A Randomized, Double-Blind, Solifenacin Succinate versus Placebo Control, Phase 4, Multicenter Study Evaluating Urinary Continence after Robotic Assisted Radical Prostatectomy

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Purpose: Bladder dysfunction influences recovery of urinary continence after radical prostatectomy. We performed a multicenter, randomized, double-blind study evaluating solifenacin vs placebo on return to continence in patients who were still incontinent 7 to 21 days after catheter removal after robot-assisted radical prostatectomy.

Materials and Methods: A wireless personal digital assistant was given to patients the day of catheter removal. Encrypted answers were transmitted daily to dedicated servers. After a 7 to 21-day treatment-free washout period, patients requiring 2 to 10 pads per day for 7 consecutive days were randomized (1:1) to 5 mg solifenacin daily or placebo. The primary end point was time from first dose to continence defined as 0 pads per day or a dry security pad for 3 consecutive days. Secondary end points included proportion of patients continent at end of study, average change in pads per day number and quality of life assessments.

Results: A total of 1,086 screened patients recorded personal digital assistant information. Overall 640 patients were randomized to solifenacin vs placebo and 17 failed to take medication. There was no difference in time to continence ($p=0.17$). Continence was achieved by study end in 91 of 313 (29%) vs 66 of 309 (21%), respectively ($p=0.04$). Pads per day change from baseline was −3.2 and −2.9, respectively ($p=0.03$). Dry mouth was the only common adverse event seen in 6.1% and 0.6%, respectively. Constipation rates were similar. The overall rate of continence in the entire population from screening to end of study was 73%.

Conclusions: There was no effect on primary outcome but some secondary end points benefited the solifenacin arm. The study provides level 1B clinical evidence for continence outcomes after robot-assisted radical prostatectomy.

Key Words: prostatic neoplasms, robotics, prostatectomy, treatment outcome, urinary incontinence

Abbreviations and Acronyms

AUASS = American Urological Association symptom score

FAS = full analysis set

ICIQ-SF = International Consultation on Incontinence Questionnaire-Short Form

PDA = personal digital assistant

PPD = pads per day

QOL = quality of life

RARP = robot-assisted radical prostatectomy

RP = radical prostatectomy

SAF = safety analysis set

UDS = urodynamics

WPAI = Work Productivity and Activity Impairment questionnaire

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Urinary continence is a pivotal end point of the desired "trifecta" outcome (continence, potency, and cancer control) after radical prostatectomy.[1,2] While cancer control outcomes are robust, prolonged or permanent urinary incontinence remains a significant problem.[3–6] Recovering postoperative

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continence after RP is largely a balance between the viability and strength of the external sphincter and the impact of bladder compliance and detrusor instability.[7–9] Rodriguez et al reported a strong association between preoperative detrusor instability and delayed return of continence after RARP.[10] Their findings echoed investigations showing detrusor instability as a cofactor in prolonged incontinence and that anticholinergics might shorten time to continence.[11–13] A phase I trial evaluating solifenacin in the post-RARP setting demonstrated that 1) there were no significant safety issues with solifenacin after RARP and 2) the prediction of severely delayed return of continence could not be established by standard baseline preoperative assessment (AUASS, prostate weight etc).[14]

Significant research has revealed that the degree of leakage in the first few days after catheter removal after RP may be the best predictor of prolonged incontinence,[15–17] as 95% become pad-free by 90 days if they only required zero or 1 pad 4 to 7 days after catheter removal.[16]

For patients with post-prostatectomy incontinence with mixed urinary incontinence symptoms and/or those with an urgency component, EAU (European Association of Urology) guidelines recommend a trial of antimuscarinics. However, the guidelines rank the evidence as C, noting the weakness of the evidence.[18] We conducted a randomized clinical trial that assessed efficacy and safety of 12 weeks of treatment with solifenacin vs placebo in patients with early moderate to severe incontinence (2 to 10 PPD) after RARP. The trial included a run-in period that eliminated those men from randomization who had minimal or no incontinence after catheter removal.

MATERIAL AND METHODS

Study Objectives and Duration

The trial was a phase 4, multicenter, randomized, double-blind, placebo controlled study to evaluate the efficacy of solifenacin[19,20] vs placebo in the recovery of urinary continence after RARP in those patients who are still incontinent 7 to 21 days after catheter removal. The purpose of the study was to assess the efficacy and safety of 12 weeks of treatment of solifenacin vs placebo in patients whose urinary incontinence required 2 to 10 PPD for 7 consecutive days after RARP catheter removal. The primary objective was the continuous assessment of time to continence during 12 weeks of treatment with solifenacin vs placebo. The secondary objectives were to assess (categorically) the treatment effect on the proportion of patients who gained continence at 4, 8 and 12 weeks and at the end of treatment, the change from baseline to average daily pad use per month, changes in QOL as measured by AUASS, ICIQ-SF, the WPAI and finally time to work resumption. The protocol received institutional review board approval (Shulman Associates IRB 905-UC-050) and was registered on clinicaltrials.gov (NCT01371994).

Study Design

Men with newly diagnosed clinically localized prostate cancer who underwent RARP were invited to participate in the study at the time of Foley catheter removal. Participants received a PDA, which is a smartphone-like device (DiaryPRO®, Invivo Data/eResearchTechnology Inc., Philadelphia, Pennsylvania). The PDA evaluated daily pad use and drug intake. The PDA was programed to ring nightly at 7 pm until the patient provided the required information regarding medication compliance and pad use. Answers were digitally encrypted and the uneditable data were securely transmitted to designated servers. No economic incentive was provided. However, all patients were given standardized pads free of charge.

There was a 7 to 21-day treatment-free screening and washout period. Those recording 2 to 10 PPD for 7 consecutive days and meeting the baseline criteria were eligible for the treatment phase of the trial, and randomized 1:1 to 5 mg solifenacin or placebo. At week 4, based on efficacy and safety, and in agreement with the investigator, the dose could be doubled to 10 mg once daily. Screening and end of treatment/week 12 visits were conducted onsite. Baseline and week 4 and 8 visits were telephone contact visits. Subjects completed the PDA survey daily during the study duration. In addition, subjects were asked to complete the AUASS with bother score, the ICIQ-SF and the WPAI at baseline and week 12 visits.

Primary and secondary end points. The primary efficacy end point was the time from the date of first dose of study drug to the date of urinary continence (defined as the date of the first of 3 consecutive days in which the subject used 0 pads or a pad for security which remained completely dry) during the 12-week study.

Secondary end points included 1) proportion of patients who gained continence at the end of 12 weeks, 2) change from baseline to each month in average daily pad use, 3) change from baseline to end of study in QOL measured by AUASS and ICIQ-SF, 4) change from baseline to end of study on work productivity as measured by the WPAI and 5) time from baseline to the first day of returning to work.

Sample size, power estimations and statistical analyses. All safety analyses were based on the safety analysis set. The SAF consists of all randomized patients who receive at least 1 dose of double-blind study medication. All efficacy analyses were based on the full analysis set. The FAS consists of SAF patients who had at least 1 post-baseline assessment in the primary efficacy variable. The primary efficacy variable is summarized by treatment group and cumulative incidence of continence over time is displayed using the Kaplan-Meier estimate. The treatment difference in time to continence was tested using a log rank test stratified by center and baseline pad use (3 or more and less than 3 PPD) at a 2-sided significance level of 0.05. Patients who did not gain continence during the study were censored at the end of 12 weeks. The number

and percentage of patients who gained continence at the end of the 12-week treatment is presented, and treatment difference were tested using a Cochran-Mantel-Haenszel test stratified by center. Change from baseline in daily pad use during the 12-week treatment period, change from baseline in the quality of life measured by AUASS and ICIQ-SF, and change from baseline in the WPAI were analyzed using the analysis of covariance (ANCOVA).

RESULTS

At 65 centers 1,125 patients consented to participate in the trial but 39 did not enter data into the device. The remaining 1,086 patients completed the screening phase and 640 (58.9%) met randomization eligibility. A total of 623 patients (solifenacin 313 and placebo 310) constituted the SAF as 17 patients (7 assigned to solifenacin and 10 assigned to placebo) did not take any study medication and were excluded from analysis. Except for 1 patient on placebo, all SAF patients were included in the FAS. Demographics and baseline characteristics for the SAF are shown in table 1. Ten patients (1.6%) reported preexisting urgency, including 8 (2.6%) randomized to solifenacin and 2 (0.6%) to placebo. Urinary incontinence was reported by 9 patients overall (1.4%), 6 (1.9%) on solifenacin and 3 (1.0%) on placebo. Nineteen patients had a history of antispasmodic medication use. Fourteen patients had prior TURP and 4 had been treated for bladder cancer, evenly distributed. Comorbidities and concurrent mediations were distributed evenly between the arms.

Table 1. *Patient demographics*

	Placebo	Solifenacin
Age:		
Mean	61.2	60.5
SD	6.72	7.21
Median	61.0	61.0
Min-Max	41—78	41—79
No. age group (%):		
Less than 65	206 (66.5)	201 (64.2)
65 or Greater	104 (33.5)	112 (35.8)
No. race (%):		
White	263 (84.8)	266 (85.0)
African-American	43 (13.9)	44 (14.0)
Other	4 (1.3)	3 (1.0)
No. ethnicity (%):		
Hispanic	26 (8.4)	29 (9.3)
NonHispanic	284 (91.6)	284 (90.7)
Body mass index:		
No.	308	310
Mean	28.66	28.40
SD	4.715	4.437
Median	28.04	28.02
Min-Max	17.1—45.1	15.4—50.1

Primary Outcome Measure Analysis

Among the 622 FAS patients there was no difference in the time to return to urinary continence (0 pads or a pad for security which remains completely dry) from baseline to end of study ($p=0.17$, see figure). The separation in continence rates between the arms starting during week 6 after randomization and evident by week 8 prompted us to assess whether it could be explained by dose titration. However, there were no differences between treatment arms among those whose dose remained at 5 mg and those increased to 10 mg daily at 4 weeks.

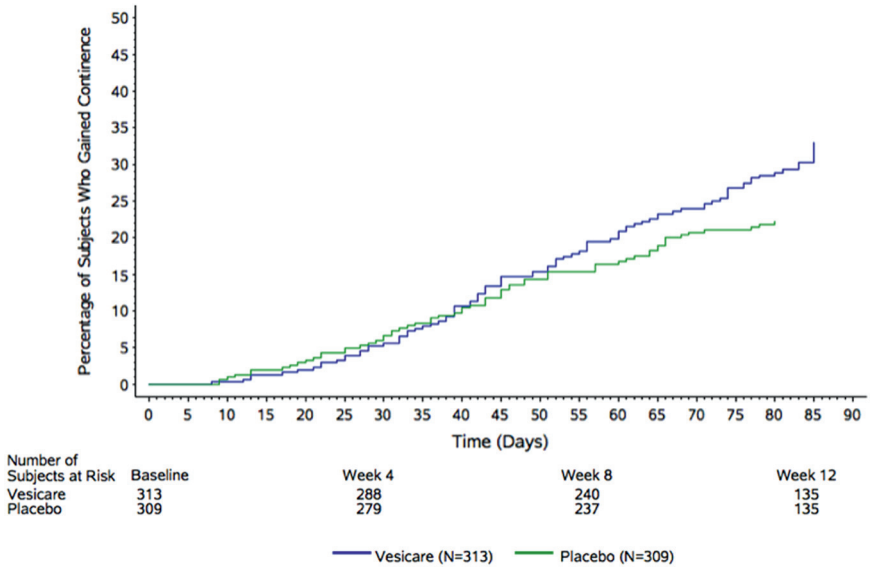
Secondary Outcome Measure Analysis

A statistically significant improvement favoring solifenacin over placebo was seen as 91 of 313 (29.1%) vs 66 of 309 (21.4%) patients, respectively, were continent at the end of the study ($p=0.04$). Overall, patients in both groups experienced a statistically significant decrease in the number of PPD used from baseline to study end. Starting at week 8, a trend between study arms ($p=0.08$) in PPD change was seen benefiting the solifenacin arm, which resulted in a significant difference by week 12 ($p=0.01$) and held by the end of study ($p=0.03$) as shown in the supplementary table (http://jurology.com/). Analysis of QOL outcomes measures showed statistically significant improvements ($p<0.001$) from baseline to end of study assessments in both arms for AUASS and AUA QOL- Bother Scores with no differences between study arms ($p=0.45$). The ICIQ-SF showed similar significant improvement from baseline in both arms ($p<0.001$) but no differences between arms by study end ($p=0.1$).

A total of 274 (44%) of the 622 FAS subjects participated in the workforce before the study and 136 of 147 (93%) and 114 of 127 (90%) of patients on solifenacin and placebo returned to work by end of study. There were no differences in work time missed, overall work impairment and activity impairment. Overall 73% of screened men became continent by the end of the trial, including the approximately 40% of men who became continent during the washout period and, therefore, were not randomized.

Adverse Events Analysis

Overall 30.3% of patients on placebo and 33.2% on solifenacin reported at least 1 treatment emergent adverse event. Dry mouth was the most common, occurring in 19 of 313 (6.1%) patients on solifenacin vs 2 of 310 (0.6%) on placebo. Constipation was observed in 2.6% of patients on solifenacin and placebo. Serious adverse events were observed in 5 patients in the placebo arm (acute coronary



Kaplan-Meier curve of time from first dose to urinary continence during 12-week treatment period, full analysis set

syndrome, cellulitis, psoas abscess, convulsion and renal failure) and in 9 in the solifenacin arm (acute coronary syndrome, cholecystitis, arthritis bacterial, infected lymphocele, bladder cancer recurrent, pulmonary embolism, and angioedema and lymphocele in 2). Adverse events occurring in more than 2% of patients are listed in table 2.

DISCUSSION

Recovery of continence after radical prostatectomy is one of the most important measures of the success of the operation for patients and surgeons alike. Ficarra et al recently reported a meta-analysis of predictors of recovery of continence.[21] It is clear from this and other studies that there is a need to generate high level evidence on how to improve the recovery of continence faster and more completely. To our knowledge this study is the first prospectively randomized, placebo controlled clinical trial which provides level 1B evidence regarding the use of antimuscarinic agents to reduce incontinence after RARP. It is important to emphasize that this trial selected a population of men at risk for prolonged or permanent incontinence. Although the primary outcome of the trial showed no statistically significant difference in the time to return to continence, there was a statistically significant 29.1% vs 21.4% improvement associated with the solifenacin treatment arm in those who became continent at end of study. This finding came at a 5% absolute risk increase in dry mouth and remarkably no difference in the incidence of constipation.

The Kaplan-Meier graph demonstrates that the curves start separating after 45 to 55 days (see figure). This is consistent with the results of Overactive Bladder Trials, in which the treatment effect of solifenacin vs placebo became noticeable after 4 to 8 weeks.[19] Since the beneficial effects of solifenacin are not apparent during the first half of the graph, no overall statistical benefit could be demonstrated. In similar fashion, when analyzed categorically,

Table 2. *Adverse events by System Organ Class (SAF)*

System Organ Class*	Preferred Term*	No. Placebo (%)	No. Solifenacin (%)
Overall		94 (30.3)	104 (33.2)
Gastrointestinal disorders:		16 (5.2)	41 (13.1)
	Constipation	8 (2.6)	8 (2.6)
	Dry mouth	2 (0.6)	19 (6.1)
	Gastroesophageal reflux disease	0 (0.0)	9 (2.9)
Infections + infestations:		24 (7.7)	35 (11.2)
	Urinary tract infection†	6 (2.0)	9 (2.9)
Musculoskeletal disorders		6 (1.9)	7 (2.2)
Renal + urinary disorders		13 (4.2)	12 (3.8)
Respiratory disorders		6 (1.9)	7 (2.2)

* Based on MedDRA (Medical Dictionary for Regulatory Activities) (v13.0).
† Including the preferred terms urinary tract infection, urinary tract infection bacterial and urinary tract infection enterococcal.

we observed a trend favoring solifenacin at 4 and 8 weeks (not statistically significant), and statistical significance was only achieved by the end of treatment. Because patients who achieved early continence during the run-in period were excluded from randomization, and our definition of continence was more stringent (patients had to report 0 or a single pad which remained dry, for 3 consecutive days) than in previously published series, the rate of recovery of continence in this study has been lower than what we assumed. If the underlying continence rate had been similar to what was prespecified in the protocol and the relative treatment difference remained the same, then our results would have been significant.

Our clinical trial was novel, measuring postoperative continence outcomes daily by each individual using a PDA, smartphone device that encrypted and transmitted the information directly to a server. Patient derived information represents the best source to evaluate quality of life outcomes including continence.[22–25] The investigators and surgeons had no influence on patient answers. It is interesting to note that during the screening period after catheter removal approximately 40% were pad-free or using just 1 pad per day during 7 consecutive days of screening. Two studies reported patients were still incontinent 1 to 3 weeks after catheter removal, have the highest risk of prolonged incontinence and are most likely to benefit from pharmacotherapy.[14,16]

Use of antimuscarinic agents after radical prostatectomy is also supported from urodynamic investigations. Initial reports focused on UDS findings in patients with urinary incontinence after radical prostatectomy.[7,11–13,26] Leach et al evaluated 38 patients and found intrinsic sphincter deficiency in 40% as well as evidence of hyperactivity, decreased contractility and impaired compliance in 62%.[13] Detrusor overactivity was reported by Goluboff et al,[11] and Ficazzola and Nitti.[26] Subsequent studies using UDS before and after RP improved our understanding of bladder dysfunction as Giannantoni et al showed that at baseline 57% had outlet obstruction, 55% had detrusor hyperactivity and 20% had impaired compliance.[27] In fact, the EAU guidelines acknowledged and suggested a role for anticholinergics in selected patients after RP.[18]

Our study has limitations. UDS to demonstrate bladder instability was not performed. Although generally held to be much more accurate than paper diaries, PDA devices may still be subject to the placebo effect.[28,29] However, it is expected that such an effect is evenly distributed among both arms of the study. We can only speculate why our study did not demonstrate QOL differences. There was gradual improvement in all QOL measures from baseline to the end of study. However, no differences were noted between the arms. It may be that other concurrent postoperative issues overshadowed the assessment of the benefits. We also did not stipulate longer followup periods such as 6 to 12 months as evidence suggests that some patients regain continence even beyond 1 year.[30] Long-term followup data on this patient population are needed.

CONCLUSIONS

The primary end point of time to urinary continence was not statistically significant. However, the secondary end points of proportion of subjects who gained continence and mean change from baseline in average daily pad use were statistically significant at the end of treatment. Dry mouth was the only solifenacin side effect that was readily identifiable as the incidence of constipation was equal in the 2 groups. There were no other notable safety observations. The study provides clinical evidence 1B of continence outcomes after RARP.

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EDITORIAL COMMENT

The authors assess antimuscarinic medications for post-prostatectomy incontinence. Improvements in current post-prostatectomy incontinence rates are directly attributable to advancements in surgical technique such as meticulous apical dissection, preservation of the neurovascular bundle and minimal disruption of the circular fibers of the bladder neck. However, certain individuals may be at increased risk for post-prostatectomy incontinence due to specific comorbidities.[1] Pelvic floor rehabilitation, now done commonly by most experienced surgeons, has to be another factor to be considered in the improved rates and can be enhanced by the use of a PDA.

Despite these advancements, a significant number of men continue to experience early incontinence (as seen in this study) and a few, unfortunately, continue to experience longer term more fixed incontinence (reference 30 in article). Those with more fixed incontinence should be assessed for detrusor storage abnormalities as that group may benefit from therapy directed at improving storage disorders (reference 18 in article).

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