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Research Article

EhretiaLaevisRoxb. for Fistula

Role of *EhretialaevisRoxb*.. (Ajan Vruksha/Khandu Chakka) Medicated Thread in Fistula- In- Ano: - Randomised Clinical Trial

Rushikesh Thakre[1], Kiran Khandare[2] and Ketaki Harne[3]

[1.] *Department of Samhita Siddhant, Mahatma Gandhi Ayurved College Hospital and Research Centre, DattaMeghe Institute of Higher Education and Research (DU) Wardha(MS) India.*

[2.] *Department of Shalya Mahatma Gandhi Ayurved College Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research (DU) Wardha(MS) India*

[3.]*Rastra Santa TukadojiMaharaj Nagpur University Nagpur (MS). India*

Abstract: *Ehretialaevisroxb*. is a traditional herbal plant used for various purposes, mainly wound healing and pain relief. This plant is also known as AjanVruksha and commercially known as Khandu Chakk. Wound healing & pain relief activities of *Ehretialaevisroxb*. (AjanVruksha/Khandu Chakka) are used for making a novel herbal medicated thread in fistula- in- ano to avoid the untoward effects of traditional *Ksharsutra,* commonly used in Ayurved practice for Fistula-in ano management. Fistula in ano is the abnormal tract having one opening inside the anal canal and one opening at the perianal skin. Many modalities are available for the treatment of fistula in ano, like *Ksharsutra*, fistulotomy, fibrin glue injection, and fistula plug. Sometimes there are many tracts. Novel herbal thread comprises *ehretialaevisroxb., Achyranthesaspera Linn., Ficusracemosa*. A novel herbal thread was applied in group A of 75 patients and in group B of 75 patients, a conventional thread was applied. The study is based on a superior clinical trial. To determine the efficacy of the composition of the present invention, the clinical parameters of pain, bleeding, discharge, itching, tenderness, hyper granulation, and unit cutting time were evaluated after every week. The novel thread was found more efficient in pain relief, discharge, etching, cutting rate, bleeding, and hyper granulation, than a conventional thread in this study. We aim to provide a medicated thread for fistula-in- ano, which can overcome deficiencies associated with the known arts and provide effective and safe treatment for affected patients. And to achieve this aim, our objectives are to assess the efficacy of Novel Medicated thread and Conventional Ksharsutra in promoting healing in fistula- in-ano, along with comparing the efficacy of both threads.

Key words: Fistula-in ano., KhanduChakka, AjanVruksha, Ksharsutra, CharmaVruksha, Bhagandar

***Corresponding Author**

Rushikesh Thakre , Department of Samhita Siddhant, Mahatma Gandhi Ayurved College Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research (DU) Wardha(MS) India.

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1. INTRODUCTION

Ehretialaevisroxb. is a traditional herbal plant used for various purposes, mainly wound healing and pain relief. This plant is also known as AjanVruksha and commercially known as KhanduChakka. Its wound healing and pain relief activities are used for making a novel herbal medicated thread in fistula-in- ano management to avoid the untoward effects of traditional *Ksharsutra*, commonly used in Ayurved practice management of Fistula-in ano management—*ehretialaevisroxb*. Plants contain many useful chemical compounds useful for healing and pain relief. Fistula in ano is the abnormal tract having one opening inside the anal canal and one opening at the perianal skin. Sometimes there are many tracts. In this study, leaves are used. The plant has various sizes of leaves, like 2 to 6.3 cm X 1.3 cm to 3.8 cm, and has small white flowers. [1] There are many modalities available for the treatment of fistula in ano, like *Ksharsutra*, fistulotomy, fibrin glue injection, and fistula plug. A seton is a draining wire placed in a fistula channel or tract whose ends are then mutually connected after one of the ends is cut to length so that the draining wire assumes a 30 form of a closed loop. The draining wire in the fistula channel ensures that the fistula channel remains open so that the risk of inflammation is reduced and healing is promoted.Some suitable materials for manufacturing setons include suture wire, rubber, and medicinal wire. Furthermore, in the Ayurveda field of medicine, a minimally invasive treatment method known as Kshara sutra is used to manage anorectal disorders. Fistula-in- ano is also the secondary complication of many diseases like STD, carcinoma, TB, inflammatory bowel diseases, Crohn's disease, and radiation. It is characterized by pain and swelling around the anus. Current modalities have some untoward effects and dependency on particular herbal drugs, which causes effects on biodiversity. Hence there is always a need for alternative treatments which has fewer side effects and are cost-effective. Hence novel herbal thread is made up of*Ehretialaevisroxb., AchyranthesAspera Linn., ficusracemosa*to reduce pain and healing of fistula tract. This novel thread can be used for other fistulas in the body whenever possible. Furthermore, very high dependency on a selected few herbal components traditionally known in the management of such therapeutic indications places a huge economic burden on the individual and health administrators, promotes random depletion of herbal resources, and triggers an unsustainable impact on biodiversity which on the whole impacts the society.However, the conventional methods existent and used in the art currently are either expensive or involve invasive procedures, or provide discomfort to the patient in the form of irritations or a combination of all of them. Anti-microbial, anti-inflammatory, anthelmintic, anti-carcinogenic, blood clotting, wound healing, and pain relief properties of *Ehretialaevisroxb*. are used in this formation. In this trial, first-time *Ehretialaevisroxb.* is used in Ksharsutra in Fistula-in ano.Thus, there is a need for providing a simpler, smoother medicated thread that is easier to apply, which does not cause any discomfort due to its presence or movement, is easily cleaned, and is effective, safe, economical, and sustainable for the management of Fistula- in-ano. Preferably there is a need in the art for a herbal composition that can be used for preparing setons that are effective, safe, less expensive, involve less invasive procedures, and overcome the shortcomings in the art. The main aim of this study is to compare the efficacy of New Medicated Ksharsutra with Conventional Ksharsutra in Fistula- in- Ano.

2. MATERIALS&METHODS

2.1. Steps involved in the selection of the plant.

Ehretialaevisroxb. Plant and leaves were authenticated by S.Noorunnisa Begum, Associate Professor, the foundation for revitalizing local health traditions. Voucher no. FRLH Col. No. 122021

2.2. *Preparation of Novel Medicated Thread*

Ehretialaevisroxb's leaves were collected from the forest, washed with distilled water, and cleaned with absolute alcohol. The leaves were then rinsed with distilled water three times and crushed in an autoclaved mortar and pestle at 25°C to 35°C temperature along with adding water. The crude extract was filtered and collected using a sterile cloth mesh and the aqueous extract was stored in a sterile bottle with all aseptic precautions for use.10 ml of *ficusracemosa*milky latex was collected from the bark of the tree by lateral cutting. The latex was filtered for impurities and stored in a sterile bottle. The process for preparing the alkaline extracts was followed as provided in Sushruta Samhita Sutra Sthana 11/11, Rasa Tarangini 14/64, AFI, Vol. 1 (2019). A 20-zero Barber's surgical linen non-absorbable thread having a diameter size of 3 mm and length of 50 cm was taken. The wire was applied with 10 to 12 coatings of crude 20 extracts of leaves of *ehretialaevisroxb.* as prepared above, by placing the surgical linen thread on a sterile cloth and manually applying the coatings on the thread and allowing for the uniform spreading of the herbal extract. It was followed by 6 to 8 coatings of milky latex of *Ficusracemosa* and 2 to 4 coatings of an alkaline solution of *Achyranthesaspera* prepared above. Between each coating, the thread was allowed to dry completely under aseptic conditions; in group A, 75 patients having Fistula-in-ano were randomly selected from the hospital and treated with medicated thread for one month. In group B, 75 patients were treated with classical *Ksharsutra* made of surgical linen thread of size 20, the latex of *Euphorbia nerifolia, Haridra (Curcuma longa), apamargakshar (Achyranthusaspera).*

2.3. Inclusion criteria

Patients are willing with consent, those with fistula-in –ano, and those irrespective of sex, occupation, and economic status are included.

2.4. Exclusion criteria

H/O anorectal surgery, infected fistula, pregnancy, metabolic diseases, systemic chronic devaluating diseases, immunocompromised patients.

2.5. Ethical Statement

The study is approved by the institutional ethical committee of MGACH & RC (DMIMS(DU) Wardha(MS) India. Ref.no. MGACHRC/IEC/August-2020/104 and registered in CTRI with no. CTRI/2020/10/028559. The study is conducted as per the declaration of Helsinki's ethical principles. To determine the efficacy of the composition of the present invention, the clinical parameters of pain, bleeding, discharge, itching, tenderness, hyper granulation, and unit cutting time were evaluated after every week.

3. STATISTICAL ANALYSIS

The data is analyzed by SPSS27.0 version software. All data related to mentioned parameters are analyzed by Mann Whitney U Test, Student's unpaired t-Test, and Chi-square Test. The data are presented as mean and standard along with frequency and percentage. Statistical significance is considered as a p-value less than 0.05.

4. RESULTS AND DISCUSSION

Table1: Comparison of pain in two groups on day 0, day 7, day 14, day 21, and day 28 Mann Whitney U Test

Day	Conventional Thread	Novel Thread	z-value	p-value
Day 0	3.17±0.81	3.09±0.61	0.96	0.33, NS
Day 7	2.78±1.00	2.25±0.71	3.55	0.0001, S
Day 14	2.09±1.10	1.49±0.79	3.41	0.001, S
Day 21	1.78±1.04	0.70±0.69	6.21	0.0001, S
Day 28	0.93±0.90	0.06±0.25	6.70	0.0001, S

Showed significant pain relief by a novel herbal thread in fistula- in –ano. NS: - Non significant S: - Significant. *Ehretialaevisroxb.* is known for pain relief activity and is mainly used in novel medicated thread, as in fistula-in-ano, there is severe pain. Its pain relief activity was found to be very effective in this case. In the next follow-up, after one week of application of the novel medicated thread, the P value is less than 0.05 and significant continuously until the last follow-up. The pain was reduced significantly compared to the conventional thread until the last follow-up in the study. Patients got relief in pain significantly by using novel thread, and hence modern painkillers could be avoided with their side effects. Hence novel thread was more efficient in pain relief than a conventional thread in this study.*Ehretialaevisroxb*. contains chemical compounds like Naphthoquinone derivative, Baurenol, ursolic acid, Rutin, Phytol, α and βamyrin, Betulin&Betulinic acid, Lupeol, β-sitosterol, Histidine, Hexadecanoic acid, Benzoic acid, Arachidonic acid show analgesic, antinociceptive and anti-inflammatory activities.[2]This plant is clinically tested on shoulder pain management [3]. *Ehretialaevisroxb*. Pain relief activity is also proven in animal models [4-5]. Pain relief activity may be due to the synergetic effects of combined herbal drugs used in a novel thread.

Table 2: Comparison of Discharge Scores in two groups on day 0, day 7, day 14, day 21, and day 28 Mann Whitney U Test

Day	Conventional Thread	Novel Thread	z-value	p-value
Day 0	1.61±1.35	1.68±1.14	0.51	0.60, NS
Day 7	1.28±1.33	1.18±1.12	0.86	0.86, NS
Day 14	0.93±1.14	0.77±0.92	0.56	0.56, NS
Day 21	0.81±1.04	0.45±0.74	2.01	0.044, S
Day 28	0.40±0.63	0.17±0.47	2.67	0.008, S

Showed a significant reduction of discharge in the group of novel threads after 21 days. Discharge may be due to infection or extra secretions from anal glands. In the first fourteen days, P values are more than 0.05; hence insignificant. But after fourteen days, on the 21st day P value is 0.04, and on the 28th day P value is 0.008. Both findings were significant. After fourteen days, discharge was significantly reduced in the group of novel threads. *Ehretialaevisroxb.* has antimicrobial activity.[6-8]. This anti-microbial activity may be responsible for reducing local infection, discharge, and irritations. The main reason for the formation of fistula-in-ano is the infection of anal glands. Hence using this novel thread made up of *Ehretialaevisroxb*. A further manifestation of diseases may be avoided. In *Ayurveda, Ehretialaevisroxb* is known as *CharmaVruksha*, and its *rasa* is *Kashay* means astringent and*Katu* means pungent, and its *Virya* is *Ushna* means, its potency is hot. [9]. According to the ancient Indian system of medicine, i.e., Ayurveda, astringent taste and hot potency are responsible for reducing discharges. When there is discharge, there is the involvement of *Kaphadosha*. Astringent and pungent taste and hot potency of *Ehertialaevisroxb*. ar responsible for the reduction of *Kaphadosha* according ayurveda[10]Hence basic principle of Ayurveda is also proven and validated in this case.

Table 3: Comparison of Itching Score in two groups on day 0, day 7, day 14, day 21, and day 28 Mann Whitney U Test

Day	Conventional Thread	Novel Thread	z-value	p-value
Day 0	0.84±0.93	0.97±1.09	0.49	0.62, NS
Day 7	0.62±0.83	0.58±0.95	0.94	0.34, NS
Day 14	0.33±0.64	0.34±0.72	0.24	0.80, NS
Day 21	0.24±0.51	0.24±0.63	0.69	0.48, NS
Day 28	0±0	0.12±0.40	2.70	0.007, S

Showed a significant reduction of itching in the group of novel threads after 21 days. Etching is due to discharge and infection. P values are not significant till 21 days, but after 21 days, on the 28th day, the P value is significant. After 21 days, there was a

significant reduction in itching in a novel thread group. After the reduction of infection and discharge in the novel thread group, etching was reduced significantly. Patients were feeling comfortable due to the relief of discharge and etching.

Table 4: Comparison of Tenderness Grading Scale Score in two groups on day 0, day 7, day 14, day 21, and day 28 Mann Whitney U Test

Day	Conventional Thread	Novel Thread	z-value	p-value
Day 0	0.88±1.05	1.38±1.14	2.89	0.004, S
Day 7	0.65±0.87	0.78±0.91	0.93	0.35, NS
Day 14	0.41±0.71	0.50±0.72	0.93	0.34, NS
Day 21	0.36±0.70	0.21±0.47	1.10	0.26, NS
Day 28	0.09±0.37	0.05±0.27	0.72	0.46, NS

There was no significant observation related to tenderness. Also, it was absent in many cases in both groups.

Table 5: Comparison of Cutting Rate per day in two groups on day 7, day 14, day 21, and day 28 Student's unpaired t Test

Day	Conventional Thread	Novel Thread	z-value	p-value
Day 7	0.031±0.02	0.050±0.03	3.92	0.0001, S
Day 14	0.034±0.01	0.052±0.03	4.15	0.0001, S
Day 21	0.033±0.01	0.054±0.03	4.77	0.0001, S
Day 28	0.038±0.01	0.064±0.02	7.41	0.0001, S

P value is less than 0.05 and significant. There is a significant finding in cutting rate by a novel thread throughout the study. Cutting rate involves cutting and healing the fistula tractmainly alkali present in both thread groups do the function of cutting. *Ehretialaevisroxb*., present in the novel thread, has a great wound-healing characteristic. [11-15] This efficacy of *Ehretialaevisroxb*. It is mainly used in the novel thread for healing purposes. According to Ayurveda the *Rasa* of this plant is *Katu*(Pungent) and *Kashay*a (Astringent) and *Virya* is *Ushna* (Hot). *Katui*.e pungent taste removes slough from the wound and promotes healing. Also, a pungent taste promotes blood circulation, promoting healing. *Kashay rasa* also helps for healing purposes.

Table 6: Comparison of Bleeding in two groups on day 0, day 7, day 14, day 21, and day 28 Chi-square Test

Day	Conventional Thread	Novel Thread	X^2-value	p-value
Day 0	51(68%)	49(65.33%)	0.12	0.73, NS
Day 7	44(58.67%)	33(44%)	3.22	0.072, NS
Day 14	36(48%)	13(17.33%)	16.03	0.0001, S
Day 21	28(37.33%)	1(1.33%)	31.16	0.0001, S
Day 28	19(25.33%)	1(1.33%)	18.69	0.0001, S

Showed significant reduction of bleeding by a novel herbal thread in fistula- in –ano.The p-value is not significant for 7 days. But on 14 days, a P value is significant. After 7 days, the bleeding stopped significantly in a novel thread group. *Ehretialaevisroxb.* has blood coagulation property[16]. And due to this property, there was a significant reduction in bleeding in a novel thread group. Also, its *Kashay rasa,* i.e., astringent taste, mainly acts to stop bleeding, and hence *Ehretialaevisroxb.* is very effective to stop bleeding.

Table 7: Comparison of Hyper Granulation in two groups on day 0, day 7, day 14, day 21, and day 28 Chi-square Test

Day	Conventional Thread	Novel Thread	X^2-value	p-value
Day 0	44(58.67%)	50(66.67%)	1.02	0.31, NS
Day 7	42(56%)	35(46.67%)	1.30	0.25, NS
Day 14	46(61.33%)	17(22.67%)	23.01	0.0001, S
Day 21	32(42.67%)	7(9.33%)	21.65	0.0001, S
Day 28	32(42.67%)	7(9.33%)	21.65	0.0001, S

Showed significant reduction of Hyper Granulation by novel herbal thread in fistula- inano from 14 days. P value is less than 0.05 on the 14th day. Hence after 14 days, there is significant noting in granulation. And no hyper granulation was present in a novel thread group. The present novel thread comprises *ehretialaevisroxb.* extract with the milky latex of *ficusracemosa*and alkaline extract solution of *achyranthesaspera Linn*. In this combination, *Snuhi latex* (*euphorbia nerifolia*) and *HaridraChurna* (Curcuma longum) were not used, and hence side effects of it were avoided. Snuhi (*eforbianerrifolia*) has cutting quality, and *Haridra*(*Curcuma longa*) has antiseptic quality. But novel herbal thread found effective. Kashay Rasa (Astringent taste) is responsible for Ropan Karma (healing) and the *ehretialaevisroxb.* has astringent taste. This study will be useful in broadening the CharmaVruksha plant's therapeutic aspect.

It will contribute to the literature related to ayurvedic sciences. Another Ksharsutra like, *Guggulu*-based *Ksharasutra* alsofound effectivein fistula in ano. (Meena RK et al. 2018.).[17]SaxenaVarsha and Singh Lakshman 2018 explained the effectiveness of *Snuhi* (*Euphorbia neriifolia*), *Guggulu*(*Commiphoramukul)*, and *Udumber* (Ficusracemosa) *Kshara Sutras* in Hemorrhoids.[18] Lobo SJ et al. 2018 explained the effects *SnuhiKsheera Sutra*, *TilanalaKsharaSutra, and ApamargaKshara Sutra* effects in fistula in ano. They found *TilanalaKshara* Sutramore effective in cutting rate.[19]Kumar PH and Sahu M2000 explained the role of *AragvadhadiSutra*consists of *Aragvadha* (*Cassia fistula*), *Haridra* (*Curcuma longa*), *Agaru*(*Aquilariaagalocha*), *Madhu* (Honey) and *Ghrita* (Ghee) in fistula in ano and found effective and comfortable.[20]Rao SD 1998 explained the effectiveness of *kshara sutra* made from papaya and snuhi latex in fistula in ano and found comfortable.[21]Gond P et al. 2013 found *GugguluChitrakaKshar Sutra* more effective than *SnuhiApamarga KsharSutra*.[22]Kalal L et al. 2018 found*VibhitakiKshara* more comfortable than *ApamargaKsharaSutra* and has a long cutting time.[23]Patel A, Salimath M. A 2019 found *TankanaKsharasutra* more comfortable than *ApamargaKshara Sutra* and has long cutting time.[24]Chetana et al 2020 mentioned various useful chemical compounds and traditional medicinal uses.[25]

5. CONCLUSION

It was observed that the patients in the Novel herbal thread fared better than the patients in the conventional thread when evaluated for the listed parameters above.The present research provided a medicated thread for fistula-in- ano, which can overcome deficiencies associated with the known arts and provide effective and safe treatment for affected patients.Furthermore, the present research provides a medicated thread that is simple, smooth, and easy to handle.Furthermore, the medicated thread of the present invention was found to act synergistically compared to the medicated thread comprising the individual herbs alone.

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7. AUTHORS CONTRIBUTION STATEMENT

Dr. RushikeshThakre designed the whole study and was the principal investigator. Dr. Kiran Khandare was Co-investigator and did a clinical study. Ms. KetakiHarne was involved in the literature review and article drafting. All authors have undergone this draft article.

8. CONFLICT OF INTEREST

Conflict of interest declared none.

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