A CLINICAL EVALUATION OF MADHUKADI TAIL AND JATYADI TAIL ALONG WITH THE KSHAR SUTRA IN THE MANAGEMENT OF BHAGANDARA (FISTULA -IN- ANO)

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ABSTRACT

Bhagandara has been described by Acharya Sushruta as one among Ashtamaharoga (eight major diseases) which is difficult to cure. This disease has been described in Ayurvedic texts in great detail. The etiopathogenesis, symptoms, types, preventive measures and curative aspects have been mentioned in detail. In kshara-sutra therapy the cutting and healing of fistulous track takes simultaneously. In some cases, it has been observed that the healing status of track was not satisfactory. In that situation the cutting of track further delayed and it takes more time to completetion the treatment of Fistula-in-ano with Kshara-sutra. An oil with wound healing property may usefulin reducing the overall treatment in Fistula-in-ano. Keeping this view and to avoid complication and promote the better healing, Madhukadi Tail and Jatyadi Tail had been used along with Ksharasutra. It was found that Madhukadi Tail and Jatyadi Tail is effective in the management of Bhagandara (Fistula-in-ano).

KEY WORDS: -BHAGANDARA, KSHARA SUTRA, MADHUKADI TAIL, JATYADI TAIL

INTRODUCTION

The Bhagandara is one among the eight troubles some disease described by Ayurveda. Bhagandara is a disease that exits since the early days of evaluation of the mankind. In India the disease was known from very early days. In Vedic period no clear-cut description in details but the Samhitas and Purana do have abundant evidences regarding the existence and treatment of this disease.

वातव्याधिःप्रमेहश्चकुष्ठमर्शोभगन्दरम्।

अश्मरीमूढगर्भश्चतथैवोदरमष्टमम्॥
अष्टावेतेप्रकृत्यैवदुश्चिकित्स्याःमहागदाः।[1] (सु.सू.33/4-5)

Fistula-in-Ano isthe most common disease of the ano-rectum which is characterized by single or multiple sinuseswith purulent discharge in the perianal area. It is a communicating track between two epithelial surfaces, commonly between hollow viscus and the skin or between two hollow viscera. The track is lined with granulation tissue which is subsequently epithelialized. It becomes a notories disease due to its anatomical situation and it is a disease of Guda which is marma. Which recurrence even after surgery done by skilled surgeon. In ayurveda classics it is known as Bhagandara and it is included in eight mahagada.

तेतुगुदभगवस्तिप्रदेशदारणाश्चभगन्दराइत्युच्यन्ते ।

अपक्वापिड़का: पक्वास्तुभगन्दराः ।।[2](सु.नि. 4/4)

So, the literary meaning of Bhagandara is 'Daran' around Bhag (yoni), Guda and Vasti area. It clearly indicates that bursting of a pakvapidika results into daran of that area and communicates with Bhag (yoni), guda orvasti with surrounding skin surface called Bhagandara.

Fistula-Long pipe like ulcer with narrow mouth suppurating canal.[3](**Oxford illustrated Dictionary**)

(L-"pipe") A deep sinuous ulcer, often leading to an internal hollow organ.[4] (**Dorland illustrated medical dictionary**)

A gold or silver tube, through which the communicants of the early church received the holy wine; it is still used by the pope.[5] (**Weber's dictionary**)

Thus,it conveys that Fistula-in-ano is a very painful, disagreeable and uncomfortable condition and always a challenging situation from the viewpoint of surgeons and a constant source of anxiety and restlessness for the sufferer.

In this study the selected drugs as Madhukadi Tail is the first choice because it decreases post ligation Kshara sutra complication, i.e. pain, burning sensation, discharge by uses locally. As well as the Kshara sutra aplliedwhich helps to the cutting in the tracked of Fistula in ano.

AIMS AND OBJECTS:

1. To study fundamental principal describe by the Sushrut Samhita inthe management of Bhagandara.

2. Comparative study of JatyadiTail and MadhukadiTail after ligation of Kshara-sutra in the management of Fistula-in-ano.

3. Taming the symptoms like pain, burning sensation, and discharge. Itching and Tenderness in management of Fistula-in-ano.

4. To compare the healing status in both groups.

5. To provide the safe, painless & economical & without recurrence management of Fistula-in-ano.

AYURVEDIC REVIEW

In Vedic period no clear-cut descriptionin details but the Samhitas and Purana do have abundant evidences regarding the existence and treatment of this disease.

In Ayurveda the word Bhagandara is formed by the combination of two words Bhaga&Darana. The words Bhaga means perineum, but it includes Basti (Bladder), Guda(Rectum) region but Darana means breaking and tearing of tissues.

According to Ayurveda Bhagandara has a deep rooted pidika(boil) around the Guda with in two angula circumference processes with fever & pain.

Acharya Sushrut has mentioned that main cause of Bhagandara is pidika, which occurs due to improper ahara-vihara. Apart from this, he also mentioned that excesive intercourse (vyawaya), straining during defecation (pravahan),uncomfortable sitting posturs (uttkatason)

and excesivehorse riding (pristhayan) can lead to generation of the disease. He alsomentioned role of krimi and foreign particles like trina and asthi which are taken along with food and can injure the passage.

Five types of Bhagandara as - Sushruta view -

i) Shataponaka (originating from Vata)
ii) Ushtragreeva (originating from Pitta)
iii) Parishravi (originating from Kapha)
iv) Shambukavarta (originating from Tridosha
v) Unmargi (caused by trauma, Agantuja)

Vagbhatta has been described three more types of Bhagandara -

vi) Parikshepi (originating from Vata and Pitta)
vii) Riju (originating from Vata and Kapha)
viii) Arsho-bhagandara (originating from Pitta and Kapha)

Acharya Sushrut has mentioned three types of asadhyaroga, which is included under updraveasadhya,because it is originally a curable disease but becomes incurable in presence of updravas (complications).

DRUG REVIEW

मधुकरोध्रकणात्रुटिरेणुकाद्विरजनीफलिनीपटुसारिवाः।
कमलकेसरपद्मकधातकीमदनसर्जरसामयरोदिकाः।।३५।।

सबीजपूरच्छदनैरेभिस्तैलंविपाचितम्।भगन्दरापचीकुष्ठमधुमेहव्रणापहम्।।३६।।(अ.हृ.उ.28/35-36)

IMPORTANCE OF DRUG

According to modern scientific interpretation, a drug is a product or any substance that can be used or intended to be used to modify or explore Physiological system or Pathological condition.

Acharya Charaka says that the wise Physician starts treatment by using medicine only after ascer training it on every Parameter of health. Thus, he never mistakes in treatment.[6] (Ch. Vi. 7/7)

Drugs needed for getting rid of various aliment knowledge of utility of these drugs is essential for every physician or Surgeon to achieve success during treatment.

Acharya Sushrutsaid about the drugs, if not fully understood and used may be as fatal as poison, fire or weapon, whereas proper use of any drug, knowing its properties fully and then used is comparable to ambrosia.

The content of Kshara sutra:

1. Snuhiksheer (Euphorbia nerifolia)

2.Apamargkshara (Achyranthus aspera)

3. Haridra (Curcuma longa)

Jatyadi Tail:According to Sharangdhara, Jatyadi tailis indicated in Nadivrana.[7](शा.सं.म.खं. 9)

Madhukadi Tail:The drug is used for present study describe inAstanga-Hridaya for Bhagandara.[8] (A.H.U. 28/35-36)

CLINICAL STUDY:

A clinical study was conducting comparing the role of Kshar sutra + Jatyadi Tail and Kshar sutra + Madhukadi Tail by their local application in the fistulous track for the management of Bhagandara(Fistula-in-ano).

Selection of Patient:

The patients who reached with a primary complaint of a discharging wound discomfort pain in the perianal region selected for this study. All necessary investigations were carried out for all the selected patients at Govt. Ayurvedic College & Hospital, Patna on the basis of patients need and necessity. The fistulography is done if required.

Patients were selected from OPD of Ano-rectal unit of Dept. of Shalya Tantra, Govt. Ayurvedic College &Hospital,Patna.

Grouping of the Patient:

For clinical trial 20 patients will be grouped in two groups of 10patients each.

Group A- Kshara sutra + JatyadiTail

Group B - Kshara sutra + MadhukadiTail

Inclusion Criteria:

Diagnosed patients of fistula-in-ano were selected, randomly irrespective of sex, length of track, type of Fistula, chronicity, prakriti etc. and were in between the age group of 16-60 years.

Exclusion Criteria:

Patients who are suffered with diabetes mellitus tuberculosis, childrens, other systemic disease like osteomyelitis of coccyx, ulcerative colitis, biopsy of the track suggestive of malignancy were excluded from the study.

Criteria of Assessment:

Efficacy of Kshara-sutra and Tail were assessed on the basis of following symptoms and signs:

Subjective-

1.Pain

2. Burning sensation

3. Tenderness

4. Itching

5.Discharge

Objective-1. Condition of wound2. Unit cutting time(U.C.T.)3. Healing status

U.C.T.=Total number of days taken for cut through

Initial length of Track (in cm)

Statistical Analysis

All information which are based on various parameters was gathered and statistical calculation were carried out in terms of mean (X), standard deviation (S.D.) standard error (S.E.), paired test (t value) and finally results were incorporated in term of probability (p) as

$P \geq 0.05$Insignificant

$P \leq 0.020$ Moderately significant

$P \leq 0.010$ Significant

$P \leq 0.001$ Highly significant

Administration of Drug:

Kshara-sutra was changed weekly till recovery.

Drug (Jatyadi&MadhukadiTail) administered after Kshara-sutraligation in Fistula-in-ano in two groups.

Doses:

According to the depth of Fistula-in-ano (standard dose 2ml) in morning and evening every day.

Duration:

Upto the cutting of fistuluous track associated symptoms were assessed (4 weeks).

Posology of trial Drug

S.N.	Patients	Group	Drug	Form	Dose	Duration
1.	**10**	**A**	**Jatyadi**	**Tail**	**2ml**	**4 weeks**
2.	**10**	**B**	**Madhukadi**	**Tail**	**2ml**	**4 weeks**

Mode of administration of Drug:

Tailadministration with the help of Syringe attached with Rubber catheter.

No. 6 pushed in the track & also in anus and dressing with bandage.

Observation:

After doing trial, the progress was observed of weekly intervals for a period of 4 weeks at the end of 4 weeks final assessment of progress i.e.results were carried out.

Follow up:

Once tract was completely excised or cut through the patients was advised to visit the anorectal unit every month for 3 months to recheck the status of the excised area of wound.

OBSERVATIONS AND RESULTS

Observations are the most important part of any research work. It provides basis of analysis of the problem and effects of the method adopted for its cure.

Average Unit Cutting Time of Group A			
Number of Patients	Initial length of track cms	Total days for cutting	U.C.T. (days/cm)
1	4.8	39	8.13
2	4.2	40	9.52
3	3.2	26	8.13
4	4.7	42	8.94
5	8.6	84	9.77
6	7.9	74	9.37
7	4.1	30	7.32
8	3.7	29	7.84
9	4.8	38	7.92
10	12.2	121	9.92
		Average U.C.T.	**8.68**

This table shows that average UCT in group A was 8.68 days /cm.

The slowest cutting rate was 9.92 days/cm and the fastest was 7.32 days/cm.

Average Unit Cutting Time (U.C.T.) Of Group B

Average Unit Cutting Time of Group B			
Number of Patients	**Initial length of track cms**	**Total days for cutting**	**U.C.T. (days/cm)**
1	3.2	22	6.88
2	4.5	33	7.33
3	5.0	37	7.40
4	6.8	46	6.76
5	7.2	51	7.08
6	9.4	66	7.02
7	8.2	58	7.07
8	7.6	55	7.24
9	6.9	52	7.54
10	16.3	116	7.12
		Average U.C.T.	**7.14**

The above table shows average U.C.T of group B which was 7.14 days /cm.

The slowest cutting rate was 7.54 days /cm and the fastest was 6.76days /cm.

Total average U.C.T. in days /cm

Total Average Unit Cutting Time in days/cm			
S. No.	**Group**	**Number of Patients**	**U.C.T. (days/cm)**
1	A	10	8.68
2	B	10	7.14

The above table shows average U.C.T of group A was 8.68days /cm and of group B was 7.14/cm respectively.

Summarized Results (Relief in criteria's)

Summarized Results (Relief in Criteria's)						
Symptoms	GROUP A			GROUP B		
	%	t-value	p-value	%	t-value	p-value
1	74.19%	7.666	<0.001	89.28%	9.302	<0.001
2	60.00%	6.194	<0.001	51.72%	9.000	<0.001
3	60.60%	7.746	<0.001	84.21%	9.798	<0.001
4	85.71%	13.50	<0.001	95.23%	13.416	<0.001
5	79.16%	4.384	<0.01	84.61%	5.659	<0.001

Data shows the comparative percentage relief in symptoms and t&p values on weekly assessment.The percentage relief in pain in group A was 74.19% and in group B was 89.28.Relief from itching in group A was 60% and in group B was 51.72%.Relief from burning sensation in group A was 60.60% and in group B was 84.21%. Relief from Tenderness in group was 85.71% and in group B was 95.23%. Relief from Discharge in group was 79.16%and in group B was 84.61%

- THE RESULTS OF GROUP- A AND GROUP- B WERE STATISTICALLY HIGHLY SIGNIFICANT AFTER 4 WEEKS.
- THE RESULT OF GROUP- B STATISTICALLY BETTER THAN GROUP- A.

Cure rate in both groups

Cure Rate in both Groups					
S. No.		GROUP A		GROUP B	
		No. of Patients	%	No. of Patients	%
1	Cured	10	100%	10	100%
2	Uncured	0	0.00%	0	0.00%

This table shows that all the patients in both groups were completely cured.

Incidences of recurrence within 3 months in both groups

Incidences of recurrences within 3 months in both groups				
S. No.	Group	Recurrences	Total No. of Patients	Total % of Patients
1	A	0	10	0.00%
2	B	0	10	0.00%

This table shows that all the patients in the clinical study no recurrances were found (follow up study)both groups were completely cured.

DISCUSSION

The surgical treatment of fistula in ano presents many drawbacks.

-Recurrence

-Sphincter damage.

-Prolonged Hospitalization.

-Post-operative complication.

In this condition, the supremacy of Kshara-sutra has been proved for its simplicity, surety and safety with least inconvenience, recurrence and is ambulatory modalities. On these accounts, the Kshara-sutra therapy has attained tremendous popularity in the country.

Merits of Kshara-sutra-

Adequate drainage of wounds.

Proper curettage.

Minimal traumatization and damage.

Negligible recurrence.

Merits of trial drugs-

Although the fistulous track starts healing naturally, but due to infection delay in healing, the need to impart some medicaments is felt essential, after Kshara-sutra ligation in order to bring down the natural healing time.

The external opening healed after some time but the process of pus formation continuous. So, it causes pain & finally burst again & suppurates& the fistulous track with the area of external opening also inflammed. To counter the pain, swelling, tenderness, itching, pus discharge and to prevent recurrence,local application of medicated Tail is necessary. Tail is vata-shamakproperty, so when Tail applicated into the rectum, which the site of vata, so Tail work as shodhan and shaman for vata (flatus).

Tailworks as lubricant medium for stool.

Ropan procedure is always associated with 'Shodhan' procedure because wound cannot heal it is not clear, therefore to produce healing of fistulous tract, trial herbal drug selected.

Selected drug had lekhana, deepana, pachana properties which actedas srotosodhan, remove the maximum local dusti or debridement. Both Tail is helpful in pain, burning sensation, itching, tendernessand discharge also.

Discussion of effect of therapy:

20 patients of Fistula-in-ano were selected and grouped in two groups randomly with 10 patients in each group. Group A was treated with Kshara-sutra and JatyadiTail Group B was treated with Ksharsutra and MadukadiTail.

In both groups thread was changed on weekly and tail was applicated twice a day after operation in the amount of 2ml.

In the present study the incidence of Bhagandara was greater in males (95%) compared to females (5%). Long hours as sedentary jobs. Excessive physical exercise like riding of vehicles, Bad dietary habits increased the incidence in males. Beside few ladies turned up in the O.P.D., may be due to lack of knowledge, education and their shy nature.

Vataj and kaphaj individual (72%) are affected to a greater extent by Bhagandara. (Kumar P and Sahu M. 1988). In the present study almost, same result was noticed. The disease was more prevalent in Kaphaj (45%) and Vataj (30%) individuals. This is probably due to the fact that Kaphaj prakriti persons are more prone to adopt sedentary life style, which is one of the main etiological factors.

In present study it was observed that the incidence of the disease was highest in age group of 30-40 (30%) and 40-50 (30%) years followed by 50-60 (20%) years. Overall 80% patients were of middle age. The disease was more prevalent in this group because, this is the most active phase of any human and hence increased travelling, improper attention to bowel movements, overstraining, local hygiene, long hours of sitting in same postures etc. Increased the incidence of the disease in the patient of this age group.

Majority of patients (45%) were from business and service class(40%). Businessman and those doing office jobs need to constantly sit in the sameposture for long hours, Constant pressure over buttock, lack of exercise, leads to constipation and culminates in the causation of fistula-in- ano in these people. The above said reasons also justify the predominance sedentary typeof life style (60%).

Out of 20 patients selected for this study (65%) were vegetarian so it is indicated that the location ofPatna where the maximum of people is choice to vegetarian.

60% patients were married in this clinical study. Common in these individuals is due to the facts that they bear maximum mental and physical stress which leads to improper attention towards the person himself. Altered sleeping routine, faulty dietary habit, less attention towards bowel movements local unhygienic were main contributory factor to these findings.

Besides this Acharyas had mentioned the role of excessive intercourse in the etiology of Bhagandara which may also be the reason of this data.

The majority of patients (30%) were having in this research work less than one-year chronicity followed by above 3 years chronicity of Bhagandara 10% Maximum patients were found chronicity of 1-3-year (60%) Lack of proper knowledge about the disease initial treatment with antibiotics or other therapy. Considering it just an abscess delays the treatment and hence by the time the patient come for treatment it is more than a year and thus we found such a high incidence in the group of 1-3 years.

In this clinical study maximum numbers of patients were suffering from parishravi type of Bhagandara (40%)

The classification mentioned in the Ayurvedic texts, is valid and scientifically proved in modern aspects. More than 75% of the patients have a parishravi type of Bhagandara (Sharma K.R. and Deshpande P.J., 1968). This may be due to a greater number of posteriorly situated where the maximum numbers of gland also present posteriorly and low anal fistula are generallyof parishravi type. Incidence of Bhagandara in the study reveals the majority of the cases (65%) were of low anal variety. Sainio (1984) reported that 90% of the fistula occurs due to non-specific infection of anal glands. These anal glands are situated in anal crypts which occur in lower portion of anal canal.

Majority of Fistula have their external opening in the posterior half. More than half of the cases have their external opening in posterior half of anal canal again this is because of location of anal glands which are numerous in numbers in the posterior half of anal canal.In this study majority of fistula (55%) were complete i.e. they had patient external and internal opening. Most of fistula are due to infection of anal gland (non-specific type) and are of low anal variety so there is more chance of complete fistula.

In this clinical study it was observed that the patients havingsingle opening were 85%. 65% of cases were found in the patients 1½ inch distance from theanus.In this clinical study it was observed that maximum patients having throbbing like pain. It indicates toward Ischio-rectal abscess.

In the present study the UCT was in the males (8.77 day/cm) and in female (7.83 days/cm). But there was only one female patient in group A. So, it was not a significant study for UCT according to sex. It is probably due to the soft skin and tissue.

The average UCT in group A was 8.68 day/cm. and in group B it was 7.14 day/cm. This is probably due to contents of madhukadiTail having shoolharanproperties. Owing to which patient can tolerate more tightening of the thread. Besides,lekhan and bhedan property, shodhan andropan properties act synergistically in cutting of the track faster in thegroup B.

In the present study,it was observed that in group A the age group of 20-30 years had the best UCT (7.31). The UCT was highest in the patients above 50 years. It was 9.06 days/cm in group A and 7.46 days/cm.in. group B.

Younger the patient, better is immune response and better is healing rates, owing to which these patients got freedom from the disease earliest. In the present study the minimum UCT in both groups was of vataj(Shatponaka) type of Bhagandara (7.75 days/cm in group A and

6.88days/cm in group B) and maximum UCT of ParishraviBhagandara (9.25days/cm in group A).

In shatponakaBhagandara, the fistulous track is not so deep and some skin to skin ligation of Kshara-sutra is needed. Hence in this condition there is minimum U.C.T.

The parishraviBhagandara are profuse pus discharging which represents good amount of infection and tracks are deep and transverse sphincteric musculature, so chance of high U.C.T. is possible.

The comparative percentage relief in symptoms and t& p values on weekly assessment. The percentage relief in pain in group A was 74.19% and in group B was 89.28. Relief from itching in group A was 60% and in group B was 51.72%. Relief in Burning sensation in group A was 60.60% and in group B was 84.21%. Relief from Tenderness in group was 85.71% and in group B was 95.23%. Relief from Discharge in group was 79.16% and in group B was 84.61%.

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CONCLUSIONS

On the basis of observations of clinical study and statistical data, following conclusion can be drawn-

By the use of kshara-sutra and madhukadiTail, total duration oftreatment was reduced thus reducing the burden of the patient interms of loss of vital man-hours and economic power.Pain, burning sensation, discharge and tenderness also reduced significantly in-group B thus increased acceptability of experimental madhukadiTail among the patient.

In itching, jatayadiTail is more effective than madhukadi Tail. The condition of wound was healthy in majority of cases during the treatment in those treated by kshara-sutra and madhukadiTail.

Post ligation complication was much reduced.

No recurrence case was reported during follow up.

So, at the end of this study final conclusion can be drawn that Madhukadi Tail is more competent and effective than JatyadiTail in the management of Bhagandara (Fistula-in-ano).

The result of group- B statistically better than group- A.

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