



## ***AshwathaKsheer Sutra* and *UdumberKsheer Sutra* in the management of *Bhagandara* (Fistula in ano): An Ayurvedic management protocol for treatment of fistula in ano**

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### ABSTRACT

Fistula in ano is tract lined by granulation tissue having internal opening in anal canal and rectum and external opening in the perianal region. The incidence of a fistula-in-ano developing from an anal abscess ranges from 26-38%. The prevalence of non-specific anal fistula has been estimated to be 8.6 to 10/100,000 of the population per year, with a male to female ratio of 8:1. In contemporary sciences *Bhagandara* can be correlated with Fistula in Ano. To compare the efficacy of *AshwathaKsheer Sutra* and *Udumber Ksheer Sutra* in the management of *Bhagandara* (Fistula in ano). The present study is designed as a Randomized single blind parallel in which 40 patients will be enrolled. Patients will be distributed in two group with 20 patients in each group. In group A *Ashwatha Ksheer Sutra* and in group B *Udumbar Ksheer Sutra* will be changed after 7 days till the cure of fistula. Assessment of the patients will be done on day 1<sup>st</sup>, 8<sup>th</sup>, 15<sup>th</sup>, and 22<sup>nd</sup> after intervention, follow up will be taken on 29<sup>th</sup> day. Results will be drawn from the observations of objective parameters. Conclusion of the study will be drawn on the basis of statistical data calculated from the collected data.



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### INTRODUCTION

*SushrutSamhita* can be compared with any book on surgery written centuries later. In context of chikitsa *AcharyaSushruta* has described almost all sort of surgical managements and some of them still have

no comparison. More over in regards of anorectal and perineal surgeries, he has expounded much and equal emphasis is given to surgical as well as para surgical measures. Anorectal diseases like *Arsha* and *Bhagandara* are said callous to be cured and among them *Bhagandara* is considered under the *AshtaMahaagad* (Eight Grave Disorders) ([Sushrut-samhita, 2012](#))

The term *Bhagandara* is etiologically originated from two Sanskrit words – *Bhaga* and *Daran* meaning tearing of perineum. Its classification and management including various local and systemic measures are the main objectives of the classical text. ([Sharma, 2015](#)) At first it is present as *Pidika* and when it become *pakwa* or suppurate it forms *Bhagandar*. It causes *Daran* in *Bhag*, *Guda* and *BastiPradesh*. ([Shastri, 2007](#))

It can be correlated to Fistula in ano in modern

medical sciences. Fistula in ano is tract lined by granulation tissue having internal opening in anal canal and rectum and external opening in the perianal region. Most fistulas are thought to arise as a result of cryptoglandular infection with resultant perianal abscess. An abscess represents the acute inflammatory event, whereas the fistula is representative of the chronic process (Williams *et al.*, 2008). The incidence of a fistula-in-ano developing from an anal abscess ranges from 26-38%. The prevalence of non-specific anal fistula has been estimated to be 8.6 to 10/100,000 of the population per year, with a male to female ratio of 8:1 (Deeba *et al.*, 2008).

At present most common surgical procedure adopted in the treatment of Fistula in ano are Fistulectomy, Fistulotomy, Flap advancement, LIFT, Glue, and Seton. These surgical management carries several complications like frequent damage to the anal sphincters muscles, faecal soiling, Rectal prolapse, anal stenosis, delayed wound healing, and even after complete excision of tract there are chances of recurrence (Deshmukh *et al.*, 2019).

The *Kshara sutra* treatment is a safe, effective, ambulatory and un-hazardous method of treatment in fistula-in-ano. A multi-centric study carried also confirmed that the method is very much effective and free from recurrence. However, the study also revealed that the time required for the treatment is essentially more than conventional surgery. It is also found that the pain factor is more in the *Kshara sutra* surgery over the fistula-in-ano. 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. In earlier studies it is reported that the latex expressed from certain plants can be very well used to prepare the *Ksheer sutra* which is having very good effect of fistula-in-ano by reducing the pain with the usual advantages of *Kshara sutra*, therefore a comparative study will be carried out to compare the effect of *Ksheer sutra* made of latex of *Ashwatha* and latex of *Udumber* (Trikamji, 2008)

## Methodology

### Trial design

Randomized single blind parallel.

### Study setting

Diagnosed patients will be selected from *Shalyatantra* OPD & IPD of M.G.A.C.H. and R.C. Wardha (Figure 1).

### Study design

Randomized clinical trial (single blind parallel)

## Inclusion Criteria

1. Patient willing with consent.
2. Patient with age group of 18 to 60 years.
3. Patients with clinical features of *Bhagandara* (Fistula in ano) will be included after screening.
4. Patients irrespective of sex, occupation and economic status will be included.

## Exclusion Criterion

1. Patients suffering with systemic disorders like Diabetes mellitus, Tuberculosis, HIV and Hepatitis will be excluded.
2. Patients having
  - I. Multiple Fistula in Ano
  - II. Hemorrhoids
  - III. Pregnancy
  - IV. Malignancy will be excluded.

## Criteria for discontinuing or modifying allocated interventions

Patients will be withdrawn from intervention if any harmful incidence, signs of drug allergy or any problem will occur; patient will be offered treatment free of cost till the disease subsided.

## Follow up period after treatment

29<sup>th</sup> day

## Secondary Outcomes

*Ashwatha Ksheer* and *Udumber Ksheer* is available throughout India and it is safe, easily available, cost effective and best remedy for the management of *Bhagandar*.

## Statistical analysis

Wilcoxon rank sum test.

## Time duration till follow up

1<sup>st</sup>, 8<sup>th</sup>, 15<sup>th</sup>, and 22<sup>nd</sup> after intervention, follow up will be taken on 29<sup>th</sup> day.

## Time schedule of enrolment, interventions

Diagnosed patients of *Fistula in Ano* will be enrolled in the present study after fulfilling the inclusion criteria (Figure 2).

## Interventions

*KsheerSutra* will be change every week till treatment. Common conservative treatment used in both the groups

1. Hot Sitz Bath- Twice a day
2. *TriphalaGuggul*- 500mg/BD
3. *Panchasakarchoorna* -5gm/HS(SOS)

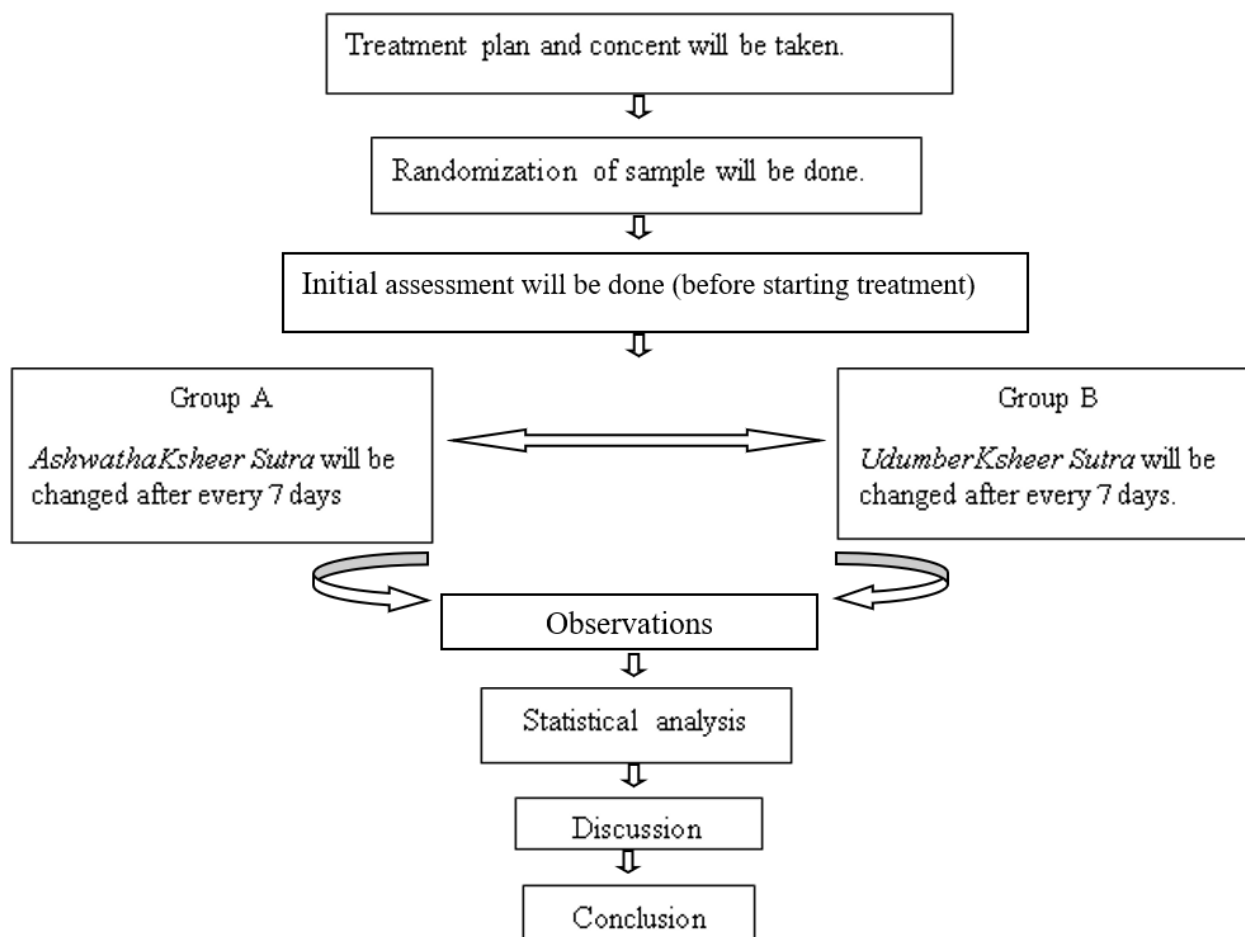


Figure 1: Flow diagram of the study procedure

Table 1: Groups of AshwathaKsheer Sutra and UdumberKsheer Sutra

Group	Group A	Group B
Sample Size	20	20
Ksheer Sutra	AshwathaKsheer Sutra	UdumberKsheer Sutra
Thread Change	After every 7 days	After every 7 days

**Groups**

2 group each with minimum of 20 patients who are fulfilling the criteria for inclusion (Table 1).

**Recruitment**

Patient will be recruited by single arm study

**Implementation**

Principal invigilator will register subject.

**Data collection methods**

Randomized

**Assessment criteria**

**a) Objective criteria**

1. Pain - Vas Scale.
2. Discharge - Asepsis scoring system.

3. Itching - Numerical Rating Scale.

**b) Subjective criteria**

1. Cutting rate per week

**Data management**

Principal investigator will do coding of data.

**Ethics and dissemination**

Permission for research has been taken from Institutional Ethical Committee ref no.: MGACHRC/IEC/July-2020/53

**Consent or assent**

Written informed consent will be obtained from the patient.

Item	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Enrollment of Volunteer								
Data collection								
Writing thesis up to methods								
Data analysis								
Writing thesis up to results and Conclusions								
Submission								

**Figure 2: Gantt Chart (Quarterly based)**

### Dissemination policy

For future research results will be disseminated and research will be published in reputed journal

### Informed consent materials

All the research related document and consent form will be given to the patients.

### DISCUSSION

*Bhagandar* is managed by various modern surgical and medical treatments, but all therapies have limitations and the chance of recurrence. Ayurved has its own way of treating *Bhagandari.eKshar Sutra* which is a minimal invasive para surgical measure capable of performing excision or *Chhedan*; by virtue of its mechanical pressure and phytochemical cauterization. Although the standard *ApamargaKshar Sutra* is used successfully, the difficulties in its preparation and application are worth noting. Different research scholars have carried out studies to find any other thread that can mitigate all these difficulties. Among these is *UdumbarKsheer Sutra*. Various researches have been conducted on this *Sutra* but the product has not comparatively evaluated with *AshwathaKsheerSutra*. The *Ashwatha (Ficus-religiosa)* has shown significant antioxidant, wound healing and anti-inflammatory activity. *AshwathaKsheer* will be used in this present research work as it posses, scavenging activity, rapid wound healing activity, analgesic, anti-microbial, anti-bacterial anti-inflammatory ([Sreelekshmi et al., 2007](#)), antiulcer, antidiabetic activity and also available in abundance and in all seasons and its latex can be easily extracted out ([Makhija et al., 2010](#)). So to evalu-

ate its efficacy in the management of *Bhagandar* as well as its comparative evaluation with the efficacy of *UdumbarKsheer Sutra*.

### Time schedule of enrolment, interventions

Thread will be changed after every 7 day till the cut through of the tract. Assessment will be done on day 1<sup>st</sup>, 8<sup>th</sup>, 15<sup>th</sup>, and 22<sup>nd</sup> after intervention, follow up will be taken on 29<sup>th</sup> day. (Figure 2)

### CONCLUSIONS

*Ashwatha* shows properties of *pitta, sleshmavranas-trajita* which means it drains out *kapha* and *pitta* from the wound. The predicted outcome of this analysis is that group A with intervention is more effective intervention to group B. It is effective in cutting rate of fistula track and subsides the symptom of Fistula in ano such as pain, discharge, itching. Patients who take all follow-up after treatment will have less chance of symptom reoccurrence.

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### Conflict of interest

The authors declare that they have no conflict of interest for this study.

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