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Systematic Evaluation and Screening of Clinical Efficacy of Anal Fistula based on Randomized Controlled Trial

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Abstract: ***Objective: To systematically evaluate the clinical efficacy of wound healing after anal fistula, screen the basic drugs, and provide evidence-based medical evidence for clinical drugs. Methods: A systematic literature search of 7 domestic and foreign databases included a randomized controlled trial (RCT) for the treatment of anal fistula, data extraction and bias assessment by two reviewers. The Cochrane risk of bias assessment tool and StataSE 15.0 software were used for quality evaluation and meta-analysis. We used the Apriori algorithm in SPSS statistics22.0 software to analyze the associations between the drugs and select the basic drugs of TCM for restoring wound healing. Results: 32 randomized controlled studies were included in 3445 patients. The results of Meta-analysis showed that, compared with the conventional postoperative wound dressing change, external treatment of TCM could effectively improve the cure rate [RR= 0.77,95%CI (0.71,0.82), P < 0.001]., Effectively shorten the wound healing time: [WMD = 6.00, 95%CI(4.58, 7.42), P< 0.001], Effective pain relief: [WMD = 0.95, 95%CI(0.51, 1.38), P< 0.001], Reduce wound exudation: [WMD = 0.49, 95%CI(0.41, 0.57), P< 0.001], Reduction of wound oedema degree [WMD = 0.43, 95%CI(0.28, 0.58), P< 0.001]. All of the differences were statistically significant. The data mining results showed that the association rules showed that the drug combination of drug-drug-drug-free and corner-drug-angelica had high support and confidence, and the cluster analysis obtained four types of prescriptions, which were the basic drugs for the treatment of anal fistula. Conclusion: External treatment of Chinese medicine greatly alleviates the pain and edema of anal fistula, significantly shortens the healing time of the wound, and the clinical cure rate is obviously better than that of conventional dressing change. This treatment is relatively safe and helps patients to recover as soon as possible to shorten the length of hospital stay.***

Keywords: Randomized control, External treatment of traditional Chinese medicine, After anal fistula, Systematic evaluation, Data mining.

1. Introduction

Anal fistula is a pathological link between the anal canal or rectum and the perianal skin, and the most common etiology is idiopathic cryptic gland infection [1], where soft, tender, fluctuating masses can be palpable by perianal palpation or internal rectal examination. It can lead to continuous discharge of purulent secretions or intermittent perianal swelling and tenderness, which seriously affects the patient' s normal life and work [2]. The incidence of anal fistula in China accounts for about 1.67% -3.6% of the number of anorectal cases, and the incidence in men is about 2:1 [3]. Anal fistula is divided into simple anal fistula and complex anal fistula, and surgery is the best way to treat anal fistula. At present, open postoperative treatment is mainly used in clinical practice, but due to the deep and irregular postoperative wound, and the special anatomical position of the anus is prone to fecal stimulation, patients have different degrees of postoperative bleeding, edema, pain, poor prognosis, and the difficulty of wound healing is great [4]. Motherland medicine that local skin through the absorption of drug ions, penetration, to dredge meridians, reconcile qi and blood, poison, supporting the role of dispel, thus effectively inhibit the wound by bacterial infection, reduce the release of inflammatory factors reduce pain, speed up the epithelial tissue regeneration and granulation tissue to promote the healing of the wound. Therefore, this study intends to systematically evaluate the clinical efficacy of traditional Chinese medicine on anal fistula, and screen out the method of fusion data mining The combination of basic Chinese medicine in the study is expected to provide more evidence-based medicine support and objective basis for clinical decision makers.

2. Data and Methods

2.1 Literature Search Strategy

Two researchers (Wei Zhang, Wenzhe Feng) independently used Pubmed, Embase, Cochrane, CNKI, W anfangD atabase、VIPDatabaseIn the search, the search terms include "Chinese medicine", "Chinese medicine fumigation", "Chinese medicine sitting bath", "anal fistula", "after anal fistula". There were no language or time constraints for the search strategy, and all titles and selected abstracts were reviewed by both authors, and the final decision on study inclusion or exclusion was made in the event that a consensus was reached. Data on relevant literature information, study objectives, outcomes and follow-up were extracted by one of the authors and reviewed by the second author.

2.2 Inclusion and Exclusion Criteria

Inclusion criteria: (1) population: patients treated by anal fistula surgery; (2) intervention measures: control group with conventional dressing, treatment group with Chinese medicine bath, fumigation and ointment; (3) literature: Chinese and English literature; (4) results: clinical cure rate, wound healing time, edema degree, pain score, and wound exudation; (5) study design: randomized controlled trial with sample size greater than 15.

Exclusion criteria: (1) literature in other languages; (2) lack of sufficient data or results; (3) repeated publication; (4) in vitro

experiments, animal experiments, non-comparative studies, reviews, letters, guidelines, case reports, abstrabstract, expert opinions, editorials, comments; and (5) inconsistent intervention methods.

2.3 Data Extraction

Two investigators independently screened the literature according to the inclusion and exclusion criteria and independently extracted information using the standard data extraction table, two researchers cross-checked one by one, and differences were resolved by discussion. If relevant data are not available, study reports will be excluded. For each study, the following information was collected: (1) study characteristics: first author, year of publication, trial protocol; (2) patient baseline: intervention method, number of patients, age, duration of disease; and (3) outcome measures.

2.4 Quality Evaluation

The full text of the included 32-item RCTs were independently read by 2 investigators for quality evaluation from allocation concealment, random sequence generation, and outcome data completeness using the Cochrane Risk of bias assessment tool. Two researchers independently evaluated, cross-checked, and the dispute was determined by a third party.

2.5 Statistical Analysis

Statistical analysis was used by using the StataSE 15.0 software. The ative risk (RR) and 95% confidence interval (95% CI) for the dichotomous variables and the standard mean difference (WMD) and 95% CI for the continuous variables. Heterogeneity was evaluated using I^2 values, and I^2 30%, 30% < I^2 < 75%, and 75% were considered to indicate low, moderate and high heterogeneity, respectively. I^2 < 50%; if I^2 50%.

2.6 Data Mining and Basic Drug Use Screening

The TCM prescriptions mentioned in the literature that have been included in the systematic evaluation were input into the Excel table, and frequency analysis was conducted. Excel tabular data were imported into IBM SPSS M odeler 18.0 software and association analysis was performed using the Apriori algorithm and plot Web regraph visualization. Excel tabular data were imported into IBM SPSS Statistics 26.0 software to cluster the data.

3. Results

3.1 Literature Search and Screening

A total of 575 articles were searched in the database. 125 duplicate studies were systematically excluded, and after reading the article titles and abstracts, 178 studies with Meta-analysis, systematic review, unrelated diseases, conference abstracts, animal experiments, sample size <15 and other reasons were excluded, and 272 studies were initially included. Subsequently, we read the full text and excluded 240 studies that did not meet the inclusion criteria. A total of 32 articles were finally included [6-37] RCT performed the statistical analysis. The literature screening process and the results are shown in Figure 1.

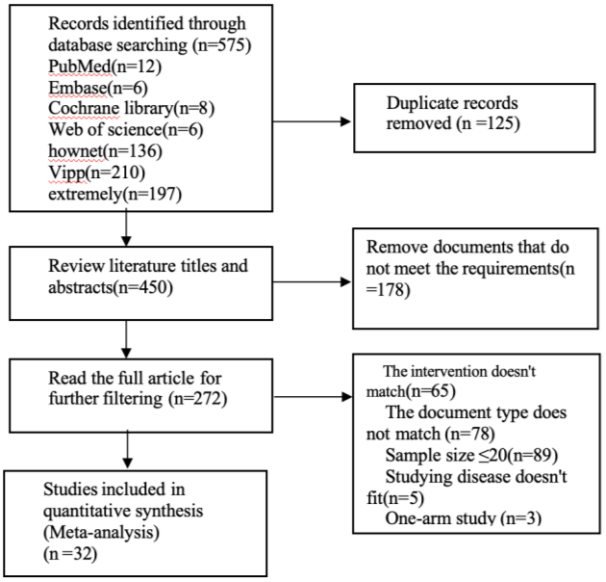

Figure 1: (Literature Selection Process Diagram)

3.2 Basic Characteristics of the Included Studies

Of the 32 studies included, 3523 patients with anal fistula were included, including 1758 in the control group and 1765 in the observation group. Study characteristics, patient baseline, and study findings of the included studies are shown in Table 1.

Table 1: Baseline characteristics of the included studies in the meta-analysis

The study author	Year (year)	Sample size (example)		Gender (male- \ -female)		Mean age (years)		Mean disease duration (years)		intervention study		Outcome indicators
		control group	observation group	control group	observation group	control group	observation group	control group	observation group	control group	observation group	
Jiarong Dong [5]	2010	30	30	23\7	21\9	41.18±10.09	37.42±9.26	NA		Vaseline yarn	Traditional Chinese medicine long skin paste	1
GelanLiu [6]	2010	58	63	36\22	38\25	33.86±5.53)	31.20±5.1	7.11	6.38	Vaseline yarn	Hemorrhoids comfortable breath sitting bath + Jiuhua cream	1
Rui Xie [7]	2010	100	92	68\32	65\27	36.5±6.0	37.2±6.8	1.3	1.2	Antibiotic + potassium permanganate sitt bath	Traditional Chinese medicine sitting bath + chemical saprophytic muscle paste	1
Haiqin Cheng [8]	2011	60	60	36\24	34\26	35.5±3.9	35.4±5.1	NA	NA	Potassium permanganate bath	Traditional Chinese medicine fumigation	1
Dianwen Liu [9]	2012	60	60	NA	NA	NA	NA	NA	NA	Potassium permanganate bath	Traditional Chinese medicine fumigation	1、2
Hui Yang [10]	2013	60	60	33\27	35\25	33.5+7.3	38.4±5.6	1.1±0.5	1.4+0.6	Regular dressing change	Traditional Chinese medicine fumigation	1
Huimin Wang [11]	2015	30	30	20\10	22\8	44.17±9.28	42.63±11.35	3.25±1.13	3.63±0.97	Potassium permanganate bath	Jing Huang smoked liquid	1、2、3
Wei Li [12]	2016	70	70	50\20	52\18	36.7±11.3	7.6±5.4	8.1±5.7	7.6±5.4	Spray with iodine solution	Traditional Chinese medicine fumigation	2、3、4、5
Yong Mei [13]	2016	41	44	25\16	27\17	43.85±3.76	42.26±3.25	3.04±1.08	2.96±1.02	Potassium permanganate bath	Bitter Qin Tang takes a bath	1、2
Shengdong Zhang [14]	2017	28	28	18\10	18\10	37.5±2.0	37.5±2.0	4.1±0.2	4.1±0.2	Regular dressing change	Traditional Chinese medicine fumigation	1、2、3、4
Xiaomin Zheng [15]	2017	40	40	22\18	24\16	43.11±4.34	42.62±4.93	4.21 ± 1.1 July	4.45 ± 1.3 July	Metronidazole was rinsed	Compound jingpu lotion fumigation and washing	1、3

Linmei Sun[16]	2017	90	90	71\19	59\31	42.03±12.65	39.58±10.73	8.03 ± 9.8 April	7.32±8.31	Regular dressing change	Traditional Chinese medicine sitting bath	1
Xiannen g Cheng[17]	2018	40	40	31\9	28\12	69.35±4.11	68.54±3.23	2.12 ± 0.74 years	1.87±0.59	Potassium permanganate bath	Traditional Chinese medicine fumigation	1、2、3、4
Yuqin CAI[18]	2018	50	50	NA	NA	NA	NA	NA	NA	Sitting in warm water	Deand the soup sit bath	2、3、4
Hui Zhang[19]	2018	30	30	19\11	18\12	36.2±1.4	36.4±1.2	NA	NA	Potassium permanganate bath	Traditional Chinese medicine fumigation	1
Jianwei Wu[20]	2018	42	42	22\20	23\19	39.91±2.04	39.89±2.05	5.75±0.55	5.74±0.52	usual care	Traditional Chinese medicine sitting bath	1、3
Ping Wang[21]	2019	41	41	23\18	20\21	47.96±9.24	48.35±8.91	5.67±1.82	6.02±2.02	Potassium permanganate sitting bath + microwave irradiation	Traditional Chinese medicine fumigation + microwave irradiation	2、3、4、5
Zehua Xia[22]	2020	52	52	32\20	29\23	31.2±3.7	31.4±3.6	7.1±2.4	7.3±2.2	Hemorrhoids wash liquid	Bais heat clearing and blood stasis	1、2、3
Jianming Fan[23]	2020	55	55	30\25	32\23	38.50±2.14	37.49±2.15	NA	NA	Regular dressing change	Traditional Chinese medicine fumigation	3、4、5
Zhenxia ng Li[24]	2020	45	45	31\14	33\12	43.2±11.6	42.5±12.9	NA	NA	Regular dressing change	Traditional Chinese medicine fumigation	1、3、5
xi Sha[25]	2020	66	66	47\19	49\17	38.9±11.0	39.8±10.5	5.30± 0.41	5.29±0.38	The septic gauze is applied externally	Compound yellow cypress liquid gauze strip external application	1、2、3、4
yan When[26]	2020	51	51	31\20	28\23	31.28±2.48	31.14±2.53	1.75±0.29	1.79±0.31	Potassium permanganate bath	Qingreanesic soup smoked washing	2、3、4、5
Tong Yang[27]	2020	42	42	28\14	26\16	40.5±5.2	40.2±5.0	4.2±1.0	4.2±1.0	Rehabilitation new yarn dressing	Traditional Chinese medicine decoction order Crossdressing	2、3、4
Fei Lan[28]	2020	50	50	22\28	21\29	43.46±2.57	43.01±2.78	6.26 ± 0.7 April	6.21 ± 0.7 August	Potassium permanganate bath	Five times sonsoup smoked wash	1、2
Fengwei Sun[29]	2021	40	40	24\16	23\17	41.32±2.43	42.37±2.56	2.34±0.41	2.27±0.42	Regular dressing change	Traditional Chinese medicine fumigation	1、2、3、5
Bin Huang[30]	2021	71	71	53\18	55\16	38.58±11.58	37.85 ±8.90	NA	NA	Pvidone iodine solution sitt bath	Traditional Chinese medicine fumigation	1、2、3
Yu Chen[31]	2021	28	32	19\9	23\9	37.52±8.64	37.85±8.82	And 4.0 ± 0.5 years	4.3±0.8	Potassium permanganate bath	Five times the soup to take a bath	1、2、3、4、5
Zeli Li[32]	2022	100	100	88\12	88\12	41.02±3.38	38.16±4.44	11.14 ± 2.31-Jan	11.45 ± 2.1 Nov	Anal tether	Traditional Chinese medicine sitting bath	3
Chen Jie[33]	2022	92	92	49\47	41\55	52.42±6.77	51.38±6.79	3.17±1.95	2.59±1.05	Potassium permanganate bath	Bitter cypress liquid smoked	2、3、4、5
Xuesong Zhao[34]	2022	71	74	53\18	50\24	40.24±6.26	41.32±6.15	26.45 ± 5.21-month	27.12 ± 5.3 June month	Potassium permanganate bath	Dispoison two yellow soup smoked washing	2、3、4、5
Jianqiao Liu[35]	2022	45	45	39\6	35\10	39.91±15.70	42.31±14.95	NA	NA	Germicidal gauze	Local dressing change of traditional Chinese medicine yam strips	1、2、3、4
Xiaojing Qin[36]	2022	80	80	54\26	55\25	42.24±5.41	42.12±5.32	6.29 ± 1.52 month	6.37 ± 1.31-Jan	petrolatum gauze	Fortify the raw muscle oil sand	1、2、3

NA: no data 1. wound healing time 2. clinical cure rate 3. Pain score 4. wound exudation 5. degree of edema

3.3 Literature Quality Evaluation

32 randomised controlled trials using the Cochrane Risk of Bias Tool (Review Manager 5.4 tool) [6-37] To evaluate. Randomization method: 16 articles were included [6,7,9,11,12,15-22,29,30,37] The random method was not accurately described, so the assessment was unclear; 14 articles [8,10,13,14,24-28,31,33-36] The specific random allocation method was mentioned, so the assessment was low risk. There are 2 [23,32] Randomization was not mentioned, and the specific grouping method is unknown, so the assessment is a high risk. Allocation concealment: 32 items are mentioned in the literature, so the assessment is unclear. Blinding: blinding was not specifically mentioned in the 32 included articles, so the assessment was unclear; the report results were not selective and showed no other bias, so it was rated as low risk. Overall assessment was a low risk of bias (Figure 2)

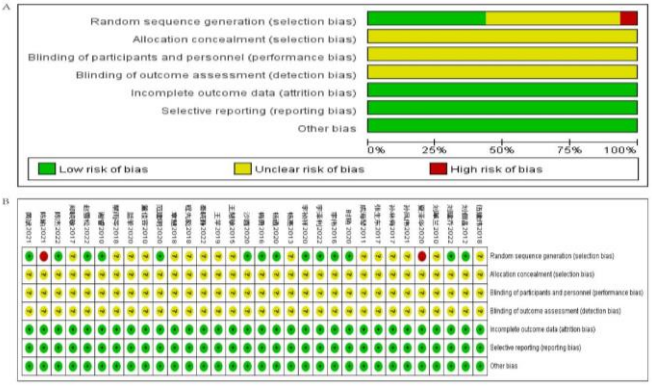

Figure 2: Risk of bias assessment in randomised controlled trials

4. The Meta-analysis Results

4.1 Clinical Cure Rate

There are 20 articles in total [10,12,13,15,18,19,22,23,26-32,34-37] Clinical cure rates were reported in the literature, with no significant heterogeneity between the 20 studies (P = 0.018, I^2= 44.4%). Therefore, we performed a meta-analysis using a fixed-effect model. The results showed (Figure 3) the cure rate in the observation group was significantly better than the control group [RR= 0.77,95%CI (0.71,0.82), P <0.001].

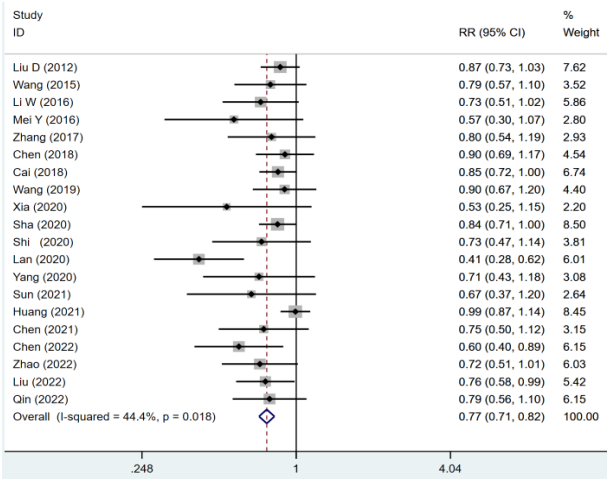

Figure 3: (Forest plot of the participating clinical cure rate data of group 2. RR: hazard ratio)

4.2 Wound Healing Time

A total of 22 [6-12,14-18,20,23,25,26,29-32,36,37] The wound healing time was reported in the literature, with high heterogeneity between studies (P <0.001, I^2= 95.5%). The reasons for the excessive heterogeneity may be due to differences in individual physical condition or postoperative nutritional intake. Therefore, we performed a Meta-analysis using a random-effect model. The results showed a significantly shorter wound healing time (Figure 4) in the observation group [WMD = 6.00,95%CI (4.58,7.42), P

<0.001].

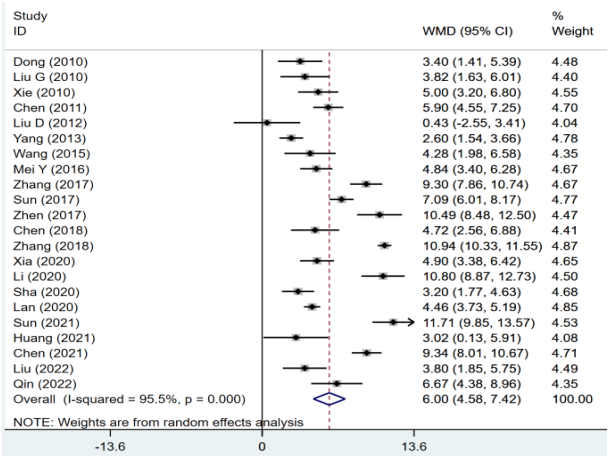

Figure 4: (Forest plot of the wound healing time data of group 2. WMD: Standard mean difference)

4.3 Pain Degree Score

A total of 22 [12,13,15,16,18,19,21-28,30-37] Pain severity scores are reported in the literature, 22 with significant heterogeneity between studies (P <0.001, I^2= 99.7%) and the source of heterogeneity may be caused by differences in the degree of pain tolerance in individual patients. Therefore, we performed a Meta-analysis using a random-effect model. The results showed (Figure 5) that the pain level in the observation group was significantly relieved [WMD = 0.95,95%CI (0.51,1.38), P <0.001].

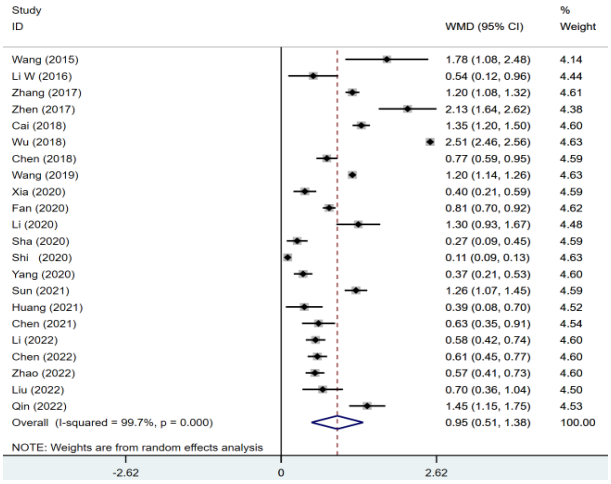

Figure 5: (Forest plot of the participating pain degree rating data in group 2. WMD: Standard mean difference)

4.4 Effate of Wound Surface

A total of 13 articles [13,15,18,19,22,24,26-28,32,34-36] The wound exudwas reported in the literature, 13 showed high heterogeneity between studies (P <0.001, I^2= 87.2%) and no source of excessive heterogeneity was found. Therefore, we performed a Meta-analysis using a random-effect model. The results showed significant infiltration (Figure 6) in the observation group [WMD = 0.49,95%CI (0.41,0.57), P <0.001].

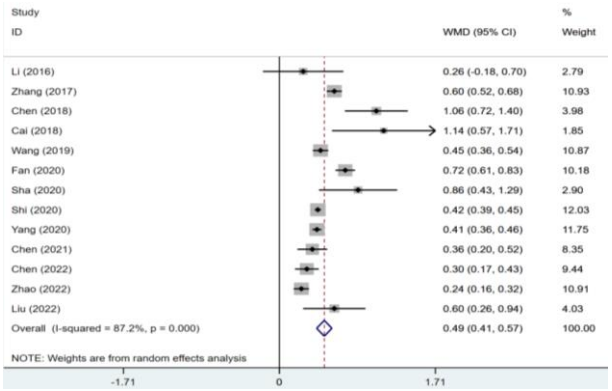

Figure 6: (Forest plot of the wound exudate data of group 2. WMD: Standard mean difference)

4.5 Degree of Oedema

A total of 9 [13,22,24,25,27,30,32,34,35] The degree of edema was reported in the literature, showing high heterogeneity between 9 studies (P < 0.001, I^2= 97.8%). Analysis of sources of heterogeneity may be due to different correlations of surgical procedures. Therefore, we performed a Meta-analysis using a random-effect model. The results showed that the degree of wound edema in the observation group [WMD = 0.43,95%CI (0.28,0.58), P < 0.001].

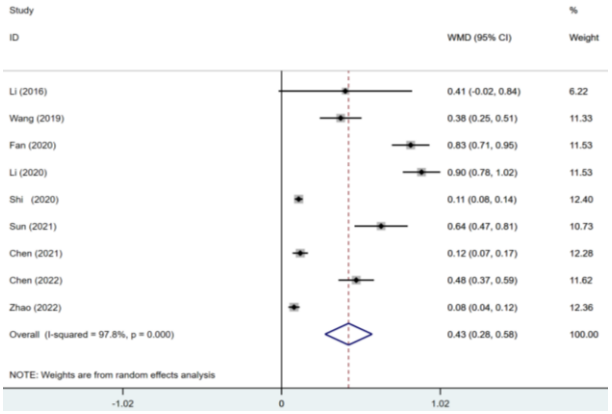

Figure 7: (Forest plot of wound edema data in group 2. WMD: Standard mean difference)

4.6 Publication Bias

A funnel plot of the wound healing time of the primary outcome measure was evaluated for publication bias. Results for overall survival (Figure 8) Egger' s P=0. 123 and Begg' s P=0. 652 indicate no significant publication bias; no significant asymmetry in the funnel plot shape and all studies were within the 95% CI.

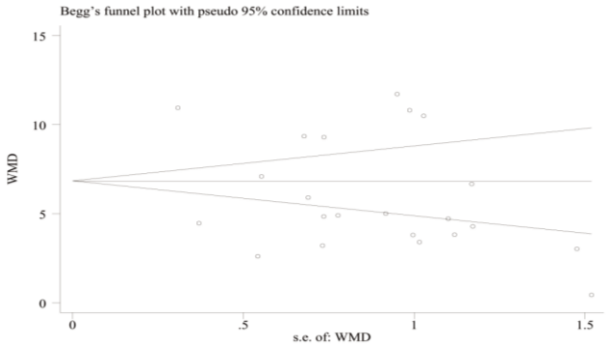

Figure 8: (overall survival publication bias)

4.7 Sensitivity Analysis

We chose the clinical cure rate for the sensitivity analysis, and Figure 9 shows the overall survival rate sensitivity analysis with a small sensitivity, indicating that the model is robust and reliable.

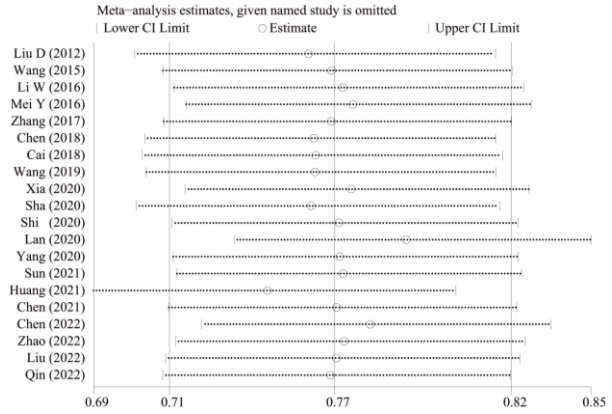

Figure 9: (a sensitivity analysis of the overall survival rate)

5. Data Mining Results

After the prescriptions were selected for the treatment of anal fistula, 3 1 prescriptions were used for 2 70 times, and 8 4 Chinese medicines were used for 153 times (2 1,1 3.7%), bitter ginseng (1 6,10.46%), puncanite (1 2,7.8 4 %), rhubarb (1 1,7.19%), and chinensis (1 1,7.19%), and the details are shown in Table 2. And to perform the association rules and cluster analysis.

Table 2: Frequency distribution 5 Comparison of the distribution of single traditional Chinese medicine

order number	medicinal	frequ ency	order number	medicinal	frequ ency
1	golden cypress	2 1	1 0	herba portulacae	7
2	kuh-seng	1 6	1 1	alum	6
3	Glauber salt	1 2	1 2	Angelica sinensis	6
4	rheum officinale	1 1	1 3	Saposhnikovia divaricata	6
5	Chinese gall	1 1	1 4	Boswellia carterii	6
6	borneol	8	1 5	radix paeoniae rubrathe root of common peony	5
7	rhizoma atractylodis	8	1 6	myrrh	5
8	dandelion	8	1 7	rhizoma smilacis glabrae	5
9	Schizonepeta	7	1 8	cordate houttuynia	5

5.1 Association Rule Analysis

Table 3: Correlation of TCM combination and angular medicine combination

order number	Drug combination	Support %	confiden ce%	Elevatio n%
1	There is no milk fragrance	80.645	100.0	1. 192
2	No medicine, frankincense, angelica	70.968	100.0	1. 192
3	Frankincense angelica, no medicine	70.968	1 00.0	1 .240

Five frequency of drug association rules analysis, using IBM SPSS M odeler 18.0 software, set the support of 70%, the confidence is 100%, the largest item is 2, get drug is no medicine, frankincense, Angle medicine is no medicine, frankincense, angelica, specific support, confidence and increase degree see table 3, network drawing set families show the largest number of 3 1, strong link lower limit is 2 2, weak link limit 1 5, see the network Figure 8.

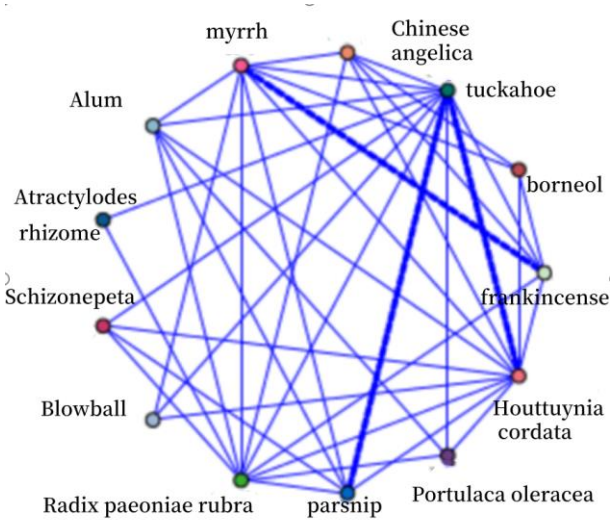

Figure 8

5.2 Cluster Analysis

For cluster analysis of 20 high-frequency drugs, SPSS Statistics 26.0 software, see Figure 9. Pearson correlation was used for the measurement tric, combined with TCM theoretical TCM cluster analysis method, as shown in Table 4.

Table 4: Cluster analysis of dendrogram drug group extraction

order number	assemble
C1	Frankincense, myrrh, borneol, angelica
C2	Misite, pentafold, purslane, rhubarb
C3	Yellow cypress, atractylodes, red peony root,
C4	Bitter ginseng, Houttuynia corttuynia, mustard, windbreak, Poria, dandelion, alum

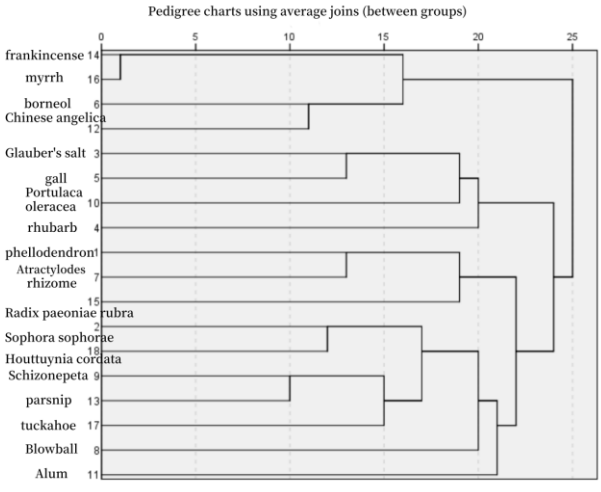

Figure 9

6. Discussion

Anal fistula is the most common clinical anorectal disease, is the anal canal and rectum under the pathological factors and the skin around the anal abnormal channel [37], most clinical surgery way to effect a radical cure, but due to the larger surgical trauma, perianal wound deep and irregular, combined

with the perianal anatomical position special vulnerable to fecal stimulation, the patients with different degrees of postoperative wound bleeding, edema, pain, poor prognosis. The postoperative potassium permanganate warm water bath and infrared local irradiation, but this often fails to effectively relieve the local pain of patients, and the postoperative wound healing time is long, which is easy to form a large area of scar tissue, and the poor effect [38]. A large number of studies have shown that traditional Chinese medicine treatment in removing pus, detoxification muscle, swelling pain has the unique advantage of more effective than western medicine treatment, through Chinese medicine treatment of blood circulation stasis pulse, make damp heat poison, gathered in the wound of poison, heat, blood stasis, virtual evil dissipate, significantly alleviate the patients with bleeding, edema, pain, granulation slow growth and wound delayed healing or nonhealing symptoms, improve the clinical cure rate.

wound healing and new capillaries and fibrobcells of granulation tissue and epithelial tissue regeneration is close to [39], according to the skin with absorption, penetration, excretion characteristics, when the skin around the wound contact drugs, drug ions can through the skin penetration into the human blood circulation, through this way of local drug directly on the target effect, at the same time drugs without the digestive tract can avoid the stimulation of the gastrointestinal tract. Chinese medicine smoked sitting bath can not only to create good moist environment, also can make the drug direct lesions, warm water sittbath can increase local skin temperature, open hair follicle, sweat glands, sebaceous glands, increase the penetration and absorption of drug ions, by promoting blood circulation, accelerate the excretion of metabolites, inflammation medium to reduce pain, reduce the production of wound leachate, relieve the wound edema degree, accelerate the healing of the wound. Traditional dry dressing change can easily cause tissue adhesion, which often increases the pain of patients during dressing change, and a large area of scar tissue is often formed after wound healing. The moist wound environment can reduce the formation of dry scab so as to avoid the mechanical damage caused by new granulation tissue by dry scab [40]. Traditional medicine believes that the wound healing process should be "simmer pus long meat" as the treatment method, In the process of wound recovery, if the evil can not dissipate, it will gather in the wound to form carrion. The ancient doctor Xue Ji pointed out that only when the carrion goes can the new meat be born. The local use of TCM ointment can accelerate the exudation of pus on the wound under the pharmacological action and thus carry evil out, playing the role of discharging pus, removing decay and muscle growth. Modern medical research has found that TCM ointment has a strong antibacterial and bactericidal effect on various bacteria including Escherichia coli, Staphylococcus aureus and Proteobacteria [41].

The KMO and Bartlett tests showed that the number of KMO sampling suitability was 0.285, and the Bartlett sphericity test (2 59.033, P <0.0001) showed statistical significance. Through the analysis of the association rules, drugs for no medicine, frankincense and Angle medicine, frankincense and angelica were selected as the basic drugs after the external treatment of Chinese medicine to anal fistula. No medicine and frankincense are both drugs for activating blood circulation and relieving pain, the efficacy is both for promoting blood circulation, promoting qi and relieving pain, reducing swelling and producing muscle, frankincense is good at regulating qi and running blood, no medicine is good at removing blood stasis and regulating blood, and the combination of the two drugs complements each other [42]. Modern pharmacology research, the combination of frankincense and no medicine has the transdermal absorption ability to achieve the treatment of inflammation [43]. Angelica is a blood tonic medicine, which has the function of regulating blood circulation, relieving pain, nourishing blood, making movement in blood, widely used in blood deficiency and blood stagnation, with frankincense, no medicine, can enhance its effect of promoting blood circulation and relieving pain. The Chinese medicine of anal fistula is mostly anal ulcer after a long time. The basic pathogenesis of anal ulcer is the obstruction of qi and blood is different, and the return to the origin is qi and blood. According to the cluster analysis, C 1 is frankincense, myrrh, borneol, and angelica. Like the middle corner medicine, the borneol compatible with frankincense-myrrh has heat and pain relief, angelica promotes blood circulation and blood tonic, four drugs combined, blood circulation and blood tonic, qi, analgesia, swelling and muscle. C2, nitrate, vetimes, purslane, rhubarb, rhubarb-nitrate compatibility can promote local blood flow, improve microcirculation, achieve swelling and anti-inflammatory effect [44] [45]. Purslane has clear heat and detoxification, cool blood and stop bleeding, five times the wet collect sores, hemostasis, four drugs combined, swelling and pain relief, wet collect sores. C3 is yellow cypress, atractylodes and red peony root. In modern research, the ingredients of Ermiao pill can act and make damp and heat injection [46] [47]. C4 Sophora, Houttuynia, Vicorta, wind, soil, poria, dandelion, alum, Jing mustard-windbreak has a significant curative effect in the clinical treatment of anal disease, and combined with other drugs, it has the function of clearing away heat and detoxification, dispersing blood stasis, reducing swelling and relieving pain [48]. In conclusion, the association rules and cluster analysis data combined with clinical studies are consistent with modern pharmacology.

This study systematically evaluated the effects of TCM fumigation, sittbath and external application on the wound recovery after anal fistula, and the results showed that TCM treatment could improve the clinical healing rate, shorten the wound healing time, reduce wound pain, reduce wound exudation and edema degree. Demonprove that this treatment is safe and effective. However, at the same time, our study also has certain limitations: (1) the literature quality of the included studies is not high enough and the sample size of a single study is small, and the design of random sequence generation method, allocation concealment and blinmethod is not rigorous enough, which may lead to a certain degree of bias. (2) some outcome indicators are too heterogeneous and cannot be eliminated, which may be due to differences in patients' age, surgical procedures, disease course, personal physical quality and postoperative nutritional status, which may affect the reliability of the results. (3) The number of TCM prescriptions included in the data mining is small, and the drug dosage is not considered, which will affect the reliability of the results.

Advantages of this study: this study combines the system evaluation and data mining, not only confirmed the Chinese

medicine after anal fistula can improve the cure rate, shorten the wound healing time has a positive effect, and further explore the Chinese medicine prescription rule, screening milk-no medicine basic drug combination, provides a more reliable evidence-based medical basis for clinical treatment. At the same time, we included all the clinical studies after the external treatment of anal fistula with traditional Chinese medicine published in high-level journals in recent years, and fully included different administration methods including traditional Chinese medicine sittbath, fumigation, and external application, and the systematic evaluation was more comprehensive and sufficient. However, considering the limitations of this study, we expect more large sample, multicenter and more rigorous clinical studies.

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