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## A study on the effectiveness of *Guggulu* based *Karanja Ksharasutra* in comparison with *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* with special reference to *Pilonidal Sinus*

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### ABSTRACT

*Shalyaja Nadivrana* is an *Agantuja* variety of *Vrana*. *Nidana Panchaka* and treatment is extensively described in *Sushruta Samhita* - *Nidhana* and *Chikitsa Sthana*. Presence of *Shalya* in the tract is an obstacle to its healing. Management of *Nadivrana* includes *Ksharasutra* therapy. The pilonidal sinus is an acquired sinus that develops in young, hirsute men, usually in the intergluteal cleft caused by the intrusion of hair into the skin, causing an abscess and gradually forming a sinus. The study was conducted on 40 randomly assigned patients at SJAUM Hospital, Bengaluru by dividing them into 2 groups - Group A and Group B. These groups were treated with *Guggulu*-based *Karanja Ksharasutra* and *Apamarga Ksharasutra* respectively. Assessment of pain, discharge, LOT, tenderness, and induration in Group A showed 91.67%, 91.3%, 99.9%, 85.19%, 95% and 75.6% improvement and Group B showed 87.5%, 86.96%, 100%, 78.6% and 97.37% improvement respectively. Group A's overall result was 89.5% and Group B's overall result was 89.9%. The mean UCT of Group A was 8.3 days/cm and Group B was 7.9 cm/day with *p*-value <0.05 which is significant. The study showed that the trial drug was as good as the control drug in the management of *Shalyaja Nadi Vrana*.

**Key words:** *Shalyaja Nadi Vrana*, *Pilonidal Sinus*, *Apamarga*, *Guggulu*, *Karanja*, *Kshara Sutra*

### INTRODUCTION

*Shalyaja Nadivrana* is a type of *Nadivrana* explained in *Sushruta Samhita*. *Nadivrana* manifests as a complication of *Vranashopha*. *Shalya* (foreign body) like *Kesha* (hair) enters into *Twagadi Dhatu* resulting in the manifestation of "*Shalyaja Nadivrana*",<sup>[1]</sup> Characteristically, non-healing tract with continuous pain, frothy, clear or blood-tinged discharge. In

contemporary medical science it can be correlated to Pilonidal sinus.<sup>[2]</sup> Broken hair tends to collect in natal cleft, eventually penetrates skin to form the Pilonidal sinus. Its incidence is about 26/1 lakh population typically seen in the hirsute male than in female in the ratio of 6:1.<sup>[3]</sup>

The current management involves radical excision of tract, evacuation & curettage which requires anaesthesia, hospitalization & long-term post-op dressing. Recurrence is as common as 20% even with adequate excision and proper dressing.

Ayurvedic management for *Shalyaja Nadivrana* includes *Bhedhana*, *Ksharasutra* and *Vartiprayoga*. *Ksharasutra* ligation is regarded as the best method as it is effective, economical and simple OPD procedure.

*Guggulu* based *Karanja Ksharasutra* has *Guggulu*, *Karanja Kshara* & *Haridra* as its ingredients. *Guggulu* has *Sukshma*, *Tridoshagna*, *Lekhana*, *Vedhana* *Stapana*, *Shodhana Guna* and acts as binding agent.

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*Karanja* has the properties of *Bhedana*, *Shothahara*, *Krimihara* and *Vranashodhana*.<sup>[4]</sup>

This study was conducted in the SJAUM hospital Bengaluru and a total of 40 patients were randomly allotted into two groups namely Group A with trial drug i.e., *Guggulu* based *Karanja Ksharasutra* and Group B with standard drug *Apamarga Kshara Sutra* with 20 patients in each group. Assessments were made on subjective (pain, discharge) and objective (Tenderness, induration and Length of the tract) parameters. Observations were before the treatment and on every 7th day of the therapy until the complete cutting of the track.

## AIM

To evaluate the effectiveness of *Guggulu* based *Karanja Ksharasutra* in comparison with *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* w.s.r. to Pilonidal Sinus.

## OBJECTIVES

1. To evaluate the individual effectiveness of *Guggulu* based *Karanja Ksharasutra* and *Apamarga Ksharasutra* in the management of *Shalyaja Nadi Vrana* with special reference to Pilonidal sinus.
2. To evaluate the comparative effectiveness of *Guggulu* based *Karanja Ksharasutra* and *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* with special reference to Pilonidal Sinus.

## Null hypothesis

*Guggulu* based *Karanja Ksharasutra* is not as effective as *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana*.

## Alternate hypothesis

*Guggulu* based *Karanja Ksharasutra* is as effective as *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana*.

## METHODOLOGY

The study was conducted during the period of December 2020 to February 2022. Source of data

Patients with classical features of *Shalyaja Nadivrana* were selected from OPD of SJAUM Hospital, Bengaluru.

## Method of collection of data

A total number of 40 patients presenting with the clinical features of *Shalyaja Nadivrana* (Pilonidal Sinus) mentioned in inclusion criteria were included in the present study.

## Inclusion criteria:

- Patients presenting with the clinical features of *Shalyaja Nadivrana* such as pain, pus discharge, and presence of a single or multiple sinus opening with tracts, not exceeding 3 in number, in the natal cleft.
- Age - 18 years to 50 years.

## Exclusion criteria

- Patients associated with uncontrolled Diabetes mellitus and Hypertension and systemic diseases like Tuberculosis.
- Patients with Osteomyelitis of Sacrum or coccyx.
- Immune compromised conditions and Malignancy.
- Pregnant women.
- Lactating women.
- Patients with congenital Spinal deformities.

## Sampling design

A total of 40 patients fulfilling the above criteria were included in the study and were randomly allotted into 2 groups namely Group-A and Group-B with 20 patients each.

## Intervention

*Ksharasutra* preparation is done as per standard method. Chemical analysis of the drugs was done at "Drug testing laboratory," Department of Ayush, Government of Karnataka.

- a) **Guggulu:** Loss on drying – 9.53%, Total Ash – 5.67, Acid insoluble ash – nil, Water Soluble Ash - 57.62%
- b) **Karanja Kshara:** Loss on drying – 6.8%, Total Ash – 84.7%, Acid insoluble Ash – 11.34%, Water Soluble

Ash – 85.75%, Specific Gravity at 270 C – 1.6597, pH – 10.3, Refractive Index – 1.3458

c) **Haridra Choorna:** pH 6.2

d) **Apamarga Kshara:** Loss on drying – 10.005%, Total Ash – 80.93%, Acid insoluble Ash – 63.11%, Water Soluble Ash – 93.82%, Specific Gravity at 270 C – 1.5472, pH – 10.82

e) **Snuhi Ksheera:** pH – 5.6

### Study Design

#### Methodology of Group - A

Patients of Group-A will be treated with *Guggulu* based *Karanja Kshara Sutra* prepared as per standard method.

#### Methodology of Group-B

Patients of Group-B will be treated with *Apamarga Kshara Sutra* prepared as per standard method.

#### Procedure of *Ksharasutra* application

Pre-operative procedure

- Written consent was taken.
- Injection TT 0.5ml IM,
- Injection xylocaine 2% 0.1 ml SC given as TD,
- Vital examination noted.

#### Operative procedure

Patient was placed in the prone position. Painting and draping done. Local anaesthesia (dose - as per the body weight) was infiltrated in required cases. Under aseptic precautions, Probing was done into the tract till the resistance was felt, following which an artificial opening was made at the site. In the case of multiple tracts, Probing was done from the primary opening till the secondary opening (farthest) is reached. A plain thread was then passed through the eye of the probe and the probe was pulled out gently, leaving behind the thread. The ends of the thread were now tied together moderately tight.

#### Post-Operative Care

Patient was advised to take sitz bath in lukewarm water once a day, for 20 minutes.

Patient was advised to attend normal day-to-day activities during the period of treatment. Instructions about personal hygiene, suitable *Pathya Apathyas*, and follow-up were given.

#### Change of *Ksharasutra*

After 3 days, the plain thread was replaced by *Guggulu* based *Karanja Ksharasutra* following the Rail-road method.

On every 7<sup>th</sup> day *Ksharasutra* was replaced by a new one, till the tract was cut.

Initial length of the tract and change in length of tract was measured on day1 and on every successive 7<sup>th</sup> day after changing the *Ksharasutra*.

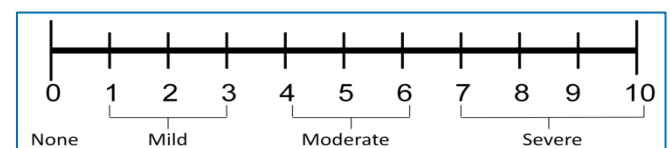
#### Follow up

Follow-up was done up to 45 days from the day of healing of tract to note if there is any recurrence.

#### Assessment Criteria

##### Subjective parameters

1. **Pain** - Assessment of pain was done using the "Numerical Rating scale": Adopted from McCaffery, M. and Beebe, A. (1989)



0 – No pain

1-3 - Mild pain

4-6 – Moderate pain

7-10 – Severe pain

##### 2. Discharge

Grade 0 - no discharge

Grade 1 - mild discharge [wets 0.5cm X 0.5cm gauze piece/day]

Grade 2 - moderate discharge [wets 1cm X 1cm gauze piece/day]

Grade 3 - severe discharge [wets >1cm X >1cm gauze piece/day]

**Objective parameters**

- 1. Length of the tract** was measured in every sitting, expressed in centimetres.
- 2. Unit cutting time [U.C.T]** the unit cutting time represents the number of days required to cut 1 cm of the tract. This was calculated by dividing the total number of days taken to cut the tract by the initial length of the tract denoted as days/cm.<sup>4</sup>

$$U.C.T = \frac{\text{Total number of days}}{\text{The initial length of the tract}}$$

- 3. Induration:** The induration around the sinus opening was measured for its diameter in millimetres using a flexible ruler and noted in every sitting and graded as follows.

- 0 - No induration
- 1 – 1 mm to 10 mm
- 2 – 11 mm to 20 mm
- 3 – 21 mm to 30 mm
- 4 – 31 mm to 40 mm
- 5 – 41 mm to 50 mm

- 4. Tenderness:** The sinus opening was gently palpated to assess the tenderness.

- 0 - No tenderness
- 1 – Tenderness without Grimace/Flinch
- 2 – Tenderness with Grimace and/or Flinch
- 3 – Tenderness with Withdrawal
- 4 – Withdrawal to Non-noxious stimuli like superficial palpation

**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 - pain, discharge, length of the tract, induration, and tenderness.

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

The result obtained was statistically analysed using the Unpaired T-test and the conclusions were drawn.

**OBSERVATION AND RESULTS**

Total 40 patients were randomly allotted into 2 groups. Observations were recorded and necessary charts and graphs were made. maximum number of patients i.e., 45% were in the age group 21 - 30 years. 75% were male patients and 25% were female. Maximum patients’ Socio-Economic Status was Middle Class i.e., 77.50%. 72.50% patients had sitting type of nature of work, 17.5% had travelling nature of work. 72.5% had history of 1 to 5 months. Maximum i.e., 80% patients had excess perspiration. Maximum i.e., 65.00% patients were with dense hair distribution. Maximum i.e., 87% were with normal weight.

**1) Pain**

**Table 1: Effect of Group-A on Pain in Shalyaja Nadivrana (pilonidal sinus)**

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT	AT	BT - AT	AT - BT					
Pain	2.40	1.90	0.50	0.90	20.83	0.513	0.118	2.39	<0.05
	14th Day	1.50	0.90	0.60	37.50	0.718	0.165	3.60	<0.05
	21st	0.80	1.60	0.80	66.67	0.598	0.137	7.80	<0.05

	Day								
	28 <sup>th</sup> Day	0.45	1.95	81.25	0.394	0.090	11.09	<0.05	
	35 <sup>th</sup> Day	0.20	2.20	91.67	0.410	0.094	15.16	<0.05	

In this work of 20 patients studied in *Shalyaja Nadivrana* (pilonidal sinus) with Group-A Pain revealed is given in detail in Table. Statistical analysis showed that the mean score which was 2.40 before the treatment was reduced to 0.80 after the treatment and after follow up it became 0.20 with a 91.67% improvement and there is a statistically significant. (P<0.05) results are graphically represented in figure.

**Table 2: Effect of Group - B on Pain of *Shalyaja Nadivrana* (pilonidal sinus)**

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT	AT	BT - AT						
Pain	2.40	7 <sup>th</sup> Day	1.80	0.60	25.00	0.503	0.115	2.92	<0.05
		14 <sup>th</sup> Day	1.45	0.95	39.58	0.686	0.157	3.97	<0.05
		21 <sup>st</sup> Day	0.70	1.70	70.83	0.571	0.131	8.56	<0.05
		28 <sup>th</sup> Day	0.40	2.00	83.33	0.562	0.129	10.57	<0.05
		35 <sup>th</sup> Day	0.30	2.10	87.50	0.447	0.103	15.16	<0.05

In this work of 20 patients studied in *Shalyaja Nadivrana* (pilonidal sinus) with Group-B Pain revealed are given in detail in Table. Statistical analysis showed that the mean score which was 2.40 before the treatment was reduced to 0.40 after the treatment and after follow up it became 0.30 with an 87.50% improvement and there is a statistically significant. (P<0.05).

**2) Discharge**

**Table 3: Effect of Group-A on Discharge of *Shalyaja Nadivrana* (Pilonidal sinus)**

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT	AT	BT - AT						
Discharge	1.15	7 <sup>th</sup> Day	0.70	0.45	39.13	0.510	0.117	3.38	<0.05
		14 <sup>th</sup> Day	0.60	0.55	47.83	0.510	0.117	3.95	<0.05
		21 <sup>st</sup> Day	0.30	0.85	73.91	0.587	0.135	6.38	<0.05
		28 <sup>th</sup> Day	0.15	1.00	86.96	0.562	0.129	8.63	<0.05
		35 <sup>th</sup> Day	0.10	1.05	91.30	0.510	0.117	9.81	<0.05

An assessment of Discharge in patients of *Shalyaja Nadivrana* (pilonidal sinus) before and after the treatment with Group-A showed a reduction in the mean score from 1.15 to 0.15 after the treatment and after follow up it became 0.10 with 91.30% improvement. It is found to be statistically significant (P<0.05). The details are shown with statistical data in Table and graphically represented in the figure.

**Table 4: Effect of Group-B Discharge of Shalyaja Nadivrana (pilonidal sinus)**

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT		AT	BT - AT					
Discharge	1.15	7 <sup>th</sup> Day	0.80	0.35	30.43	0.489	0.112	2.19	<0.05
		14 <sup>th</sup> Day	0.65	0.50	43.48	0.513	0.118	2.93	<0.05
		21 <sup>st</sup> Day	0.35	0.80	69.57	0.523	0.120	5.17	<0.05
		28 <sup>th</sup> Day	0.20	0.95	82.61	0.510	0.117	6.65	<0.05
		35 <sup>th</sup> Day	0.15	1.00	86.96	0.459	0.105	7.32	<0.05

An assessment of Discharge in patients of *Shalyaja Nadivrana* (pilonidal sinus) before and after the treatment with Group-B showed a reduction in the mean score from 1.15 to 0.20 after the treatment and after follow up it became 0.15 with 86.96% improvement. It is found to be statistically significant (P<0.05). The details are shown with statistical data in Table and graphically represented in the figure.

**3) LOT (Length of the tract)**

**Table 5: Effect of Group-A LOT of Shalyaja Nadivrana (pilonidal sinus)**

Symptom	Mean score				%	S.D (±)	S.E (±)	T value	p-value
	BT		AT	BT - AT					
LOT	3.69	7 <sup>th</sup> Day	2.80	0.89	24.00	0.268	0.062	4.19	<0.05

Day									
14 <sup>th</sup> Day	1.91	1.78	48.20	0.417	0.096	8.17	<0.05		
21 <sup>st</sup> Day	0.96	2.73	73.97	0.499	0.114	12.57	<0.05		
28 <sup>th</sup> Day	0.37	3.32	89.97	0.580	0.133	18.28	<0.05		
35 <sup>th</sup> Day	0.01	3.68	99.86	0.698	0.160	23.59	<0.05		

The magnitude of LOT in patients of *Shalyaja Nadivrana* (pilonidal sinus) before and after the treatment was assessed and analysed statistically. Patients registered in the Group-A group showed significant improvement (P<0.05). The mean score which was 3.69 before treatment reduced to 0.37 after the treatment and after follow up it become 0.01 with a 99.86% improvement. Further, the particulars are tabled below in Table and graphically represented in the figure.

**Table 6: Effect of Group-B on LOT of Shalyaja Nadivrana (pilonidal sinus)**

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT		AT	BT - AT					
LOT	3.24	7 <sup>th</sup> Day	2.37	0.87	26.80	0.182	0.042	3.76	<0.05
		14 <sup>th</sup> Day	1.44	1.80	55.44	0.221	0.051	8.08	<0.05
		21 <sup>st</sup> Day	0.59	2.65	81.78	0.387	0.089	13.50	<0.05

	Day							
	28 <sup>th</sup> Day	0.17	3.07	94.90	0.553	0.127	17.88	<0.05
	35 <sup>th</sup> Day	0.00	3.24	100.0	0.716	0.164	20.22	<0.05

The magnitude of LOT in patients of *Shalyaja Nadivrana (pilonidal sinus)* before and after the treatment was assessed and analyzed statistically. Patients registered in the Group-B group showed statistically significant improvement (P<0.05). The mean score which was 3.24 before treatment reduced to 0.17 after the treatment and after follow up it become 0.00 with 100% improvement. Further, the particulars are tabled below in Table and graphically represented in the figure.

4) Tenderness

Table 7: Effect of Group-A Tenderness of *Shalyaja Nadivrana (pilonidal sinus)*

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT	AT	BT - AT	BT - AT					
Tenderness	1.35	7 <sup>th</sup> 05	1.03	0.30	22.22	0.470	0.108	1.59	<0.05
		14 <sup>th</sup> 75	0.60	0.60	44.44	0.598	0.137	3.33	<0.05
		21 <sup>st</sup> 40	0.95	0.37	70.37	0.686	0.157	5.07	<0.05
		28 <sup>th</sup> 35	1.00	0.07	74.07	0.649	0.149	5.39	<0.05

	Day							
	35 <sup>th</sup> Day	0.20	1.15	85.19	0.587	0.135	7.18	<0.05

The magnitude of Tenderness in patients of *Shalyaja Nadivrana (pilonidal sinus)* before and after the treatment was assessed and analysed statistically. Patients registered in the Group-A group showed significant improvement (P<0.05). The mean score which was 1.35 before treatment reduced to 0.35 after the treatment and after follow up it become 0.20 with an 85.19% improvement. Further, the particulars are tabled below in Table and graphically represented in the figure.

Table 8: Effect of Group-B on Tenderness of *Shalyaja Nadivrana (pilonidal sinus)*

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT	AT	BT - AT	BT - AT					
Tenderness	1.40	7 <sup>th</sup> 15	1.25	0.15	17.86	0.444	0.102	1.24	>0.05
		14 <sup>th</sup> 80	0.60	0.60	42.86	0.598	0.137	3.13	<0.05
		21 <sup>st</sup> 45	0.95	0.86	67.86	0.686	0.157	5.40	<0.05
		28 <sup>th</sup> 40	1.00	0.43	71.43	0.795	0.182	5.72	<0.05
		35 <sup>th</sup> 30	1.10	0.57	78.57	0.788	0.181	6.47	<0.05



The magnitude of Tenderness in patients of *Shalyaja Nadivrana* (pilonidal sinus) before and after the treatment was assessed and analyzed statistically. Patients registered in the Group-B group showed statistically significant improvement ( $P<0.05$ ). The mean score which was 1.40 before treatment reduced to 0.40 after the treatment and after follow up it become 0.30 with a 78.57% improvement. Further, the particulars are tabled below in Table and graphically represented in the figure.

### 5) Induration

**Table 9: Effect of Group-A Induration of *Shalyaja Nadivrana* (pilonidal sinus)**

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT	AT	BT - AT	BT - AT					
Induration	2.25	7 <sup>th</sup> Day	1.90	0.35	15.56	0.587	0.135	1.85	<0.05
		14 <sup>th</sup> Day	1.65	0.60	26.67	0.598	0.137	2.90	<0.05
		21 <sup>st</sup> Day	1.30	0.95	42.22	0.686	0.157	3.95	<0.05
		28 <sup>th</sup> Day	0.85	1.40	62.22	0.681	0.156	6.06	<0.05
		35 <sup>th</sup> Day	0.55	1.70	75.56	0.571	0.131	9.30	<0.05

The magnitude of Induration in patients of *Shalyaja Nadivrana* (pilonidal sinus) before and after the treatment was assessed and analyzed statistically. Patients registered in the Group-A group showed significant improvement ( $P<0.05$ ). The mean score

which was 2.25 before treatment reduced to 85 after the treatment and after follow up it become 0.55 with a 75.56% improvement. Further, the particulars are tabled below in Table and graphically represented in the figure.

**Table 10: Effect of Group-B on Induration of *Shalyaja Nadivrana* (pilonidal sinus)**

Symptom	Mean score				%	S.D (±)	S.E (±)	t value	p-value
	BT	AT	BT - AT	BT - AT					
Induration	1.35	7 <sup>th</sup> Day	1.65	0.25	13.16	0.550	0.126	1.14	<0.05
		14 <sup>th</sup> Day	1.40	0.50	26.32	0.607	0.139	2.26	<0.05
		21 <sup>st</sup> Day	1.00	0.90	47.37	0.641	0.147	4.26	<0.05
		28 <sup>th</sup> Day	0.70	1.20	63.16	0.616	0.141	5.51	<0.05
		35 <sup>th</sup> Day	0.05	1.85	97.37	0.745	0.171	11.00	<0.05

The magnitude of Induration in patients of *Shalyaja Nadivrana* (pilonidal sinus) before and after the treatment was assessed and analyzed statistically. Patients registered in the Group-B group showed statistically significant improvement ( $P<0.05$ ). The mean score which was 1.35 before treatment reduced to 0.70 after the treatment and after follow up it become 0.05 with a 97.37% improvement. Further, the particulars are tabled below in Table and graphically represented in the figure.

6. UCT (Unit Cutting Time)

Table 11: Individual unit cutting rate

Group	1	2	3	4	5	6	7	8	9	10
A	7.7	9.8	7.2	7.5	8.2	7.6	8.7	7.2	8.7	8.1
B	6.5	7.5	9	8.4	6.2	7.1	8	8	7.8	8.6
Group	11	12	13	14	15	16	17	18	19	20
11	12	13	14	15	16	17	18	19	20	8.8
8	7.1	7.8	9.6	8	7.1	12.5	8.5	8	8.8	7.6
7.1	7.6	8.5	6.8	7.7	8	8.6	9.2	10	7.6	

Table 12: Showing the effect on U.C.T. in Group A and Group B

	Mean	Maximum (days/cms)	Minimum (days/cms)	Range (days/cms)
Group A	8.34	9.2	7.29	2
Group B	7.91	12	7.1	2.9

The comparative result of Unit Cutting Time (UCT) in Shalyaja Nadi Vrana in Group A is 8.34 and in Group B is 7.91, when comparing the Group A and Group B the test showed statistically very significant results.

Assessment of total effect of therapy

Table 13: Overall effect on Shalyaja Nadivrana (pilonidal sinus) Group-A

Class	Grading	No of patients
0-25%	No change	0
26%-50%	Mild	0
51% - 75%	Moderate	0
76% - 100%	Marked	20

Table 14: Overall effect on Shalyaja Nadivrana (pilonidal sinus) Group-B

Class	Grading	No of patients
0-25%	No change	0
26%-50%	Mild	0
51% - 75%	Moderate	0
76% - 100%	Marked	20

Table 15: Comparative results of Group-A and Group-B

Signs and Symptoms	Group A (Mean Score)	Group B (Mean Score)	SE	T value	P value
Pain	1.21	1.18	0.05	-0.18	<0.05
Discharge	0.55	0.50	0.06	0.48	<0.05
LOT	1.62	1.30	0.13	2.14	<0.05
Tenderness	0.75	0.68	0.06	-0.48	<0.05
Induration	1.42	1.12	0.08	1.80	>0.05

Comparative analysis of the overall effect of the treatments in both groups was done statistically with an unpaired t-test. The test shows that the treatment is equally significant in Group A when compared to Group B. Group A overall result is 89.50% and Group B's overall result is 89.97%.

Table 16: Comparative overall Assessment

Group A	Group B	Mean Difference	SE (±)	T value	P value
89.50	89.97	0.47	1.31	0.26	<0.05

Fig 1: Before Treatment



Fig 2: Probing Tract



Fig 3: Ksharasutra-in-situ



Fig 4: Healed tract



## DISCUSSION

### On selection of drug

Although the *Snuhi Kshira* based *Apamarga Ksharasutra* is standard and most successful *Ksharasutra* with almost negligible recurrence rate. Complications during the therapeutic period like burning pain, local irritation because of *Tikshna Guna* of *Snuhi Kshira* which is slightly acidic in nature (5.8 pH). To combat the above said complication during and after treatment and scanty availability of *Snuhi Kshira*

throughout the year, there is a need of drug which has binding property. *Guggulu* can be used as base/binding agent. In addition, *Guggulu* has *Vedanasthapana, Laghu, Ruksha, Vishada, Sukshma, Sara Gunas, Ushna Virya*, having *Tridosahara, Lekhanavrana Shodhana, Ropana* properties and it is available in bulk. In this regard, instead of *Snuhi Kshira*, *Guggulu* is used in this study. *Karanja* has the properties of *Vranaapaha, Krimihara, Bhedana* and *Shothaharana*. *Kshara* prepared using *Karanja* will have *Chedana, Bhedana* and *Lekhana* properties. Also, it is easily available throughout the year in abundance.

### Discussion on demographic data

**Age:** As per the literature incidence of Pilonidal Sinus is commonly seen in the age group of 21-30 years. Pilonidal Sinus is most common in 2nd and 3rd decades of life. It is probably because of physical exercises, hormonal changes in response to puberty, growth of androgenic hairs, activity of apocrine glands etc.

**Gender:** 75.00% patients were males due to presence of abundant androgenic hair, androgenic response of Sweat glands, and risk of occurrence of abscess. Hill (Jr) (1967) Charles C Thomas (1975) has reported that Abscess occur more commonly in men than women in the ratio 2:1.

**Socio- economic Status:** Pilonidal sinus was more in middle class probably due to improper hygiene.

**Nature of work:** This study shows that it is most common in Students (high androgen level pertaining to the age group). It is more common in drivers, engineers and business-like occupation who sits for long time. According to Literature, Pilonidal sinus is more common in Driver as they sit for long duration near to heat producing engines of vehicles and also go through continuous movements. Friction in sitting position breaks the brittle hairs and collect in natal cleft penetrating skin. Sitting with legs quite apart stretches buttocks and lifts skin over sacrum causing space beneath. Hair so penetrated gets insides due to suction mechanism.

**Perspiration:** Maximum patients showed excess sweating. This could be due to response of sweat gland,

sebaceous glands, apocrine glands in response to androgenic hormonal changes and sympathetic action and occupation. People who perspire have tendency to develop Skin erosion, Abscess and tract formation.

**Body hair:** Presence of excessive bodily course, dry, Brittle, dark hair is definitely a causative factor.

#### Discussion on disease related statistics

##### Subjective parameters

**Effect on pain:** Probable action of pain reduction in Guggulu based Karanja Ksharasutra is by continuous pus drainage, analgesic action of Guggulu and anti-inflammatory action of Haridra.

**Effect on discharge:** Probable effect in Group A is by, maintaining patency of tract to achieve adequate drainage, Shodhana (cleansing), Lekhana (chemical debridement action) of Kshara, Guggulu and Haridra. Kshara is Hydrosopic in nature which absorbs moisture from the substance of contact, this helps in keeping tract clean and dry. Discharge that due to secondary infection is rare during Ksharasutra therapy as alkalinity of Kshara provides no scope for bacterial growth.

##### Objective parameters

**Effect on length of tract:** Ksharana, Chedhana, Bedhana, Lekhana, action of Karanja Kshara. Karanja Kshara has 10.3 pH and Apamarga Kshara has 10.2 pH. This could be the reason for better cutting rate by Apamarga Kshara Sutra.

**Effect in tenderness:** Continuous drainage of discharges, Guggulu's analgesic impact, Haridra's anti-inflammatory activity, and Shothaharana activity (decreasing the collection) by Karanja Kshara are all probable causes for Karanja Ksharasutra's effectiveness in reducing the tenderness.

**Effect in Induration:** The probable action of Guggulu based Karanja Kshara Sutra in reduction of induration is by Ksharana, Bhedana, Shodhana and Lekhana properties of Karanja Kshara, Lekhana Guna of Guggulu.

##### Discussion on intervention

**Unit Cutting Time:** The probable action of Guggulu based Karanja Kshara Sutra regarding UCT is by

Ksharana, Bhedana, Shodhana and lekhanana properties of Karanja Kshara Sutra. UCT can be reduced by tying the Ksharasutra adequately tight and by replacing the kshara sutra with fresh one, every week.

**Discussion on Recurrence:** Patients of both the groups were followed up for 45 days for recurrence. There was no Recurrence noted. This proves Ksharasutra is an effective therapy.

##### Mode of action of Guggulu based Karanja Ksharasutra

The primary intension of the Kshara Sutra is to keep the sinus tract's 'patency,' 'cleaning,' and 'healing'. The threading procedure keeps both ends open and allows the proper drainage. As a result, gradual pus infiltration into the deeper and longer tract is prevented. Puya, commonly known as pus, is a Shalya that must be expelled from the body as quickly as possible, according to Ayurveda.

Pus is liquid in nature and therefore a source and a media for bacterial growth. Drainage of pus will reduce bacterial or any other pathogenic contamination with in sinus. Sinus which is not infected and which shows reduction in discharge is good sign towards healing.

Ayurveda aims at "Nidana Parivarjanameva Chikitsa." Hair being the cause for Pilonidal Sinus may move along with pus towards the sinus opening from where it can be manually removed in few cases. Tract free from foreign body will gradually show tendency to heal in successive stages.

Guggulu being used as a binding agent is resin of *Commiphora mukul*. Linn., such gum material which have property to adhere forms major number of 21 coating of Kshara Sutra (11+7 with Kshara + 3 with Haridra). Loose hair within the tract adheres to these substances of Kshara Sutra in-situ which is pulled out when Kshara Sutra is changed. Some tuft of hair entangles to knot of Kshara Sutra and may come out along, while thread is replaced.

'Shodhana' of Nadi – sinus tract is difficult task to achieve for any surgical instrumentation as it is narrow and deep-seated Pathology. "Shodhana" is an important treatment factor of Nadi Vrana. Guggulu,

*Karanja Kshara* and *Haridra* has *Vrana Shodhana* and *Vrana Shodhana* properties keep the tract clean. 'Hydroscopic' property of *Kshara* refers to its nature of absorbing moisture to which it comes in contact with. This property helps in absorbing tissue exudates, keeping the tract dry. *Karanja Kshara* is "Krimigna" by its phytochemical constituents and its high alkalinity.

Cutting and Healing is secondary intension of *Kshara Sutra* therapy which occurs simultaneously once the etiology is removed.

#### Cutting of tract is by virtue of:

- Pressure exerted by moderately tightened *Kshara Sutra* on skin and underlying connective tissue.
- Action of *Kshara* i.e., *Lekhana* and *Chedhana* helps in cutting of the tract.
- *Guggulu* also possess *Lekhana Guna* adding to the local wound debridement

#### Healing of tract is by virtue of:

- Both *Guggulu* and *Kshara* have *Vrana Ropana* properties.
- *Haridra Churna* is alkaline with ph of 6.2 and has *Vrana Shodhana*, *Ropana*, *Krimighna*, *Twachya* and *Varnya properties*.
- Any wound heals by natural tendency once there is adequate drainage, infection is checked and after debridement of unhealthy tissue is achieved by *Kshara Sutra*.

#### Post-operative effect of *Kshara Sutra*:

Wound healing after *Kshara Sutra* therapy shows minimal scar. Thus, the procedure has high cosmetic value. Tissue underlying skin undergo fibrotic changes and skin overlying show no hair follicles, hair or sweat pores due to action of *Kshara* therapy. This prevents recurrence of Pilonidal Sinus.

#### Overall action

It is by maintaining patency of tract by *Kshara Sutra* having properties of *Shodhana*, *Lekhana* and *Ropana*. Healing is enhanced by *Haridra*. *Kshara Sutra* is safe, effective, easy cost effective OPD procedure which requires no general anesthesia or hospitalization and

importantly heals with minimum local disfigurement. *Guggulu* is known for its analgesic action and hence counter act with pain. *Kshara* has "Naatiruk" *Guna* which means it should not cause pain on application in comparison with any other invasive procedures currently adopted for Pilonidal Sinus. Coatings in *Kshara Sutra* is such that *Haridra Churna* (ph 6.2) remains as outer most coating, making the *Teekshnata* and adds in preventing post-operative burning sensation.

#### Discussion on Dropouts

During the course of the study, only one participant dropped out and chose surgery. The dropout was replaced by a new participant.

#### Complication during procedure:

Presence of few hairs within the tract will come out entrapped with *Kshara Sutra*. But, excess of hairs which are tangled needs evacuation using artery forceps.

*Guggulu* makes thick coating on thread. The resulting *Kshara Sutra* will be thick which is bit difficult to pass through the small sinus in 1<sup>st</sup> sitting. In later sitting, as sinus opening becomes big by cutting action of *Kshara* facilitates the procedure easily. Reducing number of *Guggulu* coatings may be a solution in this regard which cannot be done as standard *Kshara Sutra* coatings has been fixed 7. Only the consistency of *Guggulu* can be made thin while coating of the thread. Knot holding capacity of a *Guggulu* coated thread becomes less due to the thickness.

#### CONCLUSION

*Shalyaja Nadivrana* is considered a *Krichrasadhya Vyadhi* because of the presence of hair as a foreign entity inside the wound. The pilonidal sinus is a chronic, recurrent disease that usually affects the sacrococcygeal region. The pilonidal sinus is diagnosed mostly through clinical examination but imaging techniques like USG may be used to confirm the diagnosis, explore the ramifications of the probable tracts, and to rule out any other associated pathology. Patients usually approach the hospital when they observe recurrent abscess formation. Assessment of pain, discharge, Length of the tract, tenderness, and

induration in Group A showed 91.67%, 91.3%, 99.9%, 85.19%, 95% and 75.6% improvement and Group B showed 87.5%, 86.96%, 100%, 78.6% and 97.37% improvement respectively. Group A's overall result was 89.5% and Group B's overall result was 89.9%. The mean UCT of Group A was 8.3 days/cm and Group B was 7.9 days/cm with a p-value <0.05 which is significant. Comparative analysis of the overall effect of the treatments in both the groups shows that they are equally effective, hence, it can be concluded that the trial drug is as effective as the standard drug. In conclusion, the results of this series provided further evidence that *Ksharasutra* therapy is a very effective procedure and *Karanja Kshara Sutra* is as effective as *Apamarga Kshara Sutra* in the management of pilonidal sinus. Thus, the alternate hypothesis - "*Guggulu based Karanja Ksharasutra* is as effective as *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* with special reference to Pilonidal sinus" is accepted.

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