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Comparative study of Kshara sutra therapy, Kshara sutra therapy with Ayurvedic compound and Kshara sutra therapy with modern medicine in treatment of fistula in ANO

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Abstract

Introduction: In Ayurveda eight *Maharogas*, (the diseases which are difficult to cure) are described and *Bhagandara* is one of them. *Bhagandara* can be considered as sinus or fistula which has got external opening, an internal opening in the ano. In Ayurveda, *Kshara sutra* is one parasurgical measure described for treating sinus and it has been widely accepted for the management of fistula in ano with high success rate.

Material & Methods: A total 60 patients of Fistula in Ano were randomly selected, fulfilling the inclusion criteria. Total numbers of cases were randomly divided into three groups. Assessment was done on clinical improvement and improvement on growth of microorganism in the culture media.

Result: All the groups presented with similar improvement in decrease in amount of discharge at the end of therapy, however the degree of improvement was more marked in cases of Group A. Total leucocyte and neutrophil counts obtained at the end of therapy showed a highly significant and remarkable decrease in Group A and B.

Discussion & Conclusion: Decrease in the neutrophil and leucocyte count was comparable in Group A and Group B. E-coli was the most prominent organism responsible for infection in Fistula in ano. Group B revealed approx. 90% of the samples to be sterile at the end of the therapy while Group A revealed only 52% and only 10% were sterile in Group C, thus showing the marked efficacy of the antibiotic therapy as compared to that of Ayurvedic compound formulation used as a trial drug.

Keywords: *Bhagandara*, *Ksharasutra*, E-coli, ayurvedic compound

Introduction

Good health is the first and foremost right of a human. In Ayurveda eight *Maharogas* (means diseases which are difficult to cure) are described and *Bhadandara* is one of them [1]. *Bhagandara* can be considered as sinus or fistula which has got external opening, an internal opening in the ano or both. In Ayurveda *Kshara sutra* is one parasurgical measure described in Ayurveda for treating sinus and it has been widely accepted for the management of fistula in ano with high success rate. A number of studies in relation to fistula in ano have been conducted at the department of *Shalya tantra*, faculty of Ayurveda, IMS, BHU. It was Dr. P S Shankaran, Dept. of Shalya Shalakyas, IMS, BHU, who taking clue from the reference of *Chakradatta*, *Rasatarangini*, decided to give the *Kshara sutra* therapy a new life. He was first designed the *Snuhi Kshara sutra*, tried out this experimentally in animals and then on a small group of patients and found remarkable results. Later on Dr. P J Deshapandey, Dr. S N Pathak, Dr. K R Sharma and others, adopted this in large number of patients and established the treatment as an affective, ambulatory and safer alternative treatment for patients with fistula in ano [2]. Although it has been postulated in earlier studies that bacterial infections are common during *Kshara sutra* therapy 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 anti-microbial properties can reduce the microbial load and promote healing of fistulous tract while using with *Kshara sutra* therapy with less side effect. So, the purpose of this study is to explore a relation between microbiological status of Fistula in Ano treatment by *Kshara Sutra therapy* and *Ayurvedic Compound*.

Aims & Objectives

- 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.

Material and Methods

Selection of patients

A total 60 patients of Fistula in Ano were randomly selected for the study, from ARC OPD & IPD of Sir Sunder Lal Hospital, Institute of Medical Sciences, BHU, Varanasi.

Inclusion Criteria

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

Exclusion Criteria

Patients with following conditions were excluded from the study:

- Below 20 years and above 70 years.
- HIV positive patients
- Tuberculosis
- Uncontrolled Diabetes mellitus
- Inflammatory bowel diseases (Crohn's disease, Ulcerative colitis)
- Hb% less than 8gm/dl
- Patients suffering from Anorectal Carcinoma
- Non willing patients.

Study design

Total 60 patients fulfilling the inclusion criteria were selected for the study and were randomly divided into three groups

Group A: Patients were treated with *Guggulu Apamarga Haridra-Kshara sutra* therapy along with oral administration of Ayurvedic Compound (1 g BD daily) for 4 weeks starting from the day of *Kshara sutra* application.

Ayurvedic compound: it has been formulated with *Shodhan* and *Ropana* properties. It contains following five drugs-

- Shatavari (*Asparagus racemosus*)
- Yashtimadhu (*Glycyrrhiza glabra*)
- Gokshura (*Tribulus terrestris*)
- Guduchi (*Tinospora cordifolia*)
- Nimba (*Azadirachta indica*)

Group B: Patients were treated with *Guggulu Apamarga Haridra-Kshara sutra* therapy and standard Antibiotic therapy (A combination of Ofloxacin 200mg & Ornidazole 500mg daily for 10 days) starting from the day of *Kshara sutra* application.

Group C: Patients were treated with *Guggulu Apamarga Haridra-Ksharasutra* therapy only.

Adjuvant Therapy

Along with this, all the patients were given following treatment for their bowel regulation and care of wound.

- Triphala guggulu 2 pills twice daily after meals.
- Isabgol powder 2 tsf with Luke warm water at night before going to sleep.
- Ushnodak avagaha*/Sitz bath (In Luke warm water 5 minutes twice daily).

All the cases were followed up at the interval of 1 week for changing of *Kshara sutra* and cleaning and dressing of the wound. Swab culture for culture & sensitivity test was taken

from the discharge of the fistulous wound at two occasions one before starting the therapy and other at the end of 4 weeks. The pus smear was sent to Department of Microbiology in the sterile container where culture and sensitivity test was carried out.

Patients were continued in follow up at 1 week interval till the complete lay opening of fistulous tract (cut through) and at 1 month interval afterwards till healing of wound.

Assessment Criteria

Assessment was done before and after treatment on the basis of effect of therapy on the growth of microorganism in the culture media after four weeks of the therapy along with total leucocytes and neutrophils count in addition to the following subjective parameters according to the following criteria:

S. No.		Pain	Tenderness	Discharge
1	0	No Pain	No Tenderness	No Discharge
2	1	Mild Pain	Mild Tenderness	Mild Discharge
3	2	Moderate Pain	Moderate Tenderness	Moderate Discharge
4	3	Severe Pain	Severe Tenderness	Severe Discharge

Statistical analysis of data: The data collected were analyzed using, paired T test to find out the significant difference within the groups. Chi square (X^2) test, unpaired t-test, ANOVA test was used to find out the significant changes between the different groups

Observations and results

In this study 60 patients of Fistula in Ano were treated in three groups of 20 patients in each. During the study period, one patient from each group dropped out of the study. So final results of the therapy were obtained for 19 patients in each group, i.e. for 57 patients in total.

At the end of therapy, results showed a highly significant improvement in pain and tenderness in each group, although maximum improvement was noticed in Group B where maximum control of infection was maximum due to targeted antibiotic therapy. In comparison to a complete relief in approx. 90% of patients in Group B, the selected Ayurvedic compound in Group A brought a complete relief in 73.7% cases. The difference was not much and comparable.

The entire group presented with similar improvement in decrease in amount of discharge at the end of therapy, however the degree of improvement was more marked in cases of Group A.

Total leucocyte and neutrophil counts obtained at the end of therapy showed a highly significant and remarkable decrease in Group A and B which clearly implies that the Ayurvedic compound showed similar efficacy on statistical scales as that of antibiotic therapy in mitigating the active inflammatory and suppurating phase. In Group C, bacteriological status remained almost unchanged even at the end of therapy. Pus culture studies from the fistulous wound revealed that the predominant organisms isolated from the samples in each group were gut derived gram negative bacteria like *E. coli*, *Enterobacter* etc. and gram positive species like *staphylococci* and *streptococci* were also found but in less number of cases.

Table 1: Showing 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%
Discharge	76%	73.64%	70%

Discussion

Every physician or surgeon always has zeal of providing the best treatment to his patients with minimum pain and discomfort. *Ksharsutra* is a kind of medicated thread which is prepared by smearing the drugs over thread (babour No 20) [3]. All the drugs taken in study are of *Tikta*, *Kasaya*, *Madhura* and *Sheeta virya*. *Tikta rasa* is said to possess the properties of *lekhana* and it causes drying up of *kapha* and *puya* from the wound, thus help in *vrana shodhana* [4]. According to Sushruta *Kashaya rasa* is *vrana shodhaka*, *vrana ropaka*, *kleda shoshaka* and its astringent properties and so it is very good for wound [5]. *Madhura rasa* has anabolic activity in the body and so it fastens the healing activities [6]. In total drug combination promotes wound healing.

Ofloxacin is a fluoroquinolone group antibiotic which possesses broad spectrum activity against gram positive and gram negative bacteria [7]. Ornidazole is a member of imidazole group of drugs possessing activities against the anaerobic infections. The drug combination is mostly recommended for gastrointestinal tract (GIT) infections.

The Ayurvedic compound showed a similar amount of relief in symptoms like pain, tenderness and amount of pus discharge as that treated with antibiotic therapy. Similarly the decrease in the neutrophil and leucocyte count was comparable in Group A and Group B. E-coli was the most prominent organism responsible for infection in Fistula in ano.

Group B revealed approx. 90% of the samples to be sterile at the end of the therapy while Group A revealed only 52% and only 10% were sterile for Group C, thus showing the marked efficacy of the antibiotic therapy as compared to that of Ayurvedic compound formulation used as a trial drug.

Summary & Conclusion

The *Kshara sutra* therapy has now been accepted worldwide for the successful treatment of fistula in ano and is regarded as simple, safe, economical, day care Para surgical measure with high success rates and low chances of incontinence.

The Ayurvedic drugs chosen for trial are of *Vrana Shodhana* and *Vrana Ropana*. Most of the drugs were *Tikta*, *Madhura* in *rasa* and *Sheet* in *veerya*, which are mostly attributable for wound cleansing and wound healing activities.

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Conflict of interest: None Declared

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