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Comparative Study of Efficacy of Standard Kshar Sutra and Udumber Ksheer Sutra in the Management of Naadi Vrana (Pilonidal Sinus)

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Abstract---Background: The term *Naadi Vrana* is meaning sinus. Its classification and management including various local and systemic measures are the main objectives of the classical text. Sinus is a granulation tissue-lined blind channel that extends from an epithelial surface into the surrounding tissues. Sinus means “Hollow” or “A bay”(Latin). There are 8 types of *Naadi Vrana* like *Vaatik naadi*, *Paitik naadi*, *Kaphaj naai*, *Vaat-Pitaj naadi*, *Pit-Kaphaj naadi*, *Vaat-Kaphaj naadi*, *Sannipatik naadi* and *Aagantuja naadi*. The prevalence of pilonidal illness is estimated to be around 26 per 100,000 people. The incidence rate of pilonidal disease is approximately 0.7%. Objective: To study the efficacy of *Standard Kshar Sutra & Udumber ksheer sutra* in the management of *Naadi Vrana (Pilonidal Sinus)*. Material & Method: The present study is designed as a Randomized clinical trial in which 36 patients will be enrolled. Sutra will be applied in *Naadi Vrana (Pilonidal Sinus)*. Assessment will be done 0th, 7th day, 14thday, 21st day and 28th day. Result:- The changes are expected to be observed in subjective parameters with objective parameters in the Healing of *Naadi Vrana (Pilonidal Sinus)*.

Keywords---naadi vrana (pilonidal sinus), pilonidal illness, standard kshar sutra, udumber ksheer sutra.

Introduction

Sushruta samhita is devine literature of *shalya tantra* (surgery) in ancient period. *Sushruta samhita* having best description of almost all surgeries among all *samhitas*. He had described *Shashtra* and *Anushastra Karma* in various disorders. *Naadi vrana* is one among them which is treated by *Anushastra karma*. There are 8 types of *Naadi Vrana* like *Vaatik naadi*, *Paitik naadi*, *Kaphaj naai*, *Vaat-Pitaj naadi*, *Pit-Kaphaj naadi*, *Vaat-Kaphaj naadi*, *Sannipatik naadi* and *Aagantuja naadi*^[1].

The term *Naadi Vrana* is meaning sinus. Its classification and management including various local and systemic measures are the main objectives of the classical text.^[2] Sinus is Blind track lined by granulation tissue leading from an epithelial surface in to surrounding tissues. Sinus means “Hollow” or “A bay”(Latin).^[3] *Naadi Vrana* can be correlated with Pilonidal Sinus in modern medical sciences. The term pilonidal is derived from Pilus i.e hairs and Nidal i.e nest. Also called Jeep bottom because it was very common in Jeep drivers.^[4] A sinus tract, or tiny tube, that may arise from the site of infection and open to the skin's surface is known as the pilonidal sinus (PNS). The pilonidal sinus is where the cyst's contents drain. A pilonidal cyst is generally uncomfortable, although the patient may not feel any discomfort once the cyst is drained.^[5] Hair, filth, and debris are common in pilonidal cysts. It can cause excruciating pain and is frequently infected. It may leak pus and blood and have a terrible odour if it becomes infected. PNS is a disease that primarily affects men but is also prevalent among young people. It's also more frequent among those who spend a lot of time sitting, such as cab drivers.^[6] Incidence of pilonidal disease is about 26 per 100,000 populations. The incidence rate of pilonidal disease is approximately 0.7%.^[7] Pilonidal disease occurs predominantly in males, at a ratio of about 3-4:1. It occurs predominantly in white patients, typically in the late teens to early twenties, decreasing after age 25 and rarely occurs after age 45.^[8]

At present most common surgical procedure adopted in the treatment of Pilonidal Sinus excision of sinus in two method open and closed. Closed methods like ‘Z’ Plasty, Karydakis Procedure, Bascom’s technique. These surgical management carries several complications like delayed wound healing, and even after complete excision of sinus there are chances of recurrence.^[9] The *Kshara Sutra* treatment for Pilonidal Sinus is a safe, effective, ambulatory, and non-hazardous technique of treatment. A multi-centric investigation also demonstrated that the approach is highly successful and has no recurrent patterns. However, the study also found that the treatment period is significantly longer than traditional surgery. It is also found that the pain factor is more in the *Kshara Sutra* therapy over the Pilonidal Sinus. Therefore, a quest is continuing to overcome certain disadvantages found with *Kshara Sutra*. India is a vast country, with varied flora and there is also a need for search of the alternate plant sources which may give better results. It has been observed in previous research that latex obtained from particular plants may be used to make the *Kshara Sutra*, which has a positive impact on the Pilonidal Sinus. So, in order to reduce pain, a comparison research will be conducted to assess the effects of the Standard *Kshara Sutra* and the *Ksheer Sutra* composed of *Udumber* latex.

Need of study

Ayurveda has a unique way of treating *Naadi Vrana* (Pilonidal Sinus). All type of *Naadi Vrana* responds well to different types of *Kshara* as well as *Ksheer Sutrās*. *Standard Kshara Sutra* application has proved effective treatment for *Naadi Vrana* (Pilonidal sinus). *Standard Kshar Sutra* having Properties like fast cutting effect and it is irritating in nature. So patient who is undergoing treatment with *Standard Kshar Sutra* having more pain during management of *Naadi Vrana* (Pilonidal sinus). Due to pain the rate of dropout of the treatment is also more. So there is need of study to improve the modalities of this *Standard Kshar Sutra* with *Udumber Ksheer Sutra* which having Properties like scavenging activity, rapid wound healing activity, analgesic, anti- microbial, anti-bacterial, anti-fungal, anti-inflammatory, anti-diabetic activity and it helps to reduce pain, not irritating in nature so study is planned on *Naadi Vrana* (Pilonidal Sinus).

Drug references

उदुम्बरोहिमोरुक्षोगुरुःपित्तकफास्रजित्मधुरस्तुवरोवर्णोन्नणशोधनरोपणः॥१॥ (भा.प्र. नि. वटादिवर्ग)

According to *Acharya Bhavprakash*, *Udumbara* shows properties like *Pitta*, *Kapha*, *Asrajita* which means it drains out *Kapha* and *Pitta* from the wound. *Vrana shodhan ropan* means cleaning & healing of the wound. *Udumbara Ksheer* will be used in this present research work as it possess, scavenging activity, rapid wound healing activity, analgesic, anti- microbial, anti-bacterial, anti-fungal, anti-inflammatory, anti-diabetic activity and also available in abundance and in all seasons and its latex can be easily extracted out.^[10]

Aim and objectives of study

- Aim: Comparative assessment of *Standard Kshar Sutra* and *Udumber Ksheer Sutra* in the management of *Naadi Vrana* (Pilonidal Sinus).
- Objectives:
 - To study the efficacy of *Udumber Ksheer Sutra* in the management of *Naadi Vrana* (Pilonidal Sinus).
 - To study the efficacy of *Standard Kshar Sutra* in the management of *Naadi Vrana* (Pilonidal Sinus).
 - To compare the efficacy of *Udumber Ksheer Sutra* and *Standard Kshar Sutra* in the management of *Naadi Vrana* (Pilonidal Sinus).

Materials and Methods

Present work will be conducted under following heading.

Drug collection/ authentication:

- The latex will be collected from the herbal garden of MGACH & RC, and will be verified form the Department of Dravyaguna of MGACH & RC, Salod (H), Wardha.
- Authentication of drugs will be done by Dravyaguna Department.

- Drug will be standardized by as per API or Analytical labs at MGACH & RC And Central lab of JNMC, Sawangi Meghe, Wardha.
- According to Need study will be carried out at MGACH & RC as recognized or recommended by DMIMS (DU).

Table 1
Ingredients of *Udumber Ksheer Sutra*

SR. NO	Name of the ingredient	Botanical Name	Part Used
1	<i>Udumber Ksheer</i>	<i>Ficus Racemosa</i> Linn. ^[11]	Latex
2	Barbour thread no. 20		

Table 2
Ingredients of *Standard Kshar Sutra*

SR. NO	Name of the ingredient	Botanical Name	Part Used
1	<i>Standard Kshar Sutra</i> (<i>Apamarga Snuhi</i> <i>Haridra Kshar Sutra</i>)	<i>Achyranthes aspera</i> Linn. ^[12] <i>Euphorbia nerifolia</i> Linn. ^[13] <i>Curcuma longa</i> Linn. ^[14]	Kshar Ksheer Kanda churna
2	I. Barbour thread no. 20		

Detail of drug preperation

Preparation of Udumber Ksheer Sutra

- *Ksheer* (Latex) will be collected in a sterile bottle from the *Udumber* (*Ficus racemosa*) by giving slit incision over the Stem.
- Every day one coating will be made on the thread with the help of sterile gauze and will be allowed to dry.
- Similarly 11 coatings of *Udumber Ksheer* will be made on thread in 11 days.
- Every time fresh *Ksheer* (latex) will be taken.
- It will be dried and preserved in *Kshar Sutra* cabinet under UV- rays for sterilization.

Preparation of Standard Kshar Sutra (Apamarga KsharSutra)

- *Ksheer* (Latex) will be collected in a sterile bottle from the *Snuhi* (*Euphorbia neriifolia*) tree by giving slit incision over the Stem.
- Every day one coating will be made on the thread with the help of sterile gauze and will be allowed to dry.
- Similarly 11 coatings of *Snuhi Ksheer* will for 11 days, 7coatings of *Snuhi Ksheer + Apamarga Kshar* for 7 days, 3coatings of *Haridra + Apamarga Kshar* for 3 days.
- Every time fresh *Ksheer* (latex) will be taken.

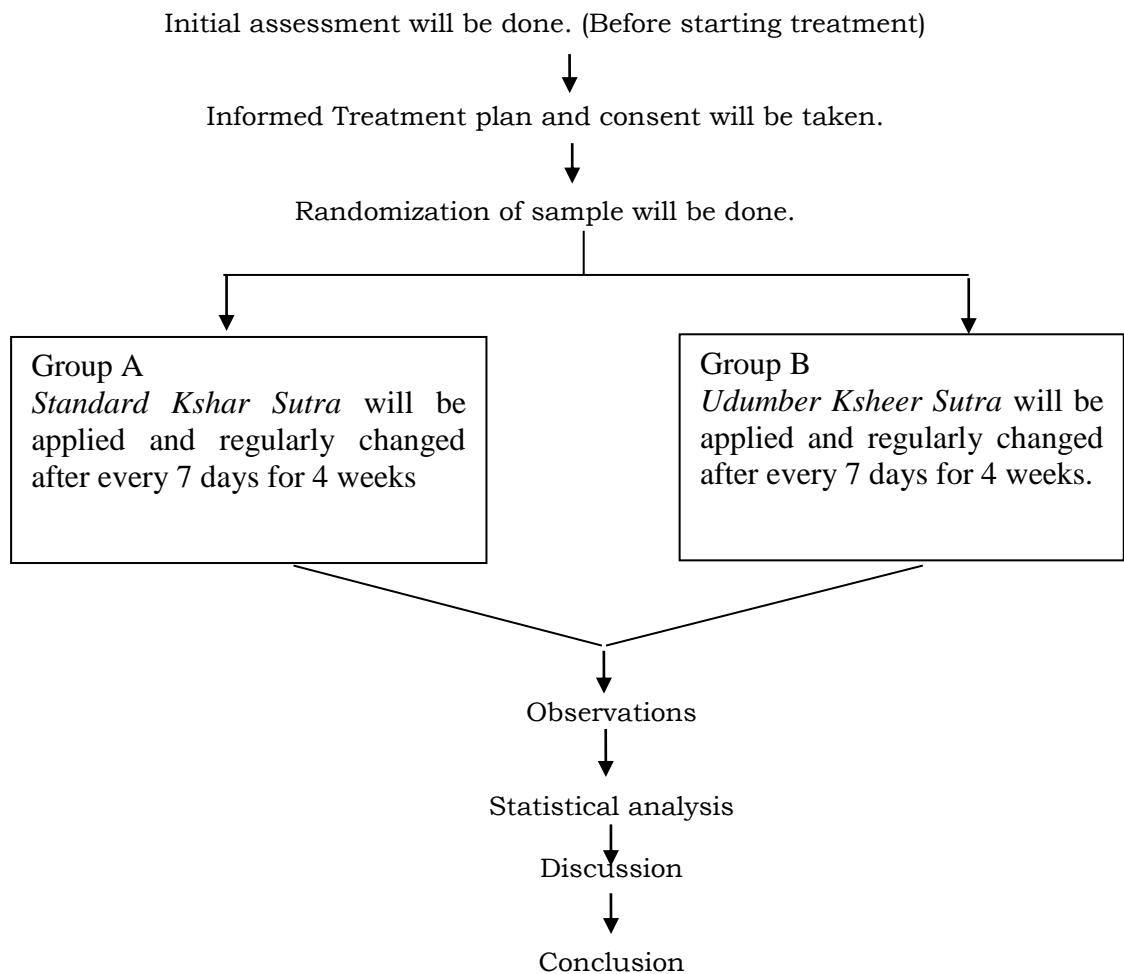
It will be dried and preserved in *Kshar Sutra* cabinet under UV- rays for sterilization.

Source of data

- Literary source : The Study will be reviewed by collecting information from various classical text.
- Clinical source : Patients of *Naadi Vrana* (Pilonidal Sinus) will be selected from Shalyatantra OPD & IPD of Mahatma Gandhi Ayurved College, Hospital and Research centre, Salod(H) Wardha.
- Drug source : The latex will be collected from herbal garden of MGACH & RC.

Type of Study : Interventional clinical study.

Study design : Randomized clinical trial.



Inclusion criteria

- Patient willing with consent.
- Patient with age group of 18 to 60 years.
- Patients with diagnosed *Naadi Vrana* (Pilonidal Sinus developed in the cleft of the buttocks) will be included after screening.
- Patients irrespective of sex, occupation and economic status will be included.

Exclusion criteria

- Patients suffering with systemic disorders like Diabetes mellitus, Tuberculosis, HIV and Hepatitis will be excluded.
- Patients having Malignancy will be excluded.
- Pregnant or lactating women.

Withdrawal criteria

- If the symptoms get aggravated during treatment then such subject will be withdrawn from study and suitable alternative treatment will be provided in free of cost.
- Patients himself wants to withdraw from clinical trial.
- Patients not giving proper follow up.

Table 3
Sample Size with 2 group

Group	Sample size	Intervention	Frequency	Duration	Follow up
Group A	18	<i>Standard Kshar Sutra</i>	Changed after every 7 days	30 days	7 th , 14 th , 21 st , 28 th day
Group B	18	<i>Udumber Ksheer Sutra</i>	Changed after every 7 days	30 days	7 th , 14 th , 21 st , 28 th day

Sample Size:- 2 group each with minimum of 18 patients who are fulfilling the criteria for inclusion.

Methodology

The volunteers will be informed about the study protocol. Willing participants will be randomly selected as per computer generated table. Clinical research format will be prepared and validated. Prior to the study approval will be taken from IEC, MGACHRC, Salod (H) Wardha and CTRI registration will be done. After selection, each participant will be tested individually and selected according to selection criteria. They are divided into two groups. In one group (18 participants) we will apply *Standard Kshar Sutra* as a standard drug and in other group (18 participants) will apply *Udumber Ksheer Sutra* for 4 weeks with day wise schedule of changing sutra. After inclusion in study protocol each participant will receive the respective treatment from day one for 4 weeks. In person follow up will be

taken on 7th, 14th, 21st and 28th day. After completion of the treatment for 4 weeks and after that each participant will be assessed with Ayurvedic and modern parameters. Individuals, who will miss even 1 application of drug in total 28 days, will be dropped out from the clinical study. Post treatment follow up will be taken for next 4 weeks.

Assessment criteria

- Objective Parameters :
 - Cutting rate per week
- Subjective Parameters :
 - Pain
 - Discharge
 - Tenderness
 - Induration

Grading of subjective parameters^[15]

Table 4
Pain on visual Analogue scale

Grade	Explanation
0	No pain
1	Mild pain (1-3)
2	Moderate pain (4-7)
3	Sever pain (8-10)

Table 5
Discharge

Grade	Explanation
0	No discharge
1	Mild - If discharge wets one pads of gauze
2	Moderate - If discharge wets two pads of gauze
3	Profuse - If discharge wets more than two pads of gauze

Table 6
Tenderness

Grade	Explanation
0	No tenderness
1	Mild Tenderness on firm pressure
2	Moderate Tenderness on gentle pressure
3	Severe Patient denies touching

Table 7
Induration

Grade	Explanation
0	No inflammatory reaction
1	Mild Inflammatory reaction with tissue oedema and cellular response
2	Moderate Reaction with involvement of reticular layer of dermis.
3	Severe – Reaction with involvement of subcutaneous tissue.

Scope and implications of the proposed study

Scope

- As the *Udumber Ksheer Sutra* is easily available in nature and cost effective.
- Less painful, reduction in unit cutting time and will have better wound healing properties.
- Might replace widely used different types of *Kshar Sutras* in *Naadi Vrana* (Pilonidal Sinus).
- Safe for internal administration.

Implications

- If *Udumber Ksheer Sutra* proved to be more effective in management of *Naadi Vrana (Pilonidal Sinus)* as compare to *Standard Kshar Sutra* then it will provide more acceptable as well as convenient treatment.

Analysis plan

- Drug analysis:
The analysis *Standard Kshar Sutra* and *Udumber Ksheer Sutra* will be done.
- Data analysis:
Data analysis will be done by using Student Paired and unpaired t test & Wilcoxon rank-sum test.

Discussion

Sushruta samhita is devine literature of *shalya tantra* (surgery) in ancient period. *Sushruta* samhita having best description of almost all surgeries among all samhitas. He had described *Shastra* and *Anushastra Karma* in various disorders. There are 8 types of *Naadi Vrana* like *Vaatik naadi*, *Paitik naadi*, *Kaphaj naai*, *Vaat-Pitaj naadi*, *Pit-Kaphaj naadi*, *Vaat-Kaphaj naadi*, *Sannipatik naadi* and *Aagantuja naadi*. *Naadi vrana* is one among them which is treated by *Anushastra karma*. The term *Naadi Vrana* is meaning sinus. Its classification and management including various local and systemic measures are the main objectives of the classical text. Sinus is a granulation tissue-lined blind channel that extends from an epithelial surface into the surrounding tissues. Sinus is Latin for "hollow" or "bay" (Latin). *Naadi Vrana* can be correlated with Pilonidal

Sinus in modern medical sciences. The term pilonidal is derived from Pilus i.e hairs and Nidal i.e nest. Also called Jeep bottom because it was very common in Jeep drivers. Pilonidal sinus (PNS): a sinus tract, or tiny channel, that can develop from an infection source and open to the skin's surface. The pilonidal sinus is where the cyst's waste is drained. A pilonidal cyst is generally uncomfortable, although the patient may not experience any discomfort once the cyst is drained. Hair, filth, and debris are common in pilonidal cysts. It can cause excruciating pain and is frequently infected [16]. It may leak pus and blood and have a terrible odour if it becomes infected. PNS is a disease that primarily affects men but is also prevalent among young people. It's also more frequent among those who spend a lot of time sitting, such as cab drivers. Incidence of pilonidal disease is about 26 per 100,000 populations. The incidence rate of pilonidal disease is approximately 0.7%.⁽¹⁷⁻¹⁹⁾

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Conclusion

If the proposed study results in the positive outcome then it will set a Standard and give best parallel modality for the management of *Naadi Vrana (Pilonidal Sinus)*.

Assessment and results

Data of all observed patients will be collected and reported in Case sheet Performa and same will be compared.

Consent and ethical approval

After obtaining ethical clearance study will be started.

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