

Penile prosthesis infection and diabetes mellitus: a systematic review and meta-analysis

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Abstract

Background: The preoperative glycemic control of diabetic patients may increase the risk of penile prosthesis (PP) infection, but the published literature remains controversial.

Aim: To systematically review and meta-analyze available evidence on the impact of diabetes mellitus (DM) and glycemic control on PP infection. The study was completed under the auspices of the European Society for Sexual Medicine Surgical Academy.

Methods: An comprehensive Medline, Embase, and Cochrane search was performed including the keywords: ("penile prosthesis" and "diabetes mellitus"). Only English-language articles published between January 1, 1969 and May 31, 2024 were included.

Outcomes: The primary outcome measure was the risk of PP infection in diabetic patients. The secondary outcome measure was the contribution of glycemic control on PP infection rate.

Results: Out of 182 retrieved articles, 11 were included in the study, summarizing 10 024 subjects with a mean age of 59.7 years, and a mean follow-up of 37.2 months. Overall, a PP infection rate of 4.3[3.9-4.8]% was observed. The PP infection rate increased according to baseline HbA1c levels, and the latter result was confirmed following adjustment for age and trial duration ($P < .0001$). Accordingly, PP infection rate was more than 2-times higher when trials with a mean HbA1c $\geq 8\%$ were compared to the rest of the sample (9.1[7.5;11.0] vs 3.8[3.2;4.5]%; $Q = 43.18$; $P < .0001$).

Clinical implications: Optimization of the preoperative glycemic control may reduce PP infection rate in diabetic patients.

Strengths and limitations: The present study provides evidence supporting a significant increased risk of PP infection for patients with DM and pre-operative HbA1c $\geq 8\%$. Analysis was primarily derived from retrospective studies, which represent a significant source of bias. The exclusion of those studies including less than 70% of diabetic patients can represent a further source of bias.

Conclusion: The present study shows a significant association between pre-operative HbA1c and PP infection rate. Further studies are advisable in order to better clarify the best threshold of HbA1c that is acceptable prior to implant surgery in diabetic patients.

Keywords: diabetes mellitus; infection; penile implants; penile prosthesis; erectile dysfunction.

Introduction

Type 2 diabetes mellitus (T2DM) is one of the largest global epidemics^{1,2} and represents a major risk factor for future cardiovascular disease (CVD) over time.³ Hence, the association between diabetes mellitus (DM) and erectile dysfunction (ED) is unsurprising,^{4,5} with a recent meta-analysis reporting a

5-fold increased risk for ED.⁶ Besides common vascular and neurological damage, hormonal factors can also contribute to the pathogenesis of ED in men with DM.^{4,5,7} Similarly, low testosterone (T) is frequently observed in subjects with T2DM.^{8–10} Therapeutic options for ED are more limited

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as diabetics tend to respond more poorly to phosphodiesterase type 5 inhibitor (PDE5i) administration, in part due to the high incidence of cardiovascular (CV) comorbidities and chronic complications.^{11,12}

Hence, penile prosthesis (PP) implantation is an important therapeutic option for DM patients, especially those who fail medical therapy such as PDE5i and intracavernosal injectable drugs.^{4,5,13} In general, PP have a high satisfaction rate (between 92% and 100%) and few long-term complications.¹⁴ Nevertheless, one of the most catastrophic complications following PP implantation is device infection necessitating surgical removal.¹³ The overall risk of PP infection is low following the advent of infection-retardant coatings on PP in January 2001,¹⁵ but the risk is around 1.5 times higher in patients with DM.¹⁶

Despite the increased risk in diabetics, it is not clearly understood how long-term glycemic control affects the relative risk for PP infection. Habous et al.¹⁷ reported that poor preoperative glycemic control (HbA1c $\geq$ 8.5%) was associated with a higher risk of PP infection, but this was not confirmed in a more recent retrospective study of 932 diabetics undergoing primary PP implantation.¹⁸

To further the understanding of this important topic, the present study systematically reviews and meta-analyzes all available studies reporting the determinants of PP infection in DM patients within the auspices of the European Society of Sexual Medicine Surgical Academy (<https://www.essm.org/education/essm-academy/essm-surgical-academy/>).

Methods

This meta-analysis was performed in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses reporting guidelines and Meta-analysis of Observational Studies in Epidemiology guidelines (Supplementary Files S1 and S2). The following PECO criteria define study eligibility¹⁹: *population*: male population $\geq$ 18 years; *exposure*: patients with ED and DM undergoing PP implantation; *comparison*: prospective or retrospective analysis from baseline; *outcomes*: PP infection rate.

The protocol of this study (CRD42024557982) was registered in the PROSPERO International prospective register of systematic reviews (<https://www.crd.york.ac.uk/prospero/#recordDetails> CRD42024557982).

Search strategy

The Medline, Embase, and Cochrane databases were search using the following key words: ((“penile prosthesis”[MeSH Terms] OR (“penile”[All Fields] AND “prosthesis”[All Fields]) OR “penile prosthesis”[All Fields]) AND (“diabetes mellitus”[MeSH Terms] OR (“diabetes”[All Fields] AND “mellitus”[All Fields]) OR “diabetes mellitus”[All Fields])). Studies in humans between January 1, 1969 and May 31, 2024, were included if published in English only. Studies independently screened by 4 of the authors (G.C., P.C., W.G.L., S.W.), and conflicts were resolved by a consensus discussion among all authors. We did not employ search software but hand-searched the bibliographies of retrieved papers for additional references. The primary source of data was derived from published articles.

Study selection

All prospective and retrospective observational trials reporting data on PP infection rates for patients with DM were included. When possible, data derived from revision cases were excluded from analysis. Further, case reports and studies not reporting infection rate in DM and/or HbA1c values were also excluded from analysis (see Figure 1 and Table 1). As post hoc selection, studies reporting a prevalence of DM less than 70% were excluded from the analysis (see Figure 1 and Table S1). The latter cut-off was selected since the only study validating a HbA1c threshold for PP infection rate had a cohort of 74.5% diabetic patients.¹⁷ In addition, data derived following implantation in a neophallus or in men who have sex with men (MSM) couples were excluded from the analysis. Data on MSM couples were not considered due to the limited number of studies and to avoid possible bias in the data synthesis.

Outcome and quality assessment

The primary outcome measure was the assessment of PP infection rate in patients with DM. The secondary outcomes included the impact of glycemic control (as assessed by HbA1c as either a continuous or dichotomous variable) on PP infection rate. The quality of the trials and risk of bias were determined using the ROBINS-E tool for observational studies (Table S2).²⁰

Statistical analysis

Heterogeneity was assessed using I^2 statistics. A random-effect model was applied even when low heterogeneity was detected because the validity of heterogeneity tests can be limited with a small number of included studies. We used funnel plots and the Begg-adjusted rank correlation test to estimate possible publication or disclosure bias.²¹ However, undetected biases may still be present because these tests have low statistical power when the number of included studies is small. The Duval and Tweedie’s “trim and fill” methods were also applied when indicated to reduce the impact of undetected bias. Unadjusted meta-regression analyses were performed to evaluate the contribution of preoperative HbA1c levels reported as a continuous variable or the impact of different devices on infection rate derived by the random-effects model. Several sensitivity analyses or regression linear adjusted models were performed where appropriate. Importantly, given the introduction of infection retardant-coated PP in January 2001,¹⁵ a sensitivity analysis was performed by excluding trials published preceding this. In addition, multivariable linear regression analyses were performed where each study was weighted according to the number of subjects enrolled. The derived infection rate was specified as the dependent variable, while HbA1c level and the number of inflatable PP were considered as potential covariates. All models were adjusted for age and/or trial duration to account for possible confounding effects.

All data were collected and summarized using Comprehensive Meta-analysis Version 2, Biostat (Englewood, NJ, USA). Multivariable linear regression models were performed on SPSS (Statistical Package for the Social Sciences; Chicago, USA) for Windows 25.1.

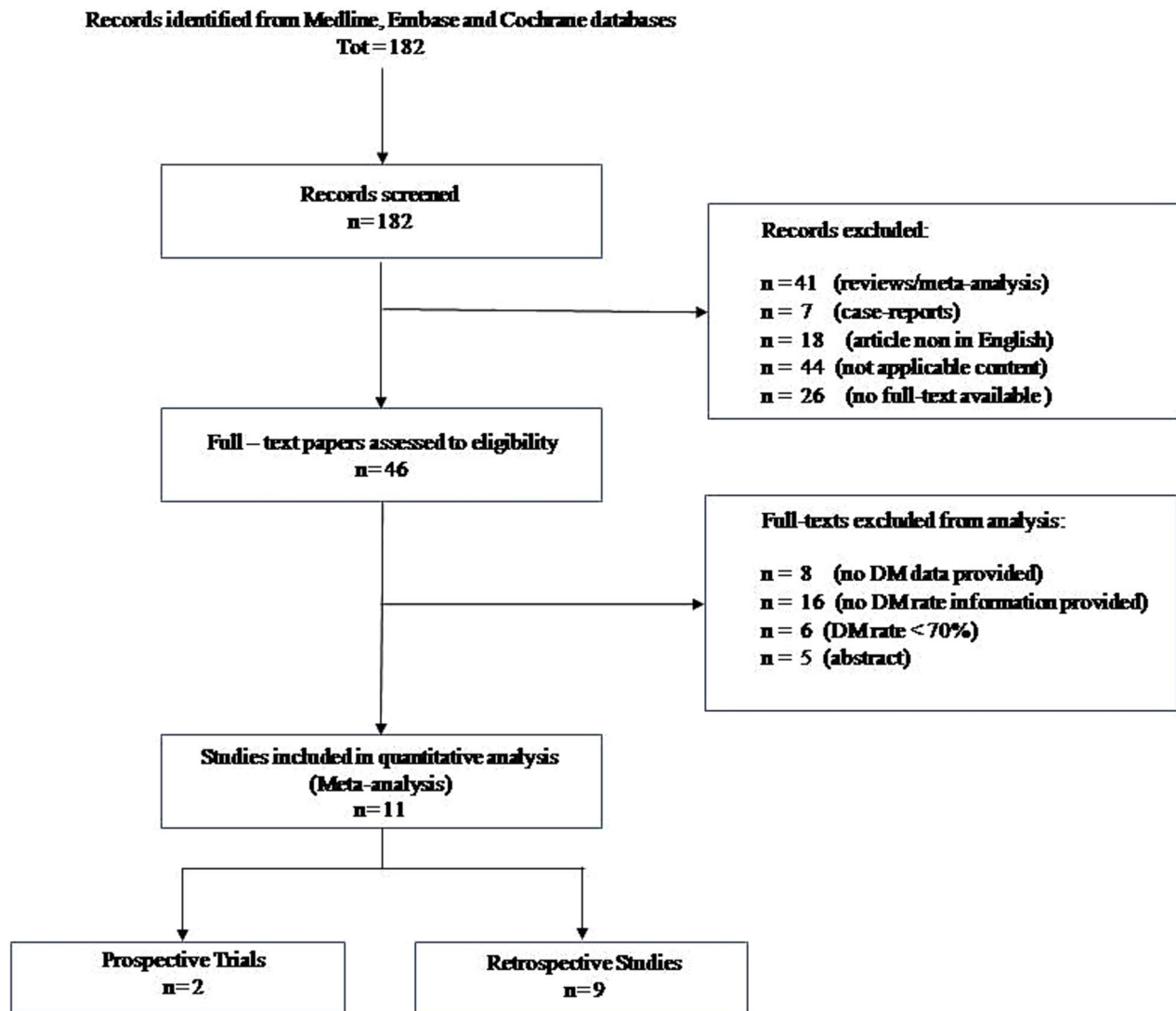


Figure 1. Flow chart of the included studies.

Table 1. Characteristics of studies included in the meta-analysis.

Author	Study design	Patients N	Duration (months)	Age (years)	Prosthesis type	% Inflatable penile prosthesis	% Revision	DM (%)	HbA1c (%)
Bishop et al., 1992 ⁽²²⁾	Prospective	32	18.0	NR	NR	NR	NR	100	13.20
Wilson et al., 1998 ^a ⁽²³⁾	Prospective	114	24.0	NR	Inflatable	100	18.4	100	8.74
Mohamed et al, 2016 ⁽²⁴⁾	Retrospective	53	42.0	42.5	Malleable	0	0	100	NR
Canguen et al., 2018 ⁽²⁵⁾	Retrospective	300	58.0	55.3	Mixed	83.7	NR	81.0	7.60
Habous et al., 2018 ⁽¹⁷⁾	Prospective	902	28.3	56.6	Mixed	24	2.1	74.8	8.00
Lipsky et al., 2019 ⁽²⁶⁾	Retrospective	4478	95.1	60.0	Inflatable	NR	0	100	NR
Scarberry et al., 2020 ⁽²⁷⁾	Retrospective	101	32	63.0	Inflatable	100	18.8	100	7.30
Chen et al., 2021 ^b ⁽²⁸⁾	Retrospective	2363	27.0	65.2	Inflatable	100	9.4	70.3	6.90
Habous et al., 2021 ^{(29)c}	Retrospective	218	36	57.7	Mixed	39	0	100	7.94
Osman et al., 2021 ⁽¹⁸⁾	Retrospective	875	NR	60.4	Mixed	99.5	0	100	7.47
Talib et al., 2021 ⁽³⁰⁾	Retrospective	599	12	59.7	Mixed	83.1	NR	100	7.58

^a Only DM subjects were considered. ^b Data related to inflatable devices were considered. ^c Infection rate provided for 207 subjects. Quantitative variables are expressed as mean. Lipsky MJ, Onyeji I, Golan R, et al. Diabetes Is a Risk factor for inflatable penile prosthesis infection: analysis of a large statewide database. *Sex Med.* 2019;7(1):35-40. <https://doi.org/10.1016/j.esxm.2018.11.007>. DM, diabetes mellitus; NR, not reported; HbA1c, glycosylated hemoglobin.

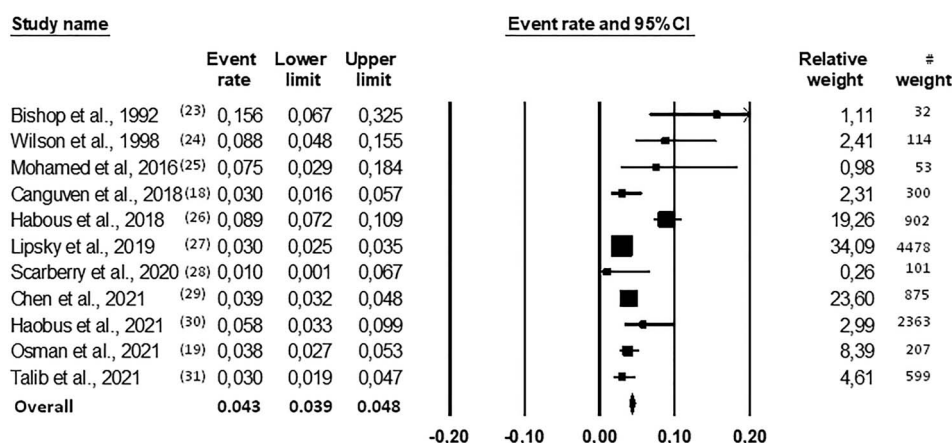


Figure 2. Weighted mean (with 95% CI) penile prosthesis infection rate (final numbers should be considered as 100×). # = number of patients included in each studies.

Results

Descriptive statistics

Of 182 screened articles, 11 were included in the study (Table 1 and Figure 1).^{17,18,22–30} Overall, 10 024 subjects were included with a mean age of 59.7 years, mean follow-up of 37.2 months, and mean HbA1c of 8.3%. Three prospective studies pooling 1048 patients were included while 8976 patients were pooled from retrospective studies (Table 1). Importantly, 8 studies enrolled only DM patients while 3 included a mixed cohort with a mean DM prevalence of 75.4%. Furthermore, 3 studies reported a mean HbA1c $\geq 8\%$ at baseline, whereas HbA1c levels were lower in the other included studies. Only limited data on the type of PP were reported (Table 1).

Patient outcomes

The I^2 in trials assessing DM-related PP infection rate was 88.37 ($P < .0001$). A funnel plot and Begg adjusted rank correlation test (Kendall's τ : 0.15; $P = .53$) suggested no publication bias.

The overall PP infection rate was 4.3[3.9–4.8]% (Figure 2). Similar results were observed when outliers^{17,23} were excluded to reduce heterogeneity ($I^2 = 67.1$; $P < .005$; infection rate 4.0[3.1;5.1]%). Duval and Tweedie's "trim and fill" revealed a non-significant difference in PP infection rate for all studies (rate = 4.5[3.2;6.2]%) or when outliers^{17,23} were excluded (rate = 3.6[2.7;4.8]%). No difference was observed when studies including both patients with and without DM^{17,25,28} were excluded from analysis (4.8[3.3;7.0]%; vs 4.9[2.5;9.4]%; $Q = 0.003$, $P = .95$ for trials with diabetic patients only^{18,22–24,26,27,29,30} vs trials with a mixed cohort^{17,25,28}; Table 1). In addition, the infection rate was higher in prospective^{17,22,23} studies compared to retrospective^{18,24–30} studies (9.1[7.5;11.0]%; vs 3.6[3.0;4.3]%; $Q = 45.03$; $P < .0001$; patient number = 1048 vs 8976; see also Table 1).

Impact of glycemic control

Meta-regression analysis showed that the PP infection rates increased according to the HbA1c levels used as

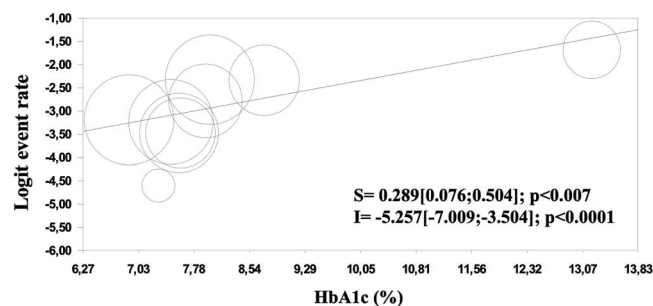


Figure 3. Impact of glycosylated haemoglobin (HbA1c = %) circulating levels on overall penile prosthesis infection. I = intercept; S = slope the dimension of the circles reflects the number of patients included in each study.

continuous variables (Figure 3). Similar results were confirmed when outliers were excluded from the analysis (Slope = 0.224[0.075;0.377] and Intercept = $-4.855[-5.977; -3.733]$; both $P < .0001$). The latter results were confirmed in the following multivariable linear regression analyses, adjusting for age and trial duration ($\beta = 2.671$ and 1.862; both $P < .0001$ for the overall population and when outliers were excluded, respectively). In addition, results were confirmed when the 2 studies published before 2001 (ie, the introduction of retardant-coated PP) were excluded from the analysis (Slope = 0.688[0.417;0.959] and Intercept = $-8.073[-10.096; -6.049]$; both $P < .0001$). Consistent with the above findings, mean HbA1c levels were significantly higher in subjects experiencing PP infection compared to the rest of the sample (Figure 4).

Accordingly, when HbA1c was used as a dichotomous variable, comparing those studies with a mean HbA1c level $\geq 8\%$ ^{17,22,23} to the rest of the sample (see also Table 1), reported PP infection rates more than doubled the rates of studies with a mean HbA1c $< 8\%$ (9.1[7.5;11.0] vs 3.8[3.2;4.5]%; $Q = 43.18$; $P < .0001$; patient number = 1048 vs 4445). Of the 3 studies with mean HbA1c levels $\geq 8\%$, the infection risk was similar between the 2 studies published before 2001 (prior to the introduction of infection retardant

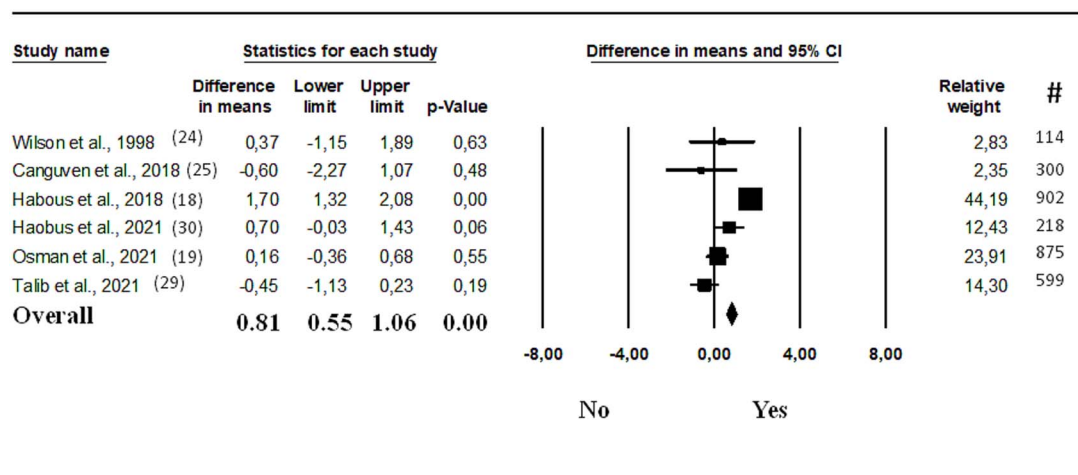


Figure 4. Weighted mean differences (with 95% CI) of pre-operative glycosylated haemoglobin (HbA1c = %) in patients with (yes) or without (no) postoperative penile prosthesis infection. # = number of patients included in each studies.

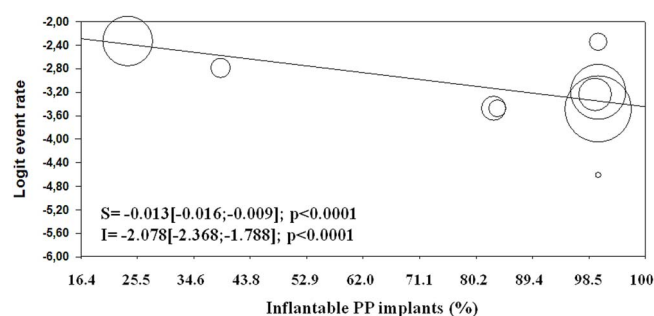


Figure 5. Impact of inflatable penile prosthesis (PP) implants on overall PP infection. I = intercept; S = slope the dimension of the circles reflects the number of patients included in each study.

coatings^{22,23} and the sole study¹⁷ published in 2018 (8.9[7.2;10.9] vs 10.8[6.2;18.3]%; $Q = 0.427$; $P = .513$; patient number = 146 vs 902).

Meta-regression analysis showed that the PP infection rate was lower in those studies including a higher proportion of inflatable PP implants (Figure 5). This association was confirmed in multivariable analysis after adjusting for age, trial duration, and HbA1c ($\beta = -0.924$; $P < .0001$) or when studies before 2001 or outliers were excluded from the analysis (data not shown). Finally, despite a paucity of data, a lower infection rate was observed in studies of only primary (virgin) cases^{18,24,26,29} compared to studies combined with revision cases^{17,23,27,28} (3.9[3.1;4.9] vs 7.4[4.1;12.9]; $Q = 4.01$; $P < .05$).

Discussion

This is the first meta-analysis specifically evaluating the contribution of preoperative glycemic control on PP infection rate in diabetic patients. We report for the first time a direct correlation between glycemic control and PP infection rate. Our analysis showed that PP infection rate was more than 2 times higher when HbA1c was higher than 8%.

The association between glycemic control and PP infection rates has been subject to conflicting reports. Nevertheless, PP infection represents a devastating complication,

leading in most cases to explantation and loss of patient satisfaction.¹⁴ Advances in design and surgical technique over the last 50 years have significantly reduced PP infection rates.^{4,5} In particular, the advent of an infection retardant coating for PP in early 2001 reduced overall PP infection rates to between 0.3% and 2% in uncomplicated primary cases.¹⁶

Several pre-, intra-, and post-operative factors are thought to play a significant role in reducing PP infection rates but often with poor supporting evidence.³¹ Surgeon experience is an important factor for PP infections with lower rates reported at high volume centers, but the definition of a high volume center has not been universally agreed.³² It is known that the surgical approach does not influence PP infection rates.^{31,32} Similarly, no clear evidence supports the prolonged (> 24 hours) use of postoperative antibiotics, shaving with clippers (rather than razors), or prepping skin with chlorhexidine-alcohol, but these practices remain broadly accepted by implanters.^{31,32} Hence, considering the available data, robust preoperative patient selection remains a crucial step. The assessment of the correlation between glycemic control and infection risk should be considered in this context.

A large body of evidence has already documented an increased risk of recurrent nosocomial and secondary infection in patients with DM encompassing other fields of surgery.³³ Several conditions related to the presence of DM, such as obesity, can increase the risk for infection. Chronic hyperglycemia and insulin resistance can induce the formation of advanced glycation end products, activation of protein kinase C and increased flux through the polyol and hexosamine pathway. This leads to increased superoxide production, chronic inflammation, and immune system dysfunction including disorders of humoral immunity, defects in neutrophil function, and lymphocyte T cell response.³³ In addition, obesity can increase the risk of surgical site infection due to excessive under-perfused adipose tissue, increased retraction-related local tissue trauma, and decreased oxygenation of subcutaneous tissue.³³ Accordingly, a previous meta-analysis, including 16 studies and 27 844 surgical procedures, clearly documented that DM increases the risk of surgical site infection irrespective of the surgical approach.

The latter study also showed that both pre- and post-operative hyperglycemia may modulate the risk.³⁴

In line with the above data, an increased risk of PP infection was seen when diabetic patients were compared to non-diabetic patients.¹⁶ Bishop et al.,²² reported, for the first time, the association between an increased risk of PP infection and elevated HbA1c in diabetic patients. They proposed that an HbA1c level > 11.5% represented a possible threshold for identifying patients at increased risk of infection.²² These results were not confirmed by Wilson et al.,²³ in a larger number of patients performed some years later. The discordant findings may be the result of differences in sample size and level of surgeon experience. Further contradictory data from a more recent study at a high-volume center including 902 implants reported that HbA1c levels were the best predictors of PP infection compared to other CV risk factors like body mass index and age.¹⁷ By applying ROC curve analysis, the authors proposed that an HbA1c level of 8.5% predicted infection with the best sensitivity and specificity.¹⁷ In contrast to this study, Osman et al.,¹⁸ retrospectively reviewed data in a large series of implants performed in diabetic patients by 18 high-volume implanters but did not find any difference in preoperative HbA1c levels between individuals with or without postoperative infection. Differences in the definition of high-volume surgeons (> 80¹⁸ vs > 5¹⁷ implants per year) may explain the conflicting findings from the 2 studies. However, it is important to emphasize that Habous et al.¹⁷ included subjects with poorer glycemic control compared to those included by Osman et al.¹⁸ By collecting available studies, Menshchikov et al.³⁵ showed that patients suffering from PP infection had significantly higher HbA1c levels compared to non-infected individuals. However, the latter study was significantly limited by the inclusion of patients with and without DM^{23,36} and duplicated patient series.^{17,37}

Our results obtained in a cohort of diabetics, showed for the first time a direct relationship between glycemic control and an increased risk of PP infection following adjustment for confounding factors. We also reported that the PP infection rates were significantly higher for men with baseline HbA1c $\geq$ 8%, irrespective of infection retardant-coated PP. This reinforces a possible role for preoperative glycemic control in preventing PP infection. Interestingly, the HbA1c threshold of 8% is similar to that previously proposed by Habous et al.,¹⁷ and also consistent with the HbA1c levels (7.85%) thought to confer an increased risk of wound infection in the first 30 days after major surgery in diabetic patients.³⁸

Further, meta-regression analysis showed that the infection rate decreased as a function of the number of inflatable PP considered. No difference was shown in infection rates when inflatable implants were compared to malleable PP.³⁹ The difference among studies in terms of baseline characteristics of the included patients may partially explain the results observed. Dedicated comparison studies are required to fully elucidate the true difference in infection rates.

These findings should prompt physicians to carefully consider preoperative HbA1c level in all diabetic patients and optimize glycemic control when planning PP implantation. Looking to the future, data derived from the PHOENIX trial, a prospective multicenter survey of PP surgery conducted by the European Association of Urology-Research Foundation (EAU-RF) may provide further clarity on the correlation.⁴⁰

Several limitations should be recognized. Most studies were retrospective with a higher likelihood of bias due to possible

confounding factors and potential data loss. In addition, a larger number of included patients may dilute the reported risk of infection. Accordingly, our data showed that prospective studies were characterized by higher infection rates compared to retrospective cohorts. Caution is needed when interpreting the limited data suggesting that infection retardant-coated PP did not alter PP infection rates in diabetics. Reassuringly, sensitivity analysis (by excluding the 2 studies from before 2001) showed consistent findings. Similarly, the limited number of included studies reporting revision cases suggests a higher risk of infection irrespective of their glycemic control, possibly due to the presence of a biofilm.⁴¹ Again, caution is required when interpreting this finding. Furthermore, the present findings should not be generalized to MSM patients with DM.

The exclusion of those studies including less than 70% of diabetic patients can represent a further source of bias. In addition, the present results could have been influenced by 1 author.¹⁷ Finally, many questions remain unanswered including the timing of HbA1c measurement in relation to the surgical date, the timing of presentation following infection and whether infection was confirmed by culture, the type of concomitant diabetic medications, and data on surgical technique, type of device, and other patient comorbidities. Similarly, more studies are needed to elucidate changes in infectious organisms over time (eg, *methicillin-resistant Staphylococcus aureus*) or the relevance of diabetic control over time. Systematic reviews and meta-analyses are a useful tool to summarize and address questions where multiple data sources are conflicting, or have low statistical power by pooling data. However, combining flawed data cannot remove biases. Nevertheless, the present systematic review has been useful to highlight the discrepancies in the literature and possible avenues for further research on a poorly considered, if not neglected, question.

In conclusion, the present study demonstrates a significant relationship between preoperative HbA1c and PP infection rate. However, it should be interpreted with caution given primarily retrospective data and likely undefined bias in the literature. Hence, well-conducted prospective studies are required to confirm this finding and further guide practice as also recognized by society guidelines.^{5,13,42} Indeed, the lack of strong data in the PP literature does not invalidate robust data in other fields of surgery showing a correlation,³⁸ so the PP community must urgently address the paucity of data in this field.

Author contributions

G.C.: Conceptualization-Lead, Data curation-Lead, Formal analysis-Lead, Methodology-Equal, Project administration-Lead, Supervision-Equal, Validation-Equal, Visualization-Equal, Writing+original draft-Lead, Writing+review & editing-Equal. P.C.: Data curation-Equal, Formal analysis-Supporting, Methodology-Equal, Software-Lead, Validation-Equal, Visualization-Equal, Writing+original draft-Supporting, Writing+review & editing-Equal. W.G.(D.)L.: Data curation-Supporting, Methodology-Supporting, Validation-Equal, Writing+original draft-Supporting, Writing+review & editing-Supporting. D.O.: Validation-Equal, Writing+original draft-Supporting, Writing+review & editing-Equal. K.V.R.: Supervision-Supporting, Validation-Equal, Visualization-Supporting, Writing+original draft-Supporting, Writing+review & editing-Supporting. J.R.-O.: Validation-Equal, Writing+original draft-Supporting, Writing+review & editing-Supporting. S.W.: Software-Equal, Validation-Equal, Writing+review & editing-Supporting. A.S.:

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Supplementary material

Supplementary material is available at *The Journal of Sexual Medicine* online.

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Conflicts of interest

None declared.

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