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A Clinical Study on Comparative Efficacy of *Guggulu*-based different *Ksharasutra* Prepared with *Apamarga*, *Aragwadh*, *Aswamar*, *Palash* and *Saptaparna* in the Management of *Bhagandara* (Fistula-in-Ano)

Author: Sarma Nayanjyoti[1]

Co Authors: Barman Pankaj Kumar[2] and Medhi Champak[3]

[1-3]Dept of Shalya Tantra, Govt, Ayurvedic College, Guwahati, Assam, India

ABSTRACT

Fistula-in-ano is one of the most troublesome disease among ano-rectal disorders which causes inconvenience to the patient and the management are also not comfortable to the surgeons. According to Sushruta, the management of fistula-in-ano can be put under category of preventive & curative with surgical and parasurgical management. *Kshara sutra* therapy is a very popular treatment modalities for Fistula in ano due to less recurrence and less complications. Sushruta has mentioned 24 types of *Kshara* in the 11th chapter of *SutraSthana*. *Kshara sutra* is a unique medicated seton that helps in both mechanical and chemical cutting of the tract as well as drainage of pus and unhealthy granulation tissue from fistulous tract. In the present study of 150 numbers of patients were treated in five different groups of 30 which were selected randomly with different types of Guggulu based *Kshara sutra* prepared from Palash, Apamarga, Aragwadh, Aswamara and Saptaparna with an aim to evaluate the comparative efficacy.

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INTRODUCTION

The description of *Bhagandara* is found in details in context of its etiology, pathogenesis, clinical features, management and complication in all the classics of *Brihatrayee* and *Laghutrayee* but Sushruta Samhita dominates all.[1,2,3] The disease described in Ayurvedic treatises as *Bhagandara* can be co-related to fistula-in-ano in modern era of surgery considering similar characteristics and principles of management. In modern medicine of treatment, surgery for fistula in ano is considered essential for decompression of acute abscesses and to prevent spread of infection. Many surgical techniques including fistulectomy, fistulotomy, seton technique, endorectal advancement flap, LIFT, VAAFT, fibringlue and fibrinplug are used for treatment of fistula-in-ano.But, gradually *Kshara sutra* therapy has

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emerged as the trustworthy treatment for fistula in ano depending upon its low rate of recurrence and low treatment cost. In this study, Apamarga (*Achyranthes aspera*), Aragwadh (*Cassia fistula*), Aswamar (*Cascabela thevetia*), Palash (*Butea monosperma*) and Saptaparna (*Alstonia scholaris*) were selected for the preparation of Ksharasutra from the 24 numbers of ksharadravya mentioned by Acharya Sushruta[4] to know the comparative efficacy in terms of short duration of therapy, lesser pain, less discharge and itching.

Aim and Objectives :

1.To study the effects of five types of Guggulu based *Kshar Sutra* prepared with Palash, Apamarga, Aragwadh, Aswamar and Saptaparna in the management of *Bhangandara* (Fistula-in-ano).

2.To compare the efficacy of the five types of *Kshar Sutra* prepared with Palash, Apamarga, Aragwadh, Aswamar and Saptaparna for their objective and subjective parameters in the management of *Bhangandara* (Fistula-in-ano).

MATERIAL AND METHODS :

Total 150 numbers of diagnosed case of *Bhagandara* (Fistula-in-ano) attending the 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 incorporating all the relevant points.

INCLUSION CRITERIAS:

- Age between 15-70 years of either sex
- All clinical diagnosed cases of Fistula-in-ano
- Fresh cases or recurred cases.

EXCLUSION CRITERIAS:

- Patient with malignancy (anus, rectum, prostate)
- Pregnancy
- Fistula-in-Ano secondary to ulcerative colitis.
- Bleeding disorders
- Fistula concerned with other organs like urethra, vagina etc.
- Uncontrolled Diabetes mellitus, Hypertension, Tubercolosis, Chronic Liver Disease, Metabolic disorders HIV, HbsAG, HCV positive patients

These 150 nos. of patients were divided into five groups as per plan of the study.

GROUP A: It included 30 numbers of diagnosed case of Bhagandara and were treated with Palash- guggulu- haridra *kshara sutra*.

GROUP B: It included 30 numbers of diagnosed case of Bhagandara and were treated with Apamarga- guggulu- haridra *kshara sutra*.

GROUP C: It included 30 numbers of diagnosed case of Bhagandara and were treated with Aragwadh- guggulu- haridra *kshara sutra*.

GROUP D: It included 30 numbers of diagnosed case of Bhagandara and were treated with Aswamar- guggulu- haridra *kshara sutra*.

GROUP E: It included 30 numbers of diagnosed case of Bhagandara and were treated with Saptaparna- guggulu- haridra *kshara sutra*.

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ASSESSEMENT CRITERIA :

Pain : Visual analogue scale allows patient to rate pain intermittently on a numbered scale such as 0-3 applied will be-

no pain – 0

Mild or bearable – 1

moderate – 2

severe - 3

Discharge-

no discharge – 0

scanty and little – 1

sero-purulent – 2

profuse purulent – 3

Color-

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

Unbearable – 2

Intractible – 3

Unit cutting time = Total no. of Days / Initial length of Tract

Unit cutting and healing Rate = Initial length of track – Length of tract Remaining / No. of Weeks taken

RESULTS AND DISCUSSION

(T1- Group A, T2 – Group B, T3 – Group C, T4 – Group D, T5 – Group E)

Table 1 One-Way ANOVA Including Tukey HSD for pain in 7th d**ay**

Result Details				
Source	SS	df	MS	
Between-treatments	3.9733	4	0.9933	F = 4.06109
Within-treatments	35.4667	145	0.2446	
Total	39.44	149		

The f-ratio value is 4.06109. The p-value is .003766. The result is significant as p <0.01. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the pain in Group A is less than other Groups.

Table 2 One-Way ANOVA Including Tukey HSD for pain in 14th day

Result Details				
Source	SS	df	MS	
Between-treatments	1.8933	4	0.4733	F = 1.57416
Within-treatments	43.6	145	0.3007	
Total	45.4933	149		

The f-ratio value is 1.57416. The p-value is .184286. The result is not significant at p < .05

Table 3 One-Way ANOVA Including Tukey HSD for pain in 21st day

Result Details				
Source	SS	df	MS	
Between-treatments	4.16	4	1.04	F = 3.64839
Within-treatments	41.3333	145	0.2851	
Total	45.4933	149		

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The f-ratio value is 3.64839. The p-value is .007296. The result is significant as p < .01. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the pain in Group A is less than other Groups.

Table 4 One-Way ANOVA Including Tukey HSD for pain in 28th day

Result Details				
Source	SS	df	MS	
Between-treatments	6.8667	4	1.7167	F = 3.89135
Within-treatments	63.9667	145	0.4411	
Total	70.8333	149		

The f-ratio value is 3.89135. The p-value is .004943. The result is significant at p < .01. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the pain in Group A is less than other Groups.

Table 5 One-Way ANOVA Including Tukey HSD for Discharge in 7th day

Result Details				
Source	***SS***	***df***	***MS***	
Between-treatments	5.2667	4	1.3167	*F* = 6.34978
Within-treatments	30.0667	145	0.2074	
Total	35.3333	149		

The f-ratio value is 6.34978. The p-value is 0.000098. The result is significant at p < 0.01. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the discharge in Group A is less than other Groups.

Table 6 One-Way ANOVA Including Tukey HSD for Discharge in 14th day

Result Details				
Source	SS	df	MS	
Between-treatments	7.4015	4	1.8504	F = 6.06402
Within-treatments	45.1606	148	0.3051	
Total	52.5621	152		

The f-ratio value is 6.06402. The p-value is 0.000151. The result is significant at p < 0.01. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the discharge in Group A is less than other Groups.

Table 7 One-Way ANOVA Including Tukey HSD for Discharge in 21st d**ay**

Result Details				
Source	SS	df	MS	
Between-treatments	5.4667	4	1.3667	F = 6.18626
Within-treatments	32.0333	145	0.2209	
Total	37.5	149		

The f-ratio value is 6.18626. The p-value is 0.000127. The result is significant at p < 0.01. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the discharge in Group A is less than other Groups.

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Table 8 One-Way ANOVA Including Tukey HSD for Discharge in 28th day

Result Details				
Source	SS	Df	MS	
Between-treatments	5.1067	4	1.2767	F = 3.56451
Within-treatments	51.9333	145	0.3582	
Total	57.04	149		

The f-ratio value is 3.56451. The p-value is 0.008344. The result is significant at $p < 0.01$. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the discharge in Group A is less than other Groups.

Table 9 One-Way ANOVA Including Tukey HSD for Itching in 7th day

Result Details				
Source	SS	df	MS	
Between-treatments	1.5733	4	0.3933	F = 1.14987
Within-treatments	49.6	145	0.3421	
Total	51.1733	149		

The f-ratio value is 0.21859. The p-value is 0.927738. The result is not significant at $p < 0.05$. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the itching in Group A is less than other Groups.

Table 10 One-Way ANOVA Including Tukey HSD for Itching in 14th day

Result Details				
Source	SS	df	MS	
Between-treatments	3.6933	4	0.9233	F = 3.30576
Within-treatments	40.5	145	0.2793	
Total	44.1933	149		

The f-ratio value is 3.30576. The p-value is 0.012614. The result is significant at $p < 0.05$. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the itching in Group A is less than other Groups

Table 11 One-Way ANOVA Including Tukey HSD for Itching in 21st day

Result Details				
Source	SS	df	MS	
Between-treatments	3.6933	4	0.9233	F = 2.64592
Within-treatments	50.6	145	0.349	
Total	54.2933	149		

The f-ratio value is 2.64592. The p-value is 0.035891. The result is significant at $p < 0.05$. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the itching in Group A is less than other Groups.

Table 12 One-Way ANOVA Including Tukey HSD for Itching in 28th day

	Result Details			
Source	SS	df	MS	
Between-treatments	3.7733	4	0.9433	F = 3.40257
Within-treatments	40.2	145	0.2772	
Total	43.9733	149		

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The f-ratio value is 3.40257. The p-value is 0.010809. The result is significant at $p < 0.05$ The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the itching in Group A is less than other Groups.

Table 13 One-Way ANOVA Including Tukey HSD for Color in 7th day

Result Details				
Source	SS	df	MS	
Between-treatments	4.1067	4	1.0267	F = 3.87337
Within-treatments	38.4333	145	0.2651	
Total	42.54	149		

The f-ratio value is 3.87337. The p-value is 0.005088. The result is significant at $p < 0.01$. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the color in Group A is less than other Groups.

Table 14 One-Way ANOVA Including Tukey HSD for Color in 14th day

Result Details				
Source	SS	df	MS	
Between-treatments	5.5333	4	1.3833	F = 5.03978
Within-treatments	39.8	145	0.2745	
Total	45.3333	149		

The f-ratio value is 5.03978. The p-value is .000785. The result is significant at $p < 0.05$ The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the color in Group A is better than other Groups.

Table 15 One-Way ANOVA Including Tukey HSD for Color in 21th day

Result Details				
Source	SS	df	MS	
Between-treatments	1.9067	4	0.4767	F = 1.74684
Within-treatments	39.5667	145	0.2729	
Total	41.4733	149		

The f-ratio value is 1.74684. The p-value is 0.142867. The result is not significant at $p < 0.05$.

Table 16 One-Way ANOVA Including Tukey HSD for Color in 28th day

Result Details				
Source	SS	df	MS	
Between-treatments	3.7733	4	0.9433	F = 2.64571
Within-treatments	51.7	145	0.3566	
Total	55.4733	149		

The f-ratio value is 2.64571. The p-value is 0.035902. The result is significant at $p < 0.05$. The Mean of T1(Group A) is smaller than the other four groups, so the mean difference suggests that the color in Group A is better than other Groups

Table 17 Mean UCT According to Groups

GROUPS	MEAN UCT (DAYS/CM)
GROUP A Palash- guggulu- haridra kshara sutra	**6.28**
GROUP B Apamarga- guggulu- haridra kshara sutra	**8.07**

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GROUP C Aragwadh- guggulu- haridra kshara sutra	**8.15**
GROUP D Aswamar- guggulu- haridra kshara sutra.	**8.89**
GROUP E Saptaparna- guggulu- haridra kshara sutra	**8.78**

Table 18 Mean UCT & HT According to Groups

GROUPS	MEAN UC&HT (CM/WEEK)
GROUP A Palash- guggulu- haridra kshara sutra	1.139633
GROUP B Apamarga- guggulu- haridra kshara sutra	0.881833
GROUP C Aragwadh- guggulu- haridra kshara sutra	0.8664
GROUP D Aswamar- guggulu- haridra kshara sutra.	0.806633
GROUP E Saptaparna- guggulu- haridra kshara sutra	0.808267

CONCLUSION

In this clinical study, efficacy of five types of guggulu based ksharasutra were assessed by changing the thread every week. Detailed assessment was done by recording different data as per standard research protocols. The findings of different subjective and objective parameters were recorded and converted to table form for details analysis. Assessment of Unit Cutting time and Cutting & Healing Rate was also considered here to understand the comparative efficacy of all the five types of *kshara sutra*. Standard statistical methods were applied in this study like One way Anova with Tukey HSD to scientifically assess the efficacy of five types of kshar sutra and it can be concluded that Palash Guggulu *Kshara sutra* is more efficacious in the management of *Bhagandara*(Fistula-in-ano) (Fistula in ano) due to following reasons:

- Palasha Guggulu ksharasutra has the lesser Unit Cutting time (Total No. of days/ Initial length of track) amongst the five types of *Kshara sutra*. (Table 17)
- Palasha Guggulu *kshara sutra* has the more Unit Cutting and Healing Rate amongst the five types of *Kshara sutra*. (Table 18)
- In Palasha Guggulu *kshara sutra* , the pain is less as compared to other ksharasutra. (Table 1- 4)
- In Palasha Guggulu *kshara sutra* , the Itching is also less as compared to other ksharasutra. (Table 9- 12)
- In Palasha Guggulu *kshara sutra*, the discharge from the tracts reduces significantly as drainage is better (Table 5- 8). So, it can be said that Palasha Guggulu *kshara sutra* is very effective as compared to Apamarga, Aragwadh, Aswamar and Saptaparna *kshara sutra* in curing Bhagandara (Fistula in ano).

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