Standardization of *Udumbar KsheerSutra* and its Clinical Efficacy in Comparison with *Apamarga KsharSutra* in the Management of *Bhagandar* (Fistula in ano) – Protocol

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ABSTRACT

Background: Acharya Sushrut, the ancient surgeon has included *Bhagandar* among the *Ashtamahagad* (8 dreadful diseases). The one which causes *Bhag* (vulva), *Guda* (anal region) and *Basti Pradesh* (urogenital area) *Daran* (cutting) are known as *Bhagandar*. As defined in modern science, this can be associated with Fistula in ano. Fistula in ano is an abnormal track in the perianal region with an external opening that interacts with the rectum or anal canal through a specific internal opening. Various modern surgical and medical treatments are trendy to manage Fistula in ano but there are certain limitations to all treatments.

Aim and Objectives: To Standardize *Udumbar KsheerSutra* and evaluates its clinical efficacy in comparison with *Apamarga KsharSutra* in the managing *Bhagandar* (Fistula in ano).

Methodology: Standardization will be done by organoleptic and physicochemical testing of *UdumbarKsheer* and *Udumbar KsheerSutra* and then the standards of *KsheerSutra* will be determined. Total of 130 participants will be equally distributed in two groups with a minimum of 65 participants in each. In a group, A *UdumbarKsheerSutra* and in group B *Apamarga KsharSutra* will be changed after 7 days till the cure of fistula. Assessment of the patients will be done on days 0, 15, 30, 45 and 60 and after the intervention, follow up will be taken on days 90 and 120.

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

Conclusion: Conclusion of the study will be drawn based on statistical data calculated from the collected data.

Key Words: Ashtamahagad, Bhagandar, Fistula in ano, *Apamarga KsharSutra*, *Udumbar Ksheer Sutra*

BACKGROUND

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. An anal fistula is an abnormal track having an external opening in the perianal region and internal opening in the anal canal and/or rectum.³ Fistula-in-ano prevalence rate is 8.6 cases for every 100,000 populations. The prevalence in men is 12.3 cases per 100,000 population, and 5.6 cases per 100,000 population

are in women.⁴ Inner wall of the anal fistula not allow for spontaneous healing because it develops fibrous tissue pyogenic membrane.⁵ Different modern surgical and medical treatment are in trend for managing anal fistula but all have certain drawbacks.

Ayurved has a special approach to fistula management. All Anal fistulas react well to different forms of *Kshar* and *Ksheer Sutra* therapy. They are nothing but the medicated seton. The thread's mechanical action and the chemical action of drugs coated on the thread work jointly to cut, cure, drain and clean the fistulous tract, thereby promoting track/

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wound healing. Though *Bhrihatrayi*, (chief three texts of Ayurved) stated the use of *Kshar Sutra*, there is no proper description of their method of preparation. In the late eleventh century, Chakrapani Datta in his book Chakradatta mentioned the preparation method for the first time with indications in *Arsha* and *Bhagandar*.⁶ It was later developed in Shalya Shalakya department Varanasi B.H.U by Prof Deshpande and his coworkers.

Apamarga Kshar Sutra is the standard *KsharSutra*, and but it has some disadvantages. A variety of other *Kshar Sutra*, as well as *KsheerSutra*, have been prepared to resolve these inconveniences of *Apamarga Kshar Sutra*. One of them is *Udumbar Ksheer Sutra* which was founded by Prof. P.J Deshpande and M.K Jalan in 1984.⁷ *Udumbar* is one among the *Nyagradhadi Gana Dravya* mentioned by Acharya Sushrut.⁸ He explained in *Bhagandar Chikitsa* that the *Nyagradhadi Gana Dravyas* are *Bhagandarnashak*.⁹ Subsequently Dr Subhashchandra Varshney carried out a study titled, "Management of Fistula in ano by *Udumbarksheer sutra*" around 800 participants were chosen, and significant results were obtained.¹⁰ Its use is in vogue from last many years but yet not standardized. As standardization of any medical drug or device or any other product is mandatory, so to maintain its quality level depending on different parameter there is a need for the standardization of the *Udumbar ksheer sutra* too. The present study is an attempt to standardize *Udumbarksheer sutra* and examine the efficacy of standardized *Udumbar ksheer sutra* over standard *Apamarga kshar sutra*. This study is also intended to evaluate antimicrobial activity and shelf life period of *Udumbar ksheer sutra*.

Standard *ApamargaKsharSutras* being used successfully in the management of *Bhagandar* but certain inconveniences regarding *ApamargaKsharSutra* preparation are worth noting. During the treatment with *Apamarga Kshar Sutra* some untoward incidences were also reported. *Apamarga's* availability is hard year-round, as it is seasonal. Even *SnuhiKsheer* (latex) use in its preparation also causes lots of problems during thread preparation. Several other *KsharSutra*, as well as *Ksheer Sutra*, were prepared to resolve these *Apamarga Kshar Sutra* inconveniences. 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) properties which are needed to treat anal fistula by aiding or promoting natural healing and cutting. Sushruta Samhita has categorized *Udumbar* in *Nyagrodhadi Gana* and the drugs in this group are mentioned to be effective in the management of *Bhagandar Udumbar* is available freely hence it is economically viable and it became easy to prepare its *Ksheer* even at remote villages which upon standardization may be useful at all levels of community

OBJECTIVES

- To standardize the preparation method of *Udumbar Ksheer Sutra* using standard operative procedure.
- To study the clinical efficacy of standardized *Udumbar KsheerSutra* in managing *Bhagandar*.
- To study the clinical efficacy of standard *Apamarga KsharSutra* in managing *Bhagandar*.
- To compare the clinical efficacy of standardized *Udumbar KsheerSutra* to that of *Apamarga Kshar Sutra* in managing *Bhagandar*.

Case definition- *Bhagandar* (Fistula in ano) diagnosed cases with more than 5 cm of a single tract.

Research question: Whether standardized *UdumbarKsheer Sutra* is less, equally or more efficient in managing *Bhagandar* than standard *ApamargaKshar Sutra*?

Hypothesis: Compared to *Apamarga Kshar Sutra*, *Udumbar Ksheer Sutra* may be more effective in managing *Bhagandar*.

Null Hypothesis: *Udumbar Ksheer Sutra* may not be effective as compared to *Apamarga Kshar Sutra* in managing *Bhagandar*.

MATERIALS AND METHODS

Trial design: A randomized control trial. Interventional study with 1:1 ratio on 2 groups as shown in Table 1.

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

Registration No.: Trial REF/2019/10/028582 has been registered. For this trial the registration number is CTRI/2019/12/022580.

Inclusion criteria:

- Participant with 18-60-year age group.
- After the screening, participants with *Bhagandar's* clinical features having single track greater than 5 cm will be included.
- Participant regardless of gender, occupation or economic status (Table 1).

Exclusion criteria:

- Participant suffering from chronic diseases such as diabetes mellitus, high blood pressure, tuberculosis, HIV, hepatitis B, reported cases of malignancy, ulcerative colitis and Crohn's disease.
- Participant with multiple anal fistulas or anal
- Participants with anal fistulas associated with anal fissures, haemorrhoids and pregnancy

Table 1: Interventions of both groups

Sr. no	Group	Intervention	Sample size	Assessment days
01	A	Udumbar Ksheer-Sutra will be changed after every 7 days	65	0, 15, 30, 45, 60
02	B	Apamarga Kshar-Sutra will be changed after every 7 days	65	0, 15, 30, 45, 60

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

Intervention period in days: 60

Follow up: On days 90 and 120

Primary Outcomes

UdumbarKsheerSutra will be useful for the management of *Bhagandar* which will reduce pain, itching, discharge and burning sensation and at the same time it will cut and heal the fistulous tract. This study also involves analytical standardization of *Udumbar Ksheer Sutra* which will set a standardized parameter for quality assurance of *Udumbar Ksheer Sutra* along with applied clinical as well as professional aspect.

Secondary Outcomes

As the ingredient for the chosen intervention is easily available all over India hence this study will contribute to cost-effective, safe, readily available, simple preparation and a good remedy for managing Shalyatantra.

Schedule of enrolment, interventions: Thread will be changed after every 7 days till the cut-through of the tract. Assessment will be done on day 0, 15, 30, 45, 60 and follow up after intervention will be taken on day 90 and 120.

Recruitment: 130 Patients (65 in each group) will be taken by simple random sampling using a computerized table method and will be enrolled.

Method: Standardization, intervention, data collection, analysis and interpretation

Standardization of *UdumbarKsheerSutra*

Standardization will be done by organoleptic and Physico-chemical testing of *Udumbar Ksheer* and *Udumbar Ksheer Sutra* and then the standards of *Ksheer Sutra* will be determined. It will be conducted at Dattatraya Rasashala, MGAC,

H and RC Salod (Hi), Wardha Maharashtra.

The analysis is conducted in three stages

- Raw material
- Intermediate (in the process) product
- Final product

Data collection

Subjective parameters:

- Pain
- Itching
- Burning Sensation

Objective Parameters:

- Discharge
- CRD (Cutting rate per day)

Statistical methods: Chi square test, Wilcoxon signed-rank test, Mann Whitney U test, student's t-test and the software will be used in the study. SPSS 22.0 version and graph pad prism version 6.0 and $p < 0.05$ is considered as significance level ($p < 0.05$).

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

REF No. : DMIMS (DU)/IEC/2018-19/7600.

Consent: Each patient shall receive informed consent before 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

Informed consent: Participants must obtain consent form along with all model details and other necessary documents.

DISCUSSION

Ayurveda has been proved successful in managing several diseases and chronic conditions.¹¹⁻²⁴ Studies on Fistula in ano were reported by Chandak et al.²⁵ and Lamture et al.²⁶ Studies from the global burden of disease are available^{27,28,29}. *Bhagandar* is managed by various modern surgical and medical treatments, but all therapies have limitations and the chance of recurrence. Ayurveda has its way of treating *Bhagandar* i.e. *Kshar Sutra* which is a minimal invasive para surgical measure capable of performing excision or *Chhedan*; under its mechanical pressure and phytochemical cauterization. Although the standard *Apamarga Kshar 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 *Udumbar Ksheer Sutra*. Various researches have been conducted on this *Sutra* but the product has not yet been fully standardized and not comparatively evaluated with *Apamarga Kshar Sutra*. With a few to lay down standards for identity and quality control of the constituent as well as the finished product, standardization is the necessity. So this study is undertaken to standardize *UdumbarKsheerSutra* and also evaluate its efficacy in the management of *Bhagandar* as well as its comparative evaluation with the efficacy of Standard *Apamarga Kshar Sutra* in a systematic way as shown in Figure 1.

If *Udumbar Ksheer Sutra* proved to be more efficient in managing *Bhagandar* compared to *Apamarga Kshar Sutra* then it will provide more acceptable as well as convenient treatment and alternative to the conventional surgical methods. Moreover, if the duration of healing is found to be less compared to *Apamarga Kshar Sutra*, then this work will have significant value in treating *Bhagandar* with minimized therapeutic duration than the current duration. This work involves multifaceted studies on *Udumbar Ksheer Sutra* therefore the work will be enough competent to be utilized for new drug developmental researches in context of *Ksheer Sutra* and *Bhagandar*.

If the study proposed results in a positive outcome then it will set a norm and provide the best parallel modality for the management of *Bhagandar* (Fistula in ano) (Figure 1).

Figure 1: GanttChart (Quarterly based).

CONCLUSION

This will be based on statistical analysis where we will get the standardization results of *Udumbar Ksheer Sutra* as well as will evaluate the comparative effects of *Udumbar Ksheer Sutra* with that of *Apamarga Kshar Sutra*.

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