



**IJAYUSH**  
*International Journal of AYUSH*  
<http://internationaljournal.org.in/journal/index.php/ijayush/>

*Panacea  
Research  
Library*

ISSN: 2349 7025

AYURVEDA, YOGA, UNANI, SIDHA AND HOMEOPATHY

Research Article

Volume 7 Issue 3

**COMPARATIVE CLINICAL STUDY TO ASSESS EFFICACY OF KUMARI HARIDRA KSHARSUTRA & APAMARGA KSHARSUTRA IN MANAGEMENT OF BHAGANDARA W.S.R. TO FISTULA-IN-ANO**

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**Article history:**

Received: 20<sup>th</sup> July 2018

Received in revised form:  
July 2018

Accepted: 31<sup>st</sup> July 2018

Available online:  
August 2018

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These authors have no conflict of interest to declare.

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**Abstract**

**INTRODUCTION:** In Anorectal disorders, Fistula in ano is a notorious disease and has high recurrence rate, it is mentioned as 'Mahagada' according to Ayurveda. Approximately 17% of all patients suffer from this disease among common anorectal disorders. Ksharsutra is considered as simple and safe remedy for Bhagandar (Fistula in ano). Various types of Ksharsutra with different ingredients have been prepared and tested such as Apamarga Ksharsutra, Guggul Ksharsutra, Arka Ksharsutra, Snuhi Ksharsutra, Udumbar Ksharsutra, Papaya Ksharsutra etc. with varied therapeutic significance.

**METHODOLOGY:** This paper reports about results of a prospective, randomized, control single blind trial to evaluate the efficacy of Kumari Haridra Ksharsutra in Bhagandara with special reference to fistula-in-ano with control of Ksharsutra (prepared by standard method). Trial group having 30 patients was treated with application of Kumari Haridra Ksharsutra having 7 coatings (without apamarga kshar) & Control group with 30 patients was treated with the application of Apamarga Ksharsutra having 21 coatings.

**RESULT:** In this study, the incidence of fistula was more common (51%) in the age group 30-40 years, more in males 81.67%. The rate of cutting and healing of fistulous tract in comparison with control group i.e. Apamarga Ksharsutra, was less by using Kumari Haridra Ksharsutra having 7 coatings (i.e. Trial group), however, it was found to be effective, gives more relief from pain and discharge of fistula in ano tract post operatively.

**CONCLUSION:** It was found that Apamarga Ksharsutra having 21 coatings according to standard method is the better for the treatment of Bhagandara (fistula in ano) by means of cutting and healing.

Similarly, it was found that Kumari Haridra Ksharsutra having 7 coatings is comparatively better for the treatment of Bhagandara (fistula in ano) by means of criteria pain and discharge of fistulous tract.

**Key Words:** Fistula in ano, Bhagandara, Kumari, Ksharsutra

## INTRODUCTION

Fistula-in-ano has been known to mankind as one of the commonest disastrous ano-rectal disease. Fistula-in-ano is defined as a tract lined by granulation tissue, which connects deeply in the anal canal or rectum and superficially on the skin around the anus. In Anorectal disorders, Fistula in ano is a notorious disease and has high recurrence rate, it is mentioned as *Mahagada* according to *Ayurveda*. Approximately 17% of all patients suffer from this disease among common anorectal disorders. The most common treatment in modern science for anal fistula includes surgical and para-surgical interventions. Surgical- Fistulectomy, Endorectal advancement flap Surgeries, bio-design anal fistula plug are most common and in Para-Surgical-Seton application, Fibrin glue etc. procedures are included. But fistula is still remaining a challenge to modern surgery due to its complications such as post operative incontinence, high recurrence rate and limitations including long term hospitalization and painful dressing. To the extent of management of fistula-in-ano by *Ayurvedic* way, *Ksharsutra* is the time tested and truly effective treatment.

Various types of *ksharsutra* with different ingredients have been prepared and tested such as *apamarga ksharsutra*, *guggul ksharsutra*, *arka ksharsutra*, *snuhi ksharsutra*, *udumbar ksharsutra*, *papaya ksharsutra* etc. with varied therapeutic significance.

In present, there are certain difficulties in preparation of *apamarga Ksharsutra*, like poor availability of *snuhiksheer* in different seasons. Similarly, it has been reported that due to *apamarga* post operative burning pain and discomfort to the patient that anvil the treatment so to overcome this hurdle we prepared *Kumari Haridra Ksharsutra* as an innovative approach to treat *Bhagandar* to establish its efficacy and significance in the management of *Bhagandar*.

**Aim of Study:** To compare the therapeutic effects of *Apamarga Ksharsutra* and *Kumari Haridra Ksharsutra* in *Bhagandar*.W.S.R. to Fistula-in-ano.

### Objectives:

1. To evaluate the effects of *Kumari Haridra Ksharsutra* in *Bhagandar*.
2. To evaluate the effects of *Apamarga Ksharsutra* in *Bhagandar*.

3. To compare the therapeutic effects of Apamarga Ksharsutra and Kumari Haridra Ksharsutra in Bhagandar.

**METHODOLOGY:**

**Materials:**

1. Kumari Haridra Ksharsutra
2. Standard Apamarg Ksharsutra

**Method of preparation of Kumari-Haridra Ksharsutra:**

The surgical linen thread of size 20 is spread throughout the length and breadth of the hanger of the specially designed cabinet known as *Ksharsutra* Cabinet. The thread is smeared with mixture of *kumari* pulp *swarasa* and *haridra* powder uniformly and carefully, all around the thread, with the help of clean gauze piece. After smearing all the threads on the hanger, the hanger is placed in the *Ksharsutra* cabinet for drying . procedure was repeated by 7 times. Finally, the ultraviolet lamp of the *Ksharsutra* cabinet is put on daily for 20-30 minutes to maintain sterile atmosphere right from the 1<sup>st</sup> day of coating.

The threads of a uniform length i.e. 30cm cut for packing. Further, the sealed air tight container [Plastic Sachet] are kept in a cabinet and exposed to ultraviolet radiation.

**Method of preparation of Apamarga Ksharsutra:[10]**

The surgical linen thread of size 20 is spread throughout the length and breadth of the hanger of the specially designed cabinet known as *Ksharsutra* Cabinet. The thread is smeared with latex, uniformly and carefully, all around the thread, with the help of clean gauze piece soaked in the *Snuhi Kshira*. After smearing all the threads on the hanger, the hanger is placed in the *Ksharsutra* cabinet for drying. After eleven such coatings with *Snuhi Kshira*, 12<sup>th</sup> coating of *Snuhi Kshira* is done and wet thread is then passed through a heap of finely powdered *Apamarga Kshara* immediately. After smearing all the threads with *Kshar*, the hanger is shaken gently allowing the excess particles of *Kshar* to fall down. This process is repeated till seven coatings of *Snuhi Kshira* and *Apamarga Kshara* is achieved, thus completing 18 coatings on the thread. The remaining 3 coatings are performed with *Snuhi Kshira* and fine powder of *Haridra* as per the above said procedure making a total 21 coatings on the thread. Finally, the ultraviolet lamp of the

*Ksharsutra* cabinet is put on daily for 20-30 minutes to maintain sterile atmosphere right from the 1<sup>st</sup> day of coating.

The threads of a uniform length i.e. 30cm cut for packing. Further, the sealed air tight container [Plastic Sachet] are kept in a cabinet and exposed to ultraviolet radiation.

**Application of *Ksharsutra*:**

**Method for application of thread (*Ksharsutra*):** In this study patient with low anal simple fistula were enrolled Fitness for procedure and for anaesthesia had been taken from Physician and anaesthetist. *Ksharsutra* application procedure had been carried out under appropriate anaesthesia if needed. This procedure had been carried out in Operation Theatre.

**Pre procedure:** For application of the thread the patient had been placed in lithotomy position and the perineum was cleaned with antiseptic lotion and draped with sterile towel. A tray containing sterilized instrument including specially designed probe of different sizes.

**Procedure:** The index finger of the hand was gently introduced into the anus and the inner opening of fistula was located. The selected probe had been passed through external opening of tract and slowly pushed in the direction of least resistance. The tip of probe had been guided by the finger in the anus in order to avoid formation false passage. The probe then guided into the anal canal through the internal opening of the tract and finally brought out of the anal aperture by rotating the handle of probe slightly. The *ksharsutra* from the sealed tube pass through the projection of eye, and probe pulled out, thus leaving thread in fistulous tract. The two ends of the thread had been tied outside the anal orifice firmly.

**Post Procedure:** It had been advised to take a simple diet and adjust bowel movement by mild laxative. It had been advised to take sitz bath for 10-15 minutes every day.

**Change of *ksharsutra* and its measurement:** This had been carried out in minor O.T. After 7 Days Old *Ksharsutra* ligated to new *Ksharsutra* and old *Ksharsutra* made to move in circular manner up to tied new *Ksharsutra* . when it is come from another end of the tract holding new *Ksharsutra*. The old *Ksharsutra* had been taken out the old *Ksharsutra* end to end had been measured. Similar method had been carried out during

every change of *Ksharsutra* (i.e. after 7 days). Procedure had been continued till the tract was cut through.

***Follow Up:***

Follow up of patients of two groups were taken weekly up to 12 weeks or up to cut through which ever occurred earlier.

Observational parameters: Length of the thread; discharge and pain were recorded at each and every follow up and unit cutting time and unit healing cutting time was taken at the end of treatment.

The record had been maintained in the form of Case Record Form.

***STUDY DESIGN:***

Study Period: 2016 to 2018 Study, Place: Dr.D.Y Patil School Of Ayurveda Nerul Navi Mumbai. This was prospective, randomized, control single blind clinical trial. They were randomly divided into two groups for further study.

Institutional ethics committee approval and regulatory compliance: Before the initiation of the study, the study protocol and related documents were reviewed and approved by Institutional Ethics Committee at Dr.D.Y.Patil School Of Ayurveda Nerul, Navi Mumbai. [IEC NO.]

The study had been carried out in following steps: A total 60 patients of fistula were randomly selected for the study which includes trial group and control group.

***Trial Group:***

In this group all 30 patients had been treated with application of *kumari haridra Ksharsutra* having 7 coatings.

***Control Group:***

In this group all 30 patients had been treated with the application of *Apamarga Ksharsutra* having 21 coatings (prepared according to standard method).

***Inclusion Criteria:***

1. All patients of fistula in ano of age between 20 to 60 years.
2. Patients having low level fistula in ano.

**Exclusion Criteria:**

1. *Fistula associated with fissure in ano, hemorrhoids, Pregnancy, Malignancy*
2. *T.B Patients*
3. *Uncontrolled D.M Patients*
4. *HIV,HbsAg Patients*
5. *High level Fistula*

**Informed consent:** Informed written consent from all participants was taken according to protocol.

**Clinical Examinations:**

Thorough history of the complaints of the patients had been taken in their chronological order. Each and every patient had been carefully examined clinically for general systemic and local examination.

**Local Examination:**

Local examination was carried out inspection, per rectum digital examination, Proctoscopy and probing to confirm type, length, depth, direction, Internal-opening, ramification, consistency of pus if any.

**Laboratory Investigations:**

1. *Fistulogram – if needed.*
2. *Heamogram, ESR, BSL.*
3. *Urine- Albumin, Sugar, Microscopic.*
4. *HIV,HbsAg.*

**Observational parameters:**

**Length:** Length of the thread is recorded in centimetres at each and every follow up and is considered as the length of the tract.

Unit cutting time of fistula in ano(day/cm) =  $\frac{\text{Total no. of days for complete cutting of tract}}{\text{Initial length of Tract (thread)}}$

Unit Healing time of fistula in ano(day/cm) =  $\frac{\text{Total no. of days for complete healing of tract}}{\text{initial length of Tract (thread)}}$

**1. Discharge:**

No discharge	0
Mild Discharge(wets 1 x 1 cm gauze piece)	1
Moderate Discharge(wets 2 x 2 cm gauze piece)	2
Profuse Discharge( wets more than 2 x 2 cm gauze piece)	3

**Table No:1 :Showing gradation parameters for Discharge****2. Pain:**

No Pain	0
Mild Pain	1-3
Moderate Pain	4-6
Sever Pain	7-10

**Table No.2: Showing gradation parameters for Pain****Criteria for cure:**

**Cured:** fistulous tract is completely cut through and healed.

**Relieved:** fistulous tract is incompletely cut or completely cut through and healing in process.

**Statistical Analysis:**

To assess the results of the study both, objective parameter (i.e. time required for complete cutting and healing of 1 cm of fistulous tract) and the subjective (i.e. discharge and pain) parameters were recorded before the commencement of treatment, at each and every follow up and completion of treatment. The level of significance was set at 5% ( $p=0.05$ ). As the sample size was small Student's 't' test was applied to know the significance of objective and subjective parameters. Unpaired 't' test was applied to compare the objective parameters (i.e. time required for complete cutting and healing of 1 cm of fistulous tract)

of Trial Group and Control Group. Paired 't' test was applied to assess the subjective parameters (i.e. discharge and pain of Trial group and control group). To apply statistics conveniently, the symptoms discharge and pain, on the day of commencement (0 day) and 12<sup>th</sup> follow up, were taken into consideration.

### RESULTS:

#### Effect of Ksharsutra on Length of tract of Fistula:

As the t value calculated is greater than the t tabulated value at  $p=0.05$

*kumariharidra ksharsutra* is significantly act on length criteria of fistula in ano.

As the t value calculated is greater than the t tabulated value at  $p=0.05$

*Apamarga ksharsutra* is significantly act on length criteria of fistula in ano.

#### Comparison Ksharsutra on length of tract in A-Trial group and B-Control group:

As the t value calculated is lower than the t tabulated value at  $p=0.05$ , where  $df = 58$ , Mean difference score of group B is more than mean difference score of Group A, and negative sign of t value suggestive of Group B is more significant than Group A

Symptom	Group-A-Length	Group-B-Length
Mean Score, B.T.	4.183	4.35
Mean Score, A.T.	0.767	0.3
S.D. ( $\pm$ )	0.788	1.38
S.E. ( $\pm$ )	0.144	0.253
T	23.72	16.01
P	<0.05	<0.05
Result	Significant	Significant

TABLE NO.3: Showing effect of Ksharsutra on Length of tract of Fistula

#### Effect of Ksharsutra on discharge from tract of Fistula:

As the mean of after treatment score was 0 (zero), it means there is 100 % result for Discharge in Group A.

As the p value is lower than the significance level  $\alpha = 0.05$ , group B is significant for Discharge criteria



### Comparison between *kumari haridra Ksharsutra* in Trial group and Control group *Apamarga Ksharsutra* on Discharge

Mean of Group A is more than mean of Group B and p value is lower than the significance level  $\alpha = 0.05$ , Group A is significant than in Group B for Discharge.

<b>Symptom</b>	<b>Group-A-Discharge</b>	<b>Group-B-Discharge</b>
Mean Score, B.T.	2.3	2.167
Mean Score, A.T.	0	0.133
S.D ( $\pm$ ), B.T.	0.65	0.791
S.D( $\pm$ ), A.T.	0	0.345
S.E.( $\pm$ ), B.T.	0.118	0.144
S.E.( $\pm$ ), A.T.	0	0.063
W	-	465
Z	-	-4.78
P	-	P<0.05
Result	-	Significant

**TABLE NO.4: Showing effect of *Ksharsutra* on discharge of tract of Fistula**

#### Effect of *ksharsutra* therapy on Pain in Trial group-A ,and control group-B:

As the mean of after treatment score was 0 (zero), it means there is 100 % result for Pain in Group A.

As the p value is lower than the significance level  $\alpha = 0.05$ , group B is significant for Pain criteria.

#### Comparison between *Ksharsutra* in Trial group and control group on Pain:

Mean of Group A is more than mean of Group B and p value is lower than the significance level  $\alpha = 0.05$ .

Group A is significant than in Group B Pain.

<b>Symptom</b>	<b>Group-A-Pain</b>	<b>Group-B-Pain</b>
Mean Score, B.T.	2.367	2.5
Mean Score, A.T.	0	0.467
S.D ( $\pm$ ), B.T.	0.49	0.628
S.D ( $\pm$ ), A.T.	0	0.507
S.E. ( $\pm$ ), B.T.	0.089	0.114

S.E. ( $\pm$ ), A.T.	0	0.092
W	-	465
Z	-	-4.78
P	-	P<0.05
Result	-	Significant

**TABLE NO.5: Showing effect of Ksharsutra on pain of tract of Fistula**

**Effect of Ksharsutra on unit cutting time and unit healing time from tract of Fistula:**

**Comparison between two groups ,group A & B for unit cutting time of fistulous tract:**

1.As the t value calculated is lower than the t tabulated value at p=0.05, where df = 58, Group A is not significant than Group B for UCT. having less CT is more effective according to medical science. Mean difference score of Group B is lesser than the mean difference score of Group A, it means Group B is more significant than Group A for UCT.

2. As the t value calculated is lower than the t tabulated value at p=0.05, where df = 58, Group A is not significant than Group B for UHT., having less HT is more effective according to medical science. Mean difference score of Group B is lesser than the mean difference score of Group A, it means Group B is more significant than Group A for UHT

<b>Symptom</b>	<b>UCT</b>	<b>UHT</b>
Mean Difference Score, Group A	17.70	19.83
Mean Difference Score, Group B	15.86	17.89
S.D ( $\pm$ ), of Group A	4.02	4.74
S.D ( $\pm$ ), of Group B	3.75	4.07
S.E. ( $\pm$ )	1.34	1.43
Unpaired t	1.83	1.35
P	>0.05	>0.05
Result	Insignificant	Insignificant

[A- Trail Group, B- Control Group]

**TABLE NO.6: showing Comparison between two groups ,group A & B for unit cutting time of fistulous tract and unit healing time of fistulous tract.**

**Overall assessment of therapy:**

Out of 30 patients about 21 patient [70%] were cured in group A and 9 patient [30%] relived, similarly in Group B Out of 30 patients about 18 patient [60%] were cured and 12 patient [40%] relived.

**RESULT:**

Effect of the Group A is and Group B on symptoms observed in *Bhagandara* w.s.r. Fistula in Ano is statistically proved to be significant on subjective criteria and objective criteria separately.

The effect of Group A is significant than Group B for subjective criteria such as Discharge, and Pain of *Bhagandara* w.s.r. Fistula in Ano.

The effect of Group B is significant than Group A for objective criteria such as Length of *Bhagandara* w.s.r. Fistula in Ano.

The effect of Group A is not significant than Group B for objective criteria – CT, HT, UCT, and UHT of *Bhagandara* w.s.r. Fistula in Ano.

**The characteristic features observed during the study were :-**

**Length:**

The mean time required for complete cutting of 1 cm of fistulous tract was found 16.67 days in trial group *kumari haridra ksharsutra* 7 coating, in control group it was found 15.75 days (i.e. *Apamarga ksharsutra* having 21 coatings).

The mean time required for complete healing of 1 cm of fistulous tract was found 18.58 days in trial group *kumari haridra ksharsutra* 7 coating, and in control group it was found 17.50 days (i.e. *Apamarga ksharsutra* having 21 coatings).

**Pain.:**

From statistical analysis it was found that A-trial group (i.e. *kumari haridra ksharsutra*) was more effective and gives more relief from pain as that of the B-control group *Apamarga ksharsutra* having 21 coatings.

**DISCUSSION:**

*Acharya Sushrut* has included *Bhagandara* in the *Ashtaumahagad*, as it is difficult to treat. However, a lot of work has been done in this perspective in the modern surgery

including the lay open technique, fistulectomy, multistage operation, advancement flap treatment, seton etc. In spite of availability of these methods management of fistula still remains a challenge. Various types of *Ksharsutra* with different ingredients had been prepared and tested such as *apamarga Ksharsutra* , *guggul Ksharsutra* , *arka Ksharsutra* , *snuhi Ksharsutra* , *udumbar Ksharsutra* , *papaya Ksharsutra* etc. with varied therapeutic significance, which referring the text we noticed that (*chakradatta 4<sup>th</sup> chapter Arshachikitsa*) in which preparation of *Ksharsutra* ,it is advocated to have only *snuhi* and *haridra* coating (wich have 7 in number) And there is no refrence of use of *Apamarga Ksharsutra* .so considerly this context ,we have prepared *kumari +haridra* insted,replacing *snuhiksheer* with *kumari* pulp (swarasa) to overcome limitation of *snuhiksheer*,such as varied availibility of *snuhiksheer* in different seasons.

A comparative study between two different no. of coatings of kshar sutra had been dealt in present study.A total 60 patients of fistula were randomly selected for the study which includes trial group and control group. The patients in the trial group were treated with *kumari haridra ksharsutra* having 7 coating .The patients in the control group were treated with *Apamarga ksharsutra* having 21 coating.

The observational parameters i.e. length of Fistulous tract, discharge and pain were recorded at weekly intervals upto the complete cutting and healing of the fistulous tract.

**The characteristic features observed during the study were :**

The incidence of fistula was more common 51% in the age group 30-40 years, while it was less common 15% in the age group 50-60 years. However, fistula is a disease of the middle age.

The incidence of fistula was more in males 81.67% whereas considerably less in females 18.33%. This may be attributed to, the no. and the size of the anal glands which are greater in males over females. It was also recorded that incidence of fistula having non vegetarian diet was much more, as 73.33% of the patients were having mixed diet, while 26.67% of the patients consumed vegetarian diet. As diet was considered it was found that the perons which consume non-vegetarian and spicy diet irregularly more suffering from fistula in ano because it may be due to this type of diet producing constipation and other anorectal disorders forming infection of anal glands and resulting into fistula formation.

The bowel habit of 60% of the patients was regular whereas it was found to be irregular in 40% of the patients.

The nature of work of 86.67% of the patients was sedentary, while it was non-sedentary in 13.33% patients.

### **The characteristic features observed in relation to the statistical analysis of the observational parameter**

#### **Length:**

Cutting of length is directly proportional to tensile strength. 7 coating *kumari haridra ksharsutra* prepared had less tensile strength than standard *ksharsutra*. Hence it may be cause for slow cutting of fistulous tract in trial group than control group.

Sufficient discharge after the change of thread explains the proper drainage of the abscess cavity and thereby in turns helps healing of the tract with fresh granulation tissue. Another observation made during the treatment of good healing in spite of the irritating property of the presence of thread as a foreign body this can be explained in the light of one concept that irritation promotes healing.

*Haridra* can promote healing process as well as it acts as antiseptic and antihistaminic property. *Kumari haridra Ksharsutra* having 7 coatings of aloe vera and haridra which promotes slow healing than *Apamarga ksharsutra* having 21 coating respectively.

Kshar powder was excessively hygroscopic which catches moisture and becomes useless if left exposed to the atmospheric air.

#### **Discharge:**

From statistical analysis it was found that A- trial group (*i.e. Kumari haridra ksharsutra*) was more effective in reduction of discharge than that of the B-control group (*Apamarga Ksharsutra*) having 21 coatings. Quantity of discharge is inversely proportional to healing of fistulous tract. Effective reduction in discharge in patients of trial group (*i.e. kumari haridra ksharsutra*) may be contributed to less healing of the tract than control group *i.e. Apamarga ksharsutra* having 21 coatings. Moreover, more healing and hence, less discharge may be due to the antimicrobial activity of haridra.

**Pain.:**

Significant reduction of pain in trial group (*i.e.kumari haridra ksharsutra*) may be contributed to more number of coatings of *kumari* and *Haridra* which directly come in contact with wound than the *Apamarga ksharsutra* having 21 coating which is coated with 7 coating of *snuhi + kshara* after 11 coating of *snuhi* followed by 3 coating of *snuhi + haridra*. Evidences are present showing antinociceptive (pain relieving agent) effect of curcumin present in *haridra*. Also it was thought to be a natural inhibitor of cox2 enzyme.

**CONCLUSION:**

Fistula is a disease of middle age, more common in males. The incidence is higher in patients with non-vegetarian and spicy diet.

In this study as sample size was 30, no conclusion drawn revealing relation between the formation of fistula and dietary habits, bowel habits, nature of work was found inconsistent.

The rate of cutting and healing of fistulous tract by using *kumari haridra ksharsutra* having 7 coatings (*i.e. Trial group*) was found to be significantly lesser than *ksharsutra* having 21 coatings (*i.e. Control group*). This clearly suggests that the duration of treatment of the fistula was considerably reduced by the use of 21 coatings of *ksharsutra* according standard method for *Bhagandara* (fistula in ano).

Hence, it was found that *Apamarga ksharsutra* having 21 coatings according to standard method is the better for the treatment of *Bhagandara* (fistula in ano) by means of cutting and healing.

Similarly, it was found that *kumari haridra ksharsutra* having 7 coatings is comparatively best for the treatment of *Bhagandara* (fistula in ano) by means of criteria pain and discharge.

**Scope for further study:**

Physiochemical analysis of *ksharsutra* having 7 coatings and 21 coatings should be carried out.

Carring out study by prepairing a Ksharsutra ,following conventional Apamarga Ksharsutra with 21 coatings but,replacing similar Ksharsutra with kumari pulp (swarasa).

Further study to evaluate relation between tensile strength and cutting ratio of Ksharsutra in fistula-in-ano should be carried out.

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**How to cite this article:**

Dwivedi Amarprakash, Bhoir Vedika, Pawar Anirudhha and Kulkarni Anjna M.; Comparative clinical study to assess efficacy of *Kumari Haridra Ksharsutra & Apamarga Ksharsutra* in management of Bhagandara W.S.R. to fistula-in-Ano; *International Journal of AYUSH 2018:7(3) 851-866*.