



ISSN: 0975-833X

Available online at <http://www.journalera.com>

INTERNATIONAL JOURNAL
OF CURRENT RESEARCH

International Journal of Current Research
Vol. 12, Issue, 10, pp.14264-14270, October, 2020

DOI: <https://doi.org/10.24941/ijcr.40019.10.2020>

RESEARCH ARTICLE

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF KADALI, ARAGVADH AND PALASH KSHARSUTRA IN THE MANAGEMENT OF VATAJ, PITTAJ AND KAPHAJ BHAGANDAR

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ARTICLE INFO

Article History:

Received 19th July, 2020
Received in revised form
27th August, 2020
Accepted 14th September, 2020
Published online 30th October, 2020

Key Words:

Fistula in ano,
Bhagandar,
Ksharasutra.

ABSTRACT

Fistula in ano resembles to Bhagandar described in Ayurvedic classics. This is one of the common disorders in anorectal surgery. Fistula in ano usually develops from the abscess in anorectal area, which bursts in anus or rectum inside and outside over skin near anus in perianal region. In spite of development of medical science in to the sky Fistula in ano is still a difficult disease to treat without recurrence. In Ayurveda ksharasutra therapy is a gold standard technique to treat this condition with minimal recurrence rate. In ksharasutra therapy a medicated thread is inserted into the fistulous track which act upon and dissolve the infection and heal the track. The most common kshara used for this therapy is Apamarga Kshara. Apamarga kshara is an excellent drug in this disease but in the due course of treatment some patient felt some kind of discomfort as excessive pain, discomfort, itching and some patients even withdraw the therapy. These discomforts may be due to involvement of different doshas in disease, so they get aggravated. So keeping in mind the Dosh predominant theory Kadali, Aragvadha and Palash are taken to use in Ksharasutra therapy of the Vataj, Pittaj and Kaphaj Bhagandar. This study was conducted in two groups and every group divided in three subgroups. Trial group patients are treated with Kadali, Aragvadha and Palash ksharasutra and control group patients were treated with Apamarga ksharasutra. Data were analysed statically and encouraging results have been found.

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Citation: Dr. Alok Kumar and Prof. Hemantha Kumar, P. 2020. "A clinical study to evaluate the efficacy of kadali, aragvadh and palash ksharasutra in the management of vataj, pittaj and kaphaj bhagandar", *International Journal of Current Research*, 12, (10), 14264-14270.

INTRODUCTION

Acharya Sushruta, the father of Indian surgery has included Bhagandar as one among Ashtamahagada¹. He has described It' Nidana, Samprapti, Bheda, Lakshana, Upadrava and Chikitsa^{2,3}. In Astanga Hridayam, it is included in "Astha Sudustara Roga"⁴ due to its notorious nature along with description of three more varieties in addition to Sushrut Samhita. 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%.⁵ One study conducted by Sainio p.⁶ Showed that the prevalence rate of Fistula-in-ano is 8.6 cases per 100,000 populations. The prevalence in men is 12.3 cases per 100,000 populations and in women is 5.6 cases per 100,000 population. The male-to-female ratio is 1.8:1. The mean age of patients is 38.3 years. A similar study conducted in India has reported that Fistula-in-ano constitutes about 15-16 % of all anorectal disorders. It is being managed by specialized Proctologists and Surgeons. But in spite of all the possible efforts, the recurrence rate is very high i.e. 20 to

30 % which is a big challenge before the surgeon's community. The development of Bhagandar is proceeded with formation of a pidika that known as Bhagandar pidika⁷ in the gud pradesh i.e. perianal area. If proper treatment of Bhagandar pidika is not employed, this will result in development of Bhagandar. It is characterized by single or multiple opening around gud pradesh (perianal area) with different types of discharge associated with severe pain. In Ayurvedic classics, Bhagandar has classified into two categories according to openings (mukha), as Bhagandar has no internal opening called Parachin Bhagandar (Bahirmukha) and Bhagandar without external opening called Arvachin Bhagandar (Antarmukha). Bhagandar resembles with the description of Fistula-in-ano as described in modern medical science. Fistula-in-ano implies a chronic granulating track connecting two epithelial lined surface⁸ i.e. anal canal and over skin surface. The anal fistula is a track with an external opening in the skin of perianal region and internal opening in the modified skin or mucosa of anal canal or rectum. Though this disease is not life threatening but produces inconveniences in routine life. It causes discomfort and pain that creates problem in day to day activities. As the wound is located in anal region, which is more prone to infection and persistent pus discharge, irritates the person.

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The anal fistula is a track called external blind fistula when one opening over the skin of perianal region and there is no internal opening in the mucosa of anal canal or rectum. The modern surgical management of Fistula-in-ano includes Fistulotomy, Fistulectomy, Seton placing⁹, Ligation of Intersphincteric Fistula Tract (LIFT)^{10,11}, Fibrin Glues, Advancement Flaps¹² and Expanded adipose derived Stem Cells (ASCs)^{13,14} etc. Ksharsutra therapy is still a gold standard technique for management of Bhagandar, employed by Ayurvedic surgeons. There are some new techniques incorporating ksharsutra as Multiple stage surgical approach¹⁵ and IFTAK¹⁶ have shown very good results in complicated fistulas. In spite of many modifications in surgical procedures, Fistula-in-ano still remains a challenge even for a meticulous and skilful surgeon. It is obvious from the data available from different sources, different operative techniques are uncertain and the recurrence is inevitable. The introduction of Ksharsutra¹⁷ into the fistulous tract was capable of dissolving the fibrous tissue and ultimately draining it out creating a healthy base for healing. But Ksharsutra therapy is having certain inconveniences regarding therapy are worth noting. During the treatment with standard Apamarga Ksharsutra patient suffers with some discomfort like pain, burning sensation, itching, inflammation etc. and most of them the treatment period is very long, which is most inconvenient for patient. In spite of all these Ksharsutra is helpful if track is open on both side and at the level of dentate line.

Acharya Sushrut mentioned many drugs for the preparation of Kshara but now days most of the Ayurvedic surgeons use only the standard Apamarga Ksharsutra for the management of Bhagandar. In spite of all Kshara having same properties but the source plant also having its own characteristics to work upon particular doshas due to having different Ras, Guna, Virya, and Vipak. Study shows that if we use different source plant for the treatment of different type of Bhagandar according to doshik classification that may be more efficient in treatment of particular doshik Bhagandar. The source plant will be chosen according to their doshaghna. By choosing doshagna specific Kshara source plant for the making of Ksharsutra for treatment of accordingly doshaj Bhagandar. The drugs selected for the study was affianced on the basis of a study¹⁸ entitled Review of source plants of Kshara for Ksharsutra preparation for the management of Fistula-in-ano commenced in department of Dravyaguna at National Institute of Ayurveda, Jaipur by Dr. Sudeept Rath et al.^{al}. Considering the above mentioned views the present study was planned entitled "A Clinical Study to evaluate the efficacy of Kadali, Aragvadh and Palash Ksharsutra in the Management of Vataj, Pittaj and Kaphaj Bhagandar" to reduce the discomforts of patients as well as acceptability of all Ksharsutra and minimizes the discomfort and time period of treatment as well as recurrence of Fistula-in-ano.

Aims & Objectives

-) To evaluate the efficacy of Kadali, Aragvadh and Palash Ksharsutra in the Management of Vataj, Pittaj and Kaphaj Bhagandar.
-) To compare the outcome of Kadali, Aragvadh and Palash Ksharsutra used for the Management of Vataj, Pittaj and Kaphaj Bhagandar with standard Apamarga Ksharsutra.

-) To evaluate the acceptability of Kadali, Aragvadh and Palash Ksharsutra in the Management of Vataj, Pittaj and Kaphaj Bhagandar.
-) To establish an alternative of Apamarga Ksharsutra for the management of Bhagandar.

MATERIALS AND METHODS

In Trial group: Patients were treated with application of Kadali, Aragvadh and Palash Ksharsutra according to their doshaghna in Vataj, Pittaj and Kaphaj Bhagandar.

In Control group: All patients of Vataj, Pittaj and Kaphaj Bhagandar were treated with application of standard Apamarga Ksharsutra

Study design: Randomized trial

Sample size: Total 60 patients (30 in each group) of Vataj, Pittaj and Kaphaj Bhagandar were registered for the trial who fulfilling the all inclusion criteria and given informed consent.

Source—Subjects were selected from O.P.D. / I.P.D. at Tertiary Ayurvedic Centre at Jaipur

Study type- Interventional.

Informed consent - The study were explained clearly to the subjects and their signed, written informed consent were taken before starting the trial.

Selection Criteria

Inclusion Criteria

- Ñ Patients of Vataj, Pittaj and Kaphaj Bhagandar from 20 - 65 years age group, irrespective of sex and economic status.
- Ñ Patients were ready to give written informed consent.

Exclusion Criteria

-) Patients having Sannipataj and Agantuj Bhagandar.
-) High level fistula having internal opening in rectum or above anorectal ring.
-) Bhagandar with systemic involvement of disease like Diabetes Mellitus, Hypertension, AIDS, Hepatitis-B, Tuberculosis, Crohn's disease and Ulcerative colitis having morbid changes.

Withdrawal Criteria

- Ñ Intolerance to therapy.
- Ñ Unwillingness to continue with the study.
- Ñ Patients with irregular follow-up.
- Ñ Development of any condition requiring any other specific management.

Selection of Sample According to Ayurvedic Features of Disease

Features of Vataj Bhagandar (Group- A1 and B1)

- Ñ Arun varna pidika

- Ñ Small multiple openings
- Ñ Phenayukta shrav (Continuous frothy discharge)
- Ñ Tadan, bhedan, chedan and Tod kind of ruja

Features of Pittaj Bhagandar (Group- A2 and B2)

- Ñ Rakta varna pidika
- Ñ Chos (Dah) type of ruja
- Ñ Durgandhit usna shrav (Foul smelling warm discharge.)

Features of Kaphaj Bhagandar (Group- A3 and B3)

- Ñ Sukla varna pidika
- Ñ Kandu (Itching)
- Ñ Pichchil shrav (Thick discharge)

Study method: For clinical trial, 60 patients were selected and allotted in two groups (30 each). Each group further divided into three subgroups having 10 patients in each group. Patient allocation in groups were done randomly. The division of patients were done according to the characteristics of Vataj, Pittaj and Kaphaj Bhagandar described in Sushrut Samhita. All the patients were receive standard regimen of Ksharsutra therapy, as primary threading with plain thread under local anesthesia followed by replacing Ksharsutra after two days, changing weekly until cut through of tract and left for healing with secondary intention.

Group A: 30 patients were subdivided in three sub groups (A1, A2 and A3) according to Dosh (Vataj, Pittaj and Kaphaj) having 10 patients in each group treated with Apamarga Ksharsutra.

Group B: 30 patients were subdivided in three sub groups (B1, B2 and B3) having 10 patients in each group receive treatment by Kadali, Aragvadh and Palash Ksharsutra in Vataj, Pittaj and Kaphaj Bhagandar.

Duration of clinical assessment and follow-up study:

Clinical assessments were done weekly after primary threading up to 8 weeks. All the Patients were assessed for the pain, discharge of pus, burning sensation, tenderness, itching, Length of tract, granulation tissue and unit cutting time every week. The overall assessment on subjective and objective parameters in all subgroups of A and B were done after eight weeks. The patients were followed up every month for further six months.

Assessment Criteria

Subjective parameters

- Ñ Pain (VAS Grading)
- Ñ Tenderness
- Ñ Burning sensation
- Ñ Itching

Objective parameters

- Ñ Pus Discharge
- Ñ Granulation Tissue
- Ñ Unit cutting time (U.C.T.)

Subjective Criteria

Pain on VAS- As the sufferer himself expressed the pain in his own terms, so this was graded, starting from mild to severe at par with the Visual Analogue Scale (VAS).

Grade: Explanation

- Ñ Grade – 0 – Absence of pain / no pain
- Ñ Grade – 1 – Pain detected between 1 to 3 mark on scale – [Pain that can easily be ignored (Mild pain)]
- Ñ Grade – 2 - Pain detected between 4 to 6 mark on scale – [Pain that cannot be ignored (Moderate pain)]
- Ñ Grade – 3 - Pain detected between 7 to 9 mark on scale – [Pain that cannot be ignored, interferes with daily routine, needs treatment time to time hot sitz bath (Severe pain)]
- Ñ Grade– 4- Pain detected more than 9 mark on scale – [Demanding constant attention, needs hot sitz bath, oral analgesic, disturbance in sleep (Intolerable pain)]

Tenderness

Grade: Explanation

- Ñ Grade 0 : No tenderness
- Ñ Grade 1: Tenderness to palpation without grimace or flinch
- Ñ Grade 2: Tenderness with grimace and /or flinch to palpation
- Ñ Grade 3: Tenderness with withdrawal(+"Jump Sign")
- Ñ Grade 4: Withdrawal(+"Jump Sign") to non-noxious stimuli (i.e. superficial palpation, pinprick gentle percussion)

Burning sensation

Grade: Explanation

- Ñ Grade 0 - No burning
- Ñ Grade 1- Negligible burning occasional in a day
- Ñ Grade 2 – Occasional burning with 4-6 hrs. gap in a day
- Ñ Grade 3 - Frequent sensation of burning in 2-3 hrs. gap in a day
- Ñ Grade 4 - Frequent burning sensation with less than 1 hr gap in a day

Itching

Grade: Explanation

- Ñ Grade 0 - No Itching
- Ñ Grade 1- Negligible itching occasional in a day
- Ñ Grade 2 - Occasional itching with 4-6 hrs. gap in a day
- Ñ Grade 3 - Frequent sensation of itching in 2-3 hrs. gap in a day
- Ñ Grade 4 - Frequent sensation with less than 1 hr gap in a day

Objective Criteria

Pus discharge

Grade: Explanation

- Ñ Grade 0...no pus discharge
- Ñ Grade 1...if wound wet 0.5x0.5 cm gauze piece
- Ñ Grade 2. if wound wet 1x1 cm gauze piece

- Ñ Grade 3... if wound wet more than 1cm gauze piece
- Ñ Grade 4 .continuous and profuse pus discharge

Granulation Tissue

Grade: Explanation

- Ñ Grade – 0 - Healthy granulation without slough.
- Ñ Grade – 1 - Mild granulation with slough.
- Ñ Grade – 2 – Moderate granulation with slough.
- Ñ Grade - 3 - Unhealthy granulation with slough or hyper granulation.
- Ñ Grade- 4 - granulation tissue absent

Unit cutting time (U.C.T.): The initial length, as well as the length of Ksharsutra at each successive sitting has been measured and recorded. The gradual shortening of thread at the following sitting evidently corresponds to the cutting of tissue, which provides an idea of the progress of a particular case. This has been termed as unit cutting time (U.C.T.). Unit cutting time may be calculated as follows.

$$\text{U.C.T.} = \frac{\text{Total number of days (from the 1st day to cut through the thread)} = \text{days}/\text{cms}}{\text{Initial length of Ksharsutra (in cm)}}$$

Assessment of tolerability: Acceptability were assessed by monitoring the base line Symptoms of the patient and reports of unwanted effects, side effects/ complications/ unwanted effects were assessed in each and every patient. After treatment, the patients were observed for the progress & it is noted in the specially prepared case sheet. The observations were analysed on the basis of assessment parameters (both subjective and objective) critically & scientifically and the results were statistically analysed for its significance with the consultation of biostatistician.

OBSERVATION AND RESULTS

After statistical analysis of intergroup comparison between group A1 and B1 data, It was observed that for pain p-value= 0.014 that shows significant improvement in reducing pain in group B1 than A1. The value of U =25.50. On comparison of tenderness p value = 0.325, there is no significant difference were observed in reducing tenderness in both the group. The U value= 45.00. When we compare burning sensation, p-value= 0.04 that shows significant improvement in reducing burning sensation in group B1 was found. U value=29.00. When we compare itching, p-value= 0.163 that shows no significant improvement in reducing itching in group B1 was found. U value=38. When we compare pus discharge p-value= 0.163 that shows no significant improvement in reducing pus discharge in group B1 was found. U value=46.50. When we compare granulation tissue, p-value= 0.02 that shows significant improvement in formation of healthy granulation tissue in group B1. U value=25.00. When we compare Average Unit cutting time p-value= 0.1533 that shows no significant difference in Average Unit cutting time in both groups. U value=36.00. After statistical analysis of intergroup comparison between group A2 and B2 data, It was observed that for pain p-value= 0.009 that shows highly significant improvement in reducing pain in group B2 than A2.

The value of U =20.00, on comparison of tenderness p value = 0.20, there is no significant difference were observed in reducing tenderness in both the group A2 and B2. The U value= 39.5. When we compare burning sensation, p-value= 0.046 that shows significant improvement in reducing burning sensation in group B2 was found. U value=25.00. When we compare itching, p-value= 0.163 that shows no significant improvement in reducing itching in group B2 was found. U value=38. When we compare pus discharge p-value= 0.282 that shows no significant improvement in reducing pus discharge in group B2 was found. U value=45.20. When we compare granulation tissue, p-value= 0.114 that shows no significant improvement in formation of healthy granulation tissue in group B2. U value=34.5. When we compare Average Unit cutting time p-value= 0.3525 that shows no significant difference in Average Unit cutting time in both groups. U value=44.5. After statistical analysis of intergroup comparison between group A3 and B3 data, It was observed that for pain p-value= 0.033 that shows significant improvement in reducing pain in group B3 than A3. The value of U =29.00, on comparison of tenderness p value = 0.174, there is no significant difference were observed in reducing tenderness in both the group A3 and B3. The U value= 38.5. When we compare burning sensation, p-value= 0.353 that shows no significant improvement in reducing burning sensation in group B3. U value=45.00. When we compare itching, p-value= 0.0250 that shows so significant improvement in reducing itching in group B3. U value=25. When we compare pus discharge p-value= 0.0488 that shows significant improvement in reducing pus discharge in group B3. U value=30. When we compare granulation tissue, p-value= 0.3014 that shows no significant improvement in formation of healthy granulation tissue in group B3. U value=43.0 When we compare Average Unit cutting time p-value= 0.2982 that shows no significant difference in Average Unit cutting time in both groups. U value=42.

The overall assessment of therapy: The table shows overall effect of therapy in both the trial and control group. The significant improvement in different parameters has been observed in trial group. In case of pain all trial drug have shown significant results. In case of tenderness no trial drug have shown significant improvement. In case of burning sensation trial drug Kadali and Aragvadh have shown significant results whereas Palash has no significant improvement in reducing burning sensation in patients. In case of itching only Palash trial drug have shown the significant results however other drug like Kadali and Aragvadh shown no significant effect. In case of pus discharge only Palash trial drug have shown the significant results however other drug like Kadali and Aragvadh shown no significant effect. In case of granulation tissue Kadali have shown significant results and rest two trial drug has no significant improvement in formation of granulation tissue. On comparing the unit cutting time of both trial and control group, no significant difference has been observed.

Follow up: Clinical assessment were done weekly after primary threading up to 8 weeks. All the patients were assessed for the pain, discharge of pus, burning sensation, tenderness, itching, length of tract, granulation tissue and unit cutting time every week. The overall assessment on subjective and objective parameters in all subgroups of A and B was done after eight weeks. The patients were followed up every month for up to six months.

Table no.1 Comparative Assessment in of group A1 and B1

| S.N. | Parameter | % relief in group A1 | % relief in group B1 | Mann-Whitney U-statistic | p-value | Remarks |
|------|---------------------------|----------------------|----------------------|--------------------------|---------|---------|
| 1 | Pain | 50% | 96% | 25.50 | 0.014 | S |
| 2 | Tenderness | 20% | 29.1% | 45.00 | 0.325 | NS |
| 3 | Burning sensation | 21.7% | 80% | 29.00 | 0.04 | S |
| 4 | Itching | 23.5% | 50% | 38 | 0.163 | NS |
| 5 | Pus discharge | 55.5% | 73% | 46.50 | 0.163 | NS |
| 6 | Granulation tissue | 17.2% | 75% | 25.00 | 0.02 | S |
| 7 | Average Unit cutting time | 11.9 days/cm | 12.49 days/cm | 36.0 | 0.1535 | NS |

Table no. 2 Comparative Assessment of group A2 and B2

| S.N. | Parameter | % relief in group A2 | % relief in group B2 | Mann-Whitney U-statistic | p-value | Remarks |
|------|---------------------------|----------------------|----------------------|--------------------------|---------|---------|
| 1 | Pain | 28% | 73% | 20 | 0.009 | HS |
| 2 | Tenderness | 24.1% | 40% | 39.5 | 0.20 | NS |
| 3 | Burning sensation | 25.0% | 85% | 25 | 0.046 | S |
| 4 | Itching | 35.7% | 41.1% | 38 | 0.163 | NS |
| 5 | Pus discharge | 34.7% | 73% | 42.5 | 0.282 | NS |
| 6 | Granulation tissue | 27.2% | 57% | 34.5 | 0.114 | NS |
| 7 | Average Unit cutting time | 12.9 days/cm | 13.3 days/cm | 44.5 | 0.3525 | NS |

Table no. 3 Comparative Assessment of group A3 and B3

| S.N. | Parameter | % relief in group A3 | % relief in group B3 | Mann-Whitney U-statistic | p-value | Remarks |
|------|---------------------------|----------------------|----------------------|--------------------------|---------|---------|
| 1 | Pain | 50% | 91% | 29.00 | 0.033 | S |
| 2 | Tenderness | 29% | 50% | 38.5 | 0.174 | NS |
| 3 | Burning sensation | 33.3% | 33.33% | 45.0 | 0.353 | NS |
| 4 | Itching | 17.2% | 83.3% | 25.0 | 0.0250 | S |
| 5 | Pus discharge | 18.5% | 68.4% | 30.0 | 0.0488 | S |
| 6 | Granulation tissue | 25.9% | 43% | 43.0 | 0.3014 | NS |
| 7 | Average Unit cutting time | 12.6 days/cm | 12.9 days/cm | 42.5 | 0.2982 | NS |

DISCUSSION

Discussion on assessment parameters Pain: Patients of group A1 felt 50% relief in pain while patients of group B1 felt 96% relief in pain. Patients of group A2 felt 28 % relief of pain while patients of group B2 felt 73% relief in pain. Patients of group A3 felt 50% relief in pain while patients of group B3 felt 91% relief in pain. So with the above data it is clear that patients of group B shows better relief in pain during treatment. These results are obtained due to the Vata-shamak properties of trial drugs for the preparation of Ksharsutra . On the comparison of group A and group B the data showed that the highest percentage of relief was seen in the patients treated with Kadali Ksharsutra , that proved the Vata-shamak property of Kadali because of its Rasa, Guna, Virya and Vipaka all are having vata-shamak function. These all vata-shamak properties are carried to the Kshara also.

Tenderness: Patients of group A1 felt 20% relief in tenderness while patients of group B1 felt 29.1% relief in tenderness. Patients of group A2 felt 24.1 % relief of tenderness while patients of group B2 felt 40.1% relief in tenderness. Patients of group A3 felt 29% relief in tenderness while patients of group B3 felt 50% relief in tenderness. So with the above data it is clear that patients of group B shows better relief in tenderness than group A. The reason behind these results is due to trial Ksharsutra which were prepared by trial drugs according to Doshaghntva of plants. The trial drugs have better vatpittashamak properties than Apamarga that's why the percentage of relief is more in the patients of trial group.

Burning sensation: Patients of group A1 felt 21.1% relief in Burning sensation while patients of group B1 felt 80% relief in Burning sensation.

Patients of group A2 felt 16 % relief of Burning sensation while patients of group B2 felt 85% relief in Burning sensation. Patients of group A3 felt 33% relief in Burning sensation while patients of group B3 felt 33.3% relief in Burning sensation. So the above data clearly show that maximum percentage of relief was observed in group B2. These results are occur due to the pittashaamak properties of Aragvadh plant that comes to the Ksharsutra prepared by Aragvadh. On comparing both group group A patients have less percentage of relief in burning sensation because the Rasa, Guna, Virya and Vipaka of Apamarga plant are Katu, Tikta, Laghu, Ruksha, Tikshna, Ushna, most of all are pitta-prakopak. Whereas the Aragvadh plant has Madhur rasa, Guru, Snigdha, Mridu guna, Sheet virya, Madhur vipaka and pitta-shamaka, properties that helps in reducing burning sensation in the patients after Ksharsutra application.

Itching: Patients of group A1 felt 23.5% relief in Itching while patients of group B1 felt 50% relief in Itching. Patients of group A2 felt 35.5% relief of Itching while patients of group B2 felt 41% relief in Itching. Patients of group A3 felt 17.2% relief in Itching while patients of group B3 felt 83.3% relief in Itching. So we see that maximum percentage of relief in the Itching at disease site was observed in group B3. These results are due to the properties of plant having that carry forward to the Ksharsutra also, that properties helps in reducing itching. As we know the itching occur due to the involvement of kapha dosh. As per our classical literature Palash plant has Rasa Katu, Tikta and Kashaya, Vipaka –Katu, Veerya–Ushna and Kaphapittahara. With the virtue of these properties Palash has worked on kapha dosha leading to the reduction of itching in the patients.

Pus discharge: Patients of group A1 felt 55.5% relief in Pus discharge while patients of group B1 felt 73 % relief in Pus discharge. Patients of group A2 felt 34.7% relief of Pus discharge while patients of group B2 felt 73% relief in Pus discharge. Patients of group A3 felt 18.5% relief in Pus discharge while patients of group B3 felt 68.4 % relief in Pus discharge. The above data shows that in only B3 group there were significant improvement in % of relief in pus discharge was observed rest other group patients there were no significant improvement was observed. The reason behind that may be rasa, guna, virya and vipaka of Palash plant. Palash also have the Lekhana, bhedana and krimighna property that helps in early leaning of dead tissue so that pus reduces significantly.

Granulation tissue: Patients of group A1 felt 17.2% relief in granulation tissue while patients of group B1 felt 75 % relief in granulation tissue. Patients of group A2 felt 27.2% relief of granulation tissue while patients of group B2 felt 57% relief in granulation tissue. Patients of group A3 felt 25.9% relief in granulation tissue while patients of group B3 felt 43 % relief in granulation tissue. The above data shows that in trial group only Kadali has significant improvement in the percentage of relief in granulation tissue formation. These results may be due to the properties of Kadali as it have madhur rasa, sheet virya, madhurvipaka, guru and snigdha guna these all properties helped in vranaropana karma. On phytochemical analysis Kadali has tryptophan, indole compounds, tannin, starch, iron, crystallisable and non-crystallisable sugars, vitamin C, B-vitamins, albuminoids, fats, mineral salts that improve the wound healing property of Kadali.

Average Unit Cutting Time: Patients of group A1 had average unit cutting time 12.6 days/cm while patients of group B1 had average unit cutting time 12.9 days/cm. Patients of group A2 had average unit cutting time 12.9 days/cm while patients of group B2 had average unit cutting time 13.3 days/cm. Patients of group A3 had average unit cutting time 12.6 days/cm, while patients of group B3 had average unit cutting time 12.9 days/cm. Above data shows that there is no significant changes were observed in the average unit cutting time of both the groups. This is may be due to that the cutting of fistulous track was depends on the mechanical pressure applied by thread on the tissue. Because the thread was tied almost equally in all the patients that's why there were no significant change in the average cutting time was observed.

Probable mode of action of trial drugs: In the present study the comparative results of both group shows that the Kshara source plant carry their phytochemical properties in the Kshara form also. Kadali has Madur Ras, Madhur Vipaka, Sheet Virya and guru Snigdha properties that helps in the improvement of pain management, burning sensation, and wound healing by improving healthy granulation tissue significantly. In phytochemical analysis it was found that Kadali is very good source of potassium and iron. It has Serotonin, nor-epinephrine, tryptophan, Indole compounds, tannin, starch, Iron, crystallisable and non-crystallisable sugars, vitamin C, B-vitamins, albuminoids, fats, mineral salts that helps in producing good granulation tissue for faster wound healing. On the Ph monitoring it was found that Kadali Kshara powder has maximum Ph that provide the better Kshara property. It pacified the vitiated Vatadosha by virtue of madur rasa, snigdha and guru guna and by madhu rvipak. The second trial drug Aragvadh has significant action in the reducing pain and

burning sensation in the patients of Pittaj Bhagandar. In Ayurveda Acharya Sushrut says wherever the pain there is Vata and wherever there is suppuration there were is pitta and wherever there is pus the kaph dosh must be involved in that body part. As per classical literature Aragvadh has madhura rasa, guru and snigdha guna, sheet virya and madhur vipaka. All these properties are Vata and pittashamak. That is why we found significant effect on pain and burning sensation. Aragvadh has pharmacological properties like Antifungal activity, Antibacterial activity, Anti-inflammatory activity, Laxative activity. Due to theses action Aragvadh Ksharsutra was very much effective in treatment of Pittaj fistula in ano with minimum discomfort. The third trial drug of the study was Palash. Results shows that Palash has significant results in reducing pain, itching and pus discharge in the patients of Kaphaj Bhagandar. As per Ayurvedic literature Palash has Katu, Tikta, and Kashaya Rasa, Katu Vipak, Ushna Virya and Lekhan Abhedana and krimighna property. By virtue of above mentioned all these properties Palash effectively pacified the vitiated Kapha dosha and works on the sign and symptoms produced by vitiated Kapha. That is why we found the significant effect of Palash Ksharsutra in the management of Kaphaj Bhagandar. On phytochemical study it was found that Palash has Antimicrobial, Antifungal activity, Antitumor activity, Wound healing and Anti helminthic activity. Due to these properties Palash work very well on the wound healing. It reduces itching and pus discharge because of having antimicrobial and anthelmintic property.

Conclusion

So at the end of this study final conclusion can be drawn that Kadali Ksharsutra is effective in the treatment of Vataj Bhagandara, Aragvadh Ksharsutra is effective in the treatment of Pittaj Bhagandar and Palash Ksharsutra is effective in the treatment of Kaphaj Bhagandar, in place of Apamarga Ksharsutra, so hypothesis behind the study was found to be correct, that the basic properties i.e. doshaghnavta of any plant drug remains in the Kshara form also. Since the clinical study was conducted on a limited number of patients it may not be claimed as final. Multicenter large sample study will be more authentic to establish the efficacy of Kadali, Aragvadh and Palash Ksharsutra in the management of Vataj, Pittaj and Kaphaj Bhagandar.

Recommendation

- 1) Study should be conducted in large sample size with multicentre trial to get more accurate results.
- 2) Some other Kshara source plant may be tried for preparation of Ksharsutra according to their doshaghnavta.
- 3) Study may be planned with the altered coatings of Kshara i.e. 3 coatings, 5 coatings and 7 coatings.

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