results in irregular diarrheal and constipation episodes. Due to ineffective empting of bowel, simultaneously liquid nature of stool stasis of fecal contents in the anal columns and undue straining causes injuries to the mucous membrane of anal column, anal gland infection and obstruction of anal gland duct, further initiates a vicious cycle of chronic and acute inflammatory processes which finally culminates into fistula in ano. Next to irregular bowel habit 15 (37.5%) patients were having constipation. However, it is interesting to note that 8 (20%) patients having normal bowel habits were also suffering from this disease.

According to Parks classification, it was observed that in present study maximum number of patient had intersphincteric type of fistula in ano, 33 (82.5%), followed by low transsphincteric fistula in ano i.e. 7 (17.5%). Literature also supported that among variety of fistula in ano, intersphincteric fistula in ano is more common (45%), (Parks AG, Gordon PH, Hardcastle JD. A classification of fistula-in-ano. Br J Surg1976; 63: 1–12.) the reason behind

it anal gland which are present in intersphincteric plane are the main source of infection according to cryptoglandular theory.

In present clinical study it is observed that according to chronicity of disease majority of patient suffering from fistula in ano, the time of notice of initial sign and symptoms by the patient were observed, it was found that out of 40 patients maximum 22 (55%) were having the disease less than 1 year of period followed by 1 –3 year of period, 8 (20%) rest more than 3-5 year and more than 5 year 5 (12.5%), 5 (12.5%) respectively. It is because due to lack of knowledge, misinformation regarding the disease, fear of failure of surgery, anatomical location, Shyness of patient and hence by the time the patient come for treatment more than a year after onset of disease.

In present clinical study according to nature of discharge from fistulous tract, out of 40 patients, 26 (65%) patients were having pus discharge from fistulous tract while rest 17.5%, 17.5% patients present with blood mixed pus discharge and gas leak from fistulous tract respectively. From this observation we can say that in case of fistula in ano the most frequent complain of patients was pus discharge through perianal region. Most of the patients 24 (60%) in this study also have itching in perianal region, the reason behind it the perianal area become moist for long time due to continuous discharges from fistulous tract and same time infection spread causing perianal dermatitis resultant irritation and itching occurs.

In this present clinical study it was observed that 16 (40%) patients have induration (cord like felling) along fistulous tract on palpation. Presence of induration along the fistulous tract because of chronicity of disease unhealthy granulation tissue present in between external and internal opening became fibrosed due to intermittent inflammatory changes.

Regarding location of external opening majority of patients 14 (35%) have external opening in between 12-3 o’ clock position while minimum patients 6(10%) has external opening in between 6-9 o’ clock while position of internal opening of fistula in ano in this study maximum patients 25 in mid line anterior and minimum patients 1 (2.5%) are lateral (radially in same line of external opening). In general most of the fistula in ano about 90% are cryptodlandular in origin, arise in intersphincterc plane due to infection of anal gland present in this plane, majority of anal glad present in posterior intersphincteric space and texts also suggest fistula in ano with internal opening posterior mid line are more common, (Ibrahim Falih Noori *Bas J Surg, June, 21, 2015*) but in this study majority of patients selected aim

fully were have anterior mid line internal opening. In relation to external opening which is unpredictable because in fistula in ano according to cryptoglandular theory sepsis arise in anal gland initially there is abscess formation then it transverses in least resistance plane and pierces the skin of near- by area.

In reference to persistence of pain in this clinical study, observed that after primary threading in group A majority of patients got relief from pain within 2-3 days of post-operative period. Where as in group B operated by LIFT procedure in majority of patients, pain persist for 4-5 days of post- operative period. The reason behind it that in Ksharsutra treatment there is almost no incision taken place during primary threading hence minimal or no tissue loss occurs, therefore chance of bleeding and inflammatory changes is very less, the only pain felt by patients due to caustic effect of Kshar present in Ksharsutra at the time of application and may hardly subside with- in 2-3 days. while in patients operated by LIFT technique, to reach up to fistulous tract in intersphincteric plane, there is cutting and splitting of tissue occur, due to cutting and splitting of more tissue in comparison to Ksharsutra treatment bleeding and inflammatory changes are more in LIFT technique therefore in patients treated by LIFT technique pain persist for 4-5 days post-operatively. But in group A during changing of Khsarsutra patient complain mild pain and its subsides with in minutes of application of Ksharsutra.

From above observation we can say that patients treated by ksharsutra got early relief in pain in comparison of patients operated by LIFT technique.

In this present study after completion of three month of treatment in group A in majority of patients 19 (95%) complete healing occurs, while in group B in 17 (85%) patients healing occurs. Earlier study also suggest that Guggulu based Apamarg ksharsutra has significant MAGS (Microscopic Angiogenesis Grading system) scores which means this really promotes neo-vascularization most effectively which is an indicative of better healing process of fistulous tract and wound.(Rather G S and Sahu M 2011) along with this property guggulu ksharsutra also facilitate drainage, debride unhealthy tissue, mechanical cutting of tract simultaneously eradicate the source of infection due to its antimicrobial activity. While in LIFT technique loss of tissue occur during procedure and if same time internal opening not closed securely then there may be increased chance of infection if patient could not do self-care of wound, faecal matter sepsis that leads to non-healing of wound. Therefore we can say that regarding healing rate ksharsutra therapy has good result in comparison to LIFT.

Regarding the recurrence rate, after completion of 3 month of treatment in group A one patient has recurrence while in group B three patients has recurrence. Earlier studies reported 2 to 4 percent recurrence rate with the *Kshar Sutra* therapy. (Shukla NK, Narang R, Nair NGK, Radhakrishna S, Satyavati GV J Med Res 1991;94:177-85.).

Lower recurrence of fistula treated with *ksharasutra* has been attributed due to better drainage, slow and gradual cutting with simultaneous healing as well as eradication of the infected anal gland by the caustic action of the thread.

More recurrence in LIFT procedure in this study is may be due to not proper localization of internal opening during procedure and other are due to post- operative infection.

In reference to perianal dermatitis group A is statistically highly significant (p value 0.008) while group B is statistically significant (p value 0.014) there is no statistical significance observed in between group. Reason behind it gradual decrease of pus discharge from fistulous tract prevent the local infection and irritation result in improvement in dermatitis.

Regarding discharge from fistulous tract after completion of treatment, it is observed that both group A and B has high statistical significance while intergroup statistical analysis was found insignificant. Because in LIFT technique ligation of tract in intersphinctric plane cut the passage and same time closer of internal opening both these factor responsible to prevent discharge from fistulous tract while in Ksharsutra therapy continuous better drainage, debridement of unhealthy granulation tissue and eradication of source of infection gradually decreases the discharges from fistulous tract.

Pre and post- operative digital rectal examination, observation about normal anal sphincter tone shows that both intragroup and intergroup results were statistically insignificant means there was no significant damage observed in reference to normal anal sphincter tone. Because both the technique compare in this study practically have very low or minimal damage to anal sphincter. From above analysis we can say that No any major disruption of sphincter takes place post operatively in both modalities of treatment of fistula in ano.

On the above observation, we can also say that even though in linear tract fistula in ano, Ksharsutra is better than new procedure LIFT.

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