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Bacterial Decolonization for Prevention of Radiation Dermatitis
A Randomized Clinical Trial

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IMPORTANCE Evidence-based approaches for the prevention of acute radiation dermatitis (ARD) are limited, and additional strategies are necessary to optimize care.

OBJECTIVE To determine the efficacy of bacterial decolonization (BD) to reduce ARD severity compared with standard of care.

DESIGN, SETTING, AND PARTICIPANTS This phase 2/3 randomized clinical trial was conducted from June 2019 to August 2021 with investigator blinding at an urban academic cancer center and enrolled patients with breast cancer or head and neck cancer receiving radiation therapy (RT) with curative intent. Analysis was performed on January 7, 2022.

INTERVENTIONS Intranasal mupirocin ointment twice daily and chlorhexidine body cleanser once daily for 5 days prior to RT and repeated for 5 days every 2 weeks through RT.

MAIN OUTCOMES AND MEASURES The primary outcome as planned prior to data collection was the development of grade 2 or higher ARD. Based on wide clinical variability of grade 2 ARD, this was refined to grade 2 ARD with moist desquamation (grade 2-MD).

RESULTS Of 123 patients assessed for eligibility via convenience sampling, 3 were excluded, and 40 refused to participate, with 80 patients in our final volunteer sample. Of 77 patients with cancer (75 patients with breast cancer [97.4%] and 2 patients with head and neck cancer [2.6%]) who completed RT, 39 were randomly assigned BC, and 38 were randomly assigned standard of care; the mean (SD) age of the patients was 59.9 (11.9) years, and 75 (97.4%) were female. Most patients were Black (33.7% [n = 26]) or Hispanic (32.5% [n = 25]). Among patients with breast cancer and patients with head and neck cancer (N = 77), none of the 39 patients treated with BD and 9 of the 38 patients (23.7%) treated with standard of care developed ARD grade 2-MD or higher (P = .001). Similar results were observed among the 75 patients with breast cancer (ie, none treated with BD and 8 [21.6%] receiving standard of care developed ARD grade ≥2-MD; P = .002). The mean (SD) ARD grade was significantly lower for patients treated with BD (1.2 [0.7]) compared with patients receiving standard of care (1.6 [0.8]) (P = .02). Of the 39 patients randomly assigned to BD, 27 (69.2%) reported regimen adherence, and only 1 patient (2.5%) experienced an adverse event related to BD (ie, itch).

CONCLUSIONS AND RELEVANCE The results of this randomized clinical trial suggest that BD is effective for ARD prophylaxis, specifically for patients with breast cancer.

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Each year, 10 million patients with cancer are treated with radiation therapy (RT).[1] The skin overlying the treated area is subjected to toxic effects, resulting in acute radiation dermatitis (ARD), which can be detrimental to quality of life and oncologic treatment plan (eFigure 1 in Supplement 1).[2] Despite the high prevalence of ARD, evidence-based treatment options are limited.[3]

We recently demonstrated that *Staphylococcus aureus* colonization is an independent risk factor for the development of grade 2 or higher ARD for patients with breast cancer or head and neck cancer receiving RT, suggesting a pathogenic role for *S aureus* and defining it as a potential therapeutic target.[4] Up to 30% of people are colonized with *S aureus*,[5] which has been shown to be proinflammatory and pathogenic in several inflammatory skin diseases.[6-8] Complications of *S aureus* colonization can be prevented by bacterial decolonization (BD), a multiday regimen of intranasal mupirocin application and chlorhexidine body cleansing, which has been shown to be safe and cost-effective in several clinical settings.[9,10]

We hypothesized that prophylactic BD would decrease the severity of ARD compared with standard of care. Here we report the results from, to our knowledge, a first-in-human randomized clinical trial testing a BD regimen to prevent ARD.

Key Points

Question Does bacterial decolonization (BD) decrease the severity of acute radiation dermatitis (ARD) for patients with cancer receiving radiation therapy compared with standard of care?

Findings In this randomized clinical trial of 75 patients with breast cancer and 2 with head and neck cancer, none treated with BD developed grade 2 or higher ARD with moist desquamation compared with 23.7% of patients treated with standard of care, a significant difference.

Meaning This trial found that BD may be a new prophylactic approach for ARD prevention, especially for patients with breast cancer.

Methods

Trial Design

We performed a phase 2/3 randomized clinical trial from June 2019 to August 2021 with investigator blinding at an urban academic cancer center comparing a BD regimen with standard of care for 80 patients with cancer receiving photon-beam RT (NCT03883828); this trial was approved by the Albert Einstein College of Medicine institutional review board (trial protocol in Supplement 2). All patients provided written informed consent. The primary end point was the development of grade 2 ARD with moist desquamation (grade 2-MD) or higher. The secondary outcome was patient quality of life via a Skindex-16 score (16-item assessment with each item graded on an analog scale ranging from 0 to 6, with 6 being worse). Responses were categorized into subscales: symptom, emotion, and function. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Patient Selection

Patients 18 years of age or older with a diagnosis of breast cancer or head and neck cancer with plans for photon-beam RT (≥15 fractions) with curative intent were eligible. Patients with prior RT, an existing dermatologic condition affecting the RT field, or an allergy to chlorhexidine or mupirocin were excluded.

Randomization

Participants were randomly assigned to BD or standard of care in a 1:1 ratio in a stratified manner within each of the 2 cancer types using a computer-generated list. After 42 patients were enrolled, we recognized the difficulty in recruiting patients with head and neck cancer; thus, we aimed to enroll 80 patients total instead of the initially projected 40 patients for each cancer type.

Treatment Characteristics

Patients in the intervention group received a standard BD regimen including intranasal mupirocin, 2%, ointment applied twice daily and chlorhexidine gluconate, 4%, body cleanser used once daily for 5 consecutive days prior to RT and repeated for 5 days every 2 weeks throughout RT.[9] Patients in the standard of care group used normal hygiene and emollients. There was no restriction on patients in either group receiving additional treatment as deemed necessary by their treating radiation oncologist.

Instruments Used for Assessments

Blinded investigators (including B.N.M.) used the Common Terminology Criteria for Adverse Events (CTCAE), version 4.03 to grade ARD via standardized photographs of the radiated field. Distinction was made between grade 2 ARD events with "moderate to brisk erythema," defined as grade 2, and "patchy moist desquamation mostly confined to skin folds and creases," defined as ARD grade 2-MD and weighted as grade 2.5 for statistical analyses. If a patient refused photographs, the scores given by the patient's treating radiation oncologist in the electronic medical record were used. Bacterial cultures were obtained via a superficial swab from the nares. The Skindex-16 instrument was completed by patients for quality-of-life assessment.

Timing of Assessments

At baseline and at the last day of RT, standardized photographs used for investigator grading were taken, and the Skindex-16 instrument was performed. Bacterial cultures were obtained at baseline, at the midpoint of RT, and at the last day of RT. If a patient experienced an adverse event due to treatment, their participation in the trial was discontinued.

Statistical Analysis

Analysis was performed on January 7, 2022. The sample size was calculated based on our observational study, in which the rate of grade 2 or higher ARD was 0.38.[4] With 30 patients in each treatment group, assuming a significance level (α) of .05, the trial had 0.80 power to detect a minimum difference of 0.29 in the incidence of grade 2 or higher ARD between the 2 groups using a 2-sided test. Assuming a 25% attrition rate, we planned to recruit 80 patients (40 in each group) to ensure a final sample

size of 60. A priori analyses were intention to treat. Analyses included all patients combined and patients stratified by cancer site. The demographic and clinical characteristics of the patients were tabulated between the 2 groups.

The primary outcome was the development of ARD grade 2-MD or higher. The protocol prespecified the primary end point as grade 2 ARD based on the aforementioned observational study.[4] However, after enrollment of 42 patients, in an unplanned midstudy adaptation, the study team modified the end point to 2-MD when a wide variation of clinical presentations among patients with grade 2 ARD was noted by the blinded investigator grading the patient photographs. The wide spectrum of toxic effects seen on the skin of patients with grade 2 ARD had not been appreciated in our prior pilot study, which relied on ARD grades extracted from the electronic medical record rather than through blinded grading of photographs by study personnel and which included a higher proportion of patients with head and neck cancer. A literature review affirmed that other research groups had similarly noted a lack of discriminatory power in the grade 2 classification of the CTCAE scale, at which point the decision was made to refine the study end point to 2-MD to include patients with moderate to brisk erythema and moist desquamation.[11-17] The investigator grading ARD remained blinded to the results throughout the duration of the trial, and the members of the study team who made the decision to modify the end point did not have any contemporaneous information regarding the primary outcome results by treatment group.

The association between BD and grade 2-MD or higher ARD was tested using the Fisher exact test. A priori multivariable logistic regression modeling using the outcome of grade 2-MD or higher ARD did not adequately converge due to a lack of patients with grade 2-MD or higher ARD in the BD group; thus, a multivariable linear regression analysis was performed to investigate the effects of BD on ARD grade dependent on other potential confounding factors, including body mass index (BMI; calculated as weight in kilograms divided by height in meters squared), concurrent chemotherapy, race and ethnicity, and radiation dose. To ensure that this model was an accurate replacement of the a priori multivariable logistic regression, exact logistic regression analysis was conducted as a comparison, and the results were found to be similar. The results are reported as estimated β coefficients, 95% CIs, and *P* values.

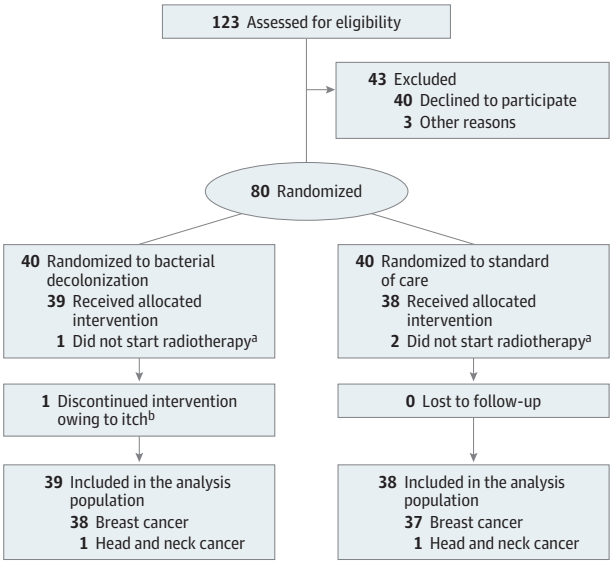
As a secondary analysis, differences in scores of patient-reported skin symptoms from the Skindex-16 before and after treatment were compared using the Wilcoxon rank sum test between the 2 treatment groups. All analyses were conducted using SAS, version 9.4 (SAS Institute). A 2-sided $P \leq .05$ was considered statistically significant.

Results

Patients and Treatment

Between June 2019 and August 2021, 80 patients were randomly assigned in a 1:1 manner to BD (n = 40) or standard of care (n = 40). Three patients (1 assigned to BD and 2 assigned to standard of care) were excluded from analysis because they did not start RT after enrollment (**Figure 1**). The final population included 77 patients with breast cancer or head and neck cancer (39 assigned to BD and 38 assigned to standard of care).

Figure 1. Consolidated Standards of Reporting Trials Diagram



[a] Follow-up data could not be collected.

[b] Acute radiation dermatitis scores after radiation therapy were extracted from the electronic medical record.

There were no differences in clinical and demographic characteristics between the 2 treatment groups (**Table 1**). The mean (SD) age of the cohort was 59.9 (11.9) years (range, 29-84 years). Most participants were female (n = 75 [97.4%]), which is due to the trial population consisting largely of patients with breast cancer (75 patients [97.4%]). Most patients were Black (33.7% [n = 26]) or Hispanic (32.5% [n = 25]). The mean (SD) BMI was 29.3 (5.7) (range, 19.4-45.2). The median total radiation dose was 52.4 Gy (IQR, 42.4-52.4 Gy) delivered at a median of 20 fractions (IQR, 16-20 fractions). Five patients (6.5%) received chemotherapy concurrently with RT, and 41 patients (53.2%) received chemotherapy prior to RT. Baseline nasal colonization with *S aureus* was present in 10 patients (13.0%). Silver sulfadiazine was prescribed to 9 patients (11.7%). Two patients (1 assigned to BD and 1 assigned to standard of care) refused photographs and were assigned ARD grades from the radiation oncologist's notes in the electronic medical record.

Efficacy

Primary End Point

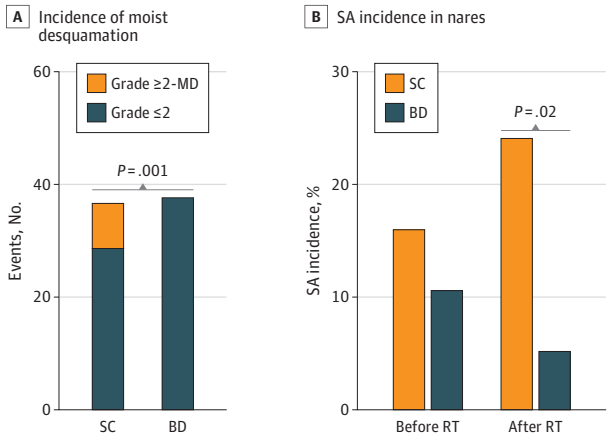
Among patients with breast cancer and patients with head and neck cancer (N = 77), none of the 39 patients treated with BD developed grade 2-MD or higher ARD compared with 9 of the 38 patients (23.7%) treated with standard of care ($P = .001$) (**Figure 2**A). When the primary analysis was repeated using the originally prespecified primary end point of grade 2 including patients with or without moist desquamation, rather than grade 2-MD, we observed results trending in the same direction (35.9% [14 of 39] treated with BD and 52.6% [20 of 38]

Table 1. Demographic and Clinical Characteristics of Patients at Baseline

Characteristic	Patients, No. (%)		
	Total (N = 77)	Standard of care (n = 38)	Bacterial decolonization (n = 39)
Age, mean (SD), y	59.9 (11.9)	60.4 (13.3)	59.4 (10.5)
Sex			
Female	75 (97.4)	38 (100)	37 (94.9)
Male	2 (2.6)	0	2 (5.1)
Cancer type			
Breast	75 (97.4)	37 (97.4)	38 (97.4)
Head and neck	2 (2.6)	1 (2.6)	1 (2.6)
Race			
Asian	1 (1.3)	0	1 (2.6)
Black	26 (33.7)	10 (26.3)	16 (41.0)
Hispanic	25 (32.5)	13 (34.2)	12 (30.7)
White	4 (5.2)	4 (10.5)	0
Unknown	21 (27.3)	11 (28.9)	10 (25.6)
BMI, mean (SD)	29.4 (5.7)	30.1 (5.2)	28.6 (6.1)
Radiation treatment characteristics			
Total radiation dose, median (IQR), Gy	52.4 (42.4-52.4)	52.4 (42.4-52.4)	52.4 (42.4-52.4)
Total No. of fractions, median (IQR)	20 (16-20)	20 (16-20)	20 (16-20)
Concurrent chemotherapy	5 (6.5)	3 (8.0)	2 (5.1)
Prior chemotherapy	41 (53.2)	20 (52.6)	21 (53.8)
Baseline nasal *S aureus*	10 (13.0)	6 (15.8)	5 (12.8)
Silver sulfadiazine use	9 (11.7)	5 (13.2)	4 (10.2)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); *S aureus*, *Staphylococcus aureus*.

Figure 2. Bacterial Decolonization (BD) Efficacy and Effects on Acute Radiation Dermatitis



A, Incidence of moist desquamation in the BD group and the standard of care (SC) group. Grade 2-MD indicates grade 2 acute radiation dermatitis with moist desquamation. B, *Staphylococcus aureus* (SA) incidence in nares per treatment group before (P = .50) and after (P = .02) radiation therapy (RT).

Table 2. Association of Bacterial Decolonization With Acute Radiation Dermatitis Grade for Patients With Breast Cancer at the Montefiore Medical Center

Factor	Estimated β (95% CI)[a]	*P* value
Intercept	0.64 (−1.61 to 2.89)	.57
Decolonization status	−0.45 (−0.75 to −0.15)	.004
Age	−0.02 (−0.03 to −0.01)	.007
Sex	−0.63 (−1.96 to 0.70)	.35
BMI	0.04 (0.01 to 0.06)	.008
Concurrent chemotherapy	0.49 (−0.19 to 1.17)	.16
Radiation dose, Gy	0.03 (0.003 to 0.062)	.03

Abbreviation: BMI, body mass index.

[a] Linear regression models of clinicopathologic factors associated with grade of acute radiation dermatitis.

treated with standard of care had ARD grade ≥2; P = .14). The mean (SD) ARD grade was significantly lower in patients treated with BD compared with patients treated with standard of care (1.21 [0.70] vs 1.62 [0.77]; P = .02).

Given that only 2 patients with head and neck cancer were enrolled, removing them from the analysis did not change the statistical significance, and limiting our analysis to breast cancer per a priori plan to stratify by cancer type was most clinically relevant because the population of patients with head and neck cancer was too small to draw meaningful conclusions. For patients with breast cancer, the results of the prevention of grade 2-MD or higher ARD were similar (ie, none treated with BD and 8 [21.6%] receiving standard of care developed ARD grade ≥2-MD; P = .002). Bacterial decolonization was associated with lower ARD grade (estimated β = −0.45 [95% CI, −0.75 to −0.15]; P = .004), even when adjusting for known ARD risk factors, of which higher BMI (estimated β = 0.04 [95% CI, 0.01-0.06]; P = .008) and radiation dose (estimated β = 0.03 [95% CI, 0.003-0.062]; P = .03) had a positive association with higher ARD severity. Older age was found to be significantly associated with lower ARD grade; however, the effect size was small (estimated β = −0.02 [95% CI, −0.03 to −0.01]; P = .007) (**Table 2**; eFigure 2 in Supplement 1).

Table 3. Differences in Patient-Reported Skin Symptoms on Skindex-16 by BD vs SC for Patients With Breast Cancer at the Montefiore Medical Center

Domain	Change in median score from before to after RT in SC group	1-Sample Wilcoxon signed rank test *P* value	Change in median score from before to after RT in BD group	1-Sample Wilcoxon signed rank test *P* value	2-Sample Wilcoxon rank sum test *P* value
Symptom	4.0	<.001	3.0	.001	.20
Emotion	0.0	.25	5.0	<.001	.05
Functioning	0.0	.11	0.0	.099	.73

Abbreviations: BD, bacterial decolonization; RT, radiation therapy; SC, standard of care.

Regarding BD regimen efficacy, nasal *S aureus* colonization rates in the BD group decreased from baseline (10.8% [4 of 37]) to after treatment (5.4% [2 of 37]), whereas the rates in the standard of care group increased from baseline (16.2% [6 of 37]) to after treatment (24.3% [9 of 37]). Rates of colonization with *S aureus* differed significantly after completion of RT between the 2 groups (5.4% [2 of 37] in the BD group vs 24.3% [9 of 37] in the standard of care group; $P = .02$), but not before RT (10.8% [4 of 37] in the BD group vs 16.2% [6 of 37] in the standard of care group; $P = .50$). (Figure 2B). Of the 39 patients who received BD, 27 (69.2%) reported adherence to the regimen, and only 1 (2.6%) withdrew from the trial due to itch.

Secondary End Point

Compared with baseline, the overall median posttreatment Skindex-16 scores were higher in both treatment groups for patients with breast cancer (BD: 5 [IQR, 0-27] vs 23 [IQR, 8-50]; standard of care: 3 [IQR, 0-14] vs 20 [IQR, 3-28]). The change in median score from baseline to after RT for each domain was not significantly different between the treatment groups (4.0 with standard of care vs 3.0 with BD in the symptom domain; $P = .20$; 0.0 with standard of care vs 5.0 with BD in the emotion domain; $P = .05$; and 0.0 with standard of care vs 0.0 with BD in the functioning domain; $P = .73$) (**Table 3**).

To further explore whether Skindex-16 was the most appropriate quality-of-life tool regarding ARD, we looked at whether higher post-RT Skindex-16 scores were associated with higher ARD grade. When ARD was present, higher ARD grades correlated with higher SD-16 scores, but we also identified higher post-RT Skindex-16 scores for patients with grade 0 ARD compared with grade 1 ARD (eFigure 3 in Supplement 1).

Discussion

This trial shows that a BD regimen can effectively reduce ARD severity and prevent moist desquamation in patients with breast cancer treated with RT. Importantly, BD as a prophylactic regimen has already been shown to be safe, easy, and cost-effective on a large scale in other clinical settings.[9,10] While topical corticosteroids have also demonstrated efficacy in decreasing ARD severity, response was not complete, and a cleanser, which should be rinsed off, may be a preferable option for some patients vs a cream or ointment, which should be left on the skin. Patients may also have another contraindication to corticosteroid use, such as skin atrophy at baseline or allergy.[18] Due to the wide variability in patient preference of topical agents, personalization of a treatment plan may enhance compliance and patient satisfaction.

Interestingly, our BD regimen was successful despite an unexpectedly low baseline incidence of *S aureus* colonization. Bacterial culture of the nares is known to have a sensitivity of 67%, so the incidence of *S aureus* colonization is higher than reflected in our data.[19] Additionally, patients may become colonized during the course of their RT, especially given frequent visits to health care facilities. For these reasons, we recommend universal BD regardless of baseline *S aureus* colonization status.

Limitations

The present study has some limitations. The primary end point was modified midstudy based on the observation of a wide variation of clinical presentations among patients with grade 2 ARD. When the prespecified primary end point of grade 2 was used rather than the modified grade 2-MD end point, results trended in the same direction but did not show a significant difference. While our results did not show a significant effect on patient quality of life, the fact that patients with grade 0 ARD had higher Skindex-16 scores than those with higher-grade dermatitis leads us to question whether the Skindex-16 questionnaire was the best tool for assessing quality of life in patients with ARD. Additionally, the pre-RT scores of the ARD grade 0 group were higher compared with those in other groups, which may explain why the post-RT median score was higher for the ARD grade 0 group. Finally, participants could not be blinded to treatment, so changes in quality of life may have partially resulted from patient expectations of positive results; however, the lack of patient blinding should not have affected our results showing the beneficial effect of BD on ARD grade.

Additionally, at the time the trial was conducted, topical corticosteroids were not considered standard of care at our institution. Given the anti-inflammatory properties of topical corticosteroids, we expect that they would work synergistically with BD, thus amplifying the effect, and this combination should be studied. The clinically useful results from this study included only patients with breast cancer from a single center; a larger-scale trial with enrollment of patients with additional cancer types is warranted.

Conclusions

The results of this randomized clinical trial suggest that BD is effective for ARD prophylaxis, specifically for patients with breast cancer, and support the further investigation of BD for ARD prophylaxis, which is a safe and widely available regimen, for patients with cancer.

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Author Contributions: Dr McLellan had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Deutsch, Nazarian, Daily, Ohri, Kabarriti, McLellan.
Acquisition, analysis, or interpretation of data: Kost, Deutsch, Mieczkowska, Nazarian, Muskat, Hosgood, Lin, Kabarriti, Shinoda, McLellan.
Drafting of the manuscript: Kost, Deutsch, Mieczkowska, Daily, Ohri, Shinoda, McLellan.
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