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CASE STUDY

EFFICACY OF GLOVE RUBBER AS SETON FOR TREATMENT OF HIGH AND COMPLEX FISTULA-IN-ANO-A RETROSPECTIVE STUDY

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ABSTRACT

Objective: Surgical outcomes of perianal fistula has a significant rate of post-operative complications such as prolonged hospitalization, pain during post operative period, high chances of recurrence and anal incontinence. We aimed to conduct this retrospective study to determine the efficacy of Glove rubber as seton in the treatment of fistula-in-ano to minimize the risk factors. We documented our experience in managing High and Complex fistulas with Glove Rubber as Seton.

Patients and Methods: This was a retrospective study of 60 patients of fistula-in-ano treated with Glove Rubber as Seton. All 60 patients were documented from 2008 to 2014 at Vydehi Institute of Medical Sciences & Research Centre. Out of 60 cases 08 were High and 52 were Complex fistula. Surgical outcome of patients treated by Glove Rubber seton for anal fistulas were analyzed. Follow-up was made for 03 years to record fistula recurrence, anal incontinence and duration of complete wound healing.

Results: The study involved 60 patients of mean age 34 years (range 20 to 60 years). Complete healing had occurred in all the patients (100%) within 4 to 6 weeks. Among 60 cases none of the patients developed recurrent fistula or incontinence.

Conclusion: Treatment of fistula-in-ano with Glove Rubber is associated with least complication rate. It can therefore be recommended as the standard treatment for High and Complex Fistulae.

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INTRODUCTION

The word fistula (in latin) means flute, pleat, groove, pipe or tube. In surgery, it implies an acute or chronic trajet of granulation tissue, connecting two epithelial surfaces that can be cutaneous, mucous or both (Luciano *et al*., 1998). Fistula in ano is an age old problem, notorious for its chronicity, recurrences and frequent acute exacerbations. Unfortunately, there are many cases where the diagnosis is delayed, by patient's ignorance, prejudice or fear (Luciano *et al*., 1998). Perianal fistula usually has a criptoglandular etiology, developing from a perianal abscess and communicating the anal mucosa with the perianal skin (Luciano *et al*., 1998). Infection of anal glands occur in 90 percent of the cases (Parks and Morson, 1962). It can also appear in the course of specific infections such as tuberculosis, actinomycosis, lymphogranulomavenereum, Crohn's disease, ulcerative rectocolitis, trauma, foreign bodies, malignant tumors of rectum, bladder, uterus or anus, Hodgkin's disease, leukemias and post-radiotherapy (Goodsall and Miles, 1900; ROSS, 1988). A number of classifications for perianal fistula have been proposed. Parks classified based on the location of fistula tract in relation to anal sphincter muscle; intersphincteric, transsphincteric, suprasphincteric or extrasphincteric (Parks *et al*., 1976). Fistula-in-ano was also classified as Complete, blind external and blind internal (Luciano *et al*., 1998). Perianal fistulae are also grouped according to the relationship of the main tract to the anal musculature such as Subcutaneous and submucosal, low anal, high anal, ano-rectal (Luciano *et al*., 1998). Simple and complexfistulas are characterized by a fistulous tract easy to identify and fistula having more than one fistulous course, subcutaneous or not respectively (Luciano *et al*., 1998). Treatment of complex fistula has potential high risk for impairment of continence due to the involvement of the anal sphincter (Mizrahi *et al*., 2002; Parks, 1961). The first surgical lay open of fistula in ano as practiced today was used by John of Arderne in 1337 (Garcia-Aguilar*et al*., 1996). Nearly 91% of the fistulae are in the category of simple fistulae (Dr. Shanthikumar D Chivate *et al*., 1986). The simple fistulae are commonly treated by lay open techniques, fistulectomy, fistulotomy, excision and skin grafting (Dr. Shanthikumar D Chivate *et al*., 1986). In fistulectomy, the chances of getting recurrence or incontinence or both cannot be ruled out in addition to wide removal of chunk of anal & perianal sensitive tissue up to the dentate line. The recurrent rate of "lay-open"

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fistulotomy is of 0%-8%. Minor and major incontinence is 34 - 64% and 2-26%, respectively (Mandache *et al*., 1962; Jackman, 1945). The other alternative techniques are application of fibrin glue and fistula plug. The healing rate after debridement and fibrin glue injection is 14-60% (Johnson *et al*., 2006). Continence may not be affected. Although moderately successful, it may preclude extensive surgery in more than one-half of these patients (Buchanan *et al*., 2003). Fistula plug in complex fistula-in-ano repair has a reported failure rate of 13%. To preserve the sphincter mechanism several strategies such as cutting setons, draining setons (Mizrahi *et al*., 2002), rectal mucosal or full thickness advancement flaps (Mandache *et al*., 1962), rerouting,two-stage setonfistulotomy (Pearl *et al*., 1993) anal fistula plug (Johnson *et al*., 2006; Buchanan *et al*., 2003), ligation of the intersphincteric fistula tract (LIFT) (Chung *et al*., 2009; Safar *et al*., 2009) have been practiced. The oldest and theoretically the simplest technique is to use Seton (Mizrahi *et al*., 2002). Seton is any string-like material which when tied through the fistula tract causes an inflammatory reaction which stimulates fibrosis and maintains sphincter continuity during cutting process (Ritchie *et al*., 2009). Various types of setons are used such assilastic tube, silk, linen, braided silk, rubber band, braided polyester, vascular loop, polypropylene, nylon, cable tie (Ritchie *et al*., 2009) and Prolene-1 (AyazAhmadMemon *et al*., 2011). Prolonged hospitalization, pain during post operative period, high chances of recurrence and anal incontinence in some of the cases of fistula encouraged us to try out a new material Glove Rubber as Seton in treatment of fistula-in-ano. We aimed to conduct this retrospective study to determine the efficacy of Glove rubber as seton in high and complex fistula along with risk factors like previous surgeries, comorbidities, inflammatory bowel disease, malignancies and trauma.

Patients and Methods

This was a retrospective study of 60 patients of fistula-in-ano treated with Glove Rubber as Seton. All 60 patients were documented from 2008 to 2014 at Vydehi Institute of Medical Sciences & Research Centre. Out of 60 cases 08 were High and 52 were Complex fistula. Surgical outcomes of patients treated by Glove Rubber seton for anal fistulas were analyzed.

The seton was prepared by cutting 2-3mm strip from the cup of glove, andsilk number 1 was tied to the either end. A detailed history with patient consent was obtained and complete clinical examination was made. Patients with high and complex fistula-in-ano were included in the study. Transrectal Ultrasound was done to define the course of tract, irrespective of level of fistula (eg.Fig.1). Patients with fistulae secondary to inflammatory bowel disease, malignancies, trauma and hemorrhoids were excluded from the study.

Procedure: Spinal or general anesthesia was used to perform surgery. Patients is positioned in lithotomy. Under aseptic precaution, rubber seton (Fig.2) is prepared. Methylene blue was injected from the external opening. Internal opening was identified as distal part of tract. Using Mosquito artery forceps with Glove Rubber seton is inserted through external opening (Fig.3) and passed through internal opening along with silk thread (Fig.4). Silk thread which is present at both margins tied over the glove rubber seton (Fig.5,6) The rubber glove seton cuts spontaneously in 2-3 weeks. Follow-up was made for 2-3 years to record the fistula recurrence anal incontinence and duration of complete wound healing.

RESULTS

The study involved 60 patients of mean age 35 years (range 20 to 60 years). Complete healing had occurred in all the patients (100%) within 4 to 6 weeks. Among 60 cases none of the patients developed recurrent fistula or incontinence.

DISCUSSION

In our study, Perianal fistula is a common disease occurring more in young males than in females. The surgical treatment of perianal fistula is followed by a high recurrence rate (41,9%) (Luciano *et al*., 1998). Some fistulae are difficult to treat, requiring more than one surgical intervention. The identification of the complete fistulous course is mandatory to avoid its partial removal and the persistence of granulation tissue, which will maintain the fistulous process. Some of the recurrences are due to incomplete resection of the fistula (Sangwan *et al*., 1994).

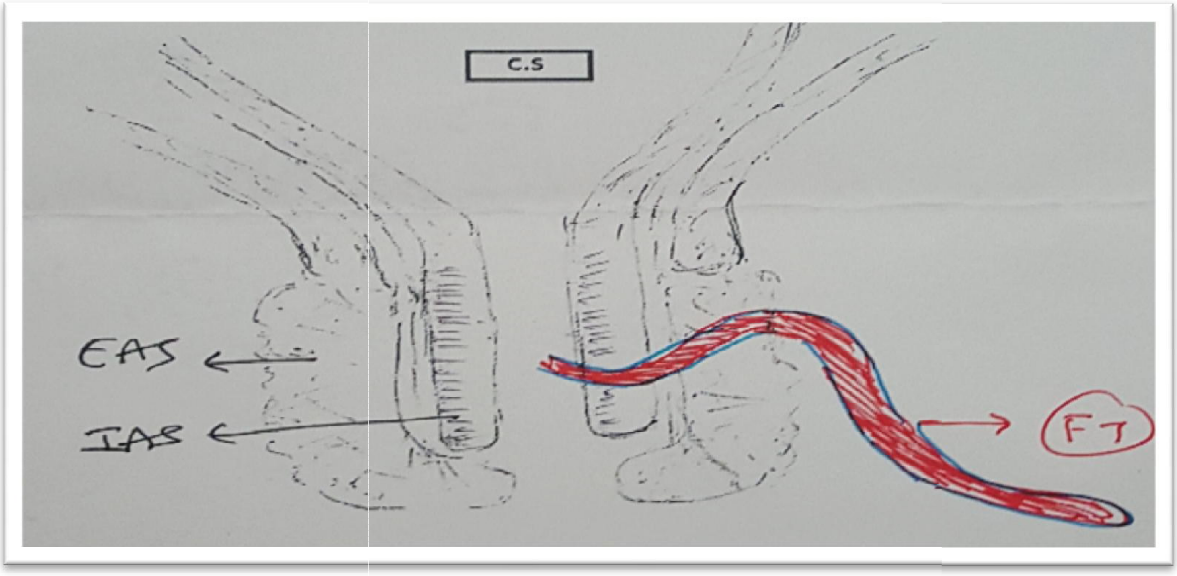

Fig.1. Transrectal ultrasound shows complex fistula

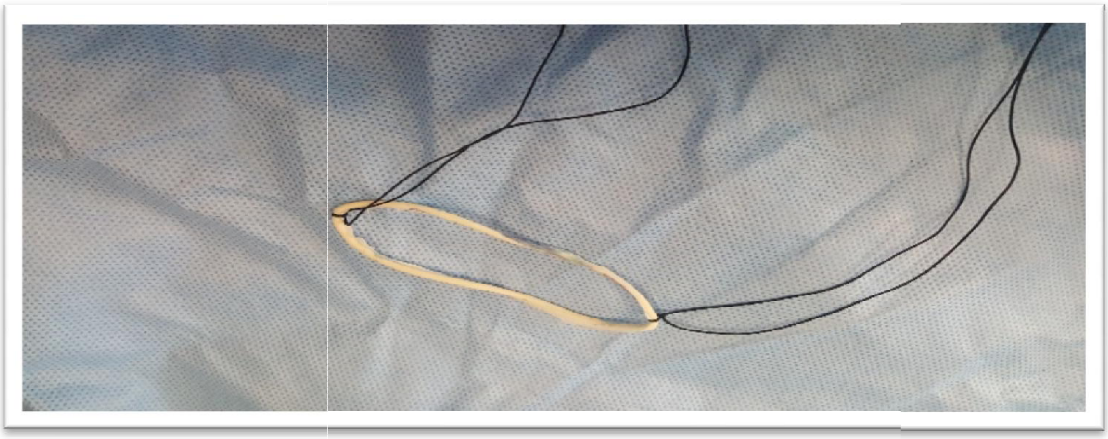

Fig.2. Rubber glove seton

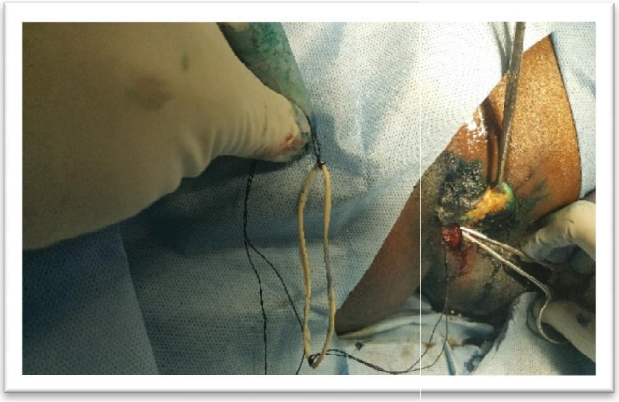

Fig. 3. Passing seton

Fig. 4. Seton introduced

Fig. 5. External ligation of seton

Fig. 6. After seton placement

The term complex fistula is modification of the Park's classification, which falls in any one of these conditions, that is, the track crosses >30% to 50% of the external sphincter, anterior in females, multiple tracks, recurrent, or the patient has preexisting incontinence, local irradiation, or Crohn's disease. Due to the involvement of the anal sphincter, the treatment of complex fistula poses a high risk for impairment of continence (Mizrahi *et al*., 2002). Fistula-in-ano is one of the common but difficult surgical problems (Zanotti *et al*., 2007), with a prevalence of 1.2 to 2.8/10,000 (Dr. Shanthikumar D Chivate *et al*., 1986; Zanotti *et al*., 2007). Due to lack of a single appropriate technique for treatment of fistula-in-ano, it is selected by the surgeon's experience and judgment (Dr. Shanthikumar D Chivate *et al*., 1986). Most of the fistula-in-ano has been conventionally treated by either fistulotomy, or fistulectomy (Parks, 1961).

Lay-open of fistula is a procedure which involves cutting the fistula open and curette (Garcia-Aguilar *et al*., 1996). Once the fistula has been laid open it will be packed on a daily basis for a short period of time to ensure that the wound heals from the inside out. It leaves behind a scar, and depending on the position of the fistula in relation to the sphincter muscle, can cause functional impairment of anal canal. All procedures are having potential danger of complications (Mandache *et al*., 1962; Jackman, 1945). Chivate *et al*. (AyazAhmadMemon *et al*., 2011) performed fistulectomy on 92 patients of Simple fistula.

They found that minimal invasive dilatation and curettage healed faster, short hospital stay and painless dressings. There was no even potential danger of incontinence. However this study was done in simple fistulas with 90% success rate.Seton has been used to manage anal fistula from hundreds of years.

Since management of high fistula-in-ano is a surgical challenge (Munir and Falah, 2014), Setons were commonly used only for high or complex anal fistula in order to avoid fecal incontinence and recurrence.Men were predominate in our study, which is in accordance with a study conducted by Luciano FD (Luciano *et al*., 1998), Out of 60 cases 44 were men.In many studies diagnosis of fistula was done using MRI. Since MRI is expensive, we used Transrectal ultrasound to define the course of the tract, irrespective of level of fistula. With Ultrasound we couldachieve the best possible diagnosis.A comprehensive review was conducted by GokulakkrishnaS *et al* on the available variations in materials andtechniques for seton treatment (Gokulakkrishna Subhas *et al*., 2012). Mentes BB1 *et al* in 2004 (Mentes *et al*., 2004) conducted a study on management of high anal fistulas with a simple modification of the cutting seton. The elastic seton was created by cutting a thin (2-3 mm) circular strip from a surgical glove, including its thicker sleeve, was inserted through the remaining tract in a double-strand fashion, and then tied on the sphincter with two knots in a slightly tight manner. They found that complete healing was achieved in 9 cases (45%) at 1 month and in all cases (100%) at 3 months postoperatively. Similarly in our study

Ege *et al.* in 2014 (2013) analyzed a retrospective review of 128 consecutive, well-documented patients with high anal fistulas, treated using a hybrid seton. The authors found that hybrid seton was an effective tool for the treatment of high anal fistulas and post-operative complications or significant pain did not exist.They suggested that the hybrid seton might be a valid alternative for the treatment of high anal fistulas. In our study, the patients complain of pain less than 2 according to visual acuity pain score during the follow-up.In the literature search, we found a wide range of incontinence rates reported after cutting seton treatment, and some authors (Ritchie *et al*., 2009) have concluded that there was no relationship betweenin continence and the frequency of tightening, type of seton,or classification of fistula. But in our study, the patients were more comfortable and showed 0% incontinence rate.Even though prolene-1 showed 0% incontinence and low recurrence rate, postoperative tighteningwas required during follow up and cuttingof remaining tissue in the loop of seton was necessary (Munir and Falah, 2014). Although the cable-tie seton is safe and cost-effective option for the treatment ofcomplex fistulae-in-ano, the authors found 5% recurrence rate (AyazAhmad Memon *et al*., 2011). Whereas the use of Glove Rubber in our study showed 0% recurrent rate and also postoperative tighteningwas not required. Hence the findings from our study suggests that diagnosis of fistula can be done using Transrectal ultrasound to define the course of the tract and use of Glove Seton is strongly recommended which has additional qualities in treatment of High and Complex fistulae with no risk factors.

Conclusion

The experience of the surgeon may play an important role for the success of treatment, decreasing the rate of recurrence. In our experience with the use of Glove Rubber as Seton, patients were more comfortable & had less absentee from their work with short hospital stay.Therefore, Glove Rubber is safe, least expensive and has low morbidity option for the treatment of fistulae-in-ano. It may be used as the standard of treatment for high and Complex fistulae-in-ano which requires seton.

Key Message

Whatever the type and the extent of fistula are, the principles of anal fistula surgery are to get rid of the fistula, prevent recurrence and preserve sphincter function. Patient's comfort should be considered as the prime importance in surgical approach and management. Glove Rubber can be used as a valid alternative Seton in the treatment of Fistula-in-ano.

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