A tool to assess the risk of surgical site complications and suitability for incisional negative pressure wound therapy

KEY WORDS
- Incisional negative pressure wound therapy
- Patient risk factors
- Prevention
- Risk assessment
- Surgical site complications

This article describes a risk assessment tool for the use of incisional negative pressure wound therapy (INPWT). Delayed surgical wound healing poses a huge financial burden to the NHS, and can significantly delay patient recovery and rehabilitation. INPWT has been identified as an effective therapy for the prevention of surgical site complications and should, therefore, be considered for high-risk patients. This article describes several risk factors and comorbidities, such as diabetes, obesity, renal failure and peripheral vascular disease, which are known to increase a person's risk of surgical site complications. The risk assessment tool, which is based on a review of these risk factors, may be used by clinicians as a simple way to assess a patient's risk of surgical wound breakdown and suitability for INPWT.

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Several factors may increase a patient's risk of delayed surgical wound healing, such as chronic obstructive pulmonary disease (COPD), obesity, diabetes, smoking, renal failure and malnutrition (Wilkes et al, 2012; Webster et al, 2014; World Union of Wound Healing Societies (WUWHS), 2016). In addition, specific risk factors are associated with some types of surgery, such as previous radiotherapy in colorectal surgery (Sandy-Hodgetts et al, 2015) and dissection of the internal mammary arteries in cardiothoracic surgery (Taggart et al, 2016). Length of surgery has also been highlighted as a potential risk factor for surgical site complication (SSC) (Matsumoto and Parekh, 2015).

Impaired wound healing can impact drastically on patients physically, psychologically, socially and financially (Andersson et al, 2010). SSC remain an issue despite the use of systemic antibiotic prophylaxis, improved surgical techniques and skin preparation (National Institute for Health and Care Excellence, 2008). In 2012/2013, the annual cost to the NHS of managing wounds was estimated at £4.5–5.1 billion, comparable to the cost of managing obesity (Guest et al, 2015). Surgical site infection (SSI) rates vary according to the type of surgery performed and geographical location, with the highest incidence of SSI occurring in large bowel surgery in the NHS (Public Health England, 2016).

Specific SSC, including SSI, wound dehiscence, haematoma and seroma, can significantly delay patient recovery and rehabilitation (Stannard et al, 2012). The prevention of SSC is particularly important for patients awaiting chemotherapy, radiotherapy or transplant surgery to avoid delays which could prove catastrophic (WUWHS, 2016). Recognising which patients are at risk of SSC is therefore vital.

Incisional negative pressure wound therapy (INPWT) is recommended to prevent SSC when placed direct to the skin at the point of surgical wound closure (World Health Organization (WHO), 2016; WUWHS, 2016). It is proposed that INPWT aids wound healing by reducing oedema and interstitial fluid, and by increasing tissue perfusion (Bovill et al, 2008). When placed over a surgical incision, INPWT has been found to reduce lateral stress by 50%, reducing the risk of shearing and wound breakdown (Wilkes et al, 2012). The protective environment provided by INPWT may also reduce the risk of wound contamination and SSI (Grauhan et al, 2014). This article describes independent risk factors for SSC and a risk assessment tool that has been designed

to help clinicians to easily identify high-risk patients who may benefit from INPWT.

RISK FACTORS ASSOCIATED WITH SSC

Diabetes

It is suggested that diabetes may contribute towards SSC (Karlakki et al, 2016). Korol et al (2013) identified 13 studies, of which 85% found a significant association between diabetes and SSI following multivariable analysis. In addition, Martin et al (2016) identified diabetes as an independent risk factor for SSI in a meta-analysis of 94 studies. The association between diabetes and SSI was found to be higher for cardiothoracic surgery.

There is evidence to suggest that diabetic wounds display defective T-cell immunity, leukocyte chemotaxis and phagocytosis (Guo and Dipietro, 2010). These defects are responsible for insufficient bacterial clearance (Loots et al, 1998), which might explain the increased risk of SSI in people with diabetes.

Smoking

In a retrospective cohort study of 56 patients who underwent abdomino-perineal resection (APR) surgery, Chadi et al (2014) identified smoking as an independent risk factor associated with SSI. In addition, in a systematic review and meta-analysis of 140 cohort studies comparing non-smokers and smokers (n=479,150 patients), Sørensen et al (2012) found smoking to be an independent risk factor for the development of SSC.

Smoking causes impaired white blood cell migration during the inflammatory phase of wound healing, reduced neutrophil bactericidal activity and lymphocyte function, therefore increasing the risk of SSI (Sørensen et al, 2012). It is contended that smoking also decreases fibroblast proliferation, reduces wound contraction and decreases extracellular matrix production (Ahn et al, 2008).

Obesity

Obesity may increase the risk of SSC (Karlakki et al, 2016). People who are obese may develop SSC as a result of the presence of excess subcutaneous adipose tissue, in which hypoperfusion and ischaemia occurs (Guo and Dipietro, 2010). Insufficient oxygen can reduce immune cell function, leading to increased risk of SSI (Sen, 2009). Obesity is also associated with wound dehiscence, because of elevated traction forces on skin sutures (Costa et al, 2015).

In a prospective cohort study of 206 NHS hospitals in England, Thelwall et al (2015) found that obesity was linked to a 1.1-fold to 4.4-fold increase in the adjusted odds ratio of developing SSI when compared with normal weight, depending on type of surgery. For patients with a BMI of 30–34.99 kg/m^2, the adjusted odds of SSI were 1.09–2.13-fold higher, with the increased risk greater for patients with a BMI >40 kg/m^2 (OR=2.71–4.40).

Winfield et al (2016) reported similar results in a retrospective data analysis of 89,148 patients who underwent abdominal procedures. Logistic regression analysis confirmed that obesity and morbid obesity were independently associated with SSI development, specifically in clean (obesity OR=1.757, morbid obesity OR=2.544, $p<0.001$) and clean-contaminated wounds (obesity OR=1.239, morbid obesity OR=1.287, $p<0.001$). The increased level of risk associated with a higher BMI is reflected in the American Society of Anesthesiologists (ASA) pre-operative assessment score (ASA, 2014).

Chronic obstructive pulmonary disease

It is reported that COPD may increase the risk of SSC (Lynam et al, 2016). Kim et al (2016) suggest that the lower partial oxygen pressure in the arterial blood of people with COPD leads to impaired wound healing, increased risk of SSI and wound dehiscence. COPD is also described as a major risk factor for wound dehiscence in sternal surgery (Olbrecht et al, 2006).

In a retrospective study, Lee et al (2010) investigated risk factors for SSC in 260 patients following cardiac surgery. Following logistic regression analysis, COPD was identified as being independently associated with SSI (OR 4.96, $p=0.024$). In addition, van Ramshorst et al (2010) analysed and evaluated the pre-operative, intraoperative and postoperative variables of 1,452 patients retrospectively using multivariable logistic regression analysis, to identify COPD as a major independent risk factor for abdominal wound dehiscence (OR 2.05, $p<0.001$).

CONGESTIVE CARDIAC FAILURE

In a multicentre study, Sun et al (2018) retrospectively analysed the records of 1510

patients who underwent orthopaedic surgery, to identify independent risk factors for SSC. Following multivariate analysis, chronic heart disease was found to have the strongest independent association with SSC (p=0.02).

Similarly, Abuzaid et al (2015) found a significant association between pre-operative ejection fraction (45% or less) and SSI (p=0.001) in a retrospective study of 80 patients who underwent coronary artery bypass graft surgery. Congestive heart failure can reduce blood circulation, increase oedema and cause tissue hypoxia; all of which are known to affect wound healing (Klein and Guha, 2014).

End-stage renal failure

In a retrospective study of 483,914 patients following cardiothoracic surgery, Cooper et al (2014) found that severe pre-operative renal failure was independently associated with deep SSI (OR=1.35), with the odds ratio increasing to 2.44 when patients required regular dialysis.

In a retrospective analysis, Cavanaugh et al (2016) compared the postoperative outcomes of 38,308 patients with chronic kidney disease (CKD)/end-stage renal failure (ESRF) with 978,378 patients without a CKD/ESRD diagnosis. Using multivariate logistic regression analysis, CKD/ESRD was independently associated with a greater risk of SSI (OR=1.4, p=0.001) and wound healing complications (OR=1.1, p=0.01) following total knee or hip arthroplasty. In addition, dialysis-dependent CKD/ESRD patients were associated with an even greater risk of SSI (OR=4.06, p<0.0001) and wound complications (OR=1.72, p=0.025), when compared with non-CKD/ESRD patients.

The underlying causes of SSC in patients with CKD are reported as the presence of uraemic toxins, chronic inflammation, reduced microcirculation and impaired immune cell response (Maroz and Simman, 2013).

Hypertension

It has been suggested that hypertension may affect surgical wound healing (Swift et al, 2015), which correlates with existing research focused on hypertension as an independent predictor for SSC. Following the multivariate regression analysis of 1,532 patients who were evaluated retrospectively for SSI, Cizik et al (2012) identified hypertension as a significant independent risk factor after spinal surgery.

Hypertension has also been identified as an independent risk factor for SSC in recent obstetric studies, following adjusted analysis (Vijayan et al, 2016; Kreiger et al, 2017).

The role of hypertension in the development of SSC might be explained by the associated increased risk of intraoperative bleeding and reduced tissue perfusion (Saeedina et al, 2015).

Peripheral vascular disease

In a prospective, comparative study of 900 patients who underwent single and bilateral internal mammary harvesting, Paulis et al (2005) found that the presence of peripheral arterial disease was an independent predictor of deep SSI (OR=3.1, p=0.02).

In addition, Bozic et al (2012) used multivariate analysis to identify peripheral vascular disease as an independent predictor of implant-associated SSI after total knee arthroplasty, in a retrospective analysis of 83,011 patient records (p=0.03).

It is contended that peripheral vascular disease predisposes wounds to bacterial contamination as a result of a prolonged stated of hypoxia (Stadelmann et al, 1998). Wound healing is, therefore, impaired because fibroblasts cannot replicate and collagen production, which is oxygen dependent, is limited (Sen, 2009).

Advanced age

Advanced age (65–75 and over) has been identified as an independent risk factor for SSI (Sun et al, 2018). In a prospective, single-centre study of 7,170 patients who underwent cardiac surgery, Lemaignen et al (2015) found advanced age (>70 years) to be an independent risk factor for SSI following multivariate analysis (p=0.03).

Sun et al (2018) found that older age (>70 years) was independently associated with SSI after open reduction and internal fixation of ankle fracture (p<0.001).

This might be explained physiologically by evidence suggesting there is a reduction in Langerhans cells by 20–50% in older people (Cerimele et al, 1990), and a decline in neutrophil activity during the inflammatory phase of wound healing (Ashcroft et al, 2002).

Malnutrition

Malnutrition reduces the body's ability to protect against infection, as a result of decreased T-cell function, phagocytic activity and complement and antibody levels (Arnold and Barbul, 2006).

A pre-operative serum albumin level of <3.5 g/dL has been reported as an independent predictor of SSC (Bohl et al, 2016). However, in a systemic review, Lee et al (2015) identified that serum albumin level alone did not reliably diagnose protein-calorie malnutrition, therefore this marker should be used in combination with a recognised nutritional assessment tool, e.g. the Malnutrition Universal Screening Tool (British Association for Parenteral and Enteral Nutrition, 2003).

Medicines

Some medications have been identified as independent risk factors of SSC: corticosteroid treatment for a chronic condition (Merkler et al, 2014), and chemotherapeutic drugs (Lieber et al, 2016).

An increased SSI rate associated with corticosteroid use has been attributed to suppressed lymphocyte function during the inflammatory phase of acute wound healing (Gosain and DiPietro, 2004).

Pre-operative chemotherapy has been found to increase the risk of SSI (Lieber et al, 2016) because of the inhibition of cell migration to the wound site and subsequent neutropenia, reducing the inflammatory response (Guo and Dipietro, 2010). Therefore, it is important to consider the impact of patient medications when assessing risk of SSC pre-operatively.

Intraoperative/procedure-related risk factors

Blood loss during surgery has been identified as a significant independent risk factor for the development of SSC (Park et al, 2016). Previous surgery at the same site or multiple procedures through the same incision have also been identified as significant risk factors for SSC (Richards et al, 2003; Bongartz et al, 2008).

Risk factors for SSC specific to surgery types include bilateral internal mammary artery harvesting in cardiothoracic surgery (Taggart et al, 2016) and the use of an implant or presence of rheumatoid arthritis in orthopaedic surgery (Bongartz et al, 2008; Kok et al, 2016). Several independent risk factors for SSC following abdominal surgery have been identified: malignancy (Ishikawa et al, 2014), previous radiotherapy (Poruk et al, 2016) and Crohn's disease (Wideroff et al, 2014). Furthermore, chorioamnionitis is independently associated with SSI following caesarean delivery (Shree et al, 2016).

EXISTING RISK CALCULATORS

Several risk calculators have previously been devised to identify potential postoperative complications for patients undergoing specific types of surgery, such as the Society of Thoracic Surgeons risk calculator for valve replacement or coronary artery bypass surgery (O'Brien et al, 2009) and the European system for cardiac operative risk evaluation (EuroSCORE) (EuroSCORE Study Group, 2011). However, these predict postoperative complications such as renal failure or pneumonia rather than SSC.

More recently, the American College of Surgeons developed a general risk calculator based on data from the National Surgical Quality Improvement Program (Bilimoria et al, 2013), to predict complications after different surgery types. Although the complications include SSI, other SSC are not included.

The WUWHS (2016) Consensus document includes recommendations for the use of INPWT, which is dependent on individual patient risk factors and types of surgery. Importantly, it highlights that patients undergoing delayed primary closure, emergency surgery or high-risk surgery, such as transplantation or left ventricular assist device implantation, are at an increased risk of SSC. Groin incision is also identified as a risk factor for SSC, for patients undergoing vascular surgery

The risk factors described in this article were compared with those identified by existing surgical classification tools, such as the Nosocomial Infection Surveillance surgical patient risk index (WHO, 2016) in order to develop an assessment tool for the use of INPWT *(Table 1)*.

USE OF THE TOOL

It is intended that clinicians use the tool as a guide to assess a patient's level of risk for SSC pre-operatively, and at the end of the surgical procedure at the point of skin closure to prevent surgical wound breakdown in high-risk patients. INPWT is recommended for adult patients who are assessed at Level 1 or Level 2 risk.

Table 1. Risk assessment tool for the use of INPWT

Level of risk	Individual patient risk factors	Intra-operative risk factors	Procedure-related risk factors
Level 1: presence of 1 risk factor = consider INPWT	BMI ≥40 kg Uncontrolled diabetes Severe left ventricular ejection failure End-stage renal disease undergoing regularly scheduled dialysis	Extended duration of surgery*	**Transplantation surgery/extensive surgery** **Previous surgery at the site/multiple incisions** **Emergency surgery** **Cardiothoracic surgery:** Left ventricular assist device Bilateral internal mammary artery harvesting Delayed primary closure **Abdominal surgery:** Delayed primary closure
Level 2: presence of 2 risk factor = consider INPWT	ASA physical status ≥II† Age >65 years BMI 30–39.9 kg Diabetes mellitus Hypertension Chronic heart failure Chronic obstructive pulmonary disease Renal insufficiency Immunosuppression Steroids for a chronic condition Chemotherapy Smoking Serum albumin <3.5 g/dl and Malnutrition Universal Screening Tool score = 2 Peripheral vascular disease	Blood transfusion Blood loss > 1 litre Cardiopulmonary bypass time extended	**Abdominal surgery:** Crohn's disease Presence of malignancy Previous radiotherapy **Orthopaedic surgery:** Rheumatoid arthritis Implant/prosthesis **Obstetric surgery:** Chorioamnionitis Pre-eclampsia **Vascular surgery** Groin incision

*Defined as >T (hours) which is dependent on the type of surgical procedure, e.g. small bowel surgery has a T of 3 hours and caesarean section has a T of 1 hour (Culver et al, 1991)

†American Society of Anesthesiologists (ASA) Pre-operative Assessment Score (ASA, 2014)

CONCLUSION

This article has described independent risk factors for SSC that have been used to develop a risk assessment tool for the use of INPWT. This risk assessment tool can be used to help clinicians identify which adult patients are at high risk of developing SSC and their suitability for INPWT. It is intended that the risk assessment tool will be used to formulate a clinical guideline for evaluation within local practice. WUK

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