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A Clinical Efficacy of *Palasha Ksharasutra* prepared with *Arka Ksheera* in the management of *Bhagandara*

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ABSTRACT

Bhagandara (Fistula in ano) is a common ano-rectal condition prevalent worldwide. *Ksharasutra* being a chief modality in management of *Bhagandara* in Ayurveda. Exploration of new plants for the preparation of *Ksharasutra* as a better substitute of *Apamarga Kshara* is need of the hour. Hence present research work was planned to evaluate the effect of *Palasha Ksharasutra* prepared with *Arka Ksheera* and to compare the effect of *Palasha Ksharasutra* prepared with *Arkaksheera* and *Apamarga Ksharasutra* in the management of *Bhagandara*. In this study sample size was 30, patients were selected by simple random sampling, 15 in Trial Group and 15 in Control Group. Trial group treated with *Palasha Ksharasutra* prepared with *Arkaksheera* and Control group treated with *Apamarga Ksharasutra* in *Bhagandara*. In both group patients were symptoms free after treating, but when compared to the cutting rate *Apamarga Ksharasutra* has average of 0.8cm and *Palasha Ksharasutra* prepared in *Arkaksheera* with an average of 0.68cm. Thus, *Palasha Ksharasutra* had equipotent effect as *Apamarga Ksharasutra*.

Key words: *Fistula-in-ano, Bhagandara, Palasha Ksharasutra, Apamarga Ksharasutra.*

INTRODUCTION

Bhagandara is a common disease occurring in anorectal region. The word *Bhagandara* is the combination of two words "*Bhaga*" and "*Daran*" which are derived from root *Bhaj* and *Dri Dhatu* respectively.^[1] The literal meaning of *Bhaga* is *Vagina*. In *Madhava Nidana*, *Bhaga* is used for *Vagina*, *Vasti* and *Guda*. In *Bhavaprakasha* it is used for *Yoni* and *Mehana*.^[3] *Bhaga* is a word, which means all the structures around the *Guda* including *Yoni* and *Basti*.

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The word *Daran* means tear of surface associated with pain. Finally it can be concluded that *Bhagandara*, is a pathological condition, which causes splitting / discontinuity / tear and pain, in the ano-rectal canal (*Guda*), *vagina (Bhaga)* or urinary bladder (*Vasthi*). The importance of this disease was first realized by *Acharya Sushruta* (800-1000 B.C.), The Father of Indian Surgery, who described it elaborately in his treatise.

In western medicine *Bhagandara* is compared with *Fistula in ano*. The word *fistula* is derived from a Latin word a reed, 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.^[12]

The anal abscess occurs in 26-38% adults in developing countries and the incidence of *Fistula* is about 8 -12% per 1,00,000 populations (Dr J Gnanaraj, 2016).

Acharya Sushruta in the 17th chapter of *Chikistastana* mentioned the application of *Ksharasutra* in *Nadi Vrana*^[4] and preparation of *Kshara* mentioned in 11th chapter *Sutrasthana*.^[2] The *Kshara Sutra* therapy was practiced and used since long with great success and without recurrences. The *Apamarga Ksharasutra* is prepared by repeated coatings of *Snuhi Ksheera*, *Apamarga Kshara* and *Haridra*.^[5] Still some of the problems are facing during the preparation and also in the course of *Ksharasutra* therapy, like collection and preservation of *Snuhi Ksheera*, burning pain during primary and successive changes, Local irritant skin reactions during course of therapy etc. 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. To overcome these disadvantages there is a need of most important preparation to make the treatment widely popular and acceptable.

Overcoming the causation of pain and burning sensation was a very important necessity because of which surgeons of *Ayurveda* came out with newer ideas. Thus it gave to many *Ksharasutras* 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 *Palasha Ksharasutra*^[2] prepared in *Arka Ksheera* was tried in the present study.

OBJECTIVES

To evaluate the effect of *Palasha Kshara Sutra* prepared in *Arkaksheera* and to compare the effect of *Palasha KsharaSutra* prepared with *Arkaksheera* and *Apamarga Kshara Sutra* in the management of *Bhagandara*.

MATERIALS AND METHODS

Present study was an open clinical study in which 30 patients were selected on the basis of simple random sampling (SRS) procedure and divided in 2 equal groups, strictly confined to the treatment of low anal fistula (sub-cutaneous). It was performed on the patients who attended the outpatient and inpatient

department of *Shalya Tantra*, Sri Siddharudha Chariatable Hospital, a teaching hospital of N.K.J. Ayurvedic Medical College and P.G Centre, Bidar.

Group I - 15 Patients were treated with *Palasha Ksharasutra* prepared in *Arka Ksheera*.

Group II - 15 Patients were treated with *Apamarga Ksharasutra* prepared in *Snuhi Ksheera*.

Inclusion Criteria

Criteria for the selection of patient were based on the following.

1. Irrespective of Age, Sex, Religion, Occupation, Economic status, Education status.
2. Patients with low anal fistula (*Bhagandara*).
3. Patients within the age of 16-65yrs.

Exclusion Criteria

Exclusion criteria were based on the following

1. Patients suffering from systemic diseases will be excluded
2. Patients with high rectal fistula will be excluded.
3. Patients suffering from CA of rectum, HbsAg and HIV will also be excluded
4. Patients suffering from ulcerative colitis, crohn's disease, Osteomyelitis of Pubic Bone will be excluded from the study.

Poorva Karma

The following instructions were advised before application of *Palasha Ksharasutra*,

- Administration of mild laxatives for regularization of bowels.
- Written Consent
- Patients were asked to maintain proper local part preparation and general hygiene.
- To control the local infection, inflammation, indurations, itching etc., with proper medicines.

- Administration of inj. Tetanus toxoid.

Pradhana Karma

Group 1: Application of Palasha Ksharasutra.

For the application of *Palasha Ksharasutra* the patients were asked to lie in lithotomy position and perianal region was cleaned with antiseptic lotions and draped. The patients were assured and gloved finger was gently introduced into the rectum. Then a suitable selected probe was passed through the external opening of fistula. The tip of the probe was forwarded along the path of least resistance being guided by the finger in rectum to reach into the lumen of anal canal through the internal opening and its tip was finally directed to come out of anal orifice. *Palasha Ksharasutra* was taken and threaded into the eye of probe, thereafter the probe was pulled out through the anal orifice to leave the thread behind in the fistulous track. The two ends of the thread were then tied together with a moderate tightness outside the anal canal.^[6]

Group 2: Application of the Apamarga Ksharasutra.

For the application of *Apamarga Ksharasutra*, the patient were asked to lie in lithotomic position and perianal region was cleaned with antiseptic lotions and draped. Thus, the patient was assured and gloved finger was gently introduced into the rectum. Then, a suitable selected probe was passed through the external opening of fistula. The tip of the probe was forwarded along the path of least resistance being guided by the finger in rectum to reach into the lumen of anal canal through the internal opening and its tip was finally directed to come out of anal orifice. *Apamarga Ksharasutra* was taken and threaded into the eye of probe. Thereafter the probe was pulled out through the anal orifice to leave the thread behind in the fistulous track. The two ends of the thread were then tied together with a moderate tightness outside the anal canal.^[6]

Paschat Karma

After Application of *Palasha Ksharasutra*;

- Patient were asked to have sitz bath daily twice or thrice from 2nd day onwards with *Triphala Kashaya*.

- Triphala Guggulu* one tablet given twice a day after food.
- To attend hospital for regular dressing and weekly change of thread.
- To take leafy vegetables, fruits, buttermilk etc., diet which would be nutritious easily digestible to develop the general condition of the patient and to avoid constipation.
- To avoid non vegetarian foods and spicy foods.
- To avoid prolong sitting and standing, riding on hard seats etc.
- To avoid straining during defecation.
- Ambulation of the patients was made a routine to encourage all the patients to remain as active as possible and to lead a perfectly normal life both physically as well as mentally.

Changing of the thread - In both the groups, thread was changed once in a week i.e. on 7th day, 14th day, 21st day and 28th day. Thread was changed by road - rail method.

Assessment Criteria

The clinical examinations of the patient were conducted before and after treatment and accordingly the effectiveness were evaluated as per the assessment criteria fixed. The subjective and objective parameters for assessment are as follows.

Subjective Parameters

Pain

Assessed by visual analog scale of pain

- G₀ - 0 - Absence of pain/no pain.
- G₁ - 1 to 3 mark on scale, Mild pain that can easily be ignored.
- G₂ - 4 to 6 mark on scale, Moderate pain that cannot be ignored, interferes with function, and needs treatment from time to time.
- G₃ - 7 to 10 marks on scale, Severe pain, that is present most of the time demanding constant attention.

Swelling

- G₀ - Absent
- G₁ - Slight swelling around the wound margin without indurations.
- G₂ - Swelling around wound margin with little area of indurations.
- G₃ - Swelling with marked indurations.

Itching

- G₀ - No itching
- G₁ - Itching sometimes but not interfering with activities and can be controlled voluntarily.
- G₂ - Itching interferes with function, involuntary and uncontrolled associated with skin patches
- G₃ - Itching that disturbs the sleep and/or demand treatment, associated with skin patches.

Discharge - was assessed by measuring the discharge by a pad of (3×3) × 1 cm.

- G₀ - No discharge
- G₁ - Mild discharge, single pad is sufficient per day.
- G₂ - Moderate discharge, 2 to 3 pads are necessary per day.
- G₃ - Profuse discharge more than three pads are necessary per day.

Objective Parameter

1) Local tenderness - was assessed by palpation of anal region.

- G₀ - No tenderness.
- G₁ - Mild tender but can be palpated.
- G₂ - Moderate tender on gentle palpation.
- G₃ - Severe tenderness, patient denies touching.

2) Indurations

- G₀ - Absent

- G₁ - Slight swelling around the wound margin without indurations.
- G₂ - Swelling around the wound margin with little area of indurations.
- G₃ - Swelling with marked indurations.

3) Length of tract (in cms)

$$\text{Unit cutting time} = \frac{\text{Initial length of the tract} - \text{Length of the tract remaining}}{\text{No. of weeks treated}}$$

Assessment of Result

For the purpose of the assessment of result we have used some grade points considering the severity of different sign and symptoms as follows.

Sign	Grade	Grade Point
+++	G ₃	3
++	G ₂	2
+	G ₁	1
-	G ₀	0

Clinical assessment of result

- **Cure** - 100% free from cardinal signs and symptoms, these are pain, swelling, discharge, itching, local tenderness, length of tract etc.
- **Max. Improvement** - 75% to 99% improvement of the above mentioned cardinal signs and symptoms.
- **Moderate Improvement** - 50% to 74% improvement of the above mentioned cardinal signs and symptoms.
- **Mild Improvement** - 25% to 49% improvement of the above mentioned cardinal signs and symptoms.
- **No. Improvement** - Less than 25% improvement of the above mentioned cardinal signs and symptom.

Study Design

According to the procedure stated above thirty patients with low anal fistula were selected for the study by random sampling technique method.

Group design

BT G ₁ vs AT G ₁	will be assessed	AT G ₁ vs AT G ₂	will be compared
BT G ₂ vs AT G ₂			

The clinical assessment was done in every 7 days interval. The initial findings were taken through clinically, pathologically and statements were compared with the result of progressive 7th day, 14th day and so on. Grading and grouping according to the assessment criteria and measurement scale concerned to each item categorically differentiated the findings among the patients in the clinical study. And finally the assessment as a whole was presented in percent value. In order to present the study in a scientific manner, the statistical assessment of the result were assessed by the result mean \pm S.D of each sign and symptom before treatment has been compared with mean \pm S.D value of after treatment. Paired t - test was used for the purpose of the test of significance. The effectiveness of *Palasha Ksharasutra* and *Apamarga Ksharasutra* were assessed through p - value.

OBSERVATION AND RESULTS

The present study was carried out on total 30 patients in two groups as prospective study by simple randomized method of selection. The patients were tested in this clinical trial for *Palasha Ksharasutra* and *Apamarga Ksharasutra*. The following observations were made during the course of the present clinical research.

Incidence according to Age and Sex

It has been observed from the study that, out of 30 patients, maximum No. of patients i.e. 09 (30.00%) were in between the age group 41 to 50 years, minimum patients reported in between the age group 61 to 70 years i.e. 03(10.00%) collectively there were 23 males and 07 female patients.

Incidence according to Religion

It was evidenced from the study that, out of 30 patients, maximum No. of patients 14 (46.67%) were Muslim, 7 (23.33%) Hindu patients reported, 6 (20%)

Christian patients were found and 3 (10%) Sikh patients were reported.

Incidence according to Marital Status

This study shows that incidence of *Bhagandara* was more in married patients with a percentage of 73.33% (22).

Incidence according to Occupation

This study shows distribution of patients according to occupation and its percentage. Incidence was more in labour class i.e. 15 patients 50.00%, service 05 (16.67%) patients, house wife 04 (13.33%) patients, student and business 03 (10%) patients were found.

Incidence according to Education

Incidence of education status revealed that 19 patients were uneducated i.e. (63.33%) and 11 patients were educated i.e. (36.67%).

Incidence according to socioeconomic status

Analysis of socio-economic status of 30 cases of Fistula-in-ano revealed that majority of patients i.e. 15(50%) belongs to poor class, 12 (40%) patients belongs to middle class and 03 (10%) patients from rich class were reported.

Incidence according to Dietary habits

The distribution of patients reveals that the maximum numbers of cases (72.6%) were habituated to take Non-vegetarian diet.

Table 1: Average unit cutting time (U.C.T.) of Group - 1

No. of patients	Initial length of Track (cms) BT.	7 th day	14 th day	21 st day	28 th day	Average U.C.T.
1.	4	4	3.5	2.4	1.2	0.7
2.	3	3	2.4	1.1	0.4	0.6
3.	4	3.8	2.7	1.9	1	0.7
4.	3.4	2.8	1.9	1.5	0.5	0.7

5.	2	2	1.4	0.6	0	0.5
6.	3	3	2.6	2	1	0.5
7.	4	4	3.2	2.1	0.9	0.7
8.	3	2.6	2	1	0.2	0.7
9.	2.5	2	1.6	1.2	0.2	0.5
10.	4	4	3.2	2	0.6	0.8
11.	4.5	4	3.1	2	0.3	1
12.	4	4	3.4	2	1.3	0.6
13.	3	2.9	2	0.7	0.2	0.7
14.	3	3	2.3	1.1	0.3	0.7
15.	4	4	3.2	2	0.5	0.8
Average U.C.T. = 0.68cm						

Table 2: Average unit cutting time (U.C.T.) of Group - 2

No. of patients	Initial length of Track (cms) BT.	7 th day	14 th day	21 st day	28 th day	Average U.C.T.
1.	6	5.8	4.9	3.7	2.2	0.9
2.	4	4	3.2	2	0.5	0.8
3.	4.5	4	2.8	1.4	0.5	1
4.	3.5	2.6	1.3	0.5	0	0.8
5.	5	4.5	3.9	2.4	1.2	0.9
6.	3	3	2.4	1.2	0	0.7
7.	4	3.8	2.6	1.4	0.5	0.8
8.	2.5	2.5	2	1.2	0	0.6
9.	4.5	4.5	3.6	2.5	1.5	0.7

10.	5	5	4	3.2	1.5	0.8
11.	3.5	3	2.5	1.5	0.7	0.7
12.	5.5	5.5	4.5	3.8	2.2	0.8
13.	3	3	2.3	1	0	0.7
14.	4	3.8	3	1.6	0.5	0.8
15.	5	4.5	3.6	2.2	1	1
Average U.C.T. = 0.8 cm						

RESULT

In the present clinical study the result of all the cases were noted on the basis of following points.

Table 3: Showing the effect of Trial group

Sign and Symptoms	BT Mean ± S.E.	Assesment	Mean ± S.E.	t	p	Effectiveness %	Remark
Pain on VAS	2.06±0.18	1	2.06±0.18	0.56	>0.05	2.85	NS
		2	1.86±0.13	3.68	<0.001	27.77	HS
		3	1.53±0.16	15.58	<0.001	27.77	HS
		4	0.86±0.13	18.66	<0.001	48.57	HS
Swelling	2.21±0.18	1	2.21±0.18	1.46	>0.05	6.66	NS
		2	2.21±0.18	1.46	>0.05	6.66	NS
		3	1.21±0.10	6.51	<0.001	45.16	HS
		4	0.42±0.13	14.50	<0.001	80.64	HS
Itching	2.06±0.18	1	2.06±0.18	0.56	>0.05	3.12	NS

		2	2.06±0.18	0.56	>0.05	3.12	NS
		3	1±0.13	9.02	<0.001	51.61	HS
		4	0.4±0.13	10.45	<0.001	80.64	HS
Discharge	2.33±0.18	1	2.33±0.18	2.25	<0.05	10.52	S
		2	1.73±0.15	4.58	<0.001	25.714	HS
		3	1.2±0.10	6.85	<0.001	48.57	HS
		4	0.46±0.13	20.54	<0.001	80	HS
Local Tenderness	2.4±0.13	1	2.4±0.13	1	>0.05	2.85	NS
		2	1.73±0.15	5.29	<0.001	27.77	HS
		3	1.2±0.10	11.2	<0.001	50	HS
		4	0.66±0.12	14.66	<0.001	72.22	HS
Length of Track	3.46±0.17	1	3.46±0.17	10.66	<0.001	28.03	HS
		2	2.50±0.17	10.26	<0.001	25.8	HS
		3	1.57±0.14	17.80	<0.001	54.52	HS
		4	0.57±0.10	19.55	<0.001	83.42	HS
Df = 14							

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, 1.53±0.16 after 21 days and 0.86±0.13 after 28 days. The test of significance shows that *Palasha* is highly significant to reduce pain with the P-value < 0.001 in AT1, AT2, AT3 and AT4 respectively.

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

Itching- The mean ± S.E. before treatment was 2.06±0.18, was same 2.06±0.18 after 7 days, 2.06±0.18 after 14 days, was reduced to 1±0.13 after 21 days and 0.4±0.13 after 28 days. The test of significance shows that *Palasha* is highly significant to reduce itching with the P-value < 0.001 in AT1, AT2, AT3 and AT4 respectively.

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

Local of Tenderness- The mean ± S.E. before treatment was, 2.4±0.13 and was same 2.4±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 *Palasha* is highly significant to reduce local tenderness with the P-value < 0.001 in AT1, AT2, AT3 and AT4 respectively.

Length of track- The mean ± S.E. before treatment was 3.46±0.17 and was same 3.46±0.17 after 7 days, were reduced to 2.50±0.17 after 14 days, 1.57±0.14 after 21 days and 0.57±0.10 after 28 days. The test of significance shows that *Palasha* is highly Significant to

reduce length of track with the P-value < 0.001 in AT1, AT2, AT3 and AT4 respectively.

Table 4: Showing the effect of Control Group

Sign and Symptoms	BT Mean ± S.E.	Assessment	Mean ± S.E.	t	p	Effectiveness %	Remark
Pain on VAS	1.53±0.16	1	1.53±0.16	4.67	>0.05	2.85	NS
		2	1.73±0.15	2.25	>0.01	10.52	S
		3	1.26±0.15	7.29	<0.001	36.84	HS
		4	0.73±0.11	8.76	<0.001	52.94	HS
Swelling	2.13±0.16	1	2.13±0.16	1.46	>0.05	6.06	NS
		2	2.06±0.18	0.56	>0.05	3.12	NS
		3	1.13±0.135	7.24	<0.001	46.8	HS
		4	0.2±0.10	16.35	<0.001	90.625	HS
Itching	2.06±0.18	1	2.06±0.18	1.87	>0.05	9.67	NS
		2	1.86±0.13	1.87	>0.05	9.67	NS
		3	0.86±0.13	8.29	<0.005	58.06	S
		4	0.2±0.10	9.72	<0.001	90.32	HS
Discharge	2.13±0.13	1	2.13±0.13	0.56	>0.05	3.03	NS
		2	1.6±0.13	4	>0.001	25	S
		3	1±0	8.5	<0.001	53.12	HS

					1		
		4	0.2±0.10	12.61	<0.001	90.62	HS
Local Tenderness	2.4±0.13	1	2.4±0.13	1	>0.05	2.85	NS
		2	1.6±0.13	5.24	<0.001	35.13	HS
		3	1.33±0.09	10.58	<0.001	54.05	HS
		4	0.33±0.12	23.48	<0.001	86.48	HS
Length of Track	4.2±0.25	1	4.2±0.25	2.61	<0.05	21.18	S
		2	3.10±0.25	9.66	<0.001	26.03	HS
		3	1.97±0.25	1.67	<0.001	53.01	HS
		4	0.82±0.19	29.56	<0.001	80.47	HS
Df = 14							

The above statistical analysis shows that in case of

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 and 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, 1.13±0.135 after 21 days and 0.2±0.10 after 28 days. The test of significance shows that *Apamarga* is highly significant to reduce swelling with the P-value <0.001 in AT1, AT2, AT3 and AT4 respectively.

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 and 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 and AT4 respectively.

Discharge - The mean \pm S.E. before treatment was 2.13 ± 0.13 , was same 2.13 ± 0.13 after 7 days, was reduced 1.6 ± 0.13 after 14 days, 1 ± 0 after 21 days and 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 and AT4 respectively.

Local of Tenderness - The mean \pm S.E. before treatment was 2.4 ± 0.13 , was same 2.4 ± 0.13 after 7 days, was reduced to 1.6 ± 0.13 after 14 days, 1.33 ± 0.09 after 21 days and 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 and AT4 respectively.

Length of track - The mean \pm 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 and AT4 respectively.

Overall clinical assessment of therapy

In Group I, 12 patients (80%) completely cured. In group II, 14 patients (93.33%) got completely 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 2 patients i.e. (13.33%). Mild improve in 5 patients i.e. (33.33%) and not improvement was noticed in 8 patients i.e. (53.33%) whereas group- II Moderate improvement in 3 patients i.e. (20%). Mild improve in 4 patients i.e. (26.67%) and not improvement was noticed in 8 patients i.e. (53.33%).

Where at the 2nd follow up on 14th day in group - I Maximum improvement in 2 patients i.e (13.33%). Moderate improvement in 3 patients i.e. (20%). Mild

improve in 4 patients i.e. (26.67%) and not improvement was noticed in 6 patients i.e. (40%) whereas group - II Maximum improvement in 3 patient's i.e. (20%). Moderate improvement in 5 patients i.e. (33.33%). Mild improve in 3 patients i.e. (20%) and not improvement was noticed in 4 patients i.e. (26.67%)

Where at the 3rd follow up on 21st day in group - I, 1 patients i.e. (6.67%) was Cured and Maximum improve in 3 patients i.e. (20%). Moderate improvement in 6 patients i.e. (40%). Mild improve in 3 patients i.e. (20%) and not improvement was noticed in 2 patients i.e. (13.33%). Whereas group - II, 2 patients i.e. (13.33%) were Cured and Maximum improve in 5 patients i.e. (33.33%). Moderate improvement in 4 patients i.e. (26.67%) Mild improve in 3 patients i.e. (20%) and not improvement was noticed in 1 patient i.e. (6.67%).

Whereas the 4th follow up on 28st day in group - I, 12 patients i.e. (80%) was Cured and Maximum improve in 3 patients i.e. (20%). group - II 14 patients i.e. (93.33%) was Cured and Maximum improve in 1 patient i.e. (6.66%).

Table 5: Average Unit cutting time in days/cm in Control and Trial Groups

Group of Patient	pH	Mean \pm S.E.	t - value & P - value	Average CUT cms/day
<i>Apamarga Kshara Sutra</i> - 15(C.G)	9.72	4.2 ± 0.25	29.56 & < 0.001	0.80
<i>Palasha Kshara Sutra</i> - 15(T.G)	7.5	3.46 ± 0.17	19.55 & < 0.001	0.68

After comparison of all above figures of sign and symptoms in Trial and Control groups, we can conclude that the treatment used in trial group i.e. *Palasha Kshara Sutra* prepared with *Arka Ksheera* is

having equipotent effect as compared to the treatment control group *Apamarga Ksharasutra*.

DISCUSSION

The assessment of results is mainly based on parameters like pain, swelling, itching, discharge, induration, tenderness and unit cutting time (UCT).

Discussion on Pain: In the trial group before treatment mean and SE assessed over the pain were 2.06 after the treatment it was reduced to 0.86 showing highly significant effect because of *Vedana Shamaka, Ksharana, Teekshna* and *Ushnaguna* and chemical constituents butin, calotropian, glycosides are having pain relieving properties of the *Palashakshara* and *Arkaksheera* definitely debribes fistula tract followed with continuous pus drainage subsequently reduces pain.^[9]

Discussion on Swelling: In the trial group before treatment mean and SE assessed over the induration was 2.21 after the treatment it was reduced to 0.42 showing highly significant effect because of *Antikatu, Tikta, Kashaya Rasa, Laghu, Ruksha, Teekshnaguna, Ushnaveerya* of the proposed drug reduces the tissue response.^[9]

Discussion on Itching: In the trial group before treatment mean and SE assessed over the itching was 2.06 after the treatment it was reduced to 0.4 showing highly significant effect because of *Krimigna, Kandugna* properties of *Palashakshara* and *Arkaksheera* possesses the antipruritic action.^[40] Chemical constituents butin, tannin, protimin, calotropian are having antifungal property which reduces itching.^[11]

Discussion on Discharge: In the trial group before treatment mean and SE assessed over the discharge was 2.33 after the treatment it was reduced to 0.46 showing highly significant effect, debribment action of the *Ksharana, Vranaropana* properties of *Palashakshara* and *Arkaksheera* definitely reduces the different type of discharges.^[10]

Discussion on Induration: In the trial group before treatment mean and SE assessed over the induration was 2.21 after the treatment it was reduced to 0.42 showing highly significant effect because of *Antikatu,*

Tikta, Kashaya Rasa, Laghu, Ruksha, Teekshnaguna, Ushnaveerya of the proposed drug reduces the tissue response.^[9]

Discussion on Tenderness: In the trial group before treatment mean and SE assessed over the local tenderness was 2.4 after the treatment it was reduced to 0.66 showing highly significant effect because *Vedanashamaka* properties, butin, monospermin, tannin and proteolitin chemical constituents of the proposed drug increases cutting rate of the fistulas tract subsequently reduces the surrounding tenderness.^[10]

Discussion on Unit Cutting Time: Average U.C.T. is 0.8cm/day in control group compared to 0.68cm/day in trial group. In the trial group before treatment mean and SE assessed over the length of track were 3.46 after the treatment it was reduced to 0.57 showing highly significant effect. The average UCT was 0.68cms/day. Because *Palashaksharasutra* prepared with *Arkaksheera* having the *Chedana, Bhedana, Ksharana* and *Ropana* properties of proposed drug may reduce the length of the tract. *Apamarga Ksharasutra* is alkaline and its pH is 9.72, whereas *Palasha Ksharasutra* is alkaline with pH of 7.5. So the pain and burning sensation was comparatively less in trial group with U.C.T. almost equal to control group 0.8cm/day in control group compared to 0.68cm/day in trial group.

In group I, 12 patients (80%) and In group II, 14 patients (93.33%) 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 2 patients (13.33%), Mild improvement in 5 patients (33.33%) and no improvement was noticed in 8 patients (53.33%) where as in group - II; Moderate improvement in 3 patients (20%), Mild improvement in 4 patients (26.27%) and no improvement was noticed in 8 patients (53.33%),

Where at the 2st follow up on 14th day in group - I, Maximum improvement in 2 patients (13.33%). Moderate improvement in 3 patients (20%). Mild improvement in 4 patients (26.66%) and no

improvement was noticed in 6 patients (40%) where as in group - II Maximum improvement in 3 patients (20%). Moderate improvement in 5 patients (33.33%). Mild improvement in 3 patients (20%) and no improvement was noticed in 4 patients (26.66%).

Where at the 3rd follow up on 21st day in group - I, 1 patient (6.66%) was cured and maximum improvement in 3 patients (20%). Moderate improvement in 6 patients (40%). Mild improvement in 3 patients (20%) and no improvement was noticed in 2 patients (13.33%). Whereas group - II, 2 patients (13.33%) was cured and maximum improvement in 5 patients (33.33%). Moderate improvement in 4 patients (26.66%), mild improvement in 3 patients (20%) and no improvement was noticed in 1 patient (6.66%).

Whereas the 4th follow up on 28st day in Group - I, 12 patients (80%) were cured and maximum improvement in 3 patients (20%). Group - II, 14 patients (93.33%) were cured and maximum improvement in 1 patient (6.66%).

After comparison of all above figures of signs and symptoms in trial and control groups, we can conclude that the treatment used in *Bhagandara* (Fistula-in-ano) *Palashaksharasutra* prepared with *Arkaksheera* is having equipotent result as compared to *Apamargaksharasutra*.

CONCLUSION

Based on the above clinical statistical data it may be concluded that the management of *Bhagandara* by *Ksharasutra* has been proved effective by this study. The undesired effects of *Ksharasutra* management could be minimized by using *Palasha Ksharasutra* prepared with *Arkaksheera*. *Palasha Ksharasutra* prepared in *Arkaksheera* has been found very effective in relieving symptoms i.e. reduces pain, swelling, itching, discharge and local tenderness in fistula in short duration. *Palasha Ksharasutra* prepared with *Arkaksheera* is best alternative to *Apamarga Ksharasutra* prepared in *Snuhiksheera* in the management of *Bhagandara*.

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