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PrescQIPP Community Interest Company

Wound care - Negative pressure wound therapy (NPWT)

In England and Wales over £3.1 million is spent annually on prescribed consumables for use in negative pressure wound therapy (NPWT) (ePACT Sep - Nov 2015). Medicines optimisation projects in this area are aimed at ensuring that NPWT is used appropriately and at minimising wastage of the associated consumables. This bulletin reviews the place in therapy of NPWT and offers guidance for organisations considering reviewing NPWT prescribing as a medicines optimisation project.

Recommendations

- Negative pressure wound therapy is increasingly being used as a treatment option for acute, chronic and surgical wounds, and is also increasingly used within community environments, although the evidence base for this treatment is currently weak.
- Organisations should ensure they have robust systems in place for assessing patient suitability for starting NPWT, reviewing treatment, and stopping treatment at an appropriate point. This will include identifying suitably skilled personnel and defining their involvement in the process.
- As well as a clinical assessment, a risk assessment which considers the patient's environment should also be undertaken when considering the use of NPWT in a homecare setting.
- Local funding arrangements, including the route of procurement and whether funding needs to be agreed on an individual basis, should be established with input from key stakeholders.
- Minimise wastage of NPWT consumables by:
  - Ensuring consumables are compatible with the system being used.
  - Agreeing a suitable quantity that can be ordered at one time. The quantity should be sufficient to ensure availability when needed but minimise wastage if therapy is changed. Do not use repeat prescribing.
- Minimise wastage of rental fees or pump availability by ensuring pumps are returned promptly.
- Monitor prescribing data and ensure prescribing is in line with local agreements. Most systems require the supply of a pump, a step which often highlights that the therapy is being used. It may be particularly important to monitor the prescribing of systems that do not require the supply of a pump and can be prescribed entirely on FP10, e.g. PICO®, V.A.C.Via® and SNaP®.

Background

Negative pressure wound therapy (NPWT) is increasingly being used as a treatment option for acute, chronic and surgical wounds.[1] It also has specialist applications in managing open abdominal wounds (laparostomy) in which the gut and other intraperitoneal organs are exposed.[2] Use of NPWT 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 now managed by community nurses.[3] This bulletin focuses on the use of NPWT in chronic wounds, rather than areas less likely to be relevant in primary care, such as managing the open abdomen or surgical sites.

There are a number of different terms for the technique, including topical negative pressure therapy, subatmospheric pressure therapy, and Vacuum Assisted Closure® therapy. It usually comprises of a sealed dressing over a wound, a suction pump and a drainage tube sited inside the primary dressing or on its surface. The drainage tube is connected to a canister within the pump unit to collect the exudate, and the system alarms if air leaks are detected.[1] The suction-pump delivers a controlled negative pressure; most units provide a range of negative pressure somewhere between -40mmHg and -200mmHg, and the negative pressure levels used will be dependent on the patient's tolerance and wound aetiology. Some units can provide intermittent as well as continuous negative pressure.[4]

It has been proposed that NPWT may aid wound healing by:

- Maintaining a moist wound environment
- Improving blood flow to ensure oxygen and nutrient delivery
- Removing exudate
- Promoting granulation
- Increasing the rate of epithelial growth
- Reducing infection
- Pulling the wound edges together.[1]

Systems available

The V.A.C.® system was the first of its kind to be available in the UK, but there are now a number of competing products available from a number of manufacturers. Negative pressure wound therapy requires good contact between the dressing and the wound bed, and the different systems available achieve this by using either a foam or gauze dressing to fill the cavity of the wound. Dressings are generally changed every 48 hours initially, and then less frequently depending on the type of wound, although this varies depending on dressing type and manufacturer guidelines.[1] Only certain consumables for certain systems are listed in the Drug Tariff and therefore prescribable on FP10.

V.A.C® and Prevena®, KCI Medical Limited

The V.A.C.® system uses a foam dressing that is cut to the shape and size of the wound. Different types of foam are available: black open pore foam (GranuFoam) to encourage granulation, white foam with smaller pores for more comfort at dressing changes, and a version containing silver for its antimicrobial properties.[1]

A number of V.A.C. pumps are available (six in total) with different features and varying levels of portability.[5] The consumables that are compatible with each pump vary and only certain consumables for certain pump types are listed in the Drug Tariff and therefore prescribable on FP10.

KCI Medical also make Prevena®, described as an incision management system for single patient use, aimed at those with greater risk of post-operative complications e.g. wound infection or dehiscence.[6] The system cannot be prescribed on FP10.

Renasys® and PICO®, Smith and Nephew

There are two Renasys® pumps; Renasys® EZ Plus and Renasys® GO, with the latter being the more portable version. Both foam and gauze dressings are available along with a range of drains to suit different wounds.[7]

The PICO® system is canister-free, single-use therapy, provided as a complete seven day kit. The pump is designed to stop working after seven days of continuous use. The pump is attached to a dressing, and the dressing collects the wound exudate, with some moisture able to evaporate through the film of the dressing. The negative pressure generated is a continuous 80mmHg (lower than many other systems available), and the wound must be producing less than 300ml of exudate and be small enough to be covered by one of the PICO® dressing sizes available to be suitable for this system.[8]

Venturi®, Talley

There are three Venturi® systems available; Venturi® Avanti, Venturi® Compact and Venturi® Mino (listed in order of increasing portability) all of which can be used with either a foam or a gauze type dressing.[9] Consumables for the Venturi® Mino are not listed in the Drug Tariff.

A4, XLR8, Genadyne

Genadyne make two systems the A4 and the XLR8, the latter of which is the more portable version with consumables that can be prescribed on an FP10.[10]

Avance®, Molnlycke Healthcare

Two systems are available, the Avance® system and Avance® Solo (the latter of which is a single-patient, multi-week system). Both use the same dressings, which can be gauze or foam based.[11]

SNaP®, Spiracur

The SNaP® system differs from others in that it uses a spring mechanism to produce continuous negative pressure, rather than an electrically powered pump. Three types of cartridge are available providing differing levels of negative pressure (-75 mmHg, -100 mmHg and -125 mmHg). Each cartridge can hold up to 60ml of exudate and is for single use. Both foam and gauze dressings are available to use with the system, and a proprietary hydrocolloid dressing with an integrated microport is used to secure and seal the dressing.[12]

National guidance

Recently published National Institute of health and Care Excellence (NICE) guidelines on the prevention and management of diabetic foot problems advise considering NPWT after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service.[13] Evidence from two studies was considered by the Guideline Development Group (GDG); both studies were also included in a 2013 Cochrane review of NPWT in treating diabetic foot wounds, for which they contributed most of the data – see 'Clinical Effectiveness').[14,15] The GDG noted that data was limited and of low quality, and made a research recommendation concerning this treatment.

SIGN guidelines on the management of diabetes recommend that NPWT is considered in patients with active diabetic foot ulcers or postoperative wounds.[16]

For the management of pressure ulcers in adults, NICE advise against routinely offering NPWT unless it is necessary to decrease the number of dressing changes (e.g. in a wound with a large amount of exudate). They also state that NPWT should not be routinely used to treat pressure ulcers in neonates, infants, children and young people.[17]

Scottish Intercollegiate Guidelines Network (SIGN) guidance on the treatment of chronic venous leg ulcers states that there is insufficient evidence on which to base a recommendation.[18]

Clinical effectiveness

This section focuses on the use of NPWT in managing chronic wounds, rather than areas less likely to be relevant in primary care e.g. surgical sites. The majority (although not all) of studies referred to in this section used V.A.C.® devices, and hence foam rather than gauze-based dressings.

The management of surgical wounds, skin grafts and burns are not covered here. Cochrane reviews on the use of NPWT in these indications can be found at http://www.cochranelibrary.com.

Diabetic foot ulcers

A 2013 Cochrane review assessed the effects of NPWT compared with standard care for treating foot wounds in people with diabetes mellitus. The review included five studies (605 participants), although most of the data came from the two largest studies (total of 502 participants) which compared NPWT with standard moist wound dressings (non-gauze modern dressings which included alginates,

hydrocolloids, foams and hydrogel dressings). The first of these was conducted in people with post-amputation wounds and reported significantly more people healed in the NPWT group compared with the moist dressing group: (risk ratio 1.44; 95% CI 1.03 to 2.01). The second study, in people with debrided foot ulcers, also reported a statistically significant increase in the proportion of ulcers healed in the NPWT group compared with the moist dressing group: (risk ratio 1.49; 95% CI 1.11 to 2.01). The authors concluded that there is some evidence to suggest that NPWT is more effective in healing post-operative foot wounds and ulcers of the foot in people with diabetes mellitus compared with moist wound dressings, but that the findings are uncertain due to the possible risk of bias in the original studies.[15]

A 2013 evidence update on managing diabetic foot ulcers identified an RCT (n=132) conducted to determine if mechanically powered NPWT was non-inferior to electrically powered NPWT. Participants had non-infected, non-ischaemic, non-plantar lower extremity diabetic and venous wounds. The median percentage decrease in wound size with mechanically powered NPWT was shown to be non-inferior to the electrically powered approach at 4 weeks (-44.7% vs -28.6%, p=0.0030), 8 weeks (-73.8% vs -75.0%, p=0.0130), 12 weeks (-85.7% vs -82.1%, p=0.0051) and 16 weeks (-85.7% vs -94.0%, p=0.0044). The authors of the evidence update commented that the study does not provide evidence of the clinical value of NPWT itself, but that the data suggest equivalence of mechanical and electrical methods of generating negative pressure in this patient group.[19]

Pressure ulcers

A recently published Cochrane review assessed the effects of NPWT in treating pressure ulcers in any care setting. Four studies were included with a total of 149 participants, however only one study reported usable primary outcome data (complete wound healing). This study compared NPWT with modern dressings, but it was very small (n=12) and there were very few events. There were little other useful data available from the included studies on positive outcomes such as wound healing or negative outcomes such as adverse events. The authors concluded that there is currently no rigorous RCT evidence available regarding the effects of NPWT compared with alternatives for the treatment of pressure ulcers.[20]

Venous leg ulcers

A 2011 systematic review identified two relevant RCTs. One RCT (n=24) compared topical negative pressure versus simple dressings in people with any type of chronic wound (including some people with venous leg ulcers). However it was felt that this study may have been too small to detect a clinically important difference in outcomes, so it was not considered further.[21] The other RCT (n=60), which was also considered in a 2010 Health Technology Assessment, compared NPWT with usual care (hydrogel/alginate dressing with compression therapy) in people with venous or arteriovenous ulcers of at least six months' duration. This study investigated NPWT or usual care as precursor to the application of a punch skin graft, rather than as a stand-alone therapy. The study found that NPWT was significantly more effective than usual care in time to complete healing, wound bed preparation time and successful skin grafting.[1] The systematic review considered the evidence to be of very low quality and the overall conclusion was that the intervention was of unknown effectiveness in patients with venous leg ulcers.[21]

A Cochrane review investigating NPWT for treating leg ulcers has recently been published. Only one suitable study was identified (the same 60 participant study cited in the reviews above). The authors similarly concluded that there was some limited evidence of low quality that the treatment may reduce time to healing as part of a treatment that includes a punch skin graft transplant. However they noted that the applicability of this finding may be limited by the very specific context in which NPWT was evaluated. They found no RCT evidence on the effectiveness of NPWT as a primary treatment for leg ulcers.[22]

Safety

Table 1 summarises general contraindications and precautions to NPWT, based primarily on safety advice issued by the Food and Drug Administration (FDA) in the U.S in 2009 after numerous reports of injury and deaths associated with the treatment.[23] The table is adapted from an article in Wounds International and is provided for general information; individual product information should always be consulted.[4]

Table 1. General contraindications and precautions for treatment with negative pressure wound therapy

Contraindications
Osteomyelitis: NPWT is contraindicated in the presence of untreated osteomyelitis
Malignancy: NPWT is not recommended in malignant wounds because it may stimulate proliferation of malignant cells
Non-enteric and unexplored fistulae: there may be communication with underlying vulnerable organs
Exposed vasculature, nerves, anastomotic sites or organs: if directly applied to exposed structures, NPWT can cause damage or rupture vessels due to the force of negative pressure
Necrotic tissue with eschar present or thick slough in the wound bed: appropriate debridement should be performed before the application of NPWT. This therapy is not designed to debride and quicker results will be obtained if the wound is debrided prior to application of NPWT
Precautions
Weakened blood vessels: patients who have weakened blood vessels, friable vessels and infected vessels (direct negative pressure may cause trauma and bleeding)
Exposed delicate structures: patients with exposed blood vessels, delicate fascia, exposed tendons or ligaments (direct negative pressure may cause trauma and bleeding)
Bleeding: wounds that are actively bleeding or where the patient is at a high risk of bleeding or haemorrhage, receiving anticoagulant therapy and/or platelet aggregation inhibitors (negative pressure could encourage bleeding as local perfusion will be increased and therefore blood loss will be greater)
Fistulae: wounds with enteric fistulae (these require special precautions to optimise therapy). The clinician needs to refer to or take advice from a specialist in NPWT for these patients
Patients requiring certain treatments: special consideration and caution should be taken where patients require magnetic resonance imaging (MRI), hyperbaric oxygen treatment, defibrillation, etc
Additional precautions: these include patients with spinal cord injury, infected wounds, wounds with sharp edges (eg bone fragments) and vascular anastomoses
See http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm190658.htm for the FDA list of contraindications and risk factors

The size and weight of the patient should also be considered; infants, children, certain small adults and elderly patients should be closely monitored for fluid loss and dehydration.[24] Both the original FDA alert and a further update in 2011 highlighted that a significant proportion of the adverse incident reports that they received related to patients at home or in a long-term care facility.[23,25]

In January 2015 a safety alert was issued for Renasys® products concerning a risk of wound exudate accumulation, maceration, infection, loss of negative pressure or unrecognised bleeding. This related to reports of blockages beneath the film dressing, and recognition that this type of blockage may not allow the system to detect (and therefore alarm for) the blockage or any air leaks. The importance of patient monitoring during NPWT was emphasised, including the need for regular dressing checks rather than relying solely on the device's alarm to indicate a problem. A number of product changes to reduce the risk were also implemented.[26,27]

The following safety checklist has been suggested for cases where NPWT is being considered in the homecare environment:[4]

- Patient mobility – does the patient use a walking aid?
- 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?
- Is the patient/carer cognitively able to manage the therapy?
- 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?

Side effects

Pain and discomfort are the most common side effects of NPWT and can occur when the vacuum is initiated and when high pressure is being exerted. Bleeding from wound bed trauma and pain can also occur when foam is being removed and there is excessive growth of tissue into the dressing. Administering saline into the foam or tubing can help to decrease discomfort at dressing changes,[1] or the use of a non-adherent layer to line the wound bed can be considered. Some regard gauze-based dressings to be less likely to cause pain at dressing changes.[4] Analgesia may be needed but often sensitivity to treatment reduces over time.[1]

Safety communications from the FDA relating to NPWT have described bleeding to be the cause of the most serious adverse events reported to them. Also of note were wound infections, particularly related to the retention of dressing pieces in the wounds. Injury from foam dressing pieces and foam sticking to tissues or clinging to the wound were noted in many of the reports they received.[23,25]

Skin maceration has been described, and there are case reports of more serious side effects including sepsis, toxic shock syndrome and hypovolaemic shock from fluid loss, arterial erosion bleeding and amputation of an extremity.[1]

There is a variation in the noise generated by different devices and anecdotal reports of this interfering with sleep.[1]

Considerations

There are clinical, organisational and practical factors that need to be considered when providing NPWT products for use in primary care. It may be useful to consider the following questions, several of which may be best addressed as part of an overarching policy. The involvement of appropriate stakeholders, such as tissue viability nurses, community nursing leads and budget holders is essential.

- Has an appropriately trained person assessed the patient to decide if this is an appropriate treatment? Who is an appropriately trained person?
- Has that person risk-assessed the treatment with respect to both the individual and their homecare setting?
- Are appropriately trained staff available to manage the treatment, or has suitable training been

arranged? Training should include the optimal use of consumables (e.g. appropriate wear times) to minimise wastage.

- What on-going specialist support is available?
- Has a treatment goal been documented? Who will be responsible for assessing the wound to determine if that goal has been reached or if further benefit is unlikely (see 'Stopping criteria' below)?
- How will the pump and the consumables be supplied?
- What are the local funding arrangements for the treatment? Does funding need to be agreed individually?
- What consumables will be needed? Minimise wastage by:
  - » Ensuring consumables are compatible with the system being used
  - » Agreeing a suitable quantity to order, which should be sufficient to ensure availability when needed but minimise wastage if therapy is changed.
- If consumables are to be supplied via FP10, ensure that items required are listed in part IXA of the Drug Tariff and are therefore prescribable. Repeat prescriptions are not appropriate.
- Who is responsible for ensuring the pump is returned as soon as therapy is stopped?

Discontinuation of therapy

A treatment goal should be defined and NPWT should be discontinued when it is reached. Other reasons to discontinue NPWT may include:

- When uniform granulation tissue and little depth to the wound is present
- The patient is not tolerating the NPWT, or withdraws consent to treatment
- When wound volume reduction is less than 15% over a two week period
- The patient complains of extreme pain
- There is excessive bleeding
- An alternative treatment option is more suitable if there are signs of local or spreading infection.[4]

Savings

In England and Wales over £3.1 million is spent annually on prescribed consumables for use in negative pressure wound therapy (ePACT Sep - Nov 2015). Whilst this is a relatively small portion of the total spend on wound care, which is in excess of £170 million, the average cost per item is relatively high (approximately £142 per item vs less than £20 per item for wound care overall). These figures do not include spend on dressings supplied through direct procurement, for which data are not readily available. Neither does this figure include the hire or purchase of a pump to generate negative pressure, the cost of which can be significant.

Consumables are specific to the NPWT system being used, so there is no scope for making savings via simple switches.

Although not quantifiable, savings may be achieved on an individual patient basis by:

- Ensuring a robust patient selection process has been followed.
- Minimising waste by ensuring correct type and quantity of consumables are ordered.
- Ensuring treatment is not continued for longer than indicated (timely review by an appropriately trained person should be part of the care plan).

Savings may be achieved on an organisational level by:

- Negotiation regarding which NPWT system(s) will be used locally.

- Having clear processes that facilitate access to treatment where it is appropriate and prevent improper use.
- Ensuring appropriate training is provided for staff, including optimal use of consumables (e.g. appropriate wear times) to minimise wastage.
- Monitoring prescribing data to identify inappropriate items or quantities.

Summary

The evidence base for treating chronic wounds with NPWT is weak. There is some evidence of clinical benefit in treating diabetic foot wounds (including post-amputation), but its effectiveness in treating pressure ulcers and venous leg ulcers is currently unknown. Organisations require robust processes involving suitably skilled health care professionals to ensure appropriate selection of candidates for NPWT, taking into account any clinical or care-setting related precautions. Steps are also needed to ensure treatment is not continued for longer than it is likely to be of value, and to minimise wastage of consumables, which are relatively expensive compared with other wound dressings.

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Additional PrescQIPP resources

 Briefing

 Data pack

Available here: https://www.prescqipp.info/resources/viewcategory/451-wound-care-negative-pressure-wound-therapy

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