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Original Research Article

A Study on the Association of Preoperative HbA1c Levels with Postoperative Surgical Site Infection and Glycaemic Control in Non-Cardiac Elective Surgery

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ABSTRACT

Background
Surgical site infections are reported to have a high prevalence in India and are higher in those with diabetes mellitus. The association between glycaemic control and surgical site infection has been reported in a few studies. Hence, this study was conducted to analyse the association between SSI (Surgical Site Infections) and preoperative and postoperative glycaemic control.

Aims
To analyse the relationship between pre-operative and post-operative glycaemic control and surgical site infections.

Methods
64 patients with known cases of type 2 DM on OHA or insulin admitted for elective surgery in the Department of Surgery, RIMS, were included in the study. The HbA1c test was done preoperatively and postoperatively, and the results were analyzed. The patient was followed up and management of the wound infection was done according to the type of surgical site infection, i.e., major or minor.

Results
Patients who had a higher than normal BMI, diabetes with major co-morbidities, and a 6.5% or higher HbA1c level were found to have 5.6 times, 5.5 times and 10.2 times higher odds of developing SSI, respectively.

Conclusions
This study demonstrated a higher risk for post-operative surgical site infection in patients with uncontrolled HbA1c levels preoperatively. Also, we observed that patients with a higher BMI and the presence of major co-morbidities were more at risk of developing SSI post-operatively.

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Keywords: Preoperative HbA1c Levels, Postoperative Surgical Site Infection, Glycaemic Control, Non-Cardiac Elective Surgery.

INTRODUCTION

SSI (Surgical Site Infection) can be defined as an infection that is present up to 30 days after a surgical procedure if no implants are placed and up to one year if an implantable device is placed in the patient.[1] It can be divided into two types: major and minor SSI. A major SSI is defined as a wound that either discharges significant quantities of pus spontaneously or needs a secondary procedure to drain it and the patient may have systemic signs like hyperpyrexia, tachycardia and leukocytosis. Minor SSI may discharge pus or infected serous fluid but should not be associated with excessive discomfort.[2]

The global estimates of SSI vary from 0.5% to 15%, while studies in India have consistently shown higher rates ranging from 23% to 38%.[3] Diabetic patients are said to be at a greater risk of systemic and surgical site infection during the post-operative period and they are also prone to metabolic decompensation, such as fluctuating blood glucose levels and keto-acidosis.[4,5]

Hemoglobin A1c or glycated hemoglobin (HbA1c) can provide us the picture about control of blood glucose during the past 8 to 12 weeks duration. HbA1c is formed by the slow irreversible, non-enzymatic glycation of valine and lysine residues in the haemoglobin molecule.[6] WHO has recommended 6.5% as a cut-off for diagnosing diabetes. Thus, HbA1C value of 6.5% is considered as diagnostic of diabetes, while people with HbA1C values between 6.0% and 6.4%, are considered as having a high risk of developing diabetes warranting preventive measures.[7]

Due to the paucity of data and the varied findings of previous studies, this study was carried out to assess the association of preoperative HbA1c levels with postoperative surgical site infection and glycaemic control in non-cardiac elective surgery.

AIMS AND OBJECTIVES

To evaluate the association of preoperative HbA1c levels with postoperative surgical site infection in non-cardiac elective surgery and the association of preoperative HbA1c levels with postoperative glycaemic control in non-cardiac elective surgery.

MATERIALS AND METHODS

This study was a cross-sectional study conducted in the Department of General Surgery, RIMS, Imphal, Manipur.

All admitted patients in the Department of General Surgery who were known cases of type 2 DM, taking anti-diabetic medications and who were planned for non-cardiac elective surgery were enrolled.

Patients with a known case of type 2 diabetes mellitus who are on OHA (Oral Hypoglycaemic Agents) or insulin, patients with HbA1c levels up to 8.5 and patients who gave consent for the study were included. Patients not willing to participate in the study, patients whose HbA1c level is > 8.5, Patients undergoing cardiac and emergency surgeries, surgery done elsewhere, and patients not turning up for follow up were excluded. Ethical approval was obtained from the REB (Research Ethical Board), RIMS (Regional Institute of Medical Sciences).

HbA1c levels were classified as: <6.5% = controlled glycaemic level; ≥6.5% = uncontrolled glycaemic level.

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Classification co-morbidities were adapted from the Charlson Co-morbidity Index. Major co-morbidities: coronary artery disease, peripheral vascular diseases, chronic renal failure, BMI > 40, age > 80.

Minor co-morbidities: hypertension, diabetes mellitus, cardiac arrhythmias, coagulopathies, smoking, BMI > 35, age > 70.

Each patient with a known case of type 2 DM on OHA or insulin admitted for elective surgery in the Department of Surgery, RIMS, was included in the study. The patient and their relatives were explained about the study, and those who were willing and gave valid written consent were enrolled in the study. The patient's socio-demographic data and relevant clinical history were recorded in a preformed proforma, and a thorough clinical examination was carried out. The HbA1c test was done preoperatively, and based on HbA1c values, patients were divided into two groups. Group A, having an A1c <6.5%, and group B, having an A1c > or = 6.5%. Preoperative glucose control was determined by the mean glucose value in the 72-hour period prior to operation. Postoperative glucose control was determined by the mean value within a 72-hour period after the completion of the operation. The patient was followed for up to 72 hours, 1 week, and 1 month after surgery. Management of wound infection was done according to the type of surgical site infection, i.e., major or minor.

RESULTS

In this study, a total of 64 diabetic patients from the department of surgery were recruited. The age ranged from 28 to 76 years, with a mean age of 54.98±11.20 years.

Age Groups (in years)	**Frequency N (%)**
≤40	8 (12.5%)
41-50	17 (26.6%)
51-60	17 (26.6%)
>60	22 (34.4%)
Gender	**Frequency N (%)**
Male	34 (53.1%)
Female	30 (46.9%)
Occupation	**Frequency N (%)**
Student	1 (1.6%)
Housewife	15 (23.4%)
Daily Wage Labourer	20 (31.3%)
Employed	28 (43.8%)

Table 1. Sociodemographic Data

More than one-third (34.4%) of the patients belong to the >60-year-old age group, followed by 41-50 years and 51-60 years, respectively (26.6%).

BMI [wt. (in Kg) or ht. (in m)^2]	**Frequency N (%)**
Normal Weight	36 (56.3%)
Pre-Obesity	28 (43.8%)
Co-Morbidity	
Only Type 2 DM	25 (39.1%)
Type 2 DM + Minor Comorbidity	18 (28.1%)
Type 2 DM + Major Comorbidity	21 (32.8%)
Anti-Diabetic Medication	

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Anti-Diabetic Medication	**Frequency n(%)**
Oral Hypoglycaemic Agent	38 (59.4%)
Insulin	26 (40.6%)
Table 2: Distribution of Patients by BMI, Co-Morbidity and Anti-Diabetic Medications (n = 64)	

56.3% of the patients had a normal BMI, while the rest (43.8%) were pre-obese. More than one-third of the patients had only type 2 diabetes mellitus, while 32.8% of the patients had type 2 diabetes mellitus as well as other major co-morbidities. 28.1% of the patients had type-2 diabetes mellitus and a minor co-morbidity.

The majority (59.4%) of the patients were on oral hypoglycaemic agents, while 40.6% of them were on insulin. Most of the patients had 1-3 hours of surgery (n = 30), followed by 1 hour of surgery (n = 26, 40.6%), with 8 having more than 3 hours of surgery. Around one-third (35.9%) of the patients had surgical site infections. Majority (75%) of the patients had post-operative glycaemic control.

Pre-Operative Glycaemic Control (HbA1c)	**Post-Operative Glycaemic Control (HbA1c)**		**P-Value***
	<6.5%	**≥6.5%**	
<6.5%	20 (90.9%)	2 (9.1%)	**<0.05**
≥6.5%	28 (66.7%)	14 (33.3%)	
Table 3: Pre-Operative and Post-Operative Glycaemic Control			
*Chi squared test			

A significantly higher proportion of patients who had pre-operative glycaemic control were observed to have controlled post-operative glycaemic levels.

Pre-Operative Glycaemic Control (HbA1c)	**Surgical Site Infection**		**P-Value***
	Present	**Absent**	
<6.5%	3 (13.6%)	19 (86.4%)	**<0.05**
≥6.5%	20 (47.6%)	22 (52.4%)	
Table 4. Association between Pre-Operative Glycaemic Control and Surgical Site Infection			
*Chi squared test			

A significantly higher proportion of patients who had pre-operative glycaemic control were observed to have no surgical site infection.

Co-Morbidities	**Surgical Site Infection**		**P-Value***
	Present	**Absent**	
Minor	9 (20.9%)	34 (79.1%)	**<0.001**
Major	14 (66.7%)	7 (33.3%)	
Table 5. Association between Co-Morbidities and Surgical Site Infection			
*Chi squared test			

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A significantly higher proportion of patients who had major co-morbidities were observed to have surgical site infections.

Variables	COR (95%CI)	P-Value	AOR* (95%CI)	P-Value
Age	1.10 (0.98-1.08)	0.207	1.05(0.97-1.13)	0.185
Gender				
Male	**1 (Reference)**			
Female	1.06 (0.38-2.95)	0.909	2.18 (0.41-11.48)	0.356
BMI				
Normal	**1 (Reference)**			
Pre-obese	4.03 (1.37-11.90)	<0.05	5.63 (0.95-33.21)	<0.05
Co-Morbidity				
Only T2DM	**1 (Reference)**			
T2DM + Minor Comorbidity	1.14 (0.26-5.02)	0.86	1.63 (0.27-9.75)	0.587
T2DM + Major Comorbidity	8.00 (2.10-30.41)	<0.05	5.54 (0.94-32.35)	<0.05
Pre-operative HbA1c Level	4.45 (1.73-11.43)	<0.05	10.27 (2.49-42.24)	<0.05

Table 6. Logistic Regression Analysis for Various Variables and Surgical Site Infection

* Adjusted for Age, gender, BMI, Comordity and pre-operative glycaemic level

Patients who had a higher than normal BMI, diabetes with major co-morbidities, and a 6.5% or higher HbA1c level were found to have 5.6 times, 5.5 times, and 10.2 times higher odds of developing SSI, respectively.

DISCUSSION

The impact of SSIs alone on morbidity and mortality is substantial.[8] SSIs increase the post-operative length of stay, and in patients with an SSI, mortality rates reach as high as 3% with 75% of these deaths directly attributable to complications that arise from the SSI itself.[9]

Although several studies have identified an association between higher HbA1c and worse postoperative outcomes, other studies have not shown this to be true.[6,7,10] Thus, due to the varied findings of previous studies, the present study was carried out to assess the association of preoperative HbA1c levels with postoperative surgical site infection and glycaemic control in non-cardiac elective surgery.

In this study, a total of 64 diabetic patients from the department of surgery were recruited. The age ranged from 28 to 76 years, with a mean age of 54.98±11.20 years. The proportion of males and females in the study was almost equal (male 53.1% and female 46.9%). The majority (56.3%) of the patients had a normal BMI, with a mean BMI of 22.92±2.84 kg/m^2, while the rest (43.8%) were pre-obese. Firsch A et al,[11] in their study also observed similar findings, where 53.8% were female and 46.2% were male, with a mean age of 56.5±16 years and a mean BMI of 27.6±7.3 kg/m^2.

In our study, the rate of SSI among those who had a pre-operative glycaemic level <6.5% was 13.6% and 47.6% in those who had ≥6.5%, and this was found to be statistically significant ($p<0.05$). Also, a significant proportion of patients who had <6.5% HbA1c levels pre-operatively had a controlled post-operative HbA1c level ($p<0.05$). An increase in BMI, the addition of major co-morbidities, and an increase in HbA1c levels pre-operatively were found to be significant predictors of surgical site infection post-operatively.

Gabriel RA et al.[12] in their study also reported significantly higher rates of surgical site infections among patients who had higher levels of HbA1c. Vascular surgery, the presence of chronic obstructive pulmonary disease, and the diagnosis of dementia were found to be

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significant predictors of SSI in their study. Chen P et al.,[13] in their study also observed that patients with diabetes who had a higher HbA1c level had a higher incidence of postoperative infection and surgical wound problems. They stated that an elevated HbA1c result, unlike a single pre-operative glucose value, could predict difficulty in achieving postoperative glycaemic control and the development of complications. Dronge AS et al.,[14] in their retrospective study on diabetic patients who underwent non-cardiac surgery, observed that good pre-operative glycaemic control was associated with a significantly lower risk of post-operative infection after adjusting for factors that are known to influence this outcome.

On the contrary, Blankush JM et al.[15] in their study that elevated pre-operative HbA1c was not an independent indicator of post-operative infection risk. They also further suggested that other characteristics of the patient as well as the procedure, i.e., age, surgical risk classification, and wound classification, have a stronger predictive value than HbA1c alone, but elevated HbA1c does not have a predictive capacity when applied to specific patient subgroups. Jeon CY et al.,[16] also did not observe any significant association between preoperative glucose level and SSI after adjusting for variables like age, gender, type of surgery, operation time, etc.

The varied findings across different studies may be due to the association of multiple risk factors that contribute to a patient's risk of post-operative infection.[17] Despite the inconsistent findings between elevated HbA1c levels and post-operative complications, a preoperative A1C screening for all patients with diabetes is justified by the fact that a relatively inexpensive test can identify candidates for increased surveillance to prevent a potentially serious complication.

Our results suggest that higher HbA1c levels in the pre-operative period increase the risk significantly. Thus, preoperative glycaemic optimization should be seriously considered, especially for elective surgeries.

Our study has some limitations. Firstly, we chose to categorize HbA1c based on the American Diabetes Association cutoffs for normal (<6.5%) and diabetes (≥6.5%). This study does not delineate the outcomes for elevated HbA1c of more than 7%, more than 8%, or even more than 10%, where the power is lacking. Secondly, while all patients underwent a procedure in the general surgery specialty, they did not undergo the same procedure. As we did not compare the specific type of surgery with patient perioperative glucose, or HbA1c, it is possible that the results were affected. In addition, there are several potential confounders, including laparoscopic versus open procedure, indications for surgery, and antibiotic use, which were not addressed and could limit the study.

In conclusion, our study demonstrated a higher risk for post-operative surgical site infection in patients with uncontrolled HbA1c levels preoperatively. Also, we observed that patients with a higher BMI and the presence of major co-morbidities were more at risk of developing SSI post-operatively.

CONCLUSIONS

In our study, the rate of SSI among those who had a pre-operative glycaemic level <6.5% was 13.6% and 47.6% in those who had ≥6.5%, and this was found to be statistically significant ($p<0.05$). Also, a significant proportion of patients who had <6.5% HbA1c levels pre-operatively had a controlled post-operative HbA1c level ($p<0.05$). An increase in BMI, the addition of major co-morbidities, and an increase in HbA1c levels pre-operatively were found to be significant predictors of surgical site infection post-operatively.

In conclusion, this study demonstrated a higher risk for post-operative surgical site infection in patients with uncontrolled HbA1c levels preoperatively. Also, we observed that patients with a higher BMI and the presence of major co-morbidities were more at risk of developing SSI post-operatively. This result suggests that higher HbA1c in the pre-operative

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period increases the risk of SSI significantly. Thus, preoperative glycaemic optimization should be seriously considered, especially for elective surgeries.

AUTHOR CONTRIBUTION

The third author Dr. Yumnam Priyabarta Singh contributed in drafting the article.

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