



Congratulations! As of July 2010, the ValUE study reached its enrollment target of 630 women

Update of UITN Activities

By M. Albo, MD at UCSD and
S. Kraus, MD at UTHSC-San Antonio

The biggest news from the Network is the publication of the 12-month results from the **TOMUS study**. These results were published in the most prestigious medical journal, the *New England Journal of Medicine*. This means that the results are considered to be of the highest quality and consequently will be viewed by the medical community with the highest of respect.

So what did we find? At 12 months, success rates for the two mid-urethral sling approaches, transobturator (TMUS) and retropubic (RMUS), were similar. The rate of objective success, which is based on the results of your doctor's exam or on your pad test, was 81% in women who received the RMUS procedure and 78% in women who received the TMUS procedure. The rate of subjective success, based on your answers to the symptom questionnaires and the voiding diaries, was 62% in women who received the RMUS procedure and 56% in women who received the TMUS procedure.

As in the SISTEr study the success rates vary depending on what measures were used to define a successful outcome. Rates of satisfaction with the results of surgery at 12 months were similar between the two procedures as were the improvements in quality of life and reduction in bother from incontinence symptoms. We found small differences between the procedures with regard to the side effects some women experience. For instance, the retropubic sling caused more difficulties with voiding while the transobturator sling caused more temporary symptoms of numbness and/or weakness in the legs. As many of you know, we are also looking at these same results at 24 months. Everyone has completed their 24-month visit at this point, and the statisticians are busy analyzing the data. We hope to have the 24-month study results published this coming spring.

E-TOMUS follow up is still ongoing. We expect this to be a very important study since we know that we need to look at the long term results of surgery for stress incontinence. So please be sure to come back for your follow-up visit.

Congratulations are in order for everyone involved in the **ValUE study**. As of July 2010, the study reached its enrollment target of 630 women. This is the fourth major clinic trial in which the UITN has been able to achieve our enrollment targets. The credit all belongs to our incredible

patients who have shown how dedicated they are in the search for improving the treatment of urinary incontinence. This is no easy feat. Many well-designed studies have been stopped or were unable to answer the questions they were designed to answer because they could not enroll enough patients. However, before we can celebrate, there is one more major landmark. Enrollment is only half the challenge. The other half is collecting the required information at the follow up visits. Not only do we need to enroll enough patients, but we also have to have enough patients complete their follow-up visits.

For the ValUE study, that is the 12-month visit. So while we are once again both appreciative and proud of our patients for being willing to enroll in the UITN clinic trials, we want to emphasize how important it is for all of the ValUE patients to return for the 12-month follow up visit. We recently learned about a large study in Europe asking similar questions about the usefulness of urodynamic studies before incontinence surgery. They are still in the enrollment phase of their trial, but we look forward to having information from that study as well to answer this question.

We are considering several new studies to look at possible genetic causes of incontinence as well as to look for new markers which might help doctors identify incontinence and other bladder problems. Remember that TOMUS and ValUE patients might be eligible for participation in the **Specimen Repository**. So please consider it the next time you speak with the study coordinator or your physician.

REMINDERS:

- ❖ If you have not already done so, please remember to schedule your ValUE follow-up visit.
- ❖ For those who are enrolled in TOMUS, please consider continuing your study participation in E-TOMUS, as this extended study will provide valuable information about the long-term effects of surgery.
- ❖ For patients eligible for Repository Studies, please consider donating specimens.

The Costs of Urinary Incontinence

By Marina Mihova, MHA at
New England Research Institutes

Urinary incontinence is both a common and costly condition, yet little is known about costs that women pay out of pocket, the cost-effectiveness of treatment or women's willingness to pay for improvement of their incontinence condition. To learn more about the cost associated with urinary incontinence and the impact of treatment on cost, investigators included specific cost-related questions in one of the patient-completed surveys in the SISTEr, TOMUS and VaUE studies.

You probably remember answering a number of questions related to the cost of urinary incontinence and its impact on your daily life. How many and what kinds of supplies you used, possible loss of employment, time off work, or a number of questions about your ability to do things on a day-to-day basis... Well, all of these questions are part of standardized instruments often used in research studies to evaluate the cost of a condition and/or the cost-effectiveness of a certain procedure. These instruments also help researchers assess health-related quality of life.

Based on the patient survey in the SISTEr study, we have

provided evidence that urinary incontinence is associated with substantial routine care "costs". An average of \$750 per year was spent for incontinence management by the 655 women enrolled in that study. Costs increased with frequency of leakage and for women who had symptoms of both stress and urge incontinence. These patient surveys also showed that women with incontinence had a significant reduction in quality of life and that women were willing to pay nearly \$1400 per year for incontinence cure.

Cost and Urinary Incontinence is also one of the topics on the WebMD website. The following link <http://www.webmd.com/urinary-incontinence-oab/news/20100930/incontinence-surgery-helps-cut-patient-costs> discusses the costs associated with incontinence and quotes the data from our SISTEr study.

And, while it is not surprising that the article talks about how incontinence surgery helps reduce patient costs associated with urinary incontinence, it is only thanks to the dedication of our patients that investigators were able to provide statistics on the types of cost and its significant impact on quality of life.

All of you who contributed to this knowledge by completing your self-completed surveys made it possible for everyone to understand the significant impacts of urinary incontinence. Thank you for your important contribution!

Meet a UITN Team Member

Name: Halina Zyczynski

Title: Medical Director of the Women's Center for Bladder and Pelvic Health

Institution: Magee-Womens Hospital of the University of Pittsburgh Medical Center

How did you get involved in the UITN? I was invited by Mike Chancellor, MD, in 1999 to submit an application to the UITN as co-principal investigator. It was a great match of his researcher experience and our very busy clinical program dedicated to women's bladder health. It turned out to be a career altering opportunity.

What has been your favorite UITN experience so far? I have the greatest regard for the value of a patient interview and strive to teach low tech diagnostic skills to our residents and fellows. It tickled me to contribute to the VaUE study. I really look forward to learning the results.

What was your first job? In high school, I worked as a bank teller in mid-Manhattan's diamond district. It was wild. I would accept bank deposits for thousands of dollars that were carried in crumpled up brown paper bags.

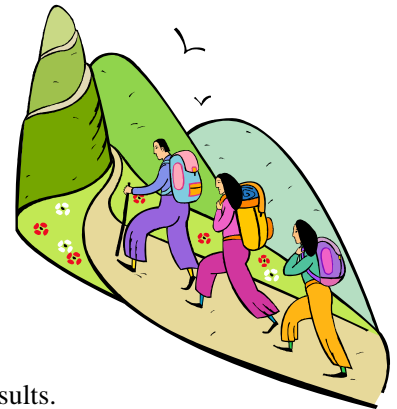
What is most rewarding about your job? I love teaching residents and fellows in the OR and office. It is very gratifying to graduate a resident or fellow as a competent doctor knowing they will impact many women's lives.

How do you relax after a long day at the hospital? I am the designated evening dog walker in our family. Joey our golden doodle and I walk each night. In usual multitasking mode, I often walk while talking to one of my two daughters away at college.

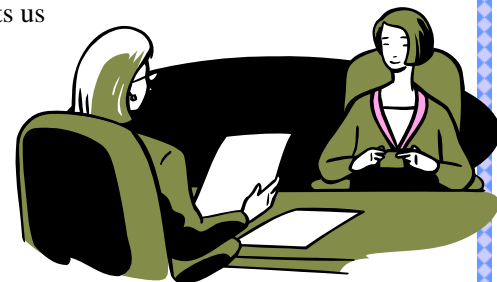
What are some things you think people don't know about you. I love beer, and pretzels. Ben Franklin was right when he said 'Beer is living proof that God loves us and wants us to be happy'.

What would you consider your perfect day? Family time together has become precious. Any day I can spend with my three children (two daughters are away at college) and my husband is a *perfect day*. Since I

get to set the itinerary, we will meet at the Bedford Springs Spa, soak in the mineral spring pool and get pedicures after a morning hike in the woods. We would end the day watching a movie, all five of us squeezed into one king size bed, comparing our choice of nail polish.



Halina Zyczynski, MD, in the middle with her two daughters





Cranberry Apple Relish



Submitted by Barb Leemon at Beaumont Hospital

This recipe is from the Zehnder's cookbook. They are famous for their meals in Frankenmouth, MI. This relish is great along with poultry and goes well as a topping for cottage cheese or even on bread! It is a must around holiday cooking time in Michigan. This recipe makes 5 cups of relish.

Ingredients:

- ◆ 1 lb. Northern Spy Apples or other moderately tart apples (about 6 ounces each)
- ◆ 1 lb. dark red cranberries
- ◆ 2 c. sugar
- ◆ 2 Whole naval oranges, peel on

Directions:

1. Wash and core apples, leaving skin intact.
2. Freeze cranberries solid.
3. In a food processor with the coarse blade, add half frozen cranberries, half apples and chop so that pieces are about 1/4" square.
4. Chop entire pound of apples/cranberries and place in a large mixing bowl and add sugar. Chop the peel-on whole naval oranges to the same consistency and mix into the apples/cranberries/sugar.
5. Refrigerate and let set 1 hour before serving.

Iced Pumpkin Cookies

Ingredients:

- ◆ 2 1/2 c. all purpose flour
 - ◆ 1 t. baking powder
 - ◆ 1 t. baking soda
 - ◆ 2 t. cinnamon
 - ◆ 1/2 t. nutmeg
 - ◆ 1/2 t. cloves
 - ◆ 1/2 t. salt
1. Mix the above dry ingredients and set aside.
 - ◆ 1/2 c. softened butter
 - ◆ 1 1/2 c. sugar
 - ◆ 1 c. canned pumpkin
 - ◆ 1 egg
 - ◆ 1 t. vanilla extract



Directions:

2. Cream butter & sugar. Mix in remaining 'wet' ingredients. Next add in the dry ingredients and mix.
3. Drop onto cookie sheet by tablespoonfuls; flatten slightly.
4. Bake for 15-20 minutes; cool, then glaze with Icing below:

Glaze Icing

- ◆ 2 c. confectioner's sugar
 - ◆ 2 T. milk
 - ◆ 1 T. melted butter
 - ◆ 1 t. vanilla extract
5. Combine above ingredients, adding more milk to achieve 'drizzle' consistency; drizzle over cool cookies.

The UITN Public website has been redesigned to include information about the UITN and participating in research. You can also find all Study Newsletters and information about UITN publications.

Website link: www.uitn.net

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

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