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# Urinary continence after radical prostatectomy: the patient perspective

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**Introduction:** To compare the commonly used 0-1 pad definition of urinary continence for postoperative functional outcome after radical prostatectomy and the correlation with self-reported urinary continence and to determine whether a patient questionnaire can deliver more accurate continence status rates.

**Material and methods:** We evaluated a cohort of 873 men who underwent radical prostatectomy (RP) at the General Hospital in Vienna between 1998 and 2006. Patients were surveyed with a questionnaire regarding their postoperative outcome and postoperative urinary incontinence. Baseline and pathological factors were examined to determine whether or not they had an impact on the continence status.

**Results and limitations:** A total of 65.2% of men ( $n = 337$ ) reported themselves to be continent, in contrast 85.1% were continent if the pad definition was applied. Of those using no

pads, 93.4% considered themselves continent, while 24.5% of patients using one pad/day did. Overall, 86.5%, 9.8% and 3.7% of continent patients regained continence within 6 months, 6 to 12 months and after 1 year of RP, respectively. A total of 71.5% of men under 65 years old reported full urinary continence, while only 57.0% of men older than 65 considered themselves continent. Men < 65 years recovered full urinary control significantly faster than men older than 65 years- 3.6 versus 4.7 months. Neurovascular bundle resection has a negative effect on continence.

**Conclusions:** The ultimate continence status should be measured with self-administered disease specific questionnaires at 24 months after RP, as it differs from standard physician reported methods. Age and neurovascular bundle resection are variables affecting continence.

We believe that patients' subjective reports of their continence are crucial and that multiple outcomes should be objectively measured. Therefore we suggest that validated questionnaires dealing with the patients' perspective postoperatively should be included in routine follow up.

**Key Words:** continence rate, radical prostatectomy, prostate cancer, urinary continence, self-reported

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## Introduction

Prostate cancer is the most common malignant tumor in men in industrialized countries with almost 240,890 new cases diagnosed in the United States in 2011, with almost 33,720 deaths.<sup>1,2</sup> Radical prostatectomy (RP) in localized prostate cancer is currently the most commonly used and paramount curative therapy modality, the most feared adverse effects of the operation are erectile

dysfunction and urinary incontinence.<sup>3,4</sup> Studies report complete erectile dysfunction in 26% to 100% of cases; stress urinary incontinence is reported in 2.5% to 87% of cases following RP.<sup>5,6</sup> Both potential side effects are critical determinants of postoperative health related quality of life (HRQoL).

The main causes of urinary leakage are external sphincter insufficiency, detrusor overactivity and decreased bladder compliance. Sphincter insufficiency is shown to be responsible, either alone or in combination with other causes, for approximately 88% of cases.<sup>7</sup> Several modification to the standard anatomical procedure have been evaluated to minimize urinary leakage; including preservation of the bladder neck,<sup>3</sup> preservation of the neurovascular bundles<sup>8</sup> and other adaptations.<sup>9,10</sup>

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Accurate assessment of continence rates is important to provide patients with realistic expectations regarding ultimate continence status, and surgeons with a measure of performance. There exists no consensus regarding the optimal criteria for assessing continence and studies have shown that the method of data collection causes significant differences in reported continence rates.<sup>11</sup> It seems that patients seek to minimize adverse outcomes when discussing them with the surgeon<sup>12</sup> and patient reported rates often indicate a lower continence rate than physician reported outcomes raising concerns that urologists may underestimate the severity of patient symptoms.<sup>13</sup> Some analyses have used validated instruments that are self-administered to minimize potential bias and address HRQoL issues.<sup>14,15</sup> Currently the most validated questionnaires available are the EPIC<sup>16</sup> and SF36- UCLA- PCI<sup>17</sup> questionnaires which give an objective insight into postoperative functional outcome. Due to our retrospective study design we intended to create a validated short and comprehensive questionnaire, to be able to focus on the patient perspective of functional outcome after radical prostatectomy. The questionnaire unites only the most important questions regarding urinary incontinence if applied in a retrospective study design. Ultimately, continence rates depend on how these responses are interpreted. Our primary goal was to identify the gap between the patients perspective of urinary continence following radical prostatectomy and a commonly used definition of urinary continence including one security pad per day regardless of the amount of urine lost during the day.

## Materials and methods

### *Lack of standard definition*

The range of continence rates reported has been attributed to a lack of one standard definition.<sup>11</sup> Continence status is usually defined with regard to absorbent pad usage or degree of urinary leakage, continence by the pad definition is reported as 0-1 pad in a 24h period.<sup>18</sup> Various definitions for urinary continence are being used in literature currently. Some authors define urinary continence as socially continence, which means that they include some sort of security pad per day into the definition<sup>10,19</sup> others tried to establish a leak free and pad free definition.<sup>20</sup>

We attempted to characterize the return of urinary continence after RP and to quantify the appropriate terms for defining continence. Our analysis specifically focuses on the discrepancy between the patient's point of view regarding urinary continence and the 0-1 pad definition of full continence.

### *Materials*

Our study was approved by the Austrian Ethics Commission, and presents the results from a survey administered to a cohort of 873 men who underwent RP from 1998 to 2006 at the General Hospital of Vienna. We generated a questionnaire, which was validated with a cohort of 120 healthy men. Questionnaire recipients received a letter of introduction and explanation of the study from the research team stating that responses were confidential and anonymous, and no surgeons were involved in data collection or analysis, allowing for candid responses. Patient responses to our survey items were collected by a data manager at our institution, who performed his tasks independent of the operating surgeons. Due to the retrospective study design questionnaires were being sent to the patients from 2008-2009. During that time data acquisition took place. To assess the patients view on his personal postoperative urinary status we used a question capturing the overall self-assessed continence according to Lepor and Kaci ("Do you consider yourself continent?": yes or no).<sup>15</sup>

We sought to compare two different definitions: the definitions of occasional dribbling or 0-1 pads during a 24 hour period versus an answer of "yes" to the question "Do you consider yourself continent?" Additionally, the patient's history was examined and pathohistological data as well as other figures were collected for all patients from 1998 to 2006. Baseline and pathological factors were examined to determine if they had any impact on the continence status using statistical analyses. Clinical and pathological stages were reported according to the 2002 TNM System. Logistic regression, the t test and Pearson's chi square test were used to compare the variables. Statistical significance was set at  $p < 0.05$ . All statistical analysis was done with Statistical Package for the Social Sciences (SPSS 16.0).

## Results

Baseline characteristics of the 873 contacted men are shown in Table 1. A total of 517 (71.6%) questionnaires were fully completed and returned, Table 2. Of these, 65.2% of men ( $n = 337$ ) answered the question: Do you consider yourself continent, with "yes" and 34.8% ( $n = 180$ ) stated that they did not consider themselves continent. When the common continence definition (0-1 pad/day) was applied, the percentage of continent patients rose to 85.1%. The difference in these values representing patients' feeling regarding urinary leakage and the commonly used definition of urinary continence are statistically significant ( $p < 0.01$ ), Figure 1. The difference between the two definitions of urinary continence used is also displayed in the continence

TABLE 1. Prostate cancer characteristics at diagnosis of men representing the study 1998-2006 (n = 873)

Diagnostic indicators	n	%
<b>Clinical stage (TNM 2002)</b>		
T1ab	3	0.3
T2a	112	12.8
T2b	226	25.9
T2c	205	23.5
T3a	192	22.0
T3b	70	8.0
T3c	3	0.3
T4	37	4.2
not defined	25	2.9
<b>PSA (ng/mL)</b>		
≤ 4	157	18.0
> 4 and < 10	423	48.5
≥ 10 and < 20	151	17.3
≥ 20	77	8.8
PSA not available	65	7.4
<b>Prostate specimen Gleason sum score</b>		
≤ 6	365	41.8
7	330	37.8
8 to 10	155	17.8
Gleason not available	23	2.6

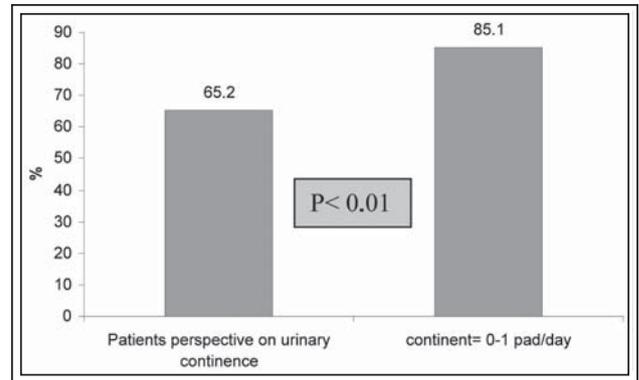


Figure 1. Urinary continence definitions (24 months post RPE).

rate after catheter removal, Table 3, and at 12 months postoperatively, Table 4: 10.5% versus 29.7% and 60.5% versus 73.8% respectively.

Average patients BMI was 26.5 (SD 3.2), further analysis showed no statistical significant correlation between BMI and urinary continence: continence was reported in 66.80%, 64.91%, 62.50% ( $p > 0.05$ ) and stress urinary incontinence after surgery was observed in 66.47%, 60.38% and 62.50% ( $p > 0.05$ ) in the groups of patients with a BMI of 18-25, 25-30 and  $> 30$ , respectively.

TABLE 2. Overview of the study

Population (1998-2006)	873
Questionnaires returned as undeliverable	151 (17.3%)
Patients who received questionnaire	722 (82.7%)
Returned questionnaires	517 (71.6% of received questionnaires)
Age at the time of survey	70.8 years (range 46.2-91.2)
<b>Questionnaire sent to patients:</b>	
(1) Did you have urinary leakage problems before RPE?	
a. yes	b. no
(2) Do you consider yourself continent?	
a. yes	b. no
(3) After the operation, when did you reach your final continence status (months)?	
a. never	b. ____ months
(4) How many pads/day did you need to help deal with urinary leakage...	
a. immediately after RPE (at the time of catheter displacement)?: ____	
(5) How many pads/day did you need to help deal with urinary leakage...	
a. after 1 year postoperatively?: ____	
(6) Do you drip urine while coughing, jogging, lifting heavy things, or on other occasions after RPE- stress urinary incontinence?	
a. no	b. yes

TABLE 3. Continence rate after catheter removal

	Urinary continent	%	Urinary incontinent	%	Patients data available
Patients answer	50	10.5	425	89.5	475
Pad definition	141	29.7	333	70.3	474

TABLE 4. Twelve months continence rates

	Urinary continent	%	Urinary incontinent	%	Patients data available
Patients answer	300	60.5	196	39.5	496
Pad definition	350	73.8	124	26.2	474

Figure 2 shows overall continence rates. The most significant difference between pad definition and patient's definition was found in 2005: 44.4% considered themselves continent whereas the pad definition would consider 86.2% continent.

We found additional differences within the 0-1 pad/day definition; 93.4% of patients using no pad considered themselves as fully continent, while only 24.5% of those using one pad considered themselves continent. This shows a variance even within the commonly accepted definition of social continence. In the group of patients that were using two pads per day, 92.7% stated to have problems with urinary leakage, Figure 3.

Of those patients who considered themselves continent, 61.8% were continent within the first 3 months after RP and 24.8% reached continence within 3 to 6 months. In other words 86.5% of those who considered themselves continent regained continence

within 6 months of RP, 9.8% within 6 to 12 months and 3.7% after 1 year, Figure 4. Furthermore, 337 (64.2%) patients who underwent RP reported stress urinary incontinence at the time of the survey, while only 24 (4.6%) patients declared that they were already incontinent before RP was performed.

It is also interesting to note that 6.6% of pad free patients did not consider themselves continent, while

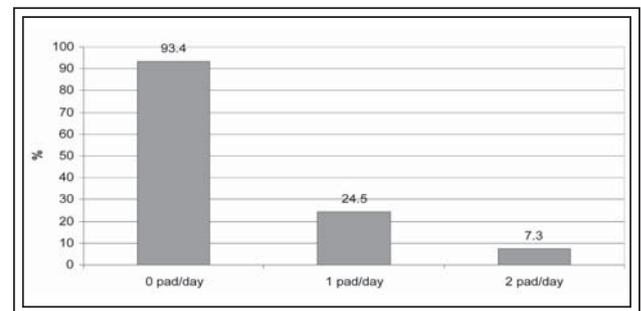


Figure 3. Pad use and patient's definition of continence (24 months post RPE).

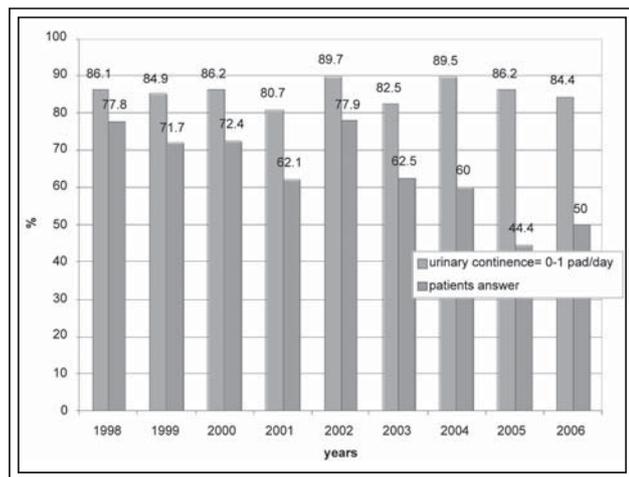


Figure 2. Continence rates.

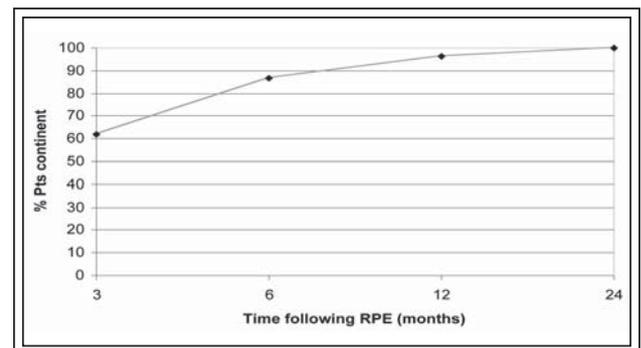


Figure 4. Time trend of continence based on pad requirement.

7.3% using two pads/day did. This could be a reflection of the patients' understanding of the terminology or more likely patients' perception of bothersomeness.

Subanalysis showed that patients younger than 65 years reported better urinary continence than those over 65 years. A total of 71.5% of men under 65 reported themselves continent, while only 57.0% of men over 65 reported themselves as such ( $p < 0.01$ ), Table 5. Younger men additionally reported continence almost a full month earlier ( $p < 0.01$ ), patients under 65 required a mean of 3.6 months to regain full urinary continence whereas the cohort of patients older than 65 years regained urinary control after 4.7 months ( $p < 0.01$ ), Table 5.

Tumor stage did not seem to affect continence; no statistically significant difference was reported ( $p > 0.05$ ). 86.1% and 84.3% of patients with  $\leq T2$  and  $\geq T3$  disease, respectively, reported to be continent when the 0-1 pad/day continence definition was used, Table 5.

Bundle preservation goes along with improved postoperative outcome; 66.8%, 53.8% and 31.4% of patients who underwent bilateral, unilateral and no nerve sparing surgery, respectively, reported to be continent. These results show that if bilateral neurovascular bundle preservation was performed, a higher postoperative continence rate was observed, this was statistically significant ( $p < 0.01$ ), Table 5.

TABLE 5. Study results

<b>Continence recovery in months</b>		
Age < 65	3.7 months	n = 223
Age $\geq$ 65	4.6 months	n = 104
	$p < 0.01$	
<b>Urinary continence and T stage (based on pad definition)</b>		
Age < 65	86.00%	n = 329
Age $\geq$ 65	84.50%	n = 187
	$p > 0.05$	
<b>Urinary continence and nerve sparing (based on patients self evaluation)</b>		
Bilateral	66.80%	n = 217
Unilateral	53.80%	n = 52
No nerve sparing	31.40%	n = 153
	$p < 0.01$	
<b>Age and urinary continence (based on patients self evaluation)</b>		
Age < 65	Age $\geq$ 65	
Urinary continence	28.7 (n = 98)	45.3 (n = 92)
Urinary incontinence	71.3 (n = 244)	54.7 (n = 111)
	$p < 0.01$	

## Discussion

Based on a large patient cohort, the study offers several clinical advantages; the large population size, questionnaire method, high response rate and the evaluation of both pad definition and patients answer. The biggest virtue of our study is, that we focused on the patients' perspective exclusively. Therefore the data reflects the daily reality of patients following RP. Nevertheless the results must be considered within the context of their limitations because of the retrospective design of the study.

The most significant finding of the study was the statistically significant difference between the continence rate reported by patients themselves and the standard pad definition. Several studies have reported much higher urinary dysfunction rates when self administered questionnaires are used in comparison to functional outcome rates assessed by surgeons.<sup>21</sup> Studies using self administered questionnaires regarding urinary continence report continence rates between 53% and 78%.<sup>22</sup> When questioned about their continence, 65.2% of men rated themselves as continent, overall rates were given as 93.4%, 24.5% and 7.3% using 0, 1 and 2 pads/day, respectively. The 0-1 pad/day definition would have rated a much higher percentage as continent; 85.1%. 0 pads per day clearly identifies those men who do not have any problem with urinary leakage (93.4%). However, our data shows quite clearly that even if one pad per day is used almost three quarters of the questioned population has the feeling of being incontinent. This shows clearly the discrepancy between the patients' perspective and the pad definition of urinary continence. The pad definition may underestimate the loss of quality of life after undergoing radical prostatectomy. Therefore a better follow up of patients with validated questionnaires should be done in order to have an insight into the own functional outcomes after surgery and to give patients adequate answers to their questions. The problem with the pad definition is that it does not differentiate between patients who need a security pad for occasional loss of urine drops and patients who really need the pad in order to prevent soaking of their pants due to mild or moderate stress incontinence.

Liss et al<sup>23</sup> evaluated the association of pad status and urinary quality of life. They could clearly demonstrate a significant loss in quality of life between no pads and the commonly used 0-1 pad definition for urinary continence. Therefore the authors concluded that urinary continence should be strictly defined as 0 pads per day. Therefore currently most authors tend to refer

to urinary continence following radical prostatectomy as a pad free state.<sup>20,24,25</sup> Patel et al reported on their experience with urinary continence following robotic assisted radical prostatectomy. Their definition of urinary continence was “no use of an absorbent pad”. Continence rates of 89%, 95% and 97% were reported at 3, 6 and 12 months respectively.<sup>26</sup> However it has to be stated that an “absorbent pad” was not clearly defined. On the other side there are more inclusive definitions for urinary continence used. Menon et al<sup>19</sup> published data of one of the largest robotic assisted radical prostatectomy series of over 1100 patients. Continence rates were as high as 95.2% with the so called socially continence definition including one security pad per day.<sup>19</sup> Tewari et al<sup>10</sup> showed similar results using a continence definition of “no pad usage or one small liner for security purposes only”. Continence rates ranged from 83%-97% at 52 weeks postoperatively depending on the technique of vesicourethral reconstruction favoring total reconstruction of the vesicourethral anastomosis.<sup>10</sup> A strict leak free and pad free definition like Reynolds et al<sup>20</sup> used it presents a valid method to prevent potential misunderstandings which are caused because of the so called “security pad”. The biggest issue is to identify those patients who use the security pad for occasional dribbling and those who really need it because of their mild or moderate stress incontinence. All in all a more inclusive definition of urinary continence underestimates the patients’ state. This is clearly shown by the discrepancy of 20% between the patients’ point of view (65.2%) and the pad definition (85.1%).

Kielb et al<sup>18</sup> showed that requiring  $\geq 2$  pads/day clearly identifies the group of patients seriously affected in their HRQoL, however in contrast, Glickman et al<sup>27</sup> advocate that men who use a single pad or experience “occasional or frequent dribbling of urine” after RP consider themselves as continent. Our data suggests that even a significant proportion of men using 1 pad per day are affected in their HRQoL. Especially in the last years of our data acquisition, significant differences between the definitions could be observed, possibly due to greater enlightenment and expectancy of patients. Patients are more knowledgeable about surgery as well as medical advances, and expect the best functional outcomes. In line, expectations of future health states have been shown to at least partially influence patient-reported HRQoL. Schroek et al<sup>28</sup> revealed that poor general health in addition to bother from urinary and sexual dysfunctions have been found to be independent predictors for regret after primary treatment. It follows that men may increasingly report themselves as incontinent, despite being deemed continent by the pad definition.

Who therefore should be considered continent? According to our study we cannot support the contention that men wearing a single pad per day can overall be considered continent. Reynolds et al<sup>20</sup> recently published their data on strict “leak free and pad free” continence following robot-assisted radical prostatectomy. The conclusion of this study is similar to our findings. The authors showed clearly that if a strict definition of urinary continence is applied, it results in a more conservative postoperative functional outcome. According to their “leak free and pad free” definition only 28% of patients were continent at 24 months post operatively.<sup>20</sup> In accordance, we believe that patients’ subjective report of their continence is crucial and that multiple outcomes should be objectively measured.

Our data shows clearly that regaining urinary continence is a time dependent process and that the majority of men ultimately regain continence. The vast majority of continent patients regained full urinary control within 6 months after surgery (61.8%); 96.3% of all continent patients at the time of the survey reached full urinary control at 12 months, and a meaningful proportion (3.7%) regained full urinary control between 12 and 24 months. Based on pad requirements, a similar finding of 6.4% was reported by Lepor and Kaci.<sup>15</sup> According to the results of the present study and the conclusions of other analyses, we believe that final continence status should be measured at 24 months after RP as well as delaying invasive treatment for moderate incontinence until 24 months after RP. However Glickman et al<sup>27</sup> stated in their study that they observed clinically significant improvements in urinary control and erectile function beyond 2 years after RP. Therefore this group of authors concluded that it should not be counseled that maximum urinary continence or erectile function are achieved by 24 months post surgery.

An interesting approach to predict the duration of urinary incontinence after RP comes from Van Poppel et al.<sup>29</sup> This group of authors showed that the amount of urine loss during the first day after catheter withdrawal was a valid predictor of the duration of urinary incontinence. Results showed that the average time to regain urinary continence was 8, 16, 29, 29 and 70 days in men who lost 2 to 50, 51 to 100, 101 to 200, 201 to 500 and more than 500 gm urine, respectively on day one after catheter removal. Therefore measurement of urine loss or pad weight would be a good option to use to be able to predict patients’ future functional outcome.

An effort was made to identify factors that predict early continence recovery, which was defined at 3 months.<sup>24,30</sup> Our statistical analysis showed that neither baseline PSA, Gleason score, tumor stage nor BMI

predicted early continence status, only age and nerve sparing procedure were found to be predictors.

A remarkable finding by Stanford et al<sup>31</sup> was that men less than 60 years old were significantly less likely to be incontinent at 2 years follow up than older men. Our data showed that 71.5% of patients less than 65 years old and only 57% of patients older than 65 years considered themselves as continent. Recently Novara et al<sup>32</sup> published similar results to our findings regarding a correlation between age and urinary continence. While the pathophysiology of this finding remains poorly understood, there are probably several age-related factors that affect urethral and detrusor function such as decreased urethral coaptation, increased detrusor instability and delayed wound healing.

Other studies have shown similar results to our findings regarding urinary continence status and neurovascular bundle preservation. Burkhard et al<sup>33</sup> showed clearly that the incidence of urinary continence correlates with the extent of neurovascular bundle preservation.

The conclusions of this study must be considered in the context of its limitations. Data was retrospectively gathered; a prospective trial would give more consistent results as well as pad weight would lead to a more objective interpretation of data. Due to the retrospective design no prospective data acquisition was possible. The timing of the administration of the questionnaire can be seen as a controversial subject. The questionnaires were sent to the patients 2-8 years postoperatively. Nevertheless we feel that the quintessence of the study is clear. The patient's perspective differs from the more inclusive pad definition of urinary continence.

A further weak point of our study is that we did not use the most common validated questionnaires (EPIC, SF36-UCLA-PCI) to get information about postoperative functional outcome. We worked with a self-generated questionnaire, because we wanted to focus on the most relevant questions and create a short and comprehensive questionnaire in order to secure the collaboration of patients. The validation of our questionnaire was not published in a peer reviewed journal which definitely limits the validity of our results. Nevertheless, we feel that the present study gives a good insight in the reality of patients after RP.

## Conclusion

Urinary continence reports based on pad definition are underestimating urinary incontinence. Our study found that there is a statistically significant difference between the continence rate reported by patients themselves (65.2%) and the more inclusive

pad definition (85.1%). According to our findings we cannot support the contention that men wearing a single pad per day can basically be considered continent. As already mentioned patients who wear one pad per day are a heterogeneous group. On the one hand we have patients losing occasionally some drops of urine, on the other hand we have those patients who really need the pad because of their mild or moderate stress incontinence. Future prospective trials focusing on the differentiation of these groups of patients are necessary. In line, we believe that patients' subjective reports of their continence are crucial and that multiple outcomes should be objectively measured. This is necessary to be able to give adequate answers to patients' questions before they undergo RP. Therefore we suggest that validated questionnaires, such as EPIC and SF36-UCLA-PCI dealing with the patients' perspective postoperatively should be included in routine follow up. □

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