DISCUSSION

The Clinical Efficacy and Cost Effectiveness of the Vacuum-Assisted Closure Technique in the Management of Acute and Chronic Wounds: A Randomized Controlled Trial

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This article out of The Netherlands by Dr. Braakenburg and colleagues details their experience with the treatment of 65 consecutive wounds comparing negative-pressure wound therapy using the V.A.C. device (KCI Medical, San Antonio, Texas) with "modern wound dressings," consisting mostly of alginates and hydrocolloids, among others. It is done in a prospective, randomized, though unblinded, fashion, and in contrast to many other studies, includes both acute and chronic wounds of all types. Their endpoints are defined as time to complete healing by secondary intention or readiness for skin grafting. Other measurements are recorded, such as the rate of granulation tissue formation, pain, bacterial burden, and cost. Ultimately, the authors assert that vacuum-assisted closure and modern dressing changes are equivalent in time to healing and cost, and that the main benefit to vacuum-assisted closure therapy is in nursing convenience and patient comfort. They also state that vacuum-assisted closure may be particularly useful in those patients with cardiovascular disease or diabetes.

Although the authors are to be commended for their efforts, several discussion points arise. In their study, 65 consecutive patients were enrolled and randomized—32 to the vacuum-assisted closure group and 33 to conventional dressing changes. A total of 18 patients dropped out of the study, including six in the vacuum-assisted closure arm and 12 in the conventional arm, representing a 27.7 percent dropout rate—alarmingly high—thereby reducing the sample sizes even further and making it difficult to determine significant differences between arms. Although the reasons are listed in their Figure 1, including death, early dismissal, refusal to cooperate, and amputation, there is no specific mention as to the demographics of these dropouts and how that may affect the patient subpopulations within each group, which may, in turn, affect the conclusions of the study. Furthermore, although the patient demographics and wound characteristics are listed in Table 2, no chi-square analysis has been performed to ascertain whether there are or are not statistically significant differences in the patient subpopulations within each arm of the study. For example, it appears that there is a difference in the wound characteristics within each group, with more chronic wounds in the vacuum-assisted closure arm (74 percent versus 56 percent). This is relevant, as it is well-known that chronic wounds, even when "clean" (i.e., not requiring necrectomy because of a lack of necrosis or infection), exhibit different wound-healing properties than the acute wound because of higher concentrations of metalloproteinases and elastases that act in an inhibitory fashion, thereby increasing the time to healing.[1,2] Therefore, these wounds would be expected to take longer to achieve the authors' predetermined endpoints unless transformed to the acute phase by debridement.[3] This would, in turn, seem to lengthen the time to healing in the vacuum-assisted closure arm and appear to make the two arms more equivalent when, in fact, this may or may not be the case.

A second point related to the patient demographics is the fact that anemia is not mentioned as an exclusion criterion. In patients with chronic disease or anemia from prior traumatic blood loss (even if not actively bleeding), anemia may have an effect on the endpoints measured.[4] Furthermore, although malnutrition was not an exclusion criterion, no objective measurements are reported to help the reader understand the arbitrary stratification of nutrition into "poor, moderate, and good." Also, as no statistical analysis was performed to determine whether there was a difference in this respect between the two groups, the consequences of this on each arm are unknown and may affect the interpretation of the data.

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With respect to the rate of granulation tissue formation, the authors found the overall rates to be equivalent between the two groups, with the vacuum-assisted closure group forming granulation tissue faster during the first week. According to the methods listed, the authors used vacuum-assisted closure at 125 mmHg of continuous negative pressure on all wounds. However, it is well known that use of the V.A.C. device on intermittent mode (if there is not excessive wound drainage, which would prohibit this) results in a higher rate of granulation tissue formation (103 percent versus 63 percent), according to the original animal studies.[5] Furthermore, alterations in the amount of negative pressure applied may also have an added effect on changes in wound size. Although it is important in this trial to keep the V.A.C. settings the same for all patients to make overall comparisons easier, in reality, V.A.C. settings can be tailored to each wound to maximize granulation tissue formation, decrease wound size, and optimize time to healing or time to grafting. This adaptability may supersede the ability of conventional dressing changes to achieve the same endpoints in the same amount of time, and further study is required.

The authors mention that one of the conventional wound care regimens involves the use of sodium hypochlorite, although the duration of treatment with this particular adjunct and the concentration used are not mentioned. The published literature has proven that sodium hypochlorite is detrimental to wound healing, especially in undiluted form.[6–9] Clinically, if used, it is usually reserved for *Pseudomonas* infection, and even then, only used at one-quarter strength for a limited time to prevent healthy tissue destruction. Although this only represents a small subset of patients studied, it may have an impact on the authors' predetermined endpoints, given the small sample size of each arm.

The hazard ratio calculated by the authors is used to attempt to demonstrate the differences in the rates of healing with the use of vacuum-assisted closure. However, at the 95 percent confidence interval, and given the small sample sizes, this is not statistically significant. The ranges given cross the boundary of 1.0 (0.74 to 2.40), again undermining the amount of useful information that can be derived from this calculation.

Finally, the authors originally postulate that vacuum-assisted closure would be more painful to use than conventional dressings. Their conclusions found otherwise. This has been our clinical experience as well. We have found vacuum-assisted closure to be more well-tolerated by nurses and patients alike. Adjunctive maneuvers such as instilling saline or lidocaine into the V.A.C. sponge 10 minutes before removal can help optimize this pain control even more.

Ultimately, this study attempts to compare vacuum-assisted closure versus conventional dressings in a prospective manner with clinically useful endpoints. Unfortunately, the dropout rate, the difference in the wound chronicity in both arms, the uncertainty of what role nutrition may have played in each group, and the suboptimal use of vacuum-assisted closure (continuous instead of intermittent pressure) make the results difficult to interpret. A recent randomized study[10] of 168 diabetic foot wounds looking at the effect of vacuum-assisted closure versus moist wound dressings on partial foot amputations found that more patients healed with vacuum-assisted closure (56 percent) than controls (39 percent). They also found that the rate of formation of granulation was more rapid with vacuum-assisted closure ($p = 0.002$). This study is important because the wounds were larger and deeper than those in traditional wound-healing studies: the area (20+ cm^2) and the depth corresponded to a University of Texas grade 2 or 3.[11]

Studies are currently needed to better define clear parameters of vacuum-assisted closure efficacy and clinical endpoints. This would enable the clinician to use vacuum-assisted closure, provided it is effective, and switch to other therapeutic options when wound healing stagnates. Finally, despite current advances in treating wounds,[1] there is no substitute for thorough and proper surgical debridement, as the authors are careful to point out. Conversion of a chronic wound to an acute one, or debridement of devitalized tissue in an acute or infected wound, remains the cornerstone of initial wound therapy and cannot be overemphasized. We commend the authors on their efforts and look forward to future studies to help solidify the role of vacuum-assisted closure in the treatment of acute and chronic wounds.

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