ISSN 0976 – 3333

Available Online at www.ijpba.info

International Journal of Pharmaceutical & Biological Archives 2017; 8(6): 42-47

RESEARCH ARTICLE

A Comparative clinical study of *Ksharsutra* ligation and Lateral Internal Sphincterotomy in the management of *Parikartika* (Chronic Fissure-in-Ano)

***Dr. Manoj Bhadja[1], Dr. T.S. Dudhamal[2]**

[1]Assistant Professor, Dept. of Shalya Tantra, IPGT&RA, Gujarat Ayurved University, Jamnagar, Gujarat. India*
[2]Associate Professor & I/c Head
Dept. of Shalya Tantra, IPGT&RA, Gujarat Ayurved University, Jamnagar, Gujarat. India

Received 30 Sep 2017; Revised 20 Oct 2017; Accepted 12 Nov 2017

ABSTRACT

Background: *Parikartika* which resembles fissure-in-ano described as a complication of various diseases in Ayurvedic texts such as *Vatika jwara*, *Vatika pakwa atisara*, *Sahaja arsha*, *Kaphaja arsha*, *Arsha purvarupa*, *Udavarta*, complication of pregnancy (*Garbhini*), unlawful administration of purgative or enema (*Basti*), complication of *Vamana* and *Virechana*. As *Ksharsutra* , proven successful treatment modality for fistula-in-ano and piles to try its efficacy in chronic fissure-in-ano. Aim: To compare *Apamarga Ksharsutra* ligation and Lateral Internal Sphincterotomy (LIS) in the management of *Parikartika* (Chronic fissure-in-ano). Materials and Methods: Total 30 patients of *Parikartika* were selected and randomly divided in to two Groups (15 in each group). In group-A, *Ksharsutra* ligation with maximum possible anal dilatation was carried out while in group-B Lateral Internal Sphincterotomy with excision of skin tag was carried out under local anesthesia. Relief in symptoms and post operative complications in subjects were assessed for 4 weeks and follow up period was 1 month. Results: In both groups, significant results were found individually but difference was statistically insignificant. Duration required for relief in post- operative pain, bleeding, swelling and wound healing was found more in group-A (*Ksharsutra*) than group-B (LIS). Conclusion: Lateral Internal Sphincterotomy produced better results in compare to *Ksharsutra* ligation in the management of *Parikartika* (Chronic Fissure-in-Ano).

Key words: *Parikartika*, Fissure-in-ano, *Ksharsutra* , Lateral Internal Sphincterotomy.

INTRODUCTION

In the Ayurvedic texts, *Parikartika* (cutting pain in Ano) is described as a symptom of various disease conditions such as *Vatika jwara*, *Vatika pakwa atisara*, *Sahaja arsha*, *Kaphaj arsha*, *Arsha purvarupa*, *Udavarta*, complication of pregnancy (*Garbhini*), unlawful administration of purgative or enema (*Basti*), complication of *Vamana* and *Virechana*. It was considered as disease first time in *Kashyapasamhita* and its types based on *Dosha* were also described. This classification was also followed in *Sharangdharasamhita* in medieval period. [1]

Fissure in ano is an elongated ulcer in the long axis of the anal canal.[2] Etiology of fissure-in-ano is primarily constipation with passing of hard stool and secondary due to many diseases like chronic amoebic dysentery, diverticulitis, irritable bowel syndrome, ulcerative colitis etc. The common site of fissure-in-ano is 6 o'clock (midline posterior) in lower half of the anal canal which is commonly found in young adults and after delivery in females. The disease has been classified into two varieties viz., acute and chronic fissure-in-ano. Acute fissure-in-ano can be subsided by conservative treatment but in chronic cases surgical intervention is needed.[3] In modern surgical treatments such as Lord's anal dilatation, fissurectomy, and sphincterotomy for anal fissure are suggested but they have their own limitations like recurrence, incontinence, etc.

Ayurvedic para-surgical procedure, *Ksharsutra* ligation, is found successful treatment modality for anorectal disorders like fistula-in-ano [4] hemorrhoids, [5] and chronic fissure-in-ano [6] but with limited data. Presently, Lateral Internal Sphincterotomy (LIS) is considered as gold standard treatment for chronic fissure-in-ano.[7] There is a need to compare both treatment procedures i.e. *Ksharsutra* ligation and Lateral Internal Sphincterotomy. Considering all these factors, present study was planned with aim to

***Corresponding Author:** Dr. Manoj Bhadja, **Email:** bhadjamanoj@gmail.com

compare *Ksharsutra* ligation and Lateral Internal Sphincterotomy in the management of *Parikartika* (Chronic fissure-in-ano).

MATERIALS AND METHODS:

Selection of Patients:

The patients of *Parikartika* (chronic fissure in ano) were selected from OPD/IPD of study centre irrespective of age, gender, occupation and religion. Clinical trial was approved by Institutional Ethics Committee (ref. no. PGT/7/-A/Ethics/2014-15/1538 dated 02.09.2014) and registered in CTRI (Reg. no. CTRI/2016/02/006679) retrospectively.

Inclusion criteria:

Patients of age group between 17-60 years of *Parikartika* (Chronic fissure-in-ano) having duration more than 6 months were included in the study.

Exclusion Criteria:

Patients of fissure-in-ano with less than 6 months duration, chronic fissure-in-ano associated with piles & fistula, malignancy of anorectum or any other organs were excluded. Positive cases for HIV, VDRL, Hepatitis-B and uncontrolled cases of Diabetes Mellitus and Hypertension were also excluded.

Diagnostic Criteria:

The patients were diagnosed on the basis of history, signs and symptoms, local examination with digital per rectal examination of and feature of chronic fissure in ano. Digital per rectal examination was carried out with 2% Xylocaine jelly to assess the sphincter tone after assessing the tolerance of pain and consent of patient. Proctoscopic examination was done after giving suitable anesthesia at the time of operation to exclude other anorectal pathologies like piles, polyp, any growth, etc.

Laboratory Investigations:

Routine Haemogram, B.T., C.T., Fasting Blood Sugar, Post Prandial Blood Sugar Renal Function Test- Blood urea, Serum Creatinine, Liver Function Test - Serum bilirubin (T), Serum Glutamic Oxaloacetic Transaminase, Serum Glutamic Pyruvic Transaminase, HIV, VDRL, HBsAg, Urine analysis- Albumin, Sugar & Microscopic was carried out. All above laboratory investigations were carried out for fitness of the patients for anesthesia and surgery. So these investigations were done only before treatment. HIV, VDRL, Australia antigen were done to avoid the contamination of Operation Theatre (OT) as well as the surgeon and paramedical staff. Chest X-Ray, ECG, USG Abdomen & Pelvis was done in cases of age above 40 years for fitness of patient.

Procedure for preparation of *Ksharsutra*

Ksharsutra prepared by *Apamarga Kshara* (*Achyranthus aspera* L.), *Snuhi Ksheera* (latex of *Euphorbia nerifolia* L.), and *Haridra Churna* (powder of *Curcuma longa* L.) and standard method described in Ayurvedic Pharmacopia of India was followed. [8]

Grouping

Patients registered for trial were randomly divided in two groups i.e. A & B. In group-A, patients were treated by standard *Apamarga Ksharsutra* ligation with transfixation of sentinel tag with maximum possible anal dilatation under local anesthesia and in group-B, patients were treated by Lateral Internal Sphincterotomy followed by excision of sentinel tag under local anesthesia. Post operative treatment such as *Panchwalkala kwatha* for sitz bath, *Jatyadi Taila Matrabasti* and 5 g *Erandbhrishta Haritaki churna* (administered orally at bed time with luke warm water) were given in both groups.

Operative procedure:

- **Common preoperative procedures adopted for both Groups:**
  The written informed consent was taken from every patient before the operation. Patient was kept nil orally, at least 6 hours before surgery. Preparation of parts i.e. shaving of perineal area was done. Soap water enema at 10 pm day before surgery and proctolysis enema at 7 am on the day of operation was given. Inj. Tetanus Toxoid, 0.5 ml, intramuscular (IM) and Intra-dermal injection of xylocaine 2% sensitivity test was done before surgery.
- **Procedure of *Ksharsutra* transfixation in Group-A:**
  The patient was laid down in the lithotomy position followed by Painting and draping of local part. Local anesthesia was given by infiltration of Inj. Xylocaine 2% with adrenaline. Anal sphincters were dilated with two fingers, forcefully in lateral direction and anterior-posterior portion of anal canal but in controlled manner. The whole fissure bed including

all fibrous tissue was incised by tissue cutting scissor and fibers of internal anal sphincter was separated with blunt dissection by gauze piece from fissure bed till anoderm, then sentinel tag was trans-fixed by *Ksharsutra* with the help of round body curved needle. After hemostasis, sterilized dressing was carried out and 'T'-bandage was applied.

- **Procedure of LIS (Lateral Internal Sphincterotomy) in Group-B:**
  Local anesthesia was given by infiltration of Inj. Xylocaine 2% with adrenaline. Inter-sphincteric groove was palpated with the index finger very well and blade (no. 15) was inserted through the perianal skin, immediately lateral to the lower edge of the internal sphincter and passed vertically upwards in the inter sphincteric plane till level of the pectinate line. By means of delicate strokes of the blade in the direction of the anal canal the lower half of the internal sphincter was divided. The care has been taken to prevent the lining of the anal canal's mucosa from penetration. Pressure packing was done for 5 minutes to reduce chances of hematoma. After that the whole fissure bed including all fibrous tissue and sentinel tag was excised with the help of scissor. After haemostasis, sterilized dressing was done and 'T'-bandage was applied.
- **Post-operative regimens for both groups:**
  Appropriate I.V. fluids, antibiotic and analgesic were used as per requirement. From next day onwards warm water along with *Panchwalkal kwatha* sitz bath, two times a day. *Matra Basti* with *Jatyadi Tail* -10 ml, once daily after sitz bath. *Erandbhrishta Haritaki churna*- 5 gm at bed time with luke warm water was administered daily. Post-operative regimens were given for four weeks.

Duration of assessment: After the *Ksharsutra* ligation or LIS, patients were assessed on weekly interval up to 4 weeks. Follow up was taken one month after completion of the treatment.

Assessment Criteria: Improvement in post operative complains were assessed by specially designed gradation method. Post operative complains such as pain, swelling, oozing and wound healing duration were evaluated.

Statistical Test: The Wilcoxan Signed rank test was used to evaluate the effect of individual treatment and the Mann Whitney Rank Sum test was applied for inter group comparison as the data were non parametric in nature.

OBSERVATIONS & RESULTS

Total 30 patients who fulfill the inclusion criteria were registered and completed in trial. They are randomly and equally allocated in both groups. No patients dropped out from the trial.

In demographic data, Maximum numbers of patients (43.33%) were found in age group between 31 and 50 years. 53.33% patients were male. 80% patients had urban back ground, Socio-economically middle class patients were maximum (60%). (Table no.1)

Table no.1- Demographic data of clinical trial

Demographic indicator	Characteristics	In group A	In Group B	Total. N, (%)
Age group	17-30 year	7	4	11 (36.67)
	31-50 year	6	7	13(43.33)
	51-70 year	2	4	6 (20)
Participants	Women	8	6	14 (46.67)
	Man	7	9	16 (53.33)
Socio-Economic situation	Rich	1	0	1 (3.3)
	Medium	9	9	18 (60)
	Poor	5	6	11 (36.7)
Literacy	Literate	11	12	23 (76.7)
	Illiterate	4	3	7 (23.3)
Dwelling status	Urban	12	12	24 (80)
	Rural	3	3	6 (20)
Marital status	Married	13	13	26 (86.7)
	Unmarried	2	2	4 (13.3)

On local examination, all the patients of chronic fissure in ano developed sentinel tag, healthy skin, and no discharge. 66.67% patients had spasmodic anal sphincter while 46.7% patients had papilla. (Table no. 2)

Table no. 2- group wise distribution of findings of local examination

Local examination	Characteristics	In group A	In Group B	Total, n (%)
Status of perianal skin	Healthy	15	15	30 (100)
	Unhealthy	0	0	0
Discharge from anal canal	Present	0	0	0
	Absent	15	15	30 (100)
Position of fissure in ano	Anterior	2	4	6 (20)
	Posterior	9	7	16 (53.3)
	Anterior and posterior	4	4	8 (26.7)
Anal sphincter tone	Spasmodic	8	12	20 (66.7)
	Normal	7	3	10 (33.3)
Anal papilla	Present	7	7	14 (46.7)
	Absent	8	8	16 (53.7)

In *Ksharsutra* treated group, Mean time required to relieve post-operative pain was 10.66±5.7 days,

while post operative swelling was relieved 100% within 4.6±1.6 days. Post operative oozing was stopped by 3.75 ±1.5 days only and Mean time for wound healing was found 24.60 ±5.9 days. (Table no. 3)

In LIS treated group, Mean time for post-operative pain was found 8 ±4.7 days, whereas post operative swelling was relieved completely within 3.25 ±1.2 days. Post operative oozing was stopped by 2.7 ±1.1 days and Mean time for wound healing was found 22.13 ±6.4 days. (Table no. 3)

Table no. 3- Average days required to relieve the post operative symptoms in both groups

post operative symptoms	Group-A, Mean±SD (In days)	Group-B, Mean±SD (In days)
Pain P/R	10.66±5.7	8 ±4.7
Swelling	4.625 ±1.6	3.25 ±1.2
Oozing of blood P/R	3.75 ±1.5	2.7 ±1.1
Wound healing	24.60 ±5.9	22.13 ±6.4

In comparison between both groups, no statistical difference was found in all the post operative complaints. (Table no. 4)

Table no. 4- comparison of post operative complaints between both the arms.

No of days required for	Groups	Medial	25%	75%	'P'
pain relieving	Group-A (n=15)	7.00	6.000	14.00	0.221 (IS)
	Group-B(n=15)	7.00	5.250	7.00	
relief in swelling	Group-A (n=8)	4.00	3.50	6.00	0.127 (IS)
	Group-B (n=8)	3.50	2.00	4.00	
stop oozing	Group-A (n=8)	3.500	2.500	5.00	0.155 (IS)
	Group-B(n=10)	2.500	2.000	4.00	
operative wound healing	Group-A (n=15)	28	21	30	0.383 (IS)
	Group-B(n=15)	21	15.75	30	

n- no. of subjects, 25%- 1st quarter, 75%- last quarter
Mann-Whitney Rank Sum Test, P <0.05 - insignificant difference,

In this study post operative complications like perianal abscess, fistula-in-ano or incontinence were not found in any group but Skin tag was developed in two patients at operated site in *Ksharsutra* treated group.

DISCUSSION

Presently fissure in ano is defined as an elongated ulcer in the long axis of the anal canal (Bailey and Love). [9] Initiating factor in the development of a fissure is trauma to the anal canal, usually in the form of the passage of a fecal bolus that is large and hard. [10] Literatures strongly suggests that LATERAL INTERNAL SPHINCTEROTOMY is the operative treatment of choice for patients with a chronic anal fissure[11] as it do not required hospitalization, it can be performed with the patient under local anesthesia, Postoperative discomfort is of short duration, and wounds heal quickly. Fecal soiling is an infrequent problem, and recurrence after this procedure is uncommon. [12]

Present study shows that all the patients of both treatment arms were completely cure which indicates 100% relief of both the procedure and there is no statistical difference on the post operative complains between both the groups However, mean time required to relieve all the post operative complaints were found minimal in LIS treated group in comparison to *Ksharsutra* treated group which may indicate to better efficacy and applicability of LIS as operative procedure for the management of *Parikartika* (Chronic fissure-in-ano). As sample size was limited in present study, power of the study may be low and thus statistical significant difference was not obtained within the arms. Therefore it is suggested to conduct clinical trial to analyze the efficacy of *Ksharsutra* ligation on fissure-in-ano (*Parikartika*) with good number of subject.

Mode of action of Ksharsutra

The *Apamarga Kshara* possesses *Chhedana* (excision), *Bhedana* (incision), *Ksharana* (debridation), *Stambhana* (haemostatic), *Shodhana* (purification/sterilization), and *Ropana* (healing) properties. ksharsutra ligated at fissure bed excises the fibrotic tissue by action of *Ksharana* and removes unhealthy fibrous tissue and debris; makes the wound healthy by *Shodhana* property.[13] The *Snuhi Ksheera* is slightly acidic in nature but also has antibacterial property[14] which helps to check secondary infection. The *Haridra* has anti-inflammatory as well as antibacterial [15] properties and hence, it is capable to make the wound clean, healthy, and promote early healing.[16] *Ksharsutra* may produce gradual but sustained chemical action which removes debris from the site of fissure bed and also helps in formation of healthy granulation tissue thereby inducing a long healing pattern in depth of the tissue. *Ksharsutra* also breaks up the fibrosed tissue and ultemately drains creating a healthy base for healing.[17]

Probable mode of action of adjuvant drugs

The *Panchavalkala Kwatha[18]* was used for *Avagaha Swedana* (warm water sitz bath);[19] has *Shodhana, Stambhana, Shothahara*

(antiinflammatory), and *Vedanahara* (analgesic) properties, which helped to relieve pain, local *Shotha* (edema) as well as to stop oozing and maintained perianal hygiene. The ingredients of *Panchavalkala Kwatha (Vata, Ududmbara, Plux, Parish, Ashwatha)* are having predominant of *Kashaya Rasa*. So when the *Kwatha* was used for sitz bath, it exhibited *Vrana Shodhana* and *Vrana Ropana* properties.[20]

Erandbhrita Haritaki churna is specially indicated for *Vibandha* (constipation),[21]

Most of the ingredients used in *Jatyadi Taila* are *Shothahara, Vedanasthapana*, and *Ropana*, which are important requirements for healing of the wound.[22] *Jatyadi Taila* was instilled per rectal 10 ml after sitz bath to reduce the swelling and pain as well as for smooth evacuation of feces. The ingredients of the Taila like *Neem* (Azadirechta indica A. Juss)[23, 24]and *Daruharidra* (Beriberis aristate DC.) are proven drugs to check bacterial growth and promotes wound healing.

Hence, it is clear that, wound healing after cut through of *Ksharsutra* from fissure bed was well achieved by per rectal instillation of *Jatyadi Tail, Avagaha Swedana* with *Panchwalkala Kwatha* and orally *Erandbrust Haritaki churna* in both groups.

CONCLUSION

In both, *Ksharsutra* treated and LIS treated groups, all the patients were cured 100 percent but mean time for relief in post operative complaints like pain, swelling and oozing were found less in LIS treated group (Lateral Internal Sphincterotomy) than *Ksharsutra* ligation. Hence, it can be concluded that the Lateral Internal Sphincterotomy with excision of skin tag is more effective treatment modality than *Ksharsutra* ligation with maximum possible anal dilatation in the management of *Parikartika* (chronic fissure in ano).

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