HbA1c over 8.5% is not predictive of increased infection rate following penile prosthesis implantation surgery in diabetic patients with erectile dysfunction

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Abstract
Diabetes mellitus is associated with increased risk of erectile dysfunction. Penile prosthesis implantation is an efficient therapeutic option for erectile dysfunction, but not without risk, as infection remains a prominent concern. This study investigates diabetes mellitus as a risk factor for penile prosthesis implantation infection and the relationship between haemoglobinA1c levels and infection rates. All diabetic patients with erectile dysfunction who underwent penile prosthesis implantation surgery between January 2012 and November 2019 at Hamad Medical Corporation, Qatar, were included in this retrospective observational study. A total of 599 diabetic patients with erectile dysfunction had penile prosthesis implantation. Mean age was 59.69 ± 31.19. Penile prosthesis implantation infection rate was 0.83% (5/599), while the mean haemoglobinA1c level was 7.58 ± 1.45 mmol/l (range: 4.1–12.6). A comparison between diabetic patients with penile prosthesis implantation infection and those without infection revealed no significant difference in the level of haemoglobinA1c between the two groups with mean haemoglobinA1c in patients with infected implants 7.14 and 7.59 for noninfected (p = 0.491). Limitations include retrospective single-centre design and low-infection rates reducing sample number. Penile prosthesis implantation infection rate in a large series of diabetic patients was low with no significant association between haemoglobinA1c level and penile prosthesis implantation infection observed.

KEYWORDS
diabetes mellitus, erectile dysfunction, haemoglobin A1c, penile prosthesis implantation

1 | INTRODUCTION

The inability to achieve and maintain a penile erection sufficient for satisfactory sexual intercourse is known as erectile dysfunction (ED). Many studies have reported increased risk of ED in men with diabetes mellitus (DM) compared with nondiabetics, with an ED prevalence ranging from 35% to 80% (Díaz-Díaz et al., 2012; Feldman et al., 1994; Johannes et al., 2000; Sharifi et al., 2012). In Qatar, the
incidence of diabetes amongst its citizens is approximately 20% and accompanying ED has a prevalence of 82.2% (Al Naimi et al., 2014). Various approaches have been utilised in the treatment of ED. The current first-line therapeutic approaches include phosphodies- terase type 5 inhibitors along with vacuum constriction devices, intra-urethral therapy and intracavernosal injection as a second-line therapy (Dhir et al., 2011). Diabetic patients often have more severe ED and are more resistant to these first and second-line therapies (Malavige & Levy, 2009). Amidst these treatment modalities, penile prosthesis implantation (PPI) remains a viable and efficient therapeutic option in treating ED refractory to medical therapy and reports indicate that diabetic patients are more likely to undergo PPI as a treatment strategy (Henry et al., 2016). In diabetics, the major concern for penile implants surgery is the post-operative infection, especially when glycosylated haemoglobin is taking a trend towards 8.5% and higher. Indeed, diabetic men are at risk for delayed wound healing and increased risk of general post-operative infection in nonurologic surgery (Kato et al., 2013; Kunutsor et al., 2016). Therefore, diabetic men undergoing PPI pose unique challenges to surgeons for identifying and reducing risk of implant infection.

Whether DM and high HbA1c levels, known to provide an objective value for degree of diabetic control, are risk factors for PPI infection is still controversial. In 1992, Bishop et al. (1992) found a distinct association between uncontrolled DM, glycated haemoglobin and PPI infection, while a larger follow-up study by Wilson, Carson and Cleves (1998) failed to establish a causal link. A recent study involving 14,969 patients found a significant association between DM and PPI infection after controlling for age, race, comorbidities, insurance status, annual surgeon volume and era of implantation (Lipsky et al., 2019). While this study supports the notion that DM is a risk factor for PPI infection, the issue of controlled versus uncontrolled diabetes was not addressed. A previous retrospective cohort study conducted in Hamad Medical Corporation attempted to establish the relationship between PPI infection and glycaemic control (Canguven et al., 2018). Prosthesis infection risk did not significantly increase with higher HbA1c levels (Canguven et al., 2018).

The present study re-evaluates the role of DM as a risk factor for PPI infection in a large population of diabetic patients. Patients undergoing PPI were tracked post-surgery and the relationship between pre-operative HbA1c levels and prosthesis infection rates was examined to evaluate a possible cause-and-effect relationship between degree of diabetic control and risk of infection complicating the operation and recovery. We aimed to define a pre-operative HbA1c threshold that can predict increased likelihood of device infection.

2 | SUBJECTS/PATIENTS AND METHODS

2.1 | Design, setting and population

A retrospective observational study was conducted in the Andrology Unit of Hamad General Hospital involving all diabetic patients with ED who had undergone PPI surgery between January 2012 and November 2019. Approximately 90% of all ED cases across Qatar were treated at the Andrology Unit of Hamad General Hospital. Ethical approval was obtained from Medical Research Committee Hamad Medical Corporation (protocol ID MRC-01–18–450).

2.2 | Case identification and data collection

All diabetic patients who opted for PPI surgery were identified and assessed for inclusion. Patients were excluded if primary PPI was not indicated; HbA1c was >11 as a result of poorly controlled diabetes and hyperinsulinaemia increasing risk of wound-healing disturbances or were receiving double implant of PPI and artificial urinary sphincter. Patient’s medical records through the CERNER healthcare system were reviewed and the following information was retrieved: patient demographics, model and size of penile prosthesis, corporal size, relevant laboratory findings including HbA1c and subsequent patient complications including infection within a post-surgery follow-up period of up to 12 months.

2.3 | Procedures and antibiotic administration

All PPI surgeries were performed at the Center of Andrology Middle East Region by the same two senior surgeons for consistency. Prior to surgery, all patients were instructed for a pre-operative bath with emphasis on genitalia hygiene and care. For the surgical procedure, a patient may receive general or spinal anaesthesia. Prior to surgery, the external genitalia hair was removed followed by scrotal wash with chlorhexidine.

Starting within 1 hr prior to surgery, patients received a peri-operative infusion of two antibiotics (vancomycin 1,000 mg/i.v./two times/day and gentamycin 80 mg/i.v./three times/day, for patients without impaired renal function or ceftriaxone 2 gm/i.v./once a day and clindamycin 600 mg/i.v./times/day for impaired renal function). A peno-scrotal or infrapubic incision was made creating an entry space for prosthesis placement. Directly before insertion of penile prosthesis components, surgical gloves are exchanged for new and new sterile drape is applied to prevent the prosthesis components from touching the skin (no touch technique, Eid et al., 2012). Dealing with concomitant fibrosis (Peyrounie’s), we used cavernotom and penile modelling or intracorporal plaque incision. The penile prosthesis reservoir (when three-piece penile prosthesis are used) is then inserted into the extra-peritoneal space (retiz space) by blind puncture through the transversalis fascia. A drain is not utilised routinely unless there is a particular concern of excess bleeding. Finally, a multilayered surgical closure was performed. During surgery, antibiotics (10 vancomycin 500 mg and 10 gentamycin 80 mg ampoules mixed with 500 ml saline for patients with normal renal function; and 10 rifampicin 600 mg and 10 gentamycin 80 mg ampoules mixed with 500 ml saline for patients with impaired renal function) were used to irrigate the corporal bodies. This duration was (mean ± SD)
47 ± 9 min. Starting from the second post-operative day, patients received ceftriaxone 2 gm i.v. once a day for 3–5 days and levofloxacin 500 mg daily for 10–14 days. Paracetamol was prescribed for post-operative pain control.

HbA1c, as indicative of average blood glucose levels in the past 3 months, was determined in fasting whole-blood samples and considering previous investigations, at least 1 week prior to surgery by immunoturbidimetric assay. This was determined to look at HbA1c as a definite tool for prediction of infections. As we looked at DM control, anthropometric parameters were not within the scope of this study.

2.4 Statistical analysis

Data are reported as mean ± standard deviation (SD) for quantitative variables, while qualitative variables were described as numbers and percentages. The association between the two or more qualitative variables was examined using the Chi-squared test or Fisher exact test to account for large or small sample sizes. Quantitative variables were examined by unpaired ‘t’ test or Mann–Whitney U test depending upon the distribution of the data. Relationships between two quantitative variables (e.g. age and HbA1c) were examined using Pearson’s or Spearman’s correlation coefficients. All statistical analyses were performed using SPSS, version 25.0 (SPSS Inc.) and Epi-info (Centers for Disease Control and Prevention) statistical software. Statistical significance was assumed at p < 0.05.

3 RESULTS

3.1 Demographic and clinical characteristics

A total of 599 diabetic patients with ED who underwent PPI surgery were identified. Mean age was 59.69 ± 31.19 (range: 2488 years), total corporal size 20.6 ± 3.9, while mean HbA1c level was 7.58 ± 1.45 (range: 4.1–12.6). PPI infection rate was 0.83% (5/599). An additional 13 patients (2.2%) had minor skin infection/wound dehiscence. There was no indication that these patients had device infection and the infection was subsequently healed by secondary intention. 31% of patients were smokers. Demographic and clinical characteristics are presented in Table 1.

3.2 Comparison between infection and no-infection groups

The comparison between patients with PPI infection (itself or its components) and those without infection is described in Table 2. Mean HbA1c for the patients with infected implants was 7.14 and for the non-infected 7.59, p = 0.491. Associated medical conditions such as arteriosclerotic cardiovascular disease and post-radical prostatectomy were found in 337 (56.3%) and 39 (6.5%) cases, respectively.

### TABLE 1 Demographic and clinical characteristics

| Characteristics                        | N(%)|
|----------------------------------------|-----|
| Age (Mean ± SD)                        | 59.7 ± 31.2 |
| Total corporal size (Mean ± SD)        | 20.6 ± 3.9 |
| HbA1c (Mean ± SD)                      | 7.58 ± 1.45 |
| 3-piece inflatables, Boston/Coloplast (N (%)) | 479 (79.9) |
| Semirigid (N (%))                      | 101 (17.3) |
| 2-piece inflatable: Ambicor (N (%))    | 19 (3.2) |
| Post-radical prostatectomy (N (%))     | 39 (6.5) |
| Peyronie’s disease (N (%))             | 50 (8.3) |
| Arteriosclerotic cardiovascular disease | 337 (56.3) |
| Smokers (N (%))                        | 186 (31.1) |

Complications outcomes

| Complication                             | N(%)|
|------------------------------------------|-----|
| Superficial wound infection or dehiscence not requiring explant (N (%)) | 13 (2.2) |
| Erosion (2 pump one reservoir and one cylinder) (N (%)) | 5 (0.8) |
| Urethral injury (N (%))                  | 2 (0.3) |
| Device failure (malfunction) (N (%))    | 8 (1.3) |

No significant difference in age and total corporal size between the two groups was shown and age and HbA1c were not correlated. No significant differences between various implants types were observed in this concern.

4 DISCUSSION

Penile prosthesis implantation infection is a distressing complication in prosthetic urology. Patients may suffer significant penile shortening and scarring of corporal bodies and reinserter of the penile prosthesis commonly results in patient dissatisfaction (Mulcahy, 2010). These consequences negatively impact patients’ well-being and contributing substantial burden to the health care system both financially and socially. PPI infections vary in timing, symptoms and underlying microbiology. Infection can occur any time from days post-hospitalisation to years after implantation with clinical features ranging from severe local signs of infection accompanied by sepsis to vague symptoms that require a higher level of clinical investigation (Lipsky et al., 2019). Recently, PPI infection rates have significantly declined as a result of anti-microbial coatings being incorporated onto implant components (Mandava et al., 2012), new skin preparation solution such as Chlorhexidine (Darouiche et al., 2010) and ‘no touch’ surgical technique (Eid et al., 2012). The prevalence of PPI infection varies from approximately 1%–3% (O’Rourke et al., 2017). Current infection rates in Hamad Medical Corporation is 0.83%, a significantly low figure despite coated implant usage not being universally employed.

Classic management of PPI infection involves either the removal of the entire device with thorough irrigation of infected spaces or Mulcahy’s salvage and washout procedure with exchange for a...
new implant (Lao et al., 2017). While these procedures have been successful in appropriately selected patients, corporal fibrosis and scarring can occur rendering subsequent implantation challenging. In addition to patient and physician devastation, the cost of treating PPI infection has been estimated at more than six times the original implant cost (Muench, 2013). Therefore, urologic surgeons need reliable and clinically viable tools to identify high-risk patients for PPI infection. If risk factors can be mitigated the risk of device infection could be lowered in these patients.

The presence of DM in a penile implant patient has long been suspected to increase the risk of PPI infection. A substantial number of studies have recognised a significant relationship between DM and PPI infection. Mulcahy and Carson (2011) found an increase in rate of PPI infection significantly increased with 1.3% of patients 8.5%, 14.7% for 8.6%–9.5%, 22.4% for >9.5% (Habous et al., 2018). This led to the authors establishing a cut-off point of >8.5 as a significant threshold predictive of PPI infection. While the present study aimed to investigate this threshold, we were unable to confirm HbA1c 8.5% as a useful cut-off in our patients. In contrast to Habous et al. (2018), a prospective study of 389 patients, failed to find a relationship between fasting blood sugar (FBS) measured on the day of surgery, HbA1c and PPI infection (Wilson et al., 1998). This study did admit that the risk of infection in diabetics was higher but HbA1c and FBS was not predictive (Wilson et al., 1998). Furthermore, in a multi-centre retrospective analysis of 875 diabetic patients undergoing primary PPI, pre-operative HbA1c and blood glucose levels within 6 hr of surgery were not associated with post-operative infection, revision, or explanation (Osman et al., 2020). In the previous study conducted in Hamad Medical Corporation (Canguven et al., 2018) together with the current report, no direct correlation between elevated HbA1c and PPI infection is shown. While the present study reports no predictive value of HbA1c, it is believed that low prevalence of infection

Beyond incidence of diabetes per se, the influence of diabetic control in these patients has emerged as an important influential factor in understanding the relationship between DM and PPI, yet its specific role has remained controversial with much debate over the past three decades. In an attempt to establish a threshold HbA1c value as a predictive indicator after which patients would be at a higher risk of complications, Bishop et al. (1992) found poorly controlled diabetics (HbA1c > 11.5) more likely to have a post-operative infection than well-controlled diabetics up to 90 days after surgery. DM control was post-operatively guided by the diabetes team. Similarly, a multi-centre prospective study identified that as HbA1c levels increased in diabetic patients, the rate of PPI infection significantly increased with 1.3% of patients with HbA1c level of <6.5%, 1.5% for 6.5%–7.5%, 6.5% for 7.6%–8.5%, 14.7% for 8.6%–9.5%, 22.4% for >9.5% (Habous et al., 2018).

### Table 2 Comparison between infection and no-infection groups

| Characteristics                        | Infection | No infection | p-Value |
|----------------------------------------|-----------|--------------|---------|
| Age (Mean ± SD)                        | 47.4 ± 6.5| 59.8 ± 31.3  | 0.377   |
| Total corporal size (Mean ± SD)        | 22.9 ± 1.3| 20.8 ± 1.9   | 0.078   |
| HbA1c (Mean ± SD)                      | 7.14 ± 1.13| 7.59 ± 1.45  | 0.491   |
| Arteriosclerotic cardiovascular disease (N %)) |           |              |         |
| Yes                                    | 5 (100)   | 330 (55.5)   | 0.038   |
| No                                     | 0 (0)     | 264 (44.5)   |         |
| Post-radical prostatectomy (N %))      |           |              |         |
| Yes                                    | 0 (0)     | 39 (6.6)     | 0.553   |
| No                                     | 5 (100)   | 555 (93.4)   |         |
| Peyronie's disease (N %))              |           |              | <0.0001 |
| Yes                                    | 3 (60)    | 47 (7.9)     |         |
| No                                     | 2 (40)    | 547 (92.1)   |         |
| Smokers (N %))                         |           |              |         |
| Yes                                    | 4 (80)    | 180 (30.3)   | 0.016   |
| No                                     | 1 (20)    | 414 (69.7)   |         |
was insufficient to assess the association of HbA1c with PPI infections to statistical significance. Therefore, large-scale studies across multiple centres are required for definitive assessment of the relationship between DM and PPI.

This study has its limitations. First, it is a retrospective study with its inherent limitations including differential losses to follow-up data which can lead to report biasing, and as records are not specifically designed for the study an absence of data on potential confounding factors may influence the analysis. Second, it is a single-centre study involving experienced implant surgeons that makes the generalisation of results questionable. Third, the number of patients who developed PPI infection was low potentially skewing the final results with cohort size limiting the quality of the data and the value of statistical analysis and power. These limitations however, are balanced by the fact that our protocol varies from generally accepted guidelines (Levine et al., 2016) lowering infection incidence by: (a) peri- and post-operative prophylactic antibiotics; (b) implanting some devices that were not coated with infection retardant substances, (c) ‘no touch’ technique; and (d) employing a specialised and dedicated team for post-operative patient follow-up. Regardless of the limitations and the variance from the generally accepted best practices, we believe that this study shows that diabetic patients can have an acceptable risk of device infection of less than 1% in our centre and that this could be replicable at other practices with experienced surgeons and well-established protocols.

5 | CONCLUSION

This study demonstrates that diabetic patients who underwent penile implants surgery had a pre- and post-operative device infection rate of less than 1% when the disinfection protocol and peri- post-operative prophylaxis and care are well standardised. Within the patients presenting with infection, an HbA1c cut-off of 8.5% was not indicative of infection incidence and was therefore not considered a useful predictive tool in this cohort.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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