



Research Article

A STUDY TO EVALUATE THE EFFECTIVENESS OF KSHARSUTRA LIGATION FOLLOWED BY FISTULECTOMY IN THE MANAGEMENT OF BHAGANDARA (FISTULA IN ANO)

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ABSTRACT

'Bhagandara' (Fistula in ano) described by *Aacharya Sushruta* can be categorized under 'Dushta Vrana' i.e., noncollapsible, unhealthy infected tunnelling wound with persistent drainage of pus. According to *Sushruta* treatment given for *Bhagandara* is 'Chedana Karma' (excision of tract i.e., Fistulectomy) along with *Ksharsutra Chikitsa*. But as the surgical techniques are opted in infected stage of wound it may lead to complications like recurrence, infection and incontinence. *Ksharsutra* (medicated seton) is a device to deliver medicine to the non-approachable wound surface causes 'Shodhana' (Purification) and 'Ropana' (Healing) of fistulous tract simultaneously. But, time duration required for this treatment is slightly longer as compared to Fistulectomy.

Methodology: The study was an open clinical trial done on five patients, clinically diagnosed as a case of low anal fistula. The aim was to minimise the duration of treatment and to evaluate the pattern and duration of healing of post fistulectomy surgical wound if it performed after achieving *Shuddhavastha* by *Ksharsutra*. Study group were treated with *Ksharsutra* ligation under local anaesthesia and as *Shuddhavastha* was achieved Fistulectomy was done under spinal anaesthesia.

Result: After *Ksharsutra* ligation *Shuddha Vranalakshana* was achieved on third or fourth sitting, whereas the Unit Healing Rate observed after fistulectomy was 0.15 sq.cm/day. No recurrence was noted in any of the 5 patients.

Conclusion: Combine therapy of *Ksharsutra* ligation followed by Fistulectomy curtail the prolong duration of treatment which is quite longer in *Ksharsutra* therapy. It also shows significant results in recurrence as surgical procedure is opted in *Shuddhavastha of Vrana*.

KEYWORDS: *Bhagandara*, Fistula in Ano, Fistulectomy, *Ksharsutra*.

INTRODUCTION

The art and science of surgery since days back to prehistoric era revolves around the 'Vrana' (wound). It denotes the discontinuity of tissue. *Sushruta* had emphasized the concept of *Vrana*^[1], its aetiopathogenesis, various types and management. He described healthy and nonhealing chronic wound as 'Shuddha Vrana'^[2] and 'Dushta Vrana'^[3] respectively. He had also described the concept of "Nadivrana"^[4] (Sinus) which can be categorized under *Dushta Vrana* that is infected non-healing ulcer which is noncollapsible and nonapproachable.

In *Su.Chi* 8/4 treatment given for *Bhagandara*^[5] (Fistula in Ano) is "Saashayet Uddharet Shastren"^[6] i.e. Radicle excision of the cavity. In modern science also the treatment given for fistula is to laid open the track i.e., Fistulotomy or excision of track i.e., Fistulectomy^[7,8]. But the main complication after surgical treatment of anal fistulae is recurrence, infection and incontinence.^[9] Leaving of the main canal, failure to find internal opening or failure to excise all ramifications are the basic errors in surgical techniques for Fistula in Ano. The observational error seen in this is the surgical techniques are opted in *Dushtavastha of Vrana* i.e. in infected stage of wound which may leads to recurrence of Fistula.

Ksharsutra^[10,11] (Ayurvedic medicated seton) application as a treatment of *Nadivrana*, cause of a non-approachable tunneling wound, was given by *Sushruta*. It is a type of *Pratisarniya Kshara*^[12]. It is a device to deliver the medicine i.e., *Kshara* (Caustic) to the non-approachable wound surface. The *Kshara* delivered to the noncollapsible surface of granulation tissue has the action of debridement. It further increases the exudates by increase osmosis and flushes out the infecting organism from patent external opening. This ultimately facilitates the cavity to collapse and heal. By using this "Shodhana" (purification) property of *Ksharsutra*, the *Vrana* is transformed into *Suddhavasta*; it ultimately leads to *Vrana "Ropana"* (healing). But the standard alone *Ksharsutra* treatment is more time consuming as compared to fistulectomy.

Hence, with objective to curtail the prolong duration of treatment by *Ksharsutra* therapy and to overcome the recurrence after operative procedures, a combine therapy of Fistulectomy followed by the achievement of *Shuddhavasta* by *Ksharsutra* insertion will be performed in present study. This is undertaken with the principle that surgically created noncontagious wound

promotes faster healing and minimize the duration of therapy and post Fistulectomy complications.

MATERIAL AND METHODS

The main aim of the study was to evaluate the reduction in duration of post Fistulectomy healing of wound when performed in *Shuddhavastha* after *Ksharsutra* ligation and to minimise the duration of treatment.

Study Design: Open Clinical Trail

Place of Study: Government Ayurved College and Hospital, Nagpur.

Inclusion Criteria

1. Selection of patient was done irrespective of age, sex, religion, occupation, economic status and education status.
2. The patients who were diagnosed as *Bhagandara* (Fistula in Ano).
3. Single track fistula.
4. Low anal fistula.
5. Track length upto 5cm.

Exclusion Criteria

1. Patient suffering from systemic diseases like TB, uncontrolled DM, Ca, Immunocompromised patients.
2. Patient with high anal fistula and more than 5 cm track length.
3. Patient suffering from Ca. of rectum, HBsAg and HIV.
4. Patient suffering from Ulcerative colitis, Crohn's disease and multiple fistulae will be excluded from the study.

Plan of Work:

1. Five patients fulfilling inclusion and exclusion criteria were selected.
2. After examining the patient by per rectal digital examination, proctoscopy and probing diagnosis was confirmed.
3. Patients were initially treated with *Ksharasutra* ligation after every five days interval until the *Shuddha Vrana Lakshana* (signs) was observed.
4. After achieving *Shuddha Vrana Lakshana* complete Fistulectomy was done under spinal anesthesia.
5. Postoperatively wound care and pain management was done and follow up of patient was done upto 6 weeks.

Preparation of *Ksharasutra*

Surgical linen Barber thread gauge number 20 was manually coated eleven times with the latex of *Snuhi* (*Euphorbia neriifolia*), followed by seven coatings of latex and alkaline powder ashes of *Apamarga* (*Achyranthes aspera*) *Kshara* alternatively, and dried. Thereafter three coatings of latex and powder of *Haridra* (*Curcuma longa*) were given alternatively. The thread hangers are placed inside the *Ksharsutra* cabinet and get dried by hot air blow followed by ultraviolet radiations to make it sterile. In these way 21 coatings over the thread was completed.

Method of *Ksharasutra* Application

1. Patient subjected for suitable anesthesia.
2. Lithotomy position was given to patient.
3. For lubrication and local anesthesia 2% xylocaine jelly was applied and probing was done for identification of fistulous track.
4. *Ksharsutra* was tied to one end of probe and probe was removed from internal opening so that by railroad technique the *Ksharsutra* was placed in the fistula track, whose two ends were then tied together.
5. Concomitant medication was given for pain management.
6. After every 5 days interval *Ksharsutra* insertion was done.

Fistulectomy

After achieving *Shuddhavastha* under spinal anaesthesia complete fistulectomy was done. After confirmation of the tract by injecting Methylene blue dye in the external opening, Probing will be done followed by division of the overlying tissue. Base of the wound will be curetted and left open to heal by secondary intention. Post-operatively appropriate wound care was taken.

Criteria To Assess *Shuddhavasta of Vrana*

Shuddha Vrana Lakshna given by Acharya Sushruta in *Su.Chi.1/7* and *Su.Sutra.24/18* are

- ✓ *Jivhatlaabho Mrudu Snidgdha Shlakshno Vigatvedanaha*
Suvyavasthito Nirastravcheti Shuddha Vranaiti || [13]
- ✓ *Tribhirdoshaihi -anakraanta Shyavoushtha Pidikisamaha*
Avedano Nirastravo Vranaha Shuddhalhochyatye || [14]

It can be assessed with surgical parameters like:

1. *Jivhatlaabho Mrudu Snidgdha Shlakshno*= Pinkish red appearance of floor of wound.
2. *Vigatvedanaha*= No pain
3. *Nirastravcheti* = No discharge
4. *Pidikisamaha* = Healthy granulation tissue
5. *Shyavoushtha* = Epithilisation of tissues of wound

Criteria to Assess *Shuddhavasta of Vrana* (Fistulous Track)

1. *Vigatvedanaha*=a) No pain or reduction in intensity of pain.
b) No tenderness.
c) No discomfort
2. *Nirastrava*= discharge or decrease in discharge
3. *Suvyavasthito*=Can be correlated with observations seen in surrounding tissue of external opening of Fistula in Ano. i.e. absence of
 - a. Erythema
 - b. Edema & Induration
 - c. Colour changes
 - i. Reddish skin tone – reflect infection
 - ii. Blue or Pallor – poor vascularity
 - d. Temperature – warmth may reflect infection

Parameters of Assessment

A. Parameter for Ksharasutra Therapy

A. Subjective Parameter :
a) Pain
NRS Pain index Score :
 No Pain : 0
 Mild Pain : 1-3
 Moderate Pain : 4-7
 Severe Pain : 7-10

B. Objective Parameter:
a) Discharge :
 No discharge : 0
 Mild discharge : 1
 Moderate discharge : 2
 Profuse discharge : 3
b) Length of track in cm

B. Parameter for Fisulectomy Wound

A. Subjective Parameter :
a) Pain
NRS Pain Index Score :
 No Pain : 0
 Mild Pain : 1-3
 Moderate Pain : 4-7
 Severe Pain : 7-10

B. Objective Parameter:
a) Discharge :
 No discharge, dry dressing: 0
 Scanty discharge occasional, wet dressing: 1
 Often discharge, needs daily dressing : 2
 Profuse discharge which needs frequent dressing : 3
b) Size of wound in cm (length x breadth x width)

c) Evaluation of granulation tissue :
 Above 50 % wound surface covered with granulation tissue: 0
 25 - 50 % wound surface covered with granulation tissue: 1
 Upto 25% wound surface covered with granulation tissue: 2
 No granulation tissue : 3

d) Evaluation of slough tissue :
 No slough : 0
 Upto 25% wound surface covered with slough : 1
 25 - 50 % wound surface covered with slough : 2
 Above 50 % wound surface covered with slough: 3

e) Healing time
 Healing time will be assessed by total number of days taken for healing.

$$UHT = \frac{\text{Initial area} - \text{last area of wound (in sq. cm)}}{\text{Total number of days taken during treatment}}$$

Table 1: Showing Patient Wise Ksharasutra Treatment Results

S.N	Age (Yrs)	Gender	Chronicity	Position	Track length (cms)	1st Sitting			2nd Sitting		
						Pain (NRS)	Discharge	Track length (cms)	Pain (NRS)	Discharge	Track length (cms)
1	25	Male	8 months	6 o'clock	2.0	7	2	2.0	4	1	1.5
2	34	Male	2 years	9 o'clock	2.5	7	2	2.5	5	1	2.1
3	40	Female	1 year	7 o'clock	3.5	6	2	3.5	5	1	3.0
4	33	Male	10 months	5 o'clock	3.0	5	1	3.0	3	1	2.4
5	45	Female	1year	1 o'clock	4	7	2	4	5	2	3.4

3rd Sitting			4th Sitting			5th Sitting			6th Sitting			Total Number of Sitting
Pain (NRS)	Discharge	Track length (cms)	Pain (NRS)	Discharge	Track length (cms)	Pain (NRS)	Discharge	Track length	Pain (NRS)	Discharge	Track length	
2	0	1.00										3
3	0	1.8										3
3	1	2.4	2	0	2							4
2	0	2	1	0	1.5							4
4	1	2.9	2	1	2.3							4

Table 2: Showing Patient Wise Post Fistulectomy Wound Healing

Patient No.	Post Op day	Pain	Discharge	Size of wound (cms) (L×B×D)	Evaluation of Slough Tissue	Evaluation of Granulation Tissue	Unit healing Rate (sq.cm/day)
1	1st	7	2	1.5×1×0.8	0	3	0.10
	7th	3	1	0.8×0.5×0.4	0	0	
	14th	2	0	0.2×0.1×0.1	0	0	
2	1st	6	1	2.5×2×1	0	3	0.20
	7th	4	2	1.5×1×0.6	1	1	
	14th	3	0	0.4×0.4×0.2	0	0	
3	1st	7	0	2.5×2×1.5	0	3	0.17
	7th	5	2	1.6×1.2×0.8	1	2	
	14th	2	0	0.5×0.5×0.1	0	0	
4	1st	6	0	2×1.5×0.8	0	3	0.13
	7th	3	2	1.2×0.8×0.4	0	0	
	14th	1	0	0.3×0.2×0.1	0	0	
5	1st	7	1	3×2×1.5	0	3	0.17
	7th	3	2	2.2×1.3×0.8	1	1	
	14th	2	1	1.2×0.6×0.4	0	0	

Table 3: Total Duration Required

Patient No.	Total length of Tract (cms)	Duration of Cure (in Days)
1	2	30
2	2.5	40
3	3.5	48
4	3.0	42
5	4.0	55

- 1) In above data of 5 patients; 3 were male and 2 were female.
- 2) Age group of all 5 patients was between 20 years to 50 years.
- 3) Track length of all 5 patients was below 5 cm.
- 4) All 5 patients had single track fistula.
- 5) All 5 patients had low anal fistula.
- 6) *Shuddhavastha* of *Vrana* (fistulous tract) obtained approximately after 3rd /4th sittings of *Ksharasutra*.
- 7) After achieving *Shuddhavastha*, Fistulectomy was performed in all the 5 patients.
- 8) The average Unit Healing Time was approximately 0.15 sq.cm/day.

DISCUSSION

The conventional surgical treatment of Fistula in Ano is Fistulectomy or Fistulotomy. Several modifications of this procedure are also reported. Despite best efforts opted in surgical techniques *Dushtavasta* of *Vrana* (infected stage of wound) may lead to recurrence of Fistula.

On the other hand use of '*Ksharasutra*' (chemical seton) for treatment of Fistula in ano along with *Nadivranais* reported in ancient Indian text. The *Kshara* (caustic) applied on the thread are anti-inflammatory, anti-slough agent and in addition have chemical curative properties. The *Ksharsutra* remains in direct contact with tract and slough out the epithelial lining, thereby allowing the fistulous tract to collapse and heal.

By considering both the techniques this pilot study was done in 5 patients where *Ksharsutra* was applied in

fistulous tract a nonapproachable tunneling wound. After achieving *Shuddhavasta* of *Vrana* the tract is surgically removed. As *Ksharsutra* needs to change periodically, patient requires to come hospital every week, hence the duration of the treatment is significantly longer which was reduced in this study by Fistulectomy procedure. According to *Acharya Sushruta* complete *Ropana* of wound is achieved only after *Shodhana Karma*. Hence, by this principle of wound healing Fistulectomy was done after achieving *Shuddha Vrana Lakshana* and recurrence was overcome. Follow up of patient was taken upto 6 months for recurrence and no patient was reported for recurrence.

Mode of Action of *Ksharsutra*

- Debridement and lysis of the tissue.
- The presence of *Ksharsutra* in the fistulous tract does not allow cavity to close down from either ends and there is continuous drainage of pus along the *Ksharsutra* itself.
- *Ksharasutra* delivers the medicine to the noncollapsible surface of granulation tissue which cause debridement and also flushes out the infecting organism from patent external opening. This ultimately facilitates the cavity to collapse and heal.
- The *Kshara* (Caustics) applied on the thread are anti-inflammatory and they have property of chemical curetting. The *Ksharsutra* remains in direct contact of the tract and therefore, it chemically curettes out the tract and sloughs out the epithelial lining, thereby allowing the fistulous tract to collapse and heal.

Benefits of Ksharsutra Ligation Followed By Fistulectomy

1. It curtails the prolong duration of the treatment by Ksharsutra therapy.
2. Early ambulation and minimum hospitalization.
3. Significant effect on recurrence rate.

CONCLUSION

Kshar sutra procedure is simple, easy, safe, feasible and cost effective in the management of Fistula in Ano. But the duration required for Ksharsutra therapy is quite longer whereas the healing of wound is faster in open method of Fistulectomy. Combination of both these techniques i.e. Shodhana of the fistulous track is done by conventional Ksharsutra therapy followed by Complete Fistulectomy will curtail the prolong duration of treatment and also overcome the recurrence after operative procedure.

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