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Complications Associated with the Use of Negative Pressure Wound Therapy for Secondary Healing of Surgical Incisions of the Abdominal Wall

*Deborah J Verran**

Department of Transplantation Services, Royal Prince Alfred Hospital, Australia

Abstract

Negative Pressure Wound Therapy is currently frequently used for dealing with either non-healing or open wounds following open abdominal surgical procedures. However, complications can arise including in particular infection, delayed and or slow wound healing, problems with device malfunction and in extreme cases failure to obtain complete healing of the abdominal wall. Due to the lack of accurate reporting of the rates of these particular complications, the true incidence remains unknown but could potentially be as high as 20% based on limited data from the last decade. The potential negative impact of NPWT on the bacterial bio burden in the abdominal wall is such that additional measures may be required to specifically address this, but evidence is lacking as to the best approach and in which patient sub groups. These particular complications can also pose additional challenges for surgeons, along with other members of the healthcare team, over and above the direct impact on patients. Even now it is difficult to obtain accurate data on the cost utility of NPWT for the optimal management of secondary healing of the abdominal wall following abdominal surgery, with context being important. Hence calls continue to be made for further Randomized Trials to be undertaken, involving larger numbers of patients, with defined entry criteria, defined clinical end points and comprehensive reporting of all complications sustained during NPWT.

Introduction

Negative Pressure Wound Therapy (NPWT) has become incorporated into clinical practice in most surgical disciplines for the management of open wounds whether they be acute or chronic in aetiology [1,2], for over a decade. With the passage of time the use of NPWT in abdominal surgery has now extended past its initial use in managing an open abdominal wall incision secondary to a superficial wound dehiscence, through to it now also being an aid in the management of fascial dehiscence [3]. On occasion NPWT has been used in the management of opportunistic infection associated with the surgical incision including in renal transplant recipients [4]. More recently NPWT has become a recommended modality in the management of the open abdomen following emergency surgery, and may be combined at times with the mesh fascial traction approach [5,6], in order to achieve abdominal wall closure. Finally, NPWT has also been used to salvage infected prosthetic mesh within the abdominal wall [7,8], following abdominal wall reconstruction surgery. However there still remain some unknowns with respect to the utility of NPWT in achieving secondary healing of the abdominal wall following open surgical procedures. In a number of Systematic Reviews on NPWT undertaken over the last decade repeated mention has been made about the lack of robust outcome data with respect to the efficacy of NPWT along with clinically relevant data on complication rates [4,5,9]. This is complicated by the heterogeneity of the types of patients both selected and entered into prospective trials, as well as the variability in both the definition and selection of endpoints, including the reporting of complications. There are very few randomized controlled trials which are adequately powered in order to detect what are the true outcomes with NWPT versus conventional wound therapy [9]. A recent pilot feasibility study in the United Kingdom of a group of outpatients being managed with NWPT for secondary wound healing for multiple indications [10] concluded that proper randomized controlled trials are now required in order to obtain better quality data on its utility for secondary wound healing. Of note only 6 patients entered into this particular study had undergone abdominal surgery. In the absence of comprehensive published guidelines, the European Wound Management Association established a working group in order to describe what was the current knowledge base pertaining to NPWT [11], including with respect to patient safety. There has been very little documented about the

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Correspondence:
Deborah J Verran, Department of Transplantation Services, Royal Prince Alfred Hospital, Australia, Tel: 61 2 9515 5416; Fax: 61 2 9515 6320; E-mail: verran@ausdoctors.net

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complications which may ensue with deployment of NPWT, along with what are the limiting factors to achieving success with NWPT, despite over 3287 publications in 685 journals between 1990 to 2015. This is because most reports on the use of NPWT in the setting of the open abdominal wall are from either retrospective reviews of experience either within an institution or within a surgical sub specialty from within a hospital setting. With respect to the current knowledge base pertaining to NWPT, the EWMA report focused on use of NPWT in the management of the open abdomen only and did not delve into the use of NPWT for gaining secondary healing of the abdominal wall following open surgery [11], Hence, in order to explore this topic further a review of the published literature over the last 10 years was undertaken with a focus on the rates of reported complications along with the NPWT efficacy rates, for patients undergoing abdominal surgery for which NPWT is required in order to achieve secondary healing of the abdominal wall. This included where mention was made of rates of healing and/or time to complete healing. Patients who required NPWT as part of the management of an open abdomen were excluded in light of the recent EWMA report. Searching of the MEDLINE, PubMed databases along with other open access literature was undertaken.

Reported Complications of NPWT

The first mention of complications with the use of NPWT was back in 2011, when the Federal Drug Administration in the United States reported that during the preceding 4 year time period they had been notified of 174 injuries and 12 deaths with the use of NPWT [1,11]. Most of the adverse outcomes were reported in patients who were being managed in the community outside of a hospital setting. The deaths were mainly due to hemorrhage, whilst wound infection requiring further management made up just over half of the reported injuries. Retention of packing material was stated to be one of the major contributors to wound infection [1], but there was no other specific information provided, nor has there ever been an update. The only other report of pooled adverse outcome data with the use of NPWT, came from interrogation of the Pennsylvania Patient Safety Reporting System [12], where between 2008 to 2009, there were 419 reports of complications associated with NPWT. Many of the reports relate to problems due to incorrect management of the device, and inadequate monitoring. Mention is made of wound infection being a consequence of NPWT but again there is no further detail on the demographics of the patients or the clinical indications for NPWT. Despite wound infection being a relatively common event in these two patient safety reports, this particular complication has rarely been reported subsequently. In the prospective study of NPWT versus usual wound care in a heterogeneous group of patients in the United Kingdom, wound infection recurred in 2/19 (10.5%) of cases undergoing NPWT *vs.* 2/21 (9.5%) undergoing usual care [10]. No further information is available as to where the actual location of the wound was in which infection then recurred. In one recently performed prospective trial of open NPWT *vs.* closed NPWT in patients with abdominal wall complications following surgery, 1/24 (4%) of the patients in the NWPT group developed new onset cellulitis of the abdominal wall for which they required antibiotics [13]. More recently there has been a report of infection recurring in the abdominal wall of 3 renal transplant recipients who were being managed with NPWT in order to achieve secondary healing of the abdominal wall [14]. All three of these renal transplant recipients required additional measures in order to deal with these infections. There is one other case report of sepsis recurring in the abdominal wall in a patient who required NPWT for surgical site sepsis of the lower abdominal wall following caesarean section [15]. However, this infection recurred once the NPWT had been ceased, necessitating that the NPWT be reinstituted in the abdominal wall until complete healing had been obtained. Yet, in the recent published series of patients being managed with NPWT for infected mesh in the abdominal wall [7,8], no mention was made of having to deal with recurrent infection in the abdominal wall.

Hence it is evident that either new or recurrent infection in the abdominal wall can occur in patients undergoing NPWT, although due to the limited amount of published information the true incidence of this particular complication remains unknown, along with what are the underlying patient risk factors apart from the factors already known to be associated with impaired wound healing [1]. One additional factor is that the bacterial bio burden in the wound may not be altered by NPWT, or in fact can be shifted away from gram negative bacteria towards gram positive bacteria as revealed in a recent systematic review [16]. This means that the wound can remain colonized with pathogens during NWPT therapy which has led to other measures being adopted in practice. This involves additional wound management practices and processes being required to manage patients who are undergoing NPWT for open wounds [17], including aggressive surgical debridement and wound irrigation. There are also reports of combining wound irrigation with NPWT (NWPTi), to reduce bacterial bio burden with some success but predominantly in different patient cohorts [18]. There is as yet no robust evidence available to support whether this particular treatment option is superior to best practice management of NWPT [11]. However, there is the potential for NWPTi to have a place in the management of the complex patient with abdominal wall complications, following the report of its use in two patients with difficult to treat abdominal wall sepsis from antibiotic resistant organisms following liver transplantation [18]. Thought may also need to be given to the choice of appropriate antibiotics for managing abdominal wall infection, following publication of data indicating that there may be poor tissue penetration in the region of an open wound of some antibiotics in patients who are undergoing NPWT [19].

Efficacy of NWPT

When it comes to other important clinical end points including either the time to complete healing or the rates of healing progression, again limited data are reported as there is still remains enormous heterogeneity in the types of patients being entered into most clinical studies. In one study where the efficacy of gauze based NPWT was being evaluated prospectively in a multicentre non-randomized study, there was evidence of a progressive reduction in the wound dimensions per week. However only half of these patients were post surgical and there was no information reported on the nature of the prior surgery [20]. By 30 days close to half of these patients still required ongoing management with NWPT, and this was more common in patients with diabetes and in whom there were ongoing issues with wound exudate. In another study where two different NPWT regimes were used to manage a small cohort of patients with superficial dehiscence of the abdominal wall, the median duration of NPWT was 37.1 days in the usual treatment arm, *vs.* 34.7 days in the modified treatment arm [21]. In a different series of patients undergoing NPWT for abdominal wall dehiscence [3], the median duration of NPWT was 17.9 days (2 to 96 days), with failure of NPWT

occurring due to patient mortality from other causes. In 16 complex patients undergoing NPWT for abdominal wall sepsis following renal transplantation, the median duration of NPWT was 37 days (6 to 111 days), with the authors mentioning the specific criteria they used for what represented poor healing through to complete abdominal wall healing in this series [22]. All 16 patients obtained complete healing; however this was facilitated in 7 patients by secondary suture of the abdominal wall once adequate healing was deemed to have occurred. In comparison in the series 3 renal transplant recipients who sustained recurrent wound infection whilst undergoing NPWT the median prolongation of wound healing was 109 days [14].

Other Complications Associated with NPWT

When it comes to other patient specific adverse outcome data being reported over the last 10 years, there again has been very little reported since the two initial reports from US agencies [1,12]. The only report which makes specific mention of this is in the prospective study from the United Kingdom in a mixed cohort of patients, where 12/19 (63%) of the patients undergoing NPWT sustained adverse events the majority of which (8/12) were related to malfunction of the device. The close monitoring of this particular cohort of patients outside of the hospital setting facilitated this data being both initially obtained and then subsequently analyzed. In the report from the EWMA specific mention is made of the lack of adequate published data on the NPWT parameters which may be adjusted in order to deal with other patient issues such as pain and tissue ischemia. Again, more in the way of published outcome data seems to be required to answer these questions. Finally, there is little doubt that patients are impacted upon by having to manage a NPWT device, particularly outside of hospital in the community for what may be an extended period of time. The EWMA report contains a number of sound consensus recommendations with respect to managing issues such as pain during wound dressing changes, through to the adequate monitoring of patients whilst they are being managed in a community setting, noting the potential for complications to arise [11]. Note is made of the different funding models and hence the differences in service delivery along with the different models of care pertaining to the delivery of NPWT between the European countries. These differences have contributed to the difficulty in trying to address the cost utility of NPWT in general.

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