Issues in Emerging Health Technologies

Vacuum Assisted Wound Closure Therapy

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Summary

- ✓ **Vacuum assisted closure (VAC) therapy is designed to promote the formation of granulation tissue for faster healing in the wound beds of patients with acute and chronic wounds.**
- ✓ **Four controlled trials and one interim analysis provide poor quality data and weak evidence that VAC therapy may be superior to conventional methods used in healing wounds.**
- ✓ **Complications with VAC therapy are uncommon.**
- ✓ **Studies are needed to evaluate the effectiveness of VAC therapy when the types of dressings are the same for patients in the groups being compared and VAC therapy is the only differing intervention.**

The Technology

Vacuum assisted closure (VAC) therapy uses topical negative pressure to treat acute wounds and to promote closure of difficult-to-heal chronic wounds. The hypothesis underlying its development is that negative pressure removes extracellular fluid and exudate, reduces edema and improves blood flow, thereby providing oxygenation and nutrition to a wound site and promoting accelerated healing.[1] Vacuum pressure is applied in the range of 50-125 mmHg (adjustable up to 200 mmHg) and may be used intermittently or continuously.[2]

A foam dressing fills the wound space and a tube is inserted into the wound and covered with adhesive drape. The vapour-permeable adhesive drape facilitates gas exchange and protects the wound base.[3] An evacuation tube applies negative pressure, creating an airtight seal around the dressing. Dressings are frequently monitored. Dressing changes are recommended every 48 hours for adults with non-infected wounds and daily for infants and adolescents.[1,2]

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Regulatory Status

VAC, manufactured by Kinetic Concepts Inc. (US) was authorized for sale by Health Canada in March, 2001 (Kathleen Savage, Therapeutic Products Directorate, Ottawa: personal communication, 2002 Sep). It was approved by the US Food and Drug Administration in 1995.[4] It appears that at this point in time, this therapy is not an insured service in most Canadian jurisdictions.

Patient Group

VAC therapy is primarily used to manage patients with acute and chronic wounds, including wounds resulting from pressure ulcers, diabetes, trauma, burns, incisions that re-open after

suturing, sternal wounds and surgical wounds secondary to abdominal reconstruction.[5] The manufacturer recommends VAC therapy for patients already receiving conventional therapy for wounds that have not healed by up to 50% of their size over a one-month period of treatment.[6] As VAC therapy is a non-invasive procedure, it has been considered suitable for patients who are poor candidates for surgery.[1]

Pressure ulcers are estimated to affect a million people annually in the US, at a cost of approximately US$1.6 billion.[7] A wide variation in the range of ulcer incidence has been reported (i.e. acute care 0.4%-38%, long term care 2.2%-24% and home care 0%-17%).[8] An incidence of 9.7% was reported by Goodridge et al. in a 1998 pressure ulcer study that included 330 patients over age 65 in four Canadian hospitals.[9]

Therapy is contraindicated for wounds involving malignancy, untreated osteomyelitis, fistulae to organ or body cavities, cancer in wound margins, exposed veins and arteries and necrotic tissue.[6] The manufacturer advises that VAC therapy should be used cautiously when there is active bleeding or if the patient is on anticoagulants.[6]

Current Practice

A wide range of skin care products are used for various types of wounds. Despite advances in medical management, chronic wounds continue to be a challenge and cause significant morbidity and mortality.[10] The treatment of complex wounds is costly and may involve prolonged hospitalization with intensive nursing care and additional surgical procedures.

The Evidence

Clinical Efficacy

The findings from four published controlled trials investigating the use of the standard VAC therapy as compared to conventional dressings are presented in Table 1.[11-14]

Joseph and colleagues compared VAC therapy to gauze dressings in patients with chronic wounds.[11] The wounds were photographed and measured by volume displacement using impression molds. VAC therapy negative pressure was found to have a statistically significant positive impact on healing rate.

McCallon and colleagues compared VAC therapy to gauze dressings in the treatment of diabetic foot wounds.[12] Photography and wound tracings were used to assess wound healing. The VAC therapy showed faster healing and a greater reduction in wound surface area.

In the third study using a within-subject control, Genecov et al. examined the rate of healing on thigh skin graft sites using the VAC therapy as compared to OpSite™.[13] VAC therapy had a statistically significant impact on the healing rate.

In the fourth study, VAC therapy was evaluated in patients undergoing elective surgery for postoperational ventral hernia at a surgical clinic in Russia.[14] The time to suture removal and the length of stay in hospital were reduced for patients receiving the VAC therapy. Statistical significance was not tested.

Results from an interim analysis of a randomized trial of VAC therapy versus the Healthpoint System (HP) in the management of pressure ulcers were recently published.[15] This system consists of three gel products to help promote the healing of ulcers at various stages. Of the 28 patients with 41 full-thickness ulcers, 22 patients with 35 wounds completed the six-week trial. Two ulcers in each group healed completely, 10% in the VAC group (n=20) and 13% in the HP group (n=15). Of 15 cases of osteomyelitis, 3 wounds (37.5%) in the VAC group showed improvement confirmed by bone biopsy or MRI, whereas no wounds showed improvement in the HP group (p=0.25). This preliminary finding suggests that VAC therapy may have a place in the management of osteomyelitis.

Table 1: VAC therapy trials

Population	N =	Comparator treatment	Duration of treatment	Study quality considerations	Outcomes
Joseph et al. 2000[16]					
Chronic, non-healing wounds	24 patients, 36 wounds	Saline gauze dressing	6 weeks	• Blinded, independent wound evaluators • Withdrawals not reported	• Changes in wound volume: 78% VAC, 30% gauze (p=0.038) • Changes in wound depth: 66% VAC, 20% gauze (p<0.00001)
McCallon et al. 2000[17]					
Post-operative diabetic foot wounds	10 patients	Saline gauze dressing	Not reported	Not reported	• Healing: 22.8 (±17.4) days VAC, 42.8 (±32.5) days gauze • Decrease in surface area: 28.4% (±24.3) VAC, 9.5% (±6.9) gauze • Statistical analysis not performed due to small sample size
Genecov et al. 1998[18]					
Patients requiring skin grafts	10 patients	OpSite ™	7 days	• Blinded, independent evaluator • Reviewed healing using a 0-4 scale • 5 patients lost to follow-up	• VAC increased rate of re-epithelialization (p≤.013)
Davydov 1994[19]					
Elective surgery patients, postoperative ventral hernia repair	Control =53 VAC =26	"Conventional treatment"	48 hours	Not reported	• Time to suture removal: 8.52 (0.23) days VAC, 8.64 (± 0.20) days control • Duration of treatment: 9.5 (± 0.4) days VAC, 11.04 (±0.47) days control • Length of stay in hospital shorter for VAC patients

In summary, four controlled trials and one interim analysis provide poor quality data and weak evidence that VAC therapy may be superior to conventional methods used in healing wounds. The studies were small, follow-up was short-term, the methods of random assignment and the adequacy of allocation concealment were questionable and control subjects received a type of dressing that differed from that of VAC patients. These problems limit the internal validity. This critical appraisal is consistent with information published in two earlier reports.[4,16]

Cost-effectiveness

An unpublished cost-effectiveness analysis, sponsored by the manufacturer, compared in-home treatment using VAC to wet-to-dry dressings for patients with chronic wounds and pressure ulcers (burns were excluded).[17] The analysis was conducted from the viewpoint of US Medicare. Resource use included services for the treatment of wounds and any related complications, including costs specific to VAC therapy of US$42/day for dressing supplies and US$65/day for pump rental. The base case results showed that for every 100 patients treated with VAC therapy, 68 patients healed and 28 progressed towards healing over six months, compared to 12 and 69, respectively, for the comparator. VAC therapy showed modestly lower average costs per patients (US$23,800 vs US$25,800).

The study concluded that VAC therapy was superior to wet-to-dry dressings in terms of improved outcomes and modestly lower costs, because patients treated with VAC had a greater chance of healing over six months, or of healing more quickly. However, some assumptions about costs and clinical practice used in the analysis may not be appropriate

for a Canadian setting (e.g. wet-to-dry dressings are not the current standard of care in Canada). In addition, it is important to note that the success rates for the alternative treatments were established using clinical expert opinion, rather than being based on trial data.

Adverse Effects

Complications of VAC therapy are uncommon. Erosion of tissue around the evacuation tube may occur if the tube is positioned directly over bone or if the patient lies directly on the tube.[5] Bleeding was associated with dressing changes when the dressing was in place for longer than 48 hours in a case series of patients with lower extremity wounds.[2]

Removal of the dressing in the presence of granulating tissue and the force of pressure on the wound bed can cause pain.[2,12,18] In most patients the pain can be managed with intravenous or oral narcotics and by decreasing suction pressure.[2] Turning off the suction pump and instilling normal saline or a topical anaesthetic agent directly into the sponge or tubing a few minutes prior to sponge removal may help to decrease pain associated with removal (Nancy Parslow, The Scarborough Hospital, Toronto: personal communication 2002 Nov 21). There is one documented case of toxic shock syndrome associated with VAC therapy.[19]

Administration and Cost

Equipment required for VAC therapy includes a pump, dressings and a canister with tubing. The pump rental fee for one day is C$65 and the cost to purchase a VAC unit with battery is C$11,500.[6] The cost of dressings depends on the size of the wound and ranges from C$380-$570 for a package of 10 dressings. VAC canisters and tubing are changed weekly or when full. The cost is C$260 for 5 canisters or C$360 for 10.

Concurrent Developments

Nonsurgical modalities produced by different manufacturers, such as exogenous application of growth factors, cultured keratinocyte grafts, electrical stimulation, therapeutic ultrasound, hyperbaric oxygen and Warm-Up® therapy,[20] may be used to heal soft tissue wounds or to help prepare wounds for surgical intervention.[21] Reconstructive surgery may be considered in the management of complex and difficult-to-heal wounds.

The manufacturer has also developed a mini-VAC. This is a small, compact device with a light-weight battery-powered unit that allows for delivery of therapy to ambulatory patients with minimally to moderately weeping wounds. The manufacturer has recently introduced a new treatment modality, the VAC Advanced Therapy System (ATS). It provides a newly-patented technology called Therapeutic Regulated Accurate Care (TRAC). This technology maintains negative pressure through constant pressure sensing at the wound site.[22]

Pump rental costs for one day for the VAC ATS is C$83 and the cost to purchase the unit is C$19,900. The cost of dressings ranges from C$425-$635 for a package of 10 dressings. The cost of 5 canisters is C$290 or C$400 for 10.[23]

Rate of Technology Diffusion

VAC therapy, first used in Canada in 1995, is currently being used in approximately 200 hospitals, 195 long-term care facilities and 70 home care programs, according to the manufacturer (Carol Robinson, KCI Medical, Mississauga, ON: personal communication, 2002 Aug). The management of wounds is a problem associated with an aging population; wider use of VAC may be expected if further evidence of the effectiveness of this therapy

becomes available. Potential benefits could include earlier hospital discharge, reduced need for surgical intervention, savings in nursing time, reductions in costs of wound care materials and improvements in quality of life for patients.[18]

Implementation Issues

More research is needed to support the available evidence. The best evidence to determine benefits of this technology will be obtained from multi-site, randomized, controlled trials that include larger sample sizes, long-term follow-up, measurements of quality of life, measurements of pain using validated tools and cost analysis. Several industry-sponsored, multi-site, controlled trials are underway to evaluate VAC therapy in patients with burns, trauma, pressure ulcers, surgical wounds, fractures and diabetic foot ulcers (Carol Robinson: personal communication, 2002 Aug). An independent economic evaluation would be useful to determine if the costs of VAC therapy justify its potential benefits.

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