ORIGINAL ARTICLE

Outcomes are Local: A Cross Sectional Patient Specific Study of Risk Factors for Surgical Site Infections in Major Abdominal Surgeries

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Abstract:

Background: Surgical Site Infections (SSI) after elective/emergency laparotomy contributes to postoperative morbidity, mortality and resource utilization. Risk factors related to abdominal SSIs are well known. Nevertheless, National data guide efforts to improve efficiency, which cannot identify specific organizational risk factors. *Aim and Objectives:* To describe the prevalence and risk factors associated with SSI in patients undergoing laparotomy. *Material and Methods:* Descriptive, observational study of elective/ emergency laparotomy patients uses institutional data from 2017-2019. Univariate and Multivariable logistic regression identified risk factors associated with SSI development. *Results:* Of 393 patients studied. 88 developed SSI (superficial 19.60%, deep 2.30%, organ space 0.50%), age (40-60 years), males, Body Mass Index (BMI) >25, smoking, diabetes, alcohol, higher wound class, low hematocrit, low serum albumin, Longer duration of surgery were associated with increased SSI rate. Associated co-morbidities, Low hematocrit and higher duration of surgery were significant independent risk factors ($p<0.05$). *Conclusion:* Institutional SSI modeling shows that many previously suggested nationally defined risk factors do not contribute to SSI, at our institution. Identifying SSI's institutional contextual predictors, rather than relying on external data assumptions, is a vital endeavor to promote quality improvements and maximize the value of quality investments.

Keywords: Surgical Site Infection, Abdominal Surgeries, Risk factor, Centre for Disease Control

Introduction:

Centre for Disease Control (CDC) has introduced the term 'Surgical Site Infection' (SSI), replacing the old terminology of wound infection in the 20th century, for every infection occurring in the postoperative incision site [1]. SSI is responsible for serious surgical outcomes and complications. This accounts for 14-17 % of overall hospital-acquired infection and nearly 38% of hospital-acquired infection in surgical patients post-operatively [2]. Morbidity and mortality are major concerns, which need to be addressed after SSI [3]. SSI is hugely responsible for economic burden over the patient, related to a prolonged hospital stay, repeated culture investigations, debridement and re suturing.

The discussion over SSI is mainly concerned with the identification of risk factor (responsible for enhancing the chance of SSI) and isolating the causative pathogen (to act specifically over-determined pathogen to control the infection). Factors responsible for increasing the risk of SSI are mainly dependent on patient factors and operative procedures. Patient factors like age, gender, co-morbidities i.e. diabetes, cardiovascular diseases, hypertension, immune-compromised state, smoking, alcohol, obesity, stress, malnutrition enhance the risk of SSI. While it is also dependent on operative intervention, emergency/

elective setting, duration of operation, perioperative infusion, type of wound and length of hospital stay [4].

SSI rate can be controlled effectively by pre-operative preparation starting from operative room intervention including proper theatre ventilation, effective sterilization method, sterilized and auto-claved instruments, timely fumigation, and auto-claved clothing [2]. Preoperatively proper anti-biotic coverage, operative skin preparation with antiseptics constitutes a quintessential part in the prevention of SSI [5].

Despite these activities, SSI is associated with a prolonged hospital stay of nearly 7-10 additional days and also responsible for 2-10 times greater mortality risk in comparison to non-infected post-surgery patients [2]. SSI needs to be addressed and has been given enough importance for better patient care. A thorough systematic approach is needed to check the incidence of SSI and guidelines should be created regarding the approach towards SSI. SSI constitutes most preventable hospital-associated infections and puts the burden on the health care system. They are responsible for mortality and morbidity all over the world. The prevention of SSI is a complex step and it requires the definitive integration of measures before, during, and after surgery [2-3]. Since there are many factors associated with increased risk of SSI which have been studied in previous researches, our aim to conduct this study was to identify risk factors for SSI in our hospital setting which would help to develop practices to reduce SSI rate which costs considerably to patients and health care system.

Material and Methods:

This prospective cross-sectional case study was conducted at Acharya Vinoba Bhave Rural Hospital, a tertiary care teaching hospital situated in the rural area of Wardha District, from September 2017 to August 2019, in patients who underwent emergency /elective major abdominal surgeries. The determination of the minimum sample size was determined using Modified Fischer's formula. For sample size determination, 6% SSI rate is used from study by Singh *et al*. [6].

Where $N \geqslant \{Z2\ 1\text{-}\alpha/2 \times P \times (1\text{-}P)\}/d2$

Z1a/2 = is standard normal variate (at 5% type 1 error (P<; 0.05) it is 1.96 and at 1% type 1 error ((P<0.01) it is 2.58). As in majority of studies P values are considered significant below 0.05 hence 1.96 is used in formula

p = Expected proportion in population based on previous studies or pilot studies.

d = Absolute error or precision, p= 6%

d= 0.05 (5% level of significance).

The minimum sample size was 88 patients.

This study included all the patients who are >14 years of age and underwent major abdominal surgeries, in the Department of Surgery in emergency as well as elective setting.

The demographic data of the patients along with the diagnostic criteria were collected. Other information including related risk variables (i.e. diabetes, obesity, steroid therapy, alcohol consumption, smoking, etc.), type and length of surgery, clinical wound assessment (considered infected if there is pus release or redness and fever with swelling) and laboratory information (including gram stain, outcomes of cultivation, identification of bacterial isolates as well as antimicrobial susceptibility) were registered on a datasheet. SSI has been categorized and diagnosed in accordance with the Disease Control and Prevention Center rules – CDC Atlanta 1999 [1]. The wound class has been categorized as clean, clean-contaminated, contaminated and dirty. Swabs were taken from the infected surgical locations from the profound portion of the wound or pus, bacterial isolates were identified and tested for antimicrobial susceptibility, the samples were examined aerobically, anaerobically on blood agar as well as in boiled meat broth for the existence of bacteria or pus and cultured, bacterial isolates has been recognized and tested for antimicrobial susceptibility. Based on the above outcomes, information was statistically evaluated to determine the variables influencing SSIs in laparotomy patients.

Statistical Analysis:

Statistical Analysis was done by using SPSS 22.0 versions. Discrete variables were described as frequency and continuous variables were described as Mean, Standard Deviation (SD). We used a multivariate linear regression model to know the association of independent risk factors to SSI and a P-value of <0.05 was considered as significant.

Results:

Demographic Profile of the Selected Subjects with SSI:

From August 2017 to May 2019, all 393 patients meeting our criteria were selected. The mean age was 58 years, roughly half 48.78% of the patients were women and 32.31% of patients were obese [Body Mass Index (BMI) of 30 or higher]. Mean operative time for all cases including elective as well as in emergency setting was 184 min (Table 1). Nearly 22.4 % of patients developed one or more SSI: 19.6% superficial, 2.3% deep and 0.5% developed organ space infection. Due to the small number of patients experiencing organ space SSI, organ space SSI was grouped along with deep SSI (Table 1).

Univariate and Multivariate Regression Model for SSI:

On univariate analysis, the development of SSI varied across patient factors (Table 1). Patients having a high risk of SSI were with age >40, low hematocrit, BMI >30, smokers, diabetics, higher wound class, higher operative duration, low serum albumin, emergency intervention ($p<0.05$). Upon multivariate analysis of all the risk factors evaluated, low hematocrit, co-morbidities and Higher duration of surgery were statistically significant ($p<0.05$) (Table 2).

Table 1: Univariate Analysis of Surgical Site Infection

Factors	SSI Present (n=88)	SSI Absent (n = 305)	*P*
1. Age	34 (34.34%)	65 (65.66%)	<0.001
<40 year	22 (26.82%)	60 (73.18%)	
41-50 year	21 (26.25%)	59 (73.75%)	
51-60 year	06 (09.37%)	58 (90.63%)	
61-70 year	05 (07.37%)	63 (92.64%)	
71-80 year			
2. Gender	54 (23.58%)	175 (76.42%)	0.50
Male	34 (20.73%)	130 (79.27%)	
Female			
3. Type of Surgery	36 (14.93%)	205 (85.07 %)	<0.001
Elective	52 (34.21%)	100 (65.79%)	
Emergency			
4. Class of Wounds	07 (03.64%)	185 (96.36%)	<0.001
Clean	19 (32.20%)	40 (67.80%)	
Clean Contaminated	27 (47.36%)	30 (52.64%)	
Contaminated	35 (41.17%)	50 (58.83%)	
Dirty			
5. Duration of Surgery	06 (8.82%)	62 (91.18%)	<0.001
< 1 Hour	13 (10.56%)	110 (89.44%)	
1-2 Hour	41 (32.53%)	85 (67.47%)	
2-3 Hour	28 (36.84%)	48 (63.16%)	
>3 Hour			
6. Hematocrit	56 (33.73%)	110 (66.27%)	<0.001
<38	32 (14.10%)	195 (85.90%)	
⩾38			
7. Serum Albumin	60 (37.50%)	100 (62.50%)	<0.001
<3.5(g/dL)	28 (12.02%%)	205 (87.98%)	
⩾3.5(g/dL)			
8. BMI (kg?m2)	38 (21.84%)	136 (78.16%)	0.14
18.5-24.99	27 (29.35%)	65 (70.65%)	
25-29.99	23 (18.11%)	104 (81.89%)	
>30			
9. Diabetes	16 (24.24%)	50 (75.76%)	0.69
Yes	72 (22.02%)	255 (77.98%)	
No			
10. Smoking	32 (35.95%)	57 (64.04%)	<0.001
Yes	56 (18.42%)	248 (81.58%)	
No			
11. Hypertension	11 (19.30%)	46 (80.70%)	0.54
Yes	77 (22.92%)	259 (77.08%)	
No			
12. Alcohol	18 (21.18%)	67(78.82%)	0.76
Yes	70 (29.41%)	238 (70.49%)	
No			

Table 2: Multivariate Regression Analysis Model for Surgical Site Infection

Coefficient	Estimate	Std Error	T Value	*P*
Age	-0.001	0.002	-0.722	0.472
BMI	0.001	0.009	0.130	0.896
Comorbidities	0.348	0.123	2.831	**0.005***
Duration of Surgery	0.100	0.041	2.441	**0.017***
Hb	-0.014	0.017	-0.866	0.389
Hematocrit	-0.013	0.005	-2.559	**0.012***
Sex	0.008	0.076	0.114	0.909
Serum Albumin	0.028	0.050	0.575	0.567
Type of Surgery	-0.105	0.095	-1.099	0.275
Type of Wound	-0.050	0.042	-1.206	0.231

Discussion:

Despite modern surgical techniques and the use of antibiotic prophylaxis, SSI is one of the most common complications encountered in surgery. SSI places a significant burden on both the patient and the health system. Despite the advances made in its control, it remains a significant limiting factor in advancing the horizons of surgery. SSI is, therefore, a significant cause of morbidity; extended hospital stays and higher health expenses. SSI is the result of the failure of the host defense system in controlling the external source inciting the infection in the human body and delaying wound healing. Chronic medical circumstances such as malnutrition, diabetes, anemia, and obesity also influence the defenses of the host and boost the probability that a surgical infection would develop [1]. The primary objective of this study was to describe the prevalence and risk factors associated with SSI in patients undergoing laparotomy. The collected data tabulated and results are described below.

Age is an important variable leading to SSI. Increasing age is associated with an increased incidence of SSI. Delayed wound healing in the elderly is associated with an altered inflammatory response such as delayed infiltration of T-cells into the wound region with changes in the manufacturing of chemokine and decreased phagocytic ability of the macrophage [7].In this study, we have observed that the mean age of SSI was 58 years.

Sex hormone plays a key role in the healing of wounds. Males were shown to have delayed wound healing compared to females. Compared to male's testosterone, female estrogens have a beneficial effect on wound healing. Estrogen controls regeneration, inflammation, matrix manufacturing, protease inhibition, and epidermal function-related genes. Therefore, women have fewer incidences of SSI as compared to males [8]. In this study, we have observed that SSIs were seen more in males as compared to females.

Emergency surgical procedures result in a higher incidence of SSI as compared to elective surgical procedures. Emergency procedures don't allow to correct existing blood abnormalities like low hemoglobin, hypoalbuminemia, etc. preoperatively which results in higher postoperative SSI, similarly, emergency surgeries usually result in dirty/contaminated wound which indirectly increases the rate of SSI, in comparison to elective procedures [9]. In this study, we have observed that SSI was seen more in emergency cases as compared to elective cases. The risk of SSI increases as the wound class moves from clean to contaminated/dirty. Contaminated and dirty wound increases the risk of bacterial invasion of the incision site from endogenous flora while clean wounds are mostly infected by the skin flora [10]. In this study, we have observed that SSI was more associated with class 4 and class 3 wounds.

Duration of surgery is an independent risk factor for SSI which is partially modifiable as compared to non-modifiable patient-related risk factors. Pre-operative preparation, surgeon's experience, paramedic staff experience, and operation theatre culture all impact the duration of surgery. The exact mechanism is not fully understood but a longer duration of surgery increases the risk of tissue contamination as there is longer exposure of incision site to environmental factors. Longer duration surgery often implicates complex surgical procedures and result in surgeons' fatigue leading to more technical errors [9]. In this study, we have observed that SSI was seen more in > 2 hours of surgery as compared to < 2 hours of surgery.

Co-morbidities put a negative impact on wound healing post-surgical wounds. Co-morbidities like smoking, alcohol consumption, diabetes, obesity, and hypertension have different mechanisms of influencing wound healing [10]. The carboxy-hemoglobin level increases and neutrophil defense mechanism decreases in smokers as compared to non-smokers resulting in tissue hypoxia which is the primary cause of reduced collagen production and wound infections in smokers [11]. Obesity causes hypoperfusion of fat tissue which results in wound infection, seroma formation. Adipose tissue secrets Adipokines which has a negative influence on the healing process [10]. In this study, we have observed that smoking, obesity, alcohol consumption, diabetes increased the risk SSI.

Obesity increases the risk of SSI substantially when the abdominal fat layer exceeds 3 cm, leading to needing larger incision, hypoperfusion of fat tissue and technical difficulty in operating which indirectly results in wound infection, seroma formation, hematoma formation, wound dehiscence and pressure ulcer. In addition to local conditions, obesity causes stress, anxiety, depression indirectly leading to impaired immune response [12]. Adipose tissue secrets Adipokines which has a negative influence on the healing process [12].In this study, we have observed that there is a positive correlation between SSI and BMI, with the Rate of SSI was seen more in BMI >25 as compared to BMI <25.

Low hematocrit in surgical patients' pre/post operatively results in the low partial pressure of oxygen at the tissue level and potentially contaminated tissue resulting in decreased oxygen tension which increases the risk of SSI [13].In this study, we have observed that SSI was seen more in low hematocrit patients, obtained preoperatively.

Malnutrition is a common problem resulting in surgical complication including SSI. Albumin is a strong predictor of the nutritional status of the patient. Hypoalbuminemia causes poor tissue healing, decreased collagen production and granuloma formation resulting in an increased risk of SSI. In acute illness, there is a reduction in serum albumin due to alteration in hepatic metabolism and loss of albumin into interstitium resulting in tissue medium which provides medium for tissue propagation. Hypoalbuminemia is also associated with impairment of immune responses and decreased macrophage activation [14]. In this study, we have observed that SSI was associated with more serum albumin <3.5 as compared to >3.5. SSI postoperatively is divided into superficial, deep and organ space infections. Superficial site infections are mostly caused by skin contaminants (i.e. hospital flora mostly), while deep/organ space infection is mostly caused by endogenous visceral flora and skin contaminants gaining entry through the incision site. Proper microbial culture and their respective antibiotic sensitivity have to be found out to decrease the rates of SSI and their intensity. Proper antibiotic coverage has to be done to cure the infected cause. In this study, we have observed that maximum SSI were caused by *E.coli* species (54.55%), followed by *Klebsiella* species (42.05%) and *Pseudomonas* species (18.18%) [15]. In this study, we have found that organisms isolated from surgical site were most sensitive to amikacin (81.81%), followed by imipenem (69.31%), colistin (55.69%) and gentamycin (39.77%).in this study, on multivariate analysis, we have found that associated co-morbidities, duration of surgery and low hematocrit were found to be independent risk factors for SSI. (P<0.05). Similarly, van Ramshorst *et al.* [16] conducted a study on 1452 patients, out of which 363 Developed SSI, in these cases significant independent risk factors were age, gender, chronic pulmonary disease, ascites, jaundice, anemia, emergency surgery and type of surgery. Adejumo *et al.*[17] studied 291 patients out of which 85 developed SSI, significant risk factors were Type of surgery, duration of surgery, class of wound, ASA Status and anemia. The study by Robert *et al.*[18] on 2376 patients and 9% developed SSI and observed that wound class, diabetes, and type of procedure were independent risk factors.

Conclusion:

Using institutional data focused on postoperative outcomes within 30 days, several risk factors previously reported to be predictors of abdominal surgery SSI were not confirmed at our institution. These results indicate that local care and case-mix variables impact results considerably and independently, making inter-institutional comparisons using national data-based models difficult. Focusing on mitigating nationally reported risk factors or implementing specific interventions developed elsewhere may not be useful at an individual institution.

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