

A CLINICAL TRIAL ON THE EFFICACY OF PALASHAGUGULUKSHARA SUTRA WITH THE APAMARGASNUHIKSHARA SUTRA IN THE MANAGEMENT OF BHAGANDARA

Bijit Das¹, Pankaj Kr. Barman²

¹PG Scholar, ²Associate Professor;

Department of ShalyaTantra, Govt. Ayurvedic College & Hospital, Guwahati, Assam, India

Email: urbijit@gmail.com

ABSTRACT

Purpose of the study: In the context of *Shalya Shastra Acharya Sushruta* has mentioned about different types of ano- rectal diseases which can be treated with different surgical and parasurgical methods of treatment. *Kshara Sutra* therapy is one which has been mentioned for the diseases so called *Bhagandara*. And for the preparation of *Kshara Sutra* a group of *Kshara* producing plants has been mentioned in the same classical text. In this present study the efficacy of *Palasha Guggulu kshara Sutra* has been compared with conventional *Apamarga Snuhi Kshara Sutra* therapy. **Material and Methods:** In this study 60 patients of *Bhagandara* were registered from OPD of Deptt. Of *Shalya Tantra*, Govt. Ayurvedic College & Hospital, Guwahati and were planned for open clinical trial. The cases were selected randomly for both the groups. The cases of control group had been treated with the application of conventional *Apamarga Snuhi Kshara Sutra* and the patients of trial group were treated with *Palasha Guggulu Kshara Sutra* after taking proper consent. The procedures were continued till cut through of the tract and required follow up done. The parameters were recorded in pre- designed proforma for statistical evaluation. **Results:** The results were found satisfactory in both the groups. But it was more significant in the trial group particularly in terms of reduction of pain and improvement in unit cutting time. **Conclusion:** *Palash guggulu Kshara Sutra* is much effective in the management of *Bhagandhara* in comparison to *Apamarga Snuhi Kshara Sutra*.

Keywords: *Bhagandara, Palasha Guggulu Kshara Sutra, Apamarga Snuhi Kshara Sutra, Unit Cutting Time.*

INTRODUCTION

Now a day the application *Kshara Sutra* therapy becoming popular day by day as in the other modes of treatment for fistula-in-ano, failure rate is too high. *Bhagandara* is the disease occurred in ano-rectal region or *Gudapradesh*. Though it is said in the etymology of *Bhagandara* that any tear in

Bhaga, Guda, Vastipradesh is called as *Bhagandara*.^[1] But as the disease affect mainly the *Guda pradesh*, & this can be correlated with different kinds of fistula in relation to anus & rectum. *Sushruta* had mentioned that *Bhagandara* is a very troublesome disease to be managed & kept it under

'*AstaMahagadas*'.^[2] *Bhagandara* have been explained which showed involvement of surrounding tissues of ano-rectal region with varying course of tracts and discharge of pus, fecal matter, urine and other products through the opening & these are the common clinical presentations. In relation to management of *Bhagandara*, *ChedanKarma* is the choice of treatment as per Ayurvedic classics. The *Chedana Karma* for *Bhagandara* can be classified into two subgroups namely *Sastrakrita* & *Anusastrakrita*.^[3] The *Sastra Karma* by the application of different kinds of *Yantra&Sastra* can be done using different kinds of incisions as described in *SushrutaSamhita* and showed different complications. But in *Anusastra Karma*, *Kshara* sutra can be used for the treatment of *Bhagandara* as mentioned in different classics of Ayurveda mainly in *BrihatTrayee*.^[4] The method of preparation of *Ksharasutra* along with its application has been narrated in *ChakrapaniTika* (11th AD) and *Rasa Tarangini*.^[5]

AIM AND OBJECTIVE:

Here in this study the efficacy of *PalashaGugguluKshara* Sutra has been compared with conventional *ApamargaSnuhiKshara* Sutra therapy considering the superiority of *Palasha* amongst the all the *Ksharadravya*.^[6]

MATERIALS AND METHODS:

A minimum 60 nos. of patients of diagnosed case of *Bhagandara* (Fistula-in-ano) attending the Out Patient Department (OPD) of *Shalya Tantra* at Govt. Ayurvedic College Hospital, Guwahati have been selected on open randomly basis for the study.

Detailed history has been taken in a designed proforma as previously prepared for the study in incorporating all the relevant points. For both the groups track length of fistula in ano has been considered as upto 10cm for therapeutical intervention.

INCLUSION CRITERIAS:

- Age-16 to 70 years
- Both the sexes
- Fresh or treated cases
- Painful or painless cases
- Discharging or non-discharging condition
- Having purulent or non-purulent discharge
- Tender or non-tender condition

EXCLUSION CRITERIAS:

- Malignant condition of anus, rectum, prostate
- Incontinence of stool or stricture anus.
- Bleeding disorder
- Fistula concerned with urethra, vagina etc.
- Uncontrolled diabetes mellitus, hypertension, tuberculosis
- Incompetent for *Ksharakarma* as per *Sushruta* eg- *Durvala*, *Sarvangasuna* etc^[7].

These 60 no. of patients have been divided into two groups as per plan of the study.

(A) Trial group: It contains 30 nos. of patients of diagnosed case of *Bhagandara* and has been treated with *Palash- guggulu- haridrakshara sutra*.

(B) Control group: This group contains 30 patients diagnosed case of *Bhagandara*, and have been treated with conventional *Aparga-snuhi-haridrakshara sutra*.

(C) Selection of cases:

The entire ano-rectal patients attending the OPD of *ShalyaTantra* department of Govt. Ayurvedic College Hospital, Guwahati have been thoroughly enquired with proper history taking, physical examination [i.e. general examination, systemic examination & local examination] The clinically diagnosed cases of *Bhagandara* (fistula-in-ano) in the OPD has been thoroughly undergone investigations(as per requirement) viz- Blood routine test (TC, DC, HB% ESR) BT, CT, Blood – sugar (fasting & post prandial), Blood urea, Serum creatinine, Urine (routine & microscopic), Stool examination [routine & microscopic & for occult blood], Sputum for AFB, Pus for AFB, HIV, HBsAg, Antigen HCV, Biopsy, Chest X-

ray (PA view), ECG, Ultrasonography. The cases were selected after considering both the exclusion & inclusion criterias.

THERAPEUTICAL INTERVENTION:

The selected cases of Control group had been treated with *ApamargaSnuhiKshara Sutra* & the cases of Trial group have been treated with *PalashaGugguluKshara Sutra* after taking proper consent. For both the groups primary threading with Mere Silk (1-0) have been done under local anaesthesia or spinal anaesthesia. The anaesthetic procedure was selected as per the convenience. On the very next day the primary silk thread was changed with prepared *kshara sutra* as per the prefixed protocol for each group. Each case has been treated with regular changing of *Kshara Sutra* per weakly basis till cut through of the tract. All the prefixed parameters had been recorded in the designed proforma for statistical evaluation.

ASSESSMENT CRITERIA FOR DIFFERENT PARAMETERS ARE AS FOLLOWS:

Subjective parameters:

A. Pain

- 0- no pain
- 1- mild pain
- 2- moderate pain
- 3- severe pain

B. Swelling

- 0 – no swelling
- 1 – presence of swelling

C. Discharge

- 0 – no discharge
- 1- presence of mild discharge
- 2- presence of profuse discharge

D. Itching

- 0- no itching
- 1- mild itching
- 2- moderate itching
- 3- severe itching

Objective parameters:

A. Condition of the wound:

- 0- healed wound
- 1- wound with healthy granulation tissue
- 2- wound with slough
- 3- wound with slough and over unhealthy granulation tissue.

B. Unit Cutting Time

OBSERVATION & RESULT:

In relation to sex incidence, male (86.6%) dominates female (13.3%). Occupational status has showed maximum number of patients belonged to business class category (33.3%). In relation with prakriti maximum number of cases has been categorized under PittajaPrakriti (41.6%). Amongst all the cases maximum have their habitat in rural area (61.6%). There has no marked difference found in relation to socio-economic status of the registered cases. In relation to nature of bowel habit maximum number of cases has showed constipated and irregular bowel habit (91.6%). Maximum number of cases categorized under *Parisravi bhagandara* (66.6%). In relation to chronicity of the disease most of the cases had less than one year of incidence. Maximum number of cases (48%) has been registered as fresh cases. Amongst all the cases 80% have been treated with the procedure of primary threading under local anesthesia and rest under spinal anesthesia. The observation has showed that the average unit cutting time is 7.4days / cm. in control group and 6.7 days/cm. in trial group.

Results of ‘Paired t’ test for Control Group:

Subjective Criteria wise:

Table 1: Itching

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
0.93	0.03	0.9	0.74	0.147	0.13	69	<0.1

Table 2: Swelling

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
0.56	0	0.56	0.5	0	0.91	6.15	<0.01

Table 3: Pain

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
2.33	0.16	2.17	0.48	0.37	0.11	19	<0.01

Discharge

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
1.96	0.13	1.83	0.18	0.34	0.13	14.07	<0.01

OBJECTIVE CRITERIA WISE:

Table 4: Condition of the wound

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
2.86	0	2.86	0.50	0	0.091	31.42	<.01

Unit Cutting Time (Average)

$$\bar{X}_{UCT(c)} = 7.4$$

Results of 'Paired t' test for Trial Group:

Subjective Criteria wise:

Table 5: Itching

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
1.16	0	1.16	0.8	0	0.14	8.2	<0.01

Table 6: Pain

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
1.76	0	1.76	0.42	0	0.076	23.1	<0.01

Table 7: Swelling

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
1.16	0	1.16	0.3.7	0	0.067	2.38	<0.01

Table 8: Discharge

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
1.73	0.1	1.63	0.44	0.40	0.10	15.07	<0.01

Objective Criteria wise:

Table 9: Condition of the wound

\bar{X}_{BT}	\bar{X}_{AT}	\bar{X}_{BT-AT}	SD_{BT}	SD_{AT}	SE	t_{29}	P
1.93	0	1.93	1.03	0.18	0.18	10.7	<0.01

Unit Cutting Time (Average)

$\bar{X}_{UCT(T)}=6.7$

Results showing comparison between control group (I/C) & Trial Group (II/T)(By ‘unpaired t’ test)

Table 10: Table showing ‘unpaired t’ test for itching in control & trial group

\bar{X}_C	\bar{X}_T	$\bar{X}_C - \bar{X}_T$	SD	SE	t_{58}	P
1.96	1.13	0.83	0.62	0.155	5.53	<0.01

Observation: $t_{58} = 5.53, P<0.01,$

Hence the result is significant at $P<0.01$ showing in trial group, the result has been found satisfactory in comparison to control group.

Table 11: Table showing ‘unpaired t test for pain in control & trial group:

\bar{X}_C	\bar{X}_T	$\bar{X}_C - \bar{X}_T$	SD	SE	t_{58}	P
2.1	1.8	0.3	0.36	0.09	3.3	$P<0.01$

Observation: $t_{58}= 3.3, P<0.01.$

Hence the result is significant at $P<0.01,$ showing in trial group, the result has been found satisfactory in comparison to control group:

Table 12: Table showing ‘unpaired t’ test for discharge in control & trial group:

\bar{X}_C	\bar{X}_T	$\bar{X}_C - \bar{X}_T$	SD	SE	t_{58}	P
1.7	1.6	0.1	0.57	0.14	0.71	$P>0.01$

Observation: $t_{58}= 0.71, P>0.01,$ hence the result is insignificant. This implies, the both result of control & trial groups have been found equal.

Table 13: Table showing ‘unpaired t’ test for swelling in control & trial group:

\bar{X}_C	\bar{X}_T	$\bar{X}_C - \bar{X}_T$	SD	SE	t_{58}	P
0.56	0.2	0.36	0.016	0.004	91.5	$P<0.001$

Observation: $t_{58}= 91.5, P<0.01,$ hence the result is significant at $P<0.001,$ showing in trial group, the result has been found satisfactory in comparison to control group.

Table 14: Table showing ‘unpaired t’ test for condition of the wound in control & trial group

\bar{X}_C	\bar{X}_T	$\bar{X}_C - \bar{X}_T$	SD	SE	t_{58}	P
2.86	1.93	1.48	0.8	0.2	2.15	$P<0.05$

Observation: $t_{58}= 2.15, P<0.05,$ hence the result is significant at $P<0.05,$ showing in trial group, the result has been found satisfactory in comparison to control group.

Unit Cutting time:

The Unit Cutting Time (average) has been compared for both the trial group (6.7 days/cm) with that of control group (7.4 days/cm). As unit cutting time is inversely proportional to healing rate, so, healing

rate in average has been found better in trial group as compared to control group.

DISCUSSION

The study has showed that the male and female ratio for occurrence of Bhagandara is 6.5:1, indicates higher incidence in male which has also found in different other previous studies. The maximum number of cases of pyogenic in origin was observed in persons of grade one profession who have to stay in sitting position for longer duration?? It has been found that more than 60% of the cases have been registered from rural areas probably due to huge mass of Assam reside in rural area. The study also showed person having constipated and irregular bowel habit are more prone to developed Bhagandara. Most of the cases presented with clinical features of huge amount of pus discharge probably due to climatic condition of north eastern region. The study signifies that there is significant reduction of unit cutting time in trial group and it is found high in geriatric group due to poor wound healing status. The reduction of pain during changing of Ksharasutra, reduction of swelling, augmentation of early granulation tissue formation have been found more significant in trial group.

CONCLUSION

After the evaluation of all the review literatures and statistical data following points to be concluded: Cases of *Bhagandara* (fistula-in- ano) found in all age group & mostly dominated in male. Most of the cases are of blind internal origin in this study (Arvachina). All the patients presented with complained of discharge of pus and intermittent pain. Unit cutting time of fistulous tract has been found less in trial group treated with Palashaguggulu- haridrakshara sutra in comparison to Apamarga-snuhi-haridrakshara sutra which indicate cutting & healing rate is good in trial group. No post-

operative complications like incontinence, recurrence etc. were observed in both the groups after six months follow up.

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