Evaluation of Recurrence rate of *Bhagandar* (Fistula in ano) managed by *Udumbar* (*Ficusglomarata*) KsheerSutra - Protocol

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ABSTRACT

Background: *Bhagandar* (Fistula in ano) is one among the *Ashtamahagad* (8 dreadful disorders). Most fistulas are thought to arise as a result of cryptoglandular infection with resultant perianal abscess. It has been a surgical problem because of the high number of postoperative complications such as incontinence of gases and faeces and recurrent course of the disease.

Aim: Evaluation of recurrence rate of *Bhagandar* (Fistula in ano) managed by *Udumbar* (*Ficusglomarata*) KsheerSutra.

Methods: Participants fulfilling the inclusion criterion will be selected. After the complete healing of the surgical wound and the external opening without any sign of recurrence the observation will start. The postoperative site will be assessed at 30th, 90th, 180th, 365th day (1, 3, 6 and 12 months) after the healing of the fistula. Failure was defined as a clinical diagnosis of fistula recurrence at any time in the postoperative follow-up defined by clinical interview and physical examination for perianal abscess or boil, pus discharge, tenderness and in durations. Faecal continence and patient satisfaction will be recorded at each follow-up visit and adverse events will be monitored.

Results: Results will be drawn from the observations of objective parameters.

Conclusion: This will be drawn based on statistical analysis of the collected data.

Key Words: Ashtamahagad, Bhagandar, Fistula in ano, Apamarga KsharSutra, Udumbar KsheerSutra

BACKGROUND AND RATIONALE

Acharya Sushrut has included *Bhagandar* among the *Ashtamahagad*.¹ At first it is present as *Pidika* (boil/abscess) in *Apakwa* (unsupported) state, become *Bhagandar* when it becomes *Pakwa* (suppurated).² As defined in modern science, it is correlated with fistula in ano. Ayurvedhas a unique way of treating fistula in ano. All type of fistula in ano responds well to different types of *Kshar sutra* as well as *Ksheer sutra* therapy. *Kshar/Ksheer sutra* is a medicated seton. *Udumbar Ksheer sutra* is one among them developed in 1984 by Prof P.J Deshpande and M.K. Jalan.³ Its use is in vogue from last many years but yet recurrence of fistula in ano managed by it is not assessed yet. To evaluate the efficiency of any treatment it is very important to evaluate the recurrence rate of the disease after the treatment because it

gave a clear contemplation of the treatment's efficacy in not only curing the disease but also in preventing the relapse of the disease. The present study is an attempt to evaluate the recurrence rate of *Bhagandar* (fistula in ano) managed by *Udumbar ksheer sutra*.

It is worth mentioning that *Udumbar* is a tree of common occurrence in India. Various researches on *Udumbar* have shown that it has *Shothagna* (anti-inflammatory), *Vranashodhan* (wound cleaning) and *Vranaropak* (wound healing) properties⁴ which are needed to treat anal fistula by aiding or promoting natural healing and cutting. *Udumbar* is available freely hence it is economically viable. *Udumbar ksheer sutra's* use in the management of *Bhagandar* is in trend since last few years. To assess its efficacy in managing the frequent complications like the recurrence of *Fistula in*

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ano this study will be conducted. In the present study we will evaluate the recurrence rate of *Bhagandar* (Fistula in ano) managed by *Udumbar Ksheer Sutra*”

OBJECTIVES

Primary Objective

- Recurrence rate of Bhagandar (Fistula in ano) managed by UdumbarKsheer sutra.

Secondary Objective

- Healing of Bhagandar (Fistula in ano) managed by UdumbarKsheer sutra.
- Late complications of Bhagandar (Fistula in ano) managed by UdumbarKsheer sutra.

Case definition: Bhagandar (Fistula in ano) managed with *UdumbarKsheerSutra*.

Research question: Weather the recurrence rate of *Bhagandar* (Fistula in ano) is negligible or more when managed by *Udumbar KsheerSutra*?

Hypothesis: Recurrence rate of *Bhagandar* (Fistula in ano) may be negligible when managed by *UdumbarKsheerSutra*

Null Hypothesis: Recurrence rate of *Bhagandar* (Fistula in ano) may be more when managed by *UdumbarKsheerSutra*

MATERIALS AND METHODS

Trial design: An observational (Prospective study) cross-sectional study with a total of 65 participants.

Study setting: Study will be conducted in Mahatma Gandhi Ayurved College Hospital and Research Centre Salod (Hi) Wardha.

Source of Data: Participants will be selected from OPD and IPD of Shalyatantra department, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha.

Eligibility criteria

Inclusion Criteria:

1. Participant over 18 years of age.
2. Participant with complex cryptoglandular anal fistula with newly-diagnosed fistula-in-ano
3. Participant want to submit to *Ksheer* sutra therapy, has signed the informed consent before the operation and are physically fit for surgery.
4. Participant irrespective of sex, occupation and economic status.

Exclusion Criteria:

1. Participant refused Ksheer sutra therapy and chose Kshar sutra or other surgical treatment

2. Systemic disorders like diabetes mellitus
3. Inflammatory bowel disease
4. Tuberculosis
5. Malignancy
6. Pregnancy
7. Immunocompromised disorders

Data collection

- With each follows up at 30th, 90th, 180th, 365th day, physical examination along with a clinical interview of the patient will be done.
- Data of all participants will be collected and reported in case sheet form.

Criteria for discontinuing or amending the interventions allocated: The subject will be removed from the study if any event, drug susceptibility or some other illness or condition occurs the subject will be given free care before the condition subsides.

Intervention period in days: 365

Follow up period: On days 30, 90, 180 and 365 day

Primary Outcomes: *Udumbarksheer sutras* use in the management of Bhagandar is in trend since last few years. To assess its efficacy in managing frequent complications like the recurrence of Fistula in ano. This study will eventually contribute to set the recurrence rate of fistula in ano managed by *Udumbarksheer sutra* along with applied clinical aspect.

Secondary Outcomes: As the ingredient, *Udumbar* is easily available all over India hence this study will contribute to cost-effective, safe, readily available, simple preparation and a good remedy for the management of *Bhagandar*. Therefore this work will serve as torch bearer in further similar research works.

Enrolment and interventions

With each follow up at 30th, 90th, 180th, 365th day viz. 1st, 3rd, 6th and 12th month respectively, physical examination along with Clinical interview of the patient will be done. Data of all participants will be collected and reported in case sheet form.

Total 65 Patients will be taken by simple random sampling using a computerized table method and will be enrolled.

Method:

- This prospective observational study will be conducted in the department of Shalyatantra, Mahatma Gandhi Ayurved College Hospital and Research centre Salod (Hi) Wardha.
- Participants fulfilling the inclusion criterion will be selected.
- After the complete healing of the surgical wound and the external opening without any sign of recurrence the observation will start.

- The postoperative site will be assessed at 30th, 90th, 180th, 365th day (1, 3, 6 and 12 months) after the healing of the fistula.
- Failure was defined as a clinical diagnosis of fistula recurrence at any time in the postoperative follow-up defined by clinical interview and physical examination for perianal abscess or boil, pus discharge, tenderness and induration.
- Faecal continence and patient satisfaction will be recorded at each follow-up visit and adverse events will be monitored.

Data collection methods

Data management: PI will code the data entry.

Statistical methods: Statistical analysis will be done by using descriptive statistics only

Ethics and Dissemination: Approval from the Committee on Research Ethics has taken.

Reference No. :DMIMS (DU)/IEC/Sept – 2019/8470

Consent: Each patient shall receive informed consent prior to beginning the study. Confidentiality of each patient will be maintained throughout the study.

Dissemination policy:

The data will be disseminated via paper publication.

Eligibility guidelines for authorship and any intended use by professional authors

DISCUSSION

Bhagandar is managed by various modern surgical and medical treatments, but all therapies have limitations and the chance of recurrence. Ayurvedhas its way of treating *Bhagandari*. *Ekshar Sutra* which is a minimal invasive para surgical measure capable of performing excision or *Chhedan*; under its mechanical pressure and phytochemical cauterization. *UdumbarKsheerSutra* is one among them. Various research work has conducted over *UdumbarKsheerSutra* in managing *Bhagandar* with a worth noting success. Therefore to assess its efficacy in managing the frequent complications like the recurrence of Fistula in ano this study will be conducted systematically as shown in *figure no. 1*. Precautions will be taken for special co-morbid conditions like diabetes⁵, cardiovascular morbidities.⁶ Lamture et al reported about entero cutaneous fistula in an operated case of total abdominal hysterectomy (*figure 1*).⁷

This study involves the evaluation of recurrence rate of *Bhagandar* managed by *UdumbarKsheersutra*. As recurrence of fistula in ano is the frequent complication of surgery so it is important to evaluate a remedy for anal fistula which is having a low recurrence rate. As the ingredient *Udumbar* is

easily available all over India hence this study will contribute to cost-effective, safe, readily available, simple preparation and a good remedy for the management of *Bhagandar*. Therefore this work will serve as a torchbearer in further similar research works. Thus this study will eventually contribute to set the recurrence rate of fistula in ano managed by *UdumbarKsheer sutra* along with applied clinical aspect.

If the proposed study results in the positive outcome i.e if recurrence rate of fistula in ano managed by *UdumbarKsheer sutra* is found to negligible then it will set a standard and give the best parallel modality for the management of *Bhagandar* (Fistula in ano).

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 1: Gantt Chart (Quarterly based).

CONCLUSION

This will be drawn based on statistical analysis where we will get the recurrence rate of *Bhagandar* (Fistula in ano) managed by *Udumbar* (*Ficus glomarata*) *Ksheer Sutra*.

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