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RESEARCH ARTICLE

A CLINICAL STUDY OF PALASHA KSHARASUTRA IN THE MANAGEMENT OF BHAGANDARA (FISTULA-IN-ANO)

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ABSTRACT

The word fistula is derived from a Latin word a red, pipe or flute. It implies a chronic granulating track connecting two epithelial-lined surfaces. The anal fistula is a single track with an external opening in the skin of perianal region and an internal opening in the modified skin or mucosa of anal canal or rectum. Fistula-in-ano is considered second to Hemorrhoids among all Ano-rectal abnormalities, is prevalent all over the world and its occurrence in a London Hospital Study (Marks & Richie, 1977) was reported to be 10% of all in patients and 4% of all new out patients. Similar study in India (Raghavaiah, 1976) reported anal fistula to constitute 1.6% of all surgical admissions. In Ayurvedic classics, this disease has been described with the name of BHAGANDARA, which has more similar signs and symptoms with anal fistula. The importance of this disease was first realized by Sushruta (800-1000 B.C.), The Father of Indian Surgery, who described it elaborately in his treatise. In Ayurvedic classics, this disease has been described with the name of BHAGANDARA, which has more similar signs and symptoms with anal fistula. The importance of this disease was first realized by Sushruta (800-1000 B.C.), The Father of Indian Surgery, who described it elaborately in his treatise.

Key words: Bhagander, Fistula in ano.

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INTRODUCTION

Fistula-in-ano is one of the most common ailments pertaining to ano-rectal region. This disease causes discomfort and pain to patient, which creates problems in routine work. In Ayurvedic classics, this disease has been described with the name of BHAGANDARA, which has more similar signs and symptoms with anal fistula and is encountered under Ashtamahagada. As the wound is located in anal region which is more prone to infection, thus takes long time to heal and the condition remains troublesome, operative procedures often leads to complications like recurrences and incontinence. To alleviate such problems in the management of this disease, it was thought to find out some technique to treat these cases without operative complications. Acharya sushruta in the 17th chapter of chikista stana mentioned the application of kshara sutra in Nadi vrana. The Kshara Sutra therapy was practiced and used in since long with great success and without recurrences. The Standard kshara sutra is prepared by repeated coatings of Snuhi ksheera, Apamarga kshara and Haridra. Still some of the problems are faced during the preparation and also in the course of Kshara sutra therapy, like collection and preservation of Snuhi ksheera, burning pain during primary and successive changes. Local irritant skin reactions during course of therapy etc. To overcome these disadvantages was of utmost importance to make the treatment widely popular and acceptable. In spite of the good rates of cutting, severe pain and burning sensation caused during the treatment with held many patients from accepting this treatment.

Thus it gave to many Kshara sutras were tried out .Though each of the thread had good cutting rates and other preparation advantages they also had some disadvantages. Keeping in view the same idea Palash Ksharasutra[1]was tried in the present study.

Aims and Objectives

- Detail and descriptive study of Bhagandara.
- To explore the efficacy of Palash ksharasutra in the management of Bhagandara.

MATERIALS AND METHODS

The most important requirement in the clinical study is a well defined protocol. So, in the present study following protocol was followed.

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Source of Data: The present clinical study on the management of mutrashmari was carried out at N.K.J.A.M.C. Bidar. This study was carried out at O. P. D. level and the work was limited according to the facilities available in the P. G. Dept. of shalya Tantra .The data was also collected by conducting camps for the purpose of clinical study.

Selection Criteria: The selection of cases was done on the bases of clinical presentation and the diagnosis was established accordingly. The patients were registered according to the proforma prepared for the study irrespective of their sex, occupation and socio – economic status.

Inclusive Criteria

- Selection of the patients will be selected 16 -70 age, irrespective sex, religion, occupation, economic status, etc.
- Low anal fistula.

Exclusion Criteria

- Patients with high rectal fistula.
- Patients suffering from systemic diseases like TB, DM, Ca Rectum, HBsAg, HIV.
- Patients suffering from ulcerative colitis and Crohn's diseases.

Study Design

Being a clinical study, 30 patients will be selected by Simple Randomized Sampling procedure. All the patients will be screened out by inclusive and exclusive criteria and registered for clinical trial divided in two equal groups.

Group 1 (Trial Group): 15 patients of Bhagandara will be treated with Palasha Ksharasutra.

Group 2 (Control Group): 15 patients of Bhagandara will be treated with Apamarga Ksharasutra.

In both the groups Ksharsutra will be changed weekly. The duration of the study will be 28 days in total. Patients will be called on every 7^{th} days and the cutting rate will be assesed in a specially prepared case sheet. Observations will be analyzed on the basis of assessment parameter (both subjective and objective) critically and scientifically before treatment and after treatment on the 7^{th}, 14^{th}, 21^{st} and 28^{th} day. Finally the result will be statistically evaluated with the help of paired't' test within the group for its significance.

Materials

- Palasha Ksharasutra
- Apamarga Kshara sutra.

Both the Kshara sutras will be prepared according to the standard method as per Dr. P.J. Deshpande

Assesment Criteria

Subjective criteria

Pain according to
Grade 0 (-)-Absolute No pain
Grade 1 (+)-Mild pain
Grade 2 (++)-Moderate pain
Grade 3 (+++)-Severe pain

Itching

Grade 0 (-)-No itching
Grade 1 (+)-Itching sometimes but not interfering with activities can be controlled voulntarily
Grade 2 (++)-Itching interference with function involuntary and uncontrolled associated with skin patches.
Grade 3 (+++)-Itching that disturbs the sleep and or demand treatment associated with nskin patches.

Discharge

Grade 0 (-)-No Dischage
Grade 1 (+)-Mild discharge single pad is sufficient per day.
Grade 2 (++)-Moderate discharge 2-3 pads necessary per day
Grade 3 (+++)-Profuse discharge more than 3 pads are necessary per day

Objective Criteria

Local tenderness: - was assessed by palpation of anal region.

G_0 – No tenderness
G_1 – mild – tender but can be palpated.
G_2- moderate – tender on gentle palpation.
G_3- Severe – patient denies touching.

Induration

G_0 - Absent
G_1 - Slight swelling around the wound margin without indurations.
G_2 - Swelling around wound margin with little area of indurations.
G_3 - Swelling with marked indurations.
Length of tract (in cm)

Unit cutting time: - $\frac{\text{Initial length of the tract – length of the tract remaining}}{\text{No of weeks taken}}$

Investigation Required

Blood Routine & Urine Examination. Culture and Sensitivity of wound discharge (if necessary), Fistulography (if necessary),

RESULTS

The above statistical analysis shows that in case of

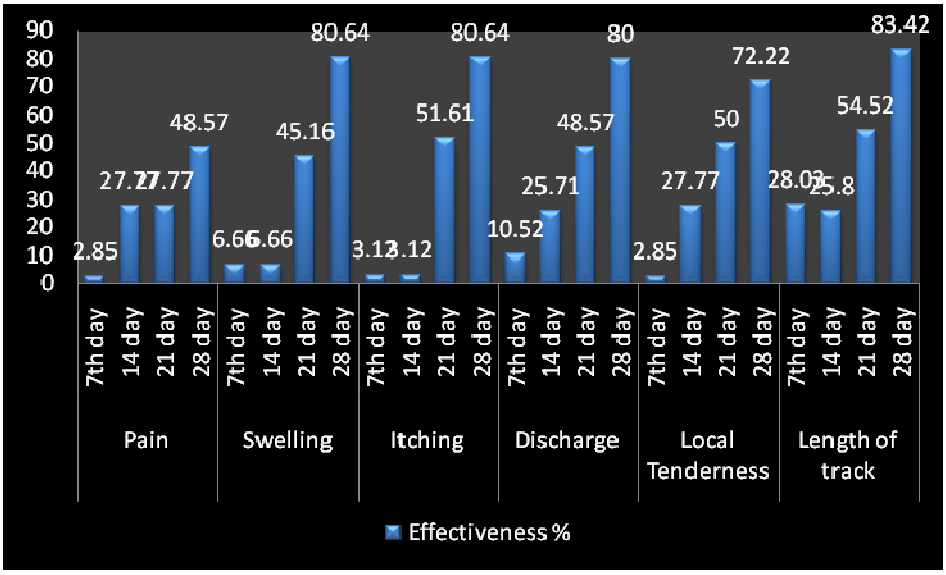
Pain: The mean ± S.E. before treatment was 2.06±0.18 and was same 2.06±0.18 after 7 days, was reduced to 1.86±0.13 after 14 days, and 1.53±0.16 after 21 days. 0.86±0.13 after 28 days. The test of significance shows that palash is highly Significant to reduce pain with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively.

Swelling

The mean ± S.E. before treatment was 2.21±0.18 and was same 2.21±0.18 after 7 days, was reduced to 2.21±0.18 after 14 days, and 1.21±0.10 after 21 days. 0.42±0.13 after 28 days. The test of significance shows that palash is highly Significant to reduce swelling with the P-value <0.001 in AT1, AT2, AT3&AT4 respectively.

Trial group result-1

Sign and Symptoms	BT Mean ± S.E.	Assesment	Mean ± S.E.	Df	T-value	p-value	p-value	Effectiveness %	Remark
Pain on VAS	2.06±0.18	1	2.06±0.18	14	0.56	0.58	>0.05	2.85	NS
		2	1.86±0.13		3.68	0.0003	<0.001	27.77	HS
		3	1.53±0.16		15.58	3.16E	<0.001	27.77	HS
		4	0.86±0.13		18.66	1.32E-11	<0.001	48.57	HS
Swelling	2.21±0.18	1	2.21±0.18		1.46	0.16	>0.05	6.66	NS
		2	2.21±0.18		1.46	0.16	>0.05	6.66	NS
		3	1.21±0.10		6.51	1.37E-05	<0.001	45.16	HS
		4	0.42±0.13		14.50	7.91-10	<0.001	80.64	HS
Itching	2.06±0.18	1	2.06±0.18		0.56	0.58	>0.05	3.12	NS
		2	2.06±0.18		0.56	0.58	>0.05	3.12	NS
		3	1±0.13		9.02	28E-07	<0.001	51.61	HS
		4	0.4±0.13		10.45	35E-08	<0.001	80.64	HS
Discharge	2.33±0.18	1	2.33±0.18		2.25	0.040	<0.05	10.52	S
		2	1.73±0.15		4.58	0.0004	<0.001	25.714	HS
		3	1.2±0.10		6.85	7.82E-06	<0.001	48.57	HS
		4	0.46±0.13		20.54	7.46-12	<0.001	80	HS
Local Tenderness	2.4±0.13	1	2.4±0.13		1	0.066	>0.05	2.85	NS
		2	1.73±0.15		5.29	0.000114	<0.001	27.77	HS
		3	1.2±0.10		11.22	2.19E-08	<0.001	50	HS
		4	0.66±0.12		14.66	6.85E-6	<0.001	72.22	HS
Length of Track	3.46±0.17	1	3.46±0.17		10.66	1.53E-07	<0.001	28.03	HS
		2	2.50±0.17		10.26	6.72E-08	<0.001	25.8	HS
		3	1.57±0.14		17.80	5.16E	<0.001	54.52	HS
		4	0.57±0.10		19.55	1.46E-11	<0.001	83.42	HS



Effectivness % of Trial Group-1

Itching: The mean ± S.E. before treatment was 2.06±0.18 and was same 2.06±0.18 after 7 days, was same to 2.06±0.18 after 14 days, and was reduced to1±0.13 after 21 days. 0.4±0.13 after 28 days. The test of significance shows that palash is highly Significant to reduce itching with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively.

Discharge: The mean ± S.E. before treatment was, 2.33±0.18 and was same2.33±0.18 after 7 days, was reduced to 1.73±0.15 after 14 days, and 1.2±0.10 after 21 days. 0.46±0.13 after 28 days. The test of significance shows that palash is highly Significant to reduce Discharge with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively.

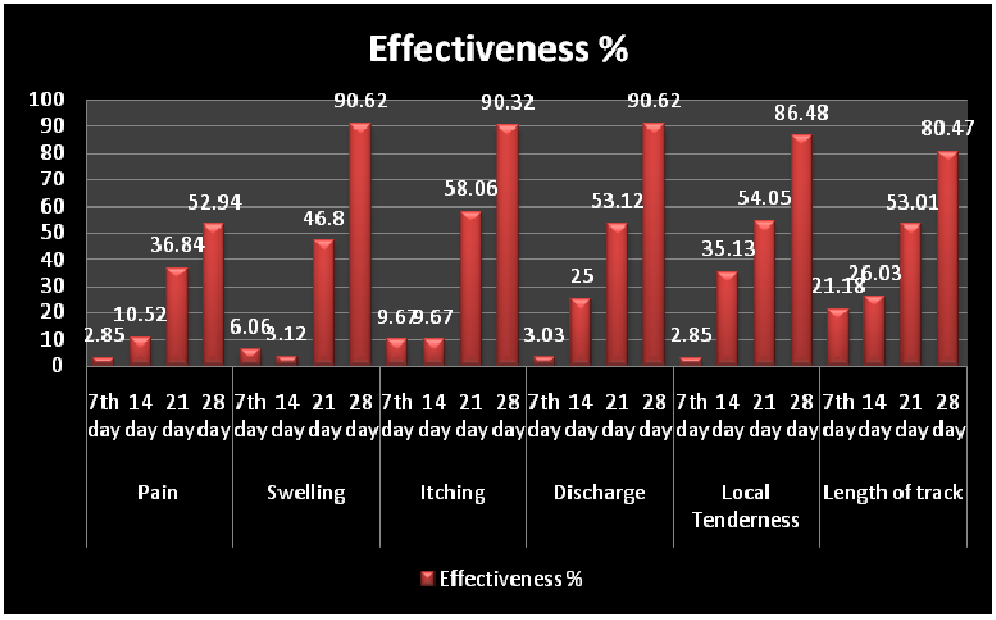
Local of Tenderness: The mean ± S.E. before treatment was, 2.4±0.13 and was same2.4±0.13 after 7 days ,was reduced to 1.73±0.15 after 14 days, and 1.2±0.10 after 21 days. 0.66±0.12 after 28 days. The test of significance shows that palash is highly Significant to reduce Local tenderness with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively.

Length of track: The mean ± S.E. before treatment was, 3.46±0.17 and was same3.46±0.17 after 7 days, was reduced to 2.50±0.17 after 14 days, and 1.57±0.14 after 21 days. 0.57±0.10 after 28 days. The test of significance shows that palash is highly Significant to reduce Length of track with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively.

Control group result:-2

Sign and Symptoms	BT Mean ± S.E.	Assesment	Mean ± S.E.	Df	T-value	p-value	p-value	Effectiveness %	Remark
Pain on VAS	1.53±0.16	1	1.53±0.16	14	4.67	0.66	>0.05	2.85	NS
		2	1.73±0.15		2.25	0.002	>0.001	10.52	S
		3	1.26±0.15		7.29	0.00011	<0.001	36.84	HS
		4	0.73±0.11		8.76	0.000131	<0.001	52.94	HS
Swelling	2.13±0.16	1	2.13±0.16		1.46	0.16	>0.05	6.06	NS
		2	2.06±0.18		0.56	0.58	>0.05	3.12	NS
		3	1.13±0.135		7.24	4.25E-06	<0.001	46.8	HS
		4	0.2±0.10		16.35	1.61E-10	<0.001	90.625	HS
Itching	2.06±0.18	1	2.06±0.18		1.87	0.08	>0.05	9.67	NS
		2	1.86±0.13		1.87	0.082	>0.05	9.67	NS
		3	0.86±0.13		8.29	9.02E-07	<0.005	58.06	S
		4	0.2±0.10		9.72	1.13E-07	<0.001	90.32	HS
Discharge	2.13±0.13	1	2.13±0.13		0.56	0.58	>0.05	3.03	NS
		2	1.6±0.13		4	0.0013	>0.001	25	S
		3	1±0		8.5	6.71E-07	<0.001	53.12	HS
		4	0.2±0.10		12.61	4.92E-09	<0.001	90.62	HS
Local Tenderness	2.4±0.13	1	2.4±0.13		1	0.33	>0.05	2.85	NS
		2	1.6±0.13		5.24	0.000124	<0.001	35.13	HS
		3	1.33±0.09		10.58	4.61E-08	<0.001	54.05	HS
		4	0.33±0.12		23.48	1.21	<0.001	86.48	HS
Length of Track	4.2±0.25	1	4.2±0.25		2.61	0.02	<0.05	21.18	S
		2	3.10±0.25		9.66	1.43E-07	<0.001	26.03	HS
		3	1.97±0.25		1.67	1.17E-10	<0.001	53.01	HS
		4	0.82±0.19		29.56	5.09E-14	<0.001	80.47	HS

The above statistical analysis shows that in case of



Effectiveness % of Control Group-2

Pain: The mean ± S.E. 1.53±0.16 before treatment was same 1.53±0.16 after 7 days, was reduced to 1.73±0.15 after 14 days, 1.26±0.15 and after 21 days. 0.73±0.11 after 28 days. The test of significance shows that Apamarga is highly Significant to reduce pain with the P-value <0.001 in AT1, AT2, AT3&AT4 respectively.

Swelling: The mean ± S.E. before treatment was 2.13±0.16 and was same 2.13±0.16 after 7 days, was reduced to 2.06±0.18 after 14 days, and 1.13±0.135 after 21 days. 0.2±0.10 after 28 days. The test of significance shows that Apamarga highly Significant to reduce swelling with the P-value <0.001 in AT1, AT2, AT3&AT4 respectively.

	GROUP-I A.T.								GROUP-II A.T.							
	7th day		14th day		21st day		28th day		7th day		14th day		21st day		28th day	
	No. of pt	%	No. of pt	%	No. of pt	%	No. of pt	%	No. of pt	%	No. of pt	%	No. of pt	%	No. of pt	%
Cured -100%	0	0%	0	0%	1	5%	16	80%	0	0%	0	0.00%	4	20%	18	90%
Max. Improved (75% to 99%)	0	0%	2	10%	5	25%	4	20%	0	0%	5	25%	8	40%	2	10%
Mod. Improved (50% to 74%)	5	25%	3	15%	7	35%	0	0%	6	30%	6	30%	3	15%	0	0%
Mild Improved (25% to 49%)	6	30%	4	20%	5	25%	0	0%	5	25%	6	30%	4	20%	0	0%
Not Improved (<25%)	9	45%	6	30%	2	10%	0	0%	9	45%	3	15%	1	5%	0	0%

Itching: The mean ± S.E. before treatment was 2.06±0.18 and was same 2.06±0.18 after 7 days, was reduced to 1.86±0.13 after 14 days, and 0.86±0.13 after 21 days. 0.2±0.10 after 28 days. The test of significance shows that Apamarga is highly Significant to reduce itching with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively.

Discharge: The mean ± S.E. before treatment was, 2.13±0.13 and was same 2.13±0.13 after 7 days, was reduced 1.6±0.13 after 14 days, and 1±0 after 21 days. 0.2±0.10 after 28 days. The test of significance shows that Apamarga is highly Significant to reduce Discharge with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively.

Local of Tenderness: The mean ± S.E. before treatment was, 2.4±0.13 and was same2.4±0.13 after 7 days ,was reduced to 1.6±0.13 after 14 days, and 1.33±0.09 after 21 days. 0.33±0.12 after 28 days. The test of significance shows that Apamarga is highly Significant to reduce Local tenderness with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively.

Length of track: The mean ± S.E. before treatment was, 4.2±0.25 and was same 4.2±0.25 after 7 days, was reduced 3.10±0.25 after 14 days, and 1.97±0.25 after 21 days. 0.82±0.19 after 28 days. The test of significance shows that Apamarga is highly Significant to reduce Length of track with the P-value <0.001 in AT1, AT2 ,AT3&AT4 respectively

Effectiveness % of Control Group-2

Overall clinical assessment of therapy

In group I, 20 patients (80%) complete cured. In group II, 20 patients (90%) got complete cured. Finally overall assessment of the therapy was analyzed clinically, Where at the 1st follow up on 7th day in group - I Moderate improvement in 5 patients i.e. (25%). Mild improve in 6 patients i.e. (30%) and not improvement was noticed in 9 patients i.e. (45%) where as group- II Moderate improvement in 6 patients i.e. (30%).Mild improve in 5 patients i.e. (25%) and not improvement was noticed in 9 patients i.e. (45%). Where at the 2st follow up on 14th day in group - I Max improvement in 2 patients i.e (10%).Moderate improvement in 3 patients i.e. (15%). Mild improve in 4 patients i.e. (20%) and not improvement was noticed in 6 patients i.e. (30%) where as group- II Max improvement in 0 patients i.e (0%). Moderate improvement in 5 patients i.e. (25%).Mild improve in 6 patients i.e. (30%) and not improvement was noticed in 3 patients i.e. (15%). Where at the3 rd follow up on 21st day in group - I 1 patients i.e. (5%) was Cured and Max improve in 5 patients i.e. (25%). Moderate improvement in 7 patients i.e. (35%).Mild improve in 5 patients i.e. (25%) and not improvement was noticed in 2 patients i.e. (10%). Whear as group - II 4 patients i.e. (20%) was Cured and Max improve in 8 patients i.e. (40%). Moderate improvement in 3 patients i.e. (15%) Mild improve in 4 patients i.e. (20%) and not improvement was noticed in 1 patients i.e. (15%). Where as the 4th follow up on 28st day in group - I 16 patients i.e. (80%) was Cured and Max improve in 4 patients i.e. (20%). group - II 18 patients i.e. (90%) was Cured and Max improve in 2 patients i.e. (10%). After comparison of all above figures of sign & symptoms in Trial and Control groups, we can conclude that the treatment used in control group i.e. Treatment of Bhagandara (Fistula-in-ano) by Apamarga ksharasutra is more effective as compared to the treatment trail group Arka ksharasutra..

Over all clinical assessment of therapy

DISCUSSION

After comparison of all above figures of signs & symptoms in Trial and Control groups, we can conclude that the treatment used in control group i.e. Treatment of Bhagandara (Fistula-in-ano) by Apamarga ksharasutra is more effective as compared to the treatment with trail group i.e. Palashksharasutra.

Conclussion

After a clinical observation and statistical evaluation the following conclusions were drawn.

- The management of fistula in ano by khara sutra has been proved effective by this study.
- The undersired effects of ksharasutra management could be minimized by using palash ksharasutra..
- Palash kshara sutra has been found very effective in relieving symptoms i.e reduces pain, swelling, itching, discharge ,and local tenderness in fistula in shorter time.
- Both the varieties are cost effective can be easily prepared and can be easily applied with less recurrence after treatment.
- Management with Apamarga ksharasutra shows superiority than Palash ksharasutra.

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