

Formulation of a Proprietary Emulsion Based Revitalizing Cream and Implementing Evidence Based Practice in the Prevention of Radiodermatitis

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Purpose of the study

Radiodermatitis is one of the most frequently observed acute side effects of radiotherapy. It can have a negative impact on quality of life. The incidence of radiodermatitis with new technology and treatment modalities is not completely understood, but 95% of patients have reported some degree of integumentary system reaction to radiotherapy. This study's aim was to formulate and investigate the radiodermatitis prevention potential of a cream that contains beeswax, proprietary extract, cocoa butter, Hypericum perforatum oil and sweet almond oil instead of petroleum-based ingredients.

Introduction

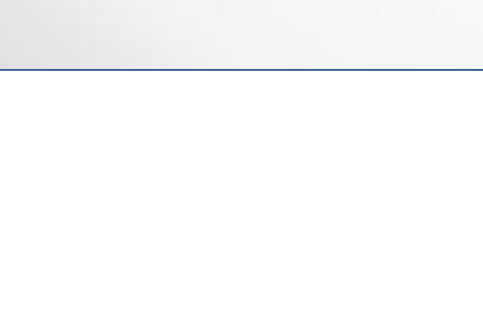
The current radiodermatitis standard of care varies. Most formulations used include petroleum-based ingredients. Petroleum gives the appearance of moisturized skin but doesn't actually contain skin nourishing properties as evidenced with data. While forming a barrier, petroleum can block skin from breathing properly, cause extra heat to build and trap bacteria resulting in further skin irritation with long term use. Petroleum can't be metabolized by the skin and there is concern that some of its components, like hydrocarbons known as serious contaminants may be stored in fat tissue and accumulate within the body. All this pointed to a need to a change in practice of using petroleum based ingredients.

Methods

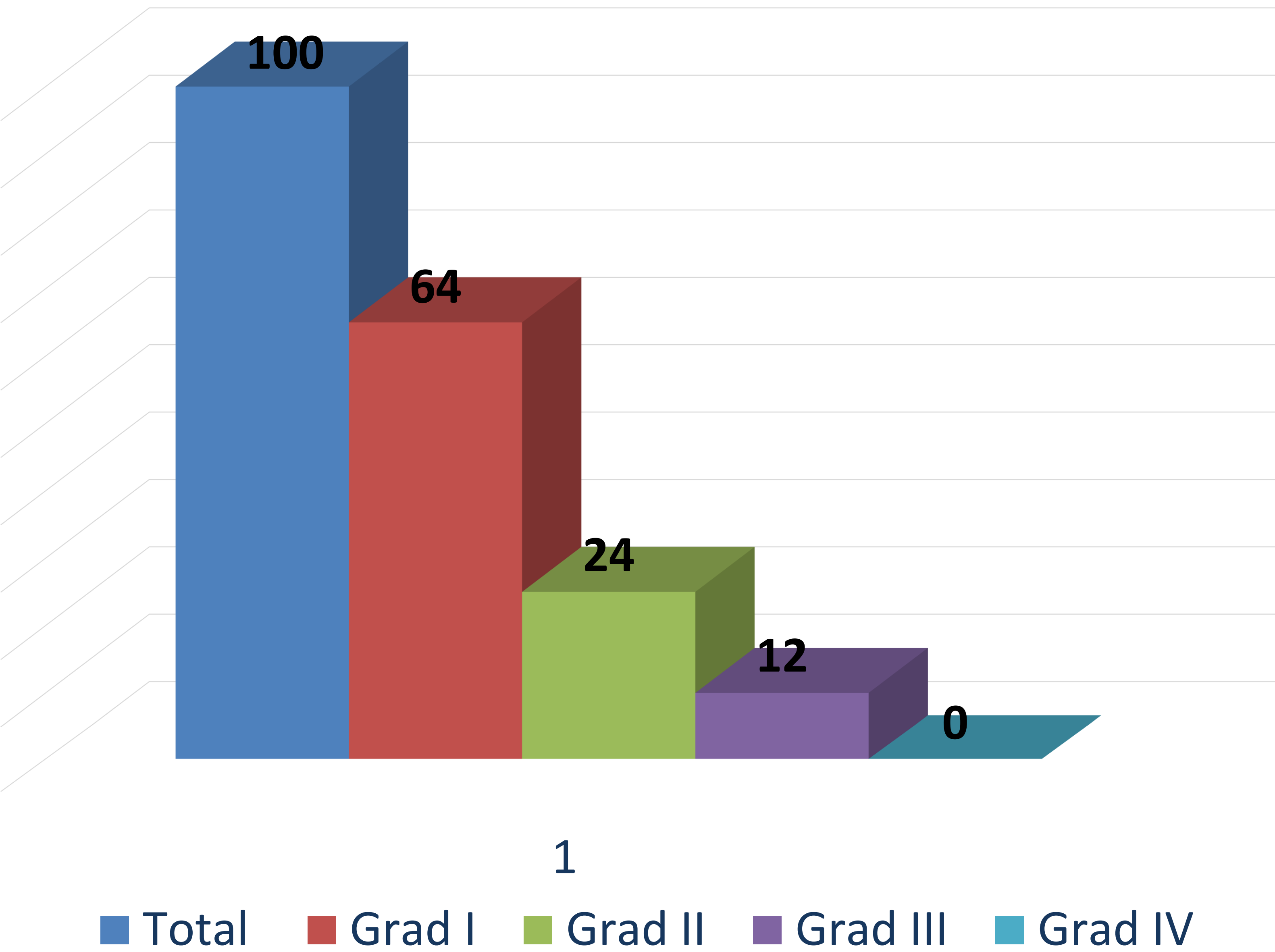
Formulation containing 20% of beeswax, proprietary extract, cocoa butter, Hypericum perforatum oil and sweet almond oil instead of liquid petrolatum or mineral oil was developed by entrapping in the inner aqueous phase of w/o emulsion. The cream was stored at different storage conditions of 8°C, 25°C, 40°C and 40°C+ 75% relative humidity to predict its stability. It is tested for sensitive skin. The formulation was evaluated for its effects on skin among cancer patients undergoing radiotherapy instead of petroleum based-creams.

RTOG Grading

Commonly used grading or scoring tools for the assessment and documentation of radiodermatitis include the Radiation Therapy Oncology Group (RTOG). The RTOG Scale is a toxicity grading scale that assesses the complications of radiation treatment involving the skin and other tissues and organs (Fisher et al., 2000; Haas, 2005). Toxicity is graded on a 0–4 scale. Toxicities manifest as erythema, pruritus, hyperpigmentation, dry desquamation, moist desquamation, ulceration, and necrosis. (Haas, 2005)

RTOG Grading Scale	
	RTOG 0 No visible change to skin
	RTOG 1 Faint or dull erythema. Mild tightness of skin and itching may occur
	RTOG 2 Bright erythema / dry desquamation. Sore, itchy and tight skin
	RTOG 2.5 Patchy moist desquamation. Yellow/pale green exudate. Soreness with oedema
	RTOG 3 Confluent moist desquamation. Yellow/pale green exudate. Soreness with oedema
	RTOG 4 Ulceration, bleeding, necrosis (rarely seen)

Effect of the Proprietary Revitalizing Cream



Results

The emulsion based revitalizing cream which contains beneficial ingredients and has no petroleum or derivatives, was used on over 100 patients over the course of a year with Head and Neck cancers undergoing daily radiation treatments. The aim was prevention and treatment of redness and irritation/rashes on skin subjected to radiotherapy. It was used two times daily during approximately 6 week treatment duration. Patients used the cream right after radiotherapy and at night before going to bed. A significant reduction was found in skin reactions compared to petroleum-based creams. Particularly important, the doctors did not need to prescribe additional creams or treatments to supplement the “revitalizing cream” which in comparison was inevitable in vast majority of cases when petroleum based creams were used.

Conclusion

Using natural products is considered one of the recent research approaches all over the World for treatment and prevention. Many hazards or safety recommendations associated with chemicals depend on a product's use and/or composition. The efficacy of various herbal remedies, extracts, tinctures and treatments is well known, and therapeutic herb products are increasingly recognized as desirable alternatives to synthetics. The Revitalizing cream is good for use as a barrier throughout radio-therapy treatments for minimizing risk of radio-dermatitis. It can also be used to relieve symptoms and help with healing if and after dermatitis occurs. The Revitalizing Cream formulated with natural efficacious ingredients instead of petrolatum or mineral oil resolved redness and irritation at a higher rate (95%) for patients undergoing radiotherapy with less adverse effects. Therefore a change in practice is recommended.

References

- Fisher, J., et all (2000). Randomized phase III study comparing best supportive care to Biafine as a prophylactic agent for radiation-induced skin toxicity for women undergoing breast irradiation: Radiation Therapy Oncology Group (RTOG) 97–13. International Journal of Radiation Oncology, Biology, Physics, 48, 1307–1310
- Ma, C.-M.C. (2005). The practice of radiation oncology. In D. Watkins Bruner, M.L. Haas, & T.K. Gosselin-Acomb (Eds.), Manual for radiation oncology nursing practice and education (3rd ed., pp. 12–21).
- McQuestion, M. (2010). Radiation-induced skin reactions. In M. Haas & G. Moore-Higgins(Eds.). Principles of skin care and the oncology patient (pp. 115–140).
- Fernández-Castro M, **Martín-Gil B. (2015)**. Effectiveness of topical therapies in patients with breast cancer that experience radiodermatitis. A systematic review. Enferm Clin. 2015 Nov-Dec;25(6):327-43