Dermatology Reports

https://www.pagepress.org/journals/index.php/dr/index

eISSN 2036-7406

Please cite this article as:

de Paula Casotti P, Gomes da Silva S, de Barros Ramos U, et al. Protective effect of Cavilon™ on radiodermatitis in breast cancer patients undergoing radiotherapy. *Dermatol Rep 2026 [Epub Ahead of Print] doi: 10.4081/dr.2026.10026*

Received: 19/04/24; - Accepted: 07/12/25.

Protective effect of Cavilon™ on radiodermatitis in breast cancer patients undergoing radiotherapy

Paula de Paula Casotti,[1] Sérgio Gomes da Silva,[1-3] Ulisses de Barros Ramos,[1] Breno Jorge Silveira,[1] Fabrizio dos Santos Cardoso,[1,4] Ana Carolina Ribeiro de Oliveira,[1] Marcos Luiz Bezerra Junior,[1] Rodrigo Bastos Tostes[1]

[1]Cancer Hospital of Muriaé, Fundação Cristiano Varella, Muriaé, Minas Gerais; [2]Afya Itaperuna University Center, Itaperuna, Rio de Janeiro; [3]D'Or Institute for Research and Education, Rio de Janeiro; [4]São Vicente de Paulo Hospital, Bom Jesus do Itabapoana, Rio de Janeiro, Brazil

Correspondence: Dr. Sérgio Gomes da Silva, Hospital do Câncer de Muriaé, Av. Cristiano Ferreira Varella, 555, Muriaé (MG), Brazil. Tel: 55-32-37297000. E-mail: sergio.silva@fcv.org.br; sgomesilva@hotmail.com

Key words: breast cancer; radiotherapy; radiodermatitis; Cavilon; radiation dermatitis; sunflower oil.

Contributions: Paula de Paula Casotti: conceptualization and design; Paula de Paula Casotti, Ulisses de Barros Ramos, Breno Jorge Silveira: data acquisition; Paula de Paula Casotti, Sérgio Gomes da Silva, Ulisses de Barros Ramos, Breno Jorge Silveira, Ana Carolina Ribeiro de Oliveira, Marcos Luiz Bezerra Junior, Rodrigo Bastos Tostes: data analysis; Paula de Paula Casotti, Sérgio Gomes da Silva, Fabrizio dos Santos Cardoso: writing – original draft, preparation of tables and creation of figures. All the authors read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Conflict of interest: the authors have no conflict of interest to declare.

Ethics approval and consent to participate: this study was performed in line with the principles of the Declaration of Helsinki. All experimental protocols were approved by the Ethics Committees of the Centro Universitário FAMINAS on June 19, 2019 (C.A.A.E. #14568819.4.0000.5105). Written informed consent was obtained from parents/guardians included in this study.

Funding: Paula de Paula Casotti and Ulisses de Barros Ramos were supported by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES). Sérgio Gomes da Silva was supported by

the Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq; # 301771/2022-7) and by the Fundação de Amparo à Pesquisa do Estado de Minas Gerais [(FAPEMIG; Rede Mineira de Pesquisa Translacional em Oncologia (RED-00059-23)].

Acknowledgments: the authors would like to thank the employees of the Hospital Registry from Hospital do Câncer de Muriaé (Brazil) for their technical assistance and support.

Abstract

Radiodermatitis is a common problem in breast cancer treatment with ionizing radiation. It may result in interruption of radiotherapy, depending on the level of the skin lesion. Therefore, the present study aimed to evaluate the efficacy of Cavilon™ (3M, St. Paul, MN, USA), a novel prophylactic agent, in preventing mammary radiodermatitis compared to conventional sunflower oil. This prospective study involved 19 breast cancer patients receiving radiotherapy. Participants received Cavilon™ on one breast quadrant and sunflower oil on the opposite quadrant. The occurrence and severity of radiodermatitis were assessed twice weekly over 25 treatment sessions. Post-treatment assessments indicated that 16% of the Cavilon™-treated quadrants exhibited no radiodermatitis (stage 0), compared to 11% in the sunflower oil-treated quadrants. The mean degree of radiodermatitis was 0.95 (95% confidence interval [CI]: 0.61-1.29) with Cavilon™ *vs.* 1.37 (95% CI: 0.97-1.77) with sunflower oil, a statistically significant difference (paired *t*-test: p=0.016; Wilcoxon signed-rank test: p=0.021). Progression to stage 3 occurred in 5% of Cavilon™-treated quadrants *vs.* 11% with sunflower oil. The findings suggest that Cavilon™ is more effective than sunflower oil in mitigating the progression of radiodermatitis in breast cancer patients undergoing radiotherapy. Its application is a beneficial addition to the skin management protocol in radiation oncology.

Introduction

Radiotherapy is a fundamental treatment for the cure of breast cancer.[1] It is estimated that 45% of all breast cancer patients receive radiotherapy treatment.[2] However, during radiation therapy treatment, 95% of breast cancer patients experience radiodermatitis, commonly referred to as skin toxicity.[3,4] It is well known that ionizing radiation on the skin involves modification in proteins, lipids, and carbohydrates, as well as DNA damage that subsequently generates skin lesions, especially the destruction and depletion of basal cells. Finally, this complex process induces desquamation.[5-8]

Among the risk factors for radiodermatitis are total radiation dose, volume of tissues irradiated, radiosensitivity of the tissues involved, and type of equipment used. Patient-related factors, such as chronic diseases, smoking, and concomitant anticancer treatment, can determine skin reactions impairing tissue healing.[9] Several studies have investigated the prevention of this adverse event.[8,10-13] However, there is still no clinically applicable treatment.

In this sense, Cavilon™ (3M, St. Paul, MN, USA) emerges as an excellent potential drug in the preventive treatment of radiotherapy-induced radiodermatitis. Cavilon™ spray is a skin protector that contains hexamethyl disiloxane, isooctane, acrylate copolymer, and polyphenylmethylsiloxane. Cavilon™ has been widely used in medical practice and general surgery for the protection of skin around ostomies, fistulas, and draining wounds, incontinence (fecal/urinary), adhesive allergic

processes (tapes), diaper rash, peri-stomata, exudative wounds, around intubation cannulae, tracheostomies, gastrostomies, dermatitis, and skin irritation.[14] Previous clinical studies have assessed Cavilon™ in breast cancer radiotherapy, with variable findings. In an integrative review, Simões *et al.*[15] reported that the Cavilon™ skin protector was more effective than sorbolene (cream with 10% glycerin), but less effective than mometasone furoate cream in reducing radiodermatitis severity. Similarly, Shaw *et al*.,[16] in a clinical trial with postoperative breast cancer patients, demonstrated that Cavilon™ No-Sting Barrier Film delayed the onset of skin reactions, although topical corticosteroids showed superior efficacy in preventing higher-grade dermatitis. Graham *et al.*[17] also found Cavilon™ to be superior to sorbolene cream in reducing moist desquamation. Taken together, these findings suggest that Cavilon™ has relevant protective properties, but its comparative effectiveness against other commonly used agents remains inconclusive.

Despite Cavilon™'s promising effects against radiation,[14,17,18] our study aimed to evaluate its protective effect on mammary radiodermatitis compared to conventional treatment (*e.g.*, sunflower oil – a widely used conventional topical agent in clinical oncology practice in Brazil). We hypothesized that Cavilon™ would be superior to sunflower oil in reducing the severity and progression of radiodermatitis in breast cancer patients undergoing radiotherapy.

Materials and Methods

Participants

In the current study, 19 women were selected on the first consultation day in the radiotherapy sector. They received general information about the study, along with an explanation of the informed consent form, which was to be signed by patients who voluntarily agreed to participate. Selected patients received radiotherapy treatment and follow-up consultations with radiation oncologists in the hospital. The study lasted 5 weeks, with 25 patients receiving radiotherapy and 10 product applications (Cavilon™ and sunflower oil). All experimental protocols were approved by the Ethics Committees of the Centro Universitário F.A.M.I.N.A.S. on June 19, 2019 (C.A.A.E. #14568819.4.0000.5105).

Inclusion and exclusion criteria

The inclusion criteria were female sex, medium to large breast volume, and age 60 years or older. The exclusion criteria were receipt of more than 25 radiotherapy sessions in the present study (as younger patients generally require a higher number of sessions) and previous breast-conserving surgery (*i.e.*, residual breast tissue).

Procedures

Breast radiodermatitis evaluation

Breast dermatitis during radiotherapy (or radiodermatitis) is clinically categorized into several stages to assess the progression and severity of skin reactions:[19] 0 represents no visible skin changes; 1 involves faint erythema and dry desquamation, where the skin appears mildly irritated but without significant discomfort; 2 is characterized by moderate to brisk erythema, patchy moist desquamation confined to skin folds and creases and moderate edema; 3 involves confluent, moist desquamation beyond skin folds, often associated with bleeding and severe pain, necessitating intensive management strategies; 4 typically denotes ulceration and necrosis, as seen in more severe dermatological assessments. These stages provide a framework for assessing the progression and severity of skin reactions in breast radiotherapy patients, facilitating targeted interventions to manage and mitigate symptoms.[19] Two trained oncologists (PPC and UBR) evaluated these stages during the radiotherapy sessions and at the end of the interventions, ensuring continuous and precise assessment throughout the treatment period.

Intervention

Cavilon™ (Cavilon™ Advanced Skin) and sunflower oil (0.1% w/w) were applied by a medical doctor post-radiotherapy. Applications occurred on Mondays and Thursdays over the residual breast, following a demarcation line (Figure 1). Treatment with Cavilon™ was compared with sunflower oil as a conventional standard of care, creating optimal conditions for evaluation. Both treatments were applied to identical skin areas on the same patient, ensuring comparable cellular and vascular characteristics and allowing for a reliable, controlled comparison. Sunflower oil was chosen as a comparator because it is widely used in Brazilian oncology practice as a conventional, low-cost emollient for radiotherapy patients, despite limited evidence in randomized trials. Cavilon™ was applied to the lower lateral quadrant, and sunflower oil was applied to the lower medial quadrant of the treated breast (Figure 1). The application protocol for Cavilon™ included: i) ensuring the skin was clean and dry; ii) applying a smooth, uniform layer from a distance of 10 to 15 cm across the desired area; iii) reapplying to any missed areas once the initial application had dried (approximately 30 seconds); iv) ensuring separation of skin contact areas in fold regions to allow the skin to dry before returning to its normal position. Sunflower oil was manually applied with a gauze previously soaked in the oil. Both products were isolated on the skin using a protective film to prevent mixing during application. In cases where patients progressed to stage 3 radiodermatitis, mometasone furoate cream 1% was introduced as an *ad hoc* safety measure, in accordance with ethical principles, to prevent progression to stage 4 and allow the continuation of radiotherapy.

The radiotherapy regimen consisted of a total dose of 50.0 Gy, delivered in daily doses of 2.0 Gy across 25 fractions, evenly covering the entire residual breast for 5 weeks. The emitted energy was 6 mega high voltage. Cavilon™ and sunflower oil applications were applied to their respective breast quadrants during the 5-week treatment period, with 10 applications each (every Monday and Thursday). Captured images (Nikon Full HD movie camera) were used to verify the condition of the breast skin lesions.

Statistical analysis

Statistical procedures were conducted using the chi-square test. All analyses used the Statistical Package for the Social Sciences (IBM SPSS Statistics, version 221.0, Chicago, IL, USA). A statistical difference was considered when the p-value was lower than 0.05.

Results

The mean age of the patients included in our study was 70.4±6.4 years. Among them, 63% self-identified as Brown and 37% as White. Regarding breast size, 58% of patients reported medium size, 32% reported large size, and 11% reported extra-large size. Detailed individual patient characteristics and radiotherapy data are presented in *Supplementary Table 1*.

In our study, 89.5% of patients (n=17) developed radiodermatitis, and 10.5% (n=2) had no skin toxicity. Post-treatment assessments indicated that in the Cavilon™-treated quadrants, 16% exhibited no radiodermatitis (stage 0), compared to 11% in the sunflower oil-treated quadrants. In the Cavilon™-treated quadrant, 74% reached stage 1, 5% stage 2, and another 5% stage 3. In the sunflower oil-treated quadrants, 53% had stage 1, 26% had stage 2, and 11% had stage 3. No patients in either group reached stage 4 radiodermatitis (Figure 2).

The mean degree of radiodermatitis was 0.95 (95% confidence interval [CI]: 0.61-1.29) in Cavilon™-treated quadrants and 1.37 (95% CI: 0.97-1.77) in sunflower oil-treated quadrants. This difference was statistically significant (paired *t*-test, p=0.016; Wilcoxon signed-rank test, p=0.021). In addition, therapeutic efficacy analysis confirmed the superiority of Cavilon™ in preventing radiodermatitis progression (chi-square test, p=0.029). These results indicate that Cavilon™ is more effective than sunflower oil in protecting against mammary radiodermatitis.

It is essential to point out that 2 patients in our study progressed to stage 3 radiodermatitis. One of them is only in the medial quadrant (sunflower oil), and the other is in both quadrants (medial [sunflower oil] and lateral [Cavilon™]). Consequently, we implemented a third medication, mometasone furoate cream (1%), for these patients to prevent further progression of skin toxicity to stage 4 radiodermatitis and potential interruption of radiotherapy.

Discussion

The present study was designed to evaluate the protective effect of Cavilon™ on breast radiodermatitis. We enrolled 19 women who underwent 25 radiotherapy sessions. Each participant received applications of Cavilon™ (lateral quadrant) and sunflower oil (medial quadrant) twice weekly. Post-radiotherapy, we noted that 16% of the women showed no radiodermatitis (stage 0) in the Cavilon™ quadrant. Seventy-four percent of the patients progressed to stage 1 radiodermatitis, 5% to stage 2, and 5% to stage 3. In contrast, in the medial quadrant of the breast with sunflower oil application, stage 0 was observed in 11% of cases (no radiodermatitis), 53% progressed to stage 1 radiodermatitis, 26% to stage 2, and 11% to stage 3. Thus, our findings show that: i) both treatments do not entirely prevent the onset of mammary radiodermatitis, as most showed stage 1 skin toxicity even with topical application of Cavilon™ and sunflower oil; ii) Cavilon™ is more effective than sunflower oil in mitigating the progression of radiodermatitis (from stage 1 to 3).

Radiodermatitis commonly develops during breast radiation therapy and varies in severity. Topical therapeutic applications have been proposed to solve this. For example, in a clinical review conducted by Kodiyan and Amber,[20] hydrocortisone 1% cream prevented post-radiotherapy skin reactions. In the study conducted by Uysal *et al.*,[21] a 54% reduction in radiodermatitis progression was found after betamethasone application in breast cancer patients undergoing radiotherapy treatment. In another study, Shukla *et al.*[22] used beclomethasone spray in the management of breast radiodermatitis, and a 36.6% (11/30) reduction in wet desquamation (stage 3) was noted. Overall, these findings support the feasibility of topical treatments in managing radiodermatitis. Based on our results, we can consider that topical application of Cavilon™ adds to preventive and protective therapy for skin toxicity promoted by breast radiotherapy treatment.

Our study noted that Cavilon™ did not entirely prevent the development of breast radiodermatitis, as most showed stage 1 skin toxicity, even with the topical application of Cavilon™ and sunflower oil. Schmudt *et al.*[23] observed similar results with topical methylprednisolone and dexpanthenol, in which both creams improved radiation radiodermatitis but did not prevent its onset. These findings show that radiation generally causes breast skin toxicity, even with adjunctive drug therapy.

It has been estimated that about 95% of women undergoing radiation therapy develop some degree of radiodermatitis.[3] This post-radiation skin reaction occurs due to this radiosensitive organ's high cell renewal capacity. When skin cells are stimulated by ionizing radiation, the molecules undergo hydrolysis, generating oxidative stress in the irradiated tissue. Consequently, the DNA of the cells is damaged, leading to acute inflammation.[9] It is possible that Cavilon™ neutralized the effects of oxidative stress through its therapeutic compounds, such as hexamethyldisiloxane, isooctane, acrylic

copolymer, and polyphenylmethyloxane. We do not know the mechanism of Cavilon™'s action in treating radiodermatitis, so further studies are needed to investigate it.

This study has some limitations that merit careful consideration. Although the sample size is adequate for preliminary findings, it is relatively small for generalizing the results across all breast cancer patients undergoing radiotherapy. Furthermore, the study's duration was limited to the immediate period of radiotherapy (the long-term effects of the treatments on skin recovery and health were not assessed). Future studies should consider these factors to validate and extend our findings.

In our study, 2 patients progressed to stage 3. One of them was only in the medial quadrant (sunflower oil), and the other was in both quadrants (medial [sunflower oil] and lateral [Cavilon™]). For ethical reasons, the authors implemented a third medication (mometasone furoate cream 1%) in patients who progressed to stage 3 radiodermatitis (2/19). The inclusion of mometasone furoate was intended to prevent the evolution of skin toxicity to stage 4. We decided to include a third medication to maintain the patient's safety and ensure the continuity of the proposed radiotherapy treatment. Thus, no patient in our study evolved to stage 4 breast radiodermatitis, nor was it necessary to discontinue radiotherapy treatment because of the side effects it could cause. It is worth noting that stage 4 radiodermatitis, in addition to interrupting treatment, can cause damage to the quality of life of breast cancer patients undergoing radiotherapy.

Conclusions

Taken together, our findings suggest that Cavilon™ may be more effective than sunflower oil in reducing the progression of breast radiodermatitis from stage 1 to 3. The study indicates the superior efficacy of Cavilon™ over sunflower oil in managing radiodermatitis in breast cancer patients. Cavilon™'s protective properties may reduce the need for treatment interruptions, thereby improving patient outcomes during radiotherapy.

References

1. Veronesi U, Zurrida S. Preserving life and conserving the breast. Lancet Oncol 2009;10:736.
2. Schnur JB, Love B, Scheckner BL, et al. A systematic review of patient-rated measures of radiodermatitis in breast cancer radiotherapy. Am J Clin Oncol 2011;34:529-36.
3. Knobf MT, Sun Y. A longitudinal study of symptoms and self-care activities in women treated with primary radiotherapy for breast cancer. Cancer Nurs 2005;28:210-8.
4. McQuestion M. Evidence-based skin care management in radiation therapy: clinical update. Semin Oncol Nurs 2011;27:e1-17.

5. Dunne-Daly CF. Skin and Wound Care in Radiation Oncology. Cancer Nurs 1995;18:144-61.
6. Aistars J. The validity of skin care protocols followed by women with breast cancer receiving external radiation. Clin J Oncol Nurs 2006;10:487.
7. Hymes SR, Strom EA, Fife C. Radiation dermatitis: clinical presentation, pathophysiology, and treatment. J Am Acad Dermatol 2006;54:28-46.
8. Zhang Y, Zhang S, Shao X. Topical agent therapy for prevention and treatment of radiodermatitis: a meta-analysis. Support Care Cancer 2013;21:1025-31.
9. Porock D. Predicting the severity of radiation skin reactions in women with breast cancer. Oncol Nurs Forum 1998;25:1019-29.
10. Bolderston A, Lloyd NS, Wong RK, et al. Supportive Care Guidelines Group of Cancer Care Ontario Program in Evidence-Based Care. The prevention and management of acute skin reactions related to radiation therapy: a systematic review and practice guideline. Support Care Cancer 2006;14:802-17.
11. Dirier A, Akmansu M, Bora H, et al. The effect of vitamin E on acute skin reaction caused by radiotherapy Clin Exp Dermatol 2007;32:571-3.
12. Salvo N, Barnes E, Van Draanen J, et al. Prophylaxis and management of acute radiation-induced skin reactions: a systematic review of the literature. Curr Oncol 2010;17:94-112.
13. Costa MM, Silva SB, Quinto ALP, et al. Phototherapy 660 nm for the prevention of radiodermatitis in breast cancer patients receiving radiation therapy: study protocol for a randomized controlled trial. Trials 2014;15:1-6.
14. Schuren J, Becker A, Gary Sibbald R. A liquid film-forming acrylate for peri-wound protection: a systematic review and meta-analysis (3M™ Cavilon™ no-sting barrier film). Int Wound J 2005;2:230-8.
15. Simões FV, Santos VO, Silva RND, Silva RCD. Effectiveness of skin protectors and calendula officinalis for prevention and treatment of radiodermatitis: an integrative review. Rev Bras Enferm 2020;73:e20190815.
16. Shaw SZ, Nien HH, Wu CJ, et al. 3M Cavilon No-Sting Barrier Film or topical corticosteroid (mometasone furoate) for protection against radiation dermatitis: A clinical trial. J Formos Med Assoc 2015;114:407-14.
17. Graham P, Browne L, Capp A, et al. Randomized, paired comparison of No-Sting Barrier Film versus sorbolene cream (10% glycerine) skin care during post-mastectomy irradiation. Int J Radiat Oncology Biol Phys 2004;58:241-6.

18. Lam AC, Yu E, Vanwynsberghe D, et al. Phase III randomized pair comparison of a barrier film vs. standard skin care in preventing radiation dermatitis in post-lumpectomy patients with breast cancer receiving adjuvant radiation therapy. Cureus 2019;11:e4807.
19. Cox JD, Stetz J, Pajak TF. Toxicity criteria of the Radiation Therapy Oncology Group (R.T.O.G.) and the European Organization for Research and Treatment of Cancer (E.O.R.T.C.) 92-04. Int J Radiat Oncol Biol Phys 1995;31:1341-6.
20. Kodiyan J, Amber KT. Topical antioxidants in radiodermatitis: a clinical review. Inter J Palliat Nurs 2015;21:446-52.
21. Uysal B, Gamsız H, Dincoglan F, et al. Comparative evaluation of topical corticosteroid and moisturizer in the prevention of radiodermatitis in breast cancer radiotherapy. Indian J Dermatol 2020;65:279-83.
22. Shukla PN, Gairola M, Mohanti BK, et al. Prophylactic beclomethasone spray to the skin during postoperative radiotherapy of carcinoma breast: a prospective randomized study. Indian J Cancer 2006;43:180-4.
23. Schmuth M, Wimmer MA, Hofer S, et al. Topical corticosteroid therapy for acute radiation dermatitis: a prospective, randomized, double-blind study. Br J Dermatol 2002;146:983-91.

Figure 1. Experimental protocol of the study: Cavilon™ (lateral quadrant) and sunflower oil (medial quadrant) were applied on Mondays and Thursdays over 5 weeks of radiotherapy.

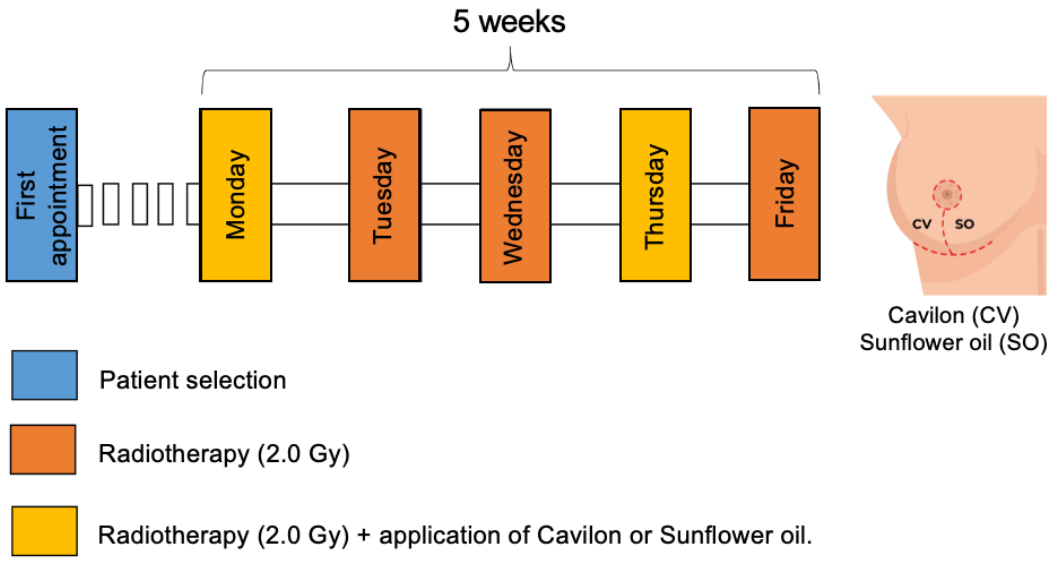

Figure 2. Stages of radiodermatitis in cancer patients undergoing radiotherapy treatment and protective topical use of sunflower oil or Cavilon™ (n=19).