LETTERS TO THE EDITOR

Information About Biafine for Radiation Dermatitis Excluded Important Information

On behalf of Medix Pharmaceuticals Americas, Inc., the U.S. distributor of Biafine®, I am writing to express deep concern over the following review article that appeared in *Oncology Nursing Forum* (Vol. 31, pp. 237–247): "Prevention and Treatment of Acute Radiation Dermatitis: A Literature Review" by Mihkaila Maurine Wickline. The article misrepresents the current state of the scientific literature and does a disservice to oncology healthcare professionals and patients alike. Although my following comments focus primarily on the author's comments and conclusions regarding Biafine, I have no reason to believe that her comments regarding other radiation therapies are valid.

Let me begin by noting the surprising failure on the part of the author to mention that Biafine has been cleared by the U.S. Food and Drug Administration (FDA) specifically for radiation dermatitis, not to mention for use on partial and full thickness wounds, first- and second-degree burns, and dry skin conditions. The FDA has reviewed much of the same literature as the author yet reached a different conclusion.

Although the author may have been unaware of the FDA's clearance of Biafine, she has no excuse for the numerous misinterpretations and misrepresentations of the study results described in the article and the failure to include the positive results observed. For example, on p. 240, in describing the findings of Szumacher et al. (2001), the author stated that "Biafine does not prevent dry or moist desquamation in patients undergoing concomitant radiotherapy and chemotherapy." Simply put, this conclusion may not be drawn from the underlying article. Although the investigators reported that prevention of grade 2 toxicity development was not demonstrated, they presented data demonstrating that the population treated with Biafine experienced significant benefits, including reduction in the quality and quantity of moist desquamation, as well as elimination of therapy interruptions because of skin breakdown.

Furthermore, with regard to Fisher et al. (2000), the author reported that the investigators found no overall difference between best supportive care and Biafine with respect to prevention of radiation-induced dermatitis. The author failed to report, however, that the investigators also found an interventional effect with Biafine and that large-breasted women receiving Biafine were more likely to have no toxicity six weeks after radiation therapy.

The author relied on these and other misinterpretations and misrepresentations of study results to draw the conclusion that Biafine has "not been proven effective and should not be used" (pp. 237, 242). In point of fact, each of the Biafine studies cited in the review article reports a benefit associated with use of the product during radiation therapy. Perhaps even more curious, despite the relative dearth of supportive data concerning the use of aloe vera during radiation therapy, the author concluded that "aloe vera may be beneficial and is not harmful" (p. 237). Although I do not necessarily question the author's conclusion with respect to the use of aloe vera, the logic with which that conclusion was drawn stands in marked contrast to the author's conclusions with respect to Biafine.

Biafine has been studied extensively, with many positive benefits reported and no evidence of any adverse events. Indeed, a continuing education piece on radiation therapy in patients with breast cancer reviewed many of the same studies cited by Wickline and drew completely opposite conclusions (Callahan, 2003). In that article, the author recommended highly the use of Biafine during radiation therapy. Thus, despite the numerous reported benefits of Biafine, Wickline reached an unsupportable—and, quite frankly, irresponsible—conclusion.

Whether because of timing or some other reason, the author failed to consider other data demonstrating the positive effects of Biafine. For example, Boisnic, Branchet-Gumila, Nizri, and Ben Slama (2003) reported Biafine's efficacy in skin subjected to 5 Gy ionizing radiation, with an increase in the mitotic number of cells in the basal layer of the epidermis. The emulsion acted on vascular permeability in the dermis after the first 24 hours. Restoration of CD34 expression after application of Biafine indicated good endothelial cell differentiation, collagen synthesis was increased, and this parameter was restored after Biafine treatment. This may offer an advantage in limiting the occurrence of postradiotherapy fibrosis. Furthermore, the effect of Biafine on interleukin (IL)-1 could be involved in the modulation of collagen synthesis observed. Results concerning IL-6 are consistent with those obtained by Coulomb, Friteau, and Dubertret (1997), who demonstrated that Biafine is chemotactic for macrophages and increases the IL-1/IL-6 ratio, chiefly by reducing IL-6 levels. Controls were treated with petroleum jelly. Biafine outperformed petroleum jelly in all the results mentioned previously, except the collagen assay, where results for both were found to be similar.

Biafine selectively recruits 3–10 times the normal amount of macrophages to a wound site while reducing the number of polymorphonuclear neutrophils recruited, thereby resulting in rapid granulation, epithelialization, and wound closure. Macrophages synthesize human collagenase and collagen and stimulate fibroblast proliferation for granulation tissue replacement. As radiation therapy destroys tissue layers that break down into moist desquamation, Biafine stimulates the body's healing mechanisms to rebuild them.

Finally, for general information, Biafine is soothing and cooling on application and can be refrigerated for additional cooling effect. Most competing products only hydrate the epidermis, but as much as 41% of the demineralized water in Biafine penetrates to the dermal level by osmosis in the first hour of application (Wepierre, 1988). Emollients in Biafine keep skin soft, supple, and elastic and fight maceration of intact periwound skin around moist desquamations. Stearic acid in Biafine's formulation replenishes the skin's natural barrier function against irritants, helping to normalize transepidermal water loss in patients whose skin often is compromised with dryness before radiation therapy starts.

The benefits of Biafine for use in patients undergoing radiation therapy are well documented in the scientific literature and recognized by the FDA. Any recommendation other than continued use of Biafine in this patient population jeopardizes the quality of care that healthcare providers may provide and patients may receive. Biafine should be a staple of the wound care armamentarium in the radiation therapy setting.

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References

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Digital Object Identifier: 10.1188/04.ONF.867-870