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## A Comparative Study of *Iftak* with Conventional *Kshar Sutra* Therapy using *Palash Guggulu Kshar Sutra* in the Management of *Bhagandara* (Fistula-In-Ano)

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### ABSTRACT

Fistula-in-ano is one of the most notorious diseases of the ano-rectal region. The disease owes its complexity to the fact that inspite of the development of newer techniques of treatment modalities it still gives varied recurrence rates. The disease is troublesome both to the patient as well to the surgeons. Earlier techniques like fistulectomy, fistulotomy leads to the disfigurement of perianal region and anal incontinence in some cases as along with the unhealthy fistula tract there is massive loss of healthy tissues. Thus, operative procedures for this disease leads to more serious complications than the disease itself initially. In Ayurveda classics, vivid description has been given about the disease as '*Bhagandara*' including its types, specific features and complexity of the disease. *Sushruta* has included it under "*Astamahagada*" which means it is a dreadful disease. *Kshara Sutra* therapy is one of best modality of treatment with very less recurrence rates. *Kshara sutra* works by curettage of unhealthy tissue, separation of debris through fistulous tract and removal of debris and cleansing of wound. However, it is observed that even *Kshar Sutra Therapy* can be difficult in the treatment of complex fistula-in-ano, because of the long duration of treatment, pain and post-operative scar as it involves a large area of the perianal region. In this study a new technique named IFTAK (Interception of Fistula Tract with Kshar Sutra Therapy) will be discussed. The technique was developed by Dr M Sahu and is being practised for treating complex and recurrent fistula-in-ano in Banaras Hindu University since 2007. In this study, 60 number of cases have been taken to compare the efficacy of IFTAK with conventional kshar sutra therapy using *Palash Guggulu Kshar Sutra* in the management of fistula-in-ano.

### KEYWORDS

*Fistula-in-ano, IFTAK, Ksharasutra*



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## INTRODUCTION

*Bhagandara* (Fistula-in-ano) is the disease occurring in ano-rectal region or *GudaPradesha*. In the etymology of *Bhagandara*, it is said that any tear in the *Bhaga*, *Guda*, *Vastipradesha* is called as *Bhagandara*. It is defined as *Pidaka*, if not suppurated but if suppuration occurs, it is termed as *Bhagandara*<sup>1</sup>.

In modern science, *bhagandara* can be related to the Fistula-in-ano, considering the similar characteristics and presentation of the sign and symptoms of the disease. A fistula is an abnormal communication between any two epithelial lined surface. A fistula in-ano is a track, lined by unhealthy granulation tissue that connects deeply in the anal canal or rectum and superficially in the skin around the anus. It mostly results from a perianal abscess which bursts spontaneously or has been drained inadequately<sup>2</sup>.

Fistula-in-ano has been explained in detail for the first time by Sushruta (1500-1000 B.C) under the heading of *Bhagandara*. Because of the severity & complexity of treatment associated with the disease, Acharya Sushruta has placed it under '*AstaMahagada*' Sushruta has mentioned it under eight dreadful diseases because of the purulent discharge and troublesome nature of the disease which effects the *bhaga*

(pelvic), *guda* (perianal region), *vasti*(bladder)<sup>3</sup>. In *Sushrut Nidana Sthana*, it is described elaborately about the types of *bhagandara* on the basis of *dosas* involved.

As can be seen from above historical review, Fistulectomy/ Fistulostomy is an ancient surgical procedure and the concept of laying open the track has been practiced for at least 2000 years. But since excision of entire tract, poses danger to the sphincter muscles & disfigurement of perianal region newer techniques have been invented by surgeons worldwide to overcome such complexities.

There has been a number of modalities of treatment for fistula-in-ano, but it still remains a challenge because of recurrence rates and post operative incontinence. The various old and recent techniques for fistula in ano include fistulotomy, seton, fibrin glue, anal fistula plug, endorectal advancement flaps, fistulectomy, LIFT(ligation of intersphincteric fistulous tract), VAAFT (video assisted anala fistula treatment), but all with variable success and recurrence rates.

In Ayurveda, *kshar* sutra therapy is a safe modality for the treatment of fistula-in-ano and complications are rarely seen. But some of the complications that may sometimes occur are pain, delayed cutting and long duration of the therapy. To overcome such



difficulties a new technique termed as IFTAK (interception of fistulous tract with *Kshar* sutra therapy) have been developed by Dr. M. Sahu and is being practiced for treating complex and recurrent fistula-in-ano in Banaras Hindu University since 2007. The main ideology behind this treatment is that the main source of infection in cryptoglandular fistula in ano is a particular infected anal crypt and eradication of the particular crypt with no or minimal damage to the anal sphincters will lead to spontaneous healing of the fistula tract. In this technique, interception of the proximal part of fistulous track is done at the level of external sphincter along with application of *kshar* Sutra from the site of interception to the infected crypt in anal canal. With high rates of success (96%), relatively low recurrence (3-7%) and practically negligible chances of complications like incontinence, IFTAK can be opted as the treatment of choice for the management of complex and recurrent fistula-in-ano<sup>4</sup>.

The present study is focused on comparative evaluation of management of Fistula-in-ano by conventional method of *kshar sutra* therapy and IFTAK technique, regarding post-operative observational assessment of healing time, rate of recurrence and anal function.

## MATERIALS & METHODS

For the present study, sixty patients between the age group 15- 60 years, registered from OPD/IPD of Department of Shalya Tantra, Government Ayurvedic College & Hospital, Guwahati with the characteristics features of fistula-in-ano were taken.

A minimum of 60 nos of patients of diagnosed case of *Bhagandara* (Fistula-in-Ano) attending the ~~Out Patient Department~~ (OPD) of Shalya Tantra at Govt. Ayurvedic College Hospital, Guwahati have been selected for comparative study between conventional method of *kshar* sutra therapy and IFTAK (interception of fistulous tract with *kshar sutra* therapy).

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

### INCLUSION CRITERIAS:

- Age between 15-60 years of either sex
- All clinically diagnosed cases of fistula-in-ano
- Fresh cases/ already treated cases/ recurred cases.

### EXCLUSION CRITERIA:

- Patient with malignancy (anus, rectum, prostate)



- Fistula-in-ano secondary to ulcerative colitis or crohn's disease.
- Bleeding disorders.
- Fistula concerned with other organs like urethra,vagina etc
- Uncontrolled diabetes mellitus, hypertension, Tuberculosis, CLD, metabolic disorder
- HIV, HbsAG, HCV positive cases
- Fistula in ano secondary to diseases like Osteomyelitis of coccyx.

#### **GROUPING OF PATIENTS:**

**A) Trial group:** The trial group consists of 30 numbers of patient. This group were treated with IFTAK (interception of fistulous tract) with *Palash Kshar, Guggulu*(as binding agent) & *Haridra*. The *Guggulu* resin was dissolved in ethanol to reduce the solid consistency and impurity. *Kshar Sutra* was prepared using Barbour's surgical thread number 20. Supportive Ayurvedic Medicines like *Avayarishta, Triphalaguggulu* etc. were used.

**B) Control Group :** The control group consists of 30 nos of patients diagnosed with *Bhagandara* and were treated with *Palash Kshar, Guggulu* (as binding agent) & *Haridra* through the conventional method of *Kshar Sutra* Therapy. Supportive

Ayurvedic medicines like *Avayarishta, Triphala Guggulu* etc were used.

**Selection of Cases:**The ano-rectal patients attending the OPD of ShalyaTantra Department of Govt Ayurvedic College Hospital, Guwahati have been thoroughly enquired with proper history taking, physical examination (i.e., general examination, systemic examination & local examination). The clinically diagnosed cases of *Bhagandara* (fistula-in-ano) in the OPD has been thoroughly undergone investigations (as per requirement) viz- Blood routine (TC, DLC, Hb%, ESR,BT, CT, Blood Sugar- Fasting & post prandial, Blood Urea, Serum Creatinine, HIV, HBsAg, Anti HCV, Chest X Ray (PA view), ECG. Other investigations like Urine (routine& microscopic), stool (routine & microscopic & for occult blood), Sputum for AFB, Pus for AFB were done optionally in required cases.

#### **Operative Procedure for IFTAK:**

- i) The perianal area was cleaned with 5% betadine solution and draped with draw sheet exposing the perianal region.
- ii) Local anaesthesia was given using 2% xylocaine with adrenaline. A gauge needle was used for infiltration and is suitable for blocking the deeper tissues in and around the anal canal. Both the sphincter muscles, external and internal anal sphincter was blocked, along with the



puddendal nerve. The ischial fossa was identified and local anesthesia was infiltrated.

iii) Assessment of fistulous track and its branching with the help of malleable probe: In all patients probing was done to identify the course and extent of the fistula track. Prolene 1-0 was ligated over the original tracts (Fig.1).

iv) Incision: 2-2.5cm linear vertical incision was given in Posterior midline between anoderm and external anal sphincter (Fig.2).

v) Dissection of fistulous track: This is done in two ways:

a) Sphincter sparing: This method is adapted when fistulous track travels anterior to the sphincter complex. In this, splitting of sphincter muscle is not required and only the fistulous track is intercepted.

b) Sphincter splitting: When the fistulous track travels under the sphincter muscle, then dissection is done by splitting the sphincter. If fistulous track is associated with an abscess cavity, then splitting of sphincter muscle helps in adequate drainage of abscess cavity and healing.

vi) Interception of fistulous track

vii) Opening of abscess cavity (if any) by fine dissection in intersphincteric space: The fistulous track or the abscess cavity was approached by making an incision at intersphincteric level and track is

intercepted. The intercepted track was widened further so that abscess cavity can be drained effectively. *Ksharasutra* was placed through the intercepted track into the internal opening to eradicate the source of infection i.e the infected anal gland. It also helps in continuous drainage of abscess cavity and continuous dressing is done for few days. The persistent effective drainage, removal of slough tissue and eradication of infected anal crypt due to application of *ksharsutra* reduces the size of abscess cavity and complex fistula thereby converted to simple one.

viii) Probing through intercepted track to the infected anal crypt: The probe was passed through the intercepted track upto the internal opening and primary threading was done with prolene 1-0 (Fig.3).

ix) Application of *Kshar Sutra*: After 7days of dressing, the prolene was removed from the original tracks and *kshar sutra* was applied to newly created artificial opening and internal opening (Fig.4).



Fig 1 Multiple fistula tracts



**Fig 2** 2-2.5cm linear vertical incision was given in Posterior midline



**Fig. 3** Prolene 1-0 is ligated over the original tracts



**Fig. 4** Application of *Kshar Sutra* to newly created artificial opening and internal opening.



**Fig 5** After completion of treatment

## DISCUSSION

The present study conducted in 60 patients diagnosed with the fistula-in-ano revealed that the disease prevalence was more in the age group 36-45 years followed by 46-55 years age group. It is seen that in the present study, the disease was found to be more prevalent in the middle age group as this is the most active phase of human life and hence more travelling, work stress, improper food habits, improper daily regimen, irregular bowel habits, lack of hygiene, prolonged hours of sitting and various other causes increases the risk of these age group to development of the disease fistula-in-ano. This fact is also supported by the literature that fistula-in-ano is more common in the 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> decade of life.

According to gender, the incidence of fistula-in-ano was found more in the males as compared to females. Out of 60 patients, 49 Patients (81.67 %) were males and only 11 (18.33%) were females. The male: female ratio was found to be 4.5:1 . Also the literature says that incidence of the disease is more in males as compared to females. This may due to long hours of travelling, sedentary jobs, unhealthy food habits.

In the study it was observed that occupation wise, majority of patients 24 numbers (40 %) had business as their main occupation,



followed by 19 numbers (31.67 %) belonging to service both government and private set ups, 10 % and 10% were farmers and homemakers respectively, lastly 8.33 % were students.

In the present study, the clinical findings for the external and internal opening was divided into 12-3o'clock, 3-6 o'clock, 6-9 o'clock ,9-12 o' clock and midline anterior,

midline posterior, lateral respectively. It was observed that majority of the cases 26 out of 60 (43.33%) had the external opening between 3-6 o'clock, 19 (31.67 %) had their external opening in between 6-9 o'clock, total 9 patients (15 %) in between 12-3 o'clock and lastly 6 numbers (10 %) in between 9-12 o'clock position.

**Table 1** Unpaired t test for Pain

Days	$\bar{X}_C$	$\bar{X}_T$	$\bar{X}_C - \bar{X}_T$	$SD_C$	$SD_T$	SED	$t_{58}$	P
Day 7	3	2.2	0.8	0.00	0.41	0.074	10.77	<0.0001
Day 14	2.30	1.53	0.77	0.65	0.51	0.151	5.086	<0.0001
Day 21	2.00	1.33	0.67	0.37	0.48	0.111	6.020	<0.0001
Day 28	1.27	0.53	0.74	0.45	0.51	0.124	5.923	<0.0001

Observation: In Table 1, The result is extremely significant at  $p < 0.0001$  for pain in days 7,14,21,28 showing that result is satisfactory in trial group in comparison to control group.

For internal opening, majority 54 patients (90% ) had their internal opening in the midline posterior, only 5 patients(8.33 %) had their internal opening in the midline anterior and 1.67 % in the lateral position (radially in the same line of external opening). In general, most of the fistula-in-ano is of crypto glandular origin, arise in the intersphincteric plane due to infection of anal gland present in this plane, majority of it lies in the posterior intersphincteric space and literary texts also suggests that that fistula-in-ano with internal opening in the posterior midline is most common. In the present study mostly posterior horse shoe shaped fistula were only taken to evaluate the efficacy of IFTAK.

In this study, for Group A, it was observed that the maximum length of tract was found

to be in between 8-11cm (50 %), followed by 11-14 cm (26.67 %), then 5-8cm (16.67%) and lastly 14 cm & above (6.67 %). For group B , before doing the IFTAK technique, when threading with prolene 1-0 was done to the original tracts, it was noted that the original length of the tracts were maximum (40 %) in between 11-14 cm, followed by 26.67% between lengths 14 cm & above, 23.33 % between 8-11 cm and lastly 10 % between 5-8cm. After the interception of the fistula tract, when new artificial window was created between anoderm and external anal sphincter, 100% of the tracts lengths were in between 5-8cm. In the present study, (table 1) persistence of pain was observed for day 7, 14, 21 and 28 days for Group A and Group B. It was found that the pain had significantly



reduced until day 28 in Group B. Only a small minimal size of wound is created, therefore significantly less pain is observed in group B. During changing of Kshar Sutra

weekly, there is complaint of mild pain by the patient which subsides after changing of kshar sutra is completed.

**Table 2** Unpaired t test for Discharge

Days	X <sub>C</sub>	X <sub>T</sub>	X <sub>C</sub> -X <sub>T</sub>	SD <sub>C</sub>	SD <sub>T</sub>	SED	t <sub>58</sub>	P
Day 7	1.90	1.23	0.67	0.31	0.43	0.096	6.923	<0.0001
Day 14	1.63	0.93	0.7	0.49	0.25	0.101	6.947	<0.0001
Day 21	1.33	0.40	0.93	0.48	0.50	0.126	7.392	<0.0001
Day 28	1.10	0.20	0.9	0.31	0.41	0.093	9.69	<0.0001

Observation: In table 2, the result is extremely significant at  $p < 0.0001$  for discharge in days 7,14,21,28 showing that result is satisfactory in trial group in comparison to control group.

In this study, (table 2) the discharge was noted in both Group A and Group B for day 7,14,21 and 28. It was observed that the amount of discharge remarkably decreased in group B by day 28. The main aim in IFTAK technique is identification and eradication of the main infected crypt. After

ligation of kshar Sutra in the new tract, it was observed that the amount of discharge decreased significantly.

Thus, it was observed that duration of treatment, degree of pain and amount of discharge was significantly reduced in Group B as compared to Group A.

**Table 3** Unpaired t test for Unit cutting time

X <sub>C</sub>	X <sub>T</sub>	SD <sub>C</sub>	SD <sub>T</sub>	SEM	t <sub>58</sub>	P
8.45	6.69	0.70	1.20	0.254	6.94	<0.0001

Observation: In table 3, the result is extremely significant at  $p < 0.0001$  for Unit cutting time showing that result is satisfactory in trial group in comparison to control group.

**Table 4** Unpaired t test for Unit cutting and healing rate

X <sub>C</sub>	X <sub>T</sub>	SD <sub>C</sub>	SD <sub>T</sub>	SEM	t <sub>58</sub>	P
0.83	1.079	0.06	0.19	0.038	6.53	<0.0001

Observation: In table 4, the result is extremely significant at  $p < 0.0001$  for Unit cutting and healing rate showing that result is satisfactory in trial group in comparison to control group.

In the present study, (table 3) it was observed that the average unit cutting time for Group A was 8.74, while for group B it was 6.69. Since, the unit cutting time is directly proportional to the number of days, the more the unit cutting time, the more is the number of days needed to complete the treatment. Thus, the unit cutting time is significantly less for group B indicating

lesser time taken for completion of treatment.

Again, in the present study, (table 4) the unit cutting and healing rate for group A was found to be 0.83 cm/week and for group B it was 1.079 cm /week. The unit cutting and healing rate is inversely proportional to the number of weeks. Thus less weeks needed for completion of treatment implies better unit cutting &



healing rate. Thus healing was better in Group B (Trial) than in Group A (Control). In this study, after completion of kshar sutra therapy presence of post-treatment scar was observed for both the groups. In group A 25 cases (83.33 %) had post operative scar while in group only 2 cases 6.67 % had scar. This may be attributed to the fact that in the conventional method, the kshar sutra debrides the unhealthy granulation tissue throughout the entire course of the track. Thus this continuous process tends to leave behind scar around a large area of perianal region. But in group B, in the IFTAK process, an external artificial opening is made in between the anoderm and external sphincter which covers only a small area and large part of perianal skin is not disfigured.

## SUMMARY & CONCLUSION

The present study was focused on comparative evaluation of management of Fistula-in-ano by conventional method of *kshar sutra* and IFTAK technique, regarding post-operative observational assessment of healing time, rate of recurrence and anal function. For this study, 60 nos of patients in the age group 15-60 years attending the Shalya Tantra OPD of Govt. Ayurvedic College Hospital,

Guwahati were selected and divided into two groups.

Group A- 30 patients treated with conventional kshar sutra therapy.

Group B- 30 patients treated by IFTAK technique.

In this study the data was analysed for observational and statistical significance. Unpaired 't' test was done for pain and discharge for day 7,14,21,28 and the result was statistically significant in trial group in comparison to control group. Also unit cutting time, unit cutting & healing rate was compared using unpaired 't' test and result was found statistically significant showing that in Group B the duration of treatment was reduced significantly and also healing rate was better in Group B.

Thus, IFTAK is a better technique for complex & recurrent fistula-in-ano than conventional method of kshar Sutra ligation due to following reasons:

- In IFTAK technique , the duration of treatment is reduced as compared to kshar sutra therapy
- In IFTAK, the wound created is small, thus takes less for healing and healing is better
- IN IFTAK, the pain is less and wound created is small and less tissue undergoes debridement
- In IFTAK, the post-operative scar is



almost nil to minimal as it doesn't cause disfigurement of perianal area. Moreover, IFTAK is a cost-effective, minimally invasive technique which has unfolded a new era of fistula-in-ano treatment with kshar Sutra therapy.



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