Chinese Nursing Research 3 (2016) 176–180

Contents lists available at ScienceDirect

Chinese Nursing Research

journal homepage: http://www.journals.elsevier.com/chinese-nursing-research

Original article

Systematic evaluation on curative effects of traditional Chinese medicine retention enemas for patients with radiation proctitis

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ARTICLE INFO

Article history:
Received 18 June 2016
Received in revised form
24 July 2016
Accepted 24 August 2016
Available online 16 November 2016

Keywords:
Traditional Chinese medicine retention enema
Radiation proctitis
Systematic evaluation
Meta-analysis
Clinical efficiency
Clinical symptoms

ABSTRACT

Objectives: To systematically evaluate the curative effects of traditional Chinese medicine retention enemas for patients with radiation proctitis.
Methods: Reports on randomized controlled trials (RCTs) on traditional Chinese medicine retention enemas in the treatment of radiation proctitis were searched in the Cochrane Library, PubMed, EMBASE, EBSCO, ISI, CNKI, VIP, WanFang Data and CBM databases. The publication dates were from inception to May 2014, and a literature screening, data extraction, quality evaluation and cross checks were independently conducted by two reviewers in accordance with the inclusion and exclusion criteria. A meta-analysis was then carried out using RevMan 5.3 software.
Results: In total, 14 RCTs were included, and of these, only 10 RCTs involving 702 patients were included in the meta-analysis. The meta-analysis showed that the total efficacy of traditional Chinese medicine retention enemas was higher for patients with radiation proctitis compared with that in control group, $RR = 4.83$, 95% *CI* (2.98, 7.84), $P < 0.000\ 01$; the results from four studies indicated that the improvement of clinical symptoms due to traditional Chinese medicine retention enemas was higher than that of the control group.
Conclusions: The implementation of traditional Chinese medicine retention enemas could improve the total efficacy of treatment and provide relief in patients with radiation proctitis.
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1. Introduction

Radiation proctitis is an intestinal tract complication induced by large doses of radiotherapy at the site of the rectum. Its clinical symptoms include diarrhea, abdominal pain, mucous and bloody stool, anal pain, tenesmus and functional and mechanical intestinal obstruction.[1,2] It is the most serious complication of the abdominal and pelvic cavity and appears within one to two weeks after radiotherapy. It has no standard effective therapy. According to medical home institutions, the prevalence of radiation proctitis is estimated to be between 10% and 20%.[1] International literature reports the prevalence of radiation proctitis to be between 5% and 20% after radiotherapy treatment for prostate cancer, rectal cancer, bladder cancer, cervical cancer, testicular cancer and uterine cancer.[3] Traditional Chinese medicine uses the role of the intestinal wall to absorb drugs and efficiently achieve the purpose of treatment. Recently, various reports have been developed on the use of traditional Chinese medicine retention enemas, which show some curative effects. However, these results are not consistent. Therefore, the purpose of this systematic review was to evaluate the curative effects of traditional Chinese medicine retention enemas for radiation proctitis and to provide more clinical and drug treatment options for this condition.

2. Materials and methods

2.1. Inclusion and exclusion criteria

Studies were included if they met all of the following criteria: (1) Type of study: randomized controlled trials; (2) Participants: patients with radiation proctitis induced by radiotherapy; age, type of

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Peer review under responsibility of Shanxi Medical Periodical Press.

http://dx.doi.org/10.1016/j.cnre.2016.11.007
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disease, length and stage of disease were not limited; languages were English and Chinese; (3) Type of intervention: studies comparing traditional Chinese medicine retention enemas with Western medicine retention enemas; the decoction of traditional Chinese medicine were not limited, and Western medicine included gentamicin, lidocaine or procaine and hormones, with or without normal saline; (4) Outcomes: ①The total efficacy; the total efficacy (%) = (total cases-ineffective cases)/total cases × 100%; inefficacy was defined as clinical symptoms and endoscopic checks having no improvement or worsening; total effectiveness included cure, significant curative effects, effectiveness and improvement; ② Clinical symptoms score.

Studies were excluded if they met the following criteria: (1) Duplicated publications; (2) Animal experiments.

2.2. Research strategy

The Cochrane Library, PubMed, EMBASE, EBSCO, ISI, CNKI, VIP, WanFang Data and CBM databases were searched from inception to May 2014. The studies' included references were also traced. The following keywords were used in the database search: coloclysis*, enema*, clys*, enteroclysis, radioactive proctitis, radioactive rectitis, radiation rectitis, radiation-induced rectitis, radiation proctopathy, radiation proctitis, radiation-induced proctitis. These terms were adjusted for each database. Google Scholar was searched as a complement to the above search.

2.3. Study selection

Two authors independently examined titles and abstracts to exclude clearly irrelevant reports. They then examined the full text of each report to determine its eligibility. Disagreements about a study's inclusion were resolved by discussions among the three authors.

2.4. Data extraction and quality evaluation

Two authors independently extracted the characteristics and assessed the methodological quality of the included studies using a piloted electronic data extraction form. The content from the data extraction included first author, year of publication, study design, participants' characteristics, drug, enema method, dosage, length of treatment and outcomes, among others. The methodological quality was assessed using the risk of bias tools in accordance with the Cochrane Handbook 5.1.0.[4] The risk of bias tools included six terms: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias. The authors of the included studies were contacted if important data were unclear or not reported. Disagreements were resolved by checks of the studies and discussion among the three authors.

2.5. Statistical analysis

Cochrane Collaboration Review Manage software (RevMan 5.3) was used for the data analysis. Dichotomous data were reported as relative risk (*RR*) with a 95% confidence interval (95%*CI*). Statistical heterogeneity was quantified using a chi-square test, and inconsistency was interpreted based on I^2. If the pooled studies lacked heterogeneity ($P > 0.1$, $I^2 < 50\%$), the fixed effects model was used; otherwise, the random effects model was used. A sensitivity analysis, subgroup analysis or Meta-regression was used when needed. If the heterogeneity was substantial, then only a descriptive analysis was applied. The level of statistical significance was 0.05.

3. Results

3.1. Included studies and study characteristics

In total, 1211 studies were retrieved. After duplicates were removed, 476 studies remained. The initial screening of reading titles and abstracts collected 109 studies. Then, full text articles were reviewed, and 14 RCTs satisfied the selection criteria. Ultimately, 10 RCTs[5–14] were included in this meta-analysis (Fig. 1). In total, 702 patients were enrolled in these studies, with 366 patients in the experimental group and 336 patients in the control group.

The study characteristics are shown in Table 1. All of studies referred to randomization; Two studies[5,9] applied a random number table, and the remaining studies provided no detailed descriptions of their method of randomization. None of the included studies mentioned allocation concealment, blinding and other bias.

3.2. Meta-analysis

3.2.1. The total efficiency

In total, the meta-analysis included 10 studies[5–14] involving 702 patients (366 patients in the experimental group, 336 patients in the control group). The meta-analysis showed that traditional Chinese medicine retention enemas significantly improved the total efficiency [OR = 4.83; 95%*CI*, (2.98, 7.84); $P < 0.000\,01$] with no significant heterogeneity ($P < 0.67$, $I^2 = 0\%$) (Fig. 2).

The sensitivity analysis showed that the random effect model and fixed effect model were consistent in indicating a stable result.

3.2.2. Clinical symptoms score

In total, 4 article[5,9,10,12] reported the clinical symptoms scores for abdominal pain, diarrhea, and tenesmus and defecation difficulty. The meta-analysis was unable to use this information because of different standards for scoring symptoms, but these studies indicated that the experimental group experienced more improvement than the control group of their tenesmus and defecation difficulty. Two studies[9,10] found that traditional Chinese medicine retention enemas were better at improving abdominal pain, while Zhang et al.[12] found no significant difference between the two groups in improvement of abdominal pain. Two studies[10,12] found no significant difference between the two groups in improvement of diarrhea.

Two articles[5,9] reported the clinical symptoms scores of hematochezia and stool characteristics and frequency. The meta-analysis was unable to use this information because of skewed data and small sample sizes, but both studies reported that the experimental group experienced more improved clinical symptoms than the control group.

3.3. Safety analysis

Only 1 study[5] reported adverse events and relapse. No adverse events were indicated in the two groups, and no recurrence was shown in the experimental group. Two cases of recurrence were reported in the control group.

3.4. Reporting bias

A funnel plot showed basic asymmetry, which indicated an unlikelihood of reporting bias among the included studies (Fig. 3).

4. Discussion

This review included 14 RCTs to compare the curative effects of traditional Chinese medicine retention enemas with Western

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