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Negative Pressure Dressings to Prevent Surgical Site Infection After Emergency Laparotomy
The SUNRRISE Randomized Clinical Trial

SUNRRISE Trial Study Group

IMPORTANCE Patients undergoing unplanned abdominal surgical procedures are at increased risk of surgical site infection (SSI). It is not known if incisional negative pressure wound therapy (iNPWT) can reduce SSI rates in this setting.

OBJECTIVE To evaluate the effectiveness of iNPWT in reducing the rate of SSI in adults undergoing emergency laparotomy with primary skin closure.

DESIGN, SETTING, AND PARTICIPANTS SUNRRISE was an assessor-masked, pragmatic, phase 3, individual-participant, randomized clinical trial. Adult patients undergoing emergency laparotomy in 22 hospitals in the UK and 12 hospitals in Australia between December 18, 2018, and May 25, 2021, were recruited. Patients were followed up for 30 days postprocedure; database closure was on August 25, 2021.

INTERVENTIONS Participants were randomized 1:1 to receive iNPWT (n = 411), which involved a specialized dressing used to create negative pressure over the closed wound vs the surgeon's choice of wound dressing (n = 410). Randomization and dressing application occurred in the operating room at the end of the surgical procedure.

MAIN OUTCOMES AND MEASURES The primary outcome measure was SSI up to 30 days postprocedure, evaluated by an assessor masked to the randomized allocation and using criteria from the US Centers for Disease Control and Prevention. There were 7 secondary outcomes, including length of hospital stay, postoperative complications up to 30 days, hospital readmission for wound-related complications within 30 days, wound pain, and quality of life.

RESULTS A total of 840 patients were randomized (536 from the UK; 304 from Australia). Overall, 52% were female; the mean age was 63.8 (range, 18.8 to 95.3) years. After postrandomization exclusions (N = 52), 394 participants per group were included in the primary analysis. The number of participants who had an SSI in the iNPWT group was 112 of 394 (28.4%), compared with 108 of 394 (27.4%) in the surgeon's preference group (relative risk, 1.03 [95% CI, 0.83-1.28]; *P* = .78). This finding was consistent across the preplanned subgroup analyses, including degree of contamination, presence of a stoma, participant body mass index, and skin preparation used, and across all preplanned sensitivity analyses. Of 7 secondary outcomes, 6 showed no significant difference, including hospital readmission, quality of life, and hospital stay (median [IQR], 8 [6-14] days in the iNPWT group and 9 [6-14.5] days in the surgeon's preference group [ratio of geometric means, 0.96 (95% CI, 0.88-1.06); *P* = .21]).

CONCLUSIONS AND RELEVANCE Routine application of iNPWT to the closed surgical wound after emergency laparotomy did not prevent SSI more than other dressings.

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Supplemental content

CME Quiz at jamacmelookup.com

Group Information: The SUNRRISE Trial Study Group authors appear at the end of the article. The nonauthor collaborators of the SUNRRISE Trial Study Group appear in Supplement 2.

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Surgical site infection (SSI) affects up to 40% of patients after emergency laparotomy[1,2] and is a substantial burden for patients, hospitals, and health care systems.[3-5] It is associated with delayed healing, wound dehiscence, long-term risk of hernia, longer inpatient stay, and increased hospital readmissions with high health care costs. Emergency abdominal surgical procedures are 1 of the 3 bellwether procedures defined by the World Health Organization (WHO) as underpinning surgical delivery worldwide.[6] They are central to the treatment of many noncommunicable diseases, such as cancer and trauma, comprising 9.1% to 21.1%[7] of total surgical activity in high- and low-income health systems, respectively. Patients undergoing emergency laparotomy are at high risk of SSI due to intra-abdominal contamination, higher rates of stoma formation, and higher physiological severity scores compared with elective surgical procedures.

One potential strategy for SSI prevention is the prophylactic application of incisional negative pressure wound therapy (iNPWT) via a single-use negative pressure dressing onto the closed incision site. These dressings consist of a small, battery-powered suction pump that delivers a negative pressure field via flexible tubing to the dressing applied to the wound. This has a unit cost of approximately US $150 to $180[8] and reduces SSI by removing exudate, increasing blood flow to the wound, and stimulating healing.

There is mixed evidence about the effectiveness of iNPWT in abdominal operations.[9,10] However, the 2018 WHO SSI prevention guidelines[11] made a conditional recommendation for its use in patients "at high-risk of SSI," which is also supported by National Institute for Health and Care Excellence guidance in the UK.[8]

To date, no trials to our knowledge have assessed the efficacy of iNPWT following emergency laparotomy. The Single Use Negative Pressure Dressing for Reduction in Surgical Site Infection Following Emergency Laparotomy (SUNRRISE) trial aimed to fill this evidence gap.

Key Points

Question Among patients undergoing emergency laparotomy, is there a difference in surgical site infection (SSI) rates when the wound is treated with incisional negative pressure wound therapy (iNPWT) vs the surgeon's choice of wound dressing?

Findings In this randomized clinical trial of 840 adults undergoing emergency laparotomy in the UK and Australia, there was no statistically significant difference in the rate of SSI at 30 days between iNPWT (28.4%) and the surgeon's choice of wound dressing (27.4%).

Meaning The findings do not support the routine use of iNPWT for the reduction of SSI in adults undergoing emergency laparotomy.

Methods

SUNRRISE was a pragmatic, international, assessor-masked, IDEAL (Idea, Development, Exploration, Assessment and Long-term follow-up) framework stage 3, individually randomized clinical trial (RCT) evaluating the use of iNPWT to reduce the risk of SSI in adults undergoing emergency laparotomy. This report complies with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for RCTs (**Figure 1**).[12]

Ethics and Governance

The trial took place in 22 centers across the UK and 12 in Australia. Ethical approval was obtained in England and Wales (18/YH/0322), Scotland (19/SS/0065), and Australia (2019/ETH00189). The trial was registered in ISRCTN (17599457) and ANZCTR (12619000496112), and the protocol was published elsewhere.[13] Independent data monitoring and steering committees monitored data quality, patient safety, and progress.

Eligibility Criteria

Any patient undergoing an emergency laparotomy at a participating site was potentially eligible. Emergency surgical procedures were defined as operations performed on the same admission as diagnosis of the condition being treated (ie, including all unplanned, expedited, and emergency cases). Patients were eligible if they were 16 years or older in the UK or 18 years or older in Australia, were undergoing a laparotomy with an incision of 5 cm or more, and with primary closure of the abdominal wall fascia and skin. Laparotomies for any indication and via any incision site were eligible, including laparoscopic-assisted cases, as long as an extraction site (or conversion) resulted in an incision of 5 cm or more. Patients were excluded if they had undergone an abdominal surgical procedure within the previous 3 months, were planned to return for reopening of their laparotomy wound within 30 days of the surgical procedure, or were not expected to survive beyond 30 days.

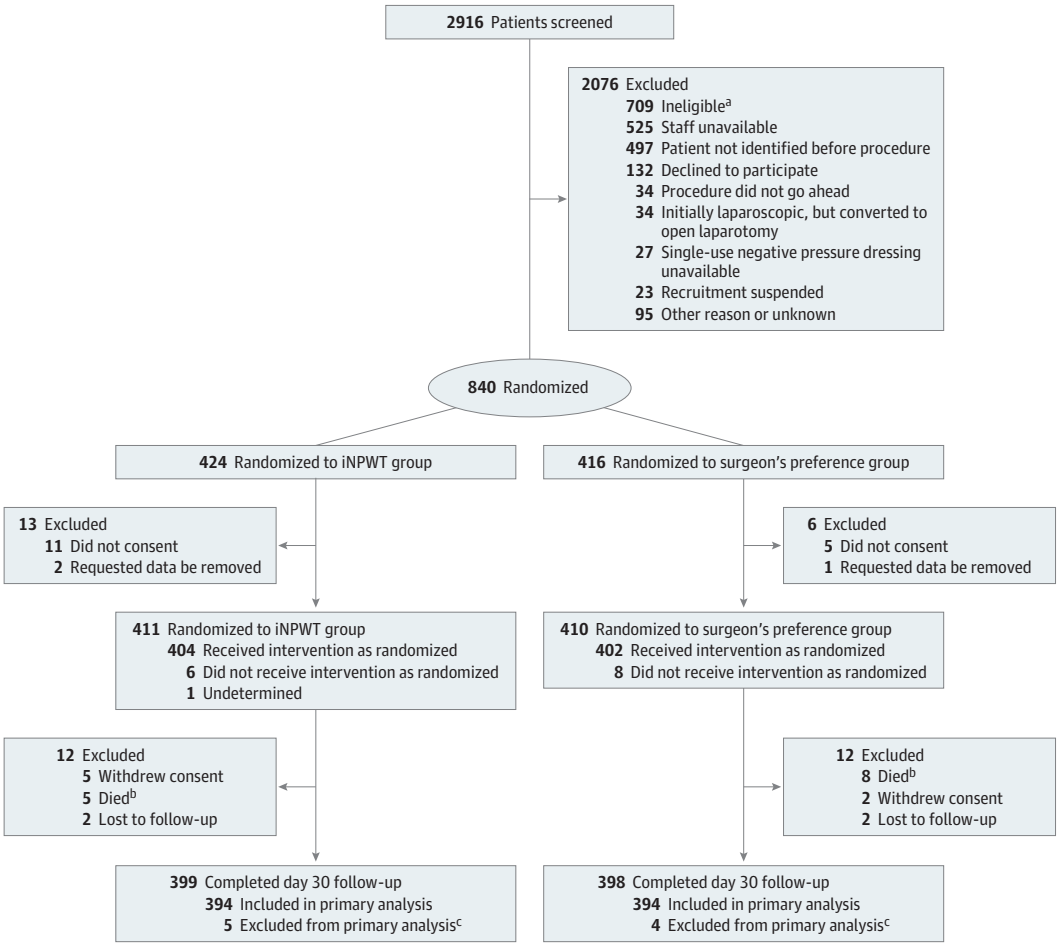
Trial Recruitment

Enrollment processes were optimized to facilitate the identification, consent, and randomization of patients in the emergency setting by surgical trainees (residents). Eligible patients were approached as soon as possible after a decision for a surgical procedure was made. Consent was obtained by a trained member of the clinical research team, typically a surgical trainee who, in both the UK and Australia, provided 24-hour coverage within the emergency surgery service. Some patients requiring an emergency laparotomy temporarily lacked the capacity to give informed consent. To facilitate their inclusion, in the UK, patients could enter the trial with the written assent or consent of a personal consultee or legal representative. Only patients able to provide written consent themselves were included in Australia.

Randomization, Blinding, and Minimization

Patients were individually randomized in a 1:1 ratio to receive either iNPWT or the operating surgeon's dressing preference. Randomization was minimization algorithm was used to ensure balance between treatment groups over variables deemed to be of the highest clinical importance,

Figure 1. Recruitment, Randomization, and Follow-Up in the SUNRRISE Trial



iNPWT indicates incisional negative pressure wound therapy.

[a]Reasons for ineligibility were abdominal operation within the preceding 3 months of randomization (286), long-term incapacity or unable to provide informed consent (114), procedure not an emergency laparotomy (100), expected to return for reopening of the laparotomy wound within 30 days (56), unwilling or unable to attend follow-up at 30 days (49), incision of less than 5 cm (47), skin not primarily closed (26), personal consultee or legal representative unavailable (22), and younger than 16 years (9).

[b]A total of 25 deaths were reported (10 in the iNPWT group and 15 in the surgeon's preference group), of which 12 participants (5 in the iNPWT group and 7 in the surgeon's preference group) provided primary outcome data prior to death and therefore were included in the primary analysis.

[c]Despite completing the day 30 follow-up, patients were missing data for US Centers for Disease Control and Prevention criteria, which resulted in the primary outcome not being computed.

including degree of contamination found at operation (clean, clean-contaminated, contaminated, or dirty), presence of a stoma at the end of the operation, and recruiting center. To ensure the randomization process was not completely deterministic, a random element was included in the minimization algorithm. Randomization was performed in the operating room by an unscrubbed team member while the skin was being closed at the end of the procedure. This policy optimized allocation concealment and minimized performance bias. It also allowed for confirmation of eligibility and minimization criteria to be based on the confirmed (rather than predicted) degree of contamination and presence of stoma. Patients and surgeons were not masked to the treatment allocation.

Trial Interventions

The randomized treatment allocation of iNPWT or the surgeon's dressing preference was immediately applied to the wound after skin closure while the patient was still in the operating room. The iNPWT used in this study was a PICO 7 topical negative pressure dressing (Smith & Nephew). This dressing provides −80-mm Hg negative pressure across the wound. Clinicians applying the iNPWT received training overseen by the product manufacturer. The iNPWT was intended to remain in place for 7 days or until discharge (whichever came first). Clinical teams were encouraged not to disturb the dressing unless necessary. Participants were provided with at least 1 replacement dressing to be used if required (allowing for assessment or wound care); immediate

replacement was not classified as nonadherence, as this reflects real-world use.

The control group was pragmatic and permitted the operating surgeon's choice of any simple dressing. This could be conventional occlusive dressings, skin glue, or no dressing, but could not be an iNPWT. As the use of silver-, honey-, or iodine-based dressings is atypical and there are limited data on the potential effectiveness of the active component, these were also not permitted. Participants in the surgeon's preference group had their dressing changed and left in place according to local practice. In both groups, centers were allowed to perform their standard perioperative SSI prevention activities.

Outcomes

The primary outcome measure was SSI up to 30 days postprocedure (with day 0 being the day of the operation), defined by the US Centers for Disease Control and Prevention (CDC) criteria (eFigure 2 in Supplement 3). Both superficial and deep incisional SSIs were included in the outcome definition; the presence of either or both was classified as a binary "yes" for analysis. Wound assessments for SSI were completed on postoperative days 7 to 10 (or on the day of discharge, if earlier), before any reoperation, and as close as possible after postoperative day 30, with the intervening period covered by a patient-completed wound diary. The 30-day assessment was performed by experienced wound assessors masked to the randomization allocation. If a patient died, withdrew consent, or was lost to follow-up and had an SSI before this point, they were included as having an SSI event. If a patient dropped out before completing the 30-day assessment and did not have an SSI before this point, they were classified as missing 30-day outcome data.

Secondary outcomes included length of stay (LOS) in the hospital; complications (classified as wound-related [excluding SSI] or other), graded using the 6-level Clavien-Dindo classification scale[14] up to 30 days after the procedure; hospital readmission for wound-related complications within 30 days; pain at the site of the primary laparotomy, assessed using a 10-point visual analog scale at days 7 and 30; health-related quality of life using the 12-Item Short Form (SF-12) health survey at days 7 and 30 and the EuroQoL 5-Dimension 5-Level (EQ-5D-5L) survey at days 7, 14, 21, and 30; and serious adverse events, including postoperative mortality up to day 30. See Supplement 4 for the full trial protocol.

Statistical Analysis

This study was powered to detect a 40% relative reduction in SSI rate (or 10% absolute difference from 25% to 15% with iNPWT) with 90% power, a type I error rate of 5% ($\alpha = .05$), and a predicted 20% attrition rate. This required 420 participants per group (840 in total). All primary analyses were based on the complete case set (ie, all available data without any imputation) and the intention-to-treat principle (ie, patients analyzed in the group they were randomized). The analyses used a model-based approach, with the minimization variables used in the randomization algorithm included as covariates in the model (center was included as a random effect) and baseline scores where appropriate. All estimates of treatment effects are presented with 95% CIs. Analyses were performed using SAS version 9.4 (SAS Institute) and Stata version 17 (StataCorp). The number of participants reporting an SSI up to 30 days postprocedure in the 2 groups was compared using a mixed-effects binomial regression model. A log link was used in the model to obtain the adjusted relative risk (RR) and an identity link was used to obtain the adjusted risk difference (RD). Sensitivity analyses were performed to assess the robustness of the results (eg, per-protocol analysis, limiting the analysis to cases where the 30-day follow-up assessment took place within the prespecified 30- to 44-day data collection window, excluding cases where an SSI was identified solely via the patient diary, and imputing best- and worst-case scenarios for SSI). A post hoc tipping point analysis was also performed to explore whether missing outcomes were missing not at random (eFigure 4 in Supplement 3).

Categorical secondary outcome measures were analyzed similarly to the primary outcome. LOS data were analyzed using a mixed-effect linear regression model; data were not normally distributed, so were log-transformed before model fitting. Model estimates were then exponentiated to obtain an adjusted ratio of geometric means. Longitudinal continuous data (SF-12 and EQ-5D-5L) were analyzed using a mixed-effect linear regression model to obtain an adjusted mean difference. A treatment × time interaction term was included in the model and an independent covariance structure was assumed.

Prespecified subgroup analyses were undertaken for the primary outcome only. These included the minimization variables, such as operative contamination and presence of a stoma, as well as operative procedure, type of skin preparation, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared), and country. Considering the pathway changes resulting from the SARS-CoV-2 pandemic, we included a subgroup analysis based on the wound assessment method and the date the global pandemic was declared (patients randomized before or after March 11, 2020). The effects of these subgroups were examined by including the relevant subgroup by treatment group interaction term in the binomial model for each subgroup analysis. The statistical analysis plan is provided in Supplement 1. A PRECIS-2 wheel was included to identify where the design sat on the pragmatic-explanatory continuum (eFigure 1 in Supplement 3).

Results

Recruitment

Between December 18, 2018, and May 25, 2021, 840 patients were randomized from 22 centers in the UK (536 participants) and 12 in Australia (304 participants). Nineteen participants were withdrawn after randomization but prior to collection of any trial-related data (16 in Australia due to issues with paperwork related to consent and 3 participants who withdrew). Of the 821 patients remaining, 411 were randomized to receive iNPWT and 410 to receive the surgeon's preference of wound dressing. Baseline data of participants (**Table 1**) and surgical procedure characteristics (**Table 2**) are presented. The

Table 1. Baseline Data

	No. of participants (%)	
	iNPWT group (n = 411)	Surgeon's preference group (n = 410)
Demographic data		
Age, mean (SD), y	63.8 (15.9)	63.7 (16.4)
Sex		
Male	204 (49.6)	186 (45.4)
Female	207 (50.4)	224 (54.6)
BMI, mean (SD) [No.]	27.1 (7.4) [398]	27.2 (7.0) [388]
Smoking status		
Total No.	405	402
Never smoked	220 (53.5)	223 (54.4)
Currently smokes	95 (23.1)	70 (17.1)
Previously smoked	90 (21.9)	109 (26.6)
Diabetes	40 (9.7)	40 (9.8)
Diabetes management, No./total No. (%)		
Diet controlled	13/40 (32.5)	9/40 (22.5)
Tablet controlled	16/40 (40.0)	21/40 (52.5)
Insulin controlled	11/40 (27.5)	10/40 (25.0)
Serum albumin level, mean (SD), g/L [No.]	33.9 (8.4) [406]	34.6 (8.0) [405]
Immunosuppressive therapy	39 (9.5)	41 (10.0)
Clinically jaundiced (or serum bilirubin >50 µmol/L)	4 (1.0)	1 (0.2)
Active malignancy	84 (20.4)	76 (18.5)
Country		
UK	264 (64.2)	265 (64.6)
Australia	147 (35.8)	145 (35.4)
Minimization variables		
Degree of operative field contamination		
Clean	98 (23.8)	99 (24.1)
Clean-contaminated	175 (42.6)	176 (42.9)
Contaminated	81 (19.7)	79 (19.3)
Dirty	57 (13.9)	56 (13.7)
Stoma present		
Preexisting	22 (5.3)	27 (6.6)
Formed during this operation	131 (31.9)	126 (30.7)
Surgical procedure data		
ASA physical status class		
I (Normal healthy)	29 (7.1)	29 (7.1)
II (Mild systemic disease)	162 (39.4)	157 (38.3)
III (Severe systemic disease)	173 (42.1)	178 (43.4)
IV (Severe systemic disease that is a constant threat to life)	43 (10.5)	43 (10.5)
V (Moribund patient who is not expected to survive without the operation)	4 (1.0)	3 (0.7)
Prophylactic antibiotics administered		
Yes (on induction)	310 (75.4)	332 (81)
Yes (during procedure)	80 (19.5)	61 (14.9)
Yes (on induction and during procedure)	8 (1.9)	8 (2.0)
Continued antibiotics postoperatively	234 (56.9)	236 (57.6)

(continued)

Table 1. Baseline Data (continued)

	No. of participants (%)	
	iNPWT group (n = 411)	Surgeon's preference group (n = 410)
Skin preparation used		
Total No.	411	409
2% Alcoholic chlorhexidine	192 (46.7)	183 (44.6)
0.5% Alcoholic chlorhexidine	56 (13.6)	62 (15.1)
Aqueous povidone-iodine	54 (13.1)	52 (12.7)
Alcoholic povidone-iodine	44 (10.7)	46 (11.2)
2% Aqueous chlorhexidine	34 (8.3)	32 (7.8)
0.5% Aqueous chlorhexidine	28 (6.8)	33 (8.0)
Other	3 (0.7)	1 (0.2)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); iNPWT, incisional negative pressure wound therapy.

SI conversion factors: to convert serum albumin to g/dL, divide by 10; serum bilirubin to mg/dL, divide by 17.104.

mean age of trial participants was 63.8 (range, 18.8-95.3) years and 390 (48%) were male. Mean BMI was 27.1 and 54% (444/821) were American Society of Anesthesiologists (ASA) classes 3 to 5. In terms of operative field contamination, 24% of participants (197/821) underwent clean, 43% (351/821) clean-contaminated, 19% (160/821) contaminated, and 14% (113/821) dirty surgical procedures.

Adherence

Randomization, allocation adherence, and exclusions are shown in the CONSORT diagram (Figure 1) (eTable 1 in Supplement 3). Adherence to trial allocation was 98% in both groups. For patients randomized to receive iNPWT, the dressings remained in place for 3 days or longer (or until discharge if discharged earlier than day 3) in 93% of participants (382/411) and for all 7 days (or until discharge if discharged earlier than day 7) in 64% of participants (264/411). Reasons for removing the iNPWT included dressing failure due to air leaks, patient dissatisfaction, and clinical need to examine the wound.

Primary Outcome

The number of participants who developed an SSI up to 30 days postprocedure was 112 of 394 (28.4%) in the iNPWT group, compared with 108 of 394 (27.4%) in the surgeon's preference group (RR, 1.03 [95% CI, 0.83-1.28]; $P = .78$) (**Table 3**) (eTable 6 in Supplement 3). This finding was robust when assessed in a variety of prespecified sensitivity analyses, including a per-protocol analysis (RR, 1.00 [95% CI, 0.80-1.25]; $P = .98$) (eFigure 3 in Supplement 3). There was no evidence that the treatment effect differed according to various participant or operative characteristics (**Figure 2**).

Secondary Outcomes

In UK participants, the median (IQR) LOS was 9 (7-15) days in the iNPWT group and 11 (7-16) days in the surgeon's preference group (ratio of geometric means, 0.91 [95% CI, 0.82-1.02]; $P = .12$). When the Australian sites were included, the median (IQR) LOS for the iNPWT group was 8 (6-14) days and 9 (6-14.5) days for the surgeon's preference group (ratio of geometric means, 0.96 [95% CI, 0.88-1.06]; $P = .21$). The number of participants with wound complications up to 30 days postprocedure (19% in the iNPWT group vs 18% in the surgeon's preference group; RR, 1.04 [95% CI, 0.78-1.39]; $P = .79$) and hospital readmission for wound-related complications within 30 days (3% in the iNPWT group vs 3% in the surgeon's preference group; RR, 1.02 [95% CI, 0.45-2.31]; $P = .96$) were similar across the 2 groups (eTables 5a-5b in Supplement 3). Participants in the iNPWT group reported lower pain at the laparotomy site at 7 days (mean [SD], 2.6 [2.1] points) compared with those in the surgeon's preference group (3 [2.2] points; mean difference, −0.41 [95% CI, −0.7 to −0.12]; $P = .01$) (Table 3). There were no differences in quality of life between the 2 groups (eTables 2-4 in Supplement 3).

Safety Outcomes

There were 496 serious adverse events (SAEs) reported (237 in the iNPWT group and 259 in the surgeon's preference group). SAEs occurred in 158 of 411 participants (38%) in the iNPWT group and 165 of 410 participants (40%) in the surgeon's preference group (individual participants may have had more than 1 SAE). Rates of specific SAEs were similar across groups, including enterocutaneous fistulae (iNPWT, 0/411; surgeon's preference, 1/410) and adverse skin reactions (iNPWT, 5/411; surgeon's preference, 2/410). Mortality within 30 days of the operation was 3%, with 10 deaths (2.4%) in the iNPWT group and 14 deaths (3.4%) in the surgeon's preference group.

Discussion

The results of this RCT demonstrate that iNPWT was not effective in reducing SSI in patients undergoing an emergency laparotomy. This finding was robust to sensitivity analyses and was consistent across all preplanned subgroups, including the degree of contamination, presence of a stoma, participant BMI, and skin preparation used. No differences were observed in the majority of secondary outcomes, apart from a small reduction in wound-related pain score at day 7 in the iNPWT group, but the difference observed was small in absolute terms (difference of 0.4 points on a 10-point Likert scale) and is therefore of uncertain clinical significance. The adherence to trial allocation (98%) was high, and the application and monitoring of the interventional dressing were ensured through standardized training and support. SUNRRISE completed on time and on target. It demonstrated

Table 2. Intraoperative Data

	No. of participants (%)	
	iNPWT group (n = 411)	Surgeon's preference group (n = 410)
Actual procedure performed		
Bowel (colonic[a])	202 (49.1)	198 (48.3)
Bowel (noncolonic[b])	97 (23.6)	99 (24.1)
Nonbowel[c]	112 (27.3)	112 (27.3)
Other	0	1 (0.2)
Surgical approach		
Open (midline)	359 (87.3)	366 (89.3)
Open (nonmidline)	18 (4.4)	9 (2.2)
Laparoscopic assisted/laparoscopic converted	34 (8.3)	35 (8.5)
Length of the incision, median (IQR), cm [No.]	20 (15-25) [395]	17.3 (14-23) [392]
WHO safety checklist used	402 (97.8)	402 (98.0)
MRSA colonization	3 (0.7)	9 (2.2)
Malignancy present	106 (25.8)	110 (26.8)
Estimated blood loss, mL		
Total No.	407	406
<100	274 (66.7)	249 (60.7)
100-500	115 (28.0)	144 (35.1)
501-1000	16 (3.9)	9 (2.2)
>1000	2 (0.5)	4 (1.0)
Intraoperative blood transfusion required	13 (3.2)	15 (3.7)
Received inotropes at the end of the operation	74 (18.0)	79 (19.3)
Wound edge protection device used[d]	107 (26.0)	99 (24.1)
Triclosan-impregnated suture used	3 (0.7)	8 (2.0)
Catheters left in place for local anesthetic infiltration	169 (41.1)	205 (50.0)
Adhesive or incise drape used[e]		
Yes (iodine-impregnated)	18 (4.4)	23 (5.6)
Yes (plain incise drape)	68 (16.5)	64 (15.6)
Wound/incision wash performed		
Yes (povidone-iodine)	72 (17.5)	73 (17.8)
Yes (saline/water)	104 (25.3)	113 (27.6)
Yes (other)	21 (5.1)	20 (4.9)
Gloves changed before closing	148 (36.0)	148 (36.1)
Instruments changed before closing	39 (9.5)	39 (9.5)
Skin closure approach		
Staples	233 (56.7)	215 (52.4)
Continuous sutures	178 (43.3)	190 (46.3)
Interrupted sutures	0	5 (1.2)
Level of operating surgeon[f]		
Consultant	319 (77.6)	318 (77.6)
Registrar	123 (29.9)	110 (26.8)
Senior house officer	4 (1.0)	1 (0.2)
Level of surgeon closing fascia[f]		
Consultant	201 (48.9)	193 (47.1)
Registrar	218 (53.0)	225 (54.9)
Senior house officer	26 (6.3)	15 (3.7)
Level of surgeon closing skin[f]		
Consultant	115 (28)	102 (24.9)
Registrar	214 (52.1)	241 (58.8)
Senior house officer	96 (23.4)	73 (17.8)
Total duration of operation, median (IQR), min [No.]	120 (90-180) [408]	120 (90-180) [405]

Abbreviations: iNPWT, incisional negative pressure wound therapy; MRSA, methicillin-resistant *Staphylococcus aureus*; WHO, World Health Organization.

[a] Involving the large intestine or rectum.

[b] Involving other parts of the abdominal gastrointestinal tract (eg, stomach, duodenum, jejunum, ileum).

[c] Involving other abdominal organs or structure.

[d] An impervious sterile plastic sheet circumferentially attached to an internal semirigid plastic ring, which protected the wound edges during the procedure; both 1- and 2-ring devices were included.

[e] An adhesive polymer film placed over the operative site prior to incision.

[f] International medical staff seniority equivalents: consultant, an attending or staff physician; registrar, those in fellowship or more senior resident roles; senior house officer, those in the first 2 years of surgical training (may be equivalent to a junior resident).

that trial delivery by surgical trainees (residents) can enable participant recruitment to trials in urgent conditions that have traditionally been challenging to recruit within. This also improved the resilience of delivery, with the trial continuing even during the SARS-CoV-2 pandemic.

This trial was initiated based on the WHO guidelines recommending using iNPWT in high-risk wounds. A meta-analysis published after SUNRRISE began reported that topical negative pressure dressings reduce the rate of SSI by an RR of 0.61.[9] However, this included all RCTs regardless of size, methodological limitations, or the organ system involved. Of the 28 RCTs that reported SSI as an outcome, only 7 had more than 100 participants per group and of these, only 2 RCTs found the dressings effective. Additionally, none of the 28 trials included focused on the emergency laparotomy population. SUNRRISE provides data to support decision-making in emergency abdominal surgical procedures. Two large, high-quality RCTs in different high-risk patient groups published in 2020 also reported a lack of benefit from negative pressure dressings in reducing SSI.[15,16]

The outcome assessment method, particularly postdischarge, is a key quality criterion in SSI trials.[17] In this trial, this was initially a face-to-face assessment at the postoperative follow-up visit to the hospital. When the Australian sites opened, follow-up assessments via videoconferencing were permitted, as this was already used within routine practice. Concurrently, due to the SARS-CoV-2 pandemic, nearly all trial

Table 3. Primary and Secondary Outcomes

Outcomes	No./total No. (%)[a]		Difference (95% CI)		P value
	iNPWT group	Surgeon's preference group	Absolute	Relative[b]	
Primary outcome (primary analysis)					
SSI within 30 d of surgical procedure	112/394 (28)	108/394 (27)	0.010 (−0.050 to 0.071)	1.03 (0.83 to 1.28)	.78
Secondary outcomes					
Length of hospital stay after procedure (UK patients only), median (IQR), d	9 (7-15)	11 (7-16)		0.91 (0.82 to 1.02)[c]	.12
Length of hospital stay after procedure (UK and Australian patients), median (IQR), d	8 (6-14)	9 (6-14.5)		0.96 (0.88 to 1.06)[c]	.21
SF-12 PCS at 30 d, mean (SD)[d]	36.1 (9.8)	37.2 (10.2)	−0.86 (−2.83 to 1.11)		.39
SF-12 MCS at 30 d, mean (SD)[d]	46.9 (11.8)	47.7 (12.0)	−1.90 (−4.28 to 0.47)		.12
Pain at site of primary laparotomy at 7 d, mean (SD)[e]	2.6 (2.1)	3.0 (2.2)	−0.41 (−0.70 to −0.12)		.01
Pain at site of primary laparotomy at 30 d, mean (SD)[e]	1.8 (1.5)	1.8 (1.6)	−0.06 (−0.28 to 0.16)		.61
Patient acceptability of the use of their dressing, mean (SD)[f]	2.5 (2.5)	2.1 (2.2)			
Secondary safety outcomes					
Hospital readmission for wound-related complications	11/399 (3)	11/398 (3)	0.010 (−0.014 to 0.034)	1.02 (0.45 to 2.31)	.96
Wound complications within 30 d postprocedure	73/392 (19)	71/397 (18)	0.007 (−0.046 to 0.060)	1.04 (0.78 to 1.39)	.79
Wound complication grading by Clavien-Dindo[g]					
I (None/conservative management or on-ward intervention)	53	47			
II (Antibiotic drug treatment)	16	17			
III (Radiological or surgical intervention)	4	7			
IV (ITU admission)	0	0			
V (Death)	0	0			
SAEs					
Patients with an SAE	158/411 (38)	165/410 (40)			
Total No. of SAEs	237	259			
Mortality within 30 d	10/411 (2)	14/410 (3)			

Abbreviations: iNPWT, incisional negative pressure wound therapy; ITU, intensive therapy unit; MCS, mental component score; PCS, physical component score; SAE, serious adverse event; SF-12, 12-Item Short-Form health survey.

[a] Unless otherwise indicated. All analyses were adjusted for minimization variables.

[b] All treatment effects are shown as the relative risk except as marked. A relative risk less than 1 (and absolute difference less than 0) favored the iNPWT group.

[c] The data for length of hospital stay were not normally distributed and therefore were log-transformed prior to analysis then exponentiated, so the treatment effect is expressed as the ratio of geometric means.

[d] Scores range from 0 to 100, with higher scores indicating better outcomes.

[e] Scores range from 1 to 10, with 1 indicating no pain at all and 10 indicating the worst possible pain.

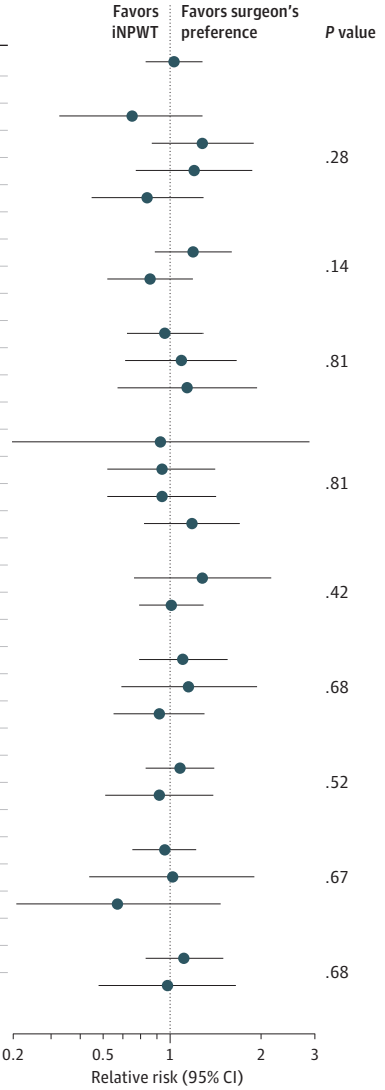
[f] Scores range from 1 to 10, with 1 indicating completely acceptable and 10 indicating totally unacceptable.

[g] For information on the Clavien-Dindo scoring system, see Dindo et al.[14]

follow-up was undertaken remotely from early 2020 onward. Although this rapid and iterative change in procedure successfully reduced attrition bias, differences in SSI rates depending on the assessment method were observed. Of the participants who underwent in-person wound review, 36% in the iNPWT group (77/214) and 37% in the surgeon's preference group (78/209) had an SSI, compared with 21% when using video assessment (iNPWT, 15/72 [21%]; surgeon's preference, 16/76 [21%]) and 14% when using phone-only follow-up (iNPWT, 9/76 [12%]; surgeon's preference, 13/76 [17%]). The difference in SSI rates observed between the methods suggests that clinicians can more readily apply the criteria for determining an SSI when able to see a wound in person than via a video link or over the phone. This raises important questions about the fidelity of the CDC SSI definitions when applied remotely. Similar differences in SSI rates according to the follow-up method have been found in other trials and a meta-analysis.[17,18] Although unlikely to have introduced differential misclassification by randomization group, the true SSI rate may be higher than reported. This is a challenging population to robustly study, given the emergency surgical setting, but the overall SSI rate of 28% is similar to the cohort of patients undergoing emergency laparotomy within the ROSSINI[19] trial and also in those identified in a meta-analysis of patients undergoing elective colorectal resection.[20] Tools such as the Bluebelle Wound Healing Questionnaire have shown utility in improving the diagnostic accuracy of remote SSI detection.[21]

Figure 2. Subgroup Analysis

Characteristic	No. of patients with SSI within 30 d of procedure: iNPWT group (n = 394)	Surgeon's preference group (n = 394)	Relative risk (95% CI)	P value
Primary analysis	112	108	1.03 (0.83-1.28)	
Degree of contamination				
Clean	18	24	0.75 (0.43-1.28)	
Clean-contaminated	44	35	1.28 (0.87-1.89)	.28
Contaminated	29	23	1.20 (0.77-1.87)	
Dirty	21	26	0.84 (0.55-1.29)	
Stoma presence				
No	70	59	1.19 (0.89-1.60)	.14
Yes	42	49	0.86 (0.62-1.19)	
Surgical procedure				
Bowel (colonic)	60	60	0.96 (0.72-1.28)	
Bowel (noncolonic)	29	28	1.09 (0.71-1.66)	.81
Nonbowel	23	20	1.14 (0.67-1.94)	
BMI				
<18.5 (underweight)	5	4	0.93 (0.30-2.89)	
18.5-24.9 (healthy weight)	33	37	0.94 (0.62-1.41)	.81
25.0-29.9 (overweight)	30	30	0.94 (0.62-1.42)	
≥30.0 (obese)	41	32	1.18 (0.82-1.70)	
Length of incision, cm				
<15	21	22	1.28 (0.76-2.16)	.42
≥15	90	81	1.01 (0.79-1.29)	
Skin preparation				
2% alcoholic chlorhexidine	51	44	1.10 (0.79-1.55)	
Aqueous povidone-iodine	19	16	1.15 (0.69-1.94)	.68
All other skin preparation	42	48	0.92 (0.65-1.30)	
Country				
UK	79	73	1.08 (0.83-1.40)	.52
Australia	33	35	0.92 (0.61-1.39)	
Assessment method				
Wound visualization in person	77	78	0.96 (0.75-1.23)	
Wound visualization remotely via video or image	15	16	1.02 (0.54-1.91)	.67
Remotely without visualization	9	13	0.67 (0.31-1.48)	
SARS-CoV-2 pandemic[a]				
Randomized before March 11, 2020	60	55	1.11 (0.83-1.50)	.68
Randomized on or after March 11, 2020	19	18	0.98 (0.58-1.65)	



BMI indicates body mass index (calculated as weight in kilograms divided by height in meters squared); iNPWT, incisional negative pressure wound therapy; and SSI, surgical site infection.

[a]UK-based patients only.

Limitations

This study has several limitations. First, the study used CDC criteria to classify SSI, but this only provided a binary yes or no outcome without detail of severity. However, study results indicate that the Clavien-Dindo scoring of all complications was equal across both groups, so it is unlikely that a meaningful reduction in the severity of SSI in the intervention group was missed. Second, while randomizing participants at the end of the operation minimized the risk of performance bias, the nature of the intervention and its obvious presence to both the participant and postoperative nursing staff meant masking was impossible. Thus, differences in postoperative inpatient care could potentially have been introduced. However, the fact that the formal wound reviewers were masked provides reassurance. Third, the study did not attempt to distinguish the type of SSI identified because it was unclear how reliable the identification of the different types of SSI would be in this context. Fourth, children were excluded, as their SSI risk, indications for a surgical procedure, acceptability of iNPWT, and treatment delivery settings were likely to be different from an adult population undergoing emergency laparotomy. It is possible that the effects of iNPWT are different in pediatric and adult populations, representing an area for future evaluation.

It is important to consider whether the results from this trial are generalizable across the entire population undergoing

emergency laparotomy. This trial captured a reliable but potentially incomplete representation of this group, likely skewed toward healthier recruited patients. The 30-day mortality rate in the current study was 2.9% compared with the most recent UK National Emergency Laparotomy Audit data of 9.6%.[22] Emergency laparotomy mortality rates in Australia are similar.[23] This may reflect that this study did not include patients unlikely to survive 30 days after the procedure (eg, ASA class 5). It also must be recognized that the study assessed a single iNPWT product; others exist but there is currently no comparative evidence available that would enable an accurate estimation of the generalizability of these findings to other products in this setting.

Conclusion

The findings of this study do not support the routine use of iNPWT for the reduction of SSI in adults undergoing emergency laparotomy.

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