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MODIFIED-2-STAGED FISTULECTOMY WITH SPHINCTER REPAIR ($_{M2}$FISR) PROCEDURE FOR TRANSPHINCTERIC FISTULA-IN-ANO: A MODIFIED SURGICAL APPROACH.

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ABSTRACT

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Keywords: Anal sphincter, Fecal incontinence, Fistula-in-ano, Recurrence, Surgical procedure ($_{m2}$FISR).

INTRODUCTION

Surgical management of transphincteric fistula-in-ano (FIA) remains a challenge despite development of various surgical techniques and novel procedures. In general, the surgical management follows the principle of 1) Drainage and eradication of sepsis, 2) Delineation of fistula tract, 3) Adequate eradication of fistula tract and internal opening, and 4) Reduce the risk of recurrence and incontinence.[1]

Many surgical approaches have been reported all over the world, including fistuloto-

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my, fistulectomy, ligation of intersphincteric fistula tract (LIFT), anal fistula plug, fibrin glue and endoanal advancement flap.[1] There is no gold standard treatment approach as most published data are of observational case series with different technical approaches and success rates. Novel techniques such as Video -Assisted Anal Fistula Treatment (VAAFT) and Fistula- Tract Laser Closure (FILAC) are not readily available and results varies in different regions.[1]

For high transphincteric FIA, several authors have described approaches that were based on the principle of fistulectomy followed by immediate sphincter reconstruction, all which are case series with a wide variation of surgical techniques.[2-5] Ratto et al recommended this approach for patients with recurrent fistula, with baseline incontinence and those at risk of incontinence.[2] Our centre approached transphincteric FIA based on the above 4 principles of surgical treatment. All our patients undergo a 2 staged surgical procedure following initial endoanal ultrasound assessment, which we named Modified 2 Staged Fistulectomy with Sphincter Repair ($_{m2}$FiSR) Procedure. The first stage is an examination under anaesthesia with insertion of draining seton for minimum of 6 months, followed by a second stage definitive fistulectomy and sphincter repair procedure. We report here our results of our $_{m2}$FiSR over a 5-year period from 1 January 2015 to 31 December 2019.

METHODOLOGY

This study is a retrospective review of medical records of patients diagnosed with transphincteric FIA who had undergone elective surgery from 1 January 2015 – 31 December 2019 (5 years) under Colorectal Unit in our centre. All patients who underwent the modified 2 staged $_{m2}$FiSR surgery were included in this study. Data were obtained from elective surgery operating notes and follow-up clinic records.

$_{m2}$FiSR Surgical procedures

All patients underwent clinical assessment and Endo-anal Ultrasound performed by a single colorectal consultant in our centre. Written informed consent were obtained from all patients. For Stage 1 of $_{m2}$FiSR, all patients underwent examination under anaesthesia (EUA) to identify and delineate transphincteric fistula tract and internal opening (Figure 1). Collections/abscesses were drained if present. Draining setons were inserted for all patients. No definitive repair was done in stage 1. Patients were discharged and follow up for 6 months.

Stage 2 of $_{m2}$FiSR was carried out after 6 months. Surgery was done under spinal anaesthesia in prone position. Fistulectomy were performed by excising the entire fibrous tract, including the internal opening with a cuff of anal mucosa (Figure 2a-e). The internal opening were closed with polyglycolic acid sutures 3/0 using figure of 8 stitch. Defects of the internal and external sphincters were repaired individually using end-to-end approximation with interrupted polyglycolic acid 3/0 sutures. Anal skin was left open for secondary healing.

Outcome Measures

Primary outcome assessed was recurrence rate at 1 year, whereas secondary outcomes assessed were complications such as wound

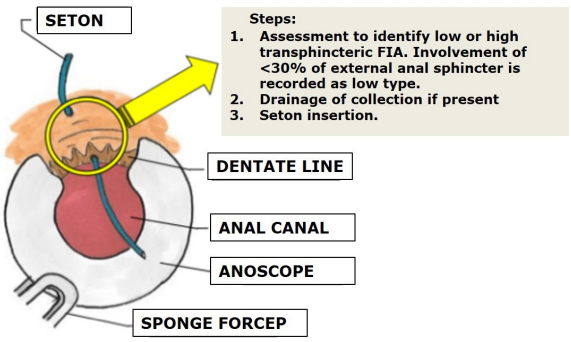
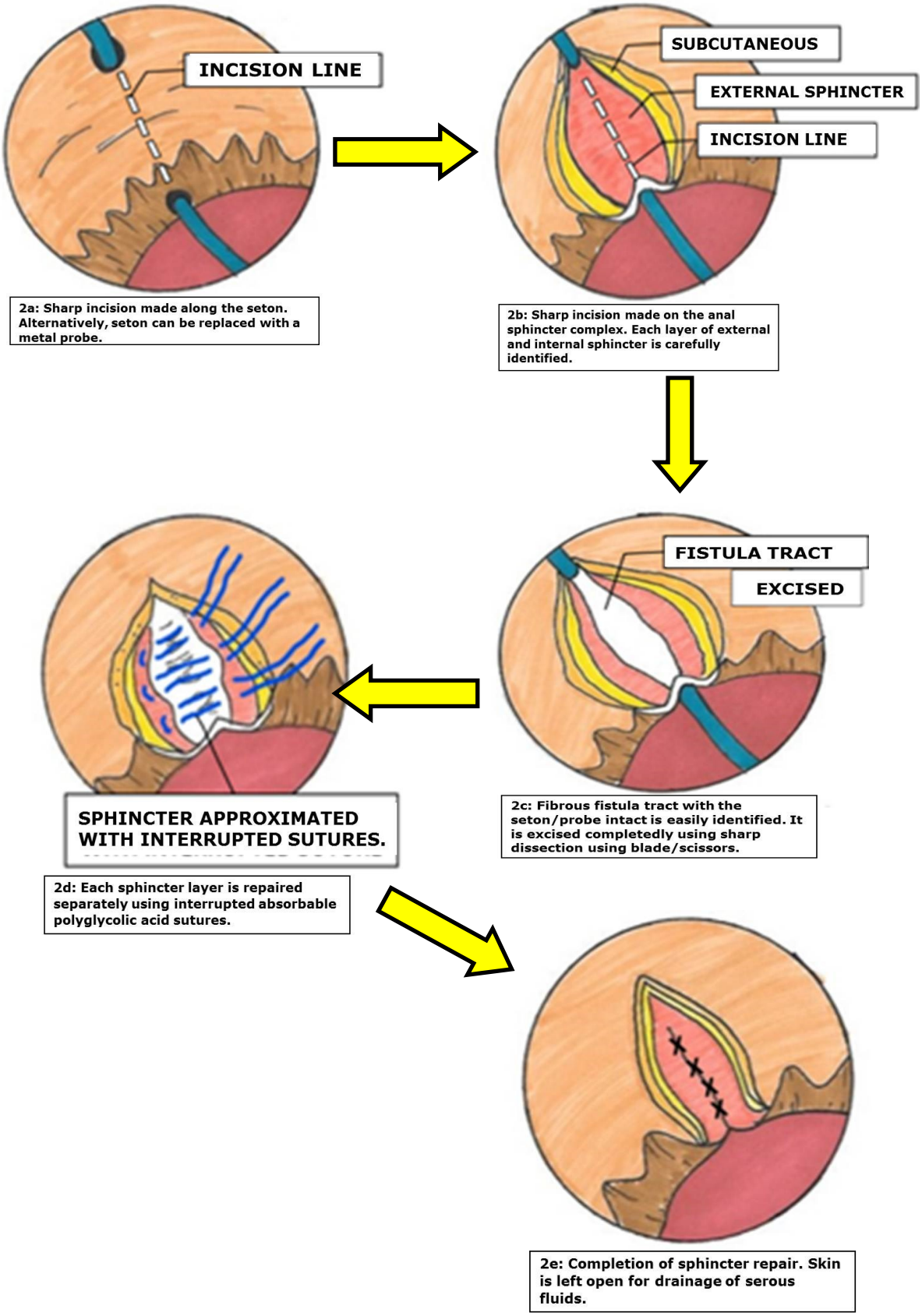


Figure 1: Diagramatic representation of $_{m2}$FiSR, Stage

Figure 2: Diagramatic representation of procedure and surgical anatomy for $_{m2}$FiSR, 2nd Stage, showing step by step approach.



2a: Sharp incision made along the seton. Alternatively, seton can be replaced with a metal probe.

2b: Sharp incision made on the anal sphincter complex. Each layer of external and internal sphincter is carefully identified.

2c: Fibrous fistula tract with the seton/probe intact is easily identified. It is excised completedly using sharp dissection using blade/scissors.

2d: Each sphincter layer is repaired separately using interrupted absorbable polyglycolic acid sutures.

2e: Completion of sphincter repair. Skin is left open for drainage of serous fluids.

infection and incontinence. Patients were followed up at 6 weeks for wound infection, and up to 1 year for recurrence and incontinence. Incontinence was assessed using Cleveland Clinic Fecal Incontinence Score (CCFIS) during each follow-up (Supplementary text).[6]

Definitions of terminologies used in this study:

Transphincteric FIA: Type II Fistula according to Park's Classification of Anal Fistula.[7]

Low Transphincteric FIA: Involvement of <30% of external anal sphincters.[8]

High Transphincteric FIA: Involvement of >30% of external anal sphincters.[8]

Statistical analysis

All data were presented as descriptive statistics. Continuous variables were presented as mean ±SD. Categorial data were presented as frequencies in percentage. Mean and standard deviation were calculated using Microsoft® Excel® version 2009.

RESULTS

Out of 47 patients initially identified, 44 were successfully included in this series. Two patients were excluded due to persistent anorectal abscesses, requiring repeated drainage and seton replacement. One patient defaulted clinic appointment and was lost to follow up. Mean age of the remaining 44 patients were 39.3 ± 13.4 years, with age ranged from 17 to 66 years-old. 82% were male and 18% were female (Table I).

For the initial stage 1 $_{m2}$FiSR assessment: 28 patients (64%) were found to have high transphincteric FIA whereas 16 patients (36%) were categorised as low transphincteric FIA. However, during stage 2 $_{m2}$FiSR procedure, 16 out of 28 patients initially diagnosed as high transphincteric FIA were reclassified as low transphincteric FIA due to migration of the internal opening distally (compared to initial documentation) after 6 months on draining seton. None of the low transphincteric FIA were reclassified (Table I).

Table I: Patients' demographics and clinical classification of transphincteric fistula at Stage 1 and 2 of $_{m2}$FISR procedure.

Variables	Mean ± SD (Range)	n(%)
Age (years)	39.3 ± 13.4 (17-66)	
Gender		
Male		36 (82%)
Female		8 (18%)
Type of fistula during stage 1		
Low transphincteric		16/44 (36%)
High transphincteric		28/44 (64%)
Type of fistula during stage 2		
Low transphincteric		32/44 (73%)
High transphincteric		12/44 (27%) *

*Rate of reclassification from high transphincteric to low transphincteric FIA: 57%

Wound infection occurred in four patients (9%), all healed after two months with antibiotics and wound care. Recurrence at same fistula site after 1 year was at 9% (total of four patients). Three out of four recurrences were superficial anal fistulas with minimal external sphincter involvement. None of the patients in our series complained of incontinence during follow-up. On CCFIS scoring, two patients scored 2 points and one patient scored 3 points at 1-year follow-up. Forty-one patients (93%) had CCFIS score 0 (Table II).

DISCUSSION

Draining seton has been long reported as an acceptable method in treatment of FIA.[1] It is postulated to convert inflammatory process into a foreign body fibrosis around the fistula tract, at the same time promotes drainage of perianal sepsis.[1] As a single modality, recurrence rate of perianal sepsis is high and spontaneous healing of anal fistula remains poor

Table II: Primary and Secondary Outcomes of $_{m2}$FiSR Procedure at 6 weeks and 1 year.

Outcome Variables	n (%)
Primary Outcome	
Recurrence at 1 year	4 (9%)
Secondary Outcomes	
Wound infection @ 6 weeks	4 (9%)
Incontinence Score @ 1 year*	
Score 0	41 (93%)
Score 1-5	3 (7%)
Score 6-15	0
Score 16-20	0

Total sample size 44;

*Cleveland Clinic Faecal Incontinence Score. Perfect Continence: 0, Mild Incontinence: 1-5,
Moderate Incontinence: 6-15, Severe Incontinence: 16-20

after removal. However, draining seton has been increasingly reported as an initial control of sepsis prior to definitive repairs such as anal advancement flap and fibrin glue treatment.[1,9] We applied loosely placed draining setons for all patients without tightening for the first stage of $_{m2}$FiSR or readjustment during follow-up.

We have observed 2 additional benefits of draining seton other than those reported above. Firstly, it was well noted in this series that after 6 months on draining seton, up to 57% of those with high transphincteric fistula had internal opening migrated to below dentate line, converting it to low transphincteric type. Extra benefit perceived is a significant reduction in the amount of sphincter cut during 2nd stage procedure. Secondly, seton is postulated to induce formation of a well-formed fibrous walled fistula tract. This ensures complete excision of the tract during 2nd stage procedure.

Our approach focused on fistulectomy to completely excise the tract together with the internal opening and a cuff of anal mucosa around it, using sharp dissection. Immediate repair of internal and external anal

Our approach focused on fistulectomy to completely excise the tract together with the internal opening and a cuff of anal mucosa around it, using sharp dissection. Immediate repair of internal and external anal sphincter separately with end to end approximation has acceptable outcome. Our study showed the highest incontinence score was 3 with no obvious disturbance of daily living. Among the 3 patients which scored mild incontinence, all had occasional symptoms of liquid stool staining, and none had gas incontinence recorded. There was no individual scoring of more than 2 at any category in this series.

Several recent publications have described fistulotomy (lay open of fistula tract) with immediate sphincter repair.[2-4] The authors have reported slightly different variation of the approach, where fistulotomy was advocated for the portion traversing the sphincter complex, whereas the external fistula tract was cored out. Repairs of anal sphincters were not uniform, and opinions on closure of internal opening and skin differ from author to author. Prior draining setons were not consistently done. Failures were seen mainly in supralevator FIAs. Our series did not include supralevator FIA. A German guideline has included this approach as an option for repair of complex FIA.[10]

Perhaps the closest comparable techniques were published more than 20 years ago. Prakash et al in 1985 followed by Christiansen et al in 1995, both described the importance of complete excision of fistula tract with primary sphincter reconstruction.[5,11] Prakash et al reported a success rate of 83.3% and incontinence rate of 3.7%. However, their method of sphincter repair varies according to surgeon's preference. Christiansen et al reported similar success rate but remarkably high incontinence rate of 21.4%. It was noted that they have a small sample size of 14 patients, where 9 had prior draining seton and supralevator FIA were included in the study.[5]

Overall success rates reported in the existing literature range between 83.3% - 97.4%.[2-5,11] Incontinence rates range between 3.7% - 21.4%, due to wide variation of surgical techniques reported and inclusion of supralevator FIA in their series.[2-5,11] By refining various surgical methods based on previous experiences and careful selection of patients based on clinical assessment and Endoanal Ultrasound assessment, we were able to produce success rate of 91% and mild incontinence score (on CCFIS) of less than 7%.[12,13] This approach summarizes a series of commonly reported surgical techniques, arranged strategically, and follows stringent surgical details to achieve the maximal benefits for patients with transphincteric FIA. Existing techniques such as Endoanal Advancement Flap and Ligation of Intersphincteric Tract (LIFT) Procedure reports variable success rates between 60% – 90% and 51% - 94% respectively.[1,8]

This cohort of patients was managed and operated by a lead colorectal consultant, assisted by another colorectal consultant and fellows. The setting of this colorectal unit is in a background of a moderate to low volume public-funded tertiary center, covering a predominantly rural population of the east coast of Peninsular Malaysia. As majority of patients were referred by general surgeons around the region, most patients had initial incision and drainage performed in other hospitals. To ensure that the results are reproducible, we should standardize the technique and approach, and extend the series to obtain a larger sample size, including multicenter recruitment. Post-operative assessment of sphincter morphology using Endo-anal Ultrasound can serve as an audit for our sphincter repair and address future issues of incontinence.

CONCLUSION

Modified 2 staged draining seton followed by fistulectomy and primary repair of sphincters ($_{m2}$FiSR) suggest promising outcome for transphincteric FIA with good success rate and low recurrence rate. However, longer follow-up and a larger series is required to ensure outcome is consistent with the current series.

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DECLARATION

The authors declare that there is no conflict of interest and no financial conflict. Initial experience and results of FiSR Procedure (First 4 years) was presented as a poster presentation in Asia Pacific Federation of Coloproctology Congress 2019 in Kuala Lumpur, Malaysia.

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Cleveland Clinic Fecal Incontinence Score

Type of incontinence	Never	Rarely (<1/month)	Sometimes (> 1/month, but < 1/week)	Usually (> 1/week but < 1/day)	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Score: 0 – Perfect continence; 20 – Complete incontinence

(0-5: Mild, 6-15: moderate, 16-20: severe)