

ERECTILE DYSFUNCTION

Comparing Risk Factors for Adverse Outcomes in Virgin Inflatable Penile Prosthesis Implantations and Revisions: A Retrospective Cohort Study



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ABSTRACT

Introduction: Recent studies place the risk of infection following inflatable penile prosthesis (IPP) implantation at 1–2%. This risk may be underestimated due to the exclusion of high-risk patients, such as patients undergoing multiple revisions or revision following IPP infection, from data.

Aim: To calculate the rate of postoperative complications for all patients undergoing IPP implantation and revision, and to determine the risk factors predictive of complications following virgin implantation and revision independently.

Methods: The charts of 280 patients undergoing 331 IPP implantations performed over the last 20 years at a large academic medical center were reviewed for postoperative complications and suspected preoperative and operative risk factors.

Main Outcome Measure: This included the prevalence of adverse operative outcomes including postoperative infection and device malfunction.

Results: 63 (20.7%) surgeries resulted in postoperative complications: 38 (12.5%) resulting in device malfunction and 25 (8.20%) resulting in infection. Smoking (odds ratio [OR] = 4.14, $P = .00$) was associated with overall postoperative complications. Within subgroups, concomitant procedures (OR = 4.77, $P = .03$) were associated with infection for those undergoing virgin implantation, but not those undergoing revision procedures. Alternatively, diabetes mellitus (DM) (OR = 28.3, $P = .02$) was associated with postoperative infection for those undergoing revision procedures, but not those undergoing virgin implantation.

Conclusion: The rate of postoperative infection for all patients undergoing IPP was found to be 8.20%, a higher estimate than historically recorded. To varying degrees, smoking, concomitant procedures, and DM were associated with adverse operative outcomes. Subset analyses revealed significant associations between postoperative infections and either concomitant procedures or DM in those undergoing virgin implantations or revision surgeries, respectively. **Miller JA, Bennett NE. Comparing Risk Factors for Adverse Outcomes in Virgin Inflatable Penile Prosthesis Implantations and Revisions: A Retrospective Cohort Study. J Sex Med 2020;8:388–395.**

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Key Words: Prosthesis; Surgical Therapy; Infection; Erectile Dysfunction

INTRODUCTION

Inflatable penile prosthesis (IPP) placement remains a common therapy for erectile dysfunction (ED) when medical therapies are unsuccessful. While IPP placement is typically reserved for

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refractory cases of ED, patients treated with IPP report higher rates of satisfaction than patients treated with other remedies.^{1,2} Despite this, adverse outcomes of IPP continue to present a burdensome problem. Postoperative complications for IPP, namely infection and device malfunction, result in harm to the patient, patient dissatisfaction, and costly interventions.³ Of these complications, postoperative infection has gained the most attention.

While historically, the infection rate following virgin IPP placements was reported at 10%,^{4,5} recent studies place this estimate closer to 0.5–3%.^{6–12} Much of the success in lowering the rate of postoperative infection is likely due to a combination

of the use of antibiotic-coated prostheses,^{7–13} “no touch” surgical technique,¹⁰ the Mulcahy salvage protocol,^{14–16} and alcohol-based skin prep regimens.^{17,18} In addition, this reduction is likely due in part to the identification of at-risk demographics.

Studies examining these demographics have identified those with diabetes mellitus (DM) and undergoing IPP revision to be at a higher risk of infection.^{4,5,7,8,12} These risk factors remain somewhat controversial as multiple studies disagree regarding the true effect of each risk factor. Regarding the most examined potential risk factor, some studies showed the risk of postoperative infection for those with DM to range up to 18%.⁴ However, more recent studies have not found a statistically significant relationship between DM and adverse surgical outcomes.^{5,12,19} Concerning patients undergoing IPP revisions, studies have shown that the rate of infection in this group is 2–3 times greater,^{5,8} and up to 10 times greater,¹² than that following virgin implantations.

Despite the improvement in infection rates and identification of those at risk, knowledge gaps remain in the current research pool. Postoperative infection rates may be underestimated due to the exclusion of high-risk groups from large studies. Many studies exclude patients undergoing revision surgeries.^{3,6,7,9,20} Even within those studies including this group, many do not discuss patients undergoing revisions following IPP infections,^{5,10,11,14} and patients requiring multiple revisions over time.^{5,8} Furthermore, studies have not fully explored whether risk factors are equally predictive for virgin implantations and revisions. In this study, we aim to determine the rates of postoperative complications following IPP implantation and revision for all patients, including patients for whom revisions are performed following infection and patients who have undergone multiple IPP revisions. In addition, we aim to determine the factors associated with postoperative complications for virgin implantations and revisions independently.

MATERIALS AND METHODS

An institutional electronic data repository, programmed to identify all patients undergoing IPP procedures, identified the charts of 280 patients undergoing 331 procedures performed at an academic medical center involved in resident teaching between January 2000 and May 2018; these charts were obtained and reviewed retrospectively. Of the 280 patients and 331 surgical encounters examined, 23 patients and 26 surgical encounters were excluded from this study due to lack of either sufficient procedure documentation or follow-up. Of the 305 remaining surgical encounters, 208 involved virgin implantations and 97 involved revision surgeries due to IPP infection, device malfunction, or patient dissatisfaction. For the patients included, the age at implantation ranged between 28 and 91 years, with an average age at implantation of 61 years, and the average follow-up time was 29 months. The demographic characteristics available for the patients included are summarized in [Table 1](#).

Implantations were performed on an outpatient basis by 14 attending surgeons following a standard surgical protocol. Implant models were recorded for all but 30 cases. The implant models used were as follows: AMS 700CX ($n = 217$), Coloplast Titan ($n = 38$), AMS Ambicor ($n = 15$), and AMS Spectra ($n = 5$). All aforementioned implants used either antibiotic coatings or hydrophilic coatings with antibiotic dips. Preoperative skin preparations were recorded for all but 22 cases. The skin preparations recorded were as follows: Betadine scrub and Chloraprep ($n = 85$), Betadine scrub and DuraPrep ($n = 56$), Chloraprep alone ($n = 43$), Betadine alone ($n = 35$), and other skin preparations used in fewer than 5 individual cases. Of these skin preparations, 242 involved the use of at least 1 alcohol-based solution. In 43 cases, patients underwent concomitant procedures ([Table 2](#)). For those undergoing revision surgeries, washout, following the 7-step Mulcahy irrigation and washout protocol¹⁷ or the modified Mulcahy washout protocol,^{14,16} was performed in all but 5 cases.

Patient charts were reviewed for postoperative complications. For those with IPPs implanted at other health care facilities prior to revision at the observed institution, previous health records were obtained and reviewed. Each patient's chart was examined for demographics, DM, hypertension, obesity, coronary artery disease, smoking, Peyronie's disease, prostate cancer, prior IPP procedures, attending surgeon, implant type, skin prep regimen, procedure duration, and concomitant procedures. Statistical analysis was performed using multiple logistic regression to determine associations between adverse postoperative outcomes and the variables mentioned earlier. Collinearity between these variables was ruled out using the variance inflation factor (VIF), with a $VIF > 5$ suggesting significant interaction between variables; variables with $VIF > 5$ were removed from the tests in which collinearity was demonstrated. Subset analyses were performed to reveal associations between the aforementioned variables and postoperative complications following virgin implantations and revision surgeries separately. Patients with missing data regarding the presence or absence of these variables were excluded from those respective analyses.

For all statistical analyses, $P < .05$ was considered statistically significant. Multiple logistic regressions involving all cases were found to have a power of 1.00 and 0.99 for large ($f^2 = 0.35$) and medium ($f^2 = 0.15$) effect sizes, respectively. For patients undergoing virgin implantation, regressions were found to have a power of 1.00 and 0.98 for large and medium effect sizes, respectively. For patients undergoing revision surgeries, regressions were found to have a power of 0.98 for large effect sizes; in this subset, analyses were underpowered in relation to medium effect sizes due to sample size.

RESULTS

The duration of each procedure ranged between 1 and 5 hours, with an average duration of 2.16 hours, and in cases

Table 1. Demographic characteristics of the study samples

Characteristic	Percentage of all cases, % (n = 305)	Percentage of virgin implantations, % (n = 208)	Percentage of revisions, % (n = 97)	P value
Age (in years)				.09
20–29	0.33 (1)	0.00 (0)	1.03 (1)	
30–39	4.59 (14)	3.85 (8)	6.19 (6)	
40–49	9.84 (30)	6.73 (14)	16.5 (16)	
50–59	26.6 (81)	29.3 (61)	20.6 (20)	
60–69	37.0 (113)	40.4 (84)	29.9 (29)	
70–79	18.7 (57)	17.3 (36)	21.6 (21)	
80–89	2.62 (8)	2.40 (5)	3.09 (3)	
90–99	0.33 (1)	0.00 (0)	1.03 (1)	
Race/ethnicity				.24
White or Caucasian	58.0 (177)	56.3 (117)	61.9 (60)	
Black or African American	25.6 (78)	25.0 (52)	26.8 (26)	
Hispanic or Latino	1.31 (4)	0.96 (2)	2.06 (2)	
Other or unreported	15.1 (46)	17.8 (37)	9.28 (9)	
Comorbidities				
Diabetes mellitus	34.8 (106)	31.2 (65)	42.3 (41)	.06
Hypertension	43.0 (131)	42.3 (88)	44.3 (43)	.77
Obesity	29.5 (90)	30.3 (63)	27.8 (27)	.64
CAD	19.3 (59)	17.3 (36)	23.7 (23)	.19
Peyronie's disease	16.1 (49)	15.9 (33)	16.5 (16)	.89
Prostate cancer	39.3 (120)	47.1 (98)	22.7 (22)	.00*
Smoking	9.51 (29)	8.17 (17)	12.4 (12)	.25
Concomitant procedures	14.1 (43)	14.4 (30)	13.4 (13)	.81

P values compare the demographic characteristics of those in the virgin implantation group and the revision group.

CAD = coronary artery disease.

*P value ≤ .05.

involving revisions or concomitant procedures taking on average 25–30 minutes longer, respectively ($P = .00$). Complications were noted in 63 of the 305 surgeries (20.7%). Of these

Table 2. Concomitant procedures performed at the time of inflatable penile prosthesis insertion or revision

Concomitant procedure	Frequency
Corporoplasty	16
AUS insertion	7
AUS insertion with penile plication	4
Vasectomy	4
Frenulectomy	2
Injection of bladder Botox	1
Circumcision	1
Scrotal abscess drainage	1
Inguinal herniorrhaphy	1
Hydrocelectomy	1
Repair of urethral perforation	1
Scrotoplasty	1
Penile skin grafting	1
Spermatoclectomy	1
UroLift implantation	1

N = 43

AUS = artificial urinary sphincter.

complications, 25 were infections (8.20%) and 38 were device malfunctions (12.5%). The nature of device malfunctions varied between cases and included pump malfunctions (n = 17), cylinder erosions (n = 12), reservoir leakage (n = 3), and device malfunctions not otherwise specified (n = 6). Complications occurring during concomitant procedures are described below (Table 3). Across all cohorts, outcomes were not significantly associated with self-reported race/ethnicity, attending surgeon, or implant type ($P > .05$). Of the variables analyzed for the overall cohort (Table 4), smoking was associated with overall complications (odds ratio [OR] = 4.14, $P = .00$) and device malfunction (OR = 3.14, $P = .04$).

For those undergoing virgin implantation, complications were noted following 36 implantations (17.3%), including 14 infections (6.73%) and 22 device malfunctions (10.6%). Within this cohort (Table 5), smoking was associated with overall complications (OR = 4.12, $P = .02$), and concomitant procedures were associated with infection (OR = 4.77, $P = .03$). For those undergoing revision surgeries, complications were noted following 27 implantations (27.8%), including 10 infections (10.3%) and 17 device malfunctions (17.5%). Within this sample (Table 6), smoking was associated with overall complications (OR = 7.85, $P = .02$), and DM was associated with infection (OR = 28.3, $P = .02$).

Table 3. Complications following concomitant procedures

Complications	Frequency
Infection	
Corporoplasty	2
AUS insertion with penile plication	1
Scrotal abscess drainage	1
Frenulectomy	1
Hydrocelectomy	1
Repair of urethral perforation	1
Device malfunction	
Corporoplasty	2
AUS insertion with penile plication	1
Vasectomy	1
Circumcision	1
Inguinal herniorrhaphy	1

N = 13.

AUS = artificial urinary sphincter.

DISCUSSION

Recent studies have found the rate of postoperative infection following IPP implantation to be between 0.5% and 3%.^{6–12} However, many of these recent studies exclude at-risk demographics, such as those with a history of prior IPP implantation,^{3,6,7,9,20} IPP infection,^{5,10,11,14} and successive revisions.^{5,8} After including these at-risk demographics, our study determined the rate of postoperative infection to be 8.20%, a rate higher than that quoted in recent studies.

Prior studies describe contradicting evidence regarding DM as a predictive factor for postoperative infection. Wilson and Delk noted this effect in their 1995 study, in which patients with DM experienced a rate of infection that was 10% greater than those without DM.⁴ However, in Mulcahy and Carson's 2011 study,

this rate was only 0.30% greater than that for patients without DM.⁷ Other studies, such as the multicenter study of Henry et al in 2012 and the study by Lotan et al in 2003 have been unable to reproduce a significant association.^{5,19} The aforementioned data may offer an explanation behind the varying effect of DM on postoperative outcomes. In the overall cohort, the odds that those with DM experienced postoperative infections was increased by nearly 3.5 times, although this effect was not significant, supporting the Henry et al and Lotan et al studies. However, when data were split between the 2 subgroups, a significant association between DM and infection was established for those undergoing revision, supporting the Wilson and Delk study. These results, and the contradicting evidence establishing DM as a predictor of infection, may be explained by the interaction between DM and a history of prior IPP implantation.

This study may also provide new information regarding the associations between other medical comorbidities and postoperative outcomes. The effects of smoking on postoperative outcomes have been extensively documented in the literature. In their large 2012 meta-analysis, Sørensen demonstrated ORs of 2.27 for wound complications and 1.79 for postoperative superficial site infections in those who smoked within 4 weeks of their procedure.²¹ The effect that smoking plays on outcomes following the placement of genitourinary prostheses was further described by Sadeghi-Nejad. As described in his study, patients with comorbidities that cause local inflammation and/or negatively affect peripheral vascular supply, including smoking, experienced higher rates of device malfunctions, specifically erosion and pump migration.²² Mirroring the findings from these studies, the OR of overall complications for active smokers was significantly increased by approximately 4 times. Of note, the majority of device malfunctions noted within this cohort, namely erosion and pump migration, match those described by

Table 4. ORs for adverse postoperative outcomes by risk factor

	Complications, OR (P value)	Infection, OR (P value)	Device malfunction, OR (P value)
Peyronie's disease (n = 49)	0.69 (.45)	0.56 (.41)	0.81 (.71)
Prostate cancer (n = 120)	0.67 (.30)	1.11 (.86)	0.60 (.29)
Diabetes mellitus (n = 106)	1.30 (.50)	2.87 (.06)	0.69 (.46)
Hypertension (n = 131)	0.88 (.74)	0.97 (.95)	0.88 (.80)
Obesity (n = 90)	0.87 (.73)	0.77 (.65)	1.03 (.95)
CAD (n = 59)	1.57 (.33)	2.11 (.22)	1.41 (.57)
Smoking (n = 29)	4.14 (.00) [†]	2.91 (.08)	3.14 (.04)*
Concomitant procedure (n = 43)	2.12 (.11)	3.14 (.05)	1.51 (.49)
Age	1.00 (.95)	0.98 (.42)	1.01 (.80)
Year of procedure	0.93 (.09)	0.97 (.60)	0.92 (.10)
Number of prior IPP surgeries	1.19 (.32)	1.15 (.59)	1.17 (.46)
Procedure duration	0.76 (.32)	0.66 (.29)	0.81 (.55)
Alcohol-based skin prep (n = 242)	0.81 (.65)	1.62 (.55)	0.58 (.27)

N = 305.

CAD = coronary artery disease; IPP = inflatable penile prosthesis; OR = odds ratio.

*P value ≤ .05.

†P value ≤ .01.

Table 5. ORs for adverse postoperative outcomes by risk factor for virgin implantations

	Complications, OR (<i>P</i> value)	Infection, OR (<i>P</i> value)	Device malfunction, OR (<i>P</i> value)
Peyronie's disease (n = 33)	0.96 (.95)	0.50 (.56)	1.19 (.80)
Prostate cancer (n = 98)	0.49 (.13)	1.19 (.81)	0.35 (.09)
Diabetes mellitus (n = 65)	0.84 (.74)	0.96 (.96)	0.90 (.87)
Hypertension (n = 88)	0.90 (.82)	1.50 (.57)	0.69 (.54)
Obesity (n = 63)	0.80 (.65)	0.98 (.98)	0.77 (.67)
CAD (n = 36)	1.54 (.46)	3.16 (.13)	1.03 (.97)
Smoking (n = 17)	4.12 (.02)*	3.18 (.21)	2.98 (.13)
Concomitant procedure (n = 30)	2.85 (.07)	4.77 (.03)*	1.76 (.46)
Age	1.02 (.35)	0.99 (.76)	1.02 (.42)
Year of procedure	0.96 (.47)	1.05 (.57)	0.91 (.15)
Procedure duration	0.74 (.46)	0.75 (.64)	0.63 (.40)
Alcohol-based skin prep (n = 168)	0.67 (.48)	2.30 (.47)	0.43 (.19)

N = 208.

CAD = coronary artery disease; OR = odds ratio.

**P* value ≤ .05.

Sadeghi-Nejad.²² Other comorbidities, namely Peyronie's disease, prostate cancer, hypertension, obesity, and coronary artery disease, were revealed to be poor predictors of postoperative complications. Similarly, no significant associations were demonstrated between postoperative outcomes and demographic factors, such as age and self-reported race/ethnicity.

Prior studies have provided varied evidence regarding the rate of postoperative complications for those undergoing IPP revision. While all but 1 study reviewed¹⁶ revealed that those undergoing revision experienced greater rates of complications,^{5,8,12} the reported complication rates for these patients have varied. While some studies quote the infection rate for these patients to be as high as 10–18%,^{5,8,12,14} other studies report that, with proper device washout and the use of other infection limiting techniques,¹⁶ this rate may be as low as 3–4%.^{8,14,19} While

patients undergoing revision procedures (10.3%) in this study experienced higher rates of postoperative infection than those undergoing virgin implantation (6.73%), a statistically significant association was not established. The disparity between the aforementioned data and the results of the described previous studies may be due to a number of causes. For one, there may be a non-linear association, which may not be detectable through linear regression. Specifically, the risk of complication may not increase with successive revisions, but rather remain constant following the first revision procedure. In addition, it may be that those who require multiple revisions are more likely to experience other risk factors, including longer procedure durations and higher rates of smoking and DM. As such, it may be that, when controlling for other variables, the association between past IPP procedures and complications becomes insignificant. Lastly, this

Table 6. Relative risk for adverse postoperative outcomes by risk factor for revision surgeries

	Complications, OR (<i>P</i> value)	Infection, OR (<i>P</i> value)	Device malfunction, OR (<i>P</i> value)
Peyronie's disease (n = 16)	0.38 (.32)	0.34 (.44)	0.32 (.36)
Prostate cancer (n = 22)	1.02 (.98)	NA	4.38 (.16)
Diabetes mellitus (n = 41)	2.56 (.20)	28.3 (.02)*	0.19 (.14)
Hypertension (n = 43)	0.94 (.95)	0.64 (.72)	3.43 (.36)
Obesity (n = 27)	1.19 (.81)	1.42 (.77)	2.40 (.41)
CAD (n = 23)	1.94 (.43)	0.59 (.67)	7.15 (.12)
Smoking (n = 12)	7.85 (.02)*	7.70 (.14)	10.3 (.06)
Concomitant procedure (n = 13)	0.91 (.92)	0.29 (.50)	1.12 (.92)
Age	0.97 (.37)	0.97 (.54)	0.93 (.25)
Year of procedure	0.87 (.11)	0.83 (.21)	0.83 (.17)
Number of prior IPP surgeries	1.35 (.31)	1.01 (.99)	1.54 (.18)
Procedure duration	0.78 (.56)	0.37 (.22)	0.98 (.97)
Alcohol-based skin prep (n = 74)	0.88 (.88)	0.76 (.84)	0.76 (.80)

N = 97.

CAD = coronary artery disease; IPP = inflatable penile prosthesis; NA = omitted due to collinearity with other variables; OR = odds ratio.

**P* value ≤ .05.

effect could be due to a limitation of the study in that the number of patients undergoing revision surgeries may not have been large enough to detect a significant association.

Regarding variations in surgical technique, the association between postoperative complications and concomitant procedures has been described previously. Multiple studies have confirmed that concomitant procedures may be performed with IPP insertion without increased risk of postoperative infections; the concomitant procedures confirmed as safe include artificial urinary sphincter insertion, circumcision, herniorrhaphy, penile plication, and penile skin grafting.^{23–27} While these reports suggest that concomitant procedures can be performed at the time of IPP insertion without significantly altering the risk of postoperative complications, it should be noted that the data reported in these reports may be limited as a result of small sample size^{23–25} and short follow-up duration.²⁷ In these data, concomitant procedures were significantly associated with postoperative infections in the virgin implantation cohort. One possible explanation for this disparity could be the inclusion of new concomitant procedures in the aforementioned data. In this study, postoperative infections were noted following procedures not previously covered in the literature, namely combined artificial urinary sphincter insertion and penile plication, corporoplasty, scrotal abscess drainage, frenulectomy, hydrocelectomy, and repair of urethral perforation. It could be that procedures requiring access to previously uninterrupted anatomy, such as with the urethral repair and hydrocelectomy, predispose patients to infection. It is also natural that certain contaminated procedures, such as abscess drainage, would predispose patients to infection. These factors could explain this new association between concomitant procedures and postoperative infection. As with the data described for DM, it also remains possible that the association between concomitant procedures and complications differs following virgin implantation and revision; more research is needed to confirm the effect described here. Otherwise, surgical factors, including attending surgeon, procedure year, procedure duration, implant type, and skin prep regimen, were not significantly associated with complications.

Regarding the latter variable, this finding appears contradictory with the results of previous studies. The use of alcohol-based solutions for surgical site antisepsis has been supported in previous studies. In their large randomized control trial, Darouiche and colleagues found that those using chlorhexidine-alcohol scrub as opposed to povidone-iodine scrub experienced significantly fewer superficial site infections with a relative risk of 0.59.¹⁷ Given these and other similar results,¹⁸ it is the recommendation of the International Consultation for Sexual Medicine that alcohol-based skin prep regimens be used prior to prosthesis placement.²⁸ As such, it is strange that no significant associations were found between the use of alcohol-based skin prep regimens and postoperative infection. Given the prevalence with which alcohol-based skin prep regimens are now used, the number of cases for which alcohol-based regimens were not used

was low ($n = 41$). As such, it is likely that this sample was too small for the findings of these previous studies to be confirmed.

Multiple limitations exist within this study. Many patients were lost to follow-up and thus excluded from the final analyses. Assuming that many patients who experience postoperative complications will need to return for continued care, especially in the case of postoperative infection, it is possible that patients lost to follow-up did not go on to experience adverse postoperative outcomes. While the exclusion of these patients allowed for a more accurate analysis to take place, it is possible that the data overestimate the rate of complications as a result of this exclusion. In addition, by organizing this study's data by surgical encounter, we were able to better examine the risk factors relevant to successive IPP revisions. However, this decision creates a risk for potential confounding effects to influence the results, as uncounted risk factors may have been included multiple times for patients undergoing successive revisions.

Given the limits imposed by the data available, the effect of certain variables of interest could not be examined, including preoperative glucose levels, preoperative body mass index, prior steroid use, spinal cord injury, and sexual activity following implantation or revision. An additional missing variable that could potentially have a large effect on the data was antibiotic prophylaxis regimen. While the majority of patients included were given preoperative and intraoperative prophylactic antibiotics, the manner in which these regimens was recorded was not consistent. As such, a reliable analysis examining the relative success of these regimens in preventing postoperative infections could not be performed. As variations in these regimens may have had a direct impact on the rates of postoperative infection, the lack of such an analysis represents a significant limitation of the study.

Given that the study performed was a retrospective cohort study, and the complication status of each patient was known prior to examining patient charts, there is potential for confirmation bias to have affected the results. This limitation was addressed by recording and analyzing only objective variables, namely laboratory data and established medical diagnoses recorded prior to surgery.

Lastly, it is possible that the sample size was too small to detect significant associations for each of the variables examined. This limitation is especially relevant for the analyses regarding prior IPP surgeries and skin prep regimens; this could potentially explain the lack of significant associations regarding these variables, though these associations have been established in the literature. In addition, this limitation imposed barriers to testing uncommon risk factors, including surgical alteration for Peyronie's disease and lack of washout during revision. While there may be significant associations linking these factors to postoperative infection, it was not feasible to analyze these variables.

Future research appears necessary to fully understand the factors associated with complications following IPP procedures.

More research is needed to investigate the results described for the first time in this study, including the association between concomitant procedures and infection. In addition, given the extensive documentation of certain variables as predictive of complications, future research should be dedicated toward developing a clinical risk score to predict complications prior to IPP procedures. With a clinical risk score, physicians may more effectively counsel patients seeking treatment for ED and prevent the negative effects encountered with postoperative complications. Lastly, future studies should further investigate if certain risk factors are more pronounced following virgin implantation or revision procedures separately, such as the effects described earlier with DM and concomitant procedures.

CONCLUSION

The rates of postoperative complications in patients undergoing IPP implantation may be underestimated due to the exclusion of high-risk patients. Our examination of the outcomes for all patients undergoing IPP procedures over 18 years found the rate of postoperative infection to be 8.20%. An investigation of potential risk factors found smoking, DM, and concomitant procedures to be associated with varying rates of complications. The differences in risk factors for patients undergoing virgin implantation and revision were examined, revealing DM to be associated with infection for those undergoing revision, and concomitant procedures to be associated with infection for those undergoing virgin implantation.

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