Journal of Tissue Viability 27 (2018) 244–248

Contents lists available at ScienceDirect

Journal of Tissue Viability

journal homepage: www.elsevier.com/locate/jtv

A retrospective systematic data review on the use of a polihexanide-containing product on burns in children

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ARTICLE INFO

Keywords:
Burns
Paediatrics
Polyhexanide
Prontosan®

ABSTRACT

Background: It is current practice for physicians to use the Prontosan® range of products in children based on their personal clinical experience, despite the lack of safety data in this population. This retrospective data review was designed to obtain information on the safety profile of the Prontosan® range of products in children in routine clinical practice.

Methods: Data from newborns, infants and children with burns treated with the Prontosan® range were collected retrospectively from patient medical records.

Results: The majority of children treated for burns (80.1%) were under the age of four. More boys than girls were subject to burn injury (58.1% *vs.* 41.9%). The majority of burns (74.7%) were partial thickness burn (IIa and IIb). Safety was analysed based on the adverse events/reactions, infections and interactions/symptoms related to Prontosan® reported in the CRFs. AEs were reported in five children after the use of Prontosan® products: itching (3 cases), rash (1 case) and hypergranulating tissue (1 case). No event was severe and all events resolved favourably with good healing results. In addition, 11 patients developed clinical signs of infection during treatment (mainly *Staphylococcus aureus*).

Conclusions: The Prontosan® range of products is demonstrated as safe and tolerable for use in children as part of burn treatment. Inclusion of this range of products in the protocol of paediatric burn care allows a good healing process starting with appropriate wound cleansing and maintaining moist wound environment.

1. Introduction

Children make up almost half of the severe burns population [1]. Paediatric burns can be more severe than in adults due to thinner skin, resulting in deeper burns [2]. Wound infection is a common problem when treating paediatric burns. Therefore, burn wound cleansing is an integral step in every wound management protocol [3]. It is important to keep the wound clean and moist in order to promote the development of healthy granulation tissue and to minimise the risk of microbial contamination, [4]. Wound cleansing involves the removal of surface contaminants, loose debris, slough, softened necrosis, microbes and/or remnants of previous dressings from the wound surface and its surrounding skin [5]. Typically, the wound must be gently irrigated, debrided to remove degraded areas, slough or necrotic tissue, re-irrigated with a cleansing solution, preferably a gentle antiseptic, followed by dressing. This first step is a part of wound bed preparation defined as an essential part of the wound healing process. It is now widely accepted that biofilm is present in the majority of chronic wounds and can potentially delay healing and may play a significant role in burn wound infection and subsequent sepsis [6].

The Prontosan® range of products consists of a wound irrigation solution and gels which have been used successfully and safely in adults for more than ten years in Europe [7,8]. Their efficacy and safety have been confirmed in clinical studies [9–11]. These products are used for cleansing and moistening acute and chronic wounds and prevention of infection and biofilm formation [7,9,12,13].

The Prontosan® range of products is not specifically labelled for use in children. It is stated in the Instruction For Use (IFU) that ‘due to

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https://doi.org/10.1016/j.jtv.2018.08.001
Received 1 April 2018; Received in revised form 29 July 2018; Accepted 6 August 2018

insufficient clinical data, all the Prontosan® range should only be used selectively and under close medical supervision in newborns and infants'. Nevertheless, it is current practice that the Prontosan® range of products is widely used in children by physicians based on their personal clinical experience.

The lack of evidence relating to the safety profile in children for these products is a dilemma for paediatricians since no evidence-based studies are available, to date, for children, newborns and infants. In addition, paediatric clinical studies are difficult to perform due to the strict regulations imposed. However, such data is essential to confirm the safety of these products in children, for the same indication, which is a necessary requirement for its IFU up-date. This data would also be extremely valuable for the development of specific standard paediatric treatment protocols.

This retrospective data review relating to the treatment of paediatric burns using the Prontosan® range of products in routine clinical practice was designed to obtain information on the safety profile of the Prontosan® range of products in children.

2. Methods

This retrospective data review was conducted in five countries in Europe and the main objective was to assess the safety of Prontosan® products in children based on occurring adverse events including allergies, infection signs and symptoms, adverse reactions related to the product or any other signs and symptoms associated with allergic reaction. Prontosan® products were used as per usual standard of treatment practice in each centre.

2.1. Inclusion and exclusion criteria

The study population consisted exclusively of children (newborns: 0–4 weeks, infants: 5 weeks to 1 year and children older than 1 year old) treated with the Prontosan® range of products at hospital. Treated wounds could be either scald, flame, contact, electric or explosion burns of any degree [14] (First degree: superficial, Second degree sub-divided in superficial partial thickness and deep partial thickness; Third degree: full thickness) with known treatment outcome. Any exclusion criteria was defined before the data collection.

2.2. Study products

The Prontosan® products (B.Braun Medical AG) are marketed as medical devices (Class III). The solution is composed of Polihexanide (PHMB), an effective broad spectrum antimicrobial agent and Betaine, a surfactant which is able to penetrate the skin and to remove biofilm and wound debris. In addition, the wound gels contain glycerol and hydroxyethylcellulose for gel consistency. The two key ingredients, Polyhexanide and Betaine allow effective cleansing of the wound. These products are specially indicated for the prevention and removal of biofilms, and for wound cleansing [9]. Prontosan® products were combined, if needed, with skin substitutes and skin grafts.

2.3. Data collection and analysis

All data from newborns, infants and children with burns treated with the Prontosan® range were collected retrospectively from patient medical records by means of a questionnaire. A systematic data review was done in all patients who fulfilled the predefined inclusion and exclusion criteria. The information collected in the medical records was transferred to a four-page Case Report Form (CRF) which was analysed at the end of data collection.

All CRFs were analysed using Statistical Analysis Software (SAS) Enterprise Guide 7.1 statistical software (S.A.S., Cary, N.C., U.S.A.). Data were then transferred from Access-Views to SAS by Open Data Base Connectivity (ODBC) driver. Demographic data (gender, age) and burn characteristics (diagnosis, wound size and location, depth of burn) were calculated and presented as mean or median with Standard Deviation (SD) or range, respectively, based on their distribution.

The following points were addressed in the CRF: previous treatment of wound, other product used including all medication (analgesics, antipyretics, sedatives, antibiotics, antihistamines and anesthesics) and all other substances taken at home before admission were collected.

For the infection rate, data were monitored for unusual occurences, including signs and symptoms of clinical local infection. Final comments and physician satisfaction all adverse events, their causality expectedness, seriousness and intensify were recorded. Also, a sub-analysis was performed on hand burns.

There were no comparisons as all patients were treated with the Prontosan® range. There was no technique to deal with missing data.

2.4. Research approvals

The appropriate authorisation was obtained from each respective ethics committee and health authority for each country participating in the review prior to starting data collection.

3. Results

The review was conducted in five countries in Europe (Germany: 2 centres (Cologne and Kassel), and Italy (Rome), Belgium (Brussels), United Kingdom (Glasgow) and Russia (Moscow): 1 centre each). Children treated between December 2012 and March 2016 were included.

Overall, 202 questionnaires were completed and four were excluded since they did not meet the inclusion criteria. Data collected in 198 questionnaires were analysed.

Centre details are described in Table 1.

3.1. Demographic characteristics

Demographic characteristics are presented in Table 2.

The majority of children treated for burns (80.1%) were under the age of four. The population included more boys than girls. Five children had a medical history of chronic disease, none of which had an impact on the healing process.

3.2. Burn characteristics

Burn wounds were characterised by their diagnosis (scald, contact, flame, electric), extent TBSA (Total Body Surface Area) [14] and depth (First degree, Second degree divided in subgroup: superficial partial thickness or deep partial thickness and Third degree [15]) (Table 3).

The majority of burns (74.7%) were partial and deep thickness burn. The most affected body parts were thorax (33.3%), hands (29.3%), upper arm (22.2%) and face (20.2%). In 46% of the patients only one site was affected by burn injury, consequently 54% had more than one site burnt.

Table 1
Details of questionnaire distribution by centre.

Institution/Centre	Number of questionnaires per centre
Cologne	62
Kassel	15
Moscow	20
Brussels	11
Glasgow	20
Rome	70

Table 2
Demographics.

Variable	Modality	Number of children (N = 198) N (%)
Gender	Girl	83 (41.9%)
	Boy	115 (58.1%)
Age class	< 5 weeks	1 (0.5%)
	5 W–1 Y	48 (24.2%)
	[1, 2)	51 (25.8%)
	[2, 3)	45 (22.7%)
	[3, 4)	15 (7.6%)
	[4, 5)	6 (3.0%)
	[5, 6)	5 (2.5%)
	[6, 8)	12 (6.1%)
	[8, 12)	9 (4.5%)
	≥12 Y	6 (3.0%)

Table 3
Characteristics of child burn wounds treated with Prontosan® products.

Variable	Modality	Number of children (N = 198) (N %)
Burn diagnosis	Scald	148 (74.7%)
	Contact	40 (20.2%)
	Flame	2 (1.0%)
	Electric	1 (0.5%)
	Explosion	–
	Other[a]	7 (3.5%)
Extent of burn injury[b]	0–4%	119 (60.1%)
	5–9%	55 (27.8%)
	10–14%	16 (8.1%)
	15–19%	7 (3.5%)
	20–30%	–
	> 30%	1 (0.5%)
Burn depth[c]	First degree	6 (3.0%)
	2nd degree: Superficial partial thickness	100 (50.5%)
	2nd degree: Deep partial thickness	48 (24.2%)
	3rd degree	44 (22.2%)

[a] Other = two cases each friction road traffic accident, treadmill and sunburn, and one each road traffic accident and chemical.
[b] Total Body Surface Area (TBSA).
[c] First degree = Superficial, 2nd degree = Superficial partial thickness, 2nd degree = Deep partial thickness, 3rd degree = Full thickness (if multiple sites, the worst case scenario was applied). Russia graded burns only as 2nd degree (instead of superficial partial thickness and Deep partial thickness) so worst

3.3. Primary outcomes

Safety was analysed based on the adverse events, adverse reactions, infections and interactions/symptoms related to Prontosan® reported in the CRFs.

For five children, AEs were reported after the use of Prontosan® products. In these patients, itching (3 cases), rash (1 case) and hypergranulating tissue (1 case) occurred. No event was severe and all but the latter case (moderate with treatment withdrawal) were mild. For these patients, no serious health worsening could be detected following Prontosan® treatment. These are known side effects with Prontosan®, which are listed in the product instruction for use.

In addition, 16 patients had clinical signs of infection. The germ was identified for 13 of the 16 cases (mainly *Staphylococcus aureus*). In five cases, infection was already present before treatment. Therefore, 11 patients developed clinical signs of infection during treatment. Antibiotics were given to eight of these 11 patients. Treatment was not changed due to clinical signs of infection, the use of Prontosan® products was continued.

3.4. Clinical practice in burns with PHMB

Other outcomes were entered in free text fields in the CRF. The comments described current clinical practice and provided information related to burn treatment in terms of protocol of care, wound healing time, scars and functionality.

The Prontosan® range was used according to standard of care. Dressings used in combination with the Prontosan® range were mainly low adherent/non-adherent/non-adhesive or basic care dressings/bandages/plasters.

Not all children were necessarily treated with a Prontosan® product for the entire healing period. In fact, slightly more than half of children (58.6%) were treated throughout the healing period and a quarter (25.3%) for more than 80% of the time. Dressings were changed on average every 2–4 days.

Due to the pain, most children (79.3%) were administered analgesics and around a third (30.3%) took antibiotics to complement burn treatment with Prontosan® products during the healing period. There were 117 surgical interventions for burns including, 46 split skin grafts, 35 debridements, 33 necrectomies and three escharotomies.

Healing time is known to be dependent on the extent of TBSA, degree of burn and surgical procedure. Healing time was not directly reported in the questionnaire for this data review. Therefore, results are based on the last day of dressing change and when wound was healed or re-epithelised. In this data review, healing time was 11.5 days for a wound TBSA of less than 5% and was around 15 days for 5–19% TBSA. Healing time ranged from 8.5 days for superficial burns, 10.9 days for superficial partial thickness burns, 13.5 days for deep partial thickness burns to 17.2 days for full thickness burns.

As described previously, hand burns represented in this data review 29.3% of burns. A subgroup analysis was performed for this group of burn due to the importance of the final outcomes in terms of function and aesthetic appearance. Almost two-thirds (64.9%) of these hand burns were contact burns and a quarter (24.3%) were scald burns. Most hand burns (81.1%) were superficial and partial thickness. There was only one case of deep burn (third degree) which required a skin graft. Only four patients had a small scar documented. The Prontosan® range of products has been shown to be safe to use in children for hand burns with no restriction in functionality.

Finally, physicians were asked to report their satisfaction with the Prontosan® treatment on a scale from 1 to 5 (Unsatisfied, Satisfied, Good, Very good, Excellent). There was no negative feedback; all physicians were either 'Satisfied' with the treatment (73.2%), considered it 'Good' or 'Very good' (16.2% and 10.6%, respectively).

4. Discussion

The Prontosan® range of products (containing PHMB, an antimicrobial agent and Betaine, a surfactant) has been shown to be effective and safe for burn treatment in adults [16]. These products are successfully used for wound cleansing and decontamination, for debris and bacteria removal and for biofilm disruption, thus controlling bioburden and infection [10,17]. The Prontosan® range is marketed as a medical device, with good clinical data available in adults and a positive feedback from healthcare professionals [11]. Conducting clinical trials in paediatrics to obtain meaningful clinical data can be challenging. Consequently, the number of medical devices currently registered for paediatric use is limited. As a result, paediatricians often use products without adequate clinical evidence. It is only with clinical practice and experience that their efficacy and safety are confirmed. The aim of this retrospective data review was to assess the safety of the Prontosan® range of products in children.

There were no safety concerns with the use of Prontosan® products in this data review since only five AEs (*i.e.* rash, itching, and

hypergranulating tissue) were reported, which are known side effects in wound treatment with Prontosan®, none of which was serious or affected the healing process. The Sponsor assessed the reported itching as most likely related to the underlying disease. Pruritus occurs frequently during the normal healing process [18]. .

The risk of infection in paediatric burns is well known. Rashid et al. reported that 23.4% of admitted children developed infections and those with high TBSA (20–40%) had the highest risk of infection [18]. In another epidemiological study, 128 hospital acquired infections were reported for 84 of the 110 children analysed [20]. In a retrospective data review analysing the bacterial profile of paediatric burn wounds and their antibacterial sensitivity patterns, 67.8% of the 1777 patients tested positive on culture [21]. In our study, there were 11 reports (5.6%) of burn wound infection (due to *Staphylococcus aureus*), with eight children (4.0%) requiring antibiotics. These infections resolved rapidly and study treatment did not require interruption for these infections. This rate of infection in this current data review is, therefore, low compared to the literature [19–21].

This is the first retrospective data review of the use of Prontosan® products for the treatment of burns in children. Their safe use in the treatment of all types of burn wounds (1st Degree-3rd degree) in children of all ages (2 h–15 years old) with any TBSA was demonstrated. In addition, it has been shown that Prontosan® products are used routinely in combination with skin substitutes and skin grafts. Their use was not dependent on the choice of dressing. Prontosan® products did not interfere with the treatment procedures and support the wound healing process. The majority of burn injuries occurred in boys (ratio of boys to girls of 3:2) and children under four years of age (80.1%). This trend in vulnerability to burn injuries has also been reported in other studies [22].

Scalds were the most common burn type accounting for 74.7% of all children with burns, which is in line with the literature data [23]. Therefore, the data presented here can be seen as a representative overview.

In addition, in almost one third of cases, the hand is involved. In this population, it is well known that this burn location is frequent and mainly due to contact. In this data review, 64.9% of hand burns were contact burns and 24.3% were scald burns. It has been shown that an optimal management including infection control and preservation of active and passive motion is essential to ensure restoration of hand function and to minimise scarring [24,25]. The results are promising since no restrictions and only four small scars were reported for burnt hand with Prontosan® products.

Since no study has been performed previously in children, comparison can only be made with an adult population. However, children's skin may be more sensitive than adults'. It has been reported that paediatric burns can be more severe than in adults due to thinner skin, resulting in deeper burns [2]. Successful healing and healing time depend on both burn depth and burn surface area. Superficial burns usually heal within five days, superficial partial thickness burns tend to heal by re-epithelisation within 10 days and typical partial thickness burns generally heal within 21 days. The treatment of burns with Prontosan® Gel *vs.* silver sulfadiazine was compared in a randomised controlled trial including 46 adults with partial thickness burns and ≥10% TBSA and showed that burns treated with Prontosan® Gel healed after 17.8 days compared to 18.8 days with silver sulphadiazine [16]. In addition, Moore et al. investigated the use of Prontosan® products during standard of care of 70 chronic wounds of various types in 49 adults [16]. Time to wound closure varied from 29 days for venomous wounds to 92 days for diabetic ulcers. In a randomised controlled trial, Bellingeri et al. reported the statistically significant superiority of Prontosan® products compared with normal saline for inflammatory items, wound size reduction and granulation tissue improvement in 289 adults with chronic wounds [9].

The results presented here for children demonstrate a much improved healing time in children compared with the literature values for adult studies with the use of Prontosan® products. Shorter healing time in children compared to adults was also demonstrated in a previous study of Aquacel Ag Hydrofiber *vs.* silver sulphadiazine in the management of partial-thickness burns covering 5%–40% TBSA. In this study, the analysis of a sub-group of patients under the age of 16 years showed that healing was faster in the younger population compared to older patients [26].

A limitation of this data review may be its retrospective nature. A prospective study could be considered more appropriate, but the fact that the main objective was to obtain safety data and not efficacy data limits the impact. In addition, this was an international survey with the employment of different standard of treatment practices, which may have led to heterogeneous data collection. This study can serve as the basis for sample size calculation for future randomised, controlled trials in this indication.

The strength of this data review is that it is a safe and ethical way of obtaining safety data for children without the strict regulations imposed for an interventional study.

5. Conclusion

This data review demonstrates that the Prontosan® range of products, as a part of burn treatment, is safe and well tolerable for use in children. Indeed, the use of Prontosan® products in the respective burn treatment situations provided a moisture environment and supported a normal wound healing process in paediatric burn conditions. This study complements those already conducted in adults proving the safety and efficacy in wound bed preparation for the Prontosan® range products.

Sources of funding

This paper presents the results of a retrospective review of medical records in 5 paediatric burn centres. The data analysis has been made by an independent and external statistician, Professor R. Hilgers (Gleichen, Germany). The manuscript development has been performed by all authors and an external medical writer (Dellta Consultant, France). B. Braun Medical AG, Centre of Excellence, Infection Control, Sempach, Switzerland supported the costs of this retrospective data review.

Conflicts of interest

GC, SR, LB, AS, PvC, and NM have received a study grant from B. Braun Medical AG. They have no conflict of interest to disclose. The study grant received by GC has been entirely devolved to Division of Plastic Surgery as *Research funds for Children.*

Acknowledgements

The authors of this study would like to thank all the parents and patients who participated in the research. They would also like to thank the nurses and doctors in the research area for their support. Finally they like to thank BBRAUN Medical AG because of the assistance in statistics and in supporting the costs of the data review.

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