A Gathering of Urologists and Urogynecologists in Montreal

A Report from the 35th Annual Meeting of the International Continence Society, August 28–September 2, 2005, Montreal, Quebec, Canada

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For four days in late summer 2005, more than 3500 urologists and urogynecologists from around the world gathered at the convention center in Montreal for the 35th Annual Meeting of the International Continence Society (ICS).

The ICS membership includes both urologists and gynecologists. Other than the annual meeting of the American Urological Association, the ICS annual meeting is the most important educational conference for urologists interested in neuro-urology and female urology. The ICS annual meeting is a global event, and the meeting comes to North America only every 4 to 5 years. When this occurs, meeting attendance swells with many North American physicians, bringing extra excitement to the proceedings. In this review, we will highlight some of the most interesting presentations from this year's ICS meeting.

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Botulinum Toxin A for Voiding Dysfunction

Botulinum toxin A (BoNT-A) injection into the prostate in patients with voiding dysfunction is fast becoming a hot topic in urology. Chuang and colleagues[1] reported on the clinical use of BoNT-A for the treatment of patients with small prostates and symptomatic benign prostatic hyperplasia (BPH).

Sixteen men with symptomatic BPH, prostate volume less than 30 mL, peak urinary flow rate less than 12 mL/s, and who were refractory to at least 1 month of α-blocker treatment received an injection of BoNT-A (100 U) transperineally into the prostate under transrectal ultrasound surveillance. The clinical effects were evaluated at baseline and after treatment.

All patients reported subjective improvement starting at approximately 1 week and achieved maximal effects after 1 month that were maintained at 3 and 6 months. At 6 to 12 months' follow-up (mean, 10 months), no patient had recurrence of symptoms. The mean prostate volume, symptom score, and quality of life index were significantly reduced, by 13.3% (from 19.6 ± 1.2 mL to 17.0 ± 1.1 mL), 52.6% (from 18.8 ± 1.6 to 8.9 ± 1.9), and 44.7% (from 3.8 ± 0.3 to 2.1 ± 0.3), respectively. The maximal

flow rate was significantly increased, by 39.8% (from 7.3 ± 0.7 mL/s to 11.8 ± 0.8 mL/s). In 2 patients who received biopsy 1 month after BoNT-A injection, TUNEL staining demonstrated increased apoptotic activity, not only in the glandular component but also in the stromal component of the prostate tissue. No significant local or systemic side effects were observed in any of the patients.

This study suggests that BoNT-A injected into the prostate is a promising treatment for patients with small prostates and symptomatic BPH. With a total dose of 100 U of BoNT-A injected into the smaller-sized prostate, patients with a low flow rate, severe lower urinary tract symptoms, and poor quality of life experienced significant improvement. The effect was prompt and persisted at least for 6 months.

Botulinum toxin A injection into the prostate in patients with voiding dysfunction is fast becoming a hot topic in urology.

Tape Sling Procedures for Stress Urinary Incontinence

Tension-Free Vaginal Tape Versus Transobturator Tape

Recently, tape sling procedures have gained more and more popularity as mini-invasive techniques for the management of stress urinary incontinence (SUI). In a prospective, multicenter, randomized study, Porena and coworkers[2] compared outcomes after two representative tape sling procedures: tension-free vaginal tape (TVT) and transobturator tape (TOT).

Overall 90 consecutive women with SUI (mean follow-up, 13 months) were randomized to TVT (47 women) or to TOT (43 women). In the TOT group, vaginal erosion occurred in 2 patients, and mesh had to be removed in both cases after conservative treatment failed. Subjectively, 33 of 42 patients (78.6%) were dry and 9 of 42 (21.4%) improved. Objectively, TOT was successful in 41 of 42 (97.6%). Urgency improved in 19 of 23 (82.6%), worsened in 1 of 23 (4.3%), and remained unchanged in 3. Ex novo urgency and voiding symptoms developed in 1 patient (2.4%) and 2 patients (4.8%), respectively. In the TVT group, 1 patient needed blood transfusion, and 2 required self-catheterization for significant postvoid residue; suprapubic catheter was inserted in 1 patient for 20 days because of inability to perform self-catheterization. Subjectively, 33 of 47 patients (70.2%) were dry, 9 of 47 (19.1%) improved, and 5 of 47 (10.7%) were dissatisfied. Objectively, 44 of 47 (93.6%) were dry. Urgency improved in 10 of 21 women (47.6%), worsened in 2 of 21 (9.5%), and remained unchanged in 9. Ex novo urgency and voiding symptoms developed respectively in 5 patients (10.6%) and 3 patients (6.4%).

These results show that TVT and TOT procedures are effective for the treatment of SUI, with minimal complications at short-term follow-up. Outcomes after TVT seem slightly worse in patients with mixed incontinence, with more ex novo cases of urgency disturbances. Ex novo voiding symptoms were also greater, but not significantly so, in the TVT than in the TOT group. Long-term follow-up is needed to establish the efficacy and safety of both procedures.

Cost-Effectiveness

In real clinical practice, cost-effectiveness is always a major concern, especially for consumers. Researchers from Finland[3] evaluated the cost-effectiveness of the TVT procedure and laparoscopic mesh colposuspension with staples (LC) for the treatment of primary female SUI.

A multicenter randomized clinical trial (4 university teaching hospitals, 2 central hospitals), which was originally planned to compare the two procedures in terms of clinical efficacy and complications, produced data for 121 patients who had surgery for SUI. The patients were randomly allocated to TVT (n = 70) or LC (n = 51). The cost data of the two procedures were collected from one of the participating central hospitals during the study period (April 1999 to April 2001). Only true costs were calculated and not those charged by the hospital. All additional costs of operations and treatments during a follow-up period of 1 year were registered and entered in a database. Incremental cost-effectiveness ratios were calculated for three parameters: total costs including sick leave, visual analogue scale (0 = no bother from SUI, 10 = maximal bother from SUI), and Urinary Incontinence Severity Score (UISS; a disease-specific quality of life [QoL] questionnaire: 0 = no impairment of QoL, 20 = maximal impairment of QoL).

The total procedural costs (in Euros [€]), were €485.4 for TVT and €461.9 for LC. The average hospital costs were €694.7 for TVT (hospital stay, 0.7 days) and €1000.1 for LC (hospital stay, 1.8 days). The need for sick leave was 15 days in the TVT group and 24 days in the LC group. LC is more costly to perform than TVT. It also gives a poorer subjective outcome, as measured by VAS and UISS, than TVT.

Although the investigators give no data for statistical details in the abstract, they cautiously suggest that TVT is a cost-effective alternative to LC for the treatment of SUI.

Irritative Bladder Symptoms after TVT

After anti-incontinence procedures, irritative bladder symptoms are the most unwanted complication because of their enormous negative effect on QoL. In a multicenter, prospective cohort study, Schraffordt and colleagues[4] reported on changes in irritative bladder symptoms and QoL after TVT in healthy women with only SUI.

All patients were asked to complete the short versions of the Urogenital Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7) before and 36 months after the procedure. Only 37.9% (307 women) of the initial cohort (809 women) were included in the final analysis. To determine the change in irritative bladder symptoms, the "irritative" domain of the UDI-6 was used. Irritative symptoms were present in 19.2% of patients 3 years after surgery. All patients showed an improvement of QoL after TVT, and improvement was better in patients without irritative symptoms. The results of urodynamic investigation, history, and questionnaires revealed no specific pre- and/or intraoperative factor for changes in irritative bladder symptoms after TVT. This demonstrates that it is impossible to predict preoperatively which patient is more at risk for developing irritative symptoms after TVT.

The results of this study suggest that all patients should be informed preoperatively about the risk of developing irritative symptoms that can negatively impact QoL.

Complications of TOT

Every procedure has its own complications. A study from Oregon Health & Sciences University[5] clearly demonstrates that mini-invasive techniques, such as the TOT procedure, are no exception. Hamilton Boyles and colleagues reported various complications after TOT, according to the Manufacturer and User Facility Device Experience Database (MAUDE), a US Food and Drug Administration–maintained database that collects physician-initiated reports of complications associated with medical devices.

Between January 2004 and December 2004, during which time 34,000 TOT procedures were performed, 89 reports were sent to the MAUDE database: 76 with ObTape (Mentor, Santa Barbara, CA), 6 with Monarc (American Medical Systems, Minnetonka, MN), and 7 with the Gynecare TVT Obturator System (Ethicon, Somerville, NJ). Each report was a complication, and no device malfunctions were listed.

Between January 2004 and December 2004, during which time 34,000 transobturator tape procedures were performed, 89 reports were sent to the MAUDE database.

Eighty-two percent of the complications were either vaginal erosions or site-unspecified erosions. One urethral erosion was reported. Two bleeding complications were reported. One patient had an estimated blood loss of 650 mL after an uncomplicated pass of the trocar. One patient had oozing during the procedure requiring vaginal packing. Two cases of postoperative neuropathy were reported. Nineteen cases of infection were reported, and 14 were associated with mesh erosions. Two abscesses were noted: one extending 15 cm down the thigh needed drain placement and continued intravenous antibiotics for 5 additional days. Bladder perforation was reported in 3 patients. One patient experienced urinary retention after migration of her tape. Two failures were reported. One patient noted that her sling came loose during intercourse, and the other patient felt a pop and then had recurrence of her incontinence.

The three commercially available TOT systems use different polypropylene meshes and different implantation systems. These differences might affect rates of erosion and the technical difficulty associated with correct mesh placement, but as yet there is no evidence of superiority of one type of mesh over another, owing to the limited data.

Open Versus Laparoscopic Colposuspension

Investigators in the United Kingdom[6] compared the effectiveness of laparoscopic and open colposuspension in the treatment of SUI. Although many studies have been published on this subject, Smith and colleagues boast that this is the first study with a robust design, including sufficient patients with 2 years' follow-up.

Women with urodynamically proven SUI requiring surgery in the form of a colposuspension were invited to participate in a prospective, randomized trial. Randomization was performed by an external center and stratified by center, age, and previous bladder neck surgery. Primary outcomes at 2 years were both subjective (a question of satisfaction with outcome ["perfectly happy/pleased"; question 33 in the Bristol Female Lower Urinary Tract Symptoms Questionnnaire]) and objective (negative results on a 1-hour pad test). Secondary outcomes were levels of operative morbidity, time to return to work, and health economic costs to

the National Health Service and the patient.

Between April 1999 and February 2002, 291 women were recruited into the trial. The intention-to-treat analysis indicated no significant difference in cure rates between open and laparoscopic surgery. The objective cure rates for open and laparoscopic surgery were 82% and 79.7%, respectively. Subjective cure rates by satisfaction were 54.6% and 54.9% and by symptoms were 53.1% and 55.4%, respectively. There was a significant decrease in cure in both arms over time when assessed objectively but not subjectively. Significantly fewer (23%) women receiving laparoscopic surgery suffered 24-hour pain levels greater than 6, compared with those receiving open surgery (40%). The mean length of hospital stay was 5 days and 6 days in the laparoscopic and open groups, respectively. The mean time to return to work was 9 weeks and 11 weeks, respectively. Neither of these postoperative time differences was statistically significant.

These study results suggest that laparoscopic colposuspension is not inferior to open colposuspension in terms of objectively and subjectively assessed cure rates. The finding of non-inferiority in this study implies that surgical experience might have contributed to the lower success rates seen for laparoscopic colposuspension in other series.

Stem Cell Research

Human Muscle-Derived Stem Cells for the Treatment of Urinary Incontinence

A study from the University of Pittsburgh[7] is the first to demonstrate the effectiveness of human muscle-derived stem cells (hMDC) for the treatment of urinary incontinence in an animal model.

Eight-week-old female, athymic nude rats were divided into 3 experimental groups: 1) nontreated controls, 2) rats receiving sciatic nerve transection and periurethral sham injection (20 µL saline) 1 week after transection, and 3) rats receiving sciatic nerve transection and periurethral injection of hMDC (1×10^6 cells per 20 µL saline) 1 week after transection (n = 6 per group). Leak point pressure (LPP) was measured 4 weeks after injection by the vertical tilt intravesical pressure clamp method. Cryosections of the urethra were labeled with hematoxylin and eosin for general histology and immunolabeled with lamins A/C to follow the fate of the injected hMDC.

Bilateral sciatic transection resulted in a significantly lower LPP (28.5 ± 0.6 cm H_2O) compared with the control group (43.6 ± 1.1 cm H_2O; $P < .05$). LPP was restored to a significantly higher level after hMDC injection (37.9 ± 2.3 cm H_2O; $P < .05$) compared with sham injection. Importantly, no significant difference in LPP between the hMDC and control groups was detected. Histologic evaluation demonstrated periurethral muscle atrophy in the sham-injected group only. Human MDC were present in the nude rat urethra 4 weeks after injection.

This study showed that treatment with hMDC led to restoration of LPP to normal levels in an experimental model of stress urinary incontinence in nude rats. It was hypothesized that the injected hMDC differentiated into new muscle fibers and prevented periurethral muscle atrophy, but the exact mechanisms of these actions are still being investigated. The investigators suggest that hMDC might now be considered as a therapy for stress urinary incontinence.

Adipose-Derived Stem Cells for Tissue Engineering

Investigators from the University of California, Los Angeles,[8] reported the first study to show incorporation of adipose-derived stem cells (ADSC), one of the autologous sources of pluripotent cells, into the smooth muscle of the urinary tract. Rodriguez and colleagues investigated the ability of human ADSC to be delivered to and survive within the bladder and urethral smooth muscle over extended periods. In addition, they investigated a tissue-engineered bladder generated from smooth muscle cells differentiated from ADSC.

Lipoaspirate was acquired from female patients undergoing liposuction. The lipoaspirate was processed to yield a pluripotent population of ADSC. For tissue delivery, the processed lipoaspirate cells were fluorescently labeled and suspended in Hank's balanced salt solution (HBSS). To assess ADSC viability within multiple animal models, Rnu athymic rats (n = 8) and severe combined immunodeficient mice (n = 6) underwent laparotomy and injection of ADSC into the bladder and urethra. An additional 8 rats underwent sham injection of HBSS alone.

Evaluation at 2, 4, 8, and 12 weeks after injection of ADSC demonstrated the injected cells' viability and incorporation into the recipient smooth muscle. Eight weeks after injection, the ADSC demonstrated in vivo expression of α smooth muscle actin, an early marker of smooth muscle differentiation. ADSC were negative for smooth muscle markers at the time of harvest. After 3 weeks in smooth muscle–specific media, the ADSC expressed

Significantly fewer women receiving laparoscopic colposuspension suffered 24-hour pain levels greater than 6, compared with those receiving open surgery.

myosin heavy chain (MHC), a late specific smooth muscle marker present only in contractile cells. The 3-dimensional PLGA (poly D, L-lactide-co-glycolide) grafts remained pliable and stable in culture for up to 4 weeks. The differentiated ADSC adhered to the scaffold at 80% confluence, and they maintained MHC expression for up to 4 weeks in vitro on the scaffold. Bladders augmented with the engineered scaffolds had superior capacity and compliance compared with partial cystectomy. The engineered bladder walls had progressive urothelial coverage along the luminal surface at 1 and 2 weeks in vivo.

Evaluation at 2, 4, 8, and 12 weeks after injection of adipose-derived stem cells demonstrated the injected cells' viability and incorporation into the recipient smooth muscle.

These results suggest that ADSC might provide a feasible and cost-effective cell source for urinary tract reconstruction, both for injectable forms of smooth muscle substitution in intrinsic sphincter deficiency and for tissue engineering of the bladder and lower urinary tract.

Binding Characteristics of Recently Developed Muscarinic Receptor Antagonists

Recent studies in humans and animals have indicated that muscarinic receptors are present on both mucosa and detrusor of the urinary bladder. In an informative study from Australia,[9] Mansfield and coworkers investigated the binding characteristics of three recently developed muscarinic receptor antagonists—darifenacin (M3 selective), trospium (nonselective), and fesoterodine (M3 preferring)—and compared them with oxybutynin.

Specimens were collected from normal areas of bladder in 10 control patients (8 male, 2 female, with no overactive bladder symptoms) undergoing open bladder surgery for cancer procedures. Radioligand binding with the muscarinic receptor ligand [3H]quinuclidinyl benzilate ([3H]QNB) was performed with membranes from the detrusor muscle and mucosa.

All antagonists displayed high affinity competition for [3H]QNB binding to both detrusor and mucosa membranes. In detrusor, the order of potency was oxybutynin ≥ fesoterodine > trospium > darifenacin, whereas in mucosa the order was trospium > oxybutynin > fesoterodine > darifenacin. Fesoterodine demonstrated high affinity binding (35% high-affinity sites) in mucosal membranes but not in detrusor membranes. The high affinity component of darifenacin binding to mucosa and detrusor membranes represented 21% and 24% of total binding sites, respectively. Oxybutynin and fesoterodine were able to compete with equal affinity for [3H]QNB for binding to muscarinic receptors on both mucosa and detrusor membranes. Trospium and darifenacin seemed to have different affinities in the two regions, though this finding would need confirmation.

This study clearly demonstrated that antimuscarinic agents currently being used to treat patients bind with high affinity to the muscarinic receptors in the mucosa and detrusor. These results suggest that mucosal muscarinic receptors might represent a novel site of action for muscarinic antagonists.

Nerve Stimulation for Voiding Dysfunction

Researchers from the William Beaumont Hospital in Detroit[10] reported the first blinded, crossover trial to compare sacral nerve stimulation (SNS) with pudendal nerve stimulation (PNS) for voiding dysfunction. SNS (InterStim; Medtronic, Minneapolis, MN) selecting only S3 has a limitation in that only one of the three afferent pathways inducing the inhibitory reflex is stimulated. Selection of the pudendal nerve as a site of stimulation provides afferent stimulation of S2, S3, and S4.

Thirty subjects who were undergoing SNS to treat their voiding dysfunction and who consented to having a second electrode placed at the pudendal nerve were enrolled in this trial. Their mean age was 50.6 years (range, 25–80 years). A quadripolar tined lead was successfully placed at the sacral and pudendal sites in all subjects. Each lead was stimulated for 7 days, and subjects completed voiding diaries and global response assessment. Subjects rated their improvement (as a percentage) on each lead in a blinded fashion and chose the one to be implanted to a permanent generator on the basis of clinical response.

Sacral nerve stimulation selecting only S3 has a limitation in that only one of the three afferent pathways inducing the inhibitory reflex is stimulated.

Out of 30 subjects, 24 (80%) had a significant clinical response and had a pulse generator implanted, with 19 of 24 (79.2%) choosing pudendal and 5 of 24 (20.8%) choosing sacral stimulation. The order in which the leads were stimulated had no impact on the

final lead implanted. PNS produced significantly greater improvement in symptoms than SNS (51% versus 37%; $P = .02$). On a 7-point scale from markedly worse to markedly better, PNS was superior to SNS for pelvic pain ($P = .024$), urgency ($P = .005$), frequency ($P = .007$), and bowel function ($P = .049$). No differences between SNS and PNS were seen for vaginal pain, sexual function, or incontinence. There was no migration of the sacral lead and one forward migration of a pudendal lead. No infections or erosions occurred.

The investigators suggest that PNS is feasible with the use of a tined quadripolar lead. They are currently conducting a prospective post-implant follow-up to assess durability of response, complications, and reoperation.

Ajulemic Acid for Overactive Bladder

Ogawa and colleagues[11] conducted an investigative study of ajulemic acid (IP751), a new potential medication targeting overactive bladder. IP751 is a potent analogue of tetrahydrocannab28pinol (THC)-11-oic acid, which is a major metabolite of THC, the principal psychotropic constituent of cannabis. IP751 reportedly shows potent anti-inflammatory activity and is a powerful analgesic agent, though the underlying mechanisms are still unknown.

Ajulemic acid (IP751) significantly suppressed bladder overactivity in both acute and subacute models without affecting bladder contractility.

In this animal study with rats, intravesical infusion of acetic acid was used to create an acute bladder irritation model and intraperitoneal injection of cyclophosphamide for subacute bladder irritation.

In the acute irritation model, 0.25% acetic acid infusion induced significant bladder overactivity, evidenced by a reduction in intercontraction intervals (ICIs) to 42.9% of the control value. This reduction in ICIs was suppressed by IP751 at a dose of 10 mg/kg to 112.4% of the control value ($P < .05$, $n = 6$) but not by IP751 at doses of 1 mg/kg and 3 mg/kg (45.2% and 51.1% of the control value, respectively). IP751 at a dose of 10 mg/kg also increased the pressure threshold to 127.2% of the control value, whereas vehicle, 1 mg/kg, or 3 mg/kg of IP751 did not produce such increases (87.1%, 74.1%, and 94.1% of the control value, respectively). There were no significant changes in maximum voiding pressure (MVP) and baseline pressure (BP). In the subacute irritation model, bladder overactivity indicated by significant ICI reductions was observed 1 day after cyclophosphamide (CYP) injection. Administration of IP751 at a dose of 10 mg/kg (intravenously) significantly

Main Points

- Patients with a smaller-sized prostate and low flow rate, severe lower urinary tract symptoms, and poor quality of life experienced significant improvement with an injection of 100 U of botulinum toxin A; the effect was prompt and persisted at least for 6 months.
- Tension-free vaginal tape (TVT) and transobturator tape procedures are effective for the treatment of stress urinary incontinence (SUI), with minimal complications at short-term follow-up; the TVT procedure is less costly and has a better subjective outcome than laparoscopic mesh colposuspension with staples.
- It is impossible to predict preoperatively which patient is more at risk for developing irritative symptoms after the TVT procedure; patients should be informed preoperatively about the risk of developing irritative symptoms.
- Laparoscopic colposuspension is not inferior to open colposuspension in terms of objectively and subjectively assessed cure rates.
- In the area of stem cell research, treatment with human muscle-derived stem cells led to restoration of leak point pressure to normal levels in an experimental model of stress urinary incontinence in nude rats, and adipose-derived stem cells might provide a feasible and cost-effective cell source for urinary tract reconstruction.
- In a study of nerve stimulation for voiding dysfunction, pudendal nerve stimulation produced significantly greater improvements in pelvic pain, urgency, frequency, and bowel function than sacral nerve stimulation.
- Ajulemic acid (IP751) could be a promising medication for reducing pain and urinary frequency symptoms in patients with painful bladder syndrome or interstitial cystitis.

suppressed CYP-induced bladder overactivity, as evidenced by the increase of ICIs to 5.14 minutes from the control value (3.65 minutes), whereas vehicle did not alter ICIs (3.89 vs 3.94 minutes) in CYP-treated rats. There were no significant changes in MVP, pressure threshold, and BP after IP751 administration. Therefore, IP751 at a dose of 10 mg/kg significantly suppressed bladder overactivity in both acute and subacute models without affecting bladder contractility.

These results suggest that IP751 can suppress bladder nociceptive responses induced by bladder irritation, probably owing to suppression of bladder sensory activity. Thus, IP751 could be a promising medication for reducing pain and urinary frequency symptoms in patients with painful bladder syndrome or interstitial cystitis. ■

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