What is the appropriate skin cleaning method for nasopharyngeal cancer radiotherapy patients? A randomized controlled trial

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Abstract
Purpose To determine the effect of various cleaning methods for skin with acute radiation dermatitis (RD) in patients treated for nasopharyngeal carcinoma (NPC).
Methods A total of 168 NPC inpatients were randomized, while 152 patients completed the whole trial and the data were analyzed. Patients were randomly divided into the non-washing group (Group 1), washing with water alone group (Group 2), and washing with water and soap group (Group 3). All three groups received intensity-modulated radiation therapy (IMRT) with other treatments. Follow-up from recruitment or the initial radiotherapy dose to 1 month after the final radiotherapy dose. CONSORT checklist was applied as the reporting guidelines for this study. The study evaluated a range of endpoints, including incidence, timing, severity of acute RD, and quality of life (QOL).

Results There were no allergic reactions or aggravating in both washing groups during the whole treatment. The incidence of acute RD was 100% in all three groups, while the incidence of severe RD (grades 2–3) differed among groups (Group 1 vs. Group 2 vs. Group 3: 51% vs. 23.5% vs. 18%; \( P = 0.001 \)), washing moderately reduced severity compared with patients without washing. Washing also delayed the onset time of acute RD; the incidence of acute RD was significantly lower than non-washing during the first 20 fractions (\( P < 0.001 \)). What is more, washing reduced the incidence of moist desquamation (25.5% vs. 5.9% vs. 6%; \( P = 0.003 \)) and helped relieve itching (6.49 ± 2.09 vs. 4.90 ± 1.90 vs. 4.00 ± 1.58; \( P < 0.001 \)). There were no significant differences among groups with respect to pain or burning sensation. Washing improved QOL on physical (64.37 ± 4.08 vs. 67.41 ± 4.05 vs. 71.30 ± 4.87; \( P < 0.001 \)), emotional (61.47 ± 4.75 vs. 65.75 ± 3.46 vs. 70.80 ± 3.27; \( P < 0.001 \)), and social functional dimensions (62.64 ± 3.57 vs. 64.87 ± 3.88 vs. 68.04 ± 4.89; \( P < 0.001 \)) at the end of radiotherapy, and the outcome was similar at 1 month after radiotherapy (\( P < 0.05 \)). Washing with water and soap was the most effective way to reduce itching and improving QOL among the three groups (\( P < 0.05 \)).

Conclusion Washing irradiated skin reduces the occurrence and severity of acute radiation dermatitis.

Clinical trial information ChiCTR2000038231, date of registration 09.18.2020

Keywords Skin care · Radiation dermatitis · Radiotherapy · Nursing · Nasopharyngeal Neoplasms · Quality of life

Introduction

Nasopharyngeal carcinoma (NPC) in China accounts for 38.29% and 40.14% of the worldwide morbidity and mortality of NPC, respectively. The associated morbidity and mortality are higher than the world average (1.2/10 million, 0.7/10 million), ranking 18th and 23rd in terms of incidence and mortality, respectively [1]. Radiation dermatitis is a kind of radiation damage to the epithelial and underlying structures of the skin, which is characterized by erythema, dry or moist desquamation, and even ulcers [2]. The proportions of dry and moist desquamation were higher in patients receiving treatment to the head and neck than in other diseases [3]. During radiotherapy, 90–95% of NPC patients suffer from acute radiation dermatitis, one-third to develop moist desquamation, causing substantial pain. Moist desquamation resulting from radical radiotherapy treatment was reported in more than 60% of patients [4]. The causes of the high incidence of RD of the neck skin include thinner skin, active
Because radiotherapy plays an important role in NPC treatment, RD occurs frequently. More patients and practitioners participate in skin cleaning during radiotherapy than ever before. Although both ONS [5] and MASCC [2] guidelines have been published to recommend skin washing as a way to maintain clean irradiated skin. Nevertheless, there are a lot of questions for patients and healthcare professionals, such as “Can cleaning damage the skin? Is soap washing irritating?” What is more, evidence is controversial regarding the necessity to use mild soap during radiotherapy treatment [6]. Thus, some people are still conservative about cleaning.

Other than providing cleanliness and comfort, the effect of cleaning irradiated skin during radiation therapy is unclear. Only a few randomized trials aimed at this problem can be found in the literature. In a three-arm randomized trial of breast cancer patients treated with radiotherapy, less RD was observed in washing groups than in a non-washing group [7]. Another randomized controlled trial of breast cancer patients who received radiotherapy compared washing with water and soap and no washing [8], with similar results. A clinical trial of patients receiving cranial radiotherapy found that the severity of RD was greater in a group that was not cleansed with shampoo [9]. But it is unclear whether it is safe or effective to clean irradiated skin during radiotherapy for NPC patients or patients receiving head and neck radiotherapy. Therefore, the objective of the present study was to determine the effects of washing irradiated skin with or without soap on acute RD and associated symptoms.

**Methods**

**Study design**

Three-arm prospective randomized controlled trial, as illustrated in Fig. 1.

The study followed guidelines for reporting parallel group randomized trials [10]; the CONSORT checklist as CONSORT guidelines was checked out (Supplementary file 1).

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**Fig. 1 Enrollment and data collection process**

Excluded (n=88)
- Not meeting inclusion criteria (n=37)
- Declined to participate (n=51)
- Other reasons (n=0)

Randomized (n=168)

Group 1: Non-washing (n=56)
- Elimination (n=5)
  - Withdrew (n=1)
  - Transferred to other center (n=1)
  - Blood routine abnormalities (n=2)
  - Metastases (n=1)
- Analysed (n=51)

Group 2: Washing with water alone (n=56)
- Elimination (n=5)
  - PRO unfinished (n=2)
  - Blood routine abnormalities (n=2)
  - Metastases (n=1)
- Analysed (n=51)

Group 3: Washing with water and soap (n=56)
- Elimination (n=6)
  - Transferred to other center (n=1)
  - PRO unfinished (n=1)
  - Blood routine abnormalities (n=3)
- Analysed (n=50)

Analysed (n=51)

Analysed (n=51)

Analysed (n=50)
Participants and setting

We enrolled patients with NPC who were transferred to the Radiotherapy Center of Tianjin Medical University Cancer Institute and Hospital of China for initial radiotherapy from September 2020 to September 2021. All patients were inpatients and received IMRT.

The effective rate of moist desquamation incidence is the main outcome measure that we used to calculate the sample size. In a pilot study, 22% of patients had moist desquamation in Group 1, and 10% of patients had it in Group 3. Therefore, the highest effective rate was 12%. The study was able to detect a 12% reduction in the incidence of moist desquamation. The power was 80%, and the degree of significance alpha was 0.05 (one-sided test). To achieve this power, we needed 51 patients in each group. Considering a 10% loss to follow-up, we recruited 56 patients for each group. Before the start of the study, we set 168 as the sample size.

Before the beginning of radiotherapy, 168 patients were randomly divided into three groups: patients who did not wash their skin during radiotherapy (Group 1), patients washed with water (Group 2), and patients washed with water and soap (Group 3). The inclusion criteria were as follows: (a) NPC diagnosed with a definitive pathological report; (b) initially received radiotherapy on the head and neck, plans to receive head and neck IMRT treatment with a total prescription dose of more than 60 Gy and a dose fraction of more than 28; (c) age > 18 years; and (d) provision of written informed consent. The exclusion criteria were as follows: (a) diabetes or severe illnesses of the heart, liver, kidney, or hematopoietic system; (b) with skin ulceration or other skin diseases in the radiotherapy field; (c) communication disorder or mental illness; and (d) inability to be followed up.

The primary nurse in the ward is responsible for completing and supervising the cleaning methods of patients. There was no chance for patients on 3 different floors to communicate either in wards or in the radiotherapy rooms because their treatment time is assigned into different time intervals.

Intervention

Potentially eligible patients were interviewed during the simulation or before the first treatment by two researchers for enrollment. Eligible patients were randomly allocated before starting radiotherapy by a special nurse who was only charged for assigning them to interventions. Before recruiting patients, the random allocation sequence was generated by specialist researchers in the clinical trial center, who did not participate in the clinical work. The assignment numbers were placed into an opaque envelope only known by him. When a patient consented to participate in the study, the next patient number in chronological order was assigned to him and the corresponding envelope was unsealed, revealing assignment to one of the three groups. Patients were asked not to tell healthcare professionals or other patients which group they belonged to. For technical reasons, cleaning methods could not be blinded to the patients and the interveners. Therefore, only outcome measurers were blind.

Patients used various cleaning methods for irradiated skin during radiotherapy: non-washing irradiated skin (Group 1), gentle washing irradiated skin with warm water (35–40°C) (Group 2), and gentle washing irradiated skin with warm water (35–40°C) and mild soap (Dove®) (Group 3), followed by rinsing with water to remove residual soap. Patients in Group 2 and 3 were instructed to wash correctly but were not permitted to shower or bathe. Frequencies of cleaning in Group 2 and 3 were 2 or 3 times a day. The cleaning time should be at least half an hour removed from the radiotherapy time. Towels and Dove® Soap were provided by the researchers. Trained nurses from three different floors completed the intervention for the patients in the wards on that floor separately. Supportive Care Guidelines Group (2005) defines “mild” soap as a pH balanced product that does not contain lanolin. The Dove® Soap used in Group 3 was low irritant, which was lanolin free and non-alkaline with a mild pH. What is more, Dove® is a popular brand which is considered mild by the general public and may be used more frequently [6].

General recommendations for all three groups were as follows: (a) remove dentures, earrings, necklaces, and other metal products before radiotherapy to avoid increased radiation absorption; (b) consume a high-protein diet, with daily consumption of more than 2000 ml water to reduce a systemic radiation response during radiotherapy; (c) wear loose soft cotton or silk clothing, and do not scratch the radiation field skin; and (d) avoid using deodorant, lotion, cream, perfume, cosmetics; avoid direct sunlight on the radiation field skin; avoid pasting medical dressings and using iodine, alcohol, or other irritating disinfectants; avoid hot or cold stimulation, such as hot compresses and ice pack. The three groups were consistent in the use of skin protectants during radiotherapy.

All patients received IMRT with positioning under the simulator, resting on the head and neck, with a fixed mask and personalized lead blocks. IMRT was utilized to treat primary tumors to the dose of 2.12 Gy/fraction of 70 Gy, and all regional lymph nodes were treated with the dose of 1.8 Gy/fraction to 60 Gy simultaneously. The following treatment measures may or may not be provided: (1) Induction chemotherapy: intravenous chemotherapy with TPF regimen before radiotherapy, docetaxel 80 mg/m² on day 1, cisplatin 80 mg/m² from days 1 to 3, and tegafur 1000 mg from days 2 to 6. There were two or three cycles before radiotherapy; (2) Concurrent chemotherapy with cisplatin: intravenous chemotherapy was performed on the first day of radiotherapy,
and cisplatin was used as single-drug chemotherapy at 80 mg/m², on days 1, 22, and 43; or (3) Synchronous targeting therapy: intravenous targeting therapy with nituzumab 200 mg once per week during radiotherapy.

**Measures**

The main outcomes were the incidence of acute RD and moist desquamation; the secondary outcomes were the severity of subjective symptoms (pain, burning, itching) and quality of life (QOL). RD and moist desquamation were scored by two principal authors according to the Chinese version [11] of the RTOG acute toxicity scale in the radiotherapy oncology group [12]. Two lead authors accountable for results evaluation were trained by the enterostomy therapist (ET) who had been certified internationally. When physicians did not agree on RD grade or whether moist desquamation occurred, ET determined. RD and moist desquamation were assessed every day from the beginning of radiotherapy to 1 month after the completion of radiotherapy.

Because moist desquamation worsens quality of life, this was recorded separately. Before starting treatment, we used a questionnaire to record socio-demographic data. We recorded scores of pain, itching, and burning using patient-reported outcome software every day, and we measured symptoms using a visual analogue scale (VAS). VAS is the international commonly used scale in pain or other subjective feelings; the reliability of which has been confirmed in China [13]. We used the maximal score of the symptoms to compare among three groups.

QOL was assessed at three time points for the Chinese version of EORTC QOL-C30 (V3.0) as an instrument at the beginning, the end and 1 month after the completion of radiotherapy. EORTC QOL-C30 is a cross-cultural quality of life measurement tool for cancer patients, which the Chinese version has been verified to have good reliability (Cronbach’s alpha ≥ 0.70) and validity (r > 0.81) [14]. Socio-demographic data was computed with the use of a questionnaire before the beginning of treatment. Other data from this study included the type of cleaning, the frequency of cleaning, characteristics related to tumors and previous treatments, radiation techniques, treatment interruptions, and adjuvant treatments. If we did not see a patient during the follow-up, they would receive a questionnaire by email or written form by express delivery and were required to replay photos of the irradiated skin through e-mail transmission.

**Statistical analysis**

The chi-squared test was used to compare the frequency of RTOG acute toxicity severity in each group, as well as other categorical variables. Differences between groups (age, BMI, and patient-reported outcome symptom score) were determined by ANOVA. Subsequent Bonferroni correction was used to calculate whether the differences between groups were statistically significant. A P-value < 0.05 was considered significant, and all P values were two-tailed.

**Results**

Patients were enrolled from September 2020 to September 2021. A total of 256 patients with NPC were assessed for eligibility, of which 168 (65.6%) met the criteria and agreed to participate in the study. Of the 168 patients, 16 did not reach the end of the study and 152 patients were available for analysis (Fig. 1). There were 51 patients in Group 1, 51 in Group 2, and 50 in Group 3. Table 1 summarizes the baseline characteristics. As shown in Table 2, QOL were assessed before radiotherapy. There were no allergic reactions or other unsafe events in all 168 patients.

Table 3 showed that there was a statistically significant difference in the severity of RD between the three groups. We set grades 0–1 as mild and grades 2–3 as severe. With this grouping, the incidence of severe RD in three groups was 51% vs. 23.5% vs. 18% (P = 0.001). These findings suggest that washing irradiated skin reduces the incidence of grades 2–3 acute RD. The differences in severity between Group 1 and 2 (51% vs. 23.5%) and between Group 1 and 3 (51% vs. 18%) were statistically significant (P < 0.05). There was no significant difference between Group 2 and 3 (23.5% vs. 18%; P > 0.05). However, there was a decreasing trend toward the incidence of severe RD in the mild soap group. What is more, the differences in occurrence time of acute RD in the three groups were statistically significant (P < 0.001). The occurrence of acute RD in Group 1 was earlier than that of Group 2 (P < 0.05) and 3 (P < 0.05). There was no significant difference between Group 2 and 3 (P > 0.05). The Table of time comparison was provided in Supplementary file 2 for the limit of table numbers.

Table 4 showed that the incidence of moist desquamation among three groups during radiotherapy was different (25.5% vs. 5.9% vs. 6%; P = 0.003); Group 2 and Group 3 significantly differed with Group 1 (P < 0.05).

Table 5 showed that the peak score of pain did not significantly differ between the three arms (4.60 ± 0.66 vs. 4.64 ± 0.66 vs. 4.59 ± 0.67; P = 0.916). And peak score of burning did not significantly differ between the three arms (4.63 ± 1.31 vs. 4.70 ± 1.46 vs. 4.70 ± 1.37; P = 0.143). However, the peak score of itching did significantly differ between three arms (6.49 ± 2.09 vs. 4.90 ± 1.90 vs. 4.00 ± 1.58; P < 0.001); Group 2 and Group 3 significantly differed with Group 1; Group 3 significantly differed with Group 2 (P < 0.05).

The data were evaluated at the end of radiotherapy and one month after radiotherapy with the Chinese version...
### Table 1 Comparison of socio-demographic data and disease-related data among three groups

| Items                        | Group 1 non-washing (n = 51) | Group 2 washing with water alone (n = 51) | Group 3 washing with water and soap (n = 50) | Stats (F/2) | P-value |
|------------------------------|-------------------------------|------------------------------------------|---------------------------------------------|-------------|---------|
| Age                          | 51.0 ± 13.2                   | 52.4 ± 13.2                              | 52.2 ± 13.1                                 | 0.160*      | 0.853   |
| Gender                       |                               |                                          |                                             |             |         |
| Male                         | 70.6% (n = 36)                | 72.5% (n = 37)                           | 64% (n = 32)                                | 0.946*      | 0.623   |
| Female                       | 29.4% (n = 15)                | 27.5% (n = 14)                           | 36% (n = 18)                                |             |         |
| BMI (Kg/m²)                  | 25.7 ± 3.4                    | 26.5 ± 4.0                               | 26.4 ± 3.5                                  | 0.160*      | 0.853   |
| Education                    |                               |                                          |                                             |             |         |
| Primary school               | 11.8% (n = 6)                 | 9.8% (n = 5)                             | 14% (n = 7)                                 | 0.923*      | 0.988   |
| Middle school                | 31.4% (n = 16)                | 29.4% (n = 15)                           | 34% (n = 17)                                | 2.483*      | 0.870   |
| High school                  | 31.4% (n = 16)                | 33.3% (n = 17)                           | 28% (n = 14)                                |             |         |
| College and above            | 25.5% (n = 13)                | 27.5% (n = 14)                           | 24% (n = 12)                                |             |         |
| Occupations                  |                               |                                          |                                             |             |         |
| Farmer                       | 31.4% (n = 16)                | 35.3% (n = 18)                           | 30% (n = 15)                                | 0.039*      | 0.843   |
| Worker                       | 19.6% (n = 10)                | 17.6% (n = 9)                            | 22% (n = 11)                                |             |         |
| Public officials             | 19.6% (n = 10)                | 27.5% (n = 14)                           | 20% (n = 10)                                |             |         |
| Else                         | 29.4% (n = 15)                | 19.6% (n = 10)                           | 28% (n = 14)                                |             |         |
| Smoking                      |                               |                                          |                                             |             |         |
| Yes                          | 49.0% (n = 25)                | 47.1% (n = 24)                           | 46% (n = 23)                                | 0.078*      | 0.780   |
| No                           | 51.0% (n = 26)                | 52.9% (n = 27)                           | 54% (n = 27)                                |             |         |
| Diabetes                     |                               |                                          |                                             |             |         |
| Yes                          | 15.7% (n = 8)                 | 13.7% (n = 7)                            | 16% (n = 8)                                 | 0.885*      | 0.927   |
| No                           | 84.3% (n = 43)                | 86.3% (n = 44)                           | 84% (n = 42)                                |             |         |
| Stage                        |                               |                                          |                                             |             |         |
| II                           | 15.6% (n = 8)                 | 13.7% (n = 7)                            | 16% (n = 8)                                 | 0.885*      | 0.927   |
| III                          | 29.4% (n = 15)                | 27.5% (n = 14)                           | 22% (n = 11)                                |             |         |
| IV                           | 54.9% (n = 28)                | 58.8% (n = 30)                           | 62% (n = 31)                                |             |         |
| Pathological type            |                               |                                          |                                             |             |         |
| Squamous cell carcinoma      | 39.2% (n = 20)                | 37.3% (n = 19)                           | 34% (n = 17)                                | 0.487*      | 0.975   |
| Non-keratinizing cell carcinoma | 21.6% (n = 11)            | 25.5% (n = 13)                           | 25% (n = 13)                                |             |         |
| Undifferentiated carcinoma   | 39.2% (n = 20)                | 37.3% (n = 19)                           | 40% (n = 20)                                |             |         |
| Treated sites of RT          |                               |                                          |                                             |             |         |
| Nasopharynx only             | 29.4% (n = 15)                | 29.4% (n = 15)                           | 32% (n = 16)                                | 0.885*      | 0.927   |
| Nasopharynx and Supraclavicular | 70.6% (n = 36)           | 70.6% (n = 36)                           | 68% (n = 34)                                |             |         |
| Boost                        |                               |                                          |                                             |             |         |
| Yes                          | 72.5% (n = 37)                | 70.6% (n = 36)                           | 76% (n = 38)                                | 0.384*      | 0.825   |
| No                           | 27.5% (n = 14)                | 29.4% (n = 15)                           | 24% (n = 12)                                |             |         |
| Bolus                        |                               |                                          |                                             |             |         |
| Yes                          | 21.6% (n = 11)                | 23.5% (n = 12)                           | 20% (n = 10)                                | 0.186*      | 0.911   |
| No                           | 78.4% (n = 40)                | 76.5% (n = 39)                           | 80% (n = 40)                                |             |         |
| Dose on Nasopharyngeal       | 68.2 ± 2.6                    | 69.4 ± 4.2                               | 67.1 ± 3.4                                  | 0.168*      | 0.732   |
| Dose on cervical positive lymph nodes | 66.2 ± 5.4            | 68.3 ± 6.2                               | 64.3 ± 3.6                                  | 0.398*      | 0.836   |
| Fractions                    |                               |                                          |                                             |             |         |
| 28                           | 27.5% (n = 14)                | 29.4% (n = 15)                           | 32% (n = 16)                                | 0.318*      | 0.853   |
| 29 – 33                      | 72.5% (n = 37)                | 70.6% (n = 36)                           | 68% (n = 34)                                |             |         |
| Induction chemotherapy       |                               |                                          |                                             |             |         |
| TPF                          | 31.4% (n = 16)                | 27.5% (n = 14)                           | 36% (n = 18)                                | 0.856*      | 0.652   |
| No                           | 68.6% (n = 35)                | 72.5% (n = 37)                           | 64% (n = 32)                                |             |         |
| Concurrent chemotherapy      |                               |                                          |                                             |             |         |
| Cisplatin                    | 58.8% (n = 30)                | 54.9% (n = 28)                           | 52% (n = 26)                                | 0.480*      | 0.787   |
| No                           | 41.2% (n = 21)                | 45.1% (n = 23)                           | 48% (n = 24)                                |             |         |
| Concurrent targeted therapy  |                               |                                          |                                             |             |         |
| Nitzuzumab                   | 25.5% (n = 13)                | 21.6% (n = 11)                           | 20% (n = 10)                                | 0.467*      | 0.792   |
| No                           | 74.5% (n = 38)                | 78.4% (n = 40)                           | 80% (n = 40)                                |             |         |

*a*F*-statistic for ANOVA  
*b*Chi-squared values
### Table 2  Comparison five functions of QOL among the three groups

| Function dimensions | T0: at the beginning of radiotherapy | T1: at the end of radiotherapy | T2: at 1 month after the end of radiotherapy |
|---------------------|-------------------------------------|---------------------------------|---------------------------------------------|
|                     | Mean(SD)                            | Mean(SD)                        | Mean(SD)                                    |
|                     | Group 1    | Group 2    | Group 3    | F    | P value | Group 1    | Group 2    | Group 3    | F    | P value | Group 1    | Group 2    | Group 3    | F    | P value |
| Physical function   | 81.12 (3.94) | 80.94 (4.23) | 80.88 (3.86) | 0.048 | 0.953 | 64.37 (4.08) | 67.41* (4.05) | 71.30ab (4.87) | 32.246 | <0.001* | 69.40 (4.09) | 72.49* (4.08) | 76.35ab (4.85) | 32.307 | <0.001* |
| Role function       | 83.20 (2.76) | 83.22 (2.86) | 82.80 (3.23) | 0.317 | 0.729 | 63.82 (3.70) | 64.37 (3.94) | 64.22 (3.91) | 0.276 | 0.759 | 85.72 (2.86) | 85.69 (2.68) | 85.31 (3.38) | 0.301 | 0.741 |
| Emotional function  | 69.96 (3.70) | 69.92 (3.77) | 69.86 (3.90) | 0.009 | 0.991 | 61.47 (4.75) | 65.75a (3.46) | 70.80ab (3.27) | 72.817 | <0.001* | 66.06 (3.51) | 76.10a (3.67) | 79.43ab (4.23) | 168.816 | <0.001* |
| Cognitive function  | 84.65 (2.41) | 84.57 (2.39) | 84.88 (2.07) | 0.251 | 0.779 | 78.94 (2.31) | 79.25 (2.58) | 79.33 (2.43) | 0.362 | 0.697 | 87.14 (2.27) | 87.90 (2.50) | 88.06 (2.32) | 2.194 | 0.115 |
| Social function     | 75.65 (3.41) | 74.96 (3.75) | 75.10 (3.48) | 0.532 | 0.589 | 62.64 (3.57) | 64.87a (3.88) | 68.04ab (4.89) | 21.618 | <0.001* | 73.32 (3.73) | 79.14a (3.78) | 83.52ab (3.49) | 98.407 | <0.001* |

*Group 1: non-washing (n = 51); *Group 2: washing with water alone (n = 51); *Group 3: washing with water and soap (n = 50)

QOL, quality of life; PP, per protocol; SD, standard deviation

* p < 0.05

*Compared with Group 1, p < 0.05, Bonferroni correction

*Compared with Group 2, p < 0.05; Bonferroni correction
of EORTC QLQ-C30 V3.0. Only five functional dimensions were listed by convenience. The item of pain was compared separately as the main subject symptom of RD. No differences were detected in the other eight individual items (fatigue, nausea and vomiting, dyspnea, insomnia, anorexia, constipation, diarrhea, and economic difficulties) during the entire course of the study ($P > 0.05$). So, we compared five functional dimensions of QOL. Table 2 shows that there were significant differences in physical function ($64.37 \pm 4.08$ vs. $67.41 \pm 4.05$ vs. $71.30 \pm 4.87$), emotional function ($61.47 \pm 4.75$ vs. $65.75 \pm 3.46$ vs. $70.80 \pm 3.27$), and social function ($62.64 \pm 3.57$ vs. $64.87 \pm 3.88$ vs. $68.04 \pm 4.89$) among three groups at the end of radiotherapy. We further compared the scores of the three groups, from high to low, as follows: Group 3 > Group 2 > Group 1 ($P < 0.05$). The outcome was similar at one month after radiotherapy ($P < 0.05$).

### Discussion

We found that cleaning irradiated skin reduced the incidence of severe acute RD in grades 2 and 3. Compared with the non-washing group, washing with or without soap both reduced the incidence of severe RD (51% vs. 23.5% vs. 18%; $P = 0.001$), consistent with the study [8]. In a study of head skin care of patients receiving whole skull radiotherapy, cleaning the skin did not increase the severity of acute radiation injury [9]. In the present study, the incidence of acute RD in Group 2 and 3 was significantly lower than Group 1 ($P < 0.05$) during the first 20 fractions (cumulative radiation dose less than 42.4 Gy). These findings suggest that washing delays the occurrence of RD.

Cleaning reduces the number of bacteria on the surface of the skin and reduces the peeling and scraping caused by RD. We further compared the scores of the three groups, from high to low, as follows: Group 3 > Group 2 > Group 1 ($P < 0.05$). The outcome was similar at one month after radiotherapy ($P < 0.05$).
by itching, enhancing the protective mechanism of epithelial cells, and reducing the stimulation of epithelial tissue caused by tissue compensation to radiotherapy. We showed that washing reduced moist desquamation (25.5% vs. 5.9% vs. 6.2%, P = 0.003), consistent with the study [8]. Additionally, washing helped relieve itching (6.49 ± 2.09 vs. 4.90 ± 1.90 vs. 4.00 ± 1.58; P < 0.001), and the symptoms in the soap group were lower than the water group (P < 0.05), consistent with the study [7]. In our study, there was no significant difference in the incidence of RD between Group 2 and 3. At the minimum, we demonstrated the safety of mild soap. The use of mild soap had different results in Group 2 and 3 in terms of itching and QOL. Washing with mild soap did not increase the incidence of RD or moist desquamation. This finding suggests that mild soap is friendly to the skin and there is no residual soap liquid on the skin if the patient uses the correct washing technique. Next, we may try prolonging the contact time of mild soap on irradiated skin to explore the role of mild soap.

There has been a longstanding debate about whether irradiated skin can be cleaned in the irradiation field. If patients receiving radiotherapy are strictly restricted from washing, their normal hygiene and cleaning habits will be changed. Feelings of being dirty and offensive odors have negative impacts on QOL, psychological status, and social functions [15]. Studies have shown that unlimited skin cleaning during radiotherapy can increase physical comfort and pleasure [16]; encouraging patients to wash can reduce their anxiety and other adverse psychological emotions [17]. The effect of RD on the QOL of patients is significant [18], especially for NPC. RD limits the head and neck movement of patients with NPC which severely affects self-image and self-esteem [19]. Cleaning irradiated skin can improve the physiological and emotional and social functions of QOL.

Radiation reactions often exacerbate existing functional difficulties and may severely limit normal life [20]. Few studies examined what happened when radiotherapy ended. It was recommended to extend the intervention and observation time regarding acute and long-term toxicity following radiotherapy [21]. In our study, a considerable amount of dry desquamation occurred within 1 month after radiotherapy; fortunately, moist desquamation did not occur. The patients were instructed not to tear or pull the dry skin that had not been shed so as to maintain the integrity of the skin because maintaining the integrity of the skin has long been considered to be of great importance [16, 17].

Washing irradiated skin is cost-effective. Pharmacological interventions were effective to prevent or treat RD in patients with head and neck cancer [22–25]. A systematic review concluded that topical interventions prevent acute RD in patients with head and neck cancer [26]. There was no strong evidence that indicated differences between topical pharmacological and non-pharmacological interventions (such as washing) in the prevention of acute RD. Obviously, washing irradiated skin is effective and economical.

The present study has some limitations. Firstly, the participants could not be blinded to skin cleaning treatment. Thus, positive changes in QOL may have partially resulted from the Hawthorne effect. Secondly, this study involved in one center, so a larger-scale RCT is needed.

To our knowledge, this is the first study providing the result of whether it is safe or effective for cleaning irradiated skin during radiotherapy for NPC patients or patients receiving head and neck radiotherapy. And this research may have an impact on the prevention care of acute RD of diseases which have similar characteristics as irradiated skin has many skin wrinkles or the high dose of radiation regimen. It provides positive clinical evidence, especially for some people still conservative about cleaning.

**Conclusion**

In conclusion, washing irradiated skin with water or mild soap can reduce the severity of RD, delay its occurrence, reduce itching, and improve QOL. Patients should be encouraged to wash irradiated skin correctly following their cleansing habits with or without mild soap.

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**Data availability** Data that support the findings of this study are available from the corresponding author upon reasonable request.

**Declarations**

**Ethics approval** The study was approved by the Institutional Research Ethics Committee of our hospital (No. bc2019085). The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

**Consent to participate** Informed consent was obtained from all individual participants included in the study.
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