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STUDY ON MICROBIOLOGICAL STATUS OF FISTULA IN ANO TREATED BY KSHARASUTRA THERAPY AND AYURVEDIC COMPOUND

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Abstract: *Total number of 60 patients of Fistula in ano were randomly selected for the present study from the Ano rectal OPD and IPD of Sir Sunder Lal Hospital, Institute of Medical Sciences, Banaras Hindu University. 57 patients completed the treatment out of 60 and 3 patients left the treatment from each group (3 groups, A B & C) before completion of the therapy. The aims of the study was to study the microbiological status in cases of Fistula in Ano, to evaluate therapeutic efficacy of selected Ayurvedic compound in eradicating the microbial load in fistula-in-ano and to compare the efficacy of Ayurvedic compound with standard antibiotic therapy. The treatment schedule was Group A-Ksharasutra along with oral administration of Ayurvedic compound (1g BD daily) for 4 weeks. Group B- Ksharasutra therapy and standard Antibiotic therapy. Group C-Ksharasutra therapy only. All the cases were followed up at the interval of 1 week for changing of Ksharasutra and cleaning and dressing of the wound. At the end of 4 weeks, swab culture for culture & sensitivity test was taken from the discharge from fistulous wound. On the basis of observations and the results of this present study it can be concluded that effect of the trial therapy is efficacious in alleviating the symptoms like pain, tenderness etc. and it has the effect of anti-inflammatory, antiseptic and immunomodulatory activities.*

Keywords: *Ayurveda, Fistula In Ano, Kshara sutra, Ayurvedic compound*

Introduction: Good health is the first and foremost right of a human. Ayurveda[1], considered as the fifth Veda [2] itself, gives equal importance to mitigation of diseases along with preservation of good health. It throws light on a right conduct of living so that the diseases can be prevented as well as treated. Among various diseases described, [3] there are eight diseases which have been named as Maharogas or Mahagadas, means the diseases which are difficult to cure and Bhagandara is one of them. Sushruta[4] (500BC), the father of Indian Surgery, has given a detailed description of this disease in his treatise, Sushruta Samhita.

Bhagandara [5] can be considered as a sinus or fistula, which has got external opening (s), an from anus to genitalia and cause tear or destruction of the involved region [6]. Sushruta has also pointed out that the swelling if in un suppurated stage, is called Bhagandara pidaka and when it bursts open, it is called as Bhagandara. It clearly mentions an inflammatory process in the perianal region which undergoes suppuration followed by bursting open in the form of a chronic discharging sinus which may be deep rooted and involve whole of the perineum and the structures around the anus such as rectum, bladder, genital region etc. Such features are similar to the condition known as fistula in ano as described in modern literature. Therefore, Bhagandara is correlated with fistula in ano.

In Ayurveda, Sushruta [7] has advocated surgical procedure, Chedana or excision as the primary treatment for all types of fistula in ano but other para surgical options like Jalaukavcharana, Ksharakarma and Agnikarma etc. has also been proposed according to the type of fistula and patient compliance. Ksharasutra therapy [8] is one such parasurgical measure described in Ayurveda for treating sinus and fistulizing diseases and it has been widely

accepted for the management of fistula in ano with high success rate and low incidence of complications like incontinence. However, the role of Guggulu ksharasutra therapy has not been evaluated so far in mitigating the microbial afflictions of fistulizing infections of anal glands.

Although it has been postulated in earlier thesis works that bacterial infections are common during Ksharasutra therapy [9] but they do not affect the cutting and healing of fistulous tract, it may not be wrong to state that the systemic use of drugs possessing Shodhana and Ropana activities as well as anti inflammatory and antimicrobial properties can reduce the microbial load and promote healing of fistulous tract while using with ksharasutra therapy with least side effects. Therefore, traditionally practised ayurvedic compound has used here in eradicating the microbial load in fistula tract. Keeping the above objective in mind, the present study entitled to study the microbiological status in cases of Fistula in Ano, to evaluate therapeutic efficacy of selected Ayurvedic compound in eradicating the microbial load in fistula-in-ano & to compare the efficacy of Ayurvedic compound with standard antibiotic therapy.

Method

Plan of Study

Patients	Treatment	Follow up
Group – A	Ksharasutra along with oral administration of Ayurvedic compound (1g two times daily) starting from the day of Ksharasutra application	4 weeks.
Group -B	Ksharasutra therapy and standard Antibiotic therapy. (A combination of Ofloxacin 200mg & Ornidazole 500mg BD daily for 10 days) starting from the day of Ksharasutra application	4 weeks.
Group – C	Patients were treated with Ksharasutra therapy only.	4 weeks.

Along with this, all patients were given following treatment for their bowel regulation and care of wound: Triphala guggulu 2 pills twice daily after meals., Isbagol powder 2 tsf with lukewarm water at night before going to sleep, Awagaha sweda / Sitz bath (in lukewarm water 5 minutes twice daily). All the cases were followed up at the interval of 1 week for changing of Ksharasutra and cleaning and dressing of the wound. At the end of 4 weeks, swab culture for culture & sensitivity test was taken from the discharge from fistulous wound. Patients were continued in follow up at 1 week interval till the complete lay opening of Fistulas track (cut through) and at 1 month interval afterwards till healing of wound.

Pus for Culture and Sensitivity Test: As mentioned earlier, pus from the external opening or the fistulous wound was taken for culture and sensitivity test at two occasions: before starting the therapy and at the end of 4 weeks of starting the therapy.

Inclusion Criteria: Patients with both low anal as well as high anal fistula who were willing to participate in the trial, were selected for the study irrespective of their, sex, occupation, socioeconomic status and chronicity.

Exclusion Criteria

1. Below 20 years & above 70 years of age
2. HIV positive status
3. Tuberculosis
4. Uncontrolled Diabetes Mellitus
5. Inflammatory bowel diseases (Crohn's disease, Ulcerative colitis)
6. Hb% less than 8 gm/dl
7. Patients suffering from Ano rectal Carcinoma.
8. Non willing patients.

Study Design: Total 60 patients fulfilling the inclusion criteria were selected for the study and were randomly divided into three groups, namely Group A, Group B, and Group C with 20 patients in each group. History was carefully taken and thorough clinical examination was done. Diagnosis was confirmed on the basis Digital Rectal Examination as well as radiological investigations like X-ray fistulogram, Magnetic Resonance (MR) fistulogram, Trans Rectal Ultrasonography (TRUS) etc.

Preparation of the Drug: A compound oral formulation contains following drugs which had taken equal quantity to prepare the powder form as choorna of the drug [10].

- Shatavari (*Asparagus Racemosa*)
- Yastimadu (*Glycyrrhiza Globra)*
- Gokshura *(Tribulus Terrestris)*
- Guduchi *(Tinospora Cardifolia)*
- Nimba (*Azadirachta indica*)

Preparation of Guggulu-Apamarga-Haridra Ksharsutra (GKS) [11]

Material Required

- Pure Guggulu (*Commiphora mukul*) dissolved in 70% ethyl alcohol semi solid media.
- Apamarga (*Achyranthus aspera)* kshar
- Fine powder of Haridra (*Curcuma longa*)
- Barbour's surgical linen thread No.20
- Hangers for tying the threads for uniform coating
- Ksharsutra cabinet for drying

Process of Preparation: The Barbour's surgical linen thread no. 20 is tied on a specially designed hanger. Freshly collected latex of Guggulu is soaked in gauze piece and smeared over the thread. Once the thread is soaked with latex, the hanger is placed in a drying cabinet at a temperature of 40°C for a period of 6 hours. The process is repeatedly done for 11 times to achieve desire quantity of latex to adhere on the thread. The above thread is again smeared with latex and passed through fine powder of anhydrous Apamarga kshar spread in a fine uniform layer and allow to dry in a cabinet. The process is repeated for 7 times. Similarly the above thread is smeared with Guggulu latex and passed through the fine powder of Haridra (*Curcuma longa).* The procedure is done for 3 times. Thus total number of coating is done for 21 times. After final coating and drying, the threads are cut from the corners of hanger, sterilized, and finally sealed in glass tubes.

Ofloxacin and Ornidazole: Standard Antibiotic therapy. (A combination of Ofloxacin 200mg & Ornidazole 500mg capsule two times daily for 10 days.

Clinical Assessment

The overall improvement in symptoms at the end of treatment

Symptoms	Group A	Group B	Group C
Pain	83.33%	92.30%	64%
Tenderness	83.33%	93.33%	50%
Pus discharge	76%	73.64%	70%

The Effect of Treatment on Pain: The effect of treatment was assessed on the basis of different parameters i.e. severity of pain in perianal area, tenderness, amount of pus formation, total leukocyte count, neutrophil count in DLC and the results of pus culture test.

Table-1

Group	Grade	No and % of cases BT	No and % of cases AT	Within the group comparison Wilcoxon Signed Rank test
Group-A	0	1 5.3%	14 73.7%	Z = 3.602 p < 0.001
	1	9 47.4%	5 26.3%	
	2	6 31.6%	0 0%	
	3	3 15.8%	0 0%	
Group-B	0	0 0	17 89.5%	Z = 3.874 p < 0.001
	1	12 63.2%	2 10.5%	
	2	7 36.8%	0 0%	
	3	0 0%	0 0%	
Group-C	0	0 0%	10 52.6%	Z = 3.557 p < 0.001
	1	14 73.7%	9 47.4%	
	2	4 21.1%	0 0%	
	3	1 5.3%	0 0%	
Between the group Comparison Chi-square test		χ^2= 7.409 P = 0.285	χ^2 = 6.43 P = 0.040	

P = 0.000 ⟶ p < 0.001 *(BT – Before Treatment, AT- After Treatment)*

Effect of Treatment on Degree of Tenderness: Table 02 shows the same pattern of improvement in tenderness in the subjects as that in the symptom of pain. In group A, 84.2% patients had mild to moderate degree of tenderness before therapy but after therapy, same no. of patients were completely relieved

Table-2

Group	Grade	No and % of cases BT	No and % of cases AT	Within the group comparison Wilcoxon Signed Rank test
Group-A	0	3 15.8%	16 84.2%	Z = 3.638 p < 0.001
	1	14 73.7%	3 15.8%	
	2	2 10.5%	0 0%	

	3	0 0%	0 0%	
Group-B	0	5 26.3%	18 94.7%	Z = 3.300 p = 0.001
	1	13 68.4%	1 5.3%	
	2	1 5.3%	0 0%	
	3	0 0%	0 0%	
Group-C	0	6 31.6%	11 61.1%	Z = 2.333 p = 0.020
	1	12 63.2%	7 38.9%	
	2	1 5.3%	0 0%	
	3	0 0%	0 0%	
Between the group Comparison Chi-square test		$\chi^2 = 1.654$ P = 0.799	$\chi^2 = 6.892$ P = 0.032	

P = 0.000 ⟶ p < 0.001 (BT – Before Treatment, AT- After Treatment)

Effect of Treatment on Amount of Pus Discharge: Table 03 shows the improvement in amount of pus discharge in subjects from initial level to the end of therapy, however mild serous discharge persisted in each group in 31.6%, 26.3% and 31.6% patients respectively due to open raw wound after cut through. The improvement in each group was comparable and very highly significant statistically also but the difference in between the groups was not significant on statistical terms.

Table 03

Group	Grade	No and % of cases		Within the group comparison Wilcoxon Signed Rank test
		BT	AT	
Group-A	0	1 5.3%	13 68.4%	Z = 3.576 p < 0.001
	1	13 68.4%	6 31.6%	
	2	3 15.8%	0 0%	
	3	2 10.5%	0 0%	
Group-B	0	0 0%	14 73.7%	Z = 3.742 p < 0.001
	1	19 100%	5 26.3%	
	2	0 0%	0 0%	
	3	0 0%	0 0%	
Group-C	0	0 0%	13 68.4%	Z = 3.742 p < 0.001
	1	18 94.7%	6 31.6%	
	2	1 5.3%	0 0%	
	3	0 0%	0 0%	
Between the group Comparison Chi-square test		$\chi^2 = 10.740$ P = 0.097	$\chi^2 = 0.168$ P = 0.920	

P = 0.000 ⟶ p < 0.001 (BT – Before Treatment, AT- After Treatment)

Effect of Treatment on Microbial Status of Fistula in Ano: In this study, only single organisms were cultured in all cases. No case of mixed infection was noted. Gram negative organisms were more prominent in the pus culture of patients. Escherichia coli were the most common organism (38.3%) isolated from 57 pus culture samples followed by Enterococcus faecalis in 18.3% cases. Proteus vulgaris was next common in Group C followed by Staphylococcus, Citrobacter and Streptococcal species. However in Group A, Staphylococcus and Citrobacter were more commonly found organism followed by Streptococci and Proteus while in Group B, Staphylococcus, Streptococcus and Proteus species were found in 10.5% cases each.

At the end of therapy, there was significant reduction in microbial growth in fistulous track. In Group B, 89.5% samples were sterile on culture followed by 52.7% in case of Group A. But in Group C, only 10.5% cases produced a sterile culture at the end of therapy. In Goup B, after antibiotic therapy, Proteus, Staphylococcus, Streptococcus, and Citrobacter positive cultures became completely sterile and a significant improvement was noted in E. coli and Enterococcal positive cultures. In Group A, study supported a fair antimicrobial activity of the trial drug on E coli and Enterococcal species mainly. Results for other species were not that much significant.

Micro Organism	Group A		Group B		Group C	
	BT	AT	BT	AT	BT	AT
	No %	No %	No %	No %	No %	No %
Escherichia Coli	8 42.1%	3 15.8%	9 47.3%	1 5.3%	7 36.8%	6 31.6%
Enterococcus faecalis	4 21.1%	1 5.3%	3 15.8%	1 5.3%	4 21.1%	3 15.8%
Proteus vulgaris	1 5.3%	1 5.3%	2 10.5%	0 0%	4 21.1%	4 21.1%
Citrobacter	2 10.5%	1 5.3%	1 5.3%	0 0%	1 5.3%	1 5.3%
Staphylococcus	3 15.8%	2 10.5%	2 10.5%	0 0%	2 10.5%	2 10.5%
Streptococci	1 5.3%	1 5.3%	2 10.5%	0 0%	1 5.3%	1 5.3%
Absent		10 52.7%		17 89.5%		2 10.5%
Total	19	19	19	19	19	19

Table 04

Probable Mode of Action of Trial Drugs: In this study, Guggulu-Apamarga-Haridra Ksharasutra has been used. Apamarga [12] is the most preferred plant for obtaining Kshara due to its easy and wider availability and high yield of Kshara. Guggulu and Haridra are known for their antiseptic, anti-inflammatory and wound healing properties. In addition, Guggulu has a strong binding property. According to Ayurvedic principles of management of wound [13], the treatment should aim at *Shodhana* and *Ropana* of the sinus track. Therefore, following five drugs were chosen to be used as a compound oral formulation which are attributed with *shodhana* and *ropana* properties.

All of these drugs are of Tikta [14], Kashaya, Madhura rasa and Sheeta veerya. Tikta rasa is said to possess the properties of lekhana and it causes drying up of Kapha and Puya from the wound, thus helping in Vrana Shodhana. Kashaya rasa, is vrana shodhaka, vrana ropaka, kleda shoshsaka and has astringent properties and so is considered to be good for healing of wounds. Madhura rasa has anabolic activity in body and so it fastens the healing activity in wounds. Moreover, the drugs used in this combination are also known to possess properties that are helpful in promoting the healing of wounds. For example, Nimba [14] is known for its antimicrobial, anti-inflammatory, antiseptic activities whereas Guduchi has been proved to be an excellent immunopotentiating and antioxidant drug. Mulethi has been shown to possess anti inflammatory effect comparable to hydrocortisone and oxyphenabutazone. Other two drugs are also known to possess the anti inflammatory and wound healing properties.

To compare the efficacy of the research drug, standard antibiotic treatment comprising a combination of ofloxacin 200mg with ornidazole 500mg was chosen as control in bid dose for 10days. Ofloxacin [15] is a fluoroquinolone antibiotic which possess broad spectrum activity against various aerobic Gram +ve and Gram –ve bacteria like Streptococci, Staphylococci, E. Coli, Citrobacter, Enterobacter, Proteus, Klebsiella etc. species. Ornidazole is a member of imidazole group of drugs possessing activities against the anaerobic infections. The drug combination is mostly recommended for GI tract infections as broad spectrum coverage for a period of 5-10 days depending upon the severity of infection. In this study also, most of the bacteria isolated in the culture test were same as mentioned above and the therapy was given for a period of 10days.

Conclusion: Gut derived microorganisms like E. coli, Enterobacter etc. are more prevalent in causing infection of anal glands which may lead to fistula in ano. Most of them are Gram negative

aerobes. Ofloxacin–Ornidazole combination therapy has remarkable efficacy against the microorganisms causing pathogenic infections in anorectal region.

The compound Ayurvedic drug formulation used in the study is efficacious in alleviating the symptoms like pain, tenderness etc. because of the anti-inflammatory, antiseptic and immunomodulatory activities of the constituent drugs like Nimba, Guduchi, Mulethi etc. A fair decrease in microbial positive cultures after using the compound Ayurvedic drug formulation in addition to Ksharasutra therapy is encouraging and further researches with big sampling in this direction are needed.

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