The Journal of Radiation Oncology (ISSN 2995-6382)

Safety And Feasibility Of Silverlon Dressing For The Management Of Radiation Dermatitis.

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Short title: Silverlon dressing for radiation dermatitis.

Received Date : December 19, 2024
Accepted Date : December 20, 2024
Published Date : February 04, 2025

ABSTRACT

Introduction: Radiation dermatitis (RD) occurs in up to 95% of patients receiving radiation therapy (RT) for cancer treatment, affecting 800,000 patients annually. We evaluated the safety and feasibility of Silverlon dressing for RD management in breast cancer patients undergoing RT.

Methods: This single arm, single institution, open-label clinical trial assessed the safety and feasibility of Silverlon dressing for managing RD in breast cancer patients undergoing RT (n=30). RD severity (e.g., RTOG grade; Radiation Induced Skin Reaction Assessment Scale (RISRAS)) was captured mid-RT, end-RT, and 2-weeks post-RT. Dermatology Life Quality Index was administered at baseline, mid-RT, end of RT, and 2-weeks post-RT. Potential efficacy was explored using a historical 3:1 matched control cohort of 90 patients who received standard RD care during RT as a comparator group. All statistical analyses were conducted at a significance level of 0.05.

Results: Minimal withdrawals and adverse events, high patient compliance, and patient recommendation of Silverlon dressing underscore its safety for RD management. Silverlon-treated subjects did not experience increased RD severity compared to historical matched controls using standard of care (1.27 [1.07, 1.46] vs. 1.39 [1.25, 1.52], p=0.351). Additional comparison to a published cohort of 169 breast cancer patients suggests that Silverlon may be better than standard care management for RD (1.27 [1.07, 1.46] vs. 1.57 [1.42, 1.68], p=0.027).

Conclusions: This study established the safety, feasibility, and potential benefit of Silverlon dressing for RD management. Further, Silverlon may have reduced the need for multiple topical treatments for skin reactions during RT. Larger and more diverse clinical trials should examine the extent of Silverlon's therapeutic benefit for skin during RT.

INTRODUCTION

Up to 95% patients receiving radiation therapy (RT) for cancer will experience radiation dermatitis (RD)[1]. Notably, breast cancer patients receiving RT will face a significant impact, with up to 76% developing grade 2 or higher and approximately 36% experiencing severe skin reaction involving moist desquamation[2, 3]. Unfortunately, the current landscape lacks standardized treatment guidelines for preventing radiation-induced skin toxicity[2, 4-17]. The clinical arena reveals "significant heterogeneity in clinical practice" coupled with a "relative lack of high-quality evidence to support specific management strategies"[2, 4]. Consequently, no single product is universally successful or recognized as the optimal solution. The spectrum of products utilized for treating radiation dermatitis is expansive, with around 20 products holding US Food and Drug Administration (FDA) indication of radiation dermatitis.

The Silverlon® Dressings (Silverlon® Wound/Burn Contact Dressings, Bravida Medical, Geneva IL) are non-adherent silver-nylon dressings with FDA clearance for use on intended for use up to seven days on partial and full-thickness wounds, and burns [18-21]. Several clinical investigations conducted in Canada have substantiated the effectiveness of silver-nylon dressings in addressing radiation dermatitis[22, 23].. Our study focused on the safety and feasibility of employing Silverlon dressings to manage radiation dermatitis within a cohort of 30 breast cancer patients undergoing radiation

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therapy. Potential efficacy for reducing RD severity was explored with comparison to a matched historical cohort who received standard care with a broad spectrum of products during radiation therapy. After conduct of this trial, Silverlon dressings received FDA indication for radiation dermatitis followed by the first and currently only, FDA clearance for treating cutaneous radiation injuries.

METHODS

Clinical Trial

This single-site, open-label, single-arm clinical trial evaluated the safety and feasibility of Silverlon dressing for the management of RD in breast cancer patients. The clinical trial was conducted by University of Rochester Medical Center (URMC) under the approval of University Research Subjects Review Board (RSRB, STUDY00004587). The clinical trial enrolled adult females (age ≥22 years) with diagnosis of primary breast cancer scheduled to receive a prescribed radiation dose of 35-66 Gy in 15-40 fractions at 1.8-3.0 Gy per fraction, with or without boost dose, to the whole breast. For this study, conventional RT was defined as fractionated doses of 1.8-2.0 Gy for 25-40 fractions, with or without boost and short-course RT was defined as fractionated doses of 2.0-3.0 Gy for 15-20 fractions, with or without boost. Patient who received chest wall irradiations, bolus, and intensity-modulated radiation therapy (IMRT) were eligible. Key exclusion criteria included: known allergy to silver, partial breast irradiation; previous radiation to chest or breast area; active dermatological issues or unhealed wounds in the breast or chest area; diagnosis of medullary or inflammatory breast cancer, autoimmune disease, connective tissue disorder, or radiosensitivity disorder; or chronic concurrent chemotherapy or systemic therapies (i.e., epidermal growth factor inhibitors).

All subjects provided informed consent and agreed to wear the Silverlon dressing daily throughout their prescribed course of RT starting the first day of RT until two-weeks after completion of RT. Subjects were asked to remove the Silverlon dressing for receiving RT, bathing, showering, and/or swimming. Each subject received two dressings weekly and used the same dressing for up to 7 days. Subjects were provided with an appropriately sized Silverlon dressing (i.e., 8"x16" or 16"x16") to fully cover the breast area receiving RT and securely positioned by the individual's bra. Full coverage of the axilla, inframammary fold, and supraclavicular area may not have been feasible in all patients given the sizing and shape of the Silverlon dressings. Therefore, standard care topical treatments were exclusively allowed in skin regions not covered by the dressing. However, if deemed necessary by the treating radiation oncologist to minimize patient discomfort and/or prevent infection, standard care topical treatments were permissible if reapplication of the dressing was delayed at least one hour. Participants documented the time of day, rationale for the removal and application, and use of the same or new dressing in a daily compliance log. Subjects completed four study visits (baseline, the midpoint of RT (Mid-RT), end of RT (End-RT), and 2-weeks post-RT). RD severity was assessed using Radiation Therapy Oncology Group (RTOG) scale[24, 25]. A 90-day post-RT phone assessment captured recommendation of Silverlon dressing during RT.

Primary and secondary analyses were performed on the 30 subjects that fully completed the trial. The primary analysis for safety evaluated the overall adverse event rate for all patients that initiated Silverlon treatment and for all patients who fully completed the study. The secondary analyses evaluated feasibility by compliance rates and withdrawals from the study.

Compliance was calculated based on the number of days the dressing was worn by the patient divided by the number of days the dressing should have been worn for the prescribed treatment course. Additionally, we captured the average number of hours per day the dressing was worn to further assess the number of hours subjects are willing to wear the dressing. Exploratory analyses evaluated the trends in radiation dermatitis severity. All statistical analyses (Pearson chi square tests and ANOVA) were performed at significance level of 0.05 using JMP Pro 16.0.

Retrospective matched historical control

A historical matched control cohort (N=90) was created through retrospective chart review of breast cancer patients who underwent radiation therapy at URMC during January 2017 to December 2021. This retrospective chart review was approved by University RSRB (STUDY00004868) and met criteria for exemption. For each participant in the clinical trial, three historical controls were matched to one trial subject (i.e., 3:1) on the following parameters: age within ±10 years; race; ethnicity; body mass index (BMI) within ±6; total radiation dose (encompassing whole breast with or without boost) within ±10%; total fractionation sessions within ±10%. The documented RD grade in the chart note at the conclusion of radiation therapy was utilized as the End-RT RTOG score for the comparative analyses.

RESULTS

Safety and Feasibility

These results focus on the 30 subjects who effectively utilized Silverlon dressing during RT and 2 weeks post-RT (**Figure 1**). Most subjects were non-Hispanic (93.3%) white (86.7%) females with mean age of 57±12 years receiving short-course RT (76.7%) for Stage I breast cancer (80.0%) (**Table 1**). Among these 30 subjects, only one unrelated adverse event (AE) was

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reported. This AE was characterized as an open area in the inframammary fold which was attributed to the effects of radiation therapy and given an RTOG score of 2. The overall compliance rate for wearing Silverlon dressing was 99.9% with Silverlon worn for a mean of 45.0±7.6 days. As instructed, subjects removed the dressings for radiation sessions and bathing/showering (30/30, 100%). Although subjects averaged wearing the dressing for 22.0/day hours, subjects reported temprorary removal of the dressing for sleeping (9/30, 30%), topical treatment application (6/30, 20%), and discomfort/itchiness (5/20, 17%). At the 90-day post-RT assessment, all subjects (28/28, 100%) recommended the use of the Silverlon dressing to fellow patients.

Figure 1. CONSORT Diagram. This figure outlines the number of subject screened, eligible, approached, consented, and their flow through the clinical trial.

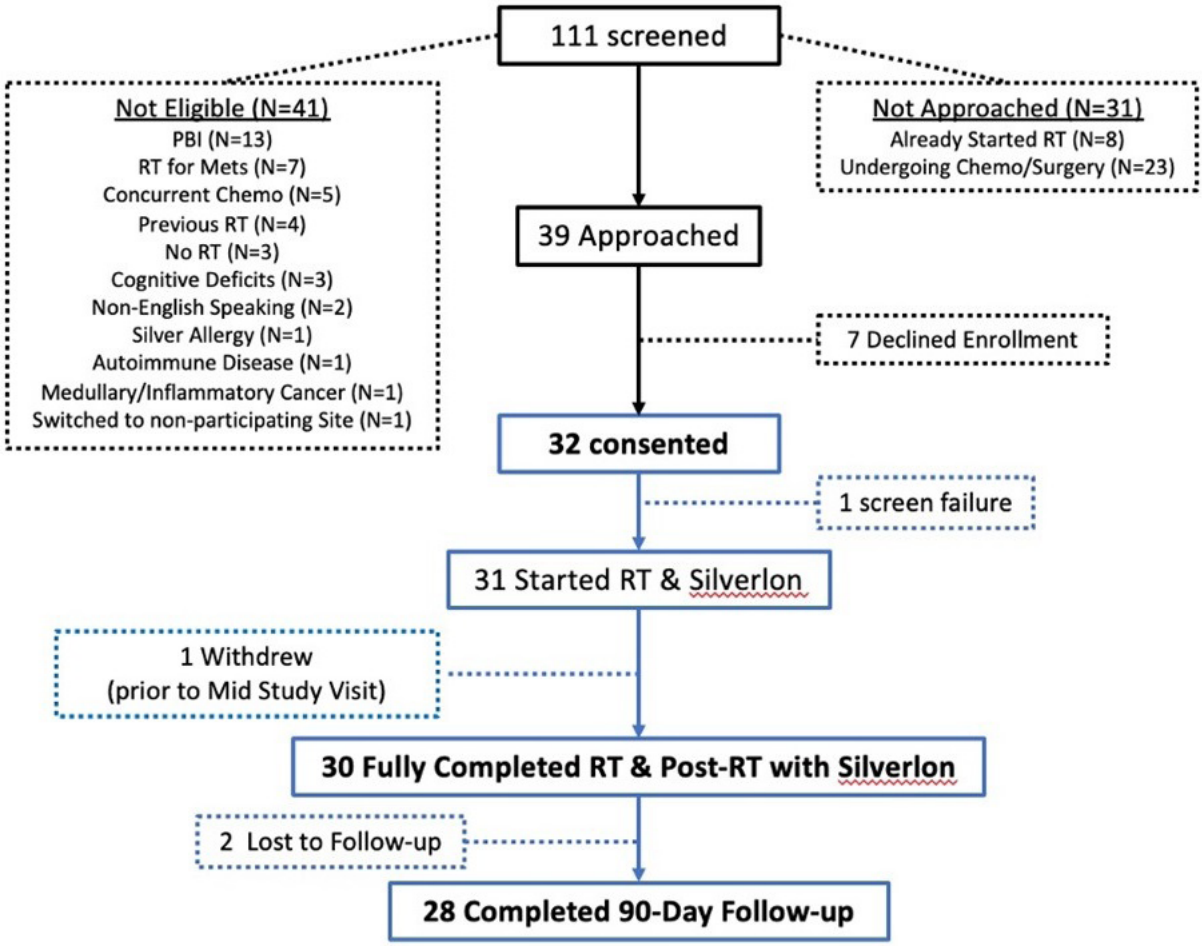

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Table 1: Characteristics of Trial Subjects and Matched Historical Controls

Characteristic	Total Subjects (N=31)	Fully Evaluable Subjects (N=30)	Historical Matched Cohort (N=90)
Age, years			
Mean (SD)	57.6 (11.9)	57.4 (12.0)	57.0 (11.0)
Race, N (%)			
White/Caucasian	27 (87.1)	26 (86.67)	81 (90.00)
Black/African American	1 (3.23)	1 (3.33)	4 (4.44)
American Indian/Alaskan Native	1 (3.23)	1 (3.33)	0 (0.00)
Unknown/Not Reported	2 (6.45)	2 (6.67)	0 (0.00)
			5 (5.56)
Ethnicity, N (%)			
Hispanic	1 (3.23)	1 (3.33)	3 (3.33)
Non-Hispanic	29 (93.50)	28 (93.33)	82 (91.11)
Unknown/Not Reported	1 (3.23)	1 (3.33)	5 (5.56)
BMI			
Mean (SD)	37.21 (7.32)	29.89 (6.85)	29.48 (5.97)
BMI Grouping, N (%)			
Normal	9 (29.03)	9 (30.00)	23 (25.56)
Overweight	12 (38.71)	12 (40.00)	25 (27.78)
Obese	10 (32.26)	9 (30.00)	42 (46.67)
Tumor Stage, N (%)			
DCIS	1 (3.23)	1 (3.33)	9 (10.00)
I	24 (77.42)	24 (80.00)	62 (68.89)
II	5 (16.13)	4 (13.33)	11 (12.22)
III	1 (3.23)	1 (3.33)	8 (8.89)
Radiation Course			
Conventional Course	8 (25.81)	7 (23.33)	26 (28.89)
Short Course	23 (74.19)	23 (76.67)	64 (71.11)
RT Type, N (%)			
3D Conformal	26 (83.87)	25 (83.33)	87 (96.67)
IMRT	5 (16.13)	5 (16.67)	3 (3.33)
Total Prescribe Dose (Gy)			
Mean (SD)	51.16 (4.67)	50.85 (4.42)	51.87 (4.43)
Total Number of RT Sessions			
Mean (SD)	22.4 (4.9)	22.1 (4.6)	22.3 (4.4)
Whole Breast Fractionation Dose			
Mean (SD)	2.45 (0.38)	2.47 (0.36)	2.44 (0.36)
Boost, N (%)			
Yes	25 (80.65)	24 (80.00)	72 (80.00)
No	6 (19.36)	6 (20.00)	18 (20.00)
Boost Fractionation Dose			
Mean (SD)	2.00 (0.00)	2.02 (0.10)	2.21 (0.25)
Surgery Prior to RT, N (%)			
Yes	30 (96.77)	29 (96.67)	87 (96.67)
No	(3.23)	1 (3.33)	3 (3.33)

Radiation dermatitis severity

The mean RTOG scores showed mild RD reaching peak severity at the End RT with an improvement in RD observed at 2-week post-RT (**Table 2**). No difference in mean RD severity was observed at End RT between Silverlon trial subjects and the historical matched cohort (1.27 [1.07, 1.46] vs. 1.39 [1.25, 1.52], p=0.351). Importantly, there were no significant differences in total prescribed radiation dose (51.85 (4.42) vs. 51.87 (4.43), p=0.279) or total radiation session number (22.1 (4.6) vs. 22.3 (4.4), p=0.672) between Silverlon subjects and the historical matched cohort. Additional comparison to the published RISREAC

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historical cohort[26] of 169 breast cancer patients with clinician-documented RD severity showed that Silverlon-treated subjects had significantly lower mean RD severity at End RT (1.27 [1.07, 1.46] vs. 1.57 [1.42, 1.68], p=0.027). These results suggest that Silverlon dressing performs similarly to and potentially better than current standard care for RD management.

Table 2: Radiation Dermatitis Severity for Silverlon Trial Subjects & Historical Matched Cohort.

RTOG Grades at End RT				
RTOG Grade	**RTOG Description**		**Clinical Trial (N=30)**	**Historical Matched Cohort (N=90)**
Grade 0	No change; Normal Skin		1 (3.3)	6 (6.7%)
Grade 1	Faint erythema; dry desquamation; epilation, decreased sweating		20 (66.7)	45 (50.0%)
Grade 2	Tender or bright erythema; moderate edema; patchy moist desquamation only in skin folds.		9 (30.0)	37 (41.1%)
Grade 3	Confluent moist desquamation in areas other than skin folds; pitting edema		0 (0.0)	2 (2.2%)
Grade 4	Ulceration; hemorrhage; necrosis		0 (0.0)	0 (0.0%)
RTOG Scores for Silverlon Trial Subjects and Historical Matched Cohort				
	Clinical Trial (N=30)			**Historical Matched Cohort (N=90)**
RTOG Scores	**Mid RT**	**End RT**	**2 Weeks Post-RT**	**End RT**
Mean 95% CI	0.70 [0.48, 0.92]	1.27 [1.07, 1.46]	1.00 [0.80, 1.20]	1.39 [1.25, 1.52]

Topical Skin Treatments

The treating radiation oncologist provided additional topical treatment in the Silverlon-treated area in six subjects (20%). The topical treatments used in these six subjects included: hydrocortisone alone (2; 33.3%); Regenacare (2, 33.3%); hydrocortisone and lidocaine ointment (1, 16.7%), and silver sulfadiazine (1, 16.7%). The primary reasons for administration of these additional topical treatments were: discomfort and itching in the areola region (4, 66.6%), irritation of inframammary fold (1, 16.7%), and folliculitis (1, 16.7%). In 20 subjects (66.7%), the Silverlon dressing did not cover all skin areas within the radiation field. These 20 subjects were provided various standard care topical treatments including aquaphor, hydrocortisone, lidocaine, Radiaplex, Regenacare, silver sulfadiazine, and Mepilex for use only on these uncovered skin areas.

The matched historical cohort showed a multitude of modalities utilized for RD as standard care, with 71% of patients receiving more than one topical treatment. Over 20 different modalities were used for RD management in the historical matched cohort (e.g., ABD Pads, Acriflavine, Topical antibiotics, Aveeno, Calendula, Calmoseptine, Cerave Lotion, Cetaphil, Clotrimazole, Cold compress, Cornstarch, Curcumin, Dove Body Wash, Eucerin, Lidocaine, Lubriderm, Miaderm, Mepilex, Moisturizing Lotion, Neosporin, Neutrogena, OTC Athlete's Cream, Pentoxifylline/Vitamin E, Regenacare, Silver Sulfadiazine (SSD), Telfa). Although this clinical trial limited the use of other topical modalities in Silverlon-treated skin areas, only six subjects required additional topical treatment.

DISCUSSION

This clinical trial demonstrates that Silverlon dressing is a safe and feasible modality for RD management in breast cancer patients undergoing RT. Based on these clinical results and additional preclinical studies, Silverlon gained FDA indications for treatment of RD, as well as cutaneous radiation injuries (CRI)[27, 28]. Silverlon is also the first and currently only device with a FDA indication for CRI management. However, there are multiple therapeutic strategies available for the prevention and management of lower severity radiation-induced skin injuries such as RD.[1, 2, 4]

Recently, the Multinational Association of Supportive Care in Cancer (MASCC) Oncodermatology Study Group published updated clinical practice guidelines, along with a series of meta-analyses, to further comprehend the effectiveness of clinically utilized modalities for prevention and management of RD[2, 4-17]. Although our clinical trial results were not included as evidence in these recently updated guidelines, silver nylon dressings did receive a near-consensus supporting recommendation of 60-74% for prevention of RD. It is clear from MASCC clinical guidelines that a combination of treatments implemented at different times during RT is the current standard care. Interestingly, only six subjects in

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our clinical trial required additional topical treatment in the Silverlon-treated area, suggesting that Silverlon may minimize the need for multiple additional topical treatments. A larger randomized clinical trial could determine if Silverlon dressing could simplify the complex management of RD and lower the cost.

The limitations of this clinical trial included a small sample size, lack of diversity within the patient population, and single-arm design. The overall purpose of this trial was safety and feasibility, which does not require a large sampling. This trial was not a comparator trial or powered to examine efficacy of Silverlon to reduce RD severity. However, these exploratory analyses suggest that Silverlon is as effective as current standard of care topical treatments, with the potential to improve RD outcomes. While this single-arm study design with a historical matched cohort is suitable for this safety study; a prospectively enrolled observational arm would allow direct real-time comparison of Silverlon treatment versus standard care or new barrier dressings or creams for RD management. Additionally, underrepresentation of all skin types (87% white) and single cancer patient population limited the generalizability of our findings, which is a common in RD trials and a critical barrier to advancement in this field[2]. Future trials should consider evaluation of Silverlon dressing in other cancer patient populations, such as head/neck cancer, and across all skin types to address gaps in the field of RD management.

Minimal withdrawals and adverse events, high patient compliance, and patient recommendation of Silverlon dressing underscore its safety for RD management. Exploratory analyses, using a historical matched cohort, suggested that Silverlon dressing provided similar RD severity reduction as standard of care and potentially reduced the need for additional topical treatments. Future larger clinical trials with Silverlon dressing are needed to provide additional evidence and confirm the therapeutic effectiveness for RD management.

Acknowledgements

Funding was provided by Biomedical Advanced Research and Development Authority (BARDA) (grant HHSO100201800022C) through a subcontract with Bravida Medical (2571 Kaneville Court, Geneva, IL 60134). Utilization of REDCap was supported by University of Rochester CTSA (UL1 TR002001) from NCATS/NIH. The authors would like to thank the radiation oncologists (Dr. Haoming Qiu, Dr. Sughosh Dhakal, Dr. Ralph Brasacchio, and Dr. Yuhchyau Chen) for their collaboration on enrollment to this clinical trial. The authors would also like to thank all the patients for their participation.

Ethics approval

The clinical trial was conducted by University of Rochester Medical Center (URMC) under the approval of University Research Subjects Review Board (RSRB, STUDY00004587). This clinical trial was registered on ClinicalTrials.gov (NCT04238728) and all subjects provided informed consent for participation. The retrospective chart review for the historical matched control cohort was approved by University RSRB (STUDY00004868) and met criteria for exemption with a waiver of consent and waiver of HIPAA authorization.

Availability of data and material (data transparency)

Research data are stored in an institutional repository and may be shared upon request to the corresponding author.

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