Diabetes and the intent-to-treat (ITT) populations. To evaluate superiority, analysis and validation was performed using the ITT and pooled site populations. The primary endpoint was to assess the percentage change in target wound area over 4 weeks of standard wound therapy.

The results from this study support the use of sNPWT for the management of chronic diabetic foot ulcers (DFUs). The superiority of PICO sNPWT was confirmed with a 41.8% reduction in wound area in the ITT population compared to a 35.2% reduction in the tNPWT group. The difference in wound area reduction was statistically significant (p=0.013). See Figure 2.

The Adjusted LS-mean percent change in the ITT population was a 45.6% reduction for PICO sNPWT and a 35.2% reduction for tNPWT. The difference in percent change in wound area reduction was also statistically significant in favor of PICO sNPWT (p=0.015, DLS=p=0.015).

In the ITT population, the mean percentage reduction in wound volume was 68.1% in the PICO sNPWT group versus 54.7% in the tNPWT group. The difference in wound volume reduction was 13.4% in favor of PICO sNPWT which was statistically significant (p=0.038).

Wound management

PICO sNPWT is a single-use negative pressure wound therapy system, designed to be simple to apply and use, and the size of the pump and the canister may be intrusive and limit patient mobility. Equivalent clinical outcomes have been noted in comparative studies of traditional Negative Pressure Wound Therapy (NPWT) systems to adult patients with chronic lower extremity wounds or DFUs for up to 6 months. Patients were screened and followed up for at least one week before being randomized to one of the two treatment groups, and were followed weekly for 12 weeks or until ulcer healing. In the study, the mean percentage reduction in wound volume was 68.1% in the PICO sNPWT group versus 54.7% in the tNPWT group. The difference in wound volume reduction was 13.4% in favor of PICO sNPWT which was statistically significant (p=0.038).

Material and methods

Randomized, controlled, multinational study designed to compare the clinical effectiveness of two different types of Negative Pressure Wound Therapy (NPWT) systems: PICO sNPWT and tNPWT.

The study was performed in compliance with the ethical principles of the Declaration of Helsinki, Good Clinical Practice (GCP), ISO 14155:2011, and under governing IRB/IEC review and approval of the study protocol. All patients provided informed consent and were enrolled in the study and treated with PICO sNPWT or tNPWT.

Conclusion

In this randomized, controlled multicenter study, PICO sNPWT met non-inferiority criteria, and further achieved statistical superiority versus tNPWT in terms of reductions in wound dimensions (area, depth, volume) over the treatment period of 12 weeks from baseline.

Acknowledgments

This study was funded by Smith & Nephew. All authors participated in the study and approved the paper content.

Results

Baseline characteristics

The ITT population included 161 subjects who were randomized, received trial treatment, and attended at least one post-baseline follow-up visit. Demographics and relevant medical history of treatment groups were similar in the ITT population. A majority of the ITT population had good mobility and no subjects were wheelchair bound.

The Adjusted LS-mean percent change in the target ulcer size from baseline to one of the two treatment groups, and were followed for 12 weeks or until ulcer healing. In the study, the mean percentage reduction in wound volume was 68.1% in the PICO sNPWT group versus 54.7% in the tNPWT group. The difference in wound volume reduction was 13.4% in favor of PICO sNPWT which was statistically significant (p=0.038).

Primary endpoint – wound area improvement

- Analysis of data from the ITT population showed a significant difference of 41.8% in favor of PICO sNPWT (p=0.013).
- After adjustment for baseline wound area, protocol site, wound type and wound duration at baseline in the ITT population, the adjusted LS-mean percent change in wound area over the 12-week treatment period showed a difference of 34% in favor of PICO sNPWT (p=0.001).
- Subgroup analysis performed on the ITT cohort, wound area, showed that the difference in wound area reduction was also statistically significant in favor of PICO sNPWT (p=0.003, DLS=p=0.003).

Wound dimensions were confirmed using a Silhouette™ wound assessment and management device (Smith & Nephew, Eastleigh, Hampshire, UK). A series designed to assess the impact of the PICO sNPWT devices on daily activities was completed by patients at the end of visit.

While wound dimensions were confirmed using a Silhouette™ wound assessment and management device (Smith & Nephew, Eastleigh, Hampshire, UK). A series designed to assess the impact of the PICO sNPWT devices on daily activities was completed by patients at the end of visit.

Secondary endpoints were the percentage change in the target ulcer size and volume over 4 weeks of standard wound therapy (NPWT).

Conclusions

In this randomized, controlled multicenter study, PICO sNPWT met non-inferiority criteria, and further achieved statistical superiority versus tNPWT in terms of reductions in wound dimensions (area, depth, volume) over the treatment period of 12 weeks from baseline.

Acknowledgments

This study was funded by Smith & Nephew. All authors participated in the study and approved the paper content.

Statistical analysis

For non-inferiority primary analysis was performed with both the per protocol (PP) population and the intent-to-treat (ITT) population. To evaluate superiority, analysis and validation were performed using the ITT population. We present here, the results of the continuous analysis.

PICO sNPWT performed well in a community care setting in patients with VUs or DFUs. The results from this study support the use of PICO sNPWT for the management of chronic leg ulcers (VUs and DFUs). When PNPWT is being considered, PICO sNPWT may be an option.