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# Comparative Study of *Ashwatha Ksheer Sutra* and *Udumber Ksheer Sutra* in the Management of *Bhagandara* (Fistula in ANO)

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**Abstract:- Bhagandar (Fistula in Ano) at modern parlance is a common anorectal condition prevalent in the populations worldwide and its prevalence is second highest after Arsha (hemorrhoids). Kshara Sutra is one of the chief modality in the treatment of Bhagandara in Ayurvedic science. Apamarga (Achyranthus aspera) Kshar Sutra is considered the standard Kshar Sutra; although this Apamarga Kshar Sutra has been a landmark success, it has certain drawbacks such as pain, burning sensation, and itching associated to it. Mechanical action of the threads and the chemical action of the drugs coated on the thread together do the work of cutting, curetting, draining, and cleaning the fistulous track, thus promoting healing of the track. Exploration of the new plants for the preparation of Kshara as a better substitute to Apamarga Kshara is the need of the hour. Even Snuhi Ksheer is used in Apamarga Kshar Sutra and it creates many problems during the preparation of thread. Udumber Ksheer Sutra application is a proven effective treatment for Bhagandar. However, Snuhi (Euphorbia nerifolia) creates many problems during the preparation of thread, for instance, a very small quantity is collected after the incision of the stem, it coagulates if not used early, and collection becomes more difficult in summer. Different research scholars have conducted investigations to find out other varieties of thread that can minimize pain and other undesired effects.Udumber Ksheer Sutra application is a proved effective treatment for Bhagandar, but Udumber creates many problems during the preparation of the thread. In view of easy processing, Ashwattha Ksheer sutra were opted for their clinical evaluation. Total 40 cases of Bhagandara were divided randomly into 2 groups, having 20 patients in each group. In Group A, Udumber Ksheera Sutra and in Group B, Ashwattha Ksheer sutra were used. Assessment was done on objective (Unit Cutting Time - UCT) and subjective parameters. Statistically insignificant difference was observed in the efficacy of treatment by subjective parameters like pain, discharge, itching . between the two groups. It was found that Ashwattha Ksheer Sutra. showed smiliar UCT as compared to UdumberKsheera Sutra. Thus Ashwattha Ksheer Sutra can be used as a substitute for UdumberKsheera Sutra can be employed in the recurrent cases of Bhagandara.**

***Keywords:-*** *Bhagandara, fistula in ano,UdumberKsheera Sutra, Ashwattha Kshara Sutra, Unit Cutting Time.*

## I. INTRODUCTION

Shalya Tantra was at its zenith in Sushruta's time and the contents of Sushruta Samhita can be compared to any book on surgery written centuries later. Bhagandara (Fistula in ano) is told callous to be cured and is considered under the Ashta Mahagadas. [1] (Eight grave disorders). According to a recent study conducted on the prevalence of anal fistula in India by Indian Proctology Society in a defined population of some states. The true prevalence of Fistula-in-ano is unknown. 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.[2] To combat such critical anorectal problems, a comprehensive approach through Ayurveda has been extended with definite and a positive outcome. It is such a simple, safe and sure remedy for anal fistula and it is becoming universally acceptable day by day. The Indian Council of Medical Research (ICMR) has validated this unique and effective approach.[3] Ksheer Sutra treatment heals the fistulous tract with the integrity of sphincters and the existing data reveal negligible chances of recurrence. Ksheera Sutra is a scientifically validated treatment in the management of Bhagandara. The Apamarga Ksheer Sutra is well proven to be an effective treatment for fistula in ano and has been standardized by Central Council for Research in Ayurvedic Sciences (CCRAS), an apex research organization of Government of India (GOI) in the field of Indian system of medicine.[4] It is quiet difficult to solely depend upon Apamarga only because of its limited availability globally. 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.[5] Sushruta has advocated the use of Pancha Valkal as Bhagandar Nashak in Bhagandara Chikitsa.Moreover, in ethnomedicine as a

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folklore treatment. Similarly, the rationale behind including the classical Ashwattha Ksheera Sutra in this study was to reduce the labor and time required in preparing Ksheer sutra, if it gives the same result as Udumber Ksheera Sutra. This concept was based on the version given by Chakradutta on Ksheer Sutra preparation.[6]UdumberKsheera possesses Shodhana as well as Ropana properties.[7] As far as the Rasa Panchaka of the drugs is considered,Ashwattha and Udumber, all the two are having Katu, Tikta Rasa; Ushna Virya; Katu Vipaka and Kapha-Pitta Shamaka properties. Hence, to develop an alternative to a Udumber Ksheera Sutra in view of easy processing, the Ashwattha Kshara Sutra in Bhagandara were opted for the clinical evaluation for the first time in its kind of study.

## II. AIMS AND OBJECTIVES OF THE STUDY

- To evaluate the cutting effect of *Ashwattha Ksheer Sutra* in *Bhagandar* (*Fistula in Ano*) applied after every 7 days in Group A.
- To evaluate the cutting effect of *Udumber Ksheer Sutra* in *Bhagandar*(*Fistula in Ano*)applied after every 7 days in Group B.
- To compare the cutting effect of *Ashwattha Ksheer sutra* and *Udumber Ksheer Sutra* in both the Groups.

## III. MATERIALS AND METHODS

*A. Selection of patients*

Patients were selected from the OPD and IPD of the Dept. of Shalya Tantra, as well as from the special surgical diagnostic camps. Total 40 patients of Bhagandara divided into two groups. In the present study, I put forward my efforts to study cutting effect of *Ashwattha Ksheer Sutra* and *Udumber Ksheer Sutra* in the management of *Bhagandar* (Fistula in Ano), is done by observing the comparative results of its cutting effect in Group A and Group B, where Group A (n=20) was subjected to thread change after every 7 days and other Group B (n=20) was subjected to thread change after 7 days.

*B. Inclusion Criteria*

- Written informed consent as per Helsinki Declaration Patient with age Group of 18 to 70 years.
- Patients with clinical features of Bhagandar were included after screening.
- Patients irrespective of sex, occupation and economic status were included.

*C. Exclusion Criteria*

- Subject suffering with systemic disorders like Diabetes mellitus, Tuberculosis, HIV and Hepatitis was excluded.
- Subject having Multiple Fistula in Ano, Hemorrhoids, Pregnancy, Malignancy will be excluded.
- Systemic disorders like patient with 4thgrade anal spasm, rectal prolapse, rectalcarcinoma, chronic fissure in ano withsentinel tag, transient ischemic attack,uncontrolled hypertension, endocrinedisorders and kidney or hepatic disorder,heart and vascular surgery or majoroperations within 6 months prior to screeningvisit.and lactating females.

*D. Investigations*

- Complete blood count
- Erythrocyte sedimentation rate
- Blood sugar level
- HIV
- HbsAg

*E. Radiological examinations*

- X-ray chest PA view (in all 2 groups)

*F. Pre-operative preparation*

- Written informed consent was taken
- Part preparation was done
- Patient was kept nil orally for 6 hours
- Inj. Tetanus Toxoid, 0.5 ml, I/M was given
- Inj. Xylocaine sensitivity test was done
- Soap water enema was given twice, around 10 pm at previous day of operation and around 7 am on the day of operation.
- Preparation of operation theatre and sterilization of instruments were done.

## IV. OPERATIVE PROCEDURE

The patient was kept in lithotomy position, perianal region was cleaned with Triphalaa Kwatha and draping was done after giving spinal anaesthesia. In some patients, local anesthesia was used and it was given after keeping the patient in lithotomy position. When the patient was assured, gloved index finger was gently introduced into the rectum and a suitable metallic probe was passed through the external opening of the fistula. The probe was forwarded along the path of least resistance to reach into the lumen of anal canal through the internal opening, guided by the index finger of the other hand inserted in to the rectum and the tip of probe was finally directed to come out of the anal orifice. In case of externally blind fistula, the tip of the probe was pushed to make the proximal opening in the anal orifice. Then a suitable length of Ksheer Sutra. was taken and threaded into the eye of the probe. Thereafter, the probe was pulled out through the anal orifice, to leave the Ksheer Sutra. in situ i.e. in the fistulous tract. The two ends of the Ksheer Sutra. were tied together with keeping the gap of index finger outside the anal canal. This procedure is termed as ‘primary threading’. After this a gauze piece (surgical pad) soaked with Jatiyadi Taila was applied, tied with the help of Gophana Bhanda (T-bandage).The same procedure was adopted for all the two groups. The Ksheer Sutra threading (KST) before treatment, during treatment and after treatment is shown in Figures 1-3, respectively.

## V. POSTOPERATIVE MEASURES

- Patient was kept nil orally till complete waving off of the anesthetic effect is achieved i.e., maximum for 6 hours.
- I/V fluids were given as per the requirement.
- Suitable analgesic and antibiotics were administered as per the requirement.
- General management Systemic drugs were advocated in all the two groups,
- Ushnodaka Avagaha (Sitz Bath) was given thrice in a day.

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- Matra Basti of Jatyadi Taila, 10 ml once daily (by anal route).
- Triphala Guggulu – 2 tabs (1 g) orally, after food, twice daily, with warm water.
- Gandhaka Rasayana 2 tabs (500 mg) orally, twice daily after food with warm milk.

*A. Changing the Ksheer Sutra by rail road method*

On every seventh day, the Ksheer Sutra. was changed with a new Sutra by the rail-road method. In this method, the Ksheer Sutra was tied at one end and the knot tightened against the knot of the thread in situ. The Ksheer Sutra at the anal verge was clamped with forceps and cut in between the knot and forceps. The Sutra was slowly pulled out and the new ksheer sutra was replaced by the old one. The knot of the new ksheer sutra was secured after cutting and removing of old ksheer sutra. The measurement of the old Sutra was recorded finally to assess the progress of cut through of the tract. The patients were advised to take rest for some time and then allowed to go back for their routine work.

*B. Duration of the treatment*

The changing of ksheer sutra every week was repeated till the ksheer sutra got cut through the tract completely and the duration solely depended on the length of the fistulous tract.

*C. Assessment criteria*

- Assessment criteria for the parameters has been prepared by considering the previous clinical research works conducted.
- Subjective parameters likePain, Discharge,Itching, were assessed by scoring patterns.

*D. Assessment Criteria*

- Grading of Subjective Parameters
- Pain

| Grade | Explanation |
|---|---|
| 0 | No pain |
| 1 | Negligible or tolerable pain. No need of any medicine |
| 2 | Locazed tolerable pain completely relieved by hot sitz bath |
| 3 | Intolerable pain, not relieved by hot sitz bath, relieved by oral analgesics. No sleep disturbance |
| 4 | Continuous and intolerable pain with sleep disturbance. Patient seek medical help as early as possible |

*E. Discharge*

| Grade | Explanation |
|---|---|
| 0 | No sign of any discharge |
| 1 | Occasional appearance of discharge and patient use single cotton pad in 24 hours |
| 2 | Frequent appearance of discharge and patient use 3-4 cotton pads in 24 hours |
| 3 | Increased frequency of discharge and patient use 5-6 cotton pads in hours |
| 4 | Continuous discharge |

*F. Itching*

| Grade | Explanation |
|---|---|
| 0 | No complaints of itching |
| 1 | Negligible itching for a few minutes a day |
| 2 | Occasional sensation of itching with 4-6 hours interval |
| 3 | Frequent Sensation of itching with 2-3 hours interval |
| 4 | Continuous Sensation of itching with 15-30 minutes interval |

## VI. OBJECTIVE PARAMETER

- Unit Cutting Time (UCT) was measured as per the formula.
- **Cutting rate per Week (CRD)**

$$\frac{\textbf{Initial length of the track – Length of the track at the end study X 7}}{\textbf{Total duration of study}}$$

- **Statistical design**
  - Paired ‘t’ – test of significance
  - Unpaired ‘t’- test for inter group comparison

- **Observations**

The observation on demographic data was presented as

- **Age**

30% of the patients in Group A and 50% in Group B were belonging to the age Group of 18-30 years, 25.,0 % of the patient in Group A and 30 % of the patient in Group B were belonging to the age Group of 31-40 years, 35.0 % of the patient in Group A were belonging to the age Group of 41-50 years, 10% of the patient in Group A and 20 % of

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the patient in Group B were belonging to the age Group 50-60 years respectively.

- **Gender**
  80% of the patients in Group A and 90 % in Group B were males and 20% of the patients in Group A and 10 % in Group B were females.

- **Habitat**
  50 % of the patients in Group A and 50 % of the patient in Group B were belonging to rural area and similarly 50 % of the patients in Group A and 50 % of the patient in Group B were belonging to urban area respectively.

- **Marital Status**
  As per their marital status reveals that 75.0 % of the patient in Group A and 75.0 % of the patient in Group B were Married and 25.0 % of the patient in Group A and 25.0% of the patient in Group B were unmarried respectively.

- **Economic status**
  Distribution of patients as per their Economic status reveals that 30.0% of the patients in Group A and 20.0 % in Group B were belonging to poor and 70 % of the patients in Group A and 75.0% in Group B were belonging to Middle Class and 5.0 % of the patient in Group B were belonging to Good economic status.

- **Educational status**
  70.0 % of the patients in Group A and 75.0 % in Group B were literate and 30 % of the patients in Group A and 25 .0 % in Group B were illiterate.

- **Occupational status**
  As per their occupational status reveals that 30% of the patients in group A and 40 % in group B were farmer, 10,0% of the patients in group A and 10.0 % in group B were govt. servant, 10 % of the patients in group A and 0% in group B were housewife, 15.0% of the patients in group A and 10.0 % in group B were private service, 10.0 % of the patients in group A and 10.0% in group B were student, 0.5 % of the patients in group A and 20 % in group B were Worker, 20% of the patients in group A and 5.0 % in group B were teacher, 0.0% of the patients in group A and 5.0 % in group B were shopeeper respectively.

- **Nature of work**
  Distribution of patients as per their nature of work shows that 45.0% in Group A and 45.0 % in Group B were performing sedentary work, 25 % in Group A and 40.0 % in Group B were moderate and 30% in Group A and 15.0 % in Group B were performing strenuous type of work.

  - Sleep
    90.0 % of the patients in Group A and 80% in Group B had disturbed sleep and 10.0 % of the patients in Group A and 20% in Group B had sound sleep.

- **Diet**
  15.0 % of the patients in Group A and 10.0 % in Group B were consuming vegetarian diet and 85.0 % in Group A and 90.0 % in Group B were consuming mixed diet.

- **Bowel Habit**
  Bowel habit was regular in 30 .0% of the patients in Group A and 10.0% of the patients in Group B and it was irregular in 70.0 % of the patients in Group A and 90.0% of the patients in Group B.

- **Menstrual History**
  Menstrual history was irregular 15.0 % of the patients in Group A and 5.0 % in Group B, 5.0 % of the patient was menopause in Group A and 00% in Group B. along with 80 % N/A in Group A and 95.0 % in Group B.

- **Hygiene**
  In 70.0 % of the patients in Group A and 75 % of the patients in Group B hygiene was poor and in 30.0 % of the patients in Group A and 25 % of the patients in Group B it was good.

- **Addiction**
  20.0 % of the patients in Group A and 5.0 % in Group B had habit of alcohol, 5.0 % of the patient in Group A and 20% in Group B had habit of kharra, 15.0 % of the patient in Group A and 5.0 % in Group B had habit of multiple, 5.0 % of the patient in Group A and 35.0 % in Group B had habit of smoking, 10.0 % of the patient in Group A and 0% in Group B had habit of tobacco respectively.

- **Psychological Condition**
  As per their psychological condition reveals that 80% of the patients in Group A and 65.0 % in Group B were worried, 20% of the patients in Group A and 25.0 % in Group B were depressed and 10,0 % of the patients in Group B were irritative.

- **Allergy**
  10.0 % of the patients in Group B had allergy and all (100%) in Group A and 90.0 % in Group B need not have any type of allergy.

- **Built**
  95.0 % of the patients in Group A and 95.0% in Group B had normal built, 5.0 % in Group A and 5.0% in Group B were slim respectively.

- **External Opening**
  Each 20.0 % of the patients in Group A and 15 .0 % of the patients in Group B had raised external opening and 80 .0 % of the patient in Group A and 85 .0 % of the patient in Group B had retractedexternal opening.

- **Distance from anus**
  60% of the patients in Group A and 55.0 % in Group B had a distance of >1.5” from anus and 40% of the patients in Group A and 45. 67% in Group B had a distance of <1.5” from anus.

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- **Surrounding skin**
  As per the distribution 15 % of the patients in Group A and 0.0 % in Group B had healthy surrounding skin and 85.0 % in Group A and 100% in Group B had unhealthy surrounding skin.

- **Type of Fistula in ano**
  As per Type of Fistula in ano 80% of the patients in Group A and 85% in Group B had high anal Fistula in ano and 20% of the patients in Group A and 15.0 % of the patients in Group B had low anal Fistula in ano respectively.

- **Type of Track of Fistula in ano**
  Distribution of patients as per track of Fistula in ano reveals that 80.0 % of the patients in Group A and 90.0 % in Group B had curved and 20.0 % in Group A and 10.0 % in Group B had straight track of Fistula in ano.

- **Height and Weight**
  Mean height of the patients in Group A was 166.75 whereas in Group B it was 169.4 and mean weight of the patients in Group A was 60.2 and in Group B it was 64.35 respectively.

| | | Mean | Std. Deviation | Std. Error Mean | z-value | p-value |
|---|---|---|---|---|---|---|
| Day 1 | Group A | 4.00 | 0.000 | 0.000 | 0.000 | 1.00,NS |
| | Group B | 4.00 | 0.000 | 0.000 | | |
| Week 1 | Group A | 3.55 | 0.510 | 0.114 | 0.967 | 0.333,NS |
| | Group B | 3.70 | 0.470 | 0.105 | | |
| Week 2 | Group A | 2.90 | 0.308 | 0.069 | 1.561 | 0.118,NS |
| | Group B | 2.70 | 0.470 | 0.105 | | |
| Week 3 | Group A | 1.95 | 0.394 | 0.088 | 1.752 | 0.080,NS |
| | Group B | 1.70 | 0.470 | 0.105 | | |
| Week 4 | Group A | 1.00 | 0.324 | 0.073 | 1.947 | 0.051,NS |
| | Group B | 0.75 | 0.444 | 0.099 | | |
| Week 5 | Group A | 0.25 | 0.444 | 0.099 | 1.309 | 0.190,NS |
| | Group B | 0.45 | 0.510 | 0.114 | | |

Table No.1: Comparison of mean difference of pain in two groups by Mann Whitney U Test

| | | Mean | Std. Deviation | Std. Error Mean | Z-value | p-value |
|---|---|---|---|---|---|---|
| Day 1 | Group A | 3.55 | 0.510 | 0.114 | 0.967 | 0.333,NS |
| | Group B | 3.70 | 0.470 | 0.105 | | |
| Week 1 | Group A | 3.35 | 0.489 | 0.109 | 0.000 | 1.000,NS |
| | Group B | 3.35 | 0.489 | 0.109 | | |
| Week 2 | Group A | 2.95 | 0.224 | 0.050 | 1.145 | 0.252,NS |
| | Group B | 3.10 | 0.553 | 0.124 | | |
| Week 3 | Group A | 2.70 | 0.470 | 0.105 | 0.967 | 0.333,NS |
| | Group B | 2.55 | 0.510 | 0.114 | | |
| Week 4 | Group A | 2.55 | 0.510 | 0.114 | 2.556 | 0.011,S |
| | Group B | 2.05 | 0.605 | 0.135 | | |
| Week 5 | Group A | 1.75 | 0.444 | 0.099 | 2.208 | 0.027,S |
| | Group B | 1.30 | 0.923 | 0.206 | | |

Table No. 2: Comparison of mean difference of discharge in two groups by Mann Whitney U Test

| | | Mean | Std. Deviation | Std. Error Mean | Z-value | P-value |
|---|---|---|---|---|---|---|
| Day 1 | Group A | 3.15 | 0.366 | 0.082 | 0.781 | 0.435,NS |
| | Group B | 3.25 | 0.444 | 0.099 | | |
| Week 1 | Group A | 2.85 | 0.366 | 0.082 | 0.058 | 0.953,NS |
| | Group B | 2.85 | 0.489 | 0.109 | | |
| Week 2 | Group A | 2.65 | 0.489 | 0.109 | 0.541 | 0.588,NS |
| | Group B | 2.50 | 0.688 | 0.154 | | |
| Week 3 | Group A | 2.05 | 0.224 | 0.050 | 0.624 | 0.532,NS |
| | Group B | 1.95 | 0.686 | 0.153 | | |
| Week 4 | Group A | 1.65 | 0.489 | 0.109 | 0.848 | 0.396,NS |
| | Group B | 1.45 | 0.686 | 0.153 | | |
| Week 5 | Group A | 0.95 | 0.394 | 0.088 | 2.123 | 0.034,S |
| | Group B | 0.60 | 0.681 | 0.152 | | |

Table No. 3: Comparison of mean difference in Itching Score in two groups by Mann Whitney U Test

| UCT | Mean | Std. Deviation | Std. Error Mean | Mean Diff. | t-value | P-Value |
|---|---|---|---|---|---|---|
| Group A | 0.39 | 0.02 | 0.004 | 0.01 | 0.188 | 0.852 NS |
| Group B | 0.40 | 0.01 | 0.003 | | | |

Table No. 4:Mean comparisons of UCT in two groups by Student's unpaired t Test

| SYMPTOMS | Mean | Std. Deviation | Std. Error Mean | Mean Diff. | t-value | P-Value |
|---|---|---|---|---|---|---|
| **Pain** | 93.75 | 11.10 | 2.48 | 5.00 | 1.322 | 0.194 NS |
| **Discharge** | 46.25 | 9.15 | 2.04 | 13.75 | 2.737 | 0.009 S |
| **Itching** | 47.50 | 11.18 | 2.50 | 16.25 | 3.549 | 0.001 S |

Table No. 5:Effects of ashwattha Ksheer Sutra (Group A)

| Symptoms | Mean | Std. Deviation | Std. Error Mean | Mean Diff. | t-value | P-Value |
|---|---|---|---|---|---|---|
| Pain | 88.75 | 12.76 | 2.85 | 5.00 | 1.322 | 0.194 NS |
| Discharge | 60.00 | 20.52 | 4.58 | 13.75 | 2.737 | 0.009 S |
| Itching | 63.75 | 17.15 | 3.83 | 16.25 | 3.549 | 0.001 S |

Table No. 6: Effects of udumber Ksheer Sutra (Group B)

## VII. RESULTS

Mean pain on Day 1 in Group A was 4 and in Group B was also 4 by using Mann Whitney U Test on comparing the mean pain statistically no significant result was obtained. Mean pain on Week 1 in Group A was 3.55 and in Group B was 3.70 by using Mann Whitney U Test on comparing the mean pain statistically no significant result was obtained. Mean pain on Week 2 in Group A was 2.90 and in Group B was 2.70 by using Mann Whitney U Test on comparing the mean pain statistically no significant result was obtained. Mean pain on Week 3 in Group A was 1.95 and in Group B was 1.70 by using Mann Whitney U Test on comparing the mean pain statistically no significant result was obtained. Mean pain on Week 4 in Group A was 1 and in Group B was 0.75 by using Mann Whitney U Test on comparing the mean pain statistically no significant result was obtained. Mean pain on Week 5 in Group A was 0.25 and in Group B was 0.45 by using Mann Whitney U Test on comparing the mean pain statistically no significant result was obtained. [Table 1].

Comparison of mean difference of discharge in two groups Mean Discharge on Day 1 in Group A was 3.55 and in Group B was 3.70 by using Mann Whitney U Test on comparing the mean Discharge statistically no significant result was obtained. Mean Discharge on Week 1 in Group A was 3.35 and in Group B was 3.35 by using Mann Whitney U Test on comparing the mean Discharge statistically no significant result was obtained. Mean Discharge on Week 2 in Group A was 2.95 and in Group B was 3.10 by using Mann Whitney U Test on comparing the mean Discharge statistically no significant result was obtained. Mean Discharge on Week 3 in Group A was 2.70 and in Group B was 2.55 by using Mann Whitney U Test on comparing the mean Discharge statistically no significant result was obtained. Mean Discharge on Week 4 in Group A was 2.55 and in Group B was 2.05 by using Mann Whitney U Test on

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comparing the mean Discharge statistically significant result was obtained. Mean Discharge on Week 5 in Group A was 1.75 and in Group B was 1.30 by using Mann Whitney U Test on comparing the mean Discharge statistically highly significant result was obtained. [Table 2].

On Comparison of mean difference in Itching Score in two groups reflect as Mean Itching on Day 1 in Group A was 3.15 and in Group B was 3.25 by using Mann Whitney U Test on comparing the mean Itching statistically no significant result was obtained. Mean Itching on Week 1 in Group A was 2.85 and in Group B was 2.85 by using Mann Whitney U Test on comparing the mean Itching statistically no significant result was obtained. Mean Itching on Week 2 in Group A was 2.65 and in Group B also it was 2.50 by using Mann Whitney U Test on comparing the mean Itching statistically no significant result was obtained. Mean Itching on Week 3 in Group A was 2.05 and in Group B was 1.95 by using Mann Whitney U Test on comparing the mean Itching statistically significant result was obtained. Mean Itching on Week 4 in Group A was 1.65 and in Group B also it was 1.45 by using Mann Whitney U Test on comparing the mean Itching statistically no significant result was obtained. Mean Itching on Week 5 in Group A was 0.95 and in Group B also it was 0.60 by using Mann Whitney U Test on comparing the mean Itching statistically highly significant result was obtained. [Table 3].

Mean UCT in Group A was 0.396 and in Group B was 0.4 by using Student's unpaired t Test, Statistically no significant difference was found. [Table 4].

After Kshara Sutra application all patients were assessed for relief in sign and symptoms. In patients of Group-A statistically non significant results were observed in pain and while significant results were seen in itching sensation and discharge [Table 5]. In patients of Group-B statistically non significant results were observed in pain and while significant results were seen in itching sensation and discharge [Table 6].

## VIII. DISCUSSION

Priorities of man have been changed from time to time. Once health was considered as the greatest wealth and they had spent enough time to maintain the state of physical, mental and social wellbeing. Now everyone is in hurry to achieve their own targets and pay less attention to health. To cope up with the busy schedule of life, the pattern of diet and regimen are totally modified with the use of fast foods and junk foods along with more non-vegetarian items and soft drinks. Increased Food adulterations use of spices and added preservatives also harms the health to a great extent. Adopting a sedentary life style is a favorable factor for developing diseases. Prolonged riding over vehicles is yet another challenging issue and holding natural urges is an added factor in disease pathology.

All these life style modification ultimately affect the gastro intestinal system. Increased incidence of constipation may result in constant injury to the anal canal. The liver should work continuously to detoxify the unwanted substances ingested with food. Alterations in the functions of liver may result in various other systemic changes. In such persons there may be increased chance of developing abscess in various parts. The altered *doshas* along with other get localizes in skin and produce *pidikas*. In Anal Fistula there may be a history of anorectal abscess. Most of the people suppress the condition by the use of antibiotics or do minor surgical drainage of the abscess along with the use of antibiotics. After some days they again resume with the unhealthy diet and regimens so that the condition reoccurs and progress as Fistula in ano. Majority of them adopt surgical management at this condition. But surgical techniques have many complication and the patients are ready to adopt the parasurgical procedures.

Ayurved has 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*. *Kshar Sutra* or *Ksheer Sutra* is a medicated seton. Mechanical action of the *Sutra*s and the chemical action of drugs coated on the *Sutra* together do the work of cutting, curreting, draining, and cleaning the fistulous track, thus promoting healing of the track *Kshar Sutra* even though not described vividly by Bruhattrayi but it has been described and practiced in Ayurved for Anorectal disorders and also for those conditions which demands gradual excision. *Kshar Sutra* was first mentioned by the Acharya Sushrut in his text named Sushrut Samhita. Although Bhrihattrayi the chief three texts of Ayurved mention the use of *Kshar Sutra* but there is no description of their preparation properly.

It was Chakrapani Datta in late eleventh century in his book Chakradatta , first mentioned the method of preparation with a clear indication of its use in *Bhagandar* and *Arsha*. Later it was standardized in the department of *Shalya-Shalakya* B.H.U by Prof. P. J. Deshpande and his coworkers. *Kshar Sutra* is a medicated Seton. Mechanical action of the thread and chemical action of the drug coated over the thread together do the work of cutting, curetting, scraping, draining and healing of Fistula in ano.Preparation of this *Ksheer Sutra* is very simple. *Udumber Ksheer Sutra* application is a proved effective treatment for *Bhagandar* but *Udumber* creates many problems during the preparation of thread like very little amount is collected after the incision of stem, it coagulates if not used early, collection becomes very difficult in summer, therefore in order to overcome such problem associated with *Udumber ksheer*, *Ashwattha ksheer* will be used in this present research work as it is available in abundance and in all seasons and its latex can be easily extracted out. *Ashwattha* and *Udumber Ksheer Sutra* is changed after every 7 days.

### *A. Disscussion on probable mode of action of Ashwattha Ksheer Sutra*

Acharya Sushrut included ***Ashwattha*** in *Naygrodhadi gana*.[8] In *Bhagandar Chikitsa* he explained that Ashwatthadi *gana dravyas* are *Bhagandar Nashak*. It has *Rasa- Kashaya , madhura, Guna – Guru, ruksha.,Veerya – Sheeta.,Vipak – Katu.. Karma – Kaphapittashamak*. [9]It has *Vranaropak, Krimighna, Shothhar*and *Shoolhar* properties. Fistula in ano is a track lines by unhealthy granulation tissue. As it is a chronic disease, it takes long term management for healing. So we need a treatment

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modality which can ensure the fast cutting and healing of the track simultaneously. The Whole parts of the plant exhibit wide spectrum of activities such as antidiabetic[10] Anti-inflammatory Activity[11]Analgesic Activity[12]anticancer, antioxidant,[13], antimicrobial[14], wound healing [15] antiulcer,[16] anthelmintic, [17]the existence of multiple polyphenols as well as flavonoids within *F. religiosa* may be responsible for free-radical scavenging as well as antioxidant properties. It is present in *Ashwattha* helps in destruction of the unhealthy tissue and provides a healthy environment for the healing purpose. Proper drainage is ensured after its application and prevents the accumulation of pus in the cavities. The *Vranaropak* property of the *Ashwattha* acts on the inherent tissue damage of the area to reduce inflammation to a great extent. The *Krumighna* property of *Ashwattha* created an antimicrobial path for faster healing. The adjuvant drugs were prescribed to achieve better outcome of the surgical management in all the groups.Triphala Guggulu helps in the post operative wound healing.[18] During the entire trial period maximum for 5 months use of Triphala Guggulu was recorded and did not cause any adverse effect. Gandhaka Rasayana[19] was found equally effective in preventing the infection as the chances of infection is high because there is presence of discharge from the tract till the thread is in situ. The specially designed Ano rectal chair was used for Avagaha Sveda (Sitz Bath). Avagaha Sveda[20] using Sphatikadi Yoga helped in maintaining the hygiene of the perineal part and reduced the Shotha (inflammation) as well as pain. MatraBasti[21] of 10 ml Jaati Kalpa Taila, daily helped in Shamana of the aggravated Vata and provided soothing effect to ano rectum from pain with easy evacuation of stools.

*B. Discussion on results*

The length of the track, cut by the *Ksheer Sutra* per weeks was measured as the Cutting rate per week. Cutting rate per Week is the most quantitative and principle objective of this study.

There are several factors, which affects the Cutting rate per week as follows:

- *C.R.W.* is less in low anal Fistulae.
- *C.R.W.* is high in cases of fibrosed / tough scar tissue which generally created after the previous operation done for Anal Fistulas and in cases of high rectal Fistulae, Fistulae with abscess and trans- sphincteric Fistulae.
- Presence of infection and inflammation delays the Cutting rate per day.

When the Principle Objective Parameter C.R.W is considered, mean C.R.D in Group A was found to be **0.39 cm/day** and in Group B was **0.040cm/day**. By using students unpaired t test statistically non -significant difference was found in mean C.R.D (in cm per day) in both the Groups. Hence we can say that C.R.D in Group B is more as compares to Group A. The Cutting effect or *Chhedana Karma* of *Ashwattha KsheerSutra* is facilitated by its *Vrana Shodhana, Vrana Ropana, Shothhara* and *Krimighna Karma*. It reduces inflammation by *Shothahara* Karma. With the *Vrana Shodhana* property, it keeps the track clean, providing the *SuddhaVranaAvasthaa* and only a *SuddhaVrana* can heal properly. Due to *VranaRopana Karma* of the Ashwattha Ksheer *Sutra* and mechanical action of the *Sutra*, healing and cutting process runs simultaneously. As a whole, we say that the *Ksheer Sutra* acts by gradual chemical excision of the *Bhagandar* (Fistula - in - ano) with simultaneous healing.

Considering all these observation and results of Subjective and Objective parameters, Statistical analysis and interpretations in this study of 40 randomly selected patients, Alternate Hypothesis is accepted and Null Hypothesis is rejected. Changing of *Ashwattha Ksheer Sutra* after every 7 days is found to be equally effective in the management of *Bhagandar* as compare to *Udumbar Ksheer Sutra* changing after every 7 day.

- Statistically there was no much significant difference in efficacy of treatment between the two groups.
- No recurrence was seen in the 3 months of follow-up.
- There was no adverse effect of any of the drugs observed during the course of study.

## IX. CONCLUSION

The current study recommends that Ashwattha Ksheer Sutra is equally effective when compared with Udumber Ksheer Sutra. By comparing the advantages of Ashwattha Ksheer Sutra with Udumber Ksheer Sutra, it can be concluded that Ashwattha Ksheer Sutra may be used as a good alternative of Udumber Ksheer Sutra in the management of Bhagandar.

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