OHTAC Recommendation

Negative Pressure Wound Therapy

July 21, 2006

OHTAC Ontario Health Technology Advisory Committee

Negative Pressure Wound Therapy

The Ontario Health Technology Advisory Committee (OHTAC) met on July 21, 2006 and reviewed the effectiveness of negative pressure wound therapy (NPWT) compared to standard care for the treatment of wounds. This report is an update from the Medical Advisory Secretariat's (MAS) previous review of Vacuum Assisted Closure (VAC) therapy in 2004. At that time OHTAC recommended that no additional funding be provided for VAC therapy, and that a provincial approach should be established to address the lack of multidisciplinary community-based chronic wound care in Ontario. The request for this update came from the Home Care and Community Support Branch whose attention had been drawn to a new study of effectiveness of NPWT published in 2005. OHTAC, further to its terms of reference, offers the following advice to the Ministry of Health and Long-term Care (MOHLTC) for its consideration.

OHTAC Findings

Briefly, negative pressure wound therapy (NPWT) involves placing a piece of foam directly over a wound. A drain tube is placed over the foam. Then, a large piece of transparent tape is placed over the whole area, including the healthy tissue, to secure the foam and drain. The tube is connected to a vacuum source, and excess fluid is drawn from the wound through the foam into a disposable canister. In this way, the entire wound area is subjected to negative pressure. NPWT may be used for patients with chronic and acute wounds, diabetic wounds or pressure ulcers, meshed grafts or flaps.

NPWT is currently being used across many health sectors in Ontario, and is widely diffused. In 2004, there were about 380 NPWT units rented from the manufacturer in Ontario: 152 systems were rented through CCACs, 110 by long-term care homes and 103 in hospitals. NPWT is typically performed by nurses or enterostomal therapists.

One new randomized controlled trial was published since the 2004 review, and formed the basis for this update. The study included 162 patients who had acute, surgical wounds from partial foot amputations. The patients were randomized to receive NPWT or standard care, and were followed for 16 weeks to assess complete wound closure in that time period. However, during the 16 weeks some patients also underwent surgical wound closure. The decision to undergo surgical wound closure was at the physician's discretion. More patients in the NPWT group than in the control group underwent surgical wound closure (16% vs. 9%). According to a MAS calculation, the proportion of patients with complete wound closure without surgical wound closure in the NPWT compared to those in the control group was 40.3% versus 29.4%, respectively ($P = .15$). It is important to note that this is a post hoc analysis with low

statistical power to detect a significant difference between groups (Type II error). When all patients (including those undergoing surgical wound closure) were analyzed there was a significant difference, favouring NPWT, in the rate of complete wound closure (56% vs. 39%, *P*=.04). Since surgical closure was not a randomized intervention, the study did not permit OHTAC to assess whether patients were achieving complete wound closure in response to surgery or to NPWT, or a combination of both.

When the rate of wound infection was assessed separately, the rate of infection for NPWT was higher compared to the control group (17% vs 6%, P=.04 [MAS calculation]).

In summary, based on the review and analysis of this study, OHTAC found that:

- due to methodological limitations, existing data from controlled trials do not convincingly support a benefit of NPWT over standard care for the rate of complete wound closure;
- it is not possible to reliably comment on the time needed to complete wound closure; and
- there may be an increased rate of wound infection associated with NPWT compared to standard care.

OHTAC Recommendations:

Based on this evidence and the general dearth of evidence of effectiveness, OHTAC now recommends in regard to negative pressure wound therapy and wound healing:

- There is insufficient new evidence of effectiveness of NPWT to modify OHTAC's 2005 recommendation to not provide additional funding for negative pressure wound therapy.
- Given the large numbers of patients requiring chronic wound care in community practice and the increasing diffusion of NPWT based on poor quality evidence, a field evaluation study should be undertaken through consultation with providers of wound care (Plastic and general surgeons, nurse practitioners, enterostomal therapists and other wound specialists) identifying any potential indications for the use of NPWT.
- While the field evaluation is being conducted, negative pressure wound therapy should only be prescribed by wound specialists or nurse practitioners who are part of a multidisciplinary wound care team.

We are informed that if the Ministry is in agreement with the OHTAC recommendations, the Medical Advisory Secretariat will initiate the field evaluation study through the Program for the Assessment of Technologies in Health (PATH) and in consultation with a panel of providers involved in wound care. MAS will continue to liaise with the Home Care and Community Support Branch regarding prescribing for NPWT following further advice from the panel.