

## **Clinical study on herbal fumigation of detumescence and pain relieving Shengji decoction in wound repair after anal fistula surgery.**

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### **Abstract**

**Objective:** To study the effects of herbal fumigation of detumescence and pain relieving Shengji decoction on wound repair after anal fistula surgery.

**Methods:** From March 2015 to March 2017, 90 patients with low anal fistula enrolled in Health Service Center of Ngamring County were collected. All patients were randomly divided into the observation group (n=45) and the control group (n=45). In the control group, the patients were treated with conventional western medicine while patients in the observation group were given the treatment of herbal fumigation of detumescence and pain relieving Shengji decoction. The treatment effect, wound repair, incidence of adverse reaction and quality of life were analyzed and compared between those two groups.

**Results:** The treatment effect of the observation group (95.6%) was obviously higher than that of the control group (73.3%). The wound repair and quality of life in the observation group was better than those in the control group. The incidence of adverse reaction of the observation group (2.2%) was significantly lower than that of the control group (20%).

**Conclusion:** Herbal fumigation of detumescence and pain relieving Shengji decoction can effectively promote the wound repair after anal fistula surgery, reduce the incidence of adverse reaction and improve the quality of life, thus worth clinical application.

**Keywords:** Detumescence, Pain relieving Shengji decoction, Low anal fistula, Wound repair.

*Accepted on August 16, 2017*

### **Introduction**

Anal fistula, also known as “anorectal fistula”, refers to the abnormal communication between the epithelialized surface of the anal canal and the perianal skin. It can be described as a narrow tunnel with its internal opening in the anal canal and its external opening in the skin near the anus. Anal fistulae commonly occur in people with a history of anal abscesses, where it can form when anal abscesses do not heal properly. Anal fistulae originate from the anal glands, which are located between the internal and external anal sphincter and drain into the anal canal. Even though anal fistula is generally harmful, it can be very painful. Moreover, recurrent abscesses of anal fistula may lead to significant short term morbidity from pain and initiate systemic infection. Thereafter, treatment is essential to allow drainage and prevent infection.

Surgery is the most prevalent strategy used to treat anal fistula. Nevertheless, because the extremely rich nerves in the surgical

site, anal fistula surgery makes wound pain and time-consuming healing after the surgery prevalent in patients [1]. Herbal fumigation of detumescence and pain relieving Shengji decoction can help to heal the wound after surgery in the shortest time with significant effects and few adverse reactions followed by remarkable improvement of living conditions [2]. But whether herbal fumigation of detumescence and pain relieving Shengji decoction can help to heal the wound after anal fistula surgery is unknown. In our study, we examine the effect of herbal fumigation of detumescence and pain relieving Shengji decoction on alleviating pain caused by anal fistula surgery. We conclude that it is helpful in relieving pain caused by anal fistula surgery to use herbal fumigation of detumescence and pain relieving Shengji decoction.

## Materials and Methods

### General materials

From March 2015 to 2017, 90 patients with low anal fistula were collected and randomly divided into the observation group (n=45) and the control group (n=45). In the observation group, there were 33 males and 12 females, aged from 16 to 65 with the average age of  $40.52 \pm 24.15$  and with the disease course of 1-8 y,  $4.56 \pm 3.14$  y on the average. In the control group, there were 29 males and 16 females aged from 17 to 63 with the average age of  $40.52 \pm 22.05$  and with the course of 1-7 y,  $4.09 \pm 3.02$  y on the average. There was no significant difference in baseline data between the two groups of comparability  $P > 0.05$ .

### Inclusion criteria

(1) The patients had anal fistula diagnosed. (2) The patients were approved by the ethics committee. (3) The patients and their families signed the informed consent form with our hospital before the study [3].

### Exclusion criteria

(1) The patients suffered major organs diseases of liver, kidney, heart or lung. (2) The patients who were pregnant and lactating. (3) The patients had mental sickness, communication disorders, or unconsciousness. (4) The patients had hematologic diseases with coagulation disorders or contraindications to surgery. (5) The patients and their families failed to support the study [4].

### Methods

The control group received routine western medicine treatment: The wound was first fumigated and then washed with potassium permanganate solution in the proportion of 1:5000, 15 min daily at one time until the wound heals [5].

The observation group were treated with the therapy of herbal fumigation of detumescence and pain relieving Shengji Decoction (with formula variation of drug dose addition and subtraction in accordance with signs) which is composed of: *Bletilla striata* 15 g, blood scorpion 10 g, Chinese gall 15 g, mirabilite 30 g, golden cypress 12 g and prepared Radix et Rhizoma Rhei 30 g. The decoction was taken once a day with water, simmering decoction to 1000 ml, to firstly fumigate and then wash the wound for 15 min a day at a time until the wound was healed [6].

### Evaluation index

**Effect of treatment:** Significant efficiency (the range of wound surface was reduced more than 75% with clinical symptom basically disappearing and fresh granulation tissue growing out); efficiency (the range of wound surface was narrowed between 25% and 75% with clinical symptoms significant improved and very few granulation tissue growing out); inefficiency (the range of wound surface was narrowed

less than 25% with no granulation tissue growing and no obvious improvement of clinical symptoms).

Significant efficiency rate+efficiency rate=total efficiency rate [7].

**Wound repair:** The wound repair was evaluated mainly from wound healing time, disappearance time of exudant and pain disappearance time.

**The quality of life:** WHQQL-36 scale was adopted to assess the quality of life in the two groups, including physical function, body pain, vitality, social function, emotional health, mental health and general health, with the total score of 100, the higher score indicated the better quality of life [8,9].

### Statistical methods

The observation indexes of this study were analyzed by using statistical software SPSS19.0 in which the measurement data (wound repair and quality of life) were tested by t and the count data (treatment effect and adverse reaction rate) were described as "n, %" and tested by chi-square test,  $P < 0.05$  suggested the difference was obvious of statistical significance.

## Results

### Comparison of the treatment effect

The treatment effect of the observation group was 95.6% (43/45), obviously higher than that of the control group-73.3% (33/45) of statistical significance ( $P < 0.05$ ) with the details shown in Table 1.

**Table 1.** Comparison of the treatment effect.

Group	Significant efficiency	Efficiency	Inefficiency	Total rate	efficiency
Observation	19	24	2	95.6	
Control	10	23	12	73.3	
$\chi^2$	--	--	--	8.4586	
P	--	--	--	0.004	

### Comparison of wound repair

The wound healing time and disappearance time of exudant as well as pain in the observation group were much shorter than those in the control group ( $P < 0.05$ ) with the details shown in Table 2.

**Table 2.** Comparison of wound repair.

Group	Wound healing time	Disappearance time of exudant	Disappearance time of pain
Observation	$2.24 \pm 0.21$	$10.26 \pm 2.51$	$18.26 \pm 3.62$
Control	$4.36 \pm 0.37$	$7.21 \pm 2.01$	$24.75 \pm 4.14$
t	33.4274	6.3627	7.9164

P	0.021	0.035	0.039
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### Comparison of adverse reaction rate

The adverse reaction rate in the observation group was 2.2% (1/45), which was much lower than that in the control group 20% (9/45) of statistical significance ( $P < 0.05$ ) with the details shown in Table 3.

Table 3. Comparison of adverse reaction rate.

Group	Anal eczema	Pruritus ani	Adverse rate	reaction
Observation	0	1	2.2	
Control group	5	4	20	
$\chi^2$	--	--	6.0494	
P	--	--	0.014	

### Comparison of quality of life

The scores of physical functions, body pain, vitality, social function, emotional health, mental health and general health in the observation group were much higher than those in the control group ( $P < 0.05$ ) with the details shown in Table 4.

Table 4. Comparison of quality of life.

Index	Observation	Control	t	P
Physical function	76.26 ± 11.26	35.62 ± 10.25	17.9042	0.025
Body pain	96.59 ± 12.25	75.25 ± 9.11	9.3771	0.041
Vitality	78.26 ± 8.14	42.28 ± 7.44	21.8865	0.037
Social function	89.65 ± 8.25	50.25 ± 7.14	24.2243	0.021
Emotional health	85.25 ± 10.19	61.25 ± 8.19	12.3149	0.042
Mental health	88.26 ± 11.14	62.25 ± 8.14	12.6461	0.033
General health	98.25 ± 5.14	70.26 ± 3.77	24.4559	0.04

## Discussion

Anal fistula, one of common diseases in colorectal surgery and consisting of endostoma, fistula and external aperture, accounts for 30% the incidence rate in anorectal diseases. Its clinical manifestation shows local recurrent ulceration and suppuration with pain and itching, which greatly reduces the patient's quality of life [10]. Because the curative effect of conservative therapy is not satisfying and time-consuming, instead the disease is commonly treated with surgery in clinical practices, but after surgery the patients are prone to suffer a series of complications like urinary retention and pain, which seriously affects the treatment effect and prognosis [11]. This disease often requires many treatment methods like seton and incision followed by the formation of multiple incisions in the surgery, which may cause traumatic edema of the wound, rising inflammatory exudant around the wound and stool stimulation, which all will lead to slow wound healing and the patients

must prolong hospitalization time due to the unbearable pain after the operation. Postoperative wound is generally open to the bacteria and in the process of defecation the expansion of anal canal will trigger secondary damage to the wound, thus making the wound healing slower and prone to false healing, adhesion and infection. The wound repair after the operation has a greater effect on the treatment effect and the rapid wound healing can effectively shorten the treatment time with good effect [12,13].

The research data showed that the treatment effect of the observation group (95.6%) was obviously higher than that of the control group (73.3%). The wound healing time and disappearance time of exudant as well as pain in the observation group were shortening than those in the control group. The incidence of adverse reaction of the observation group (2.2%) was significantly lower than that of the control group (20%) and the scores of physical function, body pain, vitality, social function, emotional health, mental health and general health in the observation group were much higher than those in the control group of statistical significance ( $P < 0.05$ ). This is mainly because, the prepared Radix et Rhizoma Rhei is the monarch herb in the prescription of detumescence and pain relieving Shengji Decoction with the effect of Zhuyu and Tongluo as well as purge heat and detoxification, golden cypresscan has the effect of purging fire for removing toxin, heat clearing and damp drying and muscle relaxation which is significantly effective in treating eczema and itching sores [14,15]. Mirabilite, with the effect of heat cleaning and mass dissipating, is mainly used in the clinical treatment of such diseases as abscess, accumulation and abdominal mass; Chinese gall with the effect of haemostasis and detoxication, can be used for the treatment of hematochezia to promote wound healing. Blood scorpion has the efficacy of haemostasis, promoting granulation, close sores, eliminating stasis and analgesic outcome [16]. *Bletilla*, with the effect of lung tonifying, promoting granulation, removing stasis and relieving pain, can to some degree inhibit the action of *pseudomonas aeruginosa*, *Bacillus typhi*, *Bacterium dyseioteriae*, and *Bacillus coli* [17]. The mixture of various herbs in this prescription plays the function of subsidence of a swelling, pain relief, promoting granulate and clearing away heat as well as toxic materials, which can effectively accelerate the wound repair with shorter healing time, shorten the clotting time and promote the recovery [18]. Besides, it has the advantages of convenience with no irritation, toxic side effects or adverse reactions, not only improving the safety and effectiveness of treatment, but also to some extent alleviating economic burden and psychological pressure of the patients and their families, easy to be accepted by them [19,20].

To sum up the herbal fumigation of detumescence and pain relieving Shengji decoction can effectively promote the wound repair after operation of anal fistula, reduce the incidence of adverse reaction and improve the quality of life. It turns out to be safe and feasible, thus worthy of trust and promotion from most patients.

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