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Efficacy of *Tilanala Ksharasutra* in the Management of *Bhagandara* with special reference to Fistula-in-Ano

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ABSTRACT

Introduction: The disease Bhagandara is included as one among the *Ashtamahagadas*. It is one of the most common diseases pertaining to ano-rectal region. The literal meaning of *Bhagandara* is *daarana* which is splitting up/bursting up of *pakwa pidaka* in the *bhaga, guda, basti pradesha* results in the formation of a communicating tract, thus causing discomfort to the patient. Up to 26.5% recurrence rate, 40% of high risk of impaired continence and 5.6% non-healing of the wound were reported after surgical treatment. To overcome these lacunae the Ksharasutra ligation procedure has been adopted. The advantages of this procedure are; It is cost effective, needs minimal hospitalization and has least adverse effects. This can be employed efficiently in both high and low anal fistulae. This type of therapy is considered as a minimal invasive parasurgical measure at global level. *Apamarga Kshara Sutra* is standardized one, and effectively used. But pain and burning sensation during the treatment is a very often complaint of the patient and availability of *Apamarga* is also difficult throughout the year as *Apamarga* is seasonal plant in order to overcome these disadvantages, exploration of new plants for the preparation of *Kshara Sutra* hence in the present study *Apamarga* is replaced with *Tilanala.* **Aims and objectives:** To evaluate the efficacy of Tilanala Ksharasutra in the management of Bhagandara w.s.r to Fistula-in-Ano. **Materials and Methods:** 30 patients diagnosed with *Bhagandara* were randomly grouped into 2 groups with 15 patients in each group. Group A was treated with *Tilanala Ksharasutra* followed by Betadine 10% solution infiltration, Group B was treated with *Tilanala Ksharasutra* without Betadine 10% solution infiltration both were clinically evaluated.
Results: Assessment of Pain, Discharge, Itching, length of the tract in Group A showed
97.23%, 100%, 100%, 100% improvement and in Group B 97.46%, 100%, 95.85%, 100% improvement respectively. Mean UCT of Group A was 6.96 days/cm and Group B was 7.57 days/cm with p value >0.05 which is not significant which shows that Tilanala kshara sutra is effective in the management of Bhagandara.
Conclusion: Tilanala kshara sutra is much effective in the management of Bhagandara.

Key Words *Tilanala, Ksharasutra, Bhagandara*

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INTRODUCTION

The disease *Bhagandara*[1] is an Ano rectal condition explained in detail by *Sushruta*. The literal meaning of *Bhagandara* is *daarana* which is splitting up/bursting up of *pakwa pidaka* in the *bhaga, guda, basti pradesha* results in the

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formation of a communicating tract, thus causing discomfort to the patient. *Bhagandara* can be co-related with Fistula-in-ano mentioned in Allopathic medical science is considered second to haemmoroids among all ano-rectal abnormalities.

A study in India, reported that anal fistulae constitute 1.6% (Raghavaiah 1976) of all surgical admissions. Prevalence rate of fistula-in-ano is 8.6 cases per 1 lakh population. The mean age of patients is 38.3 years.

The prevalence in men is 12.3 cases & in women 5.6 cases per 1 lakh population. As the wound is located in the anal region it is more prone to get infected and results in delayed healing and unhealthy granulation tissue formation or fibrous tissue formation in the tract which hinders the healing process. Operative procedures adopted are Fistulectomy, Fistulotomy and use of a seton newer methods like fibrin plug, Endo anal flap etc., Because of the lack of satisfactory results newer techniques have constantly been adopted for its management. Up to 26.5% recurrence rate, 40% of high risk of impaired continence and 5.6% non-healing of the wound were reported after surgical treatment. In addition to this, there will be severe post-operative pain which persists for many days. Moreover surgical treatment requires hospitalization, regular dressing and post-operative care for longer duration. To overcome such problems, surgical field is planning for some alternative techniques to treat these cases with minimal operative complications, recurrences and failure.

Ayurvedic line of treatment for *Bhagandara* includes medical, para-surgical and surgical management. Parasurgical management includes *Ksharakarma*, *Agni karma* and *Varti*. The *Ksharasutra*[2] treatment was in fact first mentioned in the *Nadivrana Adhikara*, and while explaining the indication *Acharya* has mentioned *Bhagandara*. Hence the same treatment was said to be followed in *Bhagandara*. The recurrence rate of *Ksharasutra* ligation is negligible (3-5%) with a success rate of 95%. The ICMR has validated this and the *Ksharasutra* therapy is also under active consideration of the WHO for its globalization. This type of therapy is considered as a minimal invasive parasurgical measure at global level.

In present study *Tilanala* is chosen, ***Tilanala*** is mentioned under *kshara panchaka*[3] and *kshara ashtaka*[4] in the present study *Apamarga* is replaced with *Tilanala* in the preparation of *Kshara sutra* due to its easy and abundant availability.

AIMS AND OBJECTIVES

To evaluate the efficacy of *Tilanala Ksharasutra* in the management of *Bhagandara* with special reference to Fistula-in-Ano.

MATERIALS AND METHODS

Thirty patients diagnosed with *Bhagandara* at OPD of *Shalyatantra* at TGAMC Ballari were randomly grouped into 2 groups with 15 patients in each group. Group A was treated with *Tilanala*

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Ksharasutra followed by Betadine 10% solution infiltration, Group B was treated with *Tilanala Ksharasutra* without Betadine 10% solution infiltration both were clinically evaluated.

Detailed history has been taken in designed proforma as previously prepared for the study incorporating all the relevant points.

1) Inclusion Criteria:

- Patient with clinical features of Fistula-in-ano namely pain, sero purulent discharge from the tract and pruritis ani.
- Patient with single fistulous tract.
- Age group of 16-60 years irrespective of sex, religion, occupation, duration of the symptoms.

2) Exclusion criteria:

- Fistula-in- ano secondary to Tuberculosis, Crohn's disease, Ulcerative colitis and other disorders.
- Associated with any other anorectal disorders.
- Pregnancy.
- Patient suffering with other systemic disorders.
- Recurrent Fistula-in-Ano after previous surgery.

Note: The pathological conditions mentioned in exclusion criteria will be ruled out after considering the features and required investigations.

3) Criteria for diagnosis:

- Diagnosis has made on P/R examination i.e. perianal inspection, P/R digital examination followed by Proctoscopic examination for Ayurvedic & modern Classical signs & symptoms of *Bhagandara* (Fistula-in-ano) namely pain, seropurulent discharge from the tract and pruritis ani.
- A special proforma was designed to record all details of the patients.
- The routine Haematological investigations were also carried out to exclude any other pathology.

PROCESS OF DIAGNOSIS

1. **Inspection**

- The swelling of the perianal region, external opening, discharge.
- Anal verge - Fissure/Sentinel tag.

2. **Palpation** :(Digital examination)

The digital examination includes tenderness, swelling, indurations, tone of sphincter i.e. normal, spasmodic, relaxed, hypertonic or hypotonic and dimple like depression for internal opening.

3. **Proctoscopic Examination:**

Following findings of *Bhagandara* are to be noted:

1) Position – clock wise position of the internal opening i.e., 1' clock to 12' clock.

2) Polyp, hemorroids etc.,

After taking the complete history and local examination, the patients were clinically classified as well as type of *Bhagandara*, distance from the anal verge and position of fistulain-ano had been noted.

4. Laboratory investigations: CBC. CT, BT, RBS, ESR HIV, HbsAg.

STUDY DESIGN:

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A total number of 30 patients of *Bhagandara* those fulfilling the above mentioned criteria were included for the study and were randomly allotted into two groups namely Group – A and Group – B with 15 patients each.

Group A: For the patients in Group A, *Tilanala Ksharasutra* prepared as per standard methods under strict aseptic precautions were applied followed by Betadine 10% solution infiltration.

Group B: For the patients in Group B, *Tilanala Ksharasutra* prepared as per standard methods under strict aseptic precautions was applied without Betadine 10% solution infiltration.

Follow up: Successive *ksharasutra* changing was done at weekly interval. The same procedure is followed for successive changes.

Observation: The observations made before the treatment and on fresh application of *Ksharasutra* were recorded in the proforma of the case sheet prepared for the study.

Duration: Till complete cutting of the tract.

Duration fixed for observing recurrence: Duration of 30 days from the day of total cutting and healing of the fistulous tract was fixed to observe the possibility of recurrence and the same was recorded in the proforma of the case sheet prepared for the study.

4. CRITERIA FOR ASSESSMENT:

Assessments of result were made on the basis subjective parameters by scoring pattern of symptoms.

PARAMETERS:

Subjective Parameters:

1. Pain.
2. Discharge.
3. Itching (Pruritis ani)

Objective parameters

1. Position
2. Length of the tract
3. Unit cutting time

The Unit cutting time represents the number of days required to cut one cm of the tract. This is calculated by dividing the total number of days taken by a fistula to heal by the initial length of the tract denoted as days/cm.

U.C.T = Total number of days
Initial length of Tract (thread)

Grading

1. Pain

P0– no pain

P1 – mild pain (no need of analgesics)

P2– moderate pain (subsides with analgesics)

P3– severe pain (persists with analgesics)

2. Discharge

D0– No discharge

D1–Mild discharge (wets 0.5x 0.5 cm gauze piece/day-serous discharge)

D2–Moderate discharge (wets 1cmx1cm gauze piece/day-seropurulent discharge)

D3– Severe discharge (wets >1cmx1cm gauze piece/day-purulent discharge)

3. Itching (Pruritis Ani)

I0 – No itching

I1– Mild and occasional itching

I2 - Moderate and frequent itching I3 – Severe and frequent itching

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OBSERVATIONS AND RESULTS

All 30 patients of *Bhagandara* have been analysed for age, sex, *prakriti*, type of *Bhagandara*, chronicity of disease, position of external openings, length of the fistulous tract and among 30 patients 26 patient's unit cutting time were recorded and 4 patients were dropouts from the study.

1. Age Incidence: Out of total 30 patients in Group A and Group B, maximum patients were in age group of 31-40 years followed by age 41-50 years. They were 43.33% and 29.99% respectively. Group wise division: They were 40%, 33.33% and 46.66%, 26.66% respectively in Group A and and B Group.

2. Sex incidence: Out of 30 patients there were 26 male patients and 4 were female patients. It means total 86.67% were male as compared to 13.3% were female. The ratio of male and female patients was 7.5:1

3. Marital Status: Out of total 30 patients in group A and Group B, maximum patients were of Married (80%). Group wise division: In, Group A they were 80% and Group B they were 80%.

4. Religion: Out of total 30 patients in group A and Group B, maximum patients were of Hindu religion (83.33%)

Group wise division: In, Group A they were 80% of Hindus and 13.33% Muslims, 6.66% of Christians while in group B they were 86.66 % of Hindus and 13.33% Muslims.

5. Occupational Status : Occupation wise: Out of total 30 patients in Group A and Group B, maximum patients were found farmers 9 (23.33%), teachers 8 (26.66%), business 4(13.33%) cases, students 3 (10%) cases, drivers 2 (6.66%) cases, homemakers 1 (3.33%) case, tailor 1 (3.33%), contractor 1 (3.33%) and engineers 1 (3.33%) cases were recorded.

6. Socio Economic Status: Out of total 30 patients in Group A and Group B, maximum patients were Middle class (50%). Group wise division: In, Group A, upper class 6.66%, Middle class are 46.66% and Lower class are 46.66%. In, Group B, upper class 13.33% Middle class are 53.33% and Lower class are 33.33%.

7. Dietary Habit: Out of total 30 patients in Group A and Group B, maximum patients were taking mixed diet i.e., 19 (63.33%) and 11 patients were vegetarian (36.66%).

8. Incidence of *Prakriti*: The present study reveals that maximum 40 % of the patients belong to *Vatapittaja prakriti*, 32% belongs to *Pittakaphaja prakriti* and 27.5 % *Vatakaphaja prakriti*.

9. Type of *Bhangandara*: Type of *Bhagandara* was considered on the basis of description of *Sushruta* and *Vagbhata*. Out of 30 cases maximum number of patients were reported under *Parisravi* (30%), and *Riju* (60%) *Bhagandara*. Minimum number of patients was in *Ushtragreeva Bhagandara (10%)*.

10. Type of Fistula-in-ano: In total of 30 patients maximum incidence was seen in

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transsphincteric 15(50%), submucosal 6 (20%), Supra sphincteric 5 (16.66%).

11. Chronicity of Disease: In the study as a total 30 patients, Maximum patients Duration of Illness were below 1 month 17 (56.66%), more than 1 month 9 (30%) and more than 2 months are 4(13.33%) cases.

12. Clockwise Distribution of External Opening: Out of 30 patients in group A and Group B, external opening at 4 and 8 'o' clock were 4 cases each i.e., around 13.33% each. External opening at 1, 2, 6 and 9 'o'clock were 3 cases each i.e., around 10% each. External opening at 3, 5, 7, 10 and 11 'o'clock were 2 cases each i.e., around 6.66% but there were no cases at 12 'o' clock position.

13. Type of fistulous tract on Probing: All the cases were observed to have complete tracts. No blind external, blind internal cases were 2 out of 30 (6.66) and rest of the cases were complete tracts were observed.

14. Initial distance of the Fistulous Tract from the Anal Verge:

Among 30 patients, 43.33% of the patient had length of the tract around 1.1-2.0 cm. In 15 patients of Group A, 40% of the patients had length of the tract around 1.1-2.0 cm and in 15 patients of Group B, 46.66% of the patients had length of the tract aroun 1.1-2.0 cm.

15. Initial length of The Fistulous Tract:

Among 30 patients, 43.33% of the patients had length of the tract around 2.1-4.0 cm. In 15 patients of Group A, 46.66% of the patients had length of the tract around 2.1-4.0 cm and in 15 patients of Group B, 40% of the patients had length of the tract around 2.1-4.0 cm.

16. Unit cutting time:

1. Unit cutting time in relation to age group: Among 30 patients 26 patients (excluding 4 dropout patients) average unit cutting time was studied in different age groups. The minimum average unit cutting time was 7.23 days/cm in Group A in the age group of 31-40 years, while minimum U.C.T. was 6.97 days/cm in Group B belonging to the same age group. The maximum average U.C.T. was 8.55 days/cm in group A under the age group of 21-30 years while maximum average U.C.T. was 8.24 days/cm in group B under the different age group i.e., 41-50 years.

2. Unit cutting time in relation to sex group: This analysis shows that maximum U.C.T. was noted in Females in Group A 8.00 days/cm and in males 6.96 days/cm in Group A and in Group B it was 7.97 in females and 7.50 in males.

Unit cutting time in relation to *Prakriti:* Unit cutting time was calculated for different types of *prakriti*. It shows patient having maximum U.C.T in Group A belonged to *vatajapittaja prakriti* (7.94 days/cm) and in Group B belonged to Pitta*vataja*(8.68 days/cm); while minimum U.C.T. was reported in Kaphapittaja prakriti (6.85days/cm) patients in Group A and in Group B it was Vatapittaja (6.73 days/cms).

3. Unit cutting time in relation to type of *Bhagandara*: The analysis shows that minimum U.C.T. was 5.71 days/cm in *Ushtragreeva Bhagandara* and maximum U.C.T. was 8.60

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days/cm in *Parisravi Bhagandara* in Group A, where as in Group B minimum U.C.T was 6.98 days/cm in *Parisravi Bhagandara* and maximum was

8.16 days/cm in *Riju Bhagandara*.

4. Unit cutting time in relation to initial length of tract: Minimum U.C.T. was 6.65 days/cm in Group A and 6.77 in Group B with initial length of 4.1-6.0 cms; the UCT seemed to be faster in medium tracts, and delayed in larger tracts with unhealthy tracts as in table.

5. Total Average of Unit Cutting Time: Group A showed a UCT of 7.28 days/cm and Group B showed a UCT of 6.98 days/cm.

RESULTS OF PARAMETERES:

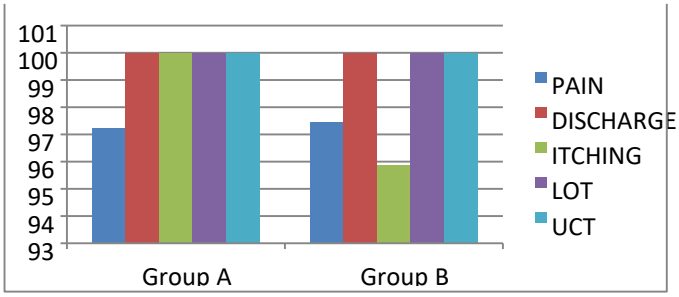
Result of all the subjective and objective parameters were noted and statistical value was calculated to know whether the prepared *ksharasutra* was highly significant or significant in the management of *Bhagandara*.

Result of Group A

The percentage of improvement in Group A on Pain is 97.23%, discharge is 100%. Itching is 100% and length of the tract is 100% as shown in Table 1 and Graph 1

Table 1 Results of Group-A and Group-B

Sign and symptoms	Group A			Group B		
	Mean score		% of relief	Mean score		% of relief
	BT	AT		BT	AT	
Pain	2.53	0.07	97.23%	2.76	0.07	97.46%
Discharge	1.46	0	100%	1.53	0	100%
Itching	1.53	0	100%	1.69	0.07	95.85%
LOT	3.31	0	100%	4.01	0	100%
UCT	6.96	0	100%	7.57	0	100%



Result of Group B

The percentage of improvement in Group B on Pain is 97.46%, Discharge is 100%. Itching is 95.85% and Length of the Tract is 100% as shown in Table 1 and Graph 1.

Graph 1 Results of Group-A and Group-B

Assessment of Overall Clinical Results of Group A and Group B Using Paired T Test

Table 2 Overall Clinical Results of Group A – Paired T Test

Cardinal symptoms	N	Mean score		% Relief	SD	SE	T	P
		BT	**AT**					
Pain	13	2.53	0.07	97.23%	0.517	0.143	17.130	<0.001
Discharge	13	1.46	0	100%	0.517	0.143	10.167	<0.001
Itching	13	1.53	0	100%	0.517	0.143	10.710	<0.001
LOT	13	3.31	0.00	100%	1.509	0.419	7.814	<0.001
UCT	13	6.96	0.00	100%	1.053	0.292	25.89	<0.001

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Since the drug intervention remains same in both the groups there is no need of comparison between the two groups, hence for analysis of the overall effect of the treatment in both the groups was done by statistically with paired t test. The test shows that the treatment is statistically highly significant (P<0.001) in all the parameters in both Group A and Group B as shown in Table 2 and 3.

Tilanala ksharasutra showed promising results in the management of *Bhagandara* (Fistula-in-ano) with significant p value.

Table 3 Overall Clinical Results of Group B–Paired T Test

Cardinal symptoms	N	Mean score		% Relief	SD	SE	T	P
		BT	**AT**					
Pain	13	2.76	0.07	97.46%	0.480	0.133	20.164	<0.001
Discharge	13	1.53	0	100%	0.518	0.144	10.680	<0.001
Itching	13	1.69	0.07	95.85%	0.630	0.175	9.668	<0.001
LOT	13	4.01	0.00	100%	1.800	0.500	8.029	<0.001
UCT	13	7.57	0.00	100%	0.959	0.266	28.45	<0.001

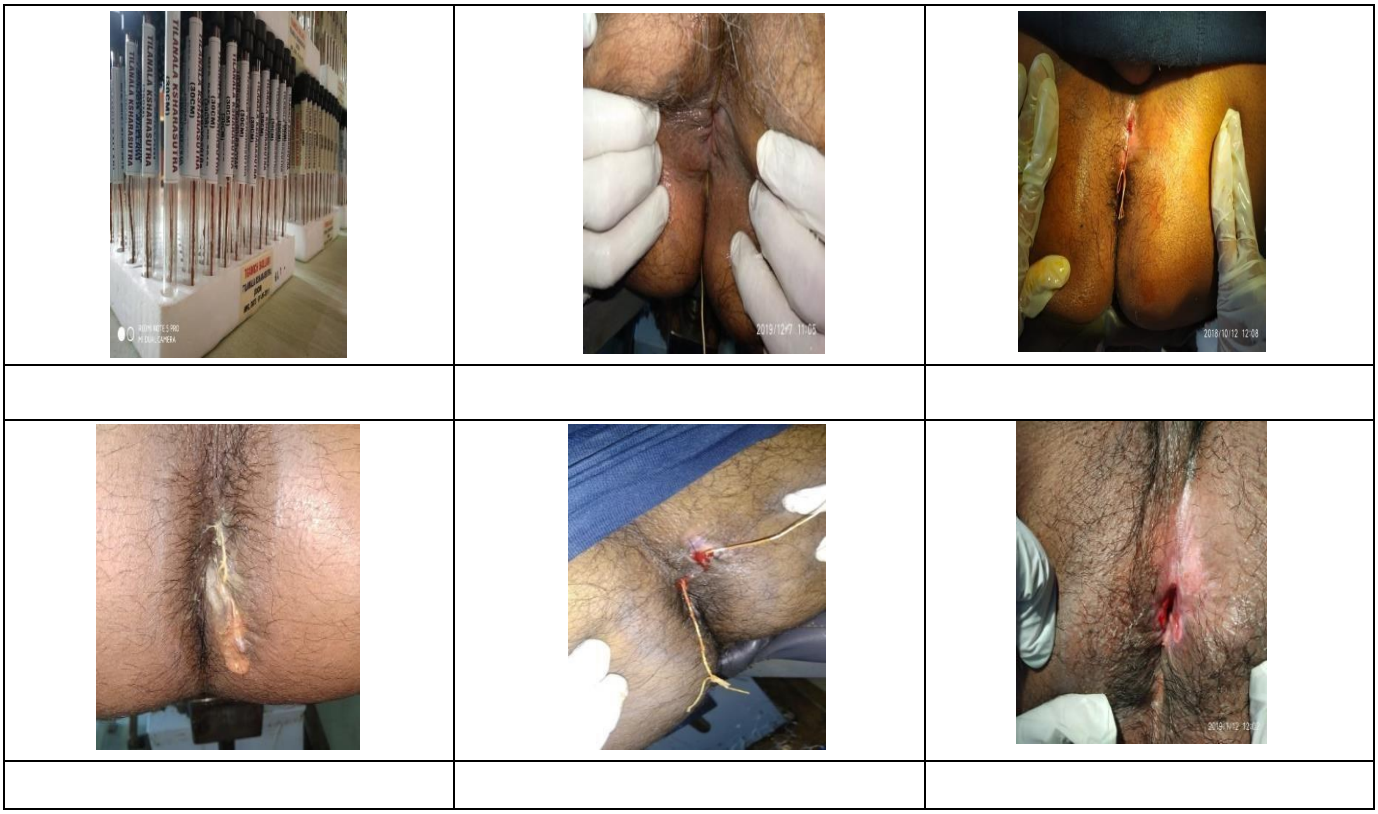

Figure 1

DISCUSSION

Among 30 patients a total of 4 patients i.e., 2 patients from each group were dropped out from the study. Hence 4 patients were excluded from the study.

Reasons for the drop out:

1. Patients were intolerant to the pain.
2. Patients were from Remote areas that they were unable to come every week for the thread change.
3. Lack of continuity in regular thread change, hence patients were excluded from the study.

In the present study one group was infiltrated with Betadine 10% solution into the fistulous tract

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along with the *ksharasutra* ligation to assess and compare the antimicrobial action of *Tilanala ksharasutra* alone with Betadine 10% solution.

Discussion on Result of the Therapy

The assessment of results is mainly based on parameters like pain, itching, discharge, and unit cutting time (UCT).

1. Discussion on Pain: Patients of both the Groups showed highly significant results on pain because of *vedanashamaka, ksharana, teekshna* and *ushnaguna* and chemical constituents Euphol, Nerifoliol, Neriifolione are having analgesic and anti -inflammatory and wound healing properties of the *Snuhi ksheera, Tilanala Kshara, haridra churna* and the thread definitely debrides fistula tract followed with continuous pus drainage subsequently reduces pain. There was slightly higher relief in group B because in Group B there was no Betadine 10% solution infiltration which might have caused little amount of pain in Group A.

2. Discussion on Discharge: Patients of both the Groups showed highly significant results on discharge due to the *ksharana, vranaropana* properties of *Snuhi Ksheera*[5], *Tilanala Kshara*[6] and *Haridra churna*[7] definitely reduces the different type of discharges and the thread helps in proper drainage of the pus.

3. Discussion on Itching (Pruritis ani): Patients of both the Groups showed highly significant effect on itching but the percentage of relief of itching was higher in group A than Group B, because of bacteriostatic and bactericidal properties of *Snuhi ksheera, Tilanala Kshara* and antiseptic property of *haridra churna* possesses the antipruritic action, in addition to these the infiltrated Betadine 10% solution in Group A might have reduced the itching by its action.

4. Discussion on Unit cutting time: Average U.C.T. is 6.96 days/cms in group A and 7.57 days/cms in group B shows that there is a slight variation in UCT, since the drug of intervention i.e., *Tilanala ksharasutra* remains the same in both the groups hence this slight difference may not be a deciding factor.

CONCLUSION

The parameters for assessment like pain, discharge, itching (pruritis ani), length of tract showed statistically highly significant improvement during the observation period. Hence both the groups showed excellent/marked response.

The average unit cutting time of Group A was 6.96 days/cm. This is almost same cutting time as of Group B which is 7.57 days/cm with p value <0.001 in both the groups which is highly significant.

Tilanala ksharasutra showed promising results in the management of *Bhagandara* (Fistula-inano). It was observed that the UCT was delayed in chronic cases and with more of fibrosed tissue. After cut through, complete healing was observed at an average of 4 days. The trial drug *Tilanala Ksharasutra* showed promising results, and hence may be used as a substitute at times when the availability of *Apamarga* may be a problem.

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