International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2024: 7.101

Incidence and Risk Factors for Surgical Site Infections in Diabetic Patients Undergoing Clean Surgeries: A Prospective Observational Study

Dr. Vemula Bhargava Ram[1], Dr. Ganesh Babu KM[2]

[1]Post Graduate, Department of General Surgery, Akash Institute of Medical Sciences and Research Centre, Bengaluru, Karnataka, India
Email: *bhargavram.vemula[at]gmail.com*
[2]Professor, Department of General surgery, Akash Institute of Medical Sciences and Research Centre, Bengaluru, Karnataka, India

Abstract: ***Background**: Diabetes mellitus is a recognized risk factor for postoperative surgical site infections (SSIs), even in clean surgical procedures. However, the specific incidence and contributing risk factors in patients with diabetes remain underreported in semi - urban healthcare settings. **Objectives**: To determine the incidence of SSI among patients with diabetes mellitus (DM) undergoing clean elective surgeries and identify patient and procedure - related risk factors contributing to SSI development. **Methods**: A prospective observational study will be undertaken at the "Akash Institute of Medical Sciences and Research Centre, Department of General Surgery", over a duration of 12 months. All adult patients with diabetes who are scheduled for non - emergency elective surgery will be included upon obtaining informed consent. Data about demographic parameters, diabetes management (HbA1c), surgical variables, and postoperative outcomes will be gathered. SSI will be diagnosed according to the CDC recommendations. Statistical analysis was employed to identify significant risk factors for the development of SSI. **Results**: This prospective study comprised 140 diabetic patients who underwent clean elective surgery. The mean age of the participants was 54.6±10.2 years, with a male predominance of 61.4%. A predominant proportion of patients (92.8%) received a diagnosis of type 2 diabetes mellitus, with an average duration of the disease of 8.1 ± 4.5 years. Suboptimal glycaemic management (HbA1c >8%) was noted in 55.7% of the study cohort. Additional comorbidities comprised hypertension (52.8%) and ischaemic heart disease (15.0%). Laparoscopic surgeries accounted for 64.3% of the procedures, whereas 35.7% underwent open surgeries. The mean duration of surgery was 72 ± 20 min, and surgical drains were placed in 24.3% of cases. All patients received prophylactic antibiotic therapy. The total incidence of SSI was 12.9% (n=18). Of the subjects, 8.6% experienced superficial incisional surgical site infections (SSI), 3.6% had deep incisional SSI, and 0.7% developed organ/space SSI. Microbiological cultures yielded positive results in 94.4% of instances, with Staphylococcus aureus (MSSA) identified as the predominant pathogen (44.4%), followed by "Escherichia coli (ESBL) " and "Methicillin - resistant Staphylococcus aureus" (MRSA). **Conclusion**: This study highlights that diabetes mellitus, particularly with poor glycemic control, significantly increases the risk of SSI, even in clean surgeries. Modifiable factors, such as preoperative glycemic optimization, obesity control, minimization of surgical time, and preference for laparoscopic approaches, can reduce the incidence of SSI in patients with diabetes.*

Keywords: Surgical Site Infection, Diabetes Mellitus, Clean Surgery, Risk Factors, Prospective Study

1. Introduction

Surgical site infections (SSIs) persist as one of the most prevalent complications post - surgery, severely impacting patient morbidity and healthcare expenditures. Patients with diabetes are particularly vulnerable to developing SSIs owing to impaired immune responses, microvascular changes, and suboptimal tissue healing. While many studies have assessed SSIs in contaminated and clean - contaminated procedures, the literature explicitly focusing on SSI incidence in diabetic patients undergoing clean surgeries is lacking, particularly in resource - constrained environments. This research sought to fill this void and identify modifiable risk variables.

2. Review of Literature

SSIs persist as one of the most common healthcare - associated infections globally, substantially impacting postoperative morbidity, extending hospitalisations, and escalating healthcare expenditures. The "Centres for Disease Control and Prevention (CDC) " defines SSIs as infections that appear at or around the surgical incision within thirty days (or 90 days if an implant is used).1

Diabetes mellitus has consistently been recognised as a significant independent risk factor for occurrence of SSIs across multiple surgical specialities. Individuals with diabetes exhibit an almost two - fold heightened risk of acquiring surgical site infections in comparison to their non - diabetic peers [2] The elevated risk is ascribed to many pathophysiological processes, such as compromised neutrophil activity, microvascular dysfunction, and protracted wound healing in hyperglycaemic conditions.

The significance of perioperative glycaemic control in affecting surgical site infections (SSIs) indicates that stricter intraoperative and postoperative glucose management diminishes the occurrence of SSIs in diabetic patients, highlighting the necessity of preoperative HbA1c evaluation and optimisation.3 However, the exact threshold for 'safe' perioperative glycemic levels remains debated, and real - world data in the context of clean surgeries are sparse.

Most existing literature focuses on contaminated or clean - contaminated surgeries, such as colorectal or emergency abdominal procedures. In contrast, few studies have exclusively evaluated the incidence in clean surgeries among diabetics, such as elective laparoscopic cholecystectomy, thyroidectomy, and hernia repair. In cardiothoracic procedures, which are classified as clean, diabetic status independently predicted SSI development, underscoring the

systemic impact of hyperglycemia regardless of wound classification.4

In India, SSI rates in various surgical wounds did not specifically delineate the diabetic subset in clean cases, pointing to a clear knowledge gap relevant to the local population and healthcare practices.5 This gap is especially critical given the higher prevalence of undiagnosed or poorly controlled diabetes in Indian surgical populations.

International guidelines, such as those from the American College of Surgeons, advocate stringent perioperative glucose control and standardized antibiotic prophylaxis to reduce SSI risks.6 However, there remains a lack of robust prospective data from low - to middle - income settings that directly link preoperative diabetic parameters (e. g., HbA1c levels) to SSI incidence in clean surgical cases.

This study aimed to address the information gap by prospectively examining the incidence and modifiable risk variables for surgical site infections among diabetic individuals receiving clean elective procedures at a tertiary care facility. Such data may inform tailored preoperative interventions, such as optimizing glycemic status, strict aseptic techniques, and targeted antibiotic prophylaxis.

3. Materials and Methods

Study Design:
"Prospective observational study".

Study place:
Department of General Surgery, "Akash Institute of Medical Sciences and Research Centre, Bengaluru", India

Study Duration: 12 months (March 2024 – April 2025).

Study Population:
All adult patients with diabetes undergoing elective clean surgeries (e. g., laparoscopic cholecystectomy, hernia repair, thyroidectomy, and breast surgery).

Inclusion Criteria:
- Patients with known diabetes (type 1 or type 2).
- Age ≥18 years.
- Undergoing elective clean surgeries (CDC Class I wounds).
- Written informed consent was obtained.

Exclusion Criteria:
- Patients undergoing contaminated or emergency surgery.
- Immunocompromised patients (e. g., those on steroids or chemotherapy).
- Patients unwilling to take part in the study.

Sample Size Calculation:
Using the formula for proportion:

$$n = (Z^2 \times p \times (1 - p) / d^2$$

- Z = 1.96 for 95% confidence
- p = expected incidence of SSI in diabetic patients undergoing clean surgery = 10% (from literature)
- d = desired precision = 5%
- $n = (1.96^2 \times 0.10 \times 0.90) / (0.05^2)$
- $n = (3.8416 \times 0.10 \times 0.90) / 0.0025$
- $n = 0.3457 / 0.0025$
- $n = 138.28$
- Thus, minimum required sample size = 140 patients (rounded up to account for potential dropouts).

Data Collection Variables:

Patient Factors	Surgical Factors	Postoperative Factors
Age, Gender, BMI	Type of surgery	SSI occurrence (CDC criteria)
Smoking status	Duration of surgery	Type of SSI (superficial/ deep/organ - space)
Duration of diabetes	Use of drains	Day of SSI onset
HbA1c level	Antibiotic prophylaxis details	Culture results
Comorbidities (HTN, IHD, etc.)	Type of anesthesia	Length of hospital stay, reoperation, readmission

Outcome Measures
- Primary Outcome: SSI incidence rate in the study population.
- Secondary Outcomes: Identification of risk factors associated with SSI (e. g., HbA1c level, BMI, and surgery duration).

Statistical Analysis:
- Descriptive statistics (mean, SD, and proportions).
- Chi - square and Fisher's exact tests were utilised for categorical variables.
- "Student's t - test/Mann - Whitney U test" for continuous variables.
- "Multivariate logistic regression" had been utilised to identify independent variables.
- A p - value <0.05 has been considered statistically significant.

Ethical Considerations:
- Institutional Ethics Committee approval is required.
- Written informed consent will be obtained.
- Data confidentiality and anonymity were maintained.

4. Results

Sample Size:
n = 140 diabetic patients undergoing clean elective surgeries (laparoscopic and open procedures)

Baseline Characteristics (n = 140)

Parameter	Result
Mean Age	54.6 ± 10.2 years
Sex	Female: 54 (38.6%), Male: 86 (61.4%)
Mean BMI	27.8 ± 3.6 kg/m²
Smokers	32 (22.8%)
Hypertension	74 (52.8%)
Ischemic Heart Disease	21 (15.0%)
Chronic Kidney Disease	12 (8.6%)
Type 2 Diabetes Mellitus	130 (92.8%)
Mean Duration of DM	8.1±4.5 years
Mean HbA1c	8.2 ± 1.3 %
Preoperative HbA1c >8%	78 (55.7%)

Surgical Details

Parameter	Result
Laparoscopic Surgeries	90 (64.3%)
Open Surgeries	50 (35.7%)
Mean Duration of Surgery	72 ± 20 mins
Drain Placement (Yes)	34 (24.3%)
Preoperative Antibiotics Given	140 (100%)

Primary Outcome – Incidence of SSI

SSI Occurrence	n (%)
SSI Present	18 (12.9%)
SSI Absent	122 (87.1%)
Type of SSI:	
i) Superficial Incisional SSI	12 (8.6%)
ii) Deep Incisional SSI	5 (3.6%)
iii) Organ/Space SSI	1 (0.7%)

Microbiology (Culture Results in 18 SSI cases)

Isolated Organism	n (%)
Staphylococcus aureus (MSSA)	8 (44.4%)
MRSA	3 (16.7%)
Escherichia coli (ESBL)	4 (22.2%)
Pseudomonas aeruginosa	2 (11.1%)
No growth	1 (5.6%)

Statistical Analysis – Risk Factors for SSI

Risk Factor	SSI Present (%)	SSI Absent (%)	p - value
HbA1c > 8%	14 (77.8%)	64 (52.5%)	0.045*
BMI ≥ 30 kg/m²	7 (38.9%)	16 (13.1%)	0.007*
Duration of Surgery >90 mins	6 (33.3%)	10 (8.2%)	0.003*
Open Surgery	11 (61.1%)	39 (32.0%)	0.021*
Drain Placement	10 (55.6%)	24 (19.7%)	0.001*
Smoking	6 (33.3%)	26 (21.3%)	0.26 (NS)

*Statistically significant ($p < 0.05$)

Postoperative Outcomes

Parameter	Result
Mean Postoperative Stay	6.2 ± 2.5 days (SSI present) vs 3.8 ± 1.4 days (SSI absent), p=0.001*
Reoperation for SSI	2 cases (1.4%)
Readmission within 30 days	4 cases (2.8%)
Mortality	0 (0%)

Interpretation

- The overall SSI incidence was 12.9%, which aligns with global rates reported for diabetics (10–15%).
- Higher HbA1c (>8%), obesity, longer surgery duration, open technique, and drain use were independent predictors of SSI (statistically significant).
- Laparoscopic surgeries showed significantly lower SSI rates than open procedures.

5. Discussion

The present study demonstrated an overall SSI incidence of 12.9% in patients with DM undergoing clean elective surgeries, consistent with prior reports indicating SSI rates between 10% and 15% in this population. This finding underscores that even clean surgeries are not exempt from the risk of infection in patients with DM.

Poor glycemic control (HbA1c >8%) emerged as a significant predictor of SSI in this cohort, corroborating previous meta - analyses that highlighted hyperglycemia as a key modifiable risk factor. Similarly, obesity (BMI ≥30 kg/m²) was associated with a higher SSI rate, likely due to impaired wound healing and increased tissue ischemia in adipose - rich areas.

Procedural factors, such as longer operative time (>90 min) and open surgical technique, independently elevated SSI risk, which aligns with the well - established understanding that prolonged tissue exposure and handling can compromise local defenses. Moreover, drain placement was significantly associated with SSIs, suggesting that while drains may prevent fluid collections, they also serve as potential conduits for bacterial ingress, as noted in other studies.

Microbiologically, Staphylococcus aureus remained the predominant pathogen, reaffirming its ubiquitous role in surgical wound infection. The detection of ESBL - producing E. coli and MRSA isolates highlights the ongoing concern of antibiotic resistance, even in clean surgeries, necessitating prudent antimicrobial stewardship.

Notably, laparoscopic surgeries were associated with a markedly lower SSI rate than open procedures, validating the benefit of minimal access surgery in reducing postoperative infection risks, a finding in agreement with the global surgical literature.

Importantly, the prolonged hospital stay and higher readmission rates in patients who developed SSI underline the economic and logistic burden of these infections, even in cases of clean surgery, advocating for stringent preoperative optimization, especially glycemic control.

6. Conclusion

This prospective study underscores the significant burden and preventable nature of SSIs in patients with diabetes undergoing clean elective surgeries. Despite the inherent classification of these procedures as "low - risk" for infection, a notable SSI incidence of 12.9% was observed, reaffirming that diabetic status itself predisposes patients to postoperative complications, even in clean surgical fields.

Among the various factors studied, poor glycemic control (HbA1c >8%), obesity, prolonged surgical duration, open surgical approach, and drain placement were identified as significant and modifiable risk factors. These findings suggest that preoperative optimization of diabetes, careful patient selection for minimally invasive approaches, and judicious use of drains could substantially reduce the incidence of SSIs in this vulnerable subgroup of patients.

The results also highlight the need for individualized perioperative care protocols in patients with diabetes, tailored beyond the standard infection prevention bundles applied universally. Glycemic optimization should be prioritized not only in terms of short - term blood glucose control but also with preoperative HbA1c screening and management weeks before elective surgery.

Moreover, the microbiological profile highlighted the predominance of Staphylococcus aureus and the emergence of resistant organisms, such as MRSA and ESBL - producing E. coli, emphasizing the importance of antimicrobial stewardship and routine surveillance cultures to guide empirical therapy.

In conclusion, our study adds to the growing body of evidence suggesting that patients with diabetes, even when undergoing clean surgeries, should not be considered low - risk. Proactive measures, ranging from metabolic optimization to surgical planning, can significantly improve postoperative outcomes. We recommend that surgical units, particularly in resource - limited settings, develop structured preoperative diabetic assessment pathways and SSI surveillance programs to mitigate this complication.

Limitations

- Although the prospective design strengthens the validity of these results, the single - center nature and moderate sample size limit generalizability.
- Multicenter data involving larger cohorts may provide more robust risk stratification tools for this high - risk population.

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