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Review Article,

Endofistular Treatment for Complex Fistula-In-Ano:

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Abstract:

Purpose: Fistula in ano is a begnin disease and should be treated like benign disease. We have used a technique of curating infected fistula lining, confirmed by fistuloscopy, and packing the tracts with collagen to reduce the dead space. Reporting our long-term outcomes were analyzed including procedural complications and fistula recurrence

Method: A retrospective analysis of collected data of the study conducted by a dedicated tertiary referral colorectal unit at a regional hospital in India between January 2010 and December 2019. Patients were included who underwent the procedure, the fistula curetting of the lining of the fistula tracts, clearing was confirmed with endoscopy and supplemented by instillation of sclerosant foam and a soft collagen. Internal opening < 1.5 cm closed with purse sting sutured. Larger opening of fistula was closed with a mucosal advancement anoplasty.

Results: The series of 189 patients with complex fistulae undergoing endofistula treatment comprising 102 highfistulas, 42 horse-shoe fistulas, 26 recurrent fistulas and 19 women with anterior fistulas. An internal opening was identifiable in all cases with 80.4% directly closed and remaining by advanced flap. The collagen extruded in 13.8% of cases usually from an intersphincteric tract extension. The primary healing rate (within 10 weeks) was 91.1% with 25 recurrences (13.2%) detected over a median follow-up of 72 months. Continence was maintained in all cases.

Conclusions: Customized curetting ablation confirmed by endoscopy is successful long-term in accurately identifying the tracts and the internal opening with satisfactory ablation and preservation of anal sphincter function. Minimum traumatic and minimum painful procedure,

Keywords: - Complex fistula, endofistula treatment, curetting, collagen, minimal pain

Introduction:

Anal fistula is one of the common problems in proctologic practice. Fistulas are typically classified as low or high and as simple or complex by virtue of the relationship of the main track (s) and abscess collection(s) to the anal sphincters and the puborectalis muscle.[1,2] Overall, high fistulas account for about 10% of the cases depending upon the nature of the referral practice.[3] Low fistulas can be managed satisfactorily by simple lay-open fistulotomy, removing the pyogenic granulation tissue of the fistula track and by closure of the internal opening.[4,5] High fistulas (including high trans-sphincteric, supra-sphincteric and extra-sphincteric cases as well as any fistulas with trans-levator extension or to supra-levator) are traditionally difficult to manage where there is a balance between fistula eradication and postoperative function. Recurrent fistulas also fall within this group since the surgical anatomy in these cases can be markedly distorted.[6]

Within this paradigm aiming at fistula cure and sphincter preservation the selective surgical options include fistulotomy, seton deployment, two-stage fistulectomy, primary fistulotomy with sphincter repair, endorectal and cutaneous advancement flap surgery, ligation of the intersphincteric fistula tract (LIFT), video-assisted anal fistula treatment (VAFFT), fibrin glue, fistula plugs and the OTSC clip.[2,7-16] Recent reported success of these newer procedures such as LIFT and VAAFT have been particularly variable.[17,18]

Since 2003 we have used a cystoscope and later

on operating hysteroscope, for evaluation of the interior of anal fistulae and confirming clearing after curettage, for ablating the pyogenic granulation tissue of all fistula tracts..[19] Dr. Chivate combined other minimum invasive procedures, had variable results like fistula plug, lift and foam sclerosants used for destruction of endothelium and sclerosis in varicose veins treatment. This retrospective study presents a cohort of patients with cryptoglandular fistulas who were managed by endofistula treatment derived by Dr. Chivate and they were followed clinically. We report complications of the procedure and the rates of primary healing and fistula recurrence.

Materials and Methods:

Ethical permission was obtained from Rahate hospital Ethics Committee. for this study. All patients provided informed consent for conduct of the procedure, after explanation of its novel characteristics and uncertainty regarding the risk of fistula recurrence. The consent was also obtained for recording of the treatment, publishing and presenting in conferences. Patients analyzed were included from surgeries performed between January 2010 until December 2019 with all cases performed at the Jeevan Jyot Hospital (Thane). Information collected included details of the medical history as it pertains to the anal fistula such as duration, a history of prior fistula surgery. The patients associated disease like inflammatory bowel disease, tuberculosis or malignancy were excluded from analysis. Simple fistulas those where the main track was < 5 cm. in length and ultralow intersphincteric or low transsphincteric fistulas were treated by simple open fistulotomy excluded from the study. Transsphincteric fistulas were regarded as low if they involved < one-third of the external anal sphincter (EAS) as demonstrated by either anal endosonography or MRI. Those fistulas associated with an abscess collection exceeding twenty cm in diameter on preoperative imaging were also excluded from analysis. Patients were examined identifying the position of the internal fistula opening and its relationship to the anorectal sphincter along with coincident benign anorectal pathology.

Procedure~

Patients were managed by endofistular approach as guided by the preoperative MRI taking into account the location of the external opening(s), the position of the internal opening(s), the coronal extent of the main fistula tract and secondary tracts and/or collections. All patients remained on clear fluids for the day prior to surgery and were administered 3 doses of 60 mL lactulose throughout the day. Procedures were generally performed under spinal anesthesia with the patient in the lithotomy position and covered with perioperative intravenous Metronidazole. Cefetrizole, and Sulbactam. The location of the internal fistula opening was confirmed with injection of methylene blue and hydrogen peroxide. After identification and the 3-dimensional impression of the fistula course. The external opening of fistula was sequentially dilated up to skin deep, using a Hegar's dilator up to No. 6. The external opening was dilated 2-4 mm diameter wider than the scope used. The widen external opening of the fistula should permit free in and out flow of normal saline irrigation fluid, without causing excessive ballooning of the fistula.

Figure 1. Flexible suction curette

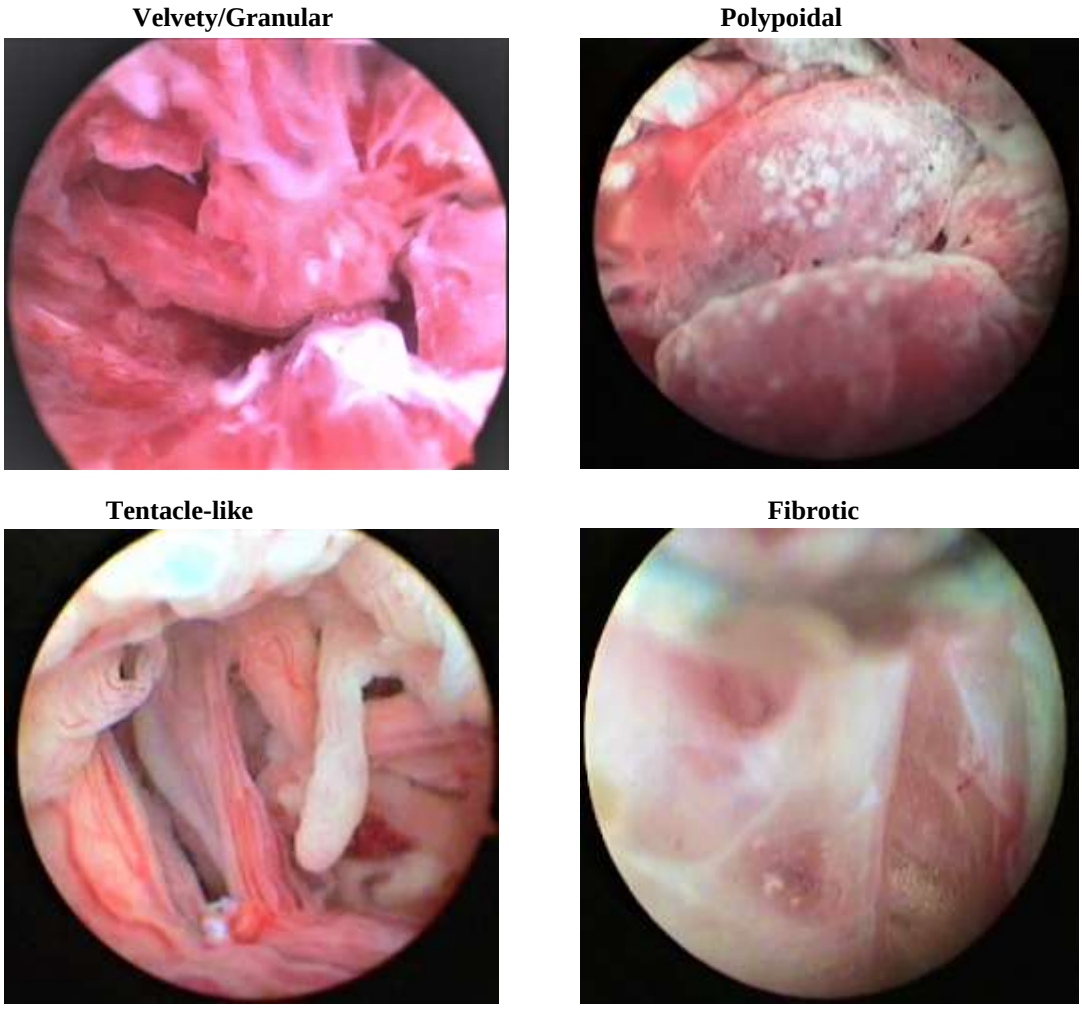

Figure 2. Endoscopic appearance of the fistula lining

The procedure is divided into a diagnostic and a therapeutic part. For our purpose, we used the operating components of either a cystoscope or a hysteroscope without a sheath with a telescope of 4mm. diameter 0^0 or 30^0 view. The operating elements are comprised of two channels, one for irrigation and another as the operative instruments. The pressure of the irrigation is adjusted so that it just opens the fistula tract and keep it open. As the tract opens, the scope is then advanced until a blind end is visualized. Entry is facilitated by gentle up-down and left-to-right movements of the scope to prevent red-out during advancement. Entry can be difficult if the track is particularly circuitous. The 30^0 scope is better able to visualize the presence of side tracts particularly when their take-off from the main tract is acute. In some cases, a decision can be made to open the point of acute curvature converting a single highly curved tract into two simpler straight tracts. When the internal opening is particularly narrow, it may be indirectly identified by the appearance of the scope light near the anal mucosa. During scope withdrawal the fistula tract is meticulously examined assessing the character of the lining, the general shape of the tract, its branches, any connected abscess cavities, the positioning and size of the internal opening as well as the overall length of the primary tract.

Second goal of the operative phase is the curettage and ablation of the fistula lining from the inside. The entire fistula tract is meticulously curetted and cleansed and confirmed under vision. Curettage may be performed more readily and rapidly using a flexible suction curette as shown in *Figure 1*. The flexible suction curette is particularly useful in the curved portion of axial fistulas which cannot be reached by the rigid curate for ablation. The rectum should be digitally examined during all ablations in order to ensure that injury is avoided. Curettage is continued until

the entire fistula tract is cleared of all necrotic and adherent infected material attached to the fistula wall. For intersphincteric fistulas it is necessary to open the intersphincteric space at Hilton's line. [20] The tract is traced as a cord-like structure from the internal opening at the anal verge. This can be best achieved with a probe inserted into the tract reaching to the internal opening and by dividing the tract over probe in two with one end leading towards the internal opening and the other into the intersphincteric plane. Following extensive curettage and cleansing and confirmation a foam sclerosant solution which combined 4ml of sodium tetradecyl sulphate (30mg/mL) with 6 ml of air was instilled via an infant feeding tube into all tracts. External openings were compressed for a 2-minute period to allow adequate distribution of the foam. The instilled material acting with the wall of fistula convert into a sticky quality. All tracts and their main branches were then packed with collagen (Eucare Pharmaceutical, Chennai India) preserved in isopropyl alcohol and repeatedly washed in normal saline so that it softens. The internal opening was then formally closed with a diamond shape or purse sting -stitch using a 2/0 polyglactin suture incorporating part of the internal anal sphincter (IAS) and some of the collagen in it.

a. Oblique **b.Elliptical** **c. Almond-shaped**

Figure 3. Endoscopic appearance of an intersphincteric tract

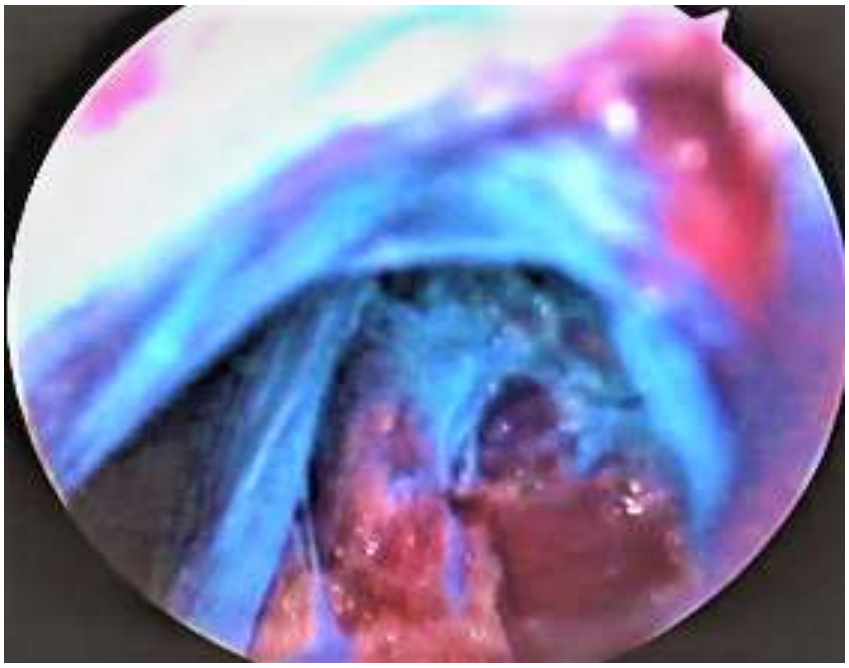

Figure 4. Granulation tissue at the internal opening evident at the point of exit of the scope (IO = internal opening) through intersphincteric space

If the diameter of the internal opening exceeded 1.5 cm. a rectal mucosal advancement flap was used for coverage. External openings were curetted and the granulation tissue removed and these small wounds kept open. All curetted tissue and excised material was submitted for histologic examination. Patients remained on antibiotics for one postoperative week with tracts irrigated where possible with normal saline twice during the first postoperative week. and healing occurs. If collagen gets extruded the fistula tube is washed every second day. Tract given saline wash with help of infant tube. Patients were reviewed in the clinic weekly after healing for the first postoperative month, monthly for the first 6 months and annually thereafter by telephone communication. Fistulas were considered healed if all external openings remained closed with no clinical evidence of active or recrudescent inflammation. Fistula sites without pain, swelling or discharge were regarded as clinically healed at the time of assessment.

Results:

There were 189 patients with complex fistulas (as defined) who underwent endofistula surgical management. In the cohort study, there were 123 males and 66 females (mean age 37.5 years; range 18-56 years). Surgeons had access to preoperative MRI films in all cases. There were 102 (54%) cases with high fistulas, 42 (22.2%) with horse-shoe fistulas, 26 (13.8%) with recurrent fistulas and 19 (10%) females with anterior fistulas. An external fistula opening was evident in every case with one external opening in 103 (54.5%) cases, 2 external openings in 47 (24.9%) patients and > 3 external openings in 39 (20.6%) of the cases. In the cohort there were 34 (17.9%) of the patients who were diabetic. Apart from detection of the site of the internal fistula opening and proximal protecting papilloma, rigid proctoscopy was otherwise normal in all cases.

The internal opening was evident in every case with 156 (82.5%) confirmed using methylene blue injection, 21(11.1%), shown by the observation of a glow of light behind the anal mucosa on endoscopy and 12 (6.3%) confirmed with a Lockhart-Mummery fistula probe. When the fistula was anterior, the internal opening was noted to lie between the 11 o'clock and the 1 o'clock positions in 26 (13.8%) of the cases and when posteriorly located between the 5 o'clock and the 7 o'clock positions in 163 (86.2%) of the patients. All internal openings were found around the dentate line. The internal opening diameter was < 1.5 cm in 152 (80.4%) cases all of which were closed with a purse-string (or diamond) suture. In 37 (19.6%) of cases the width of the internal fistula opening exceeded 1.5 cm diameter, in these patients, closure was achieved with a mucosal advancement anoplasty. The endoscopic appearance of the fistula varied with some having a velvety or granular element, whilst others were primarily polypoidal, tentacle-like or sclerotic in nature. Figure 2.

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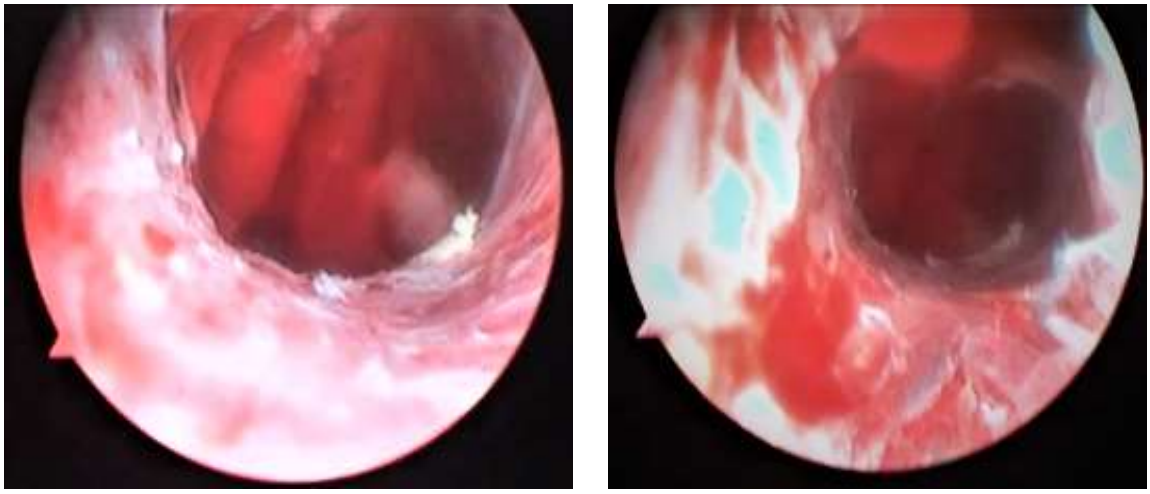
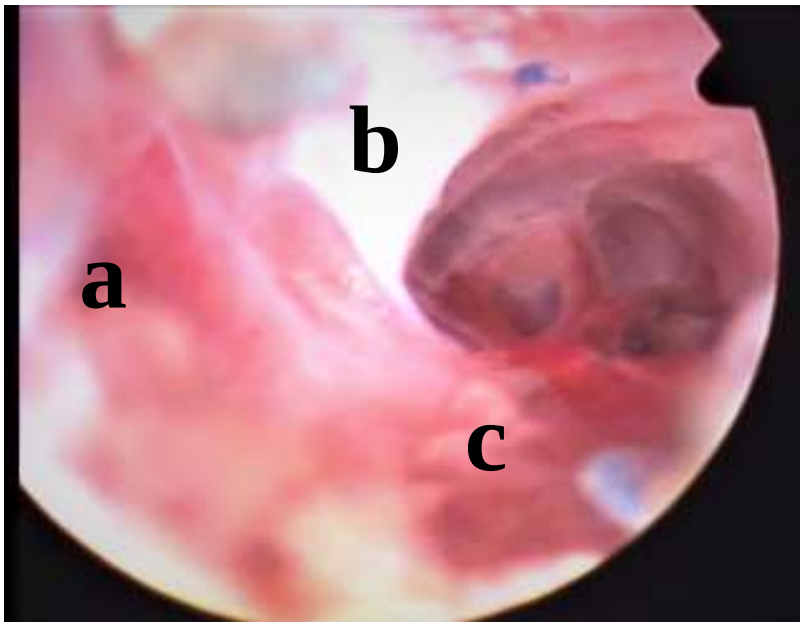


Figure 5. The cross-sectional endoscopic appearance of extrasphincteric fistula tracts (usually perfectly or roughly circular)



a - Puborectalis sling - b - Anterior Pubococcygeus component
c -Junction between the deep EAS and the puborectalis muscle

The shape of 83 intersphincteric tracts was oblique, elliptical or almond-shaped on cross-section. Figures 3 and 4 show the endoscopic appearance of these intersphincteric tracts and of the internal opening as it is reached by the scope. Extrasphincteric tracts traversing the ischiorectal space were roughly circular in cross-section (Figure 5). Two or more tracts were detected in 87 (46%) of the cases. Of those tracts which were longitudinal (parallel to the rectum and anal canal), there were 136 which ran in part outside the EAS, 83 which ran upwards primarily in the intersphincteric space and 87 where there was a combination of inter- and extrasphincteric longitudinal components. Axial tracts could be straight or circuitous. There were 49 anterior tracts, 96 posterior tracts and 34 had an anterior and posterior component. In the cohort there were 34 translevator extensions with 21 of these cases extending from a longitudinally deposed tract into the supralevator space. An endoscopic example of an intersphincteric supralevator fistula traversing the puborectalis muscle is shown in Figure 6

The histology of all cases (including the 16 recurrent fistulae) showed non-specific chronic inflammatory tissue only, in keeping with a likely cryptogenic glandular origin. In 26 patients (13.8%) the implanted collagen material partially extruded from the wound. This was more commonly found with intersphincteric fistulas (14/183; 16.9%) than with extrasphincteric tracts (4/136; 2.9%), anterior axial (3/96; 3.1%) or posterior axial (5/49; 10.2%) fistulas. There was primary wound healing by 7 days in 141 (74.6%) cases with a further 22 (11.6%) healing by 3 weeks. Of the 26 cases (13.8%) that were slow to heal, 9 fistula wounds remained after 10 weeks with 17 (8.9%) failing to heal. The median overall follow-up was 72 months (range 24-120 months). After initial healing a recurrent fistula was detected in 5 cases at 2 postoperative years and in a further 3 patients at 3 years of follow-up. Overall, there were 25 recurrences (13.2%) with follow-up patients re-examined by MRI and noting that recurrences were generally less extensive than the original fistula. To date, every recurrence has been successfully managed with repeat endoscopic ablation. All recurrent fistula patients stated that they preferred endofistular treatment as they considered it a likely less painful procedure than other surgical alternatives. Although continence status was not formally recorded, no patient complained of anal incontinence during follow-up.

Discussion:

The fistula is a benign condition, no radical treatment required, present the outcome of a cohort of 189 patients referred to a single surgical unit over a decade with high and complex cryptogenic anal fistula who were managed with a simple curating and clearing confirmed by endoscopy. In the series fistula tracts grossly divided in two different types by endoscopy, are

axial and longitudinal. The longitudinal tracts are divided in two groups. One was intersphincteric and second was extra sphincteric. Intersphincteric tract may extend upwards and open in the supralevator space. The puborectalis muscle forms the lateral border of the supralevator space in intraphincteric tracts. The extrasphincteric fistula has two verities subcutaneous and ischio rectal. The extrasphicteric fistula extends upward to the levator ani muscle. The levator / puborectalis forms the medial boarder here of the supralevator region. The axial tracts are anterior, posterior or combined. Visualized endofistula management defined an internal opening in 89.5% of the cases. In our protocol, we ablated infected lining of the fistula by curettage, which was confirmed endoscopy along with sclerosant installation, collagen implantation. The closure part of collagen to the internal opening either using direct suture. The internal opening < 1.5 cm closed by mucosal advancement anoplasty. A flexible suction curette proved useful particularly for ablation of the axial curved and which do not readily admit a strait rigid curate. In the acute point of curvature of the tract was opened so as to separate the fistula into two straight segments that could accommodate the rigid scope and curate. The sclerosants were instilled as foam which can reach to any corner of tract and because of their known capacity to destroy superficial granulation tissue without inducing necrosis. Primary healing by 10 weeks was able to be achieved in 91.1% of the patients with 25 (13.2%) of cases recurring over a median follow-up of 72 months. There were 8 (4.2%) of the patients where recurrence occurred 2 years or longer after initial endofistula treatment. Recurrent cases were generally less extensive than the primary fistula and all were successfully managed by repeat endoscopic ablation.

Endofistula alternatives in management include the LIFT procedure,[12,21,22] Filac® laser therapy,[23,24] the OTSC fistula clip [16,25] and the VAAFT procedure or its variants.[13, 18,26] It is evident that an endoscopic approach towards fistula ablation can be translated to different surgical technique.[27-30] As with any complicated cryptogenic anal fistula successful management is defined by the balance between healing, recurrence and continence. Our recurrence rate is in keeping with that reported by Emile et al.[18] of 16% in a recent meta-analysis of pooled VAAFT data obtained from 11 eligible prospective and retrospective studies. As with our study, this meta-analysis also showed a similar weighted mean rate of detection of the internal opening of 93.3% when study heterogeneity was taken into account. Comparisons of our data with other pooled studies are difficult since there are differences in the proportion and even the definition of suprasphincteric and extrasphincteric fistulas. The incidence of secondary tracts in our study (46%) significantly exceeded the rate of 25.3% reported by Emile et al.[18] We did not experience the variety of procedural complications which have been reported with VAAFT endoscopic management such as prolonged serous or bloody discharge or perianal cellulitis and which have ranged between 0-16% in pooled analyses.[6,18] In our study we dilate the external opening 2 mm wider than the diameter of the scope.

The dead space of the fistula tract is reduced by packing of collagen in the empty tract.

Implanted collagen was extruded in nearly 14% of our cases mostly when it was deployed into a vertically disposed intersphincteric tract. Such an extrusion rate of collagen is similar to that reported by Champagne et al.[15] using an anal fistula plug, with collagen about one- fortieth of the plug cost. We did not use cyanoacrylate instillation which is an integral part of the original Meinero's procedure. In this regard, these authors have reported significant glue-related allergy in about 1% of their cases.[31] Our approach of direct suture of the internal opening in the majority of cases was similar to that adopted by Giarratano et al.[32] who used a mattress suture for closure in 64/72 (88%) of their cases. Other reports have routinely used sutures only [7,33] advancement flaps [34] and staplers [13,31,35,36] for formal closure of the internal fistula opening or combined a 2-stage VAAFT approach with deployment of an anal fistula plug.[37]

It is our contention that a simple transverse or figure-of-eight suture used to close the internal opening will likely cut through during defecation as the line of pull of the suture is the same as that of the sphincters. This is not the case with a purse-string closure. Our overall primary healing rates exceeded those reported by Giarratano et al. [32] who had a 21% failure rate where one-quarter of whom had no internal opening identified. Of recurrences reported by this group, one-third were successfully managed by a repeat VAAFT with our experience suggesting a higher rate of ultimate fistula healing from repeat endoscopic management. In our series there no case lost to follow-up and we would contend that endoscopic

therapy is less painful when compared with other standard surgical fistula management.

There are several advantages of our approach. The procedure uses pre-existing equipment providing a low-cost alternative to commercial kits and dedicated fistula endoscopes. As VAAFT uses radiofrequency for fistula ablation there is the risk of lateral thermal damage and delayed healing which is not a feature of our simpler curating technique which freshens the internal part of the fistula tract helps in healing. Optics of VAAFT is 1 mm 8 degree fibro optic lens, on other hand our endoscope has 4mm rod lens gives better quality of pictures. The advantage of the technique over LIFT is the ability for fistula ablation and the detection and management of side-branches. Further, these types of endoscopic fistula procedures do not in essence compromise continence, nor are they associated with much morbidity. In our environment, the cost-effectiveness of such an approach will only be evident if there is a successful rate of fistula healing over prolonged follow-up that is comparable to other complicated procedures often attended by complications that may require readmission and revision.

There are, however, several limitations to our study. Firstly, any retrospective analysis is potentially subject to bias. Secondly, a more extended follow-up may reveal a higher recurrence rate than initially reported and the longer-term value of repeat endoscopic fistula ablation in our hands is presently unknown. Additionally, we did not formally evaluate continence in our cases except history. It is also accepted that given our resources, assessment of fistula healing and therefore apparent success rates were based largely on clinical examination where it is known that MRI can detect persistent, recurrent or recrudescent postoperative sepsis when there are no overt clinical signs.[38]

Conclusion:

The use of curating for a complex fistula and confirmed by an available rigid scope for endofistula ablation appears valuable is applicable in day-care management with minimal wounds that heal rapidly without the need for repeated painful dressings. The technique satisfies the principles of complex fistula management, namely accurate identification of the tracts and the internal opening, tract ablation and preservation of anal sphincter function.

Author Tasks:

Conflict of Interest Statement: The authors declare that they have no conflict of interest.

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