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Original Article

Chinese herbal medicine Evodia hot compress therapy improves the recovery of gastrointestinal function after abdominal surgery

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Abstract: Background and aim: To investigate the effectiveness of Chinese herbal medicine topical therapy in the recovery of gastrointestinal function after abdominal surgery in a prospective multi-center randomized controlled trial. Methods: A total of 1029 patients fell into control group, coarse salt hot compress (CS) group, evodia hot compress (ECS) group and evodia hot compress plus electro-acupuncture (ECS & EA) group. The gastrointestinal function was evaluated and compared at different time points. Results: Statistically significant difference was observed on the time to first defecation ($P < 0.05$), and the longest time to first defecation was 95.3±44.8 h in CS group. The three experimental groups had shorter time to first passing flatus on Timepoint 5 (the fifth day after surgery) than control group ($P < 0.05$). More patients in ECS & EA group reported no abdominal distention than patients in CS group (89% *vs*. 80%; $P < 0.05$) on Timepoint 2 (the second day after surgery). 77.4% of control group complained no abdominal pain on Timepoint 2, which was the lowest, and there was no difference among the four groups on other timepoints ($P > 0.05$). The difference on nausea and vomiting was only found statistically significant among the four groups on Timepoint 3 (the third day after surgery) ($P < 0.05$). Conclusion: Chinese medicine topical therapy helps the recovery of the postoperative gastrointestinal function after abdominal surgery, which may be widely introduced to the clinical practice, and the measurements enrolled in our study are efficient in evaluating the efficacy of Chinese herbal therapy.

Keywords: Chinese herb, abdominal surgery, gastrointestinal function, therapeutic efficacy

Introduction

Traditional Chinese medicine has been widely applied in treating a variety of human diseases, which is based on the integrative understanding on the disease. Considering the special features of traditional Chinese medicine, how to objectively evaluate the clinical efficacy is the core part in deepening the insight into its therapeutic potential [1, 2]. In the past, the experience was the main theory for treating patients by traditional Chinese medicine [3]. However, there is still no objective indicator for judging the curative effect of traditional Chinese medicine [3-6]. Furthermore, the introduction of evidence-based medicine also promotes the development of Chinese medicine study [7, 8], which emphasizes an objective people-oriented clinical research.

The identification of appropriate efficacy evaluation indicators is important in clinical trials [9, 10]. Currently, outcome assessment is a new focus in the international medical community. The former is the disease outcome, which is easy to reflect the real effects. The latter is not a real clinical outcome, but has been confirmed to have a correlation with important clinical outcomes and was determined to be caused by therapeutic interventions [11]. In the updated medical model, the research on Chinese medicine not only focuses on the basic theory, highlighting the characteristics, but also attaches great importance to the development of the main outcome measure in clinical evaluation and Chinese medicine clinical evaluation system [12]. Therefore, we analyzed the effect of Chinese herbal medicine topical therapy on the improvement of the gastrointestinal function after abdominal surgery and further examined the effectiveness and safety in this study, aiming to investigate the feasibility of our evaluation strategy based on a variety of clinical measurements.

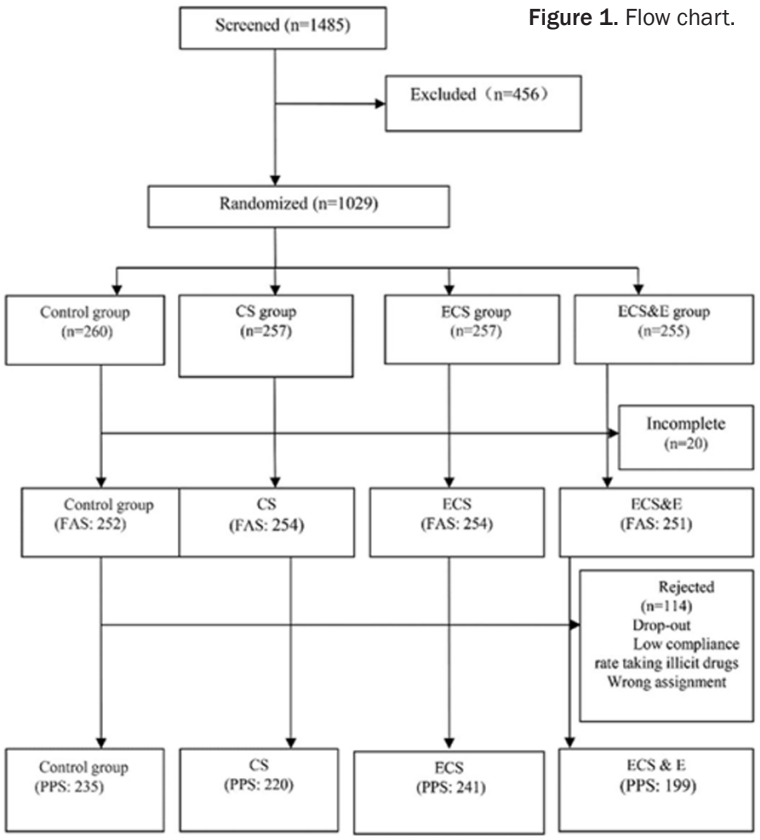

Figure 1. Flow chart.

Patients and methods

Patients

We conducted the clinical study from October 2009 to December 2011 at the Guangdong Provincial Hospital of Chinese Medicine, Tianjin Nankai Hospital, Dongzhimen Hospital affiliated with Beijing University of Chinese Medicine and the first Affiliated Hospital of Guangzhou University of Chinese Medicine. The patients included should meet the following criteria: 1) Who needed a fasting diet after abdominal surgery from the department of general surgery or anorectal surgery; 2) Aged from 18 to 75 years old; 3) Who had surgery duration of 1 to 4 hours; 4) Who had anesthesia duration of 1.5 to 5 hours; 5) Who had excess syndrome of Fu-organ caused by Qi stagnation. The exclusion criteria included: 1) Malignant tumor associated cachexia or extreme weakness; 2) Malignant tumor which needed extended radical mastectomy; 3) Severe cardiovascular, liver, kidney, brain or lung disease; 4) Mental illness; 5) The allergy to *Evodia* and acupuncture needles; 6) Severe malnutrition with serum albumin < 21 g/L or prealbumin < 0.10 g/L; 7) A second abdominal surgery with severe adhesive ileus; 8) More than 1000 ml blood loss during surgery; 9) Serious complications within 6 hours after surgery such as multiple organ dysfunction; 10) Participation in other clinical trials within a month before this trial. The study protocol was approved by the independent ethic committee (IEC) of Guangdong Provincial Hospital of Chinese Traditional Medicine, and registered at Chinese Clinical Trial Registry with the number ChiCTR-TRC-09000527 (http://www.chictr.org/cn/). Written Informed consent was obtained from all the patients.

Study design

Sample size was calculated according to the method of multi-sample comparisons. A pilot study was conducted to estimate parameters for calculating sample size. Considering that 15% may drop out, we finally estimated that a total sample size of 1008 patients was needed for this study. Participants enrolled were randomly assigned by the central interactive voice operating system into four groups for different treatments. The 4 groups included control group, coarse salt hot compress (CS) group, Evodia hot compress group (ECS) group and Evodia hot compress plus EA (ECS & EA) group. Control group was given the regimen of basic therapy and liquid therapy (balanced electrolyte solution, glucose, etc). In CS group, basic therapy and CS were administrated for 30 min twice one day with an interval of 6 hours for 7 days after surgery. ECS group accepted basic therapy and ECS for 30 min twice one day with an interval of 6 hours for 7 days after surgery. ECS & EA group were treated by basic therapy, ECS and EA (Kangmei Pharmaceutical, China) treatment for 30 min twice one day with an interval of 6 hours for 7 days after surgery, as previous reported [11].

Therapeutic efficacy evaluation

Demographic and clinical features of the patients including name, gender, age, disease duration, medical history, diagnosis, technique

Table 1. Outcome measures for the gastrointestinal function in the four groups

		Control group	CS group	ECS group	ECS & EA group	*P* value
Time to first bowel sound, h	N	242	246	244	246	0.599
	Median (95% CI)	55.0 (48.2-61.8)	59.0 (52.7-65.3)	56.0 (48.6-63.4)	51.0 (46.3-55.7)	
	Range	8.0-350.0	9.0-298.0	10.0-184.0	5.0-171.0	
Time to first passing flatus, h	N	244	248	248	247	0.344
	Median (95% CI)	44.8 (42.9-46.8)	55.5 (47.6-63.4)	47.8 (41.2-54.5)	45.8 (43.7-47.9)	
	Range	6.9-162.3	7.3-163.5	7.0-135.6	6.5-136.8	
Time to first defecation, h	N	242	246	244	246	0.025
	Median (95% CI)	70.8 (60.3-81.2)	90.9 (83.7-98.1)	79.2 (68.5-89.8)	86.2 (77.1-95.2)	
	Range	8.5-284.3	15.2-261.5	7.0-223.0	14.8-338.1	

Log rank test, all data were expressed as mean ± standard deviation.

Table 2. Subgroup comparison on the time of first passing flatus

Observation points		Control group		CS group		ECS group		ECS & EA group		X^2	*P*
		%	*N*	%	*N*	%	*N*	%	*N*		
Timepoint 1	0 points	65	26.3	56	22.3	56	22.6	55	22.1	1.668	0.644
	6 points	182	73.7	195	77.7	192	77.4	194	77.9		
Timepoint 2	0 points	140	57.6	124	50.4	137	55.2	149	60.8	5.739	0.125
	6 points	103	42.4	122	49.6	111	44.8	96	39.2		
Timepoint 3	0 points	189	81.1	192	79.3	198	81.5	202	85.2	2.944	0.400
	6 points	44	18.9	50	20.7	45	18.5	35	14.8		
Timepoint 4	0 points	207	92.8	207	90.4	220	94.8	211	96.3	7.463	0.059
	6 points	16	7.2	22	9.6	12	5.2	8	3.7		
Timepoint 5	0 points	204	95.8	209	95.9	224	98.2	208	98.2	8.416	0.038
	6 points	9	4.2	9	4.1	4	1.8	1	1.8		
Timepoint 6	0 points	203	98.5	203	97.1	215	98.6	202	100	5.977	0.113
	6 points	3	1.5	6	2.9	3	1.4	0	0.0		
Timepoint 7	0 points	236	97.9	238	98.3	237	98.3	235	99.6	2.524	0.471
	6 points	5	2.1	4	1.7	4	1.7	1	0.4		

0 points: Passing flatus existed. 6 points: No passing flatus was present.

and time of the operation, method of anesthesia, complications and the patients' compliance were collected. Blood and urine conventional indicators, liver and kidney function, electrolytes and other indicators were introduced to evaluate the safety of the treatment. The time to the first defecation, time to the first passing flatus and time to bowel sounds were used to investigate the effect of the topical therapy on gastrointestinal function after abdominal surgery. Time to the first defecation, time to the first passing flatus and time to bowel sounds referred to the time of the first observed passage of stool, the first observed passing flatus and the first observed bowel sounds since the surgery, which were recorded by patients or their families. Nausea, vomiting, bloating, abdominal pain, hunger and other gastrointestinal symptoms were recorded every morning from the 1st to the 7th days postoperatively before treatment.

Statistical analysis

Data management and data entry were completed using the web-based data management system with a double cross-checking approach (Http://www.gdadr.cn/gcphis). Data analysis was performed by the National Center for Design Measurement and Evaluation in Clinical Research of Guangzhou University of Chinese Medicine using PASS18.0 software. Categorical variables were presented as frequency and proportions, while continuous variables presented asmean ± standard deviation, min, max and median (M). The changes from baseline in outcome measurement among the four groups

Table 3. Subgroup comparison on the time of first defecation

Observation points		Control group		CS group		ECS group		ECS & EA group		x^2	*P*
		%	*N*	%	*N*	%	*N*	%	*N*		
Timepoint 1	0 points	15	6.1	8	3.2	13	5.2	10	4.0	2.772	0.428
	6 points	232	93.9	243	96.8	235	94.8	239	96.0		
Timepoint 2	0 points	68	28.0	45	18.3	60	24.2	58	23.7	6.487	0.090
	6 points	175	72.0	201	81.7	188	75.8	187	76.3		
Timepoint 3	0 points	119	51.1	102	42.1	119	49.0	109	46.0	4.309	0.230
	6 points	114	48.9	140	57.9	124	51.0	128	54.0		
Timepoint 4	0 points	145	65.0	128	55.9	161	69.4	152	69.4	12.150	0.007
	6 points	78	35.0	101	44.1	71	30.6	67	30.6		
Timepoint 5	0 points	160	75.1	159	72.9	180	78.9	175	83.7	8.245	0.041
	6 points	53	24.9	59	27.1	48	21.1	34	16.3		
Timepoint 6	0 points	176	85.48	178	85.2	189	86.7	185	91.6	4.865	0.182
	6 points	30	14.6	31	14.8	29	13.3	17	8.4		
Timepoint 7	0 points	224	92.9	219	90.5	221	91.7	230	97.5	10.297	0.016
	6 points	17	7.1	23	9.5	20	8.3	6	2.5		

0 points: Defecation was done. 6 points: Patients had no defecation.

Table 4. Subgroup comparison on the abdominal distension

Observation points		Control group		CS group		ECS group		ECS & EA group		x^2	*P*
		%	*N*	%	*N*	%	*N*	%	*N*		
Timepoint 1	0 points	182	73.7	186	74.1	204	82.3	186	74.7	6.877	0.076
	2 points	64	25.9	64	25.5	44	17.7	63	25.3		
	4 points	1	0.4	1	0.4	0	0	0	0		
Timepoint 2	0 points	202	83.1	198	80.5	219	88.3	219	89.0	9.662	0.022
	2 points	40	16.5	47	19.1	27	10.9	26	10.6		
	4 points	1	0.4	1	0.4	2	0.8	1	0.4		
Timepoint 3	0 points	215	92.3	225	93.0	234	96.3	215	90.7	6.112	0.106
	2 points	17	7.3	17	7.0	7	2.9	20	8.4		
	4 points	1	0.4	0	0	2	0.8	2	0.8		
Timepoint 4	0 points	211	95.0	216	94.3	227	98.3	212	96.8	5.800	0.122
	2 points	10	4.5	13	5.7	4	1.7	7	3.2		
	4 points	1	0.5	0	0	0	0	0	0		
Timepoint 5	0 points	206	96.7	209	95.9	224	98.2	204	97.6	2.548	0.467
	2 points	7	3.3	9	4.1	4	1.8	5	2.4		
	4 points	0	0	0	0	0	0	0	0		
Timepoint 6	0 points	202	98.1	205	98.1	214	98.2	199	98.5	0.154	0.985
	2 points	4	1.9	4	1.9	4	1.8	3	1.5		
	4 points	0	0	0	0	0	0	0	0		
Timepoint 7	0 points	236	98.3	240	99.2	236	97.9	235	99.6	3.316	0.345
	2 points	4	1.7	2	0.8	5	2.1	1	0.4		
	4 points	0	0	0	0	0	0	0	0		

0 points: No distension was present. 2 points: Distension was more obvious but tolerable. 4 points: Distension was difficult to endure and intestinal form for full abdominal distension was present.

were analyzed using ANOVA for normal distribution variables or Kruskal-Wallis test for non-normal distribution variables. The least significant difference (LSD) method for multi comparisons was performed if the tests were statistically significant. Log rank test was used to

Table 5. Subgroup comparison on abdominal pain

Observation points		Control group		CS group		ECS group		ECS & EA group		x^2	*P*
		%	*N*	%	*N*	%	*N*	%	*N*		
Timepoint 1	0 points	163	66.0	179	71.3	187	75.4	170	68.3	4.989	0.173
	2 points	81	32.8	65	25.9	54	21.8	75	30.1		
	4 points	3	1.2	7	2.8	7	2.8	4	1.6		
Timepoint 2	0 points	188	77.4	197	80.1	215	86.7	205	83.7	7.773	0.051
	2 points	54	22.2	48	19.5	29	11.7	38	15.5		
	4 points	1	0.4	1	0.4	4	1.6	2	0.8		
Timepoint 3	0 points	209	89.7	219	90.5	224	92.2	216	91.1	0.957	0.812
	2 points	24	10.3	22	9.1	19	7.8	21	8.9		
	4 points	0	0	1	0.4	0	0	0	0		
Timepoint 4	0 points	210	94.2	217	94.8	225	97.0	204	93.2	3.535	0.316
	2 points	11	4.9	11	4.8	7	3.0	14	6.4		
	4 points	1	0.4	1	0.4	0	0	1	0.5		
Timepoint 5	0 points	208	97.7	208	95.4	227	99.6	204	97.6	8.130	0.043
	2 points	5	2.3	9	4.1	1	0.4	4	1.9		
	4 points	0	0	1	0.5	0	0	1	0.5		
Timepoint 6	0 points	202	98.1	202	96.7	215	99.1	198	98.0	3.146	0.370
	2 points	4	1.9	7	3.3	2	0.9	2	1.0		
	4 points	0	0	0	0	0	0	2	1.0		
Timepoint 7	0 points	239	98.8	239	98.8	239	98.8	231	97.1	3.304	0.347
	2 points	1	0.4	2	0.8	1	0.4	5	2.1		
	4 points	0	0	1	0.4	1	0.4	0	0		

0 points: No abdominal pain was present. 2 points: Patients had mild pain, but no pain treatment was needed. 4 points: Patients had severe pain and needed pain treatment.

Table 6. Subgroup comparison on nausea and vomiting

Observation points		Control group		CS group		ECS group		ECS & EA group		x^2	*P*
		%	*N*	%	*N*	%	*N*	%	*N*		
Timepoint 1	0 points	206	83.4	206	82.1	212	85.5	208	83.5	1.138	0.768
	2 points	41	16.6	42	16.7	35	14.1	41	16.5		
	4 points	0	0	3	1.2	1	0.4	0	0		
Timepoint 2	0 points	217	89.3	225	91.5	233	94.0	229	93.1	4.796	0.187
	2 points	26	10.7	20	8.1	14	5.6	15	6.1		
	4 points	0	0	1	0.4	1	0.4	1	0.4		
Timepoint 3	0 points	219	94.0	236	97.5	235	96.3	233	97.9	8.252	0.041
	2 points	14	6.0	6	2.5	7	2.9	3	1.3		
	4 points	0	0	0	0	1	0.4	1	0.4		
Timepoint 4	0 points	215	96.4	225	98.3	228	97.4	219	100.0	4.543	0.208
	2 points	7	3.1	2	0.9	4	1.7	0	0		
	4 points	0	0	2	0.9	0	0	0	0		
Timepoint 5	0 points	209	97.7	214	98.2	223	97.8	209	99.5	5.295	0.151
	2 points	3	1.4	4	1.8	5	2.2	0	0		
	4 points	1	0.5	0	0	0	0	0	0		
Timepoint 6	0 points	203	98.5	208	99.5	217	99.5	201	99.5	2.086	0.555
	2 points	3	1.5	1	0.5	1	0.5	1	0.5		
	4 points	0	0.0	0	0.0	0	0.0	0	0.0		

Timepoint 7	0 points	239	99.6	242	100.0	239	99.2	236	100.0	3.642	0.303
	2 points	0	0.0	0	0.0	1	0.4	0	0.0		
	4 points	1	0.4	0	0.0	1	0.4	0	0.0		

0 points: No nausea and vomiting were present. 2 points: Nausea was present but without vomiting. 4 points: Patients vomited gastric juice or bile.

Table 7. Subgroup comparison on hunger

Observation points		Control group		CS group		ECS group		ECS & EA group		x^2	*P*
		%	*N*	%	*N*	%	*N*	%	*N*		
Timepoint 1	0 points	203	82.2	200	79.7	198	79.8	191	76.7	2.478	0.479
	2 points	44	17.8	47	18.7	49	19.8	55	22.1		
	4 points	0	0.0	4	1.6	1	0.4	3	1.2		
Timepoint 2	0 points	133	54.7	139	56.5	150	60.5	131	53.5	2.773	0.428
	2 points	101	41.6	101	41.1	88	35.5	102	41.6		
	4 points	9	3.7	6	2.4	10	4.0	12	4.9		
Timepoint 3	0 points	97	41.8	111	45.9	116	47.7	115	48.7	2.596	0.458
	2 points	98	42.2	100	41.3	99	40.7	82	34.7		
	4 points	37	15.9	31	12.8	28	11.5	39	16.5		
Timepoint 4	0 points	91	41.0	106	46.3	113	48.7	101	46.1	3.030	0.387
	2 points	77	34.7	73	31.9	73	31.5	73	33.3		
	4 points	54	24.3	50	21.8	46	19.8	45	20.5		
Timepoint 5	0 points	87	40.8	96	44.0	100	44.1	94	45.0	1.416	0.702
	2 points	57	26.8	62	28.4	62	27.3	57	27.3		
	4 points	69	32.4	60	27.5	65	28.6	58	27.8		
Timepoint 6	0 points	82	39.8	92	44.0	95	43.6	86	42.6	1.143	0.767
	2 points	54	26.2	46	22.0	60	27.5	47	23.3		
	4 points	70	34.0	71	34.0	63	28.9	69	34.2		
Timepoint 7	0 points	95	39.6	102	42.1	103	42.7	101	42.8	0.808	0.847
	2 points	65	27.1	49	20.2	58	24.1	39	16.5		
	4 points	80	33.3	91	37.6	80	33.2	96	40.7		

0 points: No hunger was present. 2 points: Patients had hunger and wanted to eat some food. 4 points: Patients had great hunger and wanted to eat regular diet.

analyze the event data. All statistical tests were based on two-sided probability. The actual number divided by the total number of assigned treatments during hospitalization was the percentage of compliance.

Results

From October 2009 to December 2011, 1029 patients who underwent abdominal surgery were enrolled for eligibility. Of these, 20 patients were excluded after randomization, leaving 1009 subjects for the following treatment. 114 patients were lost during the follow-up for the following reasons including drop-out (n=26), compliance rate < 80% (n=58), taking illicit drugs (n=31) and wrong assigning (n=6), and more than 2 reasons above (n=7). Thus, a total of 895 patients were included for the per protocol analysis (**Figure 1**).

Baseline demographic and clinical characteristics

The sample sizes of control group, CS group, ECS group and ECS & EA group were 252, 254, 252, and 251, respectively. The numbers of sex (male, female) were (129, 123), (127, 127), (133, 119) and (119, 132) in each group, respectively. The mean ages of each group were 53.5, 54.3, 53.7 and 53.2, respectively. No significant difference was found on the gender ratio, mean age, the number of emergency operation, elective operation and limited operation, the percentage of hepatobiliary operation and gastrointestinal operation among 4 groups

Table 8. Patient demographic and baseline characteristics

Variables	All patients	Group A	Group B	Group C	Group D	P
No.	1009	252	254	252	251	-
Age Mean (SD)	53.67±13.26	53.5±12.8	54.3±13.1	53.7±14.1	53.2±13.1	0.811
Male gender, n (%)	508 (50.3)	129 (51.2)	127 (50.0)	133 (52.8)	119 (47.4)	0.672
Occupation, n (%)	1007	252	254	251	250	
Professional and technical	53 (5.3)	15 (6.0)	15 (5.9)	13 (5.2)	10 (4.0)	0.573
Business executives and managers	21 (2.1)	3 (1.2)	6 (2.4)	3 (1.2)	9 (3.6)	
Clerks	29 (2.9)	7 (2.8)	7 (2.8)	6 (2.4)	9 (3.6)	
Commercial workers	41 (4.1)	15 (6.0)	9 (3.5)	9 (3.6)	8 (3.2)	
Service staff	44 (4.4)	12 (4.8)	8 (3.1)	8 (3.1)	16 (6.4)	
Agriculture, forestry, fishery and animal husbandry	82 (8.1)	20 (7.9)	18 (7.1)	19 (7.6)	25 (10.0)	
Manual laborers	116 (11.5)	35 (13.9)	29 (11.4)	29 (11.6)	23 (9.2)	
Others	621 (61.7)	145 (57.5)	162 (63.8)	164 (65.3)	150 (60.0)	
History of abdominal surgery, n (%)	1009	252	254	252	251	
Yes	182 (18.0)	51 (20.2)	45 (17.7)	46 (18.3)	40 (15.9)	0.659
Stool habits in previous 3 months, n (%)	846	207	211	212	216	
< 1 time/d	32 (3.8)	10 (4.8)	6 (2.8)	6 (2.8)	10 (4.6)	0.854
1 time/d	776 (91.7)	188 (90.8)	194 (91.9)	198 (93.4)	196 (90.8)	
> 1 time/d	38 (4.5)	9 (4.2)	11 (5.3)	8 (3.8)	10 (4.6)	
Stool characteristics in previous 3 months, n (%)	996	247	254	249	246	
Hard	40 (4.0)	6 (2.4)	16 (6.3)	9 (3.6)	9 (3.7)	0.553
Rotten	145 (14.6)	40 (16.2)	39 (15.4)	35 (14.1)	31 (12.6)	
Soft	135 (13.6)	40 (16.2)	29 (11.4)	35 (14.1)	31 (12.6)	
Watery	9 (0.9)	3 (1.2)	3 (1.2)	2 (0.8)	1 (0.4)	
Normal	667 (67.0)	158 (64.0)	167 (65.7)	168 (67.5)	174 (70.7)	
Underlying disease, n (%)	271	60	60	81	70	0.093
Diabetes	36 (13.3)	8 (13.3)	5 (8.3)	11 (13.6)	12 (17.1)	
Coronary heart disease	11 (4.1)	4 (6.7)	2 (3.3)	4 (4.9)	1 (1.4)	
Chronic obstructive pulmonary disease	2 (0.7)	1 (1.7)	0 (0.0)	0 (0.0)	1 (1.4)	
Hypertension	97 (35.8)	14 (23.3)	22 (36.7)	32 (39.5)	29 (41.4)	
Others	125 (46.1)	33 (55.0)	31 (51.7)	34 (42.0)	27 (38.6)	

Group A, the control group; group B, the coarse salt hot compress group; group C, the Evodia hot compress group; group D, the Evodia hot compress + electro-acupuncture group. SD: standard deviation.

(all Ps > 0.05) **Table 8**). The anesthesia method, the time of anesthesia, the time of operation, bleeding volume estimation, using postoperative analgesia pump or not, and placing gastric tube or not were also compared and no significantly statistical difference was detected (all Ps > 0.05).

Therapeutic efficacy on recovery of gastrointestinal function

The time to the first defecation was significantly different among the four groups ($P < 0.05$). Compared with the other three groups, the control group had the shortest time to defecation ($P < 0.05$), while the CS group had the longest time to defecation (95.3±44.8 h). No significant difference was observed for the other outcome measures (all *Ps* > 0.05). The primary outcome measures of the study among the four groups were summarized in **Table 1**. Seen from the **Table 2**, there was significant difference on passing flatus in Timepoint 5 (all *Ps* < 0.05), and no significant difference was observed for other observation timepoints among the four groups ($P > 0.05$). In **Table 3**, the difference on passing flatus was statistically significant in Timepoint 4, Timepoint 5 and Timepoint 7 (all *Ps* < 0.05). In the **Table 4**, there was significant difference on abdominal distension in Timepoint 2 ($P < 0.05$). While the ECS & EA group had the highest percentage of abdominal distension (89%) and the CS group had the lowest percentage (89%). There was significant difference on abdominal pain in Timepoint 2 and Timepoint 5 ($P < 0.05$) (**Table 5**). The ECS group had the highest percentage for no abdominal pain (86.7%, 99.6%) in Timepoint 2 and Timepoint 5, while the CS group had the lowest percentage (77.4%) in Timepoint 2. Significant

difference on nausea and vomiting was observed in Timepoint 3 ($P < 0.05$) and no significant differences were found on other symptoms (**Tables 6**, **7**).

Complications

A total of 14 (1.38%) adverse events were reported in this study. The number of adverse events was 5 (2.0%) in control group, 4 (1.6%) in the CS group, 1 (0.4%) in the ECS group and 4 (1.6%) in the ECS & EA group, respectively. All these adverse events were not caused by treatments. There was 1 death in the control group as a result of brain stem infarction after surgery. No significant difference was observed among the four groups on either all concomitant medications or medications related to gastrointestinal dynamics ($P > 0.05$).

Compliance evaluation and follow-up

The compliance rate was 97.22% in control group, 96.24% in the CS group, 99.79% in the ECS group and 89.65% in the ECS & EA group, with the mean rate of 94.19%. During the period of follow-up, 27 patients were dropped out in this study, including 6 from the ECS & EA group, 4 from the ECS group, 7 from the CS group and 10 from control group. The number of patients who were lost due to lack of curative effect was 1, 0, 0 and 0, and to adverse effect/adverse events was 5, 3, 3 and 3, to the decision from physician stop treatment was 2, 0, 1 and 0, and to their withdrawal from the study by themselves was 3, 3, 0 and 3 in ECS & EA group, ECS group, CS group and control group, respectively.

Discussion

The main purpose of the study was to evaluate the fast recovery of gastrointestinal function with Chinese medicine hot compress and EA, and our comprehensive evaluation analysis showed that Chinese medicine topical therapy was effective and safe. Our study showed that no significant difference was observed on sex, age, occupation and abdominal surgery history among four groups (all *P*s > 0.05). Baseline data among the four groups were balanced. Time to first passing flatus, time to first defecation and time to bowel sounds were the main outcomes for the recovery of gastrointestinal function. Our study also proved that ECS & EA can promote the recovery of gastrointestinal function after abdominal surgery by Chinese medicine hot compress and EA rather than just hot compress. It was worth investigating the evaluation method for clinical efficacy of Chinese medicine. Generally speaking, clinical efficacy evaluation indexes include objective and subjective indicators [13]. Improvement on the symptoms and quality of life for patients is the ultimate goal of the Chinese medicine treatment [4, 14]. In this study, we further emphasized the functional activity and the quality of life evaluation of the human body [15]. Clinical evaluation methods of Chinese medicine included objective indicators, subjective indicators, main outcome measures, secondary outcome evaluation. This study confirmed that the method of combining the main outcome measures and secondary outcome measures could better reflect the efficacy of Chinese medicine. However, there were still limitations. First, the sample size was not quite large. Second, nausea and vomit which could be not be accurately quantified were not investigated in this study.

Fast-track surgery combined with minimally invasive surgical techniques has greatly improved the clinical efficacy and promoted "patient-centered" modern medicine [16, 17]. The trauma of the surgery itself, the impact of anesthesia, gastrointestinal disease and other systemic conditions (such as malnutrition, infections, water and electrolyte balance and so on) will be of a certain impact on gastrointestinal function. As the operations on different parts of the gastrointestinal tract have different effects on motility, the whole gastrointestinal motion should be restored for 3 to 5 days after surgery [18, 19]. The longer the time of inhibition on gastrointestinal function was, the more likely intestinal expansion and flora after surgery would occur. The adverse events include bloating, abdominal pain, and even severe complications such as adhesions and anastomotic leakage.

Therefore, the recovery of gastrointestinal function is the key to rapid recovery after abdominal surgery. Our results verified that the topical application of traditional Chinese medicine could improve the efficacy on gastrointestinal function after abdominal surgery. However, the specific molecular mechanism remains to be investigated.

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Disclosure of conflict of interest

None.

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