



## **Draft Final Report**

# **Post Coverage Analysis of the Outcomes Following Surgical Treatments among Elderly Medicare Men with Benign Prostatic Hypertrophy**

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# **Post Coverage Analysis of the Outcomes Following Surgical Treatments among Elderly Medicare Men with Benign Prostatic Hypertrophy**

## **Executive Summary**

### **Introduction**

Benign prostatic hypertrophy (BPH) is the most common benign neoplasm in American men. Patients with BPH may experience nocturia, incomplete emptying of the bladder, urinary hesitancy, weak stream, frequency, and urgency, or even acute urinary retention. These lower urinary tract symptoms (LUTS) can negatively affect the quality of life among these patients.

Although the transurethral resection of prostate (TURP) is still the most commonly used procedure to treat BPH, the utilization of minimally invasive surgical therapies (MIST) increased during the last decade. The MIST procedures, including transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), transurethral incision of the prostate (TUIP), and transurethral or external laser therapy (Laser), have been reported to have comparable treatment effects to the TURP, but with lower complication rates (AUA, 2003; Wei, et al. 2005). However, whether these MIST procedures result in better outcomes than traditional procedures in the general clinical practice among the entire elderly population is unknown.

In order to answer this, we evaluated the post-surgical events for up to three years following the receipt of prostate surgery in the Medicare elderly population.

### **Methods and analysis**

The experience of Medicare elderly men who had one of the MIST procedures in 1999, 2000 or 2001 was compared with that of those who had a TURP during those years. The outcomes we measured were major urinary tract related surgical treatment in the post-operative period of up to 3 years: namely, reoperation using the same BPH surgery, remedial procedures to remove residual prostate tissue, surgical treatments for incontinence, and open prostatectomy. We also examined clinical outcomes including urethral abscess, fistula, and stricture; incontinence; and diagnostic and functional tests. The geographic distributions of the MIST procedures are also presented. We compared the rates of the outcomes between procedures using logistic regression that adjusted for race, age, and comorbidities identified during the year prior to surgery.

### **Results**

#### **Procedure rates**

About 79% of BPH surgeries performed were TURPs, and 18% were MIST procedures. The highest procedure rates were among those with 75-84 years of age. There was a slight decrease of TURP, TUIP and Laser procedure rates but an increase of TUMT and TUNA procedure rates from 1999 to 2001.

For the entire three-year study cohort, the procedure rate was 6.24 per 1,000 persons for TURP, 0.61 per 1,000 for TUMT, 0.20 per 1,000 for TUNA, 0.18 per 1,000 for TUIP, 0.45 per 1,000 for Laser, and 0.27 per 1,000 for prostatectomy.

## **Outcomes**

### **30-day post-operative mortality rate**

The 30-day post-operative mortality rates were low among patients following BPH surgery. Among all BPH surgeries, those with prostatectomy had the highest mortality rate. The mortality rate was similar between the TURP and TUIP groups, while it was significantly lower (about one third) among patients having TUMT or TUNA, and about two thirds among patients following Laser procedures.

### **Major urinary tract related surgical treatment after BPH surgery**

During the first post-operative month, the TURP and prostatectomy groups had higher reoperation rates than the MIST procedure groups. The difference between them decreased over the rest of the first post-operative year mainly because the reoperation rates increased in the TUMT, TUNA, and TUIP groups. There were very few reoperations among patients following Laser treatment or prostatectomy after the first post-operative month.

Although the MIST procedure groups had lower remedial procedure rates during the first post-operative month, the rates for the MIST surgery groups increased substantially after that, while the rates for the TURP and prostatectomy groups decreased significantly. During the second half of the first post-operative year, the MIST surgery groups had remedial procedure rates approximately twice as high as those following TURP or prostatectomy.

During the second and third post-operative year, the remedial procedure rates continued to decrease in all BPH surgery groups. However, the rates following MIST procedures were still significantly higher than that following TURP.

The incontinence treatment rates were higher among the TURP and prostatectomy groups than those among the MIST procedure groups. The pattern persisted over time, although the rates decreased among patients who had had TURP or prostatectomy. At the end of the first post-operative year, the TUMT and TUNA groups had about half of the incontinence treatment rates found in the TURP group, while the rates in the TUIP and Laser groups were similar to that in the TURP group.

The incontinence procedure rates also decreased in all BPH surgery groups during the second and third post-operative year. There was no significant difference in the rates between recipients of the MIST procedures and those who had TURP.

### **Clinical outcomes and diagnostic and functional tests**

Although the abscess rates were significantly higher among patients having TURP and prostatectomy than those having MIST procedures during the first few post-operative months, the rates in the former groups decreased substantially over time. After a year, the abscess rates were very low and similar in all BPH surgery groups.

The TUIP group had the highest fistula rates during the first post-operative month, while the rates were not different among other procedure groups. However, during the second half of the first post-operative year, the fistula rates were about 15-40% higher in the MIST procedure groups than that in the TURP group. Except the TUIP group, there was no difference in fistula rates between the MIST surgeries and TURP groups during the second and third post-operative year.

The TUIP group also had the highest incontinence rate among all BPH surgery groups during the first post-operative month, which resulted in about a 35% increased risk of incontinence among patients who had a TUIP compared with those who had a TURP. On the other hand, the TUMT and TUNA groups had lower rates than the TURP group, about 10-20% lower risk. The incontinence rates also decreased with time among all BPH procedure groups. At the end of the first post-operative year, the patients who received the MIST procedures had approximately a 20 - 70% higher risk of incontinence than those who had TURP. These differences persisted during the second and third post-operative years.

The prostatectomy, TUIP and TURP groups had significantly higher ureteral stricture rates than other surgery groups during the first post-operative month. Over the time, except the TUIP group which continuously had about 27% higher risk of ureteral stricture than the TURP group, the risk was not different among the other procedure groups.

During the first post-operative month, the MIST surgery groups had about 10-30% higher risk of bladder neck obstruction and urethral stricture than the TURP and prostatectomy groups. Over the time, the complication rates decreased significantly in all BPH surgery groups. However, the rate difference between the MIST procedure group and the TURP group increased. The risk of bladder neck obstruction and urethral stricture ranged about 20% higher in the Laser group to 60% higher in the TUIP group compared with the TURP group at the end of first post-operative year. These differences persisted during the extended follow-up periods.

Finally, patients with the MIST procedures had much higher rates of diagnostic and functional tests than those with the TURP or prostatectomy. Even after the significant decrease of test rates from the first post-operative month in all BPH surgery groups, the risk of having tests was still about 2 to 3 times higher in the MIST procedure groups than

that in the TURP group during the second half of post-operative year. These differences persisted during the second and third post-operative years.

## **Discussion**

During the three-year study period, there was a continuing decline in the rates of TURP in the Medicare fee-for-service population, although TURP procedure comprised approximately 79% of the procedures in our study. The continuing decline is consistent with the trend reported by Wasson, et al (Wasson, et al. 2000). While there were increases in the rates of TUMT and TUNA, the rates of the other MIST procedures were stable, or declined. The MIST procedures were more frequently followed by remedial surgery or removal of the prostate at a later time. Similarly, the diagnosis of bladder neck obstruction or urethral stricture was also 16 to 61% more frequently seen following these procedures than following TURP. Also the MIST procedures were approximately twice as likely to be followed with diagnostic and urinary functional tests as TURP. These findings are consistent with the less aggressive nature of the MIST procedures which could result in repeat or remedial treatment, as well as the need for diagnostic and functional tests to confirm the need and approach for follow-up treatment. Long-term incontinence was also more likely to be reported among men who received the MIST procedures. On the other hand, patients who had TURP had higher rates of 30-day post-operative mortality, abscess, incontinence treatment, and urinary stricture than those who had TUMT and TUNA.

The occurrence or persistence of low urinary tract symptoms, repeat visit to urologists, and higher rates of diagnostic and functional tests following the MIST procedures mentioned above may offset the lower cost of the original MIST procedures compared with TURP. Any study of comparing the cost-effectiveness the procedures needs to account for the long-term follow-up. They may be less cost-effective than TURP in the long run than it initially appears.

After the new surgeries become widely used in the general elderly population, the effectiveness and complications may vary significantly from the results from the published clinical trial results which may focus on the effectiveness and major outcomes and have relatively short follow-up periods. Therefore, monitoring of appropriate outcomes should be routinely carried out.

## **Conclusion**

The utilization of TUMT and TUNA procedures increased over past few years among elderly Medicare beneficiaries, although TURP remains the treatment of choice for the great majority of patients and physicians. Men who received TUMT and TUNA had lower rates of 30-day mortality, reoperations, remedial procedures, and reported occurrence of incontinence than patients who received the other MIST procedures. This

may explain why TUMT and TUNA procedure rates increased over the study period, but not the rates of the other MIST procedures.

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The views expressed in this study are those of the authors and do not reflect those of the Department of Health and Human Services or the Centers for Medicare & Medicaid Services.

## Introduction

Benign prostatic hypertrophy (BPH), characterized by a cellular proliferation of epithelia and stromal elements within the prostate gland, is the most common benign neoplasm in American men. Patients with BPH may experience nocturia, incomplete emptying of the bladder, urinary hesitancy, weak stream, frequency, and urgency, or even acute urinary retention. These lower urinary tract symptoms (LUTS) worsen progressively due to the continuous growth of prostate gland, primarily resultant from the lack of the hormone dihydrotestosterone within the prostate. Quality of life can be negatively affected by the LUTS (Wei, et al. 2005).

Treatment of BPH has changed dramatically during the last decade. Traditional treatments such as transurethral resection of prostate (TURP) have declined significantly (Wasson, et al. 2000; Lu-Yao, et al. 1994). Also, rates of inpatient hospitalization and length of hospital stay have decreased due to more BPH treatments being performed in outpatient clinics, as well as the general trend in the reduction of the length of hospitalization (Wasson, et al. 2000). Simultaneously, the utilization of pharmacological agents and minimally invasive surgical therapies (MIST) has been increasing (Wei, et al. 2005). The MIST procedures in this study include transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), transurethral incision of the prostate (TUIP), and transurethral or external laser therapy (Laser) (see details below). Despite the increased use of medical management, the primary BPH treatment is still surgical, thus the direct cost of BPH treatment (excluding outpatient pharmaceuticals) remains high, estimated to be \$1.1 billions in 2000 (Wei, et al. 2005).

TURP is the most common prostate surgery performed (Lu-Yao, et al. 1994; Wasson et al. 2000). In TURP, a resectoscope is threaded through the urethra and small cutting tools are used to scrape away excess prostate tissue. TURP has been established as a low risk and effective treatment (American Urology Association, AUA, 2003). In a clinical trial comparing TURP with watchful waiting, 91% patients receiving TURP had no complications within the first post-operative month, and about 2% had prostate capsule perforation. In addition, within 2.8 years, only 3% required additional surgeries for urethral stricture, and 3% patients underwent another transurethral resection, while only 1% patients had urinary incontinence (Wasson, et al. 1995).

In open prostatectomy, the inner portion of the prostate is removed through an abdominal incision, leaving the outer portion intact. An open radical prostatectomy which involves removing the entire prostate gland may also be performed. Patients with open prostatectomy are more likely to have complications such as urethral stricture, incontinence, and sexual dysfunction than those with TURP (AUA, 2003). Except for very large prostate size (for example, volumes greater than 80 to 100 ml), recent clinical guideline does not recommend either open prostatectomy method to treat BPH (AUA, 2003).



TUMT has gone through three generations with many types of machines. Basically, it employs a machine which emits microwave energy through a urinary catheter. The computer-controlled heat generated from this microwave energy destroys the inner portion of the enlarged gland (Walmsley, et al. 2004). Since the 1990s, studies have suggested that compared with sham treatments, both low and high-energy TUMT results in significant improvement in symptoms (Kellner, et al. 2004; Walmsley, et al. 2004). The most recent generation TUMT procedures also yield comparable effectiveness with the traditional TURP procedure performed. The annual post-operative rates of side effects among TUMT recipients are incontinence (2%) and urethral stricture (1%), which are lower than those among TURP (Hoffman et al. 2004; AUA, 2003). However, clinical trials using different TUMT machines have reported that about 13-20% patients with TUMT may need a re-treatment within 5 post-operative years (Floratos, et al. 2001; Walmsley, et al. 2004; AUA, 2003). About 28-70% patients treated with TUMT may also experience the post-operative irritative symptoms, while only 15% patients with TURP do. Nevertheless, it has been recommended in the American Urology Association (AUA) guideline for eligible patients with moderate prostate size (AUA, 2003).

TUNA employs radio waves which can be sent through needles inserted into the prostate gland. The heat generated by the radio waves destroys prostate tissue. Patients with prostate of 60 gram or less are ideal for this surgery (AUA, 2003). TUNA has been demonstrated as an effective treatment for BPH (Boyle, et al. 2004; Zlotta, et al. 2003; Hill, et al. 2004; AUA, 2003). It also has low rates of complications such as incontinence (less than 2%) and urethral stricture (1%), which are comparable with those of TUMT. The re-treatment rate for TUNA is similar to that of TUMT at a rate of 10-23% (AUA, 2003).

Laser therapy (Laser) involves several techniques and has involved many types of machines. They can be broadly categorized as transurethral laser coagulation (non-contact with the prostate tissue) or transurethral laser vaporization (contact with the prostate tissue), both of which use minimal amounts of laser energy to dry up and destroy excess prostate tissue (AUA, 2003). They have been shown to have similar effects as the TURP (Norby, et al. 2002; Shingleton, et al. 2001; AUA, 2003). The complication rates for incontinence (1-3%), stricture (5%), and sexual dysfunction (17-42%) are lower than those of TURP, and are also comparable with those of TUMT and TUNA. The re-treatment rate (7-8%) is only slightly higher than that of TURP (5%). However, as many as 66% of patients with laser coagulation treatment may experience post-operative irritative symptoms, compared with only 15% patients following TURP.

TUIP is not a new surgery (Orandi, et al. 1985). One or two small incisions are made into the prostate using the urethral approach. These cuts reduce the pressure on and enlarge the opening of the urethra. It is mostly limited to treat small prostate glands (30 gram or less) (AUA, 2003). It has been shown an effectiveness similar to TURP (Riehmman, et al. 1995; Tkocz, et al. 2002; AUA, 2003). On the other hand, it also has similar complication rates as those of TURP, while the re-treatment rate is much higher in TUIP than that in TURP (14% vs. 5%) (AUA, 2003).

In addition, there are other new treatments currently available. For example, transurethral electrovaporization of prostate (TUVP), employs a special metal instrument which emit a high frequency electrical current. The current cuts and vaporizes excess prostate tissue as well as sealing off the remaining tissue to prevent bleeding. The Transurethral Holmium Laser resection/Enucleation surgery is also relatively new in which the prostate is resected using the Holmium laser. However, these procedures were not performed on Medicare beneficiaries during the period for which study information was available.

Coverage for TUMT, TUNA, and Laser treatments were approved by CMS over the past several years. With the increasing use of these new MIST procedures, one issue is whether these MIST procedures result in better outcomes than traditional procedures in the general clinical practice among the general population. Our current knowledge about these MIST procedures is derived from selected patients in randomized clinical trials(Wheelahan, et al. 2000; Osterling, et al. 1995). These trials tended to have only modest size, were conducted using different machines, and thus, do not provide a complete picture of current practice and outcomes.

Our analysis was conducted to fill this void. Specifically we asked whether the MIST procedures used to treat BPH have lower complication rates than the traditional surgical treatment, namely TURP. We evaluated the post-surgical events for up to three years following surgery. These events included repeat of the initial procedure; additional prostate surgery; and the occurrence of urological complications such as bladder neck obstruction, ureteral stricture, incontinence, and death.

In addition, because the Department of Health and Human Services and CMS are interested in possible racial disparity in the utilization of surgical procedures, we also carried out analyses that specifically focused on this issue (See Part B).

## Methods

### 1. Data sources and extraction

#### 1.1 Creation of finder files

We used the Data Extraction System (DESY) at the CMS Data Center to create finder files. The Health Insurance Claim numbers (HIC) of persons with the following diagnosis or procedures were identified in the 1999-2001 100% NCH Carrier, Outpatient and Inpatient files:

HCPCS = 52450 (TUIP); 52510 (Balloon); 52601, 52612, 52614 (TURP); 52647 (Non-Contact Laser); 52648 (Contact Laser); 53850 (TUMT); 53852 (TUNA); 53853, C9700 (WIT); 55801, 55810, 55821, 55831, 55840 (Suprapubic, Retropubic, Radical Prostatectomy)

OR

ICD-9 Procedure code = 60.21 (contact/non-contact laser); 60.29 (TURP); 60.3, 60.4, 60.5, 60.62 (Suprapubic, Retropubic, Radical Prostatectomy); 60.95 (Balloon); 60.96 (TUMT); 60.97 (TUNA). The list of BPH related procedure and diagnosis codes are shown in Appendix 1.

Finder files were created after combining and cross-referencing all above HICs and eliminating duplicates.

#### 1.2 Claim extraction

Using the above finder files, all claims for these beneficiaries were extracted from the following files: 1997-2001 100% NCH Carrier, Inpatient, Outpatient, DME files. The associated Denominator records were also extracted. Interim claims and denied claims were excluded in the final datasets.

### 2. Case identification and cohort formation

BPH procedures were identified and grouped using HCPCS in Carrier and Outpatient files, and ICD-9 procedure codes in Inpatient and Outpatient files. Specifically, the line-item procedure codes in the Carrier claims, procedure codes in Inpatient and Outpatient claims, and procedure codes in the Outpatient revenue centers were searched for BPH procedures. Claims with the above BPH procedures were then extracted.

The date when the BPH procedures were performed were identified using the line-item first expense date (Carrier file), or the institutional claims file procedure date (Inpatient

and Outpatient files). If there were multiple BPH procedures during the study period, the first BPH procedure was set as the index event.

Because almost all TURPs and prostatectomies were performed in institutions, we required both an institutional and a Carrier claim for a case to be identified as a TURP or a prostatectomy. On the other hand, because the MIST procedures were performed in a wide variety of settings, the occurrence of a MIST procedure was determined by the presence of a Carrier claim for that procedure.

The place of service for the procedure was determined as follows: if a procedure had an Inpatient or Outpatient claim, it was assumed to be performed in that setting. If there was no matching Inpatient or Outpatient claim(s) for a Carrier claim(s), the procedure was then assumed to be performed in the setting indicated by the Carrier line place of service variable. In the matching of institutional claims with Carrier claims, to be considered a match, the first expense date in the Carrier line-item had to be within one week on either side of the admission or discharge date in Inpatient claim(s), or the from date or through date in the Outpatient claim(s).

Data were restricted to men only, who were not enrolled in managed care during the study period, who had both Medicare Part A and Part B coverage, and who did not have end stage renal diseases (ESRD). Also excluded were those who were less than 65 years of age and who had claims with a diagnosis of prostate cancer during the study period.

### **3. Comorbidity assessment**

The Elixhauser risk adjustment method (30 groups) was used (Elixhauser, et al. 1998; also <http://www.hcup-us.ahrq.gov/toolssoftware/comorbidity/comorbidity.jsp>). Carrier and institutional claims were searched for each case using the HICs for one year prior to the first BPH surgery. Diagnosis codes were searched for Elixhauser comorbidities. If the diagnosis code was in the Elixhauser code list, the corresponding indicator was flagged to 1, otherwise 0. If a comorbidity was present in either the Carrier or institutional claims, then the patient had that comorbidity. A pooled risk adjustment file for each 1999, 2000 and 2001 cohort was formed.

## **4. Outcomes**

### **4.1 Major urinary tract treatments following prostate surgery**

Using the line-item procedure codes (HCPCS) in the Carrier claims, we examined four major classes of complications: re-operation using the same procedure, remedial procedures to remove residual prostate tissue (including re-operation), the surgical treatment of urinary incontinence, and open prostatectomy. These procedures were of clinical importance because they implied either the failure of original BPH surgeries, or complications after the initial BPH surgery.

The Carrier line-item procedure codes (HCPCS) were searched and grouped based on code lists in Appendix 2. Duplicate claims with the same procedure and expense date were eliminated.

#### **4.2 Clinical outcomes and diagnostic and functional tests**

In addition to the above outcomes which resulted in surgical treatments to relieve symptoms or remove residual prostate tissue, we examined other important clinical outcomes. They included abscesses and fistulas which were rare but could severely affect a patient's quality of life, and ureteral stricture which was also an uncommon but severe complication. Among the more common complications we examined were incontinence, symptoms related to bladder neck obstruction or urethral stricture, and diagnostic or functional tests that might be performed in the post-operative period for reasons related to urinary symptoms.

The occurrences of one or more of these clinical outcomes or tests were determined by searching the line diagnosis in the Carrier claims, and procedure and principle diagnosis in the Inpatient and Outpatient claims (The full list of CPT and ICD-9 codes used to identify these outcomes is attached in Appendix 3). A patient who had multiple but different outcomes was included in different clinical outcome groups. To avoid double counting, duplicates within each group were removed by the time period, i.e., one patient only contributed one count for each group within each period. However, if the same complication occurred at two different time periods, it would be counted twice to indicate the prolonged existence of the complications in that patient. Therefore, the complication rates in the following analyses are actually the prevalence of having the complications during each period.

### **5. Analysis**

#### **5.1 Descriptive analysis**

The frequency of procedures and diagnosis by race, and age groups; comorbidities by procedure types are presented. The statistical comparisons are based on two sample t test for proportions or rates, and chi square tests for counts. A p-value less than 0.05 was considered as statistically significant.

#### **5.2 Geographic analysis**

Maps of procedure rates by US county are presented. Visual interpretation is provided with no statistical assessment.

#### **5.3 30-day post-operative mortality**

Mortality analyses were restricted to those occurred within 30 days after the initial BPH surgery. Crude, age-group-, race- and comorbidity-risk- adjusted rates for the MIST procedures, TURP and prostatectomy are presented. Risk adjustment used Elixhauser's 30 categories of comorbidities.

## **5.4 Outcomes**

The percent of people having urinary tract related treatments or important clinical outcomes and tests within a year following the original surgery are presented for three annual cohorts combined, and by the original procedure type. Results from the individual 1999, 2000, and 2001 cohorts separately were similar to those of three annual cohorts combined (Data not shown).

Logistic regression was used to compare outcomes between the BPH procedure groups, with TURP serving as the reference group. The outcomes were the dependent variables, and the types of surgery were the main independent variables. Models were further adjusted for race, age, and the 30 Elixhauser comorbidity groups.

Analyses were performed for the first, and the next two post-operative years separately. See below.

### **5.4.1 Outcome for the first through third post-operative years**

Every patient in this study had at least one year of follow-up. Because signs or symptoms may disappear during that time period, the first year after surgery was further separated into first month (within 30 days), 31-90 days, 91-180 days, and 181-365 days. For the ease of comparison, person month was used for the initial post-operative year. Person year was used as the denominator in the presentation of the first, second, and third year rates.

### **5.4.2 The time to the occurrence of surgical treatments**

The time to the four major urinary tract related treatments was analyzed using survival analysis (Cox regression) for each cohort. Due to the small occurrence of prostatectomy after prostate surgeries, the survival curves are presented only for the first three treatments. Only results for the three annual cohorts combined are presented. The results were similar for each annual cohort (Data not shown).

## **Results**

### **1. Procedure claims**

The numbers of claims indicating the different types of prostate surgery received are shown in Table 1. About 90% of TURPs were identified in Inpatient claims, while the MIST procedures were more likely to be identified in the Outpatient claims. Furthermore, a large percent of the MIST procedures, ranging from 66% in TUIP to 24% in Laser, could only be identified in the Carrier claims.

## **2. Cohort definition**

Table 2 presents the claim types associated with the final cohort. In 1999 and 2000, all MIST procedures except TUIP were performed mostly in outpatient settings. However, in 2001, more than half of TUMT, TUNA, and TUIP procedures were performed in physician offices or free standing clinics, while 90% of Laser procedures were still performed in the inpatient or outpatient setting. On the other hand, more than 90% of TURP and almost all prostatectomy were performed in inpatient settings in all three years.

## **3. Procedure rates**

Table 3 presents the counts and rates (per 1,000 persons) of procedures by age and year. During the period of 1999-2001, there were 193,039 TURP procedures which accounted for about 79% of all prostate surgery performed. The MIST procedures accounted for about 18% of prostate surgery. There were still about 8,444 open prostatectomies performed during the three years.

Over the three years, the annual TURP procedure rate decreased 11%, from 6.64 per 1,000 persons to 5.94 per 1,000 persons. On the contrary, the TUMT and TUNA procedure rates increased: 52%, from 0.48 per 1,000 persons to 0.73 per 1,000 persons, for TUMT; and 386%, from 0.09 per 1,000 persons to 0.33 per 1,000 persons, for TUNA. There was a slight decrease in the TUIP, and no change in the prostatectomy procedure rates.

Although more procedures were performed among those with 65-74 years of age, the highest procedure rates were found in the age group 75-84. For TUMT, TUNA, and Laser procedures, the procedure rates in the age group 65-74 were similar to those in the age group 75-84, both of which were higher than the rates in the age group 85+.

When the three annual cohorts were combined, the procedure rate was 6.24 per 1,000 persons for TURP, 0.61 per 1,000 persons for TUMT, 0.20 per 1,000 persons for TUNA, 0.18 per 1,000 persons for TUIP, 0.45 per 1,000 persons for Laser, and 0.27 per 1,000 persons for prostatectomy.

## **4. Diagnosis at the time of BPH surgeries**

Table 4 presents the line-item diagnosis from the Carrier claims for the initial BPH procedure at the time of surgery for the three annual cohorts combined. About 65% claims for TURP procedures had a diagnosis of BPH, and 20% had a diagnosis of urinary retention. Among the MIST procedures, 95% claims for TUMT and TUNA procedures had a diagnosis of BPH. On the other hand, among claims for TUIP, 14% claims had a diagnosis of urinary retention, and 30% claims had a bladder neck obstruction diagnosis. This is not surprising because the TUIP procedure involves the cutting of the bladder neck. Furthermore, claims for TURP, TUIP and prostatectomy procedures were more likely to have a diagnosis of hematuria than claims with other procedures.

## 5. Comorbidities

Table 5 presents the distribution of comorbidities identified within one year prior to the prostate surgery for the total cohort. The most common comorbidities were hypertension, cardiac arrhythmia, chronic pulmonary disease, diabetes without complications, and solid tumor. Patients who had TUMT and TUNA procedures appeared healthier than those who had TURP. Nevertheless, the comorbidity differences among patients undergoing other BPH surgeries were small in spite of statistical significance in some comparisons.

## 6. Geographic distributions of the MIST procedure rates

The geographic distributions of the procedure rates for TUMT, TUNA, TUIP and Laser are shown in Figures 1 through 4. Overall, the patterns were similar in four maps. Counties with the MIST procedures were frequently found on the East and West Coasts and in parts of the Inner-mountain West. There were areas where there was considerable overlap of the MIST procedures, although many counties had no or only one MIST procedure performed. Thus, there were clusters of counties with much high procedure rates than average. For example, the TUMT procedure rate in some counties was more than twice the national average, and the TUNA rate in some counties was more than 5 times the national average.

## 7. 30-day post-operative mortality

Mortality analyses were restricted to deaths that occurred within 30 days after the initial BPH surgery. The results are presented in Table 6 by annual cohort and procedure. Overall, patients with open prostatectomy had the highest 30-day post-operative mortality rate. The rate was similar among patients with TURP (12.2 per 1,000 persons) and those with TUIP (12.5 per 1,000 persons), both of which were higher than those of the TUMT group (3.5 per 1,000 persons) and the TUNA group (2.8 per 1,000 persons). The Laser group had an intermediate mortality rate (9.6 per 1,000 persons). There was no significant year trend of mortality rates for any procedure group. The mortality differences within all procedure groups were also similar in each year.

The multivariate analysis showed that patients who underwent TUMT, TUNA, or Laser had a significantly lower risk of dying within 30 days than those who had a TURP (Table 7). The unadjusted odds ratio (OR) was 0.28 (95% confidence interval (95%CI): 0.22-0.36) for the TUMT group, 0.23 (95%CI: 0.14-0.37) for the TUNA group, and 0.78 (95%CI: 0.66-0.93) for the Laser group. Adjustment for race, age, and comorbidities did not substantially change the inference except for those having Laser which had the same risk of dying in 30 days as those having TURP in the adjusted model. On the other hand, the risk of dying within 30 days was similar between the TUIP and TURP groups, while those with prostatectomy consistently showed a higher risk than those with TURP, with a mortality rate of 15.3 per 1,000 persons, and an odds ratio of 1.8 (95%CI: 1.50-2.17) after full adjustment.



## **8. Major urinary tract related treatments following prostate surgery**

### **8.1 Treatment rates within the first post-operative year**

Table 8 shows the first-year post-operative urinary tract treatment rates (per 1,000 person months) and table 9 presents the adjusted odds ratios comparing treatments after BPH procedures for three annual cohorts combined. The results were separated into first month (within 30 days), 31-90 days, 91-180 days, and 181-365 days. The overall rates for the first year and each of the following years are presented in the section 8.2.

#### **8.1.1 Reoperation with the same surgery**

Within the first month, and generally in the 1-3 post-operative months, patients with the MIST procedures had significantly lower reoperation rates than those with TURP and prostatectomy. For example, in the first month, the rate among the TUMT group was 0.37 per 1,000 person months versus 3.84 per 1,000 person months among the TURP group, adjusted odds ratio of 0.10 (95% CI: 0.05-0.21). Similar findings were shown for the TUNA, TUIP and Laser groups.

The reoperation rate in the TUMT group increased three-fold during the 7-12 post-operative months compared with the first month. Thus, during that time period, the rate among the TUMT group was significantly higher than the TURP group (0.93 vs. 0.78 per 1,000 person months, OR: 1.26, 95% CI: 1.03-1.56). The reoperation rate in the TUIP group was significantly greater than that in the TURP group also (1.18 vs. 0.78 per 1,000 person months. OR: 1.47, 95% CI: 1.05-2.06), while the reoperation rate in the Laser and prostatectomy groups was lowest from the 7<sup>th</sup> to the 12<sup>th</sup> post-operative month. The reoperation rates for the TUNA and Laser groups remained similar throughout the first post-operative year.

#### **8.1.2 Remedial procedures to remove residual prostate tissue**

Combining all related procedures which remove residual prostate tissue together resulted in different patterns from that of reoperation with the same procedure alone. Within the first month, the remedial procedure rates among the TUMT, TUNA and Laser groups were about one third to a half of those for the TURP and prostatectomy groups rather than one-tenth seen for reoperation with the same surgery. For example, the remedial procedure rate for the TUMT group was 4.63 per 1,000 person months, while the rate for the TURP group was 13.87 per 1,000 person months. The adjusted odds ratio for TUMT vs. TURP was 0.35 (95% CI: 0.27-0.41). Similar findings existed for TUNA and Laser. On the other hand, the remedial procedure rate for the TUIP group (11.97 per 1,000 person months) was similar to that in the TURP group.

From the end of the first month until the end of the third month after the original BPH surgery, the remedial procedure rates in the TURP and prostatectomy groups decreased by more than half. However, during this period, the risk of having remedial treatments became higher among the TUMT, TUIP, and Laser groups than that in the TURP group. The adjusted odds ratio (compared with TURP) for TUMT reached 1.32 (95% CI: 1.16-

1.50), and similar findings for TUIP and Laser. This trend persisted during the next nine months. Thus, for the second half year following the original surgery, patients who had one of the MIST procedures had a significantly greater risk of having a remedial procedure compared with the TURP group. For example, the risk was 2.77 times higher among the TUMT group than that in the TURP group. On the other hand, patients having open prostatectomy only had half of the risk of remedial procedure than those with TURP (OR: 0.52, 95%CI: 0.40-0.68).

### **8.1.3 Treatment of post-operative incontinence**

Within a month after the original BPH surgery, the TURP and prostatectomy groups had much higher incontinence procedure rates than the MIST procedure groups. For example, the rate for the TURP group was 1.89 per 1,000 person months, while the rates ranged from 0.05 per 1,000 person months for the TUMT group to 0.79 per 1,000 person months for the Laser group.

During the second and third post-operative month, the incontinence procedure rate in the TURP group decreased significantly from 1.89 to 0.66 per 1,000 person months. Reductions also occurred among the TUNA, TUIP and Laser groups. On the other hand, the incontinence procedure rate in the TUMT group increased from 0.05 to 0.21 per 1,000 person months. The incontinence procedure rate in the prostatectomy group increased by 100%, from 1.42 to 2.91 per 1,000 person months.

The patterns varied in the treatment of urinary incontinence from the second to the third post-operative period we examined. The incontinence treatment rate in the TUMT group kept increasing from 0.21 per 1,000 person months to 0.47 per 1,000 person months, a 100% increase. A smaller increase (77%) of incontinence procedure rate was also observed in the TUIP group.

During the last 180 days of the year after the original BPH surgery, the incontinence procedure rate was 0.89 per 1,000 person months in the TURP group, still more than twice of that in the TUMT group (odds ratio: 0.55, 95%CI: 0.42-0.73). The incontinence procedure rate in the TUNA group was even smaller. On the other hand, the incontinence procedure rates in the TUIP (0.82 per 1,000 person months) and Laser (0.80 per 1,000 person months) groups were now similar to that in the TURP group, and the adjusted odds ratios included 1.0, i.e., they were not statistically significantly different. In addition, the incontinence procedure rate in the prostatectomy group decreased to 1.12 per 1,000 person months and was not significantly different from that in the TURP group.

### **8.1.4 Open prostatectomy**

There were very few people who had follow-up prostatectomy. Therefore, the follow-up prostatectomy rates were very low in all time periods among all procedure groups. Because the comparisons between them were statistically unstable, we chose not to present them.

## **8.2 Treatment rates in the second and third post-operative years**

Similar to the Tables 8 and 9, Tables 10 and 11 presents the four categories of major urinary tract related treatment for the second and third follow-up year, in addition to summaries for the first year. The rates are presented as per 100 person years.

### **8.2.1 Reoperation with the same surgery**

During the first post-operative year, the reoperation rates were lower in the TUMT, TUNA, and Laser groups than that in the TURP group, while the TUIP group had a similar reoperation rate to the TURP group. During the second and the third year, the reoperation rates in the TURP group remained at about 0.86 per 100 person years. However, among the TUMT, TUNA, and TUIP groups, the reoperation rates in the second year increased. When compared with the reoperation rate in the TURP group, the reoperation rates in the TUMT and TUNA group were significantly higher than that in the TURP group; the adjusted odds ratio in the second year was 1.18 (95%CI: 0.97-1.44) for the TUMT group, and 1.49 (95%CI: 1.10-2.02) for the TUIP group.

During the third post-operative year, the reoperation rates in the TUMT, TUNA, and TUIP groups decreased to a level similar to that in the TURP group. On the other hand, the reoperation rates for the prostatectomy and Laser groups remained significantly lower than that in the TURP group during all time periods.

### **8.2.2 Remedial procedures to remove residual prostate tissue**

When all related remedial procedures involving the removal of residual prostate tissue were combined, the MIST procedure groups had significantly higher remedial procedure rates than the TURP group during all three post-operative years. In the first year, the TUMT group had the highest overall remedial procedure rates (7.4 per 100 person years). Compared with the TURP group, the TUMT group had about 66% higher risk of having remedial procedures (OR: 1.66, 95%CI: 1.57-1.76).

During the second post-operative year, the remedial procedure rates decreased in all procedure groups. The TURP group had a 54% reduction during the second year, and smaller reductions also occurred in the TUMT (27%), TUNA (10%), TUIP (33%), and Laser (38%) groups. Thus, the rate ratios between the MIST surgery groups and the TURP group were greater than those in the first year. For example, compared with TURP, the adjusted odds ratio for TUMT was 2.61 (95%CI: 2.37-2.88).

During the third post-operative year, the downward trend of remedial procedure rates persisted among all procedure groups. However, the remedial procedure rates among the MIST surgery groups were still higher than that in the TURP group. For example, the remedial procedure rate was 4.6 per 100 person years in the TUMT group, compared with 2.1 per 100 person years in the TURP group (OR: 2.37, 95%CI: 2.05-2.76). Similar results were found among other MIST procedure groups.

### **8.2.3 Treatment of post-operative incontinence**

As mentioned earlier, the rates for treatments to relieve symptoms of incontinence in the first post-operative year were lower among the MIST surgery groups than among the TURP and prostatectomy groups. For example, the incontinence procedure rate was 0.46 per 100 person years in the TUMT group, compared with 1.2 per 100 person years in the TURP group (OR: 0.38, 95%CI: 0.30-0.47). Similar findings existed for the TUNA and Laser groups. The incontinence procedure rate in the TUIP group was not significantly different from that in the TURP group (OR: 0.77, 95%CI: 0.58-1.02). As expected, the incontinence procedure rate in the prostatectomy group was higher (1.64 per 100 person years) than that in the TURP group (OR: 1.67, 95%CI: 1.42-1.96).

During the second post-operative year, the incontinence procedure rates decreased significantly in the TURP group (0.61 per 100 person years, a 49% reduction) and prostatectomy (0.55 per 100 person years, a 72% reduction) compared with those in the first post-operative year. Except for the TUNA group, the incontinence procedure rates in the TUMT, TUIP, prostatectomy and Laser groups were similar to that in the TURP. The incontinence procedure rate was 0.12 per 100 person years in the TUNA group, significantly lower than that in the TURP group (OR: 0.34 95%CI: 0.14-0.81).

During the third post-operative year, the incontinence procedure rates were also lower in all BPH surgery groups than those of previous years. Over three years, the reductions were larger in the TURP and prostatectomy groups than those in the TUMT, TUNA, and Laser groups.

### **8.2.4 Open prostatectomy**

The open prostatectomy rates were very small during the post-operative years. Because of small numbers of open prostatectomy, the comparisons were statistically unstable. Hence, these comparisons are not presented.

## **8.3 Time to the occurrence of a major urinary tract treatment following the initial prostate surgery**

As would be expected from the results already presented, survival analyses also suggested that the risk of reoperation using the same procedure was higher in the TURP group than those in the MIST procedure groups (Figure 5). From higher risk of reoperation to lower risk, the rank for the MIST procedures was TUIP, TUNA, TUMT and Laser. After one year, the risk of reoperation in the TUIP group was slightly higher than that in the TURP group, which was in accordance with the analyses presented in the previous sections.

On the other hand, the risk of having remedial procedures to remove residual prostate tissue was significantly higher in the MIST procedure groups than that in the TURP group, while the prostatectomy group had a lower risk than that in the TURP group (Figure 6). The risk of having treatments to relieve incontinence was much lower in the MIST procedure groups than those in the TURP and prostatectomy groups (Figure 7).

## **9. Clinical outcomes and diagnostic and functional tests**

Similar to the section 8, this section presents rates of different clinical outcomes and diagnostic and functional tests, as well as the related odds ratios adjusted for race, age, and comorbidities.

### **9.1 Clinical outcomes and diagnostic and function tests within a year after the original BPH surgery**

Tables 12 and 13 compare the clinical outcome and test rates among the BPH procedure groups within the first post-operative year by time periods for the three annual cohorts combined. Similar to the previous analyses, the rates are presented as per 1,000 person months.

#### **9.1.1 Abscess**

Within a month after the original BPH surgery, the prostatectomy group had the highest abscess rate (34.8 per 1,000 person months). The adjusted odds ratio for prostatectomy vs. TURP was 8.04 (95% CI: 7.03-9.20). The abscess rates were similar in the TURP (4.34 per 1,000 person months), TUIP (5.98 per 1,000 person months) and Laser (4.31 per 1,000 person months) groups, while the rates were much lower in the TUMT (2.5 per 1,000 person months) group. The adjusted odds ratio for TUMT vs. TURP was 0.64 (95% CI: 0.47-0.85).

During the next two months, the abscess rates decreased in all surgical groups. The largest decrease appeared in the prostatectomy group (from 34.82 to 5.47 per 1,000 person months, an 84% reduction). From the fourth month until the end of the first post-operative year, the abscess rates continue to decline. In the last period, the rates were not statistically different between the TURP and other BPH surgery groups.

#### **9.1.2 Fistula**

Within the first month after the original BPH surgery, except for the TUIP group, the fistula rates in the other MIST procedure groups were similar to that in the TURP group (all were around 5 per 1,000 person months). The fistula rate in the TUIP group (9.43 per 1,000 person months) was 66%, greater than the TURP group (OR for TUIP vs. TURP: 1.66, 95% CI: 1.25-2.19).

During the second and third post-operative month, the fistula rate decreased by 23% in the TURP group to 4.37 per 1,000 person months. Smaller decreases also appeared in the TUMT, TUIP, Prostatectomy and Laser groups, but a 38% increase occurred in the TUNA group to 5.42 per 1,000 person months. During the last six months of the first post-operative year, the differences of fistula rates between the MIST procedure groups and the TURP group became large and significant. The fistula rates were 4.07 per 1,000 person months, 4.69 per 1,000 person months, 5.19 per 1,000 person months, and 3.95 per 1,000 person months for the TUMT, TUNA, TUIP, and Laser groups, respectively, while the rate was 3.42 per 1,000 person months in the TURP group and 2.85 per 1,000

person months in the prostatectomy group. Compared with the TURP group, the risks of fistula were higher in the MIST procedure groups, ranging from 16% in the Laser group to 43% in the TUIP group.

### **9.1.3 Incontinence**

The results presented in Section 8.1.3 and 8.2.3 were about surgical procedures to treat incontinence. In that analysis, except for the TUIP group, the MIST procedure groups generally had lower incontinence treatment rates than that of the TURP group, while the prostatectomy group had the highest incontinence treatment rate among all BPH procedure groups.

Within the first month, the highest incontinence rate was in the TUIP group (19.58 per 1,000 person months), compared with 14.1 per 1,000 person months in the TURP group (odds ratio: 1.36, 95%CI: 1.12-1.65), while the rate in the TUMT group (10.22 per 1,000 person months) was smaller than that in the TURP group (odds ratio: 0.78, 95%CI: 0.68-0.91), which was similar to the results for the TUNA group.

Similar to that of fistula, the incontinence rates in all BPH groups decreased during the 31<sup>th</sup> to 90<sup>th</sup> post-operative days. However, the TUIP group still had the highest rate (14.82 per 1,000 person months), compared with only 10.99 per 1,000 person months in the TURP group.

For the remaining 275 days of the first post-operative year, the incontinence rates continuously decreased in all BPH surgery groups. The TUIP group still had the highest rate (8.49 per 1,000 person months). The incontinence rates in the TUMT (5.43 per 1,000 person months), TUNA (5.25 per 1,000 person months), and Laser (5.7 per 1,000 person months) groups were also higher than that in the TURP group (4.6 per 1,000 person months). The risk of incontinence in these MIST procedure groups ranged from 25% (TUNA) to 74% (TUIP) higher than that in the TURP group. All differences were statistically significant.

### **9.1.4 Ureteral stricture**

The incidence of ureteral stricture after the BPH surgery is rare because the anatomic location of the ureters is between kidney and the bladder.

Within a month after the original BPH surgery, patients undergone prostatectomy, TUIP or TURP had higher ureteral stricture rates than those with TUMT, TUNA, or Laser. The rate among the TUMT, TUNA and Laser groups were 20-48% lower than that in the TURP group.

After the first month, although the reduction was more evident in the prostatectomy, TUIP, and TURP groups, the rates of ureteral stricture decreased in all BPH groups (except the TUMT group). During the second half of the first post-operative year, the TUIP group still had a ureteral stricture rate of 2.45 per 1,000 person months (TUIP vs. TURP: odds ratio: 1.27, 95%CI: 1.00-1.62), while the rates in the other procedure groups were similar to that in the TURP group.

### **9.1.5 Bladder neck obstruction and urethral stricture**

In the first month after the BPH surgery, the rates for the bladder neck and urethral complications were higher in the MIST procedure groups than those in the TURP and prostatectomy groups. For example, the rate was 304.16 per 1,000 person months in the TUMT group, while it was 238.17 per 1,000 person months in the TURP group, indicating a 27% higher risk of urethral complications in the TUMT group than in the TURP group (OR: 1.27, 95%CI: 1.24-1.31). Similarly, there were increased risk of 9%, 13% and 26% for the TUNA, TUIP, and Laser groups, respectively.

During the second and third post-operative month, the rates of bladder neck and urethral complications in all BPH groups decreased significantly (approximately 70% reduction following all surgeries). However, except for TUNA, the rate was still significantly higher in the TUMT, TUIP, and Laser groups than in the TURP group.

The rates of the bladder neck obstruction and urethral complications in all BPH procedure groups kept decreasing during the rest of the first post-operative year. During the period 181-365 days after the original BPH surgery, the rates in all BPH groups dropped from above 200 per 1,000 person months in the first month to below 40 per 1,000 person months. Nevertheless, the rates in the TUMT (31.32 per 1,000 person months), TUNA (29 per 1,000 person months), TUIP (39.29 per 1,000 person months), and Laser (27.95 per 1,000 person months) groups were still significantly higher than that in the TURP group (23.98 per 1,000 person months). Compared with the TURP group, the adjusted odds ratio was 1.38 (95%CI: 1.33-1.44) in the TUMT group, and similar magnitude odds ratios for the TUNA and TUIP groups. On the other hand, the rate in the prostatectomy group (18.95 per 1,000 person months) was smaller than that in the TURP group (OR: 0.79, 95%CI: 0.74-0.85).

### **9.1.6 Diagnostic and functional tests**

The diagnostic and functional tests (Appendix 3) included certain examinations which could also relieve urethral symptoms. Therefore, some of these tests might actually indicate the treatment of the urethral complications.

During the first month after the original BPH surgery, the test rates were higher in the MIST surgery groups than those in both TURP and prostatectomy groups. The TUMT group (39.64 per 1,000 person months) had more than twice the test rate than the TURP group (13.75 per 1,000 person months), with an odds ratio of 2.88 (95%CI: 2.65-3.13). Similar findings were presented in the TUNA, TUIP, and Laser groups.

During the second period (31-90 post-operative days), the test rates decreased in all BPH groups. However, the MIST procedure groups still had higher rates than the TURP and prostatectomy groups.

From the fourth month until the middle of first post-operative year, the test rates did not change in the TURP and prostatectomy groups, while there was an increase in the testing rates in the TUMT, TUNA, and Laser groups. Thus, the difference of test rates between MIST procedures and TURP increased.

During the second half of the first post-operative year, the test rate differences between the MIST procedure groups and the TURP group persisted and were of the same magnitude as before. For example, the test rates in the TUMT and TUNA groups (15.87 per 1,000 person months and 17.66 per 1,000 person months, respectively) were more than three times of that in the TURP group (4.81 per 1,000 person months), and the adjusted odds ratio was 3.38 (95%CI: 3.19-3.58). The rates for the TUIP and Laser groups were also approximately 50% and 200% greater than in the TURP group.

## **9.2 Clinical outcomes and diagnostic and functional tests in the second and third years after surgery**

Similar to the analyses of the post-operative treatments described earlier, Tables 14 and 15 present the clinical outcomes and diagnostic and functional tests for the second and third post-operative years, together with summaries for the first post-operative year.

### **9.2.1 Fistula**

During the first post-operative year, the fistula rates were higher in the MIST procedure groups than that in the TURP group, e.g., TUIP (6.14 per 100 person years), compared with TURP (4.18 per 100 person years), which was equivalent to 39% higher risk of fistula in the TUIP group (OR: 1.39, 95%CI: 1.24-1.56) than that in the TURP groups. There was no difference in fistula rates between the prostatectomy and TURP groups.

Although the fistula rates were similar among most BPH procedure groups during the second and third post-operative years, there was an exception among those who had TUIP. The rate was 5.26 per 100 person years in the TUIP group compared with 4.0 per 100 person years in the TURP group during the third year, with the adjusted odds ratio of 1.36 (95%CI: 1.03-1.64), which was similar to that of the first post-operative year.

### **9.2.2 Incontinence**

During the first post-operative year, the overall incontinence rate was the highest in the TUIP group (10.4 per 100 person years) compared with 7.1 per 100 person years in the TURP group, a 41% difference (OR: 1.41, 95%CI:1.28-1.54). The slightly lower incontinence rates in the TUMT and TUNA groups were not statistically different from that in the TURP group.

During the second and third post-operative year, the incontinence rates decreased in all surgery groups. However, the TUIP group remained the highest in the second and third post-operative year. In the third year, the incontinence rate in the TUIP group still was 7.2 per 100 person years, and the adjusted odds ratio was 1.91 (95%CI: 1.56-2.33) compared with the TURP group. The rate differences between other MIST procedure groups and TURP group were not significant.

### **9.2.3 Bladder neck obstruction and urethral stricture**

The rates of bladder neck and urethral complications were much higher than any of other the clinical outcomes during the first year. The rates were higher in all MIST surgery



groups than in both TURP and prostatectomy groups. The highest complication rate was in the TUIP group (55.4 per 100 person years), followed by the TUMT (51.1 per 100 person years), Laser (49.3 per 100 person years), and TUNA (45.4 per 100 person years) groups, while the rate was 43.3 per 100 person years in the TURP group and 40.1 per 100 person years in the prostatectomy group. Thus, patients with TUIP was about 27% more likely to have urethral complications than those with TURP (OR: 1.27, 95%CI: 1.21-1.33). There was no difference in complication rates between the TURP and prostatectomy groups.

During the second post-operative year, the complication rates in all surgery groups were only about half of those of the first post-operative year. However, the rates in the MIST procedure groups were still significantly higher than that in the TURP group, range of 24% to 63% higher.

Except for the TUIP and Laser groups, the general urethral complication rates in the MIST procedure groups kept decreasing throughout the third post-operative year while the rate in the TURP group remained unchanged from the second to the third year. However, the rates in the MIST procedure groups were still significantly higher than that in the TURP group. For example, the rate was 31.1 per 100 person years in the TUIP group and was 21.7 per 100 person years in the TUMT group, compared with 18.8 per 100 person years in the TURP group, With adjusted odds ratio of 1.61 (95%CI: 1.44-1.80), and 1.16 (95%CI: 1.07-1.25), respectively, compared with the TURP group. Similar findings existed in the TUNA and Laser groups. On the other hand, the rate in the prostatectomy group (11.6 per 100 person years) became lower than that in the TURP group, with the adjusted odds ratio of 0.64 (95%CI: 0.57-0.73).

#### **9.2.4 Diagnostic and functional tests**

During the first post-operative year, the test rates in the MIST procedure groups, in particular in the TUMT and TUNA groups, were about two to three times higher than those in the TURP and prostatectomy groups. The rate was the highest in the TUNA group (23.8 per 100 person years), compared with only 7.4 per 100 person years in the TURP group. The adjusted odds ratio was 3.15 (95%CI: 2.96-3.34) for TUNA vs. TURP. On the other hand, there was no difference of test rates between the TURP and prostatectomy groups.

During the second post-operative year, similar to those of the bladder neck and urethral complications, the test rates in all BPH surgery groups decreased significantly to about half of the rates of the first year. However, the test rates were still about twice higher in the MIST surgery groups than that in the TURP group, range 72% to 146% greater.

Again except for the TUNA group, the changes of test rates from the second to the third post-operative year were small for all surgery groups. The differences of rates between MIST surgery group and TURP group also persisted, in the range of 79% to 117% greater. The greatest difference was the test rate of 8.2 per 100 person years in the TUMT group and 4.0 per 100 person years in the TURP group, with the adjusted odds ratio of 2.17 (95%CI: 1.94-2.44).

## Discussion

This is the first study we know of that reports the utilization of MIST procedure at the national level. During the study period, 1999 through 2001, there was an increase of TUMT and TUNA procedures. However, the rates of TUIP and Laser procedures decreased which was also true for the traditional surgical treatment of BPH, TURP. The decline of TURP and TUIP are consistent with previous reports and clinical observations (Wasson, et al. 2000; Wei, et al. 2005). Although the reasons for the trend of each of the MIST procedures cannot be known with certainty using claim data, the results of this report indicate advantages and disadvantages of the newer procedures compared with TURP and with each other which are likely influencing the decisions made by patients and physicians. These results include 30-day post-operative mortality (Table 6); rates of procedures that occurred up to 3 years after surgery (Tables 8-11); and clinical outcomes and diagnostic and functional tests occurring during the same time period (Tables 12-15).

Post-operative mortality is not a major concern among men considering BPH surgery. For example, the 30-day post-operative mortality rate following TURP was only 1.2% for the three annual cohorts combined (Table 6). Nonetheless, the crude and age-race-adjusted 30-day post-operative mortality rates following TUMT and TUNA were less than one-third the rate following TURP. These differences declined only slightly when the rates were adjusted for age, race, and comorbidities, thus indicating survival advantage among men who underwent TUMT or TUNA. No advantage in post-operative survival was seen following TUIP and Laser treatment compared with TURP.

Balanced against the risk of death is the risk of needing a second procedure of the same or different type to remove residual prostate tissue. In this case, the risk was much greater than the risk of death and the lowest risk was found in those who had a TURP. Although in the first 30 post-operative days, the MIST recipients were less likely to require one treatment. But by the end of the first year, the rates of these procedures were approaching or surpassing 2 times the rates following TURP. These differences were even greater in the second and third post-operative years. Thus, after TUIP, which was the MIST most frequently followed by another procedure to remove residual prostate tissue, the risk of such an operation was approximately 15% over 3 years (Table 10 and Figure 6).

Related to the need for additional procedure (Tables 8-11) was the occurrence of bladder neck obstruction and urethral stricture (Tables 12-15). Thus, as clearly shown in tables 10-11 and 14-15, the adjusted odds of having the problem (Table 15) and treating it (Table 11) always favored the TURP. We found the rates of bladder neck obstruction and urethral stricture in the MIST groups were higher than those in the TURP group during all post-operative periods. More specifically, during the second post-operative year approximately 19% of TURP recipients had the diagnosis of bladder neck obstructions and urethral strictures compared with 22% to 32% of those who had MIST procedures, and all of these elevations were statistically significant (Tables 14-15). The rates of procedure to remove the tissue occurring the problem was lower in the TURP recipients, 2% in the second year, than in the MIST recipients, 4 % to 5% (Tables 10,11). These

differences between the MIST groups and the TURP group are larger than those in the previous reports (AUA, 2003).

Interestingly, the ratio of persons with the diagnosis of bladder neck obstruction or urethral stricture to person treated to remove residual prostate tissue following TURP was always greater than the ratios following the MIST procedures (Table 16). For example, in the second post-operative year the ratio was 10.7:1 in the TURP group, and 5.5:1 to 8.8:1 in the MIST group. The ratios were always highest in the TUIP and Laser groups and lowest in the TUMT and TUNA groups, indicating a greater likelihood of surgically treating post-operative bladder neck or urethral stricture or urethral fistula in patients who had received TUMTs or TUNAs originally.

The rates of diagnostic and functional tests in the MIST groups were also higher than those in the TURP group. This is consistent with the findings for the bladder neck obstruction and urethral stricture and other clinical outcomes (Tables 12-14).

The advantage of the MIST procedures generally and for anyone of them specifically was less clear for incontinence or its treatment. As expected, the diagnosis rates for incontinence were higher than the treatment rates for incontinence, and they stabilized between 3 and 4 per 1,000 person months, or less than 5% on an annual basis, following TURP, TUMT, and TUNA. The odds ratio compared with the TURP group was greater than 1.

TUMT had been in use for several years prior to our study. We found a rate of 7.4% per year in remedial treatments to remove residual prostate tissue during the first post-operative year, which is less than 10-16% in the AUA Practice Guideline Committee summary report (AUA, 2003). The treatment rate for incontinence following TUMT (0.45%) was also less than the rate (1%) in the AUA report. Similarly, we found slightly lower rates of retreatment for residual prostate tissue and incontinence among those with TUNA compared with the results in the AUA report. However, the finding that patients who underwent TUMT and TUNA had about twice retreatment rates than those with TURP is consistent with the information in the AUA report.

We found that approximately 34% of the TUIP were performed for urinary retention or bladder neck obstruction. This diagnosis was indicated in only 4 to 5 % of the TUMT or TUNA procedure, which suggests that TUIP may be performed in a different population from those of TUMT and TUNA. This may explain why we found that the outcomes for patients following TUIP were not as good as those with TUMT and TUNA. The rate of fistula, incontinence, ureteral stricture, and bladder neck obstruction and urethral stricture were even higher in the TUIP group than those in the TURP group (Table 8-11), even though the AUA report suggested that the complication rates in the TUIP group should be similar to those in the TURP group.

Laser treatment, either contact or non-contact laser treatment, had already been in use for more than ten years prior to our study. Complications following laser were higher than following TUMT and TUNA. The remedial treatment and incontinence rates were higher

in the Laser group than the TURP group. These findings are consistent with the summary results in the AUA report.

Our study findings have another important implication in evaluating the MIST procedures. The occurrence or persistence of lower urinary tract symptoms, repeat visit to urologists, and higher rates of diagnostic and functional tests following the MIST procedures may offset the lower cost of the original MIST procedures compared with TURP. Thus, any study of comparing the cost-effectiveness of the procedures needs to account for the long-term follow-up. The MIST procedures may be less cost-effective than TURP in the long run than it initially appears.

Our finding that the MIST procedures were more likely performed in younger men is consistent with the possibility that these men likely had smaller prostates and less severe BPH symptoms. This highlights one of the important limitations of our study that we only had information from Medicare claims, which lacks information of characteristics such as prostate size, the number and severity of lower urinary tract symptoms, and prior BPH treatment history such as drug treatment. In addition, we also did not know the training and other characteristics of urologists which might influence their recommendations to patients. These factors could affect the decision regarding the type of surgery.

Our study also demonstrates the importance of monitoring the outcomes of the new procedures in the general elderly population. After new surgeries become widely used, the effectiveness and complications may vary significantly from the results from the published clinical trial results which may focus on the effectiveness and major outcomes and have relatively short follow-up periods. For example, Weinberg, et al. (Wennberg, et al. 1998) found higher perioperative mortality rates following carotid endarterectomy using claim data than those from clinical trials. On the contrary, we found that the remedial treatment rates were better following TUMT than those in the AUA summary report which was somewhat based on clinical trial data (AUA, 2003). Nonetheless, we found that patients who had TUIP and laser therapy had higher following retreatment rates; experienced higher rates of incontinence, bladder neck obstruction and urethral stricture, and diagnostic and functional tests than the traditional therapy. Therefore, as new procedures available to Medicare beneficiaries, monitoring of appropriate outcomes should be routinely carried out.

In summary, we found that patients who received TUMT and TUNA had lower 30-day mortality rates, fewer reoperations, fewer remedial procedures, and fewer reported occurrence of incontinence than patients who received the other MIST procedures. Further, patients receiving the TUIP and Laser procedures showed no better clinical outcomes than those receiving TURP. These may be the major reasons why TUMT and TUNA procedure rates increased over the study period, and others did not.

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Table 1: The number of claims indicating prostate procedures during the study period, by source and year

Year	Procedure	Carrier	Inpatient	Outpatient
1999	TURP	90,077	83,493	8,677
	TUMT	8,951	78	3,701
	TUNA	4,315	124	1,174
	TUIP	3,102	0	1,038
	Laser	5,399	1,463	3,814
	Prostatectomy	10,837	23,253	4
2000	TURP	90,323	82,761	8,390
	TUMT	7,262	29	6,617
	TUNA	1,987	45	1,670
	TUIP	2,988	0	980
	Laser	5,684	1,630	4,302
	Prostatectomy	10,313	22,355	48
2001	TURP	94,970	88,093	9,401
	TUMT	5,549	0	5,106
	TUNA	1,101	0	1,023
	TUIP	2,733	0	970
	Laser	7,033	2,084	5,713
	Prostatectomy	9,547	23,805	73
Total	TURP	275,370	254,347	26,468
	TUMT	21,762	107	15,424
	TUNA	7,403	169	3,867
	TUIP	8,823	0	2,988
	Laser	18,116	5,177	13,829
	Prostatectomy	30,697	69,413	125

Note: there were 1,199 balloon, and 18 water induced thermotherapy procedures performed during the study period. Because of the small numbers, they are not reported further.



Table 2: Number and percent of claim types in the final study cohort, by year

Year	Procedure	Having Inpatient		Having Outpatient		Only having Carrier		Total patients
		claims		claims		claims		
1999	TURP	61,130	91.0%	6,772	10.1%	0		67,145
	TUMT	449	9.3%	4,449	92.5%	0		4,810
	TUNA	112	12.1%	817	88.2%	0		926
	TUIP	286	15.7%	530	29.2%	1,002	55.1%	1,818
	Laser	1,570	28.4%	3,893	70.5%	60	1.1%	5,523
	Prostatectomy	2,827	99.6%	36	1.3%	0		2,839
2000	TURP	57,620	91.7%	5,789	9.2%	0		62,850
	TUMT	495	7.9%	5,710	91.0%	0		6,278
	TUNA	166	9.7%	1,433	83.9%	108	6.3%	1,707
	TUIP	266	14.3%	569	30.5%	1,030	55.2%	1,865
	Laser	1,251	28.7%	2,904	66.6%	207	4.7%	4,362
	Prostatectomy	2,762	99.6%	33	1.2%	0		2,772
2001	TURP	57,574	91.3%	5,857	9.3%	0		63,044
	TUMT	249	3.2%	3,161	41.0%	4,295	55.7%	7,705
	TUNA	122	3.5%	903	26.1%	2,435	70.4%	3,460
	TUIP	232	12.7%	510	27.8%	1,090	59.5%	1,832
	Laser	1,131	28.1%	2,486	61.8%	407	10.1%	4,024
	Prostatectomy	2,828	99.8%	16	0.6%	0		2,833
Total	TURP	176,324	91.3%	18,418	9.5%	0		193,039
	TUMT	1,193	6.3%	13,320	70.9%	4,280	22.8%	18,793
	TUNA	400	6.6%	3,153	51.7%	2,540	41.7%	6,093
	TUIP	784	14.2%	1,609	29.2%	3,122	56.6%	5,515
	Laser	3,952	28.4%	9,283	66.7%	674	4.8%	13,909
	Prostatectomy	8,417	99.7%	85	1.0%	0		8,444

Table 3: Number and rates of persons with BPH procedure, per 1,000 persons, by age and year

Year	Procedure	Age						Total	
		65-74	Rate	75-84	Rate	85+	Rate		
1999	TURP	31,119	5.46	28,997	8.25	7,029	7.85	67,145	6.64
	TUMT	2,633	0.46	1,852	0.53	325	0.36	4,810	0.48
	TUNA	566	0.10	313	0.09	47	0.05	926	0.09
	TUIP	801	0.14	808	0.23	209	0.23	1,818	0.18
	Laser	2,902	0.51	2,154	0.61	467	0.52	5,523	0.55
	Prostatectomy	1,589	0.28	1,072	0.30	178	0.20	2,839	0.28
2000	TURP	28,909	5.06	27,350	7.61	6,591	7.15	62,850	6.14
	TUMT	3,366	0.59	2,438	0.68	474	0.51	6,278	0.61
	TUNA	992	0.17	626	0.17	89	0.10	1,707	0.17
	TUIP	807	0.14	826	0.23	232	0.25	1,865	0.18
	Laser	2,249	0.39	1,705	0.47	408	0.44	4,362	0.43
	Prostatectomy	1,512	0.26	1,087	0.30	173	0.19	2,772	0.27
2001	TURP	28,851	4.88	27,651	7.41	6,542	6.81	63,044	5.94
	TUMT	4,092	0.69	3,030	0.81	583	0.61	7,705	0.73
	TUNA	1,906	0.32	1,334	0.36	220	0.23	3,460	0.33
	TUIP	783	0.13	825	0.22	224	0.23	1,832	0.17
	Laser	2,040	0.34	1,655	0.44	329	0.34	4,024	0.38
	Prostatectomy	1,547	0.26	1,140	0.31	146	0.15	2,833	0.27
Total	TURP	88,879	5.13	83,998	7.75	20,162	7.26	193,039	6.24
	TUMT	10,091	0.58	7,320	0.68	1,382	0.50	18,793	0.61
	TUNA	3,464	0.20	2,273	0.21	356	0.13	6,093	0.20
	TUIP	2,391	0.14	2,459	0.23	665	0.24	5,515	0.18
	Laser	7,191	0.41	5,514	0.51	1,204	0.43	13,909	0.45
	Prostatectomy	4,648	0.27	3,299	0.30	497	0.18	8,444	0.27

Table 4: Line diagnosis of Carrier claims for the BPH procedure at the time of surgery, three annual cohorts combined

	Total claims	BPH		Urinary retention		Bladder neck obstruction		Hematuria		Urethral obstruction, unspecified		Other	
TURP	177,926	115,325	64.8%	35,316	19.8%	10,731	6.0%	4,337	2.4%	2,609	1.5%	9,608	5.4%
TUMT	18,789	17,815	94.8%	386	2.1%	340	1.8%	13	0.1%	53	0.3%	182	1.0%
TUNA	6,092	5,762	94.6%	82	1.3%	165	2.7%	3	0.0%	6	0.1%	74	1.2%
TUIP	5,510	2,039	37.0%	767	13.9%	1,672	30.3%	165	3.0%	95	1.7%	772	14.0%
Laser	13,896	10,731	77.2%	1,230	8.9%	883	6.4%	193	1.4%	136	1.0%	723	5.2%
Prostatectomy	7,730	5,154	66.7%	1,556	20.1%	265	3.4%	126	1.6%	69	0.9%	560	7.2%

Table5: Distributions of comorbidities using Elixhauser methods, by procedure, for three annual cohorts combined

	TURP	%	TUMT	%	TUNA	%	TUIP	%	Laser	%	Prostatectomy	%
Total number	193,429		18,793		6,093		5,515		13,909		8,473	
Congestive heart failure	38,122	19.7%	3,254	17.3%	834	13.7%	1,133	20.5%	2,714	19.5%	1,183	14.0%
Cardiac arrhythmia	54,416	28.1%	4,669	24.8%	1,413	23.2%	1,584	28.7%	4,100	29.5%	2,032	24.0%
Vascular disease	28,836	14.9%	2,533	13.5%	784	12.9%	818	14.8%	2,194	15.8%	1,146	13.5%
Pulmonary circulation disease	4,749	2.5%	425	2.3%	105	1.7%	144	2.6%	365	2.6%	118	1.4%
Peripheral vascular disease	33,280	17.2%	2,710	14.4%	909	14.9%	1,102	20.0%	2,497	18.0%	967	11.4%
Hypertension	121,331	62.7%	10,903	58.0%	3,663	60.1%	3,491	63.3%	8,605	61.9%	5,007	59.1%
Paralysis	5,876	3.0%	498	2.6%	116	1.9%	204	3.7%	440	3.2%	125	1.5%
Other neurological disorders	17,876	9.2%	1,448	7.7%	401	6.6%	536	9.7%	1,218	8.8%	480	5.7%
Chronic pulmonary disease	59,221	30.6%	4,813	25.6%	1,574	25.8%	1,752	31.8%	4,380	31.5%	1,886	22.3%
Diabetes w/o chronic complications	46,644	24.1%	4,062	21.6%	1,411	23.2%	1,301	23.6%	3,410	24.5%	1,785	21.1%
Diabetes w/ chronic complications	11,018	5.7%	945	5.0%	295	4.8%	345	6.3%	796	5.7%	303	3.6%
Hypothyroidism	17,806	9.2%	1,741	9.3%	657	10.8%	584	10.6%	1,353	9.7%	633	7.5%
Renal failure	16,540	8.6%	1,023	5.4%	281	4.6%	424	7.7%	942	6.8%	688	8.1%
Liver disease	2,337	1.2%	205	1.1%	93	1.5%	73	1.3%	210	1.5%	83	1.0%
Peptic ulcer Disease or bleeding	6,995	3.6%	561	3.0%	243	4.0%	235	4.3%	575	4.1%	198	2.3%

Table 5 continued

	TURP	%	TUMT	%	TUNA	%	TUIP	%	Laser	%	Prostatectomy	%
Acquired immune deficiency syndrome	76	0.0%	8	0.0%	4	0.1%	7	0.1%	9	0.1%	2	0.0%
Lymphoma	1,983	1.0%	187	1.0%	57	0.9%	50	0.9%	132	0.9%	72	0.8%
Metastatic cancer	2,770	1.4%	145	0.8%	55	0.9%	97	1.8%	174	1.3%	108	1.3%
Solid tumor w/out metastasis	46,844	24.2%	3,370	17.9%	1,453	23.8%	2,043	37.0%	3,010	21.6%	2,135	25.2%
Rheumatoid arthritis/collagen	7,590	3.9%	704	3.7%	265	4.3%	220	4.0%	649	4.7%	253	3.0%
Coagulopathy	11,289	5.8%	1,023	5.4%	305	5.0%	360	6.5%	961	6.9%	443	5.2%
Obesity	3,916	2.0%	368	2.0%	139	2.3%	113	2.0%	283	2.0%	190	2.2%
Weight loss	3,641	1.9%	193	1.0%	57	0.9%	100	1.8%	230	1.7%	85	1.0%
Fluid and electrolyte disorders	33,048	17.1%	2,191	11.7%	607	10.0%	877	15.9%	2,038	14.7%	1,107	13.1%
Chronic blood loss anemia	6,020	3.1%	448	2.4%	164	2.7%	161	2.9%	380	2.7%	235	2.8%
Deficiency Anemia	42,515	22.0%	3,214	17.1%	1,225	20.1%	1,344	24.4%	3,018	21.7%	1,635	19.3%
Alcohol abuse	2,741	1.4%	161	0.9%	59	1.0%	85	1.5%	185	1.3%	70	0.8%
Drug abuse	511	0.3%	31	0.2%	10	0.2%	13	0.2%	34	0.2%	12	0.1%
Psychoses	11,250	5.8%	839	4.5%	224	3.7%	346	6.3%	774	5.6%	269	3.2%
Depression	3,289	1.7%	291	1.5%	79	1.3%	137	2.5%	239	1.7%	93	1.1%

Note: the small difference of total number of TURP and prostatectomy between Table 4 and 5 are due to the computation algorithm of comorbidities.

Table 6: Number of deaths and race and age adjusted rate, per 1,000 persons, within 30 days after the original prostate surgery, by year and type of surgery

Procedure	1999		2000		2001		Total	
	Death	Rate	Death	Rate	Death	Rate	Death	Rate
TURP	885	13.18	724	11.52	736	11.67	2,358	12.22
TUMT	20	4.16	16	2.55	29	3.76	65	3.46
TUNA	2	2.16	6	3.51	9	2.60	17	2.79
TUIP	26	14.30	19	10.19	24	13.10	69	12.51
Laser	51	9.23	34	7.79	48	11.93	133	9.56
Prostatectomy	51	17.96	48	17.32	29	10.24	129	15.28

Table 7: Unadjusted and adjusted of Odds Ratios (OR) and 95% confidence intervals (95% CI) of 30-day post-operative mortality for the three annual cohorts combined, with TURP as reference group

Procedure	Unadjusted		Adjusted for race and age		Adjusted for race, age and comorbidities	
	OR	95% CI	OR	95% CI	OR	95% CI
TUMT	0.28	(0.22-0.36)	0.32	(0.25-0.41)	0.36	(0.28-0.46)
TUNA	0.23	(0.14-0.37)	0.28	(0.17-0.45)	0.33	(0.21-0.54)
TUIP	1.03	(0.81-1.31)	0.97	(0.76-1.23)	0.96	(0.75-1.22)
Laser	0.78	(0.66-0.93)	0.86	(0.72-1.03)	0.85	(0.71-1.01)
Prostatectomy	1.25	(1.05-1.50)	1.50	(1.25-1.80)	1.80	(1.50-2.17)

Table 8: Number and rates, per 1,000 person months, of major urinary tract related treatments of complication after the original BPH surgery for the first post-operative year, three annual cohorts combined

Treatment	Procedure	<=30d		31-90d		91-180d		181-365d	
		No.	Rate	No.	Rate	No.	Rate	No.	Rate
Re-operation									
	TURP	741	3.84	489	1.27	457	0.82	841	0.78
	TUMT	7	0.37	8	0.21	43	0.78	101	0.93
	TUNA	5	0.82	6	0.49	18	1.00	30	0.84
	TUIP	8	1.45	8	0.73	16	1.01	36	1.18
	Laser	1	0.07	3	0.11	3	0.07	3	0.04
	Prostatectomy	104	12.32	7	0.42	2	0.08	2	0.04
Remedial procedures to remove residual prostate tissue									
	TURP	2,677	13.87	1,971	5.12	2,107	3.77	2,483	2.30
	TUMT	87	4.63	261	6.95	409	7.39	666	6.16
	TUNA	44	7.22	57	4.68	84	4.64	146	4.10
	TUIP	66	11.97	73	6.64	114	7.16	138	4.51
	Laser	120	8.63	208	7.50	235	5.80	307	3.90
	Prostatectomy	125	14.80	95	5.65	83	3.36	60	1.24
Surgical treatment of post-operative incontinence									
	TURP	364	1.89	253	0.66	729	1.30	966	0.89
	TUMT	1	0.05	8	0.21	26	0.47	53	0.49
	TUNA	3	0.49	1	0.08	2	0.11	8	0.22
	TUIP	4	0.73	7	0.64	18	1.13	25	0.82
	Laser	11	0.79	6	0.22	32	0.79	63	0.80
	Prostatectomy	12	1.42	49	2.91	60	2.43	54	1.12
Open prostatectomy									
	TURP	67	0.35	81	0.21	45	0.08	47	0.04
	TUMT	1	0.05	6	0.16	5	0.09	13	0.12
	TUNA	2	0.33	1	0.08	1	0.06	6	0.17
	TUIP	5	0.91	7	0.64	5	0.31	4	0.13
	Laser	3	0.22	5	0.18	4	0.10	6	0.08
	Prostatectomy	1	0.12	2	0.12	5	0.20	7	0.14

Table 9: Adjusted Odds Ratios (OR) and 95% confidence intervals (95%CI) for urinary tract related treatment rates within one year after the original BPH surgery, three annual cohorts combined

Treatment	Procedure	<=30d		31-90d		91-180d		181-365d	
		OR	95%CI	OR	95%CI	OR	95%CI	OR	95%CI
Re-operation									
	TUMT	0.10	(0.05-0.21)	0.17	(0.09-0.34)	1.01	(0.73-1.38)	1.26	(1.03-1.56)
	TUNA	0.22	(0.09-0.53)	0.40	(0.18-0.89)	1.25	(0.78-2.00)	1.11	(0.77-1.60)
	TUIP	0.39	(0.20-0.79)	0.58	(0.29-1.16)	1.18	(0.72-1.95)	1.47	(1.05-2.06)
	Laser	0.02	(0.00-0.14)	0.09	(0.03-0.27)	0.09	(0.03-0.29)	0.05	(0.02-0.16)
	Prostatectomy	3.08	(2.51-3.80)	0.32	(0.15-0.68)	0.10	(0.03-0.40)	0.05	(0.01-0.21)
Remedial procedures to remove residual prostate tissue									
	TUMT	0.35	(0.28-0.44)	1.32	(1.16-1.50)	1.99	(1.78-2.21)	2.77	(2.53-3.02)
	TUNA	0.55	(0.41-0.75)	0.88	(0.67-1.14)	1.23	(0.98-1.53)	1.79	(1.51-2.12)
	TUIP	0.85	(0.66-1.09)	1.31	(1.04-1.66)	1.86	(1.53-2.25)	1.91	(1.60-2.28)
	Laser	0.64	(0.53-0.77)	1.45	(1.26-1.68)	1.54	(1.34-1.76)	1.74	(1.54-1.96)
	Prostatectomy	1.12	(0.93-1.34)	1.08	(0.88-1.33)	0.88	(0.71-1.10)	0.52	(0.4-0.68)
Surgical treatment of post-operative incontinence									
	TUMT	0.03	(0.001-0.22)	0.32	(0.16-0.64)	0.35	(0.24-0.52)	0.55	(0.42-0.73)
	TUNA	0.28	(0.09-0.87)	0.12	(0.02-0.85)	0.08	(0.02-0.32)	0.24	(0.12-0.49)
	TUIP	0.35	(0.13-0.94)	0.95	(0.45-2.02)	0.83	(0.52-1.33)	0.90	(0.61-1.34)
	Laser	0.43	(0.24-0.79)	0.33	(0.15-0.74)	0.60	(0.42-0.86)	0.86	(0.67-1.12)
	Prostatectomy	0.83	(0.46-1.47)	4.17	(3.06-5.68)	1.78	(1.36-2.32)	1.26	(0.95-1.65)



Table 10: Number and rates of long term urinary tract related treatment, per 100 person years, after the original BPH surgery, three annual cohorts combined

Treatment	Procedure	<=1 yr		1-2yr		2-3yr	
		No.	Rate	No.	Rate	No.	Rate
Re-operation							
	TURP	2,,485	1.34	1,263	0.86	712	0.85
	TUMT	156	0.85	147	1.07	63	0.89
	TUNA	59	0.98	43	1.06	15	0.90
	TUIP	67	1.27	54	1.33	16	0.71
	Laser	10	0.07	4	0.04	2	0.04
	Prostatectomy	115	1.40	2	0.02	1	0.02
Remedial procedures to remove residual prostate tissue							
	TURP	8,483	4.60	3,097	2.14	1,719	2.06
	TUMT	1,363	7.44	742	5.39	327	4.61
	TUNA	312	5.21	189	4.67	64	3.86
	TUIP	343	6.54	178	4.38	83	3.70
	Laser	793	5.92	398	3.66	211	3.17
	Prostatectomy	332	4.06	39	0.59	18	0.46
Surgical treatment of post-operative incontinence							
	TURP	2,209	1.20	894	0.61	426	0.52
	TUMT	83	0.46	70	0.50	27	0.38
	TUNA	13	0.22	5	0.12	2	0.12
	TUIP	51	0.97	26	0.64	5	0.23
	Laser	104	0.78	69	0.64	37	0.55
	Prostatectomy	161	1.97	37	0.55	13	0.34
Open prostatectomy							
	TURP	240	0.13	62	0.05	35	0.05
	TUMT	25	0.13	17	0.12	11	0.16
	TUNA	10	0.17	4	0.10	1	0.06
	TUIP	20	0.38	4	0.10	2	0.08
	Laser	18	0.13	8	0.07	6	0.10
	Prostatectomy	15	0.18	9	0.13	2	0.05

Table 11: Adjusted Odds Ratios (OR) and 95% confidence intervals (95%CI) for long term urinary tract related treatments after the original BPH surgery, three annual cohorts combined

Treatment	Procedure	<=1 yr		1-2yr		2-3yr	
		OR	95% CI	OR	95% CI	OR	95% CI
Re-operation							
	TUMT	0.66	(0.56-0.77)	1.18	(0.97-1.44)	1.10	(0.80-1.51)
	TUNA	0.76	(0.58-0.98)	0.91	(0.59-1.41)	1.09	(0.56-2.12)
	TUIP	0.93	(0.73-1.19)	1.49	(1.10-2.02)	0.84	(0.46-1.53)
	Laser	0.06	(0.03-0.11)	0.05	(0.02-0.13)	0.05	(0.01-0.19)
	Prostatectomy	1.05	(0.87-1.27)			0.04	(0.01-0.28)
Remedial procedures to remove residual prostate tissue							
	TUMT	1.66	(1.57-1.76)	2.61	(2.37-2.88)	2.40	(2.07-2.79)
	TUNA	1.16	(1.03-1.30)	2.34	(1.94-2.81)	1.92	(1.37-2.70)
	TUIP	1.38	(1.23-1.54)	2.16	(1.82-2.57)	1.90	(1.45-2.49)
	Laser	1.30	(1.21-1.41)	1.84	(1.64-2.07)	1.54	(1.30-1.84)
	Prostatectomy	0.91	(0.82-1.02)	0.29	(0.20-0.41)	0.23	(0.14-0.40)
Surgical treatment of post-operative incontinence							
	TUMT	0.38	(0.30-0.47)	0.88	(0.66-1.18)	0.70	(0.42-1.15)
	TUNA	0.18	(0.10-0.31)	0.34	(0.14-0.81)	0.41	(0.10-1.64)
	TUIP	0.77	(0.58-1.02)	0.86	(0.53-1.40)	0.37	(0.12-1.15)
	Laser	0.65	(0.53-0.79)	1.11	(0.84-1.46)	1.29	(0.90-1.87)
	Prostatectomy	1.67	(1.42-1.96)	0.88	(0.60-1.29)	0.79	(0.43-1.44)

Table 12: Number and rates, per 1,000 person months, for clinical outcomes and diagnostic and functional tests within a year after the original BPH surgery, three annual cohorts combined

Outcome	Procedure	<=30d		31-90d		91-180d		181-365d	
		No.	Rate	No.	Rate	No.	Rate	No.	Rate
Abscess									
	TURP	838	4.34	949	2.47	1,120	2.00	1,732	1.60
	TUMT	47	2.50	59	1.57	89	1.61	151	1.40
	TUNA	17	2.79	23	1.89	29	1.60	55	1.54
	TUIP	33	5.98	30	2.73	50	3.14	63	2.06
	Laser	60	4.31	68	2.45	93	2.30	136	1.73
	Prostatectomy	294	34.82	92	5.47	49	1.99	69	1.43
Fistula									
	TURP	1,099	5.69	1683	4.37	2,144	3.84	3,697	3.42
	TUMT	84	4.47	153	4.07	248	4.48	440	4.07
	TUNA	24	3.94	66	5.42	74	4.09	167	4.69
	TUIP	52	9.43	77	7.00	97	6.09	159	5.19
	Laser	76	5.46	144	5.19	195	4.81	311	3.95
	Prostatectomy	52	6.16	76	4.52	84	3.41	138	2.85
Incontinence									
	TURP	2,719	14.09	4,231	10.99	4,679	8.37	4,971	4.60
	TUMT	192	10.22	322	8.57	490	8.85	587	5.43
	TUNA	71	11.65	94	7.72	161	8.90	187	5.25
	TUIP	108	19.58	163	14.82	193	12.12	260	8.49
	Laser	222	15.96	328	11.82	370	9.13	449	5.70
	Prostatectomy	128	15.16	202	12.01	195	7.90	203	4.19

Table 12 continued

Outcome	Procedure	<=30d		31-90d		91-180d		181-365d	
		No.	Rate	No.	Rate	No.	Rate	No.	Rate
Ureteral stricture									
	TURP	1,121	5.81	1,135	2.95	1,437	2.57	1,806	1.67
	TUMT	20	1.06	47	1.25	77	1.39	109	1.01
	TUNA	14	2.30	11	0.90	29	1.60	35	0.98
	TUIP	46	8.34	43	3.91	49	3.08	75	2.45
	Laser	36	2.59	56	2.02	79	1.95	116	1.47
	Prostatectomy	86	10.18	55	3.27	56	2.27	74	1.53
Bladder neck obstruction and urethral stricture									
	TURP	45,977	238.17	25,765	66.95	24,749	44.30	25,928	23.98
	TUMT	5,716	304.16	3,174	84.51	3,104	56.07	3,385	31.32
	TUNA	1,598	262.27	757	62.15	910	50.30	1,033	29.00
	TUIP	1,578	286.13	972	88.40	1,087	68.29	1,203	39.29
	Laser	4,104	295.06	2,278	82.10	2,129	52.54	2,200	27.95
	Prostatectomy	1,931	228.68	1,194	70.98	965	39.12	917	18.95
Diagnostic and functional test									
	TURP	2,655	13.75	3,575	9.29	5,636	10.09	5,201	4.81
	TUMT	745	39.64	974	25.93	2,126	38.40	1,715	15.87
	TUNA	205	33.65	311	25.53	759	41.96	629	17.66
	TUIP	142	25.75	192	17.46	221	13.88	236	7.71
	Laser	375	26.96	476	17.16	880	21.72	832	10.57
	Prostatectomy	102	12.08	191	11.35	249	10.09	226	4.67

Table 13: Adjusted Odds Ratios (OR) and 95% confidence intervals (95%CI) for clinical outcomes and diagnostic and functional tests within one year after the original BPH surgery, for three annual cohorts combined

Outcome	Procedure	<=30d		31-90d		91-180d		181-365d	
		OR	95%CI	OR	95%CI	OR	95%CI	OR	95%CI
Abscess									
	TUMT	0.64	(0.47-0.85)	0.70	(0.54-0.92)	0.90	(0.72-1.12)	0.95	(0.80-1.13)
	TUNA	0.70	(0.43-1.13)	0.83	(0.54-1.25)	0.85	(0.58-1.23)	1.02	(0.76-1.35)
	TUIP	1.30	(0.91-1.84)	1.03	(0.72-1.49)	1.44	(1.08-1.93)	1.27	(0.98-1.66)
	Laser	1.00	(0.77-1.30)	0.97	(0.75-1.25)	1.12	(0.90-1.39)	1.16	(0.97-1.38)
	Prostatectomy	8.96	(7.81-10.27)	2.49	(2.00-3.10)	1.10	(0.82-1.47)	0.95	(0.73-1.23)
Fistula									
	TUMT	0.86	(0.69-1.08)	0.98	(0.83-1.16)	1.21	(1.05-1.38)	1.26	(1.14-1.40)
	TUNA	0.74	(0.49-1.11)	1.25	(0.97-1.60)	1.06	(0.84-1.34)	1.36	(1.16-1.60)
	TUIP	1.56	(1.18-2.07)	1.49	(1.18-1.88)	1.52	(1.24-1.87)	1.43	(1.22-1.69)
	Laser	0.97	(0.77-1.23)	1.19	(1.00-1.41)	1.25	(1.08-1.45)	1.16	(1.03-1.31)
	Prostatectomy	1.17	(0.89-1.55)	1.07	(0.85-1.35)	0.91	(0.73-1.13)	0.83	(0.70-0.99)
Incontinence									
	TUMT	0.78	(0.68-0.91)	0.81	(0.72-0.91)	1.13	(1.02-1.24)	1.28	(1.17-1.40)
	TUNA	0.92	(0.73-1.17)	0.74	(0.60-0.91)	1.14	(0.97-1.34)	1.25	(1.08-1.46)
	TUIP	1.36	(1.12-1.65)	1.29	(1.10-1.52)	1.38	(1.19-1.60)	1.74	(1.53-1.99)
	Laser	1.16	(1.01-1.33)	1.09	(0.97-1.22)	1.11	(0.99-1.23)	1.28	(1.15-1.41)
	Prostatectomy	1.21	(1.01-1.45)	1.21	(1.05-1.39)	1.06	(0.92-1.23)	1.03	(0.89-1.19)

Table 13 continued

Outcome	Procedure	<=30d		31-90d		91-180d		181-365d	
		OR	95%CI	OR	95%CI	OR	95%CI	OR	95%CI
Ureteral stricture									
	TUMT	0.21	(0.13-0.32)	0.47	(0.35-0.63)	0.61	(0.48-0.77)	0.64	(0.52-0.79)
	TUNA	0.43	(0.25-0.73)	0.32	(0.17-0.57)	0.61	(0.42-0.90)	0.59	(0.42-0.83)
	TUIP	1.29	(0.96-1.74)	1.20	(0.88-1.63)	1.03	(0.77-1.37)	1.27	(1.00-1.62)
	Laser	0.48	(0.34-0.67)	0.73	(0.56-0.95)	0.80	(0.64-1.01)	0.94	(0.77-1.14)
	Prostatectomy	1.75	(1.40-2.19)	1.05	(0.80-1.39)	0.87	(0.66-1.13)	0.88	(0.69-1.13)
Bladder neck obstruction and urethral stricture									
	TUMT	1.31	(1.27-1.35)	1.31	(1.26-1.37)	1.32	(1.27-1.38)	1.38	(1.33-1.44)
	TUNA	1.15	(1.09-1.22)	0.97	(0.90-1.05)	1.21	(1.12-1.30)	1.29	(1.20-1.38)
	TUIP	1.20	(1.13-1.27)	1.34	(1.24-1.43)	1.55	(1.44-1.65)	1.62	(1.51-1.73)
	Laser	1.26	(1.21-1.30)	1.26	(1.20-1.32)	1.21	(1.16-1.27)	1.19	(1.13-1.25)
	Prostatectomy	0.99	(0.94-1.04)	1.11	(1.04-1.18)	0.91	(0.85-0.98)	0.82	(0.77-0.88)
Diagnostic and functional test									
	TUMT	2.88	(2.65-3.13)	2.80	(2.60-3.01)	3.90	(3.70-4.11)	3.38	(3.19-3.58)
	TUNA	2.43	(2.10-2.81)	2.69	(2.39-3.03)	4.19	(3.87-4.54)	3.64	(3.33-3.97)
	TUIP	1.87	(1.58-2.22)	1.86	(1.61-2.16)	1.38	(1.20-1.58)	1.56	(1.37-1.79)
	Laser	1.96	(1.76-2.19)	1.84	(1.67-2.03)	2.15	(1.99-2.31)	2.18	(2.02-2.35)
	Prostatectomy	0.86	(0.71-1.05)	1.19	(1.03-1.38)	0.96	(0.85-1.10)	0.94	(0.82-1.08)

Table 14: The number and rates, per 100 person years, for long term clinical outcomes and diagnostic and functional tests after the original BPH surgery, three annual cohorts combined

Outcome	Procedure	<=1 yr		1-2yr		2-3yr	
		No.	Rate	No.	Rate	No.	Rate
Fistula							
	TURP	7,702	4.18	5,283	3.64	3,334	4.01
	TUMT	828	4.52	490	3.56	283	3.98
	TUNA	294	4.91	168	4.15	67	4.04
	TUIP	322	6.14	196	4.81	118	5.26
	Laser	630	4.70	462	4.25	314	4.72
	Prostatectomy	304	3.72	194	2.90	150	3.84
Incontinence							
	TURP	13,020	7.06	5,865	4.03	3,349	4.02
	TUMT	1,246	6.80	642	4.67	329	4.63
	TUNA	405	6.76	182	4.50	64	3.86
	TUIP	545	10.39	287	7.06	161	7.18
	Laser	1,055	7.88	539	4.96	333	4.99
	Prostatectomy	559	6.83	192	2.88	112	2.87
Bladder neck obstruction and urethral stricture							
	TURP	79,980	43.34	27,778	19.12	15,621	18.77
	TUMT	9,351	51.08	3,377	24.53	1,537	21.66
	TUNA	2,719	45.35	980	24.20	339	20.46
	TUIP	2,908	55.44	1,307	32.12	697	31.08
	Laser	6,600	49.28	2,470	22.74	1,556	23.34
	Prostatectomy	3,284	40.14	827	12.40	455	11.64
Diagnostic and functional test							
	TURP	13,693	7.42	5,744	3.95	3,297	3.96
	TUMT	4,002	21.86	1,295	9.41	581	8.18
	TUNA	1,424	23.75	493	12.17	130	7.85
	TUIP	612	11.66	269	6.61	149	6.65
	Laser	1,942	14.51	867	7.98	521	7.81
	Prostatectomy	598	7.31	252	3.78	123	3.14

Table15: Adjusted Odds Ratios (OR) and 95% confidence intervals (95%CI) for long term clinical outcomes and diagnostic and functional tests after the original BPH surgery, for three annual cohorts combined

Outcome	Procedure	<=1 yr		1-2yr		2-3yr	
		OR	95%CI	OR	95%CI	OR	95%CI
Fistula							
	TUMT	1.10	(1.02-1.18)	1.03	(0.93-1.15)	1.07	(0.92-1.24)
	TUNA	1.21	(1.07-1.36)	1.20	(0.98-1.45)	1.04	(0.75-1.45)
	TUIP	1.46	(1.30-1.64)	1.31	(1.10-1.55)	1.36	(1.08-1.71)
	Laser	1.13	(1.04-1.23)	1.15	(1.03-1.28)	1.17	(1.01-1.34)
	Prostatectomy	0.92	(0.82-1.03)	0.82	(0.70-0.97)	0.86	(0.70-1.07)
Incontinence							
	TUMT	1.04	(0.98-1.10)	1.29	(1.17-1.43)	1.33	(1.15-1.54)
	TUNA	1.06	(0.95-1.17)	1.18	(0.97-1.45)	1.09	(0.78-1.54)
	TUIP	1.41	(1.28-1.54)	1.56	(1.35-1.81)	1.91	(1.56-2.33)
	Laser	1.14	(1.07-1.22)	1.26	(1.13-1.40)	1.27	(1.10-1.46)
	Prostatectomy	1.11	(1.01-1.21)	0.84	(0.72-1.00)	0.76	(0.60-0.97)
Bladder neck obstruction and urethral stricture							
	TUMT	1.23	(1.19-1.26)	1.35	(1.29-1.42)	1.16	(1.07-1.25)
	TUNA	1.11	(1.06-1.16)	1.30	(1.18-1.43)	1.19	(1.01-1.40)
	TUIP	1.25	(1.19-1.3)	1.63	(1.51-1.76)	1.61	(1.44-1.80)
	Laser	1.16	(1.12-1.19)	1.24	(1.18-1.31)	1.28	(1.19-1.37)
	Prostatectomy	0.98	(0.94-1.02)	0.68	(0.62-0.74)	0.64	(0.57-0.73)
Diagnostic or functional test							
	TUMT	2.94	(2.83-3.06)	2.42	(2.25-2.61)	2.17	(1.94-2.44)
	TUNA	3.15	(2.96-3.34)	2.46	(2.14-2.82)	1.90	(1.48-2.42)
	TUIP	1.55	(1.42-1.69)	1.72	(1.49-1.99)	1.74	(1.42-2.14)
	Laser	1.93	(1.84-2.03)	1.92	(1.76-2.09)	2.01	(1.80-2.25)
	Prostatectomy	0.98	(0.90-1.07)	0.93	(0.81-1.08)	0.74	(0.59-0.92)



Table 16: Ratios of rates of bladder neck obstruction and urethral stricture to rates of retreatment by length of follow up

Procedure	<= 1 yr	1-2 yr	2-3 yr
TURP	11.3	10.7	10.9
TUMT	8.2	5.5	5.6
TUNA	10.4	6.2	6.4
TUIP	10.2	8.8	10.1
Laser	10.0	7.5	8.8
Prostatectomy	11.9	25.3	30.6

Figure 1: Geographic distributions of the TUMT procedure from 1999 to 2001

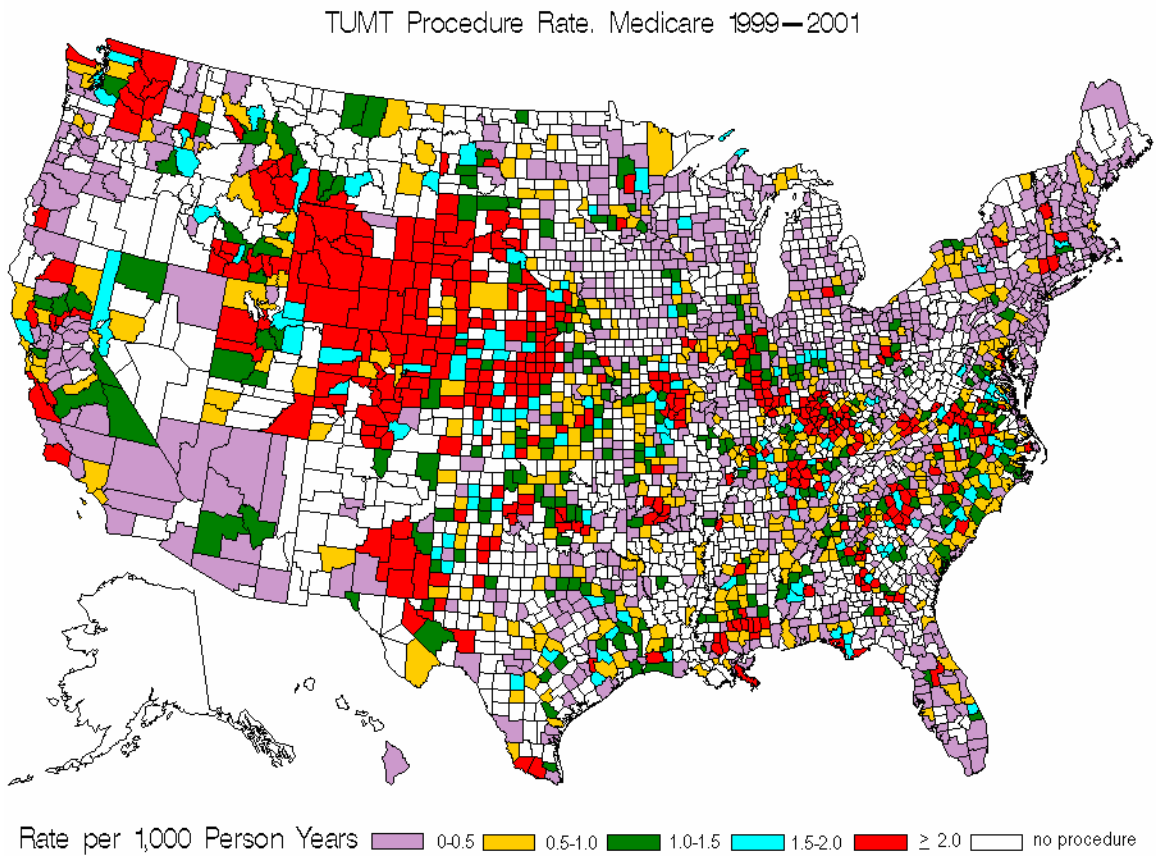


Figure 2: Geographic distributions of the TUNA procedure from 1999 to 2001

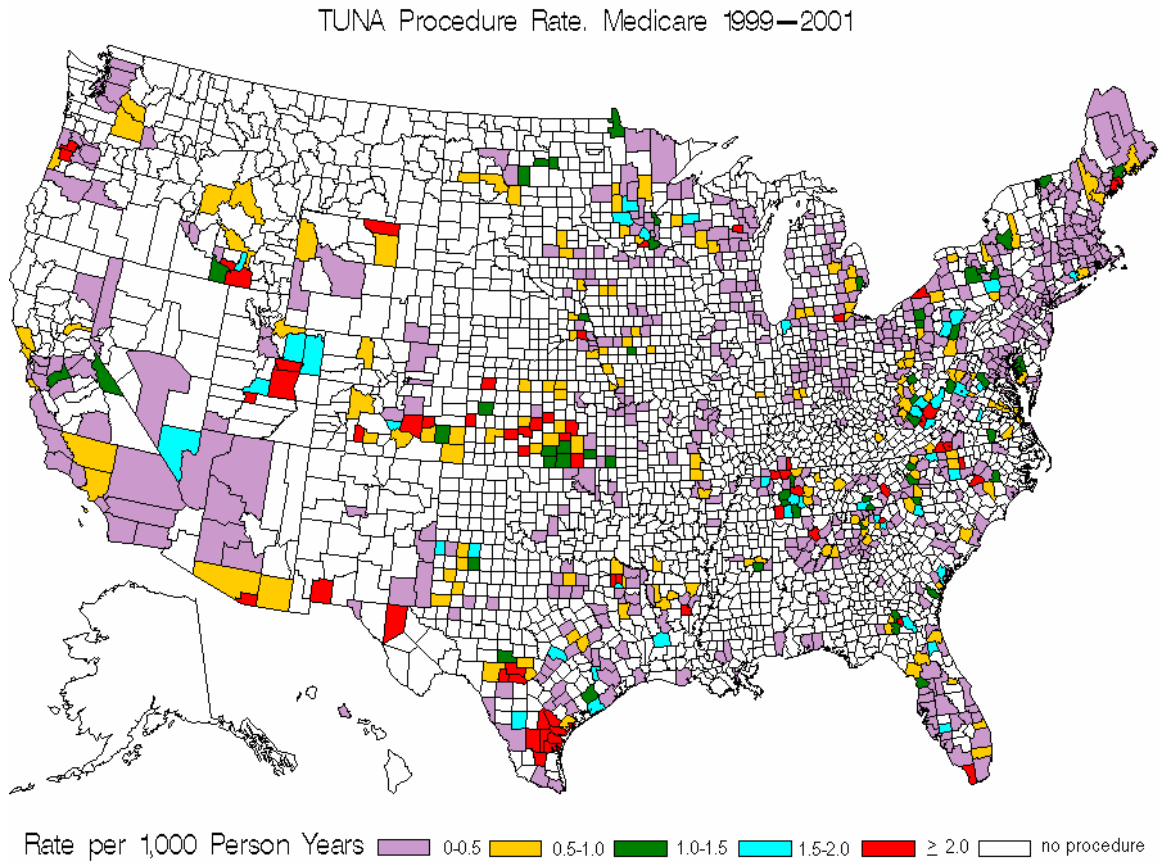


Figure 3: Geographic distributions of the TUIP procedure from 1999 to 2001

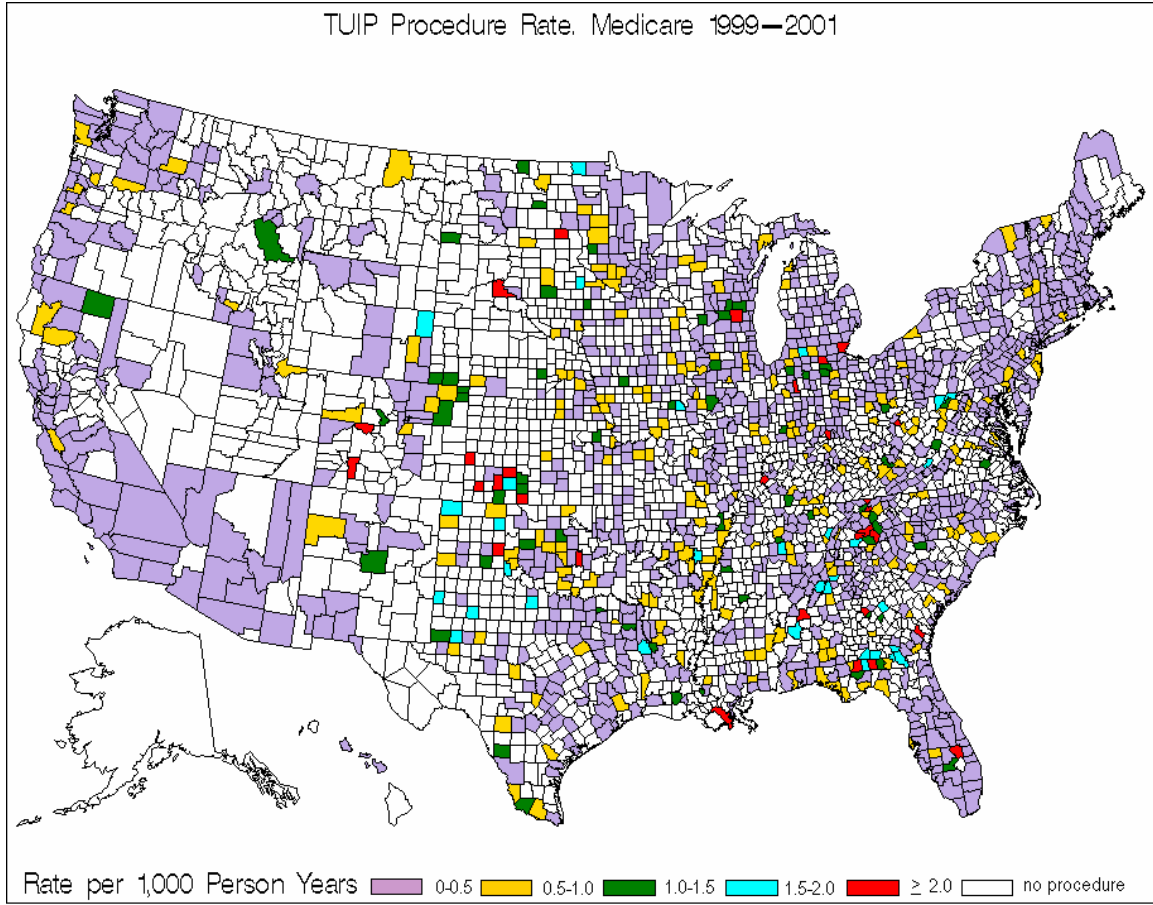


Figure 4: Geographic distributions of the Laser procedure from 1999 to 2001

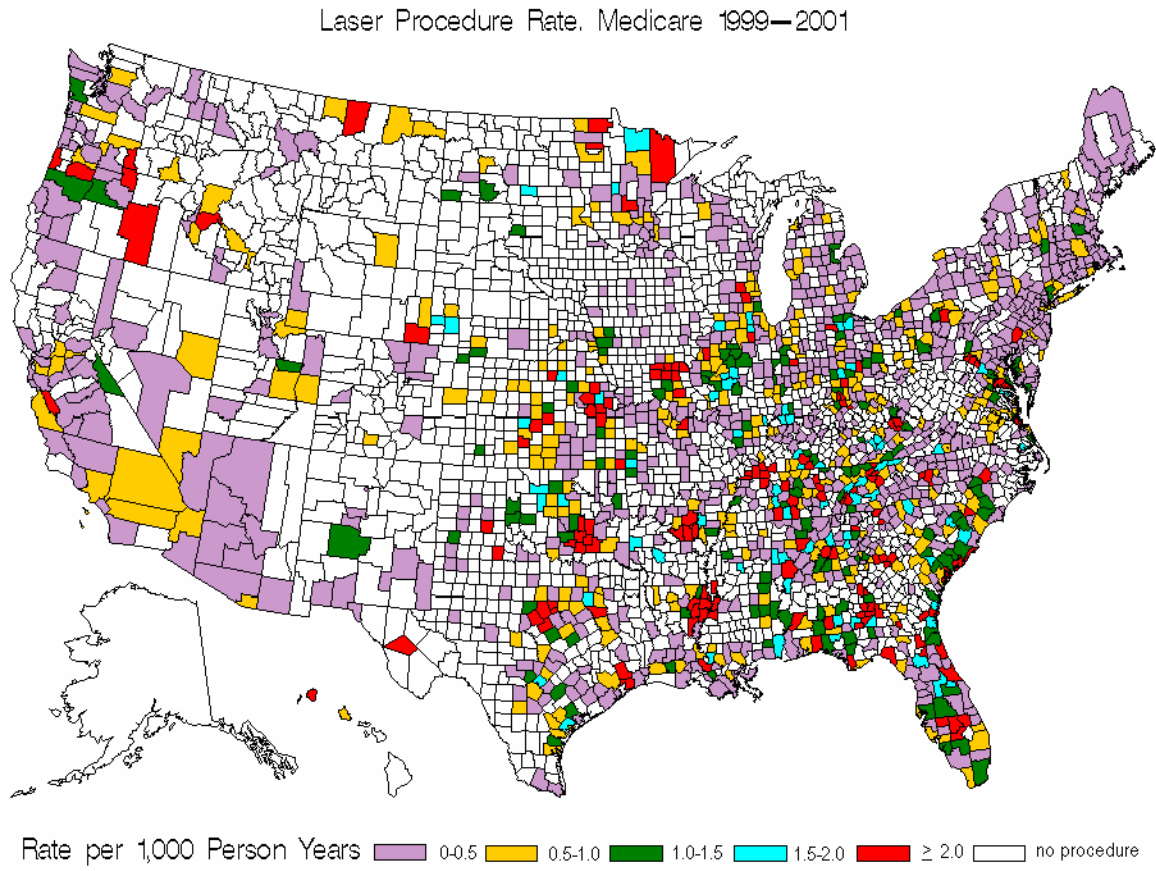


Figure 5: Survival curves for reoperation with the same procedure after the original BPH surgery, three annual cohorts combined

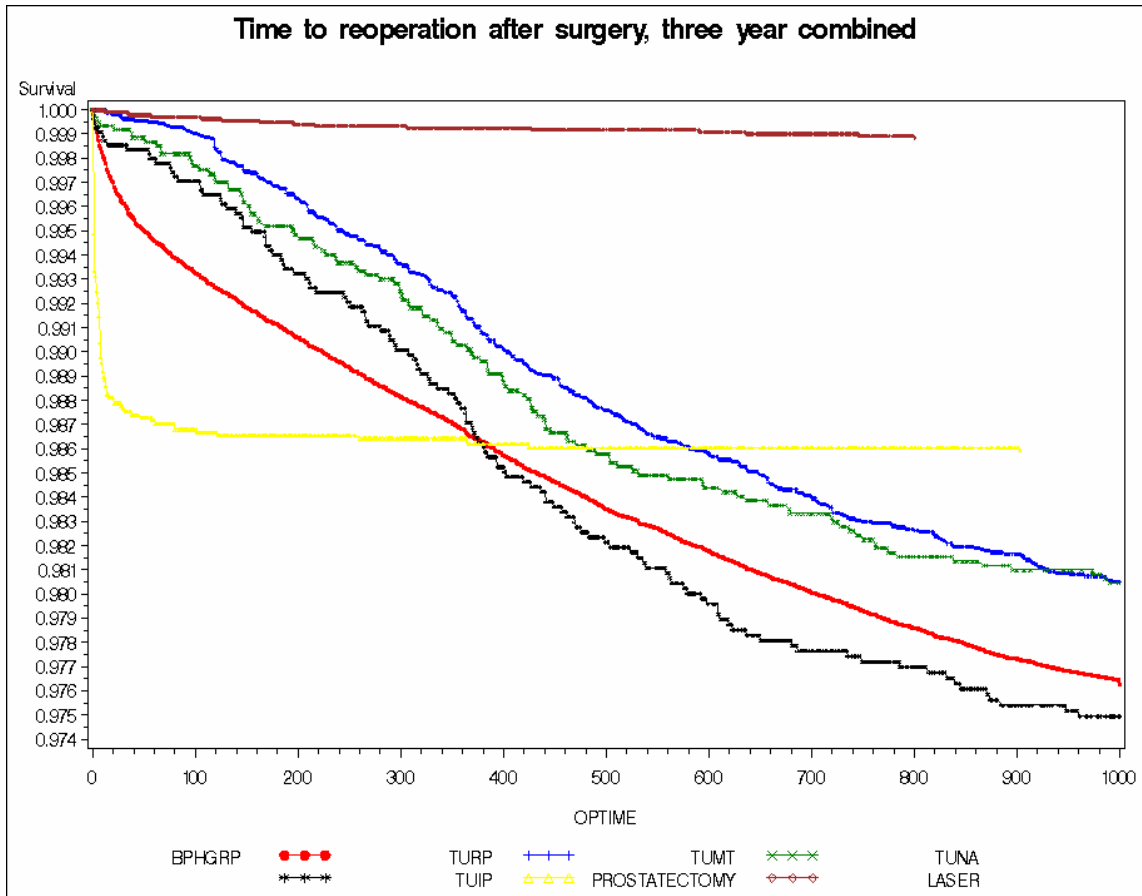


Figure 6: Survival curves for remedial procedures to remove residual prostate tissue after the original BPH surgery, three annual cohorts combined

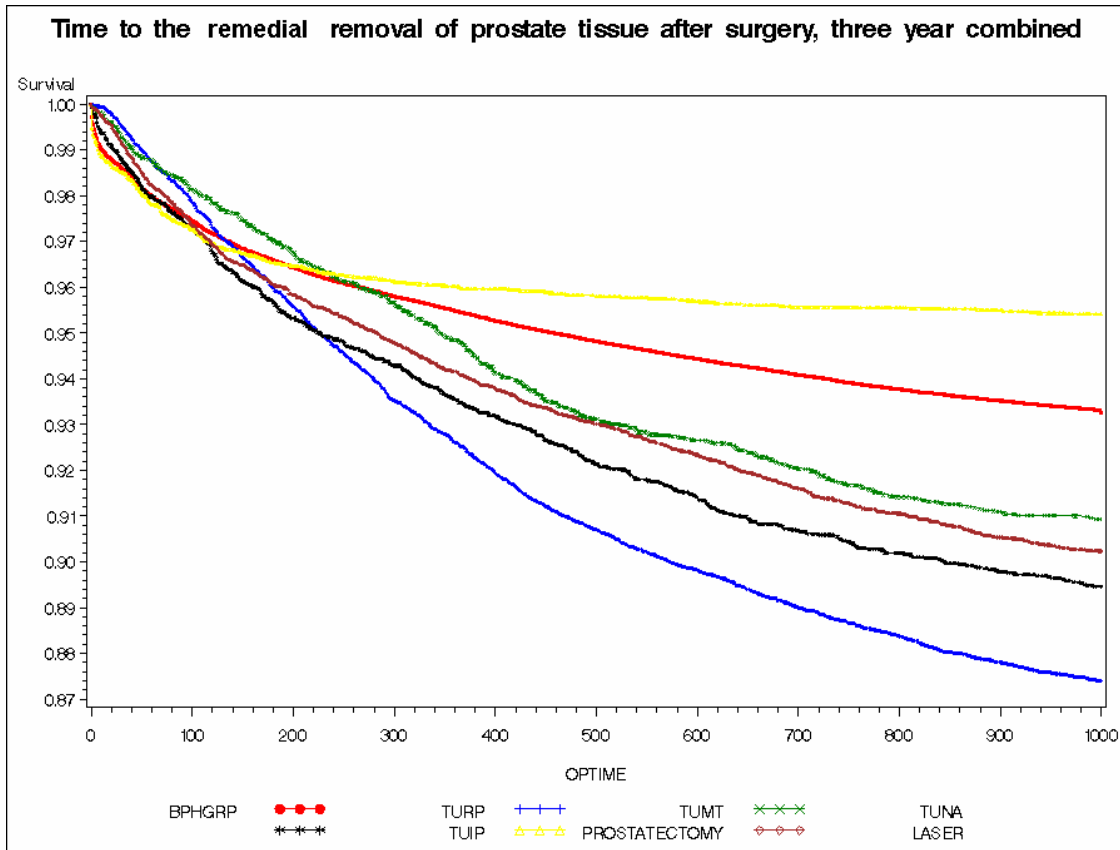


Figure 7: Survival curves for surgical treatment of post-operative incontinence after the original BPH surgery, for three annual cohorts combined

