

Combined Therapy Approach of Treatment for Complex Anal Fistula : A Prospective Study

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ABSTRACT

Aim: To evaluate the efficacy of combined therapy approach of treatment for complex anal fistula in terms of recurrence rate and anal incontinence.

Materials and Methods: Seventy six (76) patients with complex anal fistula, were managed with combined therapy approach of treatment with Surgery, Medical(ATT-anti-tuberculosis treatment), Seton (Kshara sutra) at MGM Hospital, Kakatiya Medical College, Warangal from September 2010 to October 2015. The results were analysed.

Results: Seventy six (76) patients were treated during the five years of study period with the age (mean \pm standard deviation) of 32 ± 5 years. The seton (Kshara sutra) was tightened with a median of 5 times (3–15 times range). All (76) the cases were treated initially with Surgitherapy. 62 cases required ATT (81.5%). 14 cases required setontherapy (18.4%). All the patients were followed up for incontinence and recurrence for minimum period of six months. 71 patients were cured (93.4%), three (2.6%) patients developed mild flatus incontinence (2.6%) with ugly scar and two patients had recurrent fistula (3.8%).

Conclusion: The combined therapy approach treatment with surgery, medical (ATT), seton (kshara sutra) for complex anal fistula is safe, cost effective, low morbidity option with low recurrence rate and minimal anal incontinence. Hence it should therefore be recommended as the standard of treatment for complex anal fistula.

Key words: Complex anal fistula, kshara sutra, recurrence, incontinence

INTRODUCTION

The true prevalence of fistula-in-ano is unknown. One study showed that prevalence of fistula-in-ano is 8.6 cases per 1000,000 population.^[1] A fistula-in-ano is an abnormal hollow tract or cavity that is lined with granulation tissue and that connects a primary opening inside the anal canal to a secondary opening in the in the perianal area; secondary tracts may be multiple and can extend from same primary opening.

Most of the fistulae are thought to arise as a result of cryptoglandular infection with resultant peri-anal abscess. The abscess represents the acute inflammatory event, whereas the the fistula is representative of chronic process. Multiple series have shown that formation of a fistula tract after anorectal abscess occurs in 7-40% of cases.^[2] Other fistula develop secondary to trauma(eg. Rectal foreign bodies), crohns disease, anal fissure,

carcinoma, radiation therapy, actinomycoses,tuberculosis and lymphogranuloma venereum secondary to chlamydial infection. The Parks classification^[3] relates the type of fistula to the external anal sphincter/puborectalis complex and is divided into

- Intersphincteric
- Transsphincteric
- Suprasphincteric
- Extrasphincteric

Complex anal fistula is a more severe form of anal fistula. They definitely require more complicated treatment. Any fistula that cannot be treated by simple fistulectomy may be considered as complex anal fistula which accounts around 30-40%. The complexity of anal fistula is basically dependent on: 1) The amount of anal sphincter muscle involvement (30%). 2) Presence of more than one anal

fistula(secondary tract) and/or with abscess cavity. 3) Anal fistula with tracts above the anal sphincter complex (or) with external opening further away from the anal verge. 4) Anal fistula associated with other diseases (eg.crohns disease, tuberculosis). The complications like recurrence and incontinence is very high with conventional fistulectomy or fistulotomy alone.

The Kshara sutra is a medicated thread which is prepared by applying the coatings and recoatings 15 to 21 times with plant derivatives like apamarg kshara (Acharanthaus amra) Haridra churna (Curcuma longa) with Snuhi ksheer (Euphorvia nerifolia) as binding agent. The thread sterilized by UV radiation. The mechanical action of the thread and chemical action of the drugs coated on the thread together do the work of the cutting, curetting and cleansing the fistula tract thus inducing healing by the fresh and healthy granulation tissues. The sutra is the mechanism of the drug delivery precisely at the tissue involved, It has been observed that the length of the tract reduces at 0.5-1cm per week. [4]

MATERIALS AND METHODS

The present prospective study was conducted upon seventy six (76) patients with complex anal fistula, who were managed with combined therapy approach of treatment with surgery, seton (Kshara sutra), medical(ATT) over a period of five years from September 2010 to October 2015 at Mahathma Gandhi Memorial Hospital, Kakatiya Medical College, Warangal after Institutional Ethical Committe approval and patient consent.

Inclusion criteria: For this study was the patients with complex anal fistula without anal incontinence, inflammatory bowel disease, radiationtherapy, trauma, carcinoma lymphogranuloma venereum and without either pulmonary or abdominal tuberculosis.

Exclusion criteria: Patients with existing preoperative incontinence, inflammatory bowel disease, radiation therapy, trauma, carcinoma, lymphogranuloma venereum and with either pulmonary or abdominal tuberculosis.

The diagnosis of compound anal fistulae was done under good source of light by clinical, digital and proctoscopic examination . Anal continence was assessed by integrity and function of anal sphincters. The cases were selected as per inclusion and exclusion criteria and the sigmoidoscopy was done for all cases and excluded underlying secondary pathology. For all badly infected fistulas bit of tissue taken under local anaesthesia and sent fo Histopathological examination (HPE).

These patients were treated with Antituberculosis treatment (ATT) with four drugs for two months, then

takenup for surgery. Patients were admitted from out patient department and posted for surgery after routine investigations. Surgery was done for all cases to excise the fistula tracts with external openings with a mixed technique consisting of fistulectomy-fistulotomy-cauterization of tract with caution to preserve anal sphincter. Seton(Prolene) placed for internal opening which open above the dentate line or intersphincteric for required cases. The excised specimen of fistulae tract tissues sent for HPE.

All the proved cases of tuberculosis were managed with ATT with four drugs for two months and three drugs for ten months. The patients were sent to Ayurvedic Hospital for change of seton (Kshara sutra) in place of prolene. The procedure of changing Kshara sutra was painful and was done under local anaesthesia but after about three subsequent sittings of change, the visual analogue scale (VAS) for pain has decreased and we have changed it with the pain killer diclofenac.The seton (Kshara sutra) was tightened with a median of five times (3–15 times range).

The patients were seen every other week and encouraged to walk as much as possible. On each visit the kshara tie was tightened if it found to be loose, patients were asked about the faecal incontinence according to Wexner's score^[5] till the wound heals.

Table 1: Wexner's score for faecal incontinence

Characteristic	Never	Rarely <1/month	Sometimes >1/month <1/week	Usually >1/week <7/day	Always =1/day
Flatus	0	1	2	3	4
Liquid stool	0	1	2	3	4
Solid stool	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Range (0–20); 0 = normal continence and 20 = maximum incontinence with maximum disturbance of life style.

RESULTS

Seventy six (76) patients were managed with combined therapy (fig1) approach of treatment for complex anal fistula during November 2012 to October 2015. Over a period of five years with age (mean \pm standard deviation) of 32 ± 5 years. 47 males (61.8%), 29 females (38.1%), 58 cases low socio- economic group (76.3%).18 cases high socio-economic group(23.7%), 54 cases were from rural areas, (71.1%) and 22 cases were from Urban areas (28.9%) (Table 2). All cases were iniatially treated with Surgical therapy 62 cases of patients were proven for tuberculosis on HPE (81.5%) which required drug therapy(ATT), 68 cases were with raised ESR (89.5), 14 cases are with

internal opening which required Seton therapy (18.4%). The healing time was 6months. The results are as follows: Anal continence data was determined by validated Wexner's score which is represented in (table 1). 71 patients got cured completely (93.4%) , three patients developed mild incontinence to flatus (2.6%) with ugly scar and 2 patients had recurrent fistula (3.8%) after treatment, all are significantly controlled ($p < 0.05$).

Table 2: Socioeconomic status and sex incidence of the patients

Patients status	No. of cases	%(percentage)
Male	47	61.9
Female	29	38.1
Rural	54	71.1
Urban	22	28.9
Low socioeconomic	58	76.3
High-socioeconomic	18	23.7



Figure 1: A) Surgical therapy: Combined therapy for compound anal fistula (Surgical therapy, seton therapy, drug therapy)

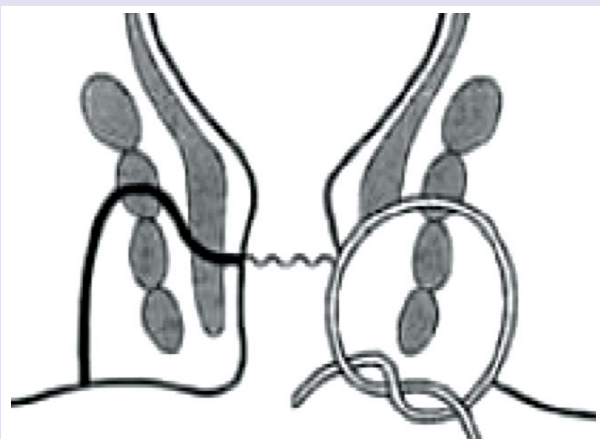


Figure 1: B) Seton therapy (Khsara)



Figure 1: C) Drug Therapy (ATT)

DISCUSSION

The data of prospective study of patients ($n=76$) with complex anal fistula treated with combined therapy was collected. Anal continence was determined by validated Wexner's score in all the patients with complete follow up, which includes incontinence to faeces as well as flatus for 6 months (healing time period).

The patients were followed for a minimum period of six months for recurrence. The anal fistula mainly occurred due to negligence of the patients or mismanagement of peri anal abscess. The complex anal fistula is considered to be notorious and most of the surgeons are afraid of its poor surgical outcome of pain, recurrence and incontinence. In an attempt to decrease these complications various single therapy procedures have been proposed to deal with these fistulae.

These include 1) Seton placement 2) Closure of fistula tract using fibrinsealant or anal fistula plug 3) Closure of primary opening using endorectal or dermal flaps 4) Ligation of inter sphincteric fistula tract (LIFT). 5) Video-assisted anal fistula treatment (VAAFT). 6) Autologous Adipose-Derived Stemcells (20 million) derived from liposuction have been used to treat these cases. But results of all these procedures are variable and they are costly. But in our study 4th procedure is cost effective and promising results.

In most complex cases (ie, crohn's) a proximal faecal diversion offer a measure of symptomatic relief only.^[6] Studies have identified the role of a drug called infliximab in crohns disease, with 50-60% response rates for perianal fistulas.^[7-8] The rate of extra pulmonary tuberculosis has increased globally in the last few years(about 5% of all cases) with display of a wide spectrum of its clinical manifestations.The anal localization is still a rare occurrence (0.7) according to

available data.^[9] This may be due to lack of data recording. In our study 90% of patients are with anal localization of disease without wide display of its clinical manifestations and without past history of tuberculosis and with this approach of treatment we are achieving curative results.

Hence it appears that the secondary fistulae with crohns disease is common in western people where as secondary fistulae with tuberculosis is common in India. These fistulae are mostly complex. Here we adopted this approach of treatment for complex anal fistula. The goals of treatment are draining infection, eradicating the fistulous tract and avoiding persistent or recurrent disease while preserving anal sphincter function.

The low rate of recurrence and incontinence in our series of patients can be attributed to; (1) Surgical therapy proper identification of fistulous tract nominal dissection and, no damage to the anal sphincter muscle complex (because only the extreme lateral portion of the fistulous tract was dissected/cored out for removal) the tract above and through the sphincter was, probed and "intubated" with a short length of prolene seton, (2) Seton therapy-The prolene seton was replaced with kshara sutra. The sphincter muscle complex is gradually cut through and healed because of chemical fistulectomy effect. 3) Medical therapy with ATT(Anti tuberculous treatment) was given for all biopsy proved cases which accounts 81.5%. Two months with four drugs and ten months with three drugs (total 12 months).

Sometimes ATT was given prior to surgery for badly infected cases for two months with four drugs, then surgery and kshara placement. For the remaining ten months ATT was given with three drugs. With this therapy, we achieved extreme level of locoregional control of disease like multidisciplinary approach of malignancy.

The factors implicated in fistula recurrence include the complexity and level of the fistula, the presence or absence of a horse shoe extension, the degree of laterality of the external opening, failure by the surgeon to identify the internal opening at initial surgery, and the overall surgical experience of the operator in complicated proctologic practice.^[10]

In our study, we were able to identify the internal opening without any radiological investigations, and if we

correlate this with the low recurrence rate, we can conclude that the most important factor is the surgeon's experience and judgment.

CONCLUSION

The combined therapy approach of treatment with surgery, Kshara sutra and ATT for the management of complex anal fistula delivers extreme level of loco regional control of disease with low recurrence rate and minimal anal incontinence. It does not carry the disadvantage of repeated anesthesia and visits to the operating theater and reduces the morbidity, inconvenience, and cost to the patient. Hence it is safe, easy and cost effective definitive curative option. It is therefore, to be recommended as a standard approach of treatment in treating complex anal fistula.

CONFLICT OF INTEREST

The authors declared no conflict of interest.

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