

Congratulations! To date, there are 491 women enrolled in the UITN TOMUS Study!

More Study Results

By Judy Gruss, RN at U. Pittsburgh

Last month, we reported the main results of the SISTER Study, and information that described the women who participated in that study. This month, we are reporting on one very important part of both the SISTER study and the TOMUS study – Urodynamics Testing (we often call it simply UDS).

Most, if not all, of the patients in SISTER and TOMUS had the UDS test done prior to their surgery and then again a year or two later. The doctors involved in the UITN have published 4 reports already from the information that we collected from UDS tests.

1. In one article entitled “Process for Development of Multicenter Urodynamic Studies” (published in the journal *Urology* in 2007), the investigators describe how they developed a process to ensure that UDS testing was performed similarly at each individual clinical center. UDS testing was performed at 9 different clinical sites, and very often by different practitioners at each site. It was very important to standardize this testing. Within the UITN there is a subgroup of investigators who developed a specific set of instructions for performing UDS testing, and then reviewed testing done at all centers to ensure that the tests were performed correctly.
2. The investigators also wanted to evaluate how similarly they interpreted the UDS testing. Typically, a technician will perform the actual test, and a physician will review the printout and interpret the results of the test. In order to do a really good job making sure the UDS testing was done similarly and adequately at each of the nine clinical centers, the subgroup of investigators who developed the process described in #1 above also reviewed UDS tests that had already been reviewed at the individual sites to see how often they agreed with the reviewers at the clinical sites. They found that there was excellent agreement between the two sets of reviewers. This was important since it supported that the UDS testing was being performed similarly and according to the instructions that they had developed for the nine clinical sites. This article, “Inter-rater Reliability of Filling Cystometrogram Interpretation in a Multicenter Study” was published in the *Journal of Urology* in 2006.
3. Although performing UDS testing is very common in the evaluation of women with urinary incontinence, there was little or no information available to the investigators when they started SISTER and TOMUS on what should be considered the ‘normal’ values for test results. For example, testers recorded the pressure in the bladder after the bladder was filled. But there were no studies done previously that looked at what a normal bladder pressure really is. Clinicians need to know these ‘normal’ numbers (or the normal range) in order to determine whether the results might be abnormal, or something else happened (like a machine malfunction) that might have caused the test to look abnormal. In the article published in *Neurology and Urodynamics* (2007) entitled “Reference Urodynamic Values for Stress Incontinent Women”, the investigators looked at the UDS test results from all of the women who had testing done in the SISTER study. This very important paper can now serve as a reference for other clinicians who perform and interpret UDS testing.
4. The investigators are also looking at specific tests included in UDS. One of the tests is called the ‘Valsalva Leak Point Pressure’. This number is the pressure in the bladder that is present (with valsalva or ‘bearing down’) during the test. Only women who had accidental leakage of urine when they were asked to bear down (or valsalva) were included in this analysis. One of the important findings in this study (titled “Clinical and Demographic Factors Associated with Valsalva Leak Point Pressure among Women Undergoing Burch Bladder Neck Suspension or Autologous Rectus Fascial Sling Procedures”, published in the journal of *Neurourology and Urodynamics* in 2007) was that the Valsalva Leak Point Pressure (or VLPP for short) is not always related to the severity of incontinence, and clinicians should be cautious in using this test result alone to decide treatment. In fact a future paper will focus on seeing whether the VLPP has any bearing on the success of the incontinence surgery.

How You Help Us

By Peggy Norton, MD at U. Utah

These studies are the first to discover and write about UDS tests in this way. The doctors really want to be able to use this test more effectively in the future to diagnose and treat women with urinary incontinence. So **we would like to thank all of you who had the test for this helpful information.** Since the TOMUS study is still in progress, many of you will have the test scheduled in the future. We have so many more important things to discover about UDS testing and how to use it in the best way to manage our patients, so **please don't forget to schedule this important test.**

TOMUS Patient Experience

Submitted by a Patient at Beaumont Hospital

Last spring, my husband and I decided that this Fall I would return to full-time teaching after working part-time for five years. I was concerned with a number of details. When would the grocery shopping get done? When will the house get cleaned? Will we be up late doing laundry? Will I enjoy my new middle school position? But, nothing concerned me more than my "little personal problem." How in the world was I going to teach for seven hours a day when every time I laughed, every time I sneezed, every time I reached to pull a map down, and every time I livened things up a bit with a hysterically fast round of "head, shoulders, knees, and toes," I leaked? Now this was something to worry about! And, this little problem seemed to be getting worse at lightning speed!

I mentioned my concern to my gynecologist. She referred me to Dr. Larry Sirls at William Beaumont Hospital in Royal Oak, MI. When I met with Dr. Sirls, he seemed to think vaginal tape surgery would have me able to "run" again. . . I told him I'm not a runner, but the chance at a new and improved quality of life sounded good to me! I met with some awesome nurses, both in his office and in the Urology Research Department, went through the required testing, and was given the "thumbs up" for surgery, which we scheduled for the end of April.

By the time summer vacation arrived, I was a new woman! It was amazing how my badminton game had improved. Last summer, every time I hit the birdie, I leaked. Not so this summer! My new job is going great, and I haven't leaked once! Ironically, my youngest daughter decided to take up cross country running this fall, and, you guessed it, Mom is running with her! Thank you, Dr. Sirls and team, for giving me the freedom to be able to run!!!



"Compliance" is the term used by researchers to describe how people in a study follow up with instructions and visits. If study participants miss appointments or can't complete study measures, this affects our ability to report the success of treatments in the Urinary Incontinence Treatment Network. But compliance is quite good in our Network, and we are constantly amazed at what our patients do to help us with studies. Some women drive several hours to get to their study visit, rearrange their schedules, or even drive through snowstorms! At the Utah center, one woman asked to be seen early because she was getting married and wanted her visit before she went on her honeymoon. Another patient called to apologize that she couldn't make her visit. She was in the hospital with a broken leg! Each and every one of you has had to make accommodations to get your study measures done, and we appreciate what a good job you are doing.

Did you know that you are a VIP? As a group, the women involved in the Urinary Incontinence Treatment Network studies are famous because the information from this research has been published in major medical journals around the world. Our colleagues in Australia, Germany, Japan, and elsewhere are impressed that so many of our patients are willing to help with research, and they continue to be followed for years after the initial study is completed. This is important to doctors and patients alike. Doctors are able use the information from our studies to counsel women about treatment options for urinary incontinence.

How can we help you to keep up with study compliance? Have we shared with you the importance of the information you are helping to generate? We are willing to schedule visits at odd times if this is more convenient for your work or family schedule. We try to do phone visits where possible, especially in long term follow-up.

How can you help us with compliance? When a woman, whom we had not seen for over a year learned of the results of the SISTER trial that are published in the New England Journal of Medicine, she phoned us. She was proud to see that she was part of important medical research, and she wanted to know if it was too late to help. We scheduled her appointment for the next week! Let us know how we can make your participation more convenient. All of the investigators, coordinators, and data managers appreciate the efforts our study patients make. And remember, if you have missed some appointments or have been late with some study measures, getting some information from you is better than no information at all.

New Directions for the UITN

By Larry Sirls, MD at Beaumont Hospital

The UITN Investigators are dedicated to high impact clinical research regarding the prevention, evaluation and management of urinary incontinence to improve the quality of life for adults. The Urinary Incontinence Treatment Network (UITN) continues to plan research studies to answer important questions in the field of Urinary Incontinence.

We are thinking about and planning how to answer some important and difficult problems in patients with urinary incontinence. Several projects are now in the development phase as future planned studies. Two protocols are in development right now, the first will help us evaluate whether urodynamic testing helps in the evaluation of patients with straight-forward stress urinary incontinence.

Patients with bladder overactivity (BOA) continue to be greatly affected by symptom bother and a negative effect on quality of life. Symptoms of urinary frequency and urgency with incontinence are typically managed with some combination of behavioral modification, pelvic floor therapy and with oral drugs. Patients who choose medication may experience potentially bothersome side effects.

We are designing two studies that will focus on patients with bladder overactivity. First is a study of patients with both bothersome stress incontinence and urge incontinence (mixed incontinence), a condition seen in over half of the patients we see. We hope to answer the question of whether treating the stress urinary incontinence component first with surgery or treating the bladder overactivity component first with behavioral modification, pelvic floor therapy and medication will provide better patient satisfaction.

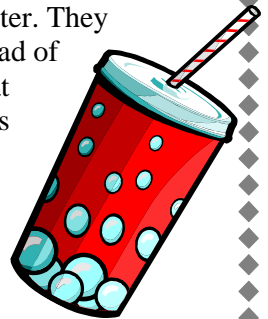
Patients who are dissatisfied with their treatment choice can be offered the other treatment option (i.e., patients who have had surgery and still have bothersome bladder overactivity symptoms can be offered the behavioral therapy and medication, whereas patients who have had behavioral therapy and medication and who are still bothered by their stress urinary incontinence symptoms can be offered surgery). In this way, we can evaluate whether approaching patients with significant symptoms of both stress urinary incontinence and bladder overactivity will benefit most from surgery, behavioral therapy with medication or ultimately, both treatments in some staged fashion.

Artificial Sweetener & Bladder Symptoms

Submitted by Laura Burr, RN at U. Utah

A study presented in August at the International Continence Society's annual scientific meeting in Rotterdam, The Netherlands, reported on a study with Coke, Diet Coke, caffeine-free Diet Coke and carbonated water. Twenty normal volunteers tried each of the products as their main source of fluid intake for one week. During each week they completed bladder diaries and recorded how much urgency to urinate they had and how many times they went to the bathroom.

They found that Diet Coke and caffeine free Diet Coke caused more urgency and frequent urination symptoms than Coke and carbonated water. They suggested that artificial sweeteners instead of caffeine might actually be the culprit that causes increased bladder symptoms. This was a preliminary study and further research is needed but you may want to consider if artificial sweeteners in your diet might be causing you bothersome bladder symptoms.



To view this article, you can visit the following website:
www.icsoffice.org/publications/2007/PDF/0019.PDF

REMINDERS:

If you have not already done so, please remember to schedule your TOMUS 12 or 24 month follow-up visit.

We would love to hear from you!!

Anonymous newsletter comments and stories can be sent via the UITN Public Website:

www.uitn.net

In order to protect your privacy as a research participant, please do not include your name or address on the comments submission.

Oyster Stew

Submitted by Lucy Howard at U. Maryland

Ingredients:

- 1 pint oysters
- 1 pint heavy cream
- 4 cups milk
- 4 stalks celery (chopped)
- 1/2 onion (chopped)
- 3 tbs butter
- 1 tbs Worcestershire sauce
- 1 tsp salt
- 1/6 tsp. cayenne
- paprika

Preparation:

Melt butter, add celery and onion and cook until tender. Drain oysters, add to mixture and cook slowly until edges curl slightly. Add cream, milk and Worcestershire sauce and heat until oysters are fully curled, being careful not to over cook. Add salt and cayenne and serve at once. Garnish with paprika. Makes 6 cups.

Double Knit Scarf Pattern

Submitted by Laura Greene at NERI



The technique used in this pattern creates a double thickness to the material for extra warmth, and it also creates a 2-sided Stockinette stitch without having it roll into a tube.

Materials: Chunky yarn. The amount will depend on the length you want. I used about 200 – 250 yards.

Needle Size: 13 US

Pattern: With straight needles, cast on 16 stitches.

Row 1: * With yarn in front (insert the needle as if to purl), slip 1 stitch purl-wise to the other needle. Bring the yarn to the back and knit 1 stitch. Repeat these two stitches across the row and for every row (Slip 1, Knit 1) until you reach the desired length, and that is all there is to it!

You will be amazed at how lovely it looks. I did mine in the picture using a chunky yarn that goes from thick to thin and it is really striking. Don't forget to add fringe if you like.

For more information about the UITN studies, please call the office nearest to you.

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