

Comparative Study on Incidence of Post-operative Wound Infection in Diabetic vs Non-diabetic Patients in Clean Surgical Procedure

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Abstract

Background: Diabetes mellitus is associated with a theoretical increase in risk of development of post-operative infections; however, literature on the subject is conflicted, with some studies negating the effect of high blood sugar on the development of surgical wound site complications.

Objectives: To compare the complications of ventral hernia repair in diabetics versus non-diabetics in terms of frequency of surgical site infection, seroma and haematoma formation

Study type, settings & duration: A prospective cohort study conducted Department of General Surgery, Combined Military Hospital, Rawalpindi from November 2019 to December 2020.

Methodology: A total of 182 patients (91 in each group) diagnosed with a ventral abdominal hernia who met the sample selection criteria were included. Patients who were diabetic were placed in Group A, while Group B patients were non-diabetic. All patients were followed up for surgical site infection, seroma and haematoma formation. Data was analyzed using SPSS 26.0.

Results: The mean age of patients was 46.54 ± 10.58 years (range 25-70 years). The patients included 113 females (62.1%) and 69 males (37.9%). A total of 9 (9.9%) patients developed surgical site infections in Group A versus 2 (2.2%) in Group B, ($p=0.029$). Seroma formation was seen in 4 (4.4%) patients of Group A versus 2 (2.2%) Group B patients, $p=0.406$. One (1.1%) case from each group developed haematomas, ($p=1.000$). The relative risk ratios in diabetics for developing surgical site infections, seromas and haematomas were RR: 4.9 (CI 95% 1.03 – 23.3), RR: 2.1 (CI 95% 0.37 – 11.5) and RR: 1.0 (CI 95% 0.06–16.2).

Conclusion: Diabetics are prone to increased rates of surgical site infection, even in clean surgeries, when compared to non-diabetics, but there was no difference in frequencies of other complications.

Key words: Diabetes mellitus, surgical site infection, ventral hernia repair.

Introduction

An approximate 463 million people suffered from diabetes mellitus in 2019, of whom a clear majority of over 70% resided in developing countries like Pakistan¹ where the prevalence of diabetes has jumped 148% since 2017, and now affects 17.1 percent of the population.¹ These

numbers are expected to rise as the world's population of diabetics is expected to increase from 2.8% in 2000 to 4.4% in 2030.² Affected individuals have a decreased life expectancy of approximately 9 years, and are more likely to develop cardio/cerebrovascular complications, malignancies and metabolic disorders.³

Purportedly, approximately half of all individuals suffering from diabetes require at least one surgery during their entire lifetime, which is quite concerning as they are at a greater risk of post-operative complications which include delayed wound healing, surgical site infections (SSIs), requirement for revision of surgery or blood transfusion, and extended hospital stay.^{4,5}

Repair of ventral hernias are amongst the most frequently performed procedures conducted worldwide: The United States and the European Union alone account for approximately 400,000 and 300,000 cases per annum, respectively.⁶ It is a procedure associated with comparatively high rates

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Authors Contribution

RQ conceptualized the project. RJ, FS & IT did the data collection. NP did the literature search. Statistical analysis, drafting, revision & writing of manuscript were done by RQ & NP. KM did the supervision and editing.

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of post-operative wound infection.⁷ Theoretically, the combined effect of a surgery prone to infection development and the presence of diabetes mellitus should increase the overall risk of developing SSI but the literature is conflicted, as the correlation is somewhat difficult to predict.⁸ Hemoglobin A1c levels are used a standard measure for evaluation of long-term blood sugar control over the preceding 90 days.⁹ High peri-operative levels of HbA1c can be predictive of the propensity to develop SSIs.¹⁰

Diabetes Mellitus and surgical repair of ventral hernias are both common in Pakistan. This study was conducted with the aim of studying the frequency of different complications including SSIs, seroma and haematoma formation in diabetics compared to non-diabetic patients operated for ventral hernias as well as the ability of pre-operative HbA1c levels to predict the possibility of developing SSIs, an aspect of this surgery that has not been currently studied in Pakistan. Determining the frequencies of these complications will sensitize the treating surgeons to remain vigilant to their development when managing such patients.

Methodology

A prospective cohort study conducted by Department of General Surgery, Combined Military Hospital, Rawalpindi from November 2019 to December 2020 on patients identified as suffering from ventral abdominal hernia and who qualified the criteria for sample selection. A written informed consent was taken before their inclusion as subjects. The sample size was calculated by using the EPI sample size calculator with two-sided confidence interval of 95%, power of test of 5%, a ratio of exposed to unexposed of 1, percent outcome in unexposed of 14%, a risk ratio of 1.43176 and an odds ratio of 1.54.¹¹ The sample size was increased to 91 patients in each group i.e. diabetics and non-diabetics, for a total of 182 patients. All patients were selected using the consecutive, non-probability technique.

Patients of either gender, between 20 and 70 years of age, suffering from uncomplicated ventral abdominal hernias were included. The exclusion criteria comprised of patients with irreducible, obstructed or strangulated hernias, American Society of Anesthesiologists (ASA) class IV or V, recurrent hernias, concurrent hepatic or renal failure, diabetic end-organ damage (history of cerebrovascular or cardiovascular accidents, diabetic retinopathy or nephropathy, and history of diabetic neuropathy), concurrent infection and any coagulopathy. Patients who developed bowel injury during surgery were excluded. Group A composed

of patients who were diabetic while Group B included patients who were non-diabetic. All patients had their HbA1c levels test 1 day before surgery, and were grouped according to their result into 3 groups: 1. Normal (<6.5%), 2. High, (6.5-7.5%) and 3. Very High (>7.5%).

All patients received appropriate antibiotics, pre-operatively: All patients were given a single dose of injection Ceftriaxone 1g intravenously, thirty minutes prior to the first incision. This was followed by laparoscopic or open ventral hernia repair as detailed by the American College of Surgeons.^{12,13} A proline mesh was positioned using the sub-lay technique, with a 5cm overlap with the abdominal wall from the margins of the defect, and secured circumferentially. Contact between intestines and mesh was avoided by utilizing a layer of peritoneum underneath the mesh. All surgeries were conducted under general anesthesia. The patients had a Radevac suction drain placed post-surgery, and were discharged on 3rd post-operative day, followed up as out-patients on the fourteenth and twenty eighth post-operative days. The suction drain was removed if the drain output was less than 20 ml in 24 hours.

All patients were followed for development of SSI (defined as the development of fever, redness or tenderness at the site of incision, discharge from the surgical wound or the development of an abscess around the wound within twenty-eight days of surgery), seroma formation (serous fluid collection pockets) and haematoma formation (localized collection of blood).

Data was analyzed using the Statistical Package for the Social Sciences version 26.0. Quantitative variables like age, body mass index, duration of diabetes and HbA1c levels were measured using mean and standard deviation. Qualitative variables like gender, HbA1c group, hernia type, and development of complications (SSI, seroma and haematoma formation) were documented as frequencies and percentages. Chi square test was applied for qualitative variables. Independent sample T-test was applied for quantitative variables. We considered a *p* value of ≤0.05 to be significant.

The ethical approval was obtained from Ethical Committee/ Institutional Review Board (IRB) of Combined Military Hospital, Rawalpindi vide IRB # 143/4/21.

Results

We studied a total of 182 patients in this study and with 91 patients in each group. The mean age of patients was 46.54±10.58 years (range 25-70

years). The patients included 113 females (62.1%) and 69 males (37.9%). Gender did not appear to have a statistically significant relationship with the development of complications in general ($p=0.919$), or the development of SSIs in particular, ($p=0.913$). Of the 182 patients, 64 (35.2%) had epigastric hernias, 84 (46.2%) had para-umbilical hernias and 34 patients (18.7%) had incisional hernias. Data for these patient characteristics distributed according to groups is displayed in Table-1. Neither age, nor BMI had a significant relationship with the development of complications, ($p=0.421$ and 0.073 , respectively), and the relationship between age and SSIs was also not significant, ($p=0.599$), however, BMI did appear to have a statistically significant relationship with the development of SSIs, ($p=0.006$).

Table 1: Patient characteristics.

	Group A (n=91)	Group B (n=91)	p value
Gender (M:F)	39 (42.9%): 52 (57.1%)	30 (32.9%): 61 (67.1%)	0.169
Age (Years)	47.3 ± 9.8	45.8 ± 11.3	0.349
BMI (kg/m ²)	28.7 ± 3.4	28.2 ± 3.3	0.319
Hernia Type			
Epigastric	37 (40.7%)	27 (29.7%)	0.245
Para-umbilical	40 (43.9%)	44 (48.4%)	
Incisional	14 (15.4%)	20 (21.9%)	

Table 2: Summary of results.

	Group A (n=91)	Group B (n=91)	p value
Procedure type			
Open	70 (76.9%)	75 (82.4%)	0.357
Laparoscopic	21 (23.1%)	16 (17.6%)	
HbA1c levels (%)	8.4 ± 1.9	5.8 ± 0.7	<0.001
Diabetes duration (Years)	11.7 ± 6.6	0 ± 0	<0.001
Complications	14 (15.3%)	5 (5.5%)	0.029
Surgical site infection	9 (9.9%)	2 (2.2%)	0.029
Seroma	4 (4.4%)	2 (2.2%)	0.406
Haematoma	1 (1.1%)	1 (1.1%)	1.000

Complications were seen in 19 (10.4%) patients, 14 (15.3%) of whom were in Group A, while 5 (5.5%) were in Group B. Table-2 presents a comparison between Group A and B with respect to complication rates, which shows a statistically significant difference regarding rates of SSI between group A and B ($p=0.029$). Rates of seroma formation were also higher in group A as compared to group B but it was not statistically significant ($p=0.406$), while rates of hematoma formation were found similar in both groups. All infected cases were managed with IV antibiotics, except one which required surgical debridement. Seromas were managed by opening the wound followed by drain insertion and closure, done under local anaesthesia.

The drain was kept in place till output became less than 20 ml in 24 hours. Lastly, raised HbA1c levels were associated with an increase in the development of SSIs, ($p=0.017$).

Table 3: Relative risk for different complications.

	Group A (n=91)	Group B (n=91)	Relative Risk (CI 95%)
Surgical site infection	9 (9.9%)	2 (2.2%)	4.9(1.03 – 23.3)
Seroma	4 (4.4%)	2 (2.2%)	2.1 (0.37 – 11.5)
Haematoma	1 (1.1%)	1 (1.1%)	1.0 (0.06 – 16.2)

Table-3 shows the relative risk for the development of SSIs, seromas and haematomas. Diabetics were shown to have a higher risk of SSIs and seromas than non-diabetics in our study, as compared to non-diabetic patients, while haematoma formation did not occur at an increased frequency in either group.

Discussion

The majority of the patients in our study were females, and no relationship was seen with gender and the development of complications/SSIs. Brahmbatt et al studied 201 patients out of whom only 53 (26.4%) were female, likely because the study was conducted in a Veterans' Affairs hospital where the population was predominantly male, and also found that there was no relationship between gender and development of SSIs, ($p=0.16$).¹⁴ The mean age of the patients in our sample was 46.54±10.58 years, which had no significance with the development of SSIs, ($p=0.599$). Kaafarani et al reported on a much older population with a mean age 60.5±9.4 years, but also arrived at the same conclusions ($p=0.977$).¹⁵ It would appear that advancing age also has no bearing on the development of SSIs in ventral hernia repair.

The present study found a statistical relationship between increasing BMI and the development of complications, ($p=0.073$), a result which was in agreement with Kaafarani et al ($p=0.972$),¹⁵ which was at odds with studies like Won et al ($p=0.009$), Brahmbatt et al and Qin et al who found a statistically significant relationship between higher BMIs and the development of complications.^{12,14,16} We attribute this difference to the overall higher prevalence of obesity in the general population in their sample as compared to ours. However, it is important to note that our study did find an increase in incidence of SSIs with increasing BMI, ($p=0.006$).

This study showed that the presence of diabetes resulted in an increase in the frequency of SSIs, $p=0.029$, a finding that was confirmed by Brahmbatt et al ($p=0.04$),¹⁴ Won et al ($p=0.044$)¹¹ and Qin et al ($p<0.001$).¹⁶ Kaafarani et al reported no relation between the presence of diabetes mellitus and the occurrence of SSIs, $p=0.209$.¹⁵ This in-congruence may be attributable to the difference in antibiotic protocols used, as well the antimicrobial susceptibility patterns in the populations studied. We demonstrated that there was no correlation between the presence of diabetes and the increased incidence of seroma formation, $p=0.406$, a finding which was congruent with Brahmbatt et al, $p=0.92$.¹⁴

We saw that increasing HbA1c levels were associated with an increase in SSIs ($p=0.017$), and while this was a previously unstudied factor in ventral hernia repair, it has been studied previously in foot surgeries, as demonstrated by Cancienne et al ($p<0.001$).¹⁰

Both open and laparoscopic repair of ventral hernias are safe procedures; serious complications are minimal. However, co-morbidities such as diabetes mellitus increase the propensity for the development of potentially dangerous sequelae such as SSIs which may be difficult to treat. A thorough medical history and physical examination for diabetes mellitus and target organ damage is imperative. In addition, adequate control of blood sugar in the peri-operative period may prove essential to minimize complications. HbA1c levels have the potential to provide a satisfactory objective method to determine the degree of blood sugar control, and may serve as an indicator for the potential to develop complications, signaling the need for greater vigilance in such patients. The sample mostly composed of female patients in our study, with a short-term follow-up of 1 month. Further research is required on the subject with a larger, more diverse sample, to objectify the role of HbA1c levels in predicting complications, and to determine long-term morbidity, mortality, and recurrence rates associated with these procedures.

Patients suffering from Diabetes Mellitus are at an increased risk of developing SSIs even in clean surgeries like laparoscopic ventral hernia repair. Optimal control of blood glucose prior to, during, and after surgery may be paramount to keep this complication to a minimum.

Conflict of interest: None declared.

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