

Urology**Update**

Focus on Trends in Clinical and Surgical Urology

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Advances in Managing Benign Prostatic Hyperplasia



Igor Frank, MD Medical Editor

INSIDE THIS ISSUE

3 Improving Surgical Management of Male and Female Urinary Incontinence

4 Decade Report: Evolving Uses of Robotic Technology in Urologic Surgery

Registry-Based Medicine: Learning from Patient Data As the baby boom generation ages and longevity increases, benign prostatic hyperplasia (BPH) and its troubling lower urinary tract symptoms will become more widespread. By age 60, approximately 50% of men develop BPH; by age 90, an estimated 90% are affected. Across the treatment continuum, considerable progress has been made to meet the rising demand for treatment, according to Mayo Clinic urologist Lance A. Mynderse, MD, editor of the *Mayo Clinic Essential Guide to Prostate Health*.

Clinical Features Guide Treatment

No single treatment serves all patients optimally. Says Dr Mynderse: "Patient selection is the key and that is the unique ability we have at Mayo. Because we can perform all of the treatments, we can select the best approach for the individual patient on the basis of his clinical features. Few centers can offer the full range that we do, from the latest in lasers, to traditional resections, injectables, and innovative clinical trials."



Figure 1. Injectable botulinum toxin is one of the newer approaches to BPH treatment. OnabotulinumtoxinA is a neurotoxin under investigation in BPH treatment for its ability to relax the musculature. Ultrasound is used to guide the injection to sites of tissue overgrowth and obstruction (arrow).

Injectable, Thermal, and Targeted Therapies Mayo Clinic urology specialists are part of the National Institutes of Health Minimally Invasive Surgical Therapies consortium investigating cost-effective, office-based BPH treatments. One promising treatment recently evaluated is intraprostatic injection of botulinum toxin, referred to by the nonproprietary name onabotulinumtoxinA (Figure 1). Results showed that injecting 100 to 300 units into the prostate was safe and effective in improving urination through 12 months, with considerable improvement in American Urological Association (AUA) symptom scores.

The results of another multicenter collaboration in which Mayo participated will be published in early 2011, reporting 5-year follow-up data from a study of transurethral microwave thermotherapy (TUMT). These results show that a high-energy, urethral-cooling TUMT was more effective and durable than previously thought, with AUA symptom score improvement of 9 to 13 points compared with the 7-point improvement typical with medical therapy. In addition, the retreatment rate was lower than many expected—less than 30% over 5 years.

Use of novel targeted injectables is an emerging therapeutic platform Mayo investigators are following. After injection of the drug, prostatespecific antigen (PSA) activates a site on the drug that liberates a toxin that destroys prostate tissue and thus urinary symptoms are improved.

Surgical Therapies: TURP Outperforms Drugs

Transurethral resection of the prostate (TURP) is the most common surgical procedure for BPH, typically indicated for moderate to severe enlargement. But prior to a recently presented Mayo study, rigorous data comparing TURP and drug therapy were lacking. Results from Mayo's 17-year study fill this evidence gap to provide a more rational basis for clinical decisions about BPH treatments.



Lance A. Mynderse, MD



Amy E. Krambeck, MD



Mitchell R. Humphreys, MD

continued from page 1

The study focused on symptoms of enlarged prostate in 2,184 men, ages 40-79, drawn from a broad community setting.

- 72% received no treatment for BPH symptoms.
- 14% took alpha-adrenergic receptor blockers.
- 9% took 5 alpha-reductase inhibitors.
- 1% had surgical laser vaporization.
- 4% underwent TURP.

Patients who underwent TURP showed the greatest improvement in both voiding symptoms and incontinence compared with other treatment groups. Amy E. Krambeck, MD, who was the study's lead urologist, comments: "The results were a little surprising, since minimally invasive techniques tend to dominate in the literature. But our data are clear that, after intervention, only the patients who had surgical resection reported a decrease in incontinence. Before TURP, the incontinence rate was 64.5%, and after TURP it was 41.9%."

Benefits of HoLEP Laser



During the HoLEP procedure, surgeons use well-defined surgical planes to target tissue

BPH Treatment Continuum

Behavioral and Medical Therapies

- · Reducing caffeine intake
- · Watchful waiting
- · Long-term medication use (alpha-blocker and/or 5-alpha reductase inhibitor)
- · Phytotherapy (saw-palmetto)

Minimally Invasive Office-Based Therapies Transurethral needle ablation (TUNA)

- Transurethral microwave thermotherapy (TUMT)
- Intraprostatic injection of botulinum toxin* · Novel targeted injectables in which tissue-
- destroying toxins are activated by prostatespecific antigen (PSA)*

* Emerging therapies

for removal (Figure 2). In skilled hands, planeguided removal affords greater precision for resolving obstruction and restoring urine flow. Benefits of the HoLEP procedure are numerous:

- HoLEP can be performed on prostate glands of any size.
- No surgical incision is required.
- Erectile function is not affected.



Figure 2. The HoLEP procedure. A) The surgeon starts by creating an initial groove down to the level of the capsule. Here the groove is at 7 o'clock lateral and proximal to the verumontanum. B) Dissection is carried around the apex of the right adenoma across the midline, then proximally to the bladder. Because the holmium laser does not char tissue, and *cutting depth can be well controlled by the 0.4-mm depth of penetration, the laser allows for accurate definition of the natural surgical plane between* adenoma and capsule. C) The anterior commissure is divided, allowing for separation of the 2 lobes of the prostate. D) The right lobe enucleation is completed by depositing the freed adenoma into the bladder, creating an open cavity. The procedure is then repeated on the left lobe. Morcellation of the adenoma in the bladder resolves obstruction.

Surgical Therapies

Photoselective vaporization of the prostate

• Transurethral incision of the prostate (TUIP)

• Transurethral resection of the prostate (TURP)

· Holmium laser enucleation of the prostate (HoLEP)

· Suprapubic or retropubic open or robotic surgical

Tissue Ablation

Tissue Debulking

enucleation of the prostate

Improving Surgical Management of Male and Female Urinary Incontinence

An estimated 13 million people in the United States experience some degree of loss of bladder control. While urinary incontinence is a daily challenge to their quality of life, surgical options exist that continue to evolve and improve outcomes.

"Because of our experience with high patient volumes and long-term follow-up, we have an objective, evidence-based platform for continual improvement and innovation to relieve patients' incontinence," explains urologic surgeon Daniel S. Elliott, MD. "For most patients, the underlying voiding pathophysiology of stress urinary incontinence (SUI) can be very well managed."

Adds his colleague, Steven P. Petrou, MD: "Studies have shown that men consider incontinence to be the most disruptive—but silent—assault on their quality of life and one of their greatest fears associated with prostate surgery. Both men and women with bladder sphincter deficiency grow fearful of coughing, sneezing, laughing, or lifting in public, so they stop going out, interacting, and enjoying life. It doesn't need to be that way."

Male Artificial Urinary Sphincter

In the year following radical prostatectomy, SUI usually improves. But chronic, severe SUIrequiring 3 pads per day or more—is estimated to occur in approximately 5% of men. For these patients, an artificial urinary sphincter (AUS) is the gold standard of care.

Mayo Clinic has been a leader in AUS implantation in the United States since the implants became available in 1972. Mayo's outcome data show that 75% of AUS patients achieve dryness; 25% have marked improvement. Literature reports suggest an eventual failure rate of first-time sphincters of 25% to 30%, typically due to erosion, urethral atrophy, or infections. For these patients, Mayo Clinic offers a range of advanced options:

• Tandem cuff, in which 2 cuffs are placed to increase sphincter control. In patients who have previously failed single cuff AUS placement, this procedure results in an average decrease in the number of daily pads used from 4.3 to 1.6, according to a Mayo Clinic study published in 2003. The study involved 18 patients in whom AUS failed, with a mean follow-up of 3.3 years. Additionally, 56% of men required 1 pad or fewer after the procedure, and 94% of patients indicated that they would recommend the procedure.

• Transcorporal cuff in which part of the corpus cavernosum is cuffed. Results show approximately 65% of patients achieve dryness, 30% have improved symptoms, and 5% have complications such as need for reoperation, device malfunction, and infection requiring device explantation. Soft tissue graft. In unusually complex cases after failure of both tandem cuff and transcorporal cuff procedures, Mayo Clinic teams are pioneering use of a collagen-based, nonimmunogenic porcine material that serves as bulk insulation around the urethra. Once this material is wrapped around the urethra, the cuff is placed over it (Figure 1). In 7 Mayo patients who have undergone the procedure since 2008, with an average follow-up of 16.5 months, 4 (57%) have achieved considerable improvement or complete dryness.

Male Suburethral Sling

The newest generation of compression-based polypropylene mesh male sling was introduced about 5 years ago. It offers men with lighter leakage (1 to 2 pads/day) relief when there is careful selection: • Patients may not lift more than 10 pounds for 6 weeks after the procedure to avoid stretching and dislodging the sling.

• Patients who have had irradiation or transurethral resection of the prostate may possibly have less success and need to be counseled appropriately. During a 30-minute minimally invasive outpatient procedure, the sling is implanted underneath the bulbous urethra to elevate and compress it, thereby preventing leakage. In carefully selected patients, 50% to 60% of patients achieve dryness; 30% have markedly improved symptoms, and approximately 10% become worse. Dr Elliott emphasizes that the potential for worsening incontinence must be emphasized in patient counseling. "This procedure should not be taken lightly, because if done incorrectly the man with a so-called little problem and a little bit of leakage may become totally incontinent," he says.

6 7 B 9 10 11





continued on page 4



Fig. 1B



Daniel S. Elliott. MD



Steven P. Petrou. MD

continued from page 3

After implanting 18 male slings, Mayo Clinic surgeons are refining anatomic locations selected for fixation and improving use of trochars and non-bone anchor fixation on the ischium and the pubis.

Female Urinary Incontinence

In women, SUI may occur alone or simultaneously with pelvic organ prolapse following hysterectomy. A transobturator or U-shaped suprapubic sling to help support and correctly position the urethra can offer substantial control.

At Mayo Clinic, the majority of slings placed are of the transobturator type, Dr Elliott explains, although the suprapubic sling is best for certain urethral movement characteristics. Fixed urethras often benefit from the U shape's ability to be drawn upward.

Introduced about 7 years ago, a newer model of synthetic mesh transobturator sling is placed vaginally during a minimally invasive, 15- to 30-minute outpatient procedure for patients with SUI or urethral hypermobility. Mayo Clinic experience approximates general outcome data showing that about 81% patients become dry; 9% have notable improvement in their symptoms; and 9% have minimal improvement.

An estimated 5% vaginal erosion rate has been reported with the transobturator sling. Mayo Clinic surgeons have reduced this rate through an improved surgical approach (Figure 2). In a series of approximately 900 patients at Mayo Clinic, only 1 case of urethral erosion has occurred.



Figure 2. *Female transobturator sling.* A *thick* (\geq 3 *mm*) vaginal flap is created to prevent the risk of mesh erosion.

Decade Report

Evolving Uses of Robotic Technology in Urologic Surgery



David D. Thiel. MD



Erik P. Castle, MD



Stephen A. Boorjian, MD

Since the use of robots to assist in urologic surgery received US Food and Drug Administration approval in 2000, robot-assisted (RA) procedures have become widespread. Radical prostatectomy for prostate cancer was one of the first applications of robotic technology, and now approximately 85% of prostatectomies in the United States are expected to be performed with robotic assistance. As a result of the robotic skills surgeons have gained and clinical success of RA procedures to treat prostate cancer, RA techniques are being applied in other clinical settings as well.

Building on the Foundation of RA Prostatectomy

Data from Mayo Clinic and other institutions have established equivalency of quality-oflife and intermediate-term cancer outcomes between RA and open prostatectomy, the traditional gold standard. The prospectively maintained Mayo Clinic Prostatectomy Registry contains extensive data on both open and RA procedures. These data enable unbiased comparison of the 2 techniques and provide a platform for judicious expansion of RA approaches to other organs.

Notes urologic surgeon Stephen A. Boorjian, MD: "Mayo has a history of research and of maintaining prospective databases on the patients treated, and that information is critical in helping determine the best uses of robotic assistance. For prostatectomy, we have longterm follow-up on both RA and traditional

procedures, so we can critically compare outcomes to test perceived advantages and to individualize treatment."

Due to the substantial experience gained over the past decade, robotic technology has now been applied to salvage post-radiation radical prostatectomy, including patients who have had combined external beam and radioactive seed therapy. While technically feasible, salvage robotic prostatectomy, like its open counterpart, is more likely to result in incontinence, impotence, and other complications than surgery in a radiation-naïve patient. Therefore, careful patient selection is paramount.

RA Nephron-Sparing Surgery

Nephron-sparing surgery has become the standard of care for patients with small renal masses that are technically amenable to such an approach. Over more than 2 decades, Mayo Clinic urologists collaborated with researchers from other institutions to demonstrate that the oncologic outcomes were equivalent for the nephron-sparing approach and radical nephrectomy, although nephron-sparing surgery offered the benefits of lower rates of renal insufficiency and failure, as well as lower long-term mortality.

Results of the first robotic partial nephrectomies performed in 2002 were published in the November 2004 issue of *Urology* by Mayo Clinic urology team Matthew T. Gettman, MD, Michael L. Blute, MD, George K. Chow, MD, et al. The intuitive interface of the surgical robot has greatly shortened the learning curve, an advantage that has led to a marked increase in popularity of minimally invasive partial nephrectomy. It is now successfully performed at all 3 Mayo sites and offers patients a minimally invasive, nephron-sparing treatment alternative." Now, in an era when small renal masses, particularly those less than 7 centimeters, are increasingly and incidentally revealed by sophisticated imaging equipment, nephron-sparing surgery or partial nephrectomy is a welcome advance," says Mayo Clinic urologic surgeon David D. Thiel, MD.

RA Radical Cystectomy

Radical cystectomy with urinary reconstruction is one of the most complex procedures urologists perform. Because of its complexity, application of minimally invasive technologies to this procedure initially was slow. However, experience from other RA procedures enabled urologists to advance to RA radical cystectomy. In the early stages, the paradigm was to perform the diversion portion of the procedure, such as ileal conduit or neobladder, extracorporeally. But with the newer intracorporeal approach, Mayo surgeons are now able to do the entire operation through laparoscopic incisions and even remove the bladder through the vagina in female patients. Since 2007, Mayo Clinic surgeons have performed more than 100 robotic technology into the armamentarium of bladder cancer treatment,

intracorporeal urinary diversion procedures (Figure 1)."By incorporating we have seen decreased transfusion rates, shorter hospital stays, and fewer complications," explains urologic surgeon Dr Erik P. Castle. "Our published intermediate survival data on RA radical cystectomy demonstrate equivalent oncologic outcomes to open procedures with an average follow-up of over 2 years and a longest follow-up of 4 to 5 years."

RA Sacrocolpopexy

In 2002, a Mayo Clinic team became the first to apply robotic technique to sacrocolpopexy, drawing on the expertise of 2 fellowship-trained specialists—1 trained in female urology and 1 trained in laparoscopic and robotic surgery. "This is an example of urologists' embracing robotic assistance to give patients a better alternative, with the result being an outpatient treatment instead of the 3-day hospitalization needed after



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Table 1: Mayo Clinic Experience with Robot-Assisted Sacrocolpopexy, 2002-2010

Patient Characteristics

· 69 patients
\cdot Median patient age: 67 years (43-83)
· Median BMI: 25.9 (18.2-59.1)
 History of abdominal surgery: 67%
 History of vaginal surgery: 62%
Operative Characteristics
\cdot Operative time (median): 165 minutes (105-300)
\cdot Estimated blood loss (median): 25 mL (10-625)
 Intraoperative Complications: Conversion (16%), Bladder injury (4%), Vaginal injury (3%)
Post-Operative Course

Median hospital stay: 1 day

Blood transfusions: 0

Patient Outcomes

Median post-operative follow-up: 4.2 years (0.1-7.6) Vaginal erosion: 3% Recurrent prolapse requiring secondary treatment: 6%

an open procedure," explains urologist Daniel S. Elliott, MD, who, with Dr Chow, devised the technique. Of the 69 patients who underwent RA sacrocolpopexy between 2002 and 2010, none after the first 5 experienced complications (Table 1).







Drs Mayo hand-recorded surgical cases by date



Rise of the ability to follow patients over time with a dossier system that aggregated all *patient data in a packet*

1910

1907



Thyroid

hyroidism

when patients with the same diagnosis were followed by medical record number



Computerized punch cards and coding system developed, making data available on patient groups



1970

Rochester Epidemiology *Project started; captured* all health care delivered to residents of Olmsted County, where the IMPROVING COMMUNITY HEALTH THROUGH RESEARCH Rochester campus of Mayo Clinic is located



Registries Created

Registry-Based Medicine Learning from Patient Data

Clinical registries are repositories of systematically collected patient and disease data. They prospectively document patient demographics, disease attributes, diagnostic test results, treatment methods, pathology and clinical reviews, complications, outcomes, and survival."Throughout medicine, registries are highly valued for their ability to assess, inform, and improve patient care," explains Mayo urologist Michael M. Lieber, MD, who recently coauthored a registry-based comparison of medical and surgical interventions for benign prostatic hyperplasia (BPH) in the community setting.

Mayo Clinic Urology Cancer Registries

Mayo's 3 urology cancer registries focus on cancers of the prostate, kidney, and bladder. Combined, they represent data from more than 50,000 patients, starting in 1970, making them one of the largest continuous patient-tracking efforts in the world.

For each of the 3 cancer registries, information is prospectively collected, organized, maintained, and analyzed by a professional staff. Staff specialists include a trained biostatistician to maintain the quality of data and analyses; a nurse abstractor to enter data from medical records; an expert urologic pathologist to standardize review of specimens; and a lead physician, who contributes patient-centered clinical insight into data applications. Staff efforts provide complete and uniform follow-up through annual letters and phone calls to patients. In addition, each cancer registry includes biospecimenssamples of tissues, tumor biopsies, urine, and blood—that are linked to annotating information on test and procedure results; patient medical and family history data; and local recurrence, metastasis, and outcomes.

"Registries are remarkably powerful tools," says Mayo urologic surgeon Bradley C. Leibovich, MD, the lead physician of the Nephrectomy Registry. "They help evaluate practice and treatment, predict outcomes, and guide research with the goal of continuously improving quality of care by providing an evidence base for making clinical decisions." Adds Horst Zincke, MD, PhD, one of the founders of Mayo Clinic registries: "It is so important that patients have complete information about the efficacy and risks of treatment options for a given condition and, most of all, that patients have confidence in the care they receive from us. A registry provides all this because it is under the full control of a statistician—we have an objective observer managing our data. Physicians cannot bias the interpretation."

In addition to its 3 cancer registries, Mayo Clinic has other urologic registry databases that include stone disease, pediatric urologic trauma, erectile dysfunction, and studies from within Mayo's large cross-discipline registry, the Rochester Epidemiology Project (see sidebar).

Practice-Changing Effects

Mayo Clinic urologists and researchers have published multiple studies based on registry data, with findings that have had practice-changing effects. For example, the Nephrectomy Registry played a major role in helping Mayo define different kidney cancer subtypes, which Mayo's analysis showed are associated with different survival expectations.

"At the time, the subtypes were not recognized as clinically important, so by going back to review and classify registry material, we were able to determine that the subtype of renal cell cancer was important in determining patient outcomes," explains registry pathologist John C. Cheville, MD, who performed the review of several thousand specimens dating back to 1970. In addition, review of registry material led to the

development of algorithms that enable urologists to predict outcomes for patients with clear cell renal cell carcinoma. This allows the urologists to appropriately tailor surgery and postsurgical follow-up for patients based on features of the renal cancer.

R. Jeffrey Karnes, MD, is the physician leader of the Prostatectomy Registry. To illustrate this registry's value in improving patient care, he cites a study published in the August 20, 2008, issue of the Journal of Clinical Oncology. For this study, the Mayo team developed a gene model to predict outcomes in high-risk radical prostatectomy patients. The goal for the model was to identify patients most at risk for disease progression and to tailor those patients' clinical care. Results showed the model could identify men with high-risk prostate cancer who may benefit from more intensive postoperative follow-up and adjuvant therapies. Notes Dr Karnes: "This would not have been possible without the contribution of the registry, both in terms of our experience and in terms of operating on men with high-risk prostate cancer. The registry allowed us to develop a case-control series with known follow-up so we could develop and validate the gene model."

Bladder cancer treatment has similarly benefited from this registry work. Says Igor Frank, MD, lead physician of the Cystectomy Registry: "We believe the Mayo Clinic Cystectomy Registry encompasses the largest single-institution collection of data on patients with bladder cancer in the world. It dates back more than 30 years and allows us to study a wide assortment of issues, ranging from responses to different therapies, to improvement in surgical and other treatment techniques, to long-term complications of treatment methods." For example, Dr Frank notes that a study published in the January 2010 issue of the Journal of Urology established that a serial-section strategy of the distal ureters at the time of cystectomy may decrease the chances of upper tract recurrence.

Information from registries impacts practice in various ways—from identifying diagnostic markers, to developing predictive scores, to validating surgical approaches—but the goal is the same: to optimize patient outcomes. Says Mayo urologist Erik P. Castle, MD: "Registry data provide a quality-control framework for both current practice and future innovations—we don't just try something new because it occurs to us. The data guide us to low-risk, high-impact improvements in patient outcomes."

Adds Alexander S. Parker, PhD, a Mayo Clinic epidemiologist: "From a clinical perspective, a clear benefit of these registries is the ability to conduct research that provides evidence-based messages. Ultimately, we want our physicians to be able to sit down with their patients and tell them how the last 100 patients with similar histories fared with a given treatment. We want them to be able to consider everything, from potential adverse effects and length of stay in the hospital to the risk of cancer recurrence and quality of life."

Mayo Clinic Clinical Urology Trials

A ayo Clinic Department of Urology has an extensive IVI research program that is actively recruiting enrollees, including those for studies of:

- Prostate cancer Kidney cancer
- Bladder cancer
- Incontinence

For information, see **ClinicalTrials.gov**

Pioneers in Registry-Based Medicine: Rochester Epidemiology Project

Ago Clinic's use of patient medical Mercords to understand diseases has deep roots. In 1966, the Rochester Epidemiology Project (REP) was begun by Leonard T. Kurland, MD, and it has since dramatically impacted the understanding and treatment of many diseases. Says Mayo urologist Michael M. Lieber, MD: "The REP gives Mayo Clinic a unique asset for advancing patient care; this is one of the few places in the world where disease natural history, etiology, and outcomes can be analyzed in such depth."

The REP is a collaborative effort to share patient data among health care providers in Olmsted County, Minnesota, where the Rochester campus of Mayo Clinic is located. As one of the oldest, largest, most stable population-based registries in the United States, the REP benefits from a relatively well-defined, isolated urban population, nearly all of which seeks health care from participating institutions.

Since the REP began, many investigators have used these data to understand hundreds of different diseases and conditions. To date, more than 2,000 peer-reviewed publications have been supported by the REP.



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Future Watch

NOTES Prostatectomy

In June 2010, a Mayo Clinic surgical urology team performed a radical prostatectomy using natural orifice translumenal endoscopic surgery (NOTES). This paradigm-changing approach to prostatectomy involves accessing the prostate and performing a vesicourethral anastomosis through the urethra. Prostate tissue was removed through a 2-cm incision above the pubic bone so that the entire prostate gland was available for pathologic assessment.

Higher-Powered Laser for Photoselective Vaporization of Prostate

A new, higher-powered system using a 180-watt laser covers a larger swatch of tissue than previous models and will be available at Mayo Clinic. It is intended to improve treatment of select cases of benign prostatic hyperplasia (BPH) and related disorders by increasing the light-to-tissue contact area. Mayo Clinic expects to be using the laser in upcoming clinical trials.

Selected Highlights of Recent Publications

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