

COMPRATIVE STUDY OF THE EFFECT OF MODIFIED KSHAR SUTRA WITH THAT OF STANDARD KSHARSUTRA IN THE TREATMENT OF FISTULA IN ANO

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ABSTRACT

Fistula-in-ano is an abnormal tract with an external opening in the perianal area that is communicating with the rectum or anal canal by an identifiable internal opening. *Sushruta*, the great surgeon of ancient time described a disease called *Bhagandara* is very much similar to Fistula-in-ano. The treatment of fistula-in-ano remains challenging. Surgery is the treatment of option with the goals of draining infection, eradicating the fistulous tract and avoiding recurrent disease to preserve functions of anal sphincter. But, after surgery it is often noticed that the function of anal sphincter is not preserved while *Khsar sutra* the mainstay of treatment of fistula in ano in Ayurveda do preserve the function of anal sphincter. Keeping this in view this study was planned in which 100 patients of both sexes were randomly selected from the OPD & IPD of Hospital of University college of Ayurved, Dr. S. R. Rajasthan Ayurved University, Jodhpur, Rajasthan, India and divided in to two groups: Group S- 50 patients were treated with Standard *Kshar Sutra* and Group M- 50 patients were treated with Modified *Kshar Sutra*. Both types of Kshar Sutra were prepared in pharmacy of University college of *Ayurved*, Jodhpur. After application of *Kshar sutra* all the patients were instructed to attend the *Shalya Tantra* O.P.D at every 8th day till cutting of fistulous tract totally. Then the patients were treated on the line of wound management till the wound heal completely. It was observed that average Unit Cutting Time (UCT) in both groups show almost similar result with slight better healing in modified *Ksharsutra*.

Key words: Fistuta in ano, *Bhagandara*, *Kshar Sutra*, Unit Cutting Time (UCT)

INTRODUCTION

Fistula-in-ano is an abnormal tract or cavity with an external opening in the perianal area that is communicating with the rectum or anal canal by an identifiable internal opening. Most fistulas are thought to arise as a result of crypto glandular infection with resultant perirectal abscess. The abscess represents the acute inflammatory event, whereas the fistula is chronic. The treatment of fistula-in-ano remains challenging. Surgery is the treatment of option with the goals of draining

infection, eradicating the fistulous tract, and avoiding persistent or recurrent disease while preserving anal sphincter function.^[1, 2]

A fistula-in-ano is a hollow tract lined with granulation tissue, connecting a primary opening inside the anal canal to a secondary opening in the perianal skin. Secondary tracts may be multiple and can extend from the same primary opening. The fascination with fistula-in-ano for more than 2000 years is manifested by the numerous papers and books on the subject. Hippocrates, in about 430 BC, made reference to

surgical therapy for fistulous disease and he was the first person to advocate the use of a seton (from the Latin seta, a bristle). In 1376, the English surgeon John Arderne (1307-1390) wrote Treatises of Fistula in **Ano**; which described fistulotomy and seton use. Historical references indicate that Louis XIV was treated for an anal fistula in the 18th century. Salmon established a hospital in London (St. Mark's) devoted to the treatment of fistula-in-ano and other rectal conditions.^[3]

In the late 19th and early 20th centuries, prominent physician/surgeons, such as Goodsall and Miles, Milligan and Morgan, Thompson, and Lockhart-Mummery, made substantial

Contributions to the treatment of anal fistula. These physicians offered theories on pathogenesis and classification systems for fistula-in-ano.^[4, 5]

Since this early progress, little has changed in the understanding of the disease process. In 1976, Parks refined the classification system that is still in widespread use. Over the last 30 years, many authors have presented new techniques and case series in an effort to minimize recurrence rates and incontinence complications, but despite 2,000 years of experience, Fistula-in-ano remains a perplexing surgical disease.

Perianal and Perirectal Abscess

Pathophysiology

Suppuration of the anal glands as the origin of most anorectal infections (cryptoglandular theory) is generally well accepted. The anal glands number 10-15, are more concentrated in the posterior midline, empty into the anal canal at the level of spaces, including the intersphincteric, perianal, ischiorectal, and supralelevator spaces. Approximately 10% of anorectal abscesses will originate from a non-cryptoglandular source, including Crohn's disease, atypical infection (e.g., tuberculosis, lymphogranulom venereum), malignancy, or trauma.

Evaluation

Pain and swelling are the most common complaints, and may have been present for many days. Fevers and local bleeding or discharge may also be presenting symp-

oms. On evaluation, a tender swelling may be readily apparent, possibly accompanied by local erythema, warmth and fluctuance. An inflammatory process confined to the area of the anal verge most likely represents a perianal abscess, while involvement of the buttock beyond the sphincter complex suggests a perirectal abscess. Complaints of pain and findings of focal tenderness in the anal canal with or without local swelling or fluctuance may represent an intersphincteric abscess. Finally, a supralelevator abscess may present with pelvic pain and dysuria, with or without obvious external physical findings; digital rectal exam in these patients may find induration or fluctuance in the deep perianal tissues. Certainly any patient with anorectal pain and inability to tolerate an exam in the office should undergo exam under anesthesia to rule out the presence of an infectious process.

Classification of fistula in ano

A well accepted classification scheme of anal fistulous disease was proposed by Parks, Gordon and Hardcastle in 1976. In this classification, fistulae are categorized into one of four general categories, with variations found in each category. They are labeled according to their relationship with the external sphincter, as essentially all anal fistulae involve the portion of the internal sphincter beyond the dentate line.

Intersphincteric fistula. Accounting for approximately 70% of cases, the tract in this fistula passes between the sphincters, with possible extension cephalad as a high blind intersphincteric tract. Additionally, it may originate as a pelvic abscess, or may extend into the supralelevator space as a high blind tract.

Transsphincteric fistula. In Parks' study, approximately 23% presented with a fistula whose tract extended through the external sphincter at some level. High blind tracts can extend as far as the supralelevator space.

Suprasphincteric fistula. Approximately 5% of patients will present with a fistula passing from the dentate line completely

around the external sphincter via the supralevator space.

Extrasphincteric fistula. Only 2% of patients will present with this type of fistula. While rarely an extension of an ischiorectal abscess will extend and erode into the rectum above the level of the sphincter, more likely the majority of this uncommon type of fistula originate as a caudad extension of a pelvic infection or malignant process, or develop secondary to trauma, either spontaneous or iatrogenic, as may be seen with overly vigorous probing of high, blind tracts extending cephalad from an ischiorectal abscess cavity.

Symptoms of anal fistulas

Possible symptoms include:

- Pain, which is usually constant, throbbing and worse when sitting down
- Skin irritation around the anus including swelling, redness and tenderness
- Discharge of pus or blood
- Constipation or pain associated with bowel movements
- Fever

Diagnosis of anal fistulas

Usually, a clinical evaluation - including a digital rectal examination and proctoscopy is sufficient to diagnose an anal fistula, but some patients may require additional tests to screen for:

- Sexually transmitted infections
- Inflammatory bowel disease
- Diverticular disease
- Rectal cancer

In rare cases, an examination may be done under anaesthesia. The doctor may also ask for an ultrasound, a CT scan or an MRI and Fistulography.

Treatment of anal fistulas

The type of surgery will depend on the position of your anal fistula. The options include:

- **Fistulotomy.** This is used in 85-95% of cases and involves cutting open the whole length of the fistula in order for the surgeon to flush out the contents.

This heals after one to two months into a flattened scar.

- **Seton techniques.** A seton is a piece of thread which is left in the fistula tract. This may be considered if you are at high risk of developing incontinence when the fistula crosses the sphincter muscles. Sometimes several operations are necessary.
- **Advancement flap procedures.** This option is usually when the fistula is considered complex, or is there is a high risk of incontinence. The advancement flap is a piece of tissue that is removed from the rectum or from the skin around the anus. During surgery, the fistula tract is removed and the flap is reattached where the opening of the fistula was situated. The operation is effective in about 70% of cases.
- **Fibrin glue.** This is currently the only non-surgical treatment option. The glue is injected into the fistula to seal the tract, then the opening is stitched closed. It is a simple, safe and painless procedure, but long term results for this method are poor. Initial success rates as high as 77% drop to 14% after 16 months.
- **Bioprosthetic plug.** This is a cone shaped plug made from human tissue, which is used to block the internal opening of the fistula. Stitches keep it in place. However, this does not completely seal the fistula, so that it can continue to drain. New tissue usually grows around the plug to heal the fistula. Two trials show success rates of over 80% for this method, but long term success rates are uncertain and the method is currently only used in clinical trials

Bhagandara

Sushruta describes the disease in an elaborate fashion giving the nidana, samprapti, lakshana and chikitsa. He also classified the disease into Satponaka, Ustragriva, Parisravi, Sambhukavrata, Unmargi Bhagandara^[6].

AIMS & OBJECTIVES

- To evaluate the effect of modified Ksharsutra in comparison with that of standard Ksharsutra.
- To evaluate the safety & efficacy of modified Ksharsutra in the treatment of fistula in ano.

MATERIALS AND METHODS

Selection of patients

100 patients of age group 20-60 years of both sexes diagnosed with fistula in ano were randomly selected from the OPD & IPD of Hospital of University College of Ayurved, Dr. S.R. Rajasthan Ayurved University, Jodhpur, Rajasthan, India. They were divided in to two groups.

Group S- 50 patients were treated with Standard *Kshar Sutra*.

Group M- 50 patients were treated with Modified *Kshar Sutra*.

Inclusion criteria

- Patient of fistula in ano of age group 20 - 60 yrs satisfying both sexes.
- Fresh and recurrent cases of fistula in ano are satisfying both sexes.

Exclusion criteria

- Patients less than 20 and more than 60 year age group.

- Patients having systemic diseases like malignancy, ulcerative colitis, crohn's disease etc were excluded from the study.

Diagnostic criteria

- **Clinical criteria-** On the basis of clinical history.
- **Investigation** Specific investigations like Mantoux test, Pus culture and sensitivity test, Tissue biopsy [in suspected cases] and Fistulogram along with the routine investigations were carried out

Criteria of assessment

Unit cutting time [UCT]- It is an important parameter to assess the efficacy of the Ksharsutra, which indicates the average time in days taken to cut and to heal 01 cm. of fistulous tract. The UCT is calculated by the following formula.

$$UCT = \frac{\text{Total number of days taken to cut through the tract}}{\text{Initial length of the Ksharsutra in cm.}}$$

The initial length of the *Ksharsutra* in cm. = Time taken [in days] to cut 01cm. of fistulous tract with simultaneous healing.

PREPARATION OF KSHAR SUTRA

Collected and dried *panchanga* (whole plant) *Apamarga* [*Achyranthus aspera*] was burnt. The ash was collected and used for the preparation of *Ksharsutra*;

Table no. K Preparation of *Ksharsutra*

STANDARD <i>KSHARSUTRA</i> [S]	
Ingredient	No. of coatings
<i>Snuhi ksheer</i>	11
<i>Snuhi ksheer</i> + <i>Apamarga kshara</i>	07
<i>Snuhi ksheer</i> + <i>Haridra powder</i>	03
MODIFIED <i>KSHAR SUTRA</i> [M]	
<i>Arka ksheer</i> + <i>papaya ksheer</i>	11
<i>Arka ksheer</i> + <i>papaya ksheer</i> + <i>Tankan kshar</i>	07
<i>Arka ksheer</i> + <i>papaya ksheer</i> + <i>Mulethi churna</i>	03

In above preparations barber's surgical thread no.20 was used

Preparation of patients

- Administration of a laxative powder for bowel preparation.
- The patients were asked to clean and shave the part.
- Consent was taken to all selected patients.

- Inj. Xylocaine sensitivity test were done.
- Administration of Tetanus toxoid.

APPLICATION OF *KSHARSUTRA*

Application through external opening;

After keeping the patient in lithotomy position, good assessment of the tract was

made by using the probe [Eshani]. The technique followed in the present study is the concept of *Sushruta* i.e. application of *Ksharsutra* with improved asepsis. The extent of the tract is assessed by introducing a probe from the external opening. Then *Kshar sutra* is entered into the probe's eye and is taken out through anal canal to the exterior, which ultimately draws thread in the tract. Then the probe is discarded and two ends of the thread are tied. In certain cases the internal opening of the tract was so high that the simple probe was a failure. Hence a sickle shaped special probe is being used which posses usually an eye or ridge at its proximal ends. This procedure was done under local anaesthesia.

Change of *Ksharsutra*

This is done by rail road technique. *Ksharsutra* is applied lateral to the knot of previous thread. Then artery forceps is applied medial to the same knot. Then old thread is cut between the artery forceps and the knot pulling of the artery forceps along with the thread ultimately replaces the old thread by new *Ksharsutra*. Two ends are ligated and bandaging is done. The same procedure is followed for suc-

cessive changes of *Ksharsutra* at in interval of one week.

Adjuvant medical treatment

1. Analgesics- on the day of primary threading, to alleviate pain mild analgesic was advised.
2. *Anu taila Basti*- Patients were advised to take *Jatyadi Taila basti* by pushing of 5 ml of *Jatyadi Taila* into anal canal with the help of syringe and rubber catheter no.7 before defecation.
3. *Ushnodaka avagaha*[Hot sitz bath]- Patients were also instructed to take hot sitz bath after defecation to keep the wound clean and to reduce the pain and inflammation.
4. *Vinfresh powder*[*Vindhya* pharma]- It was advised daily at bed time.
5. Ambulation of the patient- The patients were allowed for all routine works.

Follow up

All the patients were instructed to attend the *Shalya Tantra* O.P.D at every 8th day till cut through of the fistulous tract. Then the patients were treated on the line of wound management till the wound heal completely.

Table no.1 Incidence of Age

Age group[In years]	No. of patients Group 'S'[standard <i>Ksharsutra</i>]	No. of patients Group 'M' [modified <i>Ksharsutra</i>]	Total
Up to20	1	2	3
21-30	14	12	26
31-40	26	16	42
41-50	8	12	20
51-above	1	8	9
Total	50	50	100

Table no.2 Incidence of sex

Sex	No. of patients in Group 'S'	No. of patients in Group 'M'	Total
Male	41	46	87
Female	09	04	13
Total	50	50	100

Table no.3 Incidence of chronicity

Chronicity [In Yrs]	No. of patients Group 'S'	No. of patients Group 'M'	Total
Up to 01	07	03	10
1-2	30	16	46
2-3	10	17	27
03 and above	03	14	17
Total	50	50	100

Table no.4 Incidence of Prakriti

Prakriti	No. of patients		Total
	Group 'S'	Group 'M'	
Vata	9	19	28
Pitta	36	28	64
Kapha	5	3	8
Total	50	50	100

Table no.5 Incidence of Bhagandar

Type of Bhagandar	No. of patients		Total
	Group 'S'	Group 'M'	
Satponaka	4	3	7
Ustragriva	18	20	28
Parisravi	27	26	53
Sambhukavrata	1	1	2
Unmargi	0	0	0
Total	50	50	100

Table no.6 Incidence of type of fistula in ano

Fistula in ano	No. of Patients		Total
	Group 'S'	Group 'M'	
Sub mucous	2	5	7
Sub cutaneous	3	1	4
Low Anal	39	33	72
High Anal	6	11	17
Total	50	50	100

Analysis of 100 patients of Fistula in Ano in terms of Milligan and Morgan's Classification was made.

Table no.7 Incidence of recurrent and fresh cases

Type of cases	No. of patients		Total
	Group 'S'	Group 'M'	
Operated[Recurrent]	6	13	19
Non operated[Fresh]	44	37	81
Total	50	50	100

Cases were analysed in view of previously operated [Recurrent] and non operated [Fresh] cases in fistula in ano.

Table no.8 Incidence of no. of external opening

No. of external openings	No. of patients		Total
	Group 'S'	Group 'M'	
Single	45	46	91

Two	5	2	7
Three	0	2	2
Total	50	50	100

Table no.9 Incidence of clock wise position of fistulous opening;

O' clock position	No. of patients Group 'S'	No. of patients Group 'M'	Total
1	01	2	3
2	6	7	13
3	10	10	20
4	04	2	6
5	5	4	9
6	9	09	18
7	3	4	7
8	7	6	13
9	2	2	4
10	2	2	4
11	1	1	2
12	0	1	1
Total	50	50	100

Table no.10 Incidence of initial length of tract;

Length in cm.	No. of patients Group 'S'	No. of patients Group ' M'	Total
Up to 5 cm.	25	26	51
5 -10 cm	20	19	39
10 -15 cm	04	5	9
Up to 15 cm	01	0	1
Total	50	50	100

RESULT

Table no.11 Unit cutting time in relation to age group;

Age group [In years]	Average unit cutting time[Uct] [in days/cm.]	
	Group 'S'	Group 'M'
Up to 20	6.80	8.50
21to30	7.00	4.08
31 to40	5.64	5.70
41-50	6.35	5.00
51-&above	7.80	6.60

Table no.12 Unit cutting time in relation to chronicity of the disease

Chronicity [In years]	Average unit cutting time [In days\cm.]	
	Group 'S'	Group 'M'
Up to1	6.20	4.26
1-3	7.83	5.03
Up to3	5.37	6.01

Table no.13 Unit cutting time in relation to different O clock position-

'O' clock position	Average unit cutting time [In days /cm.]	
	Group 'S'	Group 'M'

1	5.70	0
2	6.50	5.14
3	5.97	5.74
4	7.00	5.18
5	6.30	5.08
6	6.75	3.90
7	7.18	5.80
8	6.64	7.60
9	4.35	5.15
10	10.00	0
11	8.25	5.60
12	4.20	0

Table no.14 Unit cutting time in previously operated and non –operated case

Type of case	Average unit cutting time[in days\cm.]	
	Group ‘S’	Group ‘ M’
Non- operated [Fresh]	6.48	4.99
Operated[Recurrent]	9.37	5.93

Table no.15 Unit Cutting Time in relation to initial length of tracts

Initial length of tact in cm.	Average unit cutting time [in days/cm.]	
	Group ‘S’	Group ‘ M’
Up to5.0	6.71	4.89
05.1-10.0	6.98	5.54
10.1-15.0	6.52.	5.80
Up to15.1	4.10	0

Table no.16 Comparative result of average unit cutting time

Group	Average unit cutting time in days/cm
S[Standard Ksharsutra]	6.60
M[Modified Ksharsutra]	5.33

DISCUSSION & CONCLUSION

1. The incidence of fistula in ano is more common between 31-40years of age group. (Table no.1)
2. Males were more prone to this disease in comparison to females. (Table no.2)
3. Maximum numbers of cases were reported having the chronicity of 1-2 years of duration. (Table no.3)
4. In this study number of patients of *pitta prakriti* was more in comparison to *vata* and *kapha* parkriti. (Table no.4)
5. Maximum patients were reported having the *parisravi* type of *Bhagandara* in comparison to others. (Table no.5)
6. In present study the *Bhagandara* was classified to *Sushruta* and no case was registered under *unmargi* type of *Bhagandara*.
7. As per modern classification low anal type of fistula in ano were found maximum in number in comparison to sub mucus, subcutaneous and high anal fistula. (Table no.6)
8. Fresh cases [Non-operated] were more in number than previously operated cases. (Table no.7)
9. Cases having single external opening were more than multiple openings. (Table no.8)

10. Maximum numbers of fistulous openings were found at 2, 3, 6 and 8 o' clock positions. (Table no.9)
11. Average UCT in relation to age group had shown the maximum 7.80 days/cm. in Standard group above the age of 50 years while in Modified group. It was maximum 8.50 days/cm. in up to 20 years of age group. (Table no.10)
12. It was observed that the average UCT was less in Modified group up to 01 year and 2-3 years of duration of illness while it was maximum in Standard group in the same duration of illness. (Table no.11)
13. The UCT was minimum 4.2days/cm at 12 O' clock in Standard group while it was minimum 3.90 days/cm.at 6 O' clock in Modified treated group. (Table no.13)
14. The UCT was more in previously operated cases than in fresh cases in both groups.
15. It was observed that lesser the length of the tract slower the cutting and longer the tract faster the cutting in Standard control group while it was contrary in Modified group. (Table no.14)
16. Comparison of average UCT in both groups had shown almost similar results with slight tendency towards better results by modified *Ksharsutra*. UCT in Standard Group was 6.6 days/cm while in Modified Group it was 5.33 days/cm. (Table no.16)
17. Using modified *Ksharsutra* in comparison to standard *Ksharsutra* reduced the total duration of treatment.
18. Out of 50 cases treated with modified *Ksharsutra* no recurrence has been reported even after a long term follow up.

On the basis of above study it is concluded that modified *Ksharsutra* is best to treat fistula in ano as compare to standard *Ksharsutra*.

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