


Nationwide, population-based study of post radical prostatectomy urinary incontinence correction surgery

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Objectives: To assess the use of post radical prostatectomy (RP) urinary incontinence (PPI) surgery and to investigate factors related to its use.

Methods: Cohort study in Prostate Cancer database Sweden (PCBaSe) of men who underwent primary RP between 1998 and 2012. PPI correction procedures were identified in the Patient Registry. Hazard ratios (HR) and 95% confidence intervals (CIs) of PPI surgeries were estimated.

Results: Seven hundred eighty-two out of 26 280 (3%) men underwent PPI surgery at a median time of 3 years after RP. There was an eightfold increase in the absolute number of PPI surgeries during 2000-2014 and a threefold increase in the number per 1000 RPs performed. Factors associated with high use PPI surgery were age >70, HR 1.96 (1.54-2.50), and high hospital RP volume (>100 RPs/year), HR 0.81 (0.66-0.99). There was a 10-fold difference in use of PPI surgery per 1000 RPs between the county with the highest versus lowest use. In a subgroup of men with Patient-Reported Outcome Measures (PROM); severe PPI was reported by 7% of men and 24% of them underwent PPI surgery.

Conclusions: Three percent of all men received PPI surgery, with a 10-fold variation among health care providers. Only a quarter of men with severe PPI underwent PPI surgery, suggesting that PPI surgery remains underutilized.

KEYWORDS

artificial urinary sphincter, population based, post radical prostatectomy urinary incontinence, PROM

1 | INTRODUCTION

Post radical prostatectomy urinary incontinence (PPI) is an adverse effect that decreases quality of life.¹ Given the long life expectancy after radical prostatectomy (RP) for localized prostate cancer, many men suffer from PPI for decades.²⁻⁵ There are several treatment

options for PPI including behavioral therapy, pelvic floor exercises, pharmacotherapy, injectable bulking agents, sling procedures, and compression devices, for example, artificial urethral sphincter (AUS) implants.⁶ PPI correction surgery, in particular AUS, is indicated to men with moderate-to-severe urinary incontinence not amenable to conservative treatment, although there is no consensus on the

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TABLE 1 Baseline characteristics for men diagnosed with prostate cancer from 1998 to 2012 in Prostate Cancer data Base Sweden (PCBaSe) 3.0 treated with radical prostatectomy (RP) stratified by receipt of post prostatectomy urinary incontinence (PPI) correction surgery

	PPI surgery n (%) n = 782 (100)	All n (%) n = 26 280 (100)
Age at RP (years)		
Median (IQR)	64 (60-68)	63 (59-67)
<60	166 (21)	7410 (28)
60-64	256 (33)	8267 (31)
65-69	240 (31)	7814 (30)
≥70	120 (15)	2789 (11)
Aggregated risk category ^a		
Favorable-risk	629 (80)	22 175 (84)
Aggressive disease	141 (18)	3745 (14)
Missing	12 (2)	360 (1)
Year of RP		
1998-2000	56 (7)	1727 (7)
2001-2003	120 (15)	3474 (13)
2004-2006	240 (31)	6794 (26)
2007-2009	235 (30)	6762 (26)
2010-2012	131 (17)	7523 (29)
Year of PPI correction surgery		
2000-2002	27 (3)	27 (3)
2003-2005	80 (10)	80 (10)
2006-2008	171 (22)	171 (22)
2009-2011	260 (33)	260 (33)
2012-2014	244 (31)	244 (31)
Multiple PPI correction surgeries		
No	586 (75)	
Yes	196 (25)	
Time to PPI correction surgery (years)		
Median (IQR)	2.8 (1.8-4.3)	
<1 year	29 (4)	
1-2 years	204 (26)	
2-3 years	202 (26)	
3-4 years	118 (15)	
>4 years	229 (29)	
Charlson comorbidity index		
0	672 (86)	23 319 (89)
1	74 (9)	1804 (7)
2+	36 (5)	1157 (4)
Marital status		
Married	593 (76)	19 362 (74)
Not married	189 (24)	6904 (26)
Missing	0 (0)	14 (0)

(Continues)

TABLE 1 (Continued)

	PPI surgery n (%) n = 782 (100)	All n (%) n = 26 280 (100)
Education level ^b		
High	212 (27)	8044 (31)
Intermediate	329 (42)	10 784 (41)
Low	238 (30)	7333 (28)
Missing	3 (0)	119 (0)
RP center volume ^c		
<50	358 (46)	12 402 (47)
50-99	217 (28)	6619 (25)
100+	207 (26)	7259 (28)
PPI correction surgery center volume ^d		
<10	684 (87)	23 165 (88)
10-15	37 (5)	1156 (4)
>15	61 (8)	1959 (7)

IQR, interquartile range.

PPI correction surgery defined by KDK00: diagnostic code for urinary incontinence surgery of the NOMESCO Classification of Surgical Procedures (NCSP), version 1.16.

^aProstate cancer risk categories according to modified NCCN categorisation: Low-risk = T1-2, Prostate-specific antigen (PSA) <10 ng/mL and Gleason score (GS) ≤6; Intermediate-risk = T1-2, PSA <20 ng/mL and PSA 10-19.9 ng/mL or GS 7; High-risk = T1 2, PSA <50 ng/mL with GS 8 10 or PSA 20-49.9 ng/mL; Locally advanced = T3 and PSA <50 ng/mL; Regionally metastatic = PSA <100 ng/mL with T4 or PSA 50-99.9 ng/mL or N1; Distant metastases = PSA ≥100 ng/mL or M1. Aggregated risk categories: favorable-risk included low-risk and intermediate-risk cancer; aggressive disease included high-risk, locally advanced, regionally metastatic, and distant metastases.

^bEducation level is low: <10 years of education; middle: 10-12 years; high: >12 years.

^cRP center volume: number of RPs performed at a center in the year before the RP in this study.

^dPPI surgery center volume the number of PPI surgeries performed in the year before the study RP.

definition of moderate-to-severe urinary incontinence.^{6,7} Moreover, sphincter implants are costly and have a high revision rate.⁸ Little is known about the proportion of men with severe PPI who receive correction surgery and how the use of PPI surgery varies among health care providers. The aim of this study was to assess the use of PPI surgery in a nationwide population-based cohort and to investigate factors associated with PPI correction surgery.

2 | METHODS

2.1 | Study population

We performed a cohort study in the National Prostate Cancer Register (NPCR) of Sweden of men who had been diagnosed with prostate cancer between 1998 and 2012 and who had received RP as primary treatment.⁹⁻¹¹ Since 1998, NPCR captures 98% of all incident prostate cancer cases in Sweden as compared with the Cancer Register, to

which reporting is mandatory by law. NPCR contains detailed information on cancer characteristics and primary treatment. By use of the unique Swedish personal identity numbers, NPCR has been linked to other population-based healthcare registers and demographic databases to form the Prostate Cancer data Base Sweden (PCBaSe).⁹ The Charlson Comorbidity Index (CCI) was calculated by the use of data on discharge diagnoses in the Patient Registry as previously described.^{9,12}

Men who underwent PPI correction surgery were identified by use of the procedure code KDK00 in the NOMESCO Classification of Surgical Procedures (NCSP), version 1.16, in the Patient Registry. This code is intended to be used only for sphincter implants, but since there are no codes for other forms of PPI surgeries, such as sling procedures and non-circumferential compression devices, this code was also used for other PPI surgeries. However, during the study period these alternative procedures were rarely performed in Sweden (personal communication RP and DV).

Information on educational level was retrieved from Longitudinal integration database for health insurance and labor market studies database (acronym in Swedish "LISA"). The educational level was categorized into low (<10 years of education), intermediate (10-12 years), and high (>12 years).

Center volume of RP and PPI surgery was defined as the number of respective surgeries performed at that center in the preceding 365 days.

Since 2008, NPCR aims to distribute Patient Reported Outcome Measures (PROMs) questionnaires before and 1, 3, and 5 years after RP.^{9,13} Severe urinary incontinence was defined at one year after RP with one of the following responses to the question "Do you have urinary leakage?": "I use pads all the time and they have to be changed because they are wet" or "I use pads all the time and they have to be changed continuously because they are wet."

2.2 | Statistical analyses

To assess the use of PPI correction surgery, these procedures were weighted by the number of RPs performed 2 years preceding date of PPI surgery.¹⁴ Cox proportional hazard regression models were used to estimate hazard ratios (HR) with 95% confidence intervals (CI) for the event PPI surgery in uni- and multivariable analysis. The variables in the analysis were: aggregated cancer risk category, age at RP, CCI, educational level, marital status, post-operative radiotherapy, and center volume of RP and PPI surgery. Patients were considered at risk from the date of RP until PPI surgery, death, or the last follow-up date, whichever occurred first.

3 | RESULTS

In total, 26 280 men underwent RP as primary treatment for prostate cancer between 1998 and 2012. Of these, 782 (3%) men underwent PPI correction surgery after a median time of 3 years (IQR 1.8-4.3) after RP (Table 1). There was an eightfold increase in PPI surgery during the study period, from less than 10 procedures per year in 2001 to 70-80 procedures per year in 2009 and onwards. This rise occurred in parallel with an increase in the numbers of RP per year. The number of PPI surgeries per year per 1000 RPs performed two years preceding PPI surgery similarly increased from less than 10 procedures in 2001 to around 30 in 2009 and onwards (Figure 1). A quarter (196/782) of men who underwent PPI surgery had repeated procedures. RPs were performed in approximately 40 centers, whereas PPI surgery was performed in 18 centers. The majority (60%) of all PPI procedures were performed at three centers. A large proportion of men who underwent PPI surgery (39-56%) at one of these three centers had received their RP at another center (Supplementary Figure S1).

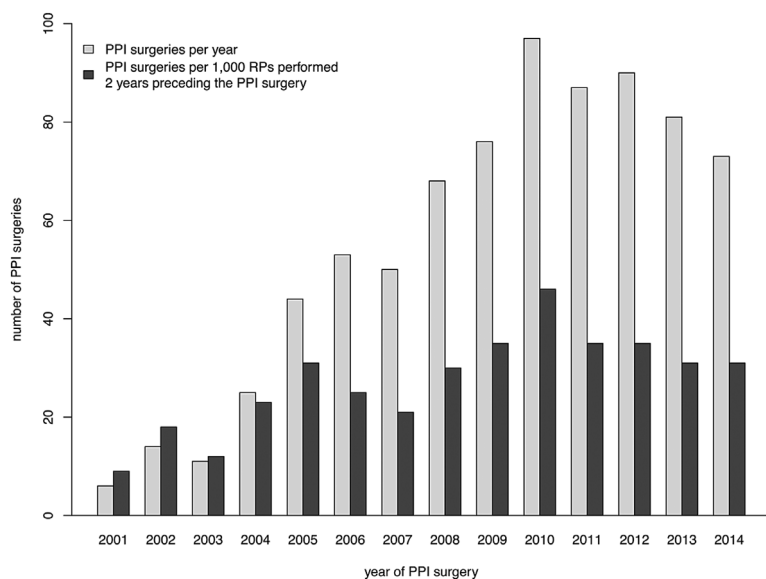


FIGURE 1 Numbers of post prostatectomy urinary incontinence (PPI) correction surgery per year and PPI correction surgery per 1000 radical prostatectomies performed during 2 preceding years. RP: radical prostatectomy

Patient characteristics associated with risk of PPI surgery included old age at RP: >70 years versus <60, HR 1.96 (1.54-2.50); moderate comorbidity: CCI = 1 versus 0, HR 1.36 (1.06-1.73); and aggressive prostate cancer versus favorable-risk: HR 1.29 (1.07-1.55). RP at a high-volume RP center was associated with a lower risk of a

subsequent PPI procedure: >100 RPs/year versus <50 RPs/year, HR 0.81 (0.66-0.99) (Table 2), whereas, having RP at a high-volume PPI surgery center was associated with a higher likelihood of PPI surgery: >15 PPI procedures/year versus <10 PPI procedures/year, HR 1.71 (1.27-2.30).

TABLE 2 Hazard ratios (HR) and 95% confidence intervals (CI) for post prostatectomy urinary incontinence (PPI) correction surgery

	n (events)	Univariable analysis		Multivariable analysis	
		HR	95%CI	HR	95%CI
Age at RP (years)					
<60	7299 (165)	1.00	(Ref.)	1.00	(Ref.)
60-64	8128 (254)	1.41	1.16-1.72	1.37	1.13-1.67
65-69	7674 (233)	1.43	1.17-1.75	1.37	1.12-1.67
≥70	2700 (115)	2.13	1.68-2.70	1.96	1.54-2.50
Charlson comorbidity index					
0	22 954 (658)	1.00	(Ref.)	1.00	(Ref.)
1	1792 (73)	1.46	1.15-1.86	1.36	1.06-1.73
2+	1055 (36)	1.30	0.93-1.82	1.19	0.85-1.67
Aggregated risk category ^a					
Favorable-risk	22 080 (627)	1.00	(Ref.)	1.00	(Ref.)
Aggressive disease	3721 (140)	1.39	1.15-1.66	1.29	1.07-1.55
Post-operative radiotherapy					
No	23 750 (697)	1.00	(Ref.)	1.00	(Ref.)
Yes	2051 (70)	1.19	0.93-1.52	1.08	0.84-1.39
RP center volume ^b					
<50	12 199 (380)	1.00	(Ref.)	1.00	(Ref.)
50-99	6529 (207)	1.13	0.95-1.33	1.07	0.90-1.27
>100	7073 (180)	0.91	0.76-1.08	0.81	0.66-0.99
PPI correction surgery center volume ^c					
<10	22 796 (675)	1.00	(Ref.)	1.00	(Ref.)
10-15	1093 (34)	1.18	0.83-1.66	1.42	0.99-2.05
>15	1912 (58)	1.42	1.08-1.86	1.71	1.27-2.30
Education level ^d					
Low	7240 (237)	1.00	(Ref.)	1.00	(Ref.)
Intermediate	10 637 (322)	0.95	0.80-1.12	0.99	0.84-1.17
High	7924 (208)	0.83	0.69-0.99	0.86	0.71-1.04
Marital status					
Married	19 044 (581)	1.00	(Ref.)	1.00	(Ref.)
Not married	6757 (186)	0.93	0.79-1.10	0.95	0.81-1.12

PPI correction surgery defined by KDK00: diagnostic code for urinary incontinence surgery of the NOMESCO Classification of Surgical Procedures (NCSP), version 1.16.

^aProstate cancer risk categories according to modified NCCN categorisation: Low-risk = T1-2, Prostate-specific antigen (PSA) <10 ng/mL and Gleason score (GS) ≤6; Intermediate-risk = T1-2, PSA <20 ng/mL and PSA 10-19.9 ng/mL or GS 7; High-risk = T1 2, PSA <50 ng/mL with GS 8 10 or PSA 20-49.9 ng/mL; Locally advanced = T3 and PSA <50 ng/mL; Regionally metastatic = PSA <100 ng/mL with T4 or PSA 50-99.9 ng/mL or N1; Distant metastases = PSA ≥100 ng/mL or M1.

^bRP center volume: number of RPs performed at a center in the year before the RP in this study.

^cPPI correction surgery center volume the number of PPI surgeries performed in the year before the study RP.

^dEducational level is low: <10 years of education; middle: 10-12 years; high: >12 years. Aggregated risk categories: favorable-risk included low-risk and intermediate-risk cancer; aggressive disease included high-risk, locally advanced, regionally metastatic, and distant metastases.

There was an up to 10-fold crude (Figure 2) and adjusted variation between counties in the use of PPI surgery: from HR 0.29 (95%CI 0.09-0.92) to HR 3.44 (2.50-4.73), with the most populous county (Stockholm) as reference (Figure 3).

PROM data at 12 months after RP were available for a subgroup of 2876 men and severe incontinence was reported by 215 (7%) of these men. Out of these, 51/215 (24%) had a PPI procedure at a median time of 2.3 years (IQR 2-2.8) after RP (Supplementary Table S1).

Use of PPI surgery was higher after RP at a PPI surgery center compared with RPs performed at a center not performing PPI surgery 155/6209 (2.5%) versus 280/17 299 (1.6%), $P < 0.001$ despite the fact that severe PPI at PROM was equally common after RPs performed at PPI surgery centers compared with centers not performing PPI surgery, 84/1250 (6.7%) versus 131/1626 (8.1%), $P = 0.20$ (Supplementary Table S2).

4 | DISCUSSION

In this population-based, nationwide study in Sweden, 3% of men who underwent RP subsequently received PPI correction surgery, with an increase between 2000 and 2014 in parallel to the increase in the number of RPs. Use of PPI surgery varied up to 10-fold between counties, and only a quarter of men with severe PPI on PROM underwent PPI surgery, suggesting that PPI surgery was underutilized.

The main limitation of this study is the use of administrative data for defining the end-point. However, since the reimbursement to the

departments performing surgery is based on the number of procedures reported to the National Patient Register, this register captures virtually all in-patient surgical procedures.¹⁵ Strengths of our study include the use of comprehensive data in nationwide population-based health care registers with high quality and a virtually complete capture of cases and treatments with less than 1% loss of men during follow-up.^{11,16} PROM data allowed us to assess the proportion of men with self-reported severe incontinence that received corrective surgery for PPI.

Overall, 3% of men who underwent RP subsequently had PPI surgery, indicating that severe urinary incontinence cannot be regarded as a “rare adverse event.”¹⁷ There are several possible explanations for the increase in use of PPI surgery during the study period. Active surveillance became more common, which reduced the number of RPs performed in men with low-risk prostate cancer who have a lower risk of PPI¹⁸ and the proportion of men with low-risk prostate cancer among men who underwent RP decreased from 47% in 1998-2003 to 34% in 2010-2012, whereas, the proportion of men with pT3 disease increased from 14% in 2007 to 33% in 2012. Most likely, vigilance for severe PPI and willingness to perform PPI surgery for urinary incontinence increased during the study period.

The proportion of men who had multiple PPI surgeries 196/782 (25%) in our study are in agreement with previous reports.⁸ Old age, moderate comorbidity, and aggressive cancer were associated with an increased use of PPI surgery, also in accordance with previous studies.¹⁹⁻²¹

There was up to ten-fold difference in use of PPI surgery between counties, despite equal access within the tax-financed Swedish health

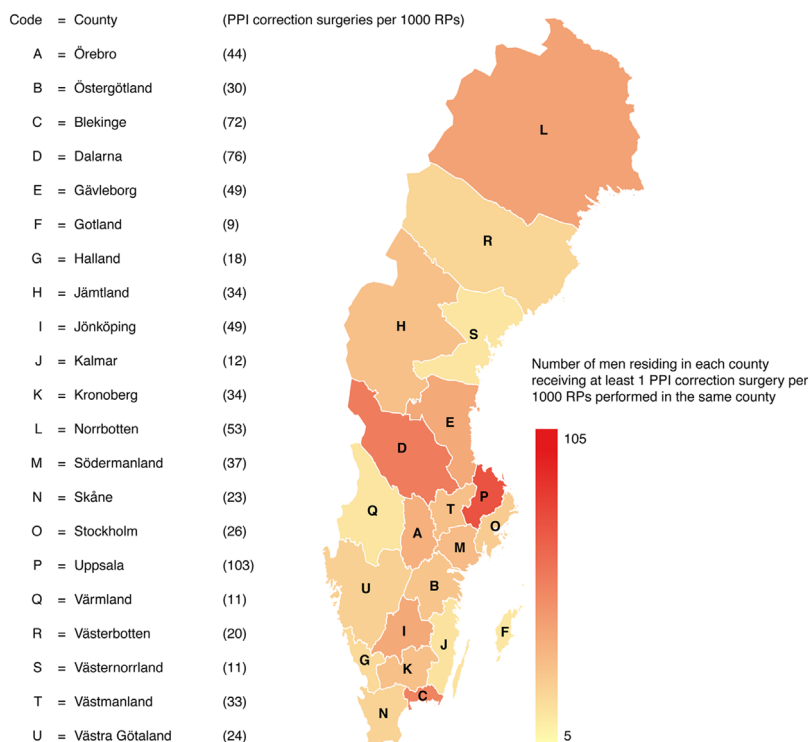


FIGURE 2 Proportion of men who underwent a post prostatectomy urinary incontinence (PPI) correction surgery per county of residence. A (since 2011), B, N, O, P, R, and U are counties with a university hospital

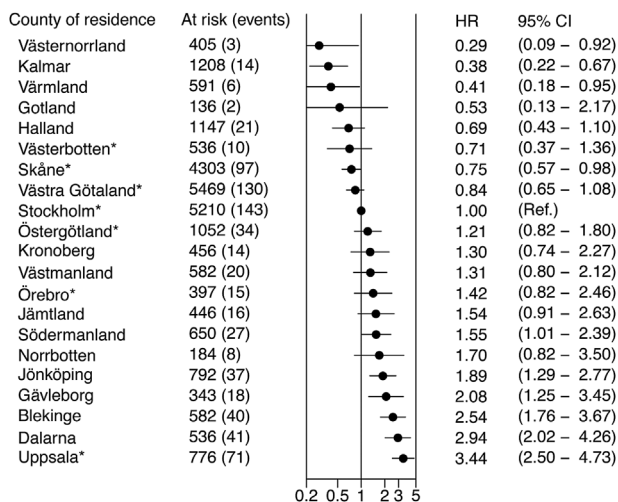


FIGURE 3 Multivariable adjusted hazard ratios (HRs) and 95% confidence intervals (CIs) for receipt of post prostatectomy urinary incontinence correction surgery according to the county of residence. Model adjusted for: age at RP, CCI, education, marital status, RP center volume, PPI surgery center volume, risk category, post-operative radiotherapy. At risk: number of RPs. Events: number of PPI correction surgery. PPI correction surgery = KDK00, diagnostic code for urinary incontinence surgery of the NOMESCO Classification of Surgical Procedures (NCSP), version 1.16. Educational level is low: <10 years of education; middle: 10-12 years; high: >12 years. Favorable-risk includes low-risk and intermediate-risk cancer. Aggressive disease includes high-risk, locally advanced, regionally metastatic, and distant metastases. Prostate cancer risk categories according to modified NCCN categorisation: Low-risk = T1-2, Prostate-specific antigen (PSA) <10 ng/mL and Gleason score (GS) ≤6; Intermediate-risk = T1-2, PSA <20 ng/mL and PSA 10-19.9 ng/mL or GS 7; High-risk = T1 2, PSA <50 ng/mL with GS 8 10 or PSA 20-49.9 ng/mL; Locally advanced = T3 and PSA <50 ng/mL; Regionally metastatic = PSA <100 ng/mL with T4 or PSA 50-99.9 ng/mL or N1; Distant metastases = PSA ≥100 ng/mL or M1. RP center volume: number of RPs performed at a center in the year before the RP in this study. PPI correction surgery center volume the number of PPI correction surgeries performed in the year before the study RP. **County with a university hospital

care system. To the best of our knowledge there is no previous report on differences in use of PPI surgery between health care providers. After adjustment for confounders, RP at a high-volume center was associated with a significantly decreased risk of PPI surgery. Moreover, PPI surgery was more common in men who had RP at a center where PPI surgery was performed, despite a similar rate of patient reported incontinence, suggesting that PPI is particularly underutilized among men who have RP at centers where PPI surgery is not performed. Our results indicate that the health care provider is more important than patient characteristics in determining if a man with severe PPI receive correction surgery.

The proportion of men in our study who underwent PPI surgery is essentially in accordance with previous reports on the use of PPI correction surgery.²²⁻²⁵ In the Ontario Health Insurance Plan Register, 3% of men who had undergone RP had received a PPI

surgery within a median time of 3 years after RP.²³ Based on sale number for AUS by AMS in 2005 combined with the number of RPs performed in 2003 in the US, 6% of men who had undergone RP were estimated to have received an AUS.¹⁴ This calculation was based on the assumption that there was 2-year delay from RP to implant of sphincter device and that the number of devices represented a primary procedure. According to data in SEER Medicare,²² 6% of men who underwent RP from 2007 to 2010 received a PPI procedure after a median time of 20 months. We observed an eightfold increase in the number of PPI procedure during the study period. A similar increase was observed in a study based on the English Hospital Episode Statistics database²⁴ and in a study based on case log data of US certified urologists.²⁵ To the best of our knowledge, our report is the first to assess the proportion of men with severe urinary incontinence according to self-reported PROM who received PPI surgery.

5 | CONCLUSION

In this nationwide population-based study, 3% of men who had undergone RP subsequently received PPI correction surgery. There was an up to 10-fold difference in the use of PPI surgery between health care providers. Only a quarter of men with severe urinary incontinence on PROM underwent PPI surgery, suggesting that PPI surgery remains underutilized.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTIONS

Study concept and design: PS, SC, OA, EJ. Acquisition of data: PS, SC, OA. Analysis and interpretation of data: EV, YF, PS. Drafting of the manuscript: EV, OB, PS. Critical revision of the manuscript for important intellectual content: All. Statistical analysis: EV, YF. Obtaining funding: PS. Administrative, technical, or material support: PS. Supervision: PS. Other: None.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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