MASTER CLASS

Sacral Colpopexy

BY CHARLES E. MILLER, M.D.

No area of gynecologic surgery has undergone greater transformation over the past decade than the treatment of pelvic floor prolapse. Among other innovative surgical therapies, vaginal prolapse repair kits are now available to essentially replace the patient's pelvic floor.

Although these approaches are both novel and exciting, studies to date are lacking. Unfortunately, these procedures are too new to have stood the test of time.

Given this situation, it is imperative that the gynecologic surgeon who is involved in the treatment of pelvic floor prolapse maintain within his/her surgical armamentarium "tried-and-true" surgical techniques.

Because of its long-standing use, with excellent long-term outcomes, as can be noted in this edition of the Master Class in gynecologic surgery, the accepted standard continues to be the sacral colpopexy.

It seems especially fitting that this procedure, now a half century old, be reviewed based on approach (laparotomy, laparoscopy, robot-assisted), use of mesh material (biologic versus synthetic), technique (fixation of mesh at S1 versus S3, use of split mesh anterior and posterior versus mesh sheet anterior and posterior), and use of concomitant procedures (paravaginal defect repair, culdoplasty, prophylactic retropubic suspension, prophylactic midurethral slings).

Our discussant is Dr. Marie Paraiso, codirector of the Center for Female Pelvic Medicine and Reconstructive Surgery at the Cleveland Clinic Foundation. Despite the fact that she completed her fellowship training only a little more than 10 years ago, Dr. Paraiso has authored/coauthored 60 peer-reviewed journal articles and 13 book chapters, all pertaining to pelvic floor prolapse and urinary incontinence.

She is a much sought-after lecturer, and is routinely an invited speaker at American Association of Gynecologic Laparoscopists, the American College of Obstetricians and Gynecologists, Society of Gynecologic Surgeons, and American Urological Association.

Currently Dr. Paraiso is senior investigator of a prospective trial of robot-assisted laparoscopic sacral colpopexy versus traditional laparoscopic sacral colpopexy and the principal investigator of a cohort study evaluating the implementation of synthetic mesh for pelvic organ prolapse.

DR. MILLER, a reproductive endocrinologist in private practice in Schaumburg, Ill., and Naperville, Ill., is the medical editor of this column.

Still the Standard

BY MARIE PARAISO, M.D.

Despite an increasing interest in minimally invasive surgery, including vaginal route procedures, the abdominal sacral colpopexy is believed by many to be the accepted standard surgical treatment for severe vaginal apex prolapse—and rightly so.

Vaginal prolapse repair kits have gained popularity, as has laparoscopic sacral colpopexy. The learning curve associated with laparoscopic suturing has also fostered an interest in robotic-assisted laparoscopic approaches. Behind this changing landscape, however, is a long history of experience with open abdominal sacral colpopexy.

It is an approach with a record of success that we should know, appreciate, and retain in our armamentarium of surgical options while at the same time continuing to investigate which procedures for vaginal apex prolapse provide optimal effectiveness and safety.

Key Studies on Cure Rates

The sacral colpopexy, introduced in 1957, is a procedure that bridges the support tissue of the anterior and posterior vaginal apex to the anterior longitudinal ligament of the sacrum. A modification of the procedure, called sacral colpoperineopexy, was developed later to treat patients with vaginal apex prolapse and perineal descent; it results in contiguous posterior vaginal wall support from the anterior longitudinal ligament to the perineum.

Indications for sacral colpopexy include a previously failed vaginal route apex suspension procedure, a foreshortened vagina, a weak or denervated pelvic floor, chronic increases in abdominal pressure related to medical comorbidities and/or heavy manual labor, collagen disorders, and the need for concomitant abdominal surgery. Some physicians argue that sacral colpopexy is undoubtedly indicated in young women with severe uterine or vaginal apex prolapse.

A literature review of over 90 articles with outcomes data on sacral colpopexy published in 2004 by Dr. Ingrid E. Nygaard and members of the Pelvic Floor Disorders Network showed anatomic cure rates of 78%-100% when cure was defined as lack of apical prolapse postoperatively, and cure rates of 58%-100% when cure was defined more broadly as lack of any postoperative prolapse (anterior, posterior, apical).

Of interest, the review showed that concomitant paravaginal defect repair or culdoplasty neither improved anatomic cure nor decreased the recurrence of prolapse.

The follow-up for most of the studies in Dr. Nygaard's review ranged from 6 months to 3 years. The longest follow-up duration was almost 14 years in a study conducted by Dr. W.S. Hilger and associates. This long-term outcomes analysis of abdominal sacral colopopexy showed a cure rate of 74%.

A few randomized clinical trials have compared abdominal sacral colpopexy to other vaginal apex suspension procedures for the treatment of vaginal prolapse, with variable outcomes but with an overriding message that abdominal sacral colpopexy is an effective procedure.

In 1996 Dr. J.T. Benson and associates reported an optimal anatomic cure rate of 58% in patients who underwent abdominal sacral colpopexy with concomitant vaginal reconstructive procedures, and 29% in patients who underwent bilateral sacrospinous ligament suspension with pelvic reconstruction. Because of the significant failure rate associated with vaginal surgery, however, this trial was aborted prior to reaching adequate power.

In 2004, Dr. C.F. Maher and associates compared abdominal sacral colpopexy and concomitant Burch procedure with vaginal sacrospinous colpopexy and concomitant Burch procedure. Anatomic cure was similar in both groups after a 2-year follow-up, but abdominal sacral colpopexy was associated with more posterior vaginal wall recurrences, and vaginal sacrospinous colpopexy was associated with more anterior vaginal wall recurrences.

Of recent importance for the future practice of abdominal sacral colpopexy are the results of a randomized, multicenter clinical trial conducted by the Pelvic Floor Disorders Network that compared open sacral colpopexy with or without concomitant Burch colposuspension in women without preoperative stress incontinence.

COURTESY DR. MARIE PARAISO

Two strips of polypropylene mesh are attached to the anterior and posterior vaginal muscularis and passed through a retroperitoneal tunnel.

Investigators of the CARE trial (Colpopexy and Urinary Reduction Efforts) found that stress incontinence was prevalent 3 months postoperatively in almost twice as many women who did not undergo the Burch procedure as in those who did (approximately 44% vs. 24%).

The results, which were reported by Dr. L. Brubaker and associates in the New England Journal of Medicine, clearly support the value of performing a prophylactic retropubic suspension for potential urinary incontinence along with abdominal sacral colpopexy. (These data do not extrapolate to midurethral slings as prophylactic procedures concomitant with sacral colpopexies.)

Regarding the issue of laparoscopic versus open abdominal sacral colpopexies, my colleagues and I found through a chart review of 117 consecutive patients that the two approaches have comparable clinical outcomes. Laparoscopic sacral colpopexy was associated with both a significantly decreased hospital stay and a significantly longer operating room time.

Key Studies on Mesh

The use of various types of mesh material is an issue that has been addressed to some extent in the literature. Certainly there is no ideal biologic or synthetic mesh. But in general, outcomes data addressing any type of biologic graft in abdominal repair of apical prolapse are sparse and inconsistent, while there is good literature to support the use of nonabsorbable synthetic implants.

The overall rate of mesh erosion in Dr. Nygaard's review of abdominal sacral colpopexy (using various types of mesh) was 3.4%, with good evidence to support the use of polypropylene mesh.

Dr. A.G. Visco and associates published a series in 2001 evaluating the prevalence of synthetic mesh erosion (predominantly Mersilene mesh) between abdominal sacral colpopexy and various colpoperineopexy procedures. The erosion rate overall was 4.5%. Vaginally introduced mesh, however, was associated with an erosion rate of 40%, compared with an erosion rate of 16% when sutures were placed by the vaginal route and attached to abdominally placed mesh.

In a more recently published study, Dr. P. J. Culligan and associates randomized patients undergoing sacral colpopexy to receive polyprophylene mesh or solvent-dehydrated cadaveric fascia lata. Of the patients who returned for 1-year follow-up, 91% of the synthetic mesh group, and 68% of the fascia group, were classified as cured. Several case series have had similar results.

With the available data, I see little reason to use biologic tissue. One indication, though, may be sacral colpopexy with concomitant sigmoid resection rectopexy. I prefer a macroporous polypropylene mesh for sacral colpopexy.

The Surgery

Whether we perform abdominal sacral colpoplexy through an open, laparoscopic, or even robotic technique, we must always remember that when working within the presacral space there is a risk of life-threatening bleeding.

For this reason, I always dissect the presacral space first. I have learned to be prepared for many variables: Older

women sometimes have undetected aneurysms of the blood vessels bordering this area, and the anatomy of the sacrum can vary.

Surgeons handle bleeding in various ways. Some surgeons prophylactically cauterize the middle sacral vessel. For venous bleeding, I have success when I am working laparoscopically with inserting a sponge through a port and holding pressure for 5 minutes. Sterile thumbtacks, bone wax, and hemostatic agents can also be of value.

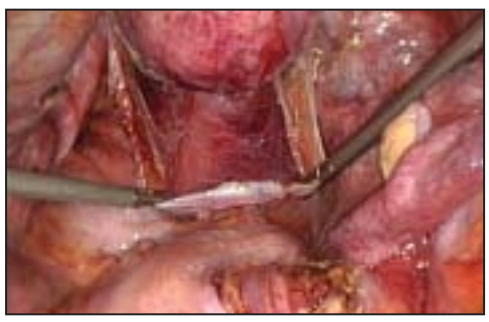
Once I've made my presacral dissection, I proceed all the way down into the cul-de-sac, having already visualized or palpated both ureters. I make sure I am at least 4 cm medial to the right ureter when I make my incision in the peritoneum overlying the sacral promontory.

I dissect all the way down to the rectovaginal space in the cul-de-sac. Lately, in laparoscopic surgery, I have been making a tunnel between the sacrum and cul-de-sac, because the peritoneum easily lifts off the retroperitoneal structures.

I usually use end-to-end anastomosis sizers for vaginal manipulation, but others will use vaginal palpation or Lucite probes. I dissect into the rectovaginal space first, which consists of areolar tissue.

I believe that when we're treating vaginal apex prolapse, we must attach the graft over a significant portion of the posterior vaginal length and, in cases of perineal descent, all the way down to the perineum.

There's now a caveat to this procedural modification, however, in that there is a new colorectal procedure used for treatment of outlet dysfunction constipation called the STARR procedure (Stapling Transanal Rectocele Resection). Unfortunately, a patient with mesh running all the way down to her perineum may not be able to undergo this colorectal procedure because of the risk of rectovaginal fistula. I inform my colpopexy patients that this is a contraindication to the STARR procedure.



COURTESY DR. MARIE PARAISO

Dissection of the presacral space and rectovaginal space: "I always dissect the presacral space first. I have learned to be prepared for many variables."

In laparoscopic and some open cases, I will retrograde fill the bladder in order to delineate the bladder and facilitate the anterior dissection. This may be difficult if a patient has undergone an anterior colporrhaphy in the past.

I like to attach the anterior graft all the way down to the bladder base. Often times, what are thought to be stage III or stage IV cystoceles are in fact high anterior apical prolapses. Aggressive anterior vaginal wall dissection results in a more extensive attachment of the anterior vaginal mesh and decreased need for a paravaginal defect repair. Obviously, keeping the bladder from harm is very important.

The beauty of this procedure is that once you've suspended the anterior and posterior vaginal apex to the anterior longitudinal ligament, you're home free.

Surgeons often use a Y-shaped graft for sacral colpopexy. I currently use two pieces of 4-by-15-cm type 1 polypropylene mesh—a macroporous, monofilament mesh. I tension the posterior and anterior straps separately so as to avoid excess tension on the mesh and hence the vagina, and subsequently attach them to the anterior longitudinal ligament of the sacrum at the level of S1 or S2.

Many believe that if you don't stitch (or tack) at the S3 level, you're not allowing the vagina to be in its normal axis—that by going up to S1, you risk exposing the vagina posteriorly to increases in pressure that change the axis and increase posterior vaginal wall recurrence.

There have not been any studies precisely comparing mesh placement sites and their effect on anatomic success, but after doing a large number of these procedures, it does seem clear to me that it may not be necessary to attach the graft at the level of S3.

There are several reasons: For one, the anterior longitudinal ligament of the sacrum has been shown to have the greatest tensile strength at the level of the sacral promontory. Secondly, attachment of the mesh without tension to S1 or S2 has the same resultant vaginal axis because of retroperitoneal scarring of the mesh in the right pararectal space aided by intraabdominal pressure. Lastly, we risk venous plexus bleeding at the level of S3.

Surgeons use different types of sutures to fix the mesh, and I think there is some literature to support the use of monofilament sutures. I tend to use a braided polyester suture when performing the procedure laparoscopically because it ties much better.

Tying the mesh fairly loosely without strangulating tissue may reduce the risk of mesh erosion. I also tend to treat my patients with vaginal estrogen preoperatively and postoperatively to prevent mesh erosion.

Finally, I always retroperitonealize the mesh in order to decrease the risk of bowel obstruction and bowel adherence to the mesh. This may not be necessary with Mersilene mesh, which is multifilament but possesses macroporous and microporous elements (Type III).

Where We Stand Today

The problem with our literature is that we do not have enough adequately powered comparative trials for any of our vaginal apex suspension procedures. Our lack of adequate outcomes data is of particular concern when it comes to vaginal surgeries for apical prolapse.

The lack of data designating a preferred vaginal-route apical suspension procedure leads most surgeons to argue that abdominal sacral colpopexy is the accepted standard procedure.

In all circumstances, surgeons should do what is best for their patients. Ideally, though, we should have at least one abdominal approach—whether it be open, laparoscopic, or robotic—and at least one vaginal route to offer our patients because no procedure is best for all complaints, anatomic variations, and medical conditions.

Clearly, the pendulum has swung toward minimally invasive approaches for vaginal apex prolapse, as it has for many other conditions, but there are many questions that will remain unanswered until further randomized trials comparing abdominal and vaginal approaches, and new variations of each, are completed. This does not mean, in the meantime, that we should throw out the old. ■

Hysterectomy or Endometrial Ablation for Bleeding?

BY BETSY BATES
Los Angeles Bureau

SAN DIEGO — Both hysterectomy and endometrial ablation were highly effective short-term treatments for dysfunctional uterine bleeding in a randomized, multicenter trial, but about one-third of women who underwent endometrial ablation eventually needed more surgery.

Dr. Malcolm G. Munro, professor of obstetrics and gynecology at the University of California, Los Angeles, School of Medicine, reported results of the Surgical Treatments Outcomes Project for Dysfunctional Uterine Bleeding (STOP-DUB) on behalf of 25 study sites at the annual meeting of the American College of Obstetricians and Gynecologists.

The STOP-DUB research group enrolled 237 women with DUB between January 1998 and June 2001 in a trial to compare three forms of hysterectomy (vaginal, laparoscopic, and abdominal low approach) under general or regional anesthesia, to two forms of endometrial ablation (rectoscopic ablation using radiofrequency electrodesiccation/coagulation or vaporization and nonrectoscopic endometrial ablation with a thermal balloon.)

Once patients were assigned to a category—hysterectomy or endometrial ablation—the specific choice of technique was left to the discretion of the treating gynecologist, although supracervical hysterectomy was not permitted. The majority of hysterectomies were performed vaginally.

To be eligible, patients had to have failed medical therapy for DUB. They could be anovulatory, ovulatory, or of indeterminate ovulatory status and were required to have a normal endometrial cavity of limited size. Leiomyomas could be intramural or subserosal, but not submucosal. Among the 237 eligible patients, 41 entered the trial after being in an observational arm.

"The vast majority of women reported that the major problem they named at baseline was solved at 12 months," the study group reported in its poster presentation. Specifically, among the 103 women who underwent hysterectomy and 107 who had endometrial ablation and answered the question, 96 and 94, respectively, said their major problem had been solved. This beneficial effect persisted in the majority of women out to 48 months of follow-up.

In addition, other symptoms cited by women, such as bleeding, pain, and fatigue, also were effectively resolved by 12 months in most women in both groups. Hysterectomy was more effective in resolving bleeding.

In general, perioperative adverse events were more common in women who underwent hysterectomy. A total of five major adverse events were reported. Two cystotomies, both of which occurred during vaginal hysterectomy, were diagnosed and treated intraoperatively. Three uterine perforations occurred during endometrial ablation and required treatment.

Institutional length of stay was significantly longer for women assigned to hysterectomy (1-2 days), particularly among women who underwent abdominal hysterectomy (3 days), compared with those who underwent endometrial ablation, an outpatient procedure.

Of note was the finding that by 48 months, 32 of 110 women who initially underwent endometrial ablation required reoperation, usually hysterectomy.

The authors noted that length of stay is reduced with vaginal hysterectomy and that complications of endometrial ablation have been reportedly reduced with nonrectoscopic techniques such as balloon ablation. Both techniques are safe and effective, they noted, but both have relative disadvantages—hysterectomy's longer length of stay and greater perioperative morbidity, and endometrial ablation's lack of long-term durable effect in some women.

"It is reasonable to recommend that women select the type of surgery they receive for treatment of DUB based on their individual preferences and situations," they concluded. ■

Human Tissue Suppliers OK'd

Inspections of 153 major human tissue recovery firms found no major industrywide problems in the process that could put tissue recipients at risk for transmission of disease, according to a Food and Drug Administration report released this summer.

Based on information collected during what the FDA called an inspection "blitz," the Human Tissue Task Force concluded that these companies were in "substantial compliance" with the agency's risk-based tissue regulations that went into effect in May 2005. The task force was formed in August 2006 to evaluate the effectiveness of the regulations governing companies that recover human musculoskeletal tissues used in surgical procedures. The inspections were conducted from October 2006 through March 2007.

More than 2,000 active cell and tissue establishments are registered with the FDA. The task force recommended that these establishments continue to be inspected every 2-3 years.

More information on this topic is available at CBER's human tissue Web page, www.fda.gov/cber/tiss.htm.

—Elizabeth Mechcatie