International Journal of Current Advanced Research
ISSN: O: 2319-6475, ISSN: P: 2319-6505, Impact Factor: 6.614
Available Online at www.journalijcar.org
Volume 9; Issue 06(A); June 2020; Page No.22407-22411
DOI: http://dx.doi.org/10.24327/ijcar.2020.22411.4417

Research Article

COMPARATIVE STUDY ON DIFFERENT TREATMENT MODULES IN THE MANAGEMENT OF FISTULA-IN-ANO (BHAGANDARA)

G.V.P. Samaranayake[1], A.A.J. Pushpakumara[2] and K.P.P. Peiris[3]

[1]Lecturer (Probationary), Department of Ayurveda Basic Principles, Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Sri Lanka
[2,3] Senior Lecturer, Department of Shalya Shalakya, , Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Sri Lanka

A R T I C L E I N F O

Article History:
Received 12th March, 2020
Received in revised form 23rd April, 2020
Accepted 7th May, 2020
Published online 28th June, 2020

Key words:
Bhagandara, fistula-in-ano, *Kshara sutra*

A B S T R A C T

Bhagandara is a common disease occurring in the ano-rectal region. *Acharya Susruta*, the father of surgery has included this disease as one among the *Ashtamahagada*. It can be correlated with Fistula-in-ano as described in western medical science. Fistula-in-ano is a track lined by granulation tissue which opens deeply in the anal canal or rectum and superficially on the skin around the anus. The incidence of a Fistula-in-ano developing from an anal abscess ranges from 26-38%. The prevalence in men is 12.3 cases per 100,000 populations and in women are 5.6 cases per 100,000 populations. The male to female ratio is 1.8:1. The mean age of patients is 38.3 years. This randomized prospective cohort clinical study was done to compare and evaluate the effect of new herbal formulation consisting of *Vitex nigundo*(root), *Crativa adansoni* (bark), *Ricinus communis* (bark), *Plumbago indica*(root) in managing fistula-in-ano conditions of patients in comparison to the effect of *tripala* decoction and *kshara sutra*. The patients were selected according to the selection criteria and randomly assign in to 2 groups (Group A, Group B) consisting of 20 patients for each. The patients of Group A was be treated with, *Tripala* decoction, *kshara sutra* and prescribed dietary management. The patients of group B were treated with, new herbal formulation, *kshara sutra* and prescribed dietary management during the period of 8 weeks. In the group A and group B mean changes or decrement of pain, burning sensation, itching and discharge, P values = 0.00 95% confidence level $P < 0.05$ both groups are same P=0.000. Therefore, no difference between both groups and it shows statistically significant. In the group A mean decrement of length of the fistulous track P value $p = 0.005$ at confidence level $P < 0.05$. It shows a significant decrement of the length of fistulous track statistically in 95% confidence level. In the group B mean decrement of length of fistulous track P value $p = 0.000$ at 95% confidence level $P < 0.05$. It shows a significant decrement of the length of fistulous track statistically in 95% confidence level. But mean decrement of length of fistulous track of the group B greater than that of group A, which means group B more statistically significant. Finally, based on the observed results and the pharmacodynamic properties of both treatment protocols, it may be concluded that new herbal formulation + *kshara sutra* + dietary management treatment module is more effective than *Tripala* decoction + *kshara* sutra + dietary management in the management of fistula-in-ano.

INTRODUCTION

Fistula-in-ano is an age old problem involving the ano-rectal region. It is notorious for its chronicity, recurrence and frequent acute exacerbations. Various treatments have been tried to cure fistula-in-ano including fistulectomy with skin grafting for the routine surgical treatment employed today is fistulectomy and fistulotomy.

Corresponding author:* **G.V.P. Samaranayake
Lecturer (Probationary), Department of Ayurveda Basic Principles, Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Sri Lanka

Thus in principle the surgical treatment of fistula-in-ano has mentioned the same without much improvement.

More over the need of prolonged hospitalization, extensive mutilation of ano-rectal region, chances of recurrence and anal incontinence in some of the cases of high level fistula have encouraged us to try out a new indigenous ambulatory treatment of fistula-in-ano. Great Indian Surgeon *Susruta* narrated in his teachings the case of *kshara* for cure of fistula-in-ano. *Kshara sutra* is a medicated alkaline thread. Application of this thread in fistulous track causes simultaneous cutting and healing of the wound and allows

better wound drainage. According to the previous clinical experiences and evidence observed in the case studies *kshara sutra* has showed some stagnant in healing process in 55% of patients due to the various reasons. Therefore internal medication can apply with the *kshara sutra* for the significant reduction of signs and symptoms of fistula-in-ano. The present study was conducted to evaluate the effect and efficacy of the different treatment modules in the management of fistula-in-ano. Therefore it is needed to validate the effective formulation through different clinical trials.

On other hand, the present study was conducted to evaluate the effect of the new herbal formulation in the management of fistula-in-ano. The formula was selected from the authentic Ayurvedic book named in *Vaidayaka Sarasankshepa* written by Rajaguru Sri Chandra. All material of this formulation was herbal, can easily be found, easily prepared and cost effective. According to the scientific evidence, that ingredients having anti-microbial, anti-oxidant properties.

METHODOLOGY

This study is a randomized prospective cohort study. The patients were selected according to the selection criteria and randomly assign in to 2 groups (Group A, Group B) consisting of 20 patients for each. The patients of group A were treated with *Tripala* decoction, *kshara sutra* and prescribed dietary management. The patients of group B was treated with new herbal formulation, *kshara sutra* and prescribed dietary management.

Subjective Parameters

- Pain
- Burning sensation
- Itching
- Discharge

Objective Parameters

Length of the fistulous track

Exclusion Criteria

- Patients not willing to participate in the trial
- Patients who are below 25 years of age or above 60 years of age
- Pregnant women
- Patients having possibility of Tuberculosis, AIDs

Inclusion Criteria

- Patients willing to participate in the trial
- Patients between age 25-60 years of age
- Either sex
- Patients selected for trail on clinical examination

Method of Preparation of New Herbal Formulation

The new herbal formulation consists of four plants materials given in the following table.

Scientific Name	Family Name	Sanskrit Name	Parts Used
Vitex nigundo	Lamiaceae	*Nirgundi*	Root
Crativa adansoni	Capparaceae	*Warana*	Bark
Ricinus communis	Euphorbiaceae	*Eranda*	Bark
Plumbago indica	Plumbaginaceae	*Chitraka*	Root

New herbal formulation is prepared by boiling 1 part of following coarse powder of herbs with 16 parts of water in an open vessel on mild fire till it reduce to 8-1of the original quantity.

After the preparation of decoction add following ingredients and used.

Saidava Lawana	-	3g
Castor Oil	-	10ml

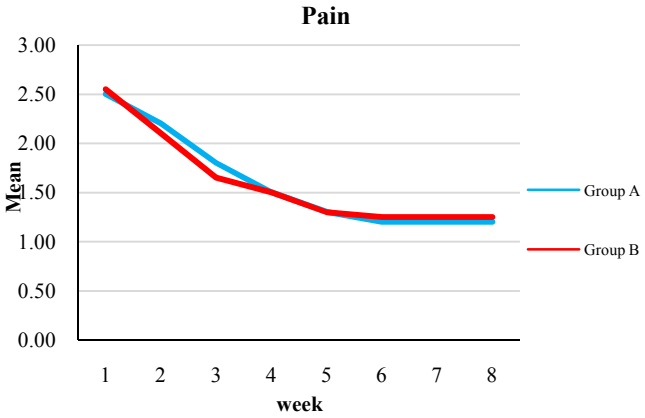
Dosage & Administration

Patients of group A were instructed to take 2 table spoonful of prepared *Tripala* decoction of before food at 6am and 6pm. And also externally apply *Apamarga kshara sutra* through the external opening of the fistula and it was replaced by a new one after an interval of one week. Patients of group B were instructed to take 2 table spoonful of prepared decoction of new herbal formulation before food at 6am and 6pm. And also externally apply *Apamarga kshara sutra* through the external opening of the fistula and it was replaced by a new one after an interval of one week.

RESULTS

Pain

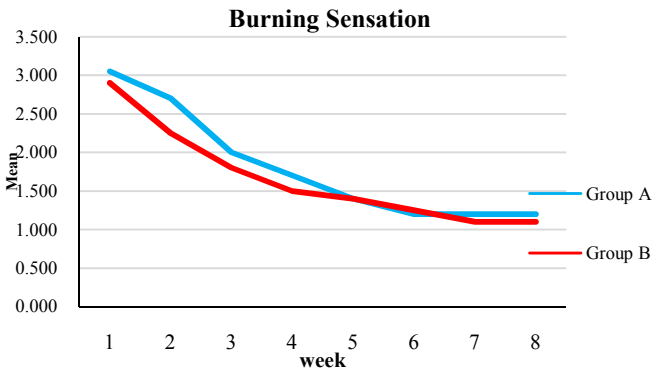
Then calculate the mean value of the pain is every week for group A and group B separately. Pain decrement can be represented are as follows.



P values of both groups are same (P=0.00). Therefore, no difference between both groups the reduction of pain.

Burning Sensation

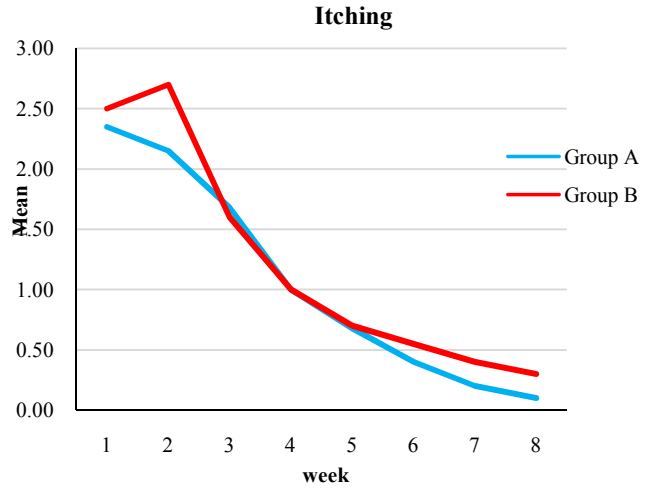
Calculate the mean value of the burning sensation is monitored every week for group A and group B separately. Burning sensation changes can be represented are as follows.



P values of both groups are same (P=0.000). Therefore no difference between both groups in the Burning Sensation changes.

Itching

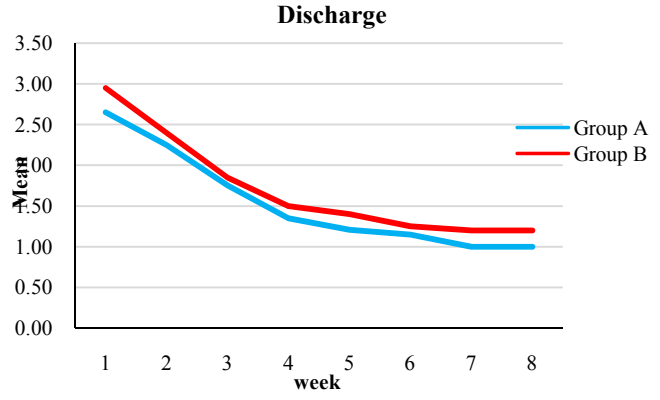
Calculate the mean value of the itching is monitored every week for group A and group B separately. Itching changes can be represented are as follows.



P values of both groups are same (P=0.000). Therefore no difference between both groups in the itching changes.

Discharge

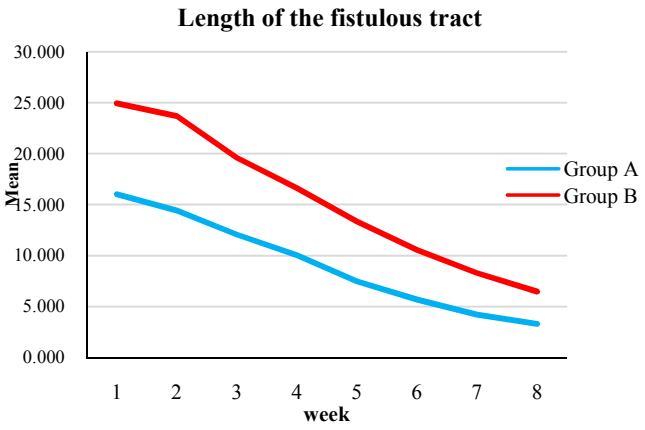
Calculate the mean value of the discharge is monitored every week for group A and group B separately. Discharge changes can be represented are as follows.



P values of both groups are same (P=0.000). Therefore, no difference between both groups the Discharge change.

Length of the fistulous tract

Calculate the mean value of the length of the fistulous tract is every week for group A and group B separately. Length decrement can be represented are as follows.



P values of group A (P=0.005) > P values of group B (P=0.000), therefore reduction of the length of the fistulous tract in the group B is more significant than group A.

DISCUSSION

The present study revealed that, the incidence of fistula in ano (*bhagandara)* was greater in males (57.5%) compared to females (42.5%). Long hours of sedentary jobs, local unhygienic, and distribution of hairs, increased sweating and unhealthy food habits may have increased the incidence in males Majority of the patients are belonged to the age group of 51-60 years (48%) and patients below the age of 30 years are in 0% least numbers.

Most of the patients are habituated to a non-vegetarian diet. (Kumar H and Sahu M, 1996) According to *Susruta, Charaka, Vagbhata* and contemporary surgeons, all have emphasized that fish and other bone pieces, egg shell etc., consumed in the food by people, is also one of the causative agents of fistula in ano. Similar observation were recorded in this study, wherein a greater percentage (92.5%) of patients following a non-vegetarian diet (Table 4.3).Most of the patients i.e., 55% were form middle income group and 30% were low income group. Lack of hygiene and lack of care regarding maintaining healthy food habits and bowel movements, causes and increased incidence in these people. It is owing to these reasons; the disease is also seen in significant percentage in patients belonging to the poor and middle class families.

Lack of roughage in the food of non-vegetarians leads to constipation repeatedly, which is one of the causes known to aggravate the condition. The present study revealed that 52.5% had constipated hard bowels.

This result in long hours of straining and ineffective emptying of bowels, stasis of fecal contents in the anal columns and repeated straining injuries in the mucous membrane of anal column, which then initiates a chain of chronic and acute infective processes, finally terminating as a fistula in ano.

The patients of fistula in ano had varying chronicity from few weeks to 15 years. Majority of the cases (45%) belonged to the group having chronicity of 1-3 years. Lack of knowledge regarding the disease, misinformation regarding the disease

and or being treated by surgically had recurrences and hence by the time the patients come for treatment after more than a year and thus, found such as high incidence in this group of 1-3 years of chronicity.

Accidental finding, greater percentage of cases (52.5%) with fistula in ano had track lengths varying from 5 to 10 cm. No particular reason is attributed to the higher percentage of track length of this particular measure. Majority of the cases 47.5% had undergone surgery twice before coming to Ayurvedic treatment. 30% of the patients had undergone surgery once and 22.5% of the patients had undergone surgery more than twice for the same track of fistula.

Majority of the cases were high anal variety, 67.5% and the rest of the patients, 32.5% had a low anal fistula. It was observed that majority of the fistulous track 40% were completed. However 35% of the fistula tracks were belonged to the *Ushtragreeva* type accounting 45% and least number of cases were belonged to the *Riju* type was accounting 2.5%.

Majority of the cases that 45%, belonged to the fistulae *ushtragreeva* variety (fistulae having curved or radial tracks) and very few cases (15%) belonged to the fistulae with multiple external varieties. There was no any case of fistula in ano described in Ayurveda as *unmargi bhagandara* were not found during the study. Accordingly it was observed that 60% of the tracks were intersphincteric and 25% of them were transsphincteric, 5%were horseshoe fistula and 2.5% were suprasphincteric fistulae and found in very few cases of subcutaneous fistula were found 7.5%.

Generally, it was observed that external opening may be single or multiple but the internal opening is usually single. In this study, 70% of the cases had single internal opening, whereas, 30% of the cases had multiple external opening with a single internal opining. Usually it was observed that only when the primarily formed external opening gets fibrosed or blocked, the pus does not get an opening to discharge.

It then finds some other route of least resistance, trickles out forming another external opening, thus leading to multiple openings. In the study it was observed that the disease was most prevalent in 25% *vata prakriti* individuals followed by 40% *kapha* and *vatakapha* individuals were 15% .

The fistula in ano assessment criteria were evaluated group A and group B separately for start of treatment (1st week) and end of treatment (8th week).

The group A pain mean value for 1st week 2.50, 8th week 1.20. The mean difference is 1.300. The group B pain mean value for 1st week 2.55, 8th week 1.25. The mean difference is 1.300. Therefore, no difference between both groups reduction of pain.

The group A burning sensation mean value for 1st week 3.050, 8th week 1.200. The mean difference is 1.8500. The group B burning sensation mean value for 1st week 2.900, 8th week 1.100. The mean difference between is 1.800. Therefore mean difference for burning sensation group B 0.05 greater than group A.

The group A, itching mean value for 1st week 2.35, 8th week 0.100. The mean difference is 2.2500. The group B, itching mean value for 1st week 2.50, 8th week 0.30. The mean difference is 2.200. Mean difference for itching group A greater than group B.

The group A condition of discharge mean value for 1st week 2.65, 8th week 1.00. The mean difference is 1.6500. The group B condition of discharge mean value for 1st week 2.95, 8th week 1.20. The mean difference is 1.750. Mean difference for condition of discharge, group B greater than group A.

The group A length of fistulous track mean value for 1st week 16.017, 8th week 3.286. The mean difference is 12.731. The group B length of track mean value for 1st week 24.951, 8th week 6.472. The mean difference is 18.478. Therefore mean difference for length of the fistulous track group B greater than group A.

Vitex nigundo, *Crativa adansoni, Ricinus communis and Plumbago indica* have been used for wound healing since time immemorial. Identified mechanisms behind these healing effects are its ability to accelerate re-epithelialization, improve antioxidant enzyme activity and stimulate higher collagen cross-linking within the tissue being repaired and action of pharmacodynamic properties, anti-inflammatory, analgesic, anti-oxidant muscles relaxant and anti-microbial properties which give wound healing.

New herbal formulation comprises only, *Vitex nigundo*, *Crativa adansoni, Ricinus communis and Plumbago indica. Vitex nigundo* has major chemical constituents of casticin, isoorientin, chrysophenol D, luteolin, fructose, sabinine, linalool, terpinen-4 ol and α-guainene. It improves skin quality, helps in quick healing, helps to relieve pain and inflammation, detoxifies skin and relieves itching and infested wounds. (Rai *et al*., 2008) *Crativa adansoni*bark yields ceryl alcohol, friedelin, lupeol, betulinic acid and diosgenin. It has anti-inflammatory, diuretic, lithontriptic, demulcent and tonic properties.(Nascimento *et al*., 2003)

Ricinus communis, the reported constituents should be presence of flavanoids, phytosterol, phenolic compounds, fatty acids, amino acids and terpenoids. The compounds have been reported to eshibit anti-conceptive, anti-diabetic, anti-inflammatory, anti-microbial, and anti-oxidant and wound healing activities.(Cowan *et al*., 1999).

Plumbago indica root contains plumbagine, sucrose, fructose and protease. It is antiseptic and anti-pyretic in nature. It also has antibacterial and anti-oxidant property.(Dev *et al*., 1996)

Early reduction of inflammatory cells indicates anti-inflammatory property of new herbal formation. Long time persistence of inflammatory cells microscopic abscess reduction showed cleansing and healing (*shodhana, ropana)* properties significant granulation tissue and occurrence of early collagen laying, vascular proliferation and fibroblastic proliferation, also proved *vrana ropana* property of above herbal drugs.

During administration of new herbal formulation, there is a continuous drainage of fistulous track and ingredients used in the thread help in healing. Therefore it helps to enhancing the drainage by giving support to the *kshara sutra*. It has been proved as the anti-bacterial, anti-fungal and anti-inflammatory action of the new herbal formulation.

The effects include (a) correction of the unhealthy tissues (b) Enhancement of the healthy granulation tissue formation (c) enhancement of fibrolysis (d) separation of debris through the fistulous track (e) removal of debris and cleansing wound.

In general all the ingredients of new herbal formulation were showed significance antibacterial activities. This indicates that potential use of the new herbal formulation as topical antibacterial agent against fistula in ano causing pathogens.

CONCLUSIONS

In the group A and group B mean difference of pain is same. Burning sensation, discharge and length of fistulous track mean differences are, group B greater than group A. Itching mean difference is, group A greater than group B. Therefore, both treatment modules are effective and statistically significant, But group B, treatment module is more effective than group a treatment module.

Finally, based on the observed results and the pharmaco dynamic properties of both treatment protocols, it may be concluded that new herbal formulation + *Kshara sutra* + Dietary management treatment module is more effective than *Tripala* decoction + *Kshara sutra* + Dietary management.

References

Samaranayake G.V.P., Chandimal K.M., Interactivity in Goodsalls' Rule and Fistula-in-ano, International Journal of Trend in Scientific Research and Development (IJTSRD), Volume 4, Issue 4, 1417-1418pp.

https://scholar.google.com/citations?user=H_OygxEAAAAJ&hl=en#d=gs_md_cita-d&u=%2Fcitations%3Fview_op%3Dview_citation%26hl%3Den%26user%3DH_OygxEAAAAJ%26citation_for_view%3DH_OygxEAAAAJ%3AhFOr9nPyWt4C%26tzom%3D-330

Pushpakumara A.A.J., Jayarathne D.L., Samaranayake G.V.P., Antibacterial Activity of Euphobia antiquorum latex, International Journal of Applied Pharmaceutical Science and Research, Volume 2, Issue 2, 15-17pp https://scholar.google.com/citations?user=H_OygxEAAAAJ&hl=en#d=gs_md_cita-d&u=%2Fcitations%3Fview_op%3Dview_citation%26hl%3Den%26user%3DH_OygxEAAAAJ%26cstart%3D20%26pagesize%3D80%26citation_for_view%3DH_OygxEAAAAJ%3AY0pCki6q_DkC%26tzom%3D-330

https://www.researchgate.net/publication/334250560_Antibacterial_Activity_of_different_extract_of_Curcuma_longa_in_the_management_of_Fistula_in_ano

https://www.researchgate.net/publication/334250735_Antibacterial_activity_of_Euphorbia_antiquoram_latex/references

How to cite this article:

G.V.P. Samaranayake, A.A.J. Pushpakumara and K.P.P. Peiris (2020) 'Comparative Study on Different Treatment Modules in the Management of Fistula-In-Ano (Bhagandara)', *International Journal of Current Advanced Research,* 09(06), pp. 22407-22411. DOI: http://dx.doi.org/10.24327/ijcar.2020. 22411.4417

****