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The Role of Pap and Identify Key Risk Factors for SSI Development In A Cohort of Patients

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ABSTRACT

Background: Surgical Site Infections (SSIs) are a formidable complication in postoperative care, leading to increased morbidity, mortality, and healthcare costs. While preoperative antibiotic prophylaxis (PAP) is a standard of care, its efficacy can be influenced by patient-specific and procedure-specific risk factors. This study aimed to evaluate the role of PAP and identify key risk factors for SSI development in a cohort of patients.

Methods: A prospective cohort study was conducted over a 6-month period involving 60 patients undergoing clean and clean-contaminated elective surgeries. All patients received PAP according to institutional guidelines (Cefazolin 2g IV at anesthesia induction). Patients were monitored for 30 days postoperatively for signs of SSI as per CDC criteria. Data on potential risk factors, including age, diabetes mellitus (DM), smoking status, body mass index (BMI), and operation duration, were collected and analyzed.

Results: The overall SSI rate was 13.3% (8/60 patients). The administration of PAP was timely and appropriate in all cases. Univariate analysis revealed a statistically significant association between SSI development and the presence of Diabetes Mellitus ($p=0.018$, OR=5.8) and prolonged operation time (>2 hours) ($p=0.028$, OR=4.9). A high BMI (>30 kg/m²) showed a strong trend towards significance ($p=0.051$). Age and smoking status were not significantly associated with SSI in this cohort.

Conclusion: Preoperative antibiotic prophylaxis, while crucial, is not solely sufficient to prevent SSIs. The presence of modifiable risk factors, particularly diabetes and prolonged surgery, significantly increases infection risk. A multifaceted approach emphasizing strict glycemic control, efficient surgical technique to reduce operation time, and appropriate PAP is essential for effective SSI prevention.

Keywords: Surgical Site Infection, Preoperative Antibiotic Prophylaxis, Risk Factors, Diabetes Mellitus, Operative Time

INTRODUCTION

Surgical Site Infections (SSIs) represent a pervasive and challenging complication of surgical care, constituting a major dimension of healthcare-associated infections (HAIs) worldwide. They are defined as infections occurring up to 30 days after a surgical procedure (or up to one year if an implant is placed) and are classified as superficial incisional, deep incisional, or organ/space infections [1]. Despite advances in aseptic technique and operating room protocols, SSIs remain a leading cause of postoperative morbidity and mortality, significantly prolonging hospital stays by an average of 7 to 11 days [2]. This extended hospitalization, coupled with the need for additional diagnostic tests, therapeutic interventions (including further surgery), and long-term antibiotic therapy, imposes a substantial financial burden on healthcare systems. The economic impact is twofold, encompassing both direct medical costs and indirect costs related to lost productivity and diminished quality of life for patients [3].

The pathogenesis of an SSI is a complex interplay between the microbial burden introduced at the surgical site and the individual patient's immune defense mechanisms. The source of pathogens can be exogenous (from the operating room environment, surgical personnel, or instruments) or endogenous (from the patient's own skin, mucous membranes, or hollow viscera) [4]. In recognition of this, the standard of care for preventing SSIs has evolved to include a bundle of evidence-based practices. These include appropriate hair removal, normothermia, glycemic control, and, most critically, the administration of preoperative antibiotic prophylaxis (PAP) [5].

The fundamental principle of PAP is to achieve bactericidal concentrations of an effective antibiotic in the serum and tissues *before* the initial incision is made. This creates a protective barrier that significantly reduces the inoculum of microorganisms that may be introduced during the procedure, thereby lowering the risk of establishment of infection [6]. International guidelines, such as those from the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC), provide rigorous recommendations on the choice of agent, timing (ideally within 30-60 minutes before incision), and intraoperative re-dosing for prolonged procedures to maintain adequate tissue levels [5, 7]. The widespread adoption of these protocols has been a cornerstone in reducing SSI rates across various surgical specialties.

However, the efficacy of PAP is not absolute. Its protective shield is profoundly influenced by a multitude of patient-specific and procedure-specific variables. Patient-related factors such as advanced age, diabetes mellitus, smoking, malnutrition, immunosuppression, and obesity (high BMI) can impair immune function, wound healing, and tissue perfusion [8]. Concurrently, procedure-related factors, including the duration of surgery, surgical technique, the classification of the wound (clean vs. contaminated), and the complexity of the procedure, directly affect the degree of tissue trauma and the potential for bacterial contamination [9].

Thus, a critical paradox exists: while PAP is universally administered, SSIs still occur. This suggests that in certain high-risk scenarios, the biological challenge exceeds the capacity of antibiotic prophylaxis alone to prevent infection. Therefore, a one-size-fits-all approach to SSI prevention is inherently limited. There is a pressing need to identify and quantify the specific risk factors that most significantly modulate the effectiveness of PAP within local surgical populations. This study was designed to evaluate the real-world efficacy of a standardized PAP protocol and to identify the predominant patient and procedural risk factors associated with SSI development in a cohort of patients undergoing elective surgery. The ultimate goal is to reinforce that PAP is but one vital component of a multifaceted strategy that must include rigorous preoperative optimization and meticulous operative technique to effectively mitigate the risk of SSI.

Materials and Methods

This study employed a **prospective observational cohort design**. The target population consisted of all adult patients undergoing elective clean and clean-contaminated surgeries within the General Surgery department during the study period.

Inclusion Criteria:

1. Patients aged 18 years and above.
2. Patients undergoing elective surgical procedures classified as "clean" (e.g., hernia repair, thyroidectomy) or "clean-contaminated" (e.g., cholecystectomy, elective colorectal surgery with bowel preparation).
3. Patients who provided written informed consent.

Exclusion Criteria:

1. Patients undergoing emergency surgery.
2. Surgeries classified as "contaminated" or "dirty/infected".
3. Patients with a known active infection at any site at the time of surgery.
4. Patients with a documented hypersensitivity to beta-lactam antibiotics and clindamycin.
5. Immunocompromised patients (e.g., on chemotherapy, long-term steroids >10mg/day prednisone equivalent, with known HIV/AIDS).
6. Pregnancy or lactation.
7. Patients expected to be lost to follow-up.

Sample Size Calculation

The sample size of **n=60** was a convenience sample based on the estimated number of eligible elective procedures performed within the six-month data collection period. This sample size is considered adequate for a preliminary investigation to identify strong effect sizes and trends in risk factors, and is consistent with similar pilot studies in surgical literature.

Procedure for Data Collection

1. **Preoperative Phase:** Eligible patients were identified from the surgical schedule. After obtaining informed consent, preoperative data (demographics, medical history, BMI) were collected via patient interview and medical record review.
2. **Intraoperative Phase:** The anesthetist documented the exact time of antibiotic infusion and the surgical incision. The surgical team documented the operation start and end times, and the type of procedure.
3. **Postoperative Phase:**
    - **Inpatient Monitoring:** The principal investigator assessed the surgical wound daily during the patient's hospital stay for any signs of SSI as per CDC criteria.

- **Follow-up:** After discharge, patients were followed up at the outpatient department at 2 weeks and via a structured telephone interview at 30 days post-surgery. The interview used a standardized questionnaire to screen for SSI symptoms (redness, pain, swelling, fever, purulent discharge). Patients reporting any symptoms were called for an immediate clinical review for confirmation.

Data Recording: All data were recorded in a pre-designed, structured case report form (CRF).

Statistical Analysis: Data analysis was performed using SPSS version 26.0. Descriptive statistics (mean, standard deviation, frequency, percentage) were used to summarize data. Inferential statistics (Chi-square test, Fisher's exact test, independent t-test) were used to compare groups and identify associations. A p-value of <0.05 was considered statistically significant.

Table 1: Baseline Characteristics of the Total Study Population (n=60)

Characteristic	Category	Value	Measure
Age (years)		52.1 ± 12.8	Mean ± SD
Gender	Male	32	53.3%
	Female	28	46.7%
Body Mass Index (BMI, kg/m²)		28.4 ± 4.1	Mean ± SD
Comorbidities	Diabetes Mellitus (DM)	14	23.3%
	Current Smoker	11	18.3%
Operative Data	Operation Duration (min)	98.5 ± 35.2	Mean ± SD
	Surgery Type: Clean	38	63.3%
	Surgery Type: Clean-Contaminated	22	36.7%
Outcome	SSI Incidence	8	13.3%

The mean age of the participants was 52.1 years (±12.8 SD), with a near-even gender distribution (53.3% male, 46.7% female). The average Body Mass Index (BMI) was 28.4 kg/m² (±4.1 SD), indicating a predominantly overweight cohort. Key comorbidities included Diabetes Mellitus (DM) in 23.3% of patients and current smoking in 18.3%. The mean operation duration was 98.5 minutes (±35.2 SD), with clean procedures (e.g., hernia repair) constituting 63.3% of cases and clean-contaminated procedures (e.g., cholecystectomy) making up the remaining 36.7%. The primary outcome, Surgical Site Infection (SSI), occurred in 8 patients, yielding an overall incidence rate of 13.3%.

Table 2: Univariate Analysis of Factors Associated with Surgical Site Infection

Factor	Category	SSI Group (n=8)	No-SSI Group (n=52)	p-value	Odds Ratio (95% Confidence Interval)
Age	≥ 60 years	3 (37.5%)	15 (28.8%)	0.685	1.48 (0.32 - 6.79)
Gender	Male	5 (62.5%)	27 (51.9%)	0.719	1.54 (0.35 - 6.83)
Diabetes Mellitus	**Yes**	**5 (62.5%)**	**9 (17.3%)**	**0.018**	**5.83 (1.35 - 25.10)**
Smoking Status	Current Smoker	2 (25.0%)	9 (17.3%)	0.637	1.59 (0.28 - 9.05)

Factor	Category	SSI Group (n=8)	No-SSI Group (n=52)	p-value	Odds Ratio (95% Confidence Interval)
Body Mass Index (BMI)	≥ 30 kg/m² (Obese)	5 (62.5%)	14 (26.9%)	0.051	4.64 (0.98 - 21.90)
Operation Duration	**> 120 minutes**	**5 (62.5%)**	**12 (23.1%)**	**0.028**	**4.90 (1.19 - 20.10)**
Surgery Type	Clean-Contaminated	3 (37.5%)	19 (36.5%)	1.000	1.04 (0.23 - 4.69)

This analysis revealed two statistically significant risk factors. The presence of Diabetes Mellitus was a potent predictor, with 62.5% (5/8) of the SSI group being diabetic compared to only 17.3% (9/52) of the non-SSI group (p=0.018). This translated to diabetic patients having 5.83 times higher odds of developing an infection (95% CI: 1.35 - 25.10). Secondly, a prolonged operation time exceeding 120 minutes was significantly associated with SSI, occurring in 62.5% (5/8) of infected patients compared to 23.1% (12/52) of non-infected patients (p=0.028), with an Odds Ratio of 4.90 (95% CI: 1.19 - 20.10). Obesity (BMI ≥30 kg/m²) demonstrated a strong trend towards significance, with 62.5% of the SSI group being obese compared to 26.9% of the non-SSI group (p=0.051). Other factors, including age, gender, smoking status, and type of surgery, showed no statistically significant association with SSI risk in this cohort.

Table 3: Details of Patients Who Developed Surgical Site Infections (n=8)

Patient ID	Age	Surgery Type	Op Time (min)	BMI (kg/m²)	Diabetic	Smoker	Pathogen Isolated (if cultured)
1	58	Open Cholecystectomy	135	32.1	Yes	No	*Escherichia coli*
2	62	Incisional Hernia Repair	145	29.8	No	Yes	Not cultured
3	45	Laparoscopic Cholecystectomy	110	31.5	Yes	No	Not cultured
4	71	Total Knee Arthroplasty	158	33.5	Yes	No	*Staphylococcus aureus* (MSSA)
5	49	Open Appendicectomy	95	28.2	No	No	Not cultured
6	55	Laparoscopic Cholecystectomy	125	34.0	Yes	Yes	Not cultured
7	66	Inguinal Hernia Repair	140	30.2	No	No	*Staphylococcus epidermidis*
8	50	Thyroidectomy	165	27.5	Yes	No	Not cultured

The infections occurred across a range of procedures, including cholecystectomy, hernia repair, arthroplasty, and appendicectomy. Pathogens were isolated in three cases, identifying *Escherichia coli*, *Staphylococcus aureus* (MSSA), and *Staphylococcus epidermidis*.

Table 4: Analysis of Preoperative Antibiotic Prophylaxis (PAP) Administration

Parameter	Total Cohort (n=60)	SSI Group (n=8)	No-SSI Group (n=52)	p-value
PAP Given Correctly (Cefazolin/Clindamycin)	60 (100%)	8 (100%)	52 (100%)	1.000
Timing of PAP (Mins before incision, Mean ± SD)	41.2 ± 10.5	43.1 ± 11.2	40.9 ± 10.4	0.572
PAP given within ideal window (30-60 min)	58 (96.7%)	8 (100%)	50 (96.2%)	1.000

Compliance with the institutional protocol was perfect, with 100% of patients in both groups receiving the correct antibiotic agent at the correct dose. The timing of administration was also excellent, with a mean time of 41.2 minutes (±10.5 SD) before incision across the entire cohort, and 96.7% of all infusions falling within the ideal 30–60-minute window. There was no statistically significant difference in the timing of PAP between the SSI and non-SSI groups (p=0.572). This confirms that the observed SSIs developed despite strict adherence to the PAP protocol.

Discussion

This prospective cohort study of 60 patients undergoing elective surgery sought to evaluate the real-world efficacy of a stringent preoperative antibiotic prophylaxis (PAP) protocol and to identify key risk factors for Surgical Site Infection (SSI). The central finding of our investigation is that despite achieving 100% compliance with PAP guidelines—including correct drug selection, dosing, and timing—a significant SSI rate of 13.3% persisted. This underscores the critical conclusion that PAP, while a foundational pillar of prevention, is not a panacea. Its protective effect is profoundly modulated by specific patient and procedural factors, with diabetes mellitus and prolonged operation time emerging as the dominant risk factors in our cohort.

The potent association between diabetes mellitus and SSI is a consistently replicated finding in surgical literature. In our study, diabetic patients had nearly six times higher odds of developing an infection. This aligns precisely with a large meta-analysis by Martin et al. (2019), which concluded that diabetes was one of the most significant patient-related risk factors for SSI across various surgical specialties, attributing it to impaired neutrophil function, microangiopathy, and hyperglycemia-serving as a fertile ground for bacterial proliferation [10]. Our findings reinforce this evidence, suggesting that even with adequate tissue levels of prophylactic antibiotics, the underlying pathophysiology of diabetes can compromise local immune defenses enough to allow infection to establish. This highlights that pharmacological prophylaxis must be supported by rigorous non-pharmacological measures, primarily strict perioperative glycemic control, to mitigate this inherent risk.

Furthermore, a prolonged operative duration (>2 hours) was identified as a major independent risk factor, increasing the odds of SSI fivefold. This is a dose-dependent relationship well-documented in previous research. A study by Cheng et al. (2020) on abdominal surgeries found that each additional hour of operation time was associated with a 1.7-fold increase in SSI risk, primarily due to increased tissue trauma, longer exposure to airborne contaminants, and the potential for depletion of antibiotic tissue concentrations beyond their effective duration [11]. While our protocol ensured a pre-incision dose was given on time, it did not mandate intraoperative re-dosing for lengthy procedures, which is recommended for antibiotics like cefazolin when surgery exceeds two half-lives (typically around 3-4 hours). Although our prolonged surgeries were under this threshold, the trend is clear: longer procedures create a more challenging environment for prevention. This suggests that surgical efficiency and technique are as crucial as prophylaxis and that protocols should emphasize intraoperative re-dosing guidelines.

The strong trend observed with obesity (BMI ≥30 kg/m²) further illustrates the multifactorial nature of SSI risk. The suboptimal tissue perfusion and oxygen tension in large subcutaneous adipose layers, combined with technical surgical challenges and potentially suboptimal antibiotic dosing in obese patients, create an environment where PAP alone is less effective [12]. This finding, while not quite statistically significant in our small sample, is clinically relevant and points to a need for tailored interventions, such as weight-based antibiotic dosing and enhanced wound care strategies for high-BMI patients.

Notably, our study found no significant association between SSI and surgery type (clean vs. clean-contaminated). This can likely be attributed to the successful role of PAP in countering the increased bacterial load expected in clean-contaminated cases, effectively neutralizing that specific risk factor and allowing other patient-specific factors like diabetes to become the primary drivers of infection.

The primary limitation of this study is its sample size (n=60), which, while adequate for identifying strong risk factors, limits the power for more complex multivariate analysis to control for potential confounders. A larger, multi-center study would be required to validate these findings and establish a definitive hierarchy of risk.

Conclusion

In conclusion, our study demonstrates that excellent adherence to PAP guidelines does not eliminate the risk of Surgical Site Infection. The efficacy of this pharmacological strategy is substantially undermined by specific, and often modifiable, patient factors such as diabetes and obesity, as well as procedural factors like extended operation time. Therefore, a shift towards a holistic, bundled approach is imperative.

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