A CLINICO-COMAPARATIVE STUDY OF INGUDI KSHARASUTRA AND APAMARGA KSHARASUTRA IN THE MANAGEMENT OF BHAGANDARA W.S.R.TO PARISRAVI BHAGANDARA

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ABSTRACT:

Bhagandara (Fistula in Ano) at modern parlance is a common anorectal condition prevalent in the populations worldwide and its prevalence is second highest after Arsha (hemorrhoids). Ksharasutra (K.S.) is one of the chief modality in the treatment of Bhagandara in Ayurvedic science. Exploration of the new plants for the preparation of Kshara as a better substitute to Apamarga Kshara is the need of the hour. To find out an effective alternative to Apamarga ksharasutra in view of easily available, an Ingudi Ksharasutra was taken for its clinical evaluation. Total 40 cases of Bhagandara were divided randomly into 2 groups, having 20 patients in each group. In Group A, Ingudi Ksharasutra; in Group B, Apamarga Ksharasutra were used. Assessment was done on objective (Unit Cutting Time - UCT) and subjective parameters. Statistically significant difference was observed in the efficacy of treatment by subjective parameters like pain, discharge, etc. between the two groups. It was found that Ingudi Ksharasutra showed higher U.C.T. (8.60 days), as compared to Apamarga Ksharasutra(8.40 days). Thus Ingudi Ksharasutra can be used as a substitute for Apamarga Ksharasutra in the management of Kaphaja Bhagandara.

Keywords: Bhagandara, Fistula in Ano, Ingudi Ksharasutra, Apamarga Ksharasutra, U.C.T.(Unit Cutting Time.)

INTRODUCTION:

Shalya Tantra was at its zenith in Sushruta's time and the contents of Sushruta Samhita can be compared to any book on surgery written centuries later. Bhagandara (Fistula in ano) is told callous to be cured and is considered under the Ashta Mahagadas.[1]

According to a recent study conducted on the prevalence of anal fistula in India by Indian Proctology Society in a defined population of some states, approx. varied from 17 to 20%, while in a London hospital approximately 10% of all patients and 4% of new patients were reported to suffer from this disease among the anorectal disorders.[2]

It is notorious for its chronicity, recurrences and frequent acute exacerbations. Hippocrates (460 B.C.) described the use of seton to cure fistula in ano. He also favored use of knife if not cured by seton. Various treatments have been tried to cure fistula in ano including fistulectomy with primary closure and fistulectomy with skin grafting.[3,4] Minor variations in classical operation of lay open have been added by Hanlay[5] and Parks.[6] The routine surgical treatment employed today is fistulectomy and fistulotomy. Thus, in principle the surgical treatment of fistula in ano has remained the same without much improvement. Moreover, the need of prolonged hospitalization, extensive mutilation of Anorectal 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 Sushruta narrated the different types of treatment modalities for the disease Bhagandara, out of that the use of Ksharasutra is mentioned in the management of Nadi vrana (Su.Chi.17/32). Acharya Chakrapani Datta (Chi.6/148), described the method of preparation and treatment of Fistula In Ano by the use of Ksharasutra (K.S.). Many studies have been published by Ayurvedic surgeons recently with encouraging results for treatment of Fistula In Ano by the use of Kshara Sutra.[7,8,9,10]

To combat such critical Anorectal problems, a comprehensive approach through Ayurveda has been extended with definite and a positive outcome. Ksharasutra is such a simple, safe and sure remedy for anal fistula and it is becoming universally acceptable day by day. The Indian Council of Medical Research (ICMR) has validated this unique and effective approach.[11]

Ksharasutra treatment heals the fistulous tract with the integrity of sphincters and the existing data reveal negligible chances of recurrence. Ksharasutra is a scientifically validated treatment in the management of Bhagandara. The Apamarga Ksharasutra is well proven to be an effective treatment for fistula in ano and has been standardized by Central Council for Research in Ayurvedic Sciences (CCRAS), an apex research organization of Government of India (GOI) in the field of Indian system of medicine.[12]

It is quiet difficult to solely depend upon Apamarga only because of its limited availability globally. India is a vast country, with varied flora and there is also a need for search of the alternate plant sources which may give better results. Ingudi is a drug mentioned by Sushrutacharya in Kaphasamshamana varga (Su.Su.39/9) and Arkadi gana (Su.Su.38/7), having properties like Kaphaghna, Medoghna, Krimighna, Vishaghna, Vrana shodhaka and its Kshara is mentioned in Charak samhita (Chi.1-3/5), while explaining the preparation method of Louhadi Rasayana. As far as the Rasa Panchaka of the drug is concern, Ingudi is having Katu, Tikta Rasa; Ushna Virya, Katu Vipaka and Kapha-Pitta Shamaka properties. Due to its useful Kaphagna gunas the Ksharasutra prepared from its Kshara can be effectively used in the management of Kaphaja Bhagandara. The present study was conducted to evaluate the efficacy of Ingudi Ksharasutra in the management of Kaphaja Bhagandara and the results were compared with standard Apamarga Ksharasutra.

AIM -

To see the effect of Ingudi Ksharasutra in the management of Kaphaja Bhagandara.

OBJECTIVE OF STUDY-

1. To evaluate the efficacy of Ingudi Ksharasutra in comparison with standard Apamarga Ksharasutra in the management of Kaphaja Bhagandara.
2. To introduce a simple, safe and best alternative modality in the management of Bhagandara.

MATERIAL AND METHODS

Source of data :

1. Patients attending the OPD and IPD of Shri. J.G.C.H.S. Ayurvedic hospital, Ghataprabha, were taken for this clinical study.

2. The patients referred from other practitioners, hospitals, institutions were also taken for this study.

Methods of Collections of Data :

It was a single blind clinical study with minimum of 20 patients in each group were selected randomly, the clinical features were recorded on the Performa designed for the study.

Selection Criteria-

A) Inclusive Criteria:

1. The patients with irrespective of age, sex, religion were included for the study.
2. Patients with clinical features of Kaphaja Bhagandara were taken for study after proper screening**.**
3. Both high and low anal fistulae were taken for study.

B) Exclusive Criteria:

1. Fistula in Ano secondary to some other pathological conditions such as Tuberculosis, HIV, HbsAg etc. were excluded for the study.
2. Pregnancy.
3. Uncontrolled diabetes.
4. Horse shoe fistulae, multiple fistulae, fistula associated with Fissure In Ano, Hemorrhoids, Ulcerative colitis, Crohns disease were excluded.

STUDY DESIGN (INTERVENTIONS):

The screened patients of Kaphaja Bhagandara were randomly classified into two groups. Group A and Group B.

Group A – (TRIAL GROUP):

Application of Ingudi Ksharasutra in the fistulous track was done under strict aseptic precautions and the periodical change of Ksharasutra was done on weekly basis till complete cutting and healing of the fistulous track taken place.

Group B – (CONTROL GROUP):

Application of Apamarga Ksharasutra in the fistulous track was done under strict aseptic precautions and periodical change of Ksharasutra will be done on weekly basis till complete cutting and healing of the fistulous track taken place.

FOLLOW UP:

The patients of both the group were followed up once in a week, until complete cutting and healing of fistulous track taken place after that once in month for three months.

ASSESSMENT CRITERIA:

Assessment was done based on subjective and objective criteria before, during and after the treatment. The data collected was subjected to students paired ‘t’ test for analysis within the groups and unpaired ‘t’ test for analysis between the groups.

SUBJECTIVE PARAMETERS :-

1. Pain (mild/moderate/severe)
2. Itching (mild/moderate/severe)

OBJECTIVE PARAMETERS:-

1. Discharge (mild/moderate/severe)
2. U.C.T. (Unit cutting time)
3. Length of fistula
4. Direction and course of track by using malleable probe.

OBSERVATIONS & RESULTS:

- The clinical study reveals that, out of 40 patients maximum no. of patients i.e.28(70%), were from the age group of 20-40 years, minimum patients reported in age group 60-80 i.e. only 2 patients (5%), 10(25%), patients were reported in 40-60. Totally there were 31 males and 9females patients.
- In the present study it was found that 31 patients(77.5%) were from Hindu religion, second to that was Muslim 08 patients(20%) followed by 1 Christian patient.
- In marital status of the study, only 1 patient was unmarried.

- In the present study more of the patients were farmers (37.5%) followed by labor (35%) and only 1 patient was student.
- Most of the patients were of lower middle 21 patients (52.5%) S-E status, followed by poor 14 patients (35%) only 1 patient was rich.
- Chief complaint wise-All the patients of study were having pain, discharge, pruritis ani as chief complaints.
- Associated complaint wise, 14 patients (35%) were having fever and 38 patients (95%) were having wetting of under garments as associate complaints.
- Bowel habit wise- Most of the patients 16(40%) were having regular bowel habit and 12 patients were having irregular and constipated.
- Dietary habit wise - 29 patients (72.5%) were taking mixed diet, 21 patients (52.5%) were taking spicy food.
- Position of external opening wise In case of external opening the most common position (50%) was found in left lower quadrant followed by right lower quadrant (25%) least patients were found in right upper quadrant (10%)
- Length of the tract wise In the present study, 57.5% were having the length of track between1-3cm followed by 40% having within 3-6cm and only 1 patient was having more than 6cm.
- Type of discharge wise -b17 patients (42.5%) were having muco-purulant discharge next to that was pus discharge 25% followed by mucus 17.5% and serous 15%.
- Direction of tract wise- In the present study, 90% of patients were having radial track and 10% were having curved track.

TABLE NO. 1 -EFFECT OF INGUDI KSHARASUTRA ON CARDINAL FEATURES OF BHAGANDARA (GROUP-A):

Symptoms	Mean score ±S.E.		Mean decrease	%	SD	SE	"t"	P
	BT	AT						
Pain	1.6±0.15	0.1±0.06	1.5	93.7	0.51	0.11	13.63	<0.001
Itching	2.2±0.15	0.0±0.0	2.2	100	0.67	0.15	14.66	<0.001
Discharge	2.6±0.11	0.0±0.00	2.6	100	0.51	0.11	23.63	<0.001
Length of tract	3.04±0.31	0.0±0.0	3.04	100	1.38	0.31	9.8	<0.001

TABLE NO. 2 -EFFECT OF APAMARGA KSHARASUTRA ON CARDINAL FEATURES OF BHAGANDARA (GROUP-B):

Symptoms	Mean score ±S.E.		Mean decrease	%	SD	SE	"t"	P
	BT	AT						
Pain	1.45±0.15	0.2±0.41	1.25	93.1	0.51	0.15	13.63	<0.001
Itching	2±0.14	0.1±0.006	1.9	95	0.62	0.14	17.27	<0.001

Discharge	2.45±0.13	0.0±0.00	2.45	100	0.58	0.13	18.84	<0.001
Length of tract	3.03±0.22	0.0±0.0	3.03	100	1.38	0.31	13.77	<0.001

TABLE NO. 3 -COMPARISON BETWEEN GROUP-A AND GROUP-B:

Symptoms	$S.D._1$	$S.D._2$	Mean difference	Unpaired 't' test	Test of significance
Pain	0.67	0.58	0.15	T=0.424	Not significant
Discharge	0.49	0.58	0.15	T=0.458	Not significant
Itching	0.67	0.62	0.20	T=0.555	Not significant
Length Of Track	1.38	0.98	0.01	T=0.02	Not significant

DISCUSSION-

The management of fistula-in-ano by Setons is the contribution of Hippocrates (460-356 BC) but the idea of the setons is derived from the Ksharasutra treatment which is being used for treating the disease Bhagandara, since the period of Sushruta. Sushruta and Vagbhata have told Asthi Shalya as one of the causative factors of fistula-in-ano and this holds true even today i.e., by impaction of foreign body in the terminal part of the Guda either causes an abscess in the vicinity of the anal canal which ultimately develops the Bhagandara/Fistula in ano. Goligher in his text book of Surgery of the anus, rectum and colon mentions that "Occasionally a foreign body, such as a rabbit or fish-bone or particle of egg-shell may be lodged in the anorectal region, helping to cause the chronic infective process and as a formation of fistula." The description of Bhagandara Pidaka (fistulous abscess) clearly shows that Sushruta had an idea regarding the occurrence of a fistulous abscess and he was also well aware that, not all abscesses in this region lead to the causation of fistula-in-ano but only Bhagandara Pidika (fistulous abscess) is converted in to Bhagandara (Fistula in ano). The description of blind internal, blind external fistula, the detailed techniques of surgery i.e., excision or fistulectomy, are available in detail and it shows the advancements that had taken place for the management of Bhagandara at the time of Sushruta. In fact it may be remarked that the present day modern techniques are just a reflection of his principles.

All the patients were having pain, discharge, pruritis ani as chief complaints. In most of the cases pain was of mild type but in case of discharge which was more of a profuse in nature because of Kaphaja bhagandara associated with itching. Fever was present in the patients who were acutely attached (35%) along with wetting of undergarments. But most of the patients were having gradual onset. Most of the patients were having irregular and constipated bowel habit, which might contribute to pathology of bhagandara. Most of the patients were taking mixed type of diet and excessive spicy food which leads to irregular and constipation of bowel. Acharya sushruta also told Asthi as one of the cause of bhagandara which does guda darana.

Statistically there was no significant difference observed in the efficacy of treatment between the two groups. No recurrence was seen in the 3 months of follow-up. The treatment modality is non-invasive, cost effective and can be conducted at OPD level. It involves no significant post-operative complications. It can be used for the treatment of Bhagandara as a substitute along with standard Apamarga Ksharasutra.

CONCLUSIONS:

The trial drug Ingudi Ksharasutra is having good Kaphagna properties and shown good results in case of Kaphaja Bhagandara.The UCT of Ingudi Ksharasutra was higher (8.6 days) compared to the standard Apamarga group (8.4) but it did not produce any complications like burning sensation, abscess, etc. Thus Ingudi Ksharasutra can be effectively used in the management of Bhagandara in the place of Apamarga Ksharasutra in its non availability.

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