Preoperative predictive model of recovery of urinary continence after radical prostatectomy

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Abstract

Purpose: There is a dearth of multivariable predictive models of urinary continence recovery after radical prostatectomy. We built a predictive model of urinary continence recovery following radical prostatectomy that incorporates magnetic resonance imaging parameters and clinical data.

Patients and Methods: Data from 2,849 patients who underwent pelvic staging magnetic resonance imaging prior to radical prostatectomy from November 2001 to June 2010 were collected. Multivariable logistic regression was used to create our model.

Results: In total, 68% (n=1,742/2,559) and 82% (n=2,205/2,689) regained function at 6 and 12 months, respectively. In the base model, age, body mass index, and American Society of Anesthesiologists (ASA) score were significant predictors of continence at 6 or 12 months on univariate analysis ($p < 0.005$). Among the preoperative magnetic resonance imaging measurements, membranous urethral length, which showed great significance, was incorporated into the base model to create the full model. For continence recovery at 6 months, the addition of membranous urethral length increased the AUC to 0.664 for the validation set, an increase of 0.064 over the base model. For continence recovery at 12 months, the AUC was 0.674, an increase of 0.085 over the base model.

Conclusions: Using our model, the likelihood of continence recovery increases with membranous urethral length and decreases with age, body mass index, and ASA score. This model could be used for patient counseling and for the identification of patients at high risk for

urinary incontinence in whom to study changes in operative technique that improve urinary function after radical prostatectomy.

INTRODUCTION

Urinary incontinence following RP has a major impact on quality of life[1-4] in 5% to 72% of patients.[3] Preoperative risk factors associated with delayed continence recovery after RP include advanced age, high BMI, large prostate size, presence of comorbidities, history of TURP, history of incontinence, or history of lower urinary tract symptoms.[5, 6] Membranous urethral length, based on preoperative imaging, is also associated with urinary continence recovery.[7, 8] In our pilot study membranous urethral length, urethral volume, and levator muscle anatomically closely related to the membranous urethra on preoperative MRI were all independently associated with continence recovery at 6 and 12 months postoperatively,[9] with membranous urethral length the greatest predictor and easiest to measure.

While numerous nomograms have been developed to aid physicians and patients in choosing suitable treatment by predicting pathological features and progression-free probability after RP,[10, 11] there is a dearth of predictive models of urinary continence recovery after RP. A preoperative predictive model would not only be useful for patient counseling, but also for identifying patients at high risk for incontinence. Changes in surgical technique to improve continence could be studied in this group of patients; alternatively, intraoperative maneuvers that improve postoperative continence, such as concomitant male slings,[12] could be offered to these patients.

We created a predictive model of urinary continence recovery following RP using only those clinical and MRI variables known preoperatively.

PATIENTS AND METHODS

After receiving institutional review board approval, we identified 4,053 patients who underwent pelvic staging MRI prior to RP performed by 1 of 7 dedicated prostate surgeons from November 2001 to June 2010. Patients were ineligible for analysis if they received neoadjuvant or adjuvant radiation therapy (n=225) or were preoperatively incontinent (n=84). Of the remaining 3,744 patients, those with missing follow up information for continence (n=872) or missing the necessary covariates (n=23) were excluded, leaving 2,849 patients eligible for analysis. Some patients only had follow up information for 6 (n=160) or 12 months (n=290), and were only included in analysis for which they had information.

Due to interval censoring, we converted the time-to-event data into binary variables for the outcome of continence at 6 and 12 months. Patients who regained function before 6 or 12 months after surgery were considered continent. Patients who were incontinent before and after 6 or 12 months were considered incontinent.

Outcome Assessment

At our institution, pre- and postoperative urinary continence is assessed using a 5-point scale (Table 1) that is completed at each visit by the physician and patient or proxy and recorded. Level 1 (no pad usage/no security pad) is considered continent; levels 2 to 5 are considered incontinent. We also investigated a less strict definition of continence, which included levels 1 (no security pad) and 2 (leaks only during heavy activity); levels 3 to 5 were considered incontinent. This second definition of continence or “social continence” (level 1 or

2) was of interest because patients have a much better quality of life compared to those with levels 3 to 5. We developed models using both of these definitions.

MRI Measurements and Imaging Interpretation

MRI measurements were performed on the axial, sagittal, and coronal planes on preoperative endorectal MRI by one rater who was blinded to all clinical and pathological data. All measurements were defined by an experienced radiologist, as previously described.[9] The accuracy of the measurements was confirmed by the radiologist.

MRI data were acquired on 1.5 Tesla (n= 2,530) and 3 Tesla (n= 319) MR units (GE Medical Systems, Milwaukee, WI) using a body coil for excitation and a pelvic phased array coil in combination with an endorectal coil (Medrad, Pittsburgh, PA) for signal reception. MRI parameters for anatomic images were as follows: for 1.5 Tesla, transverse T1-weighted (repetition time/echo time, 400–600/8–10 msec; section thickness, 5 mm; intersection gap, 1 mm; field of view, 24–36 cm; matrix, 256 × 192) and transverse, coronal, and sagittal T2-weighted fast spin-echo (repetition time/echo time, 4,000–6,000/96–120 msec; echo train length, 12–16; section thickness, 3 mm; intersection gap, 0 mm; field of view, 12–16 cm; matrix, 256 × 192); for 3 Tesla, transverse T1-weighted (repetition time/echo time, 600–750/10–14 msec; section thickness, 5 mm; intersection gap, 1 mm; field of view, 24–36 cm; matrix, 256 × 192) and transverse, coronal, and sagittal T2-weighted fast spin-echo (repetition time/echo time, 3500/120 msec; echo train length, 12–16; section thickness, 3 mm; intersection gap, 0 mm, field of view, 12–16 cm; matrix, 256 × 192).

Statistical Methods

Our aim was to create a multivariable model that included preoperative clinical and MRI variables to predict continence recovery at 6 and 12 months. We split the cohort into training (n=1899) and validation (n=950) data sets; we created the model on the training set and tested it on the validation set.

We first used the training set to explore which preoperative clinical variables to include in the model. Age, PSA, clinical stage (≤T1C, T2A, and ≥T2B), biopsy Gleason score (≤6, 7, and ≥8), BMI, ASA score (I/II vs. III/IV), number of comorbidities (0, 1, 2, >3), and history of TURP (Y/N) were all considered. Morbidities included coronary artery disease, peripheral vascular disease, stroke, diabetes, hypertension, hyperlipidemia, and hypercholesterolemia. Including ASA score or number of comorbidities with age and BMI did not markedly make a difference in the predictive accuracy of the training set. ASA score was selected over number of comorbidities for simplicity, since the outcomes resulting from their inclusion in the model were similar. Multivariable logistic regression was used to create a "base" model, including the covariates of age entered as a non-linear term using restricted cubic splines with knots at the tertiles to account for its nonlinear association with outcome, BMI, and ASA score to predict continence at 6 or 12 months.

We then used logistic regression to evaluate the association between each MRI variable and continence at 6 or 12 months, adjusting for age, BMI, and ASA score. Multivariable logistic regression was used to create a "full" model consisting of the above-mentioned clinical variables and the MRI variables that were found to be statistically independently significant ($p < 0.05$).

Both the base and full models were evaluated using ROC analysis and calibration plots; the results reported are those from applying the models to the validation sets. A nomogram was constructed using the multivariable logistic regression models. These analyses were repeated for our alternate definition of continence.

For a sensitivity analysis to investigate if neoadjuvant or adjuvant hormone therapy had an effect on continence recovery, we excluded patients who had any form of neoadjuvant or adjuvant therapy (n=102). For a second sensitivity analysis to explore if there were any differences in outcome between procedure types (open, laparoscopic, or robotic), we incorporated procedure type into our models.

All analyses were conducted using Stata 11.0 (StataCorp LP, College Station, TX).

RESULTS

Patient characteristics are presented in Table 2; MRI variables are presented in Table 3. Median age was 60 years. The majority of patients had clinical stage T1 (66%) and clinical Gleason score of <6 (52%). In total, 68% (n=1,742/2,559) and 82% (n=2,205/2,689) regained urinary continence at 6 and 12 months, respectively.

In the base model, age, BMI, and ASA score were significant predictors of continence at 6 or 12 months on univariate analysis (p <0.005) (Table 4). As only 1% of our cohort had a history of TURP, this variable was not included in our model. The AUC for the base model applied to the validation set was 0.600 and 0.589 for continence at 6 and 12 months, respectively.

We compared the discrimination of the base model, which included age, BMI, and ASA score, with that of the full model, which also incorporated MRI variables. The association between each MRI variable and continence is represented in Table 5. After adjusting for age, BMI, and ASA score, greater membranous urethral length and urethral volume were significantly associated with an increased probability of regaining continence at 6 and 12 months. Larger ILD and OLD were significantly associated with a decreased probability of regaining continence at 6 and 12 months. Greater prostate depth was associated with a decreased probability of regaining continence at 6 and 12 months. Among the preoperative MRI measurements, membranous urethral length, an MRI variable that showed great significance and is easy to measure, was incorporated into the base model to create the full model. All other MRI variables when added to the model alongside membranous urethral length did not notably increase its accuracy. For this reason, membranous urethral length was the only MRI variable included in the full model. For continence at 6 months, incorporating membranous urethral length increased the AUC to 0.664 for the validation set, an increase of 0.064 over the base model. For continence at 12 months, the AUC was 0.674, an increase of 0.085 over the base model. The inclusion of MRI data improved the discrimination of our model.

When our analyses were repeated for our second definition of continence (levels 1 or 2), the results were similar. For continence at 6 and 12 months, the AUCs for the base model applied to the validation set were 0.640 and 0.662, respectively. Incorporating membranous urethral length increased the AUC of the validation set to 0.729 for continence at 6 months, a difference of 0.089, and to 0.709 for continence at 12 months, a difference of 0.047.

In our first sensitivity analysis, excluding patients who had neoadjuvant or adjuvant therapy had little effect on our findings. For example, the AUC of the base model for continence at 6 months improved with the addition of membranous urethral length by 0.048, compared to the 0.064 increase in the main analysis. In our second sensitivity analysis, adjusting for procedure type (open, laparoscopic, or robotic) had little effect on our findings. Incorporating membranous urethral length to the base model, including procedure type, increased the AUC for continence at 12 months by 0.056, compared to 0.085 in the main analysis.

The predicted probability of continence recovery after RP by membranous urethral length on preoperative MRI, controlling for age, ASA score, and BMI, is given in Table 6. The likelihood of continence recovery increased with membranous urethral length and decreased with age and ASA score. Nomograms were developed to visually represent our models (Figures 1 & 2).

DISCUSSION

We present a preoperative predictive model of urinary continence recovery after RP that includes age, BMI, and ASA score in a base model. The inclusion of the MRI parameter membranous urethral length further increases the discrimination of our model for continence at 6 and 12 months.

A preoperative model based on known risk factors has been elusive. Previous studies suggested that advancing age at the time of RP, increasing BMI, medical comorbidities, history of TURP, previous radiotherapy for prostate cancer, presence of preoperative lower urinary tract symptoms, and decreased membranous urethral length may be preoperative risk factors for urinary incontinence after RP.[5, 7, 9, 13-15] In this study, we used preoperative MRI to predict continence recovery in patients after RP., In the pilot study we assessed predictors of continence recovery after RP and identified soft tissue dimensions on preoperative MRI that were associated with continence recovery.[9] We also showed that membranous urethral length, urethral volume, and anatomically close relation between the levator muscle and membranous urethra on preoperative MRI are independent predictors of continence recovery after RP, after adjusting for age, BMI, and ASA score. The current study confirms these findings and also shows that greater prostate depth on preoperative MRI was associated with decreased probability of regaining continence at 6 and 12 months. This might represent higher surgical difficulty possibly due to a steep or narrow pelvis. Multiple intraoperative maneuvers have been proposed to improve urinary continence, including neurovascular bundle-sparing surgery,[15-17], bladder neck preservation,[18] and novel reconstruction of tissue around the vesicourethral anastomosis.[19] Surgeon experience and technique are also related to urinary outcomes after RP.[20]

Using our model, we can reasonably predict which patients will not recover continence after RP – a useful adjunct for patient counseling. Further benefit of this model is the identification of a cohort of patients with a high rate of incontinence who may be suitable for the study of maneuvers designed to improve urinary continence.

Intraoperative maneuvers, such as fascial slings, have been studied as a way to improve continence in patients thought to be at high risk for urinary incontinence. Jorion[21] demonstrated improved time to continence for patients who had slings made of rectus fascia placed underneath the urethrovesical anastomosis (treatment group), compared to the control group: 100% of men in the treatment group were dry at 6 months. However, 90% of the control group was also dry at 6 months, suggesting that 90% of patients in the treatment group were over-treated.[21] Jones et al reported similar findings using a sling made of porcine material: 100% of the treatment group and 80% of the control group were dry at 6 months.[12] These maneuvers or others could potentially be offered to patients at high risk for incontinence, based on our nomogram, which would greatly decrease the number of patients subjected to these modifications unnecessarily.

In the current study, we only used age, BMI, ASA score, and membranous urethral length on preoperative MRI to identify high-risk patients. History of TURP (a significant risk factor for urinary incontinence on univariate analysis), previous radiation therapy, and other suggested risk factors were left out of the preoperative prediction model due to the small number of patients who had these suggested risk factors.

Our study has several limitations. MRI was performed preoperatively, while MRI measurements were performed retrospectively. Not all patients treated with RP in the study period had disease staged with MRI, but the distribution of pelvic dimensions is not expected to be different in patients who did vs. those who did not undergo MRI. Another potential weakness is that we did not use externally validated questionnaires to measure urinary continence. However, that the same methodology was used for continent and incontinent men means that it is unlikely to influence predictors of urinary continence.

Few men in our cohort were at sufficiently high risk of persistent urinary dysfunction to warrant either avoidance of surgery or use of adjunct therapies, such as placement of a sling. The proportion of patients who had a risk of incontinence at 12 months greater than 30%, 40%, and 50% was 5%, 1%, and <1%, respectively. For our second definition of continence, the proportion of patients was <1% for each of these risk groups. A nomogram to predict severe incontinence was not feasible because of a low number of events and only a small proportion of patients would use the model to affect decision making.

CONCLUSIONS

We developed a preoperative predictive model in the form of a nomogram that shows the risk of persistent urinary incontinence after RP at 6 and 12 months. Using our model, the likelihood of continence recovery increases with membranous urethral length and decreases with age, BMI, and ASA score. This model could be used for patient counseling and to identify patients at high risk for urinary incontinence in whom to study changes in operative technique that improve urinary function after RP.

Acknowledgments. The authors thank Dagmar Schnau of Memorial Sloan-Kettering Cancer Center for her editorial assistance with the preparation of this manuscript.

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Figure 1. Preoperative nomogram for predicting the probability of continence recovery after RP (12 months)

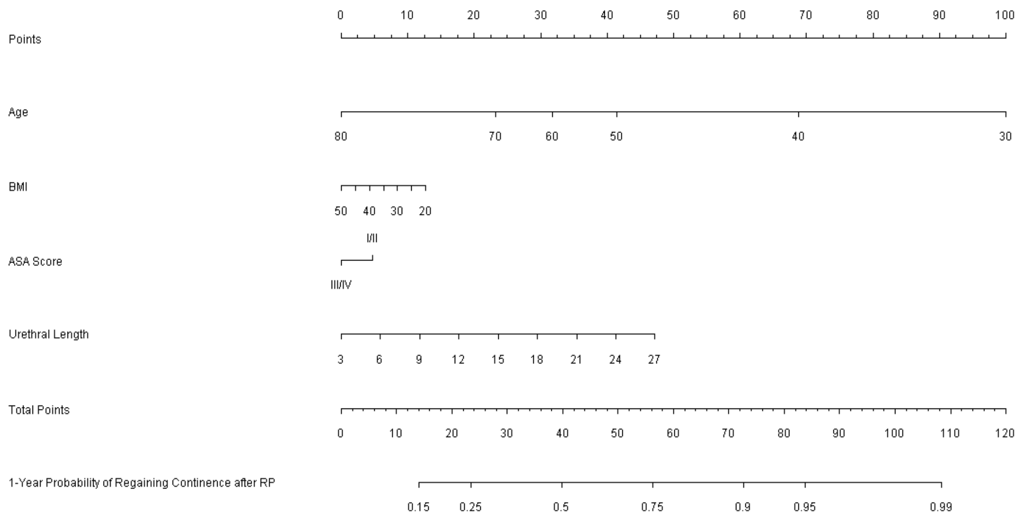

Figure 2. Preoperative nomogram for predicting the probability of recovery of “social continence” after RP (12 months)

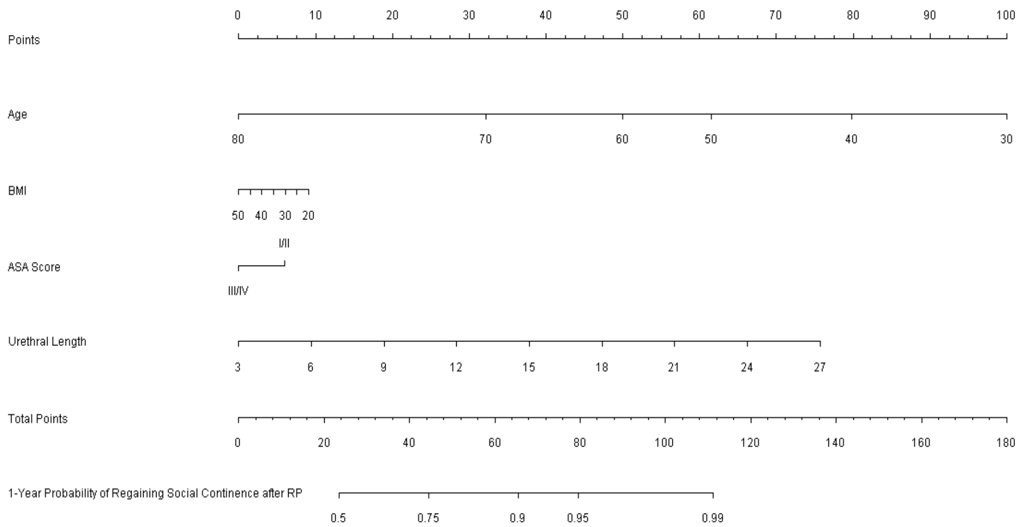

Table 1: Five-point scale for grading urinary continence

Continence Level	Level Definition
1	Continent (no security pad)
2	Mild SUI (leaks only during heavy activity; 1–2 pads)
3	Moderate SUI (leaks with moderate activity; 3–4 pads)
4	Severe SUI (leaks at normal activity, dry at night and rest)
5	Total incontinence (continuous leakage of urine at rest)

Table 2. Patient characteristics. All values are either median (IQR) or frequency (proportion).

	n = 2,849
Age at Surgery, yrs	60 (55, 65)
BMI, kg/m^2	28 (25, 30)
PSA, ng/ml	5 (4, 7)
History of TURP	38 (1%)
Clinical Stage	
≤T1C	1,873 (66%)
T2A	495 (17%)
≥T2B	481 (17%)
Biopsy Gleason Score	
≤6	1,487 (52%)
7	1,141 (40%)
≥8	221 (8%)
ASA Score	
I/II	2,350 (82%)
III/IV	499 (18%)
Comorbidities	
0	1,146 (40%)
1	1,017 (36%)
2	528 (19%)
3+	158 (6%)
Nerve-Sparing Status	
Both preserved	2,130 (75%)
Unilateral preservation	447 (15%)
Both resected	272 (10%)
Year of Surgery	
2001–2005	940 (33%)
2006–2010	1,909 (67%)
Surgical Approach	
Open	1,487 (52%)
Laparoscopic	931 (33%)
Robotic	431 (15%)
Continence Outcomes	
Continent at 6 months, n=2,559	1,742 (68%)

Continent at 12 months, n=2,689	2,205 (82%)

Table 3. MRI variables. All values are median (IQR).

	n=2,849
ILD (mm)	16 (15, 18)
OLD (mm)	39 (37, 42)
Levator Thickness (mm)*	12 (10, 13)
Urethral Width (mm)	12 (11, 13)
Membranous Urethral Length (mm)	12 (10, 15)
Urethral Volume (mm^3)**	1,357 (1021, 1726)
Prostate Width (mm)	51 (47, 55)
Prostate Length (mm)	28 (25, 33)
Prostate Height (mm)	43 (39, 49)
Prostate Volume (cm^3)***	31 (24, 44)
Prostate Depth (mm)	25 (21, 31)
Bony Width (mm)	104 (99, 109)
Lower Conjugate (mm)	105 (99, 110)
Midpelvic Area (cm^2)****	86 (79, 92)
Symphysis Angle (degree)	42 (38, 47)

* calculated: (OLD – ILD)/2

** calculated: membranous urethra length x π x (urethra width/2)^2

*** calculated: prostate width x prostate length x prostate height x π/6/1000 (cm^3)

**** calculated: (bony width x lower conjugate x π)/400 (cm^2)

Table 4. Univariate analysis of clinical and demographic variables of interest

	Continence at 6 Months		Continence at 12 Months	
	OR (95% CI)	**p-value**	**OR (95% CI)**	**p-value**
Age*	-	<0.0001	-	<0.0001
BMI	0.97 (0.95, 0.99)	0.01	0.98 (0.96, 1.01)	0.1
ASA Score (III/IV vs. I/II)	0.71 (0.57, 0.87)	0.001	0.63 (0.49, 0.80)	0.0002
PSA	0.99 (0.97, 1.00)	0.1	1.00 (0.99, 1.02)	0.9
Clinical Stage		0.06		0.02
≤T1C	Ref.	Ref.	Ref.	Ref.
T2A	1.01 (0.81, 1.27)	-	1.15 (0.87, 1.52)	0.3
≥T2B	0.76 (0.61, 0.95)	-	0.74 (0.57, 0.95)	0.018
Clinical Gleason Score		0.1		0.2
≤6	Ref.	Ref.	Ref.	Ref.
7	0.84 (0.71, 1.00)	-	0.90 (0.73, 1.10)	-
≥8	0.82 (0.60, 1.12)	-	0.72 (0.50, 1.04)	-
Year of Surgery (>2005 vs. ≤2005)	0.83 (0.70, 0.99)	0.04	1.21 (0.99, 1.48)	0.07
History of TURP	0.37 (0.19, 0.72)	0.003	0.27 (0.14, 0.52)	0.0001

*Age was modeled using non-linear terms, so the OR and 95% CI are not provided.

Table 5. Associations between significant MRI variables and continence at 6 or 12 months, after adjustment for age, BMI, and ASA. AUC values for each MRI variable when added to the base model.

	Continence at 6 Months				Continence at 12 Months			
	OR	95% CI	P value	AUC	OR	95% CI	P value	AUC
Urethral Width (mm)	0.97	0.92, 1.03	0.3	0.612	0.96	0.90, 1.0	0.14	0.616
Urethral Length (mm)	1.12	1.09, 1.15	<0.0005	0.664	1.14	1.10, 1.17	<0.0005	0.674
OLD (mm)	0.98	0.96, 0.99	0.035	0.618	0.96	0.94, 0.99	0.004	0.622
ILD (mm)	0.94	0.91, 0.97	<0.0005	0.639	0.98	0.97, 1.0	0.023	0.625
Levator Thickness (mm)	1.08	1.03, 1.13	0.003	0.616	1.06	1.0, 1.1	0.039	0.612
Prostate Height (mm)	0.99	0.98, 1.0	0.032	0.616	0.99	0.98, 1.0	0.3	0.610
Prostate Length (mm)	1.0	0.99 , 1.02	0.6	0.612	1.0	0.99, 1.0	0.4	0.612
Prostate Width (mm)	0.99	0.98, 1.0	0.16	0.611	0.99	0.97, 1.0	0.12	0.610
Prostate Depth (mm)	0.97	0.96, 0.99	<0.0005	0.629	0.97	0.96, 0.99	<0.0005	0.628
Bony width (mm)	0.99	0.98, 1.0	0.042	0.615	0.98	0.97, 1.0	0.008	0.620
Lower Conjugate (mm)	0.99	0.99, 1.01	0.3	0.612	0.99	0.98, 1.0	0.065	0.615
Symphysis Angle (degree)	0.99	0.98, 1.0	0.15	0.613	1.0	0.99, 1.02	0.4	0.609
Urethral Volume (per 100 mm^3)	1.06	1.04, 1.08	<0.0005	0.645	1.06	1.04, 1.09	<0.0005	0.650
Prostate Volume (per 100 cm^3)	0.83	0.56, 1.24	0.4	0.611	0.95	0.59, 1.51	0.8	0.610
Midpelvic Area (per 100 cm^2)	0.44	0.19, 1.04	0.062	0.615	0.23	0.09, 0.63	0.004	0.621

Table 6. Predicted continence recovery after RP (%) (Values are for median BMI of 28 kg/m^2. Probabilities range from the worst characteristics, older with shorter membranous urethral length, to the best characteristics, young with longer membranous urethral length.)

		Membranous Urethral Length (mm)				
Age	ASA	3–6	6–9	9–12	12–15	≥15
50–53	I/II	69%–80%	76%–85%	82%–89%	87%–92%	91%–98%
	III/IV	65%–77%	73%–83%	80%–88%	85%–91%	89%–98%
54–57	I/II	64%–75%	73%–82%	79%–87%	85%–90%	89%–97%
	III/IV	61%–72%	69%–79%	77%–85%	83%–89%	87%–97%
58–61	I/II	62%–72%	70%–79%	77%–84%	83%–89%	88%–97%
	III/IV	58%–69%	66%–76%	74%–82%	81%–87%	86%–96%
62–65	I/II	56%–69%	65%–76%	73%–83%	80%–87%	85%–96%
	III/IV	52%–66%	62%–73%	70%–80%	77%–85%	83%–96%
66–69	I/II	47%–63%	57%–72%	65%–79%	73%–84%	80%–95%
	III/IV	43%–60%	53%–68%	62%–76%	70%–82%	77%–95%
70–73	I/II	36%–54%	44%–63%	54%–71%	63%–78%	71%–93%
	III/IV	32%–50%	41%–59%	50%–68%	59%–75%	68%–92%
74–77	I/II	23%–41%	31%–50%	39%–60%	48%–68%	58%–89%
	III/IV	21%–37%	28% - 46%	36%–56%	45%–65%	54%–88%
78–80	I/II	16%–28%	22%–36%	28%–44%	37%–54%	46%–82%
	III/IV	14%–25%	19%–32%	25%–41%	33%–50%	42%–80%

X%– Y% would represent the range of probability for a 53-year-old patient with ASA score I/II, BMI of 28 kg/m^2, and membranous urethral length of 3 mm to a 50-year-old patient with ASA score I/II, BMI of 28 kg/m^2, and membranous urethral length of 6 mm.