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Uroflow Stop Test and Potency Recovery: a Surrogate for Pelvic Floor Integrity Post Robotic Assisted Radical Prostatectomy?

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Abstract

Objective

To study the relation between *uroflow Stop Test* and early recovery of potency following RARP. We recently showed that the ability to completely stop urine flow during voiding, measured objectively by uroflowmetry at the time of catheter removal (*uroflow Stop Test*) can predict early urinary continence recovery following RARP.

Methods

In this prospective observational cohort, data was collected on 108 patients operated by a single surgeon (AEH). Eighty patients had a positive uroflow Stop Test (group one) and 28 had a negative Stop Test (group two). Patients were followed for a minimum of 2 years. Covariates included age, BMI, IPSS and SHIM scores, PSA, tumor stage, prostate volume, nerve sparing status and EBL.

Results

Preoperative characteristics were comparable between both groups except nerve sparing and PSA which were statistically higher in group one ($p < 0.05$). Early 3- and 6-months recovery of erectile function was significantly higher in group one. Potency rates in group one and two at 1, 3, 6, 9, 12, 18 and 24 months were 25% vs. 14.3% ($p = 0.241$), 54.5% vs. 18.5% ($p = 0.001$), 55.4% vs. 18.5% ($p = 0.001$), 56.4% vs. 36% ($p = 0.084$), 66.6% vs. 50% ($p = 0.141$), 65.5% vs. 56% ($p = 0.404$) and 73.2% vs. 57.7% ($p = 0.160$) respectively. Uroflow Stop Test was independent predictor of early potency recovery on multivariate regression analysis at 6 months [OR 6.042 (CI95% 1.496-24.413) $p = 0.012$].

Conclusion

Although simple, Uroflow stop test may help predict early potency recovery post RARP.

Introduction

Erectile dysfunction (ED) is highly prevalent following radical prostatectomy irrespective of technical approach. Potency recovery was reported in a wide range among different studies although no standard definition had been used. A recent large meta-analysis reported 12- and 24-months erectile function recovery rates after robot-assisted radical prostatectomy (RARP) at 54%-90% and 63%-94%, respectively ¹.

There is evidence to suggest some interplay between potency recovery and urinary continence recovery post prostatectomy ². Both are multifactorial and share similar documented risk factors including age, body mass index, comorbidities and surgical technique particularly nerve sparing status³. Furthermore, it has been found in two recent studies that nerve-sparing technique correlates with early return of urinary continence post RARP ^{4,5}.

As recently described by our group, the novel uroflow Stop Test, consisting of the ability to completely stop urine flow for three seconds during voiding at the time of catheter removal, is a powerful independent predictor of early 3-months urinary continence recovery post RARP ⁶

The aim of this study is to evaluate whether the *uroflow Stop Test* can predict early recovery of potency following RARP

Material and Methods

In this prospective observational cohort, data was collected on 108 consecutive patients operated between October 2006 and January 2010 by a single fellowship-trained surgeon (AEH) after institutional review board approval. RARP was performed using the athermal robotic technique⁷, with few modifications⁸. None of the patients received neo-adjuvant or adjuvant therapy within 6-months of surgery and follow-up was performed during a minimum of 2 years. All patients had uroflow Stop Test at the time of catheter removal. Reported predictors for potency and urinary continence recovery were recorded including age, body mass index (BMI), international prostate symptom score (IPSS), sexual health inventory for men (SHIM), prostate specific antigen (PSA), tumor stage, prostate volume, nerve sparing status and estimated blood loss (EBL). Patients and investigators were blinded to the results of uroflow Stop Test.

Uroflow Stop Test:

Normal Saline (150 ml) was instilled intravesically prior to catheter removal on postoperative day 7, without cystogram. Patients were instructed to void freely into the uroflowmetry device (Urocap-II™ Uroflowmetry, Laborie Medical Technologies Corp), and to attempt to completely stop urine flow for as long as they could, at least once. A positive Stop Test was defined as the ability to completely stop urine flow voluntarily for more than 3 seconds provided that a maximum flow rate of 15 ml/sec was reached (figure 1A). All other results were considered negative Stop Test (figure 1B).

Main Outcome Measures:

All patients filled SHIM and erection hardness scale (EHS) pre- and post-operatively. Potency was defined as successful penetration during intercourse and/or EHS score of $\geq 3/4$, with or without phosphodiesterase type 5-inhibitor (PDE5-I). EHS score 3 indicates, *penis is hard enough for penetration but not completely hard* and EHS score 4, *penis is completely hard and fully rigid*. Patients were followed at 1, 3, 6, 9, 12, 18 and 24 months. Potency status was recorded at each visit. All patients were offered sexual rehabilitation with daily or as needed PDE5-I dosing schedule, and pelvic floor rehabilitation with Kegel exercises.

Statistical analysis:

Univariate and multivariate regression analyses were performed. All tests were two-sided and considered a p-value of 0.05 to determine statistical significance. The IBM SPSS Statistics package (IBM Corporation, version 21, Armonk, New York) was used for analysis. The distribution of the variables was evaluated using the Shapiro-Wilk's test and a visual inspection of their Q-Q plots. Data were summarized using descriptive statistics, and central tendency was measured with the median followed by the first and third quartiles (25%-75%). Group differences were determined using the chi-square test statistic or the Fisher's exact test for categorical variables. The Mann Whitney U test was used for continuous not-normally distributed variables. A direct logistic regression model was used to assess the impact of a number of factors on the likelihood of respondents reporting early recovery of potency.

Results

Eighty patients (74.1%) had a positive uroflow Stop Test (group 1) and 28 (25.9 %) had a negative Stop Test (group 2). Baseline demographics, clinical and pathologic data for each group are summarized in Table 1. Age, BMI, IPSS, pathological tumor stage, prostate volume and EBL were comparable between the two groups. PSA and nerve sparing status were statistically higher in group 1 (p 0.042 and p 0.015, respectively). None of the patients received neo-adjuvant or adjuvant therapy within 6-months of surgery. Overall the 12-, 18-, and 24- months' potency rates of the entire cohort were 61.8%, 62.8%, and 68.3%, respectively.

Early 3- and 6-months recovery of erectile function was significantly higher in group 1. Potency rates in group one and two at 1, 3, 6, 9, 12, 18 and 24 months were 25% vs. 14.3% (p 0.241), 54.5% vs. 18.5% (p 0.001), 55.4% vs. 18.5% (p 0.001), 56.4% vs. 36% (p 0.084), 66.6% vs. 50% (p 0.141), 65.5% vs. 56% (p 0.404) and 73.2% vs. 57.7% (p 0.160) respectively (table 2). The median time (range) to intercourse in group one was 4 months (1.0-12.0), compared to 10.5 months (8.3-19.5) in group two (p 0.003). At six months, the sensitivity, specificity, positive predictive value and negative predictive value of uroflow Stop Test were 87.8% (36/41), 43.1% (22/51), 55.4% (36/65), and 81.48% (22/27), respectively.

We also evaluated erectile function recovery in patients with preoperative SHIM \geq 15. Results were similar with significant differences only at 3 and 6 months between positive and negative Stop Test groups. Potency recovery rates of those particular patients at 1, 3, 6, 9, 12, 18 and 24 months for positive and negative Stop Test were 24% (12/50) vs. 16% (3/18) (p 0.520), 44.7% (21/47) vs. 11.1% (2/18) (p 0.011), 56.5% (26/46) vs. 11.1% (2/18) (p <0.001), 52.2% (23/44) vs. 42.8% (6/14) (p 0.539), 60% (27/45) vs. 58.8% (10/17) (p 0.933), 65.1% (28/43) vs. 62.5% (10/16) (p 0.820), 67.5% (27/40) vs. 64.7% (11/17) (p 0.838), respectively.

Considering that potency recovery rates were significantly different between both groups at 3 and 6 months, we conducted univariate and multivariate regression analysis at each of those

time points. Table 3 shows the results of univariate and multivariate analysis of potent and impotent patients of both groups at 3 months and 6 months after surgery encompassing for ten independent variables.

As shown in table 3, uroflow Stop Test was the strongest independent predictor of early potency recovery on multivariate regression analysis at 6 months with an odds ratio (OR) of 6.042 (CI95% 1.496-24.413, $p=0.012$). This indicated that respondents who had a positive Stop Test were 6.042 times more likely to report 6-months potency than those who had a negative Stop Test, controlling for all other factors in the model.

Similarly, age and BMI were also significant contributors to the model at 6 months with an OR of 0.905 (CI95% 0.823-0.996, $p=0.041$) and OR 0.813 (CI 95 0.686-0.964, $p=0.017$), respectively. In context, this meant that for each unit decrease in age or BMI, patients were respectively 1.10 or 1.23 times more likely to report 6 months potency, controlling for all other factors in the model. On the other hand, nerve sparing and SHIM score were only statistically significant on univariate analysis at 3 and 6 months, respectively.

Comment

Post prostatectomy ED is multifactorial and may be vasculogenic, anatomical, neurogenic, and/or psychogenic in origin. Our knowledge of post prostatectomy ED has been augmented by the cumulative literature describing prostate anatomy and prostatic fascia in relation to the course of cavernous nerves^{9,10}. Several preoperative and operative parameters have been reported as risk factors for post prostatectomy ED, including age, BMI, baseline potency status, comorbidity index, and nerve sparing status¹. Neurovascular preservation and restoration of pelvic floor anatomy are crucial for early return of urine continence and erectile function after RARP¹¹.

ED and urinary incontinence following RARP are major source of patients' anxiety as they negatively impact quality of life^{12,13}. There is a definite need for accurate pre and postoperative predictive models to counsel patients specifically and direct them for appropriate rehabilitation programs. The classically recognized risk factors^{1,13} do not discriminate sufficiently between patients; therefore any additional independent new predictive test will positively contribute to better prognosticate and personalize patients' care and enhance recovery.

We recently described a novel and powerful predictor of early urinary continence recovery post RARP that we named the *uroflow Stop Test*. It was shown that the ability to completely stop urine flow during voiding, measured objectively by uroflowmetry at the time of catheter removal on day 7 postoperatively is an independent predictor of early 3-months continence recovery [OR 2.87 (95%CI 1.34–4.38, P<0.001)]¹⁴. Interestingly, this simple test was the only statistically significant variable on multivariate regression analysis in that study, overshadowing all other classically reported predictors of continence recovery¹⁴. We therefore thought to evaluate whether uroflow Stop Test could independently predict early potency recovery post RARP.

To the best of our knowledge, this is the first study that investigated uroflow Stop Test in the prediction of potency recovery after RARP. The study design was prospective/longitudinal observational cohort, which is the best possible design for this particular research.

Randomization was not possible, as the results of uroflow Stop Test were not known *a priori*. All 108 patients were subjected to an uroflow Stop Test at the time of urethral catheter removal 7 days post operatively. Eighty had a positive uroflow Stop Test (group 1) and 28 had a negative Stop Test (group 2). Early 3- and 6-months potency recovery was significantly higher in group 1. Potency rates in group one and two at 3 and 6 months were 54.5% vs. 18.5% (p 0.001) and 55.4% vs. 18.5% (p 0.001). The median time to intercourse in group one was 4 months compared to 10.5 months in group two, with a significant difference of 6.5 months (p 0.003). Preoperative characteristics were comparable between both groups except nerve sparing and PSA, which were statistically higher in group 1. Both parameters, however, did not show statistical significance on multivariate analysis at 3 or 6 months between potent and impotent patients.

In this study, uroflow Stop Test was the strongest independent predictor of early potency recovery on multivariate regression analysis at 6 months. Age and BMI were also predictors at 6 months. Woo et al recently found in a study of 483 patients, that young age (<60), preoperative potency, and bilateral preservation of neurovascular bundles were predictors of potency recovery following RARP¹⁵. A prospective study of over 700 patients, published by Kim et al, reported that patient age and higher preoperative serum testosterone were independent prognostic factors for potency recovery after radical prostatectomy¹⁶. Another study of 293 patients by Gallina et al indicated that age, preoperative erectile function and Charlson comorbidity index were independent predictors of potency recovery after bilateral nerve sparing radical prostatectomy¹⁷. The aforementioned reports support our finding that age is an independent predictor of potency recovery. Another report of 765 patients by Campeggi et al found that recovery of continence and potency in obese men are significantly lower compared to non-obese men after laparoscopic radical prostatectomy¹⁸. This conclusion validates our findings that lower BMI was associated with faster recovery of potency after RARP.

In our study however, nerve sparing and preoperative SHIM score were only statistically significant on univariate analysis at 3 and 6 months, respectively. In fact, unilateral and bilateral nerve sparing accounted for 12% and 84%, respectively, totalling 96% of the entire cohort; so it was not possible to find the predictive value of nerve sparing due to very high nerve sparing strategy in this quite young group of patients with relatively high preoperative erectile function. In addition, median preoperative SHIM score was 21/25 in both groups;

therefore it was similarly difficult to tease out the effect of preoperative erectile function across various categories. Indeed, the 12-, 18-, and 24-months' overall potency rates of the entire cohort were fairly high at 61.8%, 62.8%, and 68.3%, respectively, notwithstanding patients with moderate and severe preoperative ED that were all included in analysis. We also performed the analysis for patients with preoperative SHIM \geq 15 and found exactly same results with statistically significant differences at 3 and 6 months postoperatively.

Hypothetically, uroflow Stop Test alike the Kegel maneuver is a voluntary contraction of the striated external urinary sphincter, which is part of the pelvic diaphragm or levator ani complex. The striated urethral sphincter's somatic innervation, similar to the erectile tissue, originates from the pudendal and pelvic nerves which arise from S2-S4 segments ¹⁹. Although simple, uroflow Stop Test may have complex physiological implications, and may represent a crude evaluation of neural, muscular, vascular, and tendinous integrity of the pelvic floor. The degree of pelvic structures preservation or damage as previously shown ¹¹, may be directly or indirectly correlated with the ability to achieve a positive result on uroflow Stop Test in the early postoperative period. Notwithstanding the underlying neurophysiological rationale behind Stop Test, the latter may well be a surrogate or a composite measure of various factors involved in erectile function status and potency recovery.

For potency definition we used the customary and widely used definition of successful penetration during intercourse, in addition to a more constructive metric, the EHS score of \geq 3/4, with or without PDE5-I. The EHS is an effective, simple, and validated questionnaire for potency which is commonly used in clinical practice for assessing patients with ED. Scores 4 study showed very good relationship between EHS and all other patient-reported outcome questionnaires, including erectile function, erection quality, overall sexual experience, and ED-related psychosocial factors ²⁰. All our patients were offered and encouraged to pursue sexual rehabilitation with daily or as needed PDE5-I dosing schedule, and pelvic floor rehabilitation with Kegel exercises and pelvic physiotherapy/ biofeedback as needed. Specific data on PDE5-I actual use and compliance were not available in this study, so potency definition had to include possible use of PDE5-I. And specific contribution of PDE5-I use to the model was unknown. However, it was fair to presume that PDE5-I use was

evenly distributed among both groups since patients and investigators were blinded to the results of uroflow Stop Test. Likewise, while all patients were offered pelvic floor physical therapy instructions, our previous study on continence recovery did not analyze specifically this variable for the same reasons ¹⁴.

Few studies reported on some objective test in predicting potency recovery after radical prostatectomy. Rabbani et al found that the maximum percentage change in penile girth after radical prostatectomy was an independent predictor of erectile function recovery ²¹. Klotz et al showed in a prospective randomized trial that the response to stimulation of the proximal cavernous nerves with tumescence monitoring immediately after removing the prostate accurately predicted the return of erectile function postoperatively ²². Other reports addressed adjunctive tools that could be used intraoperatively to help identify either blood flow in neurovascular bundle using Doppler ultrasound probe ²³, or to improve visualization of the periprostatic nerve fibers using diffusion tensor imaging technique ²⁴. These tests/tools are somewhat time-consuming, complex, and may not be sufficiently familiar to most urologists preventing their wide spread use in clinical practice.

This study was not devoid of some limitations including single institution, single surgeon, and small sample size. As for the sample size, based on the significant difference between the two groups, at 6 months (> 25%), a sample size calculation with 90% power and a 0.05 level of significance would yield an even smaller number to detect such difference. Another limitation is the arbitrary definition of positive uroflow Stop Test. The 3 seconds full stop was chosen in order to ascertain that the patient could stop flow unequivocally on printed flow chart for a clinically significant amount of time that would reproduce the Kegel exercise. The maximum flow rate of at least 15 ml/sec was also chosen to mimic a non-obstructed normal flow.

In this pilot study we showed the ability of simple uroflow Stop Test to predict potency recovery post RARP, after controlling for known covariates. Uroflow Stop Test may be used to counsel patients and select those who may benefit from more aggressive sexual rehabilitation, such as intracorporeal injections. Patient conception of recovery can be inaccurate despite counseling and the impact of ED and other side effects on daily life is

often underestimated by patients ²⁵. Therefore, improved counseling is important to help patients prepare and cope.

Future interesting directions include investigating the usefulness of repeating uroflow Stop Test at subsequent intervals in those who did not recover early potency and/or continence to verify if it can further predict later recovery. Another important objective is to verify the preoperative value of uroflow Stop Test in predicting postoperative potency and/or continence recovery. The best use of uroflow Stop Test is as a stratification parameter in prospective randomized studies of sexual or pelvic floor rehabilitation. Many such studies did not show significant difference in rehabilitation strategies, most likely because they included all comers and diluted the effect of intervention. Lastly, uroflow Stop Test needs to be externally validated in a larger, ideally multi-surgeon, multi-institutional study.

Conclusions

This pilot study suggests that a positive uroflow Stop Test may help predict early potency recovery following RARP. This test is familiar to urologists and urology nurses, simple, not labor intensive, and easy to interpret. Larger multi-surgeon and multi-institutional study is needed to validate our findings.

Figure 1 legend

A: Positive uroflow Stop Test. Patient stopped voiding from maximum flow of 20 ml/sec to 0 ml/sec for 6 sec. The distance between 2 dots on the horizontal axis represents 2 sec. **B:** Negative uroflow Stop Test. Patient could not stop flow to 0 ml/sec.

List of abbreviations (by alphabetical order):

Body mass index (BMI)

Erectile dysfunction (ED)

Estimated blood loss (EBL)

International prostate symptom score (IPSS)

Lower urinary tract symptoms (LUTS)

Phosphodiesterase type 5 inhibitor (PDE5-I)

Prostate specific antigen (PSA)

Robotic-assisted radical prostatectomy (RARP)

Sexual health inventory for men (SHIM)

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| Table 1. Baseline Characteristics | | | | |
|---|---------------|---|---|----------------|
| | | Group 1 (n=80) Positive Stop Test | Group 2 (n=28) Negative Stop Test | P value |
| Age (years) [Median (Q ₁ -Q ₃)] | | 60.00 (56.26-65.00) | 62.50 (57.25-66.50) | 0.242 |
| BMI (kg/m²) [median (Q ₁ -Q ₃)] | | 26.62 (25.10-29.73) | 26.88 (24.93-29.39) | 0.707 |
| Preoperative SHIM [Median (Q ₁ -Q ₃)] | | 21 (15-24) | 21 (10-24) | 0.694 |
| IPSS [Median (Q ₁ -Q ₃)] | | 5 (2-9) | 7 (3-9) | 0.309 |
| PSA (ng/ml) [Median (Q ₁ -Q ₃)] | | 5.70 (4.57-7.09) | 4.7 (3.5-6.8) | 0.042* |
| Tumor p Stage [n (%)] | T2 | 53 (66) | 24 (86) | 0.0861 |
| | T3 | 27 (34) | 4 (14) | |
| Prostate volume [Median (Q ₁ -Q ₃)] | | 42.00 (35.00-50.00) | 43.50 (37.50-53.75) | 0.251 |
| Nerve sparing [n (%)] | Unilateral | 6 (8) | 7 (25) | 0.015* |
| | Bilateral | 72 (90) | 19 (68) | |
| | Wide excision | 2 (2) | 2 (7) | |
| EBL (ml) [Median (Q ₁ -Q ₃)] | | 300 (200-400) | 300 (200-500) | 0.882 |

BMI, body mass index; IPSS, international prostate symptom score; SHIM, sexual health inventory for men; PSA, prostate specific antigen; EBL, estimated blood loss.

| Follow up (months) | Positive test | Negative test | P value |
|---------------------------|----------------------|----------------------|----------------|
| 1 | 20/80 (25%) | 4/28 (14.3%) | 0.241 |
| 3 | 36/66 (54.5%) | 5/27 (18.5%) | 0.001* |
| 6 | 36/65 (55.4%) | 5/27 (18.5%) | 0.001* |
| 9 | 35/62 (56.4%) | 9/25 (36%) | 0.084 |
| 12 | 42/63 (66.6%) | 13/26 (50%) | 0.141 |
| 18 | 40/61 (65.5%) | 14/25 (56%) | 0.404 |
| 24 | 41/56 (73.2%) | 15/26 (57.7%) | 0.160 |

Table 3. Logistic Regression (Univariate and Multivariate) of multiple perioperative potential predictive factors of potency at 3 and 6 months postoperatively

| | 3 months postoperative analysis | | | | 6 months postoperative analysis | | | |
|---|---|---|------------|--------------|---|--|------------|--------------|
| | Potent (n=41) | Impotent (n=52) | Univariate | Multivariate | Potent (n=41) | Impotent (n=51) | Univariate | Multivariate |
| Age (years) [median (Q ₁ -Q ₃)] | 59 (56-62) | 62 (58-67) | 0.047* | 0.704 | 59 (55-62) | 63 (58-67) | 0.030* | 0.041* |
| BMI (kg/m²) [median (Q ₁ -Q ₃)] | 26.11 (24.88-27.04) | 27.76 (25.25-30.16) | 0.04* | 0.581 | 26.15 (24.38-27.24) | 27.61 (25.28-29.99) | 0.041* | 0.017* |
| Preoperative SHIM [median (IQR)] | 23.00 (18.50-25.00) | 20.00 (13.25-24.00) | 0.12 | - | 22.5 (19.0-24.75) | 19.0 (12.5-23.0) | 0.040* | 0.378 |
| IPSS [median (Q ₁ -Q ₃)] | 4.00 (1.75-7.00) | 7.00 (3.00-10.00) | 0.116 | - | 4.0 (2.0-7.5) | 7.0 (3.0-11.0) | 0.119 | - |
| PSA (ng/ml) [median (Q ₁ -Q ₃)] | 5.40 (4.56-6.92) | 5.48 (4.1-6.85) | 0.413 | - | 5.19 (4.18-6.35) | 5.79 (4.23-7.02) | 0.838 | - |
| Tumor p stage [n (%)] | T2 29 (70.7) T3 12 (29.3) | T2 38 (73.1) T3 14 (26.9) | 0.802 | - | T2 29 (70.7) T3 12 (29.3) | T2 38 (74.5) T3 13 (29.5) | 0.686 | - |
| Prostate volume [median (Q ₁ -Q ₃)] | 38.00 (33.00-45.00) | 43.00 (35.00-50.25) | 0.280 | - | 39.0 (35.0-49.4) | 44.0 (37.0-53.0) | 0.063 | - |
| Nerve sparing [n (%)] | Unilateral 2 (4.9) Bilateral 39 (95.1) | Unilateral 10 (20.4) Bilateral 39 (79.6) | 0.046* | 0.136 | Unilateral 3 (7.5) Bilateral 37 (92.5) | Unilateral 9 (20.5) Bilateral 35 (79.5) | 0.103 | - |
| EBL (ml) [median (Q ₁ -Q ₃)] | 300 (200-475) | 300 (200-450) | 0.829 | - | 300 (200-400) | 300 (200-475) | 0.517 | - |
| Positive Stop Test [n (%)] | 36 (87.8) | 30 (57.7) | 0.003* | 0.153 | 36 (87.8) | 29 (56.9) | 0.002* | 0.012* |

At 6 months:

Age odds ratio is 0.905 CI95% 0.823-0.996, $p= 0.041$

BMI Odds ratio is 0.813 (CI 95 0.686-0.964) $p=0.017$

Stop test odds ratio is 6.042 (CI95% 1.496-24.413) $p= 0.012$

ACCEPTED MANUSCRIPT

Figure 1

