Patient-Reported Outcome Measures compared to Clinician Reported Outcomes regarding incontinence and erectile dysfunction in localized prostate carcinoma after Robot Assisted Radical Prostatectomy: impact on management

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Research Article

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Abstract

Purpose/ Background: To examine whether a discrepancy between patient reported outcomes (PROs) and clinician reported outcomes (CROs) impacts the management of urinary incontinence (UI) and erectile dysfunction (ED) after robot assisted radical prostatectomy (RARP).

Methods: Up to 1 year after RARP, UI and ED recovery of 312 men with localized and locally advanced prostate cancer were assessed using the International Consultation Incontinence Questionnaire Short Form (ICIQ-SF) and the International Index of Erectile Function (IIEF-EF) and CROs by interview. Discrepancies between PROs and CROs were studied in light of treatment offered and management.

Results: The ICIQ-SF Score matched with CROs in all sum score categories except in ICIQ sum score 6-12; here the UI was underreported by clinicians in 58% and 59% of patients at 8 and 12 months ($p<.001$). Furthermore, at 8 and 12 months postoperatively, clinicians underreported UI in 29% and 23% of patients with ICIQ score 13-18 ($p<.001$). The clinician significantly over-reported the recovery of erectile function ("normal erection") ($p<.001$), especially in men with IIEF-EF sum score 6-16. Independently of ICIQ-SF/IIEF-EF scores, discrepancy between PROs and CROs did not affect rate of health care offered to patients.

Conclusions: This is to our knowledge the first study that compared the PROs with clinician reported functional outcomes and the impact of discrepancies on the management of side effects of RARP in prostate cancer. Observed discrepancies between the PROs and CROs did not affect offered management and counseling of UI and ED.

Introduction

Robot-Assisted Radical Prostatectomy (RARP) is one of the treatment options for patients with localized prostate cancer. The most bothersome side effects of RARP are urinary incontinence (UI) and erectile dysfunction (ED). Identification of cancer recurrence and side effect monitoring by clinicians are the basis for prostate cancer follow-up care. Nowadays, it is common practice to include patient-reported outcomes (PROs) in routine clinical follow-up (FU) to monitor the side effects of treatments from patient’s perspective.

Patient-Reported Outcome Measures (PROMs) are well known in uro-oncology and are widely used to evaluate and compare the side effects between the different treatments in localized prostate cancer. Clinicians acknowledge that the use of PROMs in clinical practice is useful for FU after treatment of prostate cancer but the results of the PROMs are rarely taken into account during the consultation with the clinician.

The importance of using PROMs in clinical FU has been demonstrated before as it improves the communication between clinicians and patients as well as patients’ satisfaction. There is empirical evidence that clinicians underreport patients’ symptoms which could result in under-recognition and undertreatment of these symptoms.
The primary aim of this study was to compare PROs and Clinician Reported Outcomes (CROs) concerning urinary continence and erectile function after RARP. Secondarily, we hypothesized that clinicians would underestimate UI and ED compared to PROs and that this may impact the management of UI and ED, which could potentially lead to undertreatment of these common side effects.

Methods

1.1 Study population

Between August 2016 and January 2020, men were prospectively enrolled in a cohort study at the Netherlands Cancer Institute (NCI). All men had a localized or locally advanced prostate cancer and underwent primary or salvage RARP with or without lymph node dissection. Only patients with at least 1 year FU and available PROs and CROs were included. The institutional review board of the NCI approved the study (IRBd20-368).

1.2 Data

The following data were collected from the institutional database: age at the time of first consultation, body mass index (BMI), pre-operative prostate-specific membrane antigen (PSA) level, clinical tumor (cT) stage, pathological tumor (pT) stage, pathological nodal (pN) stage, postoperative Gleason score, preoperative comorbidity status as assessed by the Charlson index, and marital status. The patient files were evaluated for clinicians’ advice on additional treatment (medication / physiotherapy) for UI and ED.

1.3. Outcome assessment

The primary outcome was to compare the PROs with CROs.

PROs:

We sent questionnaires to patients preoperatively, at 6 and 12 months after RARP. The PRO assessment of recovery of continence was done with the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short form (ICIQ-SF) in order to evaluate the severity of urinary incontinence. The answers from ICIQ-SF resulted in a sum score, with a minimum score of 0, and a maximum score of 21. To assess the severity of UI the ICIQ-SF total scores (questions 1-3) were recoded into four levels of incontinence: slight (1-5), moderate (6-12), severe (13-18), and very severe (19-21).

The erectile function (EF) was assessed using the International Index of Erectile Function (IIEF) questionnaire. The answers from the erectile function domain of the IIEF (IIEF-EF) resulted in a score between 1-30 and were categorized as: no ED (26-30), mild ED (22-25), mild to moderate ED (17-21), moderate ED (11-16) and severe ED (1-10).

CROs:
CROs were obtained during the 8 and 12 months postoperative consultations. The clinician prescribed medicine or referred patients to manage postoperative symptoms. CROs obtained at 8 and 12 months were compared with PROs at 6 and 12 months postoperatively, respectively.

During FU visits the patients were asked if they had any involuntary loss of urine. The answer was noted as: “continence”, “drops”, “use of 1 diaper a day” or “use of more than 1 diaper a day”. At the time of consultation with the clinician, the patient was interviewed about the status of EF. The answer was noted as: “normal EF”, “weak EF”, “no EF”, use of phosphodiesterase type 5 inhibitor (PDE-5i)”, “use of intracavernosal injection (ICI)”. The clinician proposed help for UI and ED and it was defined as: “help not needed by patients”, “referring/prescription”. When the clinician did not proposed help, it was noted as: “help not offered by clinician”. The extent of per-operative nerve sparing was obtained using the Fascia Preservation (FP) Score\textsuperscript{13} and ranged from 0 to 12.

1.3 Statistics

Data were summarized by frequency and percentage for categorical variables and mean (standard deviation) for continuous variables.

Descriptive analysis was performed for CROs collected at 8 and 12 months postoperative and for PROs at 6 and 12 months postoperative.

CROs and PROs about side effects of RARP were correlated with medical treatment or referral for sexual counseling/pelvic floor exercises proposed (or not) by clinician.

We dichotomized the ICIQ-SF score in 0-5 (continence, loss of urinary drops) and >5 (moderate, severe, very severe urinary incontinence) and the IIEF-EF score in 1-16 (no erection, ED) and 17-30 (normal EF). Data of the clinician reports were dichotomized for urinary continence (continence/drops versus incontinence (use of layers)) and for erectile function (erection=normal erection/and weak erection versus erectile dysfunction=no erection, use of PDE-5i or ICI).

We analyzed the discrepancy between PROs and CROs by dividing patients in agreement and disagreement groups. Agreement for continence/incontinence was defined as ICIQ-SF 0-5 and continence to use of 1 safety pad or ICIQ-SF 6-21 and use of 1 or more pads, while disagreement was defined as ICIQ 0-5 and use of 1 or more pads / ICIQ 6-21 and 0-1 safety pad. Agreement for erection/ED was defined as IIEF-EF 17-30 and erection or IIEF-EF 0-16 and ED, while disagreement was defined as IIEF-EF 17-30 and ED/ IIEF-EF 1-16 and erection.

All statistical tests were two-sided, and discrepancies were considered statistically significant with p-values \( \leq 0.05 \). Statistical analysis was carried out with IBM SPSS Statistics V27.0 (SPSS INC., Chicago, Ill).

Results
2.1 Patients characteristics

Data were available for 312 patients. Most patients had cT1-2 (87%) and pT2 (53%) stage prostate cancer. Patients’ characteristics are presented in Table 1.
Table 1
Patients characteristics (n = 312)

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>n (%) or mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years at the time of first consultation (mean; SD)</td>
<td>66.10 (6.5)</td>
</tr>
<tr>
<td>BMI (mean; SD)</td>
<td>26 (3.27)</td>
</tr>
<tr>
<td>Charlson Index</td>
<td></td>
</tr>
<tr>
<td>≤ 2</td>
<td>138 (44)</td>
</tr>
<tr>
<td>between 3–4</td>
<td>145 (47)</td>
</tr>
<tr>
<td>≥ 5</td>
<td>29 (9)</td>
</tr>
<tr>
<td>PSA in ng/l (mean; SD)</td>
<td>11.6 (16.80)</td>
</tr>
<tr>
<td>cT status</td>
<td></td>
</tr>
<tr>
<td>cT1</td>
<td>115 (37)</td>
</tr>
<tr>
<td>cT2</td>
<td>155 (50)</td>
</tr>
<tr>
<td>cT3</td>
<td>41 (13)</td>
</tr>
<tr>
<td>cT4</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>pT status</td>
<td></td>
</tr>
<tr>
<td>pT2</td>
<td>166 (53)</td>
</tr>
<tr>
<td>pT3a</td>
<td>87 (28)</td>
</tr>
<tr>
<td>pT3b</td>
<td>57 (18)</td>
</tr>
<tr>
<td>pT4</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>pN status</td>
<td></td>
</tr>
<tr>
<td>pNx</td>
<td>121 (39)</td>
</tr>
<tr>
<td>pN0</td>
<td>138 (44)</td>
</tr>
<tr>
<td>pN1</td>
<td>52 (17)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Postoperative Gleason score</td>
<td></td>
</tr>
</tbody>
</table>

Note: BMI = body mass index, cT = clinical tumor status, FP-score = Fascia Preservation Score, pN = pathological nodal status, pT = pathological tumor status
### Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>21 (7)</th>
<th>242 (78)</th>
<th>18 (6)</th>
<th>20 (6)</th>
<th>2 (0.6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td></td>
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<td>9</td>
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<td>10</td>
<td></td>
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</table>

### FP-Score

<table>
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<tr>
<th>Score</th>
<th>194 (62)</th>
<th>118 (38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6–12</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marital status

<table>
<thead>
<tr>
<th>Marital Status</th>
<th>280 (90)</th>
<th>32 (10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No partner</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: BMI = body mass index, cT = clinical tumor status, FP-score = Fascia Preservation Score, pN = pathological nodal status, pT = pathological tumor status

### 2.2 PROs

At 6 months postoperative, 85% (n = 265/312) and 74% (n = 232/312) of patients answered the ICIQ-SF and IIEF-EF, respectively. ICIQ-SF Score was 0–5 and 6–21 in 54% (n = 144/265) and 46% (n = 121/265) of patients, respectively. In total, 95% of patients (n = 221/232) patients had an IIEF-EF score 0–16 and 5% (n = 11/232) had an IIEF-EF Score 17–30.

At 12 months, ICIQ-SF was available in all patients and 89% of patients (n = 277/312) completed the IIEF-EF. ICIQ-SF Score was 0–5 and 6–21 in 66% (n = 205/312) and 34% of patients (n = 107/312) respectively. In total 35 (11%) did not complete the IIEF-EF. IIEF-EF score was 1–16 in 258 (93%) patients and 17–30 in 19 (7%) patients.

### 2.3 CROs

At 8 months postoperatively, CROs about continence status was missing in 5% of patients (n = 18/312). Clinician reported urinary continence/ loss of urinary droplets in 75% of patients (n = 221/294) and use of ≥ 1 pads daily in 25% (n = 73/294). Clinician did not ask for EF in 10% of patients (n = 32/312). The majority of patients had no erection (67%; n = 188/280), 15% (n = 42/280) had normal/weak EF and 20% (n = 57/280) used PDE-5i or ICI for ED.
CROs were available in all patients at 12 months. Clinician did not ask for continence status and for EF in 3% (n = 10/312) and 10% (n = 32/312) of patients respectively. Clinicians reported urinary continence/loss of urinary droplets in 80% (n = 243/302) of patients and use of ≥ 1 pads daily in 19% (n = 57/302). According CRO, 63% (n = 177/280) of patients did not have erection, 20% (n = 55/280) had normal/weak EF and 17% (n = 48/280) used PDE-5i or ICI for ED.

2.4 Side effects after RARP: PROs versus CROs

2.4.1 Urinary continence

At 8 months (CRO) and 6 months (PRO) both data were available in 253 (81%) patients. As presented in Fig. 1, in patients with ICIQ-SF of 0–5 (n = 132) and 19–21 (n = 5), the CRO was in agreement. Discrepancies between PRO and CRO were mainly observed in patients in the intermediate categories of ICIQ-SF 6–12 and 13–18 scores. In those categories, the CRO appeared to vary from no pad to > 1 pads. At 12 months, the discrepancy between PRO and CRO was again observed in the group with ICIQ scores between 6–18. As shown in Fig. 1, the UI was significantly underestimated (p < .001) by the clinician in ICIQ-SF Scores 6–12 and 13–18 (in 58% and 59% of patients with ICIQ-Score 6–12 and in 29% and 23% of patients with ICIQ score 13–18 at 8 and 12 months respectively).

2.4.2 Erectile function

At 8 months (CRO) and 6 months (IIEF-EF) both data were available in 213 (68%) patients. As shown in Fig. 2, in all time points, IIEF-EF score 0–5 matched strongly (p < .001) with the CRO. Discrepancies between PRO and CRO was mainly observed in patients with IIEF-EF score 6–16. In these categories, the CRO varied to normal/weak erection, use of PDE-5i/ICI and no erection. The clinician significantly over-reported (p < .001) the recovery of EF (“normal erection”) especially in IIEF-EF score 6–16.

2.5 (Dis)agreement PROs/ CROs and symptoms management

At 8 and 12 months postoperatively, the consultation with clinician was performed after receiving the PROs in all patients and in 221 patients (71%) respectively.

2.5.1 (Dis)agreement and symptoms management at 6 months (PROs) and 8 months (CROs) postoperatively

As described in Table 2a, ICIQ-SF score of 0–5 was reported in 53% of patients (n = 132/250) and the majority of these patients (n = 129/132) did not need help for incontinence according to CRO. In total, 73% (n = 86/118) of patients with ICIQ-SF score 6–21 did not need help according to CRO and 18% (n = 21/118) accepted help. Independently of ICIQ-SF score and agreement/disagreement with clinician report, when help was needed by patients, they received it.
Table 2a
(dis)agreement urinary continence PROs versus CROs and help proposed

<table>
<thead>
<tr>
<th>Continen ce status</th>
<th>ICIQ-SF (PRO) Pad use (CRO)</th>
<th>No help offered</th>
<th>Help declined</th>
<th>Help accepted</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 months after RARP*</td>
<td>0–5 agreement 0–1 safety pad</td>
<td>1 (0.8%)</td>
<td>128 (98.5%)</td>
<td>1 (0.8%)</td>
<td>not computed</td>
</tr>
<tr>
<td></td>
<td>0–5 disagreement ≥ 1 pads</td>
<td>0 (-)</td>
<td>1 (50%)</td>
<td>1 (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6–21 agreement ≥ 1 pads</td>
<td>8 (13%)</td>
<td>34 (56%)</td>
<td>19 (31%)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td></td>
<td>6–21 disagreement 0–1 safety pad</td>
<td>3 (5.3%)</td>
<td>52 (91%)</td>
<td>2 (3.5%)</td>
<td></td>
</tr>
<tr>
<td>12 months after RARP</td>
<td>0–5 agreement 0–1 safety pad</td>
<td>0 (-)</td>
<td>190 (99%)</td>
<td>2 (1%)</td>
<td>not computed</td>
</tr>
<tr>
<td></td>
<td>0–5 disagreement ≥ 1 pads</td>
<td>0 (-)</td>
<td>6 (86%)</td>
<td>1 (14%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6–21 agreement ≥ 1 pads</td>
<td>1 (2%)</td>
<td>28 (56%)</td>
<td>21 (42%)</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td></td>
<td>6–21 disagreement 0–1 safety pad</td>
<td>3 (6%)</td>
<td>44 (86%)</td>
<td>4 (8%)</td>
<td></td>
</tr>
</tbody>
</table>

*PRO at 6 months and CROs at 8 months. Abbreviations: RARP: Robot Assisted Radical Prostatectomy. PRO: Patient Reported Outcomes. CRO: Clinician Reported Outcomes. ICIQ-SF: Urinary Incontinence Short form

Concerning the EF, as shown in Table 2b, 10 patients had an IIEF-EF score 17–30 (5%), all were offered help, and 3 accepted help. In total, 203 patients (95%) reported an IIEF score 1–16, of whom 181 (89%) were offered help. Of these, 112 (62%) patients actually accepted help. It did not matter whether the clinician had identified ED or not, whether patients accepted help. Regardless of agreement/disagreement, help was proposed by clinician and was often declined by patients (Table 2b).
Table 2b
(dis)agreement erectile function PROs versus CROs and help proposed

<table>
<thead>
<tr>
<th></th>
<th>IIEF-EF (PRO)</th>
<th>EF (CRO)</th>
<th>No help offered</th>
<th>Help declined</th>
<th>Help accepted</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Erectile status</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>8 months after RARP</strong>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17–30 agreement Erection</td>
<td></td>
<td>0 (-)</td>
<td>6 (67%)</td>
<td>3 (33%)</td>
<td></td>
<td>not computed</td>
</tr>
<tr>
<td>17–30 disagreement ED</td>
<td></td>
<td>0 (-)</td>
<td>1 (100%)</td>
<td>0 (-)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–16 agreement ED</td>
<td></td>
<td>19 (11%)</td>
<td>55 (32%)</td>
<td>99 (57%)</td>
<td>0.27</td>
<td></td>
</tr>
<tr>
<td>1–16 disagreement Erection</td>
<td></td>
<td>3 (10%)</td>
<td>14 (47%)</td>
<td>13 (43%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>12 months after RARP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17–30 agreement Erection</td>
<td></td>
<td>0 (-)</td>
<td>3 (21%)</td>
<td>11 (79%)</td>
<td></td>
<td>not computed</td>
</tr>
<tr>
<td>17–30 disagreement ED</td>
<td></td>
<td>0 (-)</td>
<td>1 (20%)</td>
<td>4 (80%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–16 agreement ED</td>
<td></td>
<td>51 (29%)</td>
<td>58 (32%)</td>
<td>70 (39%)</td>
<td><strong>0.02</strong></td>
<td></td>
</tr>
<tr>
<td>1–16 disagreement Erection</td>
<td></td>
<td>3 (6%)</td>
<td>25 (32%)</td>
<td>23 (45%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


2.5.2 (Dis)agreement and symptoms management at 12 months (PROs and CROs) postoperatively

In total, 38% (n = 39/104) of patients with use of ≥ 1 pads according to CRO did not need help for incontinence and 47% (57/120) of patients with ICIQ-SF score of 6–21 also declined help. Patients with incontinence received help independent of agreement/disagreement between ICIQ-SF and clinician report as shown in Table 2a.

Patients did not fill out the IIEF-EF questionnaire in 11% (n = 35/312) of the cases. Of these, 17% (n = 53/312) accepted help for ED. Over one-third of patients did not need help (41%; n = 129/312). The majority of patients with IIEF-EF score 1–16 at 12 months (87%, n = 103/118) refused help. In total 13% (n = 40/312) of patients indicated they already had a treatment for ED. From these patients 77% (31/40) had IIEF-EF score < 17 with a majority of IIEF-EF score 6–10 (45%; n = 18/40) and 12% (n = 5/40) had IIEF-EF Score > 24. Agreement and disagreement between IIEF-EF and help proposed, received or declined is described in Table 2b.
Discussion

Our study is the first to demonstrate the impact of discrepancy between PROs and CROs on the management of incontinence and ED after RARP. The discrepancy between the PROs and the CROs with regard to UI mainly concerned patients with mild and moderate urinary incontinence and did not lead to a significant difference in the treatments offered. All men reporting severe urinary incontinence postoperatively were identified by clinician report. This finding confirmed that the discrepancy between PRO and CRO did not impact treatment/help proposed for UI. Similarly, EF reported by PROMS was mirrored by clinician reporting and the majority of men were offered penile rehabilitation. In our study, outpatient consultation after RARP focused on identification of cancer recurrence (PSA), UI, and ED outcomes. A previous study has shown that patient-centered communication can improve urinary symptoms after RARP through better symptom management.\(^1\) It seems that patients in our study did receive treatment of UI or ED when needed, despite the discrepancy between PROs and CROs as clinicians focused in their communication on patient centered outcomes.

Basch et al.\(^1\) compared symptoms due to treatment toxicity of chemotherapy between patients and clinicians using the Common Terminology Criteria for Adverse Events (CTCAE) and showed that the discrepancy in reporting of symptom severity related to subjective symptoms such as nausea and fatigue rarely influenced treatment decisions. Although we did not use the CTCAE to assess symptoms, our study confirmed these results as the discrepancy between PROs and CROs did not affect offered management and counseling of UI and ED. However, clinicians did not always ask for EF and did not always offer help for ED, especially at 4 months postoperatively (in 28% of patients). This result is surprising because we know that early penile rehabilitation after RARP is recommended in patients with preoperative normal EF.\(^1\)

In this study, we demonstrated the discrepancy between the PROs and CROs regarding the urinary continence and EF after RARP. The discrepancy between PROs and CROs in cancer patients care is well known and was previously demonstrated in literature.\(^1\) Rammant et al.\(^1\) described the discrepancy between PROs and CROs by using the CTCAE in prostate cancer treatment (external beam radiotherapy). A significant disagreement in UI (under-reportage of clinician) was found at all post treatment time points (95%CI 0.19 to 0.55; 0.39 to 0.69 and 0.21 to 0.55). Our analysis confirmed these results: incontinence was underreported by clinicians compared to the PROs especially in patients with moderate incontinence (ICIQ-SF score 6–12). This could be explained by the difficulty for clinicians to interpret the loss of urinary drops. Patients often report sporadic loss of urine droplets and clinicians may subjectively interpret this as continence. Basch et al.\(^1\) demonstrated that the severity of urinary frequency was under-graded by clinicians. Compared to our findings, these results confirm that subjective genitourinary symptoms are difficult to interpret by clinicians. Severe UI (ICIQ-SF score 13–18) was also underreported by clinicians at 8 and 12 months post RARP. This is surprising because severe UI is very different in severity compared to loss of urinary droplets. Thus, we did not expect underreporting by clinicians with regard to severe UI, especially since a strong correlation was shown between the use of pads (> 1 pads daily) and the ICIQ-SF
score 19–21, which demonstrated that very severe incontinence was correctly reported by clinicians. Gori et al.\(^\text{19}\) noted moderate agreement in UI after prostatectomy between the PROM (EPIC-26) and the clinical reports and developed a tool to prevent measurement bias. This tool correlated a number of questions from the EPIC-26 with incontinence versus continence. In our study, we used the ICIQ-SF as PROM. We compared UI and continence (with the use of pads or not) with the results of the ICIQ-Score. Therefore, a tool should be developed to avoid biased measurement between ICIQ-SF and CRO by using the model of Gori et al. and by classifying the answers to question 1 of ICIQ-SF (“how often do you leak urine?”) in continence (“never”, “about once a week or less often”) and incontinence (“2 or 3 times a week”, “about once a day”, “several times a day”, “all the time”). Also, to minimize and avoid the misinterpretation in moderate UI, it could be helpful to use the PROs initially during the consultation and discuss the outcomes with the patients. Moreover, when PROMs are used by clinicians during the consultation, it could improve patient-centered communication.\(^\text{14}\)

Surprisingly, clinicians significantly overestimated the recovery of EF (normal erection) in patients with IIEF-EF score 6–16. This discrepancy is difficult to explain. The difference might lie in the subjectivity of interpretation by the clinician of a normal EF or/and on the information given by patient. It also might be difficult for patients to report ED to the clinician. Chambers et al. showed that it could give them a negative image of their masculinity.\(^\text{20}\)

In this study, IIEF-EF score between 17–21 was considered as normal EF. However, there is no agreement in the literature about the optimal cutoff for normal EF in IIEF-EF score.\(^\text{21}\) It is interesting to notice that the clinician did not report normal EF 1 year after RARP in patients with IIEF-EF score between 17–21. This finding is probably due to the cutoff we have defined for normal EF (≥ 17). The results could have been different with a different cutoff IIEF-EF score.

In this study we compared the PROs with the CROs concerning the urinary continence and EF after RARP. The differences between the PROs and the CROs did not affect the treatment of these symptoms. However, it is incorrect to conclude that PROMs are not needed in clinical practice since some side effects clearly seemed underestimated. The PROMs also include other items which are primordial for the QoL of patients. According cancer survivors, clinicians do not have a good knowledge of QoL of their patients.\(^\text{22}\) The implementation of the PROs in electronic health records could help the clinician to focus on all patient-centered needs.

**Limitations**

the retrospective nature of treatment analysis is the main limitation of the presented data. CROs were retrospectively explored in medical files. It is possible that the clinician asked about side effects but did not report the finding in the medical file. Furthermore, this study was focused only on two side effects of RARP (UI and ED) which status can be subjectively interpreted by clinicians. These results do not fully reflect the importance of using PROMs during the consultation, as PROMs evaluate many other aspect of QoL.
Conclusion

This study is, to our knowledge, the first study to compare PROs with CROs analyzing the impact of discrepancies on management of UI and ED after RARP.

The clinician underreported moderate and severe incontinence and over-reported the recovery of EF (normal erection) in patients with IIEF-EF score 6–16

Regardless of discrepancies in PROs and CROs, patients received clinician help for UI and ED.

Abbreviations


Declarations

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Tillier CN: no conflict of interest or competing interest

Boekhout AH: no conflict of interest or competing interest

Veerman H: no conflict of interest or competing interest

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Figures
Figure 1

Urinary continence: PROMs versus CROs

In all time points: p<.001
**Figure 2**

Erectile function: PROMs versus CROs

In all time points: p<.001