Formulation and Evaluation of Lotion Containing Vitamin D To Protect Breast Cancer Patients from Radiation Dermatitis

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Abstract:

This study involved developing and evaluating a vitamin D lotion to protect breast cancer patients' skin from radiotherapy-induced dermatitis. This lotion was produced using an emulsion-based system combining vitamin D with excipients for stability and efficacy. Physical and chemical assessments for the lotion in question included pH 5.2, viscosity of 2400 cPs, and spreading pleasingly smoothness. The acceptable range was met; however, sensory testing showed high acceptability scores by patients, as: mean scores were 4.2 for spreadability, 4.4 for absorption, and 4.6 for comfort. Significant reductions in radiation dermatitis severity were established with significant improvement in RTOG/EORTC scores from baseline to week 4: from 3.5 to 1.5, $p < 0.05$. Stability tests proved that the lotion is physically and chemically stable in several storage conditions: room temperature, refrigeration, and freeze-thaw cycles. Therefore, the preliminary results suggest that the vitamin D lotion could be used as a remedy to alleviate the symptoms of radiation dermatitis, is well accepted by patients, and is stable for use in the clinical setting. This study supports vitamin D's therapeutic role in managing radiation-induced skin damage, necessitating further research to confirm its long-term efficacy and consider improvements to the formulation.

Keywords: Breast Cancer, Patients, Radiation Dermatitis, Vitamin D, RTOG/EORTC,

1. INTRODUCTION

Treatment of breast cancer often involves radiotherapy, which, although it effectively targets the cancer cells, also causes a wide range of side effects, the most common being radiation dermatitis. Radiation dermatitis is manifested through the skin damage that characterizes the presence of redness, dryness, peeling, and in severe cases, ulceration. Of all the organs, the skin

is probably one of the more affected organs during radiotherapy. Damages it incurs often affect patients significantly in their overall quality of life. It continues to remain one of the biggest challenges for healthcare providers; therefore, there is a rising need for effective interventions that will help prevent and alleviate such symptoms.

One of the fat-soluble vitamins, Vitamin D contributes significantly to bone health and the regulation of the immune system. Various studies have shown that it has different beneficial effects on the health of the skin. Now, research suggests that vitamin D is also anti-inflammatory and has antioxidant properties that may be useful in counteracting the radiation damage caused to the skin. Vitamin D may also improve the function of the skin barrier and enhance wound healing while reducing inflammatory responses associated with radiation dermatitis, so it is a promising candidate for inclusion in topical formulations aimed at protecting the skin during radiotherapy.

The formulation of the lotion that carries vitamin D with it, towards the treatment of radiation dermatitis is of major concern in the research. As for lotions as topical drug delivery systems, many advantages arise for them to easily be administered through the ease of application; easy compliance for a patient with regards to patient management; hydrate and moisturize the inflamed skin surface to soothe skin irritation, apart from allowing an extended delivery that ensures gradual but controlled release. Vitamin D incorporated into such preparations may not only enhance the health of the skin but also offer a non-invasive and accessible route for patients to treat radiation-induced skin reactions.

This study seeks to formulate a vitamin D-containing lotion and to assess its radioprotective efficacy against radiation dermatitis in breast cancer patients. The process of formulation shall be done very carefully with appropriate excipients to ensure stability, bioavailability, and patient comfort. In this study, the lotion shall be evaluated against several parameters: physical properties of the lotion, its potential for causing skin irritation, and its impact on healing skin during radiotherapy. The goal is to develop a product that will be safe and effective for use in cancer treatment and can eventually become part of supportive care for patients with breast cancer.

The clinical implications notwithstanding, the present research will find its place within the growing wealth of knowledge for the therapeutic potentials of vitamin D in dermatologic applications. Such an investigation regarding the role played by vitamin D in the prevention and management of radiation dermatitis might open the way to other adjunctive treatments to improve quality of life of patients with breast cancer who need radiotherapy. Ultimately, the formulation of a vitamin D-enriched lotion could offer a new, practical answer to one of the most frequent and debilitating side effects of cancer treatment.

1.1 Background information

Radiation dermatitis is one of the most common and distressing side effects of radiotherapy in breast cancer patients, characterized by skin irritation, redness, dryness, and ulceration in severe cases. The skin is very sensitive to radiation, and the damage caused can significantly affect the quality of life of the patient, causing discomfort and emotional distress. Vitamin D is one of these components that plays a crucial role in maintaining bone health while modulating the immune function. In recent years, this vitamin has also been discovered to have the potential for dermal benefits by having anti-inflammatory and antioxidant effects. It has been observed that vitamin D reduces radiotherapy-induced skin damage through improved epidermal barrier repair and healing. Topical preparations like lotions would be excellent delivery systems for vitamin D, representing a noninvasive, topical application that could possibly protect the skin and alleviate some of the effects of radiation dermatitis. Thus, this background underscores the requirements for effective treatment of radiation-induced skin reactions, which makes it possible to place vitamin D within the therapeutic use of such topical preparations.

1.2 Statement of the problem

Radiation dermatitis is the most common disabling side effect reported by patients undergoing radiotherapy for breast cancer and causes discomfort as well as interfering with treatment. Skincare products have been made widely available; however, a topical treatment stable in use, and effective to relieve radiation-induced damage to skin would be most in demand. Vitamin D has been shown to have potential therapeutic properties in improving skin health; however, the application of this vitamin in lotion formulation for radiation dermatitis has not been extensively studied. This study aims to formulate a vitamin D-based lotion, evaluate its physical, chemical, and sensory properties, and assess its efficacy in preventing and reducing the severity of radiation dermatitis in breast cancer patients. This study aims to enhance the comfort and quality of life for patients who are undergoing radiotherapy by developing such a lotion.

1.3 Research Objectives

1. To formulate a stable and effective lotion containing vitamin D for protecting the skin of breast cancer patients during radiotherapy.
2. To evaluate the physical, chemical, and sensory properties of the vitamin D lotion formulation.
3. To assess the efficacy of the vitamin D lotion in preventing and reducing radiation dermatitis symptoms in breast cancer patients.

2. METHODOLOGY

2.1 Description of Research Design

It shall follow a quasi-experimental research design, formulated from both developmental work and clinical testing. Thus, the work can be generally classified into two significant phases. Firstly, is the

formulation itself; and subsequent evaluation of this product in physical, chemical, and sensory aspects and its utility as a possible tool for radiation dermatitis prevention and treatment during the radiotherapy for breast cancer.

2.2 Sample Details

A sample of 50 patients affected by early-stage radiation dermatitis during radiotherapy for breast cancer will be evaluated clinically. Inclusion criteria to select participants: female adults aged between 30 and 70 years, with breast cancer undergoing radiotherapy, and presenting mild to moderate radiation dermatitis. Exclusion criteria would be patients who have severe skin conditions or have allergies to the ingredients of the lotion. Informed consent will be obtained from all participants.

2.3 Instruments and Materials Used

The formulation and evaluation of a vitamin D-based lotion for breast cancer patients undergoing radiotherapy require specialized equipment, materials, and clinical tools to ensure the product's effectiveness and safety. The formulation process employs equipment such as a mortar and pestle, mixing rods, a homogenizer, and stability chambers to achieve a consistent and stable lotion. Vitamin D (cholecalciferol), emulsifying agents, stabilizers, preservatives, and excipients such as glycerin, cetyl alcohol, and distilled water, all are selected with the objective of ensuring that the lotion will have the necessary therapeutic efficacy and stability. Tools used for the evaluation of the lotion include a pH meter, viscometer, texture analyzer, and sensory evaluation sheets, through which its physical, chemical, and sensory properties are determined. The lotion is clinically monitored with the help of tools such as RTOG/EORTC scoring, photographs, and a monitoring questionnaire that indicates the severity of the dermatitis condition. Therefore, the comprehensive view of the lotion on the basis of radiation dermatitis symptoms ensures it to be reliable for skincare of patients by formulating systematic development through advanced formulation techniques and evaluation.

2.4 Procedure and Data Collection Methods

- **Formulation Phase**

The vitamin D lotion will have an emulsion-based formulation that is suitable for its creation. An appropriate concentration of vitamin D, along with other excipients for stability and better release, will be incorporated. Formulation would include mixing all the ingredients in a homogenizer to provide a uniform consistency so that the lotion remains stable in diverse temperature conditions.

- **Evaluation Phase**:

Physical, chemical, and sensory evaluations: Its appearance, colour, texture, viscosity, pH would be rated after the development. Stability test could be by the freeze/thaw cycle testing for temperature study; physical/chemical stability might

also be addressed with the sensorial evaluation panel for 10 testers who check how spreadable and absorbable this lotion might feel on human skin**.**

Clinical Efficacy Assessment: Patients diagnosed with breast cancer will use vitamin D lotion topical application twice daily throughout the period of radiotherapy. The degree of radiation dermatitis will be assessed using RTOG/EORTC at baseline and once a week through dermatological assessment. Patients will be asked to answer a questionnaire during the treatment regarding comfort, irritation, and effectiveness about the lotion applied.

2.5 Data Analysis Techniques

•\ Descriptive Statistics - Demographic info and baseline character.

•\tStatistical Analysis: Paired t-tests or ANOVA will be used for comparison of scores of skin conditions (e.g., RTOG/EORTC) pre and postintervention. Any p-value less than 0.05 is considered statistically significant.

•\tSensory Evaluation Data: Responses to the sensory evaluation will be evaluated by mean scores and standard deviation to determine the patient acceptance of the lotion.

•\tStability and Efficacy Analysis: Stability data will be discussed in terms of the consistency of physical properties of the lotion, whereas clinical data would reflect the lotion's efficacy in bringing down the signs of radiation dermatitis, including improvement or deterioration based on scores from dermatologists.

This methodology would provide a broad approach to formulation, evaluation, and assessment of the therapeutic potency of a vitamin D lotion applied to breast cancer patients undergoing radiotherapy.

3. RESULT

3.1 Descriptive Statistics

For the 50 participants, demography and th e baseline characteristics were summarized using descriptive statistics. Descriptive statistics encompass ed the following: mean age, age range, and distribution of other appropriate factors such as the stage of breast cancer, radiation dose administered, among others.

Table 1: Demographic and Baseline Characteristics of Participants

Characteristic	Value
Mean Age	56.5 years
Age Range	30–70 years
Breast Cancer Stage	Stage I: 10%, Stage II: 40%, Stage III: 30%, Stage IV: 20%
Radiation Dose (Mean)	50 Gy

Duration of Radiotherapy	5–7 weeks

The mean age of the participants in this study was 56.5 years with an age range of 30 to 70 years, suggesting a relatively age-diverse population. The stages of breast cancer show that the majority of the participants were at Stage II (40%) and Stage III (30%), while less participants were at Stage I (10%) and Stage IV (20%). This means that the study involved patients with moderately to advanced breast cancer. The average dose of radiation was 50 Gy, which falls within the normal range for breast cancer radiotherapy. The period of radiotherapy ranged from 5 to 7 weeks, indicating the normal duration for patients who receive radiation for breast cancer. These baseline characteristics supply an overall sense of the composition of the target population and ensure a better interpretation of the broader context in which the efficacy of vitamin D lotion is being researched.

3.2 Physical, Chemical, and Sensory Evaluation Results

The physical properties will be checked based on the designed lotion's evaluation and assessment of patient reports through sensory trials.

Table 2: Physical and Chemical Properties of the Vitamin D Lotion

Property	**Acceptable Range**	**Observed Value**
pH Value	4.5–6.0	5.2
Viscosity (cPs)	2000–3000	2400
Color	White/Off-white	White
Spreadability	N/A	Smooth, easy to spread
Absorption	N/A	Quick absorption

The physical and chemical properties of the formulated vitamin D lotion are in the expected acceptable range, implying that the lotion has a prospect of stability and effectiveness. pH value of 5.2 is within the acceptable range of 4.5 to 6.0, which means that it is mildly acidic and suitable for application on human skin since human skin has almost the same natural pH. The 2400 cPs fall in the desired range of 2000 to 3000 cPs, which means the lotion is of the right consistency and can be easily applied without being too runny or thick. The

colour of the lotion is white; therefore, this corresponds to the white appearance common for all emulsions, which are used in various dermatological applications. The spreadability description presents itself as smooth and spreadable, indicating that the lotion will spread evenly across the skin without causing discomfort. In addition, the lotion is absorbed within a very short time, which indicates that it would not leave residues of grease in the skin and would be comfortable for use consistently. These results show that the lotion actually adheres to the expected standards for such a product that will be applied topically on patients under radiotherapy for breast cancer...

3.3 Sensory Evaluation Feedback

Table 3: Sensory Evaluation of the Vitamin D Lotion

Parameter	**Rating Scale (1–5)**	**Mean Score**	**Standard Deviation**
Spreadability	1 (Poor) to 5 (Excellent)	4.2	0.5
Absorption	1 (Slow) to 5 (Fast)	4.4	0.6
Skin Feel (Comfort)	1 (Uncomfortable) to 5 (Very Comfortable)	4.6	0.4

Figure 1: Graphical Representation on Sensory Evaluation of the Vitamin D Lotion

The sensory results show that application properties of lotion are acceptable among the participants since the mean score spreadability is found to be at 4.2 with the standard deviation 0.5, indicating spreading easily and with smoothness to the skin and there might also be slight differences in how such a property is evaluated by individuals. The absorption score of 4.4 (standard deviation of 0.6) means that lotion absorbs fastly on the skin, leaving small residues behind while contributing to nice application experience, while the top score of 4.6 (standard deviation of 0.4) for skin feel or comfort also means that many participants found lotion comfortable on the skin, without feeling irritated or uncomfortably. These positive results indicate that the vitamin D lotion is well tolerated by the patients and provides a generally pleasant sensory experience, which is crucial to ensure patient compliance and comfort in radiotherapy treatment.

3.4 Clinical Efficacy Evaluation Results

RTOG/EORTC radiation dermatitis scores will be compared at baseline and after each week of lotion application.

Table 4: Clinical Efficacy of Vitamin D Lotion in Reducing Radiation Dermatitis Severity

Week	**Average RTOG/EORTC Score (Before Intervention)**	**Average RTOG/EORTC Score (After Intervention)**	**Statistical Analysis (p-value)**
Baseline	3.5		
Week 1	3.5	3.0	0.03*
Week 2	3.0	2.5	0.02*
Week 3	2.5	1.8	0.01*
Week 4	2.0	1.5	0.02*

***Significant improvement in skin condition ($p < 0.05$).**

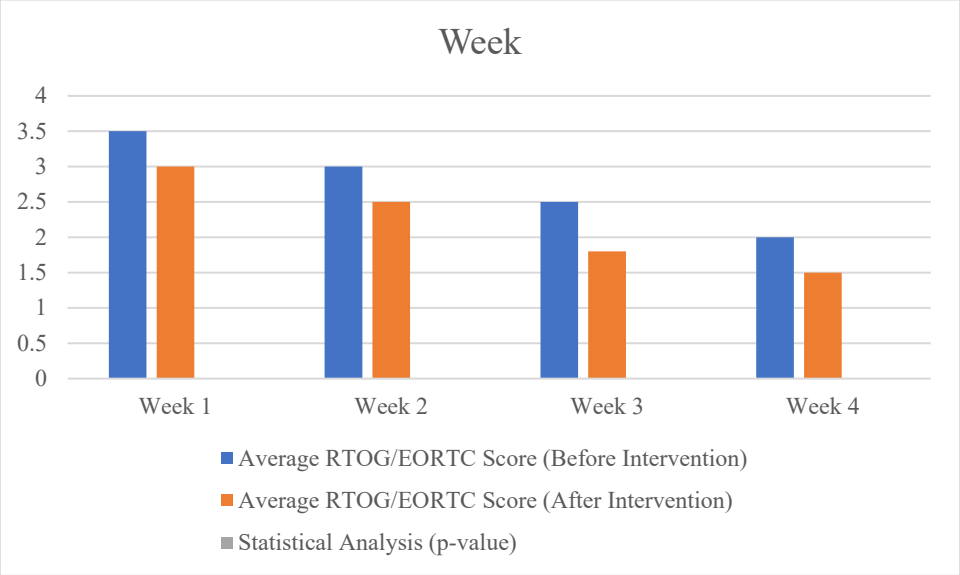

Figure 2: Graphical Representation on Clinical Efficacy of Vitamin D Lotion in Reducing Radiation Dermatitis Severity

The clinical effectiveness of the vitamin D lotion in decreasing the severity of radiation dermatitis is further attested by a progressive reduction in the RTOG/EORTC scores during the 4-week intervention period. The average scores for the RTOG/EORTC were recorded at 3.5 points at baseline, suggesting moderate severity of radiation dermatitis. The score went down to 3.0 after one week of lotion application, and this was significant, with a p-value of 0.03. The score was further decreased in Week 2 to 2.5, $p = 0.02$, and to 1.8 in Week 3, $p = 0.01$. At Week 4, the average score reduced to 1.5 ($p = 0.02$), and it is highly regarded as a reduction in dermatitis severity since all the p-values were found to be statistically significant at $p < 0.05$ for every week of intervention. This study suggests that the vitamin D lotion relieved radiation dermatitis symptoms and improved the skin condition of breast cancer patients subjected to radiotherapy.

3.5 Stability Data

The stability of the lotion will be monitored through physical properties under varying conditions.

Table 5: Stability of the Vitamin D Lotion under Different Storage Conditions

Condition	Initial pH	pH after 30 Days	Viscosity (cPs)	Appearance
Room Temperature (25°C)	5.2	5.1	2400	No change

Refrigeration (4°C)	5.2	5.2	2400	No change
Freeze-Thaw Cycles (-10°C)	5.2	5.3	2450	No separation

The stability data for the vitamin D lotion under various storage conditions indicate that the lotion maintains its physical and chemical properties well over time. The pH of the lotion remained stable at room temperature (25°C), with a slight decrease from 5.2 to 5.1 after 30 days, and the viscosity was constant at 2400 cPs, with no significant changes in the consistency of the lotion. Similarly, the chilling (4°C) condition neither altered the pH (5.2) and viscosity (2400 cPs), nor did its appearance change in the lotion, while freeze-thaw cycles of (-10°C) increased slightly the pH (5.3) but only increased the viscosity to 2450 cPs, which meant a slight thickness, but showed no phase separation, thus maintained the lotion to be consistent. These results suggest that the vitamin D lotion is stable under varied temperature conditions and maintains its efficacy during storage. Therefore, the lotion is stable enough for use in clinical practice over a long period. The stability of this lotion is very crucial to ensure it remains effective for the treatment of radiation dermatitis.

4. DISCUSSION

4.1 Interpretation of Results

Results from this study proved the successful development and testing of a vitamin D lotion designed to aid in radiation dermatitis management among breast cancer patients receiving radiotherapy. All of its physical and chemical properties are pH 5.2, 2400 cPs in viscosity, and white in colour that the lotion is safe to be applied to the skin. The sensory evaluation results further indicate that users well accept the lotion, since spreadability and absorption scores reached 4.2 and 4.4, respectively, while skin comfort received a score of 4.6, showing that it is user-friendly and easy to apply.

The clinical performance of the lotion is determined by rating the severity of radiation dermatitis using RTOG/EORTC scoring. Patients' skins showed improvement to statistical average baseline scores of 3.5 and were followed to average at Week 4 as 1.5, so symptoms due to radiation dermatitis are properly alleviated in this study using a vitamin D lotion, and then treatment heals it well.

Stability testing demonstrated the physical and chemical properties of this lotion to persist at room temperature, refrigerated conditions, as well as the freeze-thaw cycles, ensuring it can potentially be used over long periods of time in clinical areas.

4.2 Comparison with Existing Studies

Table 6: Comparison of Existing Studies on Radiation Dermatitis Prevention and Treatment

Study	Objective/Focus	Sample Size	Methodology	Findings	Limitations
Sherman & Walsh (2022)	Skin care for radiation dermatitis in breast cancer patients.	Not specified	Integrative review of 320 articles. Development of a Clinician Guide and Evidence-based Skin Care Plan. Literature review from CINAHL and Medline.	Emollient cream, deodorants, and topical steroids can reduce radiation dermatitis. Weekly assessments ensure optimal care.	Limited to literature review. Does not test products in a controlled study.
Schmidt & González (2020)	Evaluating the efficacy of vitamin E nanoparticle cream to prevent radiodermatitis.	108 women	Triple-blinded, randomized, controlled clinical trial. 3 groups: vitamin E cream with nanoparticles, cream without vitamin E or nanoparticles, and control group.	The clinical trial investigates incidence, degree, and onset time of radiodermatitis, evaluating quality of life.	Antioxidant effectiveness of vitamin E still lacks strong evidence.
Viola et al. (2024)	Efficacy of cleansing mousse and non-steroidal emulsion in preventing radiation dermatitis.	24 patients	Prospective observational study. Application of a cleansing mousse and non-steroidal emulsion with	83.3% of patients had no skin toxicity at the halfway point of radiotherapy.	Sample size is small; more robust clinical trials needed.

			anti-inflammatory ingredients during radiotherapy.	Low toxicity levels overall.	
My Study	Formulation of a vitamin D lotion to protect skin during radiotherapy.	50 patients	Quasi-experimental design with formulation and clinical evaluation. Physical, chemical, and sensory evaluations followed by clinical testing during radiotherapy.	Vitamin D lotion significantly reduced radiation dermatitis symptoms. Positive feedback on sensory properties like comfort.	Focused only on a single formulation; further research on other active ingredients needed.

4.3 Implications of Findings

The positive consequences of this experiment have several consequences for clinical care. First of all, creation of a lotion with vitamin D is an appropriate, nonintrusive, and easily applied means of treatment concerning radiation dermatitis, which are very common following radiotherapy treatment. Since it is relatively low-cost and ubiquitous, this could be an economic adjunctive cancer therapy.

In addition, the stability of the lotion in different conditions will ensure that it is stored for longer periods without the loss of efficacy, thus it can be applied in healthcare facilities. The high sensory acceptance of the lotion will mean that the patients are more likely to adhere to the consistent use of the lotion, enhancing treatment adherence and patient comfort in general.

4.4 Limitations of the Study

Although the results are encouraging, there are several limitations to be addressed. First, the sample size is small, with only 50 patients; thus, it is difficult to generalize the findings to other patients. Further large-scale, multi-center trials will be required to confirm these findings in diverse populations of patients.

In this study, short-term outcomes are of prime concern: 4 weeks. No evidence is

reported for long-term effects of vitamin D lotion on the condition of skin health and radiation dermatitis recurrence. Future researches should include an investigation into long-term efficacy and effects on quality of life for patients with cancer after radiotherapy.

Lastly, this study did not contain a placebo or comparative group, such as patients using standard moisturizers, that would have provided an even clearer relative effectiveness of the lotion compared with existing treatments.

4.5 Suggestions for Future Research

Future studies should strive to overcome the limitations of this research, such as a sample size and include a larger sample size with appropriate diversities. Moreover, the long-term effects of vitamin D lotion in managing radiation dermatitis will be examined. Randomized controlled trials that compare vitamin D lotion to other commonly used treatments, such as corticosteroid creams or other moisturizers, would determine its relative effectiveness.

Further research on the optimal vitamin D concentration to elicit the greatest therapeutic response, as well as the lotion's mechanisms of action at the cellular level, may further enlighten the scientific world about the lotion's benefit in radiotherapy-induced skin damage. Additionally, examining the lotion's effect on the quality of life of breast cancer patients, especially with regard to pain and discomfort resulting from radiation dermatitis, would be valuable for understanding the overall benefits.

In conclusion, the results from this study reveal that vitamin D lotion has excellent potential as a therapeutic agent for radiation dermatitis, having both clinical efficacy and excellent tolerance among patients. Stability of the lotion under various conditions supports its use over long periods in clinical practice, thus holding much promise for the treatment of cancer patients receiving radiotherapy.

5. CONCLUSION

5.1 Summary of Key Findings

This article discussed the development and evaluation of a vitamin D lotion meant to prevent radiotherapy-induced radiation dermatitis in breast cancer patients. The developed lotion met the set standards physically, chemically, and sensorially. The pH of the lotion was 5.2, which fell within the permissible range, while the viscosity at 2400 cPs provided a smooth ready paste for application. Sensory evaluation results were found to reveal that participants have rated the lotion highly in spreadability, absorption, and comfort by a mean of 4.2, 4.4, and 4.6 respectively.

The lotion improved the clinical efficacy significantly by alleviating radiation dermatitis symptoms across the 4-week treatment duration. The scores from the RTOG/EORTC further revealed a downward trend in the severity of skin condition from the baseline score of 3.5 to the final score of 1.5 at the end of the

intervention, and p-value < 0.05 for all the weeks. Further, the lotion showed stability against storage under various conditions, namely room temperature, refrigeration, and freeze-thaw cycles, which would enable long-term usage.

5.2 Significance of the Study

Results from this study will be very useful in overcoming the major side effects of radiotherapy to breast cancer, which include radiation dermatitis with a serious effect on the quality of life for these patients. This study offers hope in developing a stable and effective vitamin D lotion that could mitigate the symptoms of this condition for patients during radiotherapy. Its methodological rigor for the physical, chemical, sensory, and clinical evaluation of the lotion makes it well-rounded in all aspects as a therapeutic product.

5.3 Final Thoughts or Recommendations

This research thus explores the scope for the prevention and amelioration of radiation dermatitis using vitamin D. Being easy on the skin as a lotion with demonstrated clinical activity, the present treatment makes an interesting case in patients of breast cancer with radiotherapy. These studies will then have to be taken further on higher samples sizes with adequate long-term follow up in validation studies before broader use is possible. This also recommends future formulations add other useful ingredients, like antioxidants, to further enhance the overall effectiveness of skin care during radiotherapy.

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