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Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched–cohort analysis

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ABSTRACT

Background: Surgical site infection contributes to a significant proportion of postoperative morbidity in patients undergoing emergency laparotomy. Surgical site infections cause significant patient burden, increase duration of stay, and have economic implications. Closed incision negative pressure therapy has been shown to reduce surgical site infection rates in patients undergoing elective laparotomy; however, there is limited evidence for their use in the emergency setting. This study aims to compare rates of surgical site infection between patients receiving closed incision negative pressure therapy and standard surgical dressing after emergency laparotomy through a propensity matched analysis.

Methods: A registry-based, prospective cohort study was undertaken using data from the National Emergency Laparotomy Audit database at our center. The primary outcome measure was surgical site infection as defined by the Centers for Disease Control criteria. Secondary outcomes included 30-day postoperative morbidity and grade, duration of stay, 30-day mortality, and readmission rates. A propensity-score matching was performed in a 1:1 ratio to mitigate for selection bias.

Results: A total of 1,484 patients were identified from the National Emergency Laparotomy Audit data set, and propensity-score matching resulted in 2 equally matched cohorts with 237 patients in each arm. The rate of surgical site infection was significantly lower in the closed incision negative pressure therapy cohort (16.9% vs 33.8%, $P < .001$). There were no overall differences in 30-day morbidity, Clavien-Dindo grade, Comprehensive Complication Index severity, length of hospital stay, reoperation rates, and 30-day mortality between the 2 groups.

Conclusions: Prophylactic closed incision negative pressure therapy in emergency laparotomy patients is associated with a reduction in surgical site infection rates.

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Introduction

Approximately 30,000 people per annum undergo emergency laparotomy in the United Kingdom for a variety of gastrointestinal emergencies.[1] The burden of emergency surgery is significant, with reports of 30-day postoperative morbidity rates of 33% to 71% and mortality rates of 9.6% to 17%.[1–3] Surgical site infection (SSI) contributes to a significant proportion of the postoperative morbidity experienced by patients in the emergency setting, with reported rates of 25% to 40%.[4,5] SSIs cause significant patient burden, increase length of stay, and have economic implications. There have been a number of strategies implemented to reduce SSI, including the use of prophylactic antibiotics, appropriate skin preparation, maintenance of normothermia, glycemic control, optimization of tissue oxygenation, use of wound protectors, and appropriate wound lavage.[6,7]

Closed incision negative pressure therapy (CINPT) on closed surgical incisions as a prophylactic measure has been shown to reduce SSI rates in patients undergoing elective laparotomy.[8,9] CINPT consists of the continuous delivery of 125 mmHg negative

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pressure to the closed incision using vacuum therapy, thus protecting the wound from external contamination, removing fluid and debris from the wound, and assisting in maintaining wound approximation. Mechanistically, CINPT promotes angiogenesis leading to increased blood flow, modulates inhibitory contents of wound fluid such as metalloproteinases thus enabling more efficient function of growth factors, and induces cell proliferation, all of which promotes good tissue healing.[10–12] Randomized controlled trials and meta-analyses in this setting underrepresent patients undergoing emergency surgery, with Boland et al identifying a total of 43 out of 467 patients across 5 studies undergoing acute surgery.[13] Given the nature of emergency surgery, with patients presenting with varying degrees of sepsis coupled with the higher potential for peritoneal contamination, the use of CINPT in this setting could make a significant impact in reducing SSI. The aim of this study was to identify whether in patients undergoing emergency laparotomy the use of CINPT was associated with a reduction in SSI rates.

Methods

A registry-based, prospective cohort study was undertaken using data from National Emergency Laparotomy Audit (NELA) database at our center. Patient-level data were extracted from the NELA database at our center between January 2014 and December 2019. The collection of data through NELA have been previously described.[1] Data regarding admission, perioperative management, risk stratification, intraoperative details, and postoperative outcomes were all extracted from the NELA data set. These data were supplemented by specific data extracted from clinical notes on comorbidity, postoperative morbidity including surgical site infection, 30-day complication rates, and grade of complications.

The Charlson Comorbidity Index was calculated for all patients. This is a well-validated score that groups different patient comorbidity into discrete categories.[14] Patients were divided into groups; no comorbidity with a score of 0, mild with a score of 1 to 2, moderate with a score of 3 to 4, and severe with a score of 5. Operative procedures extracted from the NELA data set were classified into colorectal, upper gastrointestinal, stoma-related procedures (stoma formation or revision), small bowel, and other.

Intervention

Prophylactic CINPT device (Prevena™ Incision Management System) was applied to the midline laparotomy incision at the discretion of the operating surgeon. The CINPT dressing was applied over the closed midline incision under sterile conditions and left in situ for 7 days or until discharge if before this. An ACTIV.A.C. Therapy System was used to provide a continuous pressure of 125 mmHg. The control group consisted of patients undergoing a standard surgical dressing (Opsite dressing).

Eligibility criteria

All adult patients (>18 years old) undergoing an emergency laparotomy as recorded in the NELA data set were eligible for inclusion. Patients were excluded if they underwent emergency laparoscopic surgery, required VAC therapy for laparostomy management, or underwent a trauma laparotomy.

Outcome assessment

The primary outcome of this study was surgical site infection (SSI). SSI is assessed by the surgical team on a daily basis during the inpatient stay and diagnosed in accordance with Centers for Disease Control (CDC) criteria. If there is suspicion of a SSI in the CINPT group, the dressing is removed to enable wound assessment and appropriate diagnosis. SSI was defined in accordance with the internationally accredited CDC criteria.[15] The CDC criteria for a SSI is that an infection must occur within 30 days of the index operation, and the patient must have 1 of the following: purulent drainage from the wound, organisms detected from the wound swab, wound opened spontaneously or by a clinician, pain or tenderness at the surgical wound site localized swelling, erythema, heat or a systemic fever (>38 C), or diagnosis of SSI by a clinician or on radiological imaging. SSI was further categorized into superficial, deep, or organ space SSI in keeping with CDC criteria. Superficial SSI was defined as involving the skin and subcutaneous tissue of the incision, deep SSI was defined as involving the deep layers of the incision including the fascial and muscle layers, and organ space SSI was defined as deeper than the fascial layer of the abdominal wall.

Secondary outcomes included overall 30-day morbidity, the grade of postoperative complications using the Clavien-Dindo classification, and the Comprehensive Complication Index (CCI). The Clavien-Dindo Classification system assigns a grade to the most severe complication experienced.[16] The system is divided into 7 grades (I, II, IIIa, IIIb, IVa, IVb, and V), reflecting the varying severity of complications. The CCI is a measure of all complications experienced and is calculated as the sum of all complications weighted by severity.[17] The CCI is a continuous scale that ranks the severity of any combination of complications from 0 (no complications) to 100 (death) in a single patient. Total hospital length of stay, 30-day mortality, and 30-day reoperative rates were also assessed.

Statistical analysis

To mitigate the potential for selection bias across surgical approaches, propensity-score matching was performed using the nearest neighbor approach without replacement (caliper width 0.1 s.d.). Seven covariates were used for the propensity matching. This included patient characteristics of age; gender; American Society of Anesthesiologists (ASA) score; perioperative factors including use of preoperative antibiotics and clinical signs of sepsis at time of surgery; intraoperative findings of the presence of peritoneal contamination and the type of fluid peritoneal contamination found.

The CINPT and standard surgical dressing group were compared with respect to perioperative characteristics and postoperative outcomes. Continuous data were described using mean and SD or median and IQR if skewed, and category data were summarized as number and percentage. The chi-square test or Fisher exact test were used to compare categorical variables. The 2-tailed independent samples *t* test or Wilcoxon rank-sum test was used to compare continuous variables. Bivariate logistic regression was used to determine independent predictors of SSI, with comparison of patients with SSI with those who did not go on to develop a SSI. Odds ratios (ORs) with their respective 95% confidence intervals were used to assess for statistical associations, and *P* values of less than .05 were considered statistically significant. All analyses were conducted using IBM SPSS Statistics version 26.0.0.1 for Macintosh (IBM Corp, Armonk, NY).

Results

A total of 1,484 patients were identified as undergoing emergency surgery during the study period (Fig 1). Two hundred and ninety-nine patients were excluded because they did not fulfill the eligibility criteria. Propensity matching CINPT to standard surgical dressing identified a matched cohort of 474 patients, with 237 patients in each arm.

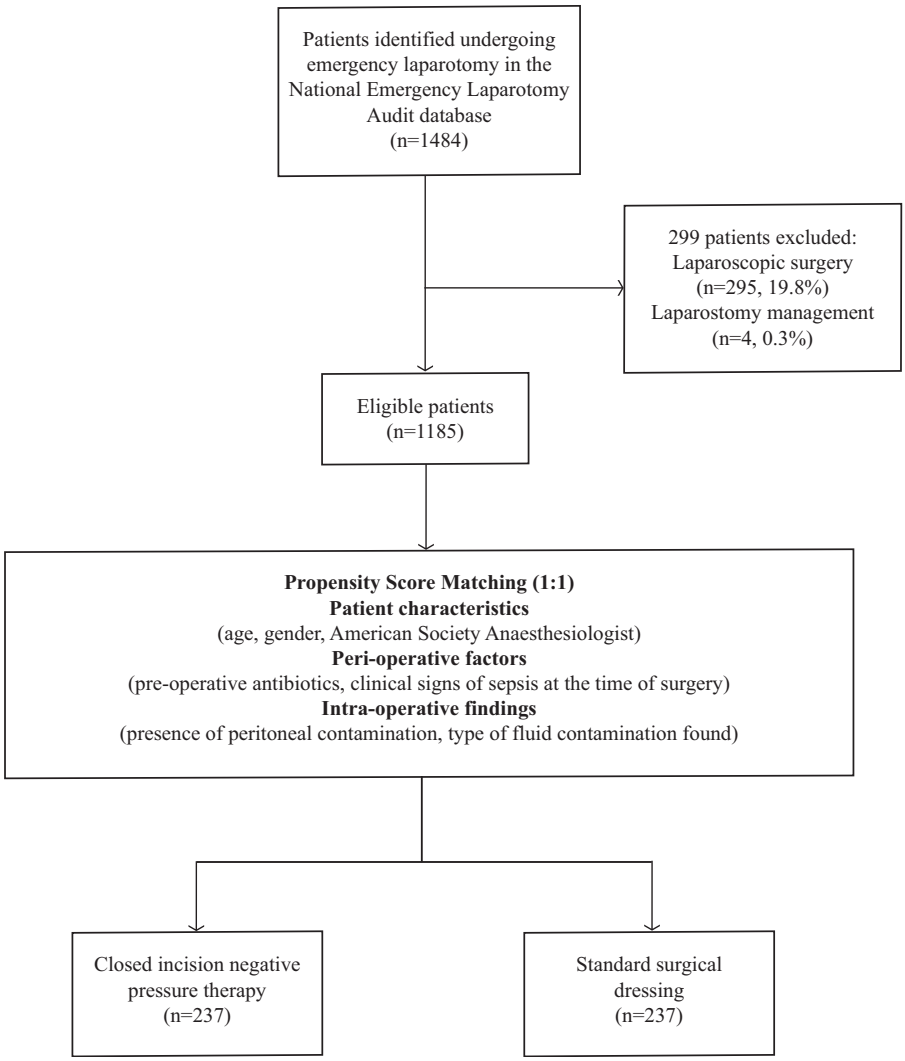

Fig. 1. Flowchart of patients included.

Patient and clinical characteristics

Patients' demographics including Charlson Comorbidity Index, ASA, and smoking status were similar between the 2 groups (Table I). The majority of patients underwent surgery for a National Confidential Enquiry into Patient Outcome and Death urgent classification. Patients receiving CINPT had a higher preoperative predicted Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM) morbidity compared to standard surgical dressing, with rates of 69.3 and 62.1%, $P < .001$, respectively, with no differences observed in predicted NELA mortality. There was no difference in preoperative antibiotic use between the 2 groups, with 89.4% ($n = 195$) in the CINPT group compared to 86.8% (171) in the standard dressing group, $P = .40$. There were significant differences in the types of preoperative skin preparation used between the 2 groups, with a higher rate of usage of 2% chlorhexidine gluconate solution in the CINPT arm ($n = 121$ [54.2%]), compared to a higher rate of povidone iodine aqueous solution used in the standard dressing arm ($n = 170$ [74.6], $P < .001$. A greater proportion of patients underwent colorectal resections in the CINPT compared to standard surgical dressing; 51.8% ($n = 117$) vs 34.7% ($n = 76$), $P < .001$ (Supplementary Material). All midline wounds were closed at the end of the operation using the principles of mass closure, with no observed differences in the techniques employed for skin closure (Supplementary Material).

Postoperative outcomes

The overall incidence of SSI was 25.3% ($n = 120$). The rate of SSI in the CINPT cohort was 16.9% compared to 33.8% in the standard surgical dressing cohort, $P < .001$. The rate of superficial and deep infections was higher in the standard dressing arm compared to the CINPT, $P < .001$ (Table II). There were no overall differences in 30-day morbidity, Clavien-Dindo grade, CCI severity, length of hospital stay, reoperation rates, and 30-day mortality between the 2 groups.

Predictors of SSI

At bivariate logistic regression, the use of a standard surgical dressing ($P = .01$) and undergoing an emergency colorectal procedure ($P = .01$) were associated with a higher risk of developing a SSI (Table III). Patient factors such as smoking status, diabetes, CMI, and ASA grade were not associated with SSI. Perioperative factors of preoperative antibiotic use and skin preparation types were not associated with SSI. The presence of peritoneal contamination was found not to be an independent predictor of SSI.

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Table I
Patient demographics and clinical characteristics

Variable	CINPT No. (%)	Standard dressing No. (%)	P value
Mean age	57	60	.14
Sex			
Male	125 (52.7)	106 (44.7)	.98
Female	112 (47.3)	131 (55.3)	
ASA			
1	23 (9.7)	24 (10.1)	.95
2	79 (33.3)	76 (32.1)	
3	94 (39.7)	96 (40.5)	
4	38 (16.0)	36 (15.2)	
5	3 (1.3)	5 (2.1)	
Smoker	40 (17.2)*	40 (18.7)	**.35**
Charlson Comorbidity Index			
0	43 (19.0)	52 (22.7)	.80
1–2	62 (27.4)	60 (26.2)	
3–4	62 (27.4)	58 (25.3)	
>4	59 (26.1)	59 (25.8)	
Missing data	11 (4.6)	8 (3.3)	
Preoperative antibiotics	195 (89.4)	171 (86.8)	.40
Skin preparation			
Povidone iodine aqueous	91 (40.8)	170 (74.6)	<.001
Chlorhexidine aqueous	18 (8.1)	9 (3.9)	
2% Chlorhexidine gluconate	121 (54.2)	55 (24.1)	
Unspecified	7 (2.9)	3 (1.2)	
Clinical signs of sepsis at time of surgery	86 (41.7)	49 (36.8)	.52
NCEPOD urgency			
Immediate (<2 h)	37 (15.6)	23 (9.8)	.70
Urgent (2–6 h)	98 (41.4)	83 (35.3)	
Urgent (6–18 h)	57 (24.1)	69 (29.4)	
Expedited (>18 h)	43 (18.1)	55 (23.4)	
Emergency: resuscitation of >2 h	2 (0.8)	7 (2.9)	
Preoperative predicted POSSUM morbidity (%)	69.3	62.1	<.001
Preoperative predicted NELA mortality (%)	11.7	10.2	.63
Operative procedure types			
Upper gastrointestinal	21 (9.3)	26 (11.9)	.01
Colorectal	117 (51.8)	76 (34.7)	
Small bowel	60 (26.5)	81 (37.0)	
Stoma	7 (3.1)	10 (4.6)	
Other	32 (13.5)	44 (18.5)	
Peritoneal fluid contamination	111 (46.8)	89 (37.6)	.86
Degree of peritoneal contamination†			
Localized	64 (57.7)	45 (50.6)	.31
Generalized	47 (42.3)	44 (49.4)	
Type of fluid contamination†			
Pus	42 (37.8)	31 (34.8)	.82
Bile	6 (5.4)	4 (4.5)	.52
Upper gastrointestinal contents	16 (14.4)	14 (15.7)	.70
Small bowel content	8 (7.2)	10 (11.2)	.63
Feculant fluid	18 (16.2)	11 (12.4)	.18
Feces	13 (11.7)	14 (15.7)	.84
Blood/Hematoma	8 (7.2)	10 (19.8)	.87

ASA, American Society of Anesthesiologists; *CINPWT*, Closed incision negative pressure wound therapy; *NCEPOD*, National Confidential Enquiry into Patient Outcome and Death; NELA, National Emergency Laparotomy Audit; POSSUM, Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity.

* Data available on smoking status in 214 patients in this cohort.

† Denominator is the presence of peritoneal contamination; n = 111 in CINPWT and n = 89 in standard dressing.

Table II
Postoperative outcomes

Variable	CINPT	Standard dressing	P value
Surgical site infection	40 (16.9)	80 (33.8)	<.001
Classification of surgical site Infection*			
Superficial	19 (47.5)	47 (58.7)	<.001
Deep	3 (7.5)	12 (15.0)	
Organ space	14 (35.0)	17 (21.2)	
Unspecified	4 (10.0)	4 (5.0)	
30-day morbidity	131 (55.3)	146 (61.6)	.16
Clavien Dindo grade			
I	18 (13.7)	37 (25.3)	.09
II	68 (51.9)	59 (40.4)	
IIIa	18 (13.7)	19 (13.0)	
IIIb	16 (12.2)	18 (12.3)	
IVa	3 (2.3)	5 (3.4)	
IVb	3 (2.3)	0 (0.0)	
V	5 (3.8)	8 (5.5)	
Comprehensive complication index†	29.3 (+/-18.1)	30.8 (+/-22.6)	.55
Critical care stay			
ICU	3.3 (4.3)	2.6 (5.4)	.19
HDU	2.3 (2.5)	2.2 (2.5)	.58
Length of stay†	15.9 (+/-13.2)	15.9 (+/-18.4)	.97
Reoperation	11 (4.6)	18 (7.6)	.29
Mortality	12 (5.1)	9 (3.8)	.07

CINPT, closed incision negative pressure therapy; *ICU*, intensive care unit; *HDU*, high dependency unit; *SSI*, surgical site infection.

* The denominator is number of patients with SSI in each group. For the CINPT cohort n = 40 and the standard cohort n = 80.

† SD, standard deviation.

Discussion

Our study is the largest to date to investigate the role of CINPT in the emergency laparotomy setting. It demonstrates the benefit of prophylactic use of CINPT in the acute setting, with reduced rates of overall SSI rates compared to standard surgical dressing: 16.9% vs 33.8%, $P < .001$. Furthermore, there was an observed reduction in SSI rates across the superficial and deep CDC categories of SSI in the CINPT cohort. However, we observed higher rates of organ space infection within the CINPT group compared to the standard dressing: 35.0% vs 21.2%, $P < .001$. This reflects the mechanism of action of CINPT, which is targeted at the abdominal wall and does not extend beyond the fascial layer, and therefore would not be expected to effect organ space infection rates. Furthermore, organ space infection rates are not typically reported in this setting.[18–20] The higher rate of organ space infection is likely to reflect the higher rate of colorectal resections undertaken in the CINPT arm compared to the standard dressing arm, with rates of 51.8% and 34.7%, $P = .01$, respectively. We identified the use of standard dressing and colorectal resection to be independent risk factors for the development of SSI in the emergency setting. Despite the lower incidence of SSI in the CINPT arm, we did not identify differences between the 2 groups with regard to overall morbidity, length of stay, reoperation, or mortality.

Prophylactic CINPT has been previously associated with reducing SSIs in clean and clean-contaminated abdominal surgery.[21,22] However, its utility in the emergency setting may be potentially more impactful given the urgent nature of surgery coupled with the greater potential for peritoneal contamination. The evidence base for the use of CINPT in the emergency setting is limited, with only 3 studies—all of which consistently report the lower rates of SSI associated with CINPT use.[18–20] Hall et al reported a SSI rate of 7% in 85 patients undergoing emergency surgery and CINPT.[18] However, this heterogenous patient population included 10 (12.3%) patients undergoing stoma reversal and 26 (31.2%) patients being initially managed with an open abdomen. A case-control study of 96 patients undergoing emergency laparotomy by Schurtz et al reported a SSI rate of 6.25% in the CINPT arm compared to 22.9% in the standard arm, $P = .04$.[19] Liu et al reported lower rates of SSI in a propensity-matched cohort study with CINPT in 70 patients compared to standard surgical dressings, with reported SSI rates of 8.6% and 27.1% $P = .006$, respectively, with the greatest benefit observed

Table III
Independent predictors of SSI

Variable	Odds ratio	95% Confidence interval	P value
Smoking			
Nonsmoker	1	0.12–1.71	.14
Smoker	0.46	0.04–1.01	
Ex-smoker	0.20		
Diabetes			
None	1	0.18–9.2	.77
Diet controlled	4.12	0.3–8.3	
NIDDM	1.79	0.7–10.9	
IDDM	2.87		
Charlson Comorbidity Index			
0	1	0.32–5.18	.71
1–2	1.29	0.32–3.79	
3–4	1.10	0.52–0.66	
>5	2.25		
ASA			
1	1	0.11–12.6	.42
2	3.75	0.21–15.0	
3	5.73	0.32–20.7	
4	8.18	0.11–6.80	
5	2.75		
Skin preparation			
Povidone iodine aqueous	1	0.4–1.48	.07
Chlorhexidine aqueous	0.74	0.6–3.85	
2% Chlorhexidine Gluconate	1.50		
Preoperative antibiotics			
Yes	1	0.4 –10.7	.32
No	2.2		
Dressing			
CIPNT	1	1.2–4.86	.01
Standard	2.4		
Operative procedure types			
Upper gastrointestinal	1	0.21–9.68	.01
Colorectal	2.38	0.41–6.71	
Small bowel	0.52	0.70–7.56	
Stoma	1.02	0.27–5.20	
Other	0.37		
Peritoneal contamination			
Yes	1	0.22–1.49	.25
No	0.57		

ASA, American Society of Anesthesiologists; *CINPT*, closed incision negative pressure therapy; *NIDDM*, non-insulin dependent diabetes mellitus; *IDDM*, insulin dependent diabetes mellitus; *SSI*, surgical site infection.

in those with clean-contaminated and dirty wounds.[20] This study had a significantly higher proportion of patients with contaminated wounds, colorectal surgery, and presenting with a systematic inflammatory response in the CINPT group. All these factors are regarded to be associated with a high risk for the development of SSIs. In our study we propensity-matched our patient population for the presence of peritoneal contamination, the type of fluid peritoneal contamination found, and clinical signs of sepsis at time of surgery, thus controlling for some of these intraoperative risk factors and eliminating potential bias in the results. Interestingly, our rates of SSI are much higher than those reported previously by these 3 studies; this is likely a reflection of the robust reporting of SSI using standardized and accepted definitions in our study and its pragmatic nature, through its inclusion of all patients undergoing emergency surgery as recorded by the NELA data set.

Reducing SSI often requires a multimodal strategy consisting of multiple interventions across the perioperative pathway.[23] In the elective setting, this process includes preoperative optimization of potentially modifiable factors; however, this is not always feasible in the emergency setting due to having an unwell, septic, and comorbid population requiring timely and urgent intervention. Consequently, preventative strategies in this setting tend to focus on intra- and postoperative interventions. The World Society of Emergency Surgery advocates the use of triclosan-coated sutures, wound protectors, intraoperative normothermia, and CINPT.[24] Similarly, the World Health Organization recommends the use of CINPT in high-risk settings, alongside a number of other interventions.[25] In this study, patients received antibiotics preoperatively when clinically indicated and were appropriately propensity scored matched. All patients underwent standard general anesthesia including employing intraoperative normothermia. In our study, we found that there was greater use of 2% chlorhexidine gluconate skin preparation in combination with CINPT compared to standard surgical dressing (54.2% vs 24.1%, $P < .001$). The usage of skin preparation was based on surgical preference and represents the lack of a standardized SSI bundle in this cohort of patients. Previous works have identified that the use of 2% chlorhexidine gluconate skin preparation and the use of wound protectors reduce the rate of SSI in patients undergoing elective and emergency colectomy.[26] Although we did not find skin preparation to be an independent predictor of SSI at bivariate analysis, it is important to acknowledge the role that multimodal strategies play in reducing SSI. The use of CINPT in the emergency setting alongside other preventative strategies may possibly lead to the aggregation of marginal gains in reducing SSI in the emergency setting and warrants further investigation. Current clinical trials such as SUNRRISE and PROPEL will provide definitive, randomized controlled trial data on whether the use of CINPT in the emergency setting is clinically and cost-effective.[27,28]

The key strength of our work is using the NELA data set to identify all patients undergoing emergency laparotomy at our center. This mandatory data set reflects pragmatic, real-world data consisting of a heterogenous emergency surgery patient population. Additional supplementary data not routinely collected within NELA were collected, including SSI rates, morbidity, and grade of morbidity to identify important outcomes. This is the first occasion where the NELA registry has been used to provide real-world data to assess the clinical effectiveness of a novel intervention in the emergency setting. The use of routinely collected data sets has a number of advantages, including ensuring representativeness of the population under investigation and generalizability of the results obtained, thus ensuring external validity. The limitations of work include the unselected manner in which patients would have received CINPT, which would have been based on surgeon preference; however, to account for this we used propensity-matching to reduce potential selection bias. However, our propensity-matching did not account for other preventative measures, which may have contributed to the observed SSI rates. Furthermore, our study did not collect outcome data on wound healing rates in patients who developed a SSI, patient-reported outcomes of pain and discomfort, and associated costs. Our study adds to the growing evidence of the utility of CINPT in the emergency laparotomy setting and its impact on reducing SSI. Further work is required to assess whether this has broader patient benefit, in terms of quality-of-life outcomes, improved postoperative recovery, and cost-effectiveness.

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Conflict of interest/Disclosure

BG has received honoria from 3M for educational projects. All other authors have no conflict of interest.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.1016/j.surg.2021.04.009.

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