

# A Comparative Evaluation on Efficacy of Rate of Healing within Four Weeks by Guggulu Based Kshara Sutra with Saptang Guggulu and Guggulu Based Kshara Sutra in Management of Nadi Vrana W.S.R. to Pilonidal Sinus

Dr. Priya<sup>1</sup>, Dr. Anamika<sup>2</sup>, Dr. Rajender Singh<sup>3</sup>

<sup>1</sup>Dr. Priya (Final year), P.G. Department of Shalya Tantra, Institute for Ayurved Studies & Research, Faculty of Ayurved, Kurukshetra, Haryana, India.

<sup>2</sup>Associated Professor, P.G. Department of Shalya Tantra, Institute for Ayurved Studies & Research, Faculty of Ayurved, Kurukshetra, Haryana, India.

<sup>3</sup>Professor, P.G. Department of Shalya Tantra, Institute for Ayurved Studies & Research, Faculty of Ayurved, Kurukshetra, Haryana, India.

**Abstract**—A Pilonidal sinus is a track which commonly contains hair. Shalyaja Nadvrana is a type of Agantuj vrana. Nowadays, young males who are primarily hirsute, are more likely to suffer from Pilonidal Sinus (PNS). It usually happens in the intergluteal cleft when hair irritates the skin, resulting in an abscess and the eventual formation of a sinus. There is a surgical risk and recurrence associated with the current surgical procedures, such as excision and skin grafting, excision with Z plasty, excision with multiple Z plasty, karydak's excision, Bascom technique, and rhomboid-limber flap that are currently available for the treatment of this illness. Kshara sutra is a well-established method in Ayurveda, however it takes longer, which leads to secondary infections and delayed wound healing. Thus, the current study attempts to assess the healing rate when nadi vrana is managed using kshara sutra alone and when kshara sutra is utilized in combination with saptang guggulu. Most cases occur in young male adults. **AIM:** To provide a non-invasive, safe, fast resulting treatment for Nadi Vrana (Pilonidal Sinus)

**OBJECTIVE:** To shorten the duration of treatment of Pilonidal Sinus with Kshara Sutra treatment by adding Saptang Guggulu.

To validate the data in terms of rate of healing.

**RESULT:**

**Index Terms**—Nadvrana, Pilonidal Sinus, Kshara Sutra

## I. INTRODUCTION

The 'Sushrut Samhita'<sup>(1)</sup> describes a condition 'Shalyaj Nadi Vrana' which is similar to 'Pilonidal Sinus'. 'Shalyaj Nadi Vrana' is a track which is described to be due to presence of pus, fibrosed unhealthy tissue & hair etc. inside left unnoticed. Sushruta has advocated a very unique minimally invasive treatment i.e., 'Kshara Sutra' procedure for management of Nadi Vrana (PNS). A Pilonidal sinus is a track which commonly contains hair. It occurs under the skin between buttocks (the natal cleft) at a short distance above the anus. The sinus track goes in a vertical direction between the buttocks. Most cases occur in young male adults. The origin of Pilonidal disease is not fully understood, although hormonal imbalance, presence of hair, friction and infection are often implicated.<sup>(2)</sup> Kshara Sutra means thread made up of caustic material which destroys or cleans the devitalized tissue and to disintegrate the skin or other tissues.<sup>(3)</sup> Chakrapani Dutta was the first person to mention the method of preparation with its indication in Bhagandara (fistula in ano) and arsha <sup>(4)</sup> (hemorrhoid). He described method of preparation as smearing a thread repeatedly in latex of Snuhi (Euphorbia neriifolia) and Haridra (turmeric) powder.<sup>(5)</sup>

## II. NEED FOR STUDY

Nadi Vrana is a disease with a high recurrence rate. Presently there are many options for treatment for this disease including many surgical invasive techniques like excision and skin grafting; excision with Z plasty, excision with multiple Z plasty, karydak's excision, Bascom technique and rhomboid – limber flap. As conservative treatment includes use of antibiotics. But all have their limitations like high recurrence rate, high cost, antibiotic resistance, hospitalization, recurrent infection, and discomfort etc. That's why we need some new methods or treatment techniques that must be effective to cure nadi vana, with minimum or no surgical intervention, without any resistance, least tissue damage, with low cost, least hospitalization, painless or easily tolerable for the patient. In Ayurveda, kshara sutra is established technique but it takes longer time during which secondary infection occurs and it causes delayed wound healing. All the previous studies done till today had not mentioned anything like rate of healing. Therefore, the present study aims in attempting to validate the rate of healing when kshara sutra is used alone and when ksharasutra is used with saptang guggulu in the management of nadi vana.

## III. HYPOTHESIS

### RESEARCH HYPOTHESIS(H1):

There is significant difference between efficacy of Kshara Sutra with Saptang Guggulu and Kshara Sutra in the management of Nadi Vrana w.s.r. to Pilonidal Sinus in terms of rate of healing.

### NULL HYPOTHESIS (H0):

There is no significance difference between efficacy of Kshara Sutra with Saptang Guggulu and Kshara Sutra in the management of Nadi Vrana w.s.r. to Pilonidal Sinus in terms of rate of healing.

### AIM:

To provide a non-invasive, safe, fast resulting treatment for Nadi Vrana (Pilonidal Sinus)

### OBJECTIVE:

1. To shorten the duration of treatment of Pilonidal Sinus with Kshara Sutra treatment by adding Saptang Guggulu.
2. To validate the data in terms of rate of healing

## CASE STUDY:

This study included selection of 60 patients from the outpatient and inpatient department who had been diagnosed with Nativrana. Patients were divided into 2 groups and given specific treatment and observations were noted during its follow up.

## STUDY DESIGN:

THE STUDY DESIGN IS AS FOLLOWS-

STUDY TYPE-	Interventional, Exploratory		
SUB-TYPE	-	Control trial	
PURPOSE	-	Treatment	
TIMING	-	Prospective	
MASKING	-	Open trial	
SAMPLING METHOD-	Computer Assisted Randomization	with	allocation concealment

SAMPLE SIZE- 60 patients in 2 groups

END POINT - Efficacy

## GROUP:

A total of 60 patients of Nadi Varna will be included in the study. The sampling method will be simple random using the closed envelope method. The patient will be randomly distributed in 2 groups namely Group A & Group B.

Groups	No. of Patients	Type of Treatment	Duration
Group-A	30	Kshara Sutra	4 Weeks
Group-B	30	Kshara Sutra with Saptang Guggulu	4 Weeks

## IV. PREPARATION OF KSHARA SUTRA

Kshar Sutra is a medicated thread (seton) coated with herbal Alkaline drugs like Apamarga Kshara (Ash of *Achyranthus aspera*), shodhit guggulu (*Commiphora mukul* Hook ex stocks) and Haridra powder (*Curcuma longa*) powder in a specific order. This combination of medicines on the thread helps in debridement and lysis of tissues, exerts antifungal, anti- bacterial, and anti-inflammatory reaction. Kshara sutra will be made in

kshara sutra cabinet and after formation of kshara sutra, it will be sealed in glass tube. The glass tube will be opened in the operation theatre only before the procedure

It is divided into 3 phases according to Trividha Karma-

Poorva Karma – Pre-operative procedure Pradhan Karma- An operative procedure Paschat Karma – Post-operative procedure

#### POORVA KARMA-

1. Written informed consent will be taken.
2. Inj. T.T. (Tetanus Toxoid) 0.5 ml I/M.
3. Inj. Lignocaine Hydrochloride 2% 0.2 ml S/C (for sensitivity)
4. All vital parameters will be examined.
5. Patient will be asked to shave & clean the affected area.
6. Tray & Trolley with instruments will be prepared.
7. Patient will be asked to lie in prone position.
8. Will Access the patient having Nadi Varna (Si Preparation of the local part- Will draped with sterile cut sheet. Clean the exposed Nadi Vrana with the surrounding area is wiped with a dry sterilized gauze piece.

Local anaesthesia – infiltration of xylocaine with adrenaline 1%.

#### PRADHAN KARMA FOR GROUP A & B

1. Patient will be asked to lie in prone position.
2. Preparation of the local part- Will draped with sterile cut sheet. Clean the exposed Nadi Vrana with the surrounding area is wiped with a dry

sterilized gauze piece.

3. Kshara Sutra will be inserted inside the Sinus tract by using probe.
4. Cover the procedure site with a sterile gauge piece soaked in antiseptic solution and fix it with micropore.

#### PASCHAT KARMA FOR GROUP A

1. Patient will be shifted to the IPD for monitoring vitals and general condition for 30 minutes.
2. Patient will be called on 1<sup>st</sup> day only after 1<sup>st</sup> procedure for an examination and prognostic review.
3. Patient is advised not to wet the dressing site and not to do vigorous exercise. But he/she can do his/her regular activities.

#### FOR GROUP - B

Paschat karma is same as for group-A. But Saptang Guggulu will be given in addition to group-A.

#### SUBJECTIVE PARAMETERS-

1. Pain
2. Tenderness
3. Pus discharge

#### OBJECTIVE PARAMETERS-

Length of the tract.

#### FOLLOW-UP:

After the completion of trial patient will be called as per following schedule:

- After 1 week
- Then, after 1 week
- Then, after 1 week

#### V. SCHEDULE OF THE STUDY: GROUP A: KSHARA SUTRA

	Day 0	Day 1st	Day 8th	Day 15th	Day 22nd	Day 29th	Day 36th	Day 43rd
Screening	√							
Treatment		√	√	√	√			
Assessment		√	√	√	√	√		
Follow-up							√	√
Observation		√	√	√	√	√	√	√

## GROUP B: KSHARA SUTRA WITH SAPTANG GUGGULU

	Day 0	Day 1st	Day 8th	Day 15th	Day 22nd	Day 29th	Day 36th	Day 43rd
Screening	√							
Treatment		√	√	√	√			
Assessment		√	√	√	√	√		
Follow-up							√	√
Observation		√	√	√	√	√	√	√

SAPTANG GUGGULU – Will be given in 2.25 gm quantity per day i.e. 250 mg 3tab TD with ushnodak anupan for four weeks.

## INVESTIGATIONS-

CBC, TLC, DLC, ESR, FBS, HbA1c, CRP, BT, CT.

2. MRI- Lower back including sacro-coccygeal (if needed)

3. Pus Culture & Sensitivity (if needed)

4. HIV, HBsAg (if needed).

## DURATION OF TREATMENT:

The duration of treatment will last upto complete healing including follow-up.

## DOSE OF SAPTANG GUGGULU-

In Bhav Prakash, its dose is prescribed in 1Aksha quantity. But in AFI, it is prescribed in 1-3 gm twice a day with triphla kwath / phaltrikadi kwath/ ushnodak. 250 mg 3 tab TD with ushnodak anupan<sup>(10)</sup>

## SAFETY ASSESSMENT OF DRUG UNDER RESEARCH-

It is a classical formulation so there might not be any requirement of safety assessment. If any adverse effect of the drug will be noticed during the research, then it will be monitored, managed and documented. The patient will be considered as drop out and next patient will be included.

VI. ASSESSMENT AND OBSERVATION –  
GRADING-

GRADE	INTENSITY	1 <sup>ST</sup> VISIT	2 <sup>ND</sup> VISIT	3 <sup>RD</sup> VISIT	4 <sup>TH</sup> VISIT
0	No Pain				
1	Mild Pain				
2	Moderate Pain				
3	Severe Pain (7-8)				
4	Severe Pain (9-10)				

## ASSESSMENT OF PAIN WILL BE DONE BY VISUAL ANALOGUE SCALE

## GRADING OF TENDERNESS: -

GRADE	EXPLANATION	1 <sup>ST</sup> VISIT	2 <sup>ND</sup> VISIT	3 <sup>RD</sup> VISIT	4 <sup>TH</sup> VISIT
0	No Tenderness				
1	Tenderness with Palapation without Grimace of Flinch				
2	Tenderness with Grimace of Flinch to Palpation				
3	Tenders with withdrawal (+ Jump Sign)				
4	Withdrawal (+ Jump Sign) to non-noxious stimuli				

GRADE	EXPLANATION	1st VISIT	2nd VISIT	3rd VISIT	4th VISIT
0	No Discharge				
1	Mild Discharge				
2	Moderate Discharge				
3	Severe Discharge				
4	Profuse Discharge				

#### Management of The Data:

The principal investigator will be responsible for coding the data.

#### ETHICS AND DISSEMINATION:

Research ethical approval after critical evaluation and presentation to the ethical committee has taken on research topic no. CTRI/2024/08/072454.

#### CONSENT AND ASSESSMENT:

Subjects will be given information in their native language regarding the specifics of their therapy in great detail. The patients will then be asked to provide their written consent before the beginning of the trial. The DISSEMINATION POLICY will take the form of presentations as well as the publication of papers.

### VII. DISCUSSION

Guggulu based Ksharasutra is medicated by Guggulu extract (11 coating), Apamarga Kshara (7 coating) and Haridra (3 coating). The combination of these medicines on thread helps in debridement and lysis of tissue and exerts anti-fungal, anti-bacterial and anti-inflammatory effects.

Saptang guggulu: As per Acharya Bhava Mishra compositions are 1. Guggulu 2. Haritaki 3. Amalki 4. Bibhitaka 5. Shunthi 6. Maricha 7. Pippali.

It is used in nadi, dusht vrana, shool, bhagander etc. As in reference it is used in dusht vrana, hence it is used in nadi vrana that is a type of vrana.

Guggulu based kshara sutra along with saptang guggulu: helps to avoid recurrence along with pus formation in nadi vrana. Thus, enhance rate of healing of nadi vrana.

### VIII. STATISTICAL ANALYSIS

Appropriate statistical method will be used to analyze the data collected in the above observations and

suitable conclusion drawn. This is a comparative study of Guggulu based kshara sutra with Saptang Guggulu and Guggulu based Kshara Sutra in the management of Pilonidal Sinus with the help of statistician.

#### CONCLUSION

Conclusion will be mentioned after the analyzing data.

#### REFERENCES

- [1] Vaidya Jadhavji Triakumji acharya, editor. Sushrut Samhita of Sushrut with the Nibandh sangraha commentary of Shree Dalhanacharya. Varanasi: Publisher Chaukhambha Surbharti Prakashan. Nidan Sthan, Chapter 10, Page no: 307-8 & Chikitsa Sthan, 2003; 17: 468.
- [2] R.C.G Russell, Norman S Willim, Christofer JK., editors. Bailey and Love's short practice of Surgery. 24th Edition. London: Publisher Holder Arnold; pp. 1249–50. [Google Scholar].
- [3] Dalhanacharya commentary Nibandhasangraha on Sushruta Samhita of Mahrishi Sushruta Sutrasthana, Chapter 11, verse 3, Varanasi: Chaukhambha Orientalia, 2002; 45.
- [4] Sri Jagdishwar Prasad Tripathi commentary on Cakradatta of Chakrapani, Nadi Vrana Chikitsa, verse 11, Varanasi: Chaukhambha Sanskrit Series office, 2008; 36 16
- [5] Sri Jagdishwar Prasad Tripathi commentary on Cakradatta of Chakrapani, Arsha Chikitsa, verse 148, Varanasi: Chaukhambha Sanskrit Series office, 2008; 91.