

**EFFECTS OF A WOUND CLEANSING SOLUTION ON WOUND
BED PREPARATION AND INFLAMMATION IN CHRONIC
WOUNDS: A SINGLE-BLIND RCT.**

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- I am one of the Authors of " Effect of a wound cleansing solution on wound bed preparation and inflammation in chronic wounds: a single-blind RCT"
- No financial support, assistance with data analysis or development of the research protocol was provided by B.Braun for the publication of this clinical paper

Declaration of interest: The authors have no conflict of interest regarding this research. This is an investigator-initiated trial. B. Braun Milano SpA kindly provided the material under investigation for both treatment groups and paid the Ethics Committees' application fees in all participating centers.

In our setting we used Prontosan® Wound Irrigation Solution

- The solution for removal of Biofilm
- The solution for acute, chronic and burn wounds
- Prontosan® contains betaine surfactant and polyhexanide



The surfactant reduces the surface tension which is needed for the removal of Biofilm

Setting/Patient

We recruited males and females aged >18 years complying with the following parameters:

- Presence of at least **one pressure ulcer stage 2 or 3** or the presence of a **partial thickness lesion of vascular origin**.

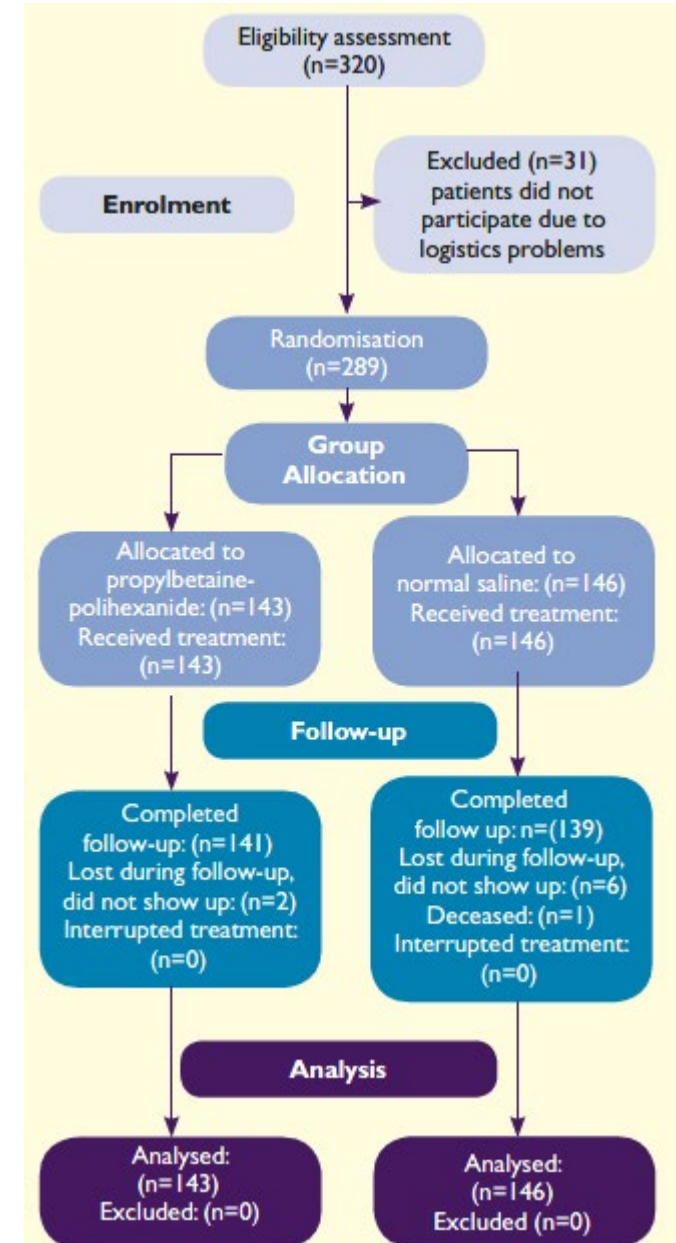
- **Wounds treated with advanced dressings:** polyurethane, alginate, hydrocolloid, hydrogel, non-adherent contact layers.

Recruited patients	PP Group n=143		NS Group n=146	
Male	58 (40.6%)		65 (44.5%)	
Female	85 (59.4%)		81 (55.5%)	
	Years	sd	Years	sd
Age (average)	79.8	12.1	77.2	15.3
	Score	sd	Score	sd
Braden Score [‡] (average)	18	3.0	20	2.9
Body mass index (BMI)				
BMI normal weight	27 (18.9%)		26 (17.8%)	
BMI obesity	37 (25.9%)		60 (41.1%)	
BMI severe obesity	15 (10.5%)		17 (11.6%)	
BMI overweight	58 (40.6%)		42 (28.8%)	
BMI underweight	6 (4.2%)		1 (0.7%)	
Comorbidities				
	Number of patients (%)		Number of patients (%)	
Diabetes	13 (9.1%)		20 (13.7%)	
Infectious pathology	9 (6.3%)		4 (2.7%)	
Thrombosis/phlebitis	32 (22.4%)		23 (15.8%)	
Pneumonia	4 (2.8%)		3 (2.1%)	

Outcome assessment

- The outcomes were measured using the **Bates-Jensen-Wound-Assessment-Tool** (13 items, score 13-60) focusing in total scores and also in **a selection of some items assessing inflammation** (Type Peripheral Tissue, Oedema & Induration, Skin Colour Surrounding Wound, Type of exudate, Exudate Amount , Type of necrotic tissue, Amount of necrotic tissue).
- The evaluation of wound evolution and inflammatory signs took place at inclusion (T0), day 7 (T1), day 14 (T2), day 21 (T3), and day 28 (T4).
- Outcomes were comparatively analyzed using two-tailed Student's t-tests, $p (T \leq t)$.

Consort Flow Chart



Treatment procedure

- Cleansing with Prontosan[®] Wound Irrigation Solution (PP)/Saline Solution (NS) after enrolment, after wards, at each dressing change (20-30 ml solution)
- Prontosan[®] Wound Irrigation Solution/Saline Solution pack for 10 minutes
- Dressing and appropriate therapy of all wound types according the hospital protocol



Baseline

Type of wounds	PP Group N: 143 (%)	NS Group N: 146 (%)	P value
Pressure Ulcers	25.9	24.0	0.75
Venous Ulcers	51.7	45.2	0.40
Mixed aetiology Ulcers (venous/arterial)	18.9	18.5	0.80
Traumatic wounds in patients with venous ulcers	3.5	12.3	0.32

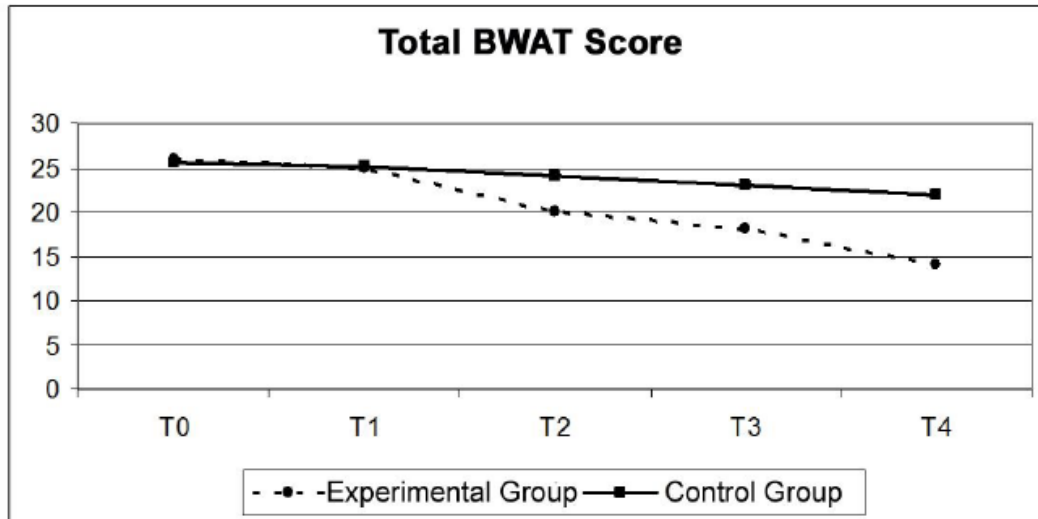
BWAT Score	PP Group N: 143 (%)	NS Group N: 146(%)	P value
Average total initial score BWAT	25.9	25.45	0.75

Primary Outcome

BWAT Score

	W0	W1	W2	W3	W4	p
PP group	25,9	25	20	18	14	p=0.0248 At T4
NS group	25,45	25,1	24	23	22	

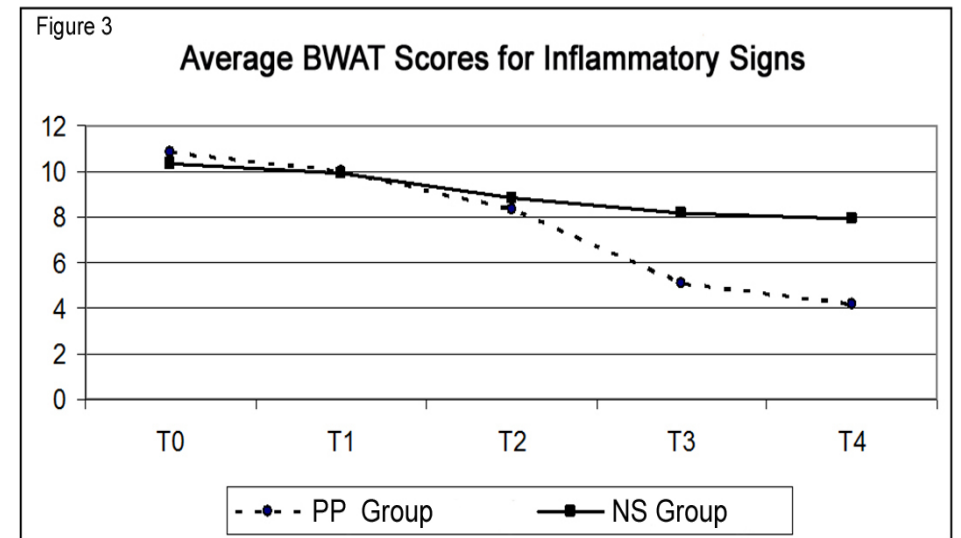
p=0.0248



Inflammation BWAT Score

	W0	W1	W2	W3	W4	p
PP group	10,8	10,0	8,3	5,1	4,2	p=0.03 At T4
NS group	10,3	9,9	8,8	8,2	7,9	

p=0.03



Secondary Outcomes

- **Pain:** Visual Analog Score similar in both group at the inclusion, average score at 3. No change during follow up
- **Safety:** No adverse events related to the treatment during the study period

Study Conclusion

- The results of the study supports the superiority of Prontosan[®] Wound Irrigation Solution compared to Saline Solution
- Prontosan[®] Wound Irrigation Solution promotes the wound bed preparation
- Prontosan[®] Wound Irrigation Solution reduces inflammatory signs and accelerates healing in venous leg ulcers and pressure ulcers

Positive effect of Prontosan[®] Wound Irrigation Solution (Betaine - Polyhexanide Solution) on wound bed preparation and inflammatory signs

Examples on case



40
DAYS

Examples on case



ONE
WEEK

Take Home Message

The study was closed
but the work isn't.

Probably we must work and study more on
antiseptic and cleansing solutions on wounds.