Title: Negative pressure wound therapy in a community setting valued therapy or vacuum of evidence?

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Abstract

Recent government documents (Department of Health 2009) have suggested that as a result of advances in tissue viability, more complex wound care can now be provided in the community setting and that therapies such as Negative Pressure Wound Therapy [NPWT] should be common place with tissue viability professionals appointed to direct service provision and ensure high standards (DH 2009). This is a major step forward in current thinking however there are still gaps in our understanding of NPWT with regard to both the mechanism of action and which wound types will respond most favourably to the therapy. Managing complex patients in the community setting can be challenging add to this scenario a device that has to remain attached for around 22 out of 24 hours a day certainly brings new challenges. It yet remains to be ascertained if it is appropriate for all patients or if some definitive exclusion criteria should be agreed. This paper will seek to explore the mechanism of action, benefits, and barriers to adoption in community settings.

Introduction

Negative Pressure Wound Therapy [NPWT] also commonly known as Topical Negative Pressure [TNP] has emerged as a non-pharmacological treatment for acute and chronic wounds, including pressure ulcers, diabetic wounds, abdominal wounds, and trauma wounds. It is primarily used for more complex chronic wounds (Kirby, 2007) although use proactively over high risk post operative incisions has recently emerged in the literature (Atkins 2009). Traditionally this type of treatment has been used within the hospital environment but as we witness more services being moved into the community/home environments there has been an increase in the use of NPWT in these areas. This paper explores the use of NPWT, the evidence underpinning its effective use and factors that may need to be considered with specific regard to use in community settings.

The move to community/home based care

Over 90% of all contact with the National Health Service takes place outside hospital, therefore primary and community care services should play a central role in helping people live healthy lives (Department of Health [DH] 2008). The DH (2008) maintain that there should be increasing access to services that help people maintain and improve their health and wellbeing with primary and community clinicians playing a lead role in promoting equality of opportunity and equality of health outcomes. The continuing advances in technology and medical treatments ensure more people will be able to receive care in community-based settings (rather than travelling to hospital) or in their own homes. The potential to use community settings for some services traditionally provided in hospitals – and in a way that really shifts the emphasis to supporting health and wellbeing rather than simply curing disease – is set to grow faster in the coming years as a result of demographic, economic and technological changes. NPWT has been cited specifically as a means of managing complex wounds in settings closer to home (DH, 2009). There is a suggestion that patients with complex wound care requirements either commenced on NPWT in a hospital or at home will have resultant benefits either by facilitating earlier discharge or preventing hospital admissions and hence may lead to fewer complications. The continued move to treat people in community settings rather than hospital settings may promote an increase in the use of NPWT in community and home settings that has implications for patients receiving therapy, their carers, community budgets and educational needs of those practitioners initiating and maintaining this treatment. Any service provision change requires careful consideration ensuring that therapy is with quantifiable resultant healthcare benefits. Clinicians that frequently use NPWT would agree that as a therapy it has revolutionised some aspects of patient care. Some of the postulated practical benefits are that it facilitates fewer dressing changes per week than conventional therapy especially in highly exudating wounds with alternative daily or twice weekly changes being the most frequently used. However anecdotal reports of pain at dressing changes and need for anaesthesia to facilitate change at dressing changes in some patient groups (McCord et al 2007) may be of concern to community practitioners.

Negative Pressure Wound Therapy

NPWT has been described as a technique designed to remove chronic oedema fluid, thereby leading to decrease in the after load to blood flow, resulting in increased localised tissue perfusion and the resultant formation of granulation tissue (Mendonca et al, 2006). The concept of using negative pressure is to create a suction force, enabling the drainage of

surgical wounds in order to promote wound healing is not new (Fox and Golden, 1976; Fay 1987). Fay (1987) suggests that if excess fluid is not adequately removed from a wound following surgery, its components may serve as both a physical and chemical deterrent to wound healing. Argenta and Morykwas (1997) asserted that the basic concept of mechanical forces influencing the shape and growth of tissues can be achieved through the use of topical negative pressure by removing excess interstitial fluid and transmitting mechanical forces to the surrounding tissues with resultant deformation of the extracellular matrix and cells. The transparent adhesive dressing employed to secure the dressing may also help to maintain a moist wound environment (Banwell, 1999; Mendez-Eastman, 1998).

To summarize the primary mechanisms of action of NPWT can be grouped into 3 physical actions that stimulate physiological pathways and have resultant clinical effects:

- Physical forces on tissue;
- Removal of excess fluid;
- Covering the wound;

This is shown in more detail in Smith & Martin's (2008) flow chart (figure 1).

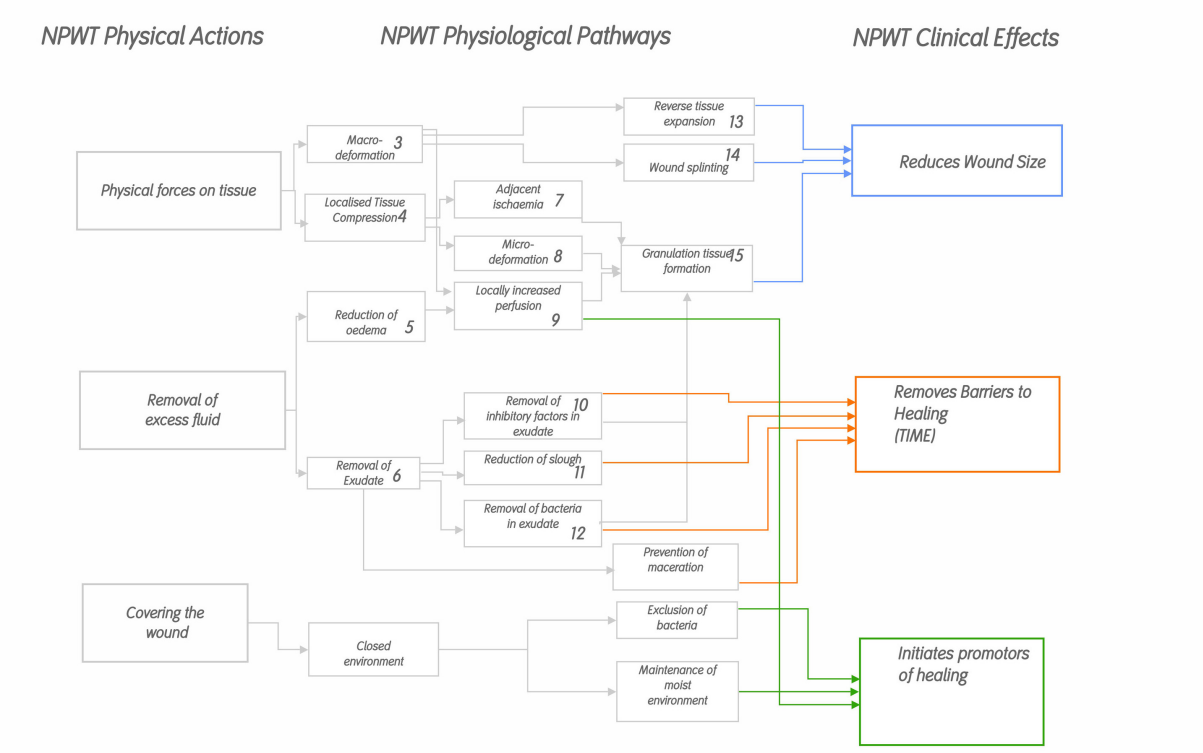

Figure 1. A model of the interactions between physical effects and clinical benefits from NPWT

Since the introduction of NPWT manufacturers and clinicians in partnership have developed additional precautions to facilitate the safe use of the therapy. Kloth (2001) advises that NPWT should be used with caution on patients when there is active bleeding in the wound,

when haemostasis is difficult following debridement, or when anticoagulant therapy is used and is contraindicated when:

- Wounds contain necrotic tissue
- Osteomyelitis is untreated
- Fistulas to body cavities or organs are present
- Malignancy is present in the wound
- Treatment would place the foam dressing directly over arteries and veins that are exposed in the wound.

Mendonca et al (2006) caution that we still do not know the precise mechanism by which negative pressure brings about wound healing. The growth factors and cytokines responsible for initiating the process of cell migration and angiogenesis are yet to be elucidated, as is any evidence to show that negative pressure influences cell growth. NPWT has been used for centuries and following its commercial introduction in 1997, NPWT is a technique that has been extensively used to enhance the rate of wound healing, prepare the wound bed for surgery and decrease the time to healing. Although case reports and retrospective studies have demonstrated enhanced wound healing in numerous wound types, there are very few randomised controlled trials and those in existence report mixed results.

The physiological basis of NPWT is based on the early work of Dersch et al (1994) who illustrated that positive pressure leads to a decrease in skin perfusion and hypoxia, while negative pressure increases skin perfusion. Morykwas et al (1997) demonstrated that peak blood flow levels were fourfold higher than baseline values in a pig model while using the technique at continuous pressures of 125 mmHg. They also found a significantly higher rate of granulation tissue formation and a significantly reduced bacterial count after 4–5 days of treatment using this technique. However more recent studies have shown that NPWT actually exerts a small positive pressure on tissue that creates a small zone of hyperaemia in the tissue in contact with the interface material and that this is surrounded in both cutaneous and muscle layers by a zone of hyperperfusion (Wakenfors et al 2007, Malmsjo 2008). This was missed by the original Morykwas (1997) study as blood flow was only measured at 2.5cm outside the wound margins as opposed to at the wound bed as was the case in the later studies. The bacterial clearance seen in these early studies has also been challenged (Weed et al 2004) with cultures taken in human subjects showing an increase in bacterial load in NPWT treated wounds. However they did comment that the wounds progressed towards healing despite this finding and suggested further study to elucidate why.

Use of NPWT in Primary, Secondary and Acute Settings

NPWT has been in common use in the acute care setting for over 10 years, but has been used less often in the community and continuing care settings for the treatment of challenging acute and chronic wounds (Beldon, 2006). In a study investigating the use of Vacuum Assisted Therapy (VAC) (Newton et al,2006) they identified that the highest use was in secondary care (67%) followed by joint nursing responsibility for primary and secondary care (18%) and then primary care (15%). It was reported that a lack of funding by the Primary Care Trust (PCT) as the greatest barrier to using negative pressure. The respondents cited a total of 64 cases where lack of PCT and hospital funding were the reasons for patients not receiving negative pressure on discharge. The lack of protocols for obtaining the therapy was an issue in 28 of the 104 responses. However, lack of education and competence among nursing staff also appeared to be an issue in relation to patient access to the therapy. The need for trained healthcare professionals must be taken into account: failure of NPWT is often due to inadequate staff education and skill as discussed by Fleck and Frizzell (2004) Healthcare professionals must also have access to the appropriate consumables to enable the application and removal of the NPWT device. Whilst NPWT consumables are available on drug tariff in the UK it is not always easy to access them as pharmacists are reluctant to keep them as stock items due to the unit costs. The authors have also experienced patients who following discharge from acute services request that negative pressure be discontinued as they find it too stressful being attached to and managing the device in their home without the reassurance of a nurse in close proximity. Or conversely alarms or the noise of some of the devices at night become problematic for partners and carers. It is clear that these factors all warrant further study especially given the new drive for both care closer to home and quality indicators especially that of patient reported outcome measures [PROM's] in recent DH (2009) communications.

Evidence Surrounding the use of NPWT

There are over three hundred papers in the medical literature regarding the use of NPWT on wounds, including the use of NPWT on chronic wounds, sternal wounds, burns, skin grafts, pressure ulcers, diabetic wounds, open fractures, abdominal wounds and fistulae (Bonner et al, 2009). There are only a small percentage that represent randomised controlled trials evaluating the clinical efficacy of NPWT (Ahmed et al, 2007; Blume et al, 2008; Braakenburg et al, 2006; Eginton et al, 2003; Llanos et al, 2006; Moisidis,et al, 2004; Moues et al, 2007; Joseph et al, 2000). However the Cochrane Group (Ubbink et al, 2007) undertook a systematic review on the application of NPWT for treating chronic wounds and reported that

only two trials met the selection criteria (Joseph et al. 2000; McCallon et al. 2000). Both trials compared the rate of wound healing with the traditional saline gauze dressings and found in favour of NPWT. However both studies were conducted with small sample sizes and Cochrane suggest their results must be interpreted with care.

A further five trials were included in the Cochrane update (Ubbink et al, 2007) review resulting in a total of seven trials involving 205 participants. The seven trials compared NPWT with five different comparator treatments. Four trials compared NPWT with gauze soaked in either 0.9% saline or Ringer's solution. The remaining three trials compared NPWT with hydrocolloid gel plus gauze, a treatment package comprising papain-urea topical treatment, and cadexomer iodine or hydrocolloid, hydrogels, alginate and foam. They concluded that the data did not show NPWT significantly increased the healing rate of chronic wounds compared with comparators (Ubbink et al, 2001).

Kirby (2007) reported that when NPWT was successfully used, it expedited wound closure resulted in shorter hospitalisations, reduced costs and reduced risks of infection. Treatment with NPWT, allowed these patients to be discharged from hospital and treated at home, where they could maintain greater mobility with improved quality of life. Within home healthcare settings, Page et al (2004) reported that NPWT may help to improve patient care and decrease costs associated with numbers of visits. They found that the risk of complications, subsequent foot surgeries, and hospital readmissions (secondary outcomes) were all reduced by 70% or more for the patients treated with NPWT, compared with patients treated with standard saline soaked gauze dressings. One limitation of this study is saline soaked gauze is not representative of standard care in the UK. There is limited evidence to date that compares NPWT to conventional advanced wound care therapies with respect to health economic benefit of one versus the other.

A reduction in the length of hospital stay when using Vacuum Assisted Therapy (VAC®) therapy for patients with diabetic foot ulcers and open abdomens has been demonstrated by Armstrong et al (2004) and Kaplan (2004). Armstrong et al (2005) re-investigated whether NPWT improved the proportion and rate of wound healing after partial foot amputation in patients with diabetes. This involved a multi-centre randomised intention - to - treat trial, involving 162 patients delivering foam based NPWT while the control group received standard moist wound care according to consensus guidelines. The results showed that more patients in the NPWT group achieved complete closure during the 16-week assessment (56% compared with 39% in the control group).

Recent studies have suggested that clinicians should look for double digit wound volume reduction week on week during treatment when using NPWT (Campbell et al 2008; WUWHS 2008). This may be an emerging marker with which to judge success however, variations in therapy use (filler choice, that is to say a choice of foam or gauze filler, negative pressure setting selection, application techniques and frequency of dressing changes differ from patient to patient and between clinical settings and specialties).This alongside some local restrictions on use, owing to the lack of evidence on which to support the use of NPWT make authoritative conclusions difficult.

Conclusion

The cost of wound care to the NHS has been estimated to be £2.3bn and £3.1billion a year (2005-2006 prices). The DH estimated that the budget for the National Health Service (NHS) in England 1996/7 was £33 billion and that the year 2008/9 it would be £96 billion (Posnett, Franks et al 2007). NPWT has been postulated to promote wound healing by increasing local blood flow, reducing interstitial oedema, controlling exudate, stimulating the formation of granulation tissue and cell proliferation whilst removing healing inhibitors (Morykwas 1997). NPWT use in acute care has been established since the late 1990's in the UK, growing pressure on hospital beds and an increasing number of commercial providers of the therapy has as a result increased the use of NPWT in community settings.

More research is needed to establish the efficacy of NPWT. In addition there is little or no data exploring patient quality of life or established guidelines to ensure both the appropriateness of patient selection for the right reasons and also ensure that patient safety is paramount at all times. Furthermore and with specific regard to the potential growth of negative pressure used to treat chronic wounds there needs to be clear guidance to inform clinicians when to discontinue the therapy. This will ensure that both patient and clinician expectations are congruent at the start of therapy and that a goal of care is established and agreed which, if met or conversely if not met, leads to discontinuation of therapy and subsequent reassessment. In the absence of definitive evidence, consensus statements offer a practical approach to guide clinician choices and inform the development of practice.

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