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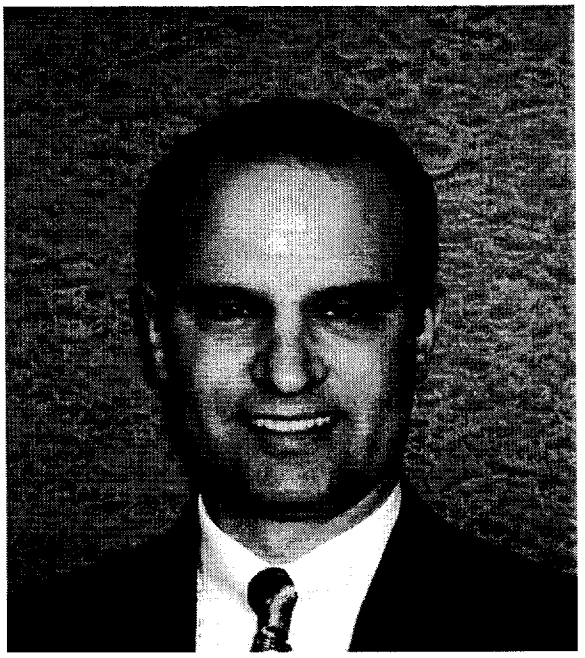
An Interview with Jeffrey R. Dell, M.D.



Jeffrey R. Dell, M.D.
Generations ObGyn
Knoxville, TN

JEFFREY R. DELL, M.D., is the director of the Institute for Female Pelvic Medicine and the director of Urogynecology and Reconstructive Pelvic Surgery at Generations ObGyn, in Knoxville, TN. He received a Bachelor of Science degree in chemistry from Southwest Missouri State University, Springfield, MO, and his M.D. degree from the University of Minnesota School of Medicine, Minneapolis. MN. Dr. Dell completed an internship and residency in obstetrics and gynecology at the University of Tennessee, Memphis, TN. He has extensive postgraduate subspecialty training in the areas of urogynecology and reconstructive pelvic surgery and directs a surgical preceptorship program through the Institute for Female Pelvic Medicine.

What is the prevalence of interstitial cystitis? Has that been increasing or decreasing? Why?

Trying to get an actual prevalence number for interstitial cystitis is extremely challenging. Many studies over the years have attempted to quantify the prevalence. One of the difficulties is that there is not a universally agreed upon, specific criteria set by which the condition is diagnosed. It remains a clinical diagnosis.

The important point here is that the understanding of what interstitial cystitis represents has been changing tremendously, and, as the understanding of the condition has changed, we see that prevalence estimates continue to increase. This likely reflects the paradigm shift in our understanding of the condition rather than an actual prevalence change. We just were not very good at recognizing it and diagnosing it in the past. Patients with classic, severe cases were the only patients previously considered to have interstitial cystitis. These patients had such severe pelvic pain and urinary symptoms that it was dramatically and negatively impacting their quality of life. What was completely missed was the far greater category of patients who had only mild symptoms—mild overactive bladder symptoms, symptoms that overlap with endometriosis and recurrent urinary tract infections. We now understand that many of those patients actually have early, mild interstitial cystitis. That is reflected in the very different prevalence numbers today.

Somewhere between 9 and 15 million women in the U.S. alone report having chronic pelvic pain. This is a very significant issue. About 40% of all laparoscopies are done to evaluate and

work-up chronic pelvic pain, 12%–15% of hysterectomies are done to work-up chronic pelvic pain, and 1 out of every 6 patients referred to a GYN center is coming for evaluation of chronic pelvic pain. Gynecologists have historically been very good at thinking of and evaluating patients for endometriosis. However, the bladder component of that pelvic pain was often missed until recent years. There are data to suggest that up to 70% or more of female patients who have chronic pelvic pain may have a bladder component to that pain.

Why is it important for gynecologists to screen for this disorder?

In gynecology, over the past couple of years, we have been using the term "screening" in a less traditional sense—that is, screening the pelvic pain population for pain of bladder origin, as opposed to screening asymptomatic women. The reason it is so important for gynecologists to be thinking about bladder origin pain and taking the next step of screening those patients is that these doctors regularly diagnose and treat patients with chronic pelvic pain that may, in fact, have a bladder component. When that component is overlooked, patients may return to the gynecologist over and over again despite receiving various treatments for their pelvic pain. We see patients who have had two, three, and even four laparoscopic procedures, perhaps progressing to the point of total hysterectomy, and, yet, they do not have improvement in their pain, and sometimes it even gets worse. On average, women will tend to have symptoms that progress for 5–7 years. They may see 6–8 different providers as they try to get answers and treatment for their pain, and, most of the time, you will find that they have not been specifically evaluated for bladder origin pain.

What is the appropriate screening approach?

It is important to understand that bladder origin pain surrounds us in every gynecologic setting. If physicians are not thinking of bladder origin pain, then they will have little chance of picking it up. We have two very good, validated screening surveys to use—PUF (Pelvic Pain Urgency Frequency Questionnaire) and ICSI (Interstitial Cystitis Symptom Index)—that take only a few minutes to complete and can point to those patients that need more specific evaluation for interstitial cystitis. The next step is physical examination, and the important point here is to check for anterior vaginal wall or bladder-based tenderness.

What are the main treatment options and what are their advantages/disadvantages for individual patients?

We know that diet plays a very significant role in interstitial cystitis; in particular, spicy and acidic foods and foods that are high in potassium are a source of symptom flare. We provide education and information on how to modify the diet to minimize symptoms. We also know that stress plays a tremendous role in interstitial cystitis, and stress management should be a component of treatment. Many patients with interstitial cystitis will develop significant pelvic floor dysfunction; we need to be aware of this and employ the expertise of specialized physical therapists that can help the patient.

More specifically, there are only two FDA [Food and Drug Administration]–approved treatments for interstitial cystitis. The only oral medication is pentosan polysulfate sodium (Elmiron,® Ortho-McNeil Pharmaceutical, Raritan, NJ). The other treatment is DMSO, dimethyl sulfoxide, for intravesicle installation. Elmiron, as an oral approved agent, provides a foundation—an important starting point for treatment. Over time, it helps a patient rebuild or resurface a defective or deficient protective lining in the bladder. Intravesicle installations have also become an important part of the treatment plan, but, these days, we have moved past DMSO in many cases to heparin cocktails, which typically contain heparin, lidocaine, and a small amount of sodium bi-

carbonate. We instill this directly into the bladder, and it provides almost immediate relief to patients who are really in significant pain.

Elmiron does not have a single drug–drug interaction. Even patients who require anticoagulation are potential candidates for this drug. There are really no contraindications to either Elmiron or intravesicle treatments unless a patient has previously had a reaction to one of the agents.

How is bulking therapy changing the way urinary stress incontinence is managed? Is it an appropriate treatment option for all patients?

One of the newest aspects of bulking therapy is the fact that the FDA, earlier this year, approved the newest product, called Tegress™ (C.R. Bard, Inc., Covington, GA), which is composed of ethylene vinyl alcohol, a copolymer that has some unique properties. This material is a very thin liquid at room temperature in a DMSO carrier. When exposed to an aqueous environment, such as human tissue, it precipitates into a soft, spongy bulk. It is the only approved bulking agent that involves precipitation technology. Only two other products are approved in the U.S. for bulking therapy—Contigen® (C.R. Bard, Inc.) and Durasphere® (Boston Scientific, Natick, MA). Contigen is a purified bovine collagen material, and we have been using that since 1993 in the U.S. The downside with Contigen is that, since it is a natural product, it is subject to enzymatic breakdown in the human body and it is not a permanent material. Even patients who have good success with this product may, over a period of months, begin to see a recurrence of their incontinence. Durasphere is a synthetic, permanent product but, because of its composition, it needs to be injected through a larger-gauge needle. It is not, in general, amenable to an office-based procedure and needs to be administered in an operating room setting.

Tegress is an important niche product because it is a permanent material and it is not subject to breakdown or migration in the body, yet can be injected through a tiny, 25-gauge needle, and this is done readily in the office setting. This material is changing the management of stress incontinence because we now have an office-based procedure in which the patient can truly walk in and walk out of the office within a 20-minute time span, with potentially no downtime and no recovery period.

Not everyone is an ideal candidate for bulking therapy, and the definition of an ideal candidate continues to evolve as we move forward. For instance, until recently, we would not have considered a 35- to 45-year old "soccer mom" as a candidate for bulking therapy because we didn't have products that lasted very long. The likelihood of recurrence of incontinence within about 6 months was too high. So we reserved bulking therapy for more complicated cases, such as patients for whom multiple previous surgeries failed or patients who might not be good candidates for surgery. Now many of these young, active women are good candidates for bulking therapy.

How has the sling procedure changed and what are the benefits of the new procedures?

The last 100 years in slings have seen a whirlwind of change. The first recorded report on slings was published in 1907 by Giordano,[1] who described the first sling technique using a part of the gracilis muscle. Through the decades, there have been multiple variations on this procedure, and slings continued to be used throughout the 1950s and 1960s, but not on a wide scale basis because there was a consensus that they were relatively difficult procedures to perform and were associated with fairly significant morbidity. They did not represent the gold standard in incontinence therapy at that time.

Then, in the late 1970s and early 1980s, McGuire[2] reintroduced the sling procedure, initially to the urology community, and subsequently to the urogynecology community. His sling involved a combined abdominal/vaginal approach using a harvested portion of the rectus fascia. In the early 1980s, that technique became a recognized "gold standard" for incontinence surgery in

women. What has changed tremendously over the past 5–7 years is the new generation of slings. The classic sling that McGuire popularized is called a pubo-vaginal sling; it was placed at the level of the bladder neck, with a very good success rate, but with quite a bit of risk and a substantial recovery.

In Europe, Ulmsten[3] began working on a totally different concept, using slings made of polypropylene mesh of various types that were placed under the mid-urethra. This represented a significant change. The slings were placed using minimally invasive surgical techniques, so the patients had far less morbidity and a more rapid recovery. These tension-free, mid-urethral slings came to the U.S. in the mid-1990s, after being used for several years in Europe. Over the past 7 years, this approach to sling therapy has changed the previous 70 years of incontinence surgery in this country in a very dramatic fashion.

The original tension-free, mid-urethral sling was introduced with a vaginal, or bottom-up approach. There is now excellent data out over the past 7 years that show tremendous efficacy with very minimal morbidity compared to other types of incontinence procedures. Many people are now saying that this represents the gold standard of incontinence therapy in this country. A variety of companies have their own types of sling on the market. After the original vaginal approach was widely adopted, two other approaches were developed: a top-down approach; and, the most recent variation, the transobdurator approach, with the sling placed from an outside-to-inside direction or from an inside-to-outside direction. There are more than 15 variations of tension-free, polypropylene, mid-urethral sling products on the market.

How do you decide which is the right sling for each patient? The bottom line is that none of these variations has been proven superior over its competitors in long-term, well-designed scientific studies. At the current time, the choice of a sling product or the direction of placement boils down to surgeon preference and training. There are many unanswered questions about specific types of patients for whom one type of sling might be better than others but this derives from clinical experience. We have a lot of work to do to answer these questions on a scientific basis.

What new surgical techniques are available for treating pelvic-organ prolapse?

Pelvic-organ prolapse includes uterine prolapse and, in patients who have had a previous hysterectomy, vaginal-vault prolapse with cytoceles and rectoceles. What is new in this arena is a totally different concept for repairing these defects that just came to the U.S in the last year and a half or so. Much of the initial work was done in France. We describe this new category of treatment as the total vaginal mesh, or TVM concept.

These approaches involve the use of varying sizes and shapes of synthetic polypropylene meshes to resuspend and support pelvic-floor defects that manifest as cystoceles, rectoceles, and vault prolapses. These procedures are done completely through a vaginal approach, using multiple passes through the obturator space in combination with some passage through the ischiorectal fossa, using six to eight different arms that are passed through these spaces to position the mesh and reconstruct the normal anatomy. We are very early on in the American experience but the French have been doing this for several years. It remains to be seen what the long-term success rates will be. It will be very important to conduct randomized, prospective trials that follow patients for at least 5 years. We feel, however, from the initial clinical experience, that the results look quite good. For the right kind of patients and using proper technique, we have seen some encouraging results. It is certainly a much less invasive approach than more traditional methods.

One of the challenges this approach presents is the need to prepare for 5%–7% erosion rates in which the material erodes through the vaginal tissue or an adjacent hollow viscus. Surgeons utilizing these techniques require adequate training in terms of proper placement techniques and patients need to be aware that there are risks.

What are the advantages of using biologic or synthetic graft materials? Is one or the other more appropriate in certain settings?

Graft materials have also undergone extensive change in the area of pelvic reconstructive surgery over the past years. We have a range of synthetic materials, most of which are variations of polypropylene mesh, and we have the so-called biologics. The biologics can be divided into three categories: human-based tissue, either donated by the patient herself (autologous material), or cadaver-donated (allograft material), or animal-donated (xenograft) materials. There are pros and cons for each category. On the positive side for the synthetics is the fact that no material is stronger. They are stronger than normal human tissue and are not subject to breakdown in the body, so permanence is not a question. The downside is that because these are not biological materials, there is a higher risk of erosion and related complications.

Biologics are very soft, supple and natural in their feel, but their permanence is not yet clear. The question remains whether they will still be there 10 years after placement or whether they are subject to breakdown and disappearance?

The three big players in TVM in the U.S. today are the Apogee™/Perigee™ system by American Medical Systems (Minnetonka, MN), the Prolift™ system by Gynecare (Johnson & Johnson, New Brunswick, NJ), and the Avaulta™ system by Bard. There are many variations: For example, some materials may have various types of coatings. The Avaulta System, for instance, utilizes a collagen coating over the synthetic mesh, which may play a significant role in reducing erosion risk. On the biologics side, since permanence is such an important factor, the porcine dermal derivates offered by Bard, primarily Pelvicol® and PelviSoft,® are crosslinked through a process that resists breakdown by enzymes in the body. There is some good animal model data and preliminary human data to suggest that crosslinking makes the material permanent.

When should a gynecologist consider doing in-office cystoscopy or hysteroscopy?

The physician's office is the ideal setting for cystoscopy and hysteroscopy in a majority of cases. The type of equipment available these days—we utilize Olympus (Olympus, America, Orangeberg, NY) or flexible fiberoptic scopes in our office—make these procedures tolerable for patients, causing a minimal amount of discomfort. The combination of the convenience—with less time lost from work and family—and the cost savings compared to the operating room make office-based procedures preferable. General gynecologists receive a fair bit of exposure to the use of diagnostic hysteroscopy in the office setting these days. Cystoscopy, however, continues to be an area in which gynecologists do not receive adequate training. In many cases the difficulty in training gynecologists has been fueled by turf battles involving urology and urogynecology.

I think we will see a progressive trend toward more and more of these procedures in an office-based setting for diagnostic purposes. The health care system is already heavily burdened, and the cost-savings on the health care system side and the recovery and morbidity issues on the patient side place the advantage in favor of an office-based setting. The advantages from the physician's perspective include the ability to provide a very important service to patients and to do so in a time- and cost-efficient manner.

As a next step, I think we will see a push toward the treatment side of the equation. We have already seen this with bulking therapy, as we now routinely do these procedures in the office setting, whereas several years ago most of these were done in the operating room. Female sterilization and even next-generation slings being developed for urinary incontinence will continue to focus on more minimally invasive approaches with a possibility of at some point moving these into an office-based setting as well.

What types of equipment are needed?

We use a variety of scopes. From a purely diagnostic standpoint, the Olympus flexible fiberoptic scopes offer tremendous image quality for the doctor and unbelievable tolerability for patients. When it comes to procedures, such as bulking therapy, this requires a different scope, and we use a rigid cystoscopy set-up designed and built for bulking therapy. For physicians who have not yet moved to office-based treatment procedures, the range of flexible scopes available is the optimal way to go for the diagnostic side of the equation.

How do you choose the distension medium? Do you use an anesthetic?

With regard to bulking therapy you can use either normal saline or sterile water as the distention medium. To do these procedures in the office, as long as a patient has someone accompany her and she does not have to drive herself home after the procedure, we usually have the patient take a 5-mg dose of diazepam to provide a little bit of extra pelvic-floor relaxation. The drug also helps reduce anxiety. When the patient arrives in the office we simply use topical Lidocaine (Amerian Regent, Shirley, NY) jelly that we place in the bladder neck with a little catheter for about 10 minutes. That is the only type of anesthesia we use. Some physicians will also inject some Lidocaine into the periurethral tissue but we do not do that routinely and we find that patients do extremely well.

Are there special documentation needs for these procedures? What type of patient records do you use in your office?

As we see the push to do more of these procedures outside of a formal operating room setting and in more of an ambulatory setting, documentation becomes an important issue. As a general rule, we try to maintain the same level of documentation for any of the procedures we do in the office as we would if we did them in the operating room. We have patients sign a full consent form reflecting all of the basic risks involved, which we keep in the charts as a part of the permanent records, and we talk through the process with patients ahead of time. Whether for hysteroscopy or cystoscopy or any of these other procedures, that is a very important template to follow considering the medical/legal climate in which we practice.

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—Interview by Vicki Glaser

Address reprint requests to:
Jeffrey R. Dell, M.D.
Generations ObGyn
9430 Parkwest Boulevard
Knoxville, TN 37922

E-mail: delli12@comcast.net