



A pilot study: role of *Nimba Kshar Sutra* in the management of *Bhagandara* (Fistula - In - Ano)

Alok Kumar¹ and Ekta Dogra²

¹Ph. D Scholar, Department of Shalya Tantra N.I.A. Jaipur, India

²Lecturer BKAMCH, Department of Swasthawrita, Daudhar, Moga Punjab

Received: 15-01-2015 / Revised: 23-02-2015 / Accepted: 25-02-2015

ABSTRACT

Fistula-in-ANO entails a chronic granulating track connecting two epithelial lined surfaces, one of the most annoying diseases in the ANO rectal region has predestined 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. *Ayurveda* has treatment modality that is more effective than conventional surgical option available in modern surgery. The present study was a pilot study, conducted on ten patient of *Bhagandara* (Fistula in ANO) with an objective to assess the efficacy and acceptability of *Nimba Ksharasutra* in the management of *Bhagandara*. The patients were selected from the OPD of and treated with *Kshara Sutra* therapy. The patients were assessed per week for continuous 8 weeks according to the assessment criteria. After observing the overall therapy, it was found that in most of the parameters *Nimba Ksharasutra* have much better results and very good acceptability with less complication as itching, pus discharge, pain etc. mostly found in standard *Apamarga Ksharasutra* therapy.

Key words: *Bhagandara*, *Nimba Ksharasutra*, *Apamarga*



INTRODUCTION

The word "*Bhagandara*"^[1] literally means *Darana* around *guda*, *yoni* and *vasti*. At first it appears as a *pidika* around *guda*, and when it bursts out, then known as *Bhagandara*.^[2] *Bhagandara* has been included one of among the *Astamahagada* described in *Sushruta Samhita*^[3]. Literally the diseases mentioned in the *Asthmahagada* are difficult to treat from patients as well as surgeon's point of view. On analyzing the symptoms described in *Ayurvedic* literature one can easily draw the conclusion that *Bhagandara* is similar, like fistula-in-ano mentioned in modern surgery literature. Fistula-in-ano^[4], suggests a chronic granulating track connecting two epithelial lined surface. Fistula-in-ano is well known for their recurrence after surgical intervention, even in most skilled hands. So causes physical, mental and social embarrassment to the patient. *Ayurveda* 'The Science of Life' serving the humankind since antiquity has given the solution to this dreadful disease which has become the treatment of choice among *Ayurvedic* practitioners currently. In last 4-5 decades *Ksharasutra*^{[5],[6]} has attained the reputation that this is most suitable treatment option for *Bhagandara* among patients. Even in

modern literature references regarding *Ksharasutra* treatment can be seen. In spite of the fact that the *Ksharasutra*, the excellent *Ayurvedic* remedy has earned an eminency as the first choice of treatment for fistula-in-ano, the further research on *Ksharasutra* is a demand of time. *Ayurveda* is till now standing there, where it was thousands years before just because of lack of proper research of its theory. No doubt, standard *Ksharasutra* is a best weapon against the enemy. Yet remodelling of standard *Ksharasutra* is a demanding fact in present situation. *Acharya Sushruta* described lot of drugs for the preparation of *kshara*, *Nimba*^[7] (*Azadiracta Indica*) is also one of them, due it's well known property of *krimighna*, indicated in some *Ayurvedic* classics. I decided to take *Nimba Ksharasutra* for my study, to assess the efficacy & acceptability of *Nimba Ksharasutra* in *Bhagandara* patients.

The modern surgical management of fistula in ano includes fistulotomy, fistulectomy, seton placing^[8], Ligation of Intersphincteric Fistula Tract (LIFT)^[9], Fibrin Glues, Advancement Flaps^[10] and Expanded adipose derived Stem Cells (ASCs)^{[11][12]} etc. All surgical procedure indicated for fistula-in-ano in modern literature having lot of drawback like long

duration treatment, more discomfort, more costly and having high rate of recurrence.

So considering the above point regarding problems during management of *Bhagandara* the study was plan in our department to manage the *Bhagandara* using *Nimba Ksharasutra* prepared with *Nimba Kshara*.

MATERIAL AND METHOD

Study Design: The study was conducted under a strict protocol to prevent bias and to reduce the error in study.

1. Randomized trial

The Patients: The study was performed with 10 patients of fistula-in-ano. All the patients were randomly selected from the I.P.D. and O.P.D. of Anorectal unit, Department of *Shalya Tantra*, National institute of *Ayurveda*, Jaipur.

The Drugs: The drug is prepared in *Ksharasutra* laboratory at department of *Shalya Tantra*, National Institute of *Ayurveda*, Jaipur. The raw material was taken from Pharmacy of National Institute of *Ayurveda*, Jaipur. The drug is used in the form of *Nimba Ksharasutra*.

Criteria for selection of the patients

Inclusion criteria:

1. All the patients of either sex, religion between the age group of 20-60 yrs.
2. All diagnosed cases of *Bhagandara* other than exclusion criteria.

Exclusion criteria: Patients suffering from fistula in ano associated with following disease/criteria were excluded from study.

1. Diabetes mellitus
2. Ulcerative colitis
3. Crohn's disease
4. Tuberculosis
5. CA of rectum
6. AIDS
7. Hepatitis B
8. Children

Diagnosis: Diagnosis made on the basis of history of patient, the general & systemic and local examination from *Ayurvedic* and modern point of view. Patients were thoroughly examined and investigated. The history and finding were noted in proforma specially prepared for the study.

Treatment schedule: 10 diagnosed cases of low anal fistula patients were treated with *Nimba Ksharasutra* therapy.

Duration of study: The duration of the study was 8 weeks.

Assessment Criteria: The improvement of patient's condition was assessed on the basis of classical signs & symptoms of Fistula-in-ano and *Bhagandara* in different text. Efficacy of *Nimba Ksharasutra* assessed on the basis of subjective and objective criteria.

- A. Assessment criteria through modern parameters
- B. Assessment criteria through Ayurvedic parameters

ASSESSMENT CRITERIA THROUGH MODERN PARAMETERS

A. Subjective criteria:

1. Pain
2. Itching
3. Burning sensation

B. Objective criteria:

1. Tenderness
2. Pus discharge
3. U.C.T.(Unit cutting time)

Grading of Assessment Criteria

Subjective Criteria: It is based on feeling of patients. It is known as simple verbal scale. In this particular research work, subjective criteria are as follows.

PAIN: Table no. I

Grade	Explanations
0	No complain of pain
1	Negligible or tolerable pain, no need of medication
2	Localized tolerable pain relief by hot sitz bath
3	Tolerable pain, not relief by hot sitz bath, relived by oral analgesic.
4	Continuous and intolerable pain with sleep disturbance

ITICHING: Table no. II

Grade	Explanations
0	No complain of itching
1	Negligible itching, with 10-12 hours gap
2	Occasional itching, with 4-6 hours gap
3	Frequent itching, with 2-3 hours gap
4	Frequent & intolerable & continuous itching sensation

BURNING SENSATION: Table no. III

Grade	Explanations
0	No complain of burning sensation
1	Negligible burning sensation
2	Occasional tolerable burning sensation, relieved by oleation.
3	Constant tolerable burning sensation, slightly relived by local oleation
4	Intolerable burning sensation makes the patient uncomfortable and makes the patient to rush for medical help.

Objective Criteria: The patients were assessed on the basis of relief of symptom and Investigation.

TENDERNESS: Tenderness is mainly graded in two types Deep & superficial, and it detected by noticing the facial expression of the patient during examination.

Table no. IV

Grade	Explanations
0	No tenderness detected
1	Slight /very pain detected on excessive pressure
2	Superficial pain detected on moderate pressure
3	Deep pain elicited on mild pressure
4	Very severe deep tenderness (pain on touch) detected.

PUS DISCHARGE: Table no.V

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

UCT (Unit cutting time): The initial length, as well as the length of *Ksharasutra* at each successive sitting were measured and recorded. The gradual shortening of thread at the following sitting evidently corresponds to the cutting of tissue, which provides an idea of the progress of a particular case. This has been termed as unit cutting time (U.C.T.).

Assessment criteria through ayurvedic parameters: *Bhagandara* (fistula in ano) is a kind of *vran*. This concept was given by both *AcharyaSushruta* and *AcharyaVagbhata*.

Qualities of SamayakaRudaVrana (Healed wound):

रुढवर्त्मानमग्रन्थिमशूनमरुजं व्रणम

त्वकसवर्ण समतलं सम्यग्रूढं विनिर्दिशेत ॥Su. Su. 23/20

There are the six status of healed *vran*a mentioned by *AcharyaSushruta*.

1. रुढवर्त्मानम्
2. अग्रन्थिम्
3. अशूनम्
4. अरुजम्
5. त्वकसवर्णम्
6. समतलम्

Remembering this, an effort was made to measuring the 'Healing status' of the *Bhagandara* through on *Ayurvedic* parameters.

According to the presence of the above mentioned six parameters, the 'Healing status' was divided in the following categories.

- 1) Complete healing: 6/6
- 2) Moderate healing : 4-5/6
- 3) Mild healing: 2-3/6
- 4) No healing: 0-1/6

Follow Up: The patients were advised for routine checkup after completion of study up to 1 month (4 week) for elicited any recurrence or improper healing of the fresh wound, any fresh bloody discharge etc.

Statistical Analysis: All in information which are based on various parameters was gathered and statistical calculation were carried out in terms of mean (x), standard deviation (S.D.) standard error (S.E.), paired test (t value) and finally results were incorporated in term of probability (p) no.

- p ≥0.50 Insignificant
- p ≤0.020 Moderately significant
- p ≤0.010 Significant
- p ≤0.001 Highly significant

OBSERVATION AND RESULTS

Subjective Assessment:

Table no. VI showing Relief in pain

Sign	Mean		Diff.	%of Change	SD	SE	T val.	P val.
	BT	AT						
Trial Group	3.53	0.07	3.47	98.11	0.64	0.17	20.98	<0.0001

Table no. VII showing Relief in itching

Sign	Mean		Diff.	%of Change	SD	SE	T val.	P val.
	BT	AT						
Trial Group	3.20	0.00	3.20	100	0.56	0.14	22.11	<0.0001

Table no. VIII showing Relief in burning sensation

Sign	Mean		Diff.	%of Change	SD	SE	T val.	P val.
	BT	AT						
Trial Group	3.20	0.27	2.93	91.67	0.88	0.27	12.86	<0.0001

OBJECTIVE CRITERIA:

Table no. IX showing Relief in intensity / severity of Tenderness

Sign	Mean		Diff.	%of Change	SD	SE	T val.	P val.
	BT	AT						
Trial Group	3.53	0.07	3.47	98.11	0.74	0.19	18.07	<0.0001

Table no. X showing Relief in pus discharge after 8 weeks

Sign	Mean		Diff.	%of Change	SD	SE	T val.	P val.
	BT	AT						
Trial Group	3.40	00	3.40	100	0.74	0.19	17.87	<0.0001

Table no. XI showing Healing status of patients according to Ayurvedic parameters

Healing Status	Number of Patients	
	Trial Group	
Complete Healing	11	73.33%
Moderate Healing	3	20%
Mild Healing	1	6.67%
No healing	0	0

Table no. XII showing Effects *Nimba ksharasutra*

S. No.	Symptom	Trial Group
1.	Pain	98.11%
2.	Itching	100%
3.	Burning sensation	91.67%
4.	Tenderness	98.11%
5.	Pus Discharge	100%
6.	Average UCT (Days/ cm)	7.29%

Finally, total average UCT of trial Group were evaluated, it shows that, average maximum UCT in *Nimba Ksharasutra* is 7.29 days/cm.

DISCUSSION ON CLINICAL STUDY

The patients were assessed per week for continuous 8 weeks and the final results are as follows according to the assessment criteria.

Pain: The percentage of relief in pain in trial group was 98.11%. The most probable cause behind the good result of *Nimba Ksharasutra* in relief of pain may be the fact that pain occurs in the fistula-in-ano due to the accumulation of pus in the cavity. It has been mentioned in *Dhanvantari Nighantu* that *Nimba* has a property which helps in suppuration of the immature *shotha* and drains the suppurated *vrana*¹³. Thus cavity gets cleaned, and consequently subsiding the pain. *Nimba* is also said to be as '*Anila-hara*', by *Acharya Sushruta*, which shows result in the relief of pain in trial group¹⁴.

Itching: In patients of trial group percentage of relief in itching was 100%. The data shows that percentage of relief in Itching was very good. The predictable cause may be the '*Kandughna*' property of *Nimba* mentioned in *Dhanvantri Nighantu*¹⁴. 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.

Burning sensation: In the patients of trial group percentage of relief in burning sensation was 91.67%. The data shows the *nimbakshara* sutra has a good *pitta shamak* property due to having *tikta* and *kashaya rasha* stated in *Sushruta Samhita*¹⁵, so that reduces the burning sensation occurs during treatment.

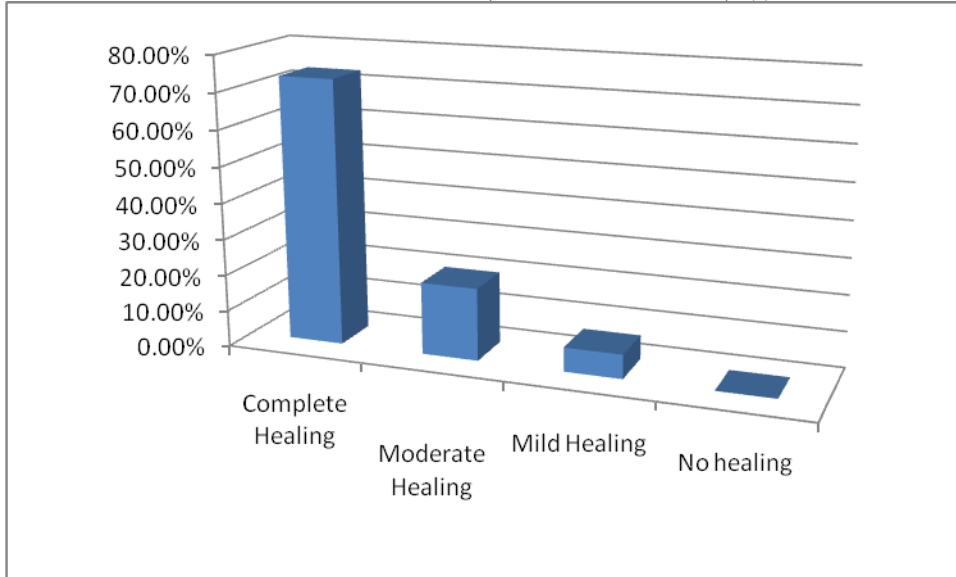
Tenderness: In the patients of trial group percentage of relief in tenderness was 98.11%. The data shows *nimbakshara sutra* shows very much

effective on tenderness most probably due to having very good effects on draining the pus by breaking the pus loculi due to their *Theeskhna guna* of *Kshara*.

Pus Discharge: In trial group the percentage of relief in pus discharge was 100%. The *Nimba Ksharasutra* is having better pus drainage quality, due to the specific property of *Nimba*, which causes *sodhan* of the *vrana*. By the *sodhan* quality it debrides necrotic tissue from the fistulous track, thus it helps in formation of healthy granulation tissue. Consequently it reduces the pus discharge. Another cause for continuous reduce of pus discharge in trial group patients, is that in most of times, pus discharge is caused by microbial infestation in the fistulous track. As *Nimba* holds the excellence of *Krimighana*, it easily destroys the microbial pores of the track.

The reason for which pus discharge increases in the initial stage of treatment is due to the *chedan* and *bhedan* properties of *Kshara*¹⁶, 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.

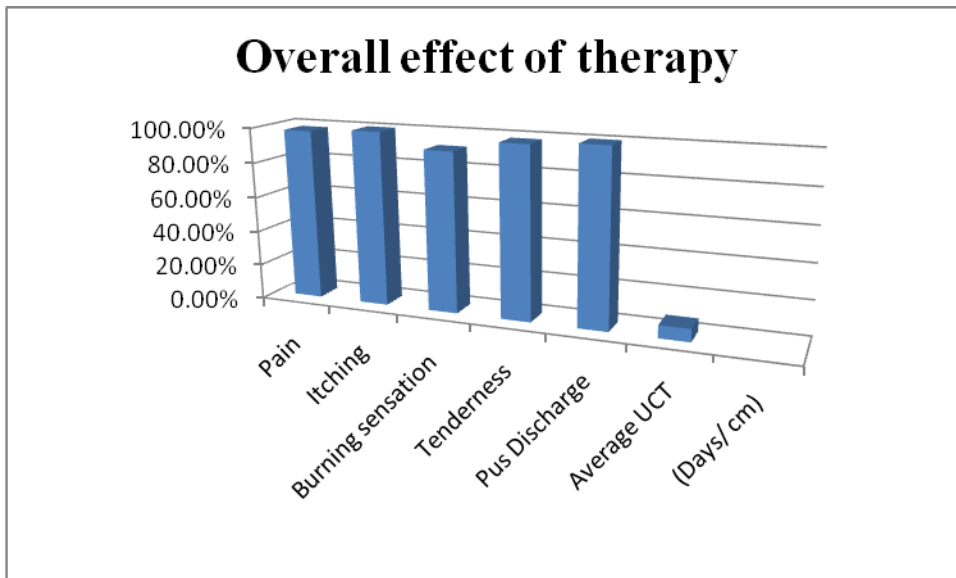
UCT: The average UCT in trial group was 7.29days/cm. The results may be due to the properties of *Nimba* viz, *laghu guna*, through which it easily enters in the tissue and *bhedana guna* helps in cutting of the fistulous track, thus providing a better UCT. Female were noticed to have little higher UCT than male. The reason could be the less pain bearing capacity in them, due to which the thread couldn't be properly tightened. The values of average UCT was high in the operated patients in trial group. It may be possibly due to the fibrosis caused by the previous surgery.



Graph no.1 showing healing status of patients

Healing status according to Ayurvedic Parameter: Among all the patients of trial group 73.33% patients achieved complete healing. To be mentioned there were 20% patients having moderate healing. It shows that trial group are

showing good results in wound healing. It might be due to the *Vranaghna* quality of *Nimba*, which helped in enhancing the healing effect of fistulous track.



Graph no. 2 showing Overall effect of the therapy

Overall effect of the therapy: After observing the overall therapy, it was found that in most of the parameters *Nimba Ksharasutra* gave much good results in symptoms like pain, itching, burning sensation, tenderness, pus discharge, etc

Probable mode of action of *Nimba Ksharasutra*: *Nimba* when combines with *Haridra* and *Snuhi ksheera* increases by *Laghu Guna* which allows it to enter the cell membrane easily. Then the

necrosed tissue is sloughed off from the track with the help of the following:

- *Bhedana & Vranasodhan* property of *Nimba*
- *Chhedan Lekhana & Bhedana* properties of *Kshara*
- *Teekshna Guna* of *Snuhi*
- *Ushnavirya* of *Snuhi* and *Haridra*.

As a result of breaking of pus pockets of the unhealthy tissue, the pus discharge gets reduced. If

anyway, the pus discharge continues to occur (due to secondary infection), the *krimighna* property of *Nimba* and *Haridra* are there to cure it. The itching is diminished by the *Kandughna* property of *Nimba* and burning sensation is relieved by *Sheeta Virya* of *Nimba*. In most of the time pain occurs due to presence of pus in cavity. As the pus discharge diminishes, pain disappears. Due to the *Vrana Sodhana* property of *Nimba*, it opens up all the concealed tracks, resulting relief in pain just in few weeks of application of *Ksharasutra*. The *Anilahara* property of *Snuhi* and *Ushna Virya* of *Snuhi* and *Haridra* synergistically reduce the *Vata*, followed by reduction in pain. The *Sothaghna* property of *Nimba* and *Snuhi* adjutely reduces the swelling. The *Raktasodhaka* property of *Haridra* also adds to it. The *Tikta Rasa* of *Nimba* and *Haridra* and the *Vranaghna* quality of both help in healing up of the fistulous track. Hence, in the above mentioned ways the three drugs work in a combined manner to give good results in curing fistula in ano.

Conclusion: On the basis of the entire study, the following the points are selected that should be concluded.

- ❖ Fistula-in-ano is found from ancient era in human being.
- ❖ The *Nimba Ksharasutra* is having better effect on pain and tenderness.
- ❖ The *Nimba Ksharasutra* is having great effect on itching.
- ❖ The *Nimba Ksharasutra* is having great effect on Pus discharge.
- ❖ The *Nimba Ksharasutra* is having low UCT. Total duration of treatment can be slightly reduced in *Nimba Ksharasutra*.
- ❖ The *Nimba Ksharasutra* provides better wound healing due to antimicrobial property of *Nimba*. Due to alkaline pH of *Kshara* pathogens does not multiply and invade the cavity.
- ❖ The *Nimba Ksharasutra* shows very good acceptability by the fistula patients having very less discomfort.

REFERENCES

1. Shastri A. D. in Sushruta Samhita: Ayurveda Tatva Sandipika, Chaukhamba Sanskrit Sansthan, nidansthanam chapter 4/4, p-244.
2. Shastri A. D. in Sushruta Samhita: Ayurveda Tatva Sandipika, Chaukhamba Sanskrit Sansthan, nidansthanam chapter 4/4, p-244.
3. Shastri A. D. in Sushruta Samhita: Ayurveda Tatva Sandipika, Chaukhamba Sanskrit Sansthan, nidansthanam chapter 33/4 p-126
4. Jhonger and Harold Nixon, Surgery of Anus, rectum and colon vol. I 5th ed. A.I.T.B.S. Publisher Krishna nagar Delhi, , Fistula in ano chapter 7, page-178.
5. Tripathi Jagdishvaraprasad, in Chakradatta Sri Chakrapanidata, edited by Bhishagratna Pt. Brahmashankara Mishra, 5th ed. Chowkhamba Sanskrit series Office, Varanasi -221001, 1983, Nadivranachikista, chapter 45/10-13.
6. Tripathi Jagdishvaraprasad, in Chakradatta Sri Chakrapanidata, edited by Bhishagratna Pt. Brahmashankara Mishra, 5th ed. Chowkhamba Sanskrit series Office, Varanasi -221001, 1983, Nadivranachikista, chapter 45/10
7. Norman S. Williams, Christopher J.K. Bulstrode, P. Ronan O'Connell in Bailey & Love's Short Practice of Surgery, 25th ed. Hodder Arnold publication, Anus and Anal Canal, fistula in ano, p-1264.
8. Rojanasakul A LIFT Procedure, a simplified technique for fistula in ano, tech coloproctol, 2009 september, 13(3), 237-40, E publication 2009 July 28.
9. Norman S. Williams, Christopher J.K. Bulstrode, P. Ronan O'Connell in Bailey & Love's Short Practice of Surgery, 25th ed. Hodder Arnold publication, Anus and Anal Canal, fistula in ano, p-1264.
10. KeeHo Song, New technique for treating an anal fistula, journal of the Korean society of Coloproctology, J Korean soccoloproctol 2012; 28 (1); 7-12.
11. <http://dx.doi.org/10.3393/jksc.2012.28.1.7>
12. Sharma P.V. in Dhanvatari-Nighantu, translated by dr. Guru Prasad Sharma, 1st ed. Chaukhamba Orientalia Varanasi, 1982, guduchyadi prathamvarg, Nimba, shlok no. 28-29, p-21.
13. Sharma P.V. in Dhanvatari-Nighantu, translated by dr. Guru Prasad Sharma, 1st ed. Chaukhamba Orientalia Varanasi, 1982, guduchyadi prathamvarg, Nimba, shlok no. 28-29, p-21.
14. Shastri A. D. in Sushruta Samhita: Ayurveda Tatva Sandipika, Chaukhamba Sanskrit Sansthan, nidansthanam chapter, 46/179 p-126.
15. Shastri A. D. in Sushruta Samhita: Ayurveda Tatva Sandipika, Chaukhamba Sanskrit Sansthan, nidansthanam chapter, 11/3 p-34.