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Clinical Effect of Tunnel-Like Fistulectomy Plus Draining Seton Combined with Incision of Internal Opening of Anal Fistula (TFSIA) in the **Treatment of High Trans-Sphincteric Anal Fistula**

Authors' Contribution: Study Design A

Data Collection B

- Statistical Analysis C
- Data Interpretation D
- Manuscript Preparation E Literature Search F
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Background:

The aim of this study was to investigate the clinical effect of tunnel-like fistulectomy plus draining seton combined with incision of internal opening of anal fistula (TFSIA) in the treatment of high transsphincteric anal

Material/Methods:

There were 80 patients with high transsphincteric anal fistula randomly divided into TFSIA group and control group, 40 cases in each group. The control group was treated with cutting seton, and the seton was tightened weekly after discharge from the hospital until the seton dropped off. In the TFSIA group, the anal fistula was dissected and resected in tunnel-like form through the external opening to the intersphinceteric space, drained with seton through the tunnel, and cut open the internal opening of the anal fistula and the intersphincteric space and expanded the drainage. The operative time, blood loss, postoperative uroschesis, anal wound pain score, healing time, Wexner anal incontinence score, keyhole-like deformity, and recurrence rate were compared between the 2 groups.

Results:

The differences of the blood loss, operative time, anal wound pain score at 6 hours after operation, postoperative uroschesis and the recurrence rate after operation were not statistically significant (P>0.05), but the TFSIA were better than the control group in the anal wound pain score at 1 week after operation, healing time, Wexner anal incontinence score, and anal keyhole-like deformity rate (P<0.05).

Conclusions:

TFSIA is effective in treating high transsphincteric anal fistula, and it can reduce adverse complications after

MeSH Keywords:

Drainage • Fistula • Postoperative Complications

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Background

Anal fistula is an ancient disease, first described in 430 B.C. [1]. About 90% to 95% of anal fistula originates from perianal abscess and is caused by infection of cryptoglandular origin [2]. High transsphincteric anal fistula is a common type of complex anal fistula. At present, this disease cannot be cured by drugs, only by surgery. Traditional surgical procedure includes cutting seton fistulotomy [3], with a seton inserting through the external opening of anal fistula and traversing through fistula tract and the internal opening can cause chronic inflammation and fibrosis, fix and prevent the contraction of amputated anal sphincter. Anorectal ring might be damaged to some extent after traditional operation, which may lead to changes in anal function and shape. Tunnel-like fistulectomy plus draining seton combined with incision of internal opening of anal fistula (TFSIA) is mainly characterized by 2 parts to recognize and treat the anal fistula, thereby reducing the damage to the anorectal ring and avoiding the occurrence of incontinence and other complications. The purpose of this study is to explore the clinical evaluation of TFSIA in the treatment of high transsphincteric anal fistula, and to provide some experience for clinical treatment.

Material and Methods

General information

There were 80 patients with high transsphincteric anal fistula admitted to Yuyao People's Hospital from January 2015 to June 2018 who were randomly divided into a TFSIA group and a control group, 40 cases in each group. In the TFSIA group, there were 35 males and 5 females, aged from 19 to 58 years old, with an average age of 41.65±11.07 years. The TFSIA group included 35 cases of high transsphincteric anal fistula through ischioanal fossa and 5 cases of high transsphincteric anal fistula through deep postanal space. There were 33 males and 7 females in the control group, aged from 20 to 66 years old, with an average age of 41.95±13.15 years. The control group included 35 cases of high transsphincteric anal fistula through ischioanal fossa and 5 cases of high transsphincteric anal fistula through deep postanal space. There was no significant difference in general data between the 2 groups (Table 1).

This study was approved by the hospital Ethics Committee with the informed consent of the patients. Inclusion criteria was as follows: 1) it was in accordance with the diagnostic criteria of high transsphincteric anal fistula. 2) Infection of cryptoglandular origin. 3) Patients voluntarily participated in the study and signed the informed consent. Exclusion criteria was as follows: 1) other types of anal fistula, such as low transsphincteric anal fistula, intersphincteric anal fistula, suprasphincteric anal fistula and extrasphincteric anal fistula; patients with recurrent anal fistula were not included. 2) Infection of non-cryptoglandular origin, such as tuberculous anal fistula and Crohn anal fistula. 3) Patients with malignant tumors or psychiatric diseases. 4) Those who quit without visiting or refused further treatment.

Methods

Treatment

All patients were examined by routine blood laboratories, electrocardiogram, colonoscopy and anal magnetic resonance imaging (MRI) before operation. All of the patients in both groups were given spinal anesthesia and placed in the prone position. We mainly made use of preoperative anal MR examination, and under anesthesia examination including probe exploration or by the injection of hydrogen peroxide or methylene blue from the external opening, to determine whether there was a secondary fistula and the location of the internal opening of the anal fistula. Patients with complex high anal fistula, such as other types of anal fistula or simultaneous high intersphincteric anal fistula, were not included in this study. The determination of the internal opening of anal fistula is also one of the difficulties in the operation of anal fistula. It is very difficult to determine the internal opening of the anal fistula in patients with fistula track fibrosis due to atresia of internal orifice of partial anal fistula. These patients were not included in the study. This is also the limitation of this study.

For the control group, we carefully explored the course and position of the anal fistula, inserted probes along the external opening of the anal fistula, traversed through fistula and the internal opening, introduced seton and tighten, and incised the anal mucosa and perianal skin between the internal and external opening of the fistula surface. The patients

Table 1. Comparisons of the baseline characteristics between the 2 groups.

| | Control | TFSIA | Τ (χ²)-value | <i>P</i> -value |
|----------------------|-------------|-------------|--------------|-----------------|
| Age | 41.95±13.15 | 41.65±11.07 | 0.110 | 0.913 |
| Gender (Male/Female) | 33/7 | 35/5 | (0.392) | 0.531 |
| Body mass index | 23.66±2.86 | 24.09±2.69 | 0.693 | 0.490 |

TFSIA - tunnel-like fistulectomy plus draining seton combined with incision of internal opening of anal fistula.

Table 2. Comparisons of the perioperative data between the 2 groups.

| | Control | TFSIA | Τ (χ²)-value | <i>P</i> -value |
|----------------------------------|-------------|-------------|--------------|-----------------|
| Operative time (min) | 37.80±12.57 | 39.45±8.07 | 0.699 | 0.487 |
| Blood loss (mL) | 21.38±6.30 | 20.43±10.36 | 0.496 | 0.622 |
| Postoperative uroschesis (%) | 5 (%) | 6 (%) | (0.105) | 0.745 |
| VAS score 6 hours postoperation | 2±0.68 | 1.93±0.73 | 0.476 | 0.636 |
| VAS score one week postoperation | 1.65±0.66 | 1.08±0.57 | 4.155 | 0.000* |

TFSIA – tunnel-like fistulectomy plus draining seton combined with incision of internal opening of anal fistula; VAS – visual analogue scale.

Table 3. Comparisons of clinical data after operation between the 2 groups.

| | Control | TFSIA | T (χ²)-value | <i>P</i> -value |
|---|------------|------------|--------------|-----------------|
| Healing time of anal wounds (d) | 41.38±7.10 | 28.58±4.27 | 9.771 | 0.001* |
| Wexner anal incontinence score after 6 months of operation | 1.23±0.73 | 0.68±0.47 | 3983 | 0.000* |
| Anal keyhole deformity 6 months after operation (cases) (%) | 8 (20%) | 2 (5%) | (4.114) | 0.043* |
| Recurrence of anal fistula 6 months after operation (cases) (%) | 6 (15%) | 5 (12.5%) | (0.105) | 0.745 |

TFSIA - tunnel-like fistulectomy plus draining seton combined with incision of internal opening of anal fistula.

were followed up weekly and the seton was tightened after discharge, until it dropped off.

For the TFSIA group, we carefully explored the course of anal fistula and the position of internal opening, made a circular incision along the external opening of anal fistula, and dissected carefully along the anal fistula tissue as if it was a tunnel until the intersphincteric space, and completed the excision of the anal fistula. Having made an incision of the internal opening of anal fistula and the internal anal sphincter, we removed the infection tissue in the intersphincteric space, and drained adequately. The seton was introduced through the tunnel. After discharging from hospital, the seton was removed after the internal opening healed.

Observation indicators

We observed the operative time, blood loss, postoperative uroschesis, the anal wound pain score at 6 hours postoperatively, the anal wound pain score at 1 week postoperatively, the healing time of the anal wound, the anal incontinence score at 6 months postoperatively, the incidence of keyhole-like anomaly at 6 months postoperatively, and the recurrence rate of anal fistula at 6 months postoperatively. The pain score was determined by visual analogue scale (VAS) [4] and anal

function was evaluated by Wexner anal incontinence score [5] at 6 months after operation.

Statistical analysis

The data were analyzed by Statistical Product and Service Solutions (SPSS) 21.0 software (IBM, Armonk, NY, USA). The measurement data were expressed by mean \pm standard deviation. The results were compared by Student t-test and chi-square test. P < 0.05 was statistically significant.

Results

The differences of the blood loss, operative time, anal wound pain score at 6 hours after operation, postoperative uroschesis, and the recurrence rate after operation were not statistically significant (P>0.05), but the TFSIA were better compared to the control group in the anal wound pain score at 1 week after operation, healing time, Wexner anal incontinence score, and anal keyhole-like deformity rate (P<0.05). (Tables 2, 3).

Discussion

The common surgical methods [6,7] for anal fistula include fistulotomy, fistulectomy, and cutting seton. High transsphincteric anal fistula is a type of high anal fistula; it is a common type of complex anal fistula. Fistulotomy or fistulectomy might lead to anal incontinence, because this kind of anal fistula involves more external anal sphincter muscle bundles. Therefore, a draining seton is placed loosely through the track to facilitate drainage of any sepsis and to preserve the sphincter. This might be converted to a cutting seton, which is periodically tightened at regular intervals to slowly cut through the involved sphincter muscle and to promote fibrosis to avoid disruption of the sphincter and the resulting incontinence. However, many patients ultimately experience some level of incontinence, more often to flatus than to liquid or solids.

Over the last decade, many minimally invasive techniques have been developed, including fistula laser closure (FiLaC) [8,9], video-assisted anal fistula treatment (VAAFT)[10], and ligation of intersphincteric fistula track (LIFT) [11–12]. These methods are mainly concerned with the closure of the internal opening, which are relatively effective (healing rate is 81.8% [9], 70% [10], and 84% respectively) [12]. In comparison with FiLaC and VAAFT which require expensive equipment, TFSIA might be more suitable for grass-roots hospitals. LIFT, which is popular all over the world, does not need special and expensive equipment and has a wide range of applications.

TFSIA mainly divides anal fistula into 2 parts to recognize and treat, which is similar to TROPIS [13]. Both of them attach great importance to the role of intersphincteric space in the pathological development of complex anal fistula. In the TROPIS operation [13], the intersphinteric space was drained and laid open through the transanal route, without cutting the external sphincter, but curettage or removal of fistula in the ischiorectal fossa, while TFSIA pays more attention to the clearance of the infective focus of anal fistula and the opening and drainage of the internal opening of anal fistula and the corresponding intersphinteric space.

The exact same method of surgery, named after TFSIA, is not found in the literature, but it is basically consistent with a recent report by Yang et al. [14]. Yang et al. analyzed the clinical effect of internal resection and opening combined with suture drainage in treatment of complex anal fistula. The results were quite similar to results of this study. The principle is to correctly seek for the original internal opening, remove

all infected lesions, drain with seton, and retain the external anal sphincter.

The results of our study showed that there was no significant difference in anal wound pain between the TFSIA group and the control group 6 hours after operation, but the anal wound pain score was significantly lower 1 week after operation. We believe that this was due to no tightening of the seton after the operation in the TFSIA group. The pain stimulation of the patients in the control group cannot be underestimated by weekly tightening therapy. Two of the patients suffered from syncope due to pain after tightening the seton. They improved only after relaxing the seton band and lying on their back quietly for a while. The results showed that the healing time of the TFSIA group was significantly shorter than that of the control group. This may be related to the complete removal of fistula lesions, adequate drainage of internal openings and reduced inflammatory factors and pain stimulation in the TFSIA group. The results of this study showed that the scores of anal incontinence and the incidence of keyhole-like anomaly in the TFSIA group were lower than those in the control group. This might be related to the fact that only a small part of the external anal sphincter was injured along the anal fistula in the TFSIA group, but most of the anal sphincters were retained. Cutting seton in high anal fistula is a process of slow cutting of external anal sphincter to lay open the anal fistula while scar healing. Anal function is impaired more or less, and anal keyhole-like anomaly is more likely to occur. The study showed that there was no significant difference in recurrence rate between the 2 groups at 6 months after operation. The main causes of recurrence in observation group might be related to inaccurate location of internal orifice of anal fistula and poor drainage of internal orifice in some patients.

Limitations of this study also existed. The sample size was small, and the follow-up time was short. The type of anal fistula was single, only for high transsphincteric anal fistula.

Conclusions

In conclusion, TFSIA has a better curative effect for patients with high transsphincteric anal fistula, with less pain, shorter healing time, and better preservation of anal function.

Conflict of interest

None.

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