# **Original Research Article**

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# A prospective comparative study of efficacy of pulse jet irrigation and conventional irrigation techniques in prevention of surgical site infections in laparotomy wounds

Sharath Kumar V.1, Naveen N.2, Purushotham T. S.2\*

<sup>1</sup>Department of General Surgery, <sup>2</sup>Department of Plastic Surgery, Adichunchanagiri Institute of Medical Sciences, B.G. Nagara, Mandya, Karnataka, India

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\*Correspondence: Dr. Purushotham T. S.,

E-mail: naveen\_uno1@yahoo.co.in

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#### **ABSTRACT**

**Background:** Surgical Site Infections (SSIs) are infections of tissues, organs or spaces exposed by surgeons during performance of an invasive procedure and continue to be a major source of morbidity following operative procedures. Wound irrigation is the steady flow of a solution across an open wound surface meant to remove cellular debris and surface pathogens contained in wound exudates or residue from topically applied wound care products.

**Methods:** This prospective comparative study was conducted to compare the effectiveness of Pressurized Pulse Irrigation (PPI) and Standard Irrigation Technique (SIT) in laparotomy wounds. Duration of the study was for a period of 12 months and included 100 consecutive patients undergoing laparotomy.

**Results:** 13% of patients who underwent laparotomy had SSI out of which 9 patients had superficial infection only. 8% of 50 patients who had PPI developed SSI, whereas 18% of those who underwent SIT had SSI. Though PPI had less incidence of SSI, statistically it was insignificant.

**Conclusions:** The study showed a decrease in the incidence of postoperative SSI in both elective and emergency laparotomy wounds irrigated with PPI compared to SIT, though the study was statistically insignificant since the p value was less than 0.005 with a odds ratio of 2.52. The study results suggested that there was decrease in the incidence of SSI in PPI patients and also that it decreases the postoperative stay, morbidity and cost.

Keywords: Laparotomy, Pressurized pulse jet irrigation, Standard irrigation, Surgical site infection

#### **INTRODUCTION**

Surgical Site Infections (SSIs) are infections of tissues, organs or spaces exposed by surgeons during performance of an invasive procedure and continue to be a major source of morbidity following operative procedures. Postoperative SSIs remain a major source of illness and a less frequent cause of death in the surgical patient. These infections number approximately 500,000 per year, among an estimated 27 million surgical procedures and account for approximately one quarter of the estimated two million nosocomial infections in the

United States each year.<sup>3,4</sup> SSIs lengthen bed stay for an average of seven days and results in higher costs.<sup>5</sup> The incidence of infection varies from surgeon to surgeon, from hospital to hospital from one surgical procedure to another and most importantly from one patient to another.<sup>6</sup> Surgical site infections are among the most common hospital acquired infections comprising 14 to 16% of inpatient infections.<sup>7</sup> Although an SSI rate of zero may not be achievable, continued progress in understanding the biology of infection at the surgical site and consistent applications of proven methods of prevention will allow further reducing the frequency, cost

and morbidity associated with SSI.<sup>8,9</sup> Methicillin resistant *Staphylococcus aureus* (MRSA) is proving to be the scourge of modern day surgery. Of particular concern are the vancomycin intermediate *Staphylococcus aureus* (VISA) strains of MRSA.

This study was conducted to systematically compare the 2 methods in the incidence of surgical site infection in elective and emergency patients. For jet irrigation effective pressure used was between 4-15psi and was achieved with 30-35ml syringe with full pressure which produces 8 to 11psi. Effective irrigation is likely to require copious amounts of fluids suggesting a volume of around 2 liters of normal saline.

The study aimed to compare the incidence of surgical site infections within 7 days of postoperative period in laparotomy wounds irrigated using pressurized pulse jet saline irrigation (<15psi with 2L normal saline) and those subjected to conventional wound irrigation technique using normal saline, immediately prior to skin closure.

#### **METHODS**

This prospective comparative study was conducted in Department of General Surgery in conjunction with Department of Plastic Surgery at Adichunchanagiri Institute of Medical Sciences, B. G. Nagara, Karnataka, India.

Patients who underwent elective and emergency laparotomies were included in the study. Patients undergoing laparoscopic surgery and non-consenting patients were excluded from the study. Duration of the study was for a period of 12 months from September 2017 to August 2018. Institutional ethical committee clearance was obtained.

The study was intended to compare the incidence of surgical site infection in pulsed pressure irrigation and standard wound irrigation technique in elective and emergency laparotomy wounds and to assess the effectiveness of pressurized pulse jet irrigation so that the same can be adopted more widely as a method of reducing post-operative wound infections and improving patient care by reducing morbidity with little cost and minimal efforts. Sample size was calculated using the formula:

 $N = (Z\alpha + Z\beta)2pq/d^2$ 

Where, N= Sample size,

 $Z\alpha = Z$  score of  $\alpha$  error (i.e. 1.96 with an  $\alpha$  error of 5%),  $Z\beta = Z$  score of  $\beta$  error (i.e. 0.8 with an  $\beta$  error of 20%), p= average prevalence according to study (P1+P2/2),

q= 100- p,

D= difference between p1 and p2.

Hence, sample size, N=35 were obtained. Variables in the study were sex, age, type of surgery and co-morbidities.

A prospective study design was undertaken in patients undergoing laparotomy procedures where those receiving pressurized pulse irrigation were grouped as 1 and other with standard irrigation method as group 2. The subjects will be matched for factors affecting wound infection like age, diabetes, nutritional status, anemia as far as possible in both elective and emergency patients. Date and time of irrigation, appearance, sloughing tissue or exudates and skin wound swabs were taken on post-operative days if any sign of clinical surgical site infection was found. Following laparotomy and completion of procedure linea alba was closed with synthetic absorbable suture PDS No. 1. In all cases wound was wiped with sterile gauze. Normal saline (luke warm) was preoperatively prepared in sterile setting. In standard irrigation group, wound was irrigated in sterile way allowing the saline or betadine to run off the edge of wound and then the wound was dried with sterile gauze and closed with skin staplers or with 3-0 Ethilon sutures. In pulse jet irrigation group, wound was irrigated in sterile way using a 35ml syringe (8-15psi) in the following way. The syringe was held just above the top edge of the wound and with full pressure fluid was instilled into the wound continuously until the syringe was empty. It was made sure that the solution flowed from the clean to dirty area of the wound and enough force was used to flush out debris but care was taken not to squirt or splash fluid and to irrigate all portions of the wound. The procedure was repeated until 2 litres of solution was administered or the solution draining from the wound was clear. Post operatively wounds were observed daily for signs of wound infection like discharge, local induration, redness, local rise of temperature for a period of one week postoperatively. Post-operative wound swabs were taken and the culture status was recorded when there was evidence of wound infection. Surgical site infection rates were analyzed statistically in matched groups and compared. Patient confidentiality has been maintained at all times. Data was collected from each individual and entered in Excel Worksheet after coding of variables and appropriate analysis was done with help of EPI-INFO. Qualitative data was analyzed with proportion, chi- square and data was depicted with pie charts, bar diagrams and appropriate methods wherever necessary. Quantitative data was analyzed using mean, standard deviation and appropriate statistical test of significance.

The study protocol was submitted to Institutional Ethics Committee (IEC) of Adichunchanagiri University and approval for the study was obtained. A written informed consent was taken from all the participants or their guardians as deemed appropriate. The information collected was used only for the purpose of study and strict confidentiality has been maintained throughout the study. No external funding was taken for the study.

### **RESULTS**

The prospective comparative study included a total of 100 consecutive patients undergoing laparotomy

(elective/emergency) of which 50 were irrigated with pressurized pulse jet irrigation and 50 with standard irrigation. The data collected was entered in Microsoft Excel and analyzed using SPSS version 16. The presence of surgical site infection in pulse irrigation and standard irrigation was associated with the socio demographic variables. For this, tests of significance such as Chisquare test, Fisher exact test were used as appropriate (when more than 20% of cells have expected value more than 5, Fisher exact test was used). When the associated factor was a binominal variable, Odds Ratio (OR) was calculated with confidence interval. Significance level for p-value was set at 0.05. Results were tabulated.

Distribution of patients according to age group was found to be 16% in group 1 comprising of patients aged <40 years, 40% in group 2 (40%) and 44% in group 3 (44%). Hence, the majority of patients who underwent laparotomy were above 40 years of age (84%) as shown in Table 1.

As shown in Table 2, out of the 100 patients included in the study, 70 were males and 30 were females. Of the 100 patients who underwent laparotomy were due to cholelithiasis (10%) duodenal perforation (10%) and carcinoma of the stomach (9%).

Other diagnosis included carcinoma of rectum, intestinal obstruction, acute cholelithiasis, blunt trauma abdomen among others (Table 3). Cholecystectomy (18%) was the most commonly performed procedure during laparotomy followed by Graham's patch (16%), intestinal resection and anastomosis (13%) and gastrectomy (10%) (Table 4).

Table 1: Age distribution with Group 1 (<40 yrs of age), Group 2 (40-60 yrs) and Group 3 (above 60 yrs).

	Group	Frequency	%	Valid %	Cumulative %
	1	16	16	16.0	16.0
¥7.a1:.d	2	40	40	40.0	56.0
Valid	3	44	44	44.0	100.0
	Total	100	100	100.0	

Table 2: Gender distribution in study group.

	Sex	Frequency	%	Valid %	Cumulative %
	F	30	30.0	30.0	30.0
Valid	M	70	70.0	70.0	100.0
'	Total	100	100.0	100.0	

Table 3: Diagnosis of patients underwent laparotomy.

	Diagnosis	Frequency	%	Valid %	Cumulative %
	CA Sigmoid	1	1.0	1.0	1.0
	Acute cholecystitis	5	5.0	5.0	6.0
	Blunt trauma abdomen	5	5.0	5.0	11.0
	CA caecum	2	2.0	2.0	13.0
	CA colon	4	4.0	4.0	17.0
	CA pancreas	2	2.0	2.0	19.0
	CA rectum	6	6.0	6.0	25.0
	CA sigmoid	4	4.0	4.0	29.0
	CA stomach	9	9.0	9.0	38.0
	CBD stricture	2	2.0	2.0	40.0
	Cholangiocarcinoma	2	2.0	2.0	42.0
	Choledocholithiasis	5	5.0	5.0	47.0
	Cholelithiasis	10	10.0	10.0	57.0
Valid	Colonic perforation	1	1.0	1.0	58.0
	DU perforation	10	10.0	10.0	68.0
	GB perforation	3	3.0	3.0	71.0
	GIST	1	1.0	1.0	72.0
	GU perforation	6	6.0	6.0	78.0
	Ileal perforation	5	5.0	5.0	83.0
	Intestinal obstruction	6	6.0	6.0	89.0
	Liver abscess rupture	3	3.0	3.0	92.0
	Meckels diverticulitis	1	1.0	1.0	93.0
	Mesentric cyst	1	1.0	1.0	94.0
	Pancreatic psuedocyst	1	1.0	1.0	95.0
	Sigmoid volvulus	3	3.0	3.0	98.0
	Splenic abscess	2	2.0	2.0	100.0
	Total	100	100.0	100.0	

Table 4: Surgical procedures performed during laparotomy.

	Type of surgical procedure	Frequency	0/0	Valid %	Cumulative %
	APR	3	3.0	3.0	3.0
	AR	3	3.0	3.0	6.0
	CBD exploration	7	7.0	7.0	13.0
	Cholecystectomy	18	18.0	18.0	31.0
	Closure	4	4.0	4.0	35.0
	Colectomy	5	5.0	5.0	40.0
	Colostomy	3	3.0	3.0	43.0
	Drainage	2	2.0	2.0	45.0
	Exploration	1	1.0	1.0	46.0
Valid	Excision	1	1.0	1.0	47.0
vanu	Exploration	7	7.0	7.0	54.0
	Gastrectomy	10	10.0	10.0	64.0
	Grahams patch	16	16.0	16.0	80.0
	Hepaticojejunostomy	2	2.0	2.0	82.0
	Panceaticojejunostomy	1	1.0	1.0	83.0
	Rescetion anastomosis	1	1.0	1.0	84.0
	Resection anastomosis	13	13.0	13.0	97.0
	Right hemicolectomy	1	1.0	1.0	98.0
	Whipples	2	2.0	2.0	100.0
	Total	100	100.0	100.0	

Out of 100 laparotomy procedures, majority (93%) were performed under general anesthesia and only 7% were performed under spinal anesthesia (Table 5). Emergency and elective laparotomies were 50 each (Table 6). Incidence of surgical site infection was 13% in the study group. 87 patients had no infection at the operated site (Table 7). Most of the SSI patients had infection on the 3<sup>rd</sup> postoperative day (8 patients out of 13) with a p value of 0.094 and degree of freedom 2. Most of the infected patients had a superficial site infection (9 patients out of 13) with a p value of 0.671 and degree of freedom 3. Rest of 4 patients had deeper infections requiring debridement and secondary closure of the wound. 25 patients who underwent laparotomy procedure were diagnosed or on treatment for diabetes mellitus at the time of surgery out of which 10 patients had SSI (Table 8).

Duration of postoperative stay of more than 10 days was noted in all the patients who had SSI with a p value of 0.372 and degree of freedom 1. Incidence of SSI in pulse irrigation was 8% (4 cases out of 50) and in standard irrigation was 18% (9 cases out of 50) with a p value of 0.137, degree of freedom 1 and odds ratio of 2.52 (Table 9).

Table 5: Type of anaesthesia used for laparotomy.

	Type of anaesthesia	Frequency	%	V: Cumulative % %
	GA	93	93.0	93 93.0
Valid	SA	7	7.0	7.( 100.0
·	Total	100	100.0	10

Table 6: Number of elective (group 1) and emergency (group 2) laparotomies.

	Group	Frequency	%	Valid %	Cumulative %
	1	50	50.0	50.0	50.0
Valid	2	50	50.0	50.0	100.0
	Total	100	100.0	100.0	

**Table 7: Incidence of surgical site infection.** 

	SSI	Frequency	%	Valid %	Cumulative %
	No	87	87.0	87.0	87.0
Valid	Yes	13	13.0	13.0	100.0
	Total	100	100.0	100.0	

Table 8: Patients with diabetes mellitus.

	Diabetes mellitus	Frequency	%	Valid %	Cumulative %
	No	75	75.0	75.0	75.0
Valid	Yes	25	25.0	25.0	100.0
	Total	100	100.0	100.0	

## **DISCUSSION**

Surgical Site Infection (SSI) is a difficult term to define accurately because it has a wide spectrum of possible clinical features. SSI is defined by the Centres for Disease Control and Prevention (CDC) as a proliferation of pathogenic micro-organisms which develops in an

incision site either within the skin and subcutaneous fat (superficial), musculofascial layers (deep) or in an organ or cavity, if opened during surgery.

Table 9: Incidence of SSI in pulse irrigation and in standard irrigation.

		Irrigation method	SSI	Total	
			No	Yes	
		Count	46	4	50
	1	% within pulse standard	92.0%	8.0%	100.0%
Pulse		% of total	46.0%	4.0%	50.0%
Std.		Count	41	9	50
	2	% within pulse standard	82.0%	18.0%	100.0%
		% of total	41.0%	9.0%	50.0%
		Count	87	13	100
Total		% within pulse standard	87.0%	13.0%	100.0%
		% of total	87.0%	13.0%	100.0%

Since, the skin was normally colonized by bacterial flora, an SSI cannot be diagnosed by the microbiological evidence alone but in conjunction with clinical signs which includes redness, rise of temperature, pain and swelling, separation of the suture line (dehiscence) or the presence of an abscess in the deeper tissues. SSI is a dangerous condition, a heavy burden on the patient and social health system. All surgical wounds are contaminated by bacteria but only a minority of wounds actually demonstrates clinical infection. The SSIs are the biological summation of several factors such as the inoculums of bacteria introduced into the wound during the procedure, the unique virulence of contaminants, the microenvironment of each wound and the integrity of the patients host defense mechanisms.

Patients may mount a Systemic Inflammatory Response Syndrome (SIRS) with an elevated white cell count, body temperature <350°C or >380°C, pulse rate >100/min, respiratory rate >20/min or in severe cases develop signs of sepsis with an attendant increase in morbidity and mortality.

The important point about inflammation was that tissue injury from the incision initiates the mobilization of phagocytes into the wound before bacterial contamination actually occurs from the procedure itself. This mobilization of the innate host defenses before significant intraoperative contamination occurs, undoubtedly gives the patient an advantage against infection as an outcome. Factors that affect surgical wound healing include:

- Microbial factors that influence the establishment of a wound infection which are bacterial inoculum, virulence and the effect of the microenvironment,
- Impaired host defenses,

- Type of procedure and anatomic location of the operation,
- Patient factors including obesity, infection at another site that may increase the risk of spreading infection through the bloodstream, immunocompromised patients and malnutrition. Also, age, race, socioeconomic status and chronic diseases, such as diabetes and malignancy, which may influence SSI occurrence but are difficult to assess because they are frequently associated with other factors that independently contribute to risk.<sup>9,10</sup>
- Wound characteristics include nonviable tissue in wound such as hematoma, foreign material including drains and sutures, dead space, poor skin preparation including shaving and pre-existent sepsis (local or distant).
- Operative characteristics include poor surgical technique, lengthy operation (>2 hrs), intraoperative contamination including infected theater staff and instruments and inadequate theater ventilation, prolonged preoperative stay in the hospital and hypothermia.<sup>11</sup>

clean surgical procedures, in which gastrointestinal, gynecologic and respiratory tracts have not been entered, Staphylococcus aureus from the exogenous environment or the patient's skin flora is the usual cause of infection.<sup>12</sup> The most common group of bacteria responsible for SSIs is Gram positive Staphylococcus and Streptococcus, gram-negative aerobes and anaerobic bacteria that contaminate skin in the groin/perineal areas. The contaminating pathogens in gastrointestinal surgery are the multitude of intrinsic bowel flora, which include gram-negative bacilli (e.g. Escherichia coli) and Gram-positive microbes, including enterococci and anaerobic organisms.<sup>13</sup> Sources of such pathogens include surgical/hospital personnel and intraoperative circumstances including surgical instruments, articles brought into the operative field and the operating room air.<sup>14</sup>

Wound irrigation is the steady flow of a solution across an open wound surface meant to remove cellular debris and surface pathogens contained in wound exudates or residue from topically applied wound care products. 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 or betadine solution, thereby improving the quality of healthcare offered to the patient. However, the ideal irrigation technique and pressure required for optimal outcome are still undetermined in the literature. Pulsed irrigation is the intermittent or interrupted pressurized delivery of an irrigant, typically measured by the number of pulses per second. Original Agency for Health Care Policy and Research (AHCPR) guidelines describe safe and effective irrigation pressures as being 4-15 pounds per square inch (psi), based on a series of different studies. 15-17 Pressure between 4-15psi can be used safely and that a pressure of 8psi appears to be effective and <4psi was ineffective and >15psi can damage wound and drive bacteria into tissue. There are studies in literature which compared the 2 techniques in elective surgical procedures.

This study was conducted to systematically compare the 2 methods and compare the incidence of surgical site infection in elective and emergency patients. For jet irrigation effective pressure used was between 4-15 pounds per square inch. This was achieved with 30-35ml syringe with full pressure produces 8-11psi. Pressure between 4 and 15psi can be used safely and that a pressure of 8psi appears to be effective and <4psi ineffective and >15psi can damage wound and drive bacteria into tissue. Effective irrigation is likely to require copious amounts of fluids suggesting a volume of around 2Litres of normal saline.

The study showed a decrease in the incidence of postoperative SSI in both elective and emergency laparotomy wounds (8%) irrigated with pressurized pulse jet irrigation with normal saline compared with standard irrigation technique (18%) though the study was statistically insignificant since the p value was less than 0.005 with a odds ratio of 2.52. The study also showed the decrease in the postoperative stay with pressurized pulse jet irrigation which decreases morbidity and cost for the patient. The study also showed that most of the SSI occurred on postoperative day 3 and most of SSI was superficial SSI only. The study showed that most of the infected patients were having diabetes mellitus as a predisposing factor for SSI. Also, it was deduced from the study result that with lesser duration of surgery, lesser was the incidence of SSI. The goal of the study was to assess whether pressurized pulse jet irrigation with normal saline of laparotomy wounds will reduce the incidence of postoperative SSI.

The study results suggested that there was decrease in the incidence of SSI in pressurized pulse jet irrigated patients compared to standard irrigation and also it decreases the postoperative stay, morbidity and cost. Thus, this study suggests that use of pressurized pulse jet irrigation with normal saline of laparotomy wounds in both elective and emergency situation decreases the incidence of postoperative SSI compared to standard irrigation technique.

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Ethical approval: The study was approved by the Institutional Ethics Committee of Adichunchanagiri University, Mandya, Karnataka, India

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