



ISSN 2456-3110

Vol 5 · Issue 5

Sept-Oct 2020

Journal of
**Ayurveda and Integrated
Medical Sciences**

www.jaims.in

JAIMS

An International Journal for Researches in Ayurveda and Allied Sciences



Charaka
Publications

Indexed

A study on the effectiveness of *Guggulu* based *Karaveera Ksharasutra* in comparison with *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* w.s.r. to Pilonidal Sinus

Dr. Monisha C. J.¹, Narmada M.G.²

¹Post Graduate Scholar, ²Professor, Department of Shalya Tantra, Government Ayurvedic Medical College and Hospital, Bengaluru, Karnataka, INDIA.

ABSTRACT

Shalyaja Nadivrana is of *Agantuja Vranabedha*. *Nidana Panchaka* is described in *Sushruta Samhita Nidhana* and *Chikitsa Sthana*. Presence of "Shalya" is hindering factor for healing. Management of *Nadivrana* includes *Ksharasutra* ligation. Pilonidal sinus is acquired sinus occurring in young hirsute men's commonly seen at inter-gluteal cleft caused by hair penetrating the skin resulting in Pilonidal abscess which gradually forms into sinus with presence of "Hair" leading to wound discharge. It is one of the troublesome diseases which doesn't respond to medical management till hair is evacuated. The current surgical procedures adopted have surgical risk and recurrence as well. *Guggulu* and *Karaveera* is abundantly available and can be preserved easily for long time. Hence can be used as substitute to the standard *Ksharasutra*. The present study "A study on the effectiveness of *Guggulu* based *Karaveera Ksharasutra* in comparison with *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* w.s.r. to Pilonidal Sinus" was conducted in SJIIM hospital Bengaluru with 40 patients randomly allotted into 2 groups namely - Group A and Group B. Assessment was done based on subjective parameters like (pain, discharge) and objective parameters like (length of tract, tenderness). Observation was done before treatment and on every 7th day till tract is completely cut and healed. Assessment of Pain, discharge, length of tract and tenderness in Group-A showed 100%, 100%, 100% and 100% improvement and in Group-B showed 97.92%, 100%, 100% and 100% respectively. UCT in Group-A is 6.58% and Group-B is 9.15%. Overall results of group A and B is 100% and 99.5% respectively. Statistical analysis revealed that the effectiveness of *Guggulu* based *Karaveera Ksharasutra* in *Shalyaja Nadivrana* is as effective as *Apamarga Ksharasutra* w.s.r. to pilonidal sinus.

Key words: *Shalyaja Nadi Vrana, Pilonidal Sinus, Kshara Sutra, Karaveera, Guggulu.*

INTRODUCTION

Negligence of the *Vranashopha* in *Pakwaavastha* can lead to various complication, amongst which "Nadivrana" is explained by *Acharya Sushruta*. The literal meaning of "Nadi" is "tube like structure", in which there is continuous pus discharge. "Bala" is a *Shareerika Shalya* which is the causative factor in

Shalyaja Nadivrana. The *Shalya Gati* to *Twagadi Dhaatu* leads to *Puya* (pus) formation. Further, *Abhyantara Gati* of *Puya* along with *Bala* forms blind tract with continuous pain and discharge towards external end.^[1]

"Sinus" is a blind tract extending from skin to the deeper tissue, lined by unhealthy granulation tissue or epithelium. The broken off hair tend to collect in the natal cleft, which eventually penetrates the skin and forms "Pilonidal sinus". On considering these similarity, the "Shalyaja Nadivrana" can be co-related with "Pilonidal sinus". Incidence is about 26 per 100,000 populations which is peak at 3rd decade of life and rare after 45 years. This disease is more common in males than in females in the ratio of 4:1.

The present management of Pilonidal sinus includes incision of tract and curettage, complete wide excision of the tract, rhomboid flapping, Z-plasty etc. Post-operative complications noted are severe pain,

Address for correspondence:

Dr. Monisha C. J.

Post Graduate Scholar, Department of Shalya Tantra, Government Ayurvedic Medical College and Hospital, Bengaluru, Karnataka, INDIA.

E-mail: cjmonisha@gmail.com

Submission Date: 17/09/2020

Accepted Date: 23/10/2020

Access this article online

Quick Response Code



Website: www.jaims.in

DOI: 10.21760/jaims.5.5.2

discomfort, complication of anesthesia, long term wound care, hospitalization and is not cost effective. Recurrence is as common as 20% even after adequate excision of the tract and proper post-surgical wound management.^[2]

Ayurvedic line of treatment includes *Taila Poorana*, *Varti*, para-surgical procedures like *Kshara Sutra* and surgical procedures like *Chedana Karma*. *Ksharasutra* procedure is simple, effective, economical, safe and cost effective and can be performed on OPD basis.

The standard *Kshara Sutra* as seen today is the result of the extensive research of Dr. P. J. Deshpande and team. *Guggulu* based *Karaveera Ksharasutra* is prepared by *Guggulu Niryasa* (*Commiphora mukul*), *Karaveera Kshara* (*Nerium indicum*, Linn,) and *Haridra Churna* (*Curcuma longa*, Linn,). *Snuhi Kshira* (*Euphorbia nerifolia*, Linn,) is used in *Apamarga Ksharasutra* (standard) is only available in *Shishira Rutu* (Feb-March). As an alternative to *Snuhi Kshira*, *Guggulu* is used because of its availability in bulk, has binding properties, long term preservable and has analgesic effect. Considering all these factors an attempt is made in this study to substitute *Snuhi Kshira* by *Guggulu Niryasa* and *Apamarga* by *Karaveera* for the preparation of *Ksharasutra*. Also to achieve shorter duration of treatment and minimize undue effects of *Ksharasutra* like pain and burning sensation. The present study aims at establishing the effectiveness of *Guggulu* based *Karaveera Ksharasutra* in the management of *Shalyaja Nadivrana*.

AIM

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

OBJECTIVES

1. To evaluate the efficacy of *Guggulu* based *Karaveera Ksharasutra* in the management of *Shalyaja Nadivrana* w.s.r to Pilonidal Sinus.
2. To evaluate the efficacy of *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* w.s.r to Pilonidal Sinus.

3. To evaluate the comparative efficacy of *Guggulu* based *Karaveera Ksharasutra* and *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* w.s.r. to Pilonidal Sinus.

Null hypothesis: *Guggulu* based *Karaveera Ksharasutra* is not as effective as *Snuhi* based *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana*.

Alternate hypothesis: *Guggulu* based *Karaveera Ksharasutra* is as effective as *Snuhi* based *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana*.

Methodology

The study was conducted during period of December 2018 to February 2020.

Source of data

Patients with classical features of *Shalyaja Nadivrana* were selected from OPD of SJM 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

- Subjects presenting with signs and symptoms of *Shalyaja Nadivrana* such as tenderness, pain, discharge, presence of tract in the natal cleft which is confirmed with probing.
- Age - 18-40 years.

Exclusion criteria

- Subjects associated with systemic diseases like Diabetes mellitus, Tuberculosis, Osteomyelitis, immune compromised conditions and Malignancy.
- Pregnancy and lactation women.

Sampling design

A total of 40 patients fulfilling the above criteria were included for the study and were randomly allotted

into 2 groups namely Group- A and Group-B with 20 patients each.

Intervention

Ksharasutra preparation done as per standard method. Chemical analysis of drugs was done at “Drug testing laboratory”, Department of Ayush, Government of Karnataka shows following result.

a) **Guggulu**: Loss on Dryness: 9.53%, Total Ash value: 5.678, Alcoholic extract: 16.827, Water soluble extract: 57.6275, Acid insoluble ash: nil, Resin content: 12.8%

b) **Karaveera Kshara**: pH: 11.71 at 250 C, Loss on dryness at 1100c: 23.81%, Total Ash value: 66.4570, Acid insoluble ash: 0.8009

c) **Haridra Choorna**: pH 6.2

Study Design

Methodology of Group-A: (Study Group)

Patients of Group-A will be treated with *Guggulu* based *Karaveera 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 put in prone position (or Jack knife position). Part painted and draped. Under aseptic measures, local anesthesia (under supervision of anesthetist) was given if necessary. Probing was done into the tract till the resistance is felt, following which an artificial opening was made at the site. Thus, converting sinus into a fistulas tract, primary threading was done using surgical Barbour linen thread No. 20. Firm knot is tied. Sterile dressing applied.

Post-operative procedure: Sits bath with tolerable warm water once a day for 20 minutes. Instruction regarding personal hygiene, periodical shaving of body hair and follow up were given.

Change of *Kshara Sutra*: On day 3, *Guggulu* based *Karaveera Ksharasutra* was changed by railroad method.

Follow up details: Further, on every 7th day *Ksharasutra* was changed by rail-road method. Patient will be advised to take sits bath.

Observation made before treatment and after *Kshara Sutra* changing.

The change in length of tract is measured on day 1 (of *Kshara Sutra*) and on every successive 7th day and is recorded in the Performa of case sheet prepared for the study. Observations were recorded till complete cutting and healing of tract.

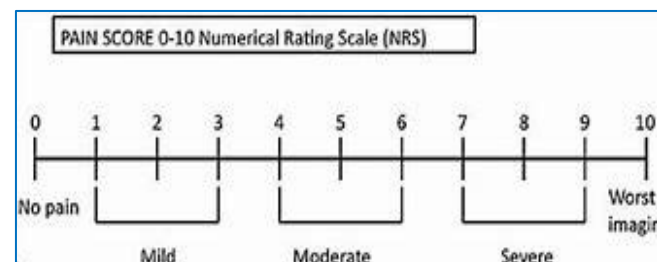
Duration of observation for recurrence: Duration of 45 days from the day of complete healing of tract was observed and recorded by clinical examination.

Same method was followed in Group B.

Assessment Criteria

Subjective parameters

Pain: Assessment of pain is done using “Numerical Rating scale” (Adopted from Mc Caffery.)



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

Length of tract: It is measured in every sitting, expressed in centimeters Unit cutting time [U.C.T]: the unit cutting time represents the number of days required to cut one cm of tract. This is calculated by dividing total number of days taken to cut and heal

the tract by the initial length of tract denoted as days/cm.

$$UCT = \frac{\text{Total number of days}}{\text{Initial length of tract}}$$

Tenderness: 0: Absent, 1: Present

Overall Assessment

The net result 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
- Mild response : >25% to <50% relief from all features
- Poor response : <25% relief from all features

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

Observation and Results

Total 40 patients were randomly allotted into 2 groups. Observations are recorded and necessary charts and graphs were made. Maximum of 27.50% and 22.50% patients seen in age group between 27-30 years and in between 19-22 years, 23-26 years respectively. 82.50% were male patients and 17.50% were female. 24 patients i.e., 60.00% belong to Lower middle class. 40.00% patients had sitting type of nature of work, 8 patient (20%) had travelling nature of work, while and 7 patient (17.5%) had travelling and vigorous exercise. 18 (45%) had history of 1 to 4 months. 15 patients had duration of 5-8 months. 22 patient (55.00%) had Dark skin color and 16 patient (40.00%) had moderate skin color. Maximum of 72.50 % i.e. 29 patients had excess perspiration and 27.5% had moderate perspiration. Maximum number of 24 (60.00%) patients were Hairy and 13 (32.5%) patients had moderate hair distribution. Maximum of 25 patient i.e. 62.50% were normal weight, 14 patient i.e. 35.00 % were overweight.

Table 1: Effect of Group-A on Pain.

Symptom	Mean score				%	S.D (±)	S.E (±)	T Value	P value
	BT	Days	AT	BT - AT					
Pain	2.80	Day 8	2.10	0.70	25.00	0.571	0.131	3.78	<0.05
		Day 15	1.25	1.55	55.36	0.510	0.117	8.40	<0.05
		Day 22	0.70	2.10	75.00	0.641	0.147	11.18	<0.05
		Day 29	0.15	2.65	94.64	0.587	0.135	18.56	<0.05
		Day 36	0.05	2.75	98.21	0.444	0.102	26.31	<0.05
		Day 43	0.00	2.80	100	0.410	0.094	30.51	<0.05
		Day 50	0.00	2.80	100	0.410	0.094	30.51	<0.05
		Day 57	0.00	2.80	100	0.410	0.094	30.51	<0.05

The mean score of Group-A on Pain was 2.80 before the treatment, reduced to 2.10 after the treatment. Statistically significant (P<0.05) results.

Table 2: Effect of Group-B on Pain.

Symptom	Mean score				%	S.D (±)	S.E (±)	T Value	P value
	BT	Days	AT	BT - AT					
Pain	2.40	Day 8	1.95	0.45	18.75	0.510	0.117	2.08	<0.05
		Day 15	1.55	0.85	35.42	0.745	0.171	3.27	<0.05
		Day 22	0.85	1.55	64.58	0.686	0.157	6.54	<0.05

	Day 29	0.50	1.90	79.17	0.641	0.147	8.78	<0.05
	Day 36	0.15	2.25	93.75	0.550	0.126	14.34	<0.05
	Day 43	0.15	2.25	93.75	0.550	0.126	14.34	<0.05
	Day 50	0.05	2.35	97.92	0.489	0.112	19.10	<0.05
	Day 57	0.05	2.35	97.92	0.489	0.112	19.10	<0.05

Mean scores in Group-B on Pain was 2.40 before the treatment was reduced to 1.95 after the treatment. Statistically significant. (P<0.05)

Table 3: Effect of Group-A on Discharge.

Symptom	Mean score				%	S.D (±)	S.E (±)	T Value	P value
	BT	Days	AT	BT - AT					
Discharge	2.30	Day 8	1.60	0.70	30.43	0.571	0.131	3.52	<0.05
		Day 15	0.80	1.50	65.22	0.688	0.158	7.45	<0.05
		Day 22	0.40	1.90	82.61	0.641	0.147	10.27	<0.05
		Day 29	0.05	2.25	97.83	0.550	0.126	16.40	<0.05
		Day 36	0.00	2.30	100	0.571	0.131	18.01	<0.05
		Day 43	0.00	2.30	100	0.571	0.131	18.01	<0.05
		Day 50	0.00	2.30	100	0.571	0.131	18.01	<0.05
		Day 57	0.00	2.30	100	0.571	0.131	18.01	<0.05

Discharge in Group-A showed reduction in the mean score from 2.30 to 1.60 after treatment. statistically significant (P<0.05).

Table 4: Effect of Group-B on Discharge.

Symptom	Mean score				%	S.D (±)	S.E (±)	T Value	P value
	BT	Days	AT	BT - AT					
Discharge	2.15	Day 8	1.70	0.45	20.93	0.510	0.117	2.28	<0.05
		Day 15	1.05	1.10	51.16	0.641	0.147	4.42	<0.05
		Day 22	0.55	1.60	74.42	0.681	0.156	6.73	<0.05
		Day 29	0.30	1.85	86.05	0.745	0.171	7.92	<0.05
		Day 36	0.20	1.95	90.70	0.759	0.174	9.02	<0.05
		Day 43	0.10	2.05	95.35	0.686	0.157	11.37	<0.05
		Day 50	0.05	2.10	97.67	0.641	0.147	13.28	<0.05
	Day 57	0.00	2.15	100	0.671	0.154	14.33	<0.05	

Discharge in Group-B showed reduction in the mean score from 2.15 to 1.70 after the treatment.

Table 5: Effect on Length of tract (LOT) of Group-A.

Symptom	Mean score				%	S.D (±)	S.E (±)	T Value	P value
	BT	Days	AT	BT - AT					
LOT	3.49	Day 8	2.34	1.15	33.00	0.136	0.031	3.17	<0.05
		Day 15	1.21	2.28	65.28	0.207	0.048	6.79	<0.05

	Day 22	0.47	3.02	86.66	0.564	0.129	10.34	<0.05
	Day 29	0.11	3.38	96.99	0.906	0.208	13.16	<0.05
	Day 36	0.01	3.48	99.71	1.084	0.249	14.02	<0.05
	Day 43	0.00	3.49	100	1.108	0.254	14.07	<0.05
	Day 50	0.00	3.49	100	1.108	0.254	14.07	<0.05
	Day 57	0.00	3.49	100	1.108	0.254	14.07	<0.05

Magnitude of LOT in Group-A group showed statistically significant improvement (P<0.05). The mean score reduced from 3.49 to 2.34.

Table 6: Effect of LOT in Group-B.

Symptom	Mean score				%	S.D (±)	S.E (±)	T Value	P value
	BT	Days	AT	BT - AT					
LOT	3.08	Day 8	2.26	0.83	26.79	0.159	0.036	2.06	<0.05
		Day 15	1.43	1.66	53.73	0.268	0.062	4.20	<0.05
		Day 22	0.74	2.35	76.14	0.416	0.095	6.33	<0.05
		Day 29	0.34	2.74	88.96	0.663	0.152	7.84	<0.05
		Day 36	0.20	2.88	93.51	0.833	0.191	8.91	<0.05
		Day 43	0.12	2.96	96.10	0.971	0.223	9.74	<0.05

	Day 50	0.06	3.03	98.21	1.119	0.257	10.36	<0.05
	Day 57	0.02	3.06	100	1.220	0.280	10.64	<0.05

Magnitude of LOT in Group-B group showed significant improvement (P<0.05). The mean score reduced from 3.08 to 2.26

Table 7: Effect of Group-A on Tenderness.

Symptom	Mean score				%	S.D (±)	S.E (±)	T Value	P value
	BT	Days	AT	BT - AT					
Tenderness	1.00	Day 8	0.75	0.25	25.00	0.444	0.102	2.52	<0.05
		Day 15	0.30	0.70	70.00	0.470	0.108	6.66	<0.05
		Day 22	0.00	1.00	100	0.000	0.000	6.66	<0.05
		Day 29	0.00	1.00	100	0.000	0.000	6.66	<0.05
		Day 36	0.00	1.00	100	0.000	0.000	6.66	<0.05
		Day 43	0.00	1.00	100	0.000	0.000	6.66	<0.05
		Day 50	0.00	1.00	100	0.000	0.000	6.66	<0.05
		Day 57	0.00	1.00	100	0.000	0.000	6.66	<0.05

Magnitude of Tenderness in Group-A group showed statistically significant improvement from 1.00 to 0.75 mean score reduction.

Table 8: Effect of Group-B Tenderness.

Symptom	Mean score				%	S.D (±)	S.E (±)	T Value	P value
	BT	Days	AT	BT - AT					
Tenderness	1.00	Day 8	0.75	0.25	25.00	0.44	0.102	2.52	<0.05
		Day 15	0.45	0.55	55.00	0.510	0.117	4.82	<0.05
		Day 22	0.20	0.80	80.00	0.410	0.094	8.72	<0.05
		Day 29	0.10	0.90	90.00	0.308	0.071	13.08	<0.05
		Day 36	0.10	0.90	90.00	0.308	0.071	13.08	<0.05
		Day 43	0.00	1.00	100	0.000	0.000	13.08	<0.05
		Day 50	0.00	1.00	100	0.000	0.000	13.08	<0.05
		Day 57	0.00	1.00	100	0.000	0.000	13.08	<0.05

Magnitude of Tenderness in Group-B show mean score reduction from 1.00 to 0.

Table 9: Effect of Group-A and B on Unit Cutting Time (UCT).

Group A	Group B	SD (±)	SE (±)	T value	P value
6.58	9.15	1.387	0.318	8.89	<0.05

Magnitude of UCT in Group-A and Group-B group showed statistically significant result (P<0.05). The mean score of UCT was 6.58 in Group A and 9.15 in Group B.

Table 10: Comparative results of Group-A and Group-B.

Signs and Symptoms	Group A (Mean Score)	Percentage of reduction in Group A	Group B (Mean Score)	% of reduction in Group B	T Value	P Value
Pain	0.78	100%	0.85	97.91%	0.50	>0.05
Discharge	0.87	100%	0.68	100%	0.87	>0.05
LOT	0.85	100%	0.91	100%	0.35	>0.05
Tenderness	0.23	100%	0.29	100%	1.46	>0.05

The comparative results of both the groups assessed based on pain, discharge, LOT and tenderness is 100%, 100%, 100% and 100% in group A and in Group B 97.91%, 100%, 100% and 100% percentage of reduction in complaint respectively. P value >0.05 of both the group shows results are highly significant.

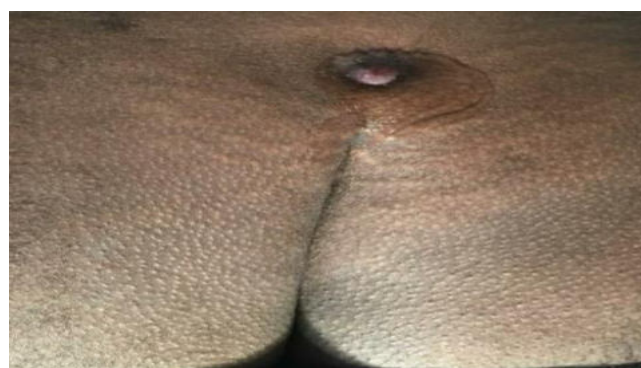


Fig. 1: Before Treatment



Fig. 2: Probing & Primary Threading.



Fig. 3: Guggulu based Karaveera Kshara Sutra.



Fig. 4: After Treatment

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 acidic in nature (5.8 pH). To combat the above said complication during and after treatment and also non availability of *Snuhi Kshira* throughout the year, there is 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.

Karaveera has *Tikshna Guna, Ushna Virya* and possesses properties of *Krimihara*. *Kshara* prepared using *Karaveera* have *Chedana, Bhedana, Lekhana,*

Shodhana and *Ropana*. *Karaveera* is available in bulk throughout the year.

Therefore, *Guggulu* based *Karaveera Ksharasutra* was substituted to *Apamarga Ksharasutra* in the present study.

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:** 82.50% (33 cases) 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 is more in Lower-middle class probably due to unhygiene.
- Nature of work:** Maximum cases of 16 (40%) have Siting type of work. 8 (20%) cases have travelling type of work. 7 (17.5%) have travelling with vigorous exercise type 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.
- Chronicity of the Disease:** 18 cases (45%) had a history of 1-4 months, 15 cases (37.5%) had 5-8

months history. This shows pilonidal sinus has chronic history

6. **Skin color:** According to literature, incidence of diseases is more in dark individuals show 55% (22 patients) has dark skin color and 40% had moderate skin tone.
7. **Perspiration:** 29 cases (72.5%) show 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.
8. **Body hair:** 24 cases (60%) were hairy, 13 cases (32.5%) have moderate distribution. Presence of excessive bodily course, dry, Brittle, dark hair is definitely a causative factor.
9. **Body mass index:** Obesity is a risk factor for Pilonidal sinus. BMI is a criteria used to measure body mass. 25 cases (62.5%) were normal weight. 14 cases (35%) over-weight.

Discussion on disease related statistics

Subjective parameters

1. **Effect on pain:** Reduction in pain in group A is 100% by 43rd day where as in group B 97.92% on 57th day. Probable action of pain reduction by Guggulu based Karaveera Ksharasutra is by continuous pus drainage, analgesic action of Guggulu and anti-inflammatory action of Haridra.
2. **Effect on discharge:** 100% reduction in discharge in group A and B is by Day 36 and Day 57 respectively. 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 Hydroscopic 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

1. **Effect on Length of tract:** 100% reduction (tract cut completely) seen by day 43 and day 57 in respective group. Ksharana, Chedhana, Bedhana, Lekhana, action of Karaveera Kshara. Karaveera Kshara has 11.7 pH, by which means the cutting rate is high. Maximum and minimum length of tract treated in study is 7cm and 1.5cm. average length of tract obtained as per statistics is 4.25cm.
2. **Effect in tenderness:** 100% reduction in group A is achieved by 25nd day and in Group B by 34th day.

Discussion on intervention

Unit cutting time in group A and B is 6.58 days and 9.15 days. The probable action of Guggulu based Karaveera Ksharasutra regarding UCT is by Teekshan Guna, Ksharana, Chedhana, Bedhana, Lekhana Karma of Karaveera Kshara. Tying of Ksharasutra adequately tight and replacing of new Ksharasutra weekly also contribute to accelerate the rate of cutting.

Recurrence: Patients of both the groups were followed up for 45 days for recurrence. Recurrence in group A and B is 10% (2 cases) and 20% (4 cases) respectively.

Discussion on result

Overall effect in the groups show marked result (76% - 100%) in all 20 patients. The comparative results of both the groups assessed based on pain, discharge, LOT and tenderness is 100%, 100%, 100% and 100% in group A and in Group B 97.91%, 100%, 100% and 100% percentage of reduction in complaint respectively. P value >0.05 of both the groups shows results are highly significant. Comparative analysis by Unpaired test showed equally significant with overall results 100% and 99.5% in Group A and Group B respectively. Thus Group A treated with Guggulu based Karaveera Ksharasutra is as effective as Apamarga Ksharasutra.

Mode of action of Guggulu based Karaveera Ksharasutra

Primary intention of Kshara Sutra is to maintain "patency" and "cleansing" the sinus tract. Threading

procedure keeps both the ends opened and provides adequate drainage of sinus. Thereby, progressive penetration of pus and tract extension is avoided. Pus is liquid media and source for bacterial growth. Sinus which shows reduction in discharge is good sign towards healing. According to Ayurveda, Puya or pus is also a *Shalya* which has to be let out of the body as soon as possible.

Hair being the cause for pilonidal sinus can be manually removed in few cases. Tract free from foreign body will gradually show tendency to heal in successive stages. Ayurveda also aims at "*Nidana Parivarjanameva Chikitsa*".

Guggulu being used as binding agent is a resin/Gum [of *Comniphora mukul.* Linn., such resin/gum material which have property to adhere] forms major number of 21 coating is *Ksharasutra* (11+7 with *Kshara* + 3 along with *Haridra*). Loose hair within the tract when adher to the these substance of *Ksharasutra* in-situ which is pulled out when *Ksharasutra* is changes.

"*Shodhana*" or "Cleansing" of Sinus is difficult task to achieve for any surgical accession/ instrumentation as it is narrow and deep seated pathology. *Guggulu*, *Kshara* and *Haridhra* has *Vrana Shodhana Karma* keeps the tract clean. "Hydroscopic" property of *Kshara* refers to its nature of absorbing moisture to which it comes in contact with thus absorbing tissue exudates, keeping the tract dry. *Kshara* is "*Krimigna / anti-microbial*" and its high alkalinity.

Cutting and healing is secondary intension in *Ksharasutra* therapy which occur simultaneously once the etiology is removed.

Cutting of tract is by virtue of: Pressure exerted by tightness of *Ksharasutra* on skin and underlying connective tissue. Action of *Kshara* i.e. *Lekhana* (scraping or chemical debridement of tissue to which it comes in contact with), *Chedhana* i.e. slow and sustain release of proteolytic enzymes (breaks down protein built up tissues). *Guggulu* also has *Lekhana Guna* adding to local wound debridement.

Healing of tract is by virtue of: Both *Guggulu* and *Kshara* has *Vrana Ropana* (accelerate tissue growth).

Haridra Choorna is alkaline with pH of 6.2, has *Vrana Shodhana*, *Lekhana*, *Ropana*, *Krimigna* (anti-septic and anti-microbial), *Kandugna* (anti-histamine), *Twachya* and *Varnaya* (helps in regeneration of skin and enhances complexion). Any Wound heals by naturally tendency once there is adequate drainage, infection is checked and after debridement of unhealthy tissue - all of this is achieved by *Kshara Sutra*.

Post-operative effect of *Kshara Sutra*: Wound Healing after *Kshara Sutra* therapy show minimal scar. Thus, the procedure has high cosmetic value. Tissue underlying skin undergo fibrotic change 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: Is by maintain patency by threading; *Shodhana* (cleansing), *Lekhana* (chemical debridement), *Chedhana* (cutting of tract), *Ropana* (healing) action of *Kshara*. Healing is enhanced by action of *Haridra*. It is Safe, effective, cost effective, easy, OPD/ day care procedure which require no 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. An ideal *Kshara* renders less pain on application in comparison with any other invasive procedures. Coatings in *Kshara Sutra* is such that *Haridra Choorna* (pH 6.2) remains as outer most coating, masking the *Teekshnata* (corrosive nature of alkaline - *Karaveera Kshara* pH-11.8). Thus, *Haridra* coatings adds in preventing post-operative burning sensation.

Discussion regarding dropouts and complication during procedure: There were 3 drop outs which were excluded from study. One of which was taken up for surgery. While other 2 unspecified reason for their discontinuation.

Complication during procedure: Presence of few hairs with in tract will come out entrapping with *Ksharasutra*. But, excess of hair which are tangles inside need evacuation using artery forceps.

Guggulu makes thick coatings on thread. The resulting *Ksharasutra* will be thick which is difficult to pass through the small sinus opening at 1st sitting. In later sitting, as sinus opening becomes big by cutting action of *Kshara*, it facilitates the procedure easily. Reducing number of *Guggulu* coatings may be a solution in this regard.

CONCLUSION

The present study, "The study on effectiveness of *Guggulu* based *Karaveera Ksharasutra* in comparison with *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* w.s.r. to Pilonidal Sinus" carried out with 20 Patients in each group, were treated as per protocol explained in methodology. Following conclusions were drawn. *Shalyaja Nadivrana* is more common in age group of 20-30 years and is more common in case of male than in female. The disease is prevalent in whom nature of work is prolonged sitting and travel. Pilonidal sinus is common in individual who are hairy (60%), dark skin colour (55%) and who perspiration in excess (72.5%). Overall effect in both the groups show marked result (76%-100%). The comparative results of both the groups assessed based on pain, discharge, LOT and tenderness is 100%, 100%, 100% and 100% in Group-A and in Group-B 97.91%, 100%, 100% and 100% percentage of reduction in complaint respectively. P value >0.05 of both the group shows results are highly significant. Hence Group-A showed statistically highly significant reduction in pain, while equal significance in discharge, LOT and tenderness compared to Group-B. Unit Cutting Time in Group-A is better with mean UCT 6.58, hence *Guggulu* based *Karaveera Ksharasutra* has better cutting rate. Group-A overall result is 100% and Group B overall result is 99.5% showing equally significance. Therefore, *Guggulu* based *Karaveera Ksharasutra* was found to be as effective, as *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* (Pilonidal Sinus). The trial drug *Guggulu* based *Karaveera Ksharasutra* showed promising results and hence can be used as a substitute at times when *Snuhi Kshira* or *Apamarga Kshara* is not available. Thus alternate hypothesis that *Guggulu* based *Karaveera Ksharasutra* is as effective

as *Apamarga Ksharasutra* in the management of *Shalyaja Nadivrana* is accepted.

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How to cite this article: Dr. Monisha C.J., Narmada M.G. A study on the effectiveness of Guggulu based Karaveera Ksharasutra in comparison with Apamarga Ksharasutra in the management of Shalyaja Nadivrana w.s.r. to Pilonidal Sinus. J Ayurveda Integr Med Sci 2020;5:9-20.
<http://dx.doi.org/10.21760/jaims.5.5.2>

Source of Support: Nil, **Conflict of Interest:** None declared.
