



Research Article

Efficacy and Tolerability of a Cream Containing Polyhexanide and Rigenase[®] for the Prevention of Bacterial Superinfections of the Skin after Minor Surgical Procedures

Stefano Veraldi^{1*}, Rossana Schianchi²

¹Department of Pathophysiology and Transplantation, Università degli Studi, Foundation IRCCS, Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy

²European Institute of Dermatology, Milan, Italy

***Corresponding author:** Stefano Veraldi, Department of Pathophysiology and Transplantation, Università degli Studi, Foundation IRCCS, Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy

Citation: Veraldi S, Schianchi R (2023) Efficacy and Tolerability of a Cream Containing Polyhexanide and Rigenase[®] for the Prevention of Bacterial Superinfections of the Skin after Minor Surgical Procedures. Clin Exp Dermatol Ther 8: 200. DOI:10.29011/2575-8268.100200

Received Date: 13 January 2023; **Accepted Date:** 14 January 2023; **Published Date:** 19 January 2023

Abstract

Introduction: Polyhexanide is a polymer that is usually employed as hydrochloride salt at the concentration of 0.1%. It is active *in vitro* against several bacteria, *Candida albicans* and *Acanthamoeba* sp. **Aim:** We present the results of a sponsor-free study about the efficacy and tolerability of a cream containing polyhexanide and Rigenase[®] for the prevention of bacterial superinfections of the skin after minor surgical procedures. **Patients and Methods:** Eighty-eight Caucasian patients (50 males and 38 females, with an age ranging from 18 to 91 years), who were affected by a total of 528 benign lesions of the skin, after minor surgical procedures (skin biopsies, electrodesiccation, cryotherapy, photodynamic therapy, laser therapy or chemical peelings) were treated with the cream (twice daily for 7 days). The treatment started the day after the surgical procedure. Nineteen patients were immunodepressed; 19 patients were in therapy with antiaggregant and/or anticoagulant. Three patients were pregnant. All patients were observed one and two weeks after the beginning of the treatment with the cream. **Results:** No cases of bacterial superinfections were observed clinically. No bacteriological examinations were carried out. Three patients reported mild irritation on the site of application of the cream; however, it was unnecessary to stop the treatment. **Conclusions:** Topical antiseptics, such as polyhexanide, rather than topical antibiotics, should be taken into consideration for the prevention of bacterial superinfections of the skin after minor surgical procedures. This philosophy could help to reduce in the near future the risks of bacterial resistance.

Keywords: Minor surgical procedures; Bacterial superinfections of the skin; Polyhexanide; Rigenase®

Introduction

Some months ago, we published on this journal the preliminary results of a sponsor-free study about the efficacy and tolerability of a cream containing polyhexanide and Rigenase® for the prevention of bacterial superinfections of the skin after minor surgical procedures (biopsies, electrodesiccation, cryotherapy, photodynamic therapy, laser therapy and chemical peelings) [1]. We present now the final results of this study.

Patients and Methods

The case list consists of 88 Caucasian patients (50 males and 38 females, with an age ranging from 18 to 91 years), who were affected by benign lesions of the skin (seborrheic keratoses, actinic keratoses, hemangiomas, fibromas, post-acne scars). A total of 528 lesions were treated. Nineteen patients were immunodepressed because of autoimmune diseases, neoplasms, transplantations, therapies with immunomodulating drugs, corticosteroids, immunodepressive drugs and antitumorals. Nineteen patients were in therapy with antiaggregants (mainly acetylsalicylic acid) and/or anticoagulants (mainly clopidogrel or dabigatran). Three patients were pregnant. Depending on the skin disorder, patients were subjected to skin biopsies, electrodesiccation, cryotherapy, photodynamic therapy, laser therapy or chemical peelings. After each specific treatment, a cream containing 0.1% polyhexanide and Rigenase® was prescribed: it was applied twice daily for 7 days; the treatment started the day after the surgical procedure. All patients were observed one and two weeks after the beginning of the treatment with the cream.

Results

No cases of bacterial superinfections were observed clinically. No bacteriological examinations were therefore carried out. Three patients reported mild irritation on the site of application of the cream; however, it was unnecessary to stop the treatment. These three patients were subsequently subjected to patch tests: results were negative.

Discussion

Polyhexanide [polyhexamethylene guanide, polyhexamethylene biguanide, poly (iminoimidocarbonyl-imino-hexamethylene) hydrochloride] is a polymer, i.e., a substance with a high molecular weight that consists of a more or less high number of structural units. The molecular formula is $(C_8H_{17}N_5)_n$. The structural formula is reported in Figure 1. Polyhexanide is usually employed as hydrochloride salt at the concentration of 0.1%. Polyhexanide is active *in vitro* against several bacteria [*Staphylococcus aureus* (also methicillin-resistant strains), vancomycin-resistant enterococci, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*], yeasts (*Candida albicans*), *Aspergillus brasiliensis* and *Acanthamoeba* sp. Many studies showed the efficacy and safety of 0.01 and 0.02% polyhexanide in the treatment of keratitis caused by *Acanthamoeba* sp. [2]. Polyhexanide is not mutagenic, cancerogenic and teratogenic: it can therefore be used with safety in pregnancy: as previously mentioned, we used it in three pregnant. Furthermore, it is neither photosensitizer nor phototoxic. In 2000, an article was published about the possible allergenic potential of polyhexanide [3]. However, seven years later, the same authors concluded that “the biocide polyhexamethylene biguanide remains an uncommon contact allergen” [4]. The indications of polyhexanide are: disinfection of contact lenses, linen disinfection, sanitization of swimming pools and spa waters in place of chlorine- or bromine-based products. In the skin, it is used in chronic ulcers, burns, for pre- and post-surgery and mucous membranes disinfection, for antiseptic of electrodesiccation, photodynamic therapy, minor incisions and biopsies. Rigenase® is a patented aqueous extract from the seeds of *Triticum vulgare*. It is rich in vitamin E, amides, phospholipids and glycolipids. Rigenase® stimulates the synthesis of fibroblasts, type I collagen, elastin and fibronectin. Furthermore, it reduces the expression of interleukin-6 and tumor necrosis factor alpha [5]. The results of our sponsor-free study can be summarized as follows: a) the cream containing 0.1% polyhexanide and Rigenase®, applied twice daily for 7 days, is effective for prevention of bacterial superinfections of the skin after minor surgical procedures (skin biopsies, electrodesiccation, cryotherapy, photodynamic therapy, laser therapy and chemical peelings); b) tolerability is excellent.

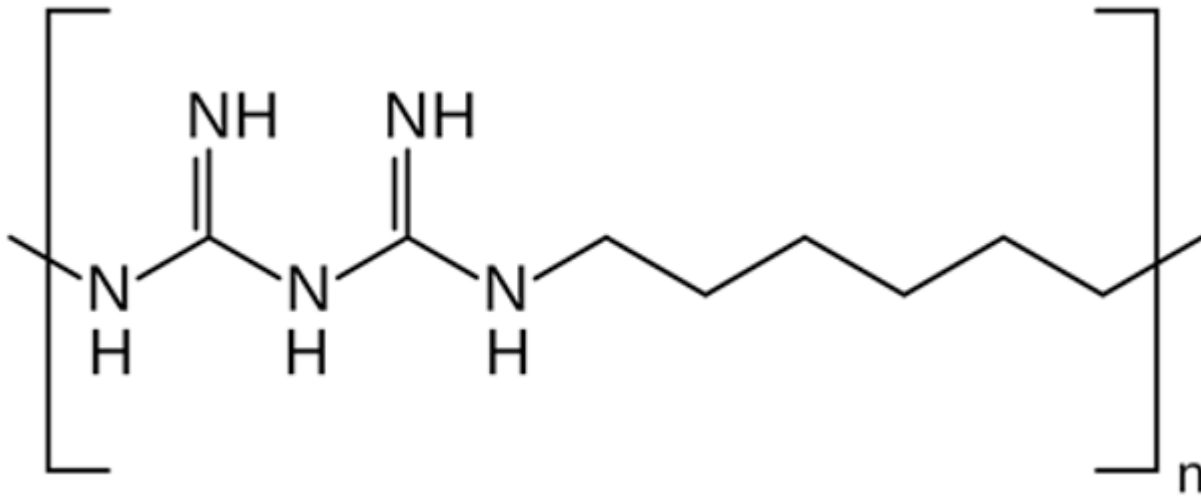


Figure 1: Structural formula of polyhexanide.

Conclusions

We do believe that topical antiseptics, such as polyhexanide, rather than topical antibiotics, should be taken into consideration for the prevention of bacterial superinfections of the skin after minor surgical procedures. This philosophy could help to reduce in the near future the risks of bacterial resistance.

References

1. Veraldi S (2022) Clinical Evaluation of the Efficacy and Tolerability of Fitostimoline® Plus Cream Following Laser Therapy, DTC or Cryotherapy: Case Series. Clin Exp Dermatol Ther 7: 174.
2. Alkharashi M, Lindsley K, Law HA, Sikder S (2015) Medical interventions for acanthamoeba keratitis. Cochrane Database Syst Rev 2015: CD010792.
3. Schnuch A, Geier J, Brasch J, Fuchs T, Pirker C, et al. (2000) Polyhexamethylenebiguanide: a relevant contact allergen? Contact Dermatitis 42: 302-303.
4. Schnuch A, Geier J, Uter W, Basketter DA, Jowsey IR (2007) The biocide polyhexamethylene biguanide remains an uncommon contact allergen. Contact Dermatitis 56: 235-239.
5. Antonucci I, Fiorentino G, Contursi P, Minale M, Riccio R, et al. (2018) Antioxidant capacity of Rigenase®, a specific aqueous extract of *Triticum vulgare*. Antioxidants (Basel) 7: 67.