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To Evaluate the Efficacy of *Kutaja Ksharasutra* in the Management of *Bhagandara* w.s.r to Fistula-In-Ano

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ABSTRACT:

Background: *Bhagandara* has been described as one of the eight grave diseases by *Acharya Sushruta* which is difficult to cure. 'Fistula-in-ano is an abnormal hollow tract lined by unhealthy granulation tissue and that connects primary opening inside the anal canal to a secondary opening in the perianal skin.
Methods: diagnosed cases of *Bhagandara* of age groups of 18-70 years of either sex are selected. *Ksharasutra* treatment is given for the period of 3 months and patients will be observed up to complete healing of fistula tract or 3 months whichever is earlier.
Observations And Results: the results of *Kutaja Ksharasutra* on criteria like pain, discharge ,itching, burning sensation were found statistically highly significant after cutting through tract. Mean U.C.T was found 8.86 approx 9 days.
Conclusion: *Kutaja Ksharasutra* can be considered best because of more acceptability, easily availability, reduction in U.C.T &better wound healing property.
Keywords- *Bhagandara*, Fistula-in-ano, *Ksharasutra*, *Ashtamahagada*, *Kutaja*.

INTRODUCTION

According to *Sushruta* "The pioneer of Surgery", *Bhagandra* is a disease that does *Darana* of *Bhaga*, *Guda and Basti Pradesh* therefore called as *Bhagandara*[1]. Even centuries before *Bhagandara* is told callous to be cured and is considered under the *Ashta Mahagada* i.e. eight grave disorders[2].

A fistula- in- ano is an abnormal hollow tract or cavity that is lined by unhealthy granulation tissue and that connects 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. Most fistulae are thought to arise as a result of perirectal abscess[3]. The abscess represents the acute inflammatory event, whereas the fistula is representative of the chronic process. Symptoms generally affect the quality of life significantly and they range from minor discomfort and drainage with resultant hygiene problems to sepsis.

In modern sciences in about 430 BCE; Hippocrates made references to surgical therapy for fistulous disease and he was the first person to advocate the rise of a seton (from Latin *seta* "bristle")[4]. In 1376 the English surgeon John Arderne (1307-1390) wrote treatise of Fistula -in-ano and Clysters which described fistulotomy and seton use[5].

In the late 19th and early 20th centuries prominent

physicians /surgeons such as Goodsall and Miles, Milligan and Morgan, Thompson and Lockhart made substantial contributions to the treatment of anal fistula[6].

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[7].

The true prevalence of fistula- in- ano is unknown. The incidence of fistula-in-ano developing from an anal abscess range from 26% to 38%[8,9]. One study showed that prevalence of fistula-in-ano is 8.6 cases per one lac population. In men the prevalence is 12.3 cases per 1 lac population and in women it is 5.6 cases per 1 lac population. The male to female ratio is 1.8:1. The mean patient age is 38.3 years[10].

Even today during summit of modern surgery fistula-in-ano is still challenge to the surgeons for its incidence of recrudescence and postoperative complications. Surgical "lay Open" technique which is most widely practiced now a days and even which is explained by *Acharya Sushruta* for the management of *Bhagandara*[11] has to face many drawbacks which are extensive wound in and around the anal canal, prolonged hospitalization, high rate of recrudescence, anal incontinence and difficult in defecation. So, to combat these conditions an extensive approach through *Ayurveda* has been extended with definite and positive outcome i.e. *Ksharasutra* therapy which is widely accepted globally.

Ksharasutra therapy is a minimal invasive *Ayurvedic* surgical procedure and time tested *Ayurvedic* technique in the anorectal disorders. It is safe, sure and cost-effective method of treatment for fistula-in-ano with minimal recrudescence rate, lesser post-operative complications and minimal hospital stay. Application of *Ksharasutra* has been mentioned by almost all authors of *Ayurveda Samhita* including the three main treatise of *Ayurveda*. The *Kshara* applied on the thread are anti-inflammatory, anti-slough agents and additional have chemical curetting properties. The *Kshara* sutra remains in direct contact with tract therefore it helps in cutting, curetting, draining and healing of the fistulous tract. It destroys and removes unhealthy tissue and promotes healing of the tract, also facilitate in draining of pus and helps in healing by controlling infection because of its microbicidal action.

Now days, *Ksharasutra* is the first choice for treating fistula-in-ano. The Indian council of medical research (ICMR) has certified it and WHO has accepted the effectiveness of this *Ayurvedic* treatment modality in treating fistula-in-ano.

Importance of present study is exploration of the new plants for the preparation of *Kshara* as a better substitute to *Apamarga Kshara* is the need of the hour. To find out an effective alternate to *Apamarga Ksharasutra* in view of easy processing, *Kutaja Ksharasutra* is being opted for clinical evaluation. It is quite difficult to solely depend upon *Apamarga* only because of its limited availability globally. India is a vast country with varied flora and there is also a need for search of the alternate plant sources which may give better results.

Sushruta has also advocated the *'Kutaja'* for the preparation of *Kshara*[13]. Hence to develop an alternative to *Apamarga Ksharasutra* in view of easy processing, *Kutaja Ksharasutra* is being opted for the clinical evaluation for the 1st time in its kind of study.

AIMS AND OBJECTIVES

To Evaluate the Efficacy of *Kutaja Ksharasutra* in the Management of *Bhagandara* w.s.r. to Fistula-In-Ano

MATERIALS AND METHODS

Data Source- After making the diagnosis of the *Bhagandara* (fistula-in-ano), the patients were selected for this study. The patients were selected from OPD/IPD of PG department of *Shalyatantra*, Jammu Institute of *Ayurveda* and hospital, Jammu, irrespective of gender, occupation, religion and caste.

Methods of Collection of Data-

Sample size- 30

Inclusion Criteria –

1. Diagnosed cases of *Bhagandara* of age groups of 18-70yrs of either sex will be selected.
2. Fistula-in-ano associated with Tuberculosis, Diabetes Mellitus, Hypertension, Anaemia, were also included in the study subjected to the disease under controlled state.

Exclusion Criteria –

1. Patient with severely compromised cardiopulmonary status
2. Patient with active history of Tuberculosis or Crohn's disease
3. Patient who are immune compromised
4. Patient with HIV infection and cancer therapies
5. Osteomyelitis of femur or pelvic bone
6. Chronic or acute ulcerative colitis
7. Pregnancy

Observation Period –

1. Patients were advised to visit OPD unit once in a week for changing *Ksharsutra.*
2. The patient will be observed up to complete healing of fistula-in-ano or 3 months whichever is earlier.
3. Assessment criteria will be recorded at intervals of 7 days during observation period.

DIAGNOSTIC CRITERIA

Examination of the Patient- Each case was thoroughly examined and investigated by detailed proforma designed for the present clinical study on *Bhagandra*. Each patient was examined under following headings.

1-History of the patient– complete history of the patients with presenting complaints like pain, discharge, onset, duration and bowel habit was noticed. Associated disease of tuberculosis, diabetes mellitus, urinary, cardiac and neurological disease were also taken to elicit the cause. History of previous treatment particularly previous surgery, no. of operations, type of operation and family history, occupation, personal history and dietic habits were taken.

2-Systemic examination- This include different systems like cardiovascular, nervous, respiratory, digestive and genitourinary. If any system was found diseased, the special investigations were carried out and confirmed to treat first.

3-Local examination-

Inspection- After lying patient in lithotomy position, the condition of the skin near fistula like colour of the perineal region, inflammation, discharging sinuses, their external opening, no. of sinuses, previous operated scars, and discolouration of adjacent area were noted.

Palpation- local temperature, tenderness, induration, fluctuation, consistency of pus, fistulous tract and its direction etc. were noted by palpation.

Digital rectal examination- digital per rectal examination was carried out with 2% xylocaine jelly to access internal opening with their positions, any associated fissure, thrombosed piles, malignancy, indurated dimple, tone of sphincter, any cavity, tenderness and prostrate in males.

Instrumentation-

A)Probing – soft malleable, curved 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 to avoid the creation of false tracts. This examination was important as it provides accurate knowledge regarding-

1. The track, whether it was complete or not.
2. The extent of the track.
3. The direction of the track.
4. Position of the internal opening.

B) Proctoscopy- This examination was carried out after digital examination. The proctoscope was slowly passed in anus in the direction of umbilicus after lubrication of proctoscope and anus with 2% xylocaine jelly. Slowly the proctoscope was withdrawn while the patient slowly bears down. It gives complete idea about the mucosa of anus and up to the middle half of rectum and all findings were noted. There may be an internal opening present, like a dimple or nodule. Site of opening was noted and if any internal pile presents that was also noted.

C) Examination with dye– Methylene blue was injected from one opening while during proctoscopy examination. If the tract was complete, it will come out from other opening which can be seen. It was helpful to locate the other (generally internal) opening. If there were multiple openings, this test will help to locate them.

Investigations –

1. Blood – CBC, ESR, BT, CT
2. Blood sugar- fasting and postprandial
3. Urine – routine and microscopic
4. MRI-Fistulogram if necessary

Application Of *Ksharasutra*:

The patient was kept in lithotomy position and the anus and peri anal area were cleaned with warm water with much diluted dettol solution. Few cotton wools soaked in weak dettol solution introduced into anal canal to clean it. Then anus and peri anal areas painted with spirit. This was followed by cleaning with Betadine solution finally. The operative area was draped with sterile cut sheet. Then lubricated index finger was introduced gently into the anal canal and with other hand suitable and lubricated probe was inserted through the external opening of the fistula. The index finger inside the anus guided the probe. The probe was progressed towards the internal opening in the less resistant area. Forceful probing was avoided. After piercing the internal opening, the tip of the probe came out through the anal canal. *Ksharasutra* was inserted into the eye of the probe. With gentle manipulation, the probe with *Ksharasutra* was passed through the tract and the *Ksharasutra* was properly placed in to the tract. The two free ends of *Ksharasutra* were tied over keeping it loose sufficiently. The part was cleaned with betadine and sterile gauze was kept over operated part. Sterile pad and 'T' bandage were applied and the patient was shifted to the

ward finally.

Successive Change Of *Ksharasutra:*

The *Ksharasutra* was changed at weekly interval time. The thread was tied to the previously applied *Ksharasutra* in position towards outer end of the knot through Rail-road technique.

Duration Of Therapy:

The therapy was continued till 3 months or when the fistulous tract got cut through finally with the *Ksharasutra* whichever is earlier.

Assessment Criteria :

The criteria will be grouped as subjective and objective criteria –

1.**Subjective Criteria-**

- Discharge
- Pain
- Itching
- Systemic symptoms if abscess become infected.

2.**Objective Criteria-**

- Length of the tract
- Position of the tract
- Number of tracts
- UCT= Total no. of days taken for cut through / Initial length of the tract in cm.

Gradings (As Per Visual Analogue Scale)

Pain-

GRADE '0'- No pain

GRADE '1'- Mild pain or tolerable pain

GRADE '2'- Moderate pain and pain relieved by hot sits bath

GRADE '3'- Severe pain and pain relieved by oral analgesics

GRADE '4'- Intolerable pain with sleep disturbances

Pus Discharge

GRADE '0'- No discharge

GRADE '1'- Very negligible pus discharge is present while probing

GRADE '2'- Scanty pus discharge is present without probing

GRADE '3'- Profuse pus discharge came out while squeezing the cavity

GRADE '4'- The cavity is filled with pus and continuous flowing of pus is elicited without squeezing the cavity.

Burning Sensation

GRADE '0'- No complain of burning sensation

GRADE '1'- Negligible burning sensation

GRADE '2'- Occasional and tolerable burning sensation relieved by oleation

GRADE '3'- Constant but tolerable burning sensation slightly relieved by oleation

GRADE '4'- Intolerable burning sensation makes the patient uncomfortable

Itching

GRADE '0'- No complain of itching

GRADE '1'- negligible itching

GRADE '2'- occasional itching with 4-6 hours gap

GRADE '4'- frequent and continuous itching sensation

GRADE '3'- frequent itching with 2-3 hours gap

Unit Cutting Time In Relation To The Initial Length Of Track:

The analysis shows that, the maximum average unit cutting time was 9.25 days/cm in the patients having initial length of track within 5-9.9 cm, while the minimum average unit cutting time was 8.48 days/cm in the patients having initial length of track within 1-4.9 cm and 10-14.9 cm. Table No. 1: Unit cutting time in relation to the initial length of track

RESULTS:

The results obtained were subjected to statistical analysis. The clinical observations like pain, discharge, itching, burning sensation and unit cutting time was analysed and the results are described here under separate headings:

Total Average Unit Cutting Time:

Finally, total average U.C.T. was evaluated. The analysis shows that average U.C.T. was 8.88 days/cm.

1.Table 2 Showing the effect on U.C.T

2. Assessment on Pain

It was observed that all the patients felt pain at the time of changing *Kutaja Ksharasutra,* the pain was reduced about 65% after the tract has been cut through. After applying the Wilcoxon Signed Rank's Test, we found the 'p' value < 0.001 is highly significant.

Table No. 3: Showing the effect on Pain

Table No. 4: Wilcoxon signed rank's test

a. Pain_ AT<Pain_BT
b. Pain_AT>Pain_BT
c. Pain_AT=Pain_BT

3. Assessment on Discharge

After applying the Wilcoxon Signed Rank's Test, we found the 'p' value < 0.001 is highly significant this means the patient have discharge from the tract during the treatment and the analysis showed that the discharge reduced to 85.2% after the tract has been cut through.

Table No. 5: Showing the effect on Discharge

Table No. 6: Wilcoxon signed rank's test

a. Discharge_ AT<Discharge_BT

b. Discharge_AT>Discharge_BT
c. Discharge_AT=Discharge_BT

4. Assessment on Itching

It was observed that all the patients felt Itching at the time of changing *Kutaja Ksharasutra*, the Itching sensation was reduced about 66.4% after the track has been cut through. After applying the Wilcoxon Signed Rank's Test, we found the 'p' value < 0.001 is highly significant.

Table No. 7: Showing the effect on Itching

Table No. 8: Wilcoxon signed rank's test

a. Itching_ AT<Itching_BT
b. Itching_AT>Itching_BT
c. Itching_AT=Itching_BT

5. Assessment on Burning Sensation

It was observed that all the patients felt burning sensation at the time of changing *Kutaja Ksharasutra*, the burning sensation was reduced about 64.6% after the track has been cut through. After applying the Wilcoxon Signed Rank's Test, we found the 'p' value < 0.001 is highly significant.

Table No. 9: Showing the effect on Burning Sensation

Table No. 10: Wilcoxon signed rank's test

a. Burning Sensation_ AT< Burning Sensation _BT
b. Burning Sensation _AT> Burning Sensation _BT
c. Burning Sensation _AT= Burning Sensation _BT

DISCUSSION ON RESULTS

Total five criteria were analysed statistically to know the effect of *Ksharasutra*. Those were **Unit Cutting Time, Pain, Discharge, Itching, Burning sensation.** Unit Cutting Time was measured in days/cm. Pain, Discharge, Itching and Burning sensation was measured in five grades each from grade 0- grade 4. The results on *Kutaja Ksharasutra* on criteria like pain, discharge, itching, burning sensation were found statistically highly significant after cutting through the tract. The analysis showed that on cut through of tract the pain was reduced about 65%, the discharge reduced to 85.2%, itching sensation was reduced to 66.4% and burning sensation has been reduced to 64.6%. Mean UCT was found 8.86 days/cm. As infection may delay the cutting by producing more discharge and reducing the efficacy of *Ksharasutra*, but highly significant results on discharge was noted. Thus, showing that *Kutaja Ksharasutra* was equally effective against infection too.

Probable Mechanism Of Action Of *Ksharasutra*

Kutaja Ksharasutra has been used in this clinical study. This *Ksharasutra* consist of three main dravya i.e. *Kutaja Kshara, Haridra churana* and *Snuhi ksheera*. The mode of action depends on the pathophysiology of disease. As the fistulous tract is lined by fibrous tissue and its treatment depends on the removal of fibrous tissue which is possible by the various methods known so far, the best is surgical removal. But the surgery also has its own limitations and complications. The most unwanted complication is the high recurrence rate and the same time the economy of the patient is badly affected. But the study of the ancient surgical treatise the "*Sushruta Samhita*" has shown all together better results over all the known methods. The properties of *Kshara* is – *Ksharana (*dislodge and melt away) and *Kshanana* (kill or destroy). The studies carried out so far with various *Ksharasutra* are having one and the same action and property. The healing is possible only that to from the base of the tract, which is possible only if the fibrous tissue is removed properly. The various action of the *Ksharasutra* is that, the *Kshara* applied over the sutra penetrates into the fibrous tissue, thereby it melts the fibrous tissue by its *Ksharana* and *Kshanana* properties and drained through the tract. At the same time, the sitz bath also helps the draining of the melted fibrous tissue and the expected healing starts from the base of the tract which is augmented by the application of *Jatayadi Taila*. So, both the action of corroding and removing or draining is possible by the properties of *kshara* applied over the *Sutra.* Hence this fact has been observed by almost all the previous research workers in this field. The particular *Ksharasutra* made with the help of *Kutaja* (Hollorhena antidysentrica) has its own properties, as *Kutaja* balances *Kapha* and *Pitta Dosha*, helps to detoxify blood, absorbs moisture, treat burning sensation, helps in relieving itching and useful in bleeding disorders.

Haridra Churana has the properties like *Raktashodhaka, Twakdoshara, Shothahara, Vatahara, Vishaghna* and it is useful in *VranaRopana.*[11]

Snuhi Ksheera has properties like *Laghu, Rooksha Guna, Ushna Veerya*[12] and it is used for *Ksharasutra* preparation due to its sticking property since ancient times.

The effect of *Ksharasutra* is the overall results of all these properties of different *Dravya's* used in the preparation of *Ksharasutra*. Thus, *Kutaja Ksharasutra* have altogether better results meaning thereby the irritation, discharge, burning sensation on the part of the tissue is very less.

The length of the tract, cut by the *Ksharasutra* was measured as Unit Cutting time. Healing from the base of the tract runs parallel to the cutting. Ultimately, one day the *Ksharasutra* comes out by cutting through the entire fistulous tract with simultaneous healing from its base. At last, a small linear scar remains at the site of fistula.

CONCLUSION

Kshara Sutra is a well-established method for perfect excision and healing of *Bhagandara* (fistula-in-ano). It is being practiced since the era of *Aacharya Sushruta*. It provides radical cure of *Bhagandara* with negligible recurrence rate. It is a minor procedure and comparatively safer than the other treatment modalities of Fistula-in-ano. Total 30 patients were registered for the present study. Majority of the patients had complained of Pain, Discharge, Itching and Burning Sensation before the treatment. There were five criteria selected for assessment of the effect of the *Ksharasutra* viz., Mean Unit Cutting Time, Pain, Discharge, Itching, and Burning Sensation. The mean Unit Cutting time of *Kutaja Ksharasutra* was 8.86 days/cm. The result of the effect of the *Kutaja Ksharasutra* on Pain, Discharge, Itching and Burning Sensation were found statistically highly significant. Overall effect of the therapies showed that pain was reduced about 65%, discharge reduced to 85.2%, itching reduced to 66.4% and burning sensation reduced to 64.6% after the tract has been cut through. No recurrences of cases were reported during 3 months of follow up. So *Kutaja Ksharasutra* can be considered best because it has more acceptability, easily availability, reduction in UCT and better wound healing property after cut through. However further studies are required to confirm the results seen in the present study.

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Conflicts Of Interest- Nil

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Table No. 1: Unit cutting time in relation to the initial length of track

INITIAL LENGTH IN CM	AVERAGE U.C.T IN DAYS/CM
1-4.9 cm	8.48
5-9.9 cm	9.25
10-14.9 cm	8.48
TOTAL	8.73

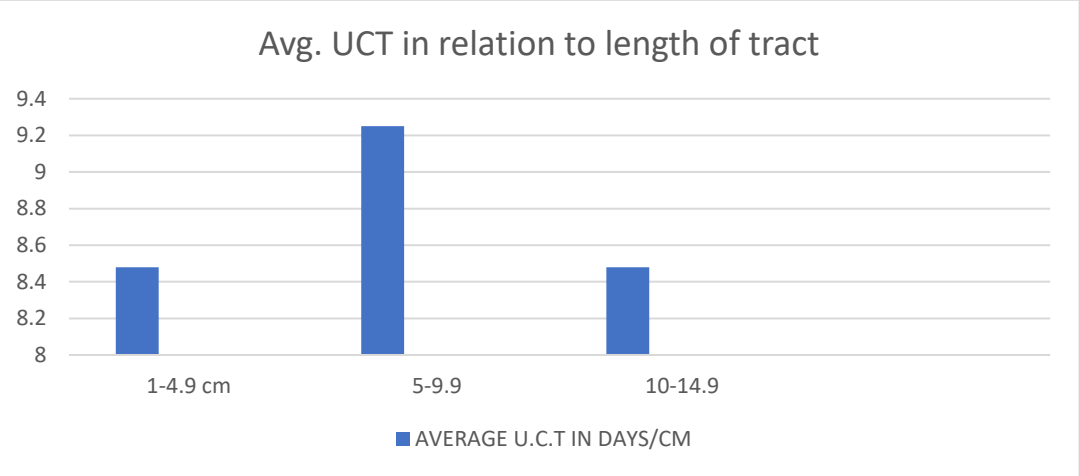


Table 2 Showing the effect on U.C.T

Mean	S.D	S.E	T	‘p’ value	Inference
8.889	1.818	0.332	26.775	0.001	Highly significant

Table No. 3: Showing the effect on Pain

Pain	N	Mean	S.D	Mean Diff	%Age
BT	30	2.83	0.592	1.23	65%
AT	30	0.40	0.498		

Table No. 4: Wilcoxon signed rank’s test

		N	MEAN RANK	SUM OF RANKS	Z	‘p’ Value	Inference
Pain AT-Pain BT	Negative Ranks	30[a]	15.50	465.00	-4.939	<0.001	Highly Significant
	Positive Ranks	0[b]	0.00	0.00			
	Ties	0[c]					
	Total	30					

Table No. 5: Showing the effect on Discharge

Discharge	N	Mean	S.D	Mean Diff	%Age
BT	30	2.43	0.728	1.84	85.2%
AT	30	0.27	0.450		

Table No. 6: Wilcoxon signed rank's test

		N	MEAN RANK	SUM OF RANKS	Z	'p' Value	Inference
Discharge_AT-Discharge_BT	Negative Ranks	30[a]	15.50	465.00	-4.998	<0.001	Highly Significant
	Positive Ranks	0[b]	0.00	0.00			
	Ties	0[c]					
	Total	30					

Table No. 7: Showing the effect on Itching

Itching	N	Mean	S.D	Mean Diff	%Age
BT	30	1.47	0.629	1.33	66.4%
AT	30	0.00	0.000		

Table No. 8: Wilcoxon signed rank's test

		N	MEAN RANK	SUM OF RANKS	Z	'p' Value	Inference
Itching_AT-Itching_BT	Negative Ranks	30[a]	15.50	465.00	-4.932	<0.001	Highly Significant
	Positive Ranks	0[b]	0.00	0.00			
	Ties	0[c]					
	Total	30					

Table No. 9: Showing the effect on Burning Sensation

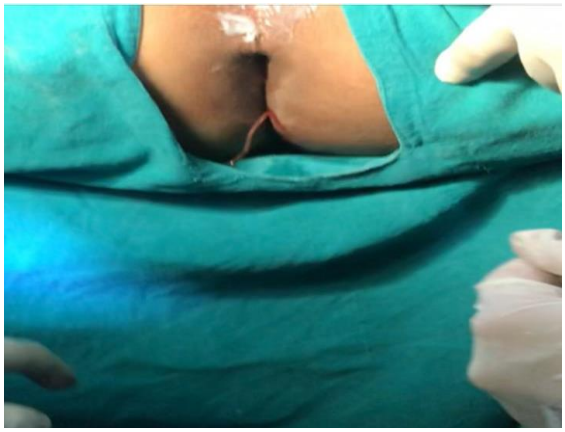
Burning Sensation	N	Mean	S.D	Mean Diff	%Age
BT	30	2.13	0.512	1.11	64.6%
AT	30	0.44	0.480		

Table No. 10: Wilcoxon signed rank's test

		N	MEAN RANK	SUM OF RANKS	Z	'p' Value	Inference
Burning Sensation_AT Burning Sensation_BT	Negative Ranks	30[a]	15.50	465.00	-4.903	<0.001	Highly Significant
	Positive Ranks	0[b]	0.00	0.00			
	Ties	0[c]					
	Total	30					

CASE REPORT IMAGES

CASE – I-ON PROBING



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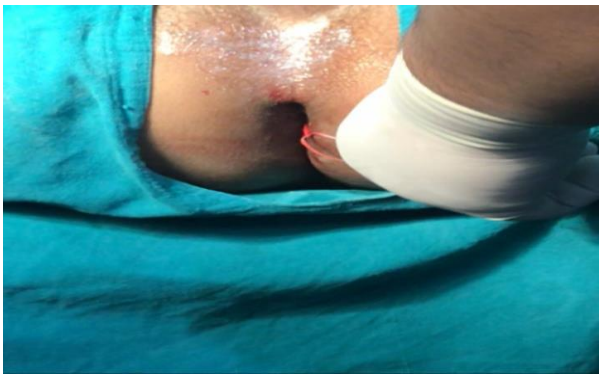

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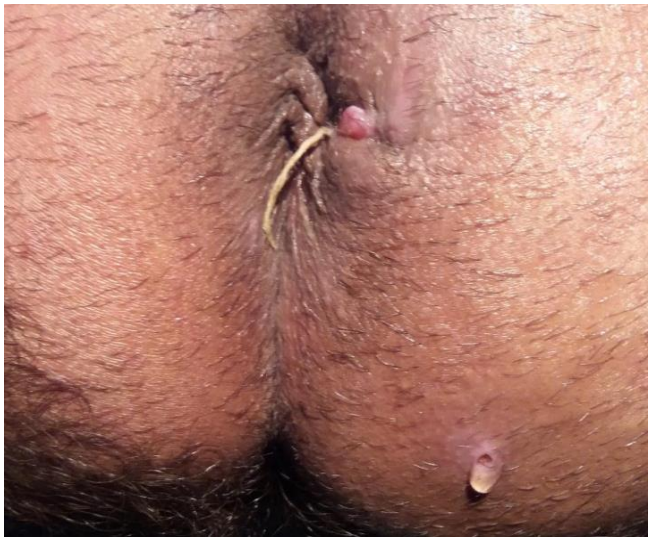

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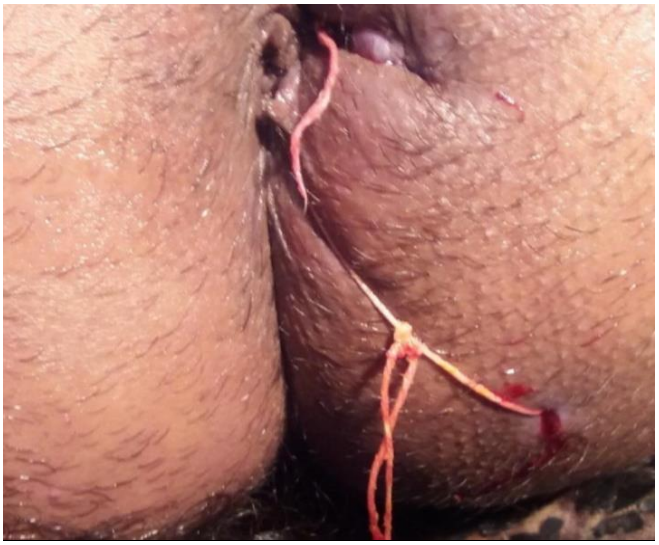

Successive change of *Ksharasutr*a