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Prevalence analysis of urinary incontinence after radical prostatectomy and influential preoperative factors in a single institution

Antonio Tienza , Jose E. Robles, Mateo Hevia, Ruben Algarra, Fernando Diez-Caballero and Juan I. Pascual

Department of Urology, Clinica Universidad de Navarra, Pamplona, Spain

ABSTRACT

Aims: To assess prevalence of urinary incontinence (UI) after radical prostatectomy (RP) and to analyze which preoperative characteristics of the patients have influence on UI.

Methods: Between 2002 and 2012, 746 consecutive patients underwent RP for clinically localized prostate cancer. We defined UI according to International Continence Society (ICS) definition: "the complaint of any involuntary leakage of urine" after 12 months of recovery, international consultation on incontinence questionnaire (ICIQ-SF) and pads/day was collected too. Clinical features and magnetic resonance imaging measurements were assessed. A multivariable logistic regression model predicting incontinence were built-in after adjust by cofounding factors and bootstrapping.

Results: About 172 (23%) of the patients were classified as incontinent according to the ICS definition. The mean value of the ICIQ-SF was 10.87 (± 4). 17.8% of patients use at least one pad/day, 11.9% use more than one pad/day. The preoperative factors independently influential in UI are: age [OR: 1.055; CI 95% (1.006–1.107), $p = .028$], urethral wall thickness [OR: 5.03; CI 95% (1.11–22.8), $p = .036$], history of transurethral resection of the prostate [OR: 6.13; CI 95% (1.86–20.18), $p = .003$] and membranous urethral length [OR: 0.173; CI 95% (0.046–0.64), $p = .009$]. The predictive accuracy of the model is 78.7% and the area under the curve (AUC) value 71.7%.

Conclusions: Urinary incontinence after radical prostatectomy has different prevalence depending on the definition. Age, prior transurethral resection of the prostate (TURP), membranous urethral length (MUL) and urethral wall thickness (UWT) were risk factors.

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Introduction

Prostate cancer (PCa) has an age-standardized incidence rate of 64 per 100,000 in Europe and is responsible of 11.3 death per 100,000 [1]. Surgical treatment is curative in selected cases though radical prostatectomy (RP). A possible secondary effect is urinary incontinence (UI), which decrease the quality of life of the patients [2].

The disease has been widely studied before reporting a huge variability in prevalence from 4% to 31% [3], which results in confusion. It is important to identify which patients have more risk to suffer UI in order to advice surgical treatment or create realistic expectations. A deep and detailed analysis of these risk factors is necessary to increase the knowledge of this secondary effect.

Our objectives are to assess prevalence of UI after RP and to analyze which preoperative characteristics of the patients have influence on UI.

Materials and methods

The present work is a retrospective cohort study of a single institution center. We included 787 consecutive patients that underwent RP from 2002 to 2012. The inclusion criteria were clinically localized PCa patient that received surgical treatment and with regular follow-up after surgery. The exclusion criteria were loss of contact, salvage RP or previous hormonal therapy. After discard 43 patients, the 746 remaining patients were subjects to analysis.

Diagnosis and treatment

If elevated prostate-specific antigen (PSA) and/or suspicious digital rectal examination (DRE) were found in regular check-ups, a prostate biopsy was indicated and performed. When pathologic diagnosis of PCa is obtained, patients were clinically staged according to

D'Amico risk categories (PSA, DRE and biopsy Gleason score).

Urinary status was assessed during preoperative consultation, recording previous low urinary tract symptoms (LUTS) including urgency and previous UI, and history of transurethral resection of the prostate (TURP).

To evaluate the extension of PCa, a magnetic resonance imaging (MRI) of the pelvis and if indicated (PSA >10 ng/ml) a bone scintigraphy were performed.

The surgical approach were open retropubic RP (RRP) and since 2004, open and laparoscopic RP (LRP), none criteria was used to select the approach. The surgical technique included bladder neck sparing, neurovascular bundle sparing technique (NST), single knots urethrovesical anastomosis.

Clinical data and variable definitions

Clinical characteristics collected were age at surgery, body mass index (BMI) (≤ 24.9 , 25–29.9, ≥ 30), PSA value, DRE (normal, abnormal), biopsy Gleason score (2–6, 7, 8–10), D'Amico risk categories (low, intermediate, high risk), history of TURP and previous LUTS.

Two board-certified radiologist performed the MRI investigations in order to evaluate extracapsular extension or seminal vesicle involvement with a 1.5-T scanner Siemens Magnetom® Aera, Symphony (Siemens AG, Germany). In previous studies of our group we took some measurements of the pelvic floor by MRI: prostate (PL), membranous urethral length (MUL) from sagittal T2-weighted TSE sequences; Levator ani muscle (LAM), obturator internus muscle (OIM) and urethral wall thickness (UWT), prostate width (WP) and height (HP) were taken from axial T2-weighted TSE sequences (Figure S1) [4]. Prostate volume (PV) was calculated from the formula: height \times length \times width \times $\pi/6$ in centimeters.

An extrafascial NST was performed in selected cases and collected retrospectively and blinded to continence status as NST, without dividing unilateral or bilateral. Pathological characteristics of the tumor were reported by a certified pathologist dedicated to urological cancer and collected as: pathological stage (pT2 vs pT3), pathological Gleason score (2–6, 7, 8–10) and surgical margins.

Urinary incontinence was defined according to the recommendations of the International Continence Society (ICS) as “the complaint of any involuntary leakage of urine” [5]. We assessed it after 12 months of recovery during follow-up. A validated and translated to Spanish questionnaire was filled by patients: the short form of the international consultation on

incontinence questionnaire (ICIQ-SF), the number of required pads/day was collected as well [6,7].

Statistical analyses

The primary end-point was prevalence of UI, followed by a risk factor analysis. The characteristics of the patients were compared between continents and incontinent patients and analyzed using T-Student or Wilcoxon test for continuous variables: age, BMI, PSA, time of surgery, measurements obtained by MRI; and χ^2 test or Fisher's exact test for categorical variables: BMI groups, prior TURP, previous LUTS, Gleason score, D'Amico risk categories, MRI result, surgical approach, NST, stage and surgical margins.

The predictive analysis to obtain the influential factors was performed by binomial logistic regression modelling.

Initial assessment was by univariate logistic regression analysis. The presence of interaction or confounding effect was assessed by Pearson correlation and rated into multivariate logistic regression with statistical significance testing. Influential variables were introduced according to biological/clinical importance in order to obtain the best model from multivariable logistic regression [8].

Predictive accuracy, sensitivity and specificity were computed from a classification table. To decrease overfitting bias and type I error, model was subjected to 1000 bootstrap resamples [9]. The accuracy was based on discrimination and calibration. Model calibration was assessed with plots to explore the correlation between predicted and observed individual probability of UI. The goodness of the model was evaluated by using the Hosmer–Lemeshow test [10]. Model discrimination was assessed using an area under the receiver operating characteristic curve (ROC-curve) [11]. The best cut-off value was calculated for informative purposes by using the minimum-description-length principle method and confirmed by using a sensitivity/1-specificity chart [12]. We drawn a graphical representation of the predictive model as of beta coefficients of the variables: a nomogram [13].

Statistical analysis was performed with SPSS® software package version 21.0 (IBM Corp., Somers, NY, USA) the calibration plots and nomogram were produced by using Orange 2.7 (<http://orange.biolab.si/>) [14]. All *p* values were two-sided, with *p* < .05 being considered significant.

Results

From 2002 to 2011, from a total of 787 eligible patients, 746 were included in the analysis.

After 12 months of recovery, 172 (23%) of the patients were classified as incontinent according to the ICS definition.

About 164 (21.9%) patients filled the ICIQ-SF. The mean value was 10.87 (± 4) (4–20), with 50 (30.5%) patients in the mild group (1–8), 83 (50.5%) patients in the moderate group (9–14), and 31 (19%) patients in the severe group (>15). The mean number of pads per day was 1.75 (± 1.2) in 132 patients; 74 patients use one pad/day (17.8% of patients use at least one pad), 44 patients use two to three pad/day, and 14 use >3 pads/day, (11.9% of patients use more than one pad), whereas the remainder reported to be incontinent and no use any pad (32 patients).

The characteristics of the patients and the results of the comparative study are shown in Table 1. The comparison of characteristics shows that age, prior TURP, previous LUTS, NST and pathological stage have differences between groups. Pathological stage was excluded because of being a post-surgical variable. The influential variables of the pelvic floor measured with MRI are PV, OIM, MUL and UWT, as reported in Table 2.

Table 3 shows the variables that achieved statistical significance in univariable logistic regression. The presence of interaction was assessed by using Pearson correlation and multivariate logistic regression, by entering terms sequentially; only age and OIM show

Table 1. Characteristics of the patients from the series.

Patient no (%)	746 (98.4%)	Continent 574 (76.9%)	Incontinent 172 (23%)	<i>p</i>
Age (years)				.000
Mean	63	62.3	65.3	
Median	63	62	66	
Range	41–83	41–81	48–83	
Body mass index (kg/m ²) (%)				.7
Mean	27.4	27.4	27.2	
Range	16.3–48	20.6–41.4	16.3–48	
≤ 24.9	169 (22.7%)	124 (21.6%)	45 (26.2%)	.437
25–29.9	433 (58%)	339 (59.1%)	94 (54.7%)	
≥ 30	143 (19.2%)	110 (19.2%)	33 (19.2%)	
Digital rectal examination				.464
Normal	477 (63.9%)	368 (64%)	108 (66.3%)	
Abnormal	217 (29.1%)	163 (28.4%)	55 (33.7%)	
PSA (ng/ml)				.535
Mean	9.27	9.17	9.6	
Median	7.06	6.8	7.73	
Range	2–136	2.2–136	2–40.9	
Prior TURP	38 (6.8%)	22 (5.1%)	16 (12.4%)	.007
Previous LUTS	91 (12.2%)	63 (10.9%)	28 (16.1%)	.030
Biopsy Gleason score				
≤ 6	500 (70%)	377 (69.2%)	117 (69.2%)	
7	149 (21%)	124 (22.8%)	33 (19.2%)	
≥ 8	63 (9%)	44 (8.1%)	19 (11.2%)	
D'Amico risk categories				.299
Low risk	380 (52%)	296 (53%)	84 (48.8%)	
Intermediate risk	222 (30.4%)	168 (30.1%)	54 (31.4%)	
High risk	129 (17.3%)	95 (17%)	34 (19.8%)	
MRI result				.661
Normal	442 (59.2%)	342 (59.6%)	100 (58.1%)	
Extraprostatic extension	145 (19.5%)	109 (18%)	36 (18.4%)	
Surgical approach				.646
RRP	545 (73.1%)	417 (72.6%)	128 (74.4%)	
LRP	201 (27%)	157 (27.4%)	44 (25.6%)	
Nerve Sparing Technique	431 (57.8%)	343 (60%)	88 (50.6%)	.028
Time of surgery (minutes)				.727
Mean	184	184	182	
Median	164	164	166	
Range	65–542	65–542	81–420	
Blood transfusion	76 (10.6%)	76 (10.6%)	24 (14%)	.063
Pathological stage				.006
T2	535 (72.1%)	424 (74.4%)	114 (66.3%)	
$\geq T3$	207 (27.9%)	146 (25.6%)	58 (33.7%)	
Pathologic Gleason score				.19
≤ 6	425 (58.1%)	337 (59.9%)	88 (52.1%)	
7	178 (24.3%)	130 (22.6%)	48 (28.4%)	
≥ 8	129 (17.6%)	96 (17.1%)	33 (19.5%)	
Surgical margins				.913
Negative	495 (66.6%)	381 (66.7%)	114 (66.3%)	
Positive	248 (33.3%)	190 (33.3%)	58 (33.7%)	

an interaction. None of variables show confusion or interaction with previous LUTS. With those significant variables, a multivariable logistic regression analysis was performed. The preoperative factors that were independently influential in the appearance of UI were: age at diagnosis, prior TURP, MUL and UWT.

CI 95% and p values are reported after 1000-resamples of bootstrapping procedure. The predictive accuracy of the model was 78.7% with a sensitivity of 61.5%, a specificity of 98.9%.

The calibration plot (Figure 1) shows that the model fits correctly to our particular cohort, especially in low probability. The Hosmer–Lemeshow test proves the good fit of the multivariate logistic regression analysis: eight degrees of freedom, a χ^2 of 5.48 and a p values of .784. A ROC-curve was drawn and an area under the curve (AUC) value of 71.7% (CI 95%: 0.63–0.79, $p = .000$) was computed (Figure 2). The best cut-off value is 20.4% [OR = 4.99; 95%CI (2.47–10.11)], with 11.6% of incontinent patients below and 39.5% over the cut-off. According to this, a patient with more than 20.4% of individual risk has an almost five-fold increased risk to develop UI.

The reported values imply that between 19% and 20.5% of incontinent patients were classified as severe (4–3.6% of the total).

With beta-coefficients of influential factors is obtained a formula:

$$P = \frac{1}{1 + e^{-(0.054 \text{ age} + 1.617 \text{ UWT} + 1.814 \text{ TURP} - 1.757 \text{ MUL})}}$$

and we draw a nomogram (Figure 3).

Discussion

The analysis of our series highlights prevalence results of UI after RP. The work underscores the variability of this prevalence depending on the definition used. In our series 23% of the patients are strictly classified as incontinent, 17.8% reported to use one pad per day or more and 11.9% use more than one pad. This wide disparity in results is present in the literature, as Ficarra et al. [3] and Bauer et al. [2] reported (range from 4% to 31%).

The succeeding objective, to analyze the influential factors on UI, is not unique and have been studied

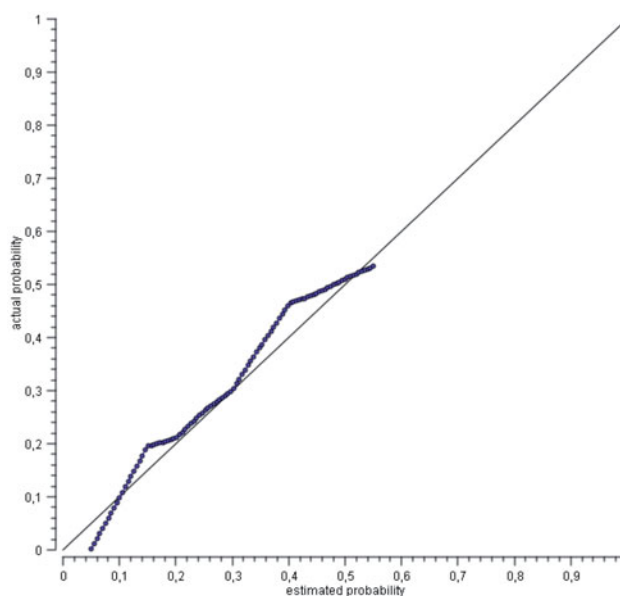


Figure 1. Calibration plot.

Table 2. Comparative analysis of measurements obtained by MRI.

	Continent	Incontinent	p
Prostate length	4.4 (± 0.89)	4.5 (± 1.01)	0.227
Prostate width	5.1 (± 0.69)	5.1 (± 0.83)	0.989
Prostate height	3.8 (± 0.69)	3.9 (± 0.83)	0.329
Prostate volume	53 (± 21)	59 (± 30)	0.027
Levator ani muscle thickness	0.51 (± 0.19)	0.51 (± 0.18)	0.868
Obturator internal muscle thickness	1.49 (± 0.46)	1.35 (± 0.48)	0.019
Membranous urethral length	1.45 (± 0.32)	1.36 (± 0.29)	0.007
Urethral wall thickness	1.36 (± 0.21)	1.44 (± 0.25)	0.020

Bold numbers represents p value < .05.

Table 3. Univariate and multivariate logistic regression analyses.

	Univariate		Multivariate	
	OR (95 % CI)	p	OR (95 % CI)	p
Age	1.068 (1.04–1.096)	.000	1.055 (1.006–1.107)	.028
Previous TURP	2.52 (1.26–4.98)	.009	6.13 (1.86–20.18)	.003
Previous LUTS	1.98 (1.21–3.26)	.007		
Obturator internus muscle thickness	0.615 (0.35–0.83)	.005		
Urethral wall thickness	4.98 (1.2–20.7)	.027	5.03 (1.11–22.8)	.036
Membranous urethral length	0.57 (0.38–0.87)	.009	0.173 (0.046–0.64)	.009

Bold numbers represents p value < .05.

several times before, but limited times including MRI measurements. Ficarra et al. [3] record that age, the presence of comorbidities, high BMI, and the presence of LUTS have a correlation with UI. Age should be balanced to make an indication to surgery, the use of geriatric assessment and other tools may reduce side effect and unnecessary treatments [15,16]. We should notice that obesity are linked to other metabolic disease like diabetes mellitus or late onset

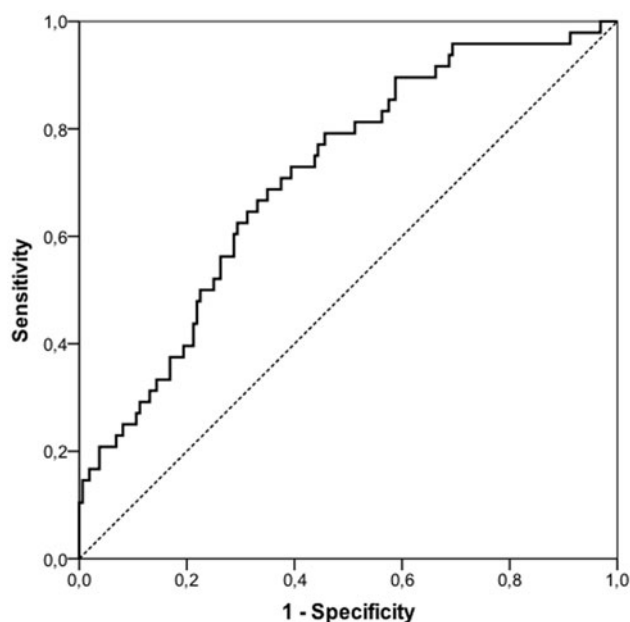


Figure 2. ROC-curve.

hypogonadism, which can influence in PCa incidence and to propitiate side effects in these patients [17,18].

In a last review performed by Heesakkers et al. in 2016, the authors address the pathophysiology and studied factors that contribute to UI after RP. Age is a widely found and accepted factor. A higher BMI is linked to UI, but is not a unanimous finding, like Wiltz et al. or our series [19,20]. Authors don't offer much evidence on the influence of previous TURP and pre-existing LUTS, concluding the influence of the last one. These patients should not be excluded because increased LUTS predicts UI [20,21], and in some cases RP could cure previous LUTS without becoming incontinent [22]. In a preliminary analysis of our series, we can give evidence that patients with LUTS are likely to present UI, but not the same patients with LUTS become incontinent after RP; history of TURP was influential by itself over UI too [20]. Heesakkers et al. [23] conclude with some surgical factors that are associated with better recovery like NST and bladder reconstruction.

Surgical technique could influence in the appearance of UI, NST have influence over it as Burkhard et al. [24] reported. Also there is an ongoing debate, between retropubic, laparoscopic and robotic surgery without differences at the present moment and the data available [25].

In another preliminary analysis of our series, focus on MRI measurements, we found that MUL, UWT and PV were risk factors, finding MUL and UWT

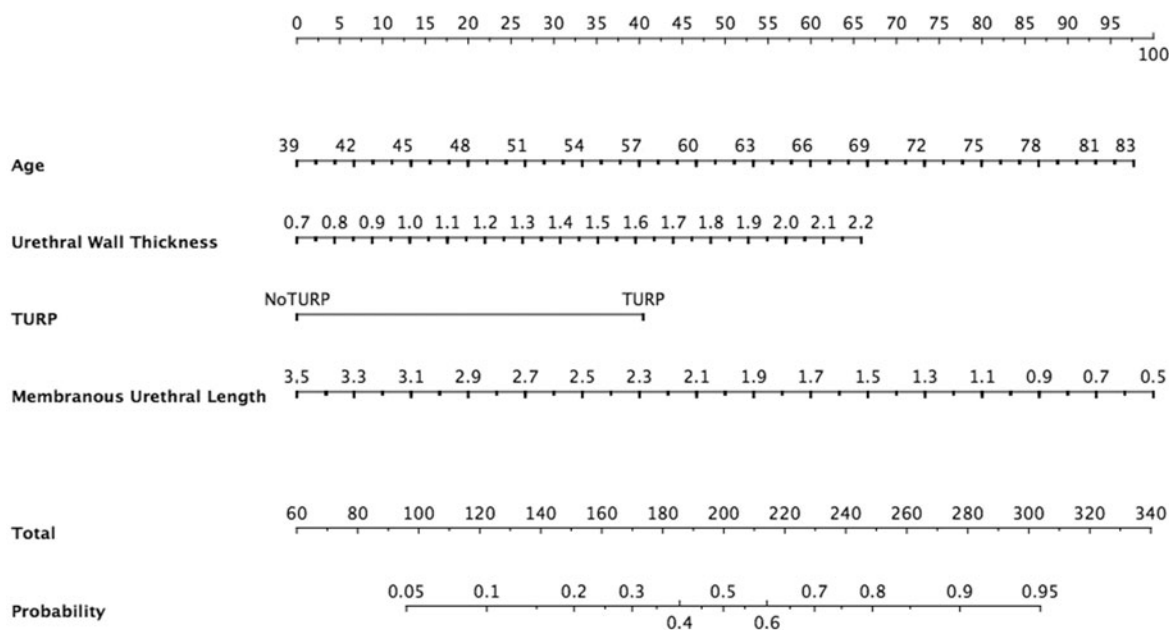


Figure 3. CUN-nomogram. Variables have a value that should be searched in each horizontal line. For each value, a score out of 100 is given in the upper horizontal line. We have to combine the scores and search the result in total score line, after drawing a perpendicular line we obtain probability.

independently influential in the present work [4]. MUL is a well-known risk factor, more urethral length, less chance of UI, as Hakimi [26], Paparel [27] and Jeong's [28] reported.

Obturator internus muscle shows in our analysis influence over UI. Only Baba et al. found a relation with UI. They performed anterior approach for total hip arthroplasty and this approach increased tension of the OIM by improving external rotation contracture of the hip joint and leg length, which could also increase and improve UI [29]. Because of this, a term not reported before and we found a relation with age we decide to exclude this measure.

Urethral wall thickness was measured in axial sequences before entering in the prostate and in its wider part [4]. Thus, a narrower urethral wall imply better UI outcome. In this case, although is another term not reported before, we found it very interesting, influential and free of interactions.

Prostate volume is other factor very discussed [2]. In our series analysis shows influence and we blamed for a wide range of prostate sizes.

A standardization of methods to measure through MRI seems necessary as well, due to the possibilities of measure and differences we found in the literature.

Other predictive models have been developed, although according to O'Callaghan et al. [30] only two tools to predict incontinence. We have to remark four articles, one from Von Bodman published in 2012 found MUL, urethral volume and an anatomically close relation between the levator muscle and membranous urethra were independent predictors of continence, in 2015 Matsushita and von Bodman in 2015 reported a model including age, BMI, ASA score and MUL. Other nomogram was published by Jeong et al. with an accuracy of 71% and variables age, MUL, robot-assisted RP, NST and PV as influential on the recovery of continence [28,31,32]. Barnoiu et al. found age-adjusted Charlson comorbidity index, International Index of Erectile Function-5, PV, NST and 24-h urine loss at one month, with an extremely high accuracy: 92.8%, only including 244 patients [33].

The limitations of our study start with a single center and retrospective analysis, most analysis are like our, being necessary multicenter and prospective analysis. Some variables could be subject to debate: NST, which is not as influential as expected and the way be collected is not free of bias; it is though that surgical approach may have influence, although there is no solid evidence, and include both approach in the analysis is a reflection of reality of some centers; our series match with other centers were RRP was implemented,

and LRP was introduced and both techniques are performed.

We drew a nomogram in order to enhance the comprehension and strength of each variable in the predictive model, the aim of this tool should be to apply it in daily practice, which require first an external validation. Finally the use of MRI is not extended in all institutions.

In conclusion, UI after radical prostatectomy have different prevalence depending on the definition. Age, prior TURP, membranous urethral length and urethral wall thickness were identified as risk factor in our series. Further studies should investigate these factors to apply in daily clinical practice and give more information and recommendation to patients.

Disclosure statement

No potential conflict of interest was reported by the authors.

ORCID

Antonio Tienza  <http://orcid.org/0000-0003-0183-5598>

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