Introduction

Wound care professionals are faced with the challenge of treating chronic wounds that fail to improve despite dedicated care. The use of negative pressure wound therapy (NPWT) has been shown to improve wound closure, reduce infection, and promote healing in patients with chronic wounds. However, the application of NPWT can be complex, and the selection of treatment options can vary significantly across different clinical settings. This study aimed to evaluate the effectiveness of a single-use NPWT device compared to a traditional NPWT system in treating chronic wounds.

Materials and methods

Randomized, controlled multicenter study designed to compare the clinical effectiveness of two different types of NPWT. The primary endpoint was to assess the percentage change in target wound area after 12 weeks of treatment. The study included patients with chronic wounds, including venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs).

Study endpoints

The primary endpoint was to assess the percentage change in target wound area over a 12-week period from baseline for non-inferiority.

Study device

PICO™ Single Use Negative Pressure Wound Therapy System demonstrated greater reduction in wound area compared to traditional negative pressure wound therapy in the treatment of Chronic Ulcers of the Lower Extremities.

Patients

Participants were adults with VLUs or DFUs present for more than four weeks, having received prior treatment, and willing to comply with the protocol instructions.

Wound management

Patients were treated following good practice guidelines and locally approved protocols. All patients were encouraged to continue with existing treatments and to follow the instructions of their healthcare providers.

Conclusions

In this study, PICO® sNPWT met non-inferiority, and further achieved statistical superiority versus INPW in terms of reductions in wound areas, depth, volume over the treatment period of 12 weeks.

PICO® Single Use Negative Pressure Wound Therapy System demonstrated greater reduction in wound area compared to Traditional Negative Pressure Wound Therapy in the treatment of Chronic Ulcers of the Lower Extremities.

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References


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Key secondary efficacy endpoints – wound depth variation and volume variation

• In the PP population, the mean percentage change in depth was 65.8% reduction for PICO® sNPWT and 57.1% for INPW (p=0.013; Figure 3).
• In the ITT population, the mean percentage change in depth was 65.1% reduction in the PICO® sNPWT group (p=0.013) vs. 17.6% increase for INPW (p=0.001) (Figure 3).
• Single Use Negative Pressure Wound Therapy (sNPWT) system showed a statistically significant difference of 79.5% (p=0.001) (Figure 4). Results from the ITT population showed reduction of volume in the PICO® sNPWT group (p=0.05) and an increase in volume in the INPW group (p=0.014) (Figure 4).
• The LS mean percentage change in the PP population was 77.9% reduction for PICO® sNPWT and a 10.5% increase for INPW after adjustment for baseline wound volume, pooled site, wound type and wound duration at baseline.
• In the ITT population, there was a percentage reduction of 48.6% with PICO® sNPWT and a 4.2% increase with INPW (p=0.001) (Figure 4).

Examples of venous leg ulcer patients enrolled in the study with PICO® sNPWT

Patient 1: 50 years old. Venous ulcer on left leg

Area & reason for enrolment

After 12 weeks of PICO® sNPWT

Figures 1 to 4: Mean and adjusted LS mean change in wound volume (% in patients with VLUs and DFUs (PP and ITT populations).