Does Negative Pressure Wound Therapy Reduce the Odds of Infection and Lower Health-Related Quality of Life in Open Fracture Patients?

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Purpose: Negative pressure wound therapy (NPWT) is commonly used to manage severe open fracture wounds. The recently completed randomized controlled trial (RCT) evaluated the effect of NPWT versus standard wound management on 12-month disability and rate of deep infection among patients with severe open fractures of the lower limb and reported no differences. Using data from the trial of open fracture patients, we aimed to evaluate the impact of NPWT on the odds of having deep infections and health-related quality of life (HRQL).

Methods: Our analyses included participants from the open fracture trial who had Gustilo II and III lower extremity fractures. To adjust for the influence of injury characteristics on type of dressing received, a propensity score was developed from the data set. A one-to-one matching algorithm was then used to pair patients with a similar propensity for NPWT. Mixed effects logistic regression was used to evaluate the association between type of wound dressing and development of a deep infection requiring operative management (dependent variable) in the matched cohort. Gustilo type, irrigation solution, fracture location, mechanism of injury, and degree of contamination were included as adjustment variables. To determine any differences in HRQL between the NPWT and standard wound dressing groups, we conducted 2 multilevel models with 3 levels (center, patient, and time) and included Short Form-12 (SF-12) Physical Component Summary (PCS) and SF-12 Mental Component Summary (MCS) as dependent variables. Gustilo type, irrigation solution, fracture location, mechanism of injury, degree of contamination, and preinjury SF-12 scores were included as adjustment variables. All tests were 2-tailed with alpha = 0.05.

Results: After applying propensity score-matching to adjust for the influence of injury characteristics on type of dressing used, there were 270 matched pairs of patients available for comparison. The odds of developing a deep infection requiring operative management within 12 months of initial surgery was 4.22 times higher in patients who received NPWT compared to those who did not receive NPWT (odds ratio [OR] 4.22, 95% confidence interval [CI] 2.26-7.87; P <0.0001). 1329 participants were included in our HRQL analysis and those treated with NPWT had significantly lower SF-12 PCS at all follow-up visits (6 weeks, 3 months, 6 months, 12 months) postfracture (P = 0.01). Participants treated with NPWT had significantly lower SF-12 MCS at 6 weeks postfracture (P = 0.03).

Conclusion: Our analysis found that patients treated with NPWT had higher odds of developing a deep infection requiring operative management and that being treated with NPWT was associated with lower physical quality of life in the 12 months postfracture. While there may have been other potential adjustment variables not controlled for in this analysis, our results suggest that the use of this treatment should be re-evaluated.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.