

Combined Single Surgical Cession Anatomical Trans-Sphincter Anal Fistulectomy and Ano-Plasty Technique Clinical Results

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1. Abstract

1.1. Background: Surgical techniques applied to treat ano-rectal fistulas has proved variable results, depending on how complex the fistula is. Many publications report promising results regarding simple and complex trans-sphincter fistulas. References have documented fecal incontinence varying from 10% up to 57%, depending on the procedure chosen. In this research we emphasize on the importance of anatomical dissection and reconstruction to reserve the anal sphincter function and avoid the traditional fistulectomy complications.

1.2. Material and Methods: This is a case series pilot study introducing anatomical surgical fistulectomy and ano-plasty technique on primary trans-sphincter fistulas. Between January 2016 AND June 2018, the study has RECRUITED 133 CONSECUTIVE patients with anterolateral, low or high primary trans-sphincter fistulas.

1.3. Results: The study has recruited 133 PATIENTS complaining of primary trans-sphincter ano-rectal fistula. There was no complication but superficial skin wound dehiscence occurred in 19 patients that healed spontaneously. No patient needed further surgical treatment with a follow up duration range of 12-42 (median 31) months. Five patients (3.8%) experienced temporary incontinence grade I for a duration ranging between 3-5 days. No case of fistula recurrence was observed in any of the cases.

1.4. Conclusions: The technique of anatomical resection and reconstruction needs surgeons to master the regional anatomy, completely resect the fistula tract and surrounding granulation, do meticulous hemostasis and reconstruct the field structures anatomically. Hesitation to achieve complete fistula excision for fear of incontinence is a major reason for fistula recurrence and non-anatomical reconstruction is a reason for incontinence. Critic is invited.

2. Keywords: Ano-rectal trans-sphincter fistula; Complex ano-rectal fistula; Low fistula; High fistula; anal sphincter incontinence; Magnetic resonance imaging.

3. Introduction

Familiarity with anorectal anatomy, pathogenesis and classification of the Anorectal Fistula (ARF) is essential to successful fistula management. The most widely used classification is the one proposed [1] describing the fistula track in relation to the anal sphincter complex. The four categories described are the intra-, trans-, supra- and extra- sphincter. No comparable classification has been described since that time yet. Defining the fistula tract has been tried by direct visualization through ano-procto-sigmoidoscopy, fistulography, endo-anal ultrasonography, and Magnetic Resonance Imaging (MRI) studies.

Continence preserving procedures without fistula tract dissection include; endo-rectal advancement flap [2], fibrin glue, biological / synthetic fistula plug [3] and the new modalities under trial such as Adipose-Derived Stem Cells (ASCS). [4] Reported success rates were 60-77%, 30-60%, 48-63% and 9-80% in order. The results are widely varying with the follow up duration and from center to another.

The Trans-Sphincter ARF (TSARF) is the most challenging type regarding the risk of recurrence with the incomplete surgical excision and fecal incontinence with the complete fistula excision. The most widely accepted model of TSARF management is the Ligation of the Inter-Sphincter part of the Fistula Tract (LIFT) procedure. The procedure consists of opening and dissection of the inter-sphincter space and identification of the fistula tract crossing that space. The tract is then ligated and cut, leaving both Internal Anal Sphincter (IAS) and External Anal Sphincter (EAS) intact. [5] This minimizes the risk of fecal incontinence, associated with surgical treatment of anal fistulas.

Based on systematic reviews; fecal incontinence varies from 10% up to 57%, depending on the procedure chosen. [6] However, as in most of the techniques utilized to treat ano-rectal fistulas the results vary, depending on how complex the fistula is in each patient. Many publications report promising results both in simple trans-sphincter [7] and complex fistulas. [8,9] There is however no consistent definition of “complex fistula”, since various authors define “complexity” of fistulas in different way. Many authors define “complex fistula” as a fistula

consisting of a minimum of two tracts with at least one tract connecting the anal canal and the skin in the vicinity of anus. This type of fistula is sometimes associated with “Extra-sphincter fistulas” in classification of Parks. [1,10] Other authors widen the definition, considering “complexity” of the fistula as “difficulty in managing”, “recurrent fistulas” or fistulas originating from certain locations. [11] The overall long term follow-up success rates reported so far vary from 62% to 73%. [8,12,13] Some authors modify the technique with implantation of plugs, meshes, or using fibrin glue (Bio-LIFT, LIFT-Plug, LIFT-Plus), but there is not enough evidence that variants in the surgical technique achieve better outcomes. [14-19] There is however some evidence, that a two-step approach (preliminary Seton drainage prior to the LIFT procedure) enhances the LIFT healing rates [15,20].

The diversity of definitions and methods of management of the ARF indicates the universally unsatisfactory overall results of such disease. The author in this research tried to apply an anatomical ARF resection and repair of the vicinity involving division and resection of the invaded part followed by repair of the anal sphincter followed by anatomical closure of opened planes in layers leaving no potential space for collection or infection.

4. Review of Theory Basis Related to Research Subject

4.1. Surgical Anatomy

4.1.1. Anal Sphincter Complex: The wall of the anal canal is composed of the mucosa, submucosa, and muscular is layers which are roughly cylindrical in form. The inner muscular layer represents an IAS and the outer layer is an EAS complex. The inner involuntary and outer voluntary sphincters keep the anal lumen closed in the form of an anteroposterior slit [21-24]. The IAS is the markedly thickened extension of the circular smooth muscle layer of the rectum and it terminates proximal to the lower part of the EAS [25]. The subjects have thicker IAS measurements with increasing age [26-29]. Age-related increase in IAS size most likely is the consequence of connective tissue infiltration rather than of true muscular hypertrophy [30, 31].

The EAS is made of skeletal muscle that does not enhance following intra-venous contrast agent as much as the IAS. According to the traditional description, the EAS has

three separate muscular fiber bundles: deep, superficial, and subcutaneous [32]. The deep part of the EAS, surrounds the upper third of the anal canal and merges proximally with the sling-like pubo-rectalis muscle [21].

The superficial part, the largest of the three, sweeps around to reinforce the bulk of the IAS on all sides and encircles the anal canal above the subcutaneous EAS. It continues within the anococcygeal ligament, which attaches posteriorly to the coccyx. This creates the small triangular space of Minor [33] behind the anal canal. Anteriorly, some fibers insert into the transverse perineal muscle. It has also anterior attachments to the perineal body [27,28].

Subcutaneous part is an annular muscle which surrounds the anal canal at the infero-lateral side of the IAS, and is situated immediately beneath the perianal skin.

4.1.2. Conjoint Longitudinal Muscle: The Conjoint Longitudinal Muscle (CLM) is a fibro-fatty-muscular layer lying between the EAS and the IAS. It continues superiorly with the longitudinal muscle layer of the rectum [25,34,35]. The CLM shows a thin hypo-intense circular configuration on MRI, it is a very thin layer with a mean thickness varies between 0.9 and 1.6 mm in normal subjects. Its fibers splitting up the inter-sphincter groove (Hilton's line) and subcutaneous EAS muscle [36,37].

4.1.3. The Inter-Sphincter Space: This is a potential space between the CLM layer and the EAS. It can be entered surgically to provide access in a variety of operations (e.g. Inter-sphincter approaches to fistula, inter-sphincter resection for low rectal cancer). Within the space lie the inter-sphincter anal glands, the source of most perianal fistulae [36,37].

4.1.4. Pubo-Rectalis Muscle: Pubo-rectalis muscle is the part of the levator ani group of muscles, which arises from the body of the pubic bone and forms a sling around the anorectal junction. This sling causes angulation of the rectum, partially preventing incontinence. It's typical "U-shaped" configuration is easily identified on the axial plane and absence of pubo-rectalis muscle in the anterior aspect of canal causes inherent weakness in this location [36].

4.1.5. Ano-Rectal Angle: The anorectal angle is one of the essential parameters of the anorectal configuration.

The lines passing from the posterior wall of the rectum and through the center of the anal canal are used to measure the anorectal angle [36,37]. Its normal range in resting state, as determined in MRI measurements in asymptomatic sub-jects, is between 93 and 108 degrees [26,37,38].

4.1.6. Ano-Coccygeal Ligament: Anococcygeal ligament (also known as ano-coccygeal raphe) is a complex musculo-tendinous structure extending between the coccyx and anal canal [39]. It is one of the critical structures for decision-making regarding rectal and upper anal canal mobilization. Its mean diameter on the axial MRI is 7.28 ± 0.17 mm [26].

4.1.7. Central Perineal Tendon: The central perineal tendon, also called the perineal body, maintains structural and functional integrity of the pelvic floor. In women, it lies within the ano-vaginal septum, between vaginal introitus and anal canal and provides anterior support of the anal canal. It is a small wedge-shaped fibromuscular tissue where several perineal muscles insert or converge. On MRI, perineal body appears to be a hypo-intense structure [36,40].

So, the above reviewed seven anatomical items of the ano-rectal constitution have to be considered during fistulectomy surgery.

4.2. Anal Sphincters and Fecal Continence

The prevalence of fecal incontinence worldwide ranges between 0.8-15% of the population, while its incidence in the United States varies from 2-7%, rising to 17% in patients >85 years [41]. The mechanism of anal continence is complex, because it relies on several integrating factors such as the capacity of rectal reservoir, the degree of rectal sensation, the consistency of fecal matter, and the integrity of the sphincter mechanism. The most important element among these factors is the integrity and function of the anal sphincter complex [42].

Fecal incontinence may be attributed to a disturbance of any of the mechanisms that are required to produce continence: sphincter function, rectal sensation, adequate rectal capacity and compliance, colonic transit time, stool consistency, and cognitive and neurologic factors [43].

IAS is in a steady state of tonic contraction and relaxes only in response to rectal distention. It is responsible for

85% of resting pressure inside the anal canal, whereas the EAS is responsible for generation of the squeeze anal pressure, which is roughly double the resting pressure [44]. The involuntary component of anal continence is carried out by the IAS supplied by enteric nerves, whereas the voluntary component is carried out by the EAS supplied by the pudendal nerve. Fecal incontinence develops when one or more of the previously mentioned factors are compromised beyond an extent that can be compensated for by the remaining factors. This explains why sphincter defects are not always symptomatic, and in contrast, some patients who have intact anal sphincters may complain of fecal incontinence [42]. The relation between the results of the physiologic tests and the clinical symptoms in cases of post-traumatic fecal incontinence is complex and inconsistent, rendering this relation a confounding factor when selecting optimal treatment for these conditions.

A recent review study has concluded that endo-rectal ultrasound, anorectal manometry, and pudendal nerve terminal motor latency are the cornerstones in evaluating patients with fecal incontinence, emphasizing that these tests help identify anal sphincter injuries and even help predict the patients who may benefit from sphincter repair [45]. Defects of anal sphincters detected by endorectal ultrasonography are correlated with anorectal manometry; both are sensitive and specific tools for assessment of anal sphincter injuries [46]. It has been suggested that endorectal ultrasonography is mainly reliable in identification of IAS defects, because evaluation of EAS is more subjective and operator-dependent and confounded by normal anatomic variations [47].

The importance of pudendal nerve terminal motor latency in evaluation of post traumatic fecal incontinence has been debated. While prolongation of pudendal nerve terminal motor latency indicates pudendal nerve damage, it cannot identify the nature and the site of the lesion. Only bilateral pudendal neuropathy is associated with compromised sphincter function and greater clinical symptom scores [48].

Various studies investigated the correlation of “sphincter defect-anal pressure” on variable scales. Hill et al [49] evaluated the impact of this correlation on clinical outcome after the operation, reporting no correlation between endo-rectal ultrasonography or manometry

findings and measurable clinical outcomes. Similarly, in healthy, asymptomatic patients, there was no correlation between sphincters thickness demonstrated by endo-rectal ultrasonography and sphincter function assessed by manometry [50].

Titi et al managed to correlate endo-rectal ultrasonography findings with the results of anal manometry concluding that integration of certain parameters of endorectal ultrasonography, such as the presence of EAS defect and its size, EAS maximum thick-ness, and quality of IAS ring, give better correlation with anal pressures for evaluation of fecal incontinence [51].

From the above review, no definite conclusion could be extracted to guide an optimistic trans-sphincter fistulectomy technique towards integrated continence. The author postulated that complete trans-sphincter fistulectomy using minimal cutting damage followed by anatomical closure of the surgical scene in planes with good hemostasis would lead to optimistic anatomical and physiological integrity.

5. Materials & Methods

5.1. Type of Study

This is a case series pilot study introducing a novel surgical fistulectomy technique in primary trans-sphincter ano-rectal fistula with intact fecal continence followed by anatomical repair anoplasty.

The research has obtained institutional board review and approval of the clinical concept, and is further approved by the research and ethics committees. All patients were adults and legally responsible to give written informed consent for the proposed procedure and follow up commitment. Patient recruitment according to the defined selection criteria was achieved.

5.2. Patient Selection Criteria

Primary, chronic, Trans-Sphincter Ano-Rectal Fistula (TSARF) with intact anal sphincter continence is the type of patient for selection. MRI is achieved for each patient to explore the trans-sphincter type, and complete morphology including whether simple or complex and dimensions. Concomitant general disease, previous fistula surgery or any degree of anal sphincter incontinence are criteria for exclusion from the study.

5.3. Patient Exclusion Criteria

Patients with clinical history of previous fistulectomy operation, Crohn's disease, hydradinitis suppurativa or ano-rectal defecation disorder of any type are all exclusion criteria.

5.4. Study Sample

Between January 2016 and June 2018, the study has recruited 133 consecutive patients with anterolateral, low or high primary trans-sphincter fistulas. Primary trans-sphincter fistula means that the fistula is never operated upon previously. All patients had a history of previous perineal suppuration drained surgically or spontaneously. Fistula tracks and internal opening were evaluated clinically and by doing MRI.

6. Definitions

6.1. Ano-Rectal Trans-Sphincter Fistula TSARF:

Ano-rectal fistula that passes through both the external and internal anal sphincters. The fistula is proved to satisfy the anatomical description pre-operatively by MRI and intra-operative exploration, otherwise the case is excluded from the study.

6.2. Complex Ano-Rectal Fistula: Defined as ano-rectal fistula of two or more tracts one at least of them passes through the anal sphincters.

6.3. Low Fistula: ano-rectal fistula with an internal opening at or below the dentate line.

6.4. High Fistula: defined as ano-rectal fistula with an internal opening above the dentate line.

6.5. Early Healing: defined as complete post-operative integrity of both ano-rectal mucosa and dermal surfaces.

6.7. Complete Healing: defined as complete integrity of both mucosal and dermal surfaces and development of firm fibrous tissue scar along the surgical procedure line. The mature fibrous tissue scar is the aimed target that theoretically takes seven months' duration after surgery.

6.8. Infection of Surgical Site: defined as purulent discharge with positive bacterial culture of non-floral organism that responds to antibiotic therapy.

6.9. Recurrence of TSARF: defined by recurrence of extra-anal secretions after a period of dryness and proved by MRI.

6.10. Healing Process Monitoring: evaluating healing progress through the ischio-rectal fossa space depth and fibrous tissue formation as estimated by MRI with time factor until complete healing.

7. Anal Sphincter Incontinence Scoring

Grade I: Incontinence to gas

Grade II: Incontinence to both liquid and gas

Grade III: Incontinence to solid, liquid and gas

8. Follow up:

Clinical follow up depends on symptoms as felt by patient and clinical assessment of the site and anal verge tone. Anal sphincter manometry is to be requested for patients with unrecovered incontinence for more than one week post-operatively.

9. TSARF Resection and Ano-Plasty Surgical Procedure

The procedure is proposed and applied to all cases of the study. The procedure is as the following steps:

1. Rectal enema was used to empty the rectum before surgery three hours before surgery.
2. Procto-sigmoidoscopy as an exploratory step and serving definition of the internal opening of the TSARF.
3. Probing of the fistula in between the external and internal openings. If the fistula is branching with multiple opening, more than one probe is introduced as needed.
4. The fistula tract is dissected using an electric cautery with a pin point end and anal sphincters are split using Metzenbaum scissors. Dissection is performed as deep in to the ischio-rectal fossa and anal sphincters as possible. The internal opening is excised using a Parks retractor to efface the slit open anal canal from the internal fistula opening vicinity cephalad till the anal verge caudally. All tissues between the internal and external openings are all excised, and all of the fistula tract is extirpated.
5. Hemostasis of the field is gained.
6. Anatomical closure in layers is achieved using absorbable suture polyglactan (Vicryl). Closure starts from in out and cephalad caudally as a rule. The first layer to close is the rectal / anal canal wall; whole thickness including the internal sphincter using Vicryl 3/0 continuous suture on round needle and the caudal

suture end is stayed.

7. The ischio-rectal fossa space is closed in two to three layers to close the potential space preventing seroma collection, using Vicryl 2/0 suture on round needle.

8. The external anal sphincter is closed using a Vicryl 2/0 transverse mattress single suture achieving approximation of the muscular margins with no tension. The subcutaneous plane is lastly closed using Vicryl 3/0 continuous suture starting from the anal verge laterally. Care is given to fix the both internal and external anal sphincters caudal attachment to the skin simulating the natural anatomy.

9. The subcutaneous tissue plane is closed using continuous Vicryl 3/0 suture leaving the skin with no suture. This serves evacuation of any fluid collection.

10. Bilateral internal pudendal nerve block against the pubic tuberosity using Xylocaine Marcaine mixture in a dose proportionate to patient's body weight.

11. Finally, anal packing with Vaseline gauze and external wound site dressing for the next day.

Absorbable suture material has been used avoiding the use of non-absorbable one that precipitates dense fibrosis that encourages infection within the hypo-perfused fibrotic tissue and might cause sphincter contracture and stenosis.

Patients are commenced post-operatively on oral Metronidazole (Flagyl 500 mg twice daily) for five days to regulate anal sphincter tone and oral analgesia (Ibuprofen 400mg twice daily) for 3 days with no dietary restriction.

Patients were instructed and educated to practice Kegel's exercise daily for the first two weeks post-operatively.

Figures 1- 6 show the detailed steps of surgery and the follow up till healing of the same patient.

10. Results & Discussion

The median age of these 133 patients (112 males and 21 females) was 32 years (range, 26-43 years). As all fistula cases were assessed by MRI; found in the anterior quadrants in 72 (54.1%) and in the posterior quadrants in 61 (45.9%) patients. The median fistula length (the longest path in branching fistula) assessed by MRI for the

anterior quadrants was 9.6 cm (range 6-15.5) and for the posterior quadrants 14.2 cm (range 8.2-17.4).

Regarding fistula level type; 31 cases showed high anal fistula and 102 had low ones. 46 patients had complex fistula and 87 had simple ones.

Procedure was performed under caudal epidural anesthesia in 87 (55.4%) and under general anesthesia in 46 (34.6%) patients, all in the supine lithotomy position with the buttocks taped widely apart. The median operative time was 48 minutes (range 31-65 minutes).

Postoperatively there was no complication namely; bleeding, hematoma, seroma collection, site infection or abscess collection. No deep wound or sphincter dehiscence occurred in any of the cases. All patients had completely healed wounds within a time range of 10-23 (median 16±4.3) days.

No patient needed further surgical treatment with a follow up duration range of 12-42 (median 30±4.3) months. Five patients (3.8%) experienced temporary partial anal incontinence; Vaizey score; one-point score for a duration ranging between 3-5 days post-operatively that all cases have resolved spontaneously. Out of these 5 patients 4 were male and one female. No case of fistula recurrence was observed in any of the cases.

(Tables 1-3) show patients' presentation clinical data, patients' operative data and post-operative follow up data.

Both fistulotomy and fistulectomy have long been accepted as the gold standard for simple fistulas. Although fistulotomy has been associated with success rates of 92%-97%, the procedure will result in some form of incontinence even for simple fistulas in approximately 12%-39% of patients [52-54].

Both traditional fistulotomy and fistulectomy techniques leave the un-epithelialized wound open, which may cause undesired pain and complications, such as bleeding and suppuration.

Fistulectomy and immediate sphincter repair for low fistulas, aim to eradicate infection and to anatomically reconstruct the muscular defect [55]. The technique described was not fixed in all cases and in addition the way of fistula tract excision and tissue closure were all non-anatomical. The study described closure of the

external anal sphincter by overlapping of the flaps and lateral sphincterotomy in some cases.

However, very few studies have been published on this technique. Dehiscence of sphincteroplasty is the most fearful complication of this technique and is responsible for its infrequent use [56]. Included 16 patients with recurrent complex fistulas in whom fistulotomy was performed with overlapping repair of the disrupted EAS. [56]. Treated 75 patients in whom most of the fistulas were complex (69%) by fistulectomy and end-to-end reconstruction of the disrupted EAS. Five recurrences in total have been described (6.7%), and the postoperative incontinence rate was 21%. Two (25%) of 8 fully continent patients developed incontinence for watery stools and flatus, which gave a recurrence rate of 6.3% (1 patient). By overlapping the sphincter muscle, the area in contact is increased and rupture of the sutures may be more unlikely. However, when the width of overlap is too long, the anal canal may narrow and drainage worsen [57].

Table 1: Patients' presentation clinical data.

Variant	Value / Range	Median	Percentage %
		(± SD)	
Total number of patients	133		
Age (years)	26-43	32±4.4	
Sex; Male : Female	112:21:00		
MRI - fistula evaluation			
Trans-sphincter fistula	133	-	100
Antero-posterior location:			
Anterior quadrants	72	-	54.1
Posterior quadrants	61	-	45.9
Length of fistula (cm):			
Anterior fistula	6-15.5	9.6±2.3	-
Posterior Fistula	8.2-17.4	14.2±1.8	-
Fistula type:			
Simple : Complex	46:87	-	-
Anatomical type:			
High : low	31:102	-	-
Previous fistula surgery	0	-	0

Table 2: Patients' operative data.

Variant	Value / Range	Median	Percentage %
		(± SD)	
Anesthesia type:			
Epidural	87	-	55.4
General	46	-	34.6
Primary fistula cannulation (upon procedure start)	91	-	68.4
Secondary fistula cannulation (completed during dissection)	44	-	31.6
Split of both EAS & IAS; the fistula tract passing through	133	-	100

Primary repair of internal & external sphincters	133	-	100
Operative time (minute)	45-85	60±11.5	
Surgical procedure:			
Complete fistulectomy and anatomical closure technique	133	-	100
Other surgical techniques	0	-	0

Table 3: Post-operative follow up.

Variant	Value / Range	Median (± SD) / Percentage %
Post-operative surgical site complication:		
Bleeding	None	-
Hematoma	None	-
Seroma	None	-
Infection	None	-
Abscess	None	-
Temporary fecal incontinence:		
Vaizey Score: One Point Score	5 Patients	3.80%
Permanent fecal incontinence	None	-
Pts showed complete surgical site healing	133 Patients	100%
Duration of complete healing (days)	23-OCT	16 ± 4.3
Need for further surgical procedure / treatment	None	
Fistula recurrence	None	
Follow up duration (months)	DEC-42	30 ±4.3



Figure 1: Trans-sphincter fistula probed.

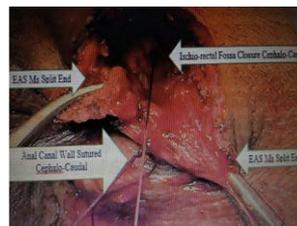


Figure 2: Transecting the EAS through which the fistula traverse.

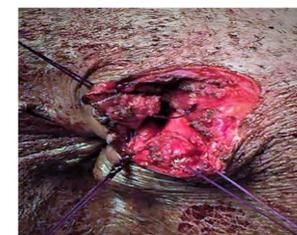


Figure 3: Ano-plasty demonstrated; the anal canal is reconstructed from cephalad caudally including the internal anal sphincter, the ischio-rectal fossa plane closure is in progress in layers, external anal sphincter is still split.



Figure 4: Anal canal including the IAS is closed (medial suture) and the EAS is closed (lateral suture on traction).



Figure 5: Ano-plasty is completed and bed of the fistula is completely closed.



Figure 6: Eighteen days' post-operative view showing complete healing of the fistula site.

11. Conclusion

Unfortunately, to date, it's technically difficult from the available literature, to determine any universally accepted method of technical management and healing of trans-sphincteric anal fistula [58,59].

In the current study the overall rate of fistula persistence or recurrence was nil and temporary minor incontinence was 4%. Such outcome reflects the effectiveness of the proposed technique in the management of TSARF either low or high. The management of anal fistulas includes 3 main goals: to cure the fistula, to prevent recurrence, and to retain anal sphincter continence. Since MRI allows recognition of the full length of the anal fistula allowing direct probing and excision including the trans-sphincter part, removal can certainly be a primary focus, which eliminates the risk of missing secondary tracts. Moreover, divided sphincters are repaired anatomically to allow proper healing and to prevent reduction of anal sphincter resting tone.

Selection of the study sample with primary TSARF aims at avoiding any additional factor rather than the applied surgical technique on the outcome. Achieving the documented results would widen the selection base to

more include complicated cases with no reservation. The technique of anatomical resection and reconstruction needs surgeons to master the regional anatomy, completely resect the fistula tract and surrounding granulation, do meticulous hemostasis and reconstruct the field structures anatomically. Hesitation to achieve complete fistula excision for fear of incontinence is a major reason for fistula recurrence and non-anatomical reconstruction is a reason for incontinence. Critic is invited.

12. Compliance with Ethical Standards' Statements

- **Conflicts of Interest:** The authors acknowledge and declare no sources of funding and potentially conflicting interest, such as receiving funds or fees by, or holding stocks and shares in, an organization that may profit or lose through the publication of your paper.

- **Funding:** No financial or material support for the research and work.

- **Ethical Approval:** the study required no institutional review approval. All procedures performed in the study were accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

- **Informed Consent:** an informed consent has been given by each of the study patients declaring acceptance to be anonymously involved in the study that involves no un-usual nor experimental management for his /her disease.

- **Statement of Disclosure:** this research complies with research ethical and scientific rules and regulations stated by the Ministry of Health, Kingdom of Saudi Arabia.

13. Statement of Author Contribution

Both authors of the work have equally participated and shared every item of the work, namely; study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, statistical analysis, administrative, technical, and material support, study supervision.

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