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# A COMPARATIVE CLINICAL STUDY OF 'CHEDANA KARMA & KSHARSUTRA (SETON) KARMA' (GUGGULU BASED) IN THE MANAGEMENT OF SHALYAJ NADI VRANA(SINUS) W.S.R. TO PILONIDAL SINUS (ASSOCIATED WITH ROPAN LEPA)

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# ABSTRACT

A Pilonidal Sinus is a common disease of the natal cleft. Pilonidal Sinus is a track which contains hairs. The incidence of the disease is calculated to be 26 per 100,000 people. Pilonidal disease has a male predominance with a ratio of 3:1. There are several methods to treat pilonidal sinus, but the recurrence rate is more in modern surgical interventions. According to Ayurveda it can be correlated to Salvajanva Nadi Vrana (pilonidal sinus), a type of Nadi Vrana (sinus). Whose etiopathology described in Nidanasthana and treatment is aspect in Chikitsasthana of Susrutha Samhita. Susrutha mentioned the application of Kshara (caustic alkali) and Ksharsutra (Seton) (Seton) in the management of Nadi Vrana (sinus). Studies show that by Ayurvedic treatment, it helps to reduce recurrence rate, even though Nadi Vrana (sinus) is said to be Kricchrasadhya (difficult to cure). Hence successful management of this disease depends on the knowledge of pathogenesis, patient's presentation and knowledge on treatment aspects. In this Clinical study, effect of *Chedana* karma & *Ksharsutra (Seton)* karma' (Guggulu based) in the management of Salyajanya Nadi Vrana (pilonidal sinus) w.s.r. To pilonidal sinus (associated with ropan lepa) is seen and conclusion in drawn.

Keywords: Chedana Karma, Ksharsutra (Seton), Nadi Vrana(sinus), Pilonidal Sinus

# INTRODUCTION

The *Sushrut Acharya* has been proclaimed as a father of ancient surgery as "*Sushruta Samhita*" is the most important document avail in the branch of surgery in this world. Achrya Sushruta given the description in detail in tenth chapter of *NidanaSthana* regarding to *Nadi* in the chapter of "*Visarpa Nadi Stanroga Nidana*" Also he defines that if inflammatory swelling is ignored even during the stage of suppuration then it may result in chronic granulating tract termed as "*Nadi*" which remains like a tube. In which the educative material remains in movement there in<sup>1</sup>.

Moreover, if such supportive swelling is neglected & not managed properly by *Shalyakarma* in time this will be responsible for the persistence of chronic *Nadi Vrana* (Sinus). The disease *Nadi Vrana* (sinus) is of eight type, among this *Salyajanya Nadi Vrana* (pilonidal sinus) or *AgartujaNadiVrana* is one that is explained by Acharya *Sushruta* in *Nidanasthana and chikitsasthana*. *Shalya (foreign body) is the cause of this type Vrana*<sup>2</sup>

The Shalyajanya Nadi Vrana (sinus) or Agantuja Nadi Vrana (sinus) is taken as it is caused by hair. Acharya Sushruta has given much importance of hair as foreign body, in the definition of ShalyaTantra. He has included hair as the foreign body or Shalya.<sup>3</sup>

Any foreign body (Remaining hidden) within the tissues mentioned earlier (skin, muscles) produces a sinus quickly, which exudes a warm liquid frothy, churned up, clear and or blood mixed, suddenly or always and accompanied with pain.<sup>4</sup>.

Hence, there is need to evaluate the role of an innovative technique for management of *ShalyajNadiVrana* (Pilonidal sinus) as to minimize recurrence, make its cost effective, with universal acceptability of minimum hospitalization.

In Sushruta Samhita, Sushruta has mentioned the treatment of NadiVrana viz. Chedana and Ksharsutra (Seton) Karma.

In this regard Acharya Sushruta has given elaborative description regarding treatment of *Shalyaj* (*Agantuja*) *Nadi Vrana (sinus)* that is *Fistulectomy* followed *by* 

Shodhana & RopanLepa and the indication of Ksharsutra (Seton).

## Aim & Objective

- 1. To evaluate the efficacy of *Chedana Karma(fistulectomy)* (Partial excision) of *ShalyajNadi Vrana(sinus)* (Pilonidal Sinus)
- 2. To evaluate the efficiency of *Ksharsutra (Seton)* karma in healing of *ShalyajNadi Vrana (sinus)* (Pilonidal Sinus)
- To Compare the efficacy of *Chedana Karma* and *Ksharsutra (Seton) Karma* in Management of Healing of *Shalayaj Nadi Vrana* w.s.r to Pilonidal Sinus

#### **Material and Methods**

#### **Inclusion** Criteria

- 1. The patients who presented with the signs & symptoms of *ShalyajNadi Vrana(sinus)* (Pilonidal Sinus)
- 2. Age Group 18 years to 50 years
- 3. Sex Both Male & Female included in these clinical trials.
- 4. Habitat Both rural & Urban
- 5. Prakriti (inherent nature) All Prakriti (inherent nature) of Shalaj Nadi Vrana
- 6. Symptoms Pain, Swelling, Discharge and Discoloration
- 7. The cases will be selected from patients attending OPD from department of *ShalyaTantra*, Govt. Ayurvedic College, Raipur.(C.G.)
- 8. Patients willing to undergo clinical trial.

# **Exclusion Criteria**

- 1) Pilonidal sinus more than 6 cm in length
- 2) Chronic Coccyx pain in periodontal diseases
- 3) Other orthopedic condition like as fracture
- 4) Known case of Diabetes Mellitus
- 5) Rheumatoid arthritis
- 6) Auto immune disorder
- 7) Malignant condition

# **Clinical Study**

For the clinical assessment of the *Chedana karma* (Partial Excision) and *Ksharsutra (Seton) Karma* (*Guggulu* 

based) in the management of *Shalaj Nadi Vrana(sinus)* (Pilonidal Sinus) **30 nos. of patients were s**elected on the basis of sign and symptoms given in the Ayurvedic Classics of Shalyatantra. Patient will be select from O.P.D. and I.P.D. of *ShalyaTantra* in the Govt. Ayurveda College/Hospital, Raipur (C.G.) The clinical study will be carried by dividing those patients in following

Groups: (Each group contain 15 patients)

Group A – Only Ksharsutra (Seton) (Guggulu based)

Group B – Cheddan Karma (Partial excision)

(*Ropanalepa* will be applied in both the groups after procedure.)

A detailed Performa was prepared to note down all details of the patient and the disease. After detailed history was taken which was followed by physical, systemic and local examinations. In addition to it *Trividha*, *Ashtavidhaand Dashvidha Pariksha* were carried out and findings related to *Nidan*, *Purvarupoa*, *Rupa and Upshaya* 

# Follow Up

After healing of the wound the patient were instructed to visit OPD in a month for examination of recurrence or any other complication.

#### **Criteria of Assessment of Cases**

The assessment of the result is purely based on major signs and symptoms (Local) of the disease presented before and after the completion of treatment. On the basis of degree of relief in the textual features of-*ShalyajaNadiVrana* (Pilonidal Sinus) and on the basis of the condition of the patients, were assessed in the form of scores under following headings referring to subjective criteria

- A. Scores of clinical features.
- B. Scores of overall result.

Subjective Criteria

- 1. Pain
- 2. Discharge
- 3. Tenderness
- 4. Indurations

An attempt was made to score the clinical features with reference to *ShalyajaNadi Vrana (sinus)as*-

# 0- No sign and symptom

1- Mild sign and symptom

## 2- Moderate sign and symptom

#### 3- Severe sign and symptom

The details of scoring pattern are as follows: -

Local Sign and Symptoms:

#### Assessment of Pain

0- No pain

1- The pain is mild as to tolerate

2- The pain is moderate while sitting and walking

3- The pain is severe and not relived in any condition

#### Assessment of discharge

0-No discharge / dry dressing

1- Scanty occasional discharge & little wet dressing.

(The area of wetness in gauze is up to  $\frac{1}{2} \times \frac{1}{2}$  cm.)

2- Discharge evident on examination and patient complain of often feeling of often feeling of wetness. (The area of wetness in gauze is up to  $1 \times 1$  cm.)

3- Professed, continuous discharge which needs frequent

Dressing. (More than 1 cm. gauze is wet)

# **Assessment of Tenderness**

0- No tenderness

- 1- The pain on deep palpation
- 2- The pain and tenderness on deep pressure.

3- The patient does not allow palpation due to pain even in touching and difficulty in sitting.

# Assessment of Healing Period (For *Chedana Karma* and *Kshara Sutra Karma*)

Healing will be assessed on the basis of total time taken by a wound to heal completely

# Procedure of Chedana Karma

Remove the visible hairs firstly and also remove the bad debris with pus from the sinus to make it ready to probing.

Step 1- Probing

Step 2- Widening of the opening

Step 3- Partial excision (Unroofing of the main track and secondary healing)

Step 4- Curettage

Step 5- Trimming of the edge

Step 6- Washing the wound by H<sub>2</sub>O<sub>2</sub>solution

Step 7- Application of MadhuGhritaLepa

Procedure of Ksharsutra (Seton) Karma

Remove the visible hairs firstly and also remove the bad debris with pus from the sinus to make it ready to probing.

Step 1- Probing

Step 2- Widening of the opening.
Step 3- Curettage
Step 4- Trimming of the edge
Step 5- Application of *Ksharsutra* (Seton)
Step 6- Application of *MadhuGhritaLepa*Statistical Analysis:

All information which was based on various parameters gathered and statistical analysis was carried out in terms of Mean(X), standard deviation (S.D.), Standard error (S.E.) paired test and finally results were incorporate in terms of probability "P".

Level of Significance P < 0.05 .....Insignificant P<0.01.....Significant P< 0.00.....Highly Significant

#### Results

1. Below table shows the gradation of sign and symptoms and percentage of relief during treatment in 15 patients of Group -A

S.No.	Sign And	Be	Before Treatment				After Treatment				Percent	
	Symptoms	G0	G1	G2	G3	Total	G0	G1	G2	G3	Total	RELIEF
1.	Pain	0	0	7	8	38	5	9	1	0	11	71.05%
2.	Tenderness	0	0	8	7	37	7	8	0	0	8	78.37%
3.	Discharge	0	2	8	5	33	6	5	4	0	13	60.60%
4.	Induration	0	4	8	3	29	8	7	0	0	7	75.86%

2. Below table showing the percentage of improvement in various sign and symptom after the treatment in 15 patients of group -B

S.No.	No. Sign And I			Before Treatment				After Treatment				Percent
	Symptoms	G0	G1	G2	G3	Total	G0	G1	G2	G3	Total	RELIEF
1.	Pain	0	0	6	9	39	11	4	0	0	4	89.74 %
2.	Tenderness	0	2	8	5	33	11	4	0	0	4	87.87 %
3.	Discharge	0	4	8	3	29	10	5	0	0	5	82.75 %
4.	Induration	0	3	9	3	30	10	5	0	0	5	83.33 %

3. Below table showing statistical analysis showing the effect of therapy in various sign and symptom after the treatment in 15 patients of group -A

S.No.	Sign And	Mean		%Relief	S.D.	S.E.	T-Value	P-Value
	Symptoms	BT	AT					
1.	Pain	2.53	0.8	71.05 %	0.816	0.210	8.22	< 0.001
2.	Tenderness	2.46	0.53	78.37 %	0.737	0.190	10.14	< 0.001
3.	Discharge	2.2	0.86	60.60 %	1.159	0.299	4.45	< 0.001
4.	Induration	1.93	0.46	75.86 %	0.743	0.91	7.64	< 0.001

4. Below table showing statistical analysis showing the effect of therapy in various sign and symptom after the treatment in 15 patients of group B

S.No.	Sign and Symp-	Mean		%	S.D.	S.E.	T-Value	P-Value
	toms	BT	AT	Relief				
1.	Pain	2.6	0.26	89.74 %	0.487	0.125	18.52	< 0.001
2.	Tenderness	2.2	0.26	87.87 %	0.703	0.181	10.64	< 0.001
3.	Discharge	1.93	0.33	82.75 %	0.632	0.163	9.79	< 0.001
4.	Induration	2	0.33	83.33 %	0.816	0.210	7.90	< 0.001

Group A	Length Of Sinus Track (In Cm)	Time Taken In Healing The Open Si-	Unit
-		nus Track (In Days)	
A1	3.0	26	8.6
A2	4.0	CONTINUE	-
A2	4.0	CONTINUE	-
A3	3.0	35	11.6
A4	2.0	30	15.0
A5	4.0	CONTINUE	-
A6	4.0	CONTINUE	-
A7	2.2	42	19.0
A8	3.0	CONTINUE	-
A9	2.0	CONTINUE	-
A10	3.0	42	14
A11	4.0	CONTINUE	-
A12	3.0	56	18.6
A13	3.2	40	12.5
A14	3.5	CONTINUE	-
A15	2.8	CONTINUE	-

## 5. Below table showing healing period in relation to depth of wound (for group A)

#### 6. Below Table Showing Complete Healing Time For Group A

No.	Healing Period	No. Of Patient	Percentage %
1	<15 DAYS	0	0%
2	16-30 DAYS	1	6.67 %
3	31-45 DAYS	5	33.33%
4	45-60 DAYS	1	6.67 %
5	MORE DAY/NO HEALING	8	53.33 %

#### 7. Below table complete healing time (for group B)

No.	Healing Period	No. Of Patient	Percentage %
1	<15 DAYS	0	0%
2	16-30 DAYS	2	13.33 %
3	31-45 DAYS	3	20.0%
4	45-60 DAYS	8	53.33 %
5	MORE DAYS/NO HEALING	2	13.34 %

#### 8. Below table showing comparative study on both group

#### According to Healing Time

No.	Healing Period	Total No. Of	Patient	Percentage %	Overall %	
		Group A	Group B	Group A	Group B	
1	<15 DAYS	0	0	0%	0%	0 %
2	16-30 DAYS	1	2	6.67 %	13.33 %	10 %
3	31-45 DAYS	5	3	33.33%	20.0%	26.66 %
4	45-60 DAYS	1	8	6.67 %	53.33 %	30 %
5	MORE DAYS/ NO HEALING	8	2	53.33 %	13.34 %	33.33 %

#### DISCUSSION

For analysis and assessment purpose four factors are considered, this criterion was taken to evaluate the normal healing time in both group, in post-operative period, among them chief complains were pain, tenderness, discharge and indurations. These factors are evaluated before the operation and values are compared for 60 days of treatment. Following are the assessment criteria before and after treatment of 60 days: -The effect of treatment studied in both group In *Chedana* Group A before treatment pain score was 38 and after treatment score was 11. So, the recovery mean value is 71.05 %, SD- 0.8165, SE 0.21082, t-value 8.22 and concerned p- value is < 0.001 so it is highly significant in recovery of pain. Because in sinus cavity pus causes pain whenever it let out the pain lows down itself. as well as we are doing there *Chedana* karma so continue healing of open wound retards the pain.

In *Ksharsutra (Seton)* Group B before treatment pain score was 39and after treatment score was 4. So, the recovery mean value is 89.74 %, SD- 0.4879, SE 0.12599, t- value- 18.52 and concerned p- value is < 0.001 so it is highly significant in recovery of pain. because, as the *Guggulu* based *Ksharsutra (Seton)* administrated in sinus cavity the action of *Guggulu* of *Putihara, VedanaSthapana (Pain Releving), Vrana-Shodhan* (purificatory of wounds) and VranaRopaka (healing) starts along with Chedana, Shodhan and *Ropan karma of Ksharsutra (Seton)*. So initially the administration of *Ksharsutra (Seton)* is more painful than other method but gradually it causes relief from pain.

# **Effect on Tenderness:**

The effect of treatment studied in both groups. In *Chedana Group* A before treatment tenderness score was 37 and after treatment score was 8. So, the recovery mean value is 78.38 %, SD- 0.73786, SE 0.19052, t- value-10.148 and concerned p- value is < 0.001 so it is highly significant in recovery of tenderness. Because in sinus cavity pus causes tenderness whenever it let out the tenderness lows down itself. as well as we are doing there *Chedana karma* so continue healing of open wound retards the tenderness. After the surgery the tenderness is more prominent but as the wound heals tenderness low downs.

In *Ksharsutra (Seton)* Group B before treatment tenderness score was 34and after treatment score was 4. So, the recovery mean value is 87.88 %, SD- 0.70373, SE 0.1817, t- value-10.64 and concerned p- value is < 0.001 so it is highly significant in recovery of tenderness. In *Ksharsutra* (Seton) *karma* tenderness more reliefs due to action of *Guggulu and Ksharsutra (Seton)* itself.

# Effect on Discharge: -

The effect of treatment studied in both group In *Chedana* group A before treatment discharge score was 33 and after treatment score was 13. So, the recovery mean value is 60.60 %, SD- 1.1595, SE 0.29938, t-value- 4.454 and concerned p- value is < 0.001 so it is highly significant in recovery of discharge. This result is low because initially discharge is down due to proper wide opening and *Madhu Ghrit* dressing than after some day when healing is to be completing, some patient who start again consumption of etiological factors those get recurrence and discharge again start. That lows mean value.

In *Ksharsutra* (Seton) Group B before treatment discharge score was 29 and after treatment score was 5. So, the recovery mean value is 82.7586 %, SD-0.70373, SE 0.1817, t- value- 9.798 and concerned pvalue is < 0.001 so it is highly significant in recovery of discharge.

In every patient continue dressing and proper weekly changing with rail- road technique and frequency of immobilization of *Guggulu based Ksharsutra (Seton)* thread leads to lowering down the discharge. This is the cause of more relief in discharge due to *Ksharasutra (Seton)*.

# Healing Period and Complete Healing of Wound (For Group A)

According to clinical data shown the healing time is scattered is due to after *Chedanaa Karma (fistulectomy)*.Every sinus take different time to heal that is depends upon the length of track, the ramification depth of the wound, patient's hygiene for the wound, size of excision etc. So, the healing takes different time person to person.

In chart no 29 healing time 53.33 % sinus were remained unhealed.6.67 % sinuses were healed within 16-30 days, 33.33 % patient within 31-45 days and 6.67 % of sinus recovered after 45- 60 days after *Chedana karma*. so overall 46.67 % pilonidal sinus cured within 60 days. Healing time differ on the condition of wound.

# **Complete Healing Time (For Group)**

According to the clinical study shows no sinus healed within 15 day of treatment with *Ksharsutra* (Seton) .13.33 % patient found relief from problem within 16-30 days. 20 % of pilonidal sinus takes complete healing period of 31-45 days and maximum 53.33 % sinus take 45-60 days of healing due to size and ramification (Branches) of the sinus. 13.34 % remain take delay healing.

#### Mode of Action of Drugs Used for *Lepana*

**1.** *Guggulu*: It is well known for having anti-inflammatory and analgesic action. It is also inhibiting platelet aggregation and is having antioxidant effect helps in relieving the spasm and promotes healing in the ulcer. Hypolipidemic, anti-bacterial, anti-viral, anti-atherosclerotic, anti-rheumatic, anti-fertility activity. It is indicated for indolent ulcer and wounds and a gargle in dental carries, weak and spongy gums Gum Resin – Having anti-inflammatory, anti-rheumatic and hypolipidaemic activity

#### 2. Apamarga

**External-** In *Karnashoola Ksharasiddha taila* is useful, Ash of this whole plant is hygroscopic in nature as well as analgesic when applied to wet intact surface and also has powerful caustic effect when applied on the wound surface.

**Internal-** G.I. system: -Appetizer, Digestive, Mild laxative and antihelmenthic.

Cardiovascular system: -Cardio tonic, cardiac stimulant.

Urogenital: - Moderate diuretic and prevents calculus formation. It renders alkaline

Reaction to urine.

Skin: - It stimulates the sweat glands and relieves itching, anti -microbial, anti

Fungal

# 3.Haridra

**External:** Extracted oil has antibacterial action on staphylococcus aures, staphylococcus albus and bacillus typhus's. Anti-septic, Anti-fungal, Anti-inflammatory. The antioxidant properties of curcuma powder are probably due to phonetic character of curcumin.

Internal: Appetizer, Mild laxative, Haematinic, Haemostatic, decrease excessive secretion of mucous,

thereby it clears the airway, Blood purifier, antiprotozoal, CNS depressant, anti-fertility, antiarthritic, hypocholesteremic, antihistaminic, antihepatotoxic. Effect of essential oil and curcumin are antibacterial and antifungal.

# Comparative Study on Both Group According to Healing Time

According to the clinical data the comparison of both procedure maximum 33.33 % sinus healed within 31-45 days by the *Chedana karma* but maximum 53.33 % sinus take 45-60 days by *Ksharsutra* (Seton). In 60 days of treatment 53.33 % sinus remain unhealed due to the length of track, the ramification depth of the wound, patient's hygiene at the wound, size of excision. They remain under improve and uncured condition. But, only 13.34 % sinus by *Ksharsutra (Seton) karma* remain unchanged.

In overall result 10 % of total patient found healing from the condition within 16-30 days. 26.66 % of pilonidal sinus take period of 31-45 days for healing and maximum 30 % sinus take 45-60 days for healing. 33.33 % sinus take delay healing they are remained uncured or under improvement condition.

#### CONCLUSION

Shalaj Nadi Vrana (sinus) is an age related and profession related condition. It is very terrible condition. Based on its symptomatology it can be co-related with Pilonidal sinus i.e. Pain, tenderness, inflammation, indurations and discharge. According to management by Modern technique depends on the disease pattern. Commonly a sinus remains as pre-infectious abscess. Although, Abscess is managed by an Incision and Drainage to release the pus, to reduce the inflammation and pain. As well as a chronic sinus may persist after the abscess cavity has healed and this usually needs to be excised or surgical opening. Therefore, in the present study it was aimed to establish and evaluate an innovative technique for management of Shalaj NadiVrana (Pilonidal sinus) as to minimize recurrence, make its cost effective with universal acceptability of minimum hospitalization with the help of Ayurvedic procedure.

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