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USE AND AFFECTIVENESS OF TOPICAL THERAPIES IN RADIODERMATITIS TREATMENT: INTEGRATIVE REVIEW

Uso e efetividade de terapias tópicas no tratamento de radiodermatites: Revisão integrativa

Uso y efectividad de terapias tópicas en el tratamiento de radiodermatitis: Revisión integrativa

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ABSTRACT

Objective: to describe, in the light of bibliographic research, the use of topical therapies in the treatment of radiodermatitis. **Method**: integrative review of randomized clinical trials in the databases: MEDLINE, LILACS, COCHRANE, CINAHL and EMBASE. After observing the inclusion criteria, there were 1,289 studies, of which, following exclusion stages, resulted in 10 studies. **Results**: they were presented in categories in a summary table including: study data, research participants, type of topical therapy used; indications, contraindications and results. **Conclusion**: gaps have been found in the studies and these need investigation. New experimental trials are suggested in order to provide answers regarding the types of topical therapies more effective in radiodermatites, which will bring better treatment conditions and will ensure the quality of care and the oncological client a better quality of life.

Descriptors: Radiodermatitis; Wounds and injuries; Review.

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RESUMO

Objetivo: descrever, a luz da pesquisa bibliográfica, o uso das terapias tópicas no tratamento de radiodermatites. **Método:** revisão integrativa de ensaios clínicos randomizados nas bases de dados: *MEDLINE*, LILACS, biblioteca COCHRANE, *CINAHL* e EMBASE. Após observância dos critérios de inclusão, encontrou-se 1.289 estudos, dos quais, após etapas de exclusão resultaram em 10 estudos. **Resultados:** foram expostos em categorias num quadro síntese incluindo: dados do estudo, participantes da pesquisa, tipo de terapia tópica utilizada; indicações, contraindicações e resultados. **Conclusão:** encontraram-se lacunas nos estudos e estas necessitam de investigação. Sugerem-se novos ensaios experimentais a fim de trazer respostas quanto aos tipos de terapias tópicas mais efetivas em radiodermatites, o que trará melhores condições de tratamento e assegurará ao enfermeiro uma assistência de qualidade e ao cliente oncológico uma melhor qualidade de vida.

Descritores: Radiodermatite; Ferimentos e lesões; Revisão.

RESUMEN

Objetivo: describir, a la luz de la investigación bibliográfica, el uso de las terapias tópicas en el tratamiento de radiodermatitis. **Método:** revisión integrativa de ensayos clínicos aleatorizados en las bases de datos: MEDLINE, LILACS, biblioteca COCHRANE, CINAHL y EMBASE. Después de la observancia de los criterios de inclusión, se encontraron 1.289 estudios, de los cuales, después de etapas de exclusión resultaron en 10 estudios. **Resultados:** fueron expuestos en categorías en un cuadro síntesis incluyendo: datos del estudio, participantes de la investigación, tipo de terapia tópica utilizada; indicaciones, contraindicaciones y resultados. **Conclusión:** se ha encontrado lagunas en los estudios y éstas necesitan investigación. Se sugieren nuevos ensayos experimentales a fin de traer respuestas en cuanto a los tipos de terapias tópicas más efectivas en radiodermatitis, lo que traerá mejores condiciones de tratamiento y asegurará al enfermero una asistencia de calidad y al cliente oncológico una mejor calidad de vida.

Descriptores: Radiodermatitis; Heridas y lesiones; Revisión.

INTRODUCTION

Surgery, chemotherapy, and radiotherapy are the main procedures for treating cancer. The choice among such therapeutic modalities varies according to the tumor type, stage, and patient's physical condition. Among these, radiotherapy is the most used and may have a curative or palliative purpose, with the main goal of achieving favorable therapeutic levels, leading malignant cells to lose their clonogenicity while preserving healthy tissues.[1]

For this, radiotherapy uses ionizing radiation, which acts on the deoxyribonucleic acid (DNA) of malignant cells, preventing them from multiplying.[2] Nevertheless, despite the unquestionable benefits of radiotherapy treatment, it does not act in a specific way, consequently damaging normal cells. Thus, various organs of individuals exposed to radiation can manifest toxicity, including the skin and mucosa. Radiodermatitis and mucositis occur when the skin and mucosa manifest toxicity, respectively.

Radiodermatitis is defined as the set of skin lesions caused by excessive exposure to ionizing radiation. It is considered a complex burn that occurs from internal to external structures and may result from secondary or iatrogenic complications.[2] Physiologically, they originate from the destruction of cells in the epidermis' basal layer (loss of permeability) with exposure of the dermis (inflammatory process), causing erythema, which may or may not evolve into exudative dermatitis and other more serious manifestations.[3-4]

Skin reactions are generally moderate, but about 90% of people undergoing radiotherapy develop some degree of skin reaction,[5] which usually begins around the second and/or third week of treatment or up to one month after the end of the radiotherapy sessions (acute reactions). Also, skin reactions may begin months to years after the end of the radiotherapy treatment (late reactions).[1]

It is important to highlight Resolution No. 211/1998 of *the Conselho Federal de Enfermagem* (COFEN) [Federal Council of Nursing], which regulates the nursing professionals' performance in Radiotherapy, Nuclear Medicine and imaging services.[6] This Resolution states that nurses must promote and disseminate preventive health measures for skin lesions caused by radiotherapy treatment, as well as participate in therapeutic protocols for the treatment of skin lesions. [7]

Therefore, the nurses' role in the treatment of radiodermatitis is of paramount importance throughout the treatment, since they need to properly evaluate the lesion and the choose the product so that the proposed treatment could not be interrupted, maintaining the patient's quality of life.[8] Besides the importance of nurses in the treatment of radiodermatitis, a limited number of studies have addressed topical therapies. This study may contribute positively to the clinical practice, especially nursing care, taking into account the need for more information on this subject.

As a result, this study sought to describe, in light of the literature, the use of topical therapies for treating radiodermatitis and identifying its types and effectiveness, as well as the indications and contraindications and for using them. This study was guided by the following research questions: *"What are the topical therapies used for treating radiodermatitis?"; "What are the indications and contraindications for using these therapies?";* and "*What results have been obtained from the proposed topical therapies*".

METHODS

This integrative literature review was performed by searching publications on the following online databases: Medical Literature Analysis and Retrieval System (MEDLINE) via PubMed, *Literatura Latino-Americana e do Caribe em Ciências da Saúde* (LILACS) [Latin American and Caribbean Literature in Health Sciences], Cochrane Database of Systematic Reviews (COCHRANE), Cumulative Index

to Nursing and Allied Health Literature (CINAHL), and EMBASE. The following terms and variations were used: radiodermatitis; radioderm*; "radiation dermatitis"; radio*; lesion; wound*; skin; injuries; treament*; management; therap*; therapy; rtog; clinical; trial; "clinical trials as topic"; "clinical trial"; random*; "random allocation"; "therapeutic use"; and "randomized controlled trial".

The literature search took place in October from 2nd to 13th, 2015. The inclusion criteria were randomized clinical trials on topical therapies used for treating radiodermatitis and publications in Portuguese, English, and Spanish. After applying the inclusion criteria, a total of 1,289 studies were found. To better manage the next selection phases, the studies were grouped in folders by using the EndNote bibliographic software.

The exclusion criteria were: studies with no abstract; studies on the prevention of radiodermatitis, in other words, on the treatment of intact skin using radiotherapy with no radiodermatitis at the beginning; studies on other routes of administration (combined or not), such as atopic, nutritional, and homeopathic therapies; in *vitro* studies; and studies applying experimental models in animals (1st phase). In this sense, 29 studies remained, which after the random exclusion of repeated texts resulted in 19 studies (2nd phase). Texts whose title and abstract readings did not make clear the subject and/or methodology used moved on to the next phase for a full reading.

After reading the studies, seven were excluded for not addressing the subject and/or inadequate methodology and two studies were excluded for not being available in full (3rd phase). Thus, the final sample was comprised of 10 studies. **Figure 1** shows a detailed description of the process for analyzing the databases in order to select potentially relevant studies.

RESULTS AND DISCUSSION

The selected studies were gathered according to categories in a summary table, which includes the following: study data, number of research participants (case and control), topical therapy; and indications, contraindications, and effectiveness for the topical therapy (**Table 1**).

Considering the studies found, 60% were published in the last ten years, the oldest in 1967 and the most recent in 2015.9, 17 Regarding the geographic location of studies, most (60%) were conducted in Europe, followed by Asia and Oceania. Among the databases, only LILACS showed no publications on the subject (Figure 1).

Concerning the irradiation sites, the main fields were head/neck and breast, which was similar to the results reported in a previous review on the subject conducted by Blecha and Guedes.19 Besides this, other factors are predisposing to radiodermatitis, such as pathology, irradiated tissue volume, form and time of exposure, type and absorbed dose, technique used, as well as individual factors of the patient, such as age, skin fragility, nutritional status, hydration level, living habits, and hygiene, association with chemotherapy treatment (strengthening of the reactions), etc.[1,20]

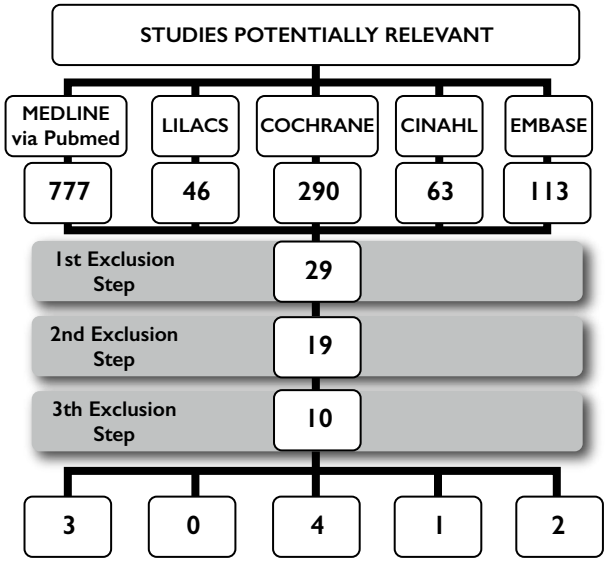

Figure 1 – Flowchart of the process for analyzing the databases.

Concerning the area of irradiation, it is worth noting the study carried out by Bjornberg and his collaborators,17 in which a thigh area was subdivided into four parts and deliberately exposed to radiation in order to cause radiodermatitis for demonstrating the use of different topical therapies. A total of 26 people participated in this study, which today could be considered ethically inappropriate according to the International Guidelines for Biomedical Research in Human Beings established by the Declaration of Helsinki.[21]

Among the therapies cited in the studies, the use of hydrocolloids and hydrogel gels was widely cited. They were used with different amounts of water. Hydrocolloids, composed of polyurethane molecules, are impermeable to liquids and bacteria, which speeds up wound healing and offers a refreshing sensation and pain relief. Hydrocolloids are indicated for a wide range of wounds in granulation and epithelialization stages, with little or no exudate. Gel Hydrogels are composed of water and a modified polymer from carboxymethyl cellulose and propylene glycol, enabling autolytic debridement of necrotic tissue, absorbing sphacel and the excess exudate. Both are used to provide a moist environment during injury.[9-11,15]

Humectants, moisturizers, and emollients were other therapies used. Among the moisturizing therapies, water-based sprays act by keeping the skin moist and thus bringing comfort and speeding up the process of wound

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healing. Concerning the moisturizers, WO1932® has water emulsion (83%), oil and linoleic acid in its formulation, acting on the skin in order to prevent or treat dryness and damage. Another cited moisturizer was Eucerine®, which is composed of urea, Natural Moisturizing Factors (NMFs), ceramide 3 and gluco-glycerol. Eucerine® and WO1932® share the same action mechanism. Among the emollients, one can mention Vaseline (a semi-solid mixture of hydrocarbons), also called petrolatum, which acts by preventing fluids from entering the wound, creating a barrier in order to protect it from bacteria and other foreign objects, preventing the loss of humidity, etc. Besides these, dry dressings are a kind of non-adherent mesh used on the lesion together with other topical therapies and/or with a secondary dressing, allowing the exchange of exudate to the external environment.[9-10,17-18]

Table 1 – Topical therapies addressed by the selected studies, their effectiveness, indications, and contraindications.

Reference	Case/ control	Topical therapy	Indications/ contraindications	Effectiveness
Bazire et al, 2015 (Radiotherapy and Oncology): France [Medline][9]	142/136	Hydrocolloid x water-based spray	Indications: painful erythema, wet shedding, and edema. No contraindications.	Both are effective. There is no significant difference between them.
Macmillan et al, 2007 (Int J Radiat Oncol Biol Phys): United Kingdom [Medline][10]	181/176	Hydrogels x dry dressings	Indications: wet shedding. No contraindications.	The dry dressings proved to be more effective and comfortable. The use of hydrogel dressings provides higher healing time without any improvement in pain, itching and comfort.
Mak et al, 2000 (Cancer Nursing): China [Medline][11]	21/18	Hydrocolloids x Violet Gentian	Indications: wet shedding. No contraindications.	The healing time was no difference between the two groups. Violet Gentian significantly reduced the size of the lesion and the intensity of the pain but received a low evaluation in relation to the dressings' aesthetics and comfort.
Ahmed et al, 2006 (J Pak Assoc Derma): Pakistan [COCHRANE][12]	25/25	0.1% betamethasone x 1%hydrocortisone	Indications: acute dermatitis, no other specifications. No contraindications.	Both are effective in treating acute radiation dermatitis, but the former produces a faster response than the latter.
Ansari et al, 2013 (Iranian Journal of Medical Sciences): Iran [COCHRANE][13]	32/31	Natural henna x 1%hydrocortisone	Indications: radiation-induced erythema. No contraindications.	Topical ointment of natural henna was most effective in healing radiation-induced dermatitis.
Delaney et al, 1997 (Australasian radiology): Australia [COCHRANE][14]	20/19	Sucralfate x no intervention	Indications: wet shedding. No contraindications.	The study was unable to demonstrate a difference in time for healing or pain relief, with or without the use of sucralfate cream.
Gollins et al, 2008 (Journal of wound care): United Kingdom [COCHRANE]15	16/14	0.5% gentian violet x hydrogels	Indications: radiation-induced wet shedding. No contraindications.	Hydrogel dressings are more likely to cure radiation-induced wet shedding and are better tolerated than 0.5% Violet Gentian.
Glees et al, 1979 (Clinical radiology): England [CINAHAL][16]	28/26	1%hydrocortisone x 0.05% clobetasone butyrate	Indications: erythema or small areas of wet shedding. No contraindications.	With regard to calming effects, neither of the two creams achieved resolutive management of radiodermatitis, although skin reactions are less intense with the use of 1% hydrocortisone cream.
Björnberg et al, 1967 (Clinical Radiology): Sweden [Embase][17]	26*	Betamethasone x Vaseline x Eucerine® x no intervention	Indications: radiodermatitis, no other specifications. No contraindications.	During the first 5 weeks after radiation, betamethasone ointment had a significantly better anti-inflammatory effect on dermatitis than conventional types of treatment.
Jensen et al, 2011 (Strahlenther Onkologie): Germany [Embase][18]	34/34	WO1932® x no intervention	Indications: radiodermatitis, no other specifications. No contraindications.	WO1932® was well tolerated, showing positive results with regard to the stratum corneum hydration and improvement of clinical symptoms such as itching.

*(4 identical fields under the thigh)

The class of topical corticosteroids was also widely discussed in the studies. Betamethasone 0.1%, Hydrocortisone 1% and Clobetasone Butyrate 0.05% were mentioned, which have local anti-inflammatory, antipruritic and vasoconstrictor effects in various skin conditions. However, it is worth noting that systemic absorption and other adverse effects, such as burning sensation, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruption and hypopigmentation

can occur by using these topical corticosteroids during prolonged periods of treatment (more than 4 weeks) and/or for treating larger areas (more than 10% of body surface). In addition, these topical corticosteroids can cause the following reactions when used in occlusive therapy: skin maceration, secondary infection, skin atrophy, etc.[12-13,16-17]

Other therapies mentioned in the studies and with a wide range of actions on lesions are sucralfate, gentian violet, and natural henna. Sucralfate is a cytoprotective agent that adheres to mucoproteins and forms a protective barrier, besides acting on angiogenesis, reducing pain and facilitating epidermis regeneration. Gentian violet has antiseptic and antimycotic action, can be used for treating burns and other skin and mucous lesions, and can cause irreversible stains, irritation and skin ulcers (also used as a primary dye in the Gram staining process). Natural Henna, originating from *Lawsonia inermis* Linnaeus (a tree species found in North Africa and South Asia), has both antibacterial and antifungal activities. For this reason, its powder has been used for more than a thousand years as a natural preservative; in addition, its flowers are used in perfumes and essential oils in Ayurvedic Medicine due to its calming and relaxing effect.[11,13-15]

Regarding the specific indications, little was reported by the studies. Most of them focused on the indications for use primarily in areas with painful erythema, edema, and skin shedding, which compromised the description of the therapies with regard to the degree of damage of the irradiated skin. In order to classify the various manifestations of radiodermatitis and help in treating it, the Radiation Therapy Oncology Group (RTOG) developed the Acute Radiation Morbidity Scoring Criteria in 1982, which has been used for over 25 years by the medical and nursing communities. These scoring criteria classify the degree of skin reaction from 0 to 4, in which 0 represents the lack of reactions and 4 the worst skin reactions.[22] Among the reviewed studies, none used the RTOG classification and some mentioned other forms of classification such as the Common Terminology Criteria for Adverse Events (CTCAE), which has been widely used in oncology as a scale for classifying and qualifying the severity of adverse events in cancer-related therapies undergoing clinical trials.[9] None of the studies pointed out contraindications for the use of these therapies.

As for the effectiveness of the topical therapies according to the studies, hydrocolloids, water-based, and WO1932® (specifically with regard to hydration and itching sprays) have been shown to be effective against radiodermatitis. Furthermore. Nonetheless, dry dressings have proved to be more effective than hydrogels, which, in turn, is more effective than gentian violet. Gentian violet is less aesthetic and comfortable than hydrocolloids. Sucralfate and 0.05% clobetasone butyrate are examples of some therapies that failed to provide a beneficial effect upon the treatment of radiodermatitis. In comparison with 1% hydrocortisone, 0.05% clobetasone butyrate caused the skin to suffer more intense reactions due to radiation. Natural henna and 0.1% betamethasone, however, demonstrated a greater effect against radiodermatitis than 1% hydrocortisone. In relation to 0.1% betamethasone, it showed a significantly better anti-inflammatory effect against radiodermatitis than conventional treatment (Eucerine® and Vaseline).

The Oncology Nursing Society (ONS) classifies topical therapies as "probably effective", "non-established efficacy" and "not recommended for practice".[23] Among the therapies analyzed in this review, some belong to the second classification (non-established efficacy): natural henna, hydrocolloids, hydrogels, and sucralfate. *Callendula officinalis* and 1% silver sulfadiazine, which belong to the "probably effective" classification, were not mentioned in the analyzed studies. Conclusively, among the "not recommended for practice" therapies, Aloe vera and Trolamine were mentioned.

Some variables related to radiodermatitis were not mentioned and deserve attention because of the degree of skin damage, such as ulceration, bleeding and necrosis (grade 4 according to the RTOG score). Some studies and institutional protocols report the use of several therapies, such as hydrofiber dressings for attenuating a hemorrhagic condition, activated charcoal for controlling large amounts of exudate in ulcerated or non-ulcerated lesions, and the various forms of debridement (instrumental, mechanical, chemical and autolytic) for treating necrosis due to radiodermatitis.[2,25] These and other therapies, although well established in clinical practice, still need to undergo experimental studies with well-defined methodological criteria to confirm their benefits and acquire greater knowledge of their adverse effects.

CONCLUSIONS

This study achieved the proposed objectives and discussed, based on scientific evidence, general ideas about topical therapies used for treating radiodermatitis. The findings will be of interest to nurses, who may improve the quality of care and create institutional protocols based on the best recommendations on the subject.

Conclusively, a number of important limitations need to be considered. First, some products are not available in the Brazilian market. Secondly, most researches do not have clear references regarding the technique used to apply the dressings, besides the care related to its application during the radiotherapy treatment. Thirdly, there were no reports on the performance of therapies not only under the immediate effects but also under the late effects of radiation, since these can happen years after the treatment.

Future research will have to investigate not only the choice of proper topical therapies but also the care related

to its use since nurses have their performance guided by the care process from the prevention to the treatment of this type of injury.

New experimental trials should be conducted, especially by nurses, in order to gain knowledge of the most effective types of topical therapies for treating radiodermatitis. These therapies may improve the treatment (less adverse effects of radiation on the skin, fewer interruptions and better radiation action on the tumor), consequently providing a better quality of life for the oncologic client.

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