ORIGINAL ARTICLE

A Comparative Study of Surgical Site Infection in Clean Surgical Procedures in Diabetics Versus Non-Diabetics at Tertiary Care Hospital, Quetta

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ABSTRACT

Objective: To determine the impact of diabetes on the frequency of surgical wound infection in patients undergoing clean surgical procedures.

Study Design: Case-control study.

Place and Duration of Study: This study was conducted at the Department of Surgery, Combined Military Hospital (CMH), Quetta, Pakistan, from June 2023 to March 2024.

Methods: A total of 74 patients who underwent clean surgical procedures were included in the study and divided into the diabetes mellitus-group (cases) and the control group based on their diabetic status. At 30 days post-operative period, patients were assessed for the presence of surgical wound infection. Surgical wound infection frequency was stratified by type of surgical procedure, and post-stratification analysis was performed using the Pearson Chi-Square test. Data was analyzed by SPSS 20.00.

Results: Mean age was 40.94 ± 9.06 years. There were 44 (59.46%) males and 30 (40.54%) females. The mean BMI of patients was 24.25 ± 2.72 kg/m2. The composite frequency of surgical wound infection in the present study was 12 (16.22%). In the diabetes mellitus group (N = 30), the frequency of surgical wound infection was 9 (30.00%), while in the cases (N = 44), it was 3 (6.82%) ($P = 0.008$; $\chi^2 = 7.055$; Odds Ratio = 0.171). No significant association was observed between surgical wound infection and any of the surgery types in patients with diabetes ($P = 0.078$) as well as without diabetes ($P = 0.717$).

Conclusion: Diabetes significantly increases the odds of developing a surgical wound infection in patients who have undergone clean surgical procedures.

Keywords: *Diabetic, Elective Surgical Procedures, Frequency, Surgical Wound Infection*.

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Introduction

The field of surgery, being one of the most ancient in the medical profession, has experienced a persistent cycle of advancement over the years, and this, at one end, is a necessity, but at the other end, is also controversial.[1] Whenever a surgery is performed, there is an inevitable disruption in the continuity of the skin barrier and underlying structures, leading to the formation of a wound, the appropriate care of which is essential to improve operative outcomes.[2] One of the most common and devastating complications involving the surgical wound is the surgical site infection (SSI) or surgical wound infection (SWI), which has a direct impact on the outcome of surgery.[3] There are several microbes that are involved in the pathogenesis of post-operative infection, including both gram-positive (such as Staphylococcus aureus and Enterococcus spp.) and gram-negative (such as Klebsiella pneumoniae, Enterobacter spp., and Escherichia coli) bacteria.[4]

Based on the structure that is being operated, surgeries and subsequent surgical wounds are classified into Class-I (clean), Class II (clean/

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contaminated), Class III (contaminated), and Class IV (dirty), amongst which the least risk of SSI/SWI is associated with clean surgeries, with a reported rate approximated at 1-5%.[5] However, one factor that has been reported, in general, to substantially increase the risk of developing SSI/SWI is diabetes.[6] Mechanism by which diabetes increases the risk of developing infection of the surgical wound is the impairment in the process of healing of the wound induced by the chronic process of inflammation caused by this condition.[7] However, whether this condition has the same effect of increasing risk of SWI specifically in clean surgical procedures is still not widely studied. In fact, in one study that focused on the impact of diabetes on SWI frequency in clean procedures, the impact was non-significant (P = 0.17), which is completely contrary to the general perception.[8]

As mentioned earlier, most previous studies that focused on the effect of diabetes on the frequency of post-op surgical wound infection have examined surgeries regardless of type. This study, however, was conducted with a focus primarily on clean surgical procedures and the effect of diabetes on the frequency of post-op surgical wound infection only among patients who undergo clean surgical procedures, and compared this frequency of post-op SSI in patients undergoing such procedures who were not suffering from diabetes. This will provide useful insight regarding a research question of whether the risk of SWI is increased by diabetes, even in clean surgical procedures.

Methods

This case-control study was conducted at the Department of Surgery, Combined Military Hospital (CMH), Quetta, Pakistan, from June 2023 to March 2024, after taking approval from the Institutional Ethical Review Board, vide letter no: 21, dated: 13th March 2023. An appropriate sample size was calculated using the WHO sample size calculator for two population proportions using the following formula:

$$N = \frac{\left\{ z_{1-\sigma/2}\sqrt{2\overline{P}(1-\overline{P})} + z_{1-\rho}\sqrt{P_1(1-P_1)+P_2(1-P_2)} \right\}^2}{(P_1-P_2)^2}$$

For calculations, the following assumptions were used: a 5% level of significance, 90% power, and anticipated frequencies of SSI/SWI in diabetics of 33.33% and in non-diabetics of 4.31%.[9] This gave a sample size of 74.

Patients aged 18 years or older, both male and female, who underwent clean surgical procedures were included in the study. Clean clinical procedures included hernia repair, exploratory laparotomy, adrenalectomy, and splenectomy. Patients who had evidence of penetrating abdominal trauma, a history of any co-morbidity other than diabetes (hypertension, chronic renal failure, chronic liver disease, collagen disease, smoking, immuno-suppression, or connective tissue disease), hypoalbuminemia, and those younger than eighteen years were excluded from the study. Co-morbidities and hypoalbuminemia were made part of the exclusion criteria as they have a direct impact on SSI/SWI.

Patients were selected by using a non-probability consecutive sampling technique. Baseline characteristics of the patients, including age (in years), gender, body mass index (BMI), diabetes status (diabetic/non-diabetic), and type of clean surgical procedure (hernia repair/exploratory laparotomy/adrenalectomy/splenectomy) performed, were documented. All patients received preoperative evaluations according to the established protocol at tertiary care through blood investigations, basic radiology, and electro-cardiogram (ECG). For all procedures, provision of a strict aseptic environment, preoperative medications, appropriate draping, and patient education regarding the procedure was ensured. All procedures were performed by the same surgical team to minimize operator bias. To assess the diabetic status of the patients, a 5ml blood sample was obtained, which, after placement in the serum vial, was sent to the laboratory to check for the patients' HbA1C% levels. If the HbA1C% value was 6.5% or higher, the patient was labeled as diabetic and placed in the DM-Group (Cases), while patients with HbA1C% values less than 6.5% were labeled as non-diabetic and placed in the No DM-Group (Controls).[10] After the surgery, appropriate post-operative care was provided to all the patients depending upon the type of clean surgical procedure that the patients underwent. All the patients were followed up till day 30 after their surgery for the presence of SSI/SWI. In the event of SSI/SWI, appropriate management was provided according to the patient's condition, including antibiotics with or without additional surgical intervention. All data collection was conducted by the principal researcher to avoid bias.

Data analysis was performed using the Statistical Package for the Social Sciences version 20. Normality of the data was assessed using the Shapiro-Wilk test. Quantitative data (age and BMI) were represented using mean ± standard deviation. Qualitative data (gender, diabetes status, type of clean surgical procedure, and SWI) were represented by using percentages and frequencies. To determine the impact of diabetes on SWI frequency, the chi-square test was applied, and the odds ratio was calculated. To control the effect modification, SWI frequency was also stratified based on the type of surgical procedures, and post-stratification analysis was done using the Pearson Chi-Square test. $P \leq 0.05$ was considered significant.

Results

In this study, 74 patients were included. Mean age was 40.94 ± 9.06 years. There were 44 (59.46%) males and 30 (40.54%) females. The mean BMI of patients was 24.25 ± 2.72 kg/m2. The most common surgical procedure performed was hernia repair, 54 (72.97%), followed by exploratory laparotomy, 13 (17.57%), adrenalectomy, 4 (5.41%), and spleenectomy, 3 (4.05%). Based on HbA1C% results, 30 (40.54%) patients were diabetics, while 44 (59.46%) patients were non-diabetics. The comparison of baseline demographic characteristics between study groups is summarized in Table 1 below.

Table 1: Comparison of baseline characteristics between groups (N = 74)

Characteristic	**DM-Group (N = 30)**	**No DM-Group (N = 44)**	**Test value**	***P*-value**
Mean Age	41.96 ± 8.98 years	40.25 ± 9.16 years	**t = 0.798	0.428
Gender				
Male	16 (53.33%)	28 (63.64%)	*X^2 = 0.786	0.375
Female	14 (46.67%)	16 (36.36%)		
Mean BMI	24.41 ± 3.10 kg/m2	24.14 ± 2.45 kg/m2	**t = 0.417	0.678
Type of clean surgical procedure				
Hernia repair	23 (76.67%)	31 (70.45%)	*X^2 = 0.583	0.900
Exploratory laparotomy	5 (16.67%)	8 (18.18%)		
Adrenalectomy	1 (3.33%)	3 (6.82%)		
Splenectomy	1 (3.33%)	2 (4.55%)		

**Chi-Square test, **Student's t- test*

Table 2: Impact of diabetes on the frequency of SWI (N = 74)

	DM-Group (N = 30)	**No DM-Group (N = 44)**	***P*-value**	***Chi-Square* test value**	**Odds ratio**
SWI	9 (30.00%)	3 (6.82%)	0.428	7.055	0.171

Table 3: SWI frequency stratification by type of surgical procedure (N = 74)

DM-group (N = 30)						
	Hernia repair (N = 23)	**Exploratory laparotomy (N = 5)**	**Adrenalectomy (N = 1)**	**Splenectomy (N = 1)**	***Chi-Square* test value**	***P*-value**
SWI	7 (30.43%)	0 (0.00%)	1 (100%)	1 (100%)	6.812	0.078
No DM-Group (N = 44)						
	Hernia repair (N = 31)	Exploratory laparotomy (N = 8)	Adrenalectomy (N = 3)	Splenectomy (N = 2)		
SWI	3 (9.68%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1.350	0.717

The composite frequency of SSI/SWI in the present study was 12 (16.22%). In DM-Group (N = 30), the frequency of SSI/SWI was 9 (30.00%), while in No DM-Group (N = 44), it was 3 (6.82%), respectively (*P* = 0.008; X^2 = 7.055; Odds Ratio = 0.171). This comparative analysis is given below in Table 2.

SWI frequency stratification based on the type of surgery (the effect modifier) demonstrated that there was no impact of this variable on the SWI frequency among diabetic and non-diabetic patients. This data is given in Table 3.

Discussion

Diabetes mellitus (DM) is a chronic metabolic condition characterized by elevated blood glucose levels due to insulin resistance and impaired insulin secretion.[11,12] Across the globe, prevalence of this condition is rapidly on the rise, with approximately more than 500 million adults suffering from diabetes, with this number being expected to cross the number of more than 780 million by the year 2045.[13] In fact, Pakistan is now amongst the leading countries globally in terms of diabetes burden.[14] From a surgical perspective, the importance of diabetes is with regard to wound healing and infection after the patient undergoes surgery, as diabetes not only impairs the healing capacity of the wound but also increases the risk of infection.[15,16] Present study focused on comparing the frequency of SSI/SWI in diabetic versus non-diabetic patients undergoing clean surgical procedures.

The most common type of clean surgical procedure performed in the present study was repair of hernia, which corresponds to the fact that among all the surgical procedures, hernia repair is one of the most commonly performed surgical procedures across the globe.[17,18] To make diagnosis of DM, glycated hemoglobin (HbA1C%) was utilized which has been reported to be a highly precise and widely used test to make a diabetes diagnosis.[19,20]

When it comes to the comparison of the frequency of SSI/SWI in diabetic versus non-diabetic patients undergoing clean surgical procedures, it was observed that in diabetics, the frequency of SSI/SWI was significantly higher as compared to patients who did not have diabetes (*P* = 0.008; OR = 0.171). In accordance with the findings of the present study, Save M et al. reported that the frequency of SWI was significantly higher among diabetic patients, in which it occurred in 34.5%, as compared to non-diabetic patients, in which this frequency was only 15.7% (*P* = 0.021).[21] Similarly, Mohan N et al. also found that the SWI was much more common among operated patients who had diabetes (14%) as compared to those without diabetes (3%), (*P* < 0.0001).[22] In accordance with the present study, Akbar MB et al. reported similar results, but in their study, instead of a clean surgical procedure, patients who were assessed underwent laparoscopic cholecystectomy, which is a clean-contaminated procedure.[9] In one study, where comparison of wound infection frequency was performed between diabetics and non-diabetics undergoing clean surgical procedures, it was found that, similar to the present study, frequency of SSI/SWI was higher in patients with diabetes mellitus (*P* = 0.024).[23] This direct relationship between diabetes and SWI, even in surgical procedures, could be attributed to the adverse effects of diabetes on the immune system, making it weak to counteract the infectious pathogens.

In another study, which focused primarily on orthopedic surgeries, although SSI frequency was higher in patients with diabetes (5.74%) as compared to non-diabetic patients (1.52%), upon univariate and multivariate analysis, they were unable to establish diabetes as a significant risk factor for the occurrence of SSI (*P* = 0.17).[8]

Upon further analysis of the impact of surgery type on SWI frequency, it was found that the type of surgical procedure did not have a significant impact on SWI frequency in either cases (*P* = 0.078) or controls (*P* = 0.717). This demonstrates that it is primarily the diabetes that alters the frequency of SWI rather than the surgery type. This aspect of the study offers a novel perspective on the relationship among SWI, diabetes, and clean surgical procedures, a relationship that has not been previously studied.

The present study demonstrates that DM is an independent contributor to the increased risk of having SSI/SWI even in clean surgeries, which are usually associated with a significantly smaller risk of being complicated by the infection of the surgical wound. One important reason behind this can be attributed to depressed immunity as well as impairment in the ability of wound healing in diabetics.[24]

Based on the results, it is recommended that diabetic patients should have a specialized and individualized post-operative care package to ensure the avoidance of SSI/SWI. The effect of glycemic control on SSI frequency was not studied in the present study, which was a limitation of the study. Therefore, it is recommended that future studies should be conducted in this regard to determine the difference in SSI/SWI frequency in diabetic patients with different degrees of glycemic control.

Conclusion

Diabetic patients had a significantly higher frequency of surgical site infection reported at 30% as compared to non-diabetic patients, 6.82%.

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Author Contributions

HM: Conception, design of the work, and approval for final submission
TMF: Manuscript writing for methodology design, investigation, and approval for final submission
MOF: Data acquisition, curation, statistical analysis, and approval for final submission
AH: Validation of data, interpretation, write-up of results, and approval for final submission
SA: Revising, editing, supervising for intellectual content, and approval for final submission
NA: Writing the original draft, proofreading, and approval for final submission
HM is the nominated guarantor and takes full responsibility for the overall content and integrity of the work