

Topical Negative Pressure for the Treatment of Decubitus Ulcers in Frail Elders

What is the evidence-based information on the applicability/usefulness of wound VAC in patients with chronic disease/terminal illness/ bedbound status in the management of pressure ulcers? (Question submitted by Ruhi R. Shariff, MD, Section of Geriatric and Palliative Care Medicine, Rush Medical College to the "Ask the Informationist" column on the Portal of Online Geriatric Education (<http://www.POGOe.org>) with response posted on 09/21/2009.)

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Vacuum Assisted Closure (VAC®) was the first and remains the most well-known device for administering "topical negative pressure" (TNP) or "negative pressure wound therapy" (NPWT). It is used for both acute wounds and chronic wounds including wounds secondary to trauma, burns, pressure ulcers, leg ulcers, diabetic ulcers, infected or dehisced wounds, necrotizing fasciitis, post operative sternal infections, as an adjunct to surgery for skin grafts, flap surgery and wound bed preparation. Hypotheses for why TNP works generally include the fact that it removes excess third space fluid; reduces bacterial load; and provides mechanical stress which draws the wound together and stimulates angiogenesis and tissue growth. Despite the growing enthusiasm for the use of TNP there have been few solid evidence-based studies to support its use for wounds in general. For its use in the treatment of decubitus ulcers in particular, only two studies were considered methodologically sound enough to be included in a recent Cochrane review,¹ and of these, only one found evidence in favor of TNP. Meta-analysis of studies about this wound care modality has been made almost impossible by the use of different end points by different studies and the use of multiple treatments with which TNP is compared. Additionally, cost issues have not been adequately addressed, nor have quality of life factors been studied such as pain associated with TNP dressing changes versus other treatments.

Little progress in terms of evidence-based information has been made since a consensus panel of experienced wound care clinicians convened five years ago and concluded, in their "Guidelines for Managing Pressure Ulcers with Negative Pressure Wound Therapy": "The current body of literature, coupled with anecdotal reports and clinical experience, suggests that NPWT can be an important part of Stage III and IV ulcer care. Clinical trials in progress should provide a clearer idea of how NPWT fits into the treatment picture for pressure ulcers."^{3(p.15)}

The VAC in Dr. Shariff's question refers to the Vacuum Assisted Closure (VAC®) system developed at the Bowman Gray School of Medicine at Wake Forest University in Winston-Salem, NC by Louis Argenta and Michael Morykwas in 1997 and now manufactured by Kinetic Concepts, Inc. (KCI) in San Antonio, TX. It is the best known of several "topical negative pressure" (TNP) or "negative pressure wound therapy" (NPWT) devices. Other names for this modality include: subatmospheric pressure, sealed surface wound suction, vacuum sealing, and foam suction dressing.¹ VAC® was the first system to be approved by the Food and Drug Administration and is probably the most familiar name to clinicians. Another device approved in 2004 is the Versatile1™ manufactured by BlueSky Medical in Carlsbad, CA. For this discussion, the term TNP will be used and should be understood to be the equivalent of NPWT of which VAC is the most well known example.

TNP is used in the treatment of many acute and chronic wounds in addition to pressure ulcers. These include: upper or lower extremity wounds secondary to trauma, burns, leg ulcers, diabetic ulcers, wounds that have become infected (though not grossly infected) or dehisced, necrotizing fasciitis, and post operative sternal infections. It can also be used as an adjunct to surgery for skin grafts, flap surgery and wound bed preparation.² It is contraindicated in the presence of: malignancy in the wound, osteomyelitis, unexplored fistulas, necrotic tissue with eschar, or where placement would involve exposed blood vessels or organs.³

Briefly, TNP involves the placing of a reticulated foam dressing within the wound cavity. This is then sealed in the wound bed by a transparent adhesive drape--thus providing a closed wound environment. Tubing connects the dressing to the VAC device which, can be activated to

apply either continuous or intermittent negative pressure, generally 125 mm Hg below atmospheric pressure. There is some indication that intermittent pressures applied for five minutes--with two minutes between cycles, provides better healing, though this can cause more discomfort to patients. Sometimes a period of continuous application is followed by an intermediate regimen. The optimum regimen has yet to be determined.² Foam dressings are changed "every 48-56 hours except in exceptional circumstances (for example, over a skin graft)".^{2(p. 354)}

Hypotheses for why TNP is effective fall into three general categories: removal of excess third space fluid; reduction of bacterial load; and mechanical stress which causes both a drawing together of wound edges and stimulation of angiogenesis and tissue growth.^{1,4}

Although there has been considerable enthusiasm about using TNP as a wound care modality, there is little evidence-based support for its superiority over other modalities. A very recent *Cochrane Review* addressing the use of topical negative pressure in the treatment of chronic wounds was published in July 2008 and republished with edits in July of 2009.¹ In the update, a total of seven trials involving 205 participants were reviewed. Within the 7 trials, five different treatments were used for comparison, four of them using gauze soaked in either 0.9% saline or Ringer's solutions, and the other three using different topical agents. The authors conclude that: "Trials comparing TNP with alternative treatments for chronic wounds have methodological flaws and data do demonstrate a beneficial effect of TNP on wound healing however more, better quality research is needed."¹

It is important to note that Ubbink et al., the authors of the *Cochrane Review* do not diminish the potential efficacy of TNP, they simply point out that so far, there is very little

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reliable data to support its use over other modalities. In reviewing the literature, the authors could only locate a total of 7 randomized controlled trials (RCTs). While other reviewers were able to find a greater number of trials, they included non-randomized studies, the designs of which are too susceptible to bias for inclusion in the *Cochrane Review*. Even within the 7 included, Ubbink et al. found serious methodological problems. Among these was the fact most study periods were relatively short in duration. Thus, definitive endpoints such as time to complete healing could not be used. Instead surrogate outcomes such as changes in wound volume were used—with no guarantee that these were indeed valid surrogates. Each study also tended to use a different surrogate/outcome as its endpoint. This, together with the great variety of treatments to which TNP was compared, made meta-analysis impossible. The authors also note that “robust information on the effects of TNP on healing, quality of life, pain and costs is lacking.”^{1(p.12)}

If the data on the use of TNP in the treatment of chronic wounds in general is lacking, data to support its use for pressure ulcers is almost non-existent. In an article published just before the *Cochrane Review*, the same group broke down evidence for the use of TNP by wound type— including mixed chronic wounds, diabetic wounds, pressure ulcers, skin grafts, and acute wounds.⁵ Only two studies addressing pressure ulcers met their criteria— the studies by Ford et al.⁶ and by Wanner et al.⁷

Ford et al. studied 28 patients with 41 full thickness decubiti and randomized them to receive either VAC or the Healthpoint (HP) System of wound gel products (“Accuzyme, Iodosorb, and Panafil—each targeted to optimize a particular macroscopic phase of wound healing”^{6 (p.56)}). Twenty-two patients completed the 6 week trial. The authors found a greater reduction in wound volume in the VAC® group compared with the HP group and an improvement in three patients with osteomyelitis treated with VAC® compared with none treated with HP.^{5, 6}

Wanner et al. studied two randomized groups of 11 patients—each with pressure ulcers greater than grade 2. One group was treated with a more traditional course of wet-to-dry/wet-to-wet gauze dressings soaked in Ringer’s solution and changed three times a day. The second group received the vacuum-assisted closure technique. The mean time to reach 50% of the initial volume was 28 days and 27 days respectively. The fact that no difference was found was surprising to the authors who had expected to find faster wound healing in the VAC treated group.⁷

Clearly, more research in this area is needed. In the interim, TNP has been found by many to be an extremely valuable adjunctive therapy. A consensus panel of experienced wound care clinicians met in 2004 to answer key questions about TNP and to create a clinical algorithm for its use. These were subsequently published in the panel’s “Guidelines for Managing Pressure Ulcers with Negative Pressure Wound Therapy” as a supplement to *Advances in Skin & Wound Care*.³ The authors of the guideline stress that pressure ulcer management is multifaceted and interdisciplinary. Attention to all aspects of treatment is vital.

This includes:

- wound cleansing and debridement to remove devitalized tissue and reduce bacterial burden
- appropriate support surfaces to redistribute pressure
- attention to the patient’s nutritional status
- dressings that promote a moist wound healing environment
- appropriate topical, oral, and/or parenteral antibiotic therapy
- use of adjunctive modalities^{3(p.5)}

The authors advocate for the use of TNP as an adjunctive modality for the treatment of Stage III and IV pressure ulcers.

It is fascinating to note that even in the only two trials felt valid enough to be included in the *Cochrane Review*, the mean ages of patients studied were quite young. In the Ford trial the mean age was 41.7 years in the VAC group, and 54.4 years in the HP group.⁶ In the Wanner trial, the mean age was 49 in the VAC group and 53 in the traditional group.⁷

Dr. Shariff’s question focuses specifically on the management of pressure ulcers in very frail patients—those with chronic disease/terminal illness/bed bound status. In these patients, time to complete healing or to readiness for definitive surgery may not be as important as quality of life and reduction of pain issues, arenas in which there is truly no solid evidence-based information. The Cochrane reviewers lament the fact that they “found surprisingly few data on quality of life or adverse effects, such as pain during foam changes. If reported, the authors rarely used a clinically validated method to measure the pain and quality of life.”^{1 (p.12)} This kind of information, perhaps even more than hard data on time to wound healing, or proportion of wounds healed, will be especially valuable for clinicians caring for frail elders.

References

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