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RESEARCH

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# Prophylactic PICO◊ dressing shortens wound dressing requirements post emergency laparotomy (EL-PICO◊ trial)

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## Abstract

**Background** Surgical site infection (SSI) is a very common complication of emergency laparotomy and causes significant morbidity. The PICO◊ device delivers negative pressure wound therapy (NPWT) to closed incisions, with some studies suggesting a role for prevention of SSI in heterogenous surgical populations. We aimed to compare SSI rates between patients receiving PICO◊ versus conventional dressing post-emergency laparotomy. Secondary objectives were to observe seroma and dehiscence rates, length of stay, days on dressing and patients' wound experience.

**Methods** This double blinded randomized controlled trial was conducted in University Malaya Medical Centre between October 2019 and March 2022. Patients undergoing emergency laparotomy requiring incisions less than 35 cm were included. Statistical analysis was performed using $\chi^2$ test for categorical variables, independent T-test or Mann–Whitney U were used for parametric or non-parametric data respectively besides logistic regression. *P* values of $< 0.05$ were considered to be significant.

**Results** Ninety-six patients were analyzed (47 interventions, 49 controls). The duration on dressing was more consistent in the intervention arm (PICO◊) versus control arm [$9.78 \pm 10.20$ vs $17.78 \pm 16.46$ days, $P < 0.001$]. There was a trend towards lower SSI [14.3 vs 4.3%, $P = 0.09$], dehiscence [27.1 vs 10.6%, $P = 0.07$] and seroma [40.8 vs 23.4%, $P = 0.08$] rates in the intervention arm but this did not reach statistical significance. Length of stay [9 (IQR: 6–14) vs 11 (IQR: 6–22.5) days, $P = 0.18$] was fairly similar between the two arms, but more patients were very satisfied with PICO◊ compared to the conventional dressing [80% vs 57.1%, $P = 0.03$].

**Conclusion** The use of NPWT in emergency laparotomy improves patients wound care experience, and was associated with trends towards fewer wound related complications. Cost effectiveness needs to be explored in order to further validate its use in the emergency setting, especially for patients with additional risk for SSI.

Trial registration

National Medical Research Registry (NMRR): NMRR-20-1975-55222.

**Keywords** Emergency laparotomy, Negative pressure wound therapy, PICO◊ dressing, Surgical site infection

## Introduction

Surgical site infection (SSI) is a common complication of emergency laparotomy, negatively impacting patients, their caregivers and healthcare facilities [1]. SSIs delay recovery, subject patients to frequent painful dressing sessions, lengthen hospital stays and

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delay commencement of adjuvant chemoradiotherapy, resulting in higher treatment costs [2–6]. The CDC classifies surgical wounds according to their risk for SSI: Class I (clean) 1–5%, Class II (clean contaminated) 3–11%, Class III (contaminated), and Class IV (dirty) > 27%. Other risk factors include long duration of surgery, diabetes and other conditions associated with immunocompromise, obesity and smoking [7]. Several studies have reported SSI rates ranging from 3 to 36.5% [8, 9].

Negative pressure wound therapy (NPWT), in which a closed sealed system connected to a vacuum pump maintains negative pressure on the wound surface [10–12]. It is traditionally used to treat wound dehiscence, but may have a role in the prevention of SSI in high-risk incisions closed by primary intention [12, 13]. Early NPWT devices used on open wounds were often bulky, which prevented mobilisation of patients, and were expensive. Devices used in closed incisions are smaller, allowing more mobility, but still have added costs [10, 12, 14].

The prophylactic use of NPWT has been shown to reduce SSI rates, cut down the incidence of seroma and dehiscence, and even shorten hospital stay, albeit in heterogenous study populations [3, 4, 14]. However, there are no randomized controlled trials addressing NPWT in preventing SSI specifically after emergency laparotomy, which are at high risk for infections [15].

We aimed to compare 30-day SSI rates, other wound complications, duration of dressing, length of hospital stay and patients' wound care experience post-emergent laparotomy between those receiving prophylactic NPWT versus conventional dressing.

## Methods

### Study design

This was a double blinded randomized controlled trial conducted in University Malaya Medical Centre (UMMC), a tertiary teaching hospital in Kuala Lumpur, Malaysia, between October 2020 and February 2022. The inclusion and exclusion criteria are shown below.

#### *Inclusion*

- Emergency laparotomies (trauma and non-trauma) for malignant and non-malignant indications involving the gastrointestinal tract
- ASA class 1 to 4
- Midline incisions
- Aged 18 years old or older and able to consent for trial
- Willing to comply with required follow up visits

#### *Exclusion*

- Pregnant patients
- Gynaecological indications
- Those with magnetic medical devices (like pacemakers or implantable cardiac device)
- Allergy to PICO dressing
- Laparotomy wounds longer than 35 cm
- Relaparotomy as index operation, or for reasons other than SSI

Emergency laparotomy was defined as surgery within 8 h of presentation for a life-threatening general surgical condition in which access to the abdominal cavity is through a midline incision [16].

Ethical approval from the institutional Medical Research Ethics Committee (MREC ID NO: 202057-8603) was obtained before date of commencement and the study was registered with the National Medical Research Registry (NMRR) with ID No. NMRR-20-1975-55222. Insurance coverage was also obtained for this study [2020-HB-L0002099-LNC]. The clinical use of the NPWT system was approved by the Biomedical Engineering Department of UMMC. Written consent was obtained from all patients enrolled in this study.

### Study intervention

The PICO$^{\diamond}$ system utilizes a single-use, portable, battery-operated pump that delivers NPWT at a pre-set pressure of − 80 mmHg. Weighing 70 g, it lasts for 7 days of continual use. Controlled by a single button, it incorporates leak detection and low-battery indicators. The dressing is made up of four layers with the capacity to absorb 200 mL of exudate, and removes wound exudate predominantly through evaporative loss [17].

### Study participants

#### *Randomization*

Patients were randomized into two arms namely the PICO$^{\diamond}$ dressing (intervention arm) or the conventional dressing (control arm) with a ratio of 1:1. Patients were randomized into blocks of eight utilizing the codes generated via the website-based randomizing tool [18]. Randomization was performed just before skin closure.

#### *Standardization*

All teams under the UMMC General Surgery Division participated in this trial. All patients who consented for this trial were provided with a patient information sheet. In all cases, intravenous antibiotics were given either as prophylaxis or for therapeutic intent, skin was prepared using povidone iodine, a wound protector was

utilized, closure of fascial layer was performed with continuous loop nylon 1/0 (Ethicon, Inc., Somerville, NJ) and skin was closed with either staplers or non-absorbable or absorbable sutures.

Patients in the intervention arm had the PICO$^{\diamondsuit}$ 7 system (30×10 cm or 40×10 cm) applied onto their laparotomy wounds in the operation theatre immediately after skin closure. The system would be turned on as soon as it was assembled so that NPWT would be delivered promptly. The device would then be secured next to the dressing in order to prevent the patient from seeing the device.

The patients in the control arm would have the conventional post operative occlusive 'island' dressing applied onto their laparotomy wounds along with a non-functioning 'dummy' PICO$^{\diamondsuit}$ device plastered next to the conventional dressing. In this way, the patient was blinded to the intervention arm they were in. The surgeon and the managing team however were not blinded to the intervention the patient received.

Demographic and surgical characteristics data was collected. Wound inspection was carried out on days 3, 7, 14 and 30 post-operatively. The wound assessor, an enterostomal and wound therapy nurse was blinded to the wound therapy used. Wounds were evaluated for SSI, seroma and dehiscence.

If a patient in the intervention arm developed SSI, they ceased to be on the PICO$^{\diamondsuit}$ dressing and were managed according to the standard of care. If there was evidence of seroma or dehiscence in the intervention arm after day 7, another cycle of PICO$^{\diamondsuit}$ was reapplied and wound was reinspected on day 14. In the control arm, SSI, seroma and dehiscence in the control arm were managed according to the standard of care. On day 14 onwards, wounds were inspected again. If wounds were healed, they were left exposed. If SSI, seroma, and/or dehiscence developed in either arm, they were treated according to the standard of care. Patients' wound experience was explored during a clinic encounter between 1 and 6 months post operatively using the Wound Experience Questionnaire by the Bluebelle Study Group [19].

#### Study parameters and outcome measures

Demographic data such as age, gender and smoking status, BMI, comorbidities, ASA physical status classification, albumin levels and exposure to steroids, chemotherapy and radiotherapy were obtained from the electronic medical records. Body mass index (BMI) was grouped according to the WHO classification and comorbidities were identified. Patients were also grouped according to their American Society of Anaesthesiologists (ASA) physical status, albumin levels (< 28, 28–35, > 35 g/L) and if they had received steroids, chemotherapy or radiotherapy.

Surgical characteristics like day (weekday or weekend), timing [day (before 8 pm) or night (after 8 pm)], classification of wounds (clean, clean contaminated, contaminated and dirty) as per CDC and surgeon status (General Surgical Trainees and Consultant) were tabulated. Diagnoses were classified into ischemia, trauma, haemorrhage, obstruction or perforation from a benign cause and obstruction or perforation from a malignant cause. Duration of surgery (in minutes), wound length (in centimetres), indication of antibiotics (prophylactic or therapeutic) and number of days on antibiotics were also noted.

Holistic assessment of outcomes is necessary to determine the value of an intervention. Our primary outcome was the rate of SSI within 30 days after emergency laparotomy in patients receiving the PICO$^{\diamondsuit}$ system dressing versus those who received the standard occlusive post-operative dressing. SSI was defined according to the CDC guidelines [7]. Wounds would be evaluated four times during the first 30 days post-operatively namely on day 3, day 7, day 14 and day 30 post operatively. Secondary outcomes like seroma and dehiscence rates as well as length of stay in days, number of days on dressing and patients' wound experience were also observed. Questions related to wound experience are listed in Table 4. Patients were given the option of four possible answers: "Not at all", "A little", "Quite a bit" or "A lot".

#### Sample size justification

Based on a retrospective audit carried out by the Division of General Surgery of University Malaya Medical Centre (UMMC), between January to June 2019, the SSI rate post-emergency laparotomy was as high as 28.9% (N = 83).

The sample size was calculated using G Power calculator by Franz Paul from the University of Germany (Version 3.1.9.4). Since SSI was the primary outcome, the ratios of reported SSI rate post-emergency laparotomy of roughly 30% and the expected reduction in SSI rate to 7% with PICO$^{\diamondsuit}$ dressing were utilized. Forty patients were required in each arm to detect a difference of 23% to achieve 80% power with an α-risk of 5%. A 20% drop out rate was expected in this study. Therefore, a total of 96 patients were required i.e. 48 in each treatment arm.

#### Statistical analysis

All outcomes were tabulated in the data proforma and transferred to spreadsheet for analysis. Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY. Categorical data was

expressed as number and percentage while continuous data was presented as mean and standard deviation if normally distributed, or median and interquartile range if non-parametric. Categorical variables (patient and study characteristics, diagnosis, CDC wound classification, level of surgeon's training, presence of SSI, seroma, dehiscence, patients' wound experience) were analysed using Chi Square test or Fisher Exact Test. The independent T test was used to analyse parametric data (i.e., wound length) while the Mann–Whitney U test was utilized for non-parametric data (i.e., duration of surgery, duration on antibodies, length of stay and duration of dressing). Further analysis using univariate and multivariate logistic regression were performed to determine possible predictors for SSI after emergency laparotomy at 30 days post-op; i.e. risk for SSI rates. *P* values < 0.05 were considered to be significant.

## Results

A total of 111 patients were randomized after eliminating those with exclusion criteria; 53 in the treatment and 58 in the control arm. Among these patients there were six drop outs in the treatment arm (11.3%) and nine in the control arm (15.5%). Eight (53.3%) patients died during the study period, five (33.3%) defaulted follow ups and two (13.3%) underwent relaparotomy for indications other than deep or organ/space SSI. Hence analyses were performed with the remaining 47 patients in the treatment arm and 49 in the control arm.

### Demographic characteristics

More than half of the patients in this trial were above the age of 65 years old (53.1%). There was a slight male predominance among our patients (54.2%). Less than half (48.9%) of the patients had a normal BMI with one third (32.3%) being overweight and 8% being obese. Eleven of the 96 patients (11.4%) were smokers. One sixth (16.7%) of our patients were diabetic and 14.6% were known to have a malignancy that is currently being treated or under investigation. While a majority of patients belonged to ASA 1 category (45.8%), it was noteworthy that more than one-fifth of the patients (22.9%) were of ASA 3 and 4. Only 37.5% of the patients had normal albumin levels (> 35 g/L) while 28.1% had albumin levels of less than 28 g/L. Six (6.3%) of the patients were undergoing chemotherapy and five (5.2%) had received radiotherapy as well as 5 (5.2%) were on chronic exogenous steroid use in the past. The demographic data for patients of this study is tabulated in Table 1. Both the intervention and control arms shared similar demographic characteristics ($P > 0.05$).

### Surgical characteristics

The most common surgical diagnosis in our patients was malignant bowel obstruction (36.5%) followed by perforated viscus due to benign causes (29.2%) and bowel obstruction from a benign cause in third place (14.6%). Most of the surgical incisions were classified as either clean contaminated (53.1%) or dirty (30.2%). A majority of the laparotomies were conducted by consultant surgeons (70.8%). The median operative time was similar between the control and intervention arms, with 167 and 170 min respectively. There was no significant difference between the duration of antibiotics between the two arms (intervention 9 days vs control 7 days). The average length of the surgical incision in both arms was 19 cm ($P = 0.314$) [Table 2].

### Outcomes

SSI was diagnosed by physician assessment in two patients (4.3%) in the intervention arm, while seven patients (14.3%) in the control arm were diagnosed by microbiology culture report and/or physician assessment. However, this trend towards lower SSI rates in the intervention arm did not reach statistical significance ($P = 0.09$). The case mix included colorectal, trauma, hepatobiliary and upper gastrointestinal conditions. Other general surgical cases included were small bowel or appendiceal conditions such as obstructed/strangulated hernias or perforated appendicitis. There was no significant difference ($P > 0.05$) in case mix between the intervention and control arms [Table 3].

Seroma and dehiscence rates in the intervention arm trended lower but did not reach statistical significance. Twenty (40.8%) patients in the control arm had wounds complicated with seroma while only 11 (23.4%) in the intervention arm had the same complication ($P = 0.083$). Dehiscence rates were much lower in the intervention arm [five (10.6%) vs 13 (26.5%), $P = 0.066$]. Patients in the intervention arm had less variability in duration of dressing, with all PICO$^{\Diamond}$ dressings removed at 7 days. Patients in the control arm had dressings for a median of 7 days, but with greater variability in range of duration (7–23 days, $P < 0.05$). This, however, did not impact the length of hospital stay (9 vs 11 days, $P = 0.179$) [Table 3].

Patient-reported wound experience was comparable between both arms. However, a larger proportion of the patients in the intervention arm were very satisfied with their dressing compared with the conventional dressing arm (80% vs 57.1%; $P = 0.031$). In addition, the majority of patients in the intervention arm reported that their wounds did not feel itchy, painful or tight. Only a small proportion experienced a pulling

**Table 1** Patient characteristics

| | Conventional dressing N = 49 (%) | PICO◊ dressing N = 47 (%) | Total N = 96 (%) | *P* value[a] |
|---|---|---|---|---|
| *Age* | | | | 0.990 |
| < 65 | 23 (46.9) | 22 (46.8) | 45 (46.9) | |
| ≥ 65 | 26 (53.1) | 25 (53.2) | 51 (53.1) | |
| *Sex* | | | | 0.983 |
| Male | 27 (55.1) | 26 (55.3) | 53 (54.2) | |
| Female | 22 (44.9) | 21 (44.7) | 43 (44.8) | |
| *BMI* (kg/m$^2$) | | | | 0.280 |
| Underweight (< 18.0) | 7 (14.3) | 3 (6.4) | 10 (10.4) | |
| Normal (18.0–24.9) | 25 (51.0) | 22 (46.8) | 47 (48.9) | |
| Overweight (25.0–29.9) | 12 (24.5) | 19 (40.4) | 31 (32.3) | |
| Obese (> 30.0) | 5 (10.2) | 3 (6.4) | 8 (8.3) | |
| Smoker | 6 (12.2) | 5 (10.6) | 11 (11.5) | 0.805 |
| DM | 6 (12.2) | 10 (21.3) | 16 (16.6) | 0.235 |
| IHD/CCF | 4 (8.2) | 3 (6.4) | 7 (7.3) | 0.877 |
| CVA | 3 (6.1) | 4 (8.5) | 7 (7.3) | 0.362 |
| BA/COPD | 4 (8.2) | 1 (2.1) | 5 (5.2) | 0.653 |
| CKD/ESRF | 2 (4.0) | 2 (4.2) | 4 (4.2) | 0.976 |
| Active malignancy | 10 (20.4) | 4 (8.5) | 14 (14.6) | 0.099 |
| *ASA* | | | | 0.664 |
| 1 | 20 (40.8) | 24 (51.1) | 44 (45.8) | |
| 2 | 17 (34.7) | 12 (25.5) | 29 (30.2) | |
| 3 | 8 (18.4) | 7 (14.9) | 16 (16.7) | |
| 4 | 3 (6.1) | 4 (8.5) | 7 (7.3) | |
| *Preoperative albumin* | | | | 0.674 |
| ≤ 35 | 32 (65.3) | 28 (59.6) | 60 (62.5) | |
| > 35 | 17 (34.7) | 19 (40.4) | 36 (37.5) | |
| Chemotherapy | 5 (10.2) | 1 (2.1) | 6 (6.3) | 0.102 |
| Radiotherapy | 4 (8.2) | 1 (2.1) | 5 (5.2) | 0.183 |
| Steroids | 2 (4.1) | 3 (6.4) | 5 (5.2) | 0.612 |

%, percentage; ASA, American Society of Anesthesiologists' Classification; BA, bronchial asthma; CCF, congestive cardiac failure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVA, history of cerebrovascular accident; DM, diabetes; ESRF, end stage renal failure; IHD, ischemic heart disease; N, number

[a] Chi square test; $P < 0.05$ denotes statistical significance

sensation, unpleasant odour or pain or anxiety during removal of dressing [Table 4].

#### *Risk of SSI*

Univariate analysis was carried out to identify risk factors for SSI in our study population. Abnormal BMI was associated with a higher SSI rate ($P = 0.013$). However, on multivariate analysis it was not an independent risk factor ($P = 0.063$). Two patients in the control arm developed burst abdomen requiring relaparotomy, while one patient in the intervention arm with this complication was managed non-operatively [Table 5].

## Discussion

SSI is a common complication following emergency laparotomy, with rates ranging from 15.9 to 22.9%, negatively impacting patients' recovery [5, 20, 21].

There is limited data on the prophylactic use of NPWT in emergency laparotomy with primary closure.

Our study shows that NPWT using the PICO◊ system reduces SSI rates by 10% (from 14.3 to 4.3%). Unfortunately, this did not reach statistical significance ($P = 0.09$), probably due to overestimation of the effect size, and underestimation of sample size. Calculation was based on similar studies which showed that SSI rates were 16–32% lower when NPWT dressing was employed [17, 20, 21]. Those trials however had a much smaller

**Table 2** Surgical characteristics

| | Conventional dressing N = 49 (%) | PICO◊ dressing N = 47 (%) | Total N = 96 (%) | *P* value |
|---|---|---|---|---|
| *Diagnosis* | | | | 0.510[a] |
| Benign obstruction | 6 (12.2) | 8 (17.0) | 14 (14.6) | |
| Benign perforation | 16 (32.7) | 12(25.5) | 28 (29.2) | |
| Malignant obstruction | 18 (26.7) | 17 (36.2) | 35 (36.5) | |
| Malignant perforation | 4 (8.2) | 1 (2.1) | 5 (5.2) | |
| Ischemia | 2 (4.1) | 5 (10.6) | 7 (7.3) | |
| Trauma | 1 (2.0) | 3 (6.4) | 4 (4.2) | |
| Bleeding | 2 (4.1) | 1 (2.1) | 3 (3.1) | |
| *CDC wound classification* | | | | 0.091[a] |
| Clean | 1 (2.0) | 6 (12.8) | 7 (7.3) | |
| Clean contaminated | 25 (51.0) | 26 (55.3) | 51 (53.1) | |
| Contaminated | 4 (8.2) | 5 (10.6) | 9 (9.4) | |
| Dirty | 19 (37.5) | 10 (21.3) | 29 (30.2) | |
| *Level of surgeon's training* | | | | 0.771[b] |
| Consultant/general surgeons | 43 (87.8) | 40 (85.1) | 83 (86.5) | |
| General surgical trainees | 6 (12.2) | 7 (14.9) | 13 (13.5) | |
| *Duration of surgery* (minutes) | | | | |
| Median (IQR) | 167 (75) | 170 (128) | | 0.838[c] |
| *Duration on antibiotics* (days) | | | | |
| Median (IQR) | 9 (8) | 7 (9) | | 0.680[c] |
| *Wound length* (in cm) | | | | |
| Mean ± SD | 19 ± 3.4 | 19 ± 3.7 | | 0.314[d] |

%, Percentage; CDC, Centre of Disease Control; IQR, interquartile range; N, number; SD, standard deviation

[a] Chi square test; [b]Fisher Exact Test; [c]Mann Whitney; [d]Independent T-test; $P < 0.05$ denotes statistical significance

population of patients and a much higher SSI rate. Although not statistically significant, a 10% reduction in the SSI rate may still be clinically relevant and have a positive impact on patient outcomes (Fig. 1).

Previous studies have shown reduction in seroma rates of as much as 32–36% in elective settings [17, 20, 21]. Seroma and dehiscence rates in our study also trended lower with the use of PICO◊ dressing, but without reaching statistical significance. Although emergency settings are associated with greater third space losses and more exudative wounds, our seroma rates overall are lower than those reported in previous studies, even under elective settings. Our practice of routinely utilizing a wound protector [22, 23] in laparotomies may have contributed to the lower-than-expected overall SSI rate. This may explain why the reduction in seromas in our intervention arm did not reach statistical significance.

The intervention arm had a more consistent duration on dressing. Despite this, the length of hospital stay was similar between arms. Emergency laparotomies are associated with other non-wound-related morbidities, like hospital acquired infections, which contribute to longer hospital stays. More than half of patients were elderly, which may have affected speed of recovery and rehabilitation. In addition, COVID 19 pandemic restrictions were in full force during the study period, in the pre-vaccination era, resulting in extended hospital stays for six patients (6.2%) as a result of contracting the virus during hospitalization or requiring quarantine due to close contact. One patient developed organ failure from SARS-CoV infection, requiring prolonged intensive care unit stay before eventually dying.

Although the duration on PICO◊ dressing was more predictable, there was no apparent difference in the patients' overall wound experience. Nevertheless, a higher percentage of patients in the intervention arm reported that they were extremely satisfied with their dressing, and this was statistically significant (Table 4). It may be that the sample size was too small to show significance despite several positive trends for PICO in terms of wound-related symptoms.

Intuitively, the use of NPWT would be expected to increase direct costs, as the cost of each PICO device was USD165. Indeed, we found that the median cost of hospital stay in the PICO arm was USD416 (range: USD333–USD554) which trended higher than the

**Table 3** Comparison of SSI outcomes post emergency laparotomy by case mix

| Outcomes | Conventional dressing N = 49 (%) | PICO◊ dressing N = 47 (%) | Total N = 96 (%) | *P* value |
|---|---|---|---|---|
| *SSI* | | | | 0.090[a] |
| Yes | 7 (14.3) | 2 (4.3) | 9 (9.4) | |
| No | 42 (85.7) | 45 (95.7) | 87 (90.6) | |
| *SSI by case mix* | | | | |
| Colorectal | | | 42 | 0.109[b] |
| Yes | 4 (8.2) | 0 (0.0) | | |
| No | 18 (36.7) | 20 (42.6) | | |
| General | | | 36 | 0.100[b] |
| Yes | 3 (6.12) | 2 (4.3) | | |
| No | 17 (34.7) | 14 (29.8) | | |
| Trauma | | | 4 | N/A |
| Yes | 0 (0.0) | 0 (0.0) | | |
| No | 1 (2.0) | 3 (6.4) | | |
| Upper GI | | | 10 | N/A |
| Yes | 0 (0.0) | 0 (0.0) | | |
| No | 4 (8.2) | 6 (12.8) | | |
| HPB | | | 3 | N/A |
| Yes | 0 (0.0) | 0 (0.0) | | |
| No | 1 (2.0) | 2 (4.3) | | |
| *Seroma* | | | | 0.083[a] |
| Yes | 20 (40.8) | 11 (23.4) | 31 (32.3) | |
| No | 29 (59.2) | 36 (76.6) | 65 (67.7) | |
| *Dehiscence* | | | | 0.066[a] |
| Yes | 13 (26.5) | 5 (10.6) | 18 (18.8) | |
| No | 36 (73.5) | 42 (89.4) | 78 (81.3) | |
| *Length of stay* (days) | | | | |
| Median (IQR) | 11 (6–22.5) | 9 (6–14) | | 0.179[b] |
| *Duration of dressing* (days) | | | | |
| Median (IQR) | 7 (7–22.5) | 7 (7–7) | | < 0.001[b] |

%, Percentage; IQR, interquartile range; N/A, not applicable as no SSI value; N, number; SD, standard deviation; SSI, surgical site infection

[a] Chi square test; [b]Mann Whitney U test; $P < 0.05$ denotes statistical significance

conventional arm, where it was USD305 (range: USD167–USD629). However, this was not statistically significant ($P = 0.12$) and the upper limit was higher in the conventional arm, which may be due to longer duration on dressing. In addition, the value of better patient satisfaction may be sufficient to offset the trend to slightly higher cost of PICO.

The only variable associated with SSI was an abnormal BMI, although this was not confirmed on multivariate analysis. However, our study was not powered to demonstrate an association with specific abnormalities in BMI, although there are theoretical bases for such an association. Theoretically, obesity could lead to a higher risk of SSI, as a thicker layer of subcutaneous fat increases dead space and retraction forces, causing impaired perfusion of fat and tissue necrosis. Phagocytic activity would also be prevented by this phenomenon, making the wound a fertile ground for infection. Adipocytes also carry pro-inflammatory mediators that cause insulin resistance further escalating the likelihood of SSI [24]. On the other hand, malnutrition in underweight patients could impair healing processes and immunological responses to infection [25].

We faced some challenges utilizing the PICO◊ system. The dressings were more likely to leak or malfunction leading to wastage, when applied to incisions that were in close proximity to stomas (N = 2, 3.7%). Four patients (7.5%) developed blisters but these were tiny (less than 1 cm) and were not detected or felt by patients but incidentally noted during the wound inspection process. The incidence of blisters in the intervention arm were lower than the previously reported incidence of 11% [26]. These blisters disappeared once the PICO◊ dressing ceased to be utilized.

**Table 4** Comparison of wound experience after emergency laparotomy between the PICO dressing and conventional dressing groups

| Aspects of wound experience | Conventional dressing N = 21 (%) | PICO◊ dressing N = 30 (%) | *P* value[a] |
|---|---|---|---|
| *Has your wound been itchy?* | | | 0.418 |
| Not at all | 10 (47.6) | 18 (60.0) | |
| A little | 9 (42.9) | 7 (23.3) | |
| Quite a bit | 1 (4.8) | 4 (13.3) | |
| A lot | 1 (4.8) | 1 (3.3) | |
| *Has your wound been painful?* | | | 0.324 |
| Not at all | 12 (57.1) | 18 (60.0) | |
| A little | 5 (23.8) | 6 (20.0) | |
| Quite a bit | 1(4.8) | 5 (16.7) | |
| A lot | 3(14.3) | 1 (3.3) | |
| *Has your wound had a pulling sensation?* | | | 0.568 |
| Not at all | 15 (71.4) | 23 (76.7) | |
| A little | 6 (28.6) | 6 (20.0) | |
| Quite a bit | 0 (0) | 1 (3.3) | |
| A lot | 0 (0) | 0 (0) | |
| *Has your wound felt tight?* | | | 0.075 |
| Not at all | 13 (61.9) | 24 (80.0) | |
| A little | 8 (38.1) | 4 (13.3) | |
| Quite a bit | 0 (0) | 2 (6.7) | |
| A lot | 0 (0) | 0 (0) | |
| *Has your wound been smelly?* | | | 0.483 |
| Not at all | 18 (85.7) | 27 (90.0) | |
| A little | 3 (14.3) | 2 (6.7) | |
| Quite a bit | 0 (0) | 1 (3.3) | |
| A lot | 0 (0) | 0 (0) | |
| *Did you feel any pain when your dressing was removed?* | | | 0.531 |
| Not at all | 13 (61.9) | 15 (50.0) | |
| A little | 5 (23.8) | 11 (36.7) | |
| Quite a bit | 1 (4.8) | 3 (10.0) | |
| A lot | 2 (9.5) | 1 (3.3) | |
| *Did you feel any anxiety when your dressing was removed?* | | | 0.832 |
| Not at all | 15 (71.4) | 22 (73.3) | |
| A little | 4 (19.0) | 5 (16.7) | |
| Quite a bit | 0 (0) | 1 (3.3) | |
| A lot | 2 (9.5) | 2 (6.7) | |
| *Has your dressing prevented you from showering or washing?* | | | 0.293 |
| Not at all | 12 (57.1) | 19 (63.3) | |
| A little | 5 (23.8) | 3 (10.0) | |
| Quite a bit | 4 (19.0) | 5 (16.7) | |
| A lot | 0 (0) | 3 (10.0) | |
| *Has your wound felt protected?* | | | 0.549 |
| Not at all | 3 (14.3) | 1 (3.3) | |
| A little | 1 (4.8) | 2 (6.7) | |
| Quite a bit | 4 (19.0) | 7 (23.3) | |
| A lot | 13 (61.9) | 20 (64.7) | |
| *Have you felt any anxiety about your wound in relation to the dressing?* | | | 0.803 |
| Not at all | 14 (66.7) | 21(70.0) | |
| A little | 4 (19.0) | 7 (23.3) | |

**Table 4** (continued)

| Aspects of wound experience | Conventional dressing N = 21 (%) | PICO◊ dressing N = 30 (%) | *P* value[a] |
|---|---|---|---|
| Quite a bit | 1 (4.8) | 1(3.3) | |
| A lot | 2 (9.5) | 1(3.3) | |
| *Are you satisfied with your dressing?* | | | 0.164 |
| Not at all | 0 (0) | 0 (0) | |
| A little | 3 (14.3) | 1(3.3) | |
| Quite a bit | 6 (28.6) | 5 (16.7) | |
| A lot | 12 (57.1) | 24 (80.0) | **0.031** |

%, Percentage; N, number

[a] Chi square test; $P < 0.05$ denotes statistical significance, presented in bold

**Table 5** Predictors for SSI after emergency laparotomy at 30 days post op

| Variable | No SSI (N = 87) N (%) | SSI (N = 9) N (%) | Univariate analysis (N = 96) | | Multivariate analysis (N = 96) | |
|---|---|---|---|---|---|---|
| | | | OR (95% CI) | *P* value | OR (95% CI) | *P* value |
| *Age* | | | | | | |
| < 65 years old | 38 (43.7) | 7 (77.8) | 4.513 (0.886–22.979) | 0.070 | | |
| ≥ 65 years old | 49 (56.3) | 2 (22.2) | Reference | | | |
| *BMI* | | | | | | **0.037** |
| Underweight | 9 (10.3) | 1 (11.1) | 5.11 (0.29–89.46) | 0.264 | 4.92 (0.24–200.91) | 0.301 |
| Overweight | 27 (31.0) | 4 (44.4) | 6.82 (0.72–64.16) | 0.093 | 8.17 (0.77–87.19) | 0.082 |
| Obese | 5 (5.7) | 3 (33.3) | 27.60 (2.40–317.97) | **0.008**[*] | 44.8 (3.25–615.84) | **0.004** |
| Normal | 46 (52.9) | 1 (11.1) | Reference | | Reference | |
| *History and comorbidities* | | | | | | |
| Smoker[#] | 11 (12.6) | 0 (0) | 0.00 (0.00–none) | 0.999 | | |
| DM[#] | 14 (16.1) | 2 (22.2) | 0.68 (0.13–3.57) | 0.640 | | |
| History of active cancer[#] | 12 (13.8) | 2 (22.2) | 0.56 (0.10–3.02) | 0.500 | | |
| *Albumin* | | | | | | |
| ≤ 35 | 53 (60.9) | 7 (77.8) | 2.25 (0.44–11.45) | 0.331 | | |
| > 35 | 34 (39.1) | 2 (22.2) | Reference | | | |
| *Treatment* | | | | | | |
| Chemotherapy[#] | 4 (4.6) | 2 (22.2) | 0.078 (0.01–0.66) | **0.019** | 12.08 (1.35–107.93) | **0.026** |
| Radiotherapy[#] | 5 (5.7) | 0 (0) | 0.00 (0.00–none) | 0.999 | | |
| Steroids[#] | 4 (4.6) | 1 (11.1) | 0.23 (0.02–2.61) | 0.237 | | |
| *Type of dressing* | | | | | | |
| PICO | 45 (51.7) | 2 (22.2) | 0.27 (0.05–1.36) | 0.111 | | |
| Conventional | 42 (48.3) | 7 (77.8) | Reference | | | |
| *Diagnosis* | | | | 0.830 | | |
| Benign obstruction | 13 (14.9) | 1(11.1) | 0.15 (0.01–3.58) | 0.244 | | |
| Benign perforation ischemia | 24 (27.6) | 4 (44.4) | 0.33 (0.02–4.60) | 0.412 | | |
| Malignant obstruction | 6 (6.9) | 1 (11.1) | 0.33 (0.01–8.18) | 0.501 | | |
| Malignant perforation | 33 (37.9) | 2 (22.2) | 0.12 (0.01–1.98) | 0.139 | | |
| Trauma | 5 (5.7) | 0 (0) | 0.00 (0.00-none) | 0.999 | | |
| Haemorrhage | 4 (4.6) | 0 (0) | Reference | | | |

[#] Reference = no/none; 95% CI, 95% confidence interval; BMI, body mass index; DM, diabetes; SSI, surgical site infection; %, percentage; N, number; OR, odd ratio

[a] Binary logistic regression; $P < 0.05$ denotes statistical significance, presented in bold

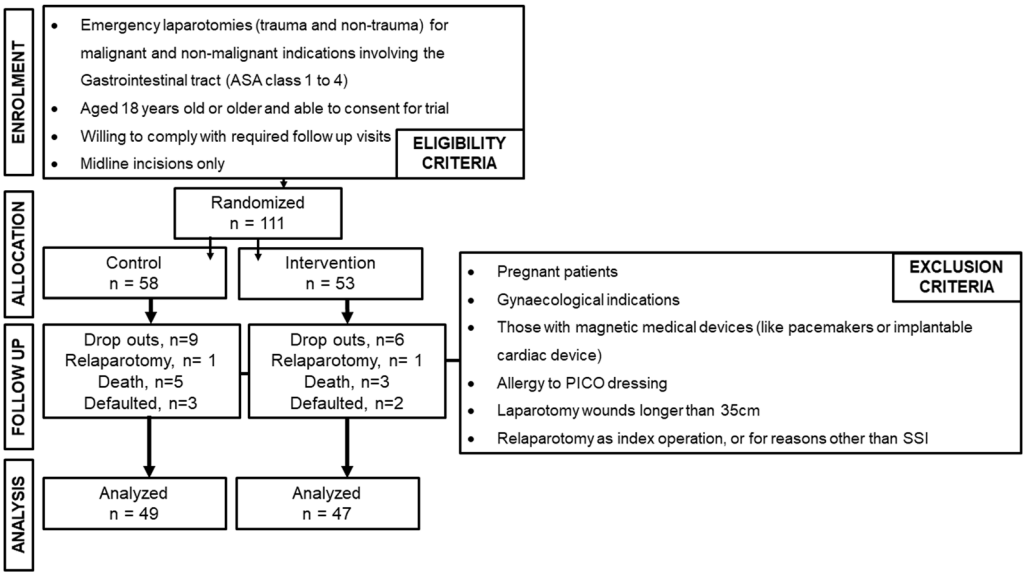


**Fig. 1** Consort diagram

Nevertheless, the reduced duration of dressing and high level of patient satisfaction suggests that there is a role for PICO$^{\Diamond}$ in the management of incisions post-emergency laparotomy, which have high risk for developing SSI. A selective approach in emergency laparotomy, utilizing PICO$^{\Diamond}$ for patients with additional risk for SSI, such as obesity, may add to cost-effectiveness, but this requires further investigation as a global multi-centre study.

## Conclusion

The prophylactic use of NPWT in primarily closed emergency laparotomy incisions provides consistently reproducible duration on dressing, but does not reduce overall length of stay. Nevertheless, patients were more likely to report favourable wound care experience with NPWT, in part due to trends towards lower SSI, seroma and dehiscence rates. Cost-effectiveness studies in the post-COVID-19 pandemic era are needed to ascertain if NPWT should be routinely used in emergency settings.

#### Abbreviations

| | |
|---|---|
| IQR | Interquartile range |
| PICO$^{\Diamond}$ | Device that delivers NPWT |
| NPWT | Negative pressure wound therapy |
| NMRR | National Medical Research Register |
| SD | Standard deviation |
| UMMC | University of Malaya Medical Centre |

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#### Author contributions

EPF: conceptualization, data curation, formal analysis, investigation, methodology, project administration; resources, software, visualization and writing—original draft. RR: formal analysis, methodology; resources; software; validation; visualization; writing—original draft and writing—review & editing. MZ: data curation, investigation; KTL: conceptualization, supervision, validation and writing—review & editing. ACR: conceptualization, data curation, formal analysis, methodology, project administration, resources; supervision, validation, writing—original draft and writing—review & editing.

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#### Availability of data and materials

No datasets were generated or analysed during the current study.

#### Code availability

Not applicable.

## Declarations

#### Ethics approval and consent to participate

Ethical approval was obtained from Institutional ethical committee prior to the commencement of the study with the number MREC ID No: 202057-8603. The study was registered with the National Medical Research Register, ID No. NMRR-20-1975-55222. Informed consent forms were signed by all patients as per ethical approval guidelines. Insurance coverage was also obtained for this study, 2020-HB-L0002099-LNC. This work consent has been obtained and authors approve the final version of the manuscript.

#### Consent for publication

This work consent has been obtained and authors approve the final version of the manuscript.

#### Competing interests

The authors declare no competing interests.

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## Publisher's Note