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Individual risk prediction of urinary incontinence after prostatectomy and impact on treatment choice in patients with localized prostate cancer

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Abstract

Aims: Individualized information about the risk of incontinence after prostatectomy could help patients in shared decision-making.

Methods: We compared a historical control cohort ($n = 254$; between June 2016 and 2017) that received standardized information about the risk of incontinence after robot-assisted radical prostatectomy (RARP) with a prospective patient cohort ($n = 254$; between June 2017 and May 2018) that received individualized information of the chance of recovery of incontinence within 6 months postoperatively based on the continence prediction tool (CPRED). We measured switch in treatment choice, health-related quality of life (QoL) in both cohorts and the accuracy of the CPRED tool.

Results: Patients in the individualized information group with RARP as initial preference switched more often to another treatment than patients who received standardized information (16% vs. 5%; $p = 0.001$). Patients in the individualized information group with a high risk of incontinence and with RARP as initial preference switched more often to other treatments than patients in intermediate/low risk of incontinence (35% vs. 9.8%; $p = 0.001$). Patients with a low risk of incontinence choosing RARP after individualized information were less likely to use more than one diaper a day at any time postoperative ($p = 0.001$) compared to men with an intermediate/high incontinence risk. Overall QoL was worse in patients with incontinence than patients with continence 6 and 12 months after RARP (respectively; $p < 0.0001$ and $p = 0.007$).

Conclusion: Personalized information about the risk of incontinence after RARP makes more patients reconsidering their initial treatment preference. The CPRED correlated strongly with continence outcome after RARP and is a useful tool for shared decision-making.

KEYWORDS

CPRED, individual predictor continence, quality of life, RARP, shared-decision making

1 | INTRODUCTION

In men with clinically localized prostate cancer (PCa) several treatment options are available¹ (i.e., radical prostatectomy [RP], external beam radiotherapy [EBRT], brachytherapy [BT], and active surveillance [AS]). Based on the well-established prognostic factors including initial prostate-specific antigen level, clinical TNM-stage, and Gleason score, along with general considerations such as baseline urinary function, comorbidities, age and patient's values and preferences, patients are counseled for treatment choice.

The incidence of major side effects varies by treatment and can impact patients' quality of life (QoL). The most common short- and long-term side effects after treatment of localized PCa include urinary symptoms, bowel symptoms, and sexual dysfunction.^{2–5} Previous studies have indicated that patients have poor knowledge and unrealistic expectations of treatment outcomes and physicians' judgments concerning patient preferences are often inaccurate.^{6,7} The use of decision aids in localized PCa can increase overall knowledge, reduce patients' anxiety, and increase their involvement in the decision-making process.⁸

However, most of the information about the side effects of treatments are standardized and largely based on previous clinical studies and patient cohorts from high volume specialized PCa centers.⁹ Patients with localized PCa may therefore have a misperception of the consequences of treatments which, in turn, may lead to decisional regret.^{10,11}

Urinary incontinence (UI) is a major side effect after RP. One year after surgery, about 60% of patients undergoing robot-assisted radical prostatectomy (RARP) still suffer from UI.¹⁰ Better outcome prediction of UI may aid patients to come to a more balanced decision avoiding RP in men with increased risk of UI. The extent of nerve preservation or fascia preservation (FP), the preoperative membranous urethral length (MUL), and the inner levator muscle distance (ILD) have been reported to affect continence recovery following RARP.¹² A comprehensive understanding of the MUL and ILD might be of value to clinicians when counseling patients in clinical practice before RARP.

The primary aim of this study was to compare treatment choice after receiving individualized information about the risk of UI (prospective cohort) versus treatment choice after standardized information (historical control cohort) among men suitable for RARP. The second objective was to evaluate the individualized continence prediction tool (CPRED) after RARP. Finally, we hypothesized that patients who have received individualized information about UI risks will report a better QoL than patients who have received standard information.

2 | METHODS

2.1 | Study population

Between June 2016 and May 2018, 508 men were enrolled in this cohort study at the Netherlands Cancer Institute (NCI). All men were newly diagnosed with biopsy-proven localized PCa and were eligible candidates for curative treatment. Only patients with a normal preoperative continence, based on the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF)¹³ who answered "never" on the item "When does urine leak?" were included for analysis. Patients who had received neoadjuvant hormonal therapy, who had previous surgical treatment for enlarged prostate, who had developed a urethral stricture and therefore underwent a urethrotomy within 1 year after RARP were excluded. Also, patients with a salvage RP after earlier local treatment or patients who received salvage radiotherapy within 6 months after RARP were excluded. Patients routinely received recommendations on pelvic floor exercises to accelerate urinary continence recovery post-operatively. None of the patients required surgery such as placement of a urinary sphincter prosthesis for post-prostatectomy UI.

Before the introduction of the CPRED tool between June 2016 and 2017, 254 patients received standardized information about the risk of incontinence after RARP. This cohort functioned as historical control (cohort standardized information).

From June 2017, 254 patients were included after the introduction of CPRED and received individualized information about the risk of UI after RARP (cohort individualized information). The institutional review board of the NCI approved the study.

2.2 | Treatment options, initial preference, and final choice

All patients were referred from other hospitals with a diagnosis of PCa. Treatment options in our institution (RARP, EBRT, BT, and AS) were discussed in the multidisciplinary team. Before the consultation, patients were asked to indicate their preferred treatment in a digital or paper questionnaire. Patients gave their final treatment preference choice within 1 week after the consultation in our institute.

2.3 | CPRED score

The CPRED score predicts the chance of full urinary continence and is based on three variables: preoperative magnetic resonance imaging (MRI)-measured MUL,

ILD, and the preoperative estimated extent of possible FP (nerve-sparing) during prostatectomy (FP) as described in a related study.¹² The CPRED score is independent of age, body mass index (BMI), surgeon's expertise, and comorbidities. The CPRED score provides the percentage chance of continence recovery within 6 months after RARP.¹² The higher the CPRED score, the higher the chance a patient will recover from incontinence (i.e., no diaper or inlay use and no involuntary urine loss) within 6 months after RARP. The CPRED score was arbitrarily divided into three categories: high risk of incontinence (CPRED between 0% and 40%), intermediate risk (41%–60%), and low risk (61%–100%).

All patients from cohort individualized information ($n = 254$) underwent an MRI of the prostate. All MRI scans were acquired using a 3T unit (Achieva dStream and Ingenia; Philips) using a body coil. The MUL was measured from the apex of the prostate to the penile bulb (bulb of the corpus spongiosum) using the sagittal T2 turbo-spin-echo images. At the midsagittal slice, a line was drawn parallel to and at the posterior side of the hyperintense urethra lumen. The landmark for the prostate apex was the lower border of the peripheral zone. The ILD was measured on the axial T2 images at the lowest slice where it is possible to draw a horizontal line between both the levator muscles crossing the hyperintense central part of the urethral lumen.

2.4 | Outcome assessment

The primary outcome was to evaluate the percent of change in treatment preference before and after the first consultation in our institute for both cohorts. Standardized information was defined as the risk of urinary leak after RARP based on published study results.⁵ The CPRED score was used to predict the individual risk of urinary leak after RARP.

The secondary outcome was to evaluate the association of the CPRED scores with postoperative incontinence, defined as any involuntary urine loss or diaper use, in patients of cohort individualized information who underwent a RARP. Continence status was obtained during the 4, 8, and 12 months postoperative consultations. The patient was asked if he had any involuntary loss of urine. The answer was noted as: "continent," "drops," "use of 1 diaper a day," or "use of more than 1 diaper a day." The recovery of continence at 6 and 12 months postoperatively was also assessed by using the validated ICIQ-SF to evaluate the severity of UI.^{13–15} The answers from ICIQ-SF result in a sum score, with a minimum score of 0, and a maximum score of 21. Only patients who answered "never" on the item "When does urine leak?" were considered continent. To assess the

severity of UI the ICIQ-SF total scores were recoded into four levels of incontinence¹⁴: slight (1–5), moderate (6–12), severe (13–18), and very severe (19–21). The International Prostate Symptom Score (IPSS) based on seven questions was used to measure the severity of lower urinary tract symptoms (LUTS).¹⁶ With a maximal score of 35, this validated tool categorizes LUTS into three categories: mild (0–7), moderate (8–19), and severe symptoms (20–35).

The third outcome was to determine the overall QoL after RARP in both cohorts. Health-related QoL was measured with the cancer-specific European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-C30.¹⁷

2.5 | Statistics

Data were summarized by frequency and percentage for categorical variables and mean and range for continuous variables. In a historical cohort, 5% of men changed preference. To detect at least 10% point change in preference with an 80% power and alpha of 0.05 when patients are informed on CPRED, two cohorts of 248 men will have to be included. Mann–Whitney rank-sum tests for continuous variables and Chi-square or Fisher's exact tests for categorical variables were used to assess differences between both groups. We used Bonferroni correction for multiple comparisons. The number of patients who changed treatment choice after standardized and individualized information regarding the incontinence prediction was expressed in frequencies and percentages. The CPRED predicted percentage of UI after RARP, of patients in cohort B, was compared to the observed percentage of UI using a two-sided *t*-test. The overall QoL scale of the EORTC C30 was analyzed using a one-way analysis of variance. All statistical tests were two-sided, and differences were considered statistically significant when $p < 0.05$. Statistical analysis was carried out with IBM SPSS Statistics V24.0 (SPSS Inc).

3 | RESULTS

3.1 | Patients and treatment choice characteristics of both cohorts

Complete data were available for 508 patients (254 patients in cohort standardized information and 254 patients in cohort individualized information). There were no differences in characteristics between the two cohorts except cT3 tumor which was more often diagnosed in patients from cohort individualized information than patients from cohort standardized information ($p = 0.004$) (Table 1).

TABLE 1 Patients characteristics, separated from each cohort

Characteristics	Cohort "Standardized information" N = 254 N (%)	Cohort "Individualized information" N = 254 N (%)	p Value
Age at the time of first consultation (mean in years)	65.6	66.6	0.570
BMI (mean)	26.2	26.4	
CT status (%)			0.004
cT1	78 (31)	66 (26)	
cT2	148 (58)	136 (53)	
cT3	28 (11)	52 (21)	
Gleason score (%)			0.206
6	74 (29)	71 (28)	
7	141 (55)	127 (50)	
8	30 (12)	36 (14)	
9	7 (3)	16 (6)	
10	1 (0.4)	2 (0.8)	
PSA (mean in ng/L)	9.5	12.28	0.599
Prostate volume (mean in cc)	44.4	44.8	0.773
<50cc (%)	178 (70)	166 (65)	
≥50cc (%)	75 (30)	88 (35)	
Comorbidity (%)			
None	120 (47)	112 (44)	0.476
TIA/CVA	12 (5)	10 (4)	0.663
Diabetes mellitus	28 (11)	21 (8)	0.293
Hypertension	97 (38)	92 (26)	0.646
Myocardial infarction	25 (10)	23 (9)	0.762
COPD/asthma	17 (7)	18 (7)	0.861
Hypercholesterolemia	26 (10)	23 (9)	0.652
Psychiatric disease	6 (2)	9 (3)	0.432
Other maligne disease	14 (5)	11 (4)	0.538
Charlson index			0.125
≤2	105 (41)	98 (39)	
Between 3–4	114 (45)	129 (51)	
≥5	35 (14)	27 (11)	
Marital status			0.294
Has partner	223 (88)	217 (85)	
No partner	31 (12)	36 (14)	

Note: Chi-square significance at $p < 0.05$.

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; CT, computed tomography; CVA, cerebrovascular accident; PSA, prostate-specific antigen; TIA, transient ischemic attack.

There were no differences between both cohorts in treatment preference before the first consultation ($p = 0.271$).

3.2 | Treatment choice after standardized and individualized information

3.2.1 | Impact of information on treatment preference

More patients in the individualized information group with RARP as initial preference opted for another treatment after consultation on CPRED score as compared to patients in the standardized information group (16% vs. 5%; $p = 0.001$). EBRT and BT were more often chosen in the individualized information group compared to the standardized information group (9% vs. 1%; $p < 0.001$).

3.2.2 | Impact of LUTS on treatment preference

There were no differences in IPSS scores between both cohorts ($p = 0.109$) before treatment. Most of the patients had mildly symptomatic LUTS (53% and 39% and 8% moderately/severely symptomatic LUTS, respectively. Patients in both cohorts with moderate and severe LUTS tended to opt for RARP as a definitive choice in 72% ($n = 128/178$) and 86% ($n = 30/35$), ($p = 0.065$) of the cases, respectively. Patients in cohort individualized information with moderate and severe LUTS and with an intermediate/high-risk CPRED ($n = 42/113$; 37%) still tended to opt for RARP ($p = 0.016$).

3.2.3 | Treatment preference cohort individualized information

Patients in cohort individualized information chose most frequently for RARP ($n = 174$; 69%) and 31% for other options ($p = 0.003$). In 64% of patients who preferred RARP a low risk of incontinence was predicted and an intermediate and high risk in 15% and 21% of patients. In patients who did not choose RARP ($n = 80$), 56% had a low risk, 16% an intermediate risk, and 28% a high risk of incontinence, respectively.

In patients who were doubting about their treatment choice (13%), 51% had a low risk, 18% an intermediate risk, and 30% a high risk of incontinence, respectively. In total 16 of these patients opted for RARP despite a high/intermediate risk of incontinence.

3.2.4 | Switching treatment in both cohorts

Preferred treatment choice and final treatment choice between both cohorts are described in Table 2. In both cohorts, 17% of patients ($n = 85/508$) opted for RARP while it was not their initial choice ($n = 14$; 16%) or they were doubting about treatment options ($n = 71$; 84%). From these patients, 55% ($n = 47$) has received standardized information and 45% ($n = 38$) individualized information. Less than half of patients from cohort individualized information had an intermediate/high risk of incontinence ($n = 16$; 42%) all of those patients did not have preference before the consultation. Five patients ($n = 5/38$; 13%) in cohort individualized information whose initial preferences were BT or EBRT definitively opted for RARP had a low risk of incontinence.

As shown in Figure 1, patients in cohort individualized information with a high risk of incontinence switched

TABLE 2 Preferred treatment choice and final treatment choice between the standardized and individualized information group

Preference to the final choice	Cohort "Standardized information" $n = 254$ n (%)	Cohort "Individualized information" $n = 254$ n (%)	p Value
RARP → RARP	143 (57)	136 (54)	0.553
No RARP → no RARP	32 (13)	24 (9.6)	0.257
RARP → no RARP	7 (3)	26 (10)	0.001
No RARP → RARP	9 (4)	5 (2)	0.278
Doubting → RARP	38 (15)	32 (12.8)	0.440
Doubting → no RARP	21 (8)	27 (10.8)	0.363

Note: no RARP = EBRT, BT, and AS; cut-off value p -value: $0.05/6 = 0.008$.

Abbreviations: AS, active surveillance; BT, brachytherapy; EBRT, external beam radiotherapy; RARP, robot-assisted radical prostatectomy.

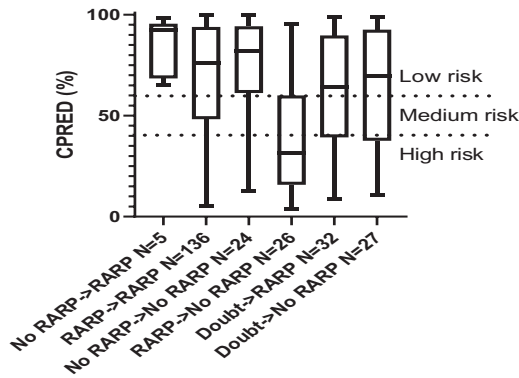


FIGURE 1 Switchers by continence prediction tool (CPRED). RARP, robot-assisted radical prostatectomy

from RARP as initial choice to other treatments more often than patients with a low or intermediate risk (14/40 [35%] vs. 12/122 [9.8%]; $p < 0.001$) and patients who were doubting about the treatment almost equally opted for RARP or other options independent of the CPRED outcome (32% vs. 27%; $p = 0.729$).

3.3 | CPRED and postoperative incontinence

For the second objective of the study, we evaluated the correlation of CPRED score with continence outcome for men receiving RALP. As shown in Figure 2, patients with a low risk of incontinence ($CPRED > 60\%$) were less likely to use more than one diaper a day at any time postoperatively, compared to patients with a high/intermediate risk (4 weeks: 30% vs. 53%; $p = 0.003$, 4 months: 5% vs. 21%; $p = 0.001$, 8 months: 1% vs. 17%; $p < 0.001$, 12 months: 1% vs. 16%; $p < 0.001$. Similarly, ICIQ-SF score at 6 and 12 months postoperatively was inversely correlated with CPRED score ($p = 0.001$ and $p = 0.028$, respectively; Figure 3).

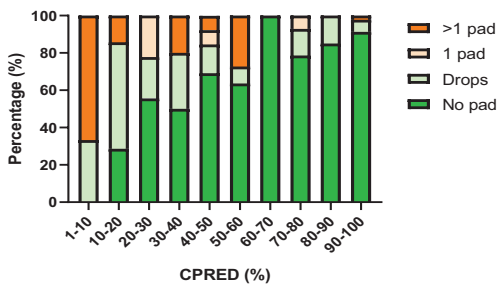


FIGURE 2 Pad use 12 months after robot-assisted radical prostatectomy (RARP). CPRED, continence prediction tool

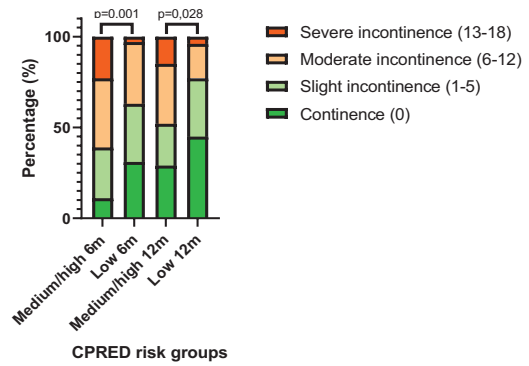


FIGURE 3 International Consultation on Incontinence Questionnaire-Short Form categories 6 and 12 m after robot-assisted radical prostatectomy. CPRED, continence prediction tool

3.4 | Health-related QoL

There was no difference between both cohorts in overall QoL preoperatively ($p = 0.24$), 6 and 12 months after surgery (respectively $p = 0.460$ and $p = 0.300$). In men who underwent RARP, incontinence, as scored by ICIQ-SF, was negatively correlated with overall QoL. The use of any diapers did affect the overall QoL outcome at 6 months ($p = 0.014$) but not anymore at 12 months ($p = 0.645$).

4 | DISCUSSION

In this study, we showed that individualized information predicting the postoperative continence outcome after RARP impact patients' decision. When patients received individualized information (obtained from the CPRED score), they switched three times more often from their initial treatment preference than patients who received standardized information about the risk of incontinence. This is not surprising, as we know that incontinence is, similar to erectile dysfunction, one of the biggest fears of patients who undergo an RP and strongly correlated with decisional regret.¹⁸ This result may suggest that the individualized information about the risk of incontinence played a role in patients' treatment decision-making since most of these patients deciding against RARP had a high or intermediate risk of incontinence after RARP.

Patients in the individualized information group who were doubting about their preferred treatment choice before being informed on their CPRED score chose RARP and other treatments irrespective of CPRED score. The motivations of these patients are not clear and we could not find any differences in all variables compared to the overall population of this study. For future research, it will be interesting to evaluate if whether these

patients do regret their treatment choice afterward, and to explore what their main reasons were for selecting RARP as the final treatment particularly in patients with high risks of incontinence.

The presence of LUTS was not associated with an increased incidence of RARP as a treatment choice before counseling at our institute. After consultation, patients with mild/severe LUTS according to the IPSS score more frequently opted for RARP. Patients from cohort individualized information suffered from mild/severe LUTS still opted for RARP despite an intermediate/high-risk CPRED. The presence of LUTS seemed to be more important than the CPRED outcome in decision-making.

Usually, when patients are asked which factors influenced their treatment preference, they argued that they chose for the treatment that offered the best chance of cure.¹⁹ Our study did not allow to affirm or disallow this argument. Neither of patients in both cohorts were invited for another consultation to evaluate if the information given was properly understood. Also, the format in which the CPRED information was provided may have affected patients' treatment preferences. The information about the risk of incontinence was given numerically (i.e., in percentage) to the patients. This could explain why few patients in both cohorts did not switch from treatment, since the perception of percentages can be difficult²⁰ and patients may have misinterpreted the provided information which may negatively impact outcome experiences.²¹

We did not notice any significant differences in overall QoL after RARP within both cohorts, but patients with urinary leakage after treatment had significantly worse QoL outcomes the first 6 months after surgery. Loss of urinary drops has been considered acceptable after prostatectomy by health care providers but our study and other studies²² clearly showed that even the loss of some drops of urine negatively impacts the QoL the first 6 months postoperative. This was confirmed by a systematic review including 18 comparative studies of Lardas et al.²³ UI is thus a serious issue to be considered when patients have to choose a treatment for localized PCa. We showed that an individual predictive tool of the risk of incontinence after RARP can help patients to consider the harms and benefits associated with prostatectomy.

In the present analysis, CPRED prediction was fairly accurate as only 2% of patients in low risk of incontinence had severe incontinence (ICIQ-SF score 13–18) at 6 and 12 months after RARP which differed from patients in high risk of incontinence (6% at 6 months and 5% at 12 months). The CPRED tool makes patients aware of their individual risk of UI and helps them in making a decision about treatment. All other tools that help patients make a treatment decision (e.g., patient decision

aids) provide standardized information about the harms and benefits of different treatments, but patients are missing individualized information.²⁴ Furthermore, perioperative patient education about UI after RARP has positive effects on long-term patient satisfaction rates.²⁵

Several studies have shown that the MUL is a strong predictive factor for the recovery of continence after RARP.²⁶ Our study confirmed these results and showed the predictive value of the CPRED tool. The CPRED is thus the first tool that can predict an individualized risk of incontinence after RARP.

This study has several limitations. First, the study, although prospective, was not in a randomized setting. The large body of evidence on the predictive value of MUL, an element of the CPRED score, for post-prostatectomy continence outcome made a randomized setup less attractive for the potential risk of contamination in the control group considering the wider use of MUL as a predictor. Second, we also cannot affirm with certainty that the personalized information has an influence on the final treatment choice of patients since other communication factors could play a role (e.g., interference of the physician/nurse practitioner). Nevertheless, we did not evaluate if the standardized/individualized risk information given to the patient was well understood or used for making a decision about treatment. Patients could have made a choice on basis of information they did not properly understand. Finally, the sample size regarding some subgroups was rather small. A larger sample size of some subgroups would allow the generalizability of the data in current form.

Therefore, future studies are needed to validate the CPRED tool.

5 | CONCLUSION

To the best of our knowledge, this is the first prospective cohort study that analyzed the impact of individualized continence outcome information on treatment decision-making in PCa patients suitable for RARP.

Compared to standardized risk information, individualized information about the risk of incontinence after RARP makes patients reconsider their initial treatment preference, particularly in patients with a high risk of UI. The CPRED scores were strongly correlated with actual continence outcomes. The CPRED tool can predict individualized UI after RARP and is useful for shared decision making as we showed that incontinence has an impact on patients' QoL of patients.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Corinne N. Tillier has developed the design of the research, analyzed of the results, and wrote the manuscript. Ruben D. Vromans, Hans Veerman, Barbara M. Wollersheim, Henricus A. M. van Muilekom, Thierry N. Boellaard, and Pim J. van Leeuwen contributed to the analysis of the results and to the writing of the manuscript. Annelies H. Boekhout and Lonneke V. van de Poll-Franse supervised the project, contributed to the analysis of the results, and to the writing of the manuscript. All authors provided critical feedback and helped shape the research, analysis, and manuscript. The data that support the findings of this study are available from the corresponding author (Corinne N. Tillier).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author (Corinne N. Tillier).

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