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AN OPEN LABELLED CLINICAL STUDY TO EVALUATE THE EFFECT OF ERANDA KARKATI KSHEERA (PAPAYA LATEX) BASED CHITRAKA KSHARASUTRA IN THE MANAGEMENT OF BHAGANDARA W.S.R TO FISTULA IN ANO

DR ADARSH MANOHAR SHAHAPURKAR,DR RAJNEESH V GIRI
P.G SCHOLAR, PROFF AND HOD ,DEPTOF SHALYA TANTRA
SDM COLLEGE OF AYURVEDA HOSPITAL AND RESEARCH CENTRE UDUPI, KARNATAKA

INTRODUCTION

Bhagandara disease was known to mankind since vedic era, it was termed as 'Durnama" [2]. for disorders of anal canal, earliesr reference we get in garuda purana where Use of Guggulū, Vyosha and Triphala prepared with ghee mention in this disease. Detailed description about the Nidana, Samprapti, Laxana and Chikitsa is available in Sushruta Samhita (1500 B.C) and Ashtanga Hridaya among Brihatrayees. While, Charaka (1000 B.C) has mentioned about the disease Bhagandara in Shotha Chikitsa Adhyaya and advocated Kshara Sutra and other remedies in the management of Bhagandara. It is considered as one among the Ashtamahagada[3]. It cause pain in bhaga, guda and Basti, which is an inflammatory tract with an external opening in the perianal skin and an internal opening in the anal canal or rectum.

Bhagandara (fistula-in-ano) is prevalent in the populations worldwide and its prevalence is second highest after haemorrhoids. According to a recent study conducted on the prevalence of anal fistula in a London hospital by Sainio P., considering the incidences and epidemiological aspects for Fistula-in-ano in a defined population; approximately 10% of all patients and 4% of new patients were reported to suffer from this disease. A similar study in India has been reported anal fistula to constitute 15-16% of all anorectal surgical admissions. This global problem is being managed by specialized proctologists and general surgeons at different renowned medical centres but; in spite of the best possible efforts, recurrence rate (20-30%) still remains, as a big challenge in front of the medical as well as surgical world.

Modern medicine holds surgery such as Fistulotomy, Fistulectomy[4]. Seton technique, Advanced flap procedure (AFP), Fibrin glue, Laser surgery, Ligation of the interspincteric fistula track (LIFT), Endoscopic ablations etc as the first line of management. Main risk involved in these techniques are high rate of recurrence and causation of anal incontinence[5], and prolonged period of hospitalization and wound care is still challenge. Hence Ksharasutra has emerged as an effective and safe remedy which has been accepted globally as a minimally invasive surgical technique with least adverse effects [6].

The Indian Council of Medical Research (ICMR) conducted randomized multi-centric clinical trials on Ksharasuthra therapy and found that, the recurrence of anal fistula was only 4% as compared to 11% in patients who had undergone conventional surgery[7].

According to classics, Snuhi Ksheera is used in the preparation of Ksharasutra. But Snuhi is not available throughout the year; the time of collection is in Adana Kala particularly in Shishira Ritu. Due to this fact, we should collect the Ksheera in February-march only. Hence as an alternative to Snuhi Ksheera, Papaya Ksheera is used as it is easily available, has binding properties, can be preserved and used for long duration. Papaya Ksheera is Vranaghna, Vedanasthapana, Krimighna and Kushtaghna. Ksharasutra is a simple, cost effective and safe procedure with high success rate (95.98%) and negligible recurrence rate (3.33%). Ksharasutra therapy can replace complicated modern procedures like Fistulectomy and Fistulotomy, as the probable complications of surgery like incontinence, stenosis and stricture are ruled out by the usage of Ksharasutra.. After the establishment of Ksharasutra as an effective treatment methodology, it has been a constant endeavour of Ayurvedic surgeons to bring in innovative and effective changes in the preparation of Ksharasutra. This work of preparation of Eranda Karkati Ksheera (Papaya latex) based Chitraka Ksharasutra is also a step in the same direction.

AIMS AND OBJECTIVES

- To evaluate the effect of Eranda Karkati Ksheera (Papaya latex) based Chitraka Ksharasutra in the management of Bhagandara w.s.r to Fistula in ano.

MATERIALS AND METHODS

Study design

- It was an open labelled, clinical study with pre-test and post-test design.

Selection of patients

Patients who presented with complaints of abscess, discharge, itching, and pain in the perianal region were asked to provide a detailed history. A comprehensive clinical examination was then conducted in the Outpatient Department of the Shalyatantra SDM College of Ayurveda and Hospital Udupi, Karnataka. Patients who met the diagnostic criteria were selected for the study.

Inclusion criteria

- Selection of patients was done irrespective of sex.
- Patients in the age group of 18 to 70 years
- Patients with clinical signs and symptoms of *Bhagandara* and Fistula in ano as explained in Ayurvedic and modern text books.

Exclusion criteria

- Patients suffering from systemic diseases like uncontrolled diabetes, Chronic Renal, Hepatic, Cardiac disorders
- Patients suffering from secondary fistula due to carcinoma, ulcerative colitis, Tuberculosis
- Patients suffering from infectious disease like H.I.V, Hepatitis-B
- High anal fistula

Method of preparation

1. Eranda Karakti Ksheera – 11 coatings
2. Eranda Karkati Ksheera + Chitraka Kshara - 7 coatings
3. Eranda Karkati Ksheera+ Haridra choorna – 3 Coatings

METHOD OF APPLICATION

The 30 patients diagnosed with Bhagandara fulfilling inclusion criterias were selected and treated with Ksharasutra as per the standard method of application, On the first day primary threading was done. Subsequently on every 7th day Ksharasutra was changed and tract length was measured. Ksharasutra change was continued till the fistulous tract completely gets cut through.

Preoprative measures

Patients were admitted to the hospital one day prior to operation. Previous day night the patient was asked to have light diet and then advised nil orally. The consent of patient in own language was taken for Ksharasutra ligation under Short G.A or SA or I.V. Sedation. The part preparation was done. Soap water enema was also given. Inj.Tetanus toxoid & Inj.Atropine were given 30 min before procedure

Operative measures

The patient will be comfortably laid in the lithotomy position. Local anesthesia in required dosage will be injected into the sphincters around the anus or SA or GA depending on the condition. Anal Dilation with lubricated gloved fingers was done and findings were reconfirmed. A malleable copper probe was introduced into the external opening and it was carefully introduced along the track. The finger kept in the anal canal for support the movement of the probe towards the internal opening. The probe was brought out of the internal opening and then it was carefully taken out through the anal canal. A Barbour's thread of suitable length will be passed through the eye of the probe and the probe will be pulled out to position the thread in the track. The two ends of the thread will be tied outside the anal orifice. Surgical pad was applied to the area and the patients were shifted to the post-operative ward.

Post operative procedures

1. Sitz bath daily with 10 ml Dettol twice per day for 15 min
2. Tab. Triphala guggulu 1 tid
3. Tab. Gandhaka rasayana 1 tid
4. Avipattikara choorna ½ tsp HS with warm water
5. Jatyadi taila Instillation of 10 ml Per rectum at Bed time till the track healed completely.

Change of Ksharasutra

The Ksharasutra was changed at weekly interval, for this railroad technique was adopted. A new Ksharasutra was tied to the previously applied Ksharasutra in position towards outer end of the knot. Then an artery forceps was applied inner to the same knot. Then the old Ksharasutra was cut between the artery forceps and the knot. Pulling of the artery forceps along with the Ksharasutra ultimately replaced the old sutra by new Ksharasutra. Then the two ends were ligated tightly and bandaging was done.

The same procedure was followed for successive changes of Ksharasutra at weekly interval. At each sitting of changing of Ksharasutra, the length of the previous Ksharasutra was measured and recorded. This gave an idea of the amount of remaining tissue to be cut through and time necessary to cut through each centimeter of the tissue.

Followup

All the patients were instructed to visit anorectal clinic of Shalyatantra OPD of SDM Hospital, Udupi once in a week to change the Ksharasutra and to make thorough follow-up of the cases.

After the track was cut through, patients were treated on the line of wound management till the wound healed completely. For each follow-up visit, patient was examined for any recurrence of the disease or any associated complications.

OBSERVATIONS

Observations were made before treatment and everytime patients came for change of ksharasutra until wound heals completely.

ASSESSMENT CRITERIA

A. Subjective criteria

1. Pain assessment

Visual Analogue scale(VAS) it has grading 0-10 , assessment of pain was done before treatment after after treatment in several intervals

VAS Scale

Grade	Desciption
0	No hurt
2	Hurts little bit
4	Hurts little more
6	Hurts even more
8	Hurts whole lot
10	Hurts worst

2. Burning sensation

Burning sensation was assessed before treatment and after treatment

0- No burning sensation
1- Mild occasional episodes of burning
2- Moderate continuous burning sensation
3- Severe burning

3. Itching

0- No itching
1- Mild occasional episodes of itching
2- Moderate continuous itching
3- Severe itching

4. Discharge

0- No discharge
1- Mild (If wound wets ½ * ½ cm guaze piece)
2- Moderate (If wound wets 1*1 cm guaze piece)
3- Severe (If wound wets more than 1*1 cm guaze piece)

4- Continuous and profuse discharge

5. The St.Mark's Score

Type of Incontinence	Frequency				
	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4
Wears pad	0	1	2	3	4

0-Complete continence

20- Complete incontinence

B. Objective criteria

- Length of the tract - Length of the tract was measured in every sitting in centimeters (once in 7 days)
- Unit cutting time (U.C.T) - The unit cutting time represents the number of days required to cut one cm of the tract. This is calculated by dividing total number of days taken by a fistula to heal by the initial length of the tract denoted as days/cm.

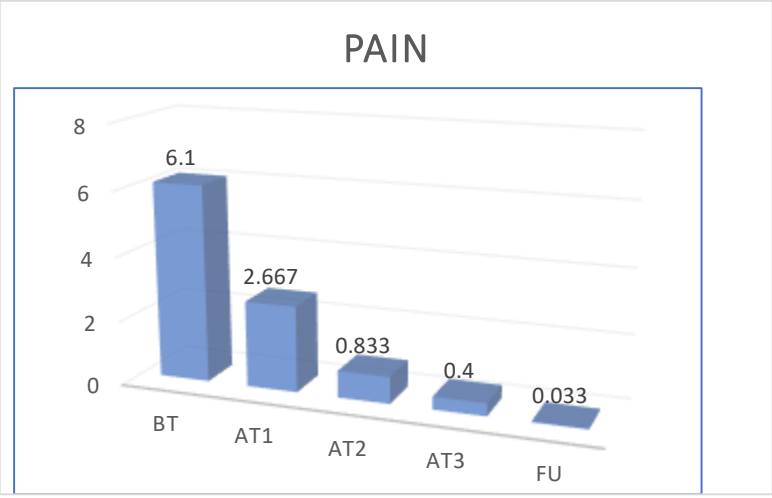
$$U.C.T = \frac{\text{Total no.of days taken to cut through the tract}}{\text{Initial length of tract in cms}}$$

STATSICAL ANALYSIS OF RESULTS

1. EFFECT ON PAIN

MEAN BT	MEAN VALUE		DIFF d	% of relief	Wilcoxon rank test			
					SD	S.E.M	P	significance
6.100	AT 1	2.667	3.433	56.27	1.322	0.241	<0.001	HS
	AT 2	0.833	5.267	86.34	0.592	0.108	<0.001	HS
	AT 3	0.400	5.7	93.4	0.563	0.103	<0.001	HS
	FU	0.033	6.067	99.45	0.183	0.033	<0.001	HS

B.T		+ VE RANK	-VE RANK
	AT 1	0	-465.000
	AT 2	0	-465.000
	AT 3	0	-465.000
	FU	465.000	0



Mean score observed before treatment was 6.100

After treatment 1 ie., on 14th day value reduced to 2.667, the effect of treatment showed 56.27% improvement in pain scale with statistically highly significant (P=<0.001).

After treatment 2 ie., on 28th day value reduced to 0.833, the effect of treatment showed 86.344% improvement in pain scale with statistically highly significant (P=<0.001).

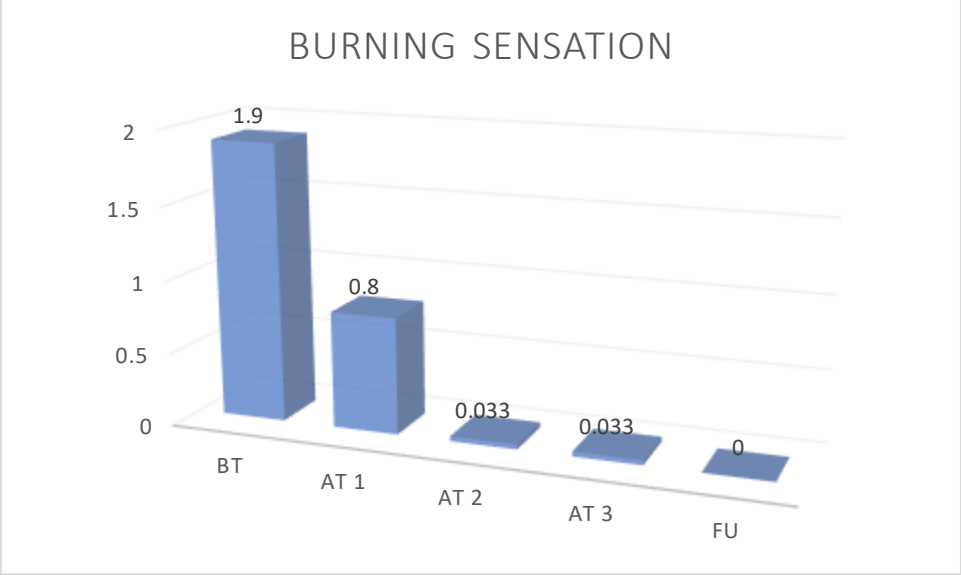
After treatment 3 ie., on 35th day value reduced to 0.400, the effect of treatment showed 93.4% improvement in pain scale with statistically highly significant (P=<0.001).

On Follow up value reduced to 0.033, the effect of treatment showed 99.45% improvement in pain scale with statistically highly significant (P=<0.001).

2. EFFECT ON BURNING SENSATION

MEAN BT	MEAN VALUE		DIFF d	% of relief	Wilcoxon rank test			
					SD	S.E.M	P	significance
1.900	AT 1	0.800	1.1	57.89	0.551	0.101	<0.001	HS
	AT 2	0.033	1.867	98.26	0.183	0.033	<0.001	HS
	AT 3	0.033	1.867	98.26	0.183	0.033	<0.001	HS
	FU	0	1	100	0	0	<0.001	HS

B.T		+ VE RANK	-VE RANK
	AT 1	11.500	-394.500
	AT 2	0	-435.000
	AT 3	0	-435.000
	FU	0	-435.000



Mean score observed before treatment was 1.900

After treatment 1 ie., on 14th day value reduced to 0.800, the effect of treatment showed 57.89% improvement in burning sensation criteria with statistically highly significant (P=<0.001).

After treatment 2 ie., on 28th day value reduced to 0.033, the effect of treatment showed 98.26% improvement in burning sensation criteria with statistically highly significant (P=<0.001).

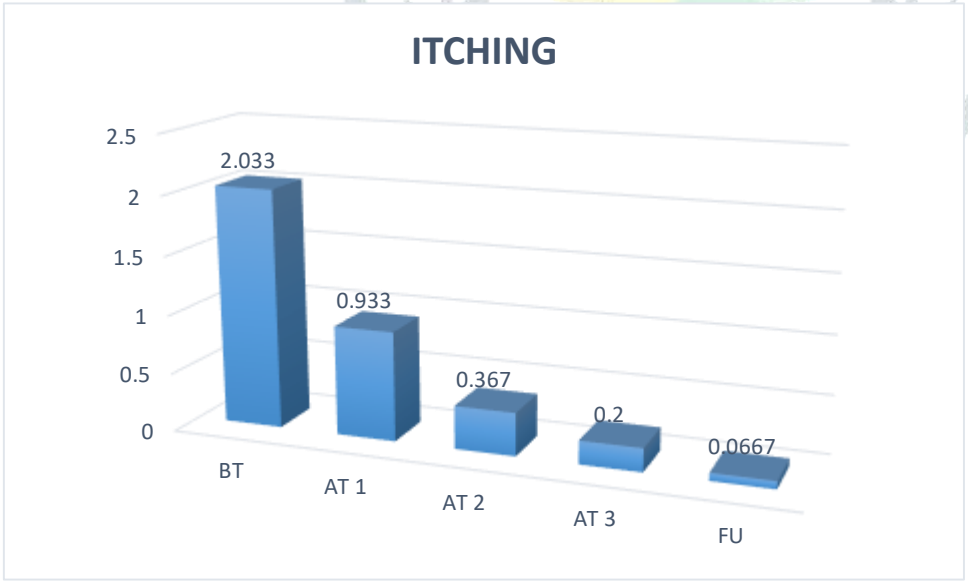
After treatment 3 ie., on 28th day value reduced to 0.033, the effect of treatment showed 98.26% improvement in burning sensation criteria with statistically highly significant (P=<0.001).

On Follow up value reduced to 0, the effect of treatment showed 100% improvement in burning sensation criteria with statistically highly significant (P=<0.001).

3. EFFECT ON ITCHING

MEAN BT	MEAN VALUE		DIFF d	% of relief	Wilcoxon rank test			
					SD	S.E.M	P	significance
2.033	AT 1	0.933	1.1	54.10	0.640	0.117	<0.001	HS
	AT 2	0.367	1.666	81.9	0.490	0.0895	<0.001	HS
	AT 3	0.200	1.833	90.16	0.407	0.0743	<0.001	HS
	FU	0.0667	1.9663	96.71	0.365	0.0667	<0.001	HS

B.T		+ VE RANK	-VE RANK
	AT 1	0	-300.000
	AT 2	0	-465.000
	AT 3	0	-465.000
	FU	0	-435.000



Mean score observed before treatment was 2.033

After treatment 1 ie., on 14th day value reduced to 0.933, the effect of treatment showed 54.10% improvement in itching criteria with statistically highly significant (P=<0.001).

After treatment 2 ie., on 28th day value reduced to 0.367, the effect of treatment showed 81.9% improvement in itching sensation criteria with statistically highly significant (P=<0.001).

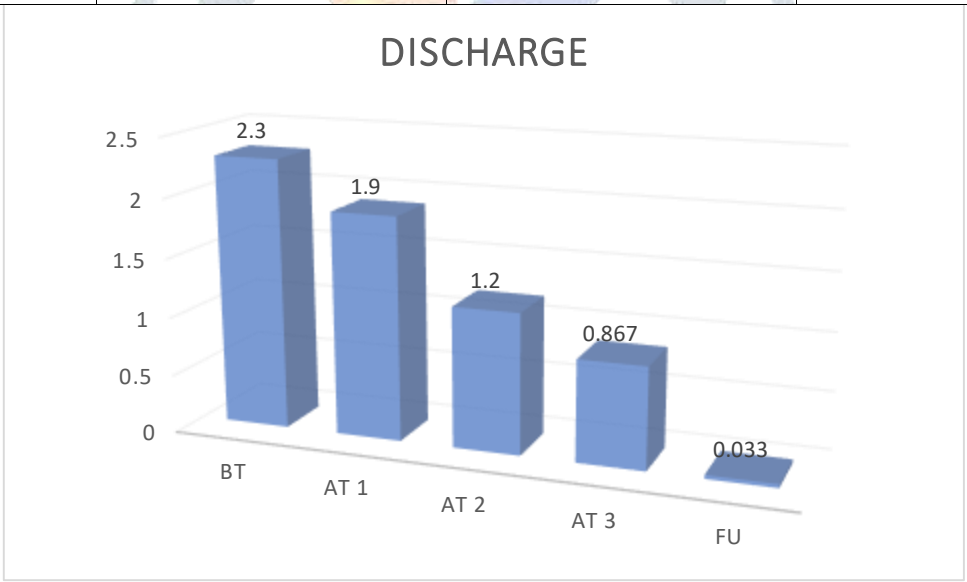
After treatment 3 ie., on 28th day value reduced to 0.200, the effect of treatment showed 90.16% improvement in itching sensation criteria with statistically highly significant (P=<0.001).

On Follow up value reduced to 0.0667, the effect of treatment showed 96.71% improvement in itching sensation criteria with statistically highly significant (P=<0.001).

4. EFFECT ON DISCHARGE

MEAN BT	MEAN VALUE		DIFF d	% of relief	Wilcoxon rank test			
					SD	S.E.M	P	significance
2.300	AT 1	1.900	0.4	17.39	0.759	0.139	0.018	S
	AT 2	1.200	1.1	47.82	0.761	0.139	<0.001	HS
	AT 3	0.867	1.433	62.30	0.730	0.133	<0.001	HS
	FU	0.033	2.267	98.55	0.183	0.033	<0.001	HS

B.T		+ VE RANK	-VE RANK
	AT 1	37.000	-153.000
	AT 2	31.000	-347.000
	AT 3	16.000	-335.000
	FU	0	-435.000



Mean score observed before treatment was 2.033

After treatment 1 ie., on 14th day value reduced to 1.900, the effect of treatment showed 17.39% improvement in discharge criteria with statistically significant (P=<0.001).

After treatment 2 ie., on 28th day value reduced to 1.200, the effect of treatment showed 47.82% improvement in discharge criteria with statistically significant (P=<0.001).

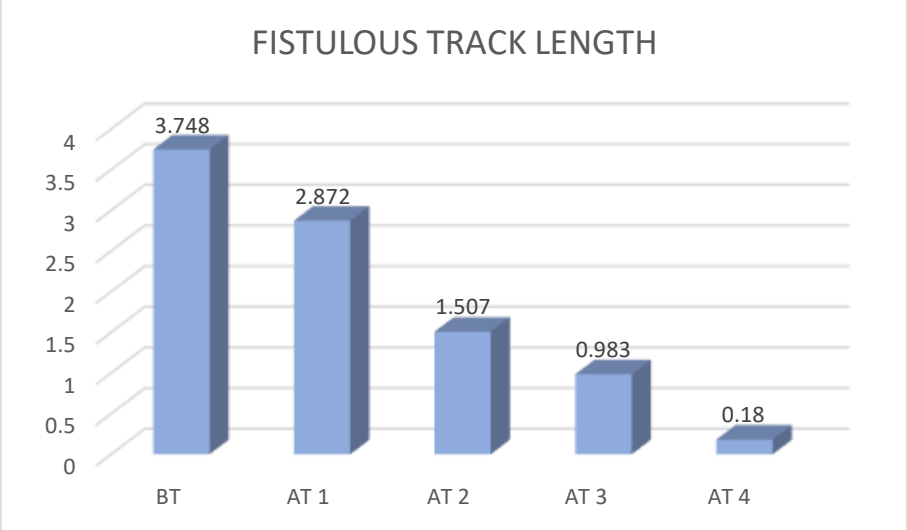
After treatment 3 ie., on 28th day value reduced to 0.867, the effect of treatment showed 62.30% improvement in discharge criteria with statistically significant (P=<0.001).

On Follow up value reduced to 0.033, the effect of treatment showed 98.55% improvement in discharge criteria with statistically significant (P=<0.001).

5. EFFECT ON FISTULA TRACK LENGTH (Paired t test)

Paired t test	BT	AT 1	AT 2	AT 3	AT 4 (56TH DAY)
MEAN	3.748	2.872	1.507	0.983	0.180
S.D	1.550	1.5540	1.493	1.306	0.488
S.E	0.288	0.286	0.276	0.238	0.0891
MD	-	0.876	2.241	2.765	3.568
MD%	-	23.37	59.79	73.77	95.19

	t	p	Significance
AT 1	2.981	0.00589	S
AT 2	7.556	<0.001	S
AT 3	9.831	<0.001	S
AT 4	12.254	<0.001	S



Mean score observed before treatment was 3.748

After treatment 1 ie., on 14th day value reduced to 2.872, the effect of treatment showed 23.37% improvement in length of fistulous track with statistically significant (P=<0.001).

After treatment 2 ie., on 28th day value reduced to 1.507, the effect of treatment showed 59.79% improvement in length of fistulous track with statistically significant (P=<0.001).

After treatment 3 ie., on 28th day value reduced to 0.983, the effect of treatment showed 73.77% improvement in length of fistulous track with statistically significant (P=<0.001).

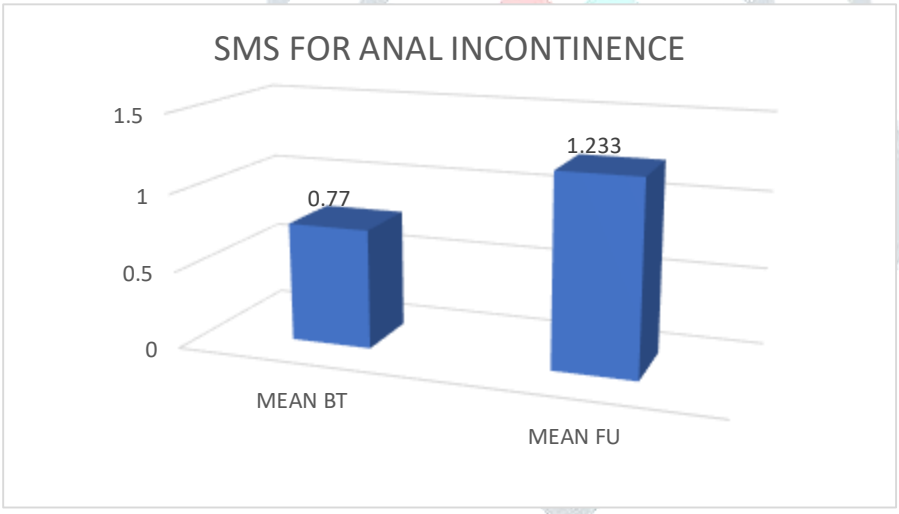
On Follow up ie., on 56th day value reduced to 0.180, the effect of treatment showed 95.19% improvement in length of fistulous track with statistically significant (P=<0.001).

6. EFFECT ON SAINT MARKS ANAL INCONTINENCE SCORE

TABLE NO 57

MEAN BT	MEAN VALUE		DIFF d	% of relief	Wilcoxon rank test			
					SD	S.E.M	P	significance
0.700	FU	1.233	-0.533	76.14↑	1.251	0.228	0.043	S

B.T		+ VE RANK	-VE RANK
	FU	+132.00	-39.00



Mean score observed before treatment for anal incontinence was 0.700

After treatment value increased to 1.233, the effect of treatment showed aggrevation of anal incontinence by 76.14% , with statistically significant P value 0.043 (P<0.001).

CASE NO 1

Before treatment

During treatment

Post op day 7

After treatment

CASE NO 2

Before treatment

During treatment

Post op day 1

After treatment

DISCUSSION

Acharya Sushruta, a pioneering figure in Ayurvedic surgery from around 1500-1000 BC, who elaborately explained about Bhagandara which made us understanding about the disease simpler, which can be co-related to fistula in ano in modern surgery, His detailed descriptions cover the etiology (causes), pathology (development), signs and symptoms, and various types of this disease. The description given by Acharya Sushruta still holds good and principles which are explained can be still used in contemporary surgical practise.

In most of the patients of fistula in ano there will be history of anorectal abscess, which burst open on its own or Surgically incised. But sometimes conditions like tuberculosis, sexually transmitted diseases, Crohn's disease or ulcerative colitis can lead to fistula in ano. Usually patients are presenting with complaints of discharge from perianal region associated with pain, Other clinical features are pain with defecation, pruritus ani, chronic drainage of pus from abscess, erythema, induration, excoriated skin and in many cases associated systemic symptoms. The patient experiences a throbbing type of pain in the perianal region and it is relieved by suppuration of the abscess followed by the pus discharge. Fistulectomy and fistulotomy are the common surgical intervetions are performed for low fistula in ano.

Ksharasutra is one of the great contribution of Ayurveda which has unique properties which heals the fistulous track without causing much damage to anal sphincters and recurrence rate is also very minimal. The Apamarga ksharasutra is well proven to be an effective treatment for fistula in ano and has been standardized by the CCRAS, an apex research organization of GOI in the field of Indian system of medicine.

Ksharasutra acts as a cutting as well as draining seton. Various scientific studies suggest that due to the effect of drugs present in Ksharasutra and mechanical pressure of tying, it gradually cuts and heals the fistulous track simultaneously.

Properties of Ksharasutra

- Kshara being alkaline in nature, cause fat saphonification and formation of alkaline proteinates which subsequently result in liquefaction necrosis when applied over tissues. It also extracts considerable water from cells due to its hygroscopic nature causing cell death and tissue damage, so by virtue of its caustic action. It destroys and removes unhealthy tissues and promotes healing of fistulous track. When Kshara applied over locally colonic mucosa of wister rats, it causes necrosis within 10 minutes of time (Sahu M., Sharma A., Dec.2014)[8].
- It destroys infected tissues and root cause of the fistula ie,. Infected anal gland.
- The active ingredients in Ksharasutra control infection by microbicidal action of drugs used for preperaraion of Ksharasutra.
- Drugs like Haridra, Guggulu etc are helpful in healing of fistulous wound by virtue of their anti-inflammatory and wound healing properties.
- It facilitates drainage of pus caused by infection and helps in healing.
- The mechanical pressure by tying Ksharasutra as well as the necrotic effect of Kshara helps in gradual cutting and laying open of the track (like multi sitting fistulotomy).

Acharya Sushruta described excision or laying open as primary treatment for fistula in ano followed by cauterization. He has described the use of Ksharasutra primarily for the use sinus disease and in persons where surgical intervention is not suitable like weak, timid, elderly persons or children etc. But, it is being used as primary mode of treatment for the management of all types of fistula in ano. We should consider other co-existing diseases like diabetes mellitus, immunocompromised states, infections like tuberculosis, crohn's disease, Ulcerative colitis, blood dyscrasis, nutritional deficiencies etc if present we should treat take care of all these before initiating treatment.

According to Classics, Snuhi Ksheera is used in the preparation of Ksharasutra. But Snuhi is not available throughout the year, the time for collection is in Adana Kala particularly in Shishira Ritu, Snuhi coagulates within few minutes of collection, hence in order to overcome these lacuna Eranda Karkati Ksheera (Papaya latex) is used, as it easily available, has binding properties and can be preserved for long duration and collection of Papaya latex is also simple and can be found everywhere and quantity is also more compared to Snuhi, hence Papaya latex was selected as base in the preperatiion of Ksharsutra in this study.

The probable mode of action

- **Papaya Ksheera**

It is having Vranaghna, Vedanasthapana, Krimighna properties and acts as anti-inflammatory, anti-microbial agent to counteract the pain, discharge and pruritis ani within short duration. Papaya Ksheera acts as enzymatic tissue debriding agent, which helps in removal of fibrosed and unhealthy granulation tissue. It enhances collagen synthesis, thus improving healthy granulation tissue, wound contraction and complete healing.

- **Chitraka**

Chitraka possessing anti-inflammatory, Wound healing action, anti-viral, anti-bacterial properties which reduced the complication of sepsis and wound healed without recurrence

1. Wound healing Action of Chitraka[9].

Wound healing effects of H. indicum, P. zeylanica and A. indica in rats. The ethanolic extracts of H. indicum, P. zeylanica and A. indica were evaluated for their wound healing Action in rats. H. indicum possesses better wound healing Action than P. zeylanica and A. indica.

2. Anti-inflammatory Action of Chitraka[10]

Experimental study to evaluate anti-inflammatory Action of Phyllanthus emblica, P. zeylanica and C. rotundus in acute models of inflammation, namely carrageenan induced rat paw edema and acetic acid induced peritonitis in mice. In carrageenan induced paw oedema, P. emblica, P. zeylanica and C. rotundus showed a trend to reduce the oedema while the combination of P. emblica + P. zeylanica (PI: 20.64%) showed results comparable to aspirin (23.74%). Whereas in a model of acetic acid induced peritonitis, all the plant drugs, that is, P. emblica, P. zeylanica, C. rotundus and a combination of P. emblica + P. zeylanica showed a significant decrease in the protein content of the peritoneal exudates compared with the disease control group ($p < 0.05$).

3. Anti-bacteria action of Chitraka[11].

Anti-bacterial Action of P. zeylanica roots on some pneumonia causing pathogens. The anti-bacterial Action of polar (aqueous) and non-polar (pet. Ether) extracts was prepared from the roots of P. zeylanica. Minimum inhibitory concentration value of this particular compound showed comparative Action resembling the commonly used tetracycline. Antiviral Action broad spectrum antibiotic,

RESULTS

- Eranda Karkati Ksheera based Chitraka Ksharasutra showed significant reduction in pain, burning sensation, discharge from perianal region and showed significant improvement in terms of incontinence.
- UCT of Eranda Karkati Ksheera based Chitraka Ksharasutra found to be 9.34

CONCLUSION

Fistula-in-Ano or Bhagandara is an infective condition caused by invasion of anal glands and ducts by various pathogenic organisms. The ingredient Papaya Ksheera which has been used as coating over the thread, induces an effective fibrolytic action, separates and removes the debris and cleanses the fistulous tract. Thus, encourages healing by fresh granulation tissue formation from the base. The contents of Eranda Karkati Ksheera (Papaya latex) based Chitraka Ksharasutra helps by reducing the infective organisms by the antibacterial property simultaneously cut and heal the track by Chedana, Bhedana, Ksharana and Kshanana action.

This combination of ingredeients of Ksharasutra has given promising results and it is cost effective too, and has good UCT , hence can be adopted by proctologists in the field of Ayurveda.

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