

Clinical effectiveness of polihexanide on biofilms in wounds

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Introduction:

Published studies on the treatment of biofilms in wounds is scarce. This paper presents the results of a literature review looking at antimicrobials, specifically polihexanide (PHMB) used for infected wounds, containing a biofilm, as well as the interim results (N=25) of a real life clinical practice study.

Literature review method :

A systematic literature review was carried out on diagnosis and treatment of biofilms in wounds, using the following keywords: *biofilm, wound, wound management, antimicrobial, polihexanide, polyhexanide, PHMB and combinations thereof*. We searched published studies, which met the following criteria: Publications from January 1, 1995 to the present (May 2010) in English, German, French or Dutch; in-vitro, in-vivo and with human subjects including reviews, reports, and meta-analyses. Databases searched: Pubmed, Medscape, Medline, Embase, Cinahl and Cochrane. In addition, we searched the EWMA Journal, Dutch Journal of Wound studies and publications issued in congress proceedings.

Results of the literature review:

For the number of studies and study types see Fig.2. Of non healing chronic and critically colonized wounds, 65-80% is associated with biofilms, leading to chronic inflammation and delayed wound healing [1-4,6,9,10]. A biofilm is an aggregate of microorganisms in which cells adhere to each other and/or to a surface [1,2,5]. These adherent cells are frequently embedded within a self-produced matrix of extracellular polymeric substance (EPS), which is generally composed of extracellular DNA, proteins, and polysaccharides. Fig.1. Bacteria living in a biofilm usually have significantly different properties from free-floating bacteria of the same species, as the dense and protected environment of the film allows them to cooperate and interact in various ways [6,3]. *Pseudomonas aeruginosa* is not only an important opportunistic pathogen but can also be considered a model organism for the study of diverse bacterial mechanisms that contribute to bacterial persistence in relation to biofilms [6,3]. The presence of fibrin in the wound bed is associated with chronic inflammation and is an ideal breeding ground for anaerobic bacteria in particular [6-8]. Interaction between aerobic and anaerobic bacteria in a biofilm, is due to increased pathogenic effect and leads to delayed wound healing [7-9].

Cleansing is easy, but to keep the wound clean and to prevent further biofilm formation, requires a combination of frequent debridement and antibacterial agents [5,10-12,14-18]. Clinical research on the effectiveness of antibacterial agents to treat biofilms in wounds, is scarce and inconclusive. In vitro, the results are often tested on a monoculture [5]. PHMB in vitro and in clinical trials is effective against broad spectrum micro-organisms, such as *Pseudomonas aeruginosa* and HIV [11,12,14-18,19-26]. 87% of biofilm was removed by PHMB in a 3 weeks in vitro study [13]. In a clinical study in 7/10 patients the biofilm in their wounds was removed after 3 weeks treatment with PHMB [14]. HydroBalance dressing + PHMB* is more effective than 10-15 minutes gauze soaked in PHMB [15]. An RCT on a HydroBalance dressing + PHMB* compare with standard silver treatment showed a greater pain reduction and improved quality of life (QoL) [16]. PHMB is suitable for critically colonized and infected chronic wounds. A reduction of biofilm was shown, good tissue tolerance and no known resistance [17,18, 21,22]. Wound cleansing with PHMB was faster than standard therapy [19].

Conclusion :

The treatment of bio-films in wounds is not yet fully explored. The presence of bio-films in infected wounds may further strengthen the pathogenic properties of the bacteria present. Various studies have indicated in-vitro that topical silver and povidone iodine have little effect. Clinical studies indicate that PHMB may have a positive impact on bio-films in infected wounds, however there are few large, conclusive clinical studies to date. It was shown that continuous application of PHMB using a HydroBalance* dressing was superior over using PHMB for cleansing during dressing changes. PHMB in practice is recommended for critical colonized and infected wounds.

Interim results (N=25) of a real life clinical practice study

Aim:

To evaluate clinical efficacy of a *HydroBalance dressing + PHMB (X+PHMB) in the treatment of chronic wounds that contain a biofilm.

Methods:

Patients that visit the outpatient clinic, with non healing wounds of various etiologies that showed clinical signs of biofilm, were included. Clinical feature of biofilms in wounds is described as a shiny translucent slimy layer on a non-healing wound surface that mostly do not respond to treatment [7-9]. Wound cleansing is conducted with saline, if required debridement is performed. *X + PHMB is covered with a **foam dressing. Dressing changes took place 2 to 3 times per week, depending on wound condition and exudate production. Patients were followed until healing. Reduction of the biofilm was scored on a 3 point scale (good/moderate/poor). Reduction in wound size was also scored on a three point scale, using planimetry and photographs.

Results :

N= 25 were included (12 female) For wound types see Fig.3.

17 Patients completed the study of which n=14 had a good reduction of the biofilm, n=2 scored moderate and n=1 had no reduction. After four weeks of treatment n=4 discontinued due to copious exudate production, n=2 were lost to follow up. 12/17 Patients had a good reduction in wound area., n=2 scored moderate, n=1 scored poor and n=2 did not have their wounds scored.

Conclusion :

The interim results indicate *X + PHMB to reduce biofilm in patients with chronic wounds. The dressing seems suitable for moderate to light exuding wounds, hence 4 patients were removed from the study after 4 weeks of treatment due to copious exudate production.



Fig 1: A critically colonized wound with a biofilm. EPS is visible

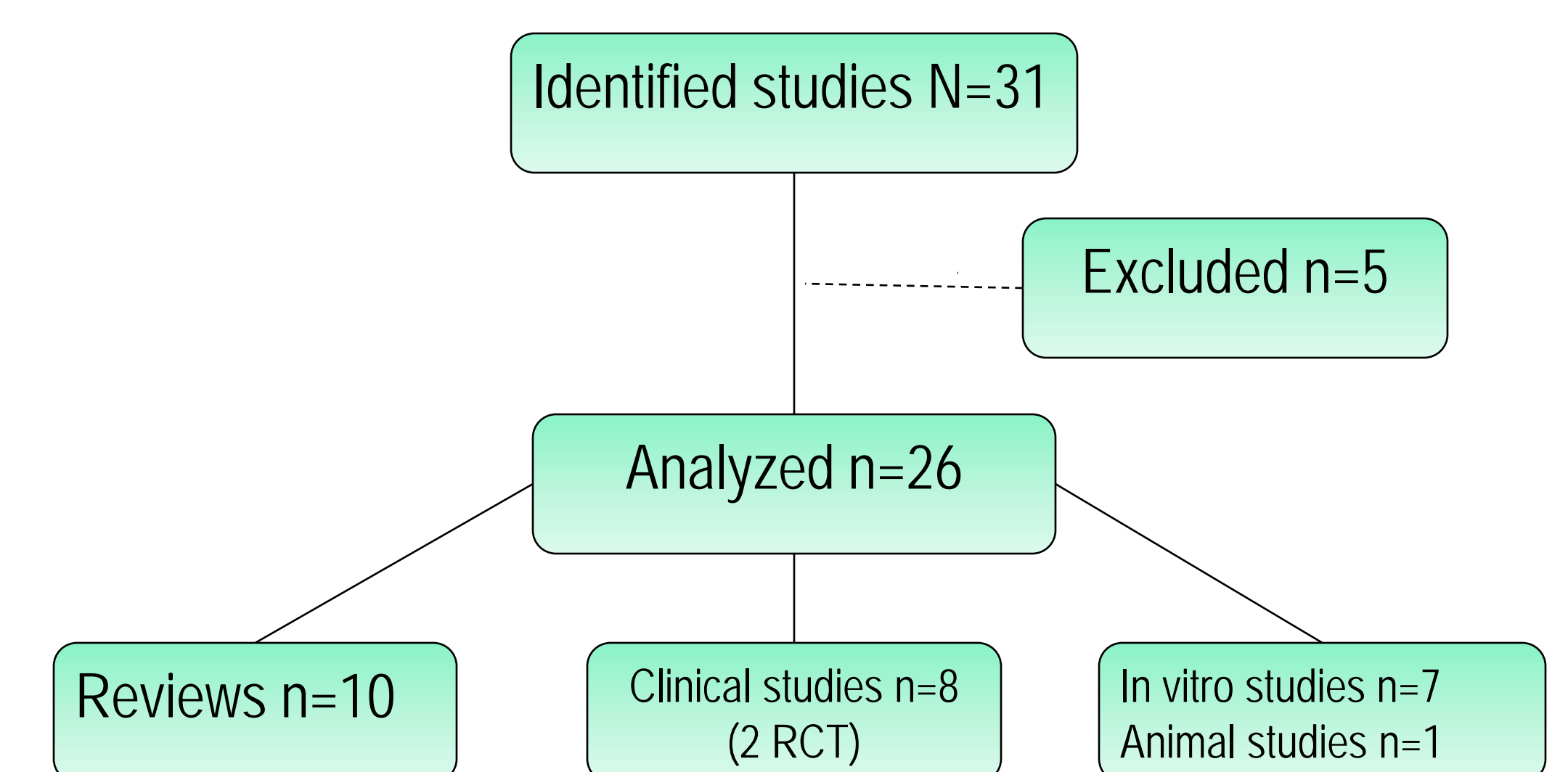


Fig 2: Results of the systematic literature review

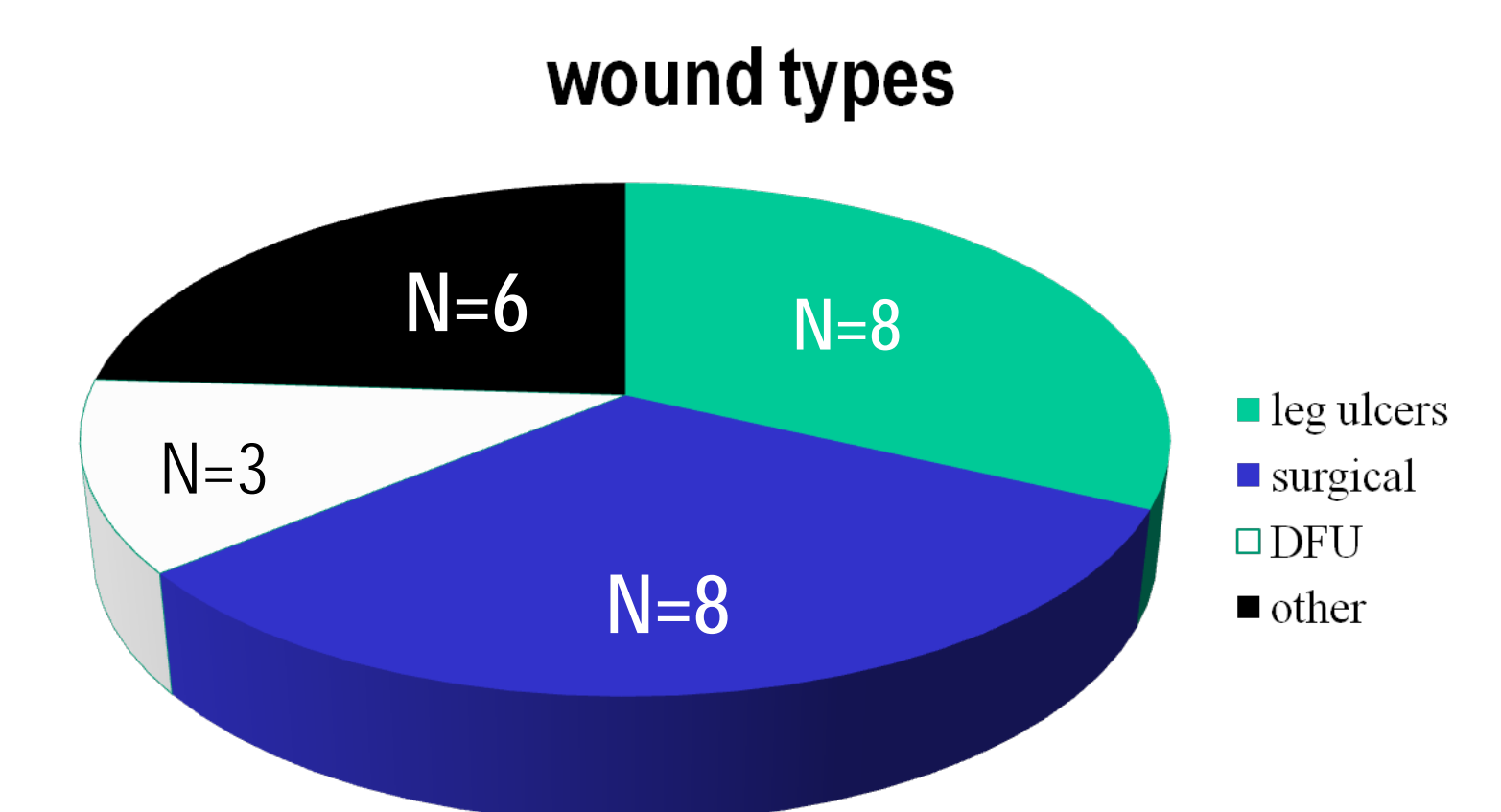


Fig.3: Wound types of patients included in the study (N=25)

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