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ARTICLE

Immediate preoperative blood glucose and hemoglobin a1c levels are not predictive of postoperative infections in diabetic men undergoing penile prosthesis placement

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Abstract

Defining the risks associated with diabetes mellitus in patients undergoing penile prosthesis implantation remains controversial. Our study aims to assess whether preoperative hemoglobin a1c and preoperative blood glucose levels are associated with an increased risk for postoperative infection in diabetic men. We performed a retrospective review of 932 diabetic patients undergoing primary penile prosthesis implantation from 18 high-volume penile prosthesis implantation surgeons throughout the United States, Germany, Belgium, and South Korea. Preoperative hemoglobin a1c and blood glucose levels within 6 h of surgery were collected and assessed in univariate and multivariate models for correlation with postoperative infection, revision, and explantation rates. The primary outcome is postoperative infection and the secondary outcomes are postoperative revision and explantation. In all, 875 patients were included in the final analysis. There were no associations between preoperative blood glucose levels or hemoglobin a1c levels and postoperative infection rates; $p = 0.220$ and $p = 0.598$, respectively. On multivariate analysis, a history of diabetes-related complications was a significant predictor of higher revision rates ($p = 0.034$), but was nonsignificant for infection or explantation rates. We conclude preoperative blood glucose levels and hemoglobin a1c levels are not associated with an increased risk for postoperative infection, revision, or explantation in diabetic men undergoing penile prosthesis implantation.

Introduction

Penile prosthesis (PP) implantation is the surgical gold standard for patients with medication-refractory erectile dysfunction (ED) [1, 2]. Due to the elective nature of the surgery, it is particularly important to appropriately counsel the patient preoperatively on the outcomes, expectations, and possible complications of surgery [3, 4]. Diabetes mellitus (DM) is one major factor that may potentially increase the risk of complications during or after surgery [5–9].

DM is a major global health epidemic and, as of 2015, the global prevalence was estimated at 415 million people [10]. DM is associated with several comorbidities such as cardiovascular disease, stroke, peripheral vascular disease, chronic kidney disease, peripheral neuropathy, and diabetic skin wounds or ulcerations [11]. Poor vascular flow in particular is what makes DM a risk factor for postoperative complication in patients undergoing PP implantation. A major consequence of poor vascular circulation is improper wound healing. This vascular compromise may lead to an infection, the most devastating complication that can occur after PP implantation, thus highlighting the importance of establishing whether or not DM control is a risk factor for infection after PP implantation.

Studies have used preoperative glycemic control cut-offs, in the form of hemoglobin a1c (HbA1c), to suggest that

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patients are at a significantly increased risk for postoperative infection [6, 7]. However, other studies have suggested that preoperative HbA1c levels are not associated with increased postoperative infection [8, 9]. These contradictory results suggest that perhaps another measure of preoperative glycemic control should be assessed in conjunction with HbA1c levels. One such variable that is assessed in only one of these studies is preoperative blood glucose (PBG) levels within 6 h of surgery. Although the aforementioned study showed that PBG levels are not predictive of PP infection, several studies in other literature from general and neurovascular surgeries, however, suggest that increased PBG levels are associated with increased postoperative complications [12, 13].

In our study, we aimed to assess whether preoperative HbA1c levels and/or immediate PBG levels are associated with an increased rate of postoperative infection, explantation, or revision in the largest cohort to date of diabetic men undergoing PP insertion.

Materials and methods

Study data and population

We examined 923 diabetic patients who underwent PP implantation for medication-refractory ED from April 2003 through August 2018 at 18 high-volume institutions from the United States, Belgium, Germany, and South Korea. All data were retrospectively collected and entered into electronic databases at respective institutions, under approved institutional review board (IRB) or quality improvement projects. Prior to transmission, data were de-identified such that they were considered nonhuman participants research under the United States Department of Health and Human Services' Office for Human Protection and did not require further IRB review or informed consent. Data use agreements were obtained per individual institutions' request. Centers collated and transmitted the datasets via an encrypted, secure, and HIPAA-compliant mail server.

Study variables and outcome measures

Twelve data points per patient were requested: preoperative HbA1c, immediate PBG (within 6 h of surgery), Charlson comorbidity index (CCI), age, race/ethnicity, body mass index, diabetes type, prior diabetes-related complications, surgical approach, reservoir location, drain placement status, and history of prior radical prostatectomy. Postoperative infection, revision, and explantation outcomes were collected at least 6 months after surgery.

Outcome measures

Preoperative diabetes control was assessed via preoperative HbA1c within 6 months of surgery and immediate PBG within 6 h of surgery. The primary outcome measure was correlation between preoperative hba1c and immediate PBG with postoperative infection. The secondary outcome measure was correlation with postoperative revision and explantation.

Statistical analysis

Statistical analysis was conducted in SPSS v25© IBM Corporation. Complete-case analysis was conducted, such that only patients with status "YES" or "NO" to all three outcome measures were included. Furthermore, patients were included in the analysis only if they had complete information regarding PBG and postoperative outcomes. Two-sided Student's t tests were used to compare continuous variables. The Fisher's exact and Pearson's chi-square tests were used to compare categorical variables. Univariate associations between patient characteristics and surgical approach were examined using Pearson correlations. Logistic regression models were generated to assess the impact of preoperative HbA1c and immediate PBG, independent of patient covariates such as prior DM-related complications, age, CCI, surgical approach, and race/ethnicity. A p value <0.05 was considered to be statistically significant, and variables that had significant univariate association were included in the final multivariate models, in addition to previously published risk factors. All analyses were repeated to assess postoperative infection, explantation, and revision.

Results

Overall 875 patients had complete records and were included in this study. Median age was 61 years (range 32–86). Median and mean PBG levels were 137 mg/dl (range 54–344) and 148.5 mg/dl ± 49.6, respectively, and median and mean preoperative HbA1c levels were 7.1% (range 4.8–16.3) and 7.5% ± 1.5, respectively. Most PP were inflatable (99.5%). Devices used were AMS/Boston Scientific (46.7%) and Coloplast (53.3%). Surgical approach used was penoscrotal in 69.9%, subcoronal in 18.2%, and infrapubic in 11.9%. Postoperative infection, revision, and explantation rates were 3.8%, 7.1%, and 4.2%, respectively. There was no association between PBG levels or HbA1c levels and postoperative infection rates; $p = 0.220$ and $p = 0.598$, respectively. Similarly, there were no associations between revision and explantation rates with PBG levels ($p = 0.332$ and $p = 0.806$, respectively), nor with HbA1c levels ($p = 0.104$ and $p = 0.662$, respectively). Complete

Table 1 Univariate analysis for postoperative infection.

	Control		Infection		
	$n = 842$		$n = 33$		
	Mean	SD	Mean	SD	p
Age	60.51	8.90	57.93	9.98	0.121
Body mass index	30.90	5.36	31.46	7.30	0.601
Preoperative HbA1c levels	7.46	1.51	7.62	1.33	0.598
Immediate preoperative glucose	148.99	49.74	135.82	43.15	0.134
Charlson comorbidity index	3.91	1.87	3.73	1.68	0.604
	No.	%	No.	%	p
Race/ethnicity	834		30		0.215
Caucasian	344	41.1%	16	53.3%	
African American	173	20.7%	8	26.7%	
Asian	200	24.0%	2	6.7%	
Hispanic	66	7.9%	3	10.0%	
Other	51	6.2%	1	3.3%	
Diabetes type	835		30		0.062
Type I	185	22.2%	11	36.7%	
Type II	650	77.8%	19	63.3%	
DM-related complications	229	33.4%	17	56.7%	**0.009**
Prior radical prostatectomy	120	14.4%	3	10.0%	0.498
Type of penile prosthesis	816		33		0.687
Inflatable	812	99.5%	33	100.0%	
Malleable	4	0.5%	0	0.0%	
Approach	754		30		**0.043**
Penoscrotal	521	69.1%	27	90.0%	
Infrapubic	91	12.1%	2	6.7%	
Subcoronal	142	18.8%	1	3.3%	
Reservoir location	842		33		0.445
SOR	566	67.2%	21	63.6%	
Submuscular	176	20.9%	4	12.1%	
Suprafascial	48	5.7%	0	0.0%	
Unspecified/Other	52	6.2%	8	24.2%	
Drain placement status	758		30		0.083
No	323	42.6%	8	26.7%	
Yes	435	57.4%	22	73.3%	

Statistically significant $p < 0.05$ values are in bold.

Table 2 Univariate analysis for postoperative explantation.

	Control		Explantation		
	$n = 824$		$n = 36$		
	Mean	SD	Mean	SD	p
Age	60.43	8.92	58.44	9.15	0.191
Body mass index	30.89	5.37	31.33	7.00	0.654
Preoperative HbA1c levels	7.47	1.52	7.60	1.07	0.654
Immediate preoperative glucose	148.89	49.53	150.97	53.82	0.806
Charlson comorbidity index	3.91	1.88	3.69	1.67	0.503
	No.	%	No.	%	p
Race/ethnicity	817		36		**0.016**
Caucasian	331	40.5%	22	61.1%	
African American	167	20.4%	10	27.8%	
Asian	200	24.5%	2	5.6%	
Hispanic	66	8.1%	2	5.6%	
Other	53	6.5%	0	0.0%	
Diabetes type	821		36		0.051
Type I	182	22.2%	13	36.1%	
Type II	639	77.8%	23	63.9%	
DM-related complications	228	27.7%	18	50.0%	**0.020**
Prior radical prostatectomy	113	13.7%	3	8.3%	0.343
Type of penile prosthesis	798		36		0.670
Inflatable	794	99.5%	36	100.0%	
Malleable	4	0.5%	0	0.0%	
Approach	736		36		**0.011**
Penoscrotal	504	68.5%	33	91.7%	
Infrapubic	91	12.4%	2	5.6%	
Subcoronal	141	19.2%	1	2.8%	
Reservoir location	824		36		0.100
SOR	556	67.5%	30	83.3%	
Submuscular	167	20.3%	3	8.3%	
Suprafascial	48	5.8%	0	0.0%	
Unspecified/other	53	6.4%	3	8.3%	
Drain placement status	740		36		**0.043**
No	311	42.0%	9	25.0%	
Yes	429	58.0%	27	75.0%	

Statistically significant $p < 0.05$ values are in bold.

data comparing patient demographics and comorbidities between those who had an infection, explantation, or revision versus those who did not can be seen in Tables 1–3, respectively.

On multivariate analysis, a history of DM-related complications was a significant predictor of higher revision rates ($p = 0.034$), but was nonsignificant for infection or explantation rates. Complete data on multivariate analyses for postoperative infection, explantation, and revision can be seen in Tables 4–6, respectively.

Discussion

Overall, there was a total of 33/875 (3.8%) infections in our cohort of diabetic patients. This percentage is similar to that

Table 3 Univariate analysis for postoperative revision.

	Control		Revision		
	$n = 811$		$n = 62$		
	Mean	SD	Mean	SD	p
Age	60.58	8.85	58.52	9.84	0.084
Body mass index	31.02	5.37	29.73	6.28	0.103
Preoperative HbA1c levels	7.44	1.48	7.87	1.73	0.109
Immediate preoperative glucose	148.13	49.10	154.47	55.47	0.332
Charlson comorbidity index	3.93	1.87	3.58	1.69	0.170
	No.	%	No.	%	p
Race/ethnicity	803		60		**0.044**
Caucasian	324	40.3%	34	56.7%	
African American	169	21.0%	12	20.0%	
Asian	196	24.4%	6	10.0%	
Hispanic	66	8.2%	3	5.0%	
Other	48	6.0%	5	8.3%	
Diabetes type	804		60		**0.041**
Type I	176	21.9%	20	33.3%	
Type II	628	78.1%	40	66.7%	
DM-related complications	213	26.3%	33	53.2%	**<0.001**
Prior radical prostatectomy	117	14.4%	6	9.7%	0.325
Type of penile prosthesis	792		56		0.138
Inflatable	789	99.6%	55	98.2%	
Malleable	3	0.4%	1	1.8%	
Approach	724		59		0.060
Penoscrotal	500	69.1%	47	79.7%	
Infrapubic	85	11.7%	8	13.6%	
Subcoronal	139	19.2%	4	6.8%	
Reservoir location	811		62		0.652
SOR	545	67.2%	42	67.7%	
Submuscular	170	21.0%	10	16.1%	
Suprafascial	43	5.3%	4	6.5%	
Unspecified/other	53	6.5%	6	9.7%	
Drain placement status	728		59		**0.017**
No	314	43.1%	16	27.1%	
Yes	414	56.9%	43	72.9%	

Statistically significant $p < 0.05$ values are in bold.

seen in the large New York statewide database of 14,969 patients who underwent PP implantation [5]. The study showed that 133/4478 (3%) of diabetic patients and 210/10,491 (2%) of nondiabetic patients developed a postoperative infection ($p < 0.001$), thus suggesting that diabetic patients are at an increased for postoperative infection. Our results support this notion however, as with this study, they also show that preoperative glycemic control cannot predict postoperative infection.

Our findings suggest that preoperative HbA1c and PBG levels are not associated with an increased risk for postoperative infection, revision, or explantation in diabetic patients. These results are contrary to what is reported in two well-known studies regarding higher HbA1c levels as a risk factor for postoperative infection. Both of these studies included both diabetic and nondiabetic patients, unlike our study that exclusively looked at diabetics.

The first of these studies was performed by Bishop et al. and is an 18-month prospective study of 90 patients undergoing PP implantation [6]. Of the 90 patients, 32 (36%) were diabetics and their long-term diabetic control was assessed by measuring HbA1c levels; poorly controlled diabetes was defined as a HbA1c level >11.5%. Five infections occurred in total and all were in the diabetic cohort, with four being in the poorly controlled group. In total, infection occurred in 31% of the poorly controlled patients in comparison to 5% of the adequately controlled, $p < 0.0003$. The authors concluded that a HbA1c level >11.5% is associated with an increased risk for postoperative infection.

The second study was performed in 2018 by Habous et al. and is a multicenter prospective study of 902 patients undergoing PP implantation between 2009 and 2015 [7]. Of these 902 patients, 674 (74.8%) were diabetic and their HbA1c levels were assessed to determine preoperative diabetic control, both continuously and sequentially by using 0.5% increasing increments. Multivariate analysis was also performed to control for age, implant type, number of vascular risk factors, Peyronie's disease, body mass index, and surgeon volume. A receiver operating characteristic (ROC) curve was generated to define a HbA1c threshold for infection prediction and was determined to be 8.5%.

Two other well-known studies suggested that preoperative HbA1c levels are not associated with postoperative infection. The first study was performed by Wilson et al. and is a 2-year prospective study of 389 patients, of which 144 were diabetics [8]. In total, 10 diabetics (8.8%) compared with 11 nondiabetics (4.0%) developed an infection ($p = 0.06$). When comparing the mean and median preoperative HbA1c levels between diabetics and nondiabetics, with or without infections, there were no significant differences ($p = 0.635$ and $p = 0.657$, and $p = 0.732$ and $p = 0.427$, respectively). These results suggested that, although infection rates may be higher in diabetic patients, HbA1c levels are not predictive of postoperative infection. This study also found a nonsignificant difference in infection rates in patients with PBG less than or greater than 180 mg/dl ($p = 0.42$).

Table 4 Multivariate analysis for postoperative infection.

	B	S.E.	Wald	df	Sig.	Exp(*B*)	95% C.I. for Exp(*B*)	
							Lower	Upper
Preoperative HbA1c levels (cont.)	0.050	0.161	0.097	1	0.755	1.052	0.766	1.443
Immediate PBG levels (cont.)	−0.006	0.005	1.125	1	0.289	0.994	0.984	1.005
DM-related complications (0 [ref] versus 1)	0.656	0.483	1.847	1	0.174	1.928	0.748	4.969
Age (cont.)	−0.027	0.027	0.981	1	0.322	0.973	0.923	1.027
Charlson comorbidity index (cont.)	−0.105	0.145	0.524	1	0.469	0.900	0.677	1.197
Penoscrotal versus other approaches (0 [ref] versus all)	−0.801	0.768	1.088	1	0.297	0.449	0.100	2.022
Constant	0.422	2.053	0.042	1	0.837	1.525		

Variable(s) entered on step 1: preoperative HbA1c levels, immediate PBG levels, DM-related complications, age, Charlson comorbidity index, penoscrotal versus other approaches.

Table 5 Multivariate analysis for postoperative explantation.

	B	S.E.	Wald	df	Sig.	Exp(*B*)	95% C.I. for Exp(*B*)	
							Lower	Upper
Preoperative HbA1c levels (cont.)	0.079	0.161	0.242	1	0.623	1.083	0.789	1.485
Immediate PBG levels (cont.)	−0.001	0.005	0.087	1	0.768	0.999	0.989	1.008
DM-related complications (0 [ref] versus 1)	0.855	0.466	3.364	1	0.067	2.352	0.943	5.865
Age (cont.)	−0.013	0.027	0.231	1	0.631	0.987	0.937	1.040
Charlson comorbidity index (cont.)	−0.156	0.145	1.154	1	0.283	0.856	0.644	1.137
Penoscrotal versus other approaches (0 [ref] versus all)	−1.732	1.046	2.742	1	0.098	0.177	0.023	1.374
Constant	0.048	2.160	0.000	1	0.982	0.953		

Variable(s) entered on step 1: preoperative HbA1c levels, immediate PBG levels, DM-related complications, age, Charlson comorbidity index, penoscrotal versus other approaches.

Table 6 Multivariate analysis for postoperative revision.

	B	S.E.	Wald	df	Sig.	Exp(*B*)	95% C.I. for Exp(*B*)	
							Lower	Upper
Preoperative HbA1c levels (cont.)	0.164	0.129	1.631	1	0.202	1.179	0.916	1.517
Immediate PBG levels (cont.)	−0.009	0.005	3.375	1	0.066	0.991	0.981	1.001
DM-related complications (0 [ref] versus 1)	0.938	0.441	4.518	1	**0.034**	2.555	1.076	6.066
Age (cont.)	−0.007	0.026	0.079	1	0.778	0.993	0.943	1.045
Charlson comorbidity index (cont.)	−0.381	0.159	5.761	1	**0.016**	0.683	0.500	0.932
Penoscrotal versus other approaches (0 [ref] versus all)	−0.040	0.561	0.005	1	0.943	0.961	0.320	2.885
Constant	−0.803	1.815	0.196	1	0.658	0.448		

Variable(s) entered on step 1: preoperative HbA1c Levels, immediate PBG levels, DM-related complications, age, Charlson comorbidity index, penoscrotal versus other approaches.

Statistically significant $p < 0.05$ values are in bold.

Another study was published in 2018 by Canguven et al. and retrospectively assessed 300 diabetic patients who had undergone PP implantation at a single institution [9]. In total, there were two infections (0.67%). Mean HbA1c in the infection group was 7.0 ± 0.14 and was 7.6 ± 1.9 without infection, Canguven et al. did not provide a p value, however stated that the difference was not significant. It was further reported that infection rate was 0.9% (2/228) amongst patients with HbA1c ≤ 9% compared with 0% (0/72) amongst those with HbA1c > 9% ($p = 0.998$). The

group size of those with an infection ($n = 2$) was small and as such it is difficult to draw conclusions from these results, however they suggest that HbA1c level is not a predictor of postoperative infection.

The findings that a history of DM-related complications is significantly associated with higher revision and explantation rates can be expected. These patients have more comorbidities and as a result are at further risk for postoperative complications. Future studies should continue to collect these variables in order to further expand on this.

The main limitation of our study is its retrospective nature and the inherent bias associated with this. In the future, a prospective randomized controlled study comparing infection rates between uncontrolled diabetics and controlled diabetics should be performed to better answer the question at hand. Nonetheless, our study is unique in that it is the largest ever cohort of exclusively diabetic men undergoing primary PP implantation. Furthermore, it is a multi-institutional study in which all performing sites included high-volume surgeons with expertise. Finally, as with the other studies mentioned, we used HbA1c as surrogates for diabetes control, but also added the use of PBG. Our results indicate that both HbA1c and PBG levels are poor predictors of postoperative PP infection rates. Perhaps other diagnostics to test insulin resistance/sensitivity, such as the lipoprotein insulin resistance index, could potentially have better predictive value and should also be investigated in the future [14, 15].

Conclusions

In this largest ever multi-institutional cohort of diabetic men undergoing PP implantation to date, neither PBG nor HbA1c was predictive of device infection, revision, or explantation. On multivariate analysis, a history of DM-related complications was a significant predictor of higher revision rates. In the future, studies should look at different predictors of postoperative complications in diabetic men undergoing PP implantation.

Compliance with ethical standards

Conflict of interest FAY reports associations with Endo Pharmaceuticals as consultant and speaker; Antares Pharma as consultant and speaker; Coloplast as speaker and advisory board; and Viome as clinical trial primary investigator. All other authors declare that they have no conflict of interest.

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