

Management of Pressure Ulcer with a Locally Constructed Negative Pressure Device (NPD) in Traumatic Paraplegia Patients: A Randomized Controlled Clinical Trial

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Abstract : Introduction: Management of Pressure Ulcer (PU) is an ongoing clinical challenge particularly in traumatic paraplegia patients in developing countries where socio economic conditions often dictate treatment modalities. When negative pressure wound therapy (NPWT) was introduced, there were a series of devices (V.A.C., KCI, San Antonio, TX) manufactured. These devices for NPWT are costly and hard to afford by patients in developing countries like India. Considering this limitation, this study was planned to design an RCT to compare NPWT by an indigenized locally constructed NPD and conventional gauze dressing for the treatment of PU. Material and Methods: This RCT (CTRI/2014/09/0050) was conducted in the Department of Orthopaedic Surgery at King George's Medical University (KGMU), India. Thirty-four (34) subjects of traumatic paraplegia having PU of stage 3 or 4, were enrolled and randomized in two treatment groups (NPWT Group & Conventional dressing group). The outcome measures of this study were surface area and depth of PU, exudates, microorganisms and matrix metalloproteinase-8 (MMP-8) during 0 to 9 weeks follow-ups. Levels of MMP-8 were analyzed in the tissues of PU at week 0, 3, 6 and week 9 by Enzyme Linked Immuno Sorbent Assay (ELISA). Results: Significantly reduced length of PU in NPWT group was observed at week 6 ($p=0.04$) which further reduced at week 9 ($p=0.001$) as compared to conventionally treated group. Similarly significant reduction of width and depth of PU was observed in NPWT at week 9 ($p<0.05$). The exudate became significantly ($p=0.001$) lower in NPWT group as compared with conventionally treated group from 6th to 9th week. Clearance and conversion of slough into red granulation tissue was significantly higher in NPWT group ($p=0.001$). At week 9, the wound culture was negative in all the subjects of NPWT group, while it was positive in 10 (41.6%) subjects of conventional group. Significantly lower level of MMP-8 was observed in subjects of NPWT group at week 6 (0.006**), and continually more reduction was observed at week 9 ($<0.0001^{**}$) as compared to the conventional group. Conclusion: NPWT by locally constructed NPD is better wound care procedure for management of PU. Our device gave similar results as commercially available devices. Reduction of level of MMP-8 and increased rate of healing was achieved by negative pressure wound therapy (NPWT) as compared to conventional dressing.

Keywords : NPWT, NPD, MMP8, ELISA

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