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Comparative Effectiveness of Medical Radiation Protection Spray and Triethanolamine Cream in Preventing and Treating Radiodermatitis in Breast Cancer Patients

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Abstract: *Objective:* This study investigates the preventive and therapeutic effects of medical radiation protection spray (Bergmann) compared to triethanolamine cream in patients undergoing radiotherapy following breast cancer surgery. *Methods:* Ninety patients with breast cancer who received postoperative radiotherapy between July 2018 and July 2021 were randomly divided into the Bergmann treatment (experimental) group and the triethanolamine cream treatment (control) group, with 45 patients in each group. Radiodermatitis severity was assessed using the RTOG radiodermatitis grading standards. *Results:* The radiation dose required to develop grade I radiodermatitis was significantly higher in the experimental group compared to the control group, at (36.13 ± 1.17 Gy) and (25.38 ± 0.63 Gy), respectively. At a radiation dose of 30 Gy, the proportion of grade I radiodermatitis cases in the experimental group was significantly lower than in the control group ($P = 0.002$). At radiation doses of 40 Gy and 50 Gy, the proportion of grade II radiodermatitis cases in the experimental group was also significantly lower than in the control group ($P < 0.001$). No cases of grade III or higher radiodermatitis were observed in the experimental group, while three cases of grade III radiodermatitis occurred in the control group, although the difference was not statistically significant. No patients in the experimental group discontinued treatment due to radiodermatitis or mucosal reactions, whereas two patients in the control group interrupted treatment due to these reactions but eventually completed therapy. *Conclusion:* Bergmann spray effectively prevents radiodermatitis in patients undergoing radiotherapy after breast cancer surgery and is more effective than triethanolamine cream in treating skin lesions. Its ease of use improves the quality of life for patients undergoing radiotherapy and ensures successful treatment completion. Bergmann is suitable for clinical promotion and application.

Keywords: Breast cancer surgery; Radiodermatitis; Triethanolamine cream; Medical radiation protection spray

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1. Introduction

Breast cancer is a malignant tumor originating in the glandular epithelial tissue of the breast. According to the 2018 GLOBOCAN global statistical report [1], the incidence and mortality rates of lung cancer are the highest among all tumors. While the incidence of breast cancer is comparable to that of lung cancer, its prognosis is generally more favorable. However, most patients require radiotherapy following radical surgery.

Radiotherapy is a critical component of comprehensive breast cancer treatment but is often accompanied by side effects. Among these, radiodermatitis is the most common side effect observed in patients undergoing radiotherapy after radical surgery. Radiodermatitis typically manifests as localized redness, swelling, blisters, and other burn-like changes within the irradiated skin area [2]. Severe radiodermatitis can cause significant pain, prolong hospitalization, increase medical costs, and adversely affect treatment outcomes.

This study aims to compare the efficacy of medical radiation protection spray (Bergmann) with triethanolamine cream in preventing and treating radiodermatitis during radiotherapy in breast cancer patients after radical surgery [3]. The objective is to provide patients with a superior option for managing radiodermatitis effectively.

2. Materials and methods

2.1. General information

A total of 90 patients diagnosed with breast cancer and treated with radical surgery at our hospital between July 2018 and July 2021 were included in the study. The patients were divided into an experimental group and a control group, with 45 patients in each group. The experimental group received Bergmann spray applied to the skin in the radiation field twice daily from the initiation of radiotherapy. When grade I skin reactions occurred, the application frequency was increased to four times daily. The control group received triethanolamine cream applied to the skin in the radiation field three times daily after the occurrence of grade I radiodermatitis following radiotherapy.

In the experimental group, patient ages ranged from 37 to 61 years, with a median age of 52 years, while in the control group, ages ranged from 37 to 69 years, with a median age of 53 years.

2.2. Treatment method

All patients were treated using an Elekta medical linear accelerator. The chest wall was irradiated with 6 MeV electron beams in conventional divisions. The chest wall irradiation field was defined as follows:

(1) Upper limit: Lower edge of the clavicle

(2) Lower limit: 2 cm below the contralateral breast fold

(3) Medial limit: Body midline

(4) Lateral limit: Midaxillary line

The radiotherapy dose was administered as DT50Gy/2Gy/25f over 5 weeks.

Patients in the experimental group used medical radiation protection spray prophylactically from the initiation of radiotherapy, applying it as follows:

(1) Prophylactic application: Once 30 minutes before and 10 minutes after radiotherapy, spray the site twice daily.

(2) With redness and swelling: Spray 2–3 times per application, 3 times daily.

(3) With skin ulceration: After debridement, spray 2–3 times per application, 4 times daily.

After completing radiotherapy, the spray was continued for an additional 7–10 days.

For the control group, once grade I radiodermatitis developed during radiotherapy, triethanolamine cream was applied locally to the radiation field three times daily. Residual cream was removed from the skin before radiotherapy sessions.

Radiotherapy doses corresponding to the onset of grade I–IV radiodermatitis were observed and recorded for all patients, along with the duration and resolution time for each grade of skin reaction.

2.3. Radiodermatitis grading standards

Radiodermatitis was graded according to the RTOG acute radiodermatitis grading standards [4,5]:

(1) Grade 0: No noticeable skin changes.

(2) Grade I: Mild erythema or dry skin reaction.

(3) Grade II: Scattered erythema, moist skin reaction, or moderate edema in skin folds.

(4) Grade III: Confluent moist skin reaction with a diameter >1.5 cm.

(5) Grade IV: Skin ulceration, necrosis, or hemorrhage.

2.4. Statistical methods

Statistical analysis was performed using SPSS 22.0. The doses corresponding to skin reactions at all levels were described using the mean ± standard deviation (SD). The χ^2 test was employed to compare categorical data, with a significance level of $P < 0.05$.

3. Results

3.1. Radiation dose for grade I radiodermatitis in the two groups

The radiation dose required to induce grade I radiodermatitis was significantly higher in the experimental group compared to the control group, with doses of 36.13 ± 1.17 Gy and 25.38 ± 0.63 Gy, respectively. This indicates that Bergmann spray effectively prevents radiodermatitis and delays its onset (see **Table 1**).

Table 1. Radiation dose for grade I radiodermatitis in the two groups of patients (mean ± SD, Gy)

Group	Number of cases	Dose for grade I radiodermatitis
Experimental group	45	36.13 ± 1.17
Control group	45	25.38 ± 0.63
P value		< 0.001

3.2. Incidence of grade I radiodermatitis at different radiation doses

At a radiation dose of 30 Gy, the proportion of patients with grade I skin reactions was significantly lower in the experimental group compared to the control group ($P = 0.002$), demonstrating a statistically significant difference. However, at doses of 10, 20, 40, and 50 Gy, no statistically significant differences were observed between the two groups ($P > 0.05$).

3.3. Incidence of grade II radiodermatitis at different radiation doses

At radiation doses of 40 Gy and 50 Gy, the proportion of patients with grade II radiodermatitis in the experimental

group was significantly lower than in the control group ($P < 0.001$). At doses of 10, 20, and 30 Gy, the differences in grade II radiodermatitis incidence between the two groups were not statistically significant ($P > 0.05$) (**Table 2**).

Table 2. Comparison of grade II radiodermatitis incidence between the two groups

Group	Number of cases	Grade II radiodermatitis [*n* (%)]	Below grade II radiodermatitis [*n* (%)]
Experimental group	45	7 (15.6%)	38 (84.4%)
Control group	45	11 (24.4%)	34 (75.6%)
P value		0.292	

3.4. Incidence of grade III skin reactions

No cases of grade III or higher radiodermatitis were observed in the experimental group, whereas 3 cases of grade III radiodermatitis occurred in the control group. The difference between the two groups was not statistically significant ($P > 0.05$).

3.5. Treatment interruptions due to severe radiodermatitis

No patients in the experimental group required treatment interruptions due to severe radiodermatitis or mucosal reactions. In the control group, 2 patients experienced interruptions due to severe radiodermatitis, but treatment was ultimately completed. The difference between the two groups was not statistically significant ($P > 0.05$).

4. Discussion

The role and significance of radiotherapy in tumor treatment have become increasingly prominent, establishing it as one of the primary methods for managing malignant tumors. Radiotherapy delivers a specific dose of radiation to tumors, damaging the DNA of tumor cells to inhibit their growth and induce cell death [6]. This damage includes direct effects of radiation and indirect effects caused by the ionization of water [7], leading to the formation of free radicals. However, normal cells within the radiation field are inevitably exposed to damage. While normal tissues possess self-repair capabilities, repeated radiation exposure can disrupt the balance between tissue damage and repair. Radiodermatitis is one of the most common tissue injuries caused by radiotherapy [8]. Statistics indicate that the incidence of skin damage among cancer patients undergoing radiotherapy is 91.4%, with 58.1% experiencing severe damage that necessitates treatment interruption. Each day of treatment delay reduces the local control rate by 1–3%, exacerbating patient discomfort, and psychological distress, and negatively impacting treatment outcomes and quality of life.

The mechanism underlying radiodermatitis is complex, involving various pathophysiological reactions, microenvironmental regulation, and both treatment-related and patient-related factors [9]. Treatment-related risk factors include the type of radiation source, radiation dose, frequency of exposure, location and area of the irradiated field, and the presence of overlapping radiation fields [10]. Furthermore, the use of radiosensitizing drugs and concurrent radiotherapy and chemotherapy increases the likelihood of radiodermatitis. Patient-specific factors also contribute to radiodermatitis [11], such as obesity, the presence of skin folds, nutritional status, smoking, ultraviolet exposure, individual sensitivity to radiation, and comorbidities such as autoimmune diseases. Rare genetic mutations have also been implicated [12-14], with current research suggesting that mutations in the *Ataxia-Telangiectasia Mutated* (*ATM*) genes increase susceptibility to severe radiodermatitis [15].

Radiotherapy remains a crucial treatment modality for breast cancer. However, it is essential to concurrently enhance understanding of its side effects and develop strategies to mitigate radiotherapy-related complications. Bergmann, the experimental drug used in this study, primarily comprises superoxide dismutase and its stabilizer. This formulation effectively and promptly removes harmful free radicals generated during radiotherapy, interrupts the free radical reaction chain, and promotes the active repair of human tissues [8]. The main component, ThSD, enhances bioavailability and efficiently neutralizes $O_2^{[-]}$ produced by ionization in local skin and mucosal tissues. This delays the onset of radiation-induced damage, mitigates its severity, and supports the continuity of radiotherapy. Additionally, the stabilizer D-DT stabilizes the protein and cell membrane structures, provides deep hydration, and resists absorption by the body, thereby protecting skin and mucosal cells from damage. Bergmann's bionic buffer system creates a catalytic environment conducive to healing, facilitating the repair of skin and mucosal tissues.

The findings of this study demonstrate that Bergmann exerts a protective effect on the skin of breast cancer patients undergoing radiotherapy, effectively reducing the incidence and severity of radiation-induced skin damage. It increases the radiation tolerance of skin in the irradiated field, aids in repairing radiation-induced skin injuries, and ensures the smooth progress of radiotherapy. This contributes to reduced pain and hospitalization costs for patients undergoing radiotherapy. Additionally, Bergmann's ease of use supports its clinical applicability and warrants further promotion.

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Disclosure statement

The authors declare no conflict of interest.

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