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Pressurized Pulse Irrigation with Saline Reduces Surgical-site Infections following Major Hepatobiliary and Pancreatic Surgery: Randomized Controlled Trial

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Abstract
Background Surgical site infections (SSI) are a significant cause of postoperative morbidity. Pressurized pulse irrigation of subcutaneous tissues may lower infection rates by aiding in the debridement of necrotic tissue and reducing bacterial counts compared to simply pouring saline into the wound.
Methods A total of 128 patients undergoing laparotomy extending beyond 2 h were randomized to treatment of wounds by pressurized pulse lavage irrigation (<15 psi) with 2 L normal saline (pulse irrigation group), or to standard irrigation with 2 L normal saline poured into the wound, immediately prior to skin closure (standard group). Only elective cases were included, and all cases were performed within a specialized hepatobiliary and pancreatic surgery unit.
Results There were 62 patients managed by standard irrigation and 68 were managed by pulse irrigation. The groups were comparable in most aspects. Overall there were 16 (13 %) SSI. Significantly fewer SSI occurred in the pulse irrigation group [4 (6 %) vs. 12 (19 %); $p = 0.032$]. On multivariate analysis, the use of pulse irrigation was the only factor associated with a reduction in SSI with an odds ratio (OR) of 0.3 [95 % confidence interval (95 % CI) 0.1–0.8; $p = 0.031$]. In contrast, hospital length of stay of greater than 14 days was associated with increased infections with an OR of 7.6 (95 % CI 2.4–24.9; $p = 0.001$).
Conclusions Pulse irrigation of laparotomy wounds in operations exceeding 2 h duration reduced SSI after major hepatobiliary pancreatic surgery. (Australian New Zealand Clinical Trials Registry, ACTRN12612000170820).

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Introduction

Surgical site infections (SSI) are a major cause of postoperative morbidity and increased hospital costs [1, 2]. The true incidence of SSI varies according to the definition used and the surgical procedure performed. Infection risks are lowest with clean operations and highest in emergency cases involving a contaminated field [3]. Patient factors, glycemic control, operative extent, compliance with basic principles such as appropriate skin preparation and antibiotic prophylaxis, along with surgical technique, are all important factors affecting the risk of SSI [3, 4].

In abdominal surgery, SSI rates are likely to be higher than reported [5]. Although most SSI are minor, many require active and often prolonged treatment, which may increase pharmaco-economic expenditure and place an additional burden on utilization of healthcare resources. Randomized trials have examined various techniques to reduce infection rates. Choice of antiseptic used and administration of preoperative antibiotics have been the foci of several large studies [6–9]. Wound protection barriers in colorectal surgery appear to have some potential benefit, especially if spillage of bowel content directly into the subcutaneous tissue is a possibility [10–12].

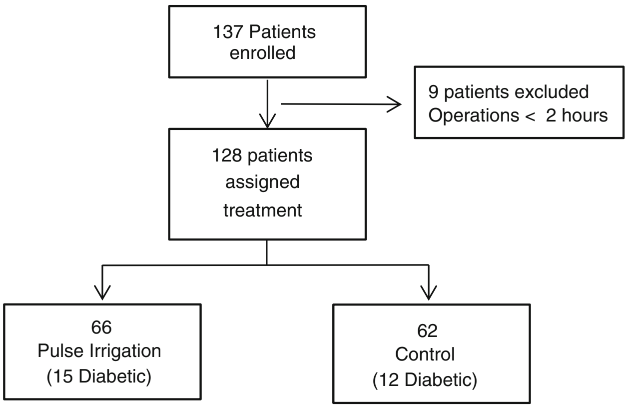

Fig. 1 Flow diagram of the progress through the phases of randomization of patients in this study. Control/standard group involved 2 L of saline poured into the subcutaneous tissue without any agitation prior to skin closure

Irrigation of wounds to reduce SSI after major abdominal surgery has not been studied in a randomized manner, with most of the data on this topic limited to the orthopedic literature, where pressurized pulse irrigation devices have been used to irrigate subcutaneous and deep tissues [13–16]. Pressurized (<15 psi) pulse irrigation of subcutaneous tissue after long operations may reduce bacterial counts and aid the removal of desiccated tissue that can act as a nidus for infection [15, 17].

In an earlier study examining the rate of laparotomy wound infections relating to major hepatobiliary and upper gastrointestinal surgery, the use of pressurized pulse irrigation to wash out laparotomy wounds with saline prior to skin closure appeared to reduce SSI [18]. However, this was not a randomized study and was limited to operative cases of 4 h or greater in duration. A randomized trial was devised to examine the effect of pressurized pulse irrigation of laparotomy wounds for elective operations exceeding 2 h within a hepatobiliary pancreatic unit.

Patients and methods

Patient population

Consecutive patients undergoing major elective abdominal operative procedures at a tertiary hepatobiliary and pancreatic surgery unit between 2010 and 2012 were enrolled. Institutional review board (IRB) approval was obtained to conduct the trial at Austin Health, Heidelberg, Melbourne, Australia, and Warringal Private Hospital, Heidelberg, Melbourne, Australia. The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN:12612000170820). All patients undergoing elective open operative procedures within the unit were identified. Those undergoing laparoscopic procedures were not included. Operations were performed by one of six specialist hepatobiliary pancreatic surgeons.

Inclusion criteria included adult patients undergoing an elective open abdominal operation that was anticipated to extend beyond 2 h. Laparoscopic procedures were excluded.

Randomization

Randomization was performed after abdominal fascial closure, immediately prior to skin closure. Grouping allocation was determined by sealed envelope selection. Blocks of 20 patients were randomized at one time. Diabetic patients were randomized separately to achieve close to even distribution in each group (Fig. 1).

Preoperative assessment

Demographic data, including, age, gender, American Society of Anesthesiologists (ASA) classification, body mass index (BMI), associated medical conditions, baseline blood tests performed in the preoperative testing clinic, and indications for surgery, were recorded.

Operative procedures

Operative details were documented. This included the indications for surgery, the organs resected, the operative time, and the need for intraoperative blood transfusions. The type of laparotomy varied according to surgeon preferences. All cases were elective operations and none was performed for treatment of an established intra-abdominal infection.

Anesthesia management

Anesthesia was managed by a group of specialist anesthesiologists using a protocol designed to standardize patient care. Induction of anesthesia was achieved with balanced technique combining intravenous midazolam 0.02–0.03 mg/kg IV (Sandoz Pty Ltd, Pyrmont, NSW, Australia), fentanyl 1–2 µg/kg IV (AstraZeneca Australia), propofol 1–3 mg/kg IV (Fresenius Kabi Australia Pty Ltd, Pymble, NSW, Australia). Following induction of anesthesia all patients received dexamethasone phosphate 8 mg IV (Aspen Pharmacare Australia Pty Ltd, St Leonards, NSW, Australia) as part of routine antiemetic prophylaxis. Anesthesia was maintained with sevoflurane or desflurane at inspired concentrations of 0.5–0.1 MAC, with a fractional inspired oxygen-air concentration of 0.5, and an infusion of remifentanil 0.1–0.3 µg/kg per min IV (Ultiva, GlaxoSmothKline Australia Pty Ltd). Mechanical ventilation maintained end tidal pCO_2 between 35 and 40 mmHg.

Routine monitoring included continuous electrocardiography, pulse oximetry, capnography, invasive arterial blood pressure, central venous pressure, urine output, and core body temperature. Intraoperative normothermia was maintained with warm fluids (Medi-Temp II, Gaymar Industries, Orchard Park, NY, USA) and a forced-air warming device (WarmAir, Convective Air Therapy, Cincinnati Sub-Zero, Cincinnati, OH, USA). Urine output was maintained at greater than 0.5 ml/kg per h, and systolic blood pressure was maintained within 20 % of the preoperative value.

In keeping with our institution's antibiotic prophylaxis protocol, at induction of anesthesia all patients received ampicillin 1 g IV (Aspen Pharmacare Australia Pty Ltd, St Leonards, NSW, Australia), gentamicin IV (2 mg/kg) (Hospira Pty Ltd, Melbourne, VIC, Australia), and metronidazole 500 mg IV (Hospira Pty Ltd, Melbourne, VIC, Australia). Antibiotics were continued for 24 h postoperatively. In cases of penicillin allergy, vancomycin 1 g IV (Hospira Pty Ltd, Melbourne, VIC, Australia) or cephazolin 1 g IV (Alphapharm Pty Ltd, Millers Point, NSW, Australia) was administered according to the particular sensitivity reaction.

Where appropriate, hair removal from the abdominal wall was performed with clippers immediately before the abdomen was prepped. The abdomen was prepped with alcohol-based iodine unless there was a contraindication. An Ioban (3 M North Ryde, NSW, Australia) steri-drape was applied prior to initial skin incision with a scalpel. The Thomson surgical retractor (Traverse City, MI) is the preferred wound retracting system, with moist saline-soaked packs applied to the wound edges and intermittently moistened during the course of the operation. Operative procedures were performed according to the given indication.

In all cases, prior to abdominal closure, the peritoneal cavity was irrigated with least 3 L of warm saline without any added antibiotics. The abdominal wall was reapproximated by mass closure with looped size 1 polydioxanone (PDS) sutures (Johnson & Johnson Co., Melbourne, Australia), or with interrupted 1 Nylon sutures (Johnson & Johnson Co., Melbourne, Australia) in some cases. If the case exceeded 2 h duration, the patient was then randomized immediately prior to skin closure to irrigation of subcutaneous tissue by standard method (Standard group), or to a pulsatile lavage irrigation device (pulse irrigation group).

Wound irrigation technique

Following closure of the fascia in the standard group, 2 L of normal saline at room temperature was poured into the subcutaneous tissue without any agitation. In the pulse irrigation group, the Surgilav irrigation device (Stryker Instruments, Portage, MI) was used after fascia closure to irrigate the surgical wound with 2 L of normal saline at room temperature. This device delivers saline at a pressure of close to 15 psi, but not exceeding it, through a cone-shaped applicator.

Excess fluid was removed from the subcutaneous tissue with application of a dry pack. Subcutaneous drainage or closure was not undertaken. The skin was reapproximated with continuous subcuticular 3/0 Monocryl sutures (Johnson & Johnson Co., Melbourne, Australia). Skin staples were not used in any case. A Duoderm dressing (Convatec, Clayton, VIC, Australia) was applied to the wound.

Postoperative outcome

Postoperatively, all patients were nursed in a high dependency or intensive care unit for at least 24 h and then transferred to the surgical ward for ongoing care. Patients were managed in a standard manner according to the operative procedure. Glycemic control (glucose <8 mmol/L) was maintained post-surgery according to an insulin sliding scale. Nasogastric tube and abdominal drain usage were recorded. Complications, length of stay hospital stay, and readmissions were noted. In cases of re-laparotomy, wound management was kept the same as initial randomization. Antibiotics were administered for only 24 h postoperatively as a routine. If antibiotics were given at any time after 24 h, this was recorded. Abdominal dressings were removed for initial wound assessment at 1 week following surgery, unless there were concerns of possible infection prior to that time. Wounds were assessed again 2 weeks after surgery and thereafter as indicated. Minimum follow-up after surgery was 1 month.

Wound infection determination

Wounds were determined as infected based on strictly defined criteria, which included: (1) purulent drainage, with or without laboratory confirmation, from the superficial incision; (2) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; (3) at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless the incision is culture-negative; (4) diagnosis of superficial incisional SSI by the surgeon or attending physician [5].

Non-wound-related complications were defined as any adverse event not considered a normal part of postoperative recovery. Patients were monitored by a dedicated acute pain service and reviewed daily for any complications arising from their analgesic regime.

Table 1 Baseline characteristics of patients according to wound treatment group

	Overall ($n = 128$)	Standard group ($n = 62$)	Pulse irrigation ($n = 66$)	p Value
Patient characteristics				
Male	78 (61 %)	36 (58 %)	42 (64 %)	0.518
Age, years	63 (18–86)	66 (18–85)	62 (33–86)	0.364
BMI	26 (18–44)	26 (18–44)	26 (18–42)	0.834
ASA class I	3 (2 %)	2 (3 %)	1 (2 %)	0.882
ASA class II	33 (26 %)	17 (27 %)	16 (24 %)	
ASA class III	85 (66 %)	40 (65 %)	45 (68 %)	
ASA class IV	7 (6 %)	3 (5 %)	4 (6 %)	
Diabetes	27 (21 %)	12 (19 %)	15 (24 %)	0.640
COAD	18 (14 %)	9 (15 %)	9 (14 %)	0.886
IHD	14 (89 %)	7 (11 %)	7 (11 %)	1.00
CLD	4 (3 %)	3 (5 %)	1 (2 %)	0.354
Immunosuppressive medications	5 (4 %)	3 (5 %)	2 (3 %)	0.673
Cigarette smoker	13 (10 %)	5 (8 %)	8 (12 %)	0.448
Previous chemotherapy	31 (24 %)	13 (21 %)	18 (27 %)	0.405
Excessive alcohol intake	24 (19 %)	11 (18 %)	13 (20 %)	0.777
Preoperative laboratory tests				
Hemoglobin (g/L)	134 (74–173)	134 (74–173)	132 (76–166)	0.590
WCC ($\times 10^9$/L)	7.0 (3.8–37.1)	7.2 (4.0–36.2)	7.0 (3.8–37.1)	0.983
Platelets ($\times 10^9$/L)	248 (112–637)	260 (121–637)	248 (112–630)	0.488
Bilirubin (μmol/L)	14 (4–503)	14 (4–503)	14 (4–233)	0.724
Albumin (g/L)	39 (19–47)	39 (19–46)	39 (23–47)	0.848
Urea (mmol/L)	5.1 (1.1–16.0)	5.1 (1.1–16.0)	5.0 (2.1–14.2)	0.699
Creatinine (μmol/L)	73 (10–447)	70 (10–169)	80 (12–447)	0.137

Data are shown as number (%) or median (range)

ASA American Society of Anesthesiologists, *BMI* body mass index, *CLD* chronic liver disease, *COAD* chronic obstructive airways disease, *IHD* ischemic heart disease, *WCC* white cell count

Statistical analysis

Sample size calculations were based on our previous study demonstrating SSI rates of ~30 % after prolonged intra-abdominal surgical procedures [18]. Assuming that the rate of SSI could be reduced from 30 to 15 % by pulse irrigation of wounds, then 128 patients (64 per group) provided an 80 % power for detecting this difference, at a significance level of 0.05 (http://stat.ubc.ca/~rollin/stats/ssize/index.html). Results are expressed as median (range) unless otherwise stated. Comparisons between categorical variables were made by the Chi square test or Fisher's exact test, where appropriate. Non-categorical variables were assessed by the Mann–Whitney U test. A statistical software package (SPSS version 19.0; IBM, Armonk, NY, USA) was used for analysis. Multivariate analysis was undertaken with a backward stepwise logistic regression model to identify factors independently associated with SSI, including all factors where the P value was less than 0.1 on univariate analysis. Odds ratios (OR) and 95 % confidence intervals (CI) were noted.

Results

Patient characteristics

A total of 137 patients were enrolled, as 8 cases did not reach the 2 h duration required for randomization. The grouping of patients is shown in Fig. 1. There were no significant differences between the groups in terms of baseline characteristics (Table 1).

Surgical details

The indications for surgery and operative details are noted in Table 2. The major indication for surgery was malignancy. Pancreatic operations included pancreaticoduodenectomy

Table 2 Operative details and pathology according to wound treatment grouping

	Overall ($n = 128$)	Standard group ($n = 62$)	Pulse irrigation group ($n = 66$)	Difference (p value)
Malignancy	99 (77 %)	50 (81 %)	49 (74 %)	0.387
Surgical indication				
Pancreatic	54 (42 %)	27 (44 %)	27 (41 %)	
Liver/biliary	57 (45 %)	30 (48 %)	27 (41 %)	0.232
Other	17 (13 %)	5 (8 %)	12 (18 %)	
Drain inserted	72 (57 %)	41 (66 %)	31 (48 %)	0.045*
Urinary catheter	123 (96 %)	60 (97 %)	63 (96 %)	1.000
Nasogastric tube placed	98 (77 %)	52 (84 %)	46 (71 %)	0.079
Feeding jejunostomy	5 (4 %)	4 (7 %)	1 (2 %)	0.197
Epidural anesthesia	44 (34 %)	20 (32 %)	24 (36 %)	0.625
Stapled skin closure	3 (2 %)	2 (3 %)	1 (2 %)	0.610
Intraoperative steroids	13 (10 %)	6 (10 %)	7 (11 %)	0.862
Cases by surgeon 1	60 (47 %)	29 (47 %)	31 (47 %)	
Cases by surgeon 2	12 (9 %)	6 (10 %)	6 (9 %)	
Cases by surgeon 3	18 (14 %)	14 (23 %)	4 (6 %)	
Cases by surgeon 4	16 (13 %)	3 (5 %)	13 (20 %)	0.023*
Cases by surgeon 5	11 (9 %)	6 (10 %)	5 (8 %)	
Cases by surgeon 6	11 (9 %)	4 (7 %)	7 (11 %)	
Previous laparotomy	47 (37 %)	24 (39 %)	23 (35 %)	0.651
Incision type				
Midline	68 (53 %)	28 (45 %)	40 (61 %)	
Rooftop	26 (20 %)	11 (18 %)	15 (23 %)	0.033*
Reverse L	34 (26 %)	23 (37 %)	11 (17 %)	
Intraoperative transfusion	16 (13 %)	6 (10 %)	10 (15 %)	0.349
Operative time (min)	360 (120–810)	330 (150–760)	390 (120–810)	0.676

Data are presented as number (%) or median (range)

*$p < 0.05$ χ^2/Fisher's exact test

and distal pancreatectomy. Liver operations included minor and major hepatectomies. Biliary operations included bile duct resections and isolated biliary bypass procedures. There were no differences in operation types between the two groups. However, an abdominal drain was more commonly used in the standard group (66 vs. 48 %; $p = 0.045$). Also in the standard group, there was a significantly greater use of a reverse L incision (37 vs. 17 %; $p = 0.033$). In this series, 47 % of cases were performed by one surgeon. Six specialists surgeons in total participated in this study, with some differences noted in the random assignment of patients to either the Standard or pulse irrigation group ($p = 0.023$). There were no other statistically significant differences between the two groups.

Postoperative outcomes and complications

The rates of overall complications and non-wound-related complications were similar between the groups (Table 3). However, there were significantly fewer wound infections in the pulse irrigation group [4 (6 %) vs. 12 (19 %); $p = 0.032$]. All four wound infections in the pulse irrigation group were of a superficial nature requiring simple drainage and a course of antibiotics. Two of 12 wound infections in the standard treatment group required major debridement, with a prolonged course of dressings. One of these patients had partial abdominal wall dehiscence. The remaining patients were managed by simple drainage and antibiotics. Of the 16 patients with wound infections, 14 (88 %) had antibiotics continued for longer than 24 h post-surgery. One patient had wound cellulitis with no wound cultures performed. Of the remaining 15 patients from whom cultures were obtained, the following were isolated: mixed skin flora (8), mixed enteric flora (3), *Enterobacter cloacae* (1), *Staphylococcus aureus* (1), *Stenotrophomonas maltophilia* (1), and in one case there was no growth although multiple samples were examined. Overall, 56 % ($n = 72$) of patients had prophylactic antibiotics continued beyond 24 h. This was based on physician request, often in response to early postoperative fever, in the absence of definite infective focus.

With regard to other postoperative outcomes, including transfusion rates, readmissions, and length of hospital stay, there were no significant differences between the groups (Table 3).

Table 3 Postoperative outcome in patients according to wound treatment grouping

	Overall ($n = 128$)	Standard group ($n = 62$)	Pulse irrigation group ($n = 66$)	Difference (p value)
Any complication	60 (47 %)	26 (42 %)	34 (52 %)	0.278
Non-wound-related	55 (43 %)	23 (37 %)	32 (49 %)	0.193
Wound infection	16 (13 %)	12 (19 %)	4 (6 %)	0.032*
Postoperative transfusion	20 (16 %)	7 (11 %)	13 (20 %)	0.191
Antibiotics >24 h	72 (56 %)	37 (60 %)	35 (53 %)	0.449
Relaparotomy	6 (5 %)	3 (5 %)	3 (5 %)	1.0
Readmission	15 (12 %)	6 (10 %)	9 (14 %)	0.486
Length of stay (days)	9 (4–71)	9 (5–45)	9 (4–71)	0.262

Data are presented as number (%) or median (range)

*$p < 0.05$ χ^2 test/Fisher's exact test/Mann–Whitney U test

Factors associated with wound infections

Various factors possibly associated with SSI were examined by univariate and multivariate analysis (Table 4). The only factor associated with reduced wound infections on multivariate analysis was pulse irrigation of laparotomy wounds [OR 0.3 (0.1–0.9); $p = 0.031$]. Length of stay of 2 weeks or longer was independently associated with wound infections in this series [OR 7.6 (2.4–24.9); $p = 0.001$].

Discussion

Wound infection rates relate to a variety of factors, some of which are potentially preventable. Infection rates after major upper gastrointestinal surgery range from 10 to 30 % [19, 20]. These infections remain a major cause of postoperative morbidity and a focus of surgical improvement strategies [19, 21, 22]. A number of randomized trials have identified factors that may lead to reduced infection rates. Some notable findings include antibiotic administration, use of alcohol-based chlorhexidine prepping solution, and abdominal wound barriers [6–12]. Irrigation of wounds after high-risk surgery may represent a simple method of reducing laparotomy wound infections, but it had not been studied in a randomized fashion until this report.

Given the large number of factors that have been implicated in the development of wound infections, controlling for all variables was difficult and was overcome in part by the sample size and the randomization strategy. We adopted universally enforced standard of care measures to reduce wound infections in this study, including routine antibiotic administration and clipping of body hair immediately before operation [5, 23]. We also controlled for distribution of patients with diabetes and maintained tight perioperative glycemic control to minimize its impact on SSI [24]. Importantly, we also implemented a consistent anesthesia protocol, standardizing antiemetic prophylaxis and the intraoperative fractional inspired oxygen concentration, although recent data had shown that neither of these variables is associated with an increased risk of SSI [25–28]. We did note that significantly more patients with drain tubes were assigned to the standard group, but this was not found to be associated with increased risk of infection on multivariate analysis. Similarly, differences were noted in the type of incision in each group, which also was not associated with an increased or decreased risk of wound infections.

Wound irrigation is not a universally enforced standard-of-care preventive measure, even though studies have shown it to remove loosely attached cellular debris and reduce bacterial contamination counts [15, 17]. It is accepted that contamination of wounds by microorganisms [29] and the presence of necrotic tissue within a wound can lead to bacterial overgrowth [29, 30]. The irrigation of wounds appears to be a simple technique with which to reduce infection rates, and the addition of pressure to the irrigation has an additive effect [17, 31]. A standard irrigation of pressure of close to but not exceeding 15 psi was tested, given that pressures beyond 15 psi may cause tissue injury and increase the risk of dissemination of contaminants into surrounding tissues [17].

In our study, pressurized pulse irrigation of laparotomy wounds was independently associated with reduced SSI. The device employed is relatively inexpensive at less than $80 AUS in or hospital. The process of wound irrigation with several liters of saline can be accomplished within several minutes.

The overall infection rate with this technique was much lower than anticipated. Based on previous studies, we had anticipated an infection rate of 30 % [5, 18, 32], and subsequently powered the study to identify a 50 % reduction in infection rates. The lower than expected infection rate may

Table 4 Factors associated with wound infections after laparotomy

	Wound infection ($n = 16$) (%)	No wound infection ($n = 112$) (%)	Univariate		Multivariate	
			Odds ratio (confidence interval)	p value	Odds ratio (confidence interval)	p value
Demographics						
Male gender	13 (81)	65 (58)	3.1 (0.8–11.6)	0.101		
BMI ≥30	2 (13)	25 (22)	0.5 (0.1–2.3)	0.520		
Age ≥70	6 (38)	37 (33)	1.2 (0.4–3.6)	0.724		
Preoperative diabetes	1 (6)	26 (23)	4.3 (1.0–19.3)	0.190		
ASA III/IV	12 (75)	80 (71)	1.2 (0.4–4.0)	1.0		
CLD	2 (13)	2 (2)	7.9 (1.0–60.3)	0.076	5.4 (0.5–64.9)	0.182
Hemoglobin ≤10 g/L	2 (13)	8 (7)	1.9 (0.4–9.6)	0.612		
Bilirubin ≥60 μmol/L	2 (19)	17 (15)	1.3 (0.3–5.0)	0.716		
Albumin ≤30 g/L	5 (31)	15 (13)	2.9 (0.9–9.7)	0.066	1.1 (0.2–4.9)	0.923
Epidural anesthesia	5 (31)	39 (35)	0.9 (0.3–2.6)	0.778		
Pathology						
Malignancy	12 (75)	87 (78)	0.9 (0.3–2.9)	1.0		
Surgical indication						
Pancreatic	7 (44)	47 (42)				
Liver/biliary	9 (56)	48 (43)	n/a	0.230		
Other	0 (0)	17 (15)				
Operative details						
Time ≥8 h	7 (44)	42 (38)	1.3 (0.4–3.7)	0.630		
Blood transfusion intraoperative	4 (25)	12 (11)	2.8 (0.8–10.0)	0.218		
Drain inserted	11 (69)	61 (56)	1.8 (0.6–5.4)	0.315		
Intraoperative steroids	5 (31)	27 (24)	1.4 (0.5–4.5)	0.537		
Previous laparotomy	8 (50)	39 (35)	1.9 (0.7–5.4)	0.239		
Incision type						
Midline	9 (56)	59 (53)				
Rooftop	3 (19)	23 (21)	n/a	1.0		
Reverse L	4 (25)	30 (27)				
Pulse irrigation	4 (25)	62 (55)	0.3 (0.08–0.9)	0.032*	0.3 (0.1–0.9)	0.031#
Postoperative details						
Relaparotomy	2 (13)	4 (4)	3.9 (0.6–23.0)	0.163		
Non-wound complications	11 (69)	44 (39)	3.4 (1.1–10.5.)	0.032*	1.7 (0.4–7.2)	0.475
Postoperative transfusion	3 (19)	17 (15)	1.3 (0.3–5.0)	0.716		
Readmission	2 (13)	13 (12)	1.1 (0.2–5.3)	1.0		
Length of hospital stay ≥14 days	11 (69)	26 (23)	7.3 (2.3–22.9)	<0.001*	7.6 (2.4–24.9)	0.001**

Data are presented as number (%) or median (range)

n/a not applicable

*$p < 0.05$ Fisher's exact test

**$p < 0.05$ multivariate logistic regression

relate to the use of saline irrigation as a control and overall improved outcomes that are associated with enrolment of patients into a study. In our study design, the control group had 2 L of normal saline poured into the wound without agitation prior to skin closure. Surgeons felt that it was not justifiable to avoid irrigation of wounds in the controls, despite a lack of convincing evidence of a benefit in prevention of laparotomy wound infections. The saline was simply poured into the wound and was not delivered under any pressure by use of a syringe or other delivery device.

Other factors, such as diabetes, were not associated with increased infection rates in this study, and this may relate to the small sample size and our practice of tight perioperative glycemic control. Other factors reported by others to be associated with wound infections, such as obesity [33] and poor nutrition, using albumin as a surrogate marker [34], were also not associated with an increase in SSI in this series, which also may relate to the small sample size.

Despite significant reductions noted in wound infection rates with the use of pulse irrigation, we can only hypothesize that the mechanisms involved are a reduction of bacterial load and debridement of desiccated tissue [29, 30]. It has been shown previously that necrotic tissue at wound margins impedes wound contraction and provides an environment that facilitates wound infection [35]. Bacterial cultures were not taken from wounds before or after wound irrigation to determine whether pulse irrigation treatment altered overall bacterial counts. Bacteria counts could be determined by real-time polymerase chain reaction (qPCR), but this analysis was not performed in our study owing to cost constraints. Rodeheaver et al. [31] have demonstrated that wound irrigation at a pressure of 15 psi resulted in removal of 84.8 % of wound contaminants, compared with 48.6 % at impact pressures of 1 psi, which is achieved with simple wound irrigation. It was also a surprise to us that the majority of wound infections, defined according to well-defined criteria [5], had mixed skin flora isolated from swabs taken. In one case *S. aureus* was isolated from the wound, and mixed enteric flora were isolated in 3 of 16 cases of SSI. Major SSI that required wound debridement occurred in only 2 of 16 cases, and only one of those was associated with partial abdominal wall dehiscence.

The use of antibiotics to reduce SSI has been the focus of several studies in the past [6, 8, 9]. Antibiotics, when given prophylactically, appear to reduce wound infection rates, with most authors suggesting that they be given before surgical incision [36]. All patients in our series received prophylactic antibiotics on induction of anesthesia. There was, however, an alarming use of antibiotics beyond 24 h based on the surgeon's preference. Most reported series do not demonstrate clear benefits of prophylactic antibiotics beyond 24–48 h [37–40]. The exact indications for this use of antibiotics could not be determined in this study, apart from the common finding of early postoperative fever associated with these major abdominal operations. There appeared to be a reluctance on the part of surgeons to cease antibiotics if patients had a mild postoperative fever. This potentially explains the high rate of negative wound culture rates, as the majority of patients with SSI were given antibiotics beyond 24 h postoperatively. Alternatively, low positive bacterial culture rates may be explained by sterile necrosis of desiccated tissues and subsequent associated inflammation, producing symptoms and signs of SSI. The majority of wound infections (88 %) occurred in patients administered antibiotics beyond 24 h.

Based on this randomized controlled trial, we advocate pressurized pulse irrigation of major laparotomy wounds after prolonged operative procedures (>2 h). There appears to be no adverse effect with the use of a pulse irrigating device, with the benefit of reduced SSI. This makes it a cost-effective infection prevention strategy.

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