

## EFFICACY OF *NIMBA KSHARSUTRA* IN THE MANAGEMENT OF FISTULA IN ANO

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### ABSTRACT

120 no of diagnosed cases with Fistula-in-ano were treated in two groups, one group by standard *Ksharsutra* therapy and other by *Nimba ksharsutra* therapy. Comparative efficacy was assessed by statistical analysis. Data related to the objectives of the study was collected. Considerable good result was noticed in the group treated with *Nimba Ksharsutra*.

**Keywords:** Fistula-in-ano, *Bhagandara*, standard *ksharsutra*, *Nimba ksharsutra*.

**INTRODUCTION:** Fistula-in-ano, one of the most annoying diseases in the ano rectal region has condemned as a brain-teaser for the patient as well as for the medical fraternity due to its outrageous site of manifestation, chronicity, recurrence and frequent acute exacerbations. According to recent study conducted on the prevalence of anal fistula in India by Indian Proctology society in a defined population, approximately varied from 17 to 20% <sup>[1]</sup>. The ranges vary from 26% to 38% <sup>[2]</sup> in developed countries. A fistula-in-ano is a track, lined by granulation tissue, which communicates with the Anal canal or Rectum by means of an internal opening and usually in continuity with one or more external openings in the perianal, perineal or ischio-rectal areas <sup>[3]</sup>. The disease of the ano-rectal region are the commonest pathological condition of the whole gastro intestinal track and they are so complicated that their management is a real problem both for patient as well as attending surgeon even today. This is probably because of close integration in the anatomical relation of the different structure surrounding the ano-rectal canal and partly because of the rich and complex network of lymphatic and blood vessels spread around this region. The surgical

management of these cases needs a careful study of anatomical relation and physiological functions of this part of the body, which have to be kept in mind on every step of any surgical procedure undertaken in this region. Due to the involvement of anal sphincter, the treatment of complex fistula poses a high risk for developing incontinence. <sup>4, 5</sup>.

Many techniques and researches has been tried since a prolong time to alleviate this ailment including Draining Setons, Cutting Setons, <sup>6,7</sup> rectal mucosal or full thickness advancement flaps, <sup>8,9</sup> Rerouting <sup>10</sup>, two stage Seton Fistulotomy, <sup>11</sup> Fistulectomy and anal plug <sup>12,13</sup> ligation of intersphincteric fistula plug (LIFT) <sup>14,15</sup>, Fistulotomy with reconstruction of the sphincter mechanism <sup>16</sup> or fibrin glue <sup>17</sup> etc. Yet, till today, fistula-in-ano remained as a back-breaking job for the modern system of medicine. On the contrary, Ayurveda named the disease as *Bhagandara* and considered as one under *Asta Mahagadas* and gained the supremacy in the field of *Bhagandar Chikitsa* due to its excellency in combating the disease. *Apamarga ksharsutra* is considered as simple, safe, and sure shot remedy for *Bhagandara* and has been standardized by CCRAS, New Delhi.

In spite of the fact that the standard *Ksharasutra* has earned an eminency as the first choice of treatment for fistula-in-ano, further research on *Ksharasutra* is a command of time.

Keeping in view these points, a new *Ksharsutra* has been designed and prepared using *Nimba* as principal ingredient. It was used and comparative study with Standard *Ksharsutra* was conducted among 120 no of patients during the period of 2011 to 2015 in Govt. Ayurvedic College and Hospital, Guwahati.

#### **MATERIALS & METHODS:**

The clinical study has been carried out exclusively in total 120 no of patients, dividing in two groups-viz.

Group-A: treated with Standard (Apamarga) *Ksharsutra*

Group-B : treated with *Nimba Ksharsutra*

A detailed performa was prepared to study the patients as well as the disease. The patients attending the Shalya O.P.D. of Govt. Ayurvedic College and Hospital were selected irrespective of their sex, cast etc.

**EXCLUSION CRITERIA:** Patients suffering from fistula- in- ano associated with following disease/criteria were excluded from the study.

1. Diabetes mellitus
2. Ulcerative colitis
3. Crohn's disease
4. Tuberculosis

5. Cancer of rectum
6. AIDS
7. Hepatitis B and Hepatitis C
8. Children up to 16 years of age

#### **INCLUSION CRITERIA**

1. All the patients were between the age group of 16-60 yrs.
2. Patients were selected randomly, irrespective of sex, economical status, educational status & marital status.
3. All diagnosed cases of fistula in ano other than exclusion criteria.

#### **DIAGNOSTIC CRITERIA:**

Patients were thoroughly examined and investigated. The history and finding were noted in Performa specially prepared for the study. Diagnosis was made on the basis of clinical findings and ano-rectal examination (visual examination of anus and surrounding area, digital rectal examination, probing and proctoscopy).

#### **Assessment Criteria**

**Subjective:** Pain, Itching, Burning sensation.

**Objective:** Swelling, Pus Discharge, Thread Length Track length,U.C.T

#### **Grading for Symptom & Sign**

- No. symptom & sign : 0
- Mild symptom & mild sign : 1
- Moderate symptom & sign : 2
- Severe symptom & sign : 3
- Very severe symptom & severe sign: 4

#### **FOLLOW UP**

**Follow up was continued up to 6 month after complete cut through of the track.**





#### During and after treatment photographs of few patients

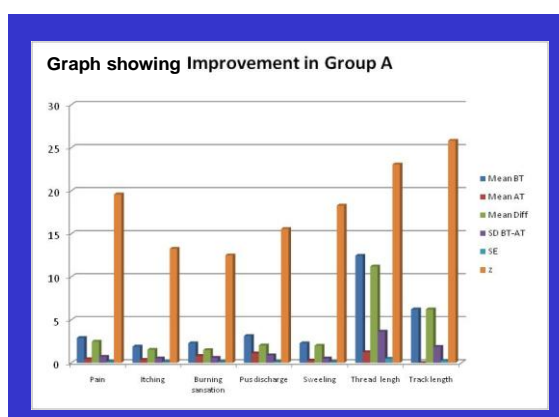
**OBSERVATION AND RESULTS:** The following results were found after completion of the procedure. Maximum number of patients of Fistula- in- ano was between 31-40 age group and their combine percentage were 50.00%. Predominantly males (83.33%), Hindus(90.83%), belongs to service class (43.33%), used to with sedentary type of work (63.33%), were married (86.67%). Maximum no. of cases (76.67%) were non-Vegetarian. possesses good appetite history (70%), holds *Vataja-pittaja prakriti*. (40%), Constipation was present in most of the cases with a percentage of 66.67%, and most of the patient approach to physician within the time period of 1 year (56.67%). skin near fistula was normal in (73.33%), whereas indurations were found in 10.00% of cases. Maximum number of patients have *Parishravi Bhagandara* (40%), abundant pus discharge with a percentage of (50%), external opening is common in maximum

cases (90%), followed by internal opening (10%), in maximum cases, (86.67%) distance of the opening from the anal verge was more than 1 1/2", highest number 6 & 8 o'clock with of cases has a external opening at 5 o'clock (23.33%) , followed by a percentage of 16.67% each .90.00% cases had a normal anal sphincter and 6.67% case had a hypertonic anal sphincter. Low anal (80%) fistula is most common , most of the patient had a blind external track (73.33%), followed by complete track (16.67%). Previous operative history was present in only 16.67% of cases, whereas most of the cases (83.33%) presented a negative history. Average U.C.T. in group A was 1.91 days/ cm. The fastest cutting rate was 1.3 days / cm and the slowest cutting rate was 2.2 days/cm. Average U.C.T. in Group-B was 1.03 days / cm. The fastest U.C.T. was 0.5 days / cm and the slowest cutting rate was 2.3 day/cm in Group B.

Overall improvement in group A was 62.04%, whereas it was 74.36% in group B.

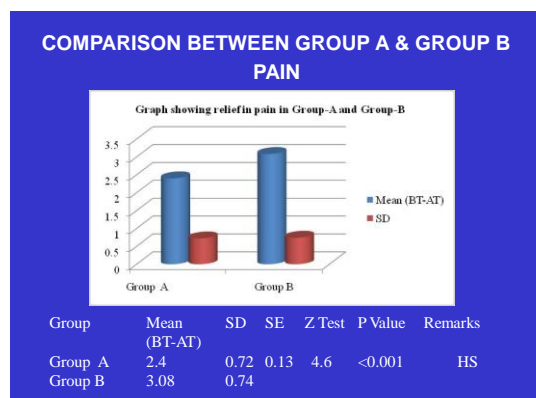
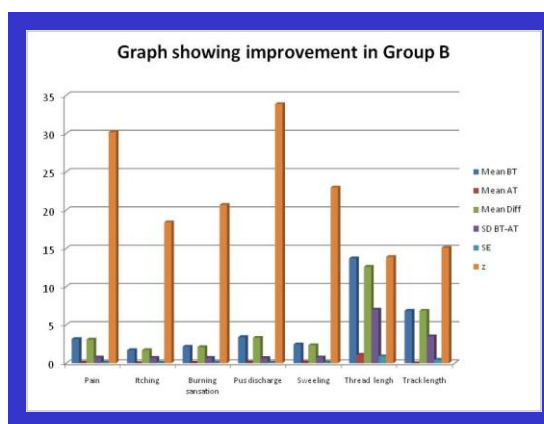
### Improvement in Group A

Criteria	Mean BT	Mean AT	Mean Diff	SD BT-AT	SE	z	p
Pain	2.9	0.43	2.47	0.72	0.12	19.58	<0.001
Itching	1.9	0.36	1.53	0.53	0.11	13.26	<0.001
Burning sensation	2.28	0.8	1.48	0.59	0.11	12.5	<0.001
Pus discharge	3.13	1.1	2.03	0.88	0.13	15.57	<0.001
Sweeling	2.28	0.28	2	0.52	0.1	18.28	<0.001
Thread length	12.45	1.25	11.2	3.64	0.48	23.07	<0.001
Track length	6.22	0	6.22	1.86	0.24	25.82	<0.001



### Improvement in Group B

Criteria	Mean BT	Mean AT	Mean Diff	SD (BT-AT)	SE	Z	P
Pain	3.16	0.083	3.08	0.74	0.10	30.19	<0.001
Itching	1.7	0.01	1.7	0.7	0.09	18.41	<0.001
Burning sensation	2.15	0.05	2.1	0.7	0.1	20.68	<0.001
Pus discharge	3.41	0.1	3.31	0.67	0.09	33.85	<0.001
Sweeling	2.46	0.11	2.35	0.75	0.1	22.95	<0.001
Thread length	13.7	1.1	12.6	6.99	0.9	13.88	<0.001
Track length	6.85	0	6.85	3.51	0.45	15.09	<0.001



## DISCUSSION

### Reason behind selection of Nimba ksharasutra:

The Nimba ksharasutra contains the following ingredients –

1. Snuhi Ksheera- 11 coating
2. Nimba kshar- 7 coating
3. Haridra- 3 coating

**Snuhi ksheera:** Snuhi ksheera has Laghu, Teekshna guna. So it might be effective in Shodhan of Bhagandara, by sloughing

away the unhealthy granulation tissue from the fistulous track. The virya of snuhi is Ushna which may be functional in reducing pus discharge through Shoshan guna. In Kaideva Nighantu Snuhi is mentioned as anila-shoola-hara, means it can help in reducing the pain in Fistula. Also it is able to breakdown the dominancy of Vata dosha, as Vata is the main dosha involved in Bhgandara. Also



it is mentioned as *Sothaghna*, so it is helpful in reducing the inflammation.

**Nimba kshara:** Most of the *acharyas* has described that *Nimba* possesses *kandughna*, *krimighna* and *Vranaghna* properties, so it can presume that *Nimba* in *ksharasutra* will definitely help in diminishing itching, destroying micro-organism and healing ulcer caused by Fistula-in-ano in a faster way. In *Dhanvantari Nighantu*, while describing about *Neem*, it is emphasized that it help in suppuration of immature *Soth* and drains the suppurated *Vran*. This is the fact which may play an enormous contribution in opening the hidden track of fistula in ano and draining the sloughs, leading to formation of healthy granulation tissue from deep to superficial part of the track. The *sheeta virya* of *Nimba* and *pittashamak* property will certainly boost in decimating the burning sensation, providing symptomatic relief to the patient. Almost in all the references that are available, specific stress was given in *krimighna* & *Vranaghna* properties of *Nimba*, which indicates its extensive impact in microcidal effect and ulcer healing quality.

Modern researchers also shown that *Nimbidin* – a terpenic ester of *Neem* showed significant result in ulcer healing activity. (Pillai, N.R. MAPA, Aug 1995, page 423). As *Neem* is *krimighna*, it also possesses immune-boosting property that was proved in laboratory experimental study. In tests for humoral immune responses, *Nimba* treated mice had higher IgM and IgG level and anti ovalbumin antibody titres, when compared to the control group. In tests for cell mediated immune response, there was an enhancement of macrophage migration inhibition after *Neem* treatment. (Banergee

BD, Roy A; Sen p. MAPA, vol.18 No.5, page 536, oct 1996)

In 2004, some researchers showed that Ether extract of *Neem* are found effective against *Klebsiella pneumoniae* with 11 mm. zone of inhibition. (upadhyay. A, Shukla. U, Tewari. A, MAPA, vol-26, no.4, 2004 Aug)

Moreover, the *kshara* of *Nimba* can do tremendous in scrubbing the necrosed tissue by using its *Chedan*, *Bbhedan* and *Lekhan* properties in the treatment of fistula in ano. In the present study, the pH of *Nimba kshara* was found 10 in the standard parameter, which is very alkaline in nature. As *Bhagandra* is a *Tridoshaja vyadhi*, the *tridoshaghna* property of *kshara* can significantly work in recuperate the disease. Again the *shleshma-arsa-pitta-nuta* properties of *Nimba* also display the action of subsiding discharge from fistulous cavity.

*Nimba* is also denoted as one which can reduce swelling in wound, in *Kaidev Nighantu*. So, obviously, the presence of *Nimba* in *Ksharasutra* may demolish the inflammation in fistula. As *Bhagandara* originates due to vitiation of *Rakta*, *Raktashodhak* property of *Nimba* will definitely play a key role in healing the disease.

Again the *shleshma-arsa-pitta-nuta* properties of *Nimba* also display the action of subsiding discharge from fistulous cavity.

**Haridra:** The *Ruksha* and *Laghu guna* of *Haridra* helps in diminishing the discharge. The *ushna virya* of *Haridra* is effective in suppressing the vitiated *Vata dosha*, thus it is able to abate the severe pain originated due to fistula.

*Haridra* owns the property of *Krimighna* to combat with micro-organism and to get rid of secondary infection. In

modern research also, it is come on focus that the aqueous extract of *Haridra* are significantly effective on *E. coli*, *Bacillus magaterium* and *Basillus piemigus* spores.(Sharma A, Gautam S, Jadhav SS,MAPA,vol 12,no.4,page465,Aug 2000) Again in another research made in 2004 *Haridra* proved sensitive against *Staphylococcus aureus*. (Gurdip singh, Kapoor, Pandey, S.K., MAPA, vol 26, no.4, page 399,a Aug 2004)

*Haridra* is described in various classic as embodied of *Raktashodhak* property. The other properties of *Haridra* are *shoshaghna*, *Vranaghna*, *kandughna*, *shodhak* etc which collectively contributes in the healing of the fistula of ano by means of its competence.

**Discussion on Results Between Group-A & Group-B:**The results are based on the Assessment criteria of the disease. Comparison was done on per week status in both groups.

**Pain:** Result shows that *Nimba Ksharsutra* has a better pain reliving 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 Nighantu it is emphasized that *Nimba* has a property which does help in suppuration of immature *Sotha* and drains the suppurated *Vran*, this lead to cleaning of the cavity, subsequently subsides the pain. Again, *Nimba* is denoted as *Anila-hara*, by Acharya Sushrut, which made an Appealing result in the relief of pain in group-B.

**Itching :** Result 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 Nighantu*. Again according to Ayurveda, itching (*Kandu*) is a property of *Kapha*, so any drug which will contain the *Kaphahara* property will definitely play a key role to dwindle the symptom. *Nimba* possesses the *Shlesma-hara* quality and helps in doing it.

**Burning Sensation:** Result indicates that Group-B, was superior in relief of burning sensation in each successive seating, in comparison to Group-A.

The cause behind it is, due to the effect of *Ushna virya* of *Apmarga kshar* ,it causes irritation and burning sensation in the fistulous wound, whereas by the effect of *Sheeta virya*, *Nimba kshar* is able to dissolve the burning sensation in group-B.

**Swelling:** *Nimba Ksharsutra* was more effective in reducing Swelling than standard *Ksharsutra*.

The better result of *Nimba Ksharsutra* is due to the fact that *Nimba* possesses the *sothahara* property as mentioned in *Kaidev Nighantu*. Modern researches also proved that *Nimba* has anti-inflammatory action against any kind of inflammation. The active principle of *Nimba*, called Nimbidine has a quality to suppress the functions of macrophages and neutrophils, relevant to inflammation.<sup>18</sup>(Kaur.G, Alam.M.S., Athar.M, page-498, vol-26, no-5, oct-2004)

The increase of swelling in 1<sup>st</sup> week may be due to the reason that *Kshara* owns the *lekhan* property, which causes irritation in the fresh wound, leading to more swelling in the fistulous track.

**Discharge :** The better result in Group-B is due to the specific property of *Nimba*, which causes *Sodhan* of the matured *Vrana*. By the *Sodhan* 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. The reason for increased pus discharge in the initial stage of treatment is due to the *Chedan* and *Bhedan* properties of *Kshar*, which breaks down the pus pockets, remained in the diseased track. Accordingly increase the amount of pus discharge. As it turns to heal up, the discharges get diminished.

Another condition for continuous reduce of pus discharge in Group-B, is that in most of times, pus discharge is caused by microbial infestation in the fistulous track. As *Nimba* holds the excellence of *Krimighna*, it easily destroys the microbial pores of the track. In current research on *Neem* revealed its inhibitory effect on wide range of micro-organisms. The most well known active compound Azadirachtin shows behavioral effect through chemoreceptor mechanisms, whereas growth related effect are due to interference with neuro-endocrine control.<sup>19</sup>

Modern researches also points out the same notification. In 2004 it has come out on research that the ether extract of *Neem* was found effective against *Klebsiella* with 11 mm zone of inhibition<sup>20</sup>

**Specific observation:** A better response and quick healing was found in Group B comparison to group A. Again in group B out of 15 patients 13 patients were found with opening all the concealed tracks within two weeks. That was most probably due to the *Vranaghna* property of *Nimba*, which helps in healing of the track and due to another specific property which causes 'suppuration of immature *Vrana* and drains the suppurated one. (D.

Ni). Thus *Nimba kshar* helped in drainage of all concealed tracks.

#### CONCLUSION:

1. *Ksharsutra* therapy is a radical cure, without complications and recurrences in the treatment of *Bhagandara*
2. In most of cases external opening is found in posterior commissure.
3. The standard *Ksharsutra* and *Nimba Ksharsutra* both are significant, though *Nimba Ksharsutra* shows better result in healing of the fistulous track.
4. *Nimba Ksharsutra* has a specific property of unsealing the concealed track, thus reduces the possibility of recurrence of the disease in future.

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