

## Clinical Efficacy of *Apamarga Kshara* Infiltration in the Management of *Bhagandara* W.S.R to Low Anal Fistula

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### ABSTRACT:

*Bhagandara* is considered difficult to be cured also it is found to be one amongst the *Ashta Mahagada*, where *Aachaarya* has explained the limitation of the treatment by considering it as *Duschikitsya Vyadhi*. *Ksharsutra* management is widely levelled procedure for *Bhagandara* and a number of research studies have been conducted on the same. But most of the times it was noted that the repeated thread changing and prolong duration of the treatment were inconvenient for the patients. Also there are many postoperative complications noted along with increasing number of recurrent cases after surgical management of fistula. Hence this study was proposed to evaluate the effect of *Kshara Karma* in *Bhagandara* by infiltration of *Apamarg Kshara*. Total 33 patients were enrolled for the study 3 patients were excluded from the study. 30 Patients fulfilling the inclusion & exclusion criteria from OPD and IPD of *ShalyaTantra* from Parul Ayurveda Hospital, Khemdas Ayurveda Hospital, as well as from special surgical diagnostic camp and Parul Sevashram Hospital were registered for the study. The assessment was done on subjective criteria like pain and objective criteria as discharge, Unit Healing Time (UHT). On every 7<sup>th</sup> day till complete healing of the track. Assessment of Pain, Discharge, and length of track showed 100% improvement in both pain and discharge with the mean healing time of 6.157days/cm. *Apamarga Kshara* infiltration has act equivalent to *Pratisaraneeya Kshara Karma* by *Shodhana* and *Ropana* resulting to complete cure of *Bhagandara*.

**KEY WORDS:** *Apamarga Pratisaraneeya Kshar*, *Bhagandara*, *Fistula-in-ano*, *Kshara* infiltration.

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### INTRODUCTION:

*Ayurveda* is an eternal branch considered as the science of life. Its prime motto is maintaining the health of healthy individual first and then curing the disease,<sup>[1]</sup> which

promotes a disease free, healthy life span.

*Ayurveda* is an abundant ocean full of knowledge consisting of eight superior branches. Amongst them *Shalya Tantra* is the prime branch rich in surgical concept.

History reveals that the period of *Aachaarya Sushrut* was the golden era of surgery where various surgical procedures were performed. More over in regards of Anorectal and Perineal Surgery, *Aachaarya* has expounded much, with an approach of emphasise both surgical and Para surgical measures.

*Bhagandara* can be screened in ancient *Ayurvedic* texts and varying systematic, scientific detailed descriptions are found. It is the common ano-rectal disease prevalent in the population worldwide. Because of its tedious nature of healing *Bhagandara* is considered difficult to be cured also it is found to be one amongst the *Ashta Mahagada*.<sup>[2]</sup> where *Aachaarya* has explained the limitation of the treatment by considering it as *Duschikitsya Vyadhi*.

In spite of that there are various treatment modalities explained by *Aachaarya's* but the most practicing modality is *Ksharasutra* ligation. *Ksharasutra* management is widely levelled procedure for *Bhagandara* and a number of research studies have been conducted on the same. But most of the times it was noted that the repeated thread changing and prolong duration of the treatment were inconvenient for the patients. Similarly in modern surgery the use of ligation, and some irritant chemicals like urethane and silver nitrate has been advised but most of the modern surgeons depends on operative treatment for this disease where they follow the radial excision of the track along with the removal of major portion of surrounding tissue, their patients require hospitalization for a long period and suffer to the great extent by physical and economical loss. Also there are many postoperative complications noted along with increasing number of recurrent cases.<sup>[3]</sup> Hence the search of better treatment protocol for *Bhagandara* was the need of hours.

*Aachaarya Sushruta* has advocated general as well as specialized approach for management of *Bhagandara*. Generalized treatment principle involves *Chedana Karma* of *Bhagandara* followed by application of *Kshara* or *Agni*.<sup>[4-5]</sup> The superiority of *Kshara Karma* amongst all the surgical and Para surgical procedure is well known.<sup>[6]</sup>

*Kshara* itself is considered as *Chedya*, *Bhedya*, *Lekhya Karnata*. If we use the marvellous actions like *Chedana*, *Bhedana*, *Lekhana*, *Sodhana* and *Ropana* properties of *Kshara* in the form of *Pratisaraneeya kshara* in low anal fistula, it may decrease the duration of treatment as well as recurrence. In this regard on screening and review of *Ayurvedic* texts reveals a change in the form of application of *Kshara*, in *Bhagandara*. Hence this study was proposed to evaluate the effect of *Kshara Karma* in *Bhagandara* by infiltration of *Apamarg Kshara*. The clinical trial was conducted on 30 patients selected as per the inclusion criteria, the end result of the therapy was assessed on various parameters, monitored cautiously, subjected to bio statistical analysis and finally inference was drawn which are put forward here by. The study has been planned with aim to evaluate the efficacy of *Apamarga Kshara* infiltration in the management of *Bhagandara*.

## MATERIAL AND METHODS:

**Study Design-** Open label single arm clinical Trial.

## Medicine Source:

- *Apamarga Kshara* was prepared in pharmaceutical unit of Parul Institute of Ayurveda as per standard classical reference from text.
- *JatyadiTalia* prepared by a GMP certified pharmaceutical Company was procured for the study.

- Concomitant medicine such as *Kaishor Guggulu* and *Gandhak Rasayan* prepared by the GMP certified pharmaceutical Company was procured for the study.

**Selection of Patients:**

33 patients were enrolled for the study, 3 patients were excluded from the study. 30 Patients fulfilling the inclusion & exclusion criteria from OPD and IPD of *Shalya Tantra* from Parul Ayurveda Hospital, Khemdas Ayurveda Hospital, as well as from special surgical diagnostic camp and Sevashram Hospital were registered for the study.

**Inclusion criteria:**

1. Diagnosed cases of *Bhagandara* (Fistulae –in – ano) of age group of 20-70 years.
2. Patients irrespective of, sex, religion, occupation and duration of symptoms.
3. Patients having Single track with both the internal and external opening.
4. Patients with Low anal fistula.

**Exclusion criteria:**

1. HIV, HBsAg, VDRL Positive patients.
2. Uncontrolled Diabetes Mellitus and Hyper Tension.
3. Secondary fistula arising due to chronic diseases like:
  - Ulcerative colitis
  - Chron's disease
  - Tuberculosis
  - Carcinoma of rectum and anal canal.
  - Osteomyelitis,
  - Veneral disease

**Criteria for diagnosis:**

1. Diagnosis will be done on the basis of *lakshanas* of *Bhagandara*.
2. Clinical examination through digital examination and probing.
3. Fistulogram was done in suspected cases to rule out for secondary tracks.

**Investigations:**

Routine Haematological and Biochemical parameters were assessed to rule out the pathological condition.

1. CBC
2. ESR
4. Blood sugar estimation (RBS)
5. VDRL, HIV and HBsAg Screening
6. BT, CT

**Urine examination:**

Urine – Routine and Microscopy

**Radiological Examinations:**

1. X- ray Chest P/A View
2. Fistulogram

Was carried out before the treatment

**PROCEDURE:****Examination of patient:**

Each case was thoroughly examined and investigated as per the detailed Performa designed for this present clinical study on *Bhagandara*. Patients were examined thoroughly through systemic and local examination.

**Pre- operative preparation:**

- Written Informed Consent was taken prior to the procedure.
- Part Preparation was done.
- Inj. Tetanus Toxoid, 0.5 ml, I/M was given.
- Inj. lignocaine sensitivity test dose was given.
- Enema was given on the day of procedure.
- Preparation of operation theatre & sterilization of Instruments were done before hand.

**Materials Required for *Apamarga Kshara* infiltration: (Fig-1)**

Sterile surgical gloves, sterile drapes, sterile swabs, sterile gauze, sterile pads were used, sponge holding forceps, artery forceps, slit proctoscope, Sims speculum, straight and

curved probes, are the instruments used during the procedure. For infiltration of *Kshara*, *Uttarbasti* cannula, 1 ml syringe, was used. *Apamarga Pratisaraniya Kshara* and *Kshara Jala* were used for infiltration; *Nimbu Swaras* was used for track cleansing.

### Operative Procedure : ( fig-2, 3, 4, 5)

Patient was made to lie comfortably in lithotomic position, under all aseptic precaution Perianal region was painted with betadine lotions and draping was done. Local anaesthesia was given.

Patient was assured; Lubricated Gloved index finger was gently introduced inside the anal canal to identify the internal opening. Slit proctoscope was used; Suitable lubricated probe was introduced through the external opening of the fistula. The probe was forwarded along the path from external towards the internal opening of the fistulous track. Guided by the finger of the other hand inserted in to the anal canal and the tip of probe was finally directed to come out of the anal orifice, hence the track length was noted and the patency of the track was checked. After this a gauze pack was kept towards the rectum. *Uttarbasti* cannula /infant feeding tube were inserted in to the track. *Apamarga Kshara* and *Ksharajala* in the ratio of 1:1 were taken in 1 ml syringe. *Kshara* was infiltrated into the track. Awaited for 100 sec, and washed with freshly taken filtered *Nimbu Swaras*. Gauze pad soaked with *Jatydi Talia* was applied to the anal region and bandaged. Patient was shifted to the post-operative ward.

### Post-operative Measures

- Vitals were monitored 6 hourly.
- Injection Ceftriaxone 1gm Intra Venous was given commencement of the procedure. Also the dose was repeated after 12 hrs. of the initial dose. Both these dosages were

given as prophylactic measure, on the day of Procedure.

### Dressing:

- From the next day after *Panchvalkar Kwath Avgahana* dressing was done.
- *Jatyadi taila* was infiltrated in the track daily in the track for dressing and packed with gauze pad.

### Concomitant medicine:

- ***Kaishor Guggulu*** - 2 tabs (500 mg)  
Two times a day after food, with plain water
- ***Gandhaka Rasayana*** -1tab (250 mg)  
Two times a day after food, with plain water

### Duration of the treatment:

Till the complete healing of the track with the closure of both internal and external opening or maximum of 7weeks whichever is earlier.

### Follow up period:

Follow up was done at an interval of 15 days for one month after the completion of treatment. For each follow-up visit, the patients were examined for any recurrence of disease or any associated lesion of the anorectal region.

### Assessment criteria:

The assessment of result was done on the basis of pain as Subjective parameter and Discharge, Unit Healing time as objective parameter. Time taken (in days) to heal one centimetre of the fistulous tract with is known as unit healing time (UHT) (Table-1)

### STATISTICAL DESIGN

#### a) Friedmens test

#### b) Wilcoxon signed rank test

All information which are based on various parameter was gathered and statistical study was carried out in terms of mean (X), Standard Deviation (S.D.), Standard Error

(S.E.), and finally result were integrated in terms of probability (p) as :-

- $p > 0.05$  - Insignificant
- $p < 0.05$  - Significant
- $p < 0.001$  - Highly significant.

### OBSERVATIONS:

Observation made in the clinical study are summarised as follow:-

In this study maximum patients were male (63.3%), in the age group of 31 to 40 years (40%) and married (83.7%). The patients belong to rural habitat were (60%), Hindu religion were (86.6%), working occupation (66.7%), doing physical work (63.3%), socioeconomically middle class (40%). Maximum numbers of patients were reported having the disease of early duration i.e. less than 6 months (46.7%). Only (23.3%) patients reported

with family history of *Bhagandara*. Previous ano-rectal surgical history was observed in (13.3%). The maximum patients of this series were not having *pidika* (90%) and (86.7%) patients had complaint of *Strave*, Whereas (93.3%) patient had complaint of *Vedna* where maximum of them had *Todavada vedana* (50%). Maximum no of patients had healthy surrounding skin (86.7%). With the external opening at a distance up to 1.5 inch in (90%) of patients. Maximum no of patients were acquiring vegetarian diet (73.30%), irregular dietary habits (63.30%), having *Vishmagani* (46.7%). The maximum patients of this series were reported with *Kathina Mall Praritti* (43.30%), *Krura Kostha* (53.13%) and maximum of them had addiction of tobacco chewing (46.60%). *Vata Pittaj Prakriti* (53.3%).

**Table- 1: Parameters used for assessment of Pain and Discharge**

| Parameter  |                               | Criteria   | Grade |
|------------|-------------------------------|--|-------|
| Subjective | Pain                          | No pain  | 0     |
|            |                               | Mild pain  | 1     |
|            |                               | Moderate pain  | 2     |
|            |                               | Severe pain  | 3     |
| Objective  | Discharge                     | Absent   | 0     |
|            |                               | Present  | 1     |
| Objective  | U.H.T.<br>(Unit Healing Time) | Total No. of days taken for healing<br>----- = Days /centimetre<br>Initial length of track in centimetre |       |

### RESULT:-Effect of Therapy on Pain:

**Table-2; Friedman's test:**

| Pain             | Mean rank |
|------------------|-----------|
| Pain BT          | 5.75      |
| Pain on 7th day  | 4.38      |
| Pain on 14th day | 2.97      |
| Pain on 21st day | 2.63      |
| Pain on 28th day | 2.63      |
| Pain AT          | 2.63      |

| Parameter | N | X <sup>2</sup> | P (value) | remark |
|-----------|---|----------------|-----------|--------|
|-----------|---|----------------|-----------|--------|

|             |    |        |       |   |
|-------------|----|--------|-------|---|
| <b>Pain</b> | 30 | 118.78 | 0.000 | S |
|-------------|----|--------|-------|---|

**Table-3: Wilcoxon signed rank test:**

| <b>Lakshanas</b> | <b>Negative Ranks</b> |       |     | <b>Positive Ranks</b> |     |     |      |       |         |         |        |
|------------------|-----------------------|-------|-----|-----------------------|-----|-----|------|-------|---------|---------|--------|
| Parameter        | N                     | MR    | SR  | N                     | MR  | SR  | Ties | Total | Z value | P value | Remark |
| Pain BT - 7D     | 23                    | 12    | 276 | 0                     | .00 | .00 | 7    | 30    | -4.355  | .000    | S      |
| Pain BT- 14 D    | 28                    | 14.50 | 406 | 0                     | .00 | .00 | 2    | 30    | -4.723  | .000    | S      |
| painBT- 21D      | 28                    | 14.50 | 406 | 0                     | .00 | .00 | 2    | 30    | -4.697  | .000    | S      |
| pain BT- 28D     | 28                    | 14.50 | 406 | 0                     | .00 | .00 | 2    | 30    | -4.697  | .000    | S      |
| Pain BT- AT      | 28                    | 14.50 | 406 | 0                     | .00 | .00 | 2    | 30    | -4.697  | .000    | S      |

**Effect of Therapy on Discharge:**
**Table-4: Friedman's test:**

| <b>Discharge</b>      | <b>Mean rank</b> |
|-----------------------|------------------|
| Discharge BT          | 5.40             |
| Discharge on 7th day  | 4.10             |
| Discharge on 14th day | 3.10             |
| Discharge on 21st day | 2.80             |
| Discharge on 28th day | 2.80             |
| Discharge at          | 2.80             |

| <b>Parameter</b> | <b>N</b> | <b>X<sup>2</sup></b> | <b>P (value)</b> | <b>remark</b> |
|------------------|----------|----------------------|------------------|---------------|
| <b>Discharge</b> | 30       | 97.674               | 0.000            | S             |

**Table-5: Wilcoxon signed rank test:**

| <b>Lakshanas</b>  | <b>Negative Ranks</b> |    |     | <b>Positive Ranks</b> |     |     |      |       |         |         |        |
|-------------------|-----------------------|----|-----|-----------------------|-----|-----|------|-------|---------|---------|--------|
| Parameter         | N                     | MR | SR  | N                     | MR  | SR  | Ties | Total | Z value | P value | Remark |
| Discharge 7D-BT   | 13                    | 7  | 91  | 0                     | .00 | .00 | 17   | 30    | -3.606  | .000    | S      |
| Discharge BT-14 D | 23                    | 12 | 253 | 0                     | .00 | .00 | 7    | 30    | -4.796  | .000    | S      |



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|                  |    |       |     |   |     |     |   |    |        |      |   |
|------------------|----|-------|-----|---|-----|-----|---|----|--------|------|---|
| Discharge BT-21D | 26 | 13.50 | 406 | 0 | .00 | .00 | 4 | 30 | -5.099 | .000 | S |
| Discharge BT-28D | 26 | 13.50 | 406 | 0 | .00 | .00 | 4 | 30 | -5.099 | .000 | S |
| Discharge BT-AT  | 26 | 13.50 | 406 | 0 | .00 | .00 | 4 | 30 | -5.099 | .000 | S |

**Table-6:- Mean Unit Healing time:**

| N  | Mean UHT      | S.D.  | SEM   |
|----|---------------|-------|-------|
| 30 | 6.152 days/cm | 0.956 | 0.174 |

Average U.H.T. Was found as 6.152 days / cm

Minimum U.H.T. Was found as 4.10 days / cm

Maximum U.H.T. Was found as 7.66days / cm



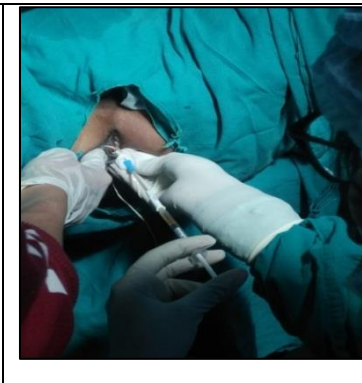
**Table-7:- Result on pain:-**






| Pain          | BT    | 7 <sup>th</sup> Day | 14 <sup>th</sup> Day | 21 <sup>st</sup> Day | 28 <sup>th</sup> Day | AT   |
|---------------|-------|---------------------|----------------------|----------------------|----------------------|------|
| No Pain       | 6.7%  | 36.7%               | 83.3%                | 100%                 | 100%                 | 100% |
| Mild Pain     | 20%   | 33.3%               | 16.7%                | -                    | -                    | -    |
| Moderate Pain | 40%   | 30%                 | -                    | -                    | -                    | -    |
| Severe Pain   | 33.3% | -                   | -                    | -                    | -                    | -    |

**Table-8:- Result on Discharge:-**

| DISCHARGE | BT    | 7 <sup>TH</sup> DAY | 14 <sup>TH</sup> DAY | 21 <sup>ST</sup> DAY | 28 <sup>TH</sup> DAY | AT   |
|-----------|-------|---------------------|----------------------|----------------------|----------------------|------|
| Absent    | 13.3% | 56.7%               | 90%                  | 100%                 | 100%                 | 100% |
| Present   | 86.7% | 43.3%               | 10%                  | -                    | -                    | -    |

## Clinical Images:

|  |  |   |
|--|--|---|
|   |    |  |
| <p>Fig-1: Dressing Trolley:- Materials Required for Apamarga Kshara infiltration</p> | <p>Fig-2: Uttar basti canula introduced from external opening of the fistula track</p> | <p>Fig-3: Apamarga Kshara Infiltration</p>  |

|   |  |   |
|---|--|---|
|  |  |   |
| Fig-4: Fistulous track washed with freshly taken filtered Nimbu Swaras.           | Fig-5: Jatyadi Tail Infiltration used for dressing                                 |   |
|  |  |  |
| Fig-6: Status Before Treatment  | Fig-7: During Treatment  | Fig-8: After Treatment  |

### RESULT AND DISCUSSION:

A special Performa was prepared to record observation, results and assess the effects of therapy on 30 patients. The assessment was done on subjective criteria like pain (from grade 0 to grade 3), discharge (grade 0 and 1), and objective criteria as Unit Healing Time (UHT). On every 7<sup>th</sup> 14<sup>th</sup>, 21<sup>st</sup> day.

Pain is one amongst the prime factors mentioned by *Aachaarya*. It was found that 33.3% of patients had severe pain, 40% of them had moderate pain and 20% of them had mild pain before treatment (Table-7). Statistical analysis was carried out on pain and it was observed that maximum reduction of pain was found on the 7<sup>th</sup> day, i.e. 36.7% of patients got relief from pain, where as 30% of them had moderate pain and 33.3% were having mild pain. On the 14<sup>th</sup> day it was observed that 83.3% of the patients got complete relief from pain whereas only 16.7% of patient had mild pain. On the 21<sup>st</sup> day all patient got complete relief from pain. This is statistically significant with the p- value

0.000. Also it was observed from the Friedman's test that the mean rank was reduced from 5.75 to 2.63. Where 53.50% result was obtained on the 7<sup>th</sup> day itself, this proves that the *Apamarga Kshara* infiltration method has shown good results in relieving pain since the first week of the treatment.

Hence the result shows that *Apamarga Kshara* infiltration is very effective in treating the chief complaint of pain in the patients of *Bhagandara* which can be proven from the mean rank change obtained with the p value 0.00 through Friedman's test (Table-2) and Wilcoxon Signed Rank Test (Table-3)

According to *Ayurveda* the causative factor for pain is *Vaata Dosha*. When other *doshas* like *pitta* and *Kapha* are *Anubandha* with *Vaata Dosha* then the *Vedana* changes to *Toda Vada Kandu Yukta* and *Daha Yukta*. *Kshara* is *Tridoshaghna* and *Vishesh kriya avacharanat*. Which helps in balancing the provoked *dosha*, also after *Shodhana karma* through *kshara* infiltration leads to



chemical debridement and stops the pus discharge and leads towards healthy granulation and ultimately reduction in pain was found. Also *Apamarga* has the property of *Sothahara* and *Vedna Sthapana* and same result was seen in the present study.

#### Result on discharge:

Discharge is another important factor mentioned by *Aachaarya*, Total 30 patients of *Bhagandara* were treated with *Apamarga Kshara* infiltration in fistulas track. The effect of the treatment on discharge was noted, is shown in following (Table No.4). First fried man test was applied, there was a statistically significant result found in discharge with chi-square value 97.674 and p -value 0.000 Also, Wilcoxon Signed Rank Test was applied along with Bonferroni correction ( $P=0.025$ ) to see the effect on discharge before treatment and after 7, 14, 21 and 28days of treatment. The test shows that it was significant after 7 days of treatment with p value 0.000

It was found that 86.7% patients had discharge before treatment, Statistical analysis was carried out on discharge and it was observed that maximum reduction of discharge was found on the 7<sup>th</sup> day, i.e. 56.7% of patients got relief from discharge on the 7<sup>th</sup> day of the treatment. On the 14<sup>th</sup> day 90% patient got complete relief from discharge. Whereas 100% relief was found on 21<sup>st</sup> day (Table no.8) which is statistically significant with the p value 0.000. Also it was observed from the Friedman's test that the mean rank was reduced from 5.40 to 2.80. Where 50.57% result was obtained on the 7<sup>th</sup> day itself, this proves that the *Apamarga Kshara* infiltration method has shown good results in preventing discharge since the first week of the treatment.

Hence result shows that *Apamarga Kshara* infiltration is very effective in treating the

chief complaint of discharge in the patients of *Bhagandara* which can be proven from the mean rank change obtained with the p value 0.000 through Fredmen;s test (Table-4) And Wilcoxon test (Table -5)

This may be because the causative factor for discharge is the *Kleda guna* of *Kapha dosha*. Through infiltration deeper penetration of *Kshara* might have occurred which does the *Chedana* and *Lekhana* of the unhealthy granulation tissue, also it has the property of *Pachana* and *Vilayana*, which does the liquification of tissue, and drains the content. Then through its *Soshana Stambhana* properties the discharge was stopped earlier as the *Sodhana* of the *Dusta Vrana* was done and it was converted to *Sudha Vrana* which later leads to the *Ropana* of *Vrana*. Hence following properties of *Kshara* might be the cause of early reduction in discharge. Also *Apamarga* has the property of *Lekhana*, *Kledahara* and *Krimighna* properties and same result was seen in the present study.

#### Result on Healing:

The Unit healing time (**UHT**) is considered as the objective parameter to assess the result. The length of the track was measured and recorded in research Performa at an interval of 7 days. The individual patients UHT were calculated and then the mean Unit healing time was carried out, and it was 6.157days/cm, (Table No.6).

- Minimal healing time obtained in the study was of 10 days, where the track length was of 2.4 cm and the UHT was of 4.10 days/cm.
- Where the maximal healing time was found of 28 days and the track length was of 3.8 cm with the UHT of 7.66 days/cm. Where the external opening was at 8 o'clock position.
- Hence it can be said that the track length and the position of the track has

role in healing tendency of fistulous track.

- Fistulous track has tedious nature of healing but the hygroscopic nature of alkalis plays important role here, it splits protein and lipids through denaturation of proteins and saponification of lipids. This helps in deeper penetration and thus removes the debris and healthy granulation develops.
- This helped in stopping discharge, removal of debris, early reduction in pain and completes healing of track. (Fig no-6,7,8)

#### **Probable Mode of Action of Apamarga Kshara**

*Kshara* is *Tridoshaghna* thus helped in equilibrium of localised vitiated *Tridosha* and facilitates quick healing. *Kshara* acts externally through its dual action of *Pachana* and *Darana*. *Pachana* acted on inflammatory condition it encourages the body factors (antibodies) to fight against pathogens (antigens) i.e. the hastening procedure. After that through its *Darana* property it ruptures –open ups the abscess cavities and resolve the swelling and leads towards debridement

*Kshara* through its *Lekhana* and *Bhedana* properties removed the unhealthy granulation tissue and through its *Shodhana* and *Vilayana* properties helped in elimination and expulsion of unwanted debris. Also the *Ushna* and *Tikshana guna* helped in debridement and draining of pus. After debridement of unhealthy tissue *Kshara* leads to healing through its *Ropana* properties. Healing requires new vascularisation, granulation tissue formation with protein and fibro cast formation, which is enhanced by the *Ropana* property of *Apamarga Kshara*.

Basically it is found that the fistulous track has the tedious nature of healing, delay in

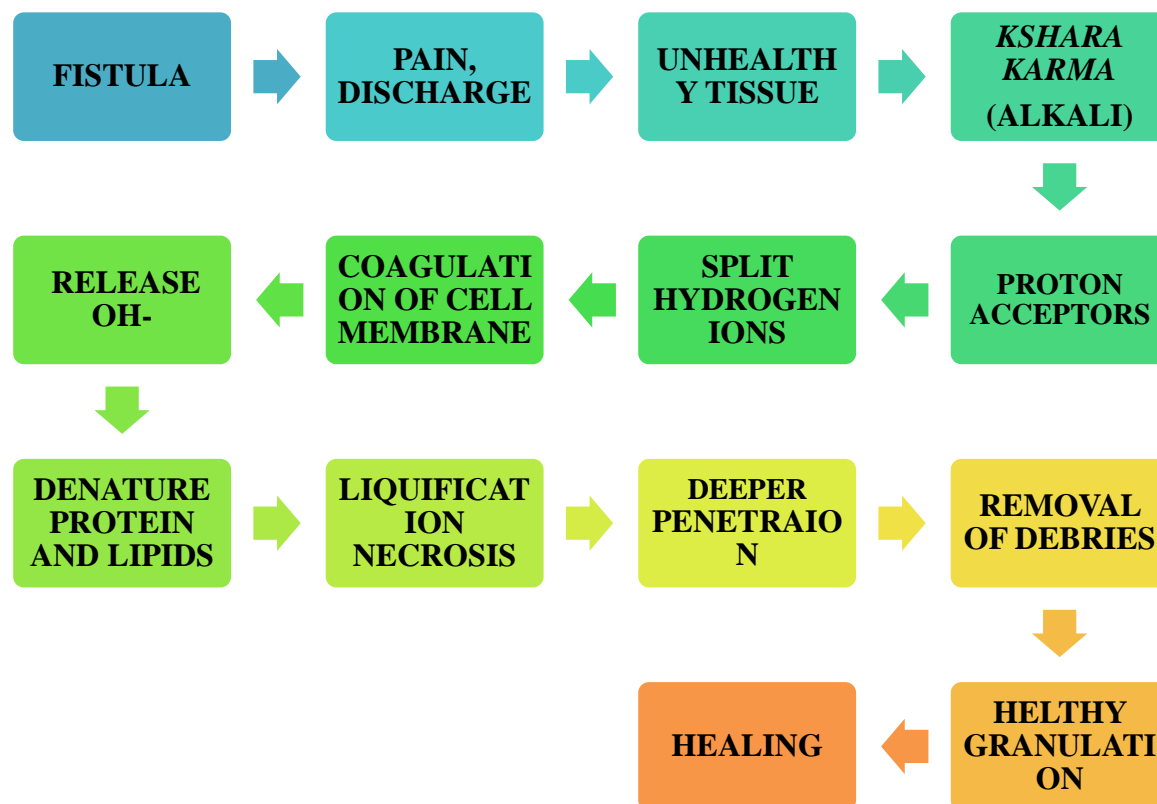
the process occur because of moisture as moisture facilitates breeding and growth of microorganism, *Shoshana* property of *Kshara* had helped in drying up and absorption of discharge. Due to the *Sthambhana* property contraction and coming together of the opposite edges of the track was found and active healing was promoted. The *Tikshna* and *Lekhana Guna* of *Kshara* has scraps the site of fibrosed tissue and flushed out the sloughed material out and the process of healing becomes faster.

Thus *Kshara* through its *Shodhana* properties helped in expulsion of unwanted and unhealthy tissues from the track through debridement and draining of pus. debridement also removes devitalized tissue which can be the source of endotoxins that inhibit fibroblast and keratinocyte migration in the wound and promoted the process of healing.

#### **Advantages of Apamarga Kshara Infiltration Method:**

The procedure of infiltration of *Kshara* is simple and minimal invasive as no surgical procedure like incision or excision is required. It is one time procedure no repeated application like *Ksharasutra* changing is required; it can be performed in minor Ot set ups. As complete *Purana* of *Kshara* in the form of infiltration is done deeper penetration of *Kshara* was found and helps in eradication of infective source. The pain and discharge factor was found minimal after the procedure. No hospitalization is required. Short duration therapy is also helpful in terms of patient's valuable time and money. The anatomy and physiology of the ano-rectal region is well protected as no damage to anal sphincter and chances of incontinence found during the study. Wound healing is significantly fast. Patient can resume his / her daily routine from the next day.

### Probable Mode of Action as per Modern Perspective:



### Probable Mode of Action of Adjuvant Drugs:

**Panchavalkala Kwatha** was advised to all the patients to take warm water sitz bath with 100 ml of *Panchavalkala Kwatha* before dressing in Morning and at bed time. It helped in cleaning the pus discharge and associated debris from the tract and promoted drainage of pus from the tract. It helped to reduce local congestion and inflammation and thus relieved associated pain by enhancing local circulation which is necessary to promote healing. It exhibited *Vrana Shodhana* and *Vrana Ropana* properties.

**Jatyadi Tail** was used for dressing purpose post *kshara* infiltration procedure, daily after *Panchavalkal Kwath Avgahana* to promote active healing. Many times it was observed that the track has the tendency of closure of external opening first without the closure of internal opening. Hence to keep

the track patient *Jatyadi Tail* was infiltrated in the track which promoted proper healing of the track from internal to external opening. Hence *Jatyadi Taila* through its *Shodhana* and *Ropana* properties has enhanced the process of healthy granulation and active healing.

**Gandhaka Rasayana and Kaishore Guggulu** has anti biotic, anti-inflammatory and anti-microbial properties which prevented the secondary source of infection and reduced pain and promotes healing.

*Apamarga Kshara* infiltration acts equivalent to *Pratisaraneeya Kshara Karma* by means of *Lekhana*, *Dahana*, *Pachana*, *Vilayana* of fistulous track, followed by *Shodhana* and *Ropana* resulting to complete cure of *Bhagandara*. The *Kshara* infiltration method is minimal invasive, cost effective, para-surgical procedure which requires minimal hospital stay and less recovery time. It can be practiced with minimum

operative set up and instruments. The *Kshara* infiltration method is simple, ambulatory and no adverse effect was noted during the research study hence we can say that it is the safe treatment modality for fistula-in-ano. *Apamarga Kshara* infiltration is effective in the management of fistula which is statistically proven by early reduction in both the subjective and objective parameters, also no recurrence was observed during the follow up period.

#### **CONCLUSION:**

Hence it can be concluded that the null hypothesis is rejected and the alternate hypothesis is stabilized i.e. *Apamarga Kshara* Infiltration is effective in the Management of *Bhagandara*.

#### **LIMITATION OF STUDY:**

Small sample size, as the study was carried out in only 30 patients further scope of the study suggests, this study can be performed on a cluster whose comparative results may give a better understanding about the *Kshara infiltration* and *Kshara Sutra* management. Standard protocol should be set regarding the duration of infiltration. This method should be practiced in all types of fistula-in-ano. This technique should be tried with other *Kshara* preparations. Effect of the procedure on wound healing with histological changes on the tissue can be checked. Bacteriological study can be carried out to establish the efficacy of the preparation. The consistency of the *Kshara* can be standardised. To rule out the recurrence rate, the study can be done on large sample and regular follow-ups for long durations would lead to better results

#### **INFORMED CONSENT:**

The written informed consent has been obtained from patient for treatment and publication of data.

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