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Ousey, Karen and Milne, Jeanette

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Exploring portable negative pressure wound therapy devices in the community

Karen J Ousey, PhD, MA, PGDE, BA, RN, Reader, School of Human and Health Sciences, Centre for Health and Social Care Research, University of Huddersfield, Queensgate, Huddersfield, West Yorkshire, United Kingdom, HD1 3DH. Tel: 0044 (1) 484473462; E-Mail: k.j.ousey@hud.ac.uk

Jeanette Milne, RGN, BSc Hon, Post Grad dip HE wound healing and tissue repair, Tissue Viability Nurse Specialist, South Tyneside Foundation Trust Community Services, Clarendon House, Windmill Way, Hebburn, Tyne & Wear, United Kingdom, NE31 1AT

Abstract

The success of effectively managing open wounds using Negative Pressure Wound Therapy has been explored and discussed within the literature. Case studies and clinical reviews support the use of this therapy in managing a range of wound types, yet very few scientific studies that fully support its effectiveness. There is evidence to suggest that the use of negative pressure in the community settings has been restricted, due to financial pressures aimed at reducing the cost of wound care. Yet it has been argued Negative Pressure Wound Therapy can provide excellent symptom management, reduce the frequency of dressing changes and can provide a cost effective alternative to traditional wound therapies due to faster healing times, leading to a reduction in overall treatment costs. Negative Pressure use within community environments is increasing as length of hospital in patient stay decreases, and many patients who would have traditionally been admitted to an acute setting with a complex or highly exuding wound, are managed by community nurses. This paper presents a narrative review surrounding Negative Pressure Wound Therapy, identifies safety precautions that require consideration and explores the application of smaller/ disposable Negative Pressure Wound Therapy systems that are now available.

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Key Words

Negative Pressure; wounds, community, quality

Declaration of Interest.

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Corresponding Author

Karen J Ousey, PhD, MA, PGDE, BA, RN, Reader, School of Human and Health Sciences, Centre for Health and Social Care Research, University of Huddersfield, Queensgate, Huddersfield, West Yorkshire, United Kingdom, HD1 3DH. Tel: 0044 (1) 484473462; E-Mail: k.j.ousey@hud.ac.uk

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Introduction

The use and effectiveness in managing wounds and promoting wound closure with negative pressure wound therapy (NPWT) has been well documented.¹⁻⁵ NPWT involves the application of controlled sub-atmospheric pressure to the wound bed, to promote wound healing.⁶⁻⁸ It has been noted to be an interventional therapy that actively supports wound healing impacting on the wound in a number of ways, including reduction of peri wound oedema, removing exudate, inducing controlled ischaemia at the wound bed thus improving blood flow in the peri wound margins, stimulation of cell mitosis as a result of mechanically induced cell stress and providing a closed, warm moist healing environment.⁹⁻¹¹ Ubbink et al.¹² defined NPWT as the application of negative pressure across a wound to aid healing. The application of NPWT wound fillers to the wound enable equal distribution of pressure at the wound bed which in turn causes microscopic deformations (microdeformation), which are thought to contribute to granulation tissue formation and increase mitosis.¹³ The effects of traditional NPWT will depend on wound aetiology, the type of filler used, the amount of pressure applied and the duration of therapy;¹⁴ traditional NPWT systems may comprise of a wound filler (foam or gauze), which is sealed with a plastic drape and the drain or port which is connected to a pump.¹⁵ When negative pressure is applied to the wound the filler is compressed into the surface of the wound leading to a reduction in microvascular blood flow at the wound bed, contraction at the wound margins (macrodeformation) and induces cell stress, excess exudate is removed via through the tubing and collected in a canister.

Clinical evidence discussing optimum pressures for NPWT state -125mmHg when using foam filler¹⁶⁻¹⁸ and -80mmHg when using a moistened gauze wound interface.^{19,20} Recent animal studies have suggested that -80mmHg is the optimum pressure for, wound contraction, microdeformation, pressure transduction that induces positive blood flow effects beyond this the therapeutic effect is continued but no additional benefit is seen with the exception of exudate removal for which the

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optimum pressure is around -120mmHg¹⁴. Interestingly new research has suggested that with pressures as low as -40mmHg therapeutic benefits are still reported.²¹

The use of NPWT to effectively manage open wounds has been explored and discussed by Bovill et al.,²² and Moues et al.²³ however, Stannard et al.,²⁴ and Atkins et al.²⁵ evaluated the use of NPWT in managing closed surgical wounds and reported positive results. Yet there are very few randomised controlled trials and those in existence report mixed results.²³⁻²⁶ The Cochrane Group²⁷ undertook a systematic review on the application of NPWT for treating chronic wounds identifying seven trials that met the selection criteria but concluded that the data did not show NPWT significantly increased the healing rate compared with comparators.²⁷ Braakenburg et al.,¹⁸ concluded from a Randomised Controlled Trial (RCT) that NPWT did not result in significantly faster granulation or wound surface reduction when compared with modern wound dressings. The benefits of NPWT are widely reported in over a 1000 peer-reviewed publications which describe clinical efficacy and safety of NPWT in varied wound types have been published in the last decade.²⁸ Its use in clinical practice has become established as gold standard in many areas such as plastics, and trauma reconstruction as discussed by Runkel et al.²⁹ in their published best practice guidance.

Choosing NPWT as a treatment option

Care must be taken when choosing NPWT as the treatment of choice and caution used if there is active bleeding in the wound when haemostasis is difficult following debridement, when anticoagulant therapy is used or for wounds with necrotic tissue.^{30,31} Additionally NPWT is contraindicated:

- Osteomyelitis is untreated
- Unexplored fistulas to body cavities or organs are present
- Malignancy (except palliative care)

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- Exposed arteries
- Treatment would place the foam dressing directly over arteries and veins that are exposed in the wound
- Severe peripheral arterial disease
- Any cavity or sinus that is not clearly visible
- Non concordant patients
- Patients with full thickness burns

Traditionally NPWT has been used in acute care settings³² however in the United Kingdom, the Department of Health³³ [DH] reported that over 90% of contact with the National Health Service took place outside of a hospital environment; the increasing move of services to community healthcare has seen a rise in NPWT being commenced and used outside of acute healthcare. In fact NPWT was identified by the DH³⁴ as an intervention that could be used to manage complex wounds in settings closer to home. NPWT devices historically have been quite large and can be cumbersome especially if the patient has reduced mobility, walks with aids or has cognitive impairment. In an attempt to ensure that NPWT devices are more acceptable to individuals requiring treatment practitioners are now able to access smaller, lightweight and disposable devices have been introduced and can be accessed via drug tariff on prescription.

Treatment Goals for using NPWT

In general, there is relatively weak evidence on which to base recommendations for any one NPWT treatment variable over another. NPWT is a generic multimodal technology, which can deliver a broad range of treatment goals. The therapeutic goal can differ from patient to patient, these goals can be achieved by altering a range of variables including the device settings (e.g. level of pressure, intermittent, continuous therapy), choice of wound filler, whether to use a wound contact layer and

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frequency of dressing change. This in turn adds to the complexity of studying the therapy as part of an RCT, in addition standardising these variables can lead to recruitment problems and in turn reduced clinical relevance with limited real world relevance and reproducibility. Practitioners must undertake and document the results of individual patient and wound assessment prior to deciding on the optimum negative pressure level, type of wound filler and contact layer. Following review of the literature the authors identified that although there is evidence to guide the practitioner to effective choices it is often difficult to locate due to the abundance of clinical studies, and conflicting results.

For the purpose of this paper the treatment goals have been grouped as follows;

Managing and protecting the wound

The ability of NPWT to protect the wound depends on the physical ability of NPWT to provide an airtight barrier between the wound and the external environment as a result of the integral adhesive drape. This provides a dual function; the drape maintains a moist wound environment, conducive to wound healing, as well as providing a barrier to external insult (e.g., contamination by particulates or microbes), it also splints the wound and can protect from external trauma. The therapy needs to be removed to allow wound inspection, however it should be noted that due to the removable nature of the therapy it can become dislodged during normal use. Patients should be advised this may occur and that an alarm will sound reassurance should be given that the NPWT wound filler and dressing will continue to protect the wound but that the fault with the therapy must be rectified as soon as possible if maximal benefits are to be achieved.

Preparing the wound for surgical closure/to progress wound healing by secondary intention

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NPWT can reduce the size and complexity of the wound in two main ways. First, upon application of negative pressure, the wound immediately contracts (macro-deformation). It is thought that, over several days, this mechanism reduces the size of the wound and stimulates wound contraction as well as the formation of granulation tissue. This mechanism may be beneficial for surgical closure and especially for wound closure by secondary intention. A granulating wound bed can improve the suitability of the wound bed (e.g., by covering exposed structures, such as tendon or bone) for closure by either flap or graft.³⁵⁻³⁷ In some circumstances, a wound with a large tissue defect may be encouraged to in-fill completely through the generation of granulation tissue induced via NPWT, so that more complex reconstructive procedures (e.g., free flaps) are no longer required and simpler procedures such as a split thickness skin grafting (STSG) can and are used instead.³⁸⁻⁴³

Improving patient comfort

Wound exudate can be well managed by NPWT, as it is diverted away from the skin and contained within the canister. However practitioners, during their assessment of the wound bed and subsequent decision of which therapy to use, must realise that exudate is often a symptom of an underlying issue preventing the wound healing process to progress in an orderly fashion. As such wound bed assessment should include investigation of the cause of excess exudate and NPWT should not be chosen for the sole purpose of managing exudate as this may lead to continued therapy without a clear end point for discontinuation. Never the less NPWT will protect the wound edges and surrounding skin from maceration and will reduce frequency of dressing changes, compared with conventional dressings¹⁸ assuming an adequate seal can be achieved and maintained at the dressing site. This can lead to reduced pain for the patient as well as reduced frequency of exposure of the wound to the external environment. Earlier patient mobilisation also contributes towards a sense of patient well-being, as has been reported in patients with skin grafts treated with NPWT.⁴

Cost Effectiveness

The use of NPWT has been shown to reduce costs compared with conventional wound therapy. This can be achieved through a combination of improved outcomes and reduced use of nursing resources.^{18,44} Despite the higher cost of an NPWT dressing compared with conventional wound care, these improved outcomes make the therapy more cost-effective. Early use of NPWT in trauma patients has been claimed to reduce overall costs compared with a delayed introduction of NPWT.⁴⁵

Effective use of NPWT in the community

NPWT can be used both in a hospital and community environment, as with any other therapy each patient must have an individual assessment / diagnosis of the wound aetiology, to ensure NPWT is the appropriate treatment of choice. If NPWT has been commenced in the community or the patient is being discharged from hospital with NPWT practitioners must undertake an individual risk assessment in relation to the patient using the device and document the results. Particular attention should be given to the ability of the patient to be able to carry the device with them, especially if they have a foot or leg wound that may cause a risk of tripping. It is also important to check with patients that their home electricity supply is safe and that there are no problems such as loose wiring. Henderson et al,⁴⁸ recommend the following checklist to be used prior to discharge or commencement of the device in the community:

Safety checklist

- Patient mobility – does the patient use a walking aids?
- Is the patient able to carry the device and manage the weight and tubing?
- Is the patient at risk of falling because of the device?

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- Is the patient/carer cognitively able to manage the therapy? For example, paediatrics and patients with learning difficulties may have problems
- Does the patient have sensory deficits, such as hearing loss or visual impairment, does the patient have sufficient hearing/vision to manage the system (e.g. hear alarms/see dial)?
- Is the patient in a psychological and social situation appropriate for NPWT?
- Is the patient's home electricity supply safe?
- Are there stairs or other obstacles that the patient will need to manoeuvre with the device?
- Do they know who to contact in an emergency and what would constitute an emergency?
- Is there a risk of potential loss of equipment?
- Do community staff have access to the equipment +/- funding

It is essential that all patient discharges are planned and communication between acute and community care agencies happens as soon as possible to aid effective and safe planning of patient care.

Quality of Life

Ousey et al.⁴⁹ published a systematic review critically reviewing and exploring the available literature with regard to the impact NPWT on patients reported quality of life. They identified five studies that met the inclusion criteria from a potential of 517 potential papers for inclusion, yet all had methodological flaws, with small sample sizes. They concluded NPWT therapy is an alternative to conventional wound dressings, but an in-depth holistic patient assessment should be undertaken prior to prescribing the treatment. However the Wound Union of Wound Healing Societies [WUWHS]⁵⁰ consensus document for NPWT argue that this therapy can have a positive impact on a patients quality of life but warn that the clinician needs to be able to present a robust economic argument focussing on using factors other than unit costs (e.g. reduction in health care resources and labour; length of stay and improvement in clinical outcome).

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In a study exploring quality of life experienced by patients undergoing negative pressure wound therapy compared to patients receiving standard wound care Ousey et al.,⁵¹ noted that there were no real differences in quality of life scores recorded by patients over the 12 week period. However they did identify that during the first 2 weeks of the application of therapy, patients in the NPWT group reported an increase in the social life domain. Quality of life outcomes in this study was measured using the Cardiff Wound Impact Schedule, a condition-specific quality of life tool, giving a profile of scores for Physical Symptoms and Daily Living, Social Life, Wellbeing, and overall quality of life.

Kirby⁵² explored the use of NPWT for patients with diabetes and vascular disease she found that NPWT accelerated wound closure resulting in shorter hospitalisations, reduced costs and reduced risks of infection. Due to the shorter in patient stay she concluded that patients could maintain improved mobility and therefore improved health related quality of life. Similarly Page et al.,⁵³ reported that those patients who were discharged to the community with NPWT were at a lower risk of complications, subsequent foot surgeries, and hospital readmissions were all reduced by 70% compared to patients treated with standard saline soaked gauze dressings. The later studies relevance to practice in the UK is questionable as advanced wound dressings with varied modalities are used in favour of saline soaked gauze.

Portable or lightweight negative pressure wound therapy devices - their increasing use in the community

There is evidence to suggest that the use of negative pressure in the community has been limited, due to financial pressures aimed at reducing the cost of wound care²⁶ yet Searle and Milne⁴⁶ argued that the use of NPWT can provide excellent symptom management, reduce the frequency of dressing changes and can provide a cost effective alternative to traditional wound therapies due to

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faster healing times, reduced frequency of dressing changes leading to a reduction in overall treatment costs. Timmons and Russell⁴⁷ suggest that the introduction of a more portable, easy-to-apply and easy-to-operate negative pressure system may help to reduce previous concerns regarding reduced mobility for patients being treated with NPWT and allow return to a normal lifestyle while using the system.

Portable NPWT systems

Industry has recently developed and introduced smaller disposable NPWT devices, allowing patients to be discharged from hospital with the NPWT pump and managed in community care. Dowsett et al⁵⁴ published the results of economic benefits of negative pressure wound therapy in the community within the National Health Service in the United Kingdom. They stated that using NPWT resulted in earlier discharge of patients from hospital saving the hospital on average £288 per day. Furthermore they reported that the incidence of minor and major amputations are reduced in patients with diabetic foot ulcers treated with NPWT.⁵⁵

Awad and Butcher⁵⁶ reported a one patient case study using a disposable device(SNaP® device Spiracur), a portable battery and mains operated NPWT system. The patient had diabetic foot ulceration with an extensive re-ulceration overlying a previous ray amputation. They evaluated the device concluding that using the NPWT device the patient, on discharge, was able to maintain self-care, including continuation of work during the latter stages of his wound management; there were no secondary infection issues and peri-wound skin health improved. Use of the device resulted in a significant reduction in wound size.

Mechanism of action of Disposable NPWT

The mechanism of action of current disposable devices differs from the larger devices available. The SNaP® system uses patented integral 'memory springs' - a proprietary spring mechanism that

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generates consistent, even levels of pressure - to drive the unit and achieve sustained sub-atmospheric pressure at pre-determined levels (3 devices are available to deliver pressure at -75mmHg, -100mmHg and -125mmHg)^[13] at the wound interface. The manufacturer reports that this makes the system silent, light, highly portable, disposable and easy to operate. The system is useful for the treatment of low to moderately exuding wounds (less than 120mls/week).

Another lightweight portable, negative pressure system PICO® (Smith and Nephew Healthcare) produces negative pressure at -80mmHg continuously. Power for the device is provided by a small pump only requiring two AA batteries and therefore negating the need for the patient requiring access to a power supply. The system is recommended for wounds that produce minimal exudate (up to 300mls per week) and may be used with either gauze or foam fillers. This device has no canister and the dressing has been designed to absorb fluid, transfer the exudate through the dressing to the top surface of the dressing, the moisture vapour is then evaporated through the film allowing the dressing to handle more fluid. Whilst its ease of use has been welcomed its standard sizes limit its use to both the wound size and wounds on flat body surfaces as the dressing cannot be cut or moulded.

Prevena™ Incision Management System (KCI) is a NPWT device intended for use on surgical incisions that continue to drain following sutured or stapled closures. Prevena™ is intended to be applied immediately post-surgery to clean closed incisions for a minimum of 2 days and up to a maximum of 7 days. It should be noted due to low amounts of silver contained in the dressing the device is unsuitable for people with a silver sensitivity.

Conclusions

Although there are no RCTs that have explored the use of NPWT and outcomes associated with wound healing, there is a plethora of clinical evidence that identifies that this therapy can improve outcomes for patients and is not detrimental to quality of life indicators. The introduction of

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lightweight portable devices removes the necessity for patients to carry bulky pieces of equipment or be confined to an area that has a power supply. These lighter devices allow patients to be mobile and to continue with activities of daily living. Community staff manage complex wounds including leg ulcers, surgical wounds, pressure ulcers and traumatic wounds on a daily basis so possess the skills and knowledge to be able to effectively manage treatments that employ NPWT in addition to being in the position to educate families, carers and patients on how to manage the device.

Recommendations

The authors recommend:

1. More RCTs are required to explore the use of NPWT in promoting wound healing
2. Training to ensure all community staff understand how to use NPWT with a range of fillers and wound dressings
3. All staff using NPWT understand and are able to effectively undertake and document risk assessments for patients either being discharged into or commenced on the therapy in a community setting who require NPWT
4. When costing use of NPWT there should be inclusion of amount of wound dressings required and nursing time in addition to the unit cost of the NPWT unit.
5. Comparative studies to ascertain the efficacy of disposable NPWT versus standard NPWT and conventional dressings

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