

Jet Cold Plasma at Atmospheric Air Pressure for Venous Ulcers: A Randomized Clinical Trial

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Abstract-

Background:

This prospective, randomized, controlled, open-label, multicenter clinical trial evaluated the efficacy and safety of air-based cold atmospheric plasma jet (CAPJ) therapy for chronic venous leg ulcers (VLU) compared with standard of care (SOC).

Methods:

Sixty adult patients with nonhealing VLUs were randomized to receive either CAPJ therapy twice weekly for 10 weeks or SOC. The primary outcome was the percentage reduction in wound area at weeks 4, 9, and 17. Secondary outcomes included granulation tissue formation, microbial burden (qualitative and quantitative), pain (visual analog scale), aesthetic satisfaction, and adverse events. Analyses were performed on an intention-to-treat basis.

Results:

Both groups demonstrated progressive reductions in wound area over time. Although the CAPJ group exhibited a greater mean reduction (–72.9% versus –56.7% at week 17), the difference was not statistically significant ($P= 0.30$). Complete healing was achieved in 42.9% of CAPJ patients compared with 30.4% in the SOC group ($P= 0.361$). CAPJ produced significant immediate decreases in microbial burden at weeks 0 and 4 ($P< 0.05$). Pain scores improved similarly in both groups, and aesthetic satisfaction was high without significant intergroup differences. No serious adverse events were attributed to the device; transient pain-related sensations were the most frequent treatment-related effects.

Conclusions:

Although not statistically superior to SOC, air CAPJ therapy resulted in clinically meaningful wound area reduction, rapid antimicrobial effects, and high patient acceptability without increased adverse events. These findings support further investigation of CAPJ as a safe, noninvasive therapy for chronic VLU management.

Index Terms-

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