



STANDARDIZATION AND CLINICAL EVALUATION OF NIMBA KSHARSUTRA IN THE MANAGEMENT OF BHAGANDAR (FISTULA IN ANO)

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ABSTRACT

Fistula-in-ano is one of the most common and notorious disease among all anorectal disorder. It is recurrent in nature which makes it more and more difficult for treatment. It produces inconveniences in routine life. It causes discomfort and pain that creates problem in day to day activities. Ksharsutra has been proved as a big revolution in the treatment of fistula in ano. It is the need of time to do further researches on ksharsutra to get more efficient ksharsutra.

In the present research work prepared Nimba ksharsutra was standardized as mentioned by Proff. S. S. Handa. 40 diagnosed cases of fistula in ano were selected from the OPD/IPD of anorectal unit of shalyatantra department of National Institute of Ayurveda Jaipur. Total patients were divided into two groups. The patients of Group A were treated with standard ksharsutra and the patients of Group B were treated with Nimba ksharsutra. Nimba ksharsutra showed better results in unit cutting time, pus discharge, burning sensation and itching.

Key Words: Standardization, Bhagandar, Fistula in Ano, Nimba Ksharsutra

INTRODUCTION

Bhagandara is a common disease occurring in the anorectal region. Acharya Sushruta, the father of surgery has included this disease as one among the Ashtamahagada¹. At first it presents as pidika around guda and when it bursts out, it is called as Bhagandara². It can be correlated with Fistula in ano as described in modern medical science. Fistula in ano is a tract lined by granulation tissue which opens deeply in the anal canal or rectum and superficially on the skin around the anus³.

At present most common surgical procedure adopted in the treatment of fistula in ano is fistulectomy and fistulotomy⁴. These surgical management carries several complications like frequent damage to the sphincter muscle resulting in incontinence of sphincter control, fecal soiling, rectal prolapse, anal stenosis, delayed wound healing and even after complete excision of the tract there are chances of subsequent recurrence⁵.

Ancient Acharyas have described the use of ksharsutra in the management of fistula in ano. Acharya chakradutta⁶ has given the idea about the preparation of ksharsutra. Revival of such ancient technique in the management of fistula in ano is proved as a boon for humanity. The preparation and technique of ksharsutra in fistula in ano is standardized by the department of shalya shalakya, BHU, Varanasi. The introduction of ksharsutra into fistulous tract gradually dissolves the tough fibrous tissue drains the pus and enhances the granulation in the tract.

Need of the study

No doubt the standard ksharsutra is being used successfully in the management of fistula in ano but ksharsutra application is proving very effective in the management of fistula in ano, so there is needed to do further researches by using different type of ksharsutra.

Certain inconveniences regarding Apamarg Ksharsutra manufacturing and during therapy are worth noting. During the treatment with standard Apamarg ksharsutra patient suffers with some discomfort like pain, burning sensation and inflammation etc. Various researches on Nimba plant have proved that it has antibacterial, antiviral, antifungal and anti-inflammatory properties⁷. Apamarga plant is predominantly available in the beginning of summer season while Nimba plant is available throughout the year. Considering the above mentioned view and the results of previous research on Nimba coated ksharsutra in the Shalya department of NIA, Jaipur were found to be very effective in the management of fistula in ano. So it was decided to do further study on nimba coated ksharsutra, because standardization of any medical drug or device or any other product is mandatory. Ksharsutra is considered as medical device, so to maintain its quality level depending on different parameters it was standardized.

Aims and objectives

Preparation of Nimba coated ksharsutra.

- 1) Standardization of Nimba coated ksharsutra
- 2) To compare the efficacy of Nimba coated ksharsutra with standard ksharsutra.

MATERIALS AND METHODS

Standardization

Analytical study of ksharsutra was carried out as mentioned at Amol pharmaceuticals Private Ltd. at Sitapura, one of the Ayush recommended analytical Lab at Jaipur, Rajasthan, India

Results of Analysis

Table 1: Nimba coated ksharsutra

SN	Test Parameters	Results
1	Length	30.7 cm
2	Diameter	2.95mm
3	Total Weight	1.63 gm
4	Weight of coated Material	1.53 gm
5	Loss on Drying	2.54 % w/w
6	Sulphate Ash	81.2% w/w
7	Water Soluble Extractive	66.1 % w/w
8	Hexane soluble Extractive	10.4 % w/w
9	pH	10.6
10	Sodium	6.64% w/w
11	Potassium	47.98 % w/w
12	Total Alkalis as Carbonate	8.84% w/w
13	Curcuminoids	0.140% w/w

Table 2: Snuhi Ksheer

SN	Test Parameters	Results
1	pH	3.59
2	Loss on drying	81.52 %w/w
3	Sulphated Ash	1.34 %w/w
4	Hexane soluble extractive	1.10%w/w

Table 3: Nimba Kshar

SN	Test Parameters	Result
1	pH	10.51
2	Loss on drying	1.94 %w/w
3	Sodium	8.88%w/w
4	Potassium	62.17 %w/w
5	Total Alkalies as carbonate	12.82%w/w

Table 4: Haridra (Turmeric Powder)

SN	Test Parameters	Results
1	Loss on drying	7.37 %w/w
2	Sulphated Ash	8.64%w/w
3	Hexane soluble extractive	0.84 %w/w
4	Curcuminoids	2.94%w/w

Study design

- Randomized control trial
- Open trial

Selection of the patient

1. 40 patients were selected randomly from OPD/IPD of Anorectal unit of Shalyatantra of National Institute of Ayurveda Hospital, Jaipur. Those patients were selected who had given 'informed consent'. The patients were explained about the purpose, procedures and possible danger of the trial.
2. Selected patients were examined thoroughly with the help of proforma especially designed for the study.
3. Ethical Clearance Number 200/RAU/08/1635

Inclusion criteria

1. All the patients were between the age group of 20-60 yrs.
2. Patients were selected randomly, irrespective to religion, economical status, educational status & marital status etc.
3. All diagnosed cases of fistula in ano, other than exclusion criteria given below.

Exclusion criteria

1. Patients below 20 yrs and above 60 yrs of age.
2. Patients who were suffering from fistula in ano associated with Tuberculosis, Diabetes mellitus, Ulcerative colitis, Crohn's disease, Ca of rectum, AIDS, Hepatitis B, and Other systemic disorders diseases were excluded from the study.

Grouping of patients

Selected 40 patients were equally divided into 2 groups: Group A (Control group): 20 patients were treated with Standard ksharsutra.

Group B (Trial group): 20 patients were treated with Nimba Coated ksharsutra.

Selection of Drug

After screening all the previous works done in case of fistula in ano, and a previous work done on Nimba ksharasutra in the management of fistula in ano, we have decided to do work on Nimba ksharasutra.

Formulations

- Standard/Apamarga ksharasutra (for control group)
- Nimba ksharsutra (for trial group)

Investigation

- a. Blood- Hb%, TLC, DLC, ESR, CT, BT, Blood Sugar-fasting & post prandial, Blood Urea, Serum Creatinine, HIV, HBsAg,
- b. Urine- routine & microscopy.
- c. Radiography - Chest X-Ray, After urograffin sensitivity test Fistulogram was done, for high anal, recurrent, previously operated cases, if necessary.

Adjuvant therapy

Hot sitz bath- Patients were instructed to take hot sitz bath after defecation and in morning & evening for about 10 to 15 minutes

Laxative- Laxative (Taruni kusumakar choorna about 3gm + isabgol about 2tsf) was advised at bed time with luke warm water.

Observational Period

Patients were instructed to visit anorectal unit once in a week for changing ksharsutra. The changing ksharsutras were done with gradual tightening of ksharsutra. The changing of ksharsutras was done until the whole length of fistulous track was cut through. Follow up period was for 4 weeks after the completion of treatment.

Assessment Criteria

1. Pain
2. Pus discharge
3. Burning sensation
4. Itching
5. UCT (Unit cutting time)

1. Pain

- Grade 0 - No Pain
- Grade 1 - Negligible pain or Tolerable pain (mild)
- Grade 2 - Pain relieved by hot sitz bath (moderate)
- Grade 3 - Pain relieved by oral analgesics (severe)
- Grade 4 - Intolerable pain with sleep disturbance (unbearable)

2. Pus Discharge

- Grade 0 - No discharge
- Grade 1 - Very negligible pus discharge was present, while probing.
- Grade 2 - Scanty pus discharge, was present without probing
- Grade 3 - Profuse pus discharge came out while squeezing the cavity.
- Grade 4 - The cavity was filled with pus and continuous flowing of pus was elicited without squeezing the cavity.

3. 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 and makes the patient to go for help

4. Itching

- Grade 0 - No complain of itching
- Grade 1 - Negligible itching, occasional in a day
- Grade 2 - Occasional itching, with 4-6 hours gap
- Grade 3 - Frequent itching, with 2-3 hours gap
- Grade 4 - Frequent & continuous itching sensation

5) UCT (Unit cutting time)

$$UCT = \frac{\text{Total No. of days taken to cut through}}{\text{Initial length of track in cms.}} = \text{days/cms.}$$

Healing status

In ksharsutra therapy, cutting and healing of the track takes place simultaneously. Here unit cutting time is useful to assess the healing status. Whenever healing is delayed, cutting also has to be suspended by keeping the thread loose.

Overall effect of therapies

- Complete Cure 100%
- Marked improvement 99-76%
- Moderate improvement 75-51%
- Mild improvement 50-26%
- No improvement < 25%

Statistical analysis

All the information which were based on various parameters were gathered and statistical study was carried out in terms of mean (x) standard deviation (S.D), standard error (S.E.) paired test. (t. value) Finally result were shown in terms of probability (P) as

OBSERVATION AND RESULTS

The observation and results were concluded in 2 groups-
 1. General demographic profile of the patients under study.

2. Clinical observation of group A and group B.

Results of assessment criteria given below

Table 5: Comparison of average unit cutting time (U.C.T.) in both Groups

SN	Groups	No. of patient	U.C.T. (Days/ cm)
1	Group –A	20	7.38
2	Group –B	20	6.65

Table 6: Summarized Results

Symptoms	Group-A		Group-B	
	%	t-value	%	t-value
Pain	87.14	22.5592***	88.41	19.8697***
Itching	93.44	34.8583***	94.83	27.6939***
Burning	91.80	20.3488***	98.08	18.8609***
Discharge	96.83	34.6198***	100	24.4451***

p>0.05: Insignificant*, p<0.05: Significant**, p<0.01 and P<0.001: Highly significant***

DISCUSSION

Discussion on demographic data

It was found that maximum number of patients (42.50%) were between the age group 31-40 yrs, male patients was obtained higher (87.50%) than female (12.50%) and in occupation service class patients (52.50%) were registered more. This study also shows that maximum cases have given the history of constipation (65%) and In most of cases external openings were found at 7 o'clock position with a percentage of 28.89%.

Comparison of Results between Group-A & Group-B

The results were based on the Assessment criteria of the disease. Comparison was done on per week status in both groups.

Pain: After 6 weeks 87.14% of pain relief was found in Group-A, where as in Group-B it was 88.41%.

This shows that Nimba ksharsutra has a little better pain relieving capacity in comparison to standard ksharsutra. This most probable cause behind the significant result of Nimba Ksharsutra in relief of pain may be the fact that pain occurs in the fistula in ano because of the accumulation of pus in the cavity. Already in Dhanvantari Nighantu⁸ it is emphasized that Nimba has a property which does help in suppuration of immature shotha and drains the suppurated vrana, this lead to cleaning of the cavity, subsequently subsides the pain in group-B.

Itching : Similarly in Itching After 6 weeks 93.44% of relief was found in Group-A, where as in Group-B it was 94.55%.

This reveals that percentage of relief in Itching was higher in each week after application of Nimba Ksharsutra than standard Ksharsutra .The predictable cause may be the 'Kandughna' property of Nimba mentioned in Dhanvantri Nighantu⁹. Besides it, according to ayurvedic texts kapha is responsible for itching. Nimba is kaphapitta shamak (Dhanwantari nighantu.), thus it helps in reducing itching effectively.

Burning Sensation: In case of Burning sensation after 6 weeks 94.55% of relief was found in Group-A, where as in Group-B it was 94.83%. Result indicates that in Group-B, relief in burning sensation in each successive seating, comparatively more than Group-A.

It may be due to the effect of ushna virya of Apamarga kshar¹⁰, it causes irritation and burning sensation in the fistulous wound, whereas by the effect of sheeta virya, Nimba kshar (Bhava Prakash)¹¹ is able to dissolved the burning sensation in group-B.

Discharge: Similarly in case of Discharge after 6 weeks 96.83% of relief was found in Group-A, where as in Group-B it was 100%.

The better result of Group-B in due to the specific property of Nimba, which causes shodhan of the matured vrana (Dhanwantari nighantu)¹². By the shodhan quality it sloughs away the debridement of necrosed tissue from the fistulous track, thus it helps in formation of healthy granulation tissue. Consequently it reduces the pus discharge. Nimba is also described as krimighna and vranaghna(kaidev nighantu)¹³, so it inhibits the secondary infection of wound and reduces pus discharge.

CONCLUSION

On the basis of findings and observations obtained after completion of current work it can be concluded that nimba ksharsutra is an effective, dependable, safe, readily available and good remedy for the management of fistula in ano.

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