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Original Research Article

Comparative Study for Effectiveness of Preoperative Intraincisional Antibiotic Infiltration in Preventing Surgical site Infections in Abdominal Surgery

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Abstract:
Introduction: surgical site infections cause increased post-operative morbidity. In initial days antibiotics were used to be given post-operatively for longer durations which led to little reduction of surgical site infections. With advent of intravenous pre-operative antibiotic administration, the incidence of SSIs reduced significantly. The antibiotic concentration rises in blood and later reaches at the wound site the where the concentration of antibiotic is lower. With modern aseptic techniques and intravenous pre-operative antibiotic administration the incidence of SSI has reduced significantly but is almost constant for many years this has led to search for innovative efforts to reduce the SSI, in view of this pre-incisional infiltration of antibiotics seems to a good candidate. Various studies have shown the measured local antibiotic level to be considerably higher in the patients getting local infiltration of antibiotics than the patients getting intravenous antibiotics alone.

Aim: To assess and compare reduction in incidence of surgical site infection between patients receiving parenteral antibiotics to patients receiving both parenteral and pre-incisional antibiotic infiltration of the wound site.

Materials and Methods: 138 patients were enrolled in the assuming Alpha error (5%) power (80%) and confidence interval (95%), randomization was done by computer generated random tables for different sub groups. Patients were divided in two main groups. Group I received both pre-incisional local and parenteral antibiotics, Group II received only parenteral antibiotics, both the groups were further divided into 3 group each as clean, clean contaminated, contaminated and dirty groups. Inclusion criteria: Patients operated in both emergency and elective operation theatres, patients who underwent abdominal surgeries, procedure lasted less than 3 hours, patients who developed infection within 30 days of surgery. Exclusion criteria: patients with skin infections and infection at other site, patients with psoriasis and other exanthema disorders.

Results: Incidence of SSI was significantly less in group receiving pre-operative intra-incisional antibiotics as compared to the group receiving only intravenous antibiotics.

Conclusions: SSI occurred in 25 out of 92 males while 5 out of 46 females which is statistically significant. Poorly controlled diabetes, smoking and poor nutritional status were associated with higher rate of SSI. SSI was significantly more in emergency patients as compared to elective cases.

Keywords: Dirty Wound, Contaminated Wound, Clean Contaminated Wound, Clean Wound, Pre-Incisional Local Infiltration, Pre-Operative Antibiotics, Surgical Site Infections.

Introduction

Surgical site infections (SSI) are cause of increased post-operative morbidity. Joseph Lister introduced aseptic measures which achieved reasonable decrease in SSI in early days [1]. With the discovery of antibiotics, it seemed possible that SSI can possibly be eliminated. Antibiotics initially were given postoperatively for long duration with little reduction of SSI but with advent of pre-operative antibiotics administration the incidence of SSI decreased significantly. The antibiotic levels rise in the blood compartment initially and later reaches wound site which is lower than the blood levels [2]. Modern aseptic technique and intravenous pre-operative administration of antibiotics had caused decrease in the incidence of SSI but it has become constant for many years. Due to this there is search for innovative methods to further decrease the incidence. SCIP (Surgical Care Improvement Project) infection prevention component is based on 3 principles: antibiotics are to be given within 1 hour before surgical incision, appropriate selection of pre-operative antibiotics, antibiotics to be discontinued within 24 hours of surgery. These efforts are to emphasize the timing of antibiotic administration should be proper, normothermia, peri-operative euglycemia, minimum usage of blood products and better operating room procedures. Pre-incisional antibiotic infiltration seems to be good candidate. Different studies have shown in past the benefits of pre-incisional antibiotic infiltration to reduce SSI. Various studies have measured the local antibiotic levels and found to be having higher levels when compared to levels obtained by intravenous antibiotics alone [3,4]. The patient is exposed less to the systemic effects of antibiotics and also the drug bypasses the fibrin effect because of patient's body response to the surgical incision which in fact act as barrier in preventing the antibiotic to reach the local site [5]. antibiotic gets fixed to the subcutaneous fat and remains at the local site in high concentration to prevent bacterial infection. Bacteria are usually present in many wounds at the time of wound closure, but not all the patients develop the SSI. Various host factors, virulence of the bacteria, amount of concentration of antibiotics also come into play. In this study we have evaluated the predisposing factors of SSIs and the role of intra-incisional antibiotic infiltration along with intravenous antibiotics in abdominal surgery to prevent SSI in emergency and elective settings.

Materials and Methods

After getting ethical clearance from institution and written informed consent from the patients, patients were inducted into the study. 138 patients were selected for the study assuming alpha error (5%) power (80 %) and confidence interval (95%). The patients were divided into two groups, Group 1 included patients who received both pre-incisional local and parenteral antibiotics, Group 2 included patients who received only parenteral antibiotics.

Randomization was done by computer generated random tables for the different subgroups. 138 subjects were randomized by computer into 10 blocks each with 10 patients and last block of 8 patients with random and equal distribution to each group. Once a patient had given consent to enter the trial, an envelope was opened and the patient was offered the allocated number from the block.

Both groups were further divided into clean wounds (B, A), clean contaminated wounds (D, C) and contaminated and dirty wounds (F, E). Table 1

Table 1: Groups were further divided into clean wounds (B, A), clean contaminated wounds (D, C) and contaminated and dirty wounds (F, E)

Groups	Group 1	Group 2
Clean	B	A
Clean contaminated	D	C
Contaminated & dirty	F	E

Inclusion Criteria:

1. Patients operated in emergency and elective settings
2. Patients who underwent abdominal surgery
3. Procedure lasted less than 3 hours
4. Patients who developed infection within 30 days of surgery

Exclusion Criteria:

1. Patients with skin infections and infections at other site.
2. Patients with psoriasis and other exanthema disorders.

Patients in group 1 were infiltrated with pre-incisional antibiotics 10 minutes prior to surgery with all aseptic precautions they also received intravenous antibiotics. The infiltrate covered more area than the actual size of the incision planned in both subcutaneous and muscular layers. Antibiotic agent used was cefotaxime, 1 gram of it was diluted with 20 ml of normal saline and was infiltrated in the area of 10 cm incision site. If the size of incision was more than 10 cm additional drug was diluted and infiltrated. Patients in group 2 were administered only intravenous antibiotics.

Intra-operative swabs from incision site at the time of incision and at the end of surgical procedure were taken from all the patients in the study. Swabs were also taken from surgeon gloves, trolley, linen, instruments.

Patients were followed up on daily basis till the day of discharge from the hospital and followed up in outpatient department once a week till 30 days: while admitted in the ward the patients were daily assessed for general signs: pulse, temperature and signs of SSI i.e pus discharge from wound site, redness around stich line, induration at the incision site, pain and tenderness around the wound site.

Samples from SSI were sent for both aerobic and anaerobic cultures in appropriate transport media. Gram-stained smears of pus were evaluated for bacteria. Aerobic organisms were plated on MacConkey's agar. Anaerobic organisms' specimen was transported in Robertson Cooked Meat medium and plated on Kanamycin blood agar incubated for 18 hours with anoxomat.6 Colonies were identified on morphology and biochemical analysis.

Results

Baseline characteristics, Table 2: All the base line data were comparable like, Group 1 had 70 while group 2 had 68 patients of age 13 years or more, group 1 had 47 males while group 2 had 45 males, group 1 had 25 females as compared to 21 females in group 2. Group 1 had 17 smokers while group 2 had 18 smokers. 9 patients in group 1 were diabetics, but 10 patients were diabetics in group 2. In group 1 36 patients were operated in elective OT while 35 patients were operated in elective OT in group 2. 33 patients were operated in emergency in group 1 while 34 patients were operated in group 2. In terms of wound category also group 1 had 24, 20, 26 patients in clean, clean contaminated and contaminated & dirty category while group 2 had 22, 24, 22 patients in respective category.

Table 2

Variable		Group 1	Group 2	
Age	13 years onwards	70	68	
Sex	Male (92)	47	45	
	Female (46)	25	21	
Smoking	Yes (35)	17	18	
	No (103)	53	50	
Diabetes mellitus	Yes (19)	9	10	
	No (119)	60	59	
Albumin	<3	14	16	
	>3	10	4	
Surgery	Elective (71)	36	35	
	Emergency (67)	33	34	
Category of wound	Clean	24	22	
	Clean contaminated	20	24	
	Contaminated & dirty	26	22	

Table 3 represents the outcomes related to Surgical Site Infections (SSIs) and compares them across the two groups (Group 1: Pre-incisional and Parenteral Antibiotics, and Group 2: Only Parenteral Antibiotics).

Contaminated & Dirty Wounds: Group 1 shows 3 cases of contaminated & dirty wounds, with 1 infection (33.33%), while Group 2 shows 7 cases, with 4 infections (57.14%). The p-value of 0.040 indicates a statistically significant difference between the two groups in terms of SSI incidence in contaminated & dirty wounds, suggesting that the pre-incisional antibiotics significantly reduced SSI rates in these wound categories.

Albumin Levels and SSI Incidence: Group 1 (low albumin <3 g/dl) had 14 patients, with 6 cases of SSI (42.86%), and Group 2 (low albumin <3 g/dl) had 16 patients, with 13 cases of SSI (81.25%). The p-value of 0.008 indicates a statistically significant difference, suggesting that low albumin levels are associated with a higher risk of SSI, and pre-incisional antibiotic infiltration may help reduce SSI risk in this group. For patients with albumin >3 g/dl, the SSI rates are similar between groups (2 out of 10 in Group 1 and 0 out of 4 in Group 2), with a p-value of 0.4462, which is not significant.

Smoking and SSI Incidence: Group 1 (smokers): 7 out of 24 smokers developed SSI (29.17%), while Group 2 (smokers): 7 out of 17 smokers developed SSI (41.18%). Group 1 (non-smokers): 7 out of 49 non-smokers developed SSI (14.29%), and Group 2 (non-smokers): 9 out of 48 non-smokers developed SSI (18.75%). The p-value of 0.002 indicates a statistically significant difference in the occurrence of SSI based on smoking status, suggesting that smoking may contribute to higher SSI rates, and pre-incisional antibiotic infiltration may be beneficial for smokers.

Sex and SSI Incidence: For males, Group 1 had 8 out of 47 males with SSI (17.02%), while Group 2 had 17 out of 45 males with SSI (37.78%). For females, Group 1 had 2 out of 25 females with SSI (8.00%), while Group 2 had 3 out of 21 females with SSI (14.29%). The p-value of 0.029 suggests a statistically significant difference between groups, indicating that males in Group 1 (who received pre-incisional antibiotics) had a significantly lower rate of SSI compared to those in Group 2.

Age and SSI Incidence: For Group 1, the SSI incidence is low across all age groups (1 out of 10 for ages 13-17, 8 out of 54 for 18-65, and 0 out of 6 for >65). For Group 2, the SSI incidence is higher for ages 13-17 (4 out of 11) and 18-65 (16 out of 52), more than 65(1 out of 5). The p-value for all age groups is NS (not significant), suggesting no statistically significant difference in the incidence of SSI by age group between the two groups.

Summary of Key Findings: Contaminated & Dirty Wounds: Pre-incisional antibiotics significantly reduce SSIs in this group (p-value =0.040).

Albumin Levels: Patients with low albumin levels (<3) showed a significant reduction in SSIs with pre-incisional antibiotic infiltration (p-value = 0.008).

Smoking: Smokers had a higher incidence of SSI, but pre-incisional antibiotic infiltration appeared to reduce SSI rates in smokers (p-value = 0.002).

Sex: Male patients had significantly fewer SSIs in Group 1 (pre-incisional antibiotics) compared to Group 2

(p-value = 0.029) while females in both the groups showed no significant p-value.

Table 3

	Variable	**Group 1 (P+I)**			**Group 2 (Only PA)**			**P value**
		Total P	**SSI**		**Total P**	**SSI**		
Age	Group 1 (13-17 Yrs)	10	1		11	4		NS (Not significant)
	Group 2 (18-65 Yrs)	54	8		52	16		NS
	Group 3 (>65 Yrs)	6	0		5	1		NS
Contaminated & dirty	Group 1	3	1		7	4		NS
	Group 2	22	8	36.67%	14	10	71.42%	0.040
	Group 3	1	0		1	1		NS
Albumin	Contaminated alb <3	14	6		16	13		0.008
	Contaminated alb >3	10	2		4	0		0.4462NS
Smoking	Yes	24	7		17	7		0.002
	No	49	7		48	9		NS
SEX	Male	47	8		45	17		0.029
	Female	25	2		21	3		

Figure 1 and Figure 2 show patients with wound infection who are administered with figure 1. both intraincisional and intravenous antibiotics and Figure 2 only intravenous antibiotics.

Figure 1: Superficial SSI in a patient of laparotomy done for ileal perforation. patient was administered intra-incisional and intravenous antibiotics.

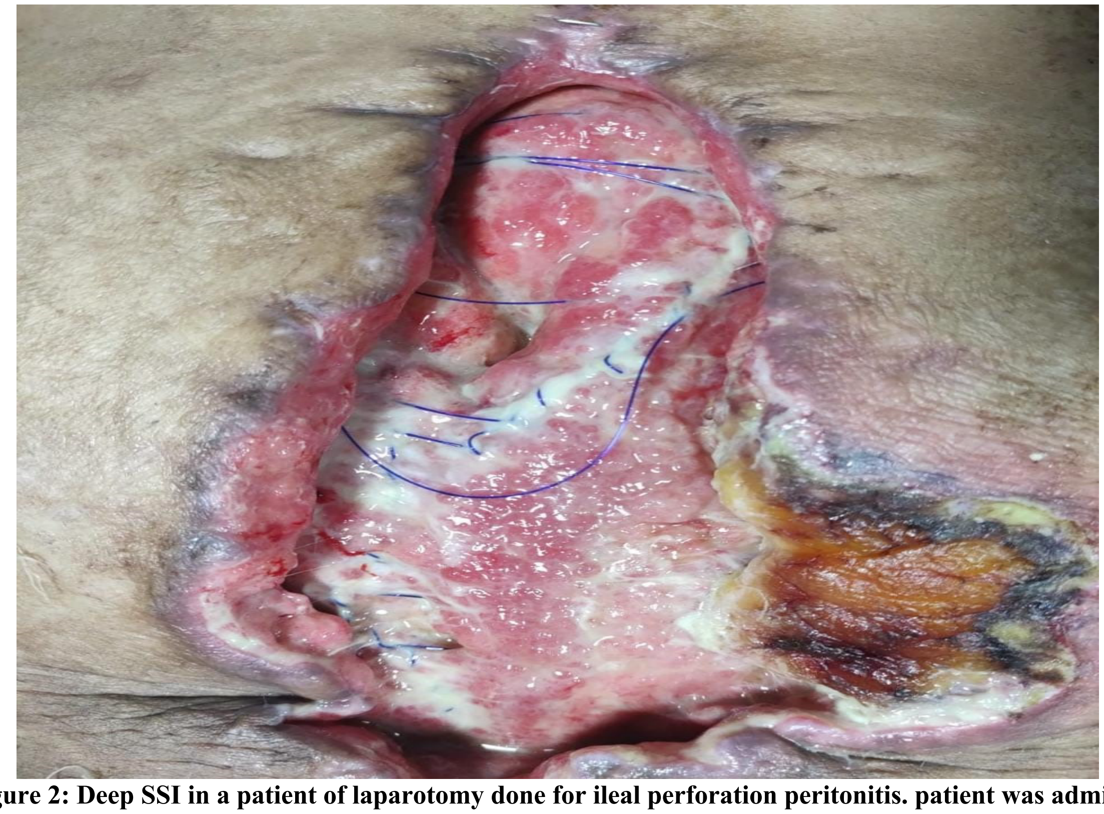

Figure 2: Deep SSI in a patient of laparotomy done for ileal perforation peritonitis. patient was administered intravenous antibiotics only.

The study indicates that pre-incisional antibiotic infiltration is particularly effective in reducing SSI rates in contaminated wounds, in patients with low albumin, and in smokers, with a marked benefit for males.

Discussion

The principles of antisepsis by Joseph Lister and Pasteur's germ cell theory in the 19th century have led to a better understanding in the etiopathogenesis of postoperative wound infection. Despite improvement in operating room practices, instrument sterilization methods and better surgical techniques, surgical site infections (SSIs) remain a major cause of post-operative morbidity and delay in discharge from hospital. It affects up to 5% patients even in the developed countries. SSI is the third most commonly reported nosocomial infections and accounts for 14-16 % of all nosocomial infections among hospital inpatients [6].

Patients with all types of surgical wound classes, clean, clean contaminated and contaminated develop SSI. At the end of surgery bacteria and other microorganisms contaminate all surgical wounds, but only a small number of patients actually develop a clinical infection. Whether an infection actually occurs depends on the number of bacteria entering the wound, type and virulence of the bacteria and host defense mechanism. Multiple factors implicated in the causation of SSI include non-modifiable factors like age, pre-existing illness, obesity, malnutrition, type of wounds, duration of surgery and virulence of bacteria and modifiable factors for reducing SSI rate which include sterility in operating rooms, proper hand washing and gowning, proper draping of patients and prophylactic antibiotics.

SSI occurs as a result of imbalance between host resistance and bacteria, when bacteria present at the time of closure of incision are more than 105 per gram of tissue and host immunity is lowered. The portal of entry is when incision is made and the ineffective organism is usually patient's own flora [7]. This time frame from making the incision till closure requires presence of antibiotics at the wound site to prevent SSI.

Early studies and trials of prophylactic antibiotic agents failed to show efficacy in preventing surgical site infections because the antibiotics were given after surgery. Burke using a guinea pig model demonstrated that administering antibiotics before or shortly after the inoculation of skin with S. aureus reduced the size of the ensuing skin lesion markedly and that with each delay of an hour in antibiotic administration, the resulting lesion became larger until the third hour. By the fourth hour, the lesion was the same size as in untreated control animal [8].

A prophylactic antimicrobial agent should be used only when indicated and selected based on its efficacy against the most common pathogens causing SSI for a specific operation and published recommendations.

1. The initial dose of prophylactic antimicrobial agent should be administered by the intravenous route, timed such that a bactericidal concentration of the drug is established in serum and tissue when the incision is made [2]. Therapeutic levels of the agent in serum and tissue should be maintained throughout the operation and until a few hours after the incision is closed.
2. The use of antibiotics preoperatively can reduce the rate of infection, particularly wound infections, after certain operations. For most procedures, an inexpensive, first or second-generation cephalosporin, which has a moderately, long half-life and is active against staphylococci and streptococci, has been effective when given intravenously (IV) 30 minutes before surgery.

Studies done by Pollok et al, Sarda et al, Dogra et al Brown et al have used intra-incisional antibiotics preoperatively in reducing SSI [3,4,9,10,11]. In our study we infiltrated the incision site 10 minutes preoperatively with cefotaxime along with intravenous antibiotics 30 minutes prior to incision.

Otrega et al found clean and clean contaminated to be less infected than contaminated and dirty wounds [12]. We also observed SSI in contaminated cases (24/30) to be more than clean (2/30) and clean contaminated (4/30) cases. Surgical site infections occur in 2-5% of patients undergoing surgery compared to 21.7% in our study [6]. The SSI in clean cases (4%), clean-contaminated (9%) and contaminated cases was (50%) found in our study was higher than that reported in literature. Similar SSI rates were observed in previous Indian studies by Sarda et al and Dogra et al [11].

In study conducted by Hodonou, M.A et al Emergency surgery resulted in a 50.0% rate of SSI (49 out of 98 patients in emergency surgery), while among the 245 patients with non-emergency surgery, 56 (22.9%) developed SSI ($p = 0.000$, Risk Ratio = 2.2; confidence interval = [1.6, 3.0]) [13]. SSI rate was significantly more in cases operated in emergency (37%) compared to elective cases (7%) in our study. The number of contaminated wounds was higher in emergency (60%) as compared to elective cases (11%).

An important observation of our study was that intra-incisional antibiotics along with intravenous antibiotics not only decreased the number of SSI but number of deep and organ space SSI even in the contaminated wounds. Intra-incisional antibiotics thus considerably reduce the morbidity of patients operated in emergency.

In our study the role of malnutrition, poorly controlled diabetes and smoking in the causation of SSI was evaluated. Age, even though it is an important predisposing factor, could not be evaluated independently since 106/138 patients were in the age group II (17-65 years).

Diabetes along with multiple transfusions has been shown to be associated with higher SSI rate in multivariate analysis as shown by Tablot et al in his study of 154 sternotomy wounds [14]. Recently a study by Takesue et al showed that diabetics with good glycemic control were less prone to SSI compared to patients with poor glycemic control [15]. In our study we also found that patients operated in emergency with poor glycemic control (60%) developed SSI more frequently than patients operated electively with good glycemic control (15%).

Malnutrition is another factor in causation of SSI. We measured hemoglobin and albumin level of patients and found that hemoglobin levels did not correlate with SSI in our study.

Albumin levels less than 3g/dl preoperatively increase the SSI as shown by Hennessey et al in his study of 524 patients undergoing abdominal surgery [16]. In our study we also found that patients with albumin less than 3 g/dl were more prone to develop SSI. The rate of SSI in patients with low albumin was significantly higher compared to patients with normal albumin levels. Intra-incisional antibiotics along with intravenous antibiotics reduced SSI in this subset of patients.

Smoking was another factor uncovered as a risk factor in our study. 40% smokers developed SSI as compared to 18.3 percent non-smokers which was statistically significant. Similar effects of smoking in development of SSI have been reported by studies of Mawalla et al and Edward Mills et al [17,18]. Patients with smoking and low albumin levels when administered intra-incisional antibiotics had low SSI rate as compared to when administered intravenous antibiotics alone.

We observed in our study prolonged stay after SSI occurring in both group of patients i.e receiving intraincisional antibiotic with intravenous antibiotic and receiving intravenous alone. Increased hospital stay was also seen in the study done by Sarda et al. in patients with SSI.

In contrast to west where SSI is mostly caused by MRSA, most common organism in our study was Escherichia coli followed by Staphylococcus aureus. This was also observed by Sarda et al, in their study most of the SSI was caused by gram negative Escherichia coli [11].

Thus, on the basis of our study it can be stated that intra-incisional antibiotics are effective in reducing SSI in all types of wounds specially the contaminated ones. Even in patients with comorbidities like malnutrition, diabetes, age >40 years and smoking who are prone to SSI intra-incisional antibiotics along with intravenous antibiotics reduce SSI. Intra-incisional antibiotics should perticularly be used in emergency settings where operated patients tend to have higher rates of SSI. One other advantage of using intra-incisional antibiotics is that even if SSI occurs it is limited to superficial SSI on most occasions. Considering none of our patients showed any complication to this technique, intra-incisional antibiotics along with intravenous antibiotics is superior to intravenous antibiotics alone in emergency and high-risk patients.

Conclusions

Pre-incisional antibiotics significantly reduce SSIs (p-value = 0.040), Patients with low albumin levels (<3) show a significant reduction in SSIs with pre-incisional antibiotic infiltration (p-value = 0.008), Smokers have a higher incidence of SSI, but pre-incisional antibiotic infiltration can reduce SSI rates in smokers (p value = 0.002).The study indicates that pre-incisional antibiotic infiltration is particularly effective in reducing SSI rates in contaminated wounds, in patients with low albumin, and in smokers.

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