An evaluation of a single use negative pressure wound therapy system in high-risk cardiac surgery patients

KEY WORDS
- Cardiac
- Evaluation
- Negative pressure wound therapy
- PICO
- Surgical Site Infection

An evaluation of the PICO◊ 7 single-use, disposable negative pressure wound therapy (NPWT) system was conducted to compare its performance against the previously used version of the PICO product, using a specified set of functionality related outcomes. Nineteen patients with sternal wound problems were included in the evaluation. The feedback revealed that 98.7% of respondents rated it 'good' or 'excellent'. 100% of feedback considered the device 'same' or 'better'. The evaluation also demonstrated the impact surgical site infections (SSIs) can have on a provider (both clinically and economically), and the level of resource SSIs require. The Trust now plans to consider the use of PICO prophylactically in high-risk cardiac surgery patients aiming to reduce this burden.

JULIE TYRER
Tissue Viability Nurse Consultant, Liverpool Heart and Chest Hospital Liverpool Heart and Chest NHS Foundation Trust, Liverpool

DAVE MYERS
Director of Market Access, Smith & Nephew Medical Ltd, Hull, UK

TIM STYCHE
Health Economics Analyst, Smith & Nephew Medical Ltd, Hull, UK

This evaluation was conducted on patients who were treated by the Tissue Viability Service at the Liverpool Heart and Chest Hospital subsequent to Coronary Artery Bypass Graft (CABG) procedures. The aim of the evaluation was to conduct a simple functionality assessment on the new PICO 7 single-use, disposable NPWT system (Smith & Nephew, Hull, UK) and to compare its performance against the previously used version of the PICO product.

The PICO system consists of a single-use pump, which produces a continuous negative pressure of -80 mmHg and is disposable after 7 days of use. It weighs approximately 70 g, is powered by two alkaline AA 1.5V batteries and therapy can be started or paused with a single button control. The PICO dressing is composed of four layers: wound contact layer, a perforated flexible silicone adhesive layer, bonded to a lower airlock layer and an upper fluid absorption layer that delivers negative pressure, removes wound exudate and aids evaporation of fluid through the high moisture vapour transmission rate upper film layer.

METHODOLOGY

The evaluation was carried out to assess the performance of PICO 7, against the previously used version of PICO, using a specified set of functionality related outcomes. These were; incidence of alarms, pump noise, ease of application, patient comfort during application, conformability, ease of achieving a seal, ability to stay in place, ability to handle exudate, ease of removal, patient comfort during removal, device portability, discreetness of device, wear time, condition of surrounding skin and wound progression.

Ethical approval was not required for the evaluation, as the PICO 7 product was already a fully approved, CE marked medical device, used only in its existing indication of use (i.e. used only where the Tissue Viability Nurse Team would routinely use PICO).

RESULTS

Nineteen patients with sternal wound complications arising subsequent to their CABG surgery were included in the evaluation. 26% of patients were under 60, 42% of patients were aged 60–69 and 32% 70–79 years old. Whilst 61.1% of patients had a body mass index (BMI) between 18.5 and 30, 11.1% were underweight (BMI <18.5) and 27.8% were obese (BMI >30). Patient demographics are listed in *Table 1*.

PICO 7 was applied post-operatively on the ward or the post-operative critical care unit; 6%

Table 1. Patient demographics		
Demographics	**n**	**%**
Age		
<30	2	10.5%
30–39	0	0.0%
40–49	1	5.3%
50–59	2	10.5%
60–69	8	42.1%
70–79	6	31.6%
BMI		
<18.5	2	11.1%
18.5–24.9	7	38.9%
25–29.9	4	22.2%
>30	5	27.8%
Gender		
Male	10	55.6%
Female	8	44.4%

Table 2. Patient risk factors		
Risk factor	**n**	**%**
Diabetes	11	57.9%
Hypertension	7	36.8%
Smoking	3	15.8%
COPD	3	15.8%

Table 3. Data relating to surgical procedures		
Surgical procedures	**n**	**%**
Elective	11	61.1%
Emergency	7	38.9%
Clean	19	100.0%
Contaminated	0	0.0%
Closure method		
Sutures	18	100.0%
Glue	4	21.1%
Other	1	6.0%
Antibiotic usage		
During procedure	17	94.4%
Post procedure	6	33.3%
Prior to procedure	3	16.7%

within 24 hours and 94% more than 48 hours post operatively. All PICO 7s were applied for post-operative wound issues.

Clinicians were asked to document risk factors and procedure details, which could influence the likelihood and severity of complications of the post-surgical wound. The most common of these, diabetes, was present in 57.9% of patients. 36.8% had hypertension, three patients were smokers and three also suffered from chronic obstructive pulmonary disease (COPD) *(Table 2)*.

All procedures documented were considered clean and all patients had their incision site closed using sutures *(Table 3)*. Some of these were complimented with glue or other closure methods (21.1%, 6% respectively). The main results of the functionality assessment are given in *Figure 1*.

Clinicians were asked to document their opinion of the PICO 7 device across several areas. Across all feedback, 98.7% of opinion achieved 'good' or 'excellent' ratings. As demonstrated in *Figure 1*, when aggregating the features into 3 key areas of device functionality, patient comfort and ease of use, feedback was consistently strong from each perspective.

Clinicians were also asked to evaluate PICO 7 in comparison to the version of PICO previously used in the hospital. 100% of feedback considered the device 'same' or 'better'. In particular, the new pump was assessed as being portable and discrete with reduced pump noise.

In addition to the other findings of the evaluation, the new PICO 7 device was also used successfully in close proximity to pacemakers in two patients. This provides some reassurance that the slightly increased strength of the magnet in the PICO 7 pump was of no clinical consequence when used on CABG patients post-surgery.

DISCUSSION

Device features that could potentially improve patient experience with PICO 7 all scored heavily in comparison to the original device, with portability, discretion and pump noise levels all receiving majority verdicts of 'better'.

All new features of the device received positive results and whilst features such as the belt clip were simple, they significantly improved patient experience, with one patient commenting that they now "had a place to put it."

Many patients had no other healthcare professional routinely involved in their care, yet were advised to leave therapy in place for the recommended 7 days where possible. The 'dressing full' indicator provided additional confidence for patients caring for their wound at home. Patients were reassured that even in cases with significant dressing saturation, therapy remained clinically effective and the dressing would not require changing. This could reduce the number of nursing interventions as well as reducing costs associated with unnecessary dressing changes. Ultimately, clinician verdict was that patient experience would be improved with PICO 7.

Once the evaluation results were available and examined in more detail, it was clear that the appropriate post-operative treatment of all wound complications warranted the Trust's attention. Of the 19 patients where PICO 7 was used to treat wound complications, 4 (21%) were patients where SSIs had arisen post-discharge and had required readmission to hospital as in-patients. These 4 SSI patients were of particular concern because of the length of their readmission and the high cost associated with this. Despite 1 patient being readmitted for only 3 days, the other 3 patients had recorded readmissions of 14, 11 and over 50 days respectively. Jenks et al (2014) put the cost of a SSI in cardiac surgery to be £11,003. For four patients with a SSI this would estimate SSI cost in just these patients at £44,012.

Avoidance of these complications, if possible, would have released up to 78 bed days. Release of bed days can be used for different purposes, such as reducing waiting lists and the ability to conduct additional higher revenue generating procedures.

It should also be noted that whilst our evaluation identified 4 patients due to their re-admission to Liverpool Heart and Chest Hospital as in-patients, limited surveillance post discharge meant we were not aware of additional SSIs that may have been treated in the community.

In order to reduce the SSI rate subsequent to CABG procedures, one consideration would

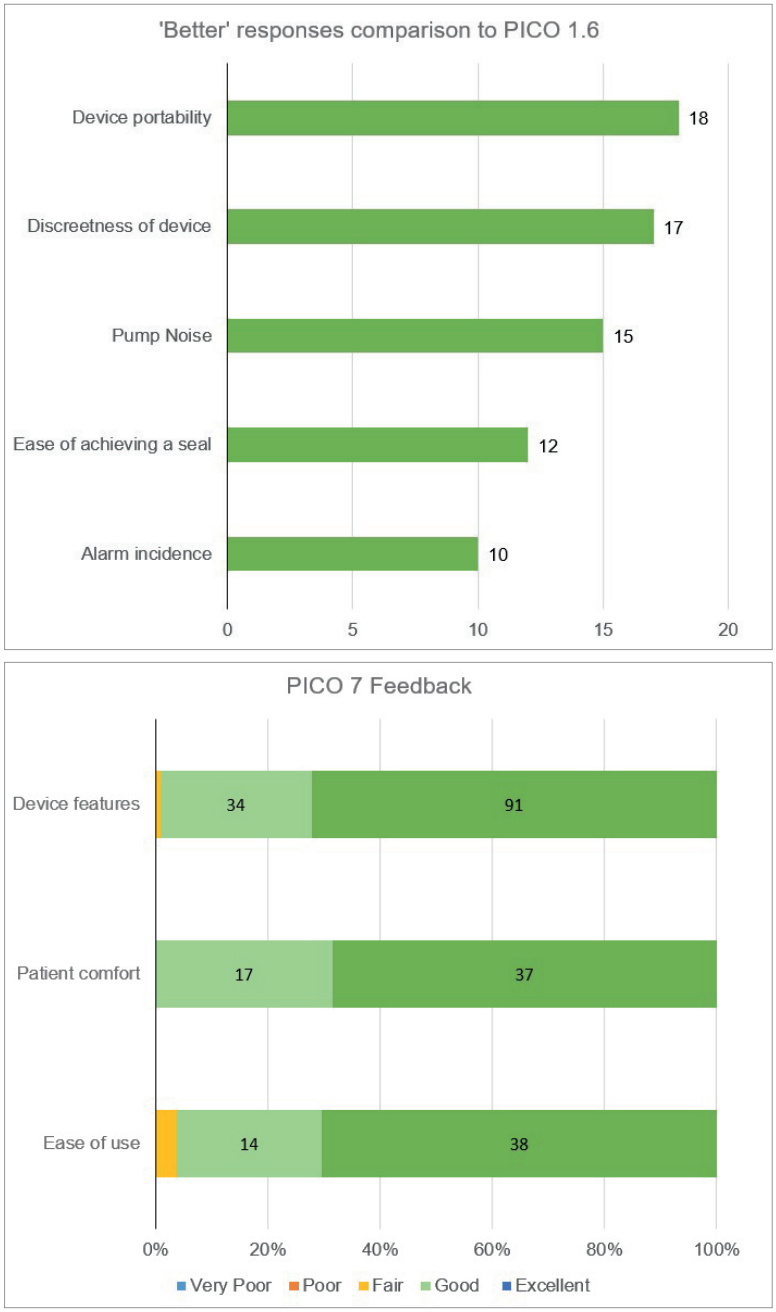

Figure 1. Results of functionally assessment

be to use the PICO 7 device prophylactically on the closed surgical incision immediately post-surgery. Currently this is not done, and PICO is only used by the Tissue Viability Service to deal with wound complications (including dehiscence and SSIs) that occur post-surgery.

There is an increasing body of evidence to suggest that NPWT can be effective in reducing the risk of postoperative wound complications including SSI (Karlakki et al, 2013; De Vries et al, 2016).

Meta-analysis based on pooled data from 16 studies shows a benefit of PICO compared to standard care in closed surgical incisions across a number of different procedures (including orthopaedic, abdominal, colorectal and caesarean section surgery) in terms of significant reduction in SSI, wound dehiscence and hospital length of stay (Strugala and Martin, 2017). In a randomised controlled trial (RCT) which evaluated wound healing in patients treated with PICO following off-pump coronary artery bypass graft (CABG) procedures, it was demonstrated that the total number of superficial SSIs was significantly lower in patients treated with PICO compared with patients treated with conventional dressings (p=0.025). Furthermore, significantly fewer SSIs in PICO treated patients required antibiotic treatment (p=0.040) and fewer patients underwent wound reopening on account of infection (Witt-Majchrzak et al, 2015). From an economic perspective, in a cost effectiveness analysis using a decision analytic model it was demonstrated that PICO can be considered a cost saving intervention that reduces surgical site complications following CABG surgery compared to standard of care. The estimated mean cost per patient was €19,986 for PICO compared to €20,572 for standard care, resulting in a cost saving of €586 (Nherera et al, 2018). Consequently, the prophylactic use of PICO 7 in all CABG patients could offer significant cost benefit to the Trust.

In a cohort of just 100 high risk patients, the cost of PICO would be £14400 (based on a cost for PICO 7 with one dressing at £144 — NHS Supply Chain). Assuming the cost of a SSI in cardiac surgery to be £11,003 (Jenks et al, 2016), this would mean that less than 2 SSIs (calculated accurately as 1.27 SSIs) would need to be avoided to hit a break-even point. This is a rather conservative estimate in terms of the potential SSI reduction rate that might be achieved when considering the wealth of evidence available for PICO.

CONCLUSION

The evaluation showed that the new PICO 7 device received very positive clinician feedback when used in post-operative wound complications in CABG patients (including use in

close proximity to a pacemaker). No issues were recorded with the device.

Furthermore, PICO 7 scored positively when compared to the version of PICO previously used in the hospital. All functionality of the device was judged to be the 'same' or 'better'. 'Better' assessments were reported for functionality factors such as noise, portability and discretion.

The evaluation also showed the impact SSI can have on a provider (both clinically and economically), and the level of resource SSI can require. An obvious next step from this small-scale evaluation would be to adapt care pathways to use PICO prophylactically in CABG patients immediately post-operatively and reduce this burden.

In addition, a randomised controlled trial using PICO in CABG patients could further validate the benefit of single-use, disposable NPWT over current standard of care (transparent film post-op dressings) in reducing SSI rates. This will be discussed more widely within the Trust in the near future, along with the implementation of a revised SSI surveillance process. WUK

DECLARATION OF INTEREST

Julie Tyrer has no conflict of interest to declare with regards to the article or its content.

The product evaluation tool was provided by product manufacturer, time spent completing the evaluations (data entry) was paid.

Dave Myers and Tim Styche are employees of Smith & Nephew.

REFERENCES

De Vries FE, Wallert ED, Solomkin JS et al (2016) A systematic review and meta-analysis including GRADE qualification of the risk of surgical site infections after prophylactic negative pressure wound therapy compared with conventional dressings in clean and contaminated surgery. *Medicine (Baltimore)* 95 (36): e4673

Jenks PJ, Laurent M, McQuarry S, Watkins R (2014) Clinical and economic burden of surgical site infection (SSI) and predicted financial consequences of elimination of SSI from an English hospital. *J Hosp Infect* 86(1): 24–33

Karlakki S, Brem M, Giannini S, Khanduja V et al (2013) Negative pressure wound therapy for management of the surgical incision in orthopaedic surgery: a review of evidence and mechanisms for an emerging indication. *Bone Joint Res* 2 (12): 276–84

Nherera LM, Trueman P, Schmoeckel M, Fatoye FA (2018) Cost-effectiveness analysis of single use negative pressure wound therapy dressings (sNPWT) compared to standard of care in reducing surgical site complications (SSC) in patients undergoing coronary artery bypass grafting surgery. *J Cardiothoracic Surg* 13 (1): 103

Strugala V, Martin R (2017) Meta-analysis of comparative trials evaluating a prophylactic single-use negative pressure wound therapy system for the prevention of surgical site complications. *Surgical Infections*, 18 (7): 810–9

Witt-Majchrzak A, Żelazny P, Snarska J (2015) Preliminary outcome of treatment of postoperative primarily closed sternotomy wounds treated using negative pressure wound therapy. *Pol Przegl Chir* 86 (10): 456–65