Journal of Rawalpindi Medical College (JRMC); 2015;19(3):209-214

Original Article

Surgical Site Infections after Elective Surgery in Pakistan: SURGIPAK Study

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Abstract

Background: To determine the incidence of surgical site infections(SSIs), and to document the causative organisms, duration of hospital stay, and therapeutic class of antibiotics administered in surgical prophylaxis in patients undergoing elective surgeries in Pakistan.

Methods: In this multicenter observational study surgeons were randomly selected. Surgical data from each investigator was collected from surgeries performed within a period of three months prior to the last month preceding the site initiation date. Patients 18 years of age or above, who had undergone elective surgeries that included gastrointestinal, biliary, pancreatic, urogenital, abdominal hernia, gynecologic procedures including caesarean section, were selected. The investigator collected data on last 10 consecutive patients preferably in the month between -2 and -1.Recruitment list of 10% investigators was validated against the Operation theatre (OT) list. For each patient, data on demography, surgical information, antibiotic usage, SSI information and laboratory analysis was captured.The data was collected on a standardized case report form (CRF). The CRF was completed by the investigator/study coordinator.

Results: Out of 858 patients, 71% were females. The mean age was 38.8±13.1 years. Three most common surgeries were gynecological including caesarean section (42.4%, 364/858), biliary (19.8%, 170/858) and abdominal hernia (18.4%, 158/858). In most cases (54.5%, 468/858), the duration of surgery was between 1–4 hours, and a majority (67.7%, 581/858) were classified as clean surgeries. In total, 6.5% patients (56/858) developed SSIs (95% confidence interval 5.1%-8.4%). All patients undergoing pancreatic surgery (n=3) developed SSI. Of the patients who developed SSIs 50% (28/56) developed it in post operative hospitalization period. The most common organisms isolated were Staphylococcus aureus (37.5%, 21/56), Escherichia coli (30.4%, 17/56) and Enterobacter (5.4%, 3/56). Significant mean difference (8.3±10.3 vs 3.3±2.9 days, p <0.001) in duration of hospital stay was observed in patients who developed SSI in comparison to those who did not. Cephalosporin (73.2%) was the most common therapeutic class used for prophylaxis, with third generation cephalosporin used in 60.7%.

Conclusions: Periodic reporting of SSI rates is essential for international benchmarking and for strategizing efforts in reducing the associated healthcare burden in developing nations.

Key Words: Surgical site infections.

Introduction

Surgical site infections (SSIs) are not only the most common complication following surgical procedures, but are also the most common type of nosocomial infections (NIs). They account for 20% of all healthcare-associated infections[1, 2] and 38% of NIs among surgical patients.[3]A pilot study in Pakistan shows that 13% of patients who underwent elective surgery had SSIs.[4]

As per the Centers for Disease Control and Prevention (CDC) National Nosocomial Infection Survey (NNIS) definition, a SSI is confirmed if one out of the following four criteria is fulfilled: (1) purulent drainage; (2) a positive culture result from wound swab; (3) local symptoms and opened by a surgeon, unless culture result is negative; (4) when the diagnosis is made by a surgeon or physician.[5] SSI is also defined as an infection occurring in surgical wound within 30 days of operation.[6] As per the classification by US CDC, SSIs have been categorized into three groups – superficial, deep, and organ/space infections.[7] The four categories of surgical wounds (on the basis of degree of microbial contamination), namely – clean, clean-contaminated, contaminated and dirty, represent the increasing risk of SSIs.[8]

SSIs are associated with adverse outcomes, which vary in severity depending on the category of surgical procedures.[9] They lead to a failure in wound healing, thus contributing to increased duration of hospital stay, greater likelihood of admission to intensive care unit (ICU), mounting treatment costs, and higher patient mortality.[2,10] Patients with SSIs are 60% more likely to spend time in an ICU and 5 times more likely to be readmitted.[11] SSIs are responsible for 77% deaths of surgical patients with NIs.[3]

Periodic reporting of SSI rates is essential for international benchmarking and for strategizing efforts in reducing the associated healthcare burden in developing nations.A World Health Organization (WHO) report indicates that 66% of developing countries have no published data on the burden of SSIs.[12] The published data of surgical prophylaxis for Pakistan is scant. The few pilot studies, documenting selected information on SSIs were conducted at single sites. The WHO suggests that studies from single hospitals cannot be considered representative of the epidemiology of health care associated infections in a given country. [12]With a view to adopting measures to decrease the incidence of SSIs, the limited local literature necessitates the collection of data, and mandates surgical audits and wound surveillance.[13]

An earlier cross-sectional study, National Audit of Surgical prophylaxis Pattern in Pakistan (NASPAK) , conducted in 2009 — to determine the rate of surgical prophylaxis administration, compliance of surgeons with clinical guidelines on surgical prophylaxis, and to document the therapeutic class of surgical antimicrobial prophylaxis administered in patients undergoing elective surgeries in Pakistan— did not necessarily reflect the overall practice at the hospital where the surgeon operated and did not collect any information pertaining to SSIs postoperatively, due to which SSI rates could not be determined (unpublished data).

This retrospective nationwide study "Burden of SURGIcal site infections in elective surgeries in tertiary care hospitals in PAKistan (SURGIPAK) was therefore designed to collect information on the magnitude of SSIs, and to document the causative organisms, duration of hospital stay, and the therapeutic class of antibiotics administered in surgical prophylaxis in patients who underwent elective surgeries.

Patients and Methods

This was a multicenter observational study conducted in accordance with the principles laid by the 18th World Medical Assembly (Helsinki, 1964) and all subsequent amendments, and also guidelines for Good Epidemiology Practice. The investigators selected were surgeons operating in various public/private tertiary care hospitals in Pakistan. The investigators were randomly selected from a list of surgeons available with Sanofi Pakistan. The list of surgeons was validated against the list of surgeons obtained from College of Physicians and Surgeons (CPSP), a certifying and registration institution of surgeons in Pakistan. An investigator's questionnaire was provided to the investigators to record their profile and information about surgical practice.

Surgical data from each investigator was collected from surgeries performed within a period of three months prior to the last month preceding the site initiation date.Patients 18 years of age or above, who had undergone elective surgeries that included gastrointestinal, biliary, pancreatic, urogenital, abdominal hernia, gynecologic procedures including caesarean section, were selected. The surgeries had been performed within a period of three months prior to the previous month of the study. Patients were excluded if they had undergone emergency surgeries, pediatric surgeries, surgeries not mentioned in the inclusion criteria, orthopedic surgeries, wound dehiscence, fecal/biliary/urinary fistulas, surgeries for malignancies, or if data was missing on culture and susceptibility (wound and/or blood) in patients with SSIs, or if the surgeries were performed during the immediate last month to site initiation date.

The investigator collected data on last 10 consecutive patients preferably in the month between -2 and -1, who met inclusion/exclusion criteria (Fig 1). Recruitment list of 10% investigators was validated against the Operation theatre (OT) list. For each patient, data on demography, surgical information, antibiotic usage, SSI information and laboratory analysis was captured.The data was collected on a standardized case report form (CRF). The CRF was completed by the investigator/study coordinator.

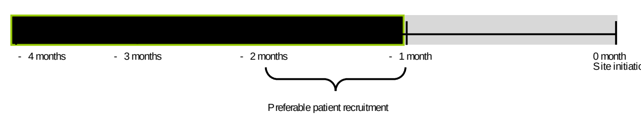

Figure 1: Period of patient recruitment

Estimates from a pilot study conducted in Pakistan were used to determine the sample size. According to this study, 13% of patients who underwent elective surgery had SSIs.[4] Assuming an error of 2% and 95% confidence level, data on 1100 patients was likely to provide an estimate of postoperative SSIs in Pakistan. Expecting 5% missing information in retrospective data, 1160 patients were considered sufficient to document the burden of SSIs. This sample size was also estimated to be sufficient to meet the secondary objectives. After data collection study documentation including CRFs, screening log and OT list were dispatched to Sanofi affiliate head office, Karachi for double entry by data punch operator and data analysis by SPSS v.18 (IBM Corp, Sorners, NY, USA).Categorical data were analyzed for percentage distribution. Continuous data were reported as mean (±standard deviation [SD]), and comparison in mean difference between hospital stay (days) in patients who developed and did not develop SSIs was determined by using independent t-test. p-value <0.05 was considered significant.

Results

The data were collected between19th May 2012 and 21st February 2013 from 84 sites (32 of the initially planned 116 sites declined to submit the data towards the end of the study period). Seventy six sites provided data for 10 patients each and 8 sites provided data for more than 10 patients. In total, 1549 patients were screened, which yielded data for 893 patients, out of which data for 858 patients were evaluated and analyzed.Demographics and surgery characteristics:TheAnalyzed mean age of the study participants was 38.8 (± 13.1) years with women constituting a majority of the study population (71%). The three most common surgeries were gynecological including caesarean section (42.4%, 364/858), biliary (19.8%, 170/858), and abdominal hernia (18.4%, 158/858) (Table 1). In most cases (54.5%, 468/858), the duration of surgery was between 1 to 4 hours, and a majority (67.7%, 581/858) were classified as clean surgeries (Table 1).

In total, 6.5% patients (56/858) developed SSIs (95% confidence interval [CI] 5.1%-8.4%). All patients undergoing pancreatic surgery (n=3) developed SSI. Patients undergoing gastrointestinal surgeries (13.6%, 8/59),patients with dirty (50%, 2/4) and contaminated wounds (29.7%, 11/37) had a higher incidence of SSIs (Table 1).

Of the patients who developed SSIs, 50% (28/56) patients developed it in the postoperative hospitalization period, whereas the other half developed it after discharge. The diagnosis of SSIs was made on the basis of purulent discharge from the incision in 50% (28/56) patients, surgeon diagnosing infection in 16.1% patients, deliberate opening of wound by surgeon in 8.9% patients, purulent discharge from the drain in 5.4% (3/56) patients, and organism isolated from culture of wound/blood in 1.8% patients. More than one diagnostic criterion was used to diagnose SSI in 17.9% cases.Skin was involved in 28% patients, subcutaneous tissue was involved in 26% and both skin and subcutaneous tissue were involved in 40% patients. Deep SSI was diagnosed in 7% patients.

In all but one patient (98.2%), the specimen used for culture reporting was collected from the wound; in one patient it was obtained from blood. In patients with SSIs, organisms were isolated in 83.9% (47/56) of the samples, the most common being Staphylococcus aureus (37.5%, 21/56), Escherichia coli (30.4%, 17/56) and Enterobacter (5.4%, 3/56) (Table 2).

SSI developed after 6.8 (± 6.3) days of surgery. Surgical wound healed in 13.2 (±5.7) days in patients who developed SSI.Overall,33.9% (n=19) patients were re-hospitalized for an average of 8 (± 4.8) days. Patients who developed SSI showed significantly higher mean duration of hospital stay (days) than those who did not develop SSIs (8.3 ± 10.3 days vs 3.3 ± 2.9 days, p <0.001).

Cephalosporin (73.2%) was the most common therapeutic class used for prophylaxis, with third generation cephalosporin used in 60.7%(Table 3).A combination of antibiotics was used in 23.8%,mostly in gynecological surgeries including caesarean section (12.8%) and gastrointestinal surgeries (3.7%). Intravenous route of administration was used in 95.7%. Patients were administered first dose of antibiotic 68 (± 270) minutes prior to surgery. The prophylactic dose was administered within one hour prior to surgery in 83% and 8% received it at the time of incision.

Table 1: Incidence of SSI and duration of antibiotic administration by type of surgery

Type of Surgery	(n=858)	(%)	Duration of antibiotic use(days) Mean±SD	SSI (%)
By wound classification				
Clean	581	67.7	3.2 ± 2.9	4.0
Clean Contaminated	233	27.2	2.9 ± 2.2	8.2
Contaminated	37	4.3	4.8 ± 3.2	29.7
Dirty	4	0.5	6.5 ± 5.5	50.0
By anatomical site				
Gynecology including CS	364	42.4	3.3 ± 2.9	2.5
Biliary	170	19.8	3.0 ± 2.7	9.4
Abdominal Hernia	158	18.4	2.6 ± 2.4	8.2
Urogenital	104	12.1	4.3 ± 3.2	9.6
Gastrointestinal	59	6.8	3.8 ± 2.6	13.6
Pancreatic	3	0.3	7.0 ± 2.6	100

Abbreviations: SD, Standard Deviation; SSI, Surgical Site Infections; CS, Cesarean Section

The mean duration of antibiotic administration was 3.3 (± 2.8) days. Antibiotics were used for a prolonged duration for urogenital surgeries (mean 4.3 ± 3.2 days). The longest duration of antibiotic use was in patients having dirty wounds (mean 6.5 ± 5.5 days) (Table 1). Irrespective of the type of surgeries, antibiotics were likely to be continued postoperatively. Antibiotics were continued postoperatively in 94%, (802/858) patients, for an average of 4 (± 3) days. In 91.1% (51/56) patients the same prophylactic antibiotic was continued postoperatively. This continuation was more common for gynecological surgeries including caesarean section (38.2%), biliary (19.5%) and abdominal surgeries (18.2%).

Table 2: Organisms isolated from samples collected from wound swab or blood

Organisms isolated	N=56	(%)
Staphylococcus aureus	21	37.5
Escherichia coli	17	30.4
Enterobacter	3	5.4
Enterococcus	2	3.6
Morganella catarrhalis	2	3.6
Klebsiella	1	1.8
Streptococcus	1	1.8

Table 3: Distribution of patients who developed SSI by prophylactic antibiotic class administered

Antibiotic class	SSIs (N=56)	(%)	Mean Dose ±SD (mg)	Mean duration ±SD (days)
Cephalosporins				
1st generation	2	3.6	750±353.5	3.0±2.8
2nd generation	5	8.9	1300.0±541.9	4.2±2.5
3rd generation	34	60.7	1080.8±293.3	5.2±5.1
Metronidazole	9	16.1	1133.3±556.7	9.7±8.5
Amoxicillin/Clavulanate	5	8.9	1080.0±109.5	5.2±3.8
Quinolone	2	3.6	350.0±212.1	22.0±0
Penicillin	1	1.8	2000.0±0.0	3.0±0.0
Aminoglycoside	2	3.6	1500.0±707.1	16.5±13.4
Ampicillin	0	0	0.0±0.0	0.0±0.0

Abbreviations: SD, Standard Deviation; SSI, Surgical Site Infections

Discussion

This multicenter observational study showed that 6.5% patients undergoing elective surgeries in Pakistan develop SSIs. Patients undergoing gastrointestinal surgeries and patients with dirty and contaminated wounds have high incidence of SSIs. Staphylococcus aureus followed by Escherichia coli and Enterobacter are the most common causative organisms. The mean duration of hospital stay increases in patients with SSIs. The most common therapeutic class used for prophylaxis in patients who develop SSI is cephalosporin (73.2%) with third generation cephalosporin administered in 60.7% of the patients. Majority of patients are administered antibiotics by the intravenous route and receive the prophylactic dose within one hour prior to surgery.

The rate of infection in a healthcare institution serves as a clinical indicator of the quality of service delivered.[10] The incidence of SSIs observed in this study (6.5%) is similar to that (6.6%) reported by a study conducted in 2009-2010 in a medical college and hospital in Pakistan.[13] However, it is lower than that (9.294%) reported by a study conducted in 2008-2009 in a tertiary care facility in Pakistan.[7] This variation in SSI rate may be due to differences in the characteristics of hospital population, the underlying diseases, differences in clinical procedures, the extent of infection control measures, and hospital environment.[14] Our study shows the highest rate of SSIs (50%) in surgeries involving dirty wounds. Highest SSI rates are seen in gastrointestinal surgeries as most are dirty cases and these can be attributed to wound contamination by gut content.[7,15]

Staphylococcus aureus(37.5%) was the most common organism isolated from samples of patients diagnosed with SSI; this was in line with other studies.[16,17] Escherichia coli and Klebsiella have been observed as the next most common organisms.[10,13] Some other studies, show a slight deviation with Escherichia coli as the most common organism.[1,2] Also, an alarming increase in Methicillin-Resistant Staphylococcus aureus (MRSA) has been observed, with 42% Staphylococcus aureus infections in Pakistan found to be methicillin-resistant.[18] In addition, gram-negative organisms like Escherichia coli isolated from patients with SSIs have also shown an increasing resistance.[19] The available data thereby emphasizes the need for antimicrobials with a wide spectrum of activity, combined with low potential for resistance development, and activity against resistant and multi-resistant strains.

Patients who developed SSIs showed a significant difference in the mean duration of hospital stay as compared to those who did not develop SSIs (8.3 ± 10.3 days vs 3.3 ± 2.9 days,$p<0.001$). This finding is supported by several past reports. [13, 15]A retrospective review in Europe, a prospective surveillance in Italy,and an observational study in India report an additional length of 9.8, 11.1 and 9.98 days hospital stay, respectively, in SSI positive patients.[17,20,21] The increased duration of hospital stay is a major contributor to the mounting costs of SSIs.[22] Nearly one-third of the patients in this study were re-hospitalized due to SSIs, further increasing the resource utilization attributable to SSIs. The clinical and economic burden caused by SSIs necessitates appropriate infection control interventions to provide valuable cost savings.

The duration of surgical procedure was ≤ 1 hour for 44.1% (378/858) surgeries, between 1 to 4 hours for 54.5% (468/858) surgeries, while seven surgeries (0.8%) lasted for > 4 hours. Prolonged duration of surgery increases risk of SSI, with higher rate seen in surgeries lasting more than 80 minutes and more than 150 minutes.[8,13] Infection rate increases almost two times by every hour of operation[23] with 6.3 times higher risk of wound infection with operations lasting for more than one hour.[15] A higher frequency of SSIs was reported in caesarean sections lasting more than 90 minutes.[2] Similar results were seen in another study, with 2.6% SSI in surgeries of duration less than 1 hour, 4.8% SSI in surgeries lasting between 1-2 hours and 5.4% SSI in surgeries of more than 2 hours duration.[24] Mangram AJ et al therefore affirm the duration of surgery as one of the three reliable predictors of SSI risk.[3]

In our study, the most common therapeutic class used for prophylaxis in patients who developed SSI, was cephalosporin (73.2%), with third generation cephalosporins administered in 60.7% patients. Our findings are in line with the observations made in the NASPAK registry conducted in 2009 wherein cephalosporins (n=743, 81.0%) were the most common therapeutic class used for surgical prophylaxis and third generation cephalosporins were the most preferred antibiotics (unpublished data). Earlier studies (conducted in 2010 and 2013) have also reported that third generation cephalosporins are prescribed most frequently (64.74% and 64.40% pre- and post-operatively, respectively).[21,25]It is evident that the cephalosporins have remained the most commonly used class of antibiotics over the past few years, probably because of their favorable pharmacokinetic profiles, low incidence of adverse effects and low costs.[26]

The study covered a varied spectrum of surgical settings as it was conducted in 84 centers across Pakistan involving both public and private sector hospitals, thus providing diversity, to the results.Design of the study allows collection of patient follow-up data such as duration of postoperative antibiotic use. However, despite best efforts the target sample size could not be achieved (it was planned to evaluate a sample of 1100 patients, but only 858 patients were evaluated). Therefore further studies with adequate sample sizes need to be conducted to extrapolate these results to the population.

Conclusion

1.This study demonstrates that 6.5% patients develop SSI after elective surgeries in Pakistan. Staphylococcus aureus is the most common causative organism.

2.Majority of patients undergoing elective surgery in Pakistan receive antibiotic prophylaxis. Cephalosporin, especially third generation cephalosporin are most widely used for prophylaxis in patients with SSI.

3.SSIs are associated with increased morbidity and mortality in surgical patients, thus imposing an extensive clinical and economic burden on a developing economy. Raising awareness at different levels, among local/national authorities and the public, calls for efforts in periodic reporting of SSIs rates and for international benchmarking.

4.Studies on the use of antibiotics in surgical prophylaxis need to be conducted to aid in monitoring and detecting the changing susceptibility patterns for SSIs that may require modification of antibiotic usage.

5.Standardizing surveillance protocols and enhancing funding of multimodal, multicenter or national intervention programs, and WHO-directed interventions, may result in increased overall patient safety and substantial reductions in healthcare expenditure related to SSIs.

Acknowledgements

We would like to thank the following participating physicians who recruited patients –

Gulzar Ahmed(Bahawalpur);Asrar Ahmad Khan(Faisalabad);Dilawiez Ahmed(Faisalabad);GhulamMahboobSubhani(Faisalabad); Muhammad Yasin(Faisalabad);Shahbaz Ahmad(Faisalabad); Bashir Ahmad(Faisalabad); Asadullah Malik(Faisalabad); Muhammad Akram(Faisalabad); Faisal Bilal Lodhi(Faisalabad); FakharHameed(Faisalabad); Haji Akhter(Gujranwala);AftabMunir(Hyderabad);AmbreenAmna, (Hyderabad); Chandra Madhudas(Hyderabad); FehmeedaMemon(Hyderabad);FirdousMumtaz(Hyderabad) ;Furkhanda Habib(Hyderabad); Gulfarin Khan(Hyderabad); Hira Shah(Hyderabad); SanoberShaikh (Hyderabad); Summaya Israr(Hyderabad); Farana

Anjum(Hyderabad); M Paryal Taggar(Hyderabad); Nishat Zehra(Hyderabad); Nusrat Lakho (Hyderabad); Pushpa Sirichand (Hyderabad); Sajda Yusfani (Hyderabad); Shazia Rani (Hyderabad); Rahil Rahman(Karachi); Iffat Javed(Karachi); Yasmeen Nauman (Karachi);Ahmad Raza (Lahore); Farogh Zahra(Lahore); Javed Sheikh (Lahore); Kamran Chaudhry(Lahore); Mansoor A Qureshi (Lahore); Muhammad Naeem(Lahore); ShabnamAsif, (Lahore); TouseefAsghar (Lahore); Ehsan-ur-Rehman(Lahore); JavedShakir(Lahore); Lubna Riaz Dar (Lahore); Safia Munir(Lahore); Malik Hussain Jalbani (Larkana); ShahidRao(Multan); Syeda Ali(Multan); Hajira Sultana(Multan); Muhammad Ayub(Multan); M Sajjad Masood(Multan); Mehnaz Khakwani (Multan); Saira Ayub (Multan); Sajjad Masood(Multan); Shahida Parveen (Multan); Abdul Qayyum(Peshawar); Ali Gohar(Peshawar); Imran Khan(Peshawar); Muhammad Muslim(Peshawar); Mah Munir(Peshawar); Hizbullah Jan (Peshawar); Ihsan-ur- Rehman(Peshawar); Muhammad Asghar(Peshawar); Mir Alam Jan (Peshawar); NaeemMumtaz(Peshawar); Parveen Naveed (Peshawar); Rukhsana Karim (Peshawar); Sajjad M Khan (Peshawar), Shahid Safdar(Rahim Yar Khan); Tariq Mehmood Rehan (Rahim Yar Khan); Arifa Manzoor (Rawalpindi); Atif Khan (Rawalpindi); Aurangzaib, (Rawalpindi); Faryal Gohar (Rawalpindi); Muhammad Hanif (Rawalpindi); NasiraTasneem (Rawalpindi); Safdar Shah (Rawalpindi); Sajid Mumtaz Qazi (Rawalpindi); Shagufta Sayal (Rawalpindi); Shahid Safdar(Rawalpindi);Usman Qureshi (Rawalpindi); Zahida Perveen, (Rawalpindi); Ziyad Afzal Kiyani (Rawalpindi).The authors acknowledge the assistance of Dr. Alina Gomes and Anahita Gouri with editing of the manuscript, references and figures, supported by Sanofi.

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