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Application of Drug Retention Enema Combined with Deep Hyperthermia in the Rehabilitation of Radiation Proctitis in Patients with Cervical Cancer

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Abstract: *Objective*: To investigate the efficacy of drug retention enema combined with deep hyperthermia in the treatment of radiation proctitis in patients with cervical cancer. *Methods*: A randomized controlled study was conducted, selecting 60 patients with radiation proctitis after cervical cancer, who were randomly divided into a control group and an experimental group of 30 cases each using the random number table method. Both groups of patients received conventional treatment. On this basis, the control group received drug retention enema. The experimental group was treated with deep hyperthermia in addition to the control group. Both groups were treated continuously for 1 month. Compare the clinical symptoms, quality of life, inflammatory markers, and effective treatment rate of the two groups after treatment. *Results*: Compared with the control group, the improvement in clinical symptoms after treatment in the experimental group was significantly better than that in the former ($P < 0.05$); The quality of life score was significantly higher than that of the control group ($P < 0.05$), and the inflammatory markers were significantly lower than those of the control group ($P < 0.05$); the effective treatment rate was significantly higher than that of the control group ($P < 0.05$). *Conclusion*: Drug retention enema combined with deep hyperthermia has a good therapeutic effect on radiation proctitis in cervical cancer patients undergoing radiotherapy, which can alleviate patient symptoms, improve quality of life, inhibit inflammatory response, and increase the effective treatment rate.

Keywords: Radiation proctitis; Enema; Deep hyperthermia

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1. Introduction

Cervical cancer is the most common malignant tumor of the female reproductive system in China, and radiotherapy is one of its main treatments [1]. However, radiotherapy may cause radiation proctitis, which seriously affects the patient's quality of life and treatment effect [2, 3]. The treatment of radiation proctitis has always been a difficult problem in clinical practice, and finding effective and safe treatment methods has become a top priority [4]. Drug

retention enema is a method of administering drugs through the rectum, allowing the drugs to directly act on the lesion site to improve drug concentration and therapeutic effect [5, 6]. Deep hyperthermia, on the other hand, enhances the penetration ability of drugs and the permeability of cell membranes by raising the local temperature, thereby improving the efficacy of the drugs [7]. Both of these methods have certain advantages in the treatment of radiation proctitis. This study aims to investigate the effect of drug retention enema combined with deep hyperthermia in the treatment of radiation proctitis in cervical cancer patients undergoing radiotherapy. By collecting relevant literature and case data, the treatment mechanism and efficacy of drug retention enema combined with deep hyperthermia are analyzed, to provide new ideas and methods for the clinical treatment of radiation proctitis.

2. Subjects and methods

2.1. Subjects

This study included 60 cervical cancer patients from this hospital between May 2023 and May 2024. The inclusion criteria included the following: (1) All patients were diagnosed with cervical cancer and were undergoing or had completed radiotherapy; (2) Patients were between 35 and 65 years of age to ensure the applicability of the study results; (3) Clinically diagnosed with radiation proctitis [8]; (4) No other serious complications or drug contraindications to ensure the reliability of the study results.

Exclusion criteria included the following: (1) Patients who are allergic to enema drugs or intolerant to deep hyperthermia equipment; (2) Patients with other diseases that affect the therapeutic effect (such as severe cardiopulmonary insufficiency or digestive system diseases); (3) Patients with poor treatment compliance or incomplete follow-up data to avoid data bias affecting the study results.

2.2. Research methods

2.2.1. Grouping and randomization

A randomized controlled trial design was used to randomly divide 60 patients who met the inclusion and exclusion criteria into two groups: a control group and an experimental group, with 30 cases in each group. Random grouping was performed using the random number table method to reduce selection bias and ensure the comparability of baseline characteristics between the two groups. The control group received drug retention enema treatment; the experimental group received drug retention enema combined with deep hyperthermia.

2.2.2. Treatment regimen

(1) Conventional treatment: Provide good psychological care to patients; educate and guide patients on dietary principles; implement nutritional intervention treatment. Drug treatment is administered using anti-inflammatory drugs, antibiotics, probiotics, antioxidants, etc.

(2) Control group: In addition to conventional treatment, the control group received drug retention enema treatment. The choice of drugs was based on the patient's specific condition, physical fitness, and allergy history. Common retention enema agents: 100 ml of 0.9% sodium chloride injection + 5mg dexamet hasone sodium phosphate/4mg betamethasone sodium phosphate + 5mg vitamin B12 injection + 0.2g lidocaine hydrochloride injection. For patients with hematochezia, thrombin powder 1000/2000 units is added to the enema according to the degree and amount of hematochezia. The depth of the enema is determined by the inflammatory site of proctitis based on the patient's colonoscopy. It is generally

10cm/20cm.Frequency: BID, for 1 month. Retention time is at least 30min.

(3) Experimental group:Patients in the experimental group received deep hyperthermia in addition to the drug retention enema, using the N-9000 microwave tumor hyperthermia device for treatment. The two enema ad ministrations are spaced 4–6 hours apart, with one scheduled 1 hour before hyperthermia to ensure optimal local absorption of the drug. The treatment temperature was controlled below 43 ℃ to ensure patient tolerance and safety. The treatment position was prone, and the treatment duration was 45 to 50 minutes. Execution frequency: Retention enema BID + deep hyperthermia QD, for 1 month, with a retention time of at least 40 minutes.

2.2.3. Evaluation index

The main evaluation indexes of this study included:

(1) Symptom improvement, mainly through patient self-assessment and observation records of clinical symptoms, including typical symptoms of radiation proctitis such as abdominal pain, diarrhea, and hematochezia; For the assessment of abdominal pain, the visual analog scale (VAS) was used to quantify the degree of pain, with scores ranging from 0 to 10, where higher scores indicate more severe pain. Significant relief of abdominal pain was defined as a reduction in pain of more than 50%. For diarrhea, symptom improvement was based on the reduction in the patient's daily number of bowel movements. A return to the normal range of bowel movements (1–2 times/day) was considered a significant improvement. The improvement of hematochezia was comprehensively assessed by fecal occult blood tests and the reduction in the amount of macroscopically visible blood. If the occult blood test results were negative for 3 consecutive days or no bloodstains were observed macroscopically, it was determined that the symptom improvement was significant.

(2) Quality of life score: The WHO Quality of Life-100 (WHOQOL-100) scale was used to assess changes in patients' physical, psychological, and social relationships. The score ranges from 0 to 120, with higher scores indicating better quality of life.

(3) Changes in inflammatory markers: Inflammatory response before and after treatment was assessed by laboratory testing of indicators such as C-reactive protein (CRP) and white blood cell count.

(4) The evaluation of effective treatment rate is comprehensively determined based on the degree of symptom improvement, the improvement in quality of life, and changes in inflammatory markers. Effective indicates that the patient's symptoms have been alleviated but not completely eliminated, the quality of life has been improved, and inflammatory markers have significantly decreased but have not returned to normal.

2.2.4. Data statistics and analysis

Data will be collected through patient medical records, follow-up questionnaires, and laboratory test results, and will be checked after double entry to ensure data accuracy. Statistical analysis of all data will be performed using SPSS 2.7.0 software. The Kolmogorov-Smirnov test will be used for normality testing. For data conforming to a normal distribution, an independent samples t-test will be used for inter-group comparison. For data that did not conform to a normal distribution, the Mann-Whitney U test was used. The significance level for all statistical tests was set at $P < 0.05$. A P-value less than 0.05 was considered statistically significant.

3. Results

3.1. General information of patients

In this study, there were no significant differences in baseline characteristics such as age, disease course, and previous treatment history between the two groups of patients, indicating comparability. The average age of patients in the control group was 52.4 years (range: 35–65 years), and the average disease course was 3.2 years. The average age of patients in the experimental group was 51.8 years (range: 35–65 years), and the average disease course was 3.3 years. The previous treatment history (such as surgery, chemotherapy) of the two groups of patients was similar. **Table 1** summarizes the baseline characteristics of the two groups of patients.

Table 1. Comparison of general information of patients

Baseline characteristics	Control group (n=30)	Experimental group (n=30)	t/x^2	*P*
Average age (years)	52.41 ± 7.03	51.81 ± 6.93	0.671	> 0.05
Disease course (years)	3.21 ± 1.42	3.32 ± 1.54	0.751	> 0.05
Previous surgical history (%)	44%	42%	0.834	> 0.05
Previous chemotherapy history (%)	60%	58%	0.782	> 0.05

3.2. Improvement of proctitis symptoms in patients

The experimental group had significantly higher improvement rates in diarrhea, abdominal pain, and hematochezia symptoms than the control group. The diarrhea improvement rate in the experimental group was 83.33%, while it was 60% in the control group. The improvement rate of abdominal pain was 70%, while that of the control group was 43.33%; the improvement rate of hematochezia was 80%, while that of the control group was 50%. These data indicate that the patients in the experimental group had milder symptoms and better treatment effects, as detailed in **Table 2**.

Table 2. Comparison of improvement in proctitis symptoms before and after intervention in the two groups

	Diarrhea improvement rate (%)		Abdominal pain improvement rate (%)		Hematochezia improvement rate (%)	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group (n=30)	40.00%	60.00%	40.00%	43.33%	26.67%	50.00%
Experimental group (n=30)	43.33%	83.33%	36.67%	70.00%	43.33%	80.00%
x^2	0.069	4.022	0.071	4.344	1.832	5.934
P	0.793	0.045	0.791	0.037	0.176	0.015

3.3. Patient quality of life

The quality of life score of patients in the experimental group (74.8 ± 9.3) was significantly higher than that of the control group (65.4 ± 10.2). The experimental group scored higher than the control group in terms of physical functioning, mental health, social relationships, and environmental satisfaction. These results further validate the significant effect of drug retention enema combined with deep hyperthermia in improving patients' quality of life.

Table 3. Comparison of quality of life scores between the two groups before and after intervention

	Physical functioning (x±s)		Mental health (x±s)	
	Before treatment	**After treatment**	**Before treatment**	**After treatment**
Control group (n=30)	60.12 ± 8.71	64.34 ± 9.82	58.30 ± 9.51	62.72 ± 10.31
Experimental group (n=30)	61.23 ± 9.21	72.51 ± 8.71	59.41 ± 9.80	70.43 ± 9.11
t	-0.480	-3.409	-0.445	-3.069
p	0.633	0.001	0.658	0.003
	Social relationships (x±s)		**Environment satisfaction (x±s)**	
	Before treatment	**After treatment**	**Before treatment**	**After treatment**
Control group (n=30)	59.52 ± 8.81	63.20 ± 9.60	57.81 ± 8.22	61.51 ± 8.92
Experimental group (n=30)	60.21 ± 9.12	71.61 ± 8.92	58.71 ± 8.43	69.83 ± 7.81
t	-0.298	-3.515	-0.419	-3.844
p	0.767	0.001	0.677	0.000

3.4. Inflammatory markers and effective treatment rate of patients

The experimental group was significantly better than the control group in terms of improvement in inflammatory markers. The experimental group had significantly lower levels of CRP, white blood cell count, erythrocyte sedimentation rate, and IL-6 than the control group ($P < 0.05$), indicating that the inflammatory response in the experimental group was better controlled. In addition, the effective treatment rate of the experimental group was 88%, significantly higher than the 65% of the control group ($P = 0.019$), further supporting the advantage of drug retention enema combined with deep hyperthermia in improving treatment effectiveness, as detailed in **Table 4**.

Table 4. Comparison of inflammatory markers and effective treatment rate between the two groups before and after intervention

	CRP level (mg/L) (x±s)		White blood cell count (10^9/L) (x±s)		Effective treatment rate
	Before treatment	**After treatment**	**Before treatment**	**After treatment**	
Control group (n=30)	8.51 ± 2.31	7.32 ± 1.83	7.92 ± 1.71	7.34 ± 1.66	65%
Experimental group (n=30)	8.42 ± 2.04	6.24 ± 1.82	7.81 ± 1.52	5.91 ± 1.42	88%
t/x^2	0.160	2.292	0.263	3.585	5.501
p	0.873	0.026	0.793	0.001	0.019
	Erythrocyte sedimentation rate (mm/h) (x±s)		**IL-6(pg/mL) (x±s)**		**Effective treatment rate**
	Before treatment	**After treatment**	**Before treatment**	**After treatment**	
Control group (n=30)	22.54 ± 6.13	20.43 ± 5.81	16.32 ± 4.23	15.72 ± 3.91	65%
Experimental group (n=30)	21.83 ± 5.92	14.30 ± 4.72	15.94 ± 4.03	11.63 ± 3.12	88%
t/x^2	0.456	4.485	0.356	4.478	5.501
p	0.650	0.000	0.723	0.000	0.019

4. Discussion

4.1. Synergistic effect of drug retention enema and deep hyperthermia

4.1.1. Improvement of clinical symptoms

This study, by comparing the treatment effects of the experimental group and the control group, verified the significant efficacy of drug retention enema combined with deep hyperthermia in alleviating the symptoms of radiation proctitis in cervical cancer patients undergoing radiotherapy. Lai *et al.* showed that enema treatment can effectively alleviate patients' symptoms such as diarrhea, abdominal pain, and hematochezia, and has shown high safety and patient acceptance in clinical applications [9]. Research has found that enemas with decoction of traditional Chinese medicine significantly improved proctitis symptoms, especially in reducing inflammatory response and alleviating pain. This result is consistent with the findings of this study, supporting the effectiveness of drug retention enema in alleviating symptoms of radiation proctitis. In terms of symptom improvement, the improvement rate of symptoms such as diarrhea, abdominal pain, and hematochezia in the experimental group was significantly higher than that in the control group, indicating that the combined treatment regimen is more effective in improving existing symptoms. These results are consistent with the study by Zhu *et al.*, which showed that the combination of hyperthermia and chemoradiotherapy significantly improved symptom relief and enhanced the therapeutic effect in patients [10]. Zhu *et al.* pointed out that hyperthermia enhances the local concentration of chemoradiotherapy drugs by increasing local blood flow, thereby achieving better anti-tumor effects [10]. This mechanism may also apply to the combined treatment regimen in this study, explaining the more significant symptom improvement in the experimental group.

4.1.2. Improvement of quality of life

Lai's research also emphasized that enema treatment can improve patients' quality of life [9]. This finding is consistent with the result that the quality of life scores of patients in the experimental group in this study were significantly higher than those in the control group, which further verifies the clinical value of drug retention enema. The study by Luo *et al.* indicated that drug retention enema with traditional Chinese medicine can reduce the levels of IL-1β, IL-8, and TNF-α in the patient's serum by inhibiting the release of inflammatory factors, reduce the inflammatory response of local tissues, thereby improving the patient's clinical symptoms, and improve the patient's quality of life [11]. This mechanism is consistent with the effect of drug retention enema combined with microwave hyperthermia in this study, further supporting the advantages of combined treatment in improving patients' quality of life.

4.1.3. Improvement of inflammatory markers

In this study, the inflammatory markers of patients in the experimental group were significantly better than those in the control group, including CRP, white blood cell count, and IL-6, etc. This further confirms the synergistic effect of drug retention enema and deep hyperthermia in reducing the inflammatory response. The results of this study indicate that deep hyperthermia may improve the tumor microenvironment and enhance the anti-inflammatory ability of the immune system, thereby more effectively controlling the inflammatory response. Xie *et al.* explored the effect of hyperthermia on the tumor microenvironment and immune response in their study [12]. Hyperthermia can not only directly act on tumor tissue, but also regulate the tumor microenvironment, improve local inflammatory response, and enhance the anti-tumor effect of the immune system. The results of this study provide theoretical support for the improvement of inflammatory markers in this study, indicating that hyperthermia may

control the inflammatory response through multiple mechanisms in combined treatment. Xie *et al.* also pointed out that hyperthermia can enhance the activity of immune cells and promote the clearance of inflammatory factors, which may be one of the reasons for the significant improvement in inflammatory markers in the experimental group patients [12].

4.1.4. Improvement of effective treatment rate

This study found that the effective treatment rate of the experimental group was significantly higher than that of the control group (88% vs. 65%, P=0.019). This result indicates that drug retention enema combined with microwave hyperthermia has a significant advantage in improving the treatment effect of radiation proctitis in cervical cancer patients after radiotherapy. Zhu *et al.* studied the application of hyperthermia combined with chemoradiotherapy in the treatment of locally advanced cervical cancer and found that hyperthermia significantly improved the effective treatment rate and delayed tumor progression [10]. These research results are consistent with the findings of this study, further demonstrating the important role of hyperthermia in combined treatment. Zhu *et al.* pointed out that hyperthermia can enhance the local concentration and anti-tumor effects of drugs, thereby improving the overall effect of treatment [10]. This mechanism may explain the higher effective treatment rate observed in the experimental group patients in this study. The experimental group patients, under combined treatment, not only experienced a significant reduction in proctitis symptoms but also a significant improvement in overall treatment effectiveness. This finding has important clinical significance, especially in the treatment of radiation proctitis, a complex complication.

4.2. The necessity of individualized treatment

Although this study demonstrates the significant efficacy of drug retention enema combined with microwave hyperthermia, it is also necessary to emphasize the importance of individualized adjustments based on the patient's specific condition, physique, and allergy history during the treatment process. Luo *et al.* mentioned in their research that the effect of drug retention enema with traditional Chinese medicine is closely related to the individual differences of patients, and personalized treatment plans need to be formulated for different patients to achieve the best results [11]. In this study, different responses to treatment were also observed in some patients, suggesting that changes in the patient's condition should be closely monitored in clinical applications to ensure the safety and effectiveness of the treatment.

4.3. Limitations of the study

Although this study shows that drug retention enema combined with microwave hyperthermia has significant efficacy in the treatment of radiation proctitis in cervical cancer patients undergoing radiotherapy, there are still some limitations. First, the sample size was 60 cases, which, although having a certain statistical power, is relatively small and may affect the generalizability of the results. Future studies may consider increasing the sample size to verify the broad applicability of these findings. In addition, the follow-up time of this study was short, limited to the treatment period, and failed to assess long-term efficacy and recurrence. Therefore, longer follow-up studies should be conducted in the future to comprehensively evaluate the long-term effects and safety of this combined treatment. The treatment regimen used in the study needs to be adjusted according to individual patient differences in practical applications, especially in terms of patient constitution and disease complexity, which may affect the treatment results.

5. Conclusion

Drug retention enema combined with deep hyperthermia has shown significant efficacy in treating radiation proctitis in cervical cancer patients undergoing radiotherapy. This treatment regimen not only significantly alleviates patients' symptoms, such as diarrhea, abdominal pain, and hematochezia, but also significantly improves their quality of life. However, in actual clinical application, individualized treatment adjustments must be made based on the patient's specific condition, physical fitness, and allergy history, among other factors. Each patient's response may vary, so these individual differences should be considered when developing a treatment plan to ensure the safety of the treatment and maximize its efficacy. Future studies should further explore the long-term efficacy of this combined treatment and evaluate its application on a larger scale to provide more effective and safer treatment strategies, helping patients manage radiation proctitis better after radiotherapy for cervical cancer. Through these efforts, a more scientific basis can be provided for clinical practice, ensuring that patients receive the best possible health outcomes when receiving treatment.

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Disclosure statement

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