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TOPIC PAPER

Trends in penile prosthesis implantation and analysis of predictive factors for removal

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Abstract

Purpose This study aims to analyze patient demographics, hospital characteristics, and clinical risk factors which predict penile prosthesis removal. We also examine costs of penile prosthesis removal and trends in inflatable versus non-inflatable penile prostheses implantation in the USA from 2003 to 2015.

Methods Cross-sectional analysis from Premier Perspective Database was completed using data from 2003 to 2015. We compared the relative proportion of inflatable versus non-inflatable penile prostheses implanted. We separated the prosthesis removal group based on indication for removal—Group 1 (infection), Group 2 (mechanical complication), and Group 3 (all explants). All groups were compared to a control group of patients with penile implants who were never subsequently explanted. Multivariate analysis was performed to analyze patient and hospital factors which predicted removal. Cost comparison was performed between the explant groups.

Results There were 5085 penile prostheses implanted with a stable relative proportion of inflatable versus non-inflatable prosthesis over the 13-year study period. There were 3317 explantations. Patient factors associated with prosthesis removal were non-black race, Charlson Comorbidity Index, diabetes, and HIV status. Hospital factors associated with removal included non-teaching status, hospital region, year of removal, and annual surgeon volume. Median hospitalization costs of all explantations were $10,878. Explantations due to infection cost $11,252 versus $8602 for mechanical complications.

Conclusions This large population-based study demonstrates a stable trend in inflatable versus non-inflatable prosthesis implantation. We also identify patient and hospital factors that predict penile prosthesis removal which has clinical utility for patient risk stratification and counseling.

Keywords Penile prosthesis · IPP · Prosthesis removal · Explant · Explantation

Introduction

Implantation of penile prosthesis is a well-established surgical option for the management of medically refractive erectile dysfunction (ED) and Peyronie's disease, often serving as a definitive treatment for both disorders [1]. Improvements in surgical technique, materials, and design over the past four decades have continued to decrease patient morbidity and increase satisfaction [2].

Modern era penile prostheses are categorized into two groups: inflatable (IPP) and non-inflatable (NIPP), otherwise known as malleable or semi-rigid. IPPs are more commonly used and considered to be the gold standard for erectile dysfunction that is pharmacologically non-responsive [3]. They most accurately replicate penile rigidity and flaccidity, have a low infection rate as well as the highest patient satisfaction among devices [2, 4]. However, NIPPs remain an acceptable

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alternative and are most often considered in patients with multiple medical comorbidities due to their low mechanical failure and infection rates [5]. They are also better suited for those with diminished strength and dexterity.

Penile prosthesis removal is a devastating outcome, most frequently due to infectious or mechanical complications. Advancements in device engineering, surgical technique, and antibiotic regimens have dramatically reduced removal rates due to these complications. Contemporary infection rates range around 0.44–4.8% for primary placement and 7–18% for re-implantation due to infection [7–14]. The three-piece device has a mechanical failure rate of 6–19% at 5 years and 24–43% at 15 years. Lower mechanical failure rates were seen with the two-piece (0.7–6.1%) and semi-rigid devices (5%), but were also associated with decreased patient satisfaction [13, 15–17]. Predictors for mechanical device failure, other than design improvements, remain unclear. Additionally, other mechanical complications including device migration and erosion are poorly studied. Thus, it is important to assess what risk factors predispose to penile prosthesis removal secondary to mechanical and infectious causes.

In this study, our primary focus is to examine patient demographics, hospital characteristics, and clinical risk factors which predict penile prosthesis removal. We also compare costs of explantation secondary to infection versus mechanical failures. As a secondary focus, we compare trends in IPP versus NIPP implantation from 2003 to 2015.

Methods

Data source and inclusion criteria

The Premier Healthcare is an all-payer, fee-supported database developed to measure resource use and quality. This database contains data from approximately 3900 hospitals in the USA representing 45% of US health systems discharges [18]. Using *International Classification of Diseases, Ninth Revision* (ICD-9) procedure codes, data were retrospectively queried from 2003 to 2015 for patients who underwent placement of IPP (ICD-9 code 64.97), NIPP (64.95), and removal of penile prosthesis (64.96). An institutional board review was not necessary in accordance with institutional policy when dealing with population-based de-identified data.

Covariates

Patient demographics and clinical risk factors assessed included race (white, black, Hispanic/other), marital status, insurance (Medicare/Medicaid vs other), diabetes status (none, uncomplicated, complicated), HIV status, the presence of long-term steroid use, and history of spinal cord injury. We also calculated a modified Charlson Comorbidity Index (CCI), taking into account our evaluation of diabetes status as a separate covariate [19, 20]. Each patient's CCI was subtracted by 1 point for uncomplicated diabetes and 2 points for complicated diabetes.

Hospital characteristics assessed included location (urban vs rural), region (West, Northeast, South, Midwest), hospital bedside (<300, 300–499, ≥ 500), year of surgery, annual hospital volume (<7 vs ≥ 7), and annual surgeon volume (<5 vs ≥ 5).

Outcome measures

We compared the proportion of IPP versus NIPP implantations throughout the study period, stratified in multiple year segments (2003–2005, 2006–2009, 2010–2012, and 2013–2015).

We assessed for factors associated with penile prosthesis removal by comparing patients diagnosed with removal of PP (ICD-9 code 64.96) versus a control group of patients who received either IPP or NIPP implantations (64.97 and 64.95) and were never explanted (negative for 64.96). The explanted patients were further stratified by the indication of prosthesis removal—Group 1: infectious (996.65) vs Group 2: mechanical (996.39) vs Group 3: all explantations.

Direct medical costs were assessed for all explantations. Cost of explantations between those due to infectious causes and those due to mechanical causes were compared.

Statistical analysis

Patient and hospital-level covariates were compared between groups using *t* test for continuous variables and Chi square test for categorical variables. Multivariate logistic regression was conducted to assess the impact of these covariates on treatment options. Direct medical costs were calculated for each group and compared using multivariate median regression.

All analyses were conducted using SAS 9.4 Software. The statistically significant level was set at $p<0.05$.

Results

From 2003 to 2015, there was a weighted total of 5085 penile prostheses implanted. The percentage of IPP implantations ranged from 89 to 96% (Fig. 1). There was a stable relative proportion of IPP versus NIPP implantations over the 13-year study period.

There were 4823 patients in the control group after exclusion of patients whose penile prostheses were subsequently removed (Table 1). The vast majority of the implanted

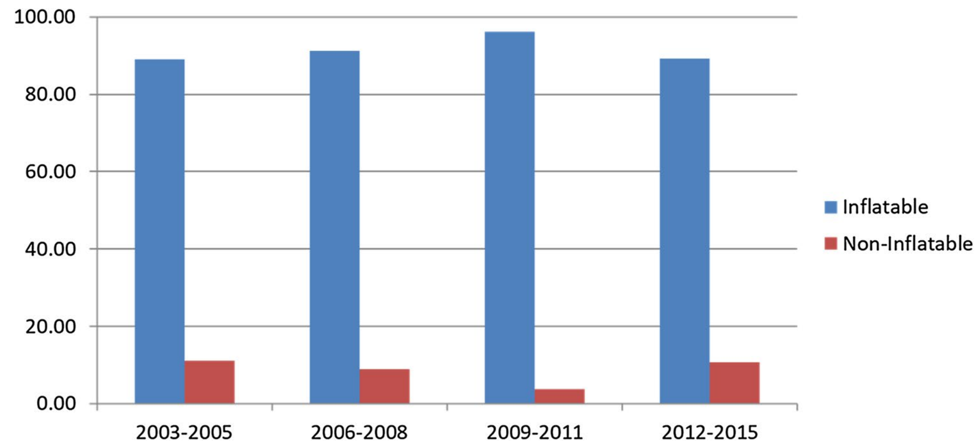

Fig. 1 Proportion (%) of inflatable vs non-inflatable penile prosthesis placed from 2003 to 2015

patients who subsequently had their devices removed had explantations completed during a different admission. There were only 13 salvage procedures.

Of the removal groups, there were 1930 patients in Group 1 (infection), 771 patients in Group 2 (mechanical), and 3317 patients in Group 3 (all explantations). The mean age of the control group was 66 ± 8 vs 71 ± 11 for Group 1, 74 ± 10 for Group 2, and 72 ± 11 for Group 3.

On multivariate analysis, patient factors which were significantly associated with penile prosthesis removal were race, CCI, diabetes status, and HIV status (Table 2). CCI ≥ 2, uncomplicated and complicated diabetes, and HIV positive status were associated with penile prosthesis removal due to infectious complications (Group 1). CCI and uncomplicated diabetes were associated with removal due to mechanical complications (Group 2). Black race was associated with less removals due to mechanical complications compared to white race. CCI, uncomplicated and complicated diabetes, and HIV positive status were associated with penile prosthesis removals inclusive of all indications (Group 3).

Hospital factors significantly associated with penile prosthesis removals included teaching status, hospital region, year of removal, and annual surgeon volume (Table 2). Teaching hospitals were significantly less likely to perform penile prosthesis removals compared across all groups. Hospitals in the Western region of the USA were the least likely to perform explantations. The Southern and Midwestern hospitals were significantly more likely to perform explantations, with the Midwest performing the most explants relative to implants. There were significantly more removals in 2012–2015 compared to 2003–2005. A higher volume surgeon was more likely to perform explantations due to infection as well as explantations of all indications.

Median hospitalization costs of all explantations was $10,878 (IQR $6838–$17,216). Removals due to infection cost $11,252 (IQR $7285–$17,227) versus $8602 (IQR $5862–$14,055) for mechanical complications. The $1580 difference in cost was not statistically significant ($p = 0.08$).

Discussion

Penile prosthesis implantation remains the final common treatment pathway for erectile dysfunction and Peyronie's disease. Both IPPs and NIPPs are viable options for restoration of erectile function. Though IPPs have higher patient satisfaction and more accurately mimic a natural erection [2, 4], NIPPs are a good option for patients with multiple comorbidities and poor manual dexterity [5]. It has also been shown that age, black race, and Medicaid are indicators favoring NIPP implantation [6, 21]. While there is limited data comparing IPPs and NIPPs, one large retrospective analysis showed that reoperation rates for infectious and noninfectious failure are equivalent between the two devices [6]. Our results underscore the continued role for NIPPs given the stable proportion implanted over 13 years.

Despite improvements in device designs and overall outcomes, complications are neither rare nor insignificant. Risk factors for infection include current urinary tract infections, infections elsewhere in the body, hematogenous spread, repair/replacement of prostheses, and surgeon inexperience [7, 22–26]. Spinal cord injury has been shown to be a predisposing factor [27], while diabetes mellitus and immunosuppression status remain controversial [7, 27]. Mechanical complication risk factors are yet to be described in the literature. Similarly, patient demographics which are associated with explantation have not reported. In our results, we demonstrated that black race appeared to be protective. This association was observed for only removal due to mechanical complications. It is unclear what proportion of these explanted prostheses were inflatable versus semi-rigid, given the common ICD-9 code for all penile prosthesis removals (64.96). It is also unclear whether these mechanical complications were due to device failure versus erosion or migration, also due to a common ICD-9 code (996.39). Given these limitations, it is difficult to postulate a rationale for the association between black race and decreased removals

Table 1 Patient demographics, hospital characteristics, and clinical risk factors of control group of implanted patients who were never subsequently explanted and explant Groups 1 (infectious complications), 2 (mechanical complications), and 3 (all explantations)

Parameter	*n* (%)			
	Control: IPP (never explanted)	Group 1: explanted + infection	Group 2: explanted + mechanical complications	Group 3: all explanted
Total	4823 (100)	1930 (58.2)	771 (23.2)	3317 (100)
Age (year) ± mean (SD)	66 ± 8	71 ± 11	74 ± 10	72 ± 11
Race				
White	3028 (62.78)	1214 (62.9)	555 (71.96)	2130 (64.21)
Black	688 (14.27)	289 (14.99)	44 (5.69)	459 (13.83)
Hispanic/other	1107 (22.95)	426 (22.08)	172 (22.35)	729 (21.97)
Marital status				
Married	2974 (61.87)	1027 (53.21)	357 (46.28)	1702 (51.31)
Single or other	1833 (38.13)	903 (46.77)	414 (53.72)	1615 (48.69)
CCI				
0	2353 (52.08)	600 (34.39)	152 (23.66)	922 (31.56)
1	1354 (29.97)	392 (22.47)	113 (17.7)	674 (23.06)
≥ 2	811 (17.95)	753 (43.15)	375 (58.64)	1326 (45.38)
Insurance				
Medicare/medicaid	3166 (65.64)	1537 (79.64)	687 (89.11)	2716 (81.88)
Other	1657 (34.36)	393 (20.36)	84 (10.89)	601 (18.12)
Hospital bed size				
< 300	1327 (27.51)	581 (30.08)	245 (31.75)	1031 (31.08)
300–499	2172 (45.03)	834 (43.19)	318 (41.24)	1358 (40.94)
≥ 500	1324 (27.45)	516 (26.72)	208 (27.01)	929 (27.99)
Teaching status				
No	3248 (67.34)	1482 (76.79)	625 (81.1)	2556 (77.06)
Yes	1575 (32.66)	448 (23.22)	146 (18.9)	761 (22.94)
Location				
Urban	4638 (96.16)	1868 (96.79)	748 (96.94)	3221 (97.11)
Rural	185 (3.84)	62 (3.23)	24 (3.06)	97 (2.92)
Region				
West	614 (12.74)	261 (13.54)	144 (18.66)	572 (17.24)
Northeast	1110 (23.01)	346 (17.94)	125 (16.21)	509 (15.34)
South	2081 (43.15)	960 (49.75)	367 (47.59)	1628 (49.08)
Midwest	1017 (21.09)	362 (18.76)	135 (17.54)	609 (18.36)
Year of surgery				
2003–2005	1234 (25.59)	432 (22.4)	178 (23.09)	749 (22.58)
2006–2008	1318 (27.33)	372 (19.28)	139 (18)	775 (23.36)
2009–2011	1338 (27.74)	409 (21.18)	222 (28.75)	755 (22.75)
2012–2015	933 (19.34)	716 (37.12)	233 (30.17)	1039 (31.32)
Annual hospital volume (no. cases)				
Low (< 7)	4162 (86.29)	1782 (92.33)	722 (93.66)	3109 (93.73)
High (≥ 7)	662 (13.72)	147 (7.64)	49 (6.34)	209 (6.29)
Annual surgeon volume (no. cases)				
Low (< 5)	4326 (89.7)	1874 (97.1)	750 (97.2)	3236 (97.56)
High (≥ 5)	497 (10.31)	56 (2.9)	22 (2.8)	82 (2.46)
Diabetes mellitus				
No	4265 (94.4)	1510 (86.53)	569 (88.91)	2516 (86.11)
Uncomplicated	48 (1.06)	58 (3.34)	21 (3.29)	126 (4.31)
Complicated	205 (4.54)	177 (10.13)	50 (7.8)	280 (9.6)

Table 1 (continued)

Parameter	n (%)			
	Control: IPP (never explanted)	Group 1: explanted + infection	Group 2: explanted + mechanical complications	Group 3: all explanted
HIV				
No	4821 (99.96)	1922 (99.59)	771 (100)	3310 (99.79)
Yes	3 (0.05)	8 (0.4)	0 (0)	8 (0.23)
Long-term steroid use				
No	4818 (99.9)	1912 (99.07)	771 (100)	3299 (99.46)
Yes	5 (0.1)	18 (0.93)	0 (0)	18 (0.54)
Spinal cord injury				
No	4797 (99.46)	1918 (99.38)	769 (99.67)	3303 (99.58)
Yes	26 (0.54)	12 (0.63)	3 (0.33)	15 (0.44)

due to mechanical complications compared to their white counterparts.

Regarding clinical risk factors, diabetes mellitus, HIV positive status, and CCI ≥ 2 were predictive of prosthesis removal. Uncomplicated diabetes was predictive for explantations in all groups. Complicated diabetes was predictive for Groups 1 and 3 and almost reached statistical significance for Group 2 (95% CI 0.97–7.74, $p = 0.06$). HIV-positive status was predictive for removals due to infectious causes which lead to statistical significance for removals of all indications. These results point to the association between immune dysregulation and the likelihood of prosthesis removal. Long-term steroid use and spinal cord injury could not be substantiated due to low numbers of patients with these diagnoses. Modified CCI ≥ 2 was predictive for explantations across all groups. This underscores the importance of comorbidities and baseline medical health as a risk factor for explantation. We chose to exclude diabetes status from the CCI to more accurately discern the individual role of diabetes as a risk factor.

As opposed to clinical risk factors which offer predictive value for explantation, hospital characteristics describe where more removal procedures occur relative to implantations. Annual surgeon volume was associated with more explantations of all causes as well as infection. This is reasonable as removal and salvage procedures can be complicated and often better suited for specialists. Interestingly, we found that teaching hospital status was a negative predictor for prosthesis removals across all groups. This may point to a skewed distribution of urologists who are more likely to perform explantations outside of teaching hospitals. There were greater numbers of explantations in the most recent years of our cohort (2012–2015) compared to the earliest years (2003–2005). This may be related to the age of implants and increased risk for explantation with older implanted devices; however, we would expect to see a statistical difference in mechanical complication group rather than infectious complication group, as mechanical failure is more related to device durability.

As infectious and mechanical complications remain a prevalent problem and health-care costs continue to increase, it is important to understand the costs associated with device explantation. It has been reported that the cost of treating an infected penile prosthesis is roughly six times more than the initial implantation [28]. However, the cost of explant secondary to mechanical failure has not been reported, nor has a cost comparison between explant procedures for infectious versus mechanical complications been conducted. We demonstrated the direct medical cost for all penile prosthesis removals to be around $10,000. Removals due to mechanical complications cost, on average, $1580 less, though this difference was not statistically significant.

This study is not without limitations. The retrospective nature of the study limits the data variables available to the study and introduces bias. Another limitation is that the Premier Database only captures inpatient admissions. We were not able to examine ambulatory cases, which we predict comprises a large proportion of contemporary primary implantations [21]. This explains the fewer than expected number of implantations relative to removals (5085 vs 3317). The lack of ambulatory data may affect the external validity of the relative proportion of IPP versus NIPP implants. A major limitation was that the level of details available was limited to the confines of the ICD-9 coding system. For prosthesis removals, we were unable to differentiate IPP versus NIPP explantation due to the common ICD-9 code (64.96). We were also unable to differentiate device failure from device erosion or migration, due to the common ICD-9 code for all mechanical complications (996.39). Another limitation was improper coding. Many of these patients carried a primary diagnosis of a comorbidity or non-specific diagnosis unrelated to their indication for explantation. 18.6% of explanted patients fell into this category. The majority of these patients were likely explanted

Table 2 Multivariate analysis of factors associated with prosthesis explantation based on the reason for removal

Parameter	Infectious complications		Mechanical complications		All explantations	
	Adjusted OR (95% CI)	*p* value	Adjusted OR (95% CI)	*p* value	Adjusted OR (95% CI)	*p* value
Total						
Race						
White	Reference		Reference		Reference	
Black	1.01 (0.6–1.69)	0.9699	0.29 (0.11–0.77)	0.0134	1.11 (0.7–1.78)	0.6517
Hispanic/other	1.04 (0.61–1.77)	0.8828	0.66 (0.32–1.35)	0.2518	0.98 (0.63–1.52)	0.9314
Marital status						
Married	Reference		Reference		Reference	
Single or other	1.22 (0.84–1.76)	0.2982	1.54 (0.82–2.91)	0.1826	1.34 (0.98–1.82)	0.0658
CCI						
0	Reference		Reference		Reference	
1	1.07 (0.67–1.72)	0.7727	1 (0.5–1.98)	0.9951	1.12 (0.76–1.66)	0.5526
≥ 2	2.82 (1.78–4.47)	< 0.0001	6.72 (3.21–14.05)	< 0.0001	3.11 (2.09–4.64)	< 0.0001
Insurance						
Medicare/medicaid	Reference		Reference		Reference	
Other	1.23 (0.71–2.13)	0.451	0.92 (0.41–2.06)	0.8411	1.16 (0.74–1.82)	0.5301
Hospital bedsize						
< 300	Reference		Reference		Reference	
300–499	1.2 (0.72–1.99)	0.4902	1.41 (0.64–3.11)	0.387	1.15 (0.74–1.78)	0.5365
≥ 500	1.29 (0.65–2.59)	0.4669	2.43 (1.05–5.63)	0.0379	1.47 (0.81–2.67)	0.2053
Teaching status						
No	Reference		Reference		Reference	
Yes	0.54 (0.31–0.92)	0.0225	0.42 (0.2–0.9)	0.0263	0.61 (0.38–0.96)	0.0343
Location						
Urban	Reference		Reference		Reference	
Rural	0.75 (0.33–1.7)	0.4867	0.6 (0.15–2.4)	0.4684	0.63 (0.3–1.32)	0.2174
Region						
West	Reference		Reference		Reference	
Northeast	0.53 (0.26–1.08)	0.0781	0.73 (0.33–1.63)	0.4392	0.84 (0.46–1.53)	0.5692
South	1.36 (0.73–2.52)	0.3291	1.41 (0.72–2.79)	0.3181	1.76 (1.04–2.97)	0.0339
Midwest	1.74 (0.89–3.42)	0.1071	2.36 (0.84–6.62)	0.1033	2.1 (1.13–3.91)	0.0199
Year of surgery						
2003–2005	Reference		Reference		Reference	
2006–2008	0.81 (0.42–1.55)	0.5147	0.91 (0.33–2.49)	0.8547	0.93 (0.55–1.57)	0.7738
2009–2011	0.98 (0.56–1.73)	0.9559	1.49 (0.58–3.85)	0.4045	0.95 (0.58–1.56)	0.8454
2012–2015	2.37 (1.41–4)	0.0013	2.15 (0.75–6.15)	0.1517	1.86 (1.13–3.06)	0.0153
Annual hospital volume (no. cases)						
Low (< 7)	Reference		Reference		Reference	
High (≥ 7)	0.63 (0.26–1.51)	0.2977	0.34 (0.1–1.22)	0.0979	0.55 (0.22–1.35)	0.1898
Annual surgeon volume (no. cases)						
Low (< 5)	Reference		Reference		Reference	
High (≥ 5)	0.22 (0.08–0.59)	0.0028	0.65 (0.22–1.93)	0.4403	0.28 (0.13–0.59)	0.0009
Diabetes mellitus						
No	Reference		Reference		Reference	
Uncomplicated	6.24 (1.23–31.77)	0.0276	4.98 (1.56–15.86)	0.0069	7.39 (1.83–29.75)	0.005
Complicated	2.55 (1.31–4.96)	0.0061	2.74 (0.97–7.74)	0.0562	2.35 (1.31–4.23)	0.0046
HIV						
No	Reference		Reference		Reference	
Yes	22.19 (3.61–136.44)	0.0009	NA	NA	17.3 (3.1–96.63)	0.0012

Table 2 (continued)

Parameter	Infectious complications		Mechanical complications		All explantations	
	Adjusted OR (95% CI)	*p* value	Adjusted OR (95% CI)	*p* value	Adjusted OR (95% CI)	*p* value
Long-term steroid use						
No	Reference		Reference		Reference	
Yes	NA	NA	NA	NA	9.38 (0.18–485.03)	0.2653
Spinal cord injury						
No	Reference		Reference		Reference	
Yes	6.62 (0.73–60.37)	0.0934	2.69 (0.23–31.24)	0.4271	4.27 (0.53–34.6)	0.1728

due to infectious or mechanical complications but were coded incorrectly. For this reason, we designated Group 3 for all explanted patients, not simply the remaining 18.6%, as we would not be able to draw any conclusions on predictive factors of prosthesis removals for unknown indications. Lastly, only 13 weighted patients had a salvage procedure (removal with re-implantation during the same operation), which were too few to perform a subgroup analysis.

This large population study demonstrates a stable proportion of IPPs versus NIPPs implanted from 2003 to 2015, illustrating the continued utility of NIPPs. We analyzed patient demographics, hospital characteristics, and clinical risk factors that were associated with penile prosthesis removal, which have not previously been described. We also demonstrated the costly nature of prosthesis removal, underscoring the importance of complication prevention. Our results support many established ideas in the field such as diabetes and HIV status as risk factors for prosthesis explantation. We also introduced new data such as black race as a protective demographic factor and Charlson Comorbidity Index as a predictor for explantation as well as regional variation of prosthesis removals. The results of this study may prove useful for patient counseling and should prompt further research to validate and better understand these associations.

Author contributions KL: protocol/project development, data management, data analysis, manuscript writing/editing. ERB: manuscript writing/editing. SLC: protocol/project development. JJL: protocol/project development, data collection. BIC: data collection, data management. YW: data analysis. JRE: protocol/project development, manuscript writing/editing.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Statement of human rights For this type of study formal consent is not required.

Statement on the welfare of animals This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent No individual participants were included in this study. Data from this study was obtained retrospectively from a database without patient identifiers.

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