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Evaluation of clinical application effect of traditional Chinese medicine fumigation technology on postoperative patients with anorectal diseases

Procena efekta kliničke primene tehnologije fumigacije tradicionalne kineske medicine na obolele od anorektalnih oboljenja u postoperatvnom periodu

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Abstract

Background/Aim. Treatment after anorectal surgery plays a key role in wound healing and reducing complications. The aim of this study was to assess the clinical efficacy of traditional Chinese medicine (TCM) fumigation in the postoperative management of anorectal diseases, comparing TCM fumigation with conventional treatments. **Methods.** This study included 100 anorectal disease patients who underwent surgery at Anhui Chest Hospital, China, from October 2021 to October 2023. The patients were randomly split into two groups – observation and control (50 patients each). TCM fumigation was administered to the observation group, while the control group received potassium permanganate *sitz baths*. Both groups received 14 days of treatment. The research assessed visual analog scale (VAS), symptom eradication, wound healing, serum substance P (SP) and interferon-gamma (IFN)-γ levels, and therapy efficacy before and after treatment. Side effects were also examined in both groups. **Results.** The overall effective rate for the observation group was 96%, and for the control group, it was 86%. The observation group's clinical efficacy exceeded the control group's clinical efficacy. VAS for pain in both groups dropped after treatment, after which the observation group had lower scores than the control group. The observation group had less anal distension, wound edema, wound fluid, and recovery time than the control group. Within both groups, higher levels of SP and lower levels of IFN-γ in serum were recorded after treatment compared to their pre-treatment values. After treatment, higher levels of SP and lower levels of IFN-γ were recorded in the observed group compared to the control group. The observation group had fewer side effects than the control group (6% vs. 28%). **Conclusion.** TCM fumigation techniques may increase clinical efficacy, mitigate clinical symptoms, surgical adverse effects, discomfort, and accelerate wound healing following anorectal disorders.

Key words:
fumigation; medicine, chinese traditional; postoperative period; rectal diseases; treatment outcome.

Apstrakt

Uvod/Cilj. Lečenje nakon anorektalne hirurgije igra ključnu ulogu u zarastanju rane i smanjenju komplikacija. Cilj ove studije bio je da se proceni klinička efikasnost fumigacije primenom tradicionalne kineske medicine (TKM) u postoperativnom lečenju anorektalnih bolesti, u poređenju sa konvencionalnim tretmanima. **Metode.** Ovom studijom obuhvaćeno je 100 bolesnika obolelih od anorektalnih bolesti operisanih u Bolnici za grudne bolesti Anhui, Kina, od oktobra 2021. do oktobra 2023. godine. Bolesnici su nasumično podeljeni u dve grupe – posmatranu i kontrolnu (50 bolesnika u svakoj). Fumigacija TKM primenjena je kod bolesnika u posmatranoj grupi, dok su u kontrolnoj grupi primenjivane kupke sa kalijum permanganatom. Tretman obe grupe je primenjivan 14 dana. Procenjivani su vizuelna analogna skala (VAS), eradikacija simptoma, zarastanje rane, nivoi supstance P (SP) i interferona (IFN)-γ u serumu i efikasnost terapije pre i nakon tretmana. Takođe, ispitivane su neželjee reakcije u obe grupe. **Rezultati.** Ukupna efektivna stopa za posmatranu grupu iznosila je 96%, a za kontrolnu grupu 86%. Klinička efikasnost u posmatranoj grupi premašila je kliničku efikasnost u kontrolnoj grupi. VAS za bol u obe grupe opao je nakon tretmana, nakon čega je posmatrana grupa imala niže skorove od kontrolne grupe. Posmatrana grupa imala je manju analnu distenziju, edem rane, sekreciju iz rane i vreme oporavka u poređenju sa

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kontrolnom grupom. Unutar obe grupe zabeleženi su viši nivoi SP i niži nivoi IFN-γ u serumu nakon tretmana u poređenju sa njihovim vrednostima pre tretmana. Nakon tretmana, u posmatranoj grupi u poređenju sa kontrolnom grupom, zabeleženi su viši nivoi SP i niži nivi IFN-γ. Posmatrana grupa je imala manje neželjenih efekata od kontrolne grupe (6% vs. 28%). **Zaključak.** Tehnike fumigacije TKM mogu povećati kliničku efikasnost, ublažiti kliničke simptome, hirurške neželjene efekte, nelagodnost i ubrzati zarastanje rane nakon anorektalnih poremećaja.

Ključne reči:
fumigacija; medicina, kineska, tradicionalna; postoperativni period; rektum, bolesti; lečenje, ishod.

Introduction

Anorectal diseases (ADs) are a general term for anal and intestinal diseases. There are many causes for ADs, primarily separated into internal and external factors [1]. Internal sources are genetic factors, anatomical structure, and congenital abnormalities of embryonic development, while the external causes are poor lifestyle habits [2]. There are more than 100 kinds of common ADs in clinical practice, many of which are often accompanied by ADs, bringing great harm to the health of patients [3]. Many ADs need to be treated surgically. Continuous treatment after anorectal surgery plays a crucial role in wound healing and reducing complications [4, 5]. Under the guidance of ancient Chinese medicine theory, the old-fashioned Chinese medicine fumigation is an external treatment method that selects certain traditional Chinese medicine (TCM) for syndrome differentiation. The medicine is dissolved in water or processed into Chinese medicine liquid or even made into powder. Then, it is mixed with hot water to carry out local fumigation and aesthetic-bath on anorectal patients [6]. It directly acts on the body through the body surface using warmth and drugs to dredge meridians, dispel wind and remove dampness, lessen edema and ease discomfort, encourage blood stasis, etc. [7]. From this point on, several researchers have concentrated on the process of fumigation. On the other hand, researchers have not comprehensively investigated the efficacy of the fumigation application [8].

TCM fumigation therapy has been used for centuries as an external treatment method to promote healing and alleviate symptoms in various diseases, including anorectal conditions. Rooted in the principles of TCM, fumigation involves using herbal steam to deliver therapeutic compounds directly to the affected area [9]. This method combines the benefits of heat therapy with the pharmacological actions of medicinal herbs, aiming to expel toxins, reduce inflammation, alleviate pain, and promote tissue repair [10]. Potassium permanganate sitz baths are commonly used in postoperative care for their antiseptic properties. However, they primarily offer antimicrobial action without additional therapeutic effects such as anti-inflammatory or analgesic benefits [11]. In contrast, TCM fumigation therapy utilizes a combination of herbs with multiple pharmacological actions, potentially offering a more holistic approach to postoperative care [12]. Therefore, further study is required to have a complete understanding of this facet. TCM, particularly fumigation therapy, has been used for its anti-inflammatory, analgesic, and wound-healing effects [12].

The aim of this study was to investigate whether TCM fumigation can complement standard postoperative care, improving outcomes in pain reduction, wound healing, and adverse reaction rates. By comparing TCM fumigation with conventional sitz baths, the study assesses its potential integration into care protocols to enhance patient outcomes.

Methods

General data

This study included 100 patients diagnosed with ADs who underwent standardized surgical procedures at Anhui Chest Hospital, China, from October 2021 to October 2023. This study was approved by the Ethics Committee of the Anhui Chest Hospital (No. 2021/TCM/FT/76456/1122). The research complies with the ethical guidelines and requirements of the Declaration of Helsinki. Surgeries were performed by the same surgical team using consistent techniques to ensure uniformity in the extent of intervention. Patients were randomly assigned into two groups (50 patients each).

Inclusion and exclusion criteria

Inclusion criteria were as follows: patients 18–80 years old diagnosed with ADs requiring surgical intervention according to the "Modern Anorectal Diagnosis and Treatment Standards" [13]; patients who underwent standardized surgical procedures with similar extents of intervention; patients with mild to moderate inflammation levels, as assessed by preoperative clinical evaluations, to minimize variability in postoperative outcomes; patients with no other cardiovascular and cerebrovascular diseases; patients with complete clinical case data and follow-up data; patients willing to participate in the study.

Exclusion criteria were as follows: patients with malignant tumors; patients with severe cardiopulmonary damage; patients with mental illnesses; patients with severe inflammation or infection that could significantly affect wound healing; patients lacking sufficient clinical data to determine efficacy.

Therapeutic method

The control group used potassium permanganate sitz bath treatment after the operation. Two pieces of potassium permanganate external tablets (Shandong Mingren Freda Pharmaceutical Co., Ltd., National Medicine Approval H20063384, specification: 0.1g) were used with 1,000 mL of water.

The water temperature of 40º C is appropriate for the potassium permanganate to completely dissolve in water. It is then stirred until it becomes pink to the naked eye, and, as such, it can be used. Patients sit in the bath for 5–10 minutes each time, once in the morning and once in the evening. This treatment is widely recognized and routinely used in clinical settings for managing postoperative symptoms in AD patients.

In the observation group, fumigation with TCM was used after the operation. Patients received TCM fumigation therapy instead of the potassium permanganate sitz bath. The fumigation treatment involved a specific herbal formula designed to promote wound healing and reduce inflammation and pain. The fumigation drug was composed of the following herbs: *Sophora flavescens* 9 g, *Houttuynia* 15 g, *Ulmus sinensis* 9 g, *Dandelion* 15 g, *Mirabilis* 3 g, *Ilex* 9 g, *Phellodendron* 9 g, *Honeysuckle* 18 g, *Schisandra chinensis* 6 g, and *Angelica* 6 g. About 2,500 mL of water is added to the herbs. The herbs are first brought to a boil and then cooked over a low flame for 20 min. The slag that is created is removed and the solution is taken while hot. Wait until the temperature is suitable for a sitz bath, and use the solution each time for 30 min, *bis in die*.

For 14 days, both groups received constant treatment.

Observational index

(1) Clinical efficacy: the therapeutic efficacy rating scale designed by our hospital was utilized to assess the clinical efficacy of the patients, comprising four sections of incision infection, pain degree, edema degree, and wound healing, with five questions in each section. There were 20 questions in total. Every question scored five points, and the total score was 100. A score of 90 or above indicates obvious effectiveness, a score of 70–89 indicates effectiveness, and a score below 70 indicates ineffectiveness. Total effective rate = (number of significantly effective cases + number of effective cases)/total number of cases × 100%. (2) Postoperative pain degree: the pain degree of patients in the two groups was assessed before the treatment and at 3, 7, and 14 days after treatment, and the degree of pain in patients was evaluated using a visual analog scale (VAS). Pain is measured on a 0 to 10 scale, with 0 indicating no pain and 10 indicating very intense pain. (3) Symptom improvement and wound healing time: the disappearance of anal distension, wound edema, wound seepage, and time of wound healing of the two groups were correlated. (4) Laboratory indicators: before and after medication, both groups had their venous blood drawn in the early morning on an empty stomach. Serum levels of substance P (SP) and interferon-gamma (IFN)-γ were measured using enzyme-linked immunosorbent assay (ELISA) (Shanghai Enzyme-linked Biotechnology Co., Ltd). (5) Compare the incidence of adverse drug reactions among the two groups: observe adverse reactions between the two groups of patients, including infection, rash, blistering, and abnormal feeling.

Statistical analysis

All statistical analyses were conducted using SPSS version 26.0 to ensure rigorous data processing and interpretation. Continuous variables were expressed as mean ± standard deviation, with between-group comparisons carried out using independent *t*-tests and within-group comparisons conducted using paired *t*-tests to evaluate changes over time within each group. Categorical data were analyzed using Chi-square tests or Fisher's exact tests, depending on the sample size and the distributional characteristics of the data. Wilcoxon rank-sum tests were utilized for ordinal variables, particularly where the normality assumption was not satisfied, thereby ensuring the appropriate handling of non-parametric data. The significance level was set at $\alpha = 0.05$ to determine statistical significance. Sample size calculations were conducted using G*Power software, incorporating a significance level of $\alpha = 0.05$, a statistical power of 0.8, and effect sizes informed by previous studies. Although a minimum of 30 participants *per* group was estimated to achieve sufficient power, we ultimately recruited 50 participants *per* group to enhance the reliability of the results and account for potential attrition.

Results

The assessment of general data among two groups is shown in Table 1.

The observation group's overall effective rate was 96% (48/50), whereas the control group's total effective

Table 1

Assessment of general data among the two groups

Parameters	Observation group (n = 50)	Control group (n = 50)	$\chi 2/t$ value	*p*-value
Age (years)	53.27 ± 12.48	54.13 ± 11.87	0.346	0.765
Gender			0.124	0.856
male	35 (70)	33 (66)		
female	15 (30)	17 (34)		
Course of disease (years)	4.87 ± 3.56	4.91 ± 3.48	0.287	0.821
Type of disease (case)			0.825	0.173
hemorrhoids	34 (68)	35 (70)		
anal fistulas	5 (10)	4 (8)		
anal fissures	4 (8)	5 (10)		
perianal abscesses	5 (10)	3 (6)		
other	2 (4)	3 (6)		

n – number. All values are given as numbers (percentages) or mean ± standard deviation.

rate was 86% (43/50). The observation group exhibited superior clinical effectiveness compared to the control group, with a statistically significant difference ($p < 0.05$) (Table 2).

Pain VAS of the two groups at 3, 7, and 14 days after treatment was progressively decreased ($p < 0.05$), and the pain VAS score of the observation group was lower than that of the control group during the same period. The difference was statistically noteworthy ($p < 0.05$) (Table 3).

The diminishing time of anal distension, wound edema, and wound seepage, and the wound healing time in the observation group was shorter compared to the control group. The difference was statistically significant ($p < 0.05$) (Table 4).

Following therapy, both groups had increases in serum SP ($p < 0.05$) and decreases in IFN-γ ($p < 0.05$). Following the treatment, the observation group's serum SP and IFN-γ levels were shown to be greater ($p < 0.05$) and lower, respectively, compared to the control group's (Table 5).

The observation group experienced 6% (3/50) of adverse reactions, whereas the control group experienced 28% (14/50). In the observation group, there was a reduced incidence of adverse reactions compared to the control group ($p < 0.05$) (Table 6).

Table 2

Assessment of clinical efficacy among the two groups

Clinical efficacy	Observation group (n = 50)	Control group (n = 50)	χ^2-value	*p*-value
Obvious	26 (52)	16 (32)		
Effective	22 (44)	27 (54)	5.421	0.018*
Ineffective	2 (4)	7 (14)		
Total effective rate	48 (96)	43 (86)		

n – number. All values are given as numbers (percentages).
***p < 0.05 compared with the control group.**

Table 3

Assessment of postoperative pain visual analog scale scores among the two groups

Parameters	Observation group (n = 50)	Control group (n = 50)	*t*-value	*p*-value
Before treatment	9.34 ± 2.45	9.28 ± 2.38	0.256	0.764
After treatment (days)				
3	6.21 ± 1.45	8.17 ± 1.48	9.257	< 0.001
7	4.42 ± 2.56	6.89 ± 2.41	8.326	< 0.001
14	3.01 ± 1.87	5.38 ± 2.14	7.458	< 0.001

n – number. All values are given as mean ± standard deviation.
A statistically significant difference ($p < 0.05$) was found before and after treatment in both groups, as well as after treatment between the two groups on all tested days.

Table 4

Assessment of symptom improvement and wound healing time among the two groups

Parameters	Observation group (n = 50)	Control group (n = 50)	*t*-value	*p*-value
Diminishing time (weeks)				
anal distension	5.48 ± 0.76	7.82 ± 1.121	6.784	< 0.001
wound edema	5.17 ± 0.62	7.31 ± 0.82	8.125	< 0.001
wound seepage	3.98 ± 0.51	5.76 ± 0.63	10.142	< 0.001
Wound healing time (weeks)	8.74 ± 1.85	11.02 ± 2.15	12.765	< 0.001

n – number. All values are given as mean ± standard deviation.

Table 5

Assessment of serum SP and IFN-γ before and after treatment among the two groups

Parameters	Observation group (n = 50)		Control group (n = 50)	
	before treatment	after treatment	before treatment	after treatment
Substance P (pg/mL)	132.45 ± 12.86	207.84 ± 22.47	133.75 ± 12.63	172.81 ± 19.65
IFN-γ (pg/mL)	45.81 ± 7.56	20.91 ± 5.18	45.36 ± 7.24	32.85 ± 6.23

n – number; IFN – interferon. All values are given as mean ± standard deviation.
A statistically significant difference ($p < 0.05$) was found before and after treatment in both groups, as well as after treatment between the two groups in both tested parameters.

Table 6

Assessment of adverse reactions among the two groups

Adverse reactions	Observation group (n = 50)	Control group (n = 50)	χ^2-value	*p*-value
Infections	1 (2)	3 (6)		
Rash	1 (2)	4 (8)		
Blistering	0 (0)	5 (10)	6.524	0.009
Feeling strange	1 (2)	2 (4)		
Total incidence	3 (6)	14 (28)		

n – number. All values are given as numbers (percentages).
A statistically significant difference ($p < 0.05$) was found between the two groups in all manifested adverse reactions.

Discussion

In the current investigation, after the anorectal surgery, the patients were administered TCM fumigation. Fumigating matrine and dandelion given on prescription, are used to clear heat and dry dampness. Houttuynia species (sp.) is a traditional herb used for clearing heat and eliminating toxins and has also been used for treating severe acute respiratory disease [12]. Honeysuckle is effective in clearing heat, detoxifying the body, eliminating carbuncles, and facilitating the discharge of pus [13]. Ulmus sp. serves to cool the blood, stop the bleeding, and facilitate detoxification to collect sore [14]. Schisandra sp. exhibits astringent properties [15]. Angelica sp. demonstrates a beneficial impact on alleviating trapped wind pain, reducing swelling, and promoting drainage [16]. It effectively moisturizes dryness, smooths the intestinal lining, promotes blood circulation, and alleviates pain [17, 18]. The study's findings demonstrated that the observation group's overall effective rate was greater than the control's, indicating that the application of TCM fumigation technology after the operation of ADs improved the treatment efficiency of patients. At the same time, the occurrence of postoperative adverse reactions in the observation group was suggestively lesser than in the control group, indicating that the application of TCM fumigation technology after the operation of ADs improved the safety of the follow-up treatment and greatly reduced the probability of postoperative adverse reactions such as infection, rash, blistering, and abnormal feeling in patients.

The study's findings demonstrated that 3, 7, and 14 days following therapy, the observation group's pain VAS was lower than the control group's. This suggests that applying TCM fumigation technology can efficiently alleviate the degree of pain in postoperative ADs.

In this study, diminishing time of anal distension, wound edema, and wound seepage, and the time of wound healing was shorter in the observation than in the control group. After treatment, serum SP increased and IFN-γ decreased in the observation group compared to the control. This suggests that the application of TCM fumigation technology after ADs can improve clinical symptoms and promote wound healing.

These results are consistent with previous research supporting the efficacy of TCM fumigation in postoperative care for ADs [1]. For instance, a study by Wang et al. [12] demonstrated that TCM fumigation significantly reduced postoperative pain and promoted wound healing in patients undergoing hemorrhoidectomy. Similarly, Kang and Yu [19] reported that the combined application of TCM fumigation and acupuncture significantly decreased edema, alleviated pain, and accelerated the healing process in patients undergoing anorectal surgery. These findings align with our study, where the observation group showed lower pain VAS scores and faster wound healing times compared to the control group. Regarding adverse reactions, our study found a significantly lower incidence in the observation group. This is in line with the Hospital Authority's report indicating that potassium permanganate sitz baths can cause skin irritation and allergic reactions in some patients [20]. In contrast, TCM fumigation therapy may have fewer adverse effects due to its gentle pharmacological properties and localized application. In summary, our study corroborates existing literature, further validating the effectiveness and safety of TCM fumigation therapy in postoperative rehabilitation for ADs. However, larger-scale, multicenter randomized controlled trials are necessary to confirm these findings and better inform clinical practice.

ADs have become common in our country, which seriously troubles people's health. Due to the great changes in the working and living style of Chinese residents, the incidence of ADs is getting higher and higher [21, 22]. In reality, people do not have a deep understanding of the harm of ADs. Therefore, ADs often do not get scientific and effective diagnosis and treatment, which can easily lead to constipation, blood stool, swelling, and unbearable pain, and in severe cases, it may transform into rectal tumors [23, 24]. ADs often require surgical treatment, but the postoperative pain and long course of the disease discourage the patients from undergoing the surgery. For that reason, finding a way to reduce pain and shorten the course of treatment is important for solving a series of clinical problems [25, 26]. With the help of thermal action, these drugs stimulate perianal and local skin, expand subcutaneous blood vessels, accelerate lymphatic and blood flow, improve local tissue nutrition, accelerate metabolism, and enable drugs to enter the body through skin absorption in order to improve the therapeutic effect [27, 28]. By exploring the reasons, we can see that TCM fumigation through the skin or the orifice directly affects the lesion and the stimulation of other organs of the human body is small. Furthermore, the effect of TCM is mild, even if it directly acts on the human skin, the chance of redness,

swelling, and blistering is very small [29, 30]. That being said, it is safe to use TCM fumigation following anorectal surgical treatment. Analyzing the reasons, not only can TCM fumigation prescription promote blood and relieve pain but also inhibit the growth of a variety of pathogenic bacteria, play the role of clearing heat and dampness, reducing swelling and releasing pain, cleaning wounds, antibacterial and anti-inflammatory, can make local Qi and blood channels run smoothly, and effectively relieve patients' postoperative pain [27, 28]. Analysis of the reason is that the direct contact of TCM liquid to the wound and blood vessels in the fumigation expansion promotes the local absorption of drugs, inhibits the proliferation of wound bacteria, and promotes the absorption of local inflammatory exudates [31, 32]. After wound formation, serum SP can promote the growth of wound fibroblasts and repair the synthesis of deoxyribonucleic acid to heal the wound. TCM fumigation can improve wound blood circulation, hasten the fiber proliferation rate and epithelial coverage, and shorten the wound recovery time [33, 34]. IFN-γ is a pro-inflammatory factor, and the increase in its level can increase the permeability of blood vessels and aggravate swelling, pain, and other symptoms [35, 36]. TCM fumigation can efficiently constrain the stimulation of inflammatory response to the body and relieve symptoms [37]. Recognizing the potential impact of surgical variability and inflammation on postoperative outcomes [38], we standardized surgical procedures for all patients and included only those with mild to moderate inflammation. This approach minimized confounding factors and allowed us to attribute differences in postoperative recovery primarily to the treatment interventions (TCM fumigation vs. potassium permanganate sitz bath).

This study has several limitations. The relatively small sample size (50 patients per group) limits the statistical power to detect rare adverse events and affects generalizability. The low incidence of adverse reactions (6%) may not adequately reflect the true risk profile, necessitating larger-scale studies for validation. Additionally, the single-center nature of the study limits external validity, as variability in practitioner expertise, institutional protocols, and patient demographics could affect outcomes in different settings. The follow-up period was restricted to 14 days, assessing only short-term outcomes like pain relief and wound healing, while long-term effects such as recurrence and late adverse reactions remain unknown. Confounding factors, such as variability in patient adherence to postoperative care, may also have influenced outcomes despite efforts to standardize treatment protocols. Future multi-center studies with larger sample sizes and extended follow-up are needed to confirm the efficacy and safety of TCM fumigation.

Conclusion

Our study demonstrates that traditional Chinese medicine fumigation therapy significantly improves postoperative outcomes for anorectal disease patients compared to potassium permanganate sitz baths. Specifically, traditional Chinese medicine fumigation was associated with greater reductions in postoperative pain, faster wound healing, enhanced symptom alleviation, and a lower incidence of adverse reactions. These findings suggest that traditional Chinese medicine fumigation may offer a viable alternative to conventional sitz bath methods for postoperative care in anorectal diseases, providing targeted therapeutic benefits with fewer side effects.

Conflicts of Interest

The authors declare no conflict of interest.

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