A Randomized Controlled Clinical Trial of Indigenized Innovative Negative Pressure Device for the Management of Stage 3 and 4 Pressure Ulcer in Traumatic Paraplegia Patients

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Purpose: A randomized controlled clinical trial was conducted to compare negative pressure wound therapy (NPWT) by our innovative negative pressure device (NPD) to conventional wound dressing of pressure ulcer (PU) in traumatic paraplegia patients.

Methods: This study was conducted in the Department of Orthopaedic Surgery at King George's Medical University, Lucknow, India. 44 traumatic paraplegia patients with sacral pressure ulcers of stage 3 and 4 were randomized into two groups: one (n = 23) received conventional wound dressing and the other (n = 21) received NPWT with innovative NPD. The outcomes variable were length, width (surface area), depth of PU, exudates, discharge, tissue type (necrotic, slough, and red granulating tissue), and cost-effectiveness during 0 to 9 weeks follow-up.

Results: Length and width were significantly ($P < 0.01$) decreased in NPWT group as compared to conventional group at week 9. At weeks 1, 2, and 3, depth was significantly ($P < 0.05$) higher in NPWT group, whereas at week 9 significant reduction ($P = 0.01$) was observed. Exudates were significantly ($P = 0.001$) less in NPWT group at weeks 4-9. Conversion of slough into red granulation tissue was significantly higher in NPWT group ($P = 0.001$). Discharge became significantly ($P = 0.001$) lower in NPWT at week 2 and no discharge after week 6. In all parameters, decrease was higher in NPWT group compared to conventional, which was significant for exudates type ($P = 0.03$) and tissue type ($P = 0.004$).

Conclusion: NPWT by our NPD is a better wound care procedure and cost-effective for management of PU.