HHS Public Access

Author manuscript

Urology. Author manuscript; available in PMC 2016 December 01.

Published in final edited form as:

Urology. 2015 December ; 86(6): 1115–1122. doi:10.1016/j.urology.2015.07.019.

Use of Medical Therapy and Success of Laser Surgery and TURP for BPH

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Abstract

Objective—To assess the impact of surgery for BPH on use of medication (5-ARIs, alpha blockers, antispasmodics), we assessed pre- and post-operative medication utilization among surgically treated men.

Materials and Methods—Using the Truven Health Analytics MarketScan® Commercial Claims Database, we defined a cohort of men < 65 years of age who had surgical therapy for BPH with either TURP or laser procedures from 2007 through 2009. Primary outcomes included freedom from medical or surgical intervention by 4 months after surgery (chi-square and multivariable logistic regression) and subsequent use of medical or surgical intervention in initial responders (Kaplan-Meier and multivariable Cox regression).

Results—We identified 6430 patients treated with either TURP (3096) or laser procedure (3334) for BPH. Pre-surgical antispasmodic use was associated with the highest risk of medication use at 4 months after surgery (OR 5.19; CI 3.16 to 8.53 versus no medication use prior to surgery). At three years after surgery, 6% (95% CI 4–8%) of laser and 4% (95% CI 2–5%) of TURP treated patients had repeat surgical intervention, and both laser and TURP treated patients had an estimated new use of medication rate of 22% (95% CI 18–25% laser and 20–25% TURP). The strongest predictor of intervention after surgery was pre-operative antispasmodic use (HR 2.49; 95% CI 1.41 to 4.43).

Conclusions—Our results show a need for effective patient counseling about continued or new use of medical therapy after laser and TURP procedures. However, most patients experience durable improvement after surgical intervention for BPH.

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Keywords

Benign Prostatic Hyperplasia; Lower urinary tract symptoms; Transurethral Resection of the Prostate; Laser Vaporization; Laser Ablation; Medical Therapy for lower urinary tract symptoms

Introduction

For most men with moderately to severely symptomatic lower urinary tract symptoms due to prostatic enlargement, surgical intervention provides excellent symptomatic relief. Over 70% of men undergoing surgery for LUTS with an enlarged prostate undergo TURP or laser therapy.[1] Regardless of modality, excellent improvements in urinary flow, symptom scores, and PVR are seen,[2–5] and the results appear to be durable in single institution series beyond 5 years[6] and randomized trials out to 2 years.[7,8]

Despite these excellent results, the use of medical therapy for BPH both before and after surgical intervention has not been well characterized. Most patients, and urologists, see surgical intervention as definitive therapy for LUTS due to BPH that should preclude the need for additional medical therapy. Furthermore, medical therapy for BPH is a significant expense for patients and insurers, and successful elimination of these medications is a goal for many patients. Thus, the effectiveness of the procedure should include a measure of whether medication therapy was used after surgery.

To better inform patients and their providers on the effectiveness of surgery for LUTS, we undertook a study of medication use before and after surgical intervention for BPH. First, we asked whether men discontinued pre-operative BPH medication use in the immediate post-operative period, and if discontinuation rates varied between TURP and laser procedures. Second, we determined the rate of initiation of new medication, or receipt of surgical therapy, over longer follow up after surgery. We hypothesized that, consistent with prior population based studies,[9,10] laser procedures would be associated with increased rates of retreatment compared to TURP.

Patients and Methods

Patient Population

Using the Truven Health Analytics MarketScan® Commercial Claims Database, a database of commercially insured patients, we identified a cohort of men < 65 years of age, who had surgical therapy for LUTS with either TURP or laser procedures from 2007 through 2009. This database contains all inpatient claims, outpatient claims, and medication data for patients while they have commercial insurance (from any insurance company) through their employer. Men over the age of 65 were not included from this database, as the data for these men may be incomplete due to Medicare being the primary insurance with the commercial insurance as the secondary coverage. Follow-up records were available through 2010.

Surgical procedures were identified from outpatient and physicians claims data using Common Procedural Terminology codes 52647 and 52648 (laser), and 52450 and 52601 (TURP). Inpatient surgical procedures were identified using International Classification of

Disease 9th edition (ICD-9-CM) procedure codes 60.21 (laser) and 60.0, 60.00, 60.2, 60.20, and 60.29 (TURP). In cases where both CPT and ICD-9 codes were available, the CPT code was used to identify the procedure. All men were required to have an ICD-9 diagnosis consistent with BPH or lower urinary tract symptoms (594.1, 599.6, 600.0, 600.2, 600.9, 788.2, 788.21, 788.29, 788.41, 788.42, 788.43, 788.61, 788.62). To help ensure patients were not receiving therapy for complications from prior surgery or for other diagnoses, we excluded men who had surgical therapy in the year prior to the index procedure, or who had a diagnosis consistent with bladder cancer, prostate cancer, Parkinson's disease, multiple sclerosis, hemi paralysis, paralysis syndrome, or cerebrovascular disease in the year prior to the index procedure. We did not include men with laser enucleation procedures (CPT code 52649).

Medication Utilization

We assessed outpatient medication use related to LUTS: 5-alpha reductase inhibitors (finasteride, dutasteride), alpha-blockers (doxazosin, terazosin, tamsulosin, alfuzosin, silodosin), and antispasmodics (oxybutynin, tolterodine, solifenacin, trospium, fesoterodine, darifenacin, propiverine)]. The data set includes filled prescriptions for medications. Pre-operative medical therapy was defined as medication possession rate of greater than 80% in the year prior to surgery. We also explored using active medication at the time of BPH related surgery as the marker of medication use, but we found no difference in percentage of men on medication at the time of surgery. We then examined the data for new filled prescriptions for BPH related medication after surgery. We required all men to have at least 4 months of insurance coverage after surgical intervention for assessment of post intervention medications use.

Effectiveness of Surgical Intervention

We developed a combined outcome for effectiveness of surgery including use of medical therapy related to LUTS or repeat surgery. Repeat surgery was identified from inpatient and outpatient claims for surgery related to BPH or complications of prior surgery using procedure codes (Appendix 1). We examined the data for use of medications or surgery up to four-months after surgery. This four-month window was used to allow discontinuation of 90-day supplied pre-operative medical therapy. By this measure of short-term effectiveness we identified a group who underwent early medical or surgical reintervention and, conversely, a group of initial responders (no early reintervention).

The long-term effectiveness of surgical intervention was similarly assessed by the combined endpoint of surgical intervention and new medical therapy starting 4 months after surgery among the group of initial responders. Men were censored at loss of their insurance coverage or at the end of the data.

Statistical Analysis

We assessed for differences in baseline characteristics between patients receiving TURP and laser therapy through chi-square testing for categorical variables and t-test for continuous variables.

Types of medications used by TURP and laser patients were compared before and 4 months after surgery by chi-square testing. We then assessed the impact of type of medication used prior to surgery, patient age, comorbidity, the year of the procedure, and type of surgery on short-term success through logistic regression analysis.

Comorbidity was defined based on inpatient and outpatient claims for the year prior to the index surgery.[11] Interactions between medication use and surgical procedure were tested and no significant results were found. Thus, we report the primary effects only.

Among initial responders, we assessed the long-term effectiveness of laser and TURP procedures through competing risk analysis accounting for surgical and medical interventions after therapy. We then examined factors associated with starting new medications or having repeat surgery including medication use prior to surgery, patient age, comorbidity, and the year of the procedure, and type of surgery with Cox proportional hazards regression analysis.

Results

We identified 6430 patients who were treated with either TURP (3096 patients) or a laser procedure (3334 patients) for BPH from 2007–2009 (Appendix 2). Patient age ($p = 0.56$), year of surgery ($p = 0.93$), and comorbidity ($p = 0.05$) were not significantly different between patients treated with TURP and laser therapy. We found no difference in the proportion of patients using BPH medication in the year prior to surgery (49% TURP, 48% laser), however laser-treated patients used slightly more alpha-blocker (34.1% versus 32.6%) and anti-spasmodic medications (1.2% versus 0.9%) while TURP patients had higher use of 5-alpha reductase inhibitors (7.9% versus 6.2%) ($p = 0.025$ for all categories).

At four months after surgery, TURP patients were less likely to be on medical therapy than patients treated with laser procedures (15% versus 18%; $p < 0.001$). Distributions and types of medication for LUTS after surgery stratified by pre-operative medication use are shown in Figure 1. Among patients who were not on medication prior to surgery, 89% of those treated with laser procedures remained off medication at 4 months after surgery compared to 92% of those treated with TURP ($p = 0.006$). Antispasmodic medication was the most common type of medication used after surgery (4.3% laser and 2.9% TURP) among patients off medication before surgery. Among men on BPH medication pre-operatively, those treated with laser therapy were less likely than those treated with TURP to be off medical therapy at 4 months post-operatively (74.7% compared to 78.7% $p = 0.001$). Alpha-blocker medications were the most common medication used in both groups. Repeat surgery within 4 months of the initial procedure occurred in a small percentage of patients (4% TURP and 4% laser).

After controlling for potential confounding (Table 1) laser procedures remained significantly associated with a higher probability of retreatment by four months after surgery (OR 1.28; 95% CI 1.13 to 1.45). However, prior medication use was associated with much higher risks of retreatment, with pre-surgical antispasmodic use associated with the highest risk of continued or new therapy (OR 5.19 CI 3.16 to 8.53 versus no medication use prior to

surgery). Older patients were more likely to have retreatment than younger patients (OR 1.06 per year increase in age; 95% CI 1.04 to 1.07). We found no association between year of the procedure and failure at 4 months.

New use of surgical or medical therapy after 4 months post-surgery was rare among the 2633 laser patients and 2547 TURP patients who were initial responders. At three years after surgery (Figure 2), 6% (95% CI 4–8%) of laser treated and 4% (95% CI 2–5%) of TURP treated patients had repeat surgical intervention, and both laser and TURP treated patients had an estimated new use of medication rate of 22% (95% CI 18–25% laser and 20–25% TURP). In a Cox proportional hazards model analyzing time to failure within 3 years after the index procedure (Table 2), the strongest predictor of intervention after surgery was pre-operative antispasmodic use (HR 2.49; 95% CI 1.41 to 4.43). Increasing age, comorbidity, and use of multiple medications prior to surgical intervention were all associated with intervention after initially successful surgery for LUTS. Laser therapy showed a higher hazard rate for subsequent intervention compared to TURP (HR 1.22; 95% CI 1.06 to 1.40).

Discussion

We found that surgery for BPH is successful in eliminating the need for medical therapy in over 75% of patients who use medication prior to surgery. However up to 10% of patients who are not using medical therapy for LUTS prior to surgery are using medications after the procedure. A significant difference exists in the risk of continued and new medical therapy comparing TURP and laser procedures. However, medication use prior to surgical intervention had a stronger association with new or continued medication use after surgery.

These results focus attention on the risks and benefits of surgical intervention for BPH. In properly selected patients, TURP and laser procedures are highly effective in decreasing LUTS.[3] These improvements in symptom scores are far greater than can be achieved with medical therapy.[12] Despite these improvements, all interventions have risks. Our results highlight the risk of new medical therapy in men who are not using medications at the time of surgery. For the 50% of patients who received surgical therapy while on no medications, this likely represents an unexpected complication of therapy. In 2008 in the Medicare program alone, over 101,000 men received surgical intervention for LUTS.[13] Therefore, a large population of men is at risk for new or continued medication use after surgery intended to definitively treat their symptoms.

The use of medical therapy around the time of surgical intervention has been poorly characterized. Many randomized studies of surgical intervention for patients with BPH do not include information on use of medications before and after surgical intervention.[14,15] When information on initial post operative medication use is provided, it is in the context of post operative urinary urgency and the use of antispasmodic medications, and specific information on discontinuation or new use of medication is not provided.[16] Furthermore, long-term efficacy results for laser and TURP procedures lack the important outcome of resumption of medical therapy. Single institution studies have provided some information on use of medications after surgery, and consistent with our study found many men were not on

medications prior to intervention and many men continued medical therapy after the procedure.[17] Our study expands on these prior results in a population-based framework.

By quantifying the risk of continued or new medical therapy after surgery, our study provides additional information for patients and surgeons on the risks and benefits of surgical intervention for BPH. A detailed discussion of intervention options is central to decision making for surgical therapy in BPH, and is called for in current AUA guidelines.[18] Full disclosure on possible continued or new medication use is needed for all patients prior to choosing surgical intervention. This information may affect decision making regarding surgery since most men with BPH who see a urologist do not choose surgery for their symptoms.[19] Also, improved knowledge of possible medication use after surgical intervention better sets patient expectations regarding surgery and will help improve satisfaction with the surgical intervention. This is especially true among men who are already using antispasmodic medications at the time of surgery who are at the highest risk for both short- and long-term retreatment. Many of these men will continue to require medication for their bladder instability, even if their overall voiding symptoms improve.

The results found in this paper need to be considered within the context of the following limitations. First, the data was from an administrative database from which patient symptom scores or objective measures of disease severity are not available. Therefore, we chose to measure success of therapy by reuse of surgery or medical therapy. Second, our population was men between 39 and 65 years of age. Over 98% of men were over 45 years of age, over 94% were older than 50 years of age, and over 42% were over 60 years of age. These men are at an age where initial LUTS symptoms and treatments occur. However, results may be different in an older group of men. Third, we examined medication use for one year prior to surgery. We cannot determine if longer use of medications prior to BPH surgery would lead to different results. Fourth, the study was observational and not randomized. There may be differences between the types of patients treated with laser and TURP that could account for the small difference in retreatment rates between the two procedures. Finally, medication use was determined by the filling of a prescription. The use of filled prescriptions likely accounts for the seemingly high rate of surgery in men receiving surgery while not on BPH related medication. In unpublished data from our own institution, we found about 25% of patients had surgery when there was no active BPH related medication on their chart. Since many patients do not fill prescribed medication, the actual use of medication at the time of surgery is likely closer to that seen in the current data set. Finally, in both administrative data and chart review, patient compliance with medication cannot be assessed. By assessing results at 4 months after surgery we assured that no men were still covered by prescriptions filled prior to or just after surgical intervention.

Conclusions

Our results show a need for effective patient counseling about continued or new use of medical therapy after laser and TURP procedures. Antispasmodic medication use prior to surgery is most associated with new or continued medication use after surgery. However, most patients experience durable improvement after surgical intervention for BPH without need for subsequent medical or surgical intervention.

Acknowledgement

Additional support for this publication was provided by the Washington University KL2 Career Development Awards Program (KL2 TR000450) and a National Institute of Diabetes and Digestive and Kidney Diseases Clinical Investigator Award (1K08DK097302-01A1).

The Center for Administrative Data Research is supported in part by the Washington University Institute of Clinical and Translational Sciences grant UL1 TR000448 from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), and Grant Number R24 HS19455 through the Agency for Healthcare Research and Quality (AHRQ).

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Appendix 1

Codes for repeat surgery

Code Type	Procedure Name	Code
	Transurethral incision of prostate	52450
	Transurethral electrosurgical resection of prostate	52601
	Transurethral resection; residual or regrowth of obstructive tissue	52620
	Transurethral resection; residual or regrowth of obstructive tissue	52630
	Transurethral resection of postoperative bladder neck contracture	52640
	Laser coagulation of prostate	52647
	Laser vaporization of prostate	52648
	Laser enucleation of prostate	52649
	Transurethral microwave therapy (TUMT)	53850
	Transurethral needle ablation (TUNA)	53852
	Prostatectomy, perineal, subtotal	55801
	Prostatectomy, suprapubic, subtotal	55821
	Prostatectomy, retropubic, subtotal	55831
ICD-9	Incision of prostate	600.0
	Transurethral prostatectomy	602.0

Code Type	Procedure Name	Code
	Ablation contact or non-contact by laser	602.1
	Other transurethral prostatectomy	602.9
	Suprapubic prostatectomy	603.0
	Retropubic prostatectomy	604.0
	Local excision of prostatic lesion	606.1
	Control of postoperative hemorrhage of prostate	609.4
	Transurethral balloon dilation of the prostatic urethra	609.5
	Transurethral microwave therapy (TUMT)	609.6
	Other transurethral destruction of prostatic tissue	609.7

Appendix 2

Demographics and Baseline Medication use in the Cohort

	TURP	Laser	p-value
Number of Patients	3096	3334	
Age (Years)	Mean 58.5 Median 60 IQR 56 to 62	Mean 58.4 Median 60 IQR 56 to 62	0.557
Follow Up Time (Days)	Mean 639 Median 573 IQR 387.5 to 857	Mean 639 Median 582.5 IQR 393 to 857	0.932
Procedure Codes (Laser)			
52647		340	
52648		2931	
60.21		63	
Procedure Codes (TURP)			
52450	245		
52601	2745		
60.0	19		
60.00	0		
60.2	0		
60.20	0		
60.29	87		
Year of Surgery			
2007	27.7%	27.8%	0.933
2008	32.4%	32.7%	
2009	39.9%	39.5%	
Comorbidity			0.048
0	75.6%	78.0%	
1	16.6%	15.5%	
≥2	7.8%	6.5%	

	TURP	Laser	p-value
Medication Use			0.047
5-alpha Reductase Inhibitor	7.85%	6.21%	
Alpha Blocker	32.62%	34.16%	
Anti-spasmodic	0.94%	1.17%	
Multiple	7.56%	6.78%	
None	51.03%	51.68%	

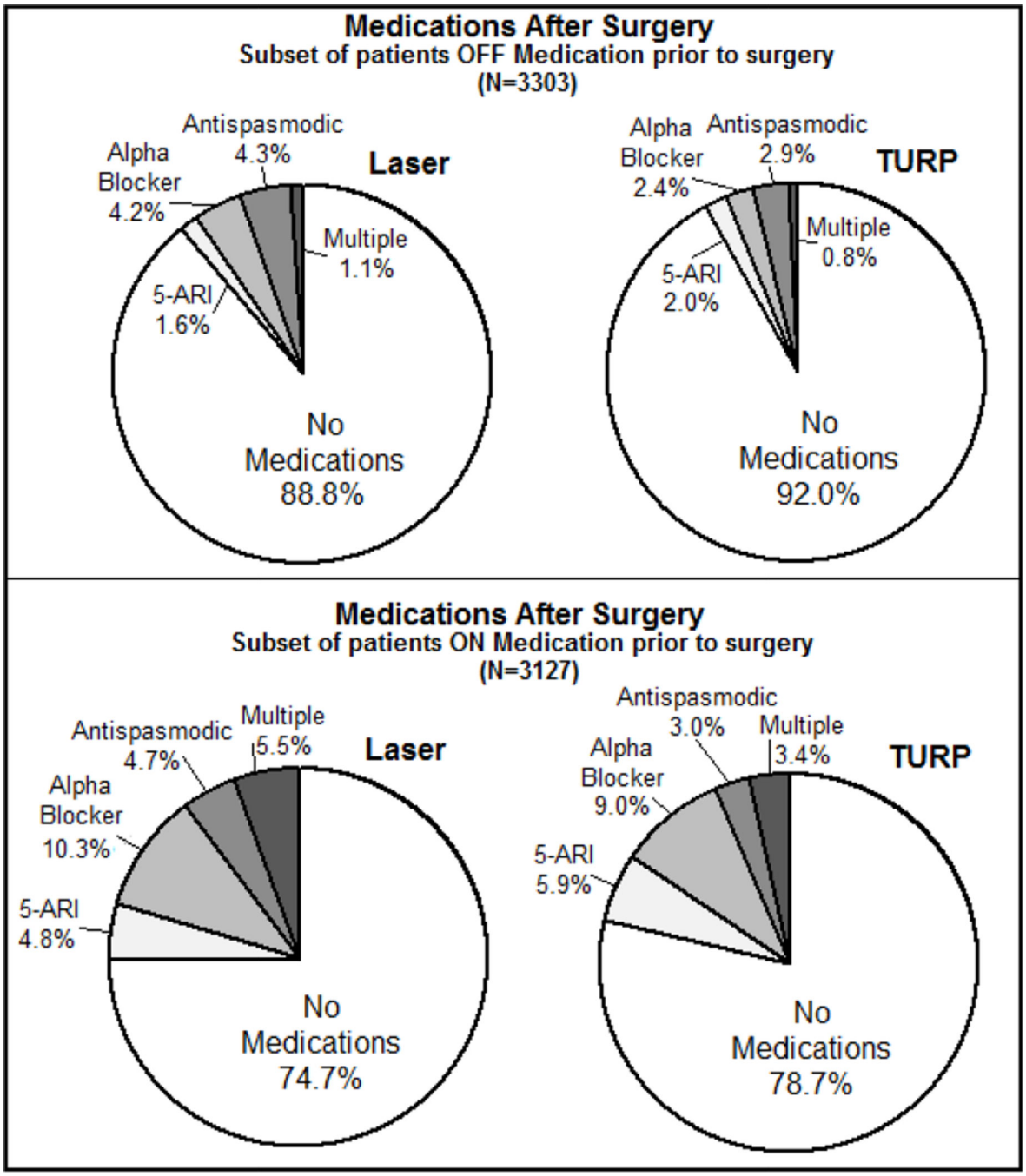

Figure 1. Medication use four months after laser and TURP procedures

TURP patients were more likely to be off medication after surgery than were laser patients regardless of medication use prior to surgery. Patients requiring new medication after surgery were split between use of alpha-blocker medication and antispasmodics. Patients continuing medication after surgery were commonly using alpha-blocker medications. Antispasmodic use was higher in laser treated patients and 5-alpha reductase inhibitor use was higher in TURP treated patients.

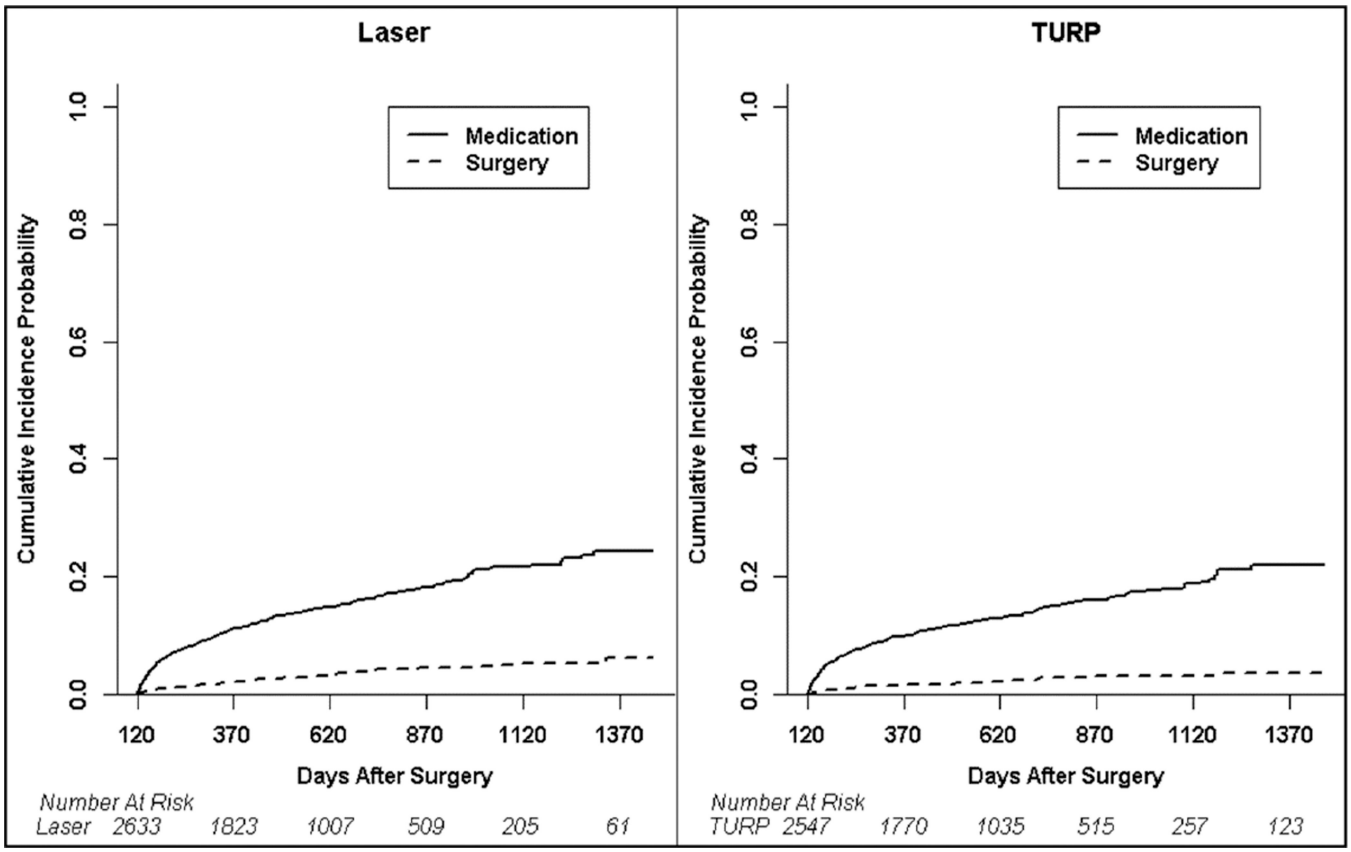

Figure 2. Efficacy of laser and TURP procedures

Patients off medical therapy and without failure by four months after surgery were examined for long-term efficacy of the procedures. The estimated probability of freedom from medical or surgical therapy at 3 years was 73.6% in the laser patients (95% CI, 71% to 76.2%) compared to 78.8% in the TURP patients (95% CI, 76.5% to 81.2%)

Table 1

Logistic regression results for probability of retreatment at 4 months after the procedure*

		95% Confidence Intervals		
Effects	**OR**	**Lower**	**Upper**	**P-values**
Medications Used before Procedure				
None	ref			
5-ARI	2.92	2.33	3.66	<0.001
Alpha Blocker	1.95	1.69	2.25	<0.001
Anti-Spasmodic	5.19	3.16	8.53	<0.001
Multiple Medications	2.49	1.98	3.13	<0.001
Age (Per year)	1.06	1.04	1.07	<0.001
Comorbidity				
0	ref			
1	1.16	0.98	1.38	0.088
>=2	1.39	1.11	1.76	0.005
Surgery Year				
2009	ref			
2007	1.02	0.87	1.20	0.776
2008	1.04	0.90	1.21	0.590
Laser vs. TURP	1.28	1.13	1.45	<0.001

* Retreatment was defined as filled prescriptions for medical therapy or surgery up to 4 months after the initial surgical procedure.

Table 2

Adjusted Analysis of Time to Intervention after TURP and Laser procedures*

		95% Confidence Intervals		
Effects	**HR**	**Lower**	**Upper**	**P-values**
Medications Used before Procedure				
None	ref			
5-ARI	0.98	0.73	1.32	0.887
Alpha Blocker	1.04	0.90	1.21	0.581
Anti-Spasmodic	2.49	1.41	4.43	0.002
Multiple Medications	1.37	1.07	1.75	0.014
Age (years)	1.08	1.06	1.10	<0.001
Comorbidity				
0	ref			
1	1.10	0.91	1.32	0.331
>=2	1.39	1.08	1.78	0.011
Surgery Year				
2009	ref			
2007	1.02	0.86	1.21	0.838
2008	0.96	0.81	1.14	0.619
Laser vs. TURP	1.22	1.06	1.40	0.004

*A Cox proportional hazards model was fit with the outcome being use of medical or surgical therapy after initial successful surgical therapy with either laser or TURP. Medication used reflect the pre-operative medications used by patients.