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Original Article

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Urinary incontinence and use of incontinence surgery after radical prostatectomy: a national study using patient-reported outcomes

Matthew G. Parry[1,2], Ted A. Skolarus[3,4], Julie Nossiter[1,2], Arunan Sujenthiran[2,5], Melanie Morris[1,2], Thomas E. Cowling[1], Brendan Berry[1,2], Ajay Aggarwal[6,7], Heather Payne[8], Paul Cathcart[9], Noel W. Clarke[10] and Jan van der Meulen[1]

[1]*Department of Health Services Research and Policy, The London School of Hygiene and Tropical Medicine (LSHTM),* [2]*Clinical Effectiveness Unit, Royal College of Surgeons of England, London, UK,* [3]*Center for Clinical Management Research, Veterans Affairs Ann Arbor Healthcare System, University of Michigan,* [4]*Department of Urology, University of Michigan, Ann Arbor, MI, USA,* [5]*Flatiron Health,* [6]*Department of Radiotherapy, Guy's and St Thomas' NHS Foundation Trust,* [7]*Department of Cancer Epidemiology, Population and Global Health, King's College London (KCL),* [8]*Department of Oncology, University College London Hospitals,* [9]*Department of Urology, Guy's and St Thomas' NHS Foundation Trust, London, and* [10]*Department of Urology, The Christie and Salford Royal NHS Foundation Trusts, Salford, UK*

Objectives

To investigate whether patient-reported urinary incontinence (UI) and bother scores after radical prostatectomy (RP) result in subsequent intervention with UI surgery.

Patients and Methods

Men diagnosed with prostate cancer in the English National Health Service between April 2014 and January 2016 were identified. Administrative data were used to identify men who had undergone a RP and those who subsequently underwent a UI procedure. The National Prostate Cancer Audit database was used to identify men who had also completed a post-treatment survey. These surveys included the Expanded Prostate Cancer Composite Index (EPIC-26). The frequency of subsequent UI procedures, within 6 months of the survey, was explored according to EPIC-26 UI scores. The relationship between 'good' (≥75) or 'bad' (≤25) EPIC-26 UI scores and perceptions of urinary bother was also explored (responses ranging from 'no problem' to 'big problem' with respect to their urinary function).

Results

We identified 11 290 men who had undergone a RP. The 3-year cumulative incidence of UI surgery was 2.5%. After exclusions, we identified 5165 men who had also completed a post-treatment survey after a median time of 19 months (response rate 74%). A total of 481 men (9.3%) reported a 'bad' UI score and 207 men (4.0%) also reported that they had a big problem with their urinary function. In all, 47 men went on to have UI surgery within 6 months of survey completion (0.9%), of whom 93.6% had a bad UI score. Of the 71 men with the worst UI score (zero), only 11 men (15.5%) subsequently had UI surgery.

Conclusion

In England, there is a significant number of men living with severe, bothersome UI after RP, and an unmet clinical need for UI surgery. The systematic collection of patient-reported outcomes could be used to identify men who may benefit from UI surgery.

Keywords

prostate cancer, radical prostatectomy, patient-reported outcomes, post-RP incontinence, urinary incontinence, incontinence surgery, national prostate cancer audit

Introduction

Patient-reported outcomes (PROs) are a tool for assessing the impact of prostate cancer treatment on symptoms, functional outcomes, and quality of the life of individual patients. Modern clinical trials use PROs for a more comprehensive outcome assessment, which includes side-effects [1]. Healthcare performance assessment projects use PROs to capture variation in health outcomes between healthcare providers. For example, the National Prostate Cancer Audit of England and Wales (NPCA) has collected survey responses from >45 000 men to better understand the between-hospital variation in the outcomes of prostate cancer treatment [2].

However, there is a lack of data on the association between side-effects of prostate cancer treatment captured by PROs and any subsequent follow-up treatment. These data are important as they would contribute to a better understanding of how the impact of the side-effects of prostate cancer treatment can be reduced. Closing 'knowledge gaps' of this type will help to identify patients who need further help and to assess whether service provision is both adequate and equitable. Quantification of 'unmet need' using PROs also provides information on the burden placed on healthcare delivery systems arising from the need for additional 'downstream' treatments after primary prostate cancer treatment [3].

The NPCA uses the Expanded Prostate Cancer Index Composite 26-item version (EPIC-26) instrument to collect functional outcomes at least 12 months after radical prostatectomy (RP) [11]. The mean EPIC-26 urinary incontinence (UI) score was reported as 70.9 on a scale of 0 (worst function) to 100 (best function) in 5505 men who had a RP between 2014 and 2016 in the English NHS [2].

We have further analysed this patient cohort to answer two questions. First, we assessed the overall use of UI surgery in the first 3 years after RP. Second, we investigated the relationship between UI, as measured with the EPIC-26 instrument, urinary bother and the subsequent use of UI surgery in the first 6 months after completing the survey.

Patients and Methods

Clinical Data

We used English Cancer Registry data [4] to identify men diagnosed with non-metastatic prostate cancer between 1 April 2014 and 31 January 2016 using the International Classification of Diseases, 10th Edition [ICD-10] [5] code 'C61'. This dataset is linked at patient level to Hospital Episode Statistics (HES), an administrative hospital database used in England [6]. Men treated by RP were identified using the procedure code 'M61' according to the Office of Population Censuses and Surveys Classification of Interventions and Procedures, version 4 (OPCS-4) [7]. Given possible effects on post-RP UI, we then identified whether men also received post-RP radiotherapy using the linked National Radiotherapy Dataset [8].

Patient characteristics including age, ethnicity, and socioeconomic deprivation status were identified using HES [9]. Ethnicity from the cancer registry was used to supplement any missing values from HES. Deprivation status was based on the Index of Multiple Deprivation, aggregated for areas with a typical population size of 1500 people. These area-based deprivation measures were grouped into national quintiles. The English Cancer Registry was used to characterise disease stage for each patient using Gleason score, PSA and TNM stage. Disease staging followed a modified D'Amico risk stratification algorithm previously developed by the NPCA [2]. Using this approach 9366 patients were identified for inclusion within the study.

Patient-reported UI

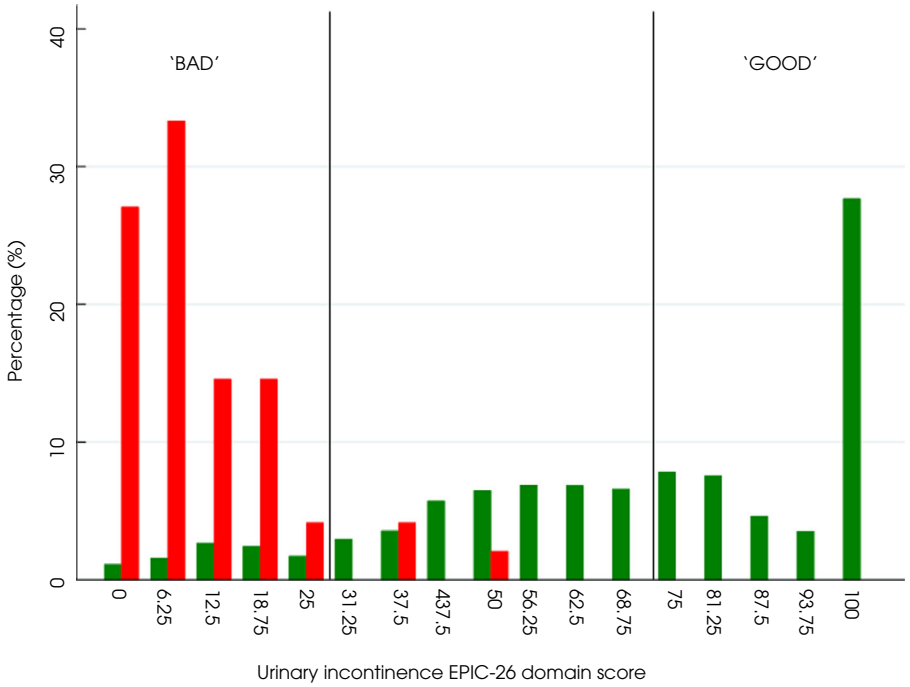
We used the NPCA survey of patients with prostate cancer (Appendix S1). In brief, the NPCA mailed surveys, including the EPIC-26 instrument, to the home address of all men with localised prostate cancer ≥18 months after diagnosis for those diagnosed between 1 April 2014 and 31 January 2016 [2]. The EPIC-26 instrument provides a UI score ranging from 0 (worst function) to 100 (best function) based on four individual EPIC-26 items [10,11]. A 'bad' UI score was defined as ≤25, and a 'good' UI score was defined as ≥75. A score of 25 was chosen as the threshold for a 'bad' score given that every patient who underwent an artificial urinary sphincter had a score of ≤25. The reciprocal threshold for a 'good' score of 75 was therefore used. A further EPIC-26 item that is not used as part of the EPIC-26 UI score asks a question about urinary bother: 'Overall, how big a problem has your urinary function been for you during the last 4 weeks?', with the responses including 'no problem', 'very small problem', 'small problem', 'moderate problem' and 'big problem'.

Study Population

A total of 11 290 men diagnosed with non-metastatic prostate cancer and treated by RP were identified. We studied the cumulative incidence of UI surgery in this target population.

A total of 9366 men received an NPCA patient survey (Fig. S1) of which 80 men were excluded because they had moved, died, or were ineligible. Of the remaining 9286 men, 7189 men had a completed patient survey (blank surveys: 1995; non-responders: 102) resulting in a response rate of 77% (see Table S1 for a comparison of responders and non-responders). We also excluded men with a missing EPIC-26 UI score (n = 335) and those who had already undergone UI

Fig. 1 EPIC-26 UI scores (completed a median of 18.6 months after RP) stratified by whether a man underwent a UI procedure within 6 months of the patient survey (black bars) or not (grey bars).



surgery prior to completing their patient survey (n = 40), as well as men with <6-months follow-up after the date of their survey (n = 1649).

Consequently, 5165 men treated by RP who had completed a post-treatment survey, after a median time of 18.6 months, were included in the analysis of the relationship between UI and subsequent use of UI surgery in the first 6 months after survey completion. The follow-up period of 6 months after survey completion was used so that the survey results remained representative of what patients were experiencing at a given point in time.

Study Measures

The following OPCS-4 codes were used to identify UI procedures: 'M642 – implantation of artificial urinary sphincter into outlet of male bladder', 'M643 – insertion of prosthetic collar around outlet of male bladder,' 'M646 – reconstruction of neck of male bladder' and 'M647 – introduction of transobturator sling.'

We defined men as candidates for UI surgery if they had a 'bad' EPIC-26 UI score (≤25) and if they reported that their urinary function had been a 'big problem' for them during the 4 weeks prior to completion of the survey.

Statistical Analysis

The 1-, 2- and 3-year cumulative incidence of UI surgery was calculated for the 11 290 men diagnosed with prostate cancer between 1 April 2014 and 31 January 2016 who subsequently underwent a RP. Follow-up started at the time of RP and men were censored at 3 years or 28 February 2018, whichever was earliest.

We used proportions to describe patient characteristics and the chi-squared test to compare proportions between patient groups.

Results

The cumulative incidence of UI surgery in the 11 290 men undergoing RP was 0.07% (95% CI 0.04–0.14%) at 1 year, 1.1% (95% CI 1.0–1.4%) at 2 years, and 2.5% (95% CI 2.2–2.8%) at 3 years (Fig. S2). Of the 277 UI operations performed up to 3 years after RP, 188 (67.9%) used an artificial urinary sphincter and 84 (30.3%) used a transobturator sling.

Of the 5165 men included in the analysis of the relationship between patient-reported UI and subsequent use of UI surgery, 47 (0.9%) went on to receive UI surgery in the first 6 months following survey completion (Table 1), of whom 93.6% had a 'bad' UI score. The median (interquartile range [IQR]) time from RP to survey was 18.6 (6.4–23.8) months. Of note, the mean UI score for men who underwent adjuvant radiotherapy was slightly worse than men who underwent RP only (67.4 vs 71.3, respectively). Figure 1 demonstrates that only men with low UI scores went on to have UI surgery given that the proportion of men who had UI surgery decreased rapidly as UI scores improved. Despite this, the

majority of men with the lowest UI scores did not go on to have UI surgery. For example, of the 71 men with a UI score of 0 (very poor function), only 11 men (15.5%) had UI surgery within 6 months of the patient survey.

Table 2 shows that 481 men (9.3%) had an EPIC-26 UI score ≤25 ('bad') and of these, only 44 men (9.1% of those with a 'bad' score) went on to undergo UI surgery within 6 months of the patient survey. These 44 men were typically younger, had fewer comorbidities, lived in less socioeconomically deprived areas, were more often from a White ethnic background, and were more likely to have locally advanced disease than the men who did not undergo UI surgery. These men also had worse urinary bother and were more likely to report at least a moderate problem with their urinary function (95.5% vs 83.9%, $P = 0.001$).

Of the 481 men with a 'bad' EPIC-26 UI score, 207 (43.0%) also reported that they had a 'big problem' with their urinary function. Only 30 of these 207 men (15.5%) underwent UI surgery (Fig. 2). Based on these results, one can estimate that 4.0% of men who undergo a RP (207 of all 5165 included men) are potential candidates for UI surgery.

Table 1 Patient characteristics of 5165 men undergoing a RP according to whether or not they had a UI procedure within 6 months of the patient survey.

Variable	No UI procedure (*n* = 5118)	UI procedure (*n* = 47)	*P*
UI score, median (IQR)	77.25 (52.25–100)	8.25 (0–16.50)	
N (%):			
Age group, years			
<60	1233 (24.1)	11 (23.4)	0.07
60–70	3058 (59.7)	34 (72.3)	
>70	827 (16.2)	2 (4.3)	
Number of comorbidities (RCS Charlson score)			
0	1647 (32.2)	20 (42.6)	0.28
1	1868 (36.5)	16 (34)	
≥2	1603 (31.3)	11 (23.4)	
Deprivation status, national quintiles			
1 (least deprived)	1426 (27.9)	14 (29.8)	0.60
2	1270 (24.8)	13 (27.7)	
3	1108 (21.6)	6 (12.8)	
4	772 (15.1)	7 (14.9)	
5 (most deprived)	542 (10.6)	7 (14.9)	
Ethnicity			
White	4672 (95.7)	46 (97.9)	0.47
Non-white	209 (4.3)	1 (2.1)	
Missing	237 (4.6)	0 (0)	
Risk group			
Locally advanced	2450 (48.1)	29 (61.7)	0.15
Intermediate risk	2580 (50.7)	18 (38.3)	
Low risk	60 (1.2)	0 (0)	
Missing	28 (0.5)	0 (0)	
Multimodal treatment			
RP only	4161 (81.3)	36 (76.6)	0.41
Adjuvant radiotherapy	957 (18.7)	11 (23.4)	

RCS, Royal College of Surgeons.

Table 2 Patient characteristics of men with an EPIC-26 UI score of ≤25 according to whether or not they had a UI procedure within 6 months of the patient survey.

Variable, *n* (%)	No UI procedure (*n* = 437)	UI procedure (*n* = 44)	*P*
Age group, years			
<60	82 (18.8)	10 (22.7)	0.06
60–70	273 (62.5)	32 (72.7)	
>70	82 (18.8)	2 (4.5)	
Number of comorbidities (RCS Charlson score)			
0	102 (23.3)	18 (40.9)	**0.03**
1	159 (36.4)	15 (34.1)	
≥2	176 (40.3)	11 (25.0)	
Deprivation status, national quintiles			
1 (least deprived)	111 (25.4)	13 (29.5)	0.90
2	110 (25.2)	12 (27.3)	
3	85 (19.5)	6 (13.6)	
4	68 (15.6)	7 (15.9)	
5 (most deprived)	63 (14.4)	6 (13.6)	
Ethnicity			
White	398 (94.5)	43 (97.7)	0.36
Non-white	23 (5.5)	1 (2.3)	
Missing	16 (3.7)	0 (0)	
Risk group			
Locally advanced	210 (48.3)	29 (65.9)	0.08
Intermediate risk	222 (51.0)	15 (34.1)	
Low risk	3 (0.7)	0 (0)	
Missing	2 (0.4)	0 (0)	
Multimodal treatment			
RP only	330 (75.5)	33 (75)	0.94
Adjuvant radiotherapy	107 (24.5)	11 (25)	
Urinary bother			
No problem	14 (3.2)	0 (0)	**0.01**
Very small problem	11 (2.5)	0 (0)	
Small problem	45 (10.3)	2 (4.5)	
Moderate problem	189 (43.3)	12 (27.3)	
Big problem	177 (40.6)	30 (68.2)	
Missing	1 (0.2)	0 (0)	

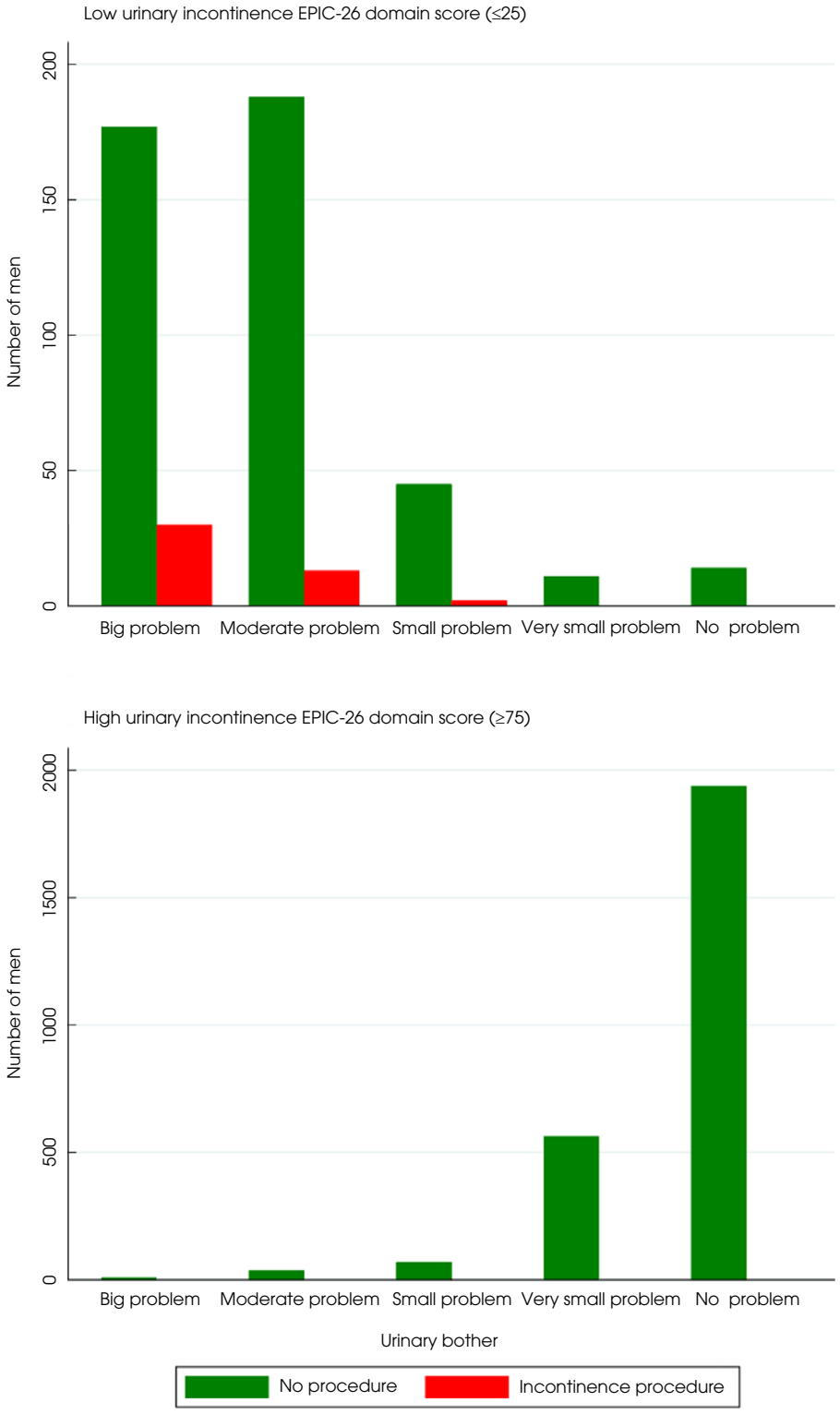
Statistical significance indicated in bold.

Discussion

Up to 3 years after a RP, 2.5% of all men underwent a procedure to correct UI. This appears low given that 9.3% of men having a RP report severe UI at around 19 months after RP. This is in line with another nationwide, population-based study from Sweden, which reported the use of UI surgery to be 3% [12]. Even if we only consider the 4.0% of patients who reported severe UI and a 'big problem' with their urinary function as candidates for UI surgery (which is likely an underestimation of the prevalence of severe, bothersome UI), our study provides evidence that UI surgery is under-utilised.

It is well reported that it can take up to 12 months for UI to improve after RP and why UI surgery is not indicated during this time [13]. Only 4.3% of men completed the survey within 12 months of their RP, so we can assume that the UI reported by almost all men included in our study reflects their longer-term urinary outcomes. This assumption is

Fig. 2 Patient-reported measures for urinary bother after a RP for men with low ('bad') and high ('good') UI scores (EPIC-26 score ≤25 and ≥75, respectively), stratified by whether a man underwent a UI procedure within 6 months of patient survey (completed a median of 18.6 months after their RP).



supported by further analyses (results not reported) that found that the EPIC-26 UI scores did not vary according to the time interval between RP and the patient survey (<12, 12–18 and >18 months).

Figures from the NPCA show that 8957 men undergo a RP in England annually [2]. Based on the results of this study, we estimate that ~224 (2.5% × 8957) will go on to receive UI surgery within 3 years of their RP. Follow-up data were not available to report the cumulative incidence of UI surgery after RP beyond 3 years, which may underestimate the use of UI surgery. However, we feel that a period of 3 years is sufficient time to allow for conservative management options, such as pelvic floor rehabilitation, to have been trialled and for any time delays in UI surgery. Any use of UI surgery beyond 3 years would still be considered under-utilisation given that these men would be living for a substantial period of time with severe, bothersome UI. Our EPIC-26 results demonstrate that there are ~358 patients (4.0% × 8957) who find their severe UI to be a 'big problem'. This equates to the potential under-treatment of more than one in every three men who are candidates for UI surgery. This figure is also likely to be an underestimation given that 40 men who had undergone UI surgery prior to the patient survey were excluded, and these are men who would have had severe UI after RP. UI surgery has also been reported to be under-utilised in Sweden where only a quarter of men with severe UI underwent UI surgery [12].

Reasons for this potential under-treatment include the lack of patient reporting and regional access to specialist continence services. Clinical guidelines issued in the UK highlight the need for specialist continence services for men with severe urinary symptoms and recommend a referral to a specialist surgeon for those with intractable stress UI [14]. The American Cancer Society prostate cancer survivorship guidelines recommend the use of an annual screening tool based on PROs, but they do not provide any threshold for symptom severity [15]. Our study suggests the EPIC-26 instrument can be used to identify those men for whom referral to a specialist continence service may be beneficial to avoid any potential under-treatment. We recommend this to be incorporated into the patient pathway as a screening tool at 12 months after RP. The clinical implication of using instruments for collecting PROs would place an extra burden on clinical teams but would help to identify the men living with severe, bothersome UI and ultimately improve the quality of life of a substantial number of prostate cancer survivors each year.

We found that UI surgery is used almost exclusively for men who report severe UI. All but three of the 47 men who underwent UI surgery in the 6 months after completing the survey had an EPIC-26 UI score of ≤25. We have shown that also using a measure of urinary bother can strengthen this to identify those who may benefit most from UI surgery.

The major strengths of our study were the high survey response rate (77%), the use of a validated instrument for collecting PROs and the inclusion of a large number of patients representing a 'real world' national population.

An important limitation is the inability to determine the cause of any UI identified from the patient surveys. Intrinsic sphincter deficiency is not the only cause of post-RP UI and there are a number of preoperative abnormalities than can be contributory. These include detrusor over- and underactivity, decreased bladder compliance, and BOO as a result of anastomotic strictures. Therefore, our estimate of the under-utilisation of UI surgery may be overestimated but given intrinsic sphincter deficiency is the most common cause of post-RP UI, we do not expect this to affect the interpretation of our results. Furthermore, PROs are helpful in identifying men with bothersome UI, irrespective of type, so that appropriate and timely management can begin. We appreciate that other factors, such as post-RP outcomes, would also help improve the identification of the optimal candidate for UI surgery but we have shown that PROs in isolation can be used as an initial screening tool.

A further potential limitation of this study relates to the accuracy of clinical coding in HES for identifying UI procedures. However, the accuracy of these data for surgery has been shown to be high when compared to clinical documentation and is sufficiently robust to support its use in research [16].

Despite the high response rate it is important to consider any potential selection bias from survey non-responders. However, as the response rate did not vary between treatment and non-treatment groups, this factor is unlikely to affect the interpretation of our findings.

In conclusion, instruments for collecting PROs, such as the EPIC-26, can be used as a screening tool at 12 months after RP to identify men who could benefit from further management of their UI, if pelvic floor rehabilitation has failed. We also found that only 2.5% of men who have a RP in the English NHS undergo UI surgery within the first 3 years of RP. However, 9.3% report severe post-RP UI and at least 4.0% state that this is a big problem for them.

Our study shows that there is a significant number of men living with severe, bothersome UI following RP in England, and UI surgery is likely being underutilised in these men.

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Disclosure of Interest

Arunan Sujenthiran is an employee of Flatiron Health, an independent subsidiary of the Roche group, and holds stock in Roche. Heather Payne has attended and received honoraria for advisory boards, travel expenses to medical meetings, and served as a consultant for AstraZeneca, Astellas, Janssen, Sanofi Aventis, Takeda, Ipsen, Ferring, Sandoz, and Novartis. Noel W. Clarke has attended and received honoraria for advisory boards, travel expenses to medical meetings, and served as a consultant for AstraZeneca, Astellas, Bayer, Janssen, Sanofi Aventis, Takeda, Ipsen and Ferring. Jan van der Meulen reports a contract with the HQIP for the provision of the NPCA (www.npca.org.uk) funded by the HQIP (www.hqip.org.uk).

Authors' Contributions

Designed the work: Matthew G. Parry, Ted A. Skolarus, Julie Nossiter, Jan van der Meulen. Analysed and interpreted data: Matthew G. Parry, Ted A. Skolarus, Julie Nossiter, Heather Payne, Noel W. Clarke, Jan van der Meulen. Drafted article: Matthew G. Parry, Ted A. Skolarus, Julie Nossiter, Heather Payne, Noel W. Clarke, Jan van der Meulen. Provided critical revision: all authors. Approved final version to be published: all authors.

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Ethics Approval

All patient data used is fully anonymised and is therefore exempt from UK National Research Ethics Committee (NREC) approval.

Data Availability Statement

The cancer registry data used for this study are based on information collected and quality assured by Public Health England's National Cancer Registration Service (www.ncras.nhs.uk). Access to the data was facilitated by the Public Health England's Office for Data Release. HES were made available by the NHS Digital (www.digital.nhs.uk; all rights reserved). Matthew G. Parry had full access to all the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis. Data are not available to other researchers as it uses a registry database of patients providing routinely collected data.

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Correspondence: Matthew G. Parry, Clinical Effectiveness Unit, Royal College of Surgeons of England, 35-43 Lincoln's Inn Fields, London WC2A 3PE, UK.

e-mail: mparry@rcseng.ac.uk

Abbreviations: EPIC-26, Expanded Prostate Cancer Index Composite 26-item version; HES, Hospital Episode Statistics; HQIP, Healthcare Quality Improvement Partnership; IQR, interquartile range; NIHR, UK National Institute of Health Research; NPCA, National Prostate Cancer Audit; OPCS-4, Office of Population Censuses and Surveys Classification of Interventions and Procedures, version 4; PRO, patient-reported outcome; RCS, Royal College of Surgeons; RP, radical prostatectomy; UI, urinary incontinence.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. NPCA patient survey.
Fig. S1. Patient selection.
Fig. S2. Cumulative incidence curve for UI surgery after RP.
Table S1. Patient, tumour, and treatment characteristics for survey responders and non-responders.