



Negative pressure wound therapy for the open abdomen

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG322.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of negative pressure wound therapy (NPWT) for the open abdomen is adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance.
- 1.2 NPWT for the open abdomen should only be carried out by healthcare professionals with specific training in the procedure: it should be done in accordance with the manufacturer's instructions when commercial products are used.
- 1.3 NICE encourages further research into the role of NPWT for the open abdomen.

 Patient selection should be documented, and research should report on efficacy outcomes such as impact on wound care and healing rates, and duration of hospital stay.

2 Indications and current treatments

- 2.1 Negative pressure wound therapy (NPWT) for the open abdomen may be used to manage open abdominal wounds (laparostomy) in which the gut and other intraperitoneal organs are exposed. These patients can be divided into 3 groups:
 - (a) patients who have had surgery that did not involve the gastrointestinal tract,

and in whom delayed primary closure is planned within about 1 week (for example, after 'damage-control' surgery for trauma or repair of a ruptured abdominal aneurysm)

- (b) patients who have had gastrointestinal tract surgery for the management of abdominal sepsis associated with severe gastrointestinal disease (including anastomotic dehiscence, visceral perforation or inflammatory bowel disease) or severe pancreatitis
- (c) patients who have had abdominal wound dehiscence.

Intestinal fistulae may occur in any of these groups, either before or after use of NPWT is considered.

Open abdomens may be managed in a number of different ways, including application of a 'Bogota bag', systems with a 'zipper' allowing lavage, or various types of dressings. NPWT is an alternative to these methods. All of these techniques may be used as a prelude to delayed primary closure of the abdomen (especially in group (a) above). Alternatively, split-thickness skin grafts, mesh repair, muscle flaps or a combination of these may be used to close the abdomen (referred to in some of the published evidence as fascial closure).

3 The procedure

- The aims of negative pressure wound therapy (NPWT) for the open abdomen include removing infected material and helping nursing care by reducing escape of fluid; its use may also influence the possibility of delayed primary closure.
- 3.2 NPWT uses a sealed suction system to remove exudate and infected material from the abdominal cavity. The systems and techniques used vary widely, but the underlying principle is that the abdominal contents are covered with a foam sponge or other porous dressing (for example, gauze), with a membrane between the sponge or dressing and the abdominal contents. The entire wound and surrounding skin are covered with an adhesive transparent membrane, which is perforated by a drainage tube attached to the suction system. This applies negative pressure and removes fluid, at the same time preventing escape of fluid,

because the membrane adheres to the skin all the way around the wound. A sensing device (a pad placed on top of the foam dressing) may be used to ensure that the prescribed amount of negative pressure is being applied to the wound.

3.3 Several different commercial systems are available for NPWT, each of which requires specific training for safe and effective use. A number of non-commercial systems have also been described.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

- A meta-analysis of 4,303 patients reported delayed primary fascial closure rates of 58% (95% confidence interval [CI] 51 to 65) for negative pressure wound therapy (NPWT), 78% (95% CI 56 to 94) for Wittmann patch, 44% (95% CI 27 to 61) for zipper, 36% (95% CI 26 to 46) for mesh, 28% (95% CI 8 to 55) for Bogota bag and 13% (95% CI 3 to 28) for packing. A non-randomised comparative study of 578 patients treated by NPWT or other temporary abdominal closure techniques reported delayed primary fascial closure rates of 45% (84 out of 187) and 61% (114 out of 187) respectively (p=0.002, matched pair analysis).
- The non-randomised comparative study of 578 patients treated by NPWT or other temporary abdominal closure techniques reported that 14% (27 out of 187) and 11% (20 out of 187) of patients respectively needed prosthetic replacement of the abdominal wall (p=0.28, matched pair analysis). A case series of 111 patients reported that 7% (8 out of 111) of patients needed abdominal wall reconstruction with a polypropylene mesh.
- 4.3 The specialist advisers listed key efficacy outcomes as reduction of exudate from the open abdomen, early fascial closure, shorter length of hospital stay, lower mortality, lower rate of secondary procedures to reconstruct the abdominal wall and improvement in patients' quality of life.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

- Mortality of 22% (95% confidence interval [CI] 18 to 28) for negative pressure wound therapy (NPWT), 33% (95% CI 25 to 42) for packing, 30% (95% CI 24 to 37) for mesh, 30% (95% CI 23 to 36) for zipper, 28% (95% CI 20 to 37) for Bogota bag and 16% (95% CI 5 to 30) for Wittmann patch were reported in the meta-analysis of 4,303 patients. Mortality of 26% (48 out of 187) for patients treated by NPWT and 29% (55 out of 187) for patients treated by other temporary abdominal closure techniques (p=0.40, matched pair analysis) were reported in the non-randomised comparative study of 578 patients. Mortality of 30% (33 out of 111) was reported in the case series of 111 patients.
- Fistulae were reported in 7% (95% CI 5 to 9) of patients treated by NPWT compared with 13% (95% CI 5 to 23) treated by zipper, 11% (95% CI 6 to 16) treated by packing, 8% (95% CI 5 to 10) treated by mesh, 8% (95% CI 2 to 16) treated by Bogota bag and 3% (95% CI 1 to 5) treated by Wittmann patch in the meta-analysis of 4,303 patients. Intestinal fistulae were reported in 8% (15 out of 187) of patients treated by NPWT and in 10% (18 out of 187) of patients treated by other techniques (p=0.58, matched pair analysis) in the non-randomised comparative study of 578 patients. Intestinal fistulae that were considered possibly to be related to NPWT were reported in 7% (8 out of 111) of patients in the case series of 111 patients (7 occurred during treatment and 1 after treatment).
- Intestinal failure (defined as the need for parenteral nutrition for more than 28 days) was reported in 15% (28 out of 187) of patients treated by NPWT and in 15% (28 out of 187) of patients treated by other techniques (p=1.00, matched pair analysis) in the non-randomised comparative study of 578 patients.
- Abscess was reported in 4% (95% CI 2 to 7) of patients treated by NPWT compared with 16% (95% CI 4 to 19) treated by zipper, 12% (95% CI 1 to 31) treated by Bogota bag, 9% (95% CI 5 to 13) treated by mesh, 7% (95% CI 2 to 16) treated by packing and 2% (95% CI 0.1 to 8) treated by Wittmann patch, in the

meta-analysis of 4,303 patients. Abdominal abscess was reported in 5% (5 out of 111) of patients in the case series of 111 patients (1 occurred during treatment and 4 after treatment).

- Intervention to control bleeding was reported in 12% (23 out of 187) of patients treated by NPWT and in 17% (31 out of 187) of patients treated by other techniques (p=0.25, matched pair analysis) in the non-randomised comparative study of 578 patients.
- The specialist advisers stated that it could sometimes be difficult to remove the foam component of NPWT because of granulation tissue that had anchored it to the wound. In addition to the adverse events described above, the specialist advisers drew attention to pain as an adverse event reported in the literature. They listed theoretical adverse events as bowel perforation, and in the longer term an increased risk of cancerous cell regeneration.

6 Committee comments

The Committee noted variations in outcome (specifically delayed closure) that seemed to be related to the type of abdominal pathology (sepsis or trauma) for which the abdomen had been left open. In addition, the Committee noted that there was a lack of evidence about efficacy outcomes of negative pressure wound therapy, such as impact on wound care, healing rates and duration of hospital stay. These considerations underpinned the recommendations in section 1.3.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.