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Original Article

Time-scheduled dotted and solid thread-ligating therapy combined with vacuum sealing drainage for treating high complex anal fistula

Hengqing Gao[1], Xiaohong Cheng[2], Lijuan Gao[1], Wei Wang[1], Xiaoqiang Wang[1], Furao Gong[1], Mengmeng Zhang[3], Jing Hu[4]

Departments of [1]Anorectal, [2]Pharmacy, [4]Science and Education, Zigong Hospital of Chinese Traditional Medicine, Zigong 643010, Sichuan Province, China; [3]Graduate School of Chengdu University of Traditional Chinese Medicine, Chengdu 610072, Sichuan Province, China

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Abstract: Objective: To investigate the treatment of high complex anal fistula with time-scheduled dotted and solid thread-ligating therapy combined with vacuum sealing drainage. Methods: A retrospective cohort study of 80 patients with high complex anal fistula admitted to the anorectal department of our hospital was conducted. The patients in the control group (n=40) were treated with traditional incision thread-ligating therapy, while the patients in the observation group (n=40) were treated with time-scheduled dotted and solid thread-ligating therapy combined with vacuum sealing drainage. The postoperative wound healing time, clinical efficacy, postoperative pain scores as well as pre- and postoperative anal function and anorectal pressure of patients in the two groups were observed. Results: The observation group had a shorter wound healing time (P<0.001), lower postoperative pain scores (P<0.05), a lower increase of Wexner score (P<0.001), a higher total effective rate (97.50% vs. 90.00%; P>0.05), a higher anal maximal contraction pressure and a larger high pressure zone than the control group (P<0.05). Compared with those before operation, the Wexner scores of patients in the two groups after operation were increased, while the anal maximal contraction pressure and high pressure zone in the control group were decreased (P<0.001). Conclusion: The treatment of complex high anal fistula with time-scheduled dotted and solid thread-ligating combined with vacuum sealing drainage has short wound healing time, high efficiency, and little influence on the postoperative function of anal sphincter. It is worthy to be popularized in clinic.

Keywords: Time-scheduled dotted and solid thread-ligating, vacuum sealing drainage, clinical efficacy, anal function

Introduction

Anal fistula refers to the pathological channel between anal canal or rectum and perirectal tissues caused by infection, trauma, tuberculosis and enteritis [1, 2]. Previous studies have shown that the incidence of this disease is 1,228 per 100,000 per year, and the incidence is higher in males than in females [3]. As one of the anal fistulas, high complex anal fistula has become one of the refractory diseases because of great difficulty in the treatment and easy damage of anal sphincter function. Surgery is the most effective method to treat high complex anal fistula [4]. However, at present, there are many surgical methods for treating high complex anal fistula, and there is no unified standard for the treatment scheme [4]. Lesion resection and wound drainage are the mainstays of surgical treatment for high complex anal fistula. However, clinical studies have found that complete resection of lesions and protection of anal function cannot be achieved simultaneously [5]. Thread-ligating therapy is the traditional Chinese medicine therapy for treating anal fistula, in which solid thread-ligating therapy is mainly aimed at radical treatment of lesions. The clinical effect of solid thread-ligating therapy is significant, but it has a disadvantage that it is not easy to grasp the timing of tightening thread. The lesions cannot be completely removed with too early tightening thread,

and the anal function can be easily damaged with too late tightening thread. The dotted thread-ligating is only hanging the thread without tightening the thread, which can protect the anal function effectively. However, it is not beneficial to the resection of lesions, and it is prone to recurrence [6, 7]. In conclusion, the dotted thread-ligating therapy is not conducive to complete resection of lesions and easy to relapse, while the solid thread-ligating therapy has great damage to anal function. Therefore, both methods have their own shortcomings [5-7]. In this study, the dotted thread-ligating therapy and solid thread-ligating therapy was combined in different periods. Moreover, vacuum sealing drainage (VSD) was improved by using modern medical materials for wound drainage. The results showed that the combination of time-scheduled dotted and solid thread-ligating and VSD for treating high complex anal fistula can not only cure the anal fistula radically, but also protect the anal function, reduce the pain, improve the quality of life, and shorten the time of hospitalization. It can help patients resume their work as soon as possible and acquire satisfying clinical outcomes.

Materials and methods

General information

A total of 40 patients with high complex anal fistula who were admitted to the anorectal department of our hospital from July 2018 to March 2020 were enrolled in the observation group. Patients aged from 17 to 58 years with a mean age of 37.5±7.9 years. At the same time, 40 patients with high complex anal fistula treated with traditional incision thread-ligating therapy were selected as the control group for this retrospective cohort study. This study was approved by the ethics committee of our hospital, with ethics board approval number of ZG2019-22.

Inclusion and exclusion criteria

Inclusion criteria: Patients who met the diagnostic criteria of high complex anal fistula; patients aged ≥16 years [8]; patients who met the treatment indications of time-scheduled dotted and solid thread-ligating therapy combined with VSD. Exclusion criteria: Patients who could not tolerate surgery; patients who had complex anal fistulas due to other causes; patients with rectal cancer or polyps; patients with mental disorders who could not cooperate with the treatment; pregnant or lactating women.

Surgical procedures

The patients in the observation group were treated with time-scheduled dotted and solid thread-ligating therapy combined with VSD [7]. The preoperative ultrasound examination was conducted to achieve initial understanding of the location of internal orifice and fistula shape. The position of the internal orifice was determined by probing the fistula with a probe entering from the external orifice and emerging from the internal orifice. In the case of a curved fistula, the fistula was cut open or removed from the external orifice along the direction of the probe until the external sphincter at the internal orifice or top of the probe was reached, then the direction of the probe was changed to the internal orifice. If the internal orifice of the fistula was located in the posterior rectal space and ischiorectal fossa, the probe was used to explore the fistula to its top, the hemostatic clamp was used to penetrate the intestinal wall through the explored top of the fistula, and then an ostomy was performed. The solid thread-ligating therapy was as follows. Under B-ultrasound guidance, the No.10 silk thread was used to knot fistula, stoma and intestinal cavity until complete closure was reached. One week after the solid thread-ligating therapy was implemented, the silk thread began to slacken because some anal sphincters and fistulas were cut off by silk thread. At this moment, although the cutting effect of silk thread had decreased obviously, the silk thread was not tightened or removed. At this time, the loose silk thread was used to drain the necrotic material adequately. The silk thread was removed until new granulation filled the fistula, which took about 15-20 days. In the early stage, the solid hanging thread played a cutting role, and in the middle stage, the dotted hanging thread played a draining role. The VSD was improved on the basis of common VSD and had thinner drainage and flushing tubes. The drainage and flushing tubes were expanded into an oval shape at the end and covered with an oval polyethylene sponge. According to the number, shape, size, and depth of the wounds, the drainage head end was connected in single, parallel

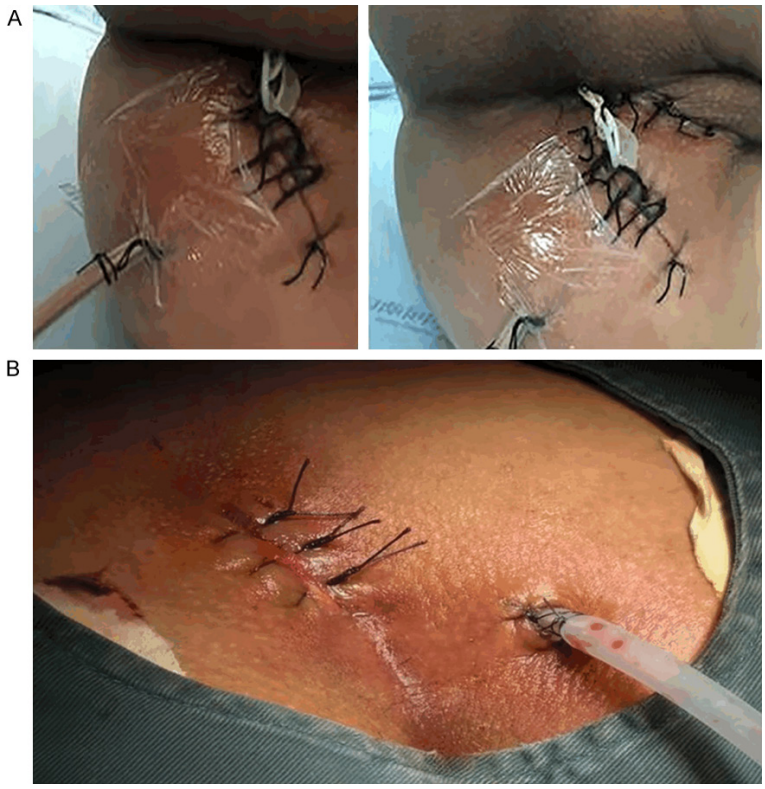

Figure 1. Postoperative patients undergoing dotted and solid thread-ligating therapy. A: Surgical hanging thread; B: Vacuum sealing drainage.

or tandem connection for draining, making VSD more suitable for anorectal wounds. See **Figure 1**.

The patients in the control group were treated with traditional incision thread-ligating therapy [6], whose operation was the same as the above solid thread-ligating method. The silk thread was tightened when it was loose 1 week after operation until the necrotic sphincter and fistula were completely cut off and the wound healed.

After operation, the patients in both groups were given a liquid diet for 2 days and antibiotic drip for 3 days to fight infection. The patients were instructed to take a sitz bath after defecation. The wound was disinfected with iodophor, and oiled gauze strips were placed on the wound until it healed.

Outcome measures

Primary outcome measures: The wound healing time of patients was observed from the first day after operation to the time of complete wound healing.

The clinical curative effect after operation was divided into cured, improved and uncured. Cured: the symptoms and signs disappear and the wound heals. Improved: symptoms and signs are improved but the wound does not heal. Uncured: there's no change in symptoms and signs. Total effective rate = (cured + improved cases)/ total number of cases × 100%.

The Visual Analogue Scale (VAS) was observed on 1, 7, 14 and 21 days after the operation. Subjective pain was quantified by using a 10 cm long scale with two stops, of which 0 represents no pain, and 10 represents the most severe pain experienced by the patient. The patients chose a point between 0 and 10 according to the degree of pain and the scale value of that point was measured as the patient's VAS score. The pain level was assessed on postoperative 1, 7, 14, and 21 days [9].

The anal function was assessed by Wexner score 6 months before and after surgery [8]. The evaluation was conducted by telephone return visit. The evaluation criteria include the aspects of solid, liquid, gas, sanitary pad and lifestyle changes (0-never, 1-seldom, 2-sometimes, 3-often, 4-always; range 0-20).

The anorectal pressure including anal rest pressure (ARP), anal maximal contraction pressure (AMCP) and anal high-pressure zone (HPZ) was measured by ZGJ-D2 intelligent double-guide anorectal pressure monitor (Microcomputer Institute of Applied Technology, Hefei, China) 6 months before and after operation.

Statistical analysis

SPSS 17.0 statistical software was used for statistical analysis. Continuous variables were expressed as mean with standard deviation ($\bar{x}$ ± sd). Data that met normal distribution and

Table 1. Comparison of general information between the two groups ($\bar{x}$±sd)

Items	Observation group (n=40)	Control group (n=40)	χ^2/t	P
Sex (male:female)	27:13	28:12	0.058	0.809
Age (years)	37.2±7.6	37.8±8.1	0.342	0.734
BMI (kg/m^2)	24.17±2.61	24.33±2.77	0.266	0.791
Number of fistulas (n)	1.89±0.87	1.84±0.89	0.254	0.800
Course of disease (years)	4.23±1.76	4.17±1.69	0.156	0.877
Type of anal fistula (n)			0.238	0.626
Horseshoe	11	13		
Semi-horseshoe	29	27		

Table 2. Comparison of wound healing time between the two groups ($\bar{x}$±sd)

Items	Observation group (n=40)	Control group (n=40)	t	P
Healing time (d)	41.98±8.67	51.21±10.36	4.321	<0.001

homogeneity of variance were compared using t-test, while those did not meet normal distribution and homogeneity of variance were compared using rank-sum test. The VAS scores at different time points and in different groups were compared using repeated-measures analysis of variance and Wilcoxon rank sum test. First, Mauchlys sphericity test was conducted. If the data met the assumption of sphericity (P>0.05), the analysis of variance was performed without degrees of freedom adjustment. The Enumeration data were expressed as percentage and analyzed by Pearson chi-square or Fisher exact tests. P<0.05 was considered statistically significant.

Results

Comparison of general information

There was no significant difference in general information such as sex, age, BMI, course of disease and type of anal fistula between the two groups, suggesting that the two groups were comparable (all P>0.05). See **Table 1**.

Comparison of wound healing time

The wound healing time in the observation group (41.98±8.67 d) was significantly shorter than that in the control group (51.21±10.36 d, P<0.001). See **Table 2**.

Comparison of clinical efficacy

The total effective rate of the observation group (97.50%) was higher than that of the control group (90.00%, P>0.05). See **Table 3**.

Comparison of postoperative pain scores

There was no significant difference in pain scores 1 d before and after operation between the two groups (P>0.05). The pain scores on 7 d, 14 d and 21 d after operation were lower in the observation group than those in the control group (all P<0.001). The pain scores on 1 d after operation in both groups were all higher than those before operation (P<0.05). The pain scores on 7 d and 14 d after operation in both groups were all lower than those on 1 d after operation (P<0.05). The pain scores on 21 d after operation in both groups were all lower than those on 1 d, 7 d and 14 d after operation and before operation (P<0.05). See **Table 4**.

Comparison of preoperative and postoperative anal function scores

There was no significant difference in Wexner scores between the two groups before operation (P>0.05). Compared with those before operation, the Wexner scores after operation in both groups were all higher (all P<0.001). The Wexner score in the observation group showed a lower increase (P<0.001). See **Table 5**.

Comparison of anal pressure before and after operation

There was no significant difference in ARP, AMCP and HPZ before operation between the two groups (P>0.05). Compared with before treatment, the AMCP and HPZ after operation in the control group were all decreased (all P<0.001). After operation, the AMCP and HPZ were both higher in the observation group than those in the control group (both P<0.01). See **Table 6**.

Table 3. Comparison of clinical efficacy between the two groups (n, %)

Group	Cured	Improved	Uncured	Total effective rate (%)
Observation group (n=40)	36 (90.00)	3 (7.50)	1 (2.50)	39 (97.50)
Control group (n=40)	32 (80.00)	4 (10.00)	4 (10.00)	36 (90.00)
χ^2		2.178		1.920
P		0.337		0.166

Table 4. Comparison of postoperative pain scores ($\bar{x}$±sd)

VAS pain score	Observation group (n=72)	Control group (n=72)	t	P
Before operation	1.96±0.49	1.89±0.47	0.875	0.383
1 d after operation	5.59±0.73*	5.56±0.71*	0.269	0.795
7 d after operation	2.65±0.52$^{\#}$	4.85±0.65$^{\#}$	22.426	<0.001
14 days after operation	1.04±0.27$^{\#}$	2.07±0.27$^{\#}$	22.889	<0.001
21 d after operation	0.37±0.36$^{*,\#,\&,@}$	1.25±0.38$^{*,\#,\&,@}$	14.249	<0.001

Note: Compared with before operation, *P<0.05; compared with 1 d after operation, $^{\#}$P<0.05; compared with 7 d after operation, $^{\&}$P<0.05; compared with 7 d after operation, $^{@}$P<0.05.

Discussion

Anal fistula is a common and frequently occurring disease in clinic. There are many causes resulting in anal fistula. At present, it is generally accepted that anal fistula is caused by anal gland infection [10, 11], and the surgery is the most effective method for the treatment of anal fistula [12, 13]. Thread-ligating therapy is the main way to treat high complex anal fistula, in which both solid thread-ligating and dotted thread-ligating are effective ways. However, it was found that the anal sphincter is slowly incised by gradually tightening the silk thread with the solid thread-ligating. This operation is to cut all anal sphincters, resulting in postoperative anal sphincter function decline, and is not conducive to postoperative recovery [14, 15]. The dotted thread-ligating is used for drainage of the necrotic fluid and promotion of the production of new granulation in the necrotic area to achieve the treatment. This operation method effectively preserves the function of anal sphincter. However, lesions tend to relapse due to incomplete removal [16]. In our study, we found some advantages in the treatment of high complex anal fistula with time-scheduled dotted and solid thread-ligating therapy combined with VSD. First, the function of sphincter and normal tissues are protected maximally. Second, the two-way drainage of inside and outside the rectal lumen is realized. Third, silk threads provide a tighter ligature and less irritation to the tissues. Fourth, hanging thread but not tightening the thread not only greatly alleviates patient suffering, but also reduces medical cost. Fifth, through the natural filling of granulation tissue, the fistula can be closed naturally and cured with strong operability, satisfactory clinical efficacy, good prognosis and easy popularization.

Wound healing is an important index to evaluate the therapeutic effect of high complex anal fistula. Wound healing is a process of local tissue self-regeneration and reconstruction after tissue loss, and wound healing is affected by many factors. Slow wound healing can be caused by major tissue loss, wound discharge caused by local inflammatory reaction and incomplete drainage of necrotic tissue [17]. The combination of time-scheduled dotted and solid thread-ligating therapy and VSD can effectively promote wound healing. The shortening of wound healing time not only improves the therapeutic effect of patients, but also reduces the degree of postoperative pain. This study also showed that this combination treatment had short wound healing time, high treatment efficiency, and low postoperative pain degree, which was consistent with the previous results [7].

The function of anal sphincter is an important postoperative index to evaluate high complex anal fistula, and it is also an important factor to influence the quality of life of patients. Anorectal pressure is an important detection method to evaluate anal movement and sensory function [18]. It can systematically detect the pressure generated by the anus in all directions, and provide objective clinical basis for the functional evaluation of anal sphincter before and after treatment [19]. The results of anorectal dynamics showed that the anal canal is a high-pressure area where ARP is 3.3-16.0

Table 5. Comparison of Wexner scores before and after treatment between the two groups ($\bar{x}$±sd)

Items	Observation group Before operation	Control group Before operation	T	P	Observation group After operation	Control group After operation	T	P
Wexner score (points)	1.32±0.91	1.39±0.93	0.340	0.735	5.46±2.27###	9.42±3.42###	6.101	<0.001

Note: Compared with before treatment within the same group, ###P<0.001.

Table 6. Comparison of anal pressure before and after operation between the two groups ($\bar{x}$±sd)

Items	Observation group Before operation	Control group Before operation	T	P	Observation group After operation	Control group After operation	T	P
ARP (mmHg)	93.21±11.88	93.65±12.08	0.164	0.870	91.85±10.11	93.25±11.76	0.571	0.570
AMCP (mmHg)	174.63±44.85	173.95±39.79	0.072	0.943	163.27±45.22	129.36±34.98###	3.751	<0.001
HPZ (cm)	5.53±1.45	5.49±1.42	0.125	0.901	5.01±1.02	4.21±1.22###	3.182	0.002

Note: Compared with before treatment within the same group, ###P<0.001.

kPa, while rectal resting pressure is only about 0.7 kPa. The pressure in the anal canal is significantly higher than that in the rectum, and much higher than that in the external air. The maximum point of ARP is near the dentate line 2 cm from the anal verge, and it decreases upward or downward from this point. ARP and rectal resting pressure together form the gradually decreased centripetal gradient. Since the internal orifice of anal fistula is mostly located at the dentate line at the maximum point of ARP, high pressure continuously presses the feces, intestinal fluid and bacteria in the intestinal cavity into the fistula through the internal orifice. However, the external orifice pressure is far lower than that of the internal orifice, and the fistula is bent, which makes the fistula often in a state of poor drainage. Therefore, the infection substances are difficult to discharge and remain in the fistula, forming long-term chronic inflammation and recurrent infection. There is evidence that the effect of anorectal pressure measurement on anal function was better than that of anal function assessment scale, and the influence of subjective misjudgment was avoided [20]. Lee et al. reported that in the resting state, ARP was higher than rectal pressure, which could form a local pressure barrier to prevent the leakage of feces, making the anus have the function of controlling fecal excretion [21]. ARP, AMCP and HPZ are all essential indicators for evaluating the function of anal sphincter. ARP reflects the overall function of internal and external sphincters, which is important for maintaining anal continence. AMCP reflects the function of external anal sphincter and puborectalis muscles, and is considered as a main factor for maintaining anal continence in stress condition. HPZ, the distribution range of internal and external anal sphincter, can also reflect the function of anal sphincter. A decrease in HPZ indicates that patients are more likely to experience outlet obstructive constipation [18]. The influencing factors of anal sphincter function in patients with anal fistula after operation are mainly the damage of local sphincter, postoperative inflammatory response, and local fibrosis after healing [22, 23]. The clinical effect of solid thread-ligating therapy is significant, but it is not easy to grasp the timing of tightening thread. The lesions cannot be completely removed with too early tightening thread, and the anal function can be easily damaged with too late tightening thread. This study showed that the application of time-scheduled dotted and solid thread-ligating therapy combined with VSD could effectively reduce the damage of anal sphincter function after operation. In this study, the principle of applying time-scheduled dotted and solid thread-ligating therapy combined with VSD to protect anal sphincter mainly includes the following. First, incision design: multiple radial incisions were designed. The radial incision could be made taking the anus as the starting point and the external orifice as the end point. An arc-shaped radial incision could be made around the anal sphincter taking the external orifice as the starting point. The radial incision could be made taking the vertical distance between the internal and external orifice as the end point. The radial incision could also be made taking the internal orifice as the starting point and the most lateral of blind end of fistula at the end point. The choice of incision is based on keeping away

from anal sphincter and protecting the muscles around the anus. Second, subsurface excision of fistula: 70% of the internal orifices of high complex anal fistula are located in the anal sinus at 6 o'clock in the lithotomy position. The type of anal fistula is mostly half horseshoe, and the internal orifices are mostly located on both sides of the anus. According to the shape of the internal and external orifices, the fistula was resected sneakily. If the fistula was thick and the resection damage was so large that the tissues around the incision collapse, the removal of the fistula wall was the main method to ensure the shape of wound. While ensuring drainage, attention should be paid to prevent anal deformity caused by scar traction after wound healing, reduce anal injury and ensure anal function. Third, special VSD for anorectal diseases: the VSD was improved on the basis of common VSD and had thinner drainage and flushing tubes. The drainage and flushing tubes were expanded into an oval shape at the end and covered with an oval polyethylene sponge. According to the number, shape, size, and depth of the wounds, the drainage head end was connected in single, parallel or tandem connection for draining, making VSD more suitable for anorectal wounds. In clinical practice, we observed that the treatment of high complex anal fistula with time-scheduled dotted and solid thread-ligating therapy combined with VSD accorded with the disease characteristics and the therapeutic effect is satisfactory [24, 25].

Nevertheless, this study has shortcomings. This study is a retrospective study with a small sample size. Multi-center prospective studies are still needed to observe the efficacy of the treatment of high complex anal fistula with time-scheduled dotted and solid thread-ligating therapy combined with VSD.

In conclusion, the treatment of high complex anal fistula with time-scheduled dotted and solid thread-ligating therapy combined with VSD has short wound healing time, high effective rate and little impact on the function of anal sphincter, which is worthy of clinical application.

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Disclosure of conflict of interest

None.

Address correspondence to: Mengmeng Zhang, Graduate School of Chengdu University of Traditional Chinese Medicine, No. 37 Twelve Bridge Road, Jinniu District, Chengdu 610072, Sichuan Province, China. Tel: +86-13330817910; E-mail: zhangmengmeng512@163.com

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