

# “A Controlled Clinical Study To Evaluate The Effectiveness Of Arka Ksheera Based Tilwaka Ksharasutra And Apamarga Ksharasutra In The Management Of Bhagandara With Special Reference To Fistula In Ano”-Case Series.

Shrenik jain<sup>1</sup>, Shilpa P N<sup>2</sup>

1. Post graduate scholar, Dept of PG studies in shalyatantra, GAMC Bangalore, Karnataka.

2. Professor, Dept of PG& Phd studies in shalyatantra, GAMC Bangalore, Karnataka.

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## ABSTRACT:

Bhagandara which is correlated to Fistula in Ano, is considered as one of the Ashta maharoga (8 major diseases) by Acharya Susrutha, that is diseases which are difficult to cure. Management of fistula in Ano have posed a great challenge to surgeons mainly due to its notorious recurrence and complication like incontinence, pain etc. Ksharasutra therapy is proven effective in the management of fistula in ano. Though Apamarga ksharasutra is previously standardized for the treatment of Bhagandara, there is always a need for a drug which is easily available, cost effective and that cause less irritation and discomfort to patient. The present study is carried out to compare the effectiveness of Tilwaka ksharasutra with Apamarga ksharasutra.

**Key words:** Bhagandara, Fistula-in-ano, Snuhi ksheera based Eranda kshara sutra, Apamarga kshara sutra

## I. INTRODUCTION:

Bhagandara is correlated to Fistula in ano. It is considered as very difficult condition to treat since ages because of its notorious recurrence. It is one of the Ashtamahagadas (dreadful diseases) according to classics, meaning the diseases which are complicated and difficult to treat. Bhagandara is combination of 2 words Bhaga and Dharana, which means pidaka situated in Bhaga, Guda, Basti pradesha and spontaneously ruptures and discharges pus, later leading to formation of track causing pain and discomfort to patient<sup>1</sup>. The earliest reference of Bhagandara seen in Garuda Purana<sup>2</sup>. The condition is explained in detail, including Nidana, Samprapti, Lakshana and treatment in all the Brhatrayees in various sections.

Fistula in ano is a common Anorectal condition second to haemorrhoids in its prevalence. The United Kingdom-standardized overall point prevalence of anal fistula as 1.80 (95%CI: 1.65-

1.94) per 10000 patients in 2017, while in the Europe standardized estimate was 1.83 (95%CI: 1.68-1.98) per 10000 patients. Both these standardized point prevalence estimates ranged from 1.89 to 2.36 between 2014-2016<sup>3</sup>.

Ayurveda advocates various medical, para surgical and surgical procedures in the management of Bhagandara. Kshara sutra therapy mentioned by Acharya Susrutha in the Nadi vrana context is modified and effectively used to treat Bhagandara<sup>4</sup>. Kshara sutra is cost effective, minimal invasive, outpatient procedure requiring no hospitalization. It has least complications and very low recurrence rate comparing to surgical excisions of the tract. It can be effectively employed even in high rectal fistulas without the fear of incontinence.

This study was conducted in SJGAU hospital, Bengaluru OF Govt Ayurveda Medical college Bangalore, between April 2021 to August 2023. Based on the inclusion and exclusion criteria a total of 40 patients were randomly allotted into two groups namely Group A with trial drug i.e., arka ksheera based Tilwaka ksharasutra and Group B with control drug i.e., Apamarga ksharasutra with 20 patients in each group. Assessment was made on subjective (discharge, pain) and objective (length of the tract, Unit Cutting time) parameters. Observations were made before the treatment and on every 7<sup>th</sup> day of the treatment duration until complete cutting of the track was achieved.

## II. AIMS AND OBJECTIVES

1. To evaluate the effectiveness of Arka Ksheera based Tilwaka Ksharasutra in the management of Bhagandara.
2. To evaluate the effectiveness of Snuhi Ksheera based Apamarga Ksharasutra in the management of Bhagandara.
3. To compare the effectiveness of Arka ksheera based Tilwaka Kshara sutra with the effectiveness of Snuhi ksheera based

Apamarga Ksharasutra in the management of Bhagandara.

### HYPOTHESES

#### NULL HYPOTHESIS:

- There is no significant effect of Arka ksheera based Tilwaka ksharasutra in the management of Bhagandara
- There is no significant effect of Snuhi ksheera based Apamarga ksharasutra in the management of Bhagandara
- There is no significant difference between Arka ksheera based Tilwaka ksharasutra and Snuhi ksheera based Apamarga ksharasutra in the management of Bhagandara.

#### ALTERNATE HYPOTHESIS:

- There is significant effect of Arka ksheera based Tilwaka ksharasutra in the management of Bhagandara
- There is significant effect of Snuhi ksheera based Apamarga ksharasutra in the management of Bhagandara
- There is significant difference between Arka ksheera based Tilwaka ksharasutra and Snuhi ksheera based Apamarga ksharasutra in the management of Bhagandara.

### METHODOLOGY

This study was conducted during the period of September 2022 to August 2023.

#### SOURCE OF DATA:

Subjects with the classical features of Bhagandara attending the outpatient and inpatient department of Government Ayurveda Medical College & hospital, Sri Jayachamarajendra Institute of Indian medicine, Bengaluru are selected for the study.

#### SAMPLING DESIGN:

A total of 40 subjects with the features of Fistula-in-ano mentioned in inclusion criteria are included for the study randomly allotted into two groups namely Group A and Group B with 20 subjects each.

#### INCLUSION CRITERIA:

- Subjects of age group 18y-60y, irrespective of Gender, Religion, Occupation and duration of symptoms.
- Subjects with clinical features of Fistula-in-ano namely Pain, peri anal swelling, Sero-purulent discharge from tract & pruritis ani, confirmed

by clinical examinations and investigations.

- Subjects with patent fistulous tract confirmed by probing.

#### EXCLUSION CRITERIA:

- Diagnosed cases of fistula-in-ano secondary to Tuberculosis, Crohn's disease, Ulcerative colitis, Osteomyelitis, Venereal disease and malignancies.
- Associated with any other diagnosed anorectal disorders.
- Pregnancy and lactating women.
- Subjects suffering with other diagnosed systemic disorders.
- Recurrent Fistula-in-ano after previous surgery.

### PROCEDURE

#### Purva karma

- Required materials are kept ready and procedure was explained to the subject & informed written consent taken.
- Part preparation done.
- Subject shall be given laghu, snigdha ahara and 5-10 g of Triphala choorna as laxative in the previous night of probing.

#### Pradhana karma

Arka Ksheera based Tilwaka ksharasutra was applied under aseptic precautions

Patient placed in lithotomy position. Under all aseptic precautions, part prepared. followed by painting and draping of the part is done. A suitable malleable probe is forwarded along the path of least resistance guided by the finger lubricated with lignocaine jelly in the anal canal to reach into its lumen. Then the tip is finally directed to come out of the anal orifice through the internal opening in the anal canal. A required length of plain thread taken and threaded in the eye of the probe. Thereafter the probe was pulled out through the anal orifice, to leave the thread behind in the fistulous tract. The two ends of the plain thread are then tied together with a moderate tightness outside the anal canal. This procedure is called Primary threading. After 3 days, primary thread is replaced by Arka ksheera based Tilwaka Ksharasutra by rail-road method.

#### Paschat karma

- Avagaha Sweda twice daily.

#### Replacing primary thread by Arka Ksheera based Tilwaka ksharasutra:

On every seventh day, the Ksharasutra is changed with a new Sutra by the rail-road method.

In this method, the Ksharasutra is tied at one end and the knot tightened against the knot of the thread in situ. The Ksharasutra at the anal verge is clamped with forceps and cut in between the knot and forceps. The Sutra then slowly pulled out and the old Ksharasutra is replaced by the new one. The knot of the new Ksharasutra is secured after cutting and removing the old Ksharasutra. The measurement of the old Sutra is recorded finally to assess the progress of cut through of the tract. The subjects are advised to take rest.

Follow-up: Ksharasutra is changed weekly till the complete tract is cut.

Observation: were made before & after application of Ksharasutra on every sitting.

Duration: Till the tract is completely cut.

#### ASSESSMENT CRITERIA:

Parameters of assessment

a)

##### Subjective criteria

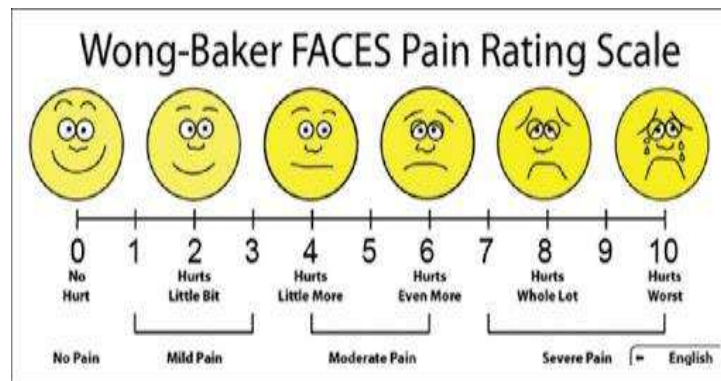
1. Pain

Grade 0 (P<sub>0</sub>) No pain

Grade 1 (P<sub>1</sub>) Mild pain (can continue with work)

Grade 2 (P<sub>2</sub>) Moderate pain (Has to take rest between work)

Grade 3 (P<sub>3</sub>) Severe pain (Unable to work)



2. Discharge

Grade 0 (D<sub>0</sub>) - No discharge

Grade 1 (D<sub>1</sub>) - Mild discharge (Wets 0.5cm x 0.5 cm of pad/day)

Grade 2 (D<sub>2</sub>) - Moderate discharge (Wets 1cm x 1cm of pad/day)

Grade 3 (D<sub>3</sub>) - Severe discharge (Wets > 1cm x 1cm of pad/day)

##### Objective criteria

- Length of the tract- Length of the tract shall be noted by measuring length of old thread that is removed while replacing new thread, in every sitting in centimeters.
- Unit cutting time (U.C.T.) – It is the number of days required to cut one cm of the tract. This is calculated by dividing total number of days taken by the fistula to cut by the initial length of the tract. Denoted as ‘Days/cm’.
- U.C.T. = Total number of days /Initial length of the tract = days/cm

##### OVERALL ASSESSMENT:

The net results obtained from various parameters of assessment by the treatment were taken into consideration to assess the overall effect of the

treatment.

➤ Marked response: > 75% - <100% relief from all the features i.e., pain, discharge, length of tract and unit cutting time.

➤ Moderate response: > 50% - < 75% relief from all features i.e., pain, discharge, length of tract and unit cutting time.

➤ Mild response: > 25% - < 50% relief from all features i.e., pain, discharge, length of tract and unit cutting time.

➤ Poor response: < 25% relief from all features i.e., pain, discharge, length of tract and unit cutting time. Results were statistically analyzed within the group using Friedman test, Wilcoxon signed rank test and between the groups using Mann Whitney U test & conclusions were drawn.

### III. OBSERVATION AND RESULTS

Statistical analysis Statistical results of Tilwaka Ksharasutra and Apamarga Ksharasutra has been studied at Department of PG Studies in Shalyatantra, at Government Ayurveda Medical College and Hospital, Bengaluru. Total 40 patients are registered in this study. Out of that all 40 patients are studied in this project. 20 patients are

in group A while 20 are in B group. Each patient is observed thoroughly and noted neatly. The observations are recorded and necessary charts and graphs are made

Effect on Pain In this work of 20 patients studied in Fistula in Ano with Group-A Pain relieved are given in detail in Table below. Statistical analysis showed that the mean score which was 2.25 before the treatment was reduced to 0.00 after the treatment with 100% improvement and there is a statistically significant. (P<0.05)

**Effects of Tilwaka Ksharasutra**  
**Effect of Group A- on Pain of Fistula in Ano**

SYMPTOM	Mean score			%	S.D (±)	S.E (±)	t value	p value	
	BT		BT-AT						
Pain	2.25	D 7	1.65	0.60	26.67	0.503	0.115	4.06	<0.05
		D 14	1.25	1.00	44.44	0.459	0.105	6.32	<0.05
		D 21	0.80	1.45	64.44	0.510	0.117	7.85	<0.05
		D 28	0.50	1.75	77.78	0.444	0.102	11.53	<0.05
		D 35	0.25	2.00	88.89	0.459	0.105	14.24	<0.05
		D 42	0.20	2.05	91.11	0.394	0.090	15.16	<0.05
		D 49	0.10	2.15	95.56	0.366	0.084	17.79	<0.05
		D 56	0.05	2.20	97.78	0.410	0.094	19.78	<0.05
		D 63	0.00	2.25	100	0.444	0.102	22.65	<0.05
		D 70	0.00	2.25	100	0.444	0.102	22.65	<0.05

**Group B**

In this work of 20 patients studied in Fistula in Ano with Group-B Pain relieved are given in detail in Table below. Statistical analysis

showed that the mean score which was 2.25 before the treatment was reduced to 0.00 after the treatment with 100% improvement and there is a statistically significant. (P<0.05)

SYMPTOM	Mean score	%	S.D (±)	S.E (±)	t value	p value
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	BT			BT-AT					
Pain	2.25	D 7	1.45	0.80	35.56	0.503	0.115	4.77	<0.05
		D 14	0.80	1.45	64.44	0.459	0.105	7.31	<0.05
		D 21	0.35	1.90	84.44	0.510	0.117	11.54	<0.05
		D 28	0.10	2.15	95.56	0.444	0.102	17.79	<0.05
		D 35	0.05	2.20	97.78	0.459	0.105	19.78	<0.05
		D 42	0.05	2.20	97.78	0.394	0.090	19.78	<0.05
		D 49	0.05	2.20	97.78	0.366	0.084	19.78	<0.05
		D 56	0.00	2.25	100	0.410	0.094	22.65	<0.05
		D 63	0.00	2.25	100	0.444	0.102	22.65	<0.05
		D 70	0.00	2.25	100	0.444	0.102	22.65	<0.05

**Effect on Discharge Group A**

An assessment of Discharge in patients of Fistula in Ano before and after the treatment with Group-A showed reduction in the mean score from

2.25 to 0.05 after the treatment with 97.78% improvement. It is found to be statistically significant (P<0.05)

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Discharge	2.25	D 7	1.75	0.50	22.22	0.513	0.118	2.65	<0.05
		D 14	1.30	0.95	42.22	0.605	0.139	5.36	<0.05
		D 21	0.75	1.50	66.67	0.607	0.139	6.99	<0.05
		D 28	0.60	1.65	73.33	0.587	0.135	7.91	<0.05
		D 35	0.35	1.90	84.44	0.553	0.127	9.79	<0.05
		D 42	0.20	2.05	91.11	0.510	0.117	12.08	<0.05
		D 49	0.10	2.15	95.56	0.489	0.112	15.25	<0.05
		D 56	0.10	2.15	95.56	0.489	0.112	15.25	<0.05
		D 63	0.05	2.20	97.78	0.523	0.120	16.57	<0.05

		D 70	0.05	2.20	97.78	0.523	0.120	16.57	<0.05
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**Group B**

An assessment of Discharge in patients of Fistula in Ano before and after the treatment with Group-B showed reduction in the mean score from

2.00 to 0.00 after the treatment with 100% improvement. It is found to be statistically significant (P<0.05)

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Discharge	2.00	D 7	1.15	0.85	42.50	0.366	0.084	10.38	<0.05
		D 14	0.85	1.15	57.50	0.587	0.135	8.76	<0.05
		D 21	0.30	1.70	85.00	0.470	0.108	16.17	<0.05
		D 28	0.15	1.85	92.50	0.366	0.084	22.58	<0.05
		D 35	0.05	1.95	97.50	0.224	0.051	39.00	<0.05
		D 42	0.00	2.00	100	0.000	0.000	0.000	0.000
		D 49	0.00	2.00	100	0.000	0.000	0.000	0.000
		D 56	0.00	2.00	100	0.000	0.000	0.000	0.000
		D 63	0.00	2.00	100	0.000	0.000	0.000	0.000
		D 70	0.00	2.00	100	0.000	0.000	0.000	0.000

**Effect on Length of the Track of Fistula in ano. Group A**

Magnitude of Length of the Track in patients of Fistula in Ano before and after the

treatment was assessed and analyzed statistically. In patients registered in GROUP-A group showed significant improvement (P<0.05)

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Length of the Track	3.35	D 7	2.76	0.59	17.61	0.265	0.061	1.40	<0.05
		D 14	2.15	1.20	35.78	0.355	0.081	2.77	<0.05
		D 21	1.48	1.88	55.97	0.534	0.123	4.21	<0.05
		D 28	1.11	2.25	67.01	0.362	0.083	5.44	<0.05
		D 35	0.73	2.62	78.21	0.495	0.114	6.70	<0.05
		D 42	0.52	2.83	84.48	0.531	0.122	7.81	<0.05
		D 49	0.33	3.03	90.30	0.685	0.157	8.90	<0.05

	D 56	0.25	3.10	92.54	0.760	0.174	9.68	<0.05
	D 63	0.18	3.18	94.78	0.868	0.199	10.41	<0.05
	D 70	0.10	3.25	97.01	1.024	0.235	11.28	<0.05

**Group B**

Magnitude of Length of the Track in patients of Fistula in Ano. before and after the

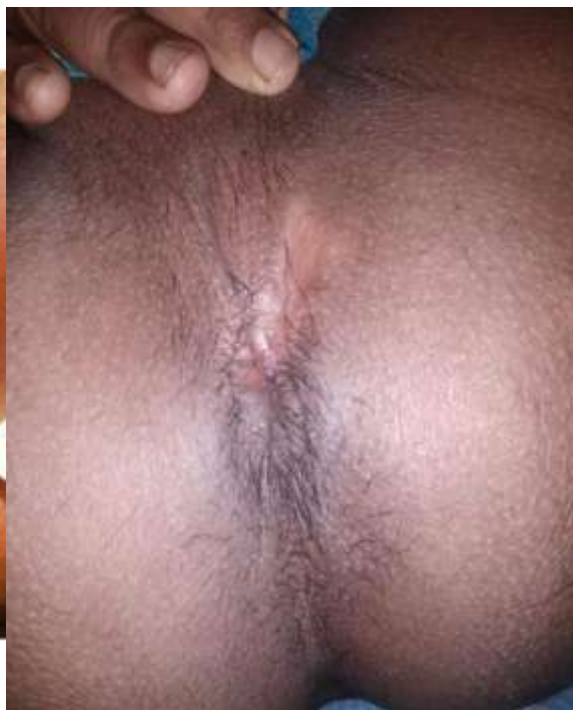
treatment was assessed and analyzed statistically. In patients registered in GROUP-B group showed significant improvement (P<0.05)

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Discharge	2.00	D 7	1.15	0.85	42.50	0.366	0.084	10.38	<0.05
		D 14	0.85	1.15	57.50	0.587	0.135	8.76	<0.05
		D 21	0.30	1.70	85.00	0.470	0.108	16.17	<0.05
		D 28	0.15	1.85	92.50	0.366	0.084	22.58	<0.05
		D 35	0.05	1.95	97.50	0.224	0.051	39.00	<0.05
		D 42	0.00	2.00	100	0.000	0.000	0.000	0.000
		D 49	0.00	2.00	100	0.000	0.000	0.000	0.000
		D 56	0.00	2.00	100	0.000	0.000	0.000	0.000
		D 63	0.00	2.00	100	0.000	0.000	0.000	0.000
		D 70	0.00	2.00	100	0.000	0.000	0.000	0.000

**Comparative results of Group A and Group B**

Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with unpaired t test. The test shows that

the treatment is equally significant in Group B when compared to Group A. Group A overall result is 98.79% and Group B overall result is 100%.

**DURING PROCEDURE****AFTER FOLLOW UP****Discussion on observations:**

In the present study, the total numbers of cases studied were 40. In Group A, Arka Ksheera based Tilwaka Ksharasutra and in Group B, Apamarga Kshara Sutra is used. Patients treated were carefully analyzed. The parameters considered were Pain, Discharge, Length of the track and Unit cutting time in (days/cm). The observation of Arka Ksheera based Tilwaka Kshara Sutra and Snuhi Ksheera based Apamarga Kshara Sutra have been made on different parameters discussed below.

**Age:** The incidence of Bhagandara is commonly seen in age group 21-60 years with peak incidence in the age group of 41- 50 years (14 cases -35 %) and 31- 40 years (11 cases -27.5 %). This clarifies incidence of Bhagandara is common in middle age group. Can be inferred as active working group, who used to sit and work for long time or riding vehicles for long time.

**Gender:** In this Study, 80% (32 cases) patients were males, 20% (8 cases) patients were female with ratio of 4:1. Hill (Jr) 1967 and Charles C Thomas has reported that Abscess & Fistula are common in males. It can be due to male are more exposed for etiological factors like prolonged sitting, continuous riding of vehicles, untimely diet, unhygienic etc. Another factor may be anatomical

variation of the male's peri-anal structures in comparison to females.

**Religion:** In relation to Religion 36 cases (90%) were Hindus and 4 cases (10%) were Muslims. This is because of demographic distribution.

**Occupation:** In relation to Occupational status, highest incidence was found in Driver's 10 cases (25.0 %), followed by house wife 6 cases (15%). Coolie were of 5 cases (12.5%). Students and Carpenter were 4(10%) cases each, engineers 3(7.5%) cases, garage worker and teacher 2 cases each (5%), marketing worker, hotel worker and security were 1 cases each. This study shows that the disease is more common in Drivers because of prolonged sitting.

**Socio-economic status:** In relation to Socio-economic status 29 cases (72.5%) were from Middle socio economic class, 4 cases (10%) were from Upper socio-economic class and 7 cases (17.5%) were from lower socio-economic class. Individual belonging to middle and lower socio-economic class seems to be higher. This is because the study was conducted in Government institution and hence upper socio-economic class prefer to go private sector. And also due to lack of nutritional supplements in these classes.

**Diet:** In relation to nature of Diet 33 cases (82.5%) were taking Mixed diet and 7 cases (17.5%) were vegetarian. The study shows incidence is more in



non-vegetarians. It might be probably due to study was conducted in population where people consume mixed diet and Acharya Sushruta also mentioned in Nidana of Bhagandara that people consuming Mamsa and Asthi are prone to this disease.

**Prakriti:** relation to the Prakriti, 21 cases (52.5%) were vatapitta, 12 cases (30%) were pittakapha and 7 cases (17.5%) were vatakaphaja. This says people having pitta prakriti are prone to Bhagandara

**Type of Bhagandara:** In relation to type of Bhagandara, 18 cases (45%) were Ushtragreeva, 16 cases (40%) were Parisravi and 6 cases (15%) were of riju variety. Ushtragreeva Bhagandara is correlated to Inter-sphincteric fistula in Ano which is again commonest variety of fistula in Ano.

**Duration:** In relation to the chronicity of the Disease, 34 cases (85%) cases were below one year and 6 (15%) cases were above 1 year. This shows people seeks medical treatment with in a year when he or she couldn't bear pain and other discomfort caused by fistula.

**Position of external opening:** Out of 40 patients, external opening in left upper quadrant i.e 1,2,3 'o' clock – 4,0,2 cases were found respectively. In left lower quadrant i.e 4,5,6 'o' clock position 5,8,1 cases were found respectively. In right lower quadrant i.e, at 7, 8 and 9 o'clock position 9,1, 4 cases were found respectively. In right upper quadrant i.e at 10,11,12 '0' clock position 0,5,1 cases were found.

From this data, it shows that fistula mostly occur in lower quadrant, i.e the most dependent part while in sitting position. Initial length of fistulous track In relation to the initial length of fistula track, 36 cases (90%) were below 6 cm, and 4 cases (10%) were in the range 6-9cm. This may be because, Inter-sphincteric fistula is the most common variety of fistula in Ano which will fall within 1-5cms. Also, low anal fistulas are common rather than high anal. (Table No.34 Graph No.12) Recurrence Out of total 40 patients in Group A and Group B, no patients had recurrence of disease for the follow up of 3 months, out of all the patients when history was noted it was found that 11 patients had Fistula in Ano before and underwent treatments like, Fistulectomy, Laser therapy and some patient underwent Ksharasutra therapy. Statistical analysis with different parameters on effect of Arka Ksheera based Tilwaka Kshara Sutra and Apamarga Ksharasutra application before and after treatment with 40 patients of Bhagandara as given below.

#### Discussion on the probable mode of action of Arka Ksheera based Tilwaka Kshara sutra

• Ksharasutra cuts the track with its Ksharana (cutting property) and Kshanana (burning property) action and simultaneously heals the track with its Ropana (healing) quality. These actions are due to its ingredients: Tilwaka Kshara, Curcuma longa and the latex of Calotropis gigantea.

• Arka ksheera acts as binding agent and it preserves kshara properties intact. Latex of Calotropis gigantea is known for its wound healing nature and also inhibits proteolysis property. Also, Arka Ksheera is corrosive and irritant in nature

• The Kshara is well known for its Ksarana and Kshanana and wound healing properties. Tilwaka Kshara applied on the thread allows chemical curettage of the fibrosed and unhealthy granulation tissue. The presence of proteolytic enzymes is capable for its corrosive, caustic, anti-microbial and bactericidal properties.

• Haridra causes vasodilation when applied on the mucous membrane. Also, haridra possess anti-inflammatory, analgesic, Kushtghna and Vranashodhaka ropaka properties which contribute to proper cutting and healing of the tract.

• Kshara sutra not only cuts the tissue, but also does continuous drainage of the wound, which enables to lay the track open

#### IV. CONCLUSION

Assessment of pain, Discharge, Length of tract in Group A showed 100%, 97.78%,97.01% improvement and in Group B 100%, 100%, 100% improvement respectively. Mean UCT in Group A was 10.754 days/cm and in Group B 8.610days/cm. Group A overall result is 99.79% and Group B overall result is 100%. The test shows that the treatment is not statistically significant in both Group A and Group B. The study showed that the trial drug was as effective as the standard drug in the treatment of Bhagandara.

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