



Improving the Safety of Negative-Pressure Wound Therapy

ABSTRACT

Negative-pressure wound therapy (NPWT) is a noninvasive therapy that uses negative pressure to treat acute and chronic wounds. NPWT has become a widely used option for treating all types of wounds. When used safely as a component of a comprehensive wound treatment program, NPWT has been associated with the promotion of wound healing. However, while NPWT may be beneficial to patients, complications have been associated with its use. Seventy-seven patient injuries and six deaths associated with NPWT in two years prompted the U.S. Food and Drug Administration to issue an alert to healthcare providers. In 2008 and 2009, the Pennsylvania Patient Safety Authority received 419 reports related to the application or management of NPWT. Complications related to NPWT were described in 112 (27%) reports and included bleeding, evisceration of bowel, retained sponges, infection, maceration, and compromise of tissue surrounding the wound. Clinicians can endeavor to prevent patient harm associated with the use of NPWT by employing risk reduction strategies such as appropriate patient selection, proper device application, and frequent monitoring. (Pa Patient Saf Advis 2011 Mar;8[1]:18-25.)

INTRODUCTION

Acute and chronic wounds affect at least 1% of the population and represent a significant risk factor for hospitalization, amputation, sepsis, and death.¹ The technique of applying negative pressure to a wound to assist in healing has been in use since the 1950s, and the practice has continued to evolve and gain in popularity. The technique is referred to as negative-pressure wound therapy (NPWT), although several other names exist for this technique, such as vacuum-assisted closure, vacuum-sealing techniques, sealed surface wound suction, subatmospheric pressure therapy, and vacuum-pack technique. The technique typically involves inserting foam or gauze dressing into a wound, cavity, or surface; connecting an evacuation tube embedded in the foam or gauze to a vacuum pump; and sealing the area with an adhesive film. The vacuum pump creates an intermittent or continuous subatmospheric pressure in the range of -50 mmHg to -125 mmHg. NPWT acts to reduce edema, promote granulation tissue perfusion and formation, and remove exudate and infectious materials.²

The popularity of NPWT as an adjunct to wound healing has been attributed to worldwide marketing, assumed safety, and overall cost-effectiveness.² NPWT is estimated to cost approximately \$100 per day. This includes the cost of dressings (\$25 to \$60 per change), a canister (\$8 to \$15 per day), and rental of the vacuum pump (\$55 to \$58 per day). NPWT has higher material costs than traditional wound treatment therapies (i.e., gauze); however, the cost may be offset by the benefits of reduced healing time, reduced nursing staff time and expense, decreased length of hospital stay, and facilitation of patient transfer to lower-cost care settings.² For example, Braakenburg et al. reported that NPWT is associated with significantly lower nursing staff expense due to fewer effort hours than treatment with conventional wound dressings.³ Similarly, a study of 51 patients in a long-term acute care facility demonstrated that despite a higher product cost, the overall cost of NPWT was lower than topical advanced moist heat strategies.⁴ The study calculated that patients treated with NPWT showed a statistically significantly higher average daily rate of volume reduction compared to an advanced moist wound healing group. The cost of wound reduction was \$11.90/cm³ in the NPWT group compared to \$30.92/cm³ in the moist wound-healing group. The authors suggest that when developing a wound-healing strategy, the cost decision should be based on overall expense and not individual product cost.

NPWT has been associated with serious complications. In 2009, the U.S. Food and Drug Administration (FDA) issued a warning to healthcare professionals and consumers regarding reports of 6 deaths and 77 injuries over a 2-year period related to NPWT.⁵ Bleeding was the most serious injury and occurred in all 6 reported deaths and in 17 of the reported injuries. Twenty-seven of the reports indicated that the patient developed an infection from the original open wound or from retention of dressing pieces in the wound. Foam dressing pieces, either adhering to tissues or embedded in the wound, were observed in 32 of the injury reports; the majority of these patients required surgical procedures to remove the retained pieces, wound debridement, and treatment of wound dehiscence, as well as additional hospitalization and antibiotics. Similarly, healthcare facilities have reported serious complications associated with NPWT to the Pennsylvania Patient Safety Authority, including bleeding, evisceration of bowel, retained sponges, infection, maceration, and compromise of tissue surrounding the wound. Authority reports also describe issues related to application and management of NPWT devices.

AUTHORITY DATA

From January 2008 to December 2009, 419 events associated with NPWT were reported to the Authority. The event reports are summarized as follows, accompanied by deidentified examples:

- Events associated with assessment (5%) include issues related to physician orders or patient assessment before initiation of treatment.

The patient arrived on unit with the vacuum set at 90 mmHg intermittent. The report from the RN [registered nurse] was that the vacuum was set at 120 mmHg continuous. There were no orders noted on the chart for wound vacuum settings. The RN failed to pick this up at time of assessment.

The admitting physician has not seen the patient since admission, nor has he designated a hospitalist to manage the patient medically. The patient also does not have a written order for NPWT currently in use. The patient does not have a wound ostomy nurse consult. The NPWT dressing has not been changed since the patient was admitted.

Patient came into the emergency department with NPWT in place. NPWT was not removed as per protocol to examine wound and then dressed with a wet to dry dressing until seen by wound care. [There was a] delay in treatment.

- Events associated with application of NPWT (21%) include issues related to a delay in application or incorrect application of NPWT.

Blood was noted in [a patient's] NPWT tubing. Tubing found lying directly on the patient's wound with a sponge covering the tubing. The dressing was removed, and the wound was cleansed with normal saline. NPWT was then placed as per manufacturer's suggestions. The physician and the nursing director were notified.

The wound care nurse noted foam and bioclusive dressing were left on the wound after NPWT was removed. Protocol was not followed per procedure; the physician was notified, and a saline dressing was applied.

NPWT dressing was due to be changed; when the wound was examined by the doctor, the dressing was found to be applied incorrectly with the tubing directly against the wound instead of on top of the sponge as directed.

When changing the NPWT dressing, staff noted that the foam had been covering intact skin and was not just in the wound bed. The skin surrounding the incision line was now very red and abraded.

- Events citing monitoring and ongoing assessment (47%) issues represent the largest number of events related to NPWT.

The suction tubing for the NPWT device was dislodged, and assessment of the site revealed a stage III pressure ulcer where the tubing had been positioned on the patient's leg. Staff repositioned tubing, and physician was to be made aware at start of the shift to assess options for therapy.

Nurse went to the bedside for NPWT dressing change and noticed that the sponge was not compressed, the machine was off, and the suction tubing connector not connected to the canister. The nurse reconnected the machine and suction was established; it was not determined how long the machine was left off.

The patient was seen for a routine visit at a local wound clinic. A call was received that NPWT dressing was done poorly prior to patient's discharge with black foam overlapping the intact skin, causing maceration of healthy tissue.

When staff removed a NPWT dressing for dressing change, the

staff member found a 4 × 4 inch sponge packed into upper section of the wound behind a piece of black sponge. The sponges were bagged in hazardous package to bring to operating room staff's attention.

- Events associated with NPWT issues after the patient's discharge from the acute care setting (7%) suggest that patient and/or family caregiver may not have received adequate NPWT home care education before discharge.

A patient who had surgery several months ago was admitted with an open wound that was very deep with tunneling. The patient had a NPWT until recently. The patient thinks he cleaned the wound with a vinegar solution.

Per patient, he noticed that NPWT suction was fluctuating while he was still an inpatient; pressure was not remaining constant at 120 mmHg as ordered by the physician. The patient reported suction issue to staff prior to discharge; staff were unable to troubleshoot and did not contact physician. Per patient, staff stated visiting nurse would rectify the problem. When wound and skin graft was assessed by visiting nurse, [the patient's tissue was] found to be macerated from the amount of drainage that built up under the dressing. The patient was instructed on troubleshooting the unit and measures to employ if needed.

The remainder of the reports (20%) involve a combination of some or all of the above categories of events.

PRINCIPLES OF NPWT

How Does It Work?

NPWT is used in the three phases of healing in acute and chronic wounds: the inflammation phase, the proliferative phase, and the maturation phase.



The inflammatory phase is characterized by hemostasis and inflammation and lasts two to five days.^{6,7} The proliferative phase is characterized by the formation of granulation tissue and epithelialization. The duration of this phase depends on the size of the wound. The maturation phase is characterized by increased collagen production and breakdown. Tissue contraction occurs during this phase, in which tissue strength reaches 80% of the strength of normal tissue.

NPWT is thought to act by several fluid-based and mechanical processes, including the following:^{8,10}

Stimulation of wound edge retraction.

Negative pressure draws the edges of the wound together.

Stimulation of granulation tissue formation.

Application of mechanical force is thought to slowly deform skin over time because skin and most tissues are visco-elastic. Stretching of the skin stimulates an increased rate of new cell growth and increases the formation of granulation tissue, which is thought to reapproximate wound edges.

Increased local blood flow. Adequate perfusion is essential to proper wound healing in order to provide nutrients and inflammatory mediators and to remove local edema. Increased blood flow also helps to remove bacteria from the wound.

Continuous removal of exudate.

Reduced interstitial edema. Removal of excess interstitial fluid around the wound margins increases capillary blood flow to the wound bed.

Reduced bacterial loads in the wound.

Reduction in the number of dressing changes decreases damage to delicate new tissue and decreases exposure of the wound to nosocomial infection.

Is It Clinically Effective?

Despite widespread use, the evidence is unclear that NPWT provides additional benefit when compared to other conventional

wound treatments, such as gel products, bolster dressings, and hydrocolloids.⁶ An Agency for Healthcare Research and Quality (AHRQ) evidence report by the ECRI Institute Evidence-Based Practice Center identified 22 systematic reviews published between 2000 and 2008 that covered NPWT.⁶ The review included studies reporting data on the use of NPWT on a number of wound types (e.g., diabetic foot ulcers, pressure ulcers, vascular ulcers, burn wounds, surgical wounds, trauma-induced wounds) and studies comparing NPWT to other wound treatments (e.g., gauze, bolster dressings, wound gels, alginates, other topical therapies). AHRQ assessed three systematic reviews as high-quality based on criteria that included duplicate study selection, the likelihood of publication bias, and conflict of interest. None concluded that NPWT provided additional benefit when compared to other conventional wound treatment. However, the systematic reviews all noted the lack of high-quality clinical evidence supporting the advantages of NPWT compared to other wound treatments. Another concern was the large number of prematurely terminated and unpublished trials of NPWT.¹¹ Nevertheless, AHRQ concluded that NPWT is a safe alternative treatment to other traditional wound treatments.⁶

Which Patients Are Candidates?

NPWT is used in healing both chronic and acute wounds. Chronic wounds are wounds that have not completed the process of healing in the expected amount of time, generally 30 days, or have not progressed through the healing process with the expected results.¹² Diabetic foot ulcers, pressure ulcers, venous leg ulcers, and infected sternal wounds are common types of chronic wounds treated with NPWT. Acute wounds are those lasting less than 30 days. Surgical wounds, burn wounds, and trauma wounds are common wounds treated with NPWT. It can also be used as an adjunct to surgery for skin grafts, flap surgery, and wound bed preparation.^{12,13}

Appropriate patient selection is important to the success of NPWT. As with any wound care regime, optimizing the patient's ability to heal is essential and requires assessment and management of underlying diseases (e.g., diabetes mellitus) and oversight of any anticoagulation and immunosuppressive therapy.¹⁴ Other factors affecting wound healing include hemodynamic stability, nutritional status, blood glucose, fluid balance, and the presence of infection.¹⁵

Bleeding and infection are serious complications associated with the use of NPWT.^{16,17} Careful consideration must be given to patients receiving anticoagulants and heparin, since these medications may increase the risk of bleeding. Frequent monitoring of activated partial thromboplastin time and/or prothrombin time with international ratio levels is necessary for these patients. Bleeding may occur with the removal of dressing that has adhered to the wound. Bleeding can also occur if the dressing is placed over exposed vessels in or around the wound that have not been covered and protected during the application of NPWT as recommended by the manufacturer.¹⁶ Wound infection may develop if pieces of dressing are retained in the wound. Desiccation, pain, erosion, odor, and maceration are additional complications associated with NPWT.¹⁰

Optimal patient selection includes evaluation for the factors that may place a patient at risk for complications during NPWT, including the following:^{5,18}

- Friable vessels and infected blood vessels
- Vascular anastomosis
- Infected wounds
- Malignancy in the wound margins
- Untreated osteomyelitis
- Exposed vessels, nerves, tendons, and ligaments (Direct contact with NPWT creates risk of desiccation or injury.)

- Sharp edges in the wound (Bone fragments or sharp edges in the wound could puncture protective barriers, vessels, or organs, causing injury or bleeding.)
- Spinal cord injury
- Hemostatic agents applied at the wound site (Certain nonsutured homeostatic agents [e.g., bone wax, absorbable gelatin sponge, spray wound sealant] may, if dislodged, increase the risk of bleeding.)
- Magnetic resonance imaging
- Hyperbaric chamber treatment
- Defibrillation
- Application near vagus nerve because of risk of bradycardia
- Circumferential dressing application

When to Stop NPWT

In the absence of complications, base the duration of NPWT on regular evaluation of wound progress and/or a predetermined treatment goal. Accurate and reproducible measurement of the wound should be recorded weekly.¹³ A 50% improvement in wound size over four weeks is a good indication that the wound will heal. In some cases, NPWT can be used until wound closure, although generally it is used until the wound is filled with granulation tissue and ready for skin graft, flap, or standard wound therapy.¹⁹

After initiation of NPWT, evaluate the wound at each dressing change for signs of deterioration, which include erythema, pain, discharge or infection, tissue necrosis, requirement of repeated debridement, surgical interventions, or increased wound size.¹⁶ Stop NPWT if any complication or deterioration of the wound occurs.

PROMOTING THE SAFE USE OF NPWT

Before initiating NPWT, healthcare practitioners should refer to facility policy and be knowledgeable about the manufacturer's instructions for the device. Regular

in-servicing and competency updates are essential to ensure safe and successful use of NPWT. Although a number of NPWT devices are available, the basic steps of NPWT are similar: accurate assessment of the patient and wound before initiation of NPWT, appropriate wound-bed preparation, application of the NPWT unit, and monitoring of progress during NPWT, which includes dressing changes and wound reassessment. Education of staff, patients, and caregivers is also essential. The Authority has received reports of events occurring during each step of the process. For each step, risk reduction strategies can promote the safe use of the device and facilitate wound healing.

Assessment

- Review the physician's order. Orders should include the wound cleansing agent, type of vacuum and dressing (i.e., foam or gauze), therapy settings (i.e., intermittent or continuous suction, negative-pressure setting), and frequency of dressing changes.^{12,18,20}
- Obtain a physician's order if an order is not present when the patient is admitted.^{12,18,20}
- Assess the patient for factors that may place the patient at risk for any complications, such as preexisting bleeding disorders and use of anti-coagulants or other medications or herbs that prolong bleeding times (e.g., nonsteroidal anti-inflammatory drugs, aspirin, ginkgo biloba).^{12,18,20}
- Assess the wound before initiating NPWT. If the periwound skin shows signs of compromise, such as breakdown or maceration, address these conditions before initiating NPWT.^{12,18,20}

Wound Preparation

Cleanse the wound according to physician order and facility policy before each dressing application.^{12,18,20}

- Apply minimal mechanical force during each cleaning.^{12,18,20}

- Consider using 0.9% sodium chloride solution instead of antiseptic or antibacterial preparations.^{12,18,20}
- Clean the periwound, and protect the intact skin around the wound to prevent breakdown. Skin preparation products provide a protective barrier between the skin and the adhesive dressing, remove skin oils to promote a better seal, and help minimize trauma when the dressing is removed.^{12,18,20}

Application

- In acute or long-term care, a registered nurse who is certified as a wound care specialist may perform the majority of NPWT applications. For all staff, particularly nursing, conduct regular in-servicing and competency updates to troubleshoot alarms, repair leaks, and observe for complications.^{12,18,20,21}
- Select and prepare the dressing type and size appropriate for the wound as directed by facility policy and manufacturers' instructions. Two types of sponges are typically available: black polyurethane and white soft foam. Gauze dressing may also be used with some NPWT systems. The dressing is used to fill all open areas of the wound while avoiding overpacking of the wound.^{12,18,20}
- Document the dressing applied, including the type and number of dressing pieces as well as any additional measures used to create an adequate seal. Document the number of dressing pieces on the outside of the adhesive film dressing and in the patient's medical record to prevent any retained gauze or sponge.^{12,18,20}
- Avoid pulling or stretching the transparent adhesive dressing used to seal the wound to prevent trauma to the periwound.^{12,18,20}
- Implement and document the ordered amount of negative pressure



and the suction cycle. Continuous therapy provides sustained tension on the cells of the wound, causing mechanical stretch and removal of fluids. Intermittent therapy applies greater mechanical stretch throughout the treatment as the unit is cycled on and off.^{12,18,20}

Ongoing Monitoring and Assessment

- Dressing changes are generally performed every 48 hours or according to manufacturer’s guidelines. At each dressing change, assess for wound deterioration, erythema, pain, purulent drainage, tissue necrosis, and increase in wound size. The dressing may need to be changed more frequently in infected wounds; the dressing change will be based on continuing evaluation of the wound and the patient’s clinical status.^{12,16-18,20}
- During each shift or per facility policy, ensure that the sponge is collapsed in the wound and the unit is on and functioning appropriately. A sponge that is not compressed may indicate a break in the seal.^{12,16,18,20}
- If NPWT use is interrupted for more than two hours, remove the old dressing and irrigate the wound. Disconnection from NPWT for more than two hours places patients at risk for development of deep

vein thrombosis and compromised pulmonary function and at increased risk for infection and/or sepsis.^{12,16,19,22}

- Avoid any new areas of pressure by ensuring that the tubing is not pressing against the patient’s skin.^{12,16,18,20}
- Closely monitor infants, children, small adults, the elderly, and patients with highly exudating wounds for fluid loss and dehydration.¹⁶
- Troubleshoot and resolve NPWT alarms according to manufacturer’s recommendations. For example, the Table contains examples of system alarms and recommended action/resolution related to the V.A.C.® Therapy unit.^{16,18}

Patient and Family Caregiver Education

Reports to the Authority indicate that patients have been readmitted because of complications of NPWT. These reports indicate that the education of patients and caregivers regarding NPWT use may have been a factor in the development of complications that resulted in readmission. Ongoing education and discharge instructions for patients and caregivers on NPWT and the use of the device includes the following:¹⁷

- Safe operation of the device (Provide printed patient instructions either

from the device manufacturer or specific to the device.)

- Troubleshooting audio and visual alarms
- Applying or reinforcing dressing application
- Recognizing signs and symptoms of complications to report
- Contacting appropriate healthcare providers, especially in an emergency situation
- Responding to emergency situations, such as the observation of bright red blood in the tubing or collection canister

In emergency situations, teach the patient/caregiver to immediately stop NPWT, apply direct manual pressure to the dressing, and activate emergency medical services.

The education of patients who will be discharged with an NPWT device and the patients’ caregivers ideally should begin upon initiation of therapy and continue throughout the patients’ hospitalization. Return demonstrations are a good way to assess the patient and/or caregiver’s understanding and skills.

CONCLUSION

By following the general principles of wound care and implementing best practices related to NPWT, healthcare providers can safely facilitate wound

Table. Troubleshooting Negative Pressure Wound Therapy Alarms

SYSTEM ALARM	ACTION/RESOLUTION
Low-pressure alarm	Check tubing for blockages, crimps, closed clamps. Ensure dressing/drape has not shifted and blocked tubing. Lower therapy unit and tubing to or below wound level.
Leakage alarm	Use leak-detection procedures/tools to help find and repair leak. Lower therapy unit and tubing to or below wound level.
Blockage alarm	Ensure dressing/drape has not shifted and blocked tubing. Ensure dressing/drape is located on a flat area of the body, avoiding a skin fold.

Source: Kinetic Concepts, Inc. V.A.C. Therapy. Clinical guidelines: a reference source for clinicians [online]. San Antonio (TX): KCI; 2010 Aug [cited 2010 Oct 29]. Available from Internet: <http://www.kci1.com>.

healing. Widespread use of NPWT suggests that a healthcare provider is very likely to encounter a patient undergoing NPWT. Safe and effective implementation of NPWT requires regular staff in-servicing and competency evaluation.

Clinical staff must be prepared to appropriately apply, monitor, and effectively troubleshoot problems with the device. Staff must also be able to recognize and respond to complications related to NPWT. Patients and family caregivers

must also be prepared to apply, monitor, and respond appropriately to issues that may arise if the patient continues NPWT at home.

NOTES

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(See Self-Assessment Questions on next page.)



LEARNING OBJECTIVES

- Recall the mechanisms of action of negative-pressure wound therapy (NPWT).
- Recognize the risk factors for complications associated with NPWT.
- Assess potential strategies to manage NPWT using available evidence.
- Select appropriate nursing interventions for a patient whose NPWT is interrupted.
- Recall components of patient and caregiver education about NPWT.

SELF-ASSESSMENT QUESTIONS

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

Case 1

An 82-year-old patient presents to the emergency department with a soft-tissue lower-extremity avulsion injury and an open fracture of his humerus as a result of a motor vehicle accident. The patient is taken to the operating room for debridement of his wounds and external fixation of the open fracture. A foam dressing is applied over the avulsion wound of the patient's lower extremity, and NPWT is initiated.

1. All of the following are considered mechanisms of action of NPWT in promoting the healing of this patient's wound EXCEPT:
 - a. Stimulation of wound-edge retraction as a result of negative pressure
 - b. Decreased capillary perfusion, which decreases interstitial edema
 - c. Stimulation of granulation tissue formation caused by mechanical force applied to the tissues
 - d. Reduction of the bacterial load in the wound
2. Which of the following factors, if present, is least likely to place this patient at risk for complications associated with NPWT?
 - a. A sacral pressure ulcer with granulation tissue
 - b. A medical history of poorly managed diabetes mellitus
 - c. Anticoagulation therapy
 - d. Exposed vessels in or around the wound edge
3. Assess the following statements about strategies for the patient discussed in case 1, using the literature about management of NPWT. Which statement is NOT accurate?
 - a. At each dressing change, assess for deterioration of the wound as evidenced by erythema, pain, purulent drainage, tissue necrosis, or an increase in the wound's size.
 - b. If NPWT is interrupted for more than two hours, do not disturb the existing dressing because this may contaminate the wound.
 - c. Closely monitor the patient for signs of dehydration if the wound has a large amount of exudate.
 - d. At least once during each shift change, ensure that the sponge is collapsed in the wound.

Case 2

A patient is admitted to the hospital from an extended care facility for surgical management of a sacral pressure ulcer. During the admission assessment, a nurse observes that a NPWT dressing covers the sacral pressure ulcer, but the dressing is not attached to a NPWT device.

4. Assess the following statements about strategies for the patient discussed in case 2, using the literature about management of NPWT. Which statement is inaccurate?
 - a. Attach a NPWT device to the dressing to initiate therapy immediately because NPWT should not be interrupted for more than two hours.
 - b. Obtain a physician's order for NPWT if an order is not present when the patient is admitted.
 - c. Assess the patient for preexisting bleeding disorders before initiating NPWT.
 - d. Assess the wound before initiating NPWT; if the periwound skin is compromised, address it before initiating therapy.

SELF-ASSESSMENT QUESTIONS (CONTINUED)

5. The patient in case 2 undergoes a magnetic resonance imaging (MRI) scan, which results in interruption of NPWT for more than two hours. Select the appropriate nursing intervention to be implemented when the patient returns from the MRI suite.
 - a. Wait for a physician's order before reinitiating NPWT.
 - b. Reinitiate NPWT without removing the dressing.
 - c. Remove the dressing, and cover the wound with sterile gauze while waiting for a physician or wound care practitioner to assess the wound.
 - d. Remove the dressing, and irrigate the wound according to facility policy.
6. NPWT education for all patients and caregivers about the management of NPWT after discharge includes all of the following EXCEPT:
 - a. How to respond to audio and visual alarms
 - b. How to perform dressing changes
 - c. How to contact the manufacturer if the device malfunctions
 - d. How to respond to emergency situations, such as bright red blood in the tubing

PENNSYLVANIA PATIENT SAFETY ADVISORY

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