

Original Research Article

Incidence of surgical site infection in patients undergoing clean, clean contaminated cases with respect to antibiotic prophylaxis: a prospective observational study

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ABSTRACT

Background: Surgical site infection (SSI) is the most surveyed and frequent type of healthcare associated infection in low-middle income countries. With the advent of antibiotics its incidence has been decreased but prolonged use of prophylactic antibiotics in clean and clean contaminated surgeries has increased substantial burden on healthcare system.

Methods: This is a single centric, prospective, observational study. In the period over 12 months, patients which were admitted for elective clean, clean contaminated surgeries were assessed preoperatively, intraoperatively and postoperatively. The patients in the study group received 1 dose of prophylactic antibiotic in clean cases and 3 doses in clean-contaminated cases according to the protocol and control group patients didn't follow this criterion.

Results: Incidence of SSI is 2.26% in study group, which was not significantly high compared to control group which was 1.97. Incidence of superficial SSI is higher in both study and control group as compared to deep SSI. The most common isolate from wound culture was *Staphylococcus aureus*. Also strain of *E. coli*, sensitive strain of *Pseudomonas* and resistant strain of *Klebsiella pneumonia* were isolated.

Conclusions: Irrational use of prophylactic antibiotics in clean and clean contaminated cases is not beneficial and just adding the cost and increasing the chances of development of antibiotic resistant strains.

Keywords: Surgical site infections, Antibiotic prophylaxis, Clean surgeries, Clean contaminated surgeries, Healthcare associated infections

INTRODUCTION

Health care-associated infections (HAIs) are acquired by patients when receiving care and are the most frequent adverse event affecting patient safety worldwide.¹ Surgical site infections (SSIs) are potential complications associated with any type of surgical procedure. SSIs are the most surveyed and frequent type of HAIs in low-middle income countries (LMIC).¹ In LMICs, the pooled incidence of SSI is 11.8/100 surgical procedures (range 1.2-23.6).¹

SSIs are defined as infections that occur 30 days after surgery with no implant, or within 1 year if an implant is placed and infection appears to be related to surgery.²

Figure 1 describes the classification of SSI. SSIs are divided into the categories of superficial incisional SSI, deep incisional SSI, and organ/space SSI depending on the depth of invasion.^{1,6}

SSI can be further classified according to severity into 'minor' where there is wound discharge without any

clinical presentation of cellulitis or deep tissue destruction and ‘major’ where there is pus discharge with tissue breakdown, partial or total dehiscence of deep fascial layers or systemic illness present.^{1,6} It can also be classified into early SSI (within 30 days), intermediate SSI (1-3 months) and late SSI (more than 3 months).¹

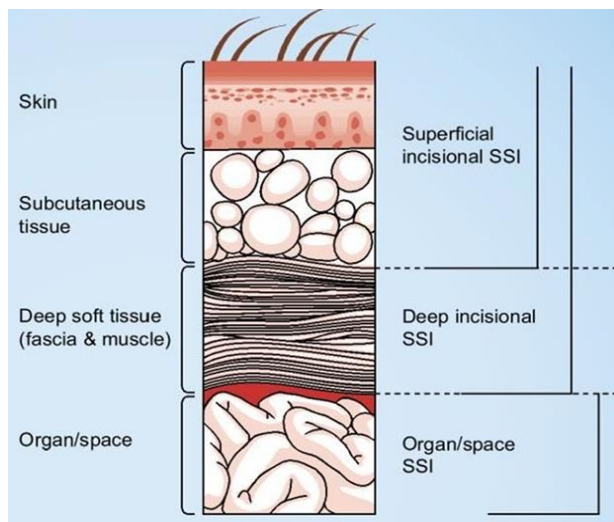


Figure 1: Classification of SSI.

The risk in SSI is related to the amount of contamination with microorganisms which is called “class” of the operation. ‘Clean cases’ are those where there is no break in aseptic condition and respiratory, alimentary or genitourinary tracts are not entered, whereas ‘clean contaminated’ are those in which respiratory, alimentary or genitourinary tracts are entered but without any spillage. These clean and clean contaminated cases have less chances of development of SSI compared to ‘contaminated’ and ‘dirty cases’.^{1,12}

The combined prevalence of SSI in elective clean and clean-contaminated surgeries in all countries analysed was 6%.³

The incidence of SSI may be influenced by factors such as pre-operative care, the theatre environment, post-operative care and the type of surgery.² The risk factors for development of SSI can be divided into ‘patient related’ like old age, diabetes, immunocompromised states, anaemia, steroid use, and prior radiation exposure or ‘local factors’ like poor skin preparation, contamination of instruments, inadequate antibiotic prophylaxis, prolonged procedure, local tissue necrosis, hypoxia, and hypothermia, or ‘microbial factors’ like resistant strains, contaminated or dirty class or prolonged hospitalisation.²

The prevention of these infections is complex and requires the integration of a range of preventive measures before, during and after surgery.⁴

According to global guidelines for the prevention of SSI by World Health Organization (WHO), the

recommendations for the prevention of SSI to be applied or considered in the pre-, intra- and postoperative periods are summarized together with the associated PICO questions and their strength and evidence quality.¹ Decolonization with mupirocin ointment with or without chlorhexidine gluconate (CHG) body wash for the prevention of *Staphylococcus aureus* infection in nasal carriers, optimal timing for preoperative surgical antibiotic prophylaxis (SAP), mechanical bowel preparation along with the use of oral antibiotics, hair removal with clippers only if absolutely necessary, use of alcohol-based antiseptic solutions based on CHG for surgical site skin preparation, surgical hand preparation with the use of scrubs using soap and water or alcohol based preparations are some of the recommendations considered with strong strength and moderate quality of evidence.^{1,7,8}

No standardised guidelines backed by evidence are currently established in India for the prevention of SSI. Hence, there is a need for an adaptable, executable national guideline for low- and middle-income countries which includes India.⁴

The observable impact of SSI is not only increased morbidity and mortality, but an increased economic burden for the entire healthcare system in developing countries.³ The SSI can be caused by either primary/endogenous source from body’s own flora where staphylococcus infection is the more common isolate or secondary/exogenous where factors such as contaminated instruments, poorly disinfected floor, poor hand washing techniques, etc are responsible.^{2,5}

Antibiotic resistance is a natural phenomenon that occurs when microorganisms are exposed to antibiotic drugs. Under the selective pressure of antibiotics, susceptible bacteria are killed or inhibited, while bacteria that are naturally (or intrinsically) resistant or that have acquired antibiotic-resistant traits have a greater chance to survive and multiply. Not only the overuse of antibiotics but also the inappropriate use (inappropriate choices, inadequate dosing, poor adherence to treatment guidelines) contribute to the increase of antibiotic resistance.¹³

Microorganisms acquire resistance through evolution and adaptation. In particular, there is concern about the rise in SSIs due to vancomycin-resistant enterococci (VRE), methicillin-resistant *Staphylococcus aureus* (MRSA), third generation cephalosporin-resistant *Escherichia coli*, and imipenem- and quinolone-resistant *Pseudomonas aeruginosa*.^{2,5}

The primary objective of our study is to know the incidence of the surgical site infection in patients undergoing clean, clean contaminated cases with respect to antibiotic prophylaxis. Secondary objective is to study the frequency of various pathogens causing SSI with their antibiotic resistance pattern in patients undergoing clean, clean contaminated cases.

METHODS

Study design

This was a single centric, observational, prospective study.

Study site

The study was conducted in department of general surgery of Nanavati Super Speciality Hospital, Vile Parle, west, Mumbai, Maharashtra, India.

Study duration

The study was conducted for a period of 12 months from January 2019 to December 2019.

Study population

The target population selected according to inclusion and exclusion criteria, patients undergoing elective clean and clean contaminated surgeries in Nanavati Super Speciality Hospital, Mumbai.

Ethical considerations

The study was initiated after obtaining approval from the institutional ethics committee and department of general surgery. A written informed consent was taken from the patients when they were stable and ready for enrolment into the study.

Selection criteria

Participants were selected based on the following selection criteria.

Inclusion criteria

All patients undergoing elective clean, clean contaminated cases were included in the study.

Clean cases included in the study are inguinal and umbilical hernia repairs (laparoscopic as well as open surgeries), thyroid and parathyroid surgeries, hydrocele excision, and lipoma excision.

Clean contaminated cases included in the study are laparoscopic cholecystectomy, laparoscopic appendectomy, laparoscopic bariatric surgeries, exploratory laparotomy done for elective resection of colonic and small intestinal malignancies, and incisional hernia repair.

Patients with age more than 18 years, in whom regular follow-up has been done, who were ready to give written informed consent, and willing to be part of the study were also included.

Exclusion criteria

Emergency surgeries, contaminated or dirty surgical cases, patients with psychiatric disease, and patients not willing to be part of study were excluded.

Statistical analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean±standard deviation (SD) and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality is rejected then non parametric tests were used. Qualitative variables were compared using Chi-square test/Fisher's exact test.

A p value of <0.05 was considered statistically significant. Odds ratio was used to determine association between variables and outcome. The data was entered in Microsoft excel spreadsheet and analysis was done using statistical package for social sciences (SPSS) version 21.0.

Study procedure

Detailed history and clinical examination were done before surgery. All the clinical features/sign-symptoms of patients were recorded in the proforma before the procedure. Patients were categorised into study group who followed the protocol and control group who didn't follow the protocol of clean, clean contaminated surgeries.

All the parameters of the protocol including preoperative bathing, surgical hand and field preparation, perioperative glucose control, normovolemia, normothermia, hair removal, mechanical bowel preparation was kept constant except the preoperative antibiotic prophylaxis.

In the study group, prophylactic dose of parenteral antibiotic was given as single dose prior to incision in clean cases and 3 doses (1st before incision and rest two at the interval of 12 hours). 3rd generation cephalosporin is used as a standard antibiotic (cefuroxime 1.5 gm intravenous route) and in case of cephalosporin resistance or allergy, vancomycin or clindamycin according to body weight was given. In the control group this preoperative antibiotic prophylaxis criterion was not followed.

All the cases were followed up on in-patient and out-patient basis on 8th, 15th and 30th post-operative day. Data also collected from microbiology department of incidence of SSI and culture and sensitivity report of the tissue or pus culture taken.

Data analysis

Surgical site infection then categorised into superficial incisional, deep incisional and organ or space related SSI.^{1,6}

Table 1: Protocol followed for patients undergoing clean, clean contaminated surgeries in the study group.

Preoperatively	Perioperatively
Preoperative bathing either with regular soap/ antimicrobial soap	Prophylactic dose of parenteral antibiotics single shot within 60 mins of incision in clean cases (single shot as prophylaxis)
Mechanical bowel preparation with oral antibiotics, if applicable	Prophylactic dose of parenteral antibiotics single shot within 60 mins of incision and continue same till 24 hours postoperative in clean contaminated cases (total 3 shots as prophylaxis)
Perioperative blood glucose control	Surgical site preparation with alcohol based (chlorhexidine gluconate) skin solution
Hair removal only with the help of clipper, if absolutely necessary	Normovolemia, normothermia and preoperative oxygenation is standardised for all the patients
Sterile drapes, gowns and gloves	
Clean environment in the operation theatre and decontamination of medical devices and surgical instruments	
Surgical hand preparation	

RESULTS

Total 513 patients were included in the study who underwent clean and clean contaminated surgeries, out of which 310 were there in the study group who followed the protocol and 203 were in the control group who didn't follow the protocol.

7 patients out of 310 of study group and 4 patients out of 203 of control group developed surgical site infections in combined clean, clean contaminated surgeries (Table 2). Clean cases which got infected were 3 out of 7 from study group and 1 out of 4 from control group. Clean contaminated cases which got infected were 4 out of 7 from study group and 3 out of 4 from control group.

Incidence of overall SSI in clean cases is 1.45% and in clean contaminated cases is 2.77%. Incidence of SSI is 2.26% in study group and 1.97% in control group.

6 patients out of 7 in study group and 3 patients out of 4 in control group have developed superficial incisional SSI.

They all were managed on out-patient basis with oral antibiotics, regular dressings and overall increased hospital stay was by 1 day. 1 out of 7 patients in study group who developed deep incisional SSI presented to us on POD10 with wound gaping and serous discharge from wound site, was managed with secondary suturing. Wound swab was sent, showed no growth in culture, hence regular follow-up and wound check was done. 1 patient out of 4 in control group developed deep SSI, presented with fever, pus discharge from wound site on POD7. Culture sensitivity report of the wound culture showed *Pseudomonas* sensitive strain and *Klebsiella* strain sensitive only to colistin. Patient managed with parenteral antibiotics for 5 days and vac dressings on inpatient and outpatient department. In these cases, prolongation of hospital stays by 3-5 days with additional cost expenditure occurred.

Most common organism isolated from wound culture is *Staphylococcus aureus*. Others include *E. coli*, sensitive strain of *Pseudomonas* and resistant strain of *Klebsiella pneumoniae*.

Table 2: Surgeries performed and cases infected in study and control group from January 2019 to December 2019.

Surgeries performed	Study group		Control group	
	No. performed	Infected cases	No. performed	Infected cases
Inguinal hernia	56	1	32	1
Umbilical hernia	28	1	22	0
Thyroid and parathyroid	6	0	3	0
Lipoma, sebaceous cyst	38	0	18	0
Hydrocele	12	0	8	0
Breast	12	1	28	0
Bariatric surgeries	56	0	0	0
Cholecystectomy	66	1	42	0
Appendectomy	18	1	26	1
Exploratory laparotomy	18	2	24	2
Total (513)	310	7	203	4

Table 3: Incidence of SSI.

Total cases (382)	Study group (310)		Control group (203)	
	Clean cases	Clean contaminated	Clean cases	Clean contaminated
No. of cases	152	156	111	92
Incidence of SSI	3	4	1	3
No SSI	149	152	110	89
Total incidence	7		4	

Table 4: Incidence proportion of SSI (number of infected cases/number of surgeries performed) × 100.

Parameters	Study group		Control group	
	Clean cases	Clean contaminated cases	Clean cases	Clean contaminated cases
SSI (%)	0.96	1.29	0.49	1.48
No SSI (%)	99.04	98.71	99.51	98.52
Total SSI (%)	2.26		1.97	

Table 5: Management of SSI.

Parameters	SSI in study group		SSI in control group	
	Clean cases	Clean contaminated cases	Clean cases	Clean contaminated cases
Superficial infection	3	3	1	2
Deep infection	0	1	0	1
Overall length of hospital stays increased (days)	1	3	1	5-6
Management	Oral antibiotics, daily dressings	Parenteral antibiotics, secondary suturing	Oral antibiotics, daily dressings	Parenteral antibiotics, Vac dressings
	No growth in 2 cases	<i>Staphylococcus aureus</i> in 1 superficial SSI, no growth in rest	<i>Staphylococcus aureus</i>	<i>Pseudomonas aeruginosa</i> , <i>Klebsiella pneumonia</i>

Table 6: Organisms isolated from the SSI.

Organisms isolated	Number
<i>Staphylococcus aureus</i> (coagulase negative)	2
Enterococcus (group D)	0
<i>Pseudomonas aeruginosa</i>	1 (sensitive strain)
<i>Escherichia coli</i>	1
<i>Klebsiella pneumonia</i>	1 (sensitive to only colistin)
<i>Candida albicans</i>	1
<i>Corynebacterium</i>	0
Beta-haemolytic <i>Streptococcus</i>	0
<i>Enterobacter cloacae</i>	0
Others	0

DISCUSSION

The wound classification system categorizes all surgeries into: clean, clean contaminated, contaminated and dirty with estimated postoperative rates of surgical site infection (SSI) being 1-5%, 3-11%, 10-17%, and over 27%

respectively.^{10,12} In our study, the incidence of overall SSI in clean cases is 1.45% and in clean contaminated cases is 2.77%, which is low as compared to the benchmark set for the developing countries at the international platform.^{1,9,11} Incidence of surgical site infection in elective clean and clean contaminated cases is possible to lower down with proper perioperative care.

Despite the advances in surgical techniques, sterile protocols, and perioperative antibiotic regimens, SSIs remain a significant problem.¹⁰ For this we had standardised the pre-operative as well as post-operative criteria as mentioned in our study protocol for study and control group except the use of surgical antibiotic prophylaxis (SAP). In the study group we had given single shot prophylactic parenteral antibiotic prior to skin incision in clean cases and total 3 shots of antibiotics in clean contaminated cases.

It had been observed that in control group, prophylactic antibiotics are used for a greater number of days either in the form of intravenous route till patient is admitted or/and via oral route for 3-5 days. The incidence of SSI is 2.26% in study group and 1.97% in control group and there is no

statistical significance noted. Hence, the prolonged use of antibiotics in control group didn't give any additional benefit but increase the additional cost and length of hospital stay in case of parenteral antibiotic use ultimately increasing the economic burden on the individual and the healthcare system. It may further lead to increase the chances of development of antibiotic resistance, drug related allergies and complications.

Superficial incisional infection is the one where only skin and subcutaneous tissues of the incision are involved and deep incisional infection is the one where deep soft tissues of the incision like fascial and muscle layers are involved.^{1,6} In our study, we have observed that 9 out of 11 patients got superficial infection and it was managed on out-patient basis with oral antibiotics, regular dressings and overall increase in length of hospital stay by 1 day.

2 out of 11 patients who got deep incisional infection were both clean contaminated cases one of each control and study group. We managed these cases with daily clinical evaluation and monitoring, usage of parenteral antibiotics for longer duration according to wound culture sensitivity reports and daily dressings with wound check. One of 2 patient also required 3 sittings with VAC dressings at the interval of 5 days and regular follow-up with wound check and antibiotics after that and another required secondary suturing due to wound gape as a complication. These patients had overall increased length of hospital stay by 3-6 days and additional cost of the treatment. Management of SSI is complex and a costly affair especially in low-middle income countries; hence, prevention of SSI is the need of an hour. The modifiable potential factors can be prevented by following and standardising the guidelines.⁴

In this study, *Staphylococcus aureus* strain was isolated from 2 patients which is the most commonly found isolate on body's own flora also known as endogenous source. In one of our patients from control group who developed deep SSI, *Pseudomonas aeruginosa* strain and *Klebsiella pneumoniae* strains were isolated. They were found to be sensitive to only colistin antibiotic, route of administration is parenteral and recovery for this patient was delayed.

Since the introduction of antibiotics in 20th century led to great improvement in surgical outcomes and decrease in SSI. Rampant use of these antibiotics came with its own set of problems like the rise in incidence of antibiotic resistant strains (MRSA) and rise in incidence of allergies and other complications.¹

Hence, irrational use of prophylactic antibiotics in clean and clean contaminated cases is not beneficial and just adding the cost and increasing the chances of development of antibiotic resistant strains. Hence standardisation of international and national guidelines for LMICs including India by carrying out a greater number of clinical trials and establishment of recommendations are required to prevent the SSI with respect to antibiotic prophylaxis.

CONCLUSION

Thus, this study is an attempt to know the need of standardised protocol to reduce the incidence of SSI in clean and clean contaminated cases with respect to antibiotic prophylaxis. There were few limitations associated with this study, that, it was a single centric study and long-term follow-up was not possible because of the nature of the study design. Secondly, we were not able to differentiate between factors responsible for SSI due to demographic variations. Thus, a large scale multicentric prospective study will help in validating the results of our study.

Recommendations

Use of single dose prophylactic antibiotic in elective clean cases and 3 shot antibiotics in elective clean contaminated cases since there is no significant difference in the incidence proportion of SSI in study and control group.

MRSA testing prior to all surgical cases can be included in the protocol. Since, *Staphylococcus aureus* is the most common organism responsible for SSI and there is significant rise in incidence of antibiotic resistant strains has been noted.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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