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A COMPARATIVE CLINICAL STUDY ON EFFICACY OF GUGGULU BASED PALASH KSHARA SUTRA WITH CHEDANA IN BHAGANDARA

Dr. Abdul Batin*[1] and Dr. Binod Kalita[2]

[1]PG Scholar, [2]Assistant Professor

Dept. of Shalya Tantra, Govt. Ayurvedic College, Guwahati.

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***Corresponding Author**
Dr. Abdul Batin
PG Scholar, Dept. of Shalya Tantra, Govt. Ayurvedic College, Guwahati.

ABSTRACT

Bhagandara is a common ano-rectal disease, on the other hand it is very difficult to treat due to its recurrence rate and complications hence Acharya Sushruta has included it in the group of *Asta Mahagada*. The clinical features of *Bhagandara* resembles with fistula-in-ano as described in modern science. *Ksharasutra* is already established as a big revolution in the treatment of fistula-in-ano and proved more effective and minimal recurrence than modern treatment alternatives like Fistulectomy, Fibrin glue, Ligation of intersphincteric fistula tract (LIFT), endo rectal advancement flap, VAAFT etc. *Ksharasutra* generally prepared with *Snuhi ksheera*, *Apamarga* and *Haridra*. Though in conventional method collection of *Snuhi ksheera* is difficult and time consuming. *Guggulu* is having similar binding property as *Snuhi ksheera* and also has anti-septic, anti-inflammatory and wound healing properties, hence in this study *Snuhi ksheera* is replaced with *Guggulu* and study is carried out to compare the efficacy of Guggulu based *Palash ksharasutra* with *chedana* in *Bhagandara*. The results showed significant relieve in subjective and objective parameters and did not cause any obstacle in patients daily routine work during the therapy period. No significant complication observed to the patients in follow up period.

KEYWORDS: *Bhagandara*, Fistula-in-ano, *Guggulu* based *Palash ksharasutra*, *chedana.*

INTRODUCTION

The disease *Bhagandara* (Fistula-in-ano) is a very common ano-rectal disease. *Acharya Sushruta* has included it in the group of *Ashtamahagada*, the disease which is very difficult to

treat. In spite of various treatment modalities available in the modern science the recurrence rate of fistula-in-ano is very high. Ayurvedic para-surgical procedure *Ksharasutra* has been proved more effective treatment in fistula-in-ano, minimum recurrence than modern treatment alternatives. In Bailey and Love's Short practice of Surgery the author has included *Ksharasutra* as a treatment method for fistula-in-ano while describing various methods for treatment in its several editions including latest 27th edition. Nowadays *Ksharasutra* become the first choice for the treatment of fistula-in-ano. Many modern hospitals, even modern medical colleges are referring patients of fistula-in-ano to Ayurvedic hospital for *Ksharasutra* therapy. The Indian Council of Medical Research (ICMR) has validated this therapy by conducting multicentric research trial and concluded that Ksharasutra is better than conventional surgery in fistula-in-ano. The conventional *Apamarga Ksharasutra* is prepared with *Snuhi ksheera*, *Haridra* powder and *Apamarga Kshara*. It is a well-proven method to treat fistula-in-ano and has been standardized by CCRAS, New Delhi. Moreover, recent studies have shown that *Guggulu*-based *Ksharasutra* is more beneficial than conventional *Apamarga Ksharasutra*. However collection of *Snuhi ksheera* is very difficult and requires specific season, time and additional labour, and also *Snuhi ksheera* can not be preserved for longer duration. *Shodhita Guggulu* was selected as an alternative to *Snuhi ksheera* for preparation of *Ksharasutra*, having binding property and also having antiseptic, anti-inflammatory and wound healing properties and all these properties can increase the therapeutic effect of *Guggulu*-based *Ksharasutra*. That is why in this study *Snuhi ksheera* is replaced by *Guggulu*.

MATERIALS AND METHODS

Selection of patients: Total 60 diagnosed cases of Bhagandara (Fistula-in-ano) were registered from OPD and IPD of Shalya Tantra Department of Govt. Ayurvedic College and Hospital, Guwahati.

Inclusion criteria

- Patients of age between 15-70 years of either sex.
- All clinically diagnosed cases of Fistula-in-ano.
- Fresh or recurrent cases

Exclusion criteria

- Patient with malignancy (anus, rectum, prostate)
- Fistula-in-ano secondary to ulcerative cholitis and Crohn's disease.

- Bleeding disorders
- Fistula concern with other organs like urethra, vagina etc.
- Uncontrolled Diabetes mellitus, Hypertension, Tuberculosis, Chronic Liver disease, Metabolic disorders etc.
- HIV, HBsAg, HCV possitive patients.
- Multiple fistula

Investigations

• Blood routine test - TC, DLC, Hb%, ESR

• BT, CT

• Blood sugar (fasting and post prandial), HbA1C (optional)

• Blood urea and serum creatinine

• Urine investigation - routine and microscopic (optional)

• Stool examination - routine, microscopic and for occult blood (optional)

• Pus for AFB & Culture and sensitivity/ CBNAAT(optional)

• Radiological examination - Fistulography or MR Fistulogram or Colonoscopy or CT scan (optional)

• HIV, HBsAg, Anti HCV

• Biopsy

• Chest X-ray

• ECG

• Ultrasonography (optional)

• Rapid Antigen Test (RAT)/ RT-PCR for COVID - 19

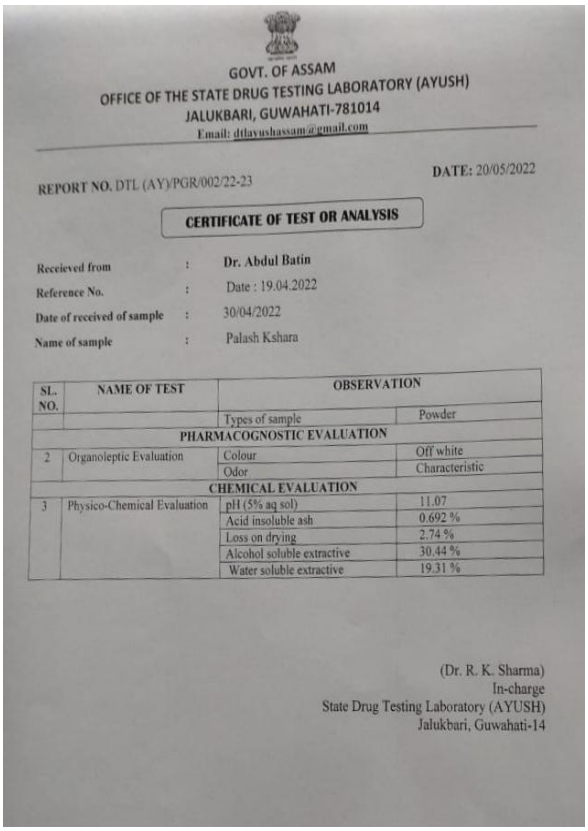
MATERIALS

- Patient (as per inclusion Criterias)
- Guggulu based palash kshara sutra will be prepared as per standard technique with the help of following materials,
- Barbour surgical liner thread no. 20
- Palash kshara (*Butea monosperma*)
- Haridra powder (*Curcuma longa Linn*)
- Purified guggulu (*Commiphora mukul*)

Preparation of *Guggulu* based Palash Ksharasutra

Barbour threads tied in the *Ksharasutra* hanger than 11 coatings of *Guggulu* were given on linen Barbour threads, seven coatings were given with *Guggulu* and Palash Kshara and then three coatings were given with *Guggulu* and *Haridra* powder. After each coating, the thread was dried in *Ksharasutra* cabinet and again coatings of above ingredients were done one by one. Total 21 coatings on the Barbour threads were done.

Pharmacognostic and Physicochemical evaluation of Palash



GOVT. OF ASSAM
OFFICE OF THE STATE DRUG TESTING LABORATORY (AYUSH)
JALUKBARI, GUWAHATI-781014
Email: dtlayushassam@gmail.com

REPORT NO. DTL (AY)/PGR/002/22-23 DATE: 20/05/2022

CERTIFICATE OF TEST OR ANALYSIS

Received from : Dr. Abdul Batin
Reference No. : Date : 19.04.2022
Date of received of sample : 30/04/2022
Name of sample : Palash Kshara

SL. NO.	NAME OF TEST	OBSERVATION	
		Types of sample	Powder
PHARMACOGNOSTIC EVALUATION			
2	Organoleptic Evaluation	Colour	Off white
		Odor	Characteristic
CHEMICAL EVALUATION			
3	Physico-Chemical Evaluation	pH (5% aq sol)	11.07
		Acid insoluble ash	0.692 %
		Loss on drying	2.74 %
		Alcohol soluble extractive	30.44 %
		Water soluble extractive	19.31 %

(Dr. R. K. Sharma)
In-charge
State Drug Testing Laboratory (AYUSH)
Jalukbari, Guwahati-14

METHODOLOGY

Trial Group

30 numbers of patient were truly treated by chedana in Bhagandara with application of guggulu based palash ksharasutra in the small tract remaining after excising the external fistulous tract upto the level of sphincter muscle.

Control group

30 numbers of patients were truly treated with application of guggulu based palash kshara sutra under anesthesia.

Ksharasutra Application Method

Patient was placed in Lithotomy position after standard pre - operative conduct. The *Ksharasutra* was inserted/applied into the fistulous tract under Spinal anesthesia (Saddle block) with the help of a specially designed malleable metal probe following all aseptic precautions. Post operatively, patient was kept in head low position and nil by mouth for about six hours, followed by liquid and semi solid diet as per set protocol. Appropriate antibiotics and analgesic drugs were given for three consecutive post-operative days. Patient was advised to start warm water Sitz bath from the next day of procedure followed by dressing with sterile gauze.

Both the groups were given the following medications through out the follow up period.

• *Triphala Guggulu* tablet, 1 g/2 tab. (500 mg of each tab.) three times a day with warm water after food was also given.

• *Triphala Churna*, 2tsf with a cup of Luke warm water at bed time also given in case constipation.

Duration of Therapy: The Ksharsutra was replaced with a newer Ksharasutra on every 7th day by 'Railroad method' till the fistulous tract completely healed up. The total duration of treatment was different for each patient as the length of tract varied from patient to patient.

Follow up: After cut through of the fistulous tract, patients were called for follow up assessment on after one month and 3 month.

Criteria for assessment

The assessment was done on the basis of objective/subjective parameters such as relief in symptoms like pain, discharge, itching and swelling in the anal region and objective parameters, i.e., UCT (Unit cutting time)

Objective parameter

Unit Cutting Time (UCT)

UCT= Total numbers of days to completely heal the tract ÷ initial length of the tract.

Unit healing rate = Initial length of the tract ÷ total numbers of weeks to completely heal the fistula tract.

Subjective parameter

- Pain: Visual analogue scale allows patient to rate pain intermittently on a numbered scale such as 0-3. It will be applied as
  - No pain- 0
  - Mild or bearable- 1
  - Moderate- 2
  - Severe- 3
- Discharge-
  - No discharge- 0
  - Scanty and little- 1
  - Seropurulent- 2
  - Profuse purulent- 3

• Colour

- Red healthy granulation tissue- 0
- Unhealthy granulation tissue without slough- 1
- Unhealthy granulation tissue with slough- 2
- Unhealthy granulation tissue with slough and surrounding edema- 3

• Itching

- No itching- 0
- Mild or bearable- 1
- Intractable- 2

OBSERVATION AND RESULT

Comparison of Effect of trial therapy and control therapy on Pain

	$\bar{x}$ T±SD	$\bar{x}$C ±SD	SE	T_{58}	P value	Remarks
F1	1.13±0.68	0.9±0.60	0.01	1.4	0.08342	Not significant
F2	1.27±0.9	0.93±0.73	0.02	1.56	0.062127	Not significant
F3	1.07±1.1	0.93±0.86	0.03	1.13	1.12749	Not significant
F4	1.07±1.0	0.93±0.78	0.03	0.88	0.19228	Not significant
F5	1.17±1.14	1.07±0.74	0.03	1.04	0.152345	Not significant
F6	1.1±1.06	0.83±0.75	0.02	2.34	0.011247	Significant

Comparison of effect of both the group on pain, on day 7, t= 1.49 & p= 0.14731, hence the result is not significant at p< 0.05. On day 14, t=1.41 & p= 0.16936, hence the result is not significant at p<0.05. Similarly on day 21,28 & 35 also, the result is not significant at p

<0.05. Thus, there is no difference in effect of both the groups on pain. On day 42, t= 2.34, p= 0.011247, hence the result is significant at p <0.05.

Comparative Effect of trial therapy and control therapy on discharge

	x̄ T±SD	x̄C ±SD	SE	T_{58}	P value	Remarks
F1	0.9±0.60	0.77±0.62	0.18	0.59	0.278112	Not significant
F2	0.87±0.68	0.7±0.65	0.2	0.68	0.246408	Not significant
F3	0.83±0.83	0.87±0.62	0.17	0.43	0.33598	Not significant
F4	0.93±0.58	1.03±0.76	0.17	1.48	0.072452	Not significant
F5	0.77±0.62	0.93±0.69	0.2	0.72	0.236831	Not significant
F6	0.8±0.61	1.13±0.63	0.17	1.68	0.048845	Significant

Comparison of effect of both the group on discharge, On day 7, t=0.57, p=0.57251, hence the result is not significant at p<0.05. Similarly on day 14, 21, 28 & 35, the result is not significant at p<0.05. on day 42, t=1.68, p= 0.048845, hence the result is significant at p< 0.05. Thus there is no difference between the effect of both the group on discharge.

Comparison of both the group for colour

	x̄ T±SD	x̄C ±SD	SE	T_{58}	P value	Remarks
F1	0.5±0.508548	1.07±0.58	0.01	4.01	0.000088	Significant
F2	0.33±0.479463	0.37±0.49	0.01	0.27	0.395484	Not significant
F3	0.5±0.508548	0.47±0.5	0.01	0.25	0.400142	Not significant
F4	0.37±0.490133	0.57±0.5	0.01	1.56	0.062316	Not significant
F5	0.47±0.507416	0.47±0.5	0.01	0	0.5	Not significant
F6	0.4±0.498273	0.53±0.5	0.01	1.03	0.154363	Not significant

Comparison of effect of both the group on colour, on day 7, t=4.01, p=0.000088, hence the result is significant at p<0.05. On day 14, t=1.15, p=0.25817, hence the result is not significant at p<0.05. Similarly on day 21, 28, 35, & 42, the result is not significant at p<0.05. Thus, there is no difference between the effect of both the group on colour of the wound.

Comparative Effect of trial therapy and control therapy on itching

	x̄ T±SD	x̄C ±SD	SE	T_{58}	P value	Remarks
F1	0.3±0.47	0.73±0.52	0.01	3.4	0.00062	Highly significant
F2	0.47±0.51	0.5±0.51	0.01	0.25	0.400142	Not significant
F3	0.6±0.5	0.53±0.51	0.01	0.51	0.304792	Not significant
F4	0.53±0.51	0.6±0.5	0.01	0.51	0.304792	Not significant
F5	0.7 ±0.47	0.47±0.51	0.01	1.85	0. 034347	Significant
F6	0.9 ±1.99	0.5±0.51	0.01	0.51	0.26381	Not significant

Comparison of effect of both the group on itching, on day 7, t=3.79, p=0.0007, hence the result is highly significant at p<0.05. On day 14, t=0.33, p=0.74501, hence the result is not

significant at P<0.05. Similarly on day 21, 28 & 42, the result is not significant at p<0.05. On day 35, t=1.85, p= 0.034347, hence the result is significant at p <0.05. Thus there is remarkably less itching in trial group than control on day 7. But on rest of the follow up there was no difference in between the effect of both the group on Itching.

Comparative Effect of trial therapy and control therapy on unit cutting time

	x̄ T±SD	x̄C ±SD	SE	T_{58}	P value	Remarks
KS_0	7.13±2.31	0.98±0.24	0.09	14.47	<0.00001	Highly significant
KS_7	8.07±2.38	1.75±0.36	0.1	14.36	<0.00001	Highly significant
KS_{14}	10.13±3.2	2.73±0.38	0.11	12.97	<0.00001	Highly significant
KS_{21}	10.78±3.1	3.7±0.4	0.17	10.89	<0.00001	Highly significant
KS_{28}	11.1±3.26	0.47±0.51	0.16	12.35	<0.00001	Highly significant
KS_{35}	11.35±3.4	0.5±0.51	0.19	9.79	<0.00001	Highly significant
KS_{42}			0.21	8.89	<0.00001	

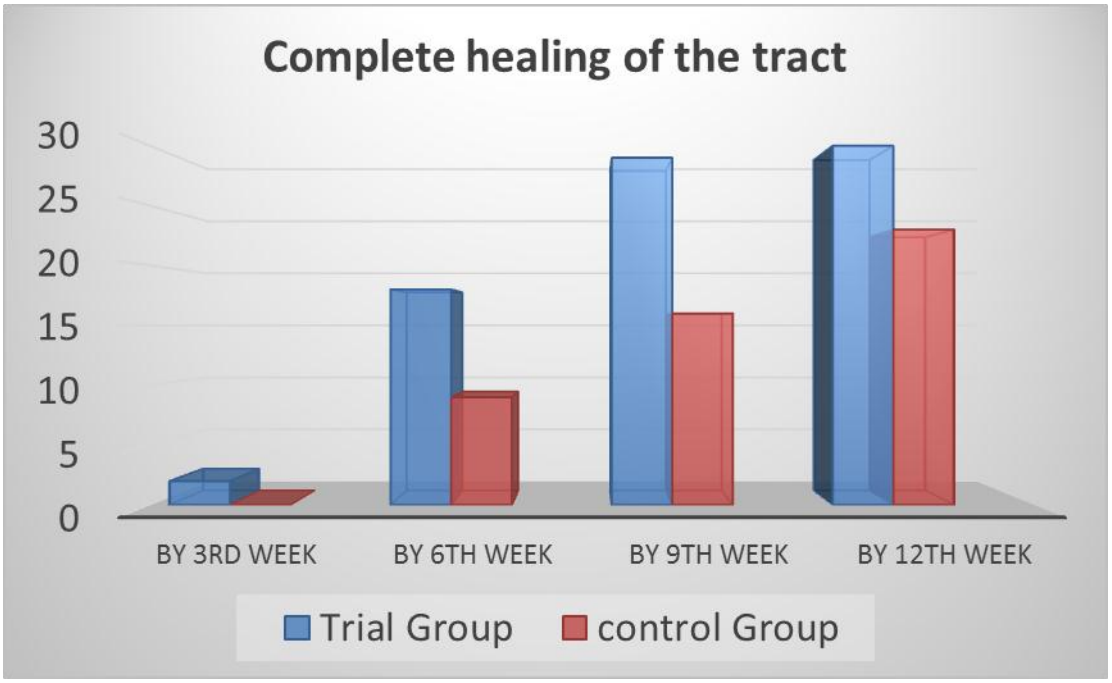
On comparison of the effect of both the therapy w.s.r unit cutting time, both the groups were significant, but the duration of the therapy was completed by 6th week in the trial group in maximum numbers of the cases whereas in control group it takes more than 12 weeks for completion of the therapy in maximum numbers of the patients.

Complete healing of the tract

Group	By 3rd week		By 6th week		By 9th week		By 12th week	
	No. of pts	%	No. of pts.	%	No. of pts.	%	No. of pts.	%
Trial Group	02	6.67%	18	60%	29	96.7%	30	100%
Control Group	00	00%	09	30%	16	53.34%	23	76.67%

It is observed that in trial group, in 2 numbers of patients (6.67%) the tract was completely healed by 3rd week, in 18 numbers of patients (60%) the tract was completely healed by 6th week and in 29 numbers of patients (96.7%) the tract was completely healed by 9th week. And in 100% of the patients the tract was completely healed by 12th week.

In control group, In 0 numbers of patients, the tract was completely healed. By 6th week, the tract was completely healed in 9 numbers of patients (30%). By 9th week, in 16 numbers of patients (53.34%), the tract was completely healed. And by 12th week in 23 numbers of patients (76.67%) the tract of the fistula was completely healed.



In this study 60 numbers of patients were studied in two groups. In the trial group, initial length of fistulous tract was measured first. Then partial *chedana* (excision) of the fistula tract along with *ksharasutra* application done. From external opening upto the sphincter muscle excision is done and the tract lying from sphincter muscle to internal opening is treated by *guggulu* based *palash ksharasutra* ligatures. The wound was dressed with *yastimadhu taila* in post operative period. And in the control group the fistulous tract was treated with the *guggulu* based *palash ksharasutra* as per conventional method. It is observed that partial fistulotomy with ksharasutra application for management of Fistula in ano has significantly reduced the duration of kshara sutra therapy in comparison to conventional ksharasutra therapy.

DISCUSSION

Ksharasutra is a time tested treatment modality for fistula-in-ano which act as chemical and mechanical cutting seton as well as helps in healing of the tract without any significant loss of continence. Pain and duration of healing is a must anticipated problem for *ksharasutra* therapy. As *guggulu* has anti-inflammatory properties, it significantly reduces the pain throughout the treatment period & *Guggulu* based *Palash kshara sutra* is very less time consuming treatment procedure for fistula in ano specially fistula in ano with long tract than conventional *ksharasutra* therapy. *Haridra* has the property for antiseptic and early tissue replacement probably act as an growth factor.

It is observed that in trial group, in 2 numbers of patients (6.67%) the tract was completely healed by 3rd week, in 18 numbers of patients (60%) the tract was completely healed by 6th week and in 29 numbers of patients (96.7%) the tract was completely healed by 9th week. And in 100% of the patients the tract was completely healed by 12th week.

In control group, In 0 numbers of patients, the tract was completely healed. By 6th week, the tract was completely healed in 9 numbers of patients (30%). By 9th week, in 16 numbers of patients (53.34%), the tract was completely healed. And by 12th week in 23 numbers of patients (76.67%) the tract of the fistula was completely healed.

SUMMARY AND CONCLUSION

In this comparative clinical study, 60 numbers of cases treated in two groups following standard protocol and guidelines for *ksharasutra* therapy. Both the group is effective for the management of fistula-in-ano but considering the duration of treatment *Palasha-Guggulu ksharasutra* with *chedana* is less time consuming than conventional *Palash-Guggulu Ksharasutra* therapy which need further multicentric scientific study.

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