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National cohort study comparing severe medium-term urinary complications after robot-assisted vs laparoscopic vs retropubic open radical prostatectomy

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Objectives

To evaluate the occurrence of severe urinary complications within 2 years of surgery in men undergoing either robot-assisted radical prostatectomy (RARP), laparoscopic radical prostatectomy (LRP) or retropubic open radical prostatectomy (ORP).

Patients and Methods

We conducted a population-based cohort study in men who underwent RARP (n = 4 947), LRP (n = 5 479) or ORP (n = 6 873) between 2008 and 2012 in the English National Health Service (NHS) using national cancer registry records linked to Hospital Episodes Statistics, an administrative database of admissions to NHS hospitals. We identified the occurrence of any severe urinary or severe stricture-related complication within 2 years of surgery using a validated tool. Multi-level regression modelling was used to determine the association between the type of surgery and occurrence of complications, with adjustment for patient and surgical factors.

Results

Men undergoing RARP were least likely to experience any urinary complication (10.5%) or a stricture-related complication (3.3%) compared with those who had LRP (15.8% any or 5.7% stricture-related) or ORP (19.1% any or 6.9% stricture-related). The impact of the type of surgery on the occurrence of any urinary or stricture-related complications remained statistically significant after adjustment for patient and surgical factors ($P < 0.01$).

Conclusion

Men who underwent RARP had the lowest risk of developing severe urinary complications within 2 years of surgery.

Keywords

prostate cancer, radical prostatectomy, stricture, urinary complications

Introduction

Robot-assisted radical prostatectomy (RARP) has been widely adopted despite a paucity of evidence for its effectiveness compared with retropubic open radical prostatectomy (ORP) or laparoscopic radical prostatectomy (LRP) in terms of both cancer and functional outcomes.

A number of studies have compared the occurrence of urinary complications according to type of prostatectomy [1–3]; however, many of these studies included patients from a single surgeon or single institution, or recruited from a tertiary centre. Population-based studies have also been performed but these mainly used US Surveillance Epidemiology and End Results (SEER)-Medicare cohorts which have exclusions based on age and insurance status, and the outcome measures used are not explicitly validated [4–6]. A recent randomized controlled trial comparing ORP and RARP showed similar patient-reported urinary function in the 3 months immediately after surgery in both groups [7];

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however, there is a gap in knowledge about the occurrence of urinary complications in the medium and longer term according to type of radical prostatectomy (RP).

In the present study, we used a validated outcome measure [8] and 'real-world' data to compare severe medium-term urinary complications after RARP, LRP and ORP in a national cohort of all men with prostate cancer who underwent RP in the English NHS system between 2008 and 2012.

Materials and Methods

Population

Using the International Classification of Diseases, 10th revision (ICD-10) codes [9], we identified men diagnosed with prostate cancer (code C61) between 1 January 2008 and 31 December 2012 within the English national cancer registry [10]. Linked records from the Hospital Episodes Statistics (HES) database were used to identify men who underwent RP using the UK Office of Population Census and Surveys classification, 4th revision (OPCS-4; code M61) [11], as well as their future hospital readmissions. HES is an administrative database of all admissions to NHS hospitals in England, and patient records contain a unique patient identifier that allows longitudinal follow-up [12].

Study Cohort and Main Exposure

The linked HES cancer registry records of 18 739 men who underwent RP between 1 January 2008 and 31 December 2012 were studied. Men were excluded if they could not be linked to an NHS provider (n = 345) or if their socio-economic background according to the Index of Multiple Deprivation [13] could not be determined (n = 41; Fig. 1). Men with an associated diagnosis of bladder cancer (n = 229, ICD-10 C61) were excluded because their surveillance often requires interval cystoscopies which could be incorrectly captured as a treatment of a urinary complication. Men who received adjuvant or salvage radiotherapy (n = 825) within 2 years were excluded because it is not possible to distinguish between complications that occurred as a consequence of RP or the subsequent radiotherapy (OPCS-4 codes defined in Table S1). As a result, we included 17 299 men for whom we had complete data and at least 2 years of follow-up.

Patients who had a code for a robot-assisted procedure (OPCS-4 Y753 or Y765) in their HES records were classified as having undergone RARP and those with a code for laparoscopic procedure (OPCS-4 Y752, Y768, Y751 or Y508) were classified as having undergone LRP. All other men who underwent RP were classified as having undergone ORP.

Covariates

We examined relevant patient and surgical characteristics. Data items in HES records were used to determine age, Royal College of Surgeons Charlson comorbidity score [14], socio-economic deprivation level [13], and whether a pelvic lymph node dissection was performed at time of RP (Table S1 includes a detailed description of the coding framework). We also determined the total number of RPs performed by each surgical centre (n = 65) during the 5-year study period. Hospitals were stratified into low- (<50 RPs/year), medium- (50–100 RPs/year) and high-volume centres (>100 RPs/year) based on volume thresholds used in the existing literature and national UK policy guidelines [15,16].

Study Outcome

We used a previously developed and validated tool to capture the occurrence of any urinary or stricture-related complications severe enough to require an intervention [8]. In brief, we determined a list of interventions based on OPCS-4 procedure codes used to treat urinary complications that can occur after RP (Table S2). The occurrence of an intervention acted as a marker of a severe urinary complication and included procedures to treat postoperative haematuria, strictures and urinary incontinence. We further refined the list of interventions so that we could identify men who required specific surgical procedures used to treat a urethral stricture. This approach confined our analyses to what were likely to be severe complications comparable with grade 3 toxicity according to the National Cancer Institute Common Toxicity Criteria for Adverse Events scoring system (i.e. requiring hospital admission or procedural intervention) [17]. All HES records of readmissions 2 years after RP were examined to identify the proportion of men experiencing any severe urinary complication and stricture-related complications. Patients were considered not to have experienced a complication if there were no hospital readmissions in the first 2 years after RP or if there were no relevant procedure codes in the procedural fields of a readmission. Our methodology met seven of the 10 Martin criteria for reporting complications after urological surgery according to the European Association of Urology guidelines [18].

Statistical Analyses

Kaplan–Meier methods were used to describe the time to the first occurrence of a severe urinary complication according to type of prostatectomy. This was also performed separately for stricture-related complications.

Multi-level regression modelling was used to assess the impact of type of prostatectomy on the occurrence of urinary complications with adjustment for patient-level factors (age,

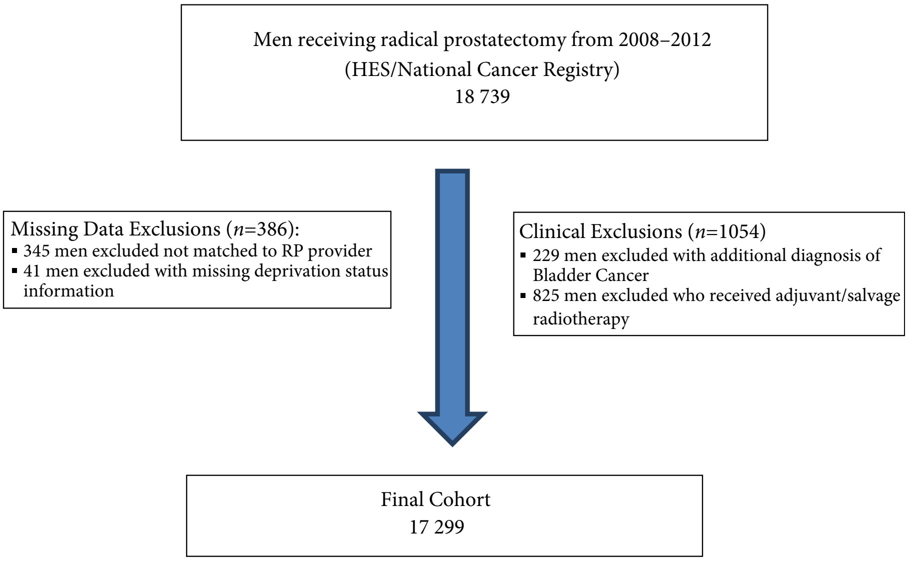


Fig. 1 Flow chart of men included in study. HES, Hospital Episode Statistics; RP, radical prostatectomy.

comorbidity and socio-economic deprivation) and surgical factors (use of pelvic lymph node dissection), and to assess the effect of RP volume as a hospital-level factor. Results are reported as odds ratios (ORs) and a *P* value < 0.05 was taken to indicate statistical significance. *P* values were based on the Wald test or the likelihood ratio test, as appropriate.

Results

Trends over Study Period

Of the 17 299 men included in the study, 6 873 (39.7%) underwent ORP, 5 479 (31.7%) underwent LRP and the remaining 4 947 (28.6%) underwent RARP (Table 1). Over the 5-year study period, the proportion of men undergoing ORP fell from 61.3% to 28.4%, while the proportion of men undergoing RARP and LRP increased from 14.0% to 40.1% and from 24.8% to 31.4%, respectively (Table 1).

Overall, patients undergoing both RARP and LRP tended to be younger and to come from more affluent backgrounds than men undergoing ORP (Table 1). Furthermore, men undergoing RARP tended to have fewer comorbidities than men undergoing LRP or ORP. Patients undergoing ORP were more likely to have a pelvic lymph node dissection than those undergoing LRP or RARP. RARP was also more likely to be performed in a high-volume centre than both LRP and ORP.

Impact of Type of Radical Prostatectomy on Urinary Complications

A total of 10.5% of men who received RARP experienced a urinary complication severe enough to require an intervention within 2 years of RP compared with 15.8% of men undergoing LRP and 19.1% of men undergoing ORP (Table 2 and Fig. 2). After adjustment, multi-level analysis showed that men who underwent RARP were less likely to experience a urinary complication than men who underwent ORP (adjusted OR 0.67; 95% CI 0.58–0.78) and the rate was also

Table 1 Patient and surgical characteristics of 17 299 men undergoing prostatectomy.

Type of RP	ORP, *n* (%)	LRP, *n* (%)	RARP, *n* (%)
No. of men receiving RP	6 873	5 479	4 947
Year of RP			
2008	1 228 (17.9)	496 (9.1)	280 (5.7)
2009	1 667 (24.3)	1 118 (20.4)	716 (14.5)
2010	1 487 (21.6)	1 255 (22.9)	952 (19.2)
2011	1 326 (19.3)	1 320 (24.1)	1 356 (27.4)
2012	1 165 (17.0)	1 290 (23.5)	1 643 (33.2)
Age			
<60 years	1 929 (28.1)	1 702 (31.1)	1 760 (35.6)
60–69 years	4 119 (59.9)	3 258 (59.5)	2 740 (55.4)
>70 years	825 (12.0)	519 (9.5)	447 (9.0)
RCS Charlson comorbidity score			
0	5 625 (81.8)	4 539 (82.8)	4 218 (85.3)
≥1	1 248 (18.2)	940 (17.2)	729 (14.8)
Socio-economic deprivation			
1 (least deprived)	1 474 (21.5)	1 383 (25.2)	1 575 (31.8)
2	1 732 (25.2)	1 287 (23.5)	1 220 (24.7)
3	1 502 (21.9)	1 168 (21.3)	920 (18.6)
4	1 187 (17.3)	970 (17.7)	731 (14.8)
5 (most deprived)	978 (14.2)	671 (12.3)	501 (10.1)
Pelvic lymph node dissection			
No	4 254 (61.9)	4 514 (82.4)	4 083 (82.5)
Yes	2 619 (38.1)	965 (17.6)	864 (17.5)
RP centre volume			
<50 RPs/year	2 808 (40.8)	2 171 (39.6)	904 (18.2)
50–100 RPs/year	3 201 (46.5)	3 053 (55.7)	2 025 (40.9)
>100 RPs/year	864 (12.6)	2 025 (4.7)	2 018 (40.8)

RARP, robot-assisted radical prostatectomy; LRP, laparoscopic radical prostatectomy; ORP, retropubic open radical prostatectomy; RCS, Royal College of Surgeons.

lower in men who underwent LRP (adjusted OR 0.86; 95% CI 0.77–0.96).

Table 2 also shows that, over the study period, there was a significant trend towards fewer men experiencing urinary complications after RP, even with adjustment for the increasing use of RARP ($P < 0.01$ for any urinary and stricture-related complications).

Impact of Type of Radical Prostatectomy on Stricture-Related Complications

A total of 3.3% of men who received RARP required a surgical intervention to treat a stricture-related urinary complication within 2 years of RP compared with 5.7% of men after LRP and 6.9% after ORP (Table 2 and Fig. 3). Multi-level analysis showed that men who underwent RARP had a significantly lower risk of experiencing a stricture-related complication than men who underwent ORP (adjusted OR 0.44, 95% CI 0.35–0.56; Table 2) and the rate was also lower in men who underwent LRP (adjusted OR 0.62, 95% CI 0.52–0.73).

A sensitivity analysis was performed including the 825 men who received adjuvant or salvage radiotherapy (n = 18 124). Multi-level analysis showed similar results to those of the primary analysis; RARP was associated with fewer urinary and stricture-related complications compared with ORP.

Discussion

Men who underwent RARP experienced significantly fewer severe urinary complications within 2 years of surgery than men who underwent either ORP or LRP. Stricture-related complications occurred most frequently in men who received ORP and least frequently in men who underwent RARP.

The present study has a number of strengths. First, we used a rigorously validated outcome measure designed to capture urinary complications severe enough to require an intervention after RP, comparable to grade 3 toxicity [17]. Second, this study reports real-world national data from the English NHS, without limits on age and socio-economic or insurance status, thereby overcoming a weakness of all existing population-based studies. Third, we captured complications requiring readmissions to all NHS hospitals and not only to tertiary centres where the surgery was performed, which is a common cause of under-reporting of complications in many existing studies.

The study period encompassed the transition from open to minimally invasive RP in England and therefore allowed a comparison of groups that were of similar size, and all included patients had at least 2 years of follow-up so that we could accurately determine medium-term urinary complications. A limitation of this approach is that a ‘learning curve’ for minimally invasive surgery may have had an impact on the results. Although we were not able to adjust for surgeon experience or volume, which has been shown to be inversely related to complications after RP [19–21], we were able to account for RP centre volume and showed that it was not significantly associated with the rates of any urinary and stricture-related complication.

A limitation of using procedure codes as a surrogate for urinary complications is that men who were symptomatic but did not undergo an intervention were not captured. Procedural codes were used as opposed to diagnostic codes as they have been shown to have a higher coding accuracy [22]. In the UK, the vast majority of procedures we used as a surrogate for complications are performed in the day-case/inpatient setting and captured in the HES extract we used. A small proportion of procedures will be performed in the outpatient setting but these data were not available. As such, the overall burden of urinary complications is likely to be an underestimate, although we would not expect this to change the comparative benefit found to be associated with RARP in the present study. The quality of HES data is dependent on the accuracy of inputted data by administrative coders, and particularly procedural codes within the context of this study; however, a systematic review compared procedural codes to medical records and found a high coding accuracy (84%) for all studies [22].

A further limitation of the present study, as with many other published population-based studies, is the lack of adjustment for tumour stage and other disease characteristics, such as PSA level, which were not available. In the English NHS this may have less of an impact than in other healthcare systems because the decision to proceed to surgery is coordinated through a multidisciplinary team using national guidelines, which limits the variation in stage for men receiving RP. Furthermore, the choice of type of surgery depends on what type is available at a particular hospital rather than on individual patient characteristics. In addition to tumour stage we were also unable to adjust for other factors including margin status and nerve-sparing status. These data are currently being collected by the National Prostate Cancer Audit [23], and data linkage has been performed which will allow adjustments for these factors in the future. We were also not able to capture specific complications such as a postoperative anastomotic leak as the operative and radiological interventions are not accurately captured within the OPCS-4 manual.

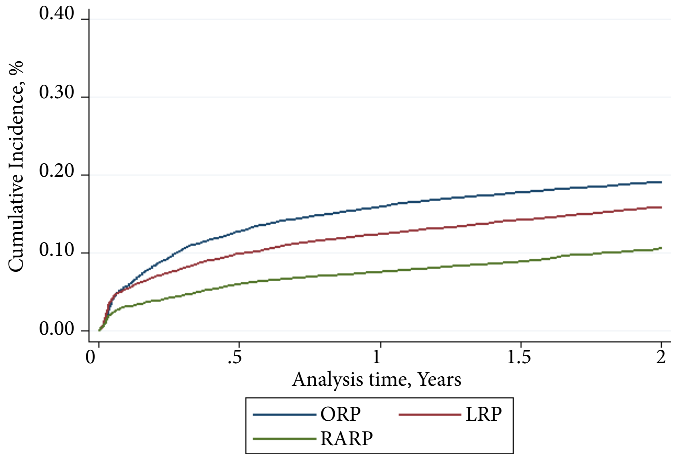
We found that stricture-related complications occurred most frequently in men who underwent ORP, followed by men who underwent LRP, and occurred least often in men who underwent RARP. Our findings are consistent with a population-based study in the USA of nearly 9000 Medicare-insured men aged ≥65 years, which recruited from 2003 to

Table 2 Relationship between patient and surgical characteristics and occurrence of any urinary complication and a stricture-related complication.

Patient characteristic	Men with at least one urinary complication (any), *n* (%)	Adjusted OR* (95% CI)	*P*	Men with at least one stricture-related complication, *n* (%)	Adjusted OR* (95% CI)	*P*
Type of RP						
ORP	1 309 (19.1)	1.0	<0.01	643 (6.9)	1.0	<0.01
LRP	866 (15.8)	0.86 (0.77–0.96)		316 (5.7)	0.62 (0.52–0.73)	
RARP	520 (10.5)	0.67 (0.58–0.78)		161 (3.3)	0.44 (0.35–0.56)	
Year of RP						
2008	349 (17.4)	1.0	<0.01	176 (8.8)	1.0	<0.01
2009	633 (18.1)	1.06 (0.92–1.23)		267 (7.6)	0.88 (0.72–1.08)	
2010	581 (15.7)	0.93 (0.80–1.08)		250 (6.8)	0.84 (0.68–1.03)	
2011	578 (14.4)	0.87 (0.75–1.02)		218 (5.5)	0.71 (0.57–0.87)	
2012	554 (13.5)	0.82 (0.70–0.95)		209 (5.1)	0.69 (0.55–0.86)	
Age						
<60 years	823 (15.3)	1.0	0.08	361 (6.7)	1.0	0.57
60–69 years	1 555 (15.4)	0.99 (0.91–1.10)		643 (6.4)	0.93 (0.81–1.07)	
≥70 years	317 (17.7)	1.17 (1.01–1.35)		116 (6.5)	0.94 (0.75–1.18)	
RCS Charlson comorbidity score						
0	2 196 (15.3)	1.0	0.09	929 (6.5)	1.0	0.75
≥1	499 (17.1)	1.10 (0.99–1.23)		191 (6.6)	0.97 (0.82–1.14)	
Socio-economic deprivation						
1 (least)	580 (13.1)	1.0	<0.01	225 (5.1)	1.0	0.08
2	661 (15.6)	1.15 (1.02–1.30)		270 (6.4)	1.16 (0.96–1.41)	
3	528 (14.7)	1.06 (0.93–1.22)		215 (6.0)	1.07 (0.88–1.31)	
4	506 (17.5)	1.30 (1.13–1.49)		211 (7.3)	1.29 (1.05–1.59)	
5 (most)	420 (19.5)	1.43 (1.23–1.67)		199 (9.3)	1.62 (1.31–2.03)	
Pelvic lymph node dissection						
No	1 919 (14.9)	1.0	0.03	793 (6.2)	1.0	0.09
Yes	776 (17.5)	1.12 (1.01–1.24)		327 (7.4)	1.14 (0.98–1.33)	
RP centre volume						
<50 RPs/year	938 (15.9)	1.0	0.37	434 (7.4)	1.0	0.65
50–100 RPs/year	1 375 (16.6)	1.12 (0.89–1.40)		537 (6.5)	1.00 (0.74–1.34)	
>100 RPs/year	382 (12.2)	0.86 (0.57–1.28)		149 (4.8)	0.79 (0.47–1.32)	

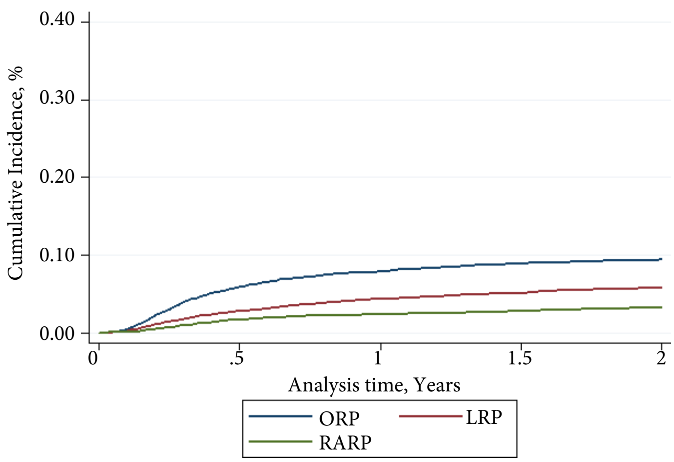
*LRP, laparoscopic radical prostatectomy; OR, odds ratio; ORP, retropubic open radical prostatectomy; RARP, robot-assisted radical prostatectomy; RCS, Royal College of Surgeons. *OR derived using multivariable logistic regression.*

Fig. 2 Kaplan–Meier failure curves for any urinary complication stratified by type of radical prostatectomy. RARP, robot-assisted radical prostatectomy; LRP, laparoscopic radical prostatectomy; ORP, retropubic open radical prostatectomy.



Numbers at risk					
Time, years	0	0.5	1	1.5	2
ORP	6873	5983	5752	5620	5509
LRP	5479	4935	4785	4680	4578
RARP	4947	4646	4559	4484	4393

Fig. 3 Kaplan–Meier failure curves for stricture-related urinary complication stratified by type of radical prostatectomy. RARP, robot-assisted radical prostatectomy; LRP, laparoscopic radical prostatectomy; ORP, retropubic open radical prostatectomy.



Numbers at risk					
Time, years	0	0.5	1	1.5	2
ORP	6873	6456	6302	6224	6167
LRP	5479	5324	5223	5174	5120
RARP	4947	4858	4817	4785	4750

2007 and demonstrated increased urethral stricture formation within 1 year in the group undergoing ORP compared with those undergoing minimally invasive RP [24]. The present findings are in contrast, however, to the results of a meta-analysis from 2009 that compared three types of RP across many outcomes measures, including stricture formation [2]. Three of the studies included in that meta-analysis examined RARP and no differences were found in stricture rates between LRP and RARP or between ORP and RARP [25–27].

Given these differences in results, it is important to note that the present study reports on a more recent cohort of men without exclusions based on age or insurance status. Also, the complications were identified with a validated tool that only considers complications that required a hospital admission or a procedural intervention, eliminating bias associated with studies based on clinician-reported complications.

The present study also shows a trend that has been reported in other US studies [28,29], which is that patients undergoing minimally invasive surgery were less likely to undergo pelvic lymph node dissection than those receiving ORP. This may be related to the learning curve of minimally invasive surgery, the extra time associated with carrying out the procedure and/or the potential desire to limit complications.

We also found that men from more deprived socio-economic backgrounds were more likely to experience urinary complications. This association has not been previously reported in prostate cancer surgery, but other studies have reported higher complications rates in patients from more deprived backgrounds after breast cancer [30] and coronary artery bypass surgery [31].

Radical prostatectomy is a modular operation consisting of a number of different steps, many of which are similar irrespective of the surgical technique. The vesico-urethral anastomosis (VUA), however, is one step of the operation that is performed differently depending on the type of RP. During RARP, the VUA is performed using a continuous suture to achieve a watertight join. This is facilitated by the robotic platform as the instruments enable the surgeon to pass the suture needle through a number of acute angles within the confined space of the bony pelvis [32]. In contrast, laparoscopic or open surgery usually uses between four and six interrupted sutures to approximate the bladder and urethra [33]. As a result, there is likely to be a higher incidence of urinary leakage from the VUA, which can result in increased scarring/fibrosis around the anastomosis, with subsequent stricture formation [34,35]. Furthermore, when performing RARP, a posterior reconstruction (Rocco) suture is often placed, which is another step often not performed during either LRP or ORP. This posterior reconstruction suture approximates the urethral rhabdosphincter, which may reduce tension on the VUA and subsequently decrease stricture formation [36].

Robot-assisted prostate cancer surgery has been rapidly adopted in many countries and has become the most common type of RP within the English NHS [37]. Attempts to estimate whether the increased healthcare costs associated with RARP are cost-effective are still hampered by uncertainty around improvements in outcomes such as cancer control and medium-term morbidity [38]. Our results emphasize that there are additional advantages to RARP in the long term, which not only improve patient outcomes but reduce subsequent treatment costs in healthcare systems. These data will be crucial in supplementing future longer-term data to be released from an ongoing RCT [7].

In conclusion, in this national population-based study in men with non-metastatic prostate cancer, we have shown that men who underwent RARP were less likely to require an intervention and hospital admission for a urinary complication than those who underwent LRP or ORP. This has long-term functional benefits for patients undergoing RP, and the morbidity outcomes from the present study provide further means by which to strengthen economic models evaluating the cost-effectiveness of RARP.

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Conflict of Interest

H. 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. J. van der Meulen reports a contract with the Healthcare Quality Improvement Partnership for the provision of a national evaluation of prostate cancer services in England and Wales during the conduct of the study. All other authors have no conflicts of interest to declare.

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Abbreviations: HES, Hospital Episodes Statistics; ICD-10, International Classification of Diseases, 10th revision; LRP, laparoscopic radical prostatectomy; OPCS-4, Office of Population Census and Surveys classification, 4th revision; OR, odds ratio; ORP, retropubic open radical prostatectomy; RARP, robot-assisted radical prostatectomy; RP, radical prostatectomy; VUA, vesico-urethral anastomosis.

Supporting Information

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

Table S1 OPCS-4 and ICD-10 codes used to identify men receiving adjuvant/salvage radiotherapy and pelvic lymph node dissection.

Table S2 List of interventions used to treat all urinary complications (stricture-related interventions shaded in grey).