

A STUDY ON EFFICACY OF GUGGULU BASED APAMARGA KSHARASUTRA IN THE MANAGEMENT OF SHALYAJA NADIVRANA W.S.R TO PILONIDAL SINUS

Mayur Sherkhane¹, Sharad Kulkarni², Durgappa. H³

¹Consultant Surgeon (Ayurveda), Arihant Hospital, Bedkihal, Karnataka, India

²PhD Scholar, Dept. of Shalya Tantra, Ayurveda Mahavidyalaya, Hubli, Karnataka, India

³Associate Professor, Dept. of Shalya Tantra, GAMC, Shivamogga, Karnataka, India

Email: mayurnsherkhane@gmail.com

ABSTRACT

Shalyaja Nadivrana (Pilonidal sinus) is a *Kashtasadhya Vyadhi* because of presence of tuft of hair (*Shalya*). Until removal of this causative factor, this disease has high rate of recurrence. Management of Pilonidal Sinus has become a challenge because of its complications like post-operative pain, wound management, seroma and recurrence. In *Ayurveda* the effective treatment is *Ksharasutra* therapy. *Snuhi* based *Apamarga Ksharasutra* is standardized and is effective treatment in the management of *Shalyaja Nadivrana* but burning pain, local irritation during the course of therapy and difficulty in manufacturing process has limited its use. To overcome these lacunas this study was carried out at SJIM hospital Bengaluru and total of 40 patients were randomly allotted into two groups namely Group A with trial drug *Guggulu* based *Apamarga Ksharasutra* and Group B with Control drug *Apamarga Ksharasutra* with 20 patients in each group. Assessment was made on subjective (Pain, Discharge) and objective (Length of the track, Tenderness) parameters. Observations were made before the treatment and on every 7th day of the therapy until complete cutting of the track. The study showed that the trial drug was as good as the standard drug in the treatment of Pilonidal sinus. Results: Assessment of Pain, Discharge, Length of track and Tenderness in Group A showed 97.2%, 95.45%, 100% and 98.14% improvement and in group B 97.5%, 90.69%, 100% and 98.24% improvement respectively. Group A overall result was 97.69% and Group B overall result was 96.60%. Mean UCT of Group A was 8.16 days/cm and Group B was 9.69 days/cm with p value equals to 0.0001 which is highly significant.

Keywords: *Shalyaja Nadivrana*, Pilonidal Sinus, *Apamarga*, *Guggulu*, *Ksharasutra*.

INTRODUCTION

Nadivrana manifests due to negligence of *Vranashopha*¹. It persists due to presence of *Shalya* like *Bala* (hair) and *Puya* (pus). *Shalyaja Nadivrana* is one among the 8 types of *Nadivrana*². *Shalyaja Nadivrana* can be co-related with Pilonidal sinus.

Pilus means hair and *Nidus* means nest. Incidence of Pilonidal sinus is about 26 per 100,000 populations, typically in 20-30 years of age³. This disease is more common in males and mostly affects hairy men. The sinus extends into the subcutaneous planes as an in-

ected tract. On histopathological studies a stratified squamous epithelial lining of varying degrees of integrity is found in about half of the cases⁴. The present day management of Pilonidal sinus includes complete radical excision of the tract. Post operatively patients will have severe pain, discomfort, need long stay in hospital and requires prolonged dressings. High recurrence is common with adequate excision of the tract and proper post surgical wound management. *Ayurvedic* line of treatment includes para-surgical and surgical management like *Taila poorana*, usage of *Varti*, use of *Ksharasutra* and *Chedana*. *Ksharasutra* ligation is regarded as best method in the management of *Nadvirana*. This procedure is simple, effective, economical, safe and cost effective and can be performed on OPD basis. Guggulu based *Apamarga Ksharasutra* is prepared by *Guggulu Niryasa*, *Apamarga Kshara* and *Haridra Churna*.

OBJECTIVES

1. To evaluate the efficacy of *Guggulu* based *Apamarga Ksharasutra* in the management of *Shalyaja Nadvirana* w.s.r. to Pilonidal sinus
2. To evaluate the efficacy of *Apamarga kshara sutra* in the management of *Shalyaja Nadvirana* w.s.r to Pilonidal sinus.
3. To evaluate the comparative efficacy of *Guggulu* based *Apamarga Ksharasutra* & *Apamarga kshara sutra* in the management of *Shalyaja Nadvirana* w.s.r to Pilonidal sinus

METHODOLOGY

This study was conducted during the period of November 2014 to April 2016.

1. Source of Data:

Patients with classical features of *Shalyaja Nadvirana* attending the outpatient and inpatient departments of SJIM Hospital, Bengaluru were selected for the study.

2. Method of Collection of Data:

Total of 40 patients presenting with the features of *Shalyaja Nadvirana* mentioned in inclusion criteria were included for the study.

3. Inclusion Criteria:

Patients having signs & symptoms of *Shalyaja Nadvirana* such as pain, pus discharge, foul smell and presence of *Nadi* (track) in the natal cleft confirmed by probing.

4. Exclusion Criteria:

Patients associated with systemic diseases.
Patients associated with malignancy.

5. Materials Required:

Dressing trolley 1
Sterile swabs QS
Sterile gauges QS
Sterile pads QS
Sterile surgical gloves- No 6 1/2 QS
Sterile kidney tray QS
Sterile Artery forceps or mosquito forceps 2
Sterile Scissors (straight cutting) 2
Sterile Syringe 10ml QS
Lignocaine jelly 2% QS
Betadine QS
Probe- curved, malleable, metallic 3 different sizes
Surgical linen thread number 20 (Barbour's thread) QS
Guggulu based *Apamarga Ksharasutra* (sealed pack) 100 medium, 100 small
Apamarga Ksharasutra (sealed pack) 100 medium, 100 small
Shadow less OT lamp 1

Table 1

Study Design:

Double arm single blind study of 40 patients with *Shalyaja Nadvirana* randomized in two groups, Group-A and Group-B with 20 patients each.

Interventions adopted in both the Groups

Group A - Application of *Guggulu* based *Apamarga Ksharasutra* till Complete cutting of tract
Group B - Application of *Snuhi* based *Apamarga Ksharasutra* till Complete cutting of tract
Preparation of *Guggulu* based *Apamarga Ksharasutra* is as follows
Guggulu niryasa– 11 coatings
Guggulu niryasa + *Apamarga Kshara* – 7 coatings

Guggulu niryasa + Haridra churna – 3 coatings

This was prepared in the hospital using Barbour's thread number 20. One coating was applied each day and kept for drying in the *Ksharasutra* cabinet. A total of 21 days was needed to complete the preparation of the thread.

After this the threads were cut in 2 sizes; Medium length- 16cm, small length-

10cm and packed in a sterile sealed pack after placing in the UV cabinet with a small pack of silica inside to absorb moisture. All these were then packed in air tight container and stored keeping it away from contact with any moisture.

Preparation of Apamarga Ksharasutra is as follows

Snuhi ksheera – 11 coatings

Snuhi ksheera + Apamarga Kshara – 7 coatings

Snuhi ksheera + Haridra churna – 3 coatings

This was prepared in the hospital using Barbour's thread number 20. One coating was applied each day and kept for drying in the *Ksharasutra* cabinet. A total of 21 days was needed to complete the preparation of the thread.

After this the threads were cut in 2 sizes; Medium length-16cm, small length- 10cm and packed in a sterile sealed pack after placing in the UV cabinet with a small pack of silica inside to absorb moisture. All of these were then packed in air tight container and stored keeping it away from contact with any moisture.

Procedure

For both the groups required materials were kept ready. Procedure was explained to the patient and informed written consent was taken.

Group A

For the patients in Group A, *Guggulu* based *Apamarga Ksharasutra* prepared as per standard methods under strict aseptic precautions was applied.

Procedure of Ksharasutra application

Patient was placed in prone position. Under aseptic precautions local anaesthesia was administered and probing was done to the sinus track starting from the

opening having discharge and wider opening (may be primary opening at midline of natal cleft or secondary opening other than midline) till the resistance was felt, then an artificial opening was made over the skin at the site of resistance thus making the sinus having two openings, if there is a direct communication between primary and secondary opening then no need of creating an artificial opening. A suitable length of plain thread was taken and threaded into the eye of probe. Then probe was pulled out through the other opening thus leaving plain thread in the track. The two ends of the Plain thread were then tied together with a moderate tightness; this procedure is called probing and primary threading. On the seventh day *Guggulu* based *Apamarga Ksharasutra* application was done. Patient was advised to attend his/her normal duty during the treatment period.

Changing of the Ksharasutra

The *Guggulu* based *Apamarga Ksharasutra* was tied to the previously applied primary thread between one opening (which is having wider mouth) and the knot. Then an artery forceps was applied to the primary thread proximal to the other opening. Then the old thread was cut between the artery forceps and the knot. Pulling of the artery forceps along with the thread ultimately replaces the old thread by *Guggulu* based *Apamarga Ksharasutra*. Then the two ends are tied snugly and a sterile pad dressing was done. This procedure is Railroad technique.

Follow up: Successive changes were done at weekly interval. The same procedure was followed for successive changes.

Observation: The observations made before the treatment and on fresh application of *Ksharasutra* were recorded in the proforma of the case sheet prepared for the study.

Duration: Till complete cutting of the tract.

Group B

For the patients in Group B, *Apamarga Ksharasutra* prepared as per standard methods under strict aseptic precautions was applied. The application and chang-

ing of *Ksharasutra* was followed similar to that in Group A

Follow up: Successive changes were done at weekly interval. The same procedure was followed for successive changes.

Observation: The observations made before the treatment and on every day of fresh application of *Ksharasutra* were recorded in the proforma of the case sheet prepared for the study.

Duration: Till complete cutting of the tract.

Post primary threading/ *Ksharasutra* threading: Patients were advised sitz bath with luke warm water twice daily for 20 minutes.

Duration fixed for observing recurrence:

Duration of 45 days from the day of total cutting and healing of the tract was fixed to observe the possibility of recurrence and the same was recorded in the proforma of the case sheet prepared for the study.

8. Assessment Criteria

a) Subjective

I. Pain

Pain was assessed by Wong-Baker faces pain reading scale

Patients were asked to choose a face which best describes how much pain he/she had

Wong-Baker FACES™ Pain Rating Scale



II. Discharge

D0– No discharge

D1–Mild discharge (wets 2x 2 cm gauze piece/ day)

D2– Moderate discharge (wets 2 x 2cm 2 gauze piece/day)

D3– Severe discharge (wets 2 x 2cm >2 gauze piece/day)

b) Objective

I. Length of the track measured at every sitting in cm.

II. Tenderness

Tenderness was assessed by Wong-Baker faces pain reading scale

Patients were asked to choose a face which best describes how much pain/discomfort he/she experienced on gradual exertion of pressure at and around the sinus track.

Wong-Baker FACES™ Pain Rating Scale



OVERALL ASSESSMENT

The net results obtained from various parameters of assessment by the treatment were taken into consideration to assess the overall effect of the treatment.

- Marked response: >75% to <100% relief in all the features i.e. pain, discharge, length of the tract and tenderness.

- Moderate response: >50% to <75% relief from all features i.e. pain, discharge, length of the tract and tenderness.
- Mild response: >25% to <50% relief from all features i.e. pain, discharge, length of the tract and tenderness.
- Poor response: <25% relief from all features i.e. pain, discharge, length of the tract and tenderness.

Results were statistically analyzed within the group and between the groups using student t test & conclusions were drawn.

OBSERVATIONS AND RESULTS

The efficacy of *Guggulu* based *Apamarga Ksharasutra* and Standard *Apamarga Ksharasutra* has been studied in 40 cases in Department of P.G Studies in *Shalyatantra* GAMC Bengaluru at SJIM Hospital and they were selected randomly and divided into two groups each containing 20 cases. Sub-

jects under Group A were treated with *Guggulu* based *Apamarga Ksharasutra* and Group B were treated with Standard *Apamarga Ksharasutra*. Subjective and objective changes were considered for the assessment of the research work. All 40 patients of *Shalyaja Nadvirana* have been analyzed for age, sex, *Prakriti*, chronicity of disease, length of the track, unit cutting time were observed and noted. The Unit cutting time means the time taken by *Ksharasutra* to cut one centimeter of fistulous track in days. This was calculated using the formula.

Unit Cutting Time = Total No. of days taken for cut through = days/Initial length of track (cm)

The average Unit Cutting Time of treated group was calculated and compared with Unit Cutting Time of standard group. The process of healing was started with the cutting of the track during the course of treatment. However, the small area was still remained to heal completely at the end of total cut through.

Table 1: Comparative results of Group-A and Group-B

Characteristics	Group-A			Group-B		
	Mean score		Percentage of relief	Mean score		Percentage of relief
Signs and Symptoms	BT	AT		BT	AT	
Pain	3.60	0.10	97.2	4.00	0.10	97.5
Discharge	2.20	0.10	95.45	2.15	0.20	90.69
Length Of The Track In Centimeter	3.02	0.00	100	3.17	0.00	100
Tenderness	5.40	0.10	98.14	5.70	0.10	98.24

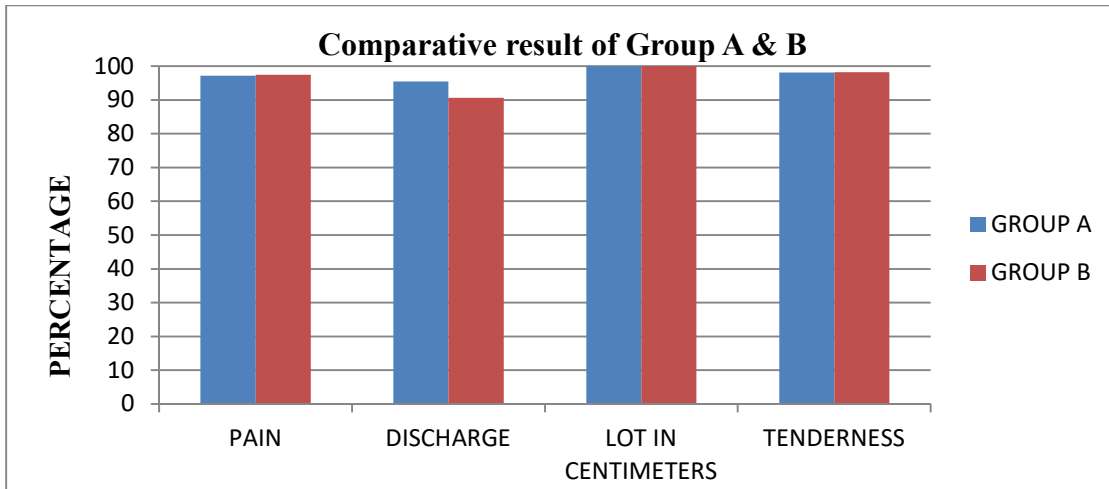
Result of Group A

The percentage of improvement in Group A on Pain was 97.2%, Discharge was 95.45%. Length of the Track in Centimeter was 100%, and in Tenderness was 98.14%.

Result of Group B

The percentage of improvement in Group B on Pain was 97.5%, Discharge was 90.69%, Length of the Track in Centimeter was 100% and Tenderness was 98.24%.

Group A	Group B	Mean Difference	S.D	SE	t value	P value
97.69%	96.60%	1.09%	4.08	2.25	0.48	0.645



Graph No. 26 Comparative results of Group-A and Group-B

Comparative analysis of the overall effect of the treatment in both the groups was done by statistically with Paired t test and Unpaired t test. The tests showed that the treatment is statistically not signifi-

cant in Group A when compared to Group B. Group A overall result is 97.69% and Group B overall result is 96.60%.

Comparative results of Group A and Group B in Percentage

Group A	Group B	Mean Difference	S.D	SE	t value	P value
97.69%	96.60%	1.09%	4.08	2.25	0.48	0.645



Comparative results of Group A and Group B in Percentage

DISCUSSION

Guggulu has Laghu, Ruksha, Vishada, Sukshma, Sara Gunas, Ushna virya, having Tridoshahara and Lekhana properties. Guggulu is safe and analgesic.

Apamarga has Laghu, Ruksha, Tikshna guna, Ushna virya and possesses properties like Vranashodhaka, Shophahara. Kshara prepared using Apamarga have Chedana, Bhedana, Lekhana, Shodhana and Ropana

properties. According to classics *Snuhi kshira* is used in the preparation of *Ksharasutra*. But *Snuhi kshira* is not available throughout the year. The time of collection is in *Adanakala* particularly in *Shishira Ritu*. Due to this fact we should collect the *Kshira* in February-March. As an alternative to *Snuhi kshira*, *Guggulu* is used because as it is available in bulk, has binding properties, can be preserved and used for long duration and it has analgesic effect. Considering all these factors an attempt is made in this study to substitute *Snuhi Kshira* by *Guggulu Niryasa* for the preparation of *Ksharasutra* used in the management of *Shalyaja Nadivrana*.

Effect of treatment on pain

The mean score of pain which was 3.60 and 4.00 in Group A and Group B before the treatment was reduced to 0.10 and 0.10 respectively after the treatment. Pain was usually observed to be more after the first application of *Ksharasutra* in Group A treated with *Guggulu Based Apamarga Ksharasutra* compared to the control Group B of *Apamarga Ksharasutra*, there was 38.89% and 52.5% on 14th day pain relief in Group A and Group B respectively. Pain is usually not a dominant feature in Pilonidal Sinus. It is present in the stage of Abscess rather than the stage of Pilonidal sinus itself. But, Pain is often complained by the patient when there is accumulation of pus, in the sinus track. This can be managed by *Vedanasthapana*, *Lekhana*, *Vrana Shodhana* and *Ropana* property of *Guggulu* in Group A.

Effect of treatment on discharge

The mean score of discharge which was 2.20 and 2.15 in Group A and Group B before the treatment was reduced to 0.10 and 0.20 respectively after the treatment. Pilonidal Sinus is basically a discharge dominant disease entity. This is one parameter which is definitely present in most of the patients. It was noted that as long as the discharge persists patient complains of pain. There was 84.1% and 71.75% relief on 28th day of treatment in Group A and Group B respectively. Pilonidal Sinus is secondary to Pilonidal abscess, which is lined with unhealthy

granulation tissue, where discharge is due to micro-organism activity. Thus Antibacterial property of *Guggulu* helped in relieving of discharge and cut the track healthy as effective as *Apamarga Ksharasutra*.

Effect of treatment on length of the tract:

Since the duration of the study was fixed up to complete cutting of the track, all the cases were followed up till it was cured. The length of the track was noted at every sitting and graph plotted to see the weekly decrease in length. The decrease in length was based on the amount of fibrotic tissue and amount of discharge, the more fibrosed tissue and discharge the slower was the decrease in the length. The decrease in length of track was faster in group A which was treated with *Guggulu based Apamarga Ksharasutra*.

Effect of treatment on Tenderness

Here the mean score of tenderness was 5.40 in group A and 5.70 in group B before treatment and was reduced to 0.10 and 0.10 after the treatment. There was 92.6% and 82.46% relief on 28th day treatment in Group A and Group B respectively. In Group A tenderness was relieved almost 100% On 35th day mostly because of anti inflammatory, *Vrana Shodhana* & *Ropana* properties of *Guggulu*.

Effect of treatment on Unit Cutting Time

The pH of drugs in Group A (*Guggulu based Apamarga Ksharasutra*) were compared with standard (*Apamarga Ksharasutra*) in Group B. The pH of the *Ksharasutra* in Group A was 9.5 and in Group B, 9.8. This shows that both the *Ksharasutra* were alkaline. In Group A the mean UCT was 8.1 days/cm and in Group B it was 9.69 days/cm. When comparing the result between the groups the test was highly statistically insignificant

Probable mode of action of Guggulu based Apamarga Ksharasutra

The *Guggulu* which has *Lekhana*, *Vrana Shodhana*, *Ropana* and anti-bacterial properties counteract the pain, discharge and tenderness easily within short duration and ensures healthy granulation tissue to develop and cuts the track completely because of *Chedana*, *Bhedana*, *Ksharana*, *Kshanana*, *Shothahara* properties of *Apamarga Kshara* is simi-

lar to standard *Snuhi* based *Apamarga Ksharasutra*. While changing the *Ksharasutra* by rail road method on every 7th day, both the old and new knots were passed through the track. While doing so, the hair which was collected inside the track got entrapped in knots and came out. These foreign bodies inhibit full healing by producing foreign body reaction, formation of foreign body giant cells and chronic inflammation. When the foreign bodies are removed it will help in faster cutting and healing of track. If hair remains inside the track there will be recurrence. In this study of 40 patients during the follow up period there was no recurrence.

SCOPE FOR FURTHER RESEARCH

1. Histopathological studies can be done to note the changes.
2. *Guggulu* based *Apamarga Ksharasutra* merits further studies with the larger sample size.

3. Needs to be compared with the available databases of *Ksharasutra* after a larger study is done.

4. Other *Kshara* such as *Palasha*, *Chitraka*, *Kadali* must be tried instead of *Apamarga Kshara* keeping *Guggulu* as base in the preparation of *Ksharasutra* which may yield still more better results.

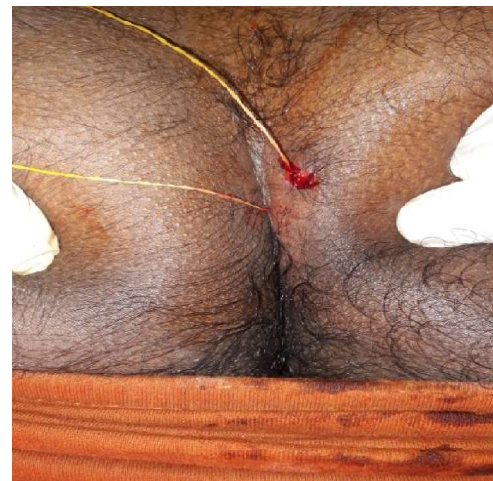
CONCLUSION

The parameters of assessment i.e. pain (Group A 97.2%, Group B 97.5%), discharge (Group A 95.45%, Group B 90.69%), length of track (Group A 100%, Group B 100%), tenderness (Group A 98.14%, Group B 98.24%) showed statistically significant improvement during the observation period. Group A overall result is 97.69% and Group B overall result is 96.60%. Hence both groups showed excellent/marked response

The trial drug *Guggulu* based *Apamarga Ksharasutra* showed promising results and hence *Guggulu* can be used as a substitute to *Snuhi kshira*.



Before Treatment



Probing and Primary Threading



Guggulu based Apamarga Ksharasutra



Tuft of hair came out during changing of

Ksharasutra



Track completely cut and healed

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