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AN OPEN LABELED RANDAMISED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF APAMARGA KSHARA SUTRA AND CHEDANA KARMA IN THE MANAGEMENT OF BHAGANDARA

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ABSTRACT

Perinium has a rich blood supply with full fat pads were inspection spreads easily. As the Fistula in Ano spreads from the inspection of anal glands present in the intersphincteric space, it spreads fast because of loose fat in the perinium. Fistula-in-Ano is track lined by unhealthy granulation tissue which connects perianal skin to anal canal and rectum. Bhagandar is stated as one among the mahagada according sushrutha. The disease which involves *bhaga, guda, basti pradesa* is. It is classified into five types viz *shataponaka, ushtra greeva, parisravi, shambukavarta, unmargi.* Acharya sushrutha explained the chedana karma as line of treatment in the management of Bhagandara. The current standard treatment modality in ayurveda for Fistula in ano (*Bhagandara)* is well managing with the application of kshara sutra ligation and application of pratisaraniya kshara. In *ksharasutra* the standard one is *Apamarga* and was compared with the *Chedhana Karma* (Excision). **Objective:** To compare the effect of *Kshara sutra* and *Chedana Karma* in the management of *Bhagandara*. **Intervention:** *Apamarga Kshara sutra* was applied in Group A patients and Group B in patients undertaken for *Chedana Karma.*

Results: On comparing the overall effect on symptoms Pain was reduced in GROUP A and GROUP B there was mild significant, Discharge was reduced in GROUP A and GROUP B there was mild significant, Size of the Wound/Tract was reduced in Group A and Group B but there was moderate significant. **Conclusion:** From the statistical results obtained after analysis, it is concluded that *Chedana karma* is slightly significant statistically but clinically there was no significant difference then the *Apamarga Ksharasutra*.

KEYWORDS: Fistula in Ano, *Bhagandara, Pratisaraniya Kshara, Ksharasutra, Chedana Karma.*

INTRODUCTION

Throughout the surgical history Fistula-in-Ano has been a troublesome pathology to both patient and physician. Anorectal diseases are most painful conditions causing great discomfort to the patient. Anal fistula is a chronic abnormal communication, usually lined to some degree by granulation tissue, which runs outwards from the anorectal lumen (the internal opening) to an external opening on the skin of the perineum or buttock.[1] With the incidence of non-specific anal fistulae has been estimated to be 8.6 to 10/100,000 of the population per year, with a male to female ratio of 1.8:1[2] And prevalence of 1.2 to 2.8/10,000[3] Main clinical features like pain, swelling around anus, pus discharge[4] etc.in modern world the medical science is so advanced in all aspects of treatments and surgical procedures but still the treatment for the Fistula-in-Ano is not yielding satisfactory because of its repeated reoccurrence rate.

Bhagandhara (Fistula-in-Ano) is one among the most common anorectal disease. It is correlated with Fistula-in-Ano in modern medicine. 5 types of *Bhagandara* have been described by *Acharya Sushruta Shataponaka(Vataja), Ushtragriva(Pittaja), Parisravi(Kaphaja), Shambhukavarta(Tridoshaja), Unmargi(Agantuja*).[5]

In present day practice, *Bhagandhara* is mainly treated by the applications of *Kshara sutra*. Kshara sutra has to be changed every week which is very painful for the patient and even patient often complaint of discomfort in their routine life. It has been already known that *ksharasutra* takes more time for cutting the fistulous track.

Acharya sushrutha mentioned the *Chedhana Karma* as main line of treatment in the management of *Bhagandara*.[6]

CHEDANA is the important surgical procedure explained in *Shushrutha samhitha*. It is one among the *Astavidha shastra karma.*[7] The various *Chedana* has been explained in *Bhagandhara Chikitsa* according to different types of *Bhagandhara* viz Shapes like *Langalaka, Arda Langalaka, Chandra Akara, Arda Chandrakara, Gotheerthaka Sarvothobhadra.*[8]

So, this work is planned carried out to evaluate the effect of *Chedana karma* in *Bhagandhara* with kshara sutra comparative study and attempt will be made to check the early healing and to minimize the discomfort to the patient and his routine life and an effectiveness of C*hedhana karma* in *Bhagandara.*

Objective

1. To compare the effect of *Apamarga Kshara sutra* and *Chedana karma* in management of *Bhagandara*.

MATERIALS AND METHODS

Sample source

A minimum 40 Patients diagnosed with *Bhagandara* attending O.P.D of *Shalya Tantra* department, S.J.G. Ayurveda Medical College and Hospital, Koppal, Karnataka shall be taken for the study.

Methodes of collection of data

A) Design of study: An open label comparative clinical study.

B) Sample size: Its of total sample size is 40, Two groups consisting minimum of 20 patients each.

C) Selection criteria

a) Diagnostic criteria

Diagnosis will be made on the basis of, Classical *Lakshanas* of *Bhagandara*, Fistulogram. Methylene blue to trace internal opening (If necessary).

b) Inclusion criteria

Patients of diagnosed as *Bhagandara* /Fistula

Patients between the age group of 30-60 years, of either sex.

Clinical signs and symptoms of all types of *Bhagandara*.

c) Exlusion criteria

High anal fistulae

Secondary fistula due to

a) Ulcerative colitis

b) Crohn's disease

c) Tuberculosis

d) Carcinoma of rectum

Patients with systemic illness like Uncontrolled Diabetic mellites, Hyper tensive, HIV and HbsAG positive patients.

D) Study group

Serial no	Group	Intervention	Duration
1	A	*Ksharasutra*	2 months
2	B	*Chedana karma*	Months

E) Duration of treatment

Treatment duration: 2 months

Assessment days**:** Every week

Follow up period**:** Every month for up to the 4 months.

TOTAL study duration: 6 months

F) Assessment criteria

a) Subjective parameters

a) Pain - Visual analogue scale

b) Discharge

c) Objective parameters

a) Size of the wound/ track

RESULT

Statistical Analysis with different parameters on effect of *Apamarga Kshara Sutra* as a GROUP A and *Chedana Karma* as a GROUP B before, during and after treatment with 20 patients of *Bhagandara* in each group are enlisted below-

Effect of treatment on pain

Within the group A

Table: Effect of Treatment within the GROUP- A (Apamarga Kshara Sutra) on PAIN

N=20	Descriptives		Repeated measures of ANOVA test						
Observations Recorded on	Mean	±SD	Tests of Measure	Source of variation	Sum of Squares	Mean Square	F	P	Remarks
BT	1.95	0.826	Within-Subjects Effects	Time	55.40	6.93	38.92	<0.001	HS
DT1	1.70	0.657		Residual	27.04	0.18			
DT2	1.25	0.444	Within-Subjects Contrasts	Time	53.34	53.34	135.57	<0.001	HS
DT3	1.00	0.000		Error	7.48	0.39			
DT4	0.95	0.224	Between-Subjects Effects	Intercept	174.05	174.05	264.44	<0.001	HS
DT5	0.85	0.366		Error	12.51	0.66			
DT6	0.65	0.489	Multivariate Tests	Value	Error df	Hypo df	F	Sig.	Remarks
DT7	0.40	0.503	Pillai's trace	0.928	12	8	19.47	0.00	HS
AT	0.10	0.308	Wilks' lambda	0.072	12	8	19.47	0.00	HS

Pairwise Comparisons By: Bonferroni			Mean Difference (I-J)	95% CI for Difference		SE	Sig.	Remarks
(I) Time	(J) Time	% Change		Lower Bound	Upper Bound			
BT	DT1	13%	0.25	-0.41	0.91	0.176	1.000	IS
	DT2	36%	0.70	0.03	1.37	0.179	0.034	MS
	DT3	49%	0.95	0.26	1.64	0.185	0.002	S
	DT4	51%	1.00	0.34	1.67	0.178	0.001	HS
	DT5	56%	1.10	0.44	1.76	0.176	0.000	HS
	DT6	67%	1.30	0.63	1.97	0.179	0.000	HS
	DT7	79%	1.55	0.92	2.19	0.17	0.000	HS
	AT	95%	1.85	1.07	2.63	0.209	0.000	HS
DT1	DT2	26%	0.45	0.02	0.88	0.114	0.031	MS
DT2	DT3	20%	0.25	-0.12	0.62	0.099	0.756	IS
DT3	DT4	5%	0.05	-0.14	0.24	0.05	1.000	IS
DT4	DT5	11%	0.10	-0.16	0.36	0.069	1.000	IS
DT5	DT6	24%	0.20	-0.14	0.54	0.092	1.000	IS
DT6	DT7	38%	0.25	-0.12	0.62	0.099	0.756	IS
DT7	AT	75%	0.30	-0.18	0.78	0.128	1.000	IS

IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.

Fig. no. 1: Showing effect of treatment within the group a on pain.

Statistical analysis in parameter of pain in GROUP A is showing that BT MEAN± SD is 1.95±0.826 it was reduced to AT as 0.10±0.308. Which is highly significant with p value of ≤0.001, when repeated measures ANNOVA test was applied within the group it shows that, by comparing BT, during treatment (DT) week and AT it was insignificant in 1 week, then moderately significant in 2nd week, Then it was significant afterwards. And when compared weekly it was moderately significant in 1st week then onwards it was insignificant.

Effect of treatment on pain

Within the group B

Table: Effect of Treatment within the GROUP -B (Chedana Karma) on PAIN									
N=20	Descriptives		Repeated measures of ANOVA test						
Observations Recorded on	Mean	±SD	Tests of Measure	Source of variation	Sum of Squares	Mean Square	F	P	Remarks
BT	2.45	0.826	Within-Subjects Effects	Time	140.58	17.57	67.37	<0.001	HS
DT1	2.45	0.759		Residual	39.64	0.26			
DT2	2.10	0.852	Within-Subjects Contrasts	Time	137.36	137.36	223.64	<0.001	HS
DT3	1.50	0.688		Error	11.67	0.61			
DT4	1.10	0.641	Between-Subjects Effects	Intercept	276.27	276.27	152.13	<0.001	HS
DT5	0.85	0.671		Error	34.51	1.82			
DT6	0.45	0.605	Multivariate Tests	Value	Error df	Hypo df	1.6	Sig.	Remarks
DT7	0.20	0.410	Pillai's trace	0.943	12	8	24.85	0.00	HS
AT	0.05	0.224	Wilks' lambda	0.057	12	8	24.85	0.00	HS
Pairwise Comparisons By: Bonferroni				Mean Difference (I-J)	95% CI for Difference		SE	Sig.	Remarks
(I) Time	(J) Time	% Change			Lower Bound	Upper Bound			
BT	DT1	0%	0%	0.00	-0.61	0.61	0.162	1.000	IS
	DT2	14%	14%	0.35	-0.48	1.18	0.221	1.000	IS
	DT3	39%	39%	0.95	0.26	1.64	0.185	0.002	S
	DT4	55%	55%	1.35	0.52	2.18	0.221	0.000	HS
	DT5	65%	65%	1.60	0.73	2.48	0.234	0.000	HS
	DT6	82%	82%	2.00	1.23	2.77	0.205	0.000	HS
	DT7	92%	92%	2.25	1.59	2.91	0.176	0.000	HS
	AT	98%	98%	2.40	1.71	3.09	0.184	0.000	HS
DT1	DT2	14%	14%	0.35	-0.14	0.84	0.131	0.550	IS
DT2	DT3	29%	29%	0.60	0.03	1.17	0.152	0.031	MS
DT3	DT4	27%	27%	0.40	-0.02	0.82	0.112	0.075	IS
DT4	DT5	23%	23%	0.25	-0.12	0.62	0.099	0.756	IS
DT5	DT6	47%	47%	0.40	-0.02	0.82	0.112	0.075	IS
DT6	DT7	56%	56%	0.25	-0.12	0.62	0.099	0.756	IS
DT7	AT	75%	75%	0.15	-0.16	0.46	0.082	1.000	IS
IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.									

Fig. no. 2: Showing effect of treatment within the group B on pain.

Statistical analysis in parameter of pain in GROUP B is showing that BT MEAN± SD is 2.45±0.826 it was reduced AT as 0.05±0.224. Which is highly significant when repeated measures ANNOVA test was applied within the group it shows that, by comparing BT, during treatment (DT) week and AT it was insignificant in 1st and 2nd week, Then it was significant afterwards. And when compared weekly it was insignificant in 1st week, moderately significant in 2nd week, Then onwards it was insignificant.

Effect of treatment on pain

GROUP A and B

Table : Comparisons Between Groups A and B in PAIN

Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks			Test Statistics			
	Group	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
DT1	Group A	1.70	0.66	20	15.25	305.0	95.0	3.02	<0.01	S
	Group B	2.45	0.76	20	25.75	515.0				
DT2	Group A	1.25	0.44	20	15.00	300.0	90.0	3.27	<0.01	S
	Group B	2.10	0.85	20	26.00	520.0				
DT3	Group A	1.00	0.00	20	16.50	330.0	120.0	3.11	<0.01	S
	Group B	1.50	0.69	20	24.50	490.0				
DT4	Group A	0.95	0.22	20	19.13	382.5	172.5	1.02	>0.05	IS
	Group B	1.10	0.64	20	21.88	437.5				
DT5	Group A	0.85	0.37	20	20.73	414.5	195.5	0.15	>0.05	IS
	Group B	0.85	0.67	20	20.28	405.5				
DT6	Group A	0.65	0.49	20	22.68	453.5	156.5	1.34	>0.05	IS
	Group B	0.45	0.61	20	18.33	366.5				
DT7	Group A	0.40	0.50	20	22.50	450.0	160.0	1.36	>0.05	IS
	Group B	0.20	0.41	20	18.50	370.0				
AT	Group A	0.10	0.31	20	21.00	420.0	190.0	0.59	>0.05	IS
	Group B	0.05	0.22	20	20.00	400.0				

IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.

Fig. no. 3: Showing Comparisons between Group A and B in Pain.

Statistically analysis for between the groups when applied the Mann-Whitney test and above test shows in the DT1, 2 and 3 group A was significant over the GROUP B with ≤0.001 of p value and then it was insignificant so there is no significant difference between the GROUP A and B, statistically with p of >0.05.

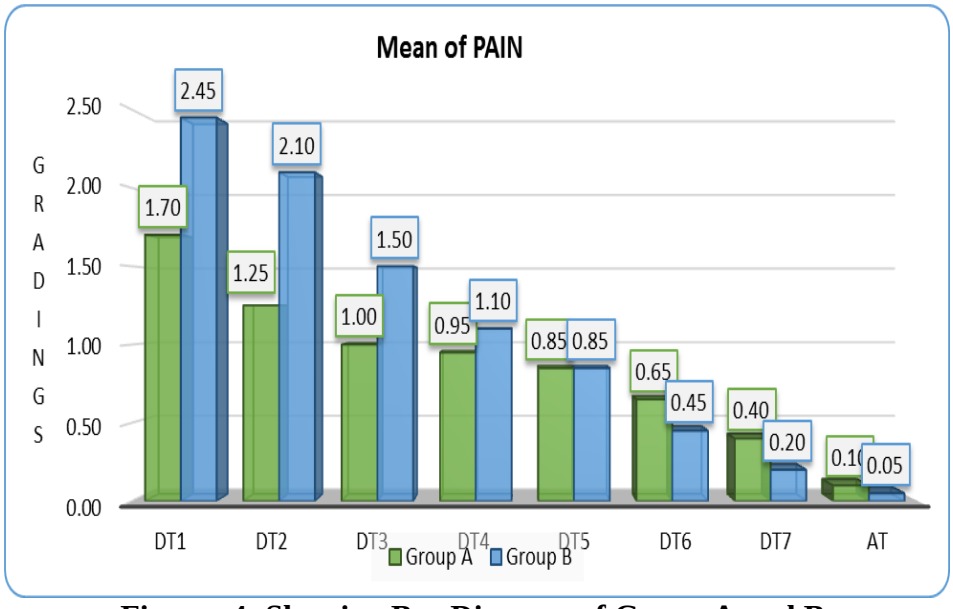

Fig. no. 4: Showing Bar Diagram of Group A and B.

Effect of treatment on discharge

In Group A

Table: Effect of Treatment within the GROUP- A (Apamarga Kshara Sutra) on DISCHARGE									
N=20	Descriptives		Repeated measures of ANOVA test						
Observations Recorded on	Mean	±SD	Tests of Measure	Source of variation	Sum of Squares	Mean Square	F	P	Remarks
BT	3.00	0.649	Within-Subjects Effects	Time	123.78	15.47	94.49	<0.001	HS
DT1	1.85	0.587		Residual	24.89	0.16			
DT2	1.35	0.489	Within-Subjects Contrasts	Time	109.20	109.20	435.59	<0.001	HS
DT3	1.25	0.444		Error	4.76	0.25			
DT4	1.00	0.000	Between-Subjects Effects	Intercept	233.47	233.47	344.91	<0.001	HS
DT5	0.75	0.444		Error	12.86	0.68			
DT6	0.60	0.503	Multivariate Tests	Value	Error df	Hypo df	F	Sig.	Remarks
DT7	0.35	0.489	Pillai's trace	0.979	12	8	71.54	0.00	HS
AT	0.10	0.308	Wilks' lambda	0.021	12	8	71.54	0.00	HS
Pairwise Comparisons By: Bonferroni				Mean Difference (I-J)	95% CI for Difference		SE	Sig.	Remarks
(I) Time	(J) Time	% Change			Lower Bound	Upper Bound			
BT	DT1	38%	38%	1.15	0.53	1.77	0.167	0.000	HS
	DT2	55%	55%	1.65	1.09	2.21	0.15	0.000	HS
	DT3	58%	58%	1.75	1.22	2.28	0.143	0.000	HS
	DT4	67%	67%	2.00	1.46	2.54	0.145	0.000	HS
	DT5	75%	75%	2.25	1.65	2.85	0.16	0.000	HS
	DT6	80%	80%	2.40	1.83	2.97	0.152	0.000	HS
	DT7	88%	88%	2.65	1.97	3.33	0.182	0.000	HS
	AT	97%	97%	2.90	2.36	3.44	0.143	0.000	HS
DT1	DT2	27%	27%	0.50	-0.01	1.01	0.136	0.057	IS
DT2	DT3	7%	7%	0.10	-0.16	0.36	0.069	1.000	IS
DT3	DT4	20%	20%	0.25	-0.12	0.62	0.099	0.756	IS
DT4	DT5	25%	25%	0.25	-0.12	0.62	0.099	0.756	IS
DT5	DT6	20%	20%	0.15	-0.16	0.46	0.082	1.000	IS
DT6	DT7	42%	42%	0.25	-0.21	0.71	0.123	1.000	IS
DT7	AT	71%	71%	0.25	-0.12	0.62	0.099	0.756	IS
IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.									

Fig. no. 5: Showing effect of treatment within the group a on discharge.

Statistical analysis in parameter of discharge in GROUP A is showing that BT MEAN± SD is 3.00±0.649 it was reduced to AT as 0.10±0.308. Which is highly significant at ≤0.001 of p value, when repeated measures ANNOVA test was applied within the group, it also shows that by comparing BT, during treatment (DT) week and AT it was insignificant.

In Group B

Table: Effect of Treatment within the GROUP -B (Chedana Karma) on DISCHARGE									
N=20	Descriptives		Repeated measures of ANOVA test						
Observations Recorded on	Mean	±SD	Tests of Measure	Source of variation	Sum of Squares	Mean Square	F	P	Remarks
BT	3.20	0.696	Within-Subjects Effects	Time	236.00	29.50	128.52	<0.001	HS
DT1	3.05	0.759		Residual	34.89	0.23			
DT2	2.40	0.754	Within-Subjects Contrasts	Time	229.69	229.69	415.79	<0.001	HS
DT3	1.85	0.671		Error	10.50	0.55			
DT4	1.20	0.696	Between-Subjects Effects	Intercept	387.20	387.20	216.94	<0.001	HS
DT5	0.90	0.718		Error	33.91	1.79			
DT6	0.40	0.598	Multivariate Tests	Value	Error df	Hypo df	2.3	Sig.	Remarks
DT7	0.15	0.366	Pillai's trace	0.962	12	8	37.93	0.00	HS
AT	0.05	0.224	Wilks' lambda	0.038	12	8	37.93	0.00	HS
Pairwise Comparisons By: Bonferroni				Mean Difference (I-J)	95% CI for Difference		SE	Sig.	Remarks
(I) Time	(J) Time	% Change			Lower Bound	Upper Bound			
BT	DT1	5%	5%	0.15	-0.34	0.64	0.131	1.000	IS
	DT2	25%	25%	0.80	0.05	1.55	0.2	0.028	MS
	DT3	42%	42%	1.35	0.73	1.97	0.167	0.000	HS
	DT4	63%	63%	2.00	1.23	2.77	0.205	0.000	HS
	DT5	72%	72%	2.30	1.58	3.02	0.193	0.000	HS
	DT6	88%	88%	2.80	2.10	3.50	0.186	0.000	HS
	DT7	95%	95%	3.05	2.36	3.74	0.185	0.000	HS
	AT	98%	98%	3.15	2.53	3.77	0.167	0.000	HS
DT1	DT2	21%	21%	0.65	0.09	1.21	0.15	0.013	MS
DT2	DT3	23%	23%	0.55	0.12	0.98	0.114	0.004	S
DT3	DT4	35%	35%	0.65	0.24	1.06	0.109	0.000	HS
DT4	DT5	25%	25%	0.30	-0.09	0.69	0.105	0.366	IS
DT5	DT6	56%	56%	0.50	0.07	0.93	0.115	0.012	MS
DT6	DT7	63%	63%	0.25	-0.12	0.62	0.099	0.756	IS
DT7	AT	67%	67%	0.10	-0.16	0.36	0.069	1.000	IS
IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.									

Fig. no. 6: Showing effect of treatment within the group b on discharge.

Statistical analysis in parameter of discharge in GROUP B is showing that BT MEAN± SD is 3.20±0.649 it was reduced to AT as 0.05±0.224 at p value ≤0.001. Which is highly significant when repeated measures ANNOVA test was applied within the group, it also shows that by comparing BT, during treatment (DT) week and AT it was insignificant in 1st week, moderately significant in 2nd week then it was highly significant. When test was applied for every week, it was moderately significant in 1st and 5th week, significant in 2nd week, highly significant in 3rd week, then insignificant in 4th, 6th and 7th week**.**

In Group A and B

Table : Comparisons Between Groups A and B in DISCHARGE										
Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks			Test Statistics			
	Group	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
DT1	Group A	1.85	0.59	20	13.08	261.5	51.5	4.27	<0.001	HS
	Group B	3.05	0.76	20	27.93	558.5				
DT2	Group A	1.35	0.49	20	13.43	268.5	58.5	4.09	<0.001	HS
	Group B	2.40	0.75	20	27.58	551.5				
DT3	Group A	1.25	0.44	20	15.63	312.5	102.5	2.97	<0.01	S
	Group B	1.85	0.67	20	25.38	507.5				
DT4	Group A	1.00	0.00	20	19.00	380.0	170.0	1.23	>0.05	IS
	Group B	1.20	0.70	20	22.00	440.0				
DT5	Group A	0.75	0.44	20	19.50	390.0	180.0	0.63	>0.05	IS
	Group B	0.90	0.72	20	21.50	430.0				
DT6	Group A	0.60	0.50	20	22.70	454.0	156.0	1.36	>0.05	IS
	Group B	0.40	0.60	20	18.30	366.0				
DT7	Group A	0.35	0.49	20	22.50	450.0	160.0	1.44	>0.05	IS
	Group B	0.15	0.37	20	18.50	370.0				
AT	Group A	0.10	0.31	20	21.00	420.0	190.0	0.59	>0.05	IS
	Group B	0.05	0.22	20	20.00	400.0				
IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.										

Fig. no. 7: Showing Comparisons between Group A and B in Discharge.

Statistically analysis for between the groups when applied the Mann-Whitney test and above test shows in the DT1 and 2-week group A was highly significant over the GROUP B and then it was insignificant so there is no significant difference between the GROUP A and B, statistically with p of >0.05.

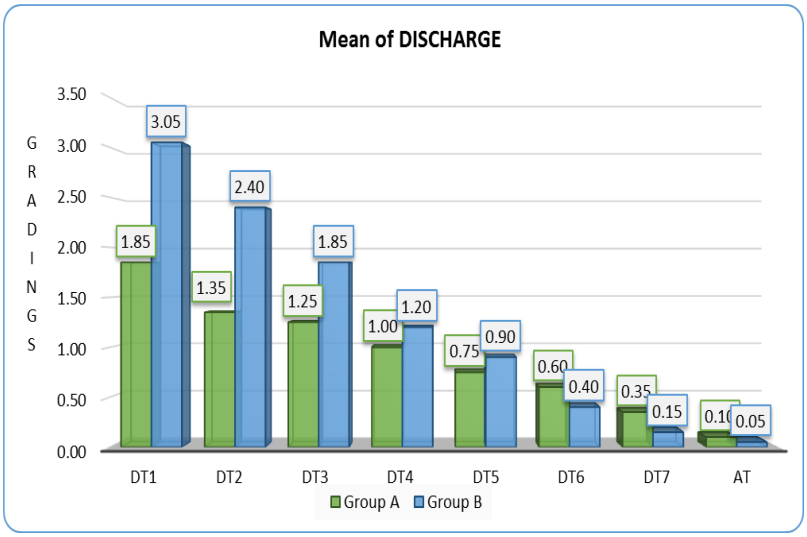

Fig. no. 8: Showing Comparisons between Group A and B in Discharge.

Effect of treatment on size

In Group A

Table: Effect of Treatment within the GROUP-A (Apamarga Kshara Sutra) on SIZE OF THE TRACT									
N=20	Descriptives		Repeated measures of ANOVA test						
Observations Recorded on	Mean	±SD	Tests of Measure	Source of variation	Sum of Squares	Mean Square	F	P	Remarks
BT	2.25	0.444	Within-Subjects Effects	Time	76.48	9.56	82.93	<0.001	HS
DT1	2.15	0.489		Residual	17.52	0.12			
DT2	1.90	0.641	Within-Subjects Contrasts	Time	75.00	75.00	296.88	<0.001	HS
DT3	1.55	0.510		Error	4.80	0.25			
DT4	1.30	0.470	Between-Subjects Effects	Intercept	309.42	309.42	260.39	<0.001	HS
DT5	0.85	0.366		Error	22.58	1.19			
DT6	0.85	0.366	Multivariate Tests	Value	Error df	Hypo df	F	Sig.	Remarks
DT7	0.55	0.510	Pillai's trace	0.949	13	7	34.75	0.00	HS
AT	0.40	0.503	Wilks' lambda	0.051	13	7	34.75	0.00	HS
Pairwise Comparisons By: Bonferroni				Mean Difference (I-J)	95% CI for Difference		SE	Sig.	Remarks
(I) Time	(J) Time	% Change			Lower Bound	Upper Bound			
BT	DT1	4%	4%	0.10	-0.16	0.36	0.069	1.000	IS
	DT2	16%	16%	0.35	-0.06	0.76	0.109	0.170	IS
	DT3	31%	31%	0.70	0.31	1.09	0.105	0.000	HS
	DT4	42%	42%	0.95	0.62	1.28	0.088	0.000	HS
	DT5	62%	62%	1.40	0.98	1.82	0.112	0.000	HS
	DT6	62%	62%	1.40	0.98	1.82	0.112	0.000	HS
	DT7	76%	76%	1.70	1.31	2.09	0.105	0.000	HS
	AT	82%	82%	1.85	1.36	2.34	0.131	0.000	HS
DT1	DT2	12%	12%	0.25	-0.12	0.62	0.099	0.756	IS
DT2	DT3	18%	18%	0.35	-0.06	0.76	0.109	0.170	IS
DT3	DT4	16%	16%	0.25	-0.12	0.62	0.099	0.756	IS
DT4	DT5	35%	35%	0.45	0.02	0.88	0.114	0.031	MS
DT5	DT6	0%	0%	0.00	0.00	0.00	0	.	IS
DT6	DT7	35%	35%	0.30	-0.09	0.69	0.105	0.366	IS
DT7	AT	27%	27%	0.15	-0.16	0.46	0.082	1.000	IS
IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.									

Fig. no. 9: Showing Effect of Treatment within the Group A on Size of Tract.

Statistical analysis in parameter of size in GROUP A is showing that BT MEAN± SD is 2.25±0.444 it was reduced to AT as 0.40±0.503, which is highly significant. When repeated measures ANNOVA test was applied within the group, it also shows that by comparing BT, during treatment (DT) week and AT it was insignificant for DT1 and 2, then onwards it was highly significant. When test was applied during the treatment weeks it was moderately significant for DT4 and in other weeks it was insignificant.

In Group B

Table: Effect of Treatment within the GROUP -B (Chedana Karma) on SIZE OF THE WOUND									
N=20	Descriptives		Repeated measures of ANOVA test						
Observations Recorded on	Mean	±SD	Tests of Measure	Source of variation	Sum of Squares	Mean Square	F	P	Remarks
BT	2.50	0.607	Within-Subjects Effects	Time	120.40	15.05	133.35	<0.001	HS
DT1	2.35	0.587		Residual	17.16	0.11			
DT2	1.80	0.523	Within-Subjects Contrasts	Time	119.07	119.07	566.05	<0.001	HS
DT3	1.45	0.510		Error	4.00	0.21			
DT4	1.20	0.410	Between-Subjects Effects	Intercept	273.80	273.80	211.09	<0.001	HS
DT5	0.85	0.489		Error	24.64	1.30			
DT6	0.60	0.503	Multivariate Tests	Value	Error df	Hypo df	1.65	Sig.	Remarks
DT7	0.25	0.444	Pillai's trace	0.979	12	8	69.72	0.00	HS
AT	0.10	0.308	Wilks' lambda	0.021	12	8	69.72	0.00	HS
Pairwise Comparisons By: Bonferroni				Mean Difference (I-J)	95% CI for Difference		SE	Sig.	Remarks
(I) Time	(J) Time	% Change			Lower Bound	Upper Bound			
BT	DT1	6%		0.15	-0.16	0.46	0.082	1.000	IS
	DT2	28%		0.70	0.31	1.09	0.105	0.000	HS
	DT3	42%		1.05	0.72	1.38	0.088	0.000	HS
	DT4	52%		1.30	0.82	1.78	0.128	0.000	HS
	DT5	66%		1.65	1.16	2.14	0.131	0.000	HS
	DT6	76%		1.90	1.53	2.27	0.1	0.000	HS
	DT7	90%		2.25	1.79	2.71	0.123	0.000	HS
	AT	96%		2.40	1.90	2.90	0.134	0.000	HS
DT1	DT2	23%		0.55	0.12	0.98	0.114	0.004	S
DT2	DT3	19%		0.35	-0.06	0.76	0.109	0.170	IS
DT3	DT4	17%		0.25	-0.12	0.62	0.099	0.756	IS
DT4	DT5	29%		0.35	-0.06	0.76	0.109	0.170	IS
DT5	DT6	29%		0.25	-0.12	0.62	0.099	0.756	IS
DT6	DT7	58%		0.35	-0.06	0.76	0.109	0.170	IS
DT7	AT	60%		0.15	-0.16	0.46	0.082	1.000	IS
IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.									

Fig. no. 10: Showing Effect of Treatment within the Group B on Size of Tract.

Statistical analysis in parameter of size in GROUP B is showing that BT MEAN± SD is 2.50±0.607 it was reduced to AT as 0.10±0.308, which is highly significant with p value of ≤0.001. When repeated measures ANNOVA test was applied within the group, it also shows that by comparing BT, during treatment (DT) week and AT it was insignificant for DT1 and 2, then onwards it was highly significant. When test was applied during the treatment weeks it was moderately significant for DT4 and in other weeks it was insignificant.

In Group A and B

Table : Comparisons Between Groups A and B in SIZE

Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks				Test Statistics		
	Group	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
DT1	Group A	2.15	0.49	20	18.60	372.0	162.0	1.23	>0.05	IS
	Group B	2.35	0.59	20	22.40	448.0				
DT2	Group A	1.90	0.64	20	21.25	425.0	185.0	0.48	>0.05	IS
	Group B	1.80	0.52	20	19.75	395.0				
DT3	Group A	1.55	0.51	20	21.50	430.0	180.0	0.63	>0.05	IS
	Group B	1.45	0.51	20	19.50	390.0				
DT4	Group A	1.30	0.47	20	21.50	430.0	180.0	0.72	>0.05	IS
	Group B	1.20	0.41	20	19.50	390.0				
DT5	Group A	0.85	0.37	20	20.58	411.5	198.5	0.06	>0.05	IS
	Group B	0.85	0.49	20	20.43	408.5				
DT6	Group A	0.85	0.37	20	23.00	460.0	150.0	1.75	>0.05	IS
	Group B	0.60	0.50	20	18.00	360.0				
DT7	Group A	0.55	0.51	20	23.50	470.0	140.0	1.91	>0.05	IS
	Group B	0.25	0.44	20	17.50	350.0				
AT	Group A	0.40	0.50	20	23.50	470.0	140.0	2.16	<0.05	MS
	Group B	0.10	0.31	20	17.50	350.0				

IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant.

Fig. no. 11: Showing Comparisons between Group A and B in Size.

Statistically analysis for between the groups when applied the Mann-Whitney test and above test shows in the AT week group B was moderately significant over the GROUP A statistically with p of <0.05.

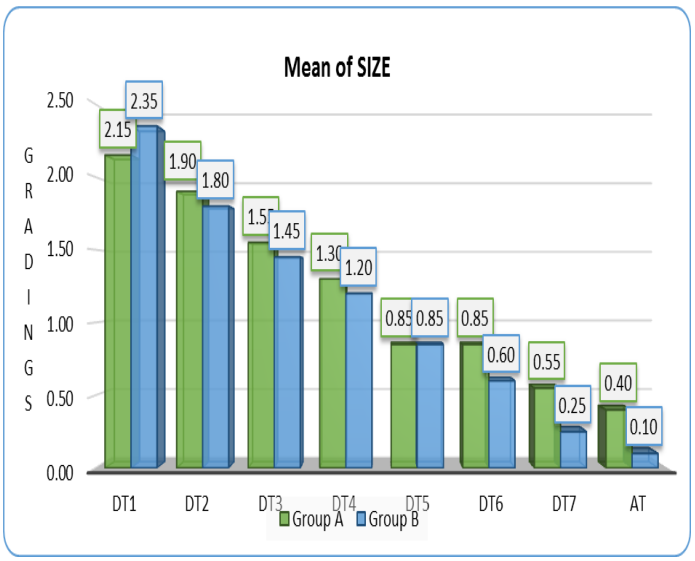

Fig. no. 12: Showing Comparisons between Group A and B in Size.

After treatment

Overall Result After Treatment				
Parameters	GROUP A		GROUP B	
	Mean	±SD	Mean	±SD
PAIN	0.10	0.308	0.05	0.224
DISCHARGE	0.10	0.308	0.05	0.224
SIZE	0.40	0.503	0.10	0.308

Fig. no. 13: Showing overall result after treatment.

The above table shows that in group A mean ±SD was for pain 0.10±0.308, discharge 0.10±0.308 and size 0.40±0.503. In group B pain 0.05±0.224, discharge0.05±0.224 and size 0.10±0.308.

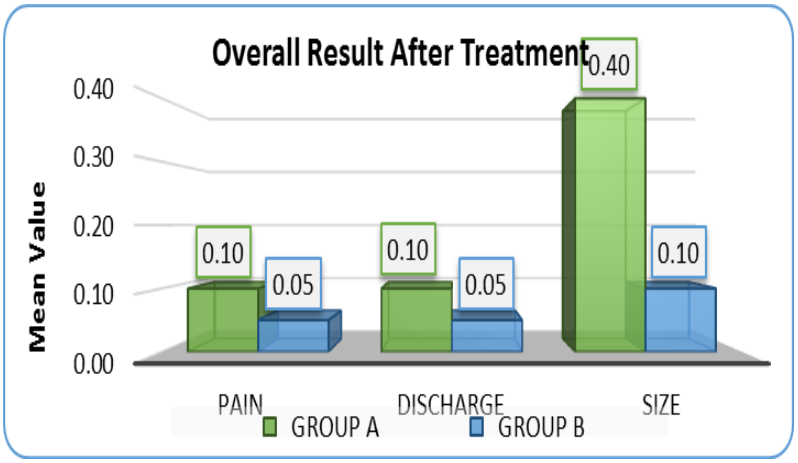

Fig. no 14 Showing overall result after treatment.

DISCUSSION

The present study is aimed to evaluate the effect of *Apamarga Kshara sutra* and *Chedana Karma* in the management of *Bhagandara*. In this section, an attempt has been made to critically discuss and interpret the whole study.

Based on pain

In Group A

BT MEAN± SD is 1.95±0.826 it was reduced to AT as 0.10±0.308. table no shows that, by comparing BT, during treatment (DT) week and AT it was insignificant in 1st week, then moderately significant in 2nd week, then it was significant afterwards. And when compared weekly it was moderately significant in 1st week then onwards it was insignificant. As there is a significant change in BT and AT, the infection will reduce by draining the collection in fistulous track, cutting and healing of tract will occur simultaneously, but when the significance is compared between every week there was no gross difference between weeks,

as there will be mild to moderate pain during changing of *ksharasutra* every week, after changing *ksharasutra* there was a pain for 2-3 days.

In Group B

BT MEAN±SD is 2.45±0.826 it was reduced AT as 0.05±0.224. table no shows that, within the Group it shows that, by comparing BT, during treatment (DT) week and AT it was insignificant in 1st and 2nd week, then it was significant afterwards. when compared weekly it was insignificant in 1st week, moderately significant in 2nd week, then onwards it was insignificant. Because of everyday dressing caused the mild pain so it was insignificant in 1st and 2nd weak, there after wound was healed.

In between the Group A and Group B

For between the Group analysis was done by applying the MANN WHITNEY U TEST and results shows that in the DT1, 2 and 3 Group A was significant because applying the *Kshara sutra* will reduce the pain immediately as it drains and removes pus and infection from the track and also there was a mild to moderate pain while changing *Kshara sutra* every week. In case Group B after *Chedana Karma* there was an open wound which was left for secondary healing so there was more in for up to 2-3 DT. After that there was a healthy granulation so there was mild pain. So, there was a clinically significance but statistically it was no significance difference after DT3.

Based on discharges

In the Group A

Discharge is showing that BT MEAN± SD is 3.00±0.649 it was reduced to AT as 0.10±0.308. which is highly significant when repeated measures ANNOVA test was applied within the group, it also shows that by comparing BT, during treatment (DT) week and AT it was insignificant. Applied *Kshara sutra* will drain the pus and *Apamarga Kshara sutra* has property of shodhana and *shoshana* so, there was significant difference between the BT and AT. While in weekly comparison there is no significant, because of cutting healing guna of *ksharasutra* so, there will be mild discharge.

In Group B

In this Group discharge is showing that BT MEAN± SD is 3.20±0.649 it was reduced to AT as 0.05±0.224. Which is highly significant when repeated measures ANNOVA test was applied within the group. Comparing BT, during treatment (DT) week and AT it was

insignificant in 1st week, moderately significant in 2nd week then it was highly significant, because after *Chedana Karma* there will open wound which secretes of profuse serosanguinous discharge so insignificant in 1st week after that there will reduction as there will be healthy granulation so there is reduction in discharge so it was significant afterwards. It also depends upon the size of the wound. week, it was moderately significant in 1st and 5th week, significant in 2nd week, highly significant in 3rd week, then insignificant in 4th, 6th and 7th week. When it compared between BT and DT1 it showing significant because there is reduction in discharge (BT is of pus, DT1 is serous) there was more reduction in DT2 and DT3 so they were significant as there is formation of granulation.

Comparing between the Group A and B

For analysis between the groups Mann Whitney U test was applied, it shows in the DT1 and 2-week Group A was highly significant over the GROUP B. because *Kshara sutra* applied was helped in the *shoshana* of track and also draining the pus, as in Group B there was there was a wound discharges serosanguinous fluid in DT1 and 2 so, when compared Group A was significant. After formation of granulation in wound of Group b, there was a mild discharge so there is no significant difference between the groups after the DT3 to AT.

Based on size

In Group A

Statistical Analysis shows that BT MEAN± SD is 2.25±0.444 it was reduced to AT as 0.40±0.503, which is highly significant. When repeated measures ANNOVA test was applied within the group, it also shows that by comparing BT, during treatment (DT) week and AT it was insignificant for DT1 and 2, then onwards it was highly significant. Because many of the bagandara involved the sphincter fibres so they took time in cutting the track so there was insignificant in DT1 and 2 after cutting and healing of sphincter remaining cut early. So, there was significant difference.

In Group B

Statistical Analysis of size in the Group B is showing that BT MEAN± SD is 2.50±0.607 it was reduced to AT as 0.10±0.30 which is highly significant. When repeated measures ANNOVA test was applied within the group, it also shows that by comparing BT, during treatment (DT) week and AT it was insignificant for DT1 and 2, then onwards it was highly significant. The size of wound was reduced after DT1 and 2, during time there was no

granulation tissue, after 2nd week there was granulation and wound was healed with in the 5th to 8th week.

Comparing Between the Group A and B

For analysis between the groups Mann Whitney U test was applied, it shows Group B was moderately significant than Group A in after treatment. As the wound heals within 45-60 days so in Group B size will completion of healing was earlier than Group A. where in Group A *Kshara sutra* was cutting 0.7 cm for week and if bhagandar involves the sphincters then cutting will be delayed it takes more to cut through. *Ksharasutra* cut and heals by its virtue of shodhana ropana *shoshana* property of *Apamarga* kshara.

Mode of action of *apamarga kshara sutra*

Apamarga Kshara sutra contains *Apamarga* which has qualities like Katu, Tikta Rasa, Laghu, Ruksha, Tikshna Gunas, Ushna Veerya, Katu Vipaka. These properties of the drugs create an unfavourable condition for the progression of the disease. As it contains *Apamarga Kshara* which has Shodhana and Ropana properties and facilitates the Vilayana of the Pooya thereby helps in the cleansing of the track. *Apamarga* drug has properties like Shothahara, Vedanasthapana, Twakadhoshahara, Vrana Shodhana, Kushthaghna, and Kandughna123 which helps to reduce the symptoms like itching, swelling, pain and burning sensation and also helps to accelerate the healing process.

By the application of *Kshara sutra* it does cutting layer by layer and there is continuous drainage of fistulous track which helps in simultaneous healing

Ksharasutra will dissolute the unhealthy tissue of the track (Debridement by the Ksharana process) and stimulate the healthy granulation tissue for healing.

By shodhana property the track will be in aseptic condition.

Applied *Kshara sutra* not only cut and heals but also give passage for draining.

Mode of action of *Chedana Karma* (Fistulectomy)

Excision of fistulous track and leaving the wound open for secondary healing, as the complete track excision takes out the unhealthy tissue, the remaining is healthy the wound will heal with in the 6 weeks.

Inflammatory Phase (Lag or Substrate or Exudative Phase)

It begins immediately after formation and lasts for 72 hours. There is initial arteriolar vasoconstriction, thrombus formation, platelet aggregation due to endothelial damage and release of adenosine diphosphate (ADP). Later vasodilatation and increased vascular permeability develop. Here haemostasis, coagulation and chemotaxis occur. All these cause features of acute inflammation rubor, calor, tumour, dolor and loss of function.

Proliferative Phase (Collagen/Fibroblastic Phase)

It begins from 3rd day and lasts for 3-6 weeks. There will be formation of granulation tissue and repair of the wound. Granulation tissue contains fibroblasts, neocapillaries, collagen, fibronectin and hyaluronic acid.

Remodelling Phase (Maturation Phase)

It begins at 6 weeks and lasts for 6 months to 1 or 2 years. There is maturation of collagen by cross linking and realignment of collagen fibres along the line of tension, which is responsible for tensile strength of the scar. There is reduced wound vascularity. Fibroblast and myofibroblast activity cause wound contraction. Type Ill collagen is replaced by type I collagen causing maturation of the collagen. Ratio of type I collagen to type Ill collagen becomes 4:1. Early extracellular matrix contains fibronectin and collagen type 111; eventually it contains glycosaminoglycans and proteoglycans; final matrix contains type I collagen. Scar strength is 3% in 1 week; 20% in 3 weeks; 80% in 12 weeks. Final matured scar is acellular and avascular.

In the management of *Bhagandara* acharya sushrutha, explained *Chedana karma* is the main line of treatment and also, he explained the different types of *Chedana karma* for different types of *Bhagandara.*

1. *Apamarga* is a seasonal plant and collection of *Snuhi Ksheera* is time consuming so as *Chedana Karma* can be easily.

   Based on the above discussion and statistical result the conclusion can be drawn as-
2. *Apamarga sutra* was highly significant within the group and over response was 55% of complete response, 40% marked response, 5% moderate response.
3. In *Chedana karma* group it was highly significant within the group and complete response in 85%, marked response in 15%.
4. When compared in between the groups, there was a slight significance statistically in the *Chedana Karma* then the *Apamarga Ksharasutra* of pain and discharge.

5. It shows moderately significant in healing (Size) in *Chedana karma* then the *Apamarga Kshara sutra*.

So *Chedana karma* is better than the *Apamarga Kshara* sutra where healing will be earlier in *Chedana Karma*, there will not be troublesome to patient as of changing *Ksharasutra* was.

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