



## **BE-DRI Study Results**

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

The results from the BE-DRI study have just been published in the prestigious medical journal *Annals of Internal Medicine* in August 2008. We thought this would be a good time to give a review of the results.

The BE-DRI study focused on women with urge urinary incontinence. Women who suffer with this form of incontinence usually experience urinary accidents in association with a sudden and strong urge to urinate that they are unable to suppress before reaching the bathroom. Urge incontinence usually occurs as part of a condition called Overactive Bladder (OAB). Treatment options for OAB include medications, behavioral therapy and sometimes a combination of both. The medications commonly used to treat the condition belong to a class of medications that reduce the ability of the bladder muscle to contract. Behavioral therapy is a treatment program that teaches women how to make changes in their drinking habits and lifestyles that may protect them from the urges, and how to strengthen their pelvic muscles in order to resist the urges if they do occur.

Many questions remain unanswered about these treatments. For example, once someone starts OAB medication how long will they need to take it? Does a combination of behavioral therapy and medication lead to higher success rates than just one therapy alone? If a woman learns the techniques of behavior modification, might that help her be able to stop her OAB medication without having a relapse of her incontinence? These were some of the questions BE-DRI tried to answer.

We enrolled 307 women who suffered from urge incontinence in the BE-DRI study. The women were randomly assigned to one of two groups; one group received only medication while the other group received medication and behavioral therapy. All women received 10 weeks of extended release tolterodine (a commonly used medication for OAB). Half the women were selected by chance to receive additional behavioral therapy consisting of visits with a pelvic floor specialist who provided instructions on pelvic floor exercises and techniques to help suppress urge incontinence. After 10 weeks, the medication was stopped in all patients. The patients in the group that had received behavioral therapy were free to continue practicing what they had learned.

We measured the effectiveness of the therapies by looking at the number of incontinence episodes at 10 weeks right before they stopped the medicine and then again 8 months later. We compared the two groups to see how many women were able to maintain the improvement they had experienced before they stopped the medicine.

Here's what we found. At the 10 week mark, incontinence had improved in both groups. While the group who received both drug and behavioral therapy reported less incontinence, the difference was not considered significant.

However, the women who received both drug and behavioral therapies reported they felt more improved and satisfied than those who received drug alone.

At the 8 month mark, there was a 41% decrease in the number of incontinence episodes in both groups but no difference in the reduction of incontinence between the group of women who received drug only vs. the group of women who received both drug and behavioral therapy. Again the women who received both drug and behavioral therapies said they felt more improved and more satisfied than those who received drug alone.

When we report the results, we have to address the original question we had asked. That is, does the addition of behavioral therapy to medication in the treatment of urge incontinence improve the chances that women can maintain their improvement after stopping the medication? The answer to that question is no, it does not. However, the BE-DRI data did suggest a number of possible benefits for women in the behavioral therapy group. They were more satisfied and felt that they were more improved than those women that received the medical therapy alone.

We will be analyzing more of the BE-DRI study's data over the next few months and will be looking at things that might help us predict who will do well and who will not do well with these treatments. We will also look at some of the other urinary symptoms that women experience with OAB.

We hope that BE-DRI will continue to add to what we know about urinary incontinence and its treatment. As always, we could not have accomplished BE-DRI without your help. From those of us in the UITN, we wish to thank you for your participation and support.

## **Clinical Trials FYI**

*Submitted by Allie Howell, RN at UAB*

A well-known chapter in the history of research with human subjects opened on December 9, 1946, when an American military tribunal opened criminal proceedings against 23 leading German physicians and administrators for their willing participation in war crimes and crimes against humanity. Among the charges were that German physicians conducted medical experiments on thousands of concentration camp prisoners without their consent. Most of the subjects of these experiments died or were permanently crippled as a result.

As a direct result of the trial, the Nuremberg Code was established in 1948, stating that "The voluntary consent of the human subject is absolutely essential," making it clear that subjects should give consent and that the benefits of research must outweigh the risks.

Although it did not carry the force of law, the Nuremberg Code was the first international document which advocated voluntary participation and informed consent.

# More Study Results

By Judy Gruss, RN at U. Pittsburgh

All three of the articles discussed below were published this year and talk about a common subject of research studies, Quality of Life. There is more than one way to decide whether a surgery is 'better' or 'successful'. From your doctor's and the perspective of the investigators in the SISTER study, your surgery was successful if you no longer leaked urine either in the office or at home when we asked you about it at your visits or during testing, a very strict way to measure success. However, you may think that your surgery was successful, even if you occasionally have an accident.

Your doctor's perspective describes 'objective' data while your feelings about the success of the surgery are 'subjective'. This subjective information tells us about your 'quality of life'. Quality of life includes how you would describe your physical, mental and social health, and it is about feeling good and being satisfied with things in general. You told us about your quality of life when you answered questions in the written questionnaire that we send to you each year.

Here are findings from three papers published in clinical journals about what we learned from SISTER participants. In all three we see the importance of considering the patient's perspective, the 'subjective' data, in the overall surgical success.

## The Expectations of Patients who Undergo Surgery for Stress Incontinence

**American Journal of Obstetrics and Gynecology  
2008;198:308.e1-308.e6, March 2008**

If we want to look at a woman's quality of life and how it is affected by surgery for stress incontinence, we know that we need to also look at what women expect from the surgery. Patients may feel very different after about their surgery (i.e. be satisfied or not) depending upon what they expected from surgery. We looked at the questionnaires that all women completed before they had their surgery to see what they expected. All of the women in this study completed these questionnaires after talking with their doctor about and after watching the video about the surgery.

We found out that women in general have very high expectations of incontinence surgery. Nearly all of the women expected that the surgery would improve or cure their urine leakage. That is good, as we think women should have high expectations that their symptoms (like urine leakage) related to stress urinary incontinence would go away after surgery, otherwise they may not want to have the surgery. However, many of the women in the study also had symptoms of urge urinary incontinence (like urgency and urinary frequency). Most of the women who had these symptoms before their surgery expected the surgery would improve the urge symptoms. But we would not expect the surgery to improve the urgency and urinary frequency that was present before surgery but not related to the stress incontinence.

This is important because it made us aware that many women did not fully understand that incontinence surgery would most likely improve urine leakage related to stress urinary incontinence, but that it probably would not improve the

urgency and urinary frequency not related to the stress incontinence. The investigators agree that we need to assess the ways that we counsel our patients about surgery to make sure that patients understand these very important details.

## High Costs of Urinary Incontinence among Women Electing Surgery to Treat Stress Incontinence (Obstetrics and Gynecology 2008;111:899-907; April 2008)

In this paper, the investigators wanted to look at both economic and non-economic costs of urinary incontinence. We asked women, before their surgery, how much money they spent on incontinence supplies, and factored in other costs like laundry and how much they would be willing to pay for treatments associated with certain percentages of improvement (25%, 50% and 100%) in incontinence symptoms. Finally, we asked women about their health-related quality of life.

The investigators found that incontinence is a great burden to women, in terms of money and in personal costs. Half of the women in the study spent almost \$500 per year for items related to incontinence. Most of the women (94%) reported that they had some costs for incontinence-related materials. In fact, this study showed higher costs than those observed in other studies of women with incontinence. Women were also willing to spend more money (up to \$118 per month on average) to have 100% improvement (or cure). Finally, the health-related quality of life before surgery was poor, and was similar to that reported by women in other studies with chronic medical conditions like stroke, cancer, diabetes and Alzheimer's.

Investigators think this information confirms the substantial costs to women who have urinary incontinence. Although not life-threatening, incontinence is a devastating condition. Developing and testing effective treatments is the very important goal of the investigators in the UITN!

## Quality of Life After Surgery for Stress Incontinence (International Urogynecology Journal 2008 doi.10.1007/s00192-008-0700-1)

Investigators were interested to find out how surgeries used in SISTER affected the quality of life of the women who participated. They compared the questionnaire information that was collected from the women before surgery with information collected after surgery to treat urinary incontinence. The investigators wanted to see if there was a general change in the quality of life (thinking that there should be an improvement). They also wanted to see whether there was greater improvement in the women who had the Burch procedure than for those who had the sling procedure.

Overall, there was a significant improvement in the women's quality of life after surgery for all women. The largest improvement occurred relatively quickly after the surgery (within 6 months) and then remained stable for about the first two years (the length of this study). When the investigators compared this improvement in quality of life between the two types of surgery, they found that the women that had the Burch procedure had a bigger improvement in quality of life than those women who had the sling. Why is this interesting?

If you remember the main results of the SISTER study, which we talked about several newsletters ago (see July 2007, Volume 5, Issue 2), the sling procedure resolved more of the symptoms of urinary incontinence. So is the sling the more



successful procedure? Remember that women who received the sling also had more problems with the bladder after surgery than the Burch procedure. And now, this study shows that the women who had the Burch procedure reported more improvement in their quality of life after their surgery. So which is the better procedure? It seems that it depends on who is asked and what is asked.

The investigators learned from these studies that it is always important to use different and complementary ways (quality of life questionnaires AND objective office testing) to assess the success of a treatment.

## Meet a UITN Team Member

**Name:** Larry T. Sirls, MD

**Title:** UITN Principal Investigator, Director of Urodynamics

**Institution:** William Beaumont Hospital

**What can you share about your pre-doctor days?**

I worked in my fathers "blue collar sit-com like" pizzeria until medical school. I was an All-American Wrestler.

**What do you enjoy now?**

I am an experienced mountain and technical rock climber whose best climbing partner, my wife, stopped difficult climbs after the birth of our first son. We have and do climb all over North America including Yosemite, Joshua Tree, the Tetons, Squamish and our recent favorite, Red Rocks outside of Las Vegas. I discovered yoga at 40, and have practiced almost 6 times a week for many years. Yoga has been an extremely powerful "biofeedback" tool to keep my weight down, which at my age is only possible by limiting how much I eat!

**Tell us about your family life:**

My life is dedicated to my family and homework. Coming from humble roots, my wife and I value academics and I do a lot of homework! My boys are entering 3rd and 6th grade, and the math is already getting difficult!

**Do you watch TV or read for pleasure?**

Unfortunately I do not watch much TV, but am a voracious reader of history, military tactics, physics and the math of the universe, etc. I enjoy understanding the world as it is. I am a technophile

who is totally Mac now, and can show in a heartbeat, a recent video of my boys and me doing some crazy adventure thing on my iPhone.

**What would**

**you consider your perfect day?**

My perfect day might be early morning yoga with my family, followed by a short easy hike to some great mountainous view. Then an easy short climb, a light dinner, a funny movie for the boys and then bed.



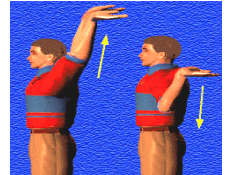
# Stretch for Health

*Submitted by Jennifer Tabaldo, MT, NCTMB from UCSD*

Many of us have a workday which includes 8 hours sitting at a workstation. These simple, entire body stretches done throughout the workday increases circulation, flexibility, improves posture, reduces tension and the chance of injury. Hold each stretch for five to ten seconds and repeat three to five times. You will feel a **slight** 'stretch or pull' on the muscle. If this becomes mildly uncomfortable (especially if you feel radiating pain), ease off or stop the stretch.

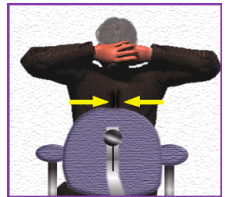
**RAISE THE ROOF:** Reduce fatigue and promote circulation.

- While standing with arms at your side inhale and reach up with both arms.
- Palms of hands parallel to the ceiling.
- Hold position for 5 seconds, return to starting position and repeat 3 times.



**THE BACK:** Reduce fatigue and improve back comfort.

- Sit upright in chair, clasp hands behind head (elbows even with ears).
- Press elbows back as far as possible, while squeezing shoulder blades together.
- Hold for 10 seconds. Relax. Repeat 3 times.



**NECK:** To improve neck, shoulder and upper back comfort.

- Sit upright with shoulders relaxed, arms to side or on lap.
- Slowly lower ear to shoulder, hold for 10 seconds & repeat to other side.

**Head tilt with arms**

- Sit upright with shoulders relaxed, arm raised and reach towards your back, dropping hand between shoulder blades.
- Slowly lower ear to shoulder to opposite side of raised arm.
- Hold for 10 seconds. Repeat sequence on each side 3 to 5 times.



**ARMS:** To improve comfort and circulation.

- Sit or stand, keep shoulders relaxed. Extend one arm in front of you, with palm facing **DOWNWARD**.
- Keeping elbow locked, slowly bend at wrist so fingers point toward ceiling, use other hand to grab fingers and gently pull fingers toward you.
- With same arm extended, and palm facing **UPWARD**, gently pull fingers down toward floor with other hand.
- Hold for 5 seconds. Relax and repeat on other arm.



**REMEMBER:** see your healthcare provider before exercising.

Source: National Institutes of Health ([www.nih.gov](http://www.nih.gov))

# Cream of Brie Soup

Serves 4 (appetizer servings)

*Submitted by Tamara Dickinson, RN at UT Dallas*

## **Ingredients:**

- 3 shallots, finely minced
- 4 Tblsp butter
- 1 large wedge Brie, thick areas of rind removed
- 1 quart chicken broth
- 1 cup heavy cream
- 4 Tbsp chopped chives (not scallions)
- Black pepper

## **Preparation:**

Melt butter in small soup pot or Dutch oven. Add shallots and sauté until very soft but do not let brown. Add brie and chicken broth and lightly simmer until cheese is nearly melted. Add heavy cream and then puree mixture. To puree either allow to cool slightly and place in blender or puree in pot with hand held blender (or what Emeril calls the “boat motor”). Reheat pureed mixture adding more heavy cream if needed.

To serve place in shallow soup bowls, garnish with chives and black pepper (freshly ground is best)



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

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