Outcome of anal Fistula Plug as a Sphincter-saving Technique in Management of Complex Ano-rectal Fistula

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ABASTRACT

Introduction: *Ano-rectal fistula stills a common surgical problem facing surgeons. For a long time fistulotomy remains standard treatment for simple fistulas. However in cases of complex fistulas, fistulotomy carries the risks of sphincter damage and incontinence. For these reasons, sphincters saving techniques come into view. These techniques include fibrin sealant, anal fistula plug (AFP), cutting seton and mucosal advancement flap. The aim of this study was to assess the outcome of AFP (Gore's plug) procedure in a group of patients with complex peri-anal fistulas, and to assess whether the results were compatible with previous international findings.* ***Patients:*** *41patients complaining of complex ano-rectal fistulae were enrolled for treatment with anal fistula plugs. Five cases were excluded and the study was completed with 36 cases filling the inclusion criteria that were put for the study. MRI was used to determine the anatomy and types of the fistulas. Accordingly, the patients in the study were 8 with recurrent inter-sphincteric fistulae, 17 with trans-sphincteric fistulae, 7 with combined inter-sphincteric and trans-sphincteric fistulae, and 9 with supra-sphincteric fistulae. Setons were used preoperatively for all patients at least one month prior to surgery.* ***Methods:*** *All patients were operated upon while in Lithotomy positions. The plug was prepared by immersing in normal saline for 5 minutes prior to use. The plug was fashioned and tailored to suit the fistulous track. After positioning inside the track, the disc of the plug was sutured at the internal opening of the fistula with non-absorbable suture. The external opening was left open to allow for drainage of the tract. In patients with 2 tracks, 2 AFPs introduction was tried. followed up included hospital stay, postoperative pain and plug dislodgement, state of continence, fistula closure and quality of life. Early dislodgement of the plug was followed by repetition of the procedure.* ***Results:*** *32 patients with single fistulous track had successful introduction of one AFP. 4 patients (11 %) had 2 fistulous tracks with 2 external openings, (all are posterior), 2 AFPs were introduced successfully inside the 2 tracks; with total 40 AFPs used primarily. Early dislodgement of the AFP occurred within the first week in 4 patients (11 %) who needed reoperations with re-insertion of other plugs. 26 patients (72.2 %) showed complete cure of their fistulae as evidenced by closure of the internal and external openings and absent discharge. The failure rate was 27.8%. Their distribution was as follow; 2 patients (5.5 %) of those who underwent repetition of the procedure (due to early dislodgement of their plugs), 3 patients (8.3 %) of those had 2 fistulous tracks (persistence of their 2 fistulae), 2 patients (5.5%) had recurrent trans-sphincteric and 3 patient (8.3 %) had supra-sphincteric fistula.* ***Conclusion:*** *Anal fistula plug appears to be a promising and safe alternative to the current treatment options for high or complex perianal fistulas in them, such options may carry the risk of recurrence or sphincter derangement with high rates of minor or major incontinence.*

Key words: *Anal fistula plug - Sphincter saving technique – Ano-rectal fistula*

INTRODUCTION

In up to 30-50 % ano-rectal fistula occurs as a sequel of perianal abscess and result from persistent anal sepsis and/or formation of an epithelialized track. The initiating event in anal fistula formation is infection of the inter-sphincteric glands, in a process known as the crypto-glandular hypothesis[(1)]. The prevalence rate of anal fistula is 8.6 cases per 100,000 with a male to female ratio of 1.8:1 and the condition occurs predominantly in the third and fourth decade of life [(2)].

Peri-anal fistulae are classified according to their relations to the anal sphincter muscles into inter-sphincteric, trans-sphincteric, supra-sphincteric or extra-sphincteric fistulae. More-over, anal fistulas are classified as simple or complex fistulas. A complex fistula is defined as

one whose treatment carries a relatively high risk of incontinence [(3)].

A successful fistula management should involve eradication of the infection process, closure of the internal opening of the fistula with the least risk to incontinence and minimal recurrence rates[(4)]. The most widespread fistula treatment has been fistulotomy. Problems with this management are due to the adverse effects on continence aroused from the inevitable division of the involved anal sphincters specially on treating a complex fistula[(5)].

Complex fistula management remains a challenge for surgeons and various types of closure techniques have been developed. Complex fistula may be treated by use of a seton and/or staged fistulotomy which have low recurrence rates (0-8%), but still carries significant rates of minor (34-63%) and major (2-26%) incontinence [(2)]. The high rates of minor and major incontinence after sphincter cutting treatment have paved the way to develop sphincter-saving techniques for the treatment of complex fistulas [(6)].

Several sphincter conserving (saving) techniques are developed, as mucosal advancement flap, fibrin glue and anal fistula plug (AFP). The older first available plug (Cook's plug), was developed from porcine intestinal mucosa, and found to have a low success rate in some series partially attributed to early dislodgement of the plug [(7)]. The next invented plug (Gore's plug) is 100 % bio-absorbable synthetic plug formed of poly-glycolic acid tri-methylene carbonate that has less liability for dislodgement and hence higher success rate in some series[(8)]. It is formed of bundled hollow tubes attached to a circular disc. The scaffolding of the synthetic material allows cells to migrate into the matrix and tissue formation begins as the body gradually absorbs the material. This synthetic material is hydrolyzed and absorbed within 3 to 6 months following introduction. After the material is hydrolyzed, no remnant material remains inside the fistula[(9)]**.** As it is absorbed the plug gradually replaced by type I collagen that gets deposited to close the fistula[(10)].

The aim of this study was to assess the outcome of AFP (Gore's plug) procedure in a group of patients with complex peri-anal fistulas, and to assess whether the results were compatible with previous international findings.

PATIENTS AND METHODS

Patients:

Forty one patients, having anal-rectal fistula diseases were enrolled for this study at the Surgery Department of October 6 University Hospital, in the period between 2013 and 2015.

Inclusion criteria were patients with complex peri-anal fistula; high or low, primary or recurrent and with single or multiple tracks. Exclusion criteria were; simple submucosal or low inter-sphincteric fistula (involving less than 30 % of the sphincters), no internal fistulous opening detected during surgery, Crohn's disease, and malignant cause.

All patients were subjected to medical history including history of previous ano-rectal surgery, and rectal examinations with clinical assessment of patient's continence.

Eleven patients have had recurrent peri-anal fistula after previous fistula surgeries, (once in 8 patients and twice in 3 patients). Seven patients were found clinically to have 2 fistulous tracks with 2 external openings (all are posterior).

Magnetic resonance imaging (MRI) was used in the preoperative assessment of fistula anatomy for all patients as it could distinguish between infection and granulation tissue from anal sphincters, identifies the course of primary tracks, demonstrate secondary tracks, horseshoe extensions, as well as identifying the internal openings**.** Accordingly, the patients were classified into 8 with recurrent inter-sphincteric, 17 with trans-sphincteric fistulae (10 are low trans-sphincteric and 7 are high trans-sphincteric fistulae), 7 with combined inter-sphincteric and trans-sphincteric fistulae, and 9 with supra-sphincteric fistulae. We used loose setons 4 to 6 weeks prior to the AFP procedure for all patients under regional or general anaesthesia. The prior use of seton was important for proper drainage and elimination of any inflammation or infection of the tracks. Five patients were excluded from the study as they found to have blind ended tracks, with final number of 36 patients prepared for AFP surgeries in this study. They included 3 patients with 2 fistulous tracks and 2 with supra-sphincteric fistulae.

Preoperative routine laboratory investigations were done for all patients. The procedure was explained for the patients and written consents were taken before the procedures.

Data recorded were age, sex, aetiology of the fistula, fistula anatomy, number of tracks, and number of previous repairs.

Methods:

The patients were prepared by repeated enemas and clear oral fluids 2 days before surgery. All procedures were done under general or regional anesthesia by the same surgical team. Lithotomy position was used in all patients. Single dose of 1 gm. cephalosporin and 0.5 gm. Metronidazole were used intra-operatively.

The plug was prepared by immersing in normal saline for 5 minutes prior to use. The disc of the plug was trimmed to suite the internal opening and the size of the plug was adjusted to suite diameter of the fistulous track by removing one or more of its limbs. The seton was removed after identification of the internal opening. The fistulous track was curetted using fistula curette and irrigated with hydrogen peroxide and metronidazole to remove any epithelial debris.

A suture is anchored to the tail of the plug **(**figure 1). A probe was inserted into the external opening emerging through the internal opening and the suture attached to the tail of the plug was grasped and pulled into the fistula tract, tail first. The suture was drawn into the tract (figure 2) until the plug securely blocks the internal opening and fitted well within the tract (figures 3, 4, 5& 6). Any remaining portions of the plug that were not implanted in the tract had been trimmed and discarded. The internal end of the plug (disc) was sutured in place by at least two 3/0 non-absorbable sutures (polyglycolic acid) (figures 7, 8).The internal sutures should close the internal opening. No external fixation sutures were placed. The external opening was left open to allow for drainage of the tract. In patients with 2 tracks, 2 AFPs introduction was tried. The patients were confined to bed for 24 hours. Postoperatively, the patients were maintained on a liquid diet for two days followed by high fiber diet. Patients were asked to avoid lifting heavy weights, straining, sexual intercourse and strenuous exercise for two weeks at a minimum. Shower was used standing up with bathing the area with water to soothe and keep it clean. We informed the patients about some drainage comes out for two to four months after the procedure until absorption of the plug had taken place, as the plug was absorbed and the fistula tract had been closed.

The patients were followed up as regards the hospital stay, postoperative pain and plug dislodgement, state of continence, fistula closure and quality of life. Early dislodgement of the plug was followed by repetition of the procedure.

Patients were followed-up at 2 weeks, 4 weeks, 8 weeks then every 2 months for 1year at the outpatient clinic. At the final follow-up, the median time of fistula closure was determined, and patient was deemed cured when the internal and external openings were closed and no discharge comes out. SPSS was used for data analysis.

Fig. 1: Suture was anchored to the plug

Fig. 2: The suture end was pulled through the track

Fig. 3

Fig. 4

Figs. 3,4: The plug gradually introduced inside the track from in out by pulling on the suture

Fig. 5

Fig. 6

Figs. 5,6: Fitting the disc of the plug to the internal opening

Fig. 7

Fig. 8

Figs. 7, 8: The disc of the plug was fixed internally by non-absorbable sutures

RESULTS

Thirty six patients with complex peri-anal fistula, filling the inclusion criteria, were the target of this study. The patients were 23 males and 13 females, with median age 38 years, range (26 - 52 years). The types and number of fistulous tracks were categorized by the MRI as shown in table 1 after exclusion of those with blind ended tracks. 25 patients (69.5 %) have primary anal fistulae following peri-anal abcess, while 11 patients (30.5%) have had recurrent peri-anal fistula after previous fistula surgeries, (one previous surgery in 8 patients and twice in 3 patients) (table 2). The types of the recurrent fistulae were trans-sphincteric in 7 and inter-sphincteric in 4 patients.

All patients with single fistulous track (32 patients) had successful introduction of one AFP. 4 patients (11 %) had 2 fistulous tracks with 2 external openings, (all are posterior), 2 AFPs were introduced successfully inside the 2 tracks; with total 40 AFPs used primarily.

Follow up of the patients postoperatively, revealed early dislodgement of the AFP within the first week in 4 patients (11 %). Reoperations were done in those patients with re-insertion of other plugs with total 40 procedures. Follow up of such group of patients, showed healing of the fistulae in 2 patients.

The hospital stay ranged from 1 to 3 days (figure 9). Patients were asked about postoperative pain whether it was mild, moderate or severe and the need for analgesics or narcotics inpatient and in different times during the follow up period. 25 patients (69.4%) experienced mild postoperative pain that had responded to NSAIDs, 9 patients (25%) announced moderate pain that needed more doses of NSAIDs and 2 patients (5.6%) experienced severe pain in the first postoperative day that necessitated narcotic administration. The pain was much improved in the follow up period. The severe pain was recorded in 2 patients of those who underwent reoperation for early dislodgement of their plugs, and in one patient with recurrent anal fistula (figure 10).

Continence was evaluated postoperatively using **Vaizey's score**. Vaizey score consists of the type (gas, fluid, solid), frequency of incontinence (scored from zero to four), alteration in lifestyle (zero to four), the need to wear a pad (zero to two), the use of constipating medication (zero to two), and the lack of ability to withhold defecation for 15 minutes (zero to four) [(11)]. The total score on the Vaizey scale ranges from 0 (complete continence) to 24 (complete incontinence). No one in our study encountered any degree of incontinence during the follow up period.

The patients were evaluated as regards fistula closure rate. The number of patients with failed fistula healing was 10 patients (27.8%). Their distribution was as follow; 2 patients (5.5 %) of those who underwent repetition of the procedure (due to early dislodgement of their plugs), 3 patients (8.3%) of those had 2 fistulous tracks (persistence of their 2 fistulae), 2 patients (5.5%) had recurrent trans-sphincteric and 3 patient (8.3%) had supra-sphincteric fistula (figure 11).

26 patients showed complete cure of their fistulae as evidenced by closure of the internal and external openings and absent discharge. The healing rate of fistula closure per patients' is 72.2% (figure 12). The healing rate per fistulous tracks is 67.5% (27/40) (figure 13). The time of fistula closure ranged from 10 weeks to 22 weeks with total 20 patients (76.9 %) showed complete healing after 16 weeks and the remaining 6 patients (23.1%) took up to 22 weeks for complete healing (figure 14).

Table 1: Types of the fistulae by MRI

Type of the fistulae	No. (36)	%
Inter-sphincteric	7	19.4
Low trans-sphincteric	10	27.7
High trans-sphincteric	8	22.2
Combined intersphincteric & trans-sphincteric	4	11
Supra-sphincteric	7	19.4
Single track fistula	32	89
2 tracks fistula	4	11

Table 2: Aetiology of the fistulae

Aetiology	No. (36)	%
Primary	25	69.4
Recurrent once	8	22.2
Recurrent twice	3	8.3

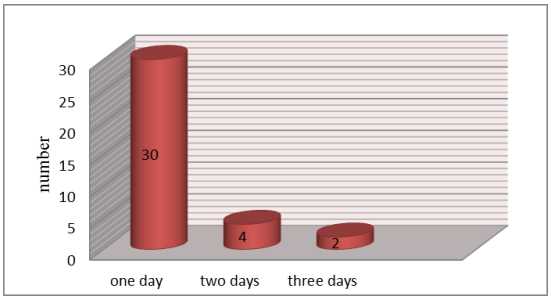

Fig. 9: Hospital stay

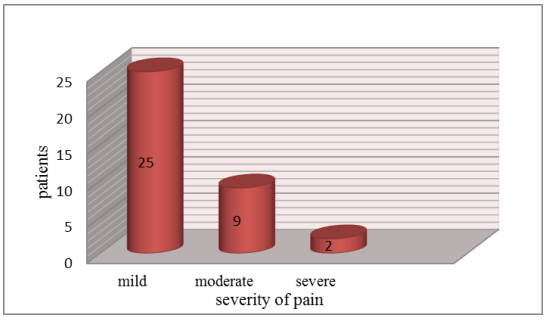

Fig. 10: Postoperative pain

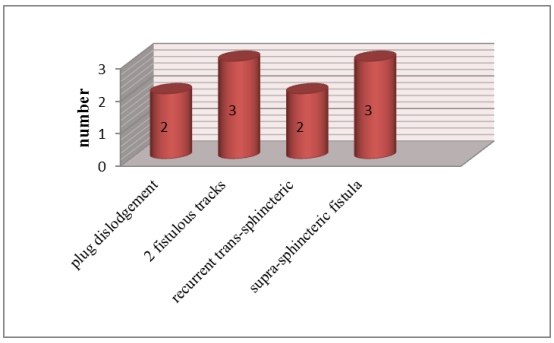

Fig. 11: Types of patients with persistent fistulae

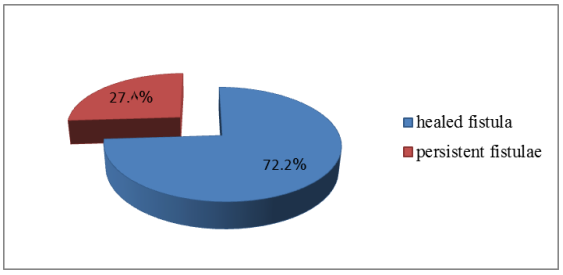

Fig. 12: Success rate per patients

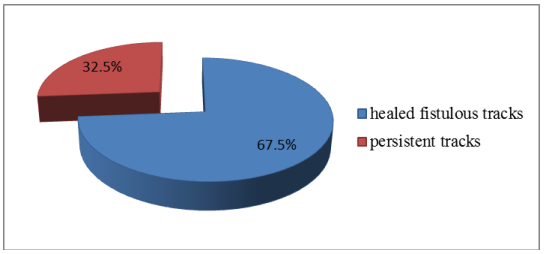

Fig. 13: Success rate per tracks

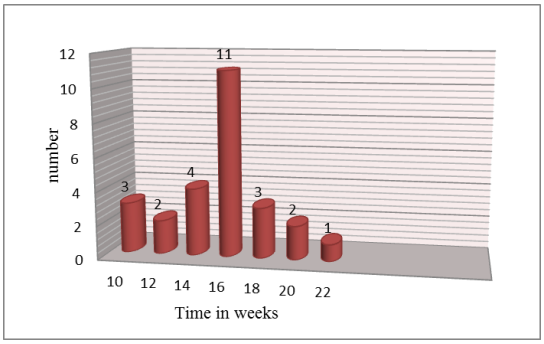

Fig. 14: Timing of fistula closure

DISCUSSION

The main aim in anal-rectal fistula surgery is to eradicate the fistulous tract while preserving anal continence mechanism. The term complex fistula is a fistula that carries a high risk of incontinence when surgically repaired. These fistula includes those with multiple external peri-anal openings, involving more than 30% of the anal sphincter complex (trans-sphincteric fistulas), extra-sphincteric, supra-sphincteric, those having high blind extensions, those with horseshoe tracts, or an anal fistula in patients with a pre-existing history of fecal incontinence [(2)]. Submucosal and low inter-sphincteric (comprising less than 30 % of anal sphincter complex) are considered simple fistulae with a lower risk of incontinence on surgical treatment[(12)].

In patients with complex anal fistula, fistulotomy is a low value procedure because of the need for significant damage of anal sphincter muscles that eventually leads to variable degrees of anal incontinence which makes more sphincter saving procedures for fistula to be reasonable choices for those patients [(13)].

These procedures include mucosal advancement flaps, loose seton placement, fibrin glue and AFP. All of these techniques have different success rates of fistula healing. Review of the literature for the mucosal flap advancement revealed a recurrence rate between 0 and 63% [14, 15]. The technique fibrin glue was used as an alternative to the mucosal advancement flap; however the success rates were low reaching16% [16]. The liquid fibrin glue might be not ideal for the purpose of closing anorectal fistulas, because the glue is easily extruded from the fistula tract by increased pressure [17].

Our series involved patients with inter-sphincteric, trans-sphincteric, supra-sphincteric, fistulae with multiple tracks and recurrent fistulae, in them fistulotomy may derange continence mechanism. We excluded patients with simple superficial or submucosal fistulae that could be operated safely by fistulotomy and patients with blind ended tracks with failed introduction of the plugs. The pre-operative use of setons in all patients, not only ensures the proper drainage and elimination of any inflammation or infection, but has been postulated to prepare the track, making the wall more fibrotic, with an increase in success rates of the AFP procedure [18, 19]**.** The rate of plug dislodgement in this study was 11% (4 cases). The previously reported rates of plug dislodgement in some series following AFP insertion ranged from 4% to 41% with an average of 19 % [20]. Those patients with early dislodgement of their plugs showed difficulty during first introduction and fixation and included patients with difficult supra-sphincteric and trans-sphincteric fistulae. Those patients were re-operated upon by re-insertion of other plugs with complete cure in 50 % of them.

Plug dislodgement constituted 20 % of the reported cases of treatment failure after re-insertion of other plugs. Other causes of plug failure related to the complexity of the fistula.

Plug dislodgement is the most commonly reported cause of failure. If we could reduce the rate of plug dislodgement by adopting a better technique or by better selection of patients, it might be possible to achieve a higher success rate.

We did not encounter any case of deranged anal continence mechanism in the present study. The rate of anal incontinence in other treatment options varies, although most studies reported incontinence rate between 3 and 7 % after fistulotomy. After using seton techniques the incontinence rate raised to 17 %, and after mucosal advancement flap procedure the incontinence rate was around 6-8%.

The closure rate of fistula per patients' was 72.2%, in a median follow up of 16 weeks, while the closure rate per procedures' was 65%, accounting for the failure rate added by the early dislodgement of the plugs in 2 patients. The closure rate per fistulous tracks' was 67.5%.

In a series of 17 patients with complex and resistant perianal fistulas including 12 with recurrent fistulae, done by Van Koperen et al, a closure rate of only 41% was found after a median follow-up of seven months [21]**.**

Champagne et al [7] reported 46 patients with complex fistula treated with anal fistula plug. Patients with high trans-sphincteric or deeper were included and after a median follow-up of 12 months, a success rate of 83 % was achieved.

Several comparative studies were done comparing various sphincter saving techniques for management of complex anal fistulas. A comparative study by Christoforidis et al reported a 63% fistula closure rate for endo-rectal advancement flap versus a 32 % closure rate for the AFP in the treatment of patients suffering from trans-sphincteric fistulas [22].

Another study done by Johnson et al, reported higher closure rates for the AFP than for fibrin glue in a prospective, non-randomized study [23]. The study stated that closure of the internal opening of a fistula tract using anal fistula plug is more effective and reliable method than fibrin glue closure. The greater efficacy of the fistula plug may be the result of the ability to suture the plug in the internal opening, therefore, closing the primary opening more effectively. Theoretically, the fistula tract also can close as the result of incorporation of the plug. In a large retrospective study, done by Chung et al, compared the AFP, anal advancement flap, fibrin glue and seton drainage in the treatment of high trans-sphincteric fistulas [24]. They reported closure rates of 59.3% for AFP, 60.4% for anal advancement flap, 39.1% for fibrin glue and 32.6% for seton drainage.

Furthermore, the advantage of the plug is that it can be used repeatedly, without risk of damaging the anal sphincter and it can preserve other treatment options. Another advantage is that installing the plug is minimally invasive with less postoperative pain.

CONCLUSIONS

In management of complex anal fistula treatment must be individualized.

Anal fistula plug appears to be a promising and safe alternative to the current treatment options for high or complex perianal fistulas in them, such options may carry the risk of recurrence or sphincter derangement with high rates of minor or major incontinence.

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