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Research Article

Use of Abzolem ® in Pressure Injuries: Experience of an Exploratory Study

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Abstract

Introduction: Pressure injuries represent a significant and prevalent public health problem in bedridden and institutionalized patients. The correct management of pressure injuries is essential for preventing complications, enhancing patient well-being, and reducing the overall burden on healthcare systems. It underscores the importance of a holistic and patient-centered approach to wound care. Preventive measures and the action of a multidisciplinary team are essential to the correct treatment of pressure injuries. There are multiple active dressings and topical solutions to treat and protect the wounds, among them the hyperoxygenated fatty acids, such as Abzolem®. Objective: Evaluate and verify the effectiveness and safety of the use of Abzolem® in the treatment of patients with pressure injuries grade I and II. Materials and methods: an exploratory study was carried out on 6 patients residing in a long-term establishment in Santiago of Chile with grade I and II pressure injuries in which Abzolem® was used for twice-daily dressings. Results: The use of Abzolem® led to a significant improvement in grade I pressure injuries in 10 ± 3 days and grade II pressure injuries in 15 ± 3 days, without related adverse events and with good tolerance by patients. Conclusion: The use of hyperoxygenated fatty acids, such as Abzolem® corresponds to a safe therapeutic alternative, easy to apply, and effective in the treatment of grade I and II pressure injuries.

Keywords

Pressure Ulcers, Pressure Injuries, Healing, Wounds, Institutionalized Patients

1. Introduction

Pressure injuries/ulcers (PIs) are defined as skin injuries that affect the skin and soft tissues, usually in relation to bony prominences. These injuries constitute a prevalent public health problem, especially in bedridden or institutionalized patients. Their occurrence is associated with complications such as increased risk of infection, intrahospital malnutrition, prolonged hospital stays, increased nursing workload, and healthcare costs [1]. In terms of prevalence, data from the National Group for the Study and Advice on Pressure Ulcers and Chronic Wounds (GNEAUPP) in Spain estimate a prev-

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alence of 7-8% for pressure injuries in acute care hospital units [2].

PI occur because of prolonged exposure of the skin and subcutaneous tissue to pressure and shear forces, for example, between a bony prominence and an external surface like a mattress or wheelchair cushion. When the pressure exerted exceeds the filling pressure of arterial capillaries (approximately 32 mmHg) and is greater than the venous drainage pressure (8-12 mmHg), blood flow is inhibited, leading to ischemic effects on tissues [3, 4].

Furthermore, PI are classified according to the NPUAP (US National Pressure Ulcer Advisory Panel) and EPUAP (European Pressure Ulcer Advisory Panel) classifications into 4 categories based on their depth and degree of progression. These categories include: grade I with blanchable erythema, grade II with the presence of blisters, grade III with involvement of deep tissues, possibly exposing muscle and tendon, and finally, grade IV with deep involvement and bone exposure, associated with the risk of osteitis or osteomyelitis [5].

A recent systematic review determined that the prevalence, incidence, and risk of developing a PI in an institutionalized patient were 11.6%, 14.3%, and 8.5%, respectively [6]. Grade I and II PI were the most common, with the most frequent locations being the heel (34.1%), sacrum (27.2%), and foot (18.4%)[6]. Another systematic review estimated that the average prevalence of PI at the time of hospital admission was 5.2%, increasing to 12.3% at discharge. It also found that the incidence of PI ranged from 4.5% to 78.4% [7].

Preventive measures include frequent position changes, the use of pressure control orthoses (anti-decubitus mattress, foam devices, among others), protection of skin integrity, moisture control, among others [8]. Regarding treatment, it should be carried out by a multidisciplinary team. For grade I and II PI, treatment involves pressure relief, nutritional optimization, and various healing alternatives, while grade III and IV injuries often require surgical debridement and reconstruction [9]. Essential for the resolution of PI are dressings with the use of various active dressings and topical solutions for cleaning and debridement. These include the topical use of silver sulfadiazine, polyhexanide, iodophors, and 0.025% sodium hypochlorite [10]. When choosing, considerations should be given to the location of the lesions, the presence of infection, and the size and quality of the perilesional skin.

As an alternative to the aforementioned methods, the use of hyperoxygenated fatty acids has been proposed as a means to protect the skin integrity of at-risk areas, proving useful in the prevention and treatment of grade I PI [11]. Among these, Abzolem® is a topical solution of hyperoxygenated fatty acids associated with centella asiatica, aloe vera, plantain, and beta-sitosterol, with a peroxide index between 200-400 milliequivalents [12].

2. Abzolem® Overview

2.1. Mechanisms of Action of Abzolem®

The ozoneides present in Abzolem® act through three main mechanisms. In in vivo and in vitro studies, it has been observed that Abzolem® activates the PI3K&Akt/mTOR signaling pathway, triggering a cascade of events that results in increased epithelial-mesenchymal transition (EMT) and, consequently, enhanced fibroblast migration. This contributes to the healing and regeneration of the affected tissues [13].

Abzolem® also activates growth factors such as PDGF, TGF-β, and VEGF, promoting neovascularization and cellular renewal, thereby improving tissue microcirculation [14].

In an in vitro study, the activity of ozoneides against various bacteria (*mycobacteria*, *enterococcus*, *streptococcus*, *staphylococcus*, *Escherichia coli*, and *Pseudomonas aeruginosa*) was investigated, showing antimicrobial activity against all strains studied. Therefore, as a third relevant mechanism, Abzolem® promotes a broad-spectrum germicidal control through the action of ozoneides and present peroxides, contributing to preventing contamination and bacterial colonization of the treated tissue [15].

Regarding other components, in an in vitro study, beta-sitosterol was found to stimulate ceramide synthesis by increasing the expression of relevant enzymes in its synthesis, such as ceramide synthase and glucosylceramide synthase [16]. Since ceramides are the main intercellular lipid present in the stratum corneum, Abzolem® could contribute to preserving and regenerating this barrier that prevents water loss and dehydration of the skin [17].

2.2. Safety Considerations

Various studies support the safety of using ozonized fatty acids, including toxicological studies (CENIC Journal, Vol. 26, Special Issue, p. 105, 1995), histological studies (CENIC Journal, Biological Sciences 20 (1-2-3), 23, 1989), mutagenic studies (CENIC Journal, Biological Sciences 20 (1-2-3): 1-4, 1989), genotoxic studies (CENIC Journal, Biological Sciences 29 (3): 200, 1998), and teratogenic studies (Proceedings of the 1st Ibero-American Congress on Ozone Applications, Havana City, Ozone in Medicine 11, 1990) (WO 03/085072 A1).

Hyperoxygenated fatty acids, including those present in Abzolem®, are part of the same family of ozonized fatty acids, differing by their higher presence of secondary ozoneides (hence their designation as hyperoxygenated). Therefore, their safety characteristics can be extrapolated.

The objective of this work is to verify, through the development of an exploratory study, the efficacy and safety of Abzolem® in the treatment of grade I and II pressure injuries.

3. Materials and Methods

To achieve the above, a clinical protocol was authorized by the ethics committee, nursing staff was trained, and the signature of informed consent or assent was obtained. A group of elderly residents from a long-stay facility in Santiago, Chile, was selected. This facility implemented all standard pressure injury prevention measures (position changes, orthoses use, etc.), but despite these measures, residents presented pressure injuries.

A total of 6 patients were included, comprising 3 men and 3 women, with an average age of 72 ± 2.5 years. In terms of functionality, all were bedridden and had multiple comorbidities: 83% had hypertension, 67% had Type 2 Diabetes Mellitus, 33% had chronic kidney disease, and 33% had cerebral organic damage, among other conditions.

The injuries were located in relation to bony prominences, with 80% in the sacral region, 30% on the heels, and 10% on elbows (2 patients had more than 1 pressure injury). Regarding depth, 70% of the injuries were classified as grade I pressure injuries (non-blanchable erythema), and 30% were grade II pressure injuries (partial skin thickness involvement, with the presence of blisters), according to the NPUAP classification. None of the injuries showed signs of active infection.

Abzolem® was included in the treatment of these patients, applied twice a day during their routine care through gentle massage. Additionally, standard measures for pressure injury prevention were maintained.

4. Results

Images of 4 out of the 6 patients in the study are presented. In Figures 1 and 2, of patients with grade I pressure injuries in the sacral area, a decrease in the depth of the injuries, increased healing and tissue regeneration, and an improvement in the conditions of the skin surrounding the injuries are evident after 7-8 days of Abzolem® use. There is also a reduction in erythema and maceration of the area.

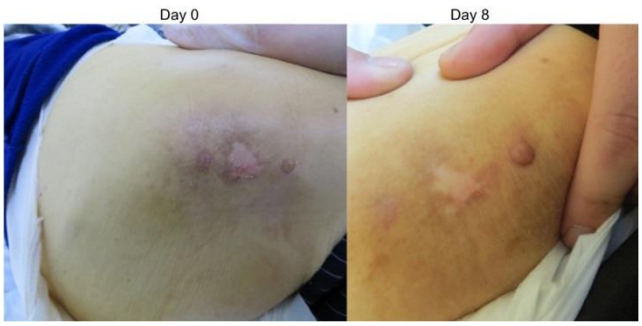

Figure 1. *Patient with Grade I sacral Pressure Injury (PI). A decrease in the depth of the injury and an improvement in the quality of the surrounding skin are observed between days 0 and 8 of treatment.*

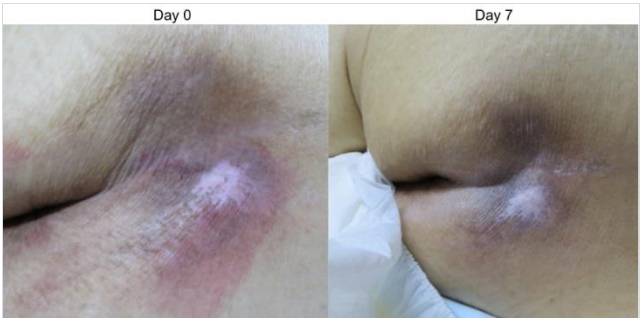

Figure 2. *Patient with Grade I sacral Pressure Injury (PI). Improvement is observed between day 0 and day 7 of treatment, with less redness and maceration of the surrounding skin, and healing in the affected area.*

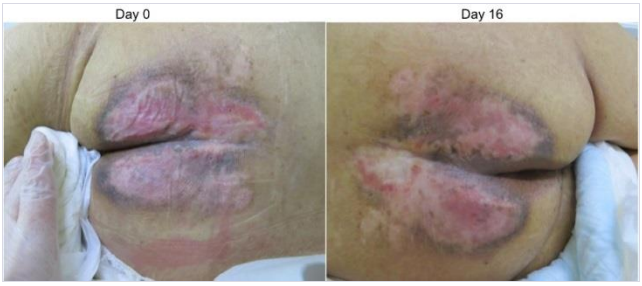

Figure 3. *Patient with Grade II Pressure Injury (PI). Between day 0 and day 16 of treatment, a healing lesion is observed with less redness and maceration of the affected skin.*

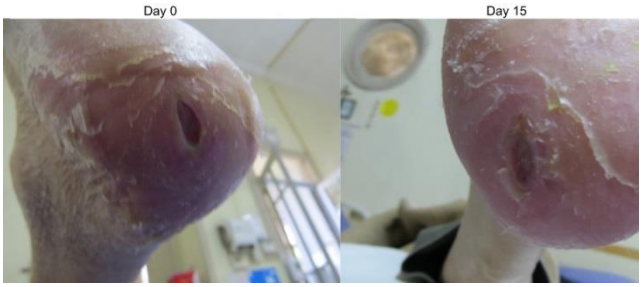

Figure 4. *Patient with Grade II Pressure Injury (PI). An injury without apparent progression is noted, with a better appearance in the surrounding skin.*

Figures 3 and 4 show a patient with a grade II sacral pressure injury and a grade II pressure injury on the heel. In both cases, after 14-15 days of treatment, there is increased tissue repair and healing, with an improved appearance of the skin surrounding the injury (similar to grade I injuries). Importantly, in no case was there progression or deepening of the injuries.

Daily use of Abzolem® led to a significant improvement in grade I pressure injuries in 10 ± 3 days and grade II pressure injuries in 15 ± 3 days, with no related adverse events and good patient tolerance. The first signs of clear improvement were evident between the third and seventh day in all patients.

5. Discussion

PI constitute a prevalent public health problem, especially in institutionalized or bedridden patients. Their occurrence is associated with complications such as an increased risk of infection, intrahospital malnutrition, prolonged hospital stays, increased nursing workload, and healthcare costs. Therefore, various preventive measures are implemented, including frequent position changes, the use of pressure relief orthoses, and general skin integrity care.

This study evaluated the effect of applying Abzolem® twice a day on different grade I and grade II PI that developed in institutionalized elderly individuals despite preventive measures. As shown in Figures 1, 2, 3, and 4, the use of Abzolem® in all cases halted the progression of the injuries and enhanced healing, with a noticeable improvement in the appearance of the surrounding skin. These effects are explained by and consistent with the previously explained mechanisms of action, as the product is designed to aid in the healing and regeneration of the skin, promote wound healing, generate new blood vessels, and stimulate ceramide synthesis, preventing water loss through the stratum corneum. This last mechanism best explains the observed change in the appearance of the perilesional skin. Therefore, it could be interesting to conduct studies evaluating the effectiveness of Abzolem® in preventing the occurrence of pressure injuries, maintaining skin integrity in at-risk patients.

A recent pilot study evaluated the use of hyperoxygenated fatty acids compounds in the cutaneous lesions of 4 pediatric patients with purpura fulminans. A total of 225 measurements were obtained, with mean pre-intervention scores of 71.17±15.65% versus 73.68±14.83% post-intervention ($p<0.001$). They conclude that the early and continued application of hyperoxygenated fatty acids in the management of sepsis-induced purpura fulminans increased the tissue microcirculation observed after the application of hyperoxygenated fatty acids, with no adverse events [18]. Another study evaluated the use of another hyperoxygenated fatty acid, Mepentol, in preventing the development of pressure ulcers. Conclude that of a total of 331 patients, the pressure-ulcer incidence was 7.32% in the intervention group versus 17.37% in the placebo group (p 0.006). Evidence that hyperoxygenated fatty acids are an effective measure was found to be cost-effective [19]. In a study that evaluated the effect of daily topical application of hyperoxygenated fatty acids emulsion on transcutaneous oxygen pressure (TcPO2) in the feet of 50 neuropathic and neuroischaemic patients with diabetes. The tested emulsion showed an increase in TcPO2 and an improvement in skin tropism in patients with neuroischaemic foot with an increase in TcPO2 values after two months that remained at month three (day 60: 42.34±10.98mmHg; p=0.006; day 90: 41.62±10.88mmHg; p=0.011) [20].

On the other hand, there are multiple systematic literature reviews regarding the use of various topical treatments and dressings in managing pressure injuries, including hyperoxygenated fatty acids, silicone dressings, hydrocolloid dressings, and hydrophilic foam dressings, among others. These reviews have established that the use of fatty acids and silicone dressings may reduce the incidence of pressure injuries. However, concerning management, there is a difficulty in making comparisons, as the existing evidence is considered of low quality, with inaccuracies regarding the percentage of wound healing and the inclusion of different treatment intervals in various studies. This is why the superiority of one type of dressing over another in the treatment of pressure injuries has not been objectively established so far. It highlights that these studies still have a low level of evidence, and more research is needed to confirm these results [21-23]. Therefore, we propose the need for randomized comparative clinical studies between Abzolem® and other healing alternatives.

6. Conclusion

The use of Abzolem® was associated with a rapid and significant improvement in pressure injuries in all patients. Furthermore, it proved to be a safe product to use, with multiple studies supporting this fact and demonstrating good tolerance, with no short-term adverse effects observed in the studied patients. Abzolem® represents a safe, easy-to-apply, and effective therapeutic alternative in the treatment of grade I and grade II pressure injuries, contributing to the management of a condition that has significant consequences for patients and healthcare systems. Managing pressure injuries poses a considerable challenge for healthcare teams, and Abzolem® emerges as a valuable option in addressing this clinical concern.

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Conflicts of Interest

The authors declare no conflicts of interest.

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