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# A Clinical Study to evaluate the efficacy of *Papaya Ksheera* based *Sphatika Ksharasutra* in *Bhagandara* w.s.r. to fistula-in-ano

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## ABSTRACT

**Background:** *Bhagandara* is one among *Ashtamahagadas* mentioned by *Acharya Sushruta* and is one of the most common ailments pertaining to ano rectal region. Management of Fistula -in-ano has become a challenge to Allopathy Surgeons because of its complications like post-operative pain, wound management, recurrence and incontinence. In Ayurveda, the effective treatment is *Ksharasutra* ligation. *Snuhi Ksheera* based *Apamarga Ksharasutra* is the standard one and is proved effective treatment in the management of Fistula-in-ano. But, burning sensation, pain, local irritation during the course of therapy and difficulty in manufacturing process has limited its use. To overcome these lacunas, present study has been carried out. **Objectives:** To evaluate the significance of Papaya *Ksheera* based *Sphatika Ksharasutra* by comparing with the efficacy of *Snuhi Ksheera* based *Apamarga Ksharasutra* in the management of *Bhagandara*. **Materials and methods:** A total of 40 patients were randomly allotted into two groups namely Group A with trail drug i.e. *Papaya Ksheera* based *Sphatika Ksharasutra* and Group B as Control group i.e. *Snuhi Ksheera* based *Apamarga Ksharasutra* with 20 patients in each group. **Results:** Assessment of Pain, Discharge, Pruritis ani, length of track was made. In Group A, overall result is 98.5% and Group B overall result is 91.5%. The test shows that the treatment is statistically not significant in Group B when compared to Group A. **Conclusion:** This study showed that the trial drug was as effective as the standard drug in the treatment of *Bhagandara.*

**Key words:** *Bhagandara, Fistula-in-ano, Apamarga, Papaya Ksheera, Sphatika, Ksharasutra.*

## INTRODUCTION

The disease *Bhagandara* is explained in Ayurveda classics. Acharya Sushruta has included *Bhagandara* as one among the *Ashtamahagadas*. It is one of the most common diseases pertaining to ano-rectal region. The earliest reference of *Bhagandara* is seen in *Garudapurana*. Detailed description about the *Nidana, Samprapti, Laxana* and *Chikitsa* is available in *Sushruta Samhita* (1500 B.C) and *Ashtanga Hridaya* among *Brihatrayees*. While, *Charaka* (1000 B.C) has mentioned about the disease *Bhagandara* in *Shotha Chikitsa Adhyaya* and advocated *Kshara Sutra* and other remedies in the management of *Bhagandara*.

The literal meaning of *Bhagandara* is *Daarana* which is splitting up/ bursting up of *Pakwa Pidaka* in *Bhaga, Guda, Basti Pradesha* resulting in the formation of a track, thus causing discomfort to the patient.

*Bhagandara* can be co-related with Fistula-in-ano mentioned in modern medical science and is considered second to haemorrhoids among all ano-rectal abnormalities. A study conducted on the

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prevalence of anal fistula by Marks and Ritchie at St Marks's hospital, London, reported 10% of all patients and 4% of all new out-patients comprising of Anal Fistula.[1] Another study conducted on the incidence and epidemiology of anal fistula in a defined population, for a period of 10 years by Mr. Sainio P; the mean incidence is 8.6 cases per 100,000 population. The incidence in men is 12.3 cases & in women it is 5.6 cases per 1, 00,000 population. The mean age of patients is 38.3 years.[2]

A study in India conducted by Mr. Raghavaiah (1976), reported that anal fistulae constitute 1.6% of all surgical admission.[3]

As the wound is located in the anal region, it is more prone to get infected and results in delayed healing. The unhealthy granulation tissue or fibrous tissue formed in the track hinders healing process. Operative procedures adopted are Fistulectomy, Fistulotomy and use of a Seton. Newer methods like Anal fistula fibrin plug, Endo anal flap, LIFT ( Ligation of Intersphincteric fistula tract procedure), Bio-LIFT, Expanded Adipose derived Stem cell therapy ( ASCs) are also being used.[4] Because of the lack of desired results newer techniques have constantly been adopted for its management. Up to 26.5 percent recurrence rate, 40 percent high risk of incontinence and 5.6 percent non healing of the wound were reported after surgery. In addition to this, there will be severe post-operative pain which persists for many days. Surgical treatment requires hospitalization, regular dressing and post-operative care for longer duration. Moreover newer surgical techniques are costly and are not affordable by common public. To overcome such problems, surgical field is planning for some alternative techniques to treat these cases with minimal operative complications, recurrence and shorter duration course of the therapy.

Ayurvedic line of treatment for *Bhagandara* includes medical, para-surgical and surgical management. Parasurgical management includes *Ksharasutra*, *Kshara Karma* and *Agni Karma*. The *Ksharasutra* treatment was first mentioned in the *Nadivrana Adhikara,* by *Acharya Sushruta* and the same treatment was said to be followed in *Bhagandara*. The method of preparation of this was mentioned much later by *Chakrapanidatta*.

*Apamarga Ksharasutra* is standardized one and effectively used. But some of the problems are faced during the preparation and also in the course of *Kshara Sutra* therapy. They are as follows;

1. Collection of *Apamarga* plant is very difficult because it is a seasonal plant available in winter and rainy season.
2. Preparation of *Kshara* is a lengthy process, but end product is very less.
3. Local irritant skin reactions occur during the course of therapy.
4. Treatment is sometimes very difficult in sensitive patients like children, females and elders.

*Sushruta* in *Ksharapaka Vidhi Adhyaya* has mentioned 23 *Vanaspathi Dravyas* from which *Kshara* can be prepared. Reference of *Ksharavarga* is also available in *Rasashastra* classics like *Tankana, Sarjakshara, Yavakshara, Sphatika, Navasadara. Sphatika* is one among the *Ksharavarga Dravyas*. *Shuddha Sphatika* is *Guru, Snigdha, Amla Rasa* and *Tridoshaghna*. It acts as *Vranaghna*, *Lekhana* and *Rakthasthambhaka*.

According to classics, *Snuhi Ksheera* is used in the preparation of *Ksharasutra*. But *Snuhi* is not available throughout the year; the time of collection is in *Adana Kala* particularly in *Shishira Ritu*. Due to this fact, we should collect the *Ksheera* in February-march only. Hence as an alternative to *Snuhi Ksheera, Papaya Ksheera* is used as it is easily available, has binding properties, can be preserved and used for long duration. *Papaya Ksheera* is *Vranaghna, Vedanasthapana, Krimighna* and *Kushtaghna*. *Ksharasutra* is a simple, cost effective and safe procedure with high success rate (95.98%) and negligible recurrence rate (3.33%). *Ksharasutra* therapy can replace complicated modern procedures like Fistulectomy and Fistulotomy, as the probable complications of surgery like incontinence, stenosis and stricture are ruled out by the usage of *Ksharasutra.*

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Considering all these factors, an attempt is made to substitute *Apamarga Kshara* and *Snuhi Ksheera* by "*Sphatika Kshara*, and *Papaya Ksheera*" respectively for the preparation of *Ksharasutra* used in the management of *Bhagandara*. The present study aims at evaluating the efficacy of *Papaya Ksheera* based *Sphatika Ksharasutra* in the management of *Bhagandara*.

## Aims and Objectives

1. To evaluate the efficacy of *Papaya Ksheera* based *Sphatika Ksharasutra* in the management of *Bhagandara*.
2. To evaluate the efficacy of *Snuhi Ksheera* based *Apamarga Ksharasutra* in the management of *Bhagandara*.
3. To evaluate the significance of *Papaya Ksheera* based *Sphatika Ksharasutra* by comparing with the efficacy of *Snuhi Ksheera* based *Apamarga Ksharasutra* in the management of *Bhagandara*.

## Materials and Methods

### Source of data

Patients with classical features of *Bhagandara* attending the outpatient and inpatient departments of Government Ayurveda Medical College and Hospital, Bengaluru, were selected for the study.

### Inclusion Criteria

- Patients of the age 16 to 60 years
- Patients irrespective of sex, religion, occupation and duration of symptoms.
- Patient with clinical features of Fistula-in-ano namely pain, sero-purulent discharge and pruritis ani.
- Patient with patent fistulous tract.

### Exclusion Criteria

- Fistula in ano secondary to Tuberculosis, Crohn's disease, Ulcerative colitis, Osteomyelitis, Veneral disease and malignancies.
- Associated with any other anorectal disorders.
- Pregnancy
- Patients suffering with other systemic disorders.
- Recurrent Fistula -in-ano after previous surgery.

**Note:** The pathological conditions mentioned in exclusion criteria was be ruled out after considering the clinical features and conducting required investigations.

### Method of preparation of *Papaya Ksheera* based *Sphatika Ksharasutra*

- *Papaya Ksheera* - 11 coatings
- *Papaya Ksheera* + *Sphatika Kshara* - 7 coatings
- *Papaya Ksheera* + *Haridra Churna* - 3 coatings

### Method of preparation of *Apamarga Ksharasutra*

- *Snuhi ksheera* - 11 coatings
- *Snuhi Ksheera* + *Apamarga Kshara* - 7 coatings
- *Snuhi Ksheera* + *Haridra Churna* - 3 coatings

**Table 1: pH of drugs used in the present study.**

| SN | Drugs | pH |
|---|---|---|
| 1. | *Papaya Ksheera* | 6.8 |
| 2. | *Sphatika Kshara* | 7.2 |
| 3. | *Apamarga Kshara* | 9.8 |
| 4. | *Snuhi Ksheera* | 5.6 |
| 5. | *Haridra Churna* | 6.2 |

### Procedure

- For both the groups required materials were kept ready. Procedure was explained to the patient and informed consent taken.
- Part preparation done.
- As a laxative, *Triphala churna,* 5-10 gms HS advised to the patients on the day prior to probing of` the fistulous tract.

For the patients in Group A, *Papaya Ksheera based Sphatika Ksharasutra* and for Group B, *Snuhi Ksheera*

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*absed Apamarga Ksharasutra,* prepared as per standard methods under strict aseptic precautions was applied.

### Procedure of *Ksharasutra* application

Patient was placed in lithotomy position. Under all aseptic precautions, painting and draping of the part done. A suitable malleable probe was forwarded along the path of least resistance and guided by the finger lubricated with lignocaine jelly in the anal canal to reach into its lumen. Then the tip was finally directed to come out of the anal orifice through the internal opening in the anal canal. A suitable length of plain thread taken and threaded in the eye of the probe. There after the probe was pulled out through the anal orifice, to leave the thread behind in the fistulous tract. The two ends of the plain thread were then tied together with a moderate tightness outside the anal canal. This procedure is called primary threading. On the 3rd day, primary thread was replaced by using *Ksharasutra* by adopting rail-road method.

Patient was advised to attend his normal duty during the treatment period.

### Change of *Ksharasutra*

The *Ksharasutra* was tied to the previously applied primary threading between external opening and outer end of the knot. Then an artery forceps was applied to the inner end of the same knot. The old thread was cut between the artery forceps and the knot. Pulling of the artery forceps along with the thread ultimately replaces the old thread by *Ksharasutra*. Then the two ends were tied snugly and a sterile pad dressing was done. This procedure is done by Rail-road technique.

### Follow up

Successive changes were done at weekly interval. The same procedure was followed for successive changes.

## OBSERVATIONS

The observations made before the treatment and on fresh application of *Ksharasutra* were recorded in the proforma of the case sheet prepared for the study.

**Duration :** Till complete cutting of the tract.

### Assessment Criteria

### Subjective criteria

#### 1) Pain

- Grade 0 ($P_0$) - No pain
- Grade 1 ($P_1$) - Mild pain( Can continue with the work)
- Grade 2 ($P_2$) - Moderate pain (Has to take rest between work)
- Grade 3 ($P_3$) - Severe pain (Unable to work)

#### 2) Discharge

- Grade 0 ($D_0$) - No discharge
- Grade 1 ($D_1$) - Mild discharge (wets 0.5cm x 0.5cm of pad/day - serous discharge)
- Grade 2 ($D_2$) - Moderate discharge (wets 1cm x 1cm of pad/day - sero-purulent discharge)
- Grade 3 ($D_3$) - Severe discharge (wets >1 cm x 1cm of pad/day - purulent discharge)

#### 3) Pruritis Ani

- $p_0$ - pruritis ani absent
- $p_1$ - pruritis ani present

### Objective criteria

1. Length of the tract - Length of the tract was measured in every sitting in centimeters (once in 7 days)
2. Unit cutting time (U.C.T) - The unit cutting time represents the number of days required to cut one cm of the tract. This is calculated by dividing total number of days taken by a fistula to heal by the initial length of the tract denoted as days/cm.

$$\text{U.C.T} = \frac{\text{Total no. of days taken to cut through the tract}}{\text{Initial length of tract in cms}}$$

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### Overall Assessment

The net results obtained from various parameters of assessment by the treatment were taken into consideration to assess the overall effect of the treatment.

- **Marked response:** >75% to <100% relief in all the features i.e, pain, discharge, pruritis ani, length of the tract and unit cutting time.
- **Moderate response:** >50% to <75% relief from all features i.e, pain, discharge pruritis ani, length of the tract and unit cutting time.
- **Mild response:** >25% to <50% relief from all features i.e, pain, discharge, pruritis ani, length of the tract and unit cutting time.
- **Poor response:** <25%relief from all features i.e, pain, discharge, pruritis ani, length of the tract and unit cutting time

Results were statistically analyzed within the group and between the groups using student 't' test & conclusions were drawn.

## RESULTS

### 1. Pain

**Table 2: Effect on Pain in Group - A and Group - B**

| Symptom | Mean score | | | % | SD (±) | SE (±) | t | p |
|---|---|---|---|---|---|---|---|---|
| | BT | AT | BT-AT | | | | | |
| Pain in Group A | 1.65 | 0.1 | 1.55 | 94 | 0.31 | 0.07 | 22.52 | <0.0001 |
| Pain in Group B | 1.55 | 0.2 | 1.35 | 87 | 0.41 | 0.09 | 14.71 | <0.0001 |

### Effect on Pain in Group A

In this work comprising 20 patients of *Bhagandara* in Group-A, Pain assessment are given in detail in Table No. 2. Statistical analysis showed that the mean score which was 1.65 before the treatment was reduced to 0.1 after the treatment with 94% improvement and there is a statistically extremely significant (P<0.0001) results are graphically represented in Graph No. 1.

### Effect on Pain in Group B

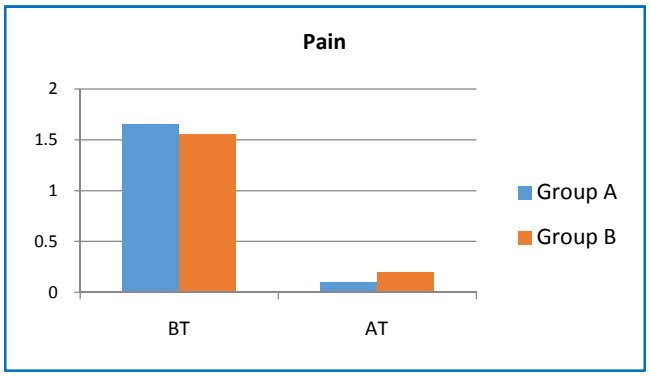
In this work comprising 20 patients of *Bhagandara* in Group-B, Pain assessment are given in detail in Table No. 2. Statistical analysis showed that the mean score which was 1.55 before the treatment was reduced to 0.2 after the treatment with 87% improvement and there is a statistically extremely significant change (P<0.0001) results are graphically represented in Graph No. 1.

**Table 3: Comparative day wise effects in patients in percentage of pain in *Bhagandara***

| Days | Group A | Group B |
|---|---|---|
| Day 7 | 15 | 7 |
| Day 14 | 25 | 17 |
| Day 21 | 55 | 36 |
| Day 28 | 78 | 52 |
| Day 35 | 84 | 62 |
| Day 42 | 93 | 87 |
| Day 49 | 96 | 79 |
| Day 56 | 100 | 83 |
| Day 63 | 100 | 88 |
| Day 70 | 100 | 93 |
| Day 77 | 100 | 96 |
| Day 84 | 100 | 98 |
| Day 91 | 100 | 98 |
| Day 98 | 100 | 100 |

This shows that there was gradual decrease in pain from the 7$^{th}$ day to the 98$^{th}$ day. 78% and 52% relief was seen on 28$^{th}$ day itself in Group A and Group B respectively. Group A showed 100% relief on 56$^{th}$ day itself. Unlike Group B which showed 100% relief in 98$^{th}$ day. The same is graphically represented in Graph no.2.

**Graph 1: Effect on Pain**



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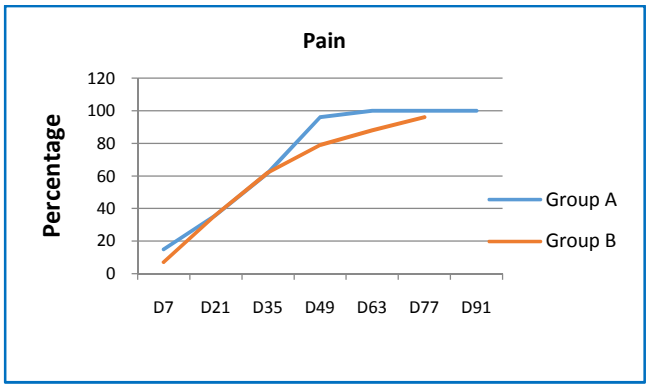
**Graph 2: Effect on Pain**




## 2. Discharge

**Table 4: Effect on Discharge in Group-A and Group- B**

| Symptom | Mean score | | | % | S.D (±) | S.E (±) | t | p |
|---|---|---|---|---|---|---|---|---|
| | BT | AT | BT-AT | | | | | |
| Discharge in Group A | 1.55 | 0.01 | 1.55 | 100 | 0.26 | 0.05 | 30.00 | <0.0001 |
| Discharge in Group B | 1.65 | 0.10 | 1.55 | 94 | 0.31 | 0.07 | 22.52 | <0.0001 |

### Effect on discharge in Group A

Assessment of discharge in patients of *Bhagandara* before and after the treatment with Group - A, showed reduction in the mean score from 1.55 to 0.01 after the treatment with 100% improvement. It is found to be statistically extremely significant (P<0.0001). The details are shown with statistical data in Table No. 4 and graphically represented in Graph No. 3.

### Effect on discharge in Group B

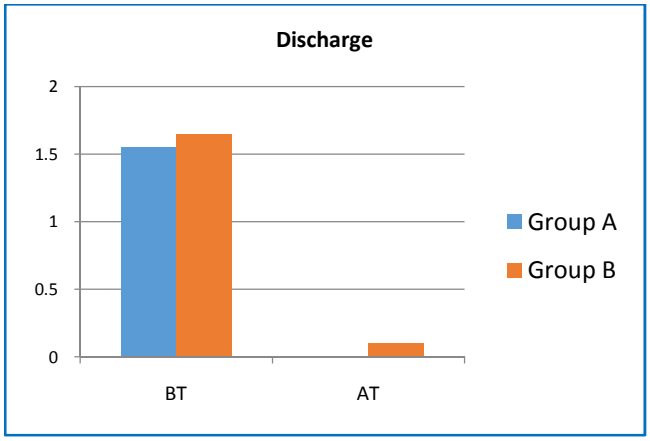
Assessment of discharge in patients of *Bhagandara* before and after the treatment with Group - B showed reduction in the mean score from 1.65 to 0.10 after the treatment with 94% improvement. It is found to be statistically extremely significant (P<0.0001). The details are shown with statistical data in Table No. 4 and graphically represented in Graph No. 3.

**Table 5: Comparative day wise effect in patients in percentage of discharge in *Bhagandara***

| Days | Group A | Group B |
|---|---|---|
| Day 7 | 16 | 11 |
| Day 14 | 45 | 19 |
| Day 21 | 67 | 37 |
| Day 28 | 83 | 55 |
| Day 35 | 83 | 60 |
| Day 42 | 87 | 74 |
| Day 49 | 96 | 74 |
| Day 56 | 100 | 83 |
| Day 63 | 100 | 91 |
| Day 70 | 100 | 95 |
| Day 77 | 100 | 98 |
| Day 84 | 100 | 98 |
| Day 91 | 100 | 98 |
| Day 98 | 100 | 100 |

This shows that there was gradual decrease in discharge from the 7$^{th}$ day to the 98$^{th}$ day. 83% and 55% relief was seen on 28$^{th}$ day itself in Group A and Group B respectively. Group A showed 100% relief on 56$^{th}$ day itself. Unlike Group B which showed 100% relief on 98$^{th}$ day. The same is graphically represented in Graph No. 4.

**Graph 3: Effect on discharge**



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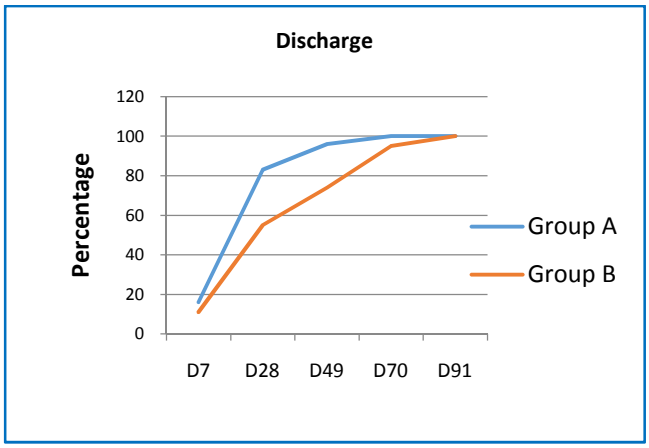
**Graph 4: Effect on discharge**




### 3. Pruritis Ani

**Table 6: Effect on Pruritis Ani in Group-A and Group-B**

| Symptom | Mean score | | | % | S.D (±) | S.E (±) | t | p |
|---|---|---|---|---|---|---|---|---|
| | BT | AT | BT-AT | | | | | |
| Pruritis Ani in Group A | 0.95 | 0.01 | 0.95 | 100 | 0.26 | 0.05 | 18 | <0.0001 |
| Pruritis Ani in Group B | 0.70 | 0.10 | 0.6 | 85 | 0.31 | 0.07 | 8.71 | <0.0001 |

**Effect on Pruritis Ani in Group A**

Magnitude of Pruritis Ani in patients of *Bhagandara* before and after the treatment was assessed and analyzed statistically. In patients registered in Group-A showed extremely significant improvement (P<0.0001). The mean score which was 0.95 before treatment reduced to 0.01 after the treatment with 100% improvement. Further the particulars are mentioned in Table no. 6 and graphically represented in Graph no. 5

**Effect on Pruritis Ani in Group B**

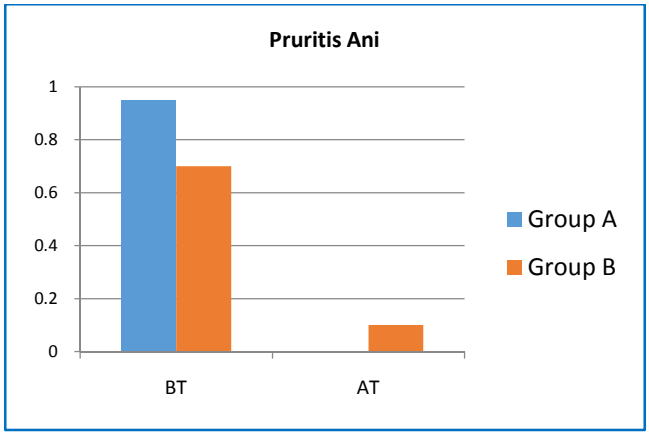
Magnitude of Pruritis Ani in patients of *Bhagandara* before and after the treatment was assessed and analyzed statistically. In patients registered in Group-B showed statistically significant improvement (P<0.0001). The mean score which was 0.70 before treatment reduced to 0.10 after the treatment with 85% improvement. Further the particulars are mentioned in Table no. 6 and graphically represented in Graph no. 5.

**Table 7: Comparative day wise effect in patients in percentage of Pruritis Ani in *Bhagandara***

| Days | Group A | Group B |
|---|---|---|
| Day 7 | 15 | 5 |
| Day 14 | 36 | 25 |
| Day 21 | 73 | 50 |
| Day 28 | 84 | 55 |
| Day 35 | 85 | 65 |
| Day 42 | 94 | 80 |
| Day 49 | 100 | 85 |
| Day 56 | 100 | 85 |
| Day 63 | 100 | 85 |
| Day 70 | 100 | 90 |
| Day 77 | 100 | 95 |
| Day 84 | 100 | 100 |
| Day 91 | 100 | 100 |
| Day 98 | 100 | 100 |

This shows that there was gradual decrease in pruritis ani from the 7$^{th}$ day to the 98$^{th}$ day. 73% and 50% relief was seen on 21$^{st}$ day itself in Group A and Group B respectively. Group A showed 100% relief on 49$^{th}$ day, unlike Group B which showed 100% relief in 84$^{th}$ day. The same is graphically represented in Graph No.6.

**Graph 5: Effect on Pruritis Ani**



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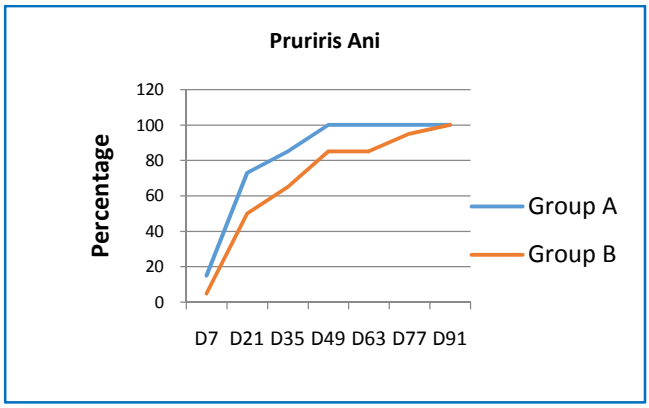
**Graph 6: Effect on Pruritis Ani**




### 4. Length of the Track in Centimeter

**Table 8: Effect on Length of the track in Group A and Group B**

| Symptom | Mean score | | | % | S.D (±) | S.E (±) | t | p |
|---|---|---|---|---|---|---|---|---|
| | BT | AT | BT-AT | | | | | |
| Length of the tract in cm | 3.95 | 0.01 | 3.07 | 100 | 0.26 | 0.05 | 78 | <0.0001 |
| Length of the tract in cm | 3.50 | 0.01 | 3.50 | 100 | 0.26 | 0.05 | 69 | <0.0001 |

**Effect on Length of the Track in Centimeter in Group A**

By the treatment, in Group-A Length of the Track in Centimeter was observed with a mean reduction of score from 3.95 to 0.01 after treatment with 100% improvement. Analysis of this data shows statistically extremely significant improvement (P<0.0001).

**Effect on Length of the Track in Centimeter in Group B**

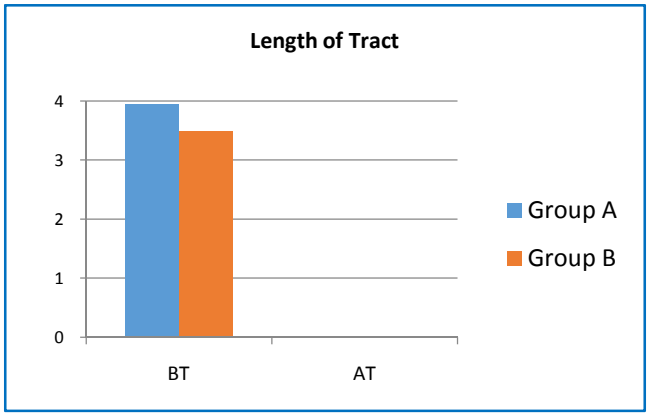
By the treatment, in Group-B Length of the Track in Centimeter was observed with a mean reduction of score from 3.50 to 0.00 after treatment with 100% improvement. Analysis of this data shows statistically extremely significant improvement (P<0.0001).

Further details are given in Table no. 8 and graphically represented in Graph no. 7.

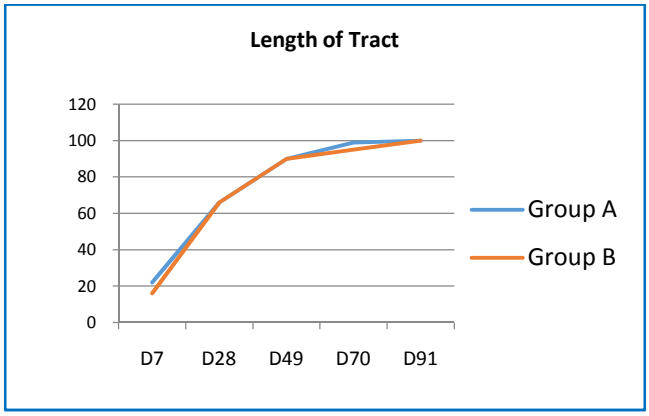
**Table 9: Comparative day wise effect in patients in percentage of length of track in cms in *Bhagandara.***

| Days | Group A | Group B |
|---|---|---|
| Day 7 | 22 | 16 |
| Day 14 | 38 | 35 |
| Day 21 | 52 | 53 |
| Day 28 | 66 | 66 |
| Day 35 | 77 | 78 |
| Day 42 | 85 | 85 |
| Day 49 | 90 | 90 |
| Day 56 | 93 | 94 |
| Day 63 | 96 | 95 |
| Day 70 | 99 | 97 |
| Day 77 | 100 | 98 |
| Day 84 | 100 | 99 |
| Day 91 | 100 | 100 |
| Day 98 | 100 | 100 |

**Graph 7: Effect on Length of the Track**




**Graph 8: Effect on Length of the Track**



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### 5. Unit Cutting Time

**Table 10: Showing the effect on U.C.T in therapy groups**

| | Mean | S.D. | S.E. | t | df | p | Inference |
|---|---|---|---|---|---|---|---|
| **Group A** | 10.77 | 2.20 | 0.05 | 21.44 | 19 | <0.0001 | ES |
| **Group B** | 13.56 | 2.20 | 0.05 | 27.02 | 19 | <0.0001 | ES |
| ES - Extremely Significant | | | | | | | |

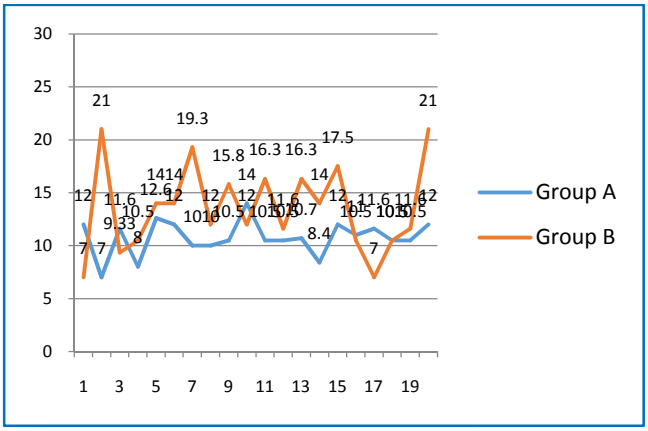
Statistically, both the groups have shown improvement, which is extremely significant with p value < 0.0001 (Table no. 10).

**Table 11: Comparative results of UCT in Group - A and Group - B**

| Group A | Group B | Mean Difference | SE (±) | t | p |
|---|---|---|---|---|---|
| 10.77 | 13.56 | 2.79 | 0.51 | 1.1041 | >0.05 |

The comparative result of Unit Cutting Time (UCT) in *Bhagandara* - Group A is 10.77 and Group B is 13.56. The test shows that the treatment is statistically not significant in Group B when compared to Group A.

**Graph 9: Unit Cutting Time in Group A and Group B**

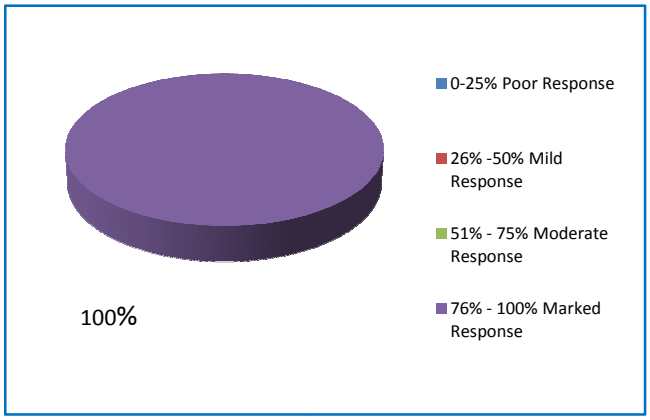



### Assessment of total effect of therapy

**Table 12: Overall effect of Group A and Group B**

| Class | Grading | No of patients in Group A | No of patients in Group B |
|---|---|---|---|
| 0-25% | Poor Response | 0 | 0 |
| 26% -50% | Mild Response | 0 | 0 |
| 51% - 75% | Moderate Response | 0 | 0 |
| 76% - 100% | Marked Response | 20 | 20 |

**Graph 10: Overall Effect of Group A**




**Graph 11: Overall Effect of Group A**

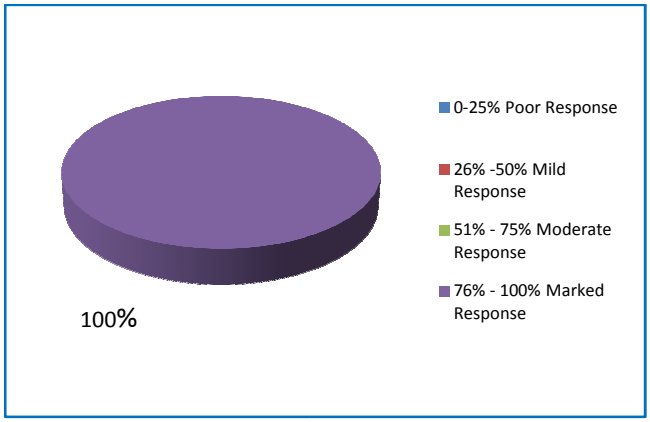



**Table 13: Comparative results of Group - A and Group - B**

| Characteristics | Group - A | | | Group - B | | |
|---|---|---|---|---|---|---|
| Signs and Symptoms | Mean score | | % of relief | Mean score | | % of relief |
| | BT | AT | | BT | AT | |
| Pain | 1.65 | 0.05 | 97 | 1.55 | 0.2 | 87 |
| Discharge | 1.55 | 0.00 | 100 | 1.65 | 0.10 | 94 |
| Pruritis Ani | 0.95 | 0.00 | 100 | 0.70 | 0.10 | 85 |
| Length of the track in centimeters | 3.95 | 0.00 | 100 | 3.50 | 0.00 | 100 |

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### Result of Group A

The percentage of improvement in Group A on Pain is 97%, Discharge is 100%, Pruritis Ani is 100% and Length of the Track in centimeters is 100%.

### Result of Group B

The percentage of improvement in Group B on Pain is 87%, Discharge is 94%, Pruritis Ani is 85% and Length of the Track in Centimeter is 100%.

**Table 14: Comparative results of Group A and Group B**

| Signs & Symptoms | Pain | Discharge | Pruritis Ani | Length of track in cms |
|---|---|---|---|---|
| Group A | 97 | 100 | 100 | 100 |
| Group B | 87 | 94 | 80 | 100 |

**Graph 12: Comparative results of Group - A and Group - B**

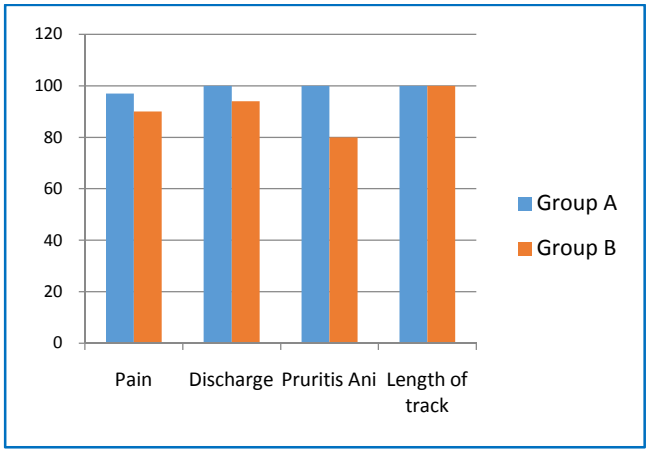


**Table 15: Comparative results of Group A and Group B**

| Group A | Group B | Mean difference | SE (±) | t | p |
|---|---|---|---|---|---|
| 98.5 | 91.5 | 7 | 5.4350 | 6.023 | >0.05 |

Comparative analysis of the overall effect of the treatments in both the groups was done statistically by paired 't' test. Group A overall result is 98.5% and Group B overall result is 91.5%. The test shows that the treatment is statistically not significant in Group B when compared to Group A.

## DISCUSSION

*Bhagandara* is one of the most common ano-rectal diseases. It is one among the 8 grave diseases (*Ashtamhagada*) mentioned by *Acharya Sushruta*. This shows the nature and seriousness of the disease. *Bhagandara* can be co-related to Fistula-in-ano described in modern medical science. Present mechanical lifestyle is increasing the rise of prevalence rate of this disease. Fistula-in-ano is treated conventionally by surgical techniques like Fistulotomy and fistulectomy. Surgical management of *Bhagandara* carries several problems and complications such as incontinence, severe pain, prolonged hospitalization and non-ambulatory life for a long period. The operative site is the potential space for infection by faeces. In all these surgical measures, cure is often not satisfactory and there is always a great possibility of recurrence.

*Kshara Sutra* therapy is the most accepted and scientifically validated procedure for the treatment of Fistula-in-ano. It has become a boon to the patients suffering from Fistula-in-ano. The existing data on *Kshara Sutra* reveals very negligible chances of recurrence by this modality of treatment.

Although *Snuhi Ksheera* and *Apamarga Kshara* are used in the preparation of *Ksharasutra* and used successfully with almost negligible recurrence, during the course of *Ksharasutra* treatment complications like burning sensation, pain, local irritation, persistence of discharge have been noticed because of the *Tikshna Guna* of *Snuhi Ksheera* and *Apamarga Kshara*.

*Snuhi* is not available throughout the year; the time of collection is in february-march only. *Snuhi Ksheera* crystallizes within few minutes of collection. It is very difficult to preserve *Snuhi Ksheera* for a long time. In order to overcome these lacunas, as an alternative to *Snuhi Ksheera*, *Papaya Ksheera* is used as it is easily available, has binding properties, can be preserved and used for long duration.

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**The probable mode of action of *Papaya Ksheera* based *Sphatika Ksharasutra.***

- ***Papaya Ksheera*** is having *Vranaghna, Vedanasthapana, Krimighna* properties and acts as anti-inflammatory, anti-microbial agent to counteract the pain, discharge and pruritis ani within short duration. *Papaya Ksheera* acts as enzymatic tissue debriding agent, which helps in removal of fibrosed and unhealthy granulation tissue. It enhances collagen synthesis, thus improving healthy granulation tissue, wound contraction and complete healing.
- ***Sphatika*** is *Tridoshahara* and acts as *Vranaghna, Lekhana* and *Rakthasthambhaka*, thus helps in curettage of the fibrosed and unhealthy granulation tissue and ensures healthy granulation tissue formation. Alum is said to be Styptic (that which stops bleeding, by contracting skin tissue) which helps to check bleeding during successive changes of *Ksharasutra*. Alum acts as bactericidal as well as bacteriostatic agent, there by reduces bacterial load, which eventually leads to faster and healthy healing of the track.

**Advantages of *Papaya Ksheera* based *Sphatika Ksharasutra***

- *Papaya Ksheera* is easily and abundantly available everywhere.
- Collection of *Papaya Ksheera* can be done in all season.
- *Papaya Ksheera* does not crystallize very soon, can be preserved for up to two hours in cold storage.
- *Shodhana* of *Sphatika* is very easy and end product is more in quantity.
- All the drugs in this *Ksharasutra* have properties which are helpful in combating the pathology involved in the disease *Bhagandara,* as mentioned above.
- UCT and wound healing is significantly fast, which in turn reduces agony of the patient in short duration.
- Short duration therapy is also helpful in terms of patient's valuable time and money by reducing the number of visits to the hospital.
- The pain factor is also considerably low.
- The usual advantages of *Ksharasutra* therapy in fistula-in-ano like non-recurrence and maintainance of continence in anal region is consistent in this *Ksharasutra* as well.

## CONCLUSION

Fistula-in-Ano or *Bhagandara* is an infective condition caused by invasion of anal glands and ducts by various pathogenic organisms. The ingredient *Papaya Ksheera* which has been used as coating over the thread, induces an effective fibrolytic action, separates and removes the debris and cleanses the fistulous tract. Thus, encourages healing by fresh granulation tissue formation from the base. The contents of *Papaya Ksheera* based *Sphatika Ksharasutra* helps by reducing the infective organisms by the antibacterial property simultaneously cut and heal the track by *Chedana, Bhedana, Ksharana* and *Kshanana* action. The parameters of assessment i.e. Pain (Group A 94%, Group B 87%), dishcarge (Group A 100%, Group B 94%), pruritis ani (Group A 100%, Group B 85%), length of track (Group A 100%, Group B 100%) showed statistically significant improvement during the observation period. Group A overall result is 98.5% and Group B overall result is 91.5%. Hence both groups showed excellent/marked response. The average unit cutting time of *Papaya Ksheera* based *Sphatika Ksharasutra* was 10.77 days/cm. Where as, the cutting time as of *Apamarga Kshara Sutra* was 13.56 days/cm with p value > 0.05 which is not significant. Comparative analysis of the overall effect of the treatments in both the groups shows that the treatment is statistically not significant in Group - B when compared to Group-A. *Papaya Ksheera* based *Sphatika Ksharasutra* was found to be as effective as *Apamarga Ksharasutra* in the management of *Bhagandara*. It was observed that irrespective of the *Ksharasutra* used, the UCT was delayed in chronic cases, with more of fibrosed tissue. After cut through, complete healing was observed at an average of 4

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days. The trial drug *Papaya Ksheera* based *Sphatika Ksharasutra* showed promising results as good as *Apamarga Ksharasutra*, and hence may be used as a substitute. Thus alternate hypothesis that *Papaya Ksheera* based *Sphatika Ksharasutra* is as effective as *Apamarga Ksharasutra* in the management of *Bhagandara* is accepted.

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