Research Article

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MANAGEMENT OF CHRONIC FISSURE IN ANO BY *KSHARASUTRA* (MEDICATED THREAD): A CLINICAL PROSPECTIVE STUDY

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ABSTRACT

Parikartika resembles fissure- in- ano as sign and symptoms are same and which is very common among all ano-rectal disorders. Chronic Fissure in ano with sentinel pile and unhealed midline ulcer due to late approach of patients for treatment or failure of conservative treatments of acute condition require surgical intervention. Total 50 patients of chronic fissure- in- ano were selected. *Ksharasutra* trans-fixation and ligation was done under spinal anaesthesia on sentinel pile with fissure bed after Lord's anal dilatation. After gradual withdrawal of *Ksharasutra*, the lesion was treated for 4 weeks and outcome was evaluated on the basis of gradation pattern adopted. 95% relief in pain was observed on 28th day, whereas 100% improvement in swelling was found on 14th day and oozing of the wound. 84% healing was found on 4th week where as 82% of patients were cured completely. *Ksharasutra* trans-fixation and ligation in chronic fissure in-ano with sentinel pile after Lord's anal dilatation is a safe with minimum complications and recurrence.

Keywords: Chronic fissure- in- ano, *Ksharasutra*, Lord's anal dilatation, *Parikartika*

INTRODUCTION

In Ayurveda, *Parikartika* is the most common cause of severe burning type of pain in anus during and after defecation resembles with condition fissure-in-ano in modern parlance due to its aetiology and etiopathogenesis. *Parikartika* means, '*Pari'* means all around and '*Kartana'* means cutting hence cutting all around the anal canal with pain is most accepted and important clinical symptom. Acute fissure is a linear crack in anoderm which can be easily seen on inspection by separating the buttocks and gentle stretching the anal canal horizontally. Prevalence of this disease is in between 20 to 40 years of age. Female are more commonly affected and the most common site is mid anterior aspect, while in males posterior aspect are more common. This affects unusual site in cases of Crohn's disease and ulcerative colitis. *Parikartika* is also mentioned in classical as a complication of the *Basti* (enema) and *Virechana* (laxation) procedures.[1] The prevalence rate of chronic fissure-in-ano is approximately 30–40 of total ano-rectal sufferings, either because of failure of available conservative treatment or delayed approach of the patients for treatments. In contemporary science, surgical procedure like Lord's anal dilatation, fissurectomy and sphincterotomy are available but they have limitations like recurrence, incontinence etc.[2] Constipation with passing of hard stool is foremost cause of fissure-in-ano while many diseases manifests as a secondary cause also surgery like haemorrhoidectomy or fistulectomy. In young adults and after delivery in females midline posterior at 6 o'clock position are commonly found.[3] Two types of Fissure in ano are mentioned i.e. Acute and chronic, in which Acute fissure-in-ano is a condition where inflammation of the anal mucosa found and which is mostly cured by conservative treatment.[4] In chronic cases, there are sentinel pile and unhealed midline ulcer which may be associated with external and internal haemorrhoids and requires surgical correction.[5] *Ksharasutra* is gaining its nationwide popularity in day-to-day practice, expanding into Western and European countries. Application of *Ksharasutra* in Fistula in ano was already established[6] and it is now time to establish *Ksharasutra* in other ano-rectal disorders like piles, fistula, fissure etc., most of the research studies are found for the management of *Parikartika* but almost all are conservative measures. As in chronic fissure-in-ano, surgery is required for complete remission. Application of *Ksharasutra* gives minimum complication and less recurrence[7] so in this study *Ksharasutra* ligation was planned.

MATERIAL AND METHODS

Total 50 patients, of *Parikartika* were registered. Standard *Apamarga Ksharasutra*, *Panchavalkala Kwatha* for sitz bath, *Eranda Bhrishta Haritaki Churna* 5 g at night, *Triphala Guggulu Vati* and *Jatyadi Taila Pichoo* (cotton swab soaked in oil) for local holding over the anal region.

Ksharasutra trans-fixation and ligation (KSL) of sentinel pile with fissure bed was done under suitable anaesthesia.

Inclusion criteria

Diagnosed patients of both sex, age 18- 60 years with *Parikartika* having sign and symptoms like fissure bed with sentinel pile, pain in ano, per rectal bleeding, history of constipation were included in the study after taking informed consent.

Exclusion criteria

Fissure-in-ano having duration less than 6 weeks, chronic fissure-in-ano associated with piles and fistula, Patient below 18 and above 60 years of age. Patients who were suffering from acute

fissure-in-ano, carcinoma of ano-rectum were not included in this study. Patients suffering from infections like Human Immunodeficiency Virus (HIV), Venereal Disease Research Laboratory (VDRL) and hepatitis-B were also excluded.

Diagnosis criteria

Patients were diagnosed on the basis of signs and symptoms as per Ayurved and modern literature i.e. *Vedana* (pain), *Malabadhhata* (Constipation) and *Raktasrava* (per rectal bleeding) also on the basis of external findings like position of fissure and external sentinel pile. Digital per rectal examinations (P/R) were performed with 2% xylocaine jelly to assess the sphincter tone. Proctoscopic examination was performed after giving appropriate anaesthesia at the time of surgery.

Investigations

Before surgery, routine blood investigations like CBC, Urine microscopic/macroscopic, BSL (blood sugar levels), KFT (kidney function test), HIV, VDRL and HbSAg and stool examination were carried out prior to the treatment for fitness of the patients for surgery and anaesthesia. Chest X-ray and ECG were carried out in patients over 40 years of age to detect any hidden pathologies related to cardiac or pulmonary functions.

Ethical consideration

IEC- PGT/7/-A/Ethics/2016-17/3937 Dated 23/02/170.

CTRI registration

(Clinical Trial Registry of India) vide no. CTRI/2017/10/009963 Dated 03/10/2017.

Preoperative procedure

The written informed consent was taken prior to the procedure. Patient was kept nil orally for 6 hours. The perianal part was prepared and given soap water enema in the morning at 8 am. TT (tetanus toxoid -0.5 ml intramuscular) and xylocaine 2% injected intra-dermal for sensitivity test insured before surgery.

Operative Procedure

After low spinal anaesthesia, the patient was given a lithotomy position, painting and draping was done. As per Lord's anal dilatation procedure, first four fingers anal stretching (anal dilatation) was performed with the help of the lubricated fingers of both hands.[8] The whole fissure bed including all fibrous tissue and sentinel pile was transfixed and ligated by *Ksharasutra* with the help of round body curved needle of appropriate size. After proper haemostasis, T-bandage was applied. Patient was then shifted to the ward in conscious and stable condition. The patient was rested down in head low position for 3-4 hour and then permitted to take liquids. Antibiotic and analgesic were given for first three days. *Avagaha Swedana* (sitz bath) with *Panchavalkala Kwatha* (PVK) was advised twice a day. From next day of operation, *Eranda Bhrishta Haritaki Churna* (EBH) - 5 gHS and *Triphala Guggulu* (TG) tablet - 500 mg TDS (thrice a day) with lukewarm water was prescribed.

Postoperative Procedure

Dressing was done once a day with instillation of 10 ml *Jatyadi Taila* (JT) per rectal. Patients were advised to take water intake in excess and fibre rich diet from next day of operation. Patients were assessed after seven days.

Follow up

Follow up period 30 days after completion of the treatment to observe re-occurrence and any untoward effects.

Assessment criteria

Assessment was done every seven days to find out the efficacy of *Ksharasutra* trans-fixation and ligation by relief in postoperative pain, swelling, oozing and days required for complete wound healing.

Statistical Analysis

Statistical test for the assessment of the result by statistical analysis, student paired t-test and unpaired t-test.

Observations

In this study, maximum numbers of patients (38.46%) were found age group between 31 and 40 years. 55.77% patients were male and 38.46% patients were labourer. Maximum patients belong to Hindu religion (90.38%) and from urban back ground (51.92%). Socio-economically middle class patients were more (94.23%) and sound sleep was found in 94.23% of patients. Also in this study maximum patients having *Madhyama Koshta* (65.38%) while *Mandagani* (65.38%) and Constipation (94.23%) were found. *Vata-Pittaja Prakriti* patients were found maximum (65.38%) than other. The 86.54% of patients had observed having irregular bowel habit with *Vishamashana* (44.23%) followed by *Adhyashana* (23.08%). Totally, 54.84 % of patients having chronicity up to one year and 16.12% patients were 1–2 years. The 48.08% patients were observed with fissure at posterior 6 o'clock position, while 34.62 having fissure at 6 and 12 O'clock position. 57.69% of patients had sentinel pile at 6 o'clock, 30.78% patients having sentinel pile at 6 and 12 O'clock both, while 61.54% patients had spasmodic anal sphincter.

RESULT

Pain relief was achieved by 28 days in all patients, swelling and oozing had stopped after 14 days. A statistically highly significant ($P < 0.001$) result has been observed in weekly interval. In case of wound healing, 6 patients required more than 28 days and significant results were seen in weekly interval. The percentage of pain relief on 14th day was 86% (Table 1).

Ksharasutra cut through from fissure bed. Oozing in the form of serous discharge was observed which was assessed every seven days; pain relief showed highly significant result i.e. $p < 0.001$ in every week. hence it can be said that the intensity of Pain decreased day by day and complete pain relief was found in maximum patients on 28th post operative day. In all patients, non-significant relief in post-operative swelling was observed by the end of 14th day. After 14 days there was no swelling present in any patients so, there is no need of further statistical evaluation of this data. The swelling due to tissue reaction after operative procedure and so less patients had swelling after operative procedure. Hence non-significant result was found (Table 2).

It reveals that oozing in form of bleeding or serous discharge from post *Ksharasutra* wound (trans-fixation of skin tag with KS) showed 82.25% relief within 7 days. From second week non patient had bleeding P/R. So, there is no need of further statistical evaluation of this data (Table 3).

Table 1: Assessment of Post-operative Pain in-ano: (n = 50)

Days	Mean B.T.	Mean A.T.	Mean Diff.	% Relief	W	S.D.	S.E.	'P'	
7th	2.67	0.94	1.73	64.00	-104	0.883	0.228	< 0.001	HS
14th	2.67	0.41	2.26	86.00	-120	0.884	0.228	< 0.001	HS
21st	2.67	0.28	2.39	91.00	-120	0.910	0.234	< 0.001	HS
30th	2.67	0.14	2.53	95.00	-120	0.742	0.193	< 0.001	HS
> 30th	2.67	0.08	2.59	96.50	-120	0.737	0.190	< 0.001	HS

B.T. - Before Treatment, A.T. - After Treatment, W - Wilcoxon rank-sum test, S.D.- Standard Deviation, S.E.- Standard error, P - Statistical probability, (P < 0.001)

Table 2: Assessment of Post-operative Swelling in ano: (n = 50)

Days	Mean B.T.	Mean A.T.	Mean Diff.	% Relief	W	S.D.	S.E.	'P'	
7th	0.27	0.14	0.13	78.76	-3	0.354	0.090	0.500	NS
14th	0.27	0.00	0.27	100	-10	0.457	0.119	0.124	NS
21st	0.27	0.00	0.27	100	-	-	-	-	-
30th	0.27	0.00	0.27	100	-	-	-	-	-

B.T. - Before Treatment, A.T. - After Treatment, NS - Non-Significant, P > 0.001

Table 3: Assessment of Post-operative oozing in ano

Days	Mean B.T.	Mean A.T.	Mean Diff.	% Relief	W	S.D.	S.E.	'P'	
7th	2.13	0.42	1.71	82.25	-91	1.032	0.268	< 0.001	HS
14th	2.13	0.00	2.13	100	120	0.990	0.255	< 0.001	HS
21st	2.13	0.00	2.13	100	-	-	-	-	-
30th	2.13	0.00	2.13	100	-	-	-	-	-

B.T. - Before Treatment, A.T. - After Treatment, HS - Highly Significant, P < 0.001

Table 4: Effect of therapies on *Vrana Ropana* (wound healing)

Wound Healing	(n = 50)	
	No. of Patient	%
7 days	00	00.00
8-14 days	00	00.00
15-21 days	02	4.00
22-30 days	42	84.00
> 30 day (5th week)	06	12.00
Total	50	100

Table 5: Overall effect of therapies

Overall Result	(n = 50)	
	No. of Patient	%
Complete Cured	41	82.00
Maximum Improvement	04	8.00
Moderate Improvement	03	6.00
Mild Improvement	02	4.00
No Relief	00	0.00
Total	50	100

Effect of therapies on *Vrana Ropana* (wound healing)

It shows that in maximum 84.00% i.e. 42 patients found wound healing in 4th post-operative week. 4.00% i.e. 2 patients were taking 3rd week for complete wound healing, while 12.00% i.e. 6 patients were taking more than 28 day for complete wound healing. None of any patients of got wound healing in 14 days (Table 4).

Overall effect of therapies

From the present study, it can be concluded that Figure 5 depicts the results of the study in 50 patients of *Parikartika* clearly shows that 41 patients (82.00%) patients were cured and 4 patients (8.00%) patients were maximum improved and in 3 patients (6.00%) patients were found moderately improved and 2 patients (4.00%) patients were mild improvement while no any of the patients showed no relief (Table 5).

DISCUSSION

In chronic fissure in ano, there are sentinel pile and anal papilla and unhealed midline ulcer which may be associated with pain, bleeding per ano and constipation. In this condition the conservative management is not more effective and needs surgical intervention. *Ksharasutra* trans-fixation and ligation of chronic fissure in-ano associated with sentinel pile is a safe, ambulatory procedure that is a good alternative to surgical management. 45% of patients were found in age group between 31 to 45 years. It can be thought that young middle aged and married patients are more prevalent due to more family responsibilities. Sound sleep was found in 98.23%, *Madhyama Koshta* (65.38%) were more and maximum patients (65.38%) were suffering from *Parikartika* having symptoms of *Mandagani* (diminished digestive power) and constipation. *Mandagani* is said to be the root cause of all diseases in Ayurveda,[9] Patients having *Vata Pittaja Prakriti* were found maximum (67.31%) which showed *Vata Dosha* predominance relation to patients of *Prakriti*. 86.54% of patients were observed to be having irregular bowel habits which might be due to *Agnimandya*, *Vishamashana* (44.23%) followed by *Viruddhashana* (32.69%). Overall, 35% of patients were reported having chronicity up to one year and 33% patients were reported 1–2 years of chronicity because of selection criteria adopted in the study that only chronic cases were included. Fissure at posterior (6 o'clock) position of the anus were observed in 87% patients because fissure bed at posterior position is mainly due to the impact of direct pressure of stool at posterior aspect of the anal canal during defecation. The sentinel pile is commonly found in cases of chronic fissure-in-ano which develops to guard fissure from more tear of the anal verge, maximum 84% of patients had developed sentinel pile included in study. These data are well supported by the authentic texts of surgical practice.[10] In this study, on per rectal digital examination; 83% patients had spasmodic anal sphincter; it is due to increased intra-rectal pressure and causes delay in healing[11] and finding also supported by previous research work. The main warning sign of

Parikartika is *Vedana* (pain in ano); after three weeks statistically highly significant relief in pain was observed, might be due to relaxation of sphincter spasm after Lord's anal dilatation as well removal of morbid tissue by KSL from fissure bed which promotes healthy and complete wound healing. Smeared *Kshara* on *Ksharasutra* is alkaline in nature (pH- 10.39) which inhibits the bacterial growth. Hence, formed wound after cut through was in *Shuddha Avastha* (clean and non-infected wound). Maximum patients showed wound healing after 21 days. Hence, study backings the principle that clean and healthy wounds take minimum of 3 weeks for complete healing. Maximum patients in both groups have relief in oozing within 7th postoperative day, and very less patients had taken 14 days to stop oozing. Discharge of serous is due to the inflammation present around the wound in early days, but use of *Jatyadi Taila* (10 ml/rectum) once daily was found helpful in controlling oozing/ discharge. The sitz bath with (PVK) and per rectal instillation of JT certainly is helped to achieve the conditions of *Shodhana* and *Ropana* of wound. In 49% patients, *Ksharasutra* ligated at fissure bed, sloughed out spontaneously on 4th postoperative day whereas 38% patients were observed sloughing out of *Ksharasutra* by 5th postoperative day. Very few patients (3%) had taken 6 days to slough out *Ksharasutra* from fissure bed. Constipation was relieved in all patients within 14 days by combined use of EBH orally acted as *Anulomaka* (laxative) and per rectal instillation of JT helpful in relieving the *Rukshata* (dryness), *Malabadhhata* and anal sphincter spasm by virtue of its *Snigdha*, *Shodhana* and soothing properties. Bleeding was stopped after *Ksharasutra* ligation in all patients within 7 days. Hence, it can be inferred that *Ksharasutra* ligation was effective to stop bleeding.

Probable mode of action of *Ksharasutra*

Ksharasutra contains *Apamarga Kshara* (*Achyranthes aspera* Linn.), *Snuhi Ksheera* (latex of *Euphorbia neriifolia* Linn.) and *Haridra Churna* (powder of *Curcuma longa* Linn.) and prepared by adopting standard operating procedure described in Ayurvedic Pharmacopeia of India (API).[12] The *Apamarga Kshara* having properties of *Chedana* (excision), *Bhedana* (incision), *Ksharana* (debridement), *Stambhana* (haemostatic), *Shodhana* (purification/sterilization), and *Ropana* (healing). *Chedana* and *Bhedana* properties of *Kshara* are helpful to excise the sentinel pile as well as fissure bed.[13] *Ksharasutra* ligated at fissure bed excises the fibrotic tissue by action of *Ksharana* and removes unhealthy fibrous tissue and debris; make the wound healthy by *Shodhana* property.[14] The *Snuhi Ksheera* is slightly acidic in nature but also has antibacterial property[15] which helped to check secondary infection. The *Haridra* has anti-inflammatory as well as anti-bacterial[16] properties and hence, it is capable to make the wound clean, healthy, and promote early healing.[17]

Probable mode of action of adjuvant drugs

The *Panchavalkala kwatha*[18] was used for *Avagaha Swedana* (warm water sitz bath); has *Shodhana* (purification), *Stambhana* (astringent), *Shotha hara* (anti-inflammatory), and *Vedana hara* (analgesic) properties which helped to relieve pain, local oedema as well as to stop oozing and maintained perianal hygiene. *Eranda Bhrishta Haritaki Churna* is specially indicated for *Vibandha* (constipation).[19] Most of the ingredients used in *Jatyadi Taila* are *Shotha hara*, *Vedanasthapana* and *Ropana* (wound healing) which are important requirements for healing of the wound.[20] *Jatyadi Taila* was instilled per rectal to reduce the swelling and pain as well as for smooth evacuation of faeces. The ingredients of the *Taila* like *Neem* (*Azadirachta indica* A. Juss)[21] and *Daruharidra* (*Berberis aristata* DC.) are proven drugs to check bacterial growth and promote wound healing.

CONCLUSION

In *Parikartika* (Chronic fissure in ano with sentinel pile and anal papilla), *Ksharasutra* ligation is a good alternative to modern surgery as it carries less postoperative pain and easy to perform. Wound remained healthy after slough out of *Ksharasutra* and average healing time of postoperative wound was within 21 days. There are no any chances of complications like bleeding; infection and also recurrence are almost negligible in this procedure. Hence, it is a good procedure to manage chronic fissure in ano.

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