

A SINGLE BLIND RCT

EFFECT OF A WOUND CLEANSING SOLUTION ON WOUND BED PREPARATION AND INFLAMMATION IN CHRONIC WOUNDS

Bellingeri A et al. (2016) JWC

The healing of chronic wounds is often affected by the presence of devitalized tissue that allows heavy growth of bacteria and the development of biofilm. The wound bed preparation including the cleaning and debridement of the wound bed as well as control of the exudate and bacterial load are principles that apply to wound management, because only a clean wound can heal. Based on current literature the combination of polihexanide and the surfactant component betaine has been found as a good candidate to accelerate wound autolytic debridement.

STUDY DESIGN

A Randomized Controlled Trial (RCT) was conducted in 6 study centers in Italy between June 2010 and December 2013. This study obtained an ethics committee approval and followed Good Clinical Practice Principles.

PRIMARY STUDY OBJECTIVE

Efficacy (wound improvement and reduction of inflammatory signs) of Prontosan Solution, containing polihexanide and betaine (PP) in comparison to normal saline (NS) - the current gold standard - in patients with pressure ulcers or vascular leg ulcers.

SECONDARY STUDY OBJECTIVES

Assessment of pain and safety performance.

METHODS

- Outcome Measurements
 - Wound improvement: Total BWAT scores
 - Reduction of inflammatory signs: BWAT scores linked to inflammation (exudates type and amount, surrounding skin colour, peripheral tissue oedema and induration)
 - Pain assessment: VAS Score
- Follow-up: Day of recruitment (T=0) day 7 (T=1), day 14 (T2), day 21 (T=3), day 28 (T=4)
- Safety performance: Collection of all reported Adverse Events

RESULTS

- Population N= 289, randomized into two groups (PP=143, NS =146)
- 67% of patients recruited presented vascular leg ulcer (venous or mixed origin) and 25% presented pressure ulcer and the others were traumatic wounds in patients with venous ulcer
- Similar characteristics (gender, age, BMI, comorbidities, wounds type) for the population in both groups.

PRIMARY OUTCOME

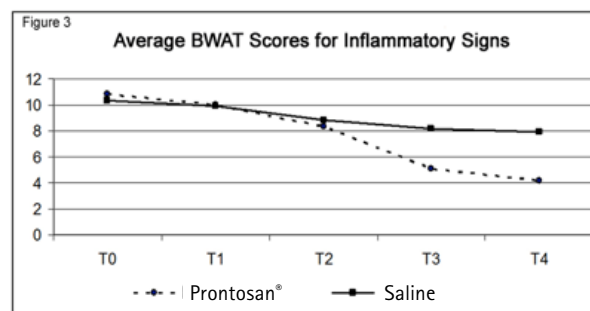
Wound improvement and reduction of inflammatory signs:

BWAT Score total

	T0	T1	T2	T3	T4	p
Prontosan® Group	25.9	25	20	18	14	p = 0.0248 At T4
Saline Group	25.45	25.1	24	23	22	

The Bates-Jensen Wound Assessment Tool (BWAT) is a valid and reliable tool to assess and monitor healing of all types of wounds. It consists of 13 attributes that are scored between 1 to 5, with 1 being the best for that attribute. After each item is assessed and scored, the 13 subscores are summed to get a total score. 5 BWAT items are linked to inflammation: exudate type and amount, surrounding skin colour, peripheral tissue oedema and peripheral tissue induration

BWAT Score inflammatory signs



Statistically significant differences between T0 and T4 for the following outcomes were found by using Prontosan® Solution (PP) compared to normal saline (NS):

- Total score BWAT (p=0.0248)
- BWAT score for inflammatory items (p=0.03)

SECONDARY OUTCOME

Pain scores were similar in both study groups, average score : 3.0, with minimal or no changes during the follow up. No adverse events related to the study device.

CONCLUSION

The results of this RCT confirms the superiority of Prontosan® Solution in efficacy as it promotes the wound bed preparation, supports the reduction of inflammatory signs and accelerates the healing of vascular leg ulcers as well as pressure ulcers.

Reference: Bellingeri A et al. Effect of a wound cleansing solution on wound bed preparation and inflammation in chronic Wounds: a single-blind RCT. J Wound Care 2016; 25: 3, 160-168.

www.bbraun.com/en/products/b/prontosan-wound-irrigationsolution.html