

**Congratulations! To date, there are 439 women enrolled in the ValUE Study!**

## What is OAB?

*By Gary Lemack, MD at UT Dallas*

For over 30 million American men and women, symptoms of urinary urgency, frequency and, often incontinence related to urinary urgency, (Overactive Bladder - OAB) create havoc in their daily lives. As health care providers in urology and urogynecology, the members of the Urinary Incontinence Treatment Network often provide care for patients with OAB, in addition to those with stress urinary incontinence (SUI) and other pelvic floor disorders such as pelvic prolapse and pelvic pain syndromes. Unlike SUI, when leakage occurs with certain activities such as coughing, working out, and moving suddenly, symptoms of OAB, which may include urge urinary incontinence (UI), are often unpredictable. As such, there is often considerable bothersomeness associated with this condition. Although the cause for OAB is not known, and likely several underlying causes are responsible, it is important to note that in the vast majority of cases, there is no concern for underlying malignancy. In general, only patients with other significant risk factors (such as extensive smoking history) or those with persistent blood in their urine should be evaluated for such an unusual cause of OAB symptoms.

For those patients in whom the symptoms of OAB persist and who desire treatment, several strategies for intervention exist. Dietary modification is a relatively easy way to try to improve symptoms related to OAB. Reducing the intake of food and beverages containing caffeine, as well as spicy and/or acidic foods may help many patients. Other lifestyle modifications include the implementation of timed voiding, to avoid periods of bladder overdistension, and smoking cessation, since smoking (nicotine and other toxins) has been linked to OAB in certain studies. Also, obesity has been associated with various types of urinary incontinence and regimented weight loss programs likely to improve incontinence in most patients. Additionally, pelvic floor muscle training programs have been shown to substantially improve various SUI, UI and mixed incontinence, a finding supported by data in the BE-DRI study recently published by the UITN. Lastly, a variety of medications are available for the treatment of OAB, which may enhance the efficacy of many of the conservative strategies mentioned.

Teaching patients how to help themselves is often the key to unlocking the lifestyle changes necessary to begin the process of improving symptoms in patients associated with overactive bladder syndrome.

### REMINDERS:

- \* If you have not already done so, please remember to schedule your ValUE 12 month 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.

## More Study Results

*By Judy Gruss, RN at U. Pittsburgh*

All of the UITN studies have a main objective. For example, in the SISTER study, the investigators wanted to find out whether the Burch or the sling resulted in better cure rates for women. Every study also has many secondary objectives. The investigators have many additional questions that they would like to answer. The answers to these additional questions are addressed in many of the articles that you read about in this newsletter.

Because of your willingness to complete telephone interviews, written questionnaires, and bladder diaries and visits, we have been able to answer these questions! **Our mothers, sisters, daughters and granddaughters thank you** for all of the work that you do to help us to get answers to these important questions.

Here are three more examples of answers to important questions that we asked from the SISTER study.

### Risk Factors Associated with Urge Incontinence after Continenence Surgery

(Journal of Urology: 182(6):2805-9)

In the SISTER study, women who had stress incontinence underwent surgical treatment for their stress incontinence. Most of the women in this study also had urge incontinence. So most of the women in this study had urine leakage with coughing and sneezing, and also had urine leakage with sudden urges or need to rush to the bathroom. This is quite common.

The investigators knew before starting this study that many women still complain about incontinence after surgery for stress incontinence. Some women who had urge incontinence before surgery still have it after surgery. Some women who did not have urge incontinence before

surgery develop it after surgery. You can imagine that women who continue to leak urine, for whatever reason, after surgery might be unhappy!

The investigators wondered if there were certain characteristics of the women that they could identify before surgery that would help them to predict which women might be at a higher risk to have urge incontinence after the stress incontinence surgery. They looked at the answers to interviews and questionnaires, medical and social history, visit information, and diary information to answer this question. Here is what they found.

1. Almost twice as many women who had a sling took medication for urge incontinence after surgery (compared to the women who had a Burch).

2. Women who said they had urge incontinence before surgery were more likely to have it after surgery. Women who took medication for urge incontinence before surgery were more likely to have urge incontinence after surgery. And women who showed what is called 'detrusor overactivity' or 'DO' during their bladder test were more likely to have urge incontinence after surgery.

These results will help the investigators make sure that they counsel their patients, particularly those who have urge incontinence, before surgery. Women who have urge incontinence before having a sling are more likely to still have these symptoms after their surgery and should be prepared for this.

### **Mixed Incontinence: Comparing Definitions in Women Having Stress Incontinence Surgery**

(Neurourology and Urodynamics: 2009;28(4):268-73)

The previous article involves women who have both stress and urge incontinence. Women who have both types of incontinence are considered to have 'mixed urinary incontinence' or 'MUI'. Most women who have incontinence have mixed incontinence, but doctors have traditionally treated the different types separately. There really is not much good, scientific information that guides doctors in how to best treat women with mixed incontinence.

The investigators were interested in trying to get a better understanding of the role of both the stress and the urge incontinence in the success or failure of the stress incontinence surgery. This information, like the information they gained in the previous article, will help them to better counsel women with MUI who are planning stress incontinence surgery.

The investigators looked again at the answers to interviews and questionnaires, medical and social history, visit information, and diary information to answer this question. Here is what they found.

Currently, doctors do not agree on the definition of MUI. This makes it difficult to both adequately counsel patients about what they can expect from a treatment (such as stress incontinence surgery), and for investigators to categorize and compare women who have MUI. For example, in the SISTEr study, very few women who complained of urge incontinence showed any signs of urge

incontinence during Urodynamics Bladder Testing. However, other investigators have reported much higher numbers of women who show urge incontinence during bladder testing.

In this study we found that there are wide variations in the characteristics and symptoms of women who have MUI. When doctors study women with MUI, they need to make sure that they have fully described the characteristics of the women involved in the study, as this varies greatly from study to study. This will make it easier for doctors to use the study results in their care of women with a similar problem.

### **Normal Preoperative Urodynamic Testing Does Not Predict Voiding Dysfunction After Burch Colposuspension Versus Pubovaginal Sling**

(Journal of Urology: 180; Nov. 2008:2076-80.)

The main results of the SISTEr study (reported in our newsletter in July, 2007) showed that the women who had the sling surgery had more problems after surgery with voiding. Women who had problems had to use a catheter to help them empty their bladder after surgery. Perhaps you were even one of these women! The investigators focused on the women who had to use a catheter for an extended period of time (6 weeks or more) and those who had to have a second operation to fix the problem.

Doctors would love to be better at knowing in advance which women might be at higher risk to need to use a catheter after surgery so that they could better prepare them. In this study, the investigators looked very closely at the Urodynamic Bladder testing that we did prior to surgery to see if it might help them to identify these at-risk women. Some doctors believe that certain parts of the test can help to identify those women who will have voiding problems after surgery, but there are no scientific studies that confirm these beliefs.

The investigators found that the Urodynamics Testing did not help them to identify which women will develop voiding problems after surgery. They caution that their definition of voiding problems was very strict, because women with voiding problems had to use a catheter for at least 6 weeks, or had such severe problems that they had to have more surgery to fix them. They would like to look at the testing information again, and look at other less severe definitions of voiding problems, to see if they find any difference in how helpful these results are.

## **When Sunshine is Not Enough The Vitamin D Deficiency Story**

*By Barb Leemon, RN at Beaumont Hospital*

Although scientists don't fully understand the way vitamin D works in the body, they know the body relies on a certain amount and many of us are just not getting enough!



Lately, we have been receiving information, even on national news programs, that vitamin D, in adequate levels, is very beneficial and is required for whole body wellness. So how do we know if our own levels are adequate? A blood test ordered by your health care professional will help determine your current level. Serum levels of 25-OH vitamin D between 25-80 ng/ml are desirable.

Multiple health problems have been associated with vitamin D deficiency. Among them are heart diseases including stroke and hypertension, chronic pain, fibromyalgia, arthritis, depression, inflammatory bowel disease, obesity, premenstrual syndrome, Crohn's Disease, cancer, MS, and other autoimmune diseases. The deficiency can lead to osteoporosis, muscle weakness and muscle wasting, birth defects and Rickets in children.

Some people are at greater risk than others for having low levels of vitamin D. Here is a list of some who require more vitamin D than others:

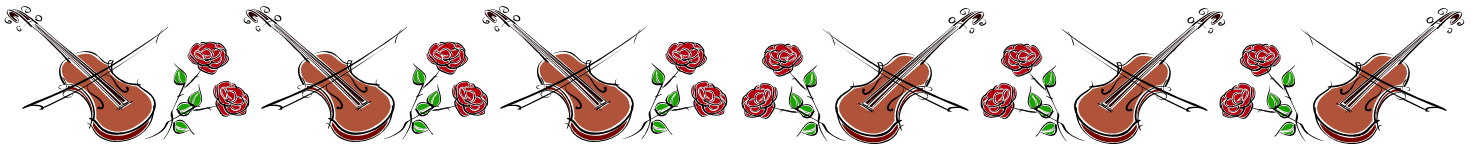
- Elderly
- Larger people
- Heavier people
- Northerners
- Dark skinned people
- Sunblock users
- People who avoid the sun
- Ill people

In order to get a proper amount of vitamin D, you would need to find a healthy balance of sunlight and dietary supplements. Unfortunately getting the desired amount of vitamin D through sun exposure and by increasing calcium intake may be challenging. Due to the risk of melanoma, it may be difficult to get the 20 minutes of unprotected sunlight a day. The amount of fortified milk and orange juice required might not be beneficial to weight control. Therefore, an additional 2000 international units of vitamin D3 (cholecalciferol, the preferred form of oral vitamin D) may be necessary to obtain adequate vitamin D levels. Under a physician's supervision, much higher amounts of supplemental vitamin D may be safely given.

Information about the importance of vitamin D is available now more than ever before. Remember to add vitamin D to your list of health issues to discuss with your healthcare practitioner at your next visit.

#### References

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**Name:** Toby C. Chai, MD

**Title:** UITN Principal Investigator, John D. Young, Jr. Professor of Surgery/Urology

**Institution:** University of Maryland School of Medicine

**What do you do in your spare time:** I enjoy increasing my repertoire of violin and fiddle tunes. Playing Celtic fiddle in an Irish wedding was great fun for me. My son and I like to play together; most recently the Bach double violin concerto in D minor. Next on the agenda is learning to play jazz violin. Trying to master golfing skills also takes up my time.

**What do you like to read:** I have to do a lot of reading, but most of it is work-related. I spend many hours reviewing research articles and grants for my peers. I do have the Bible downloaded onto my Blackberry, though, and I admit to reading Golf Digest upon occasion.

**What is your favorite food:** I wonder how I can get the job as a judge on Iron Chef America? Since I am Chinese, there is a special place in my heart for Chinese food. I also love Italian food and all different types of pasta dishes. Don't forget the chocolate.

**Tell us a little bit about your family:** I have been married 22 years to the same lovely wife who home schools our two children, ages 16 and 13. Our family has been studying philosophy together. Currently we are exploring the philosophy of aesthetics and applying what we learn in our daily lives.

**What is the most rewarding thing about your job:** I like to see the fruits of my labor. When a patient does well after surgery, or when an experiment yields exciting results, I'm grateful that I've been allowed to be a part of something good like the UITN. I've been also told that I'm never bored.



# Vietnamese Fresh Spring Rolls

Also known as Goi Cuon in Vietnamese

Submitted by Rosanna Dinh, RN at U. Maryland

## Ingredients:

- ◆ 2 ounces rice vermicelli
- ◆ 8 rice wrappers (8.5 inch diameter)
- ◆ 8 large cooked shrimp - peeled, deveined and cut in half. Cooked chicken/pork can also be used in place of shrimp
- ◆ 1 1/3 tablespoons chopped fresh Thai basil
- ◆ 3 tablespoons chopped fresh mint leaves
- ◆ 3 tablespoons chopped fresh cilantro
- ◆ 2 leaves lettuce, chopped
- ◆ 4 teaspoons fish sauce
- ◆ 1/4 cup water
- ◆ 2 tablespoons fresh lime juice
- ◆ 1 clove garlic, minced
- ◆ 2 tablespoons white sugar
- ◆ 1/2 teaspoon garlic chili sauce
- ◆ 3 tablespoons hoisin sauce
- ◆ 1 teaspoon finely chopped peanuts

## Directions

1. Bring a medium saucepan of water to boil. Boil rice vermicelli 3 to 5 minutes, or until al dente, drain.
2. Fill a large bowl with warm water. Dip one wrapper into the hot water for 1 second to soften. Lay wrapper flat. In a row across the center, place 2 shrimp halves, a handful of vermicelli, basil, mint, cilantro and lettuce, leaving about 2 inches uncovered on each side. Fold uncovered sides inward, then tightly roll the wrapper, beginning at the end with the lettuce. Repeat with remaining ingredients.
3. In a small bowl, mix the fish sauce, water, lime juice, garlic, sugar and chili sauce.
4. In another small bowl, mix the hoisin sauce and peanuts.
5. Serve rolled spring rolls with the fish sauce and hoisin sauce mixtures.



## Clinical Trials FYI: Randomization in Research Studies

By Kimberly Woodson, MPH, RN at Loyola University

When a study participant is “randomized”, she is assigned (like flipping a coin) to receive one of several interventions i.e. a treatment or procedure. The process of randomization is used to examine the effect of treatments or procedures on particular outcomes. At the end of a randomized controlled study, investigators hope to answer the question: Which treatment works best?

The act of randomizing a study participant to receive or not to receive the intervention ensures that all other possible influences are equal between the groups. It is therefore accepted that any significant differences between groups can be credited to the intervention and not to some other unidentified factor.

The 1948 Medical Research Council Trial was one of the first published studies to include all the elements of a modern randomized clinical trial. Led by Sir Austin Bradford Hill, the study’s purpose was to determine the effect of the antibiotic streptomycin on tuberculosis (a disease that affects the lungs). To settle the question, Hill arranged to have the antibiotic given to patients in some tuberculosis hospital units but not in others. His study found that the streptomycin treated group had significantly better results than the group that did not receive the antibiotic.

After Hill’s pioneering study, the number of randomized controlled research studies increased tremendously. Randomized controlled trials are recognized as one of the most important tools of modern clinical research and the cornerstone of evidence based medicine.

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

### Beaumont Hospital

Royal Oak, MI  
Barb Leemon, RN 248-551-3551

### Oakwood Hospital

Dearborn, MI  
Chaandini Jayachandran, MSc 313-436-2214

### Loyola University Medical Center

Maywood, IL  
Kathy Jesse, RN 708-216-8944  
Kimberly Woodson, MPH, RN 708-216-8495

### University of Alabama at Birmingham

Birmingham, AL  
Alice Howell, RN 205-975-8592

### UCSD Thornton Hospital

San Diego, CA  
JoAnn Columbo, BS, CCRC 858-657-6827

### Kaiser Permanente

San Diego, CA  
Gisselle Zazueta-Damian, RA 619-528-7914

### University of Maryland

Baltimore, MD  
Rosanna Dinh, RN, 410-328-7736

### University of Pittsburgh Medical Center

Pittsburgh, PA  
Judy Gruss, RN 412-641-5388  
Karen Mislavich, RN 412-641-6679

### University of Texas-Southwestern

Dallas, TX  
Tamara Dickinson, RN 214-645-8791

### University of Texas-San Antonio

San Antonio, TX  
Caren Prather, RN 210-567-0548  
Elvira Eardley, LVN, 210-567-0550

### University of Utah Medical Center

Salt Lake City, UT  
Laura Burr, RN 801-581-6874

### LDS Hospital

Salt Lake City, UT  
Laura Burr, RN 801-581-6874