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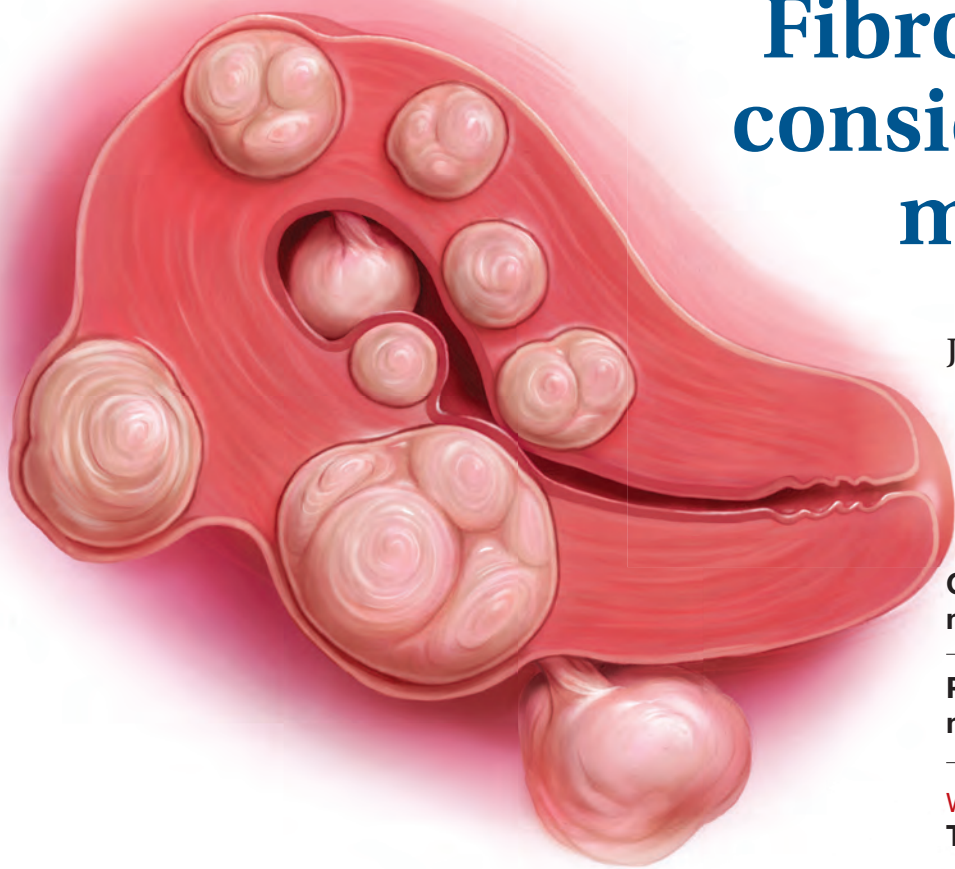
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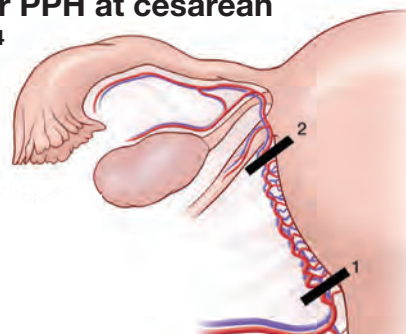
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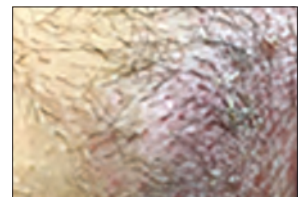
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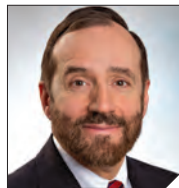
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# Uterus-sparing interventions to treat postpartum hemorrhage during cesarean delivery surgery

Cesarean delivery is often associated with postpartum hemorrhage. Frequent use of uterine-sparing interventions can help reduce total blood loss.



**Daniela Carusi, MD, MSc**  
Assistant Professor of Obstetrics,  
Gynecology, and Reproductive Biology  
Harvard Medical School  
Director of Obstetric Surgery  
Department of Obstetrics and Gynecology  
Brigham and Women's Hospital  
Boston, Massachusetts



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Postpartum blood loss greater than 1,000 mL occurs in approximately 7% of cesarean delivery (CD) procedures with the administration of oxytocin alone or oxytocin plus misoprostol.<sup>1</sup> Rapid identification and control of hemorrhage is essential to avoid escalating coagulopathy and maternal instability. In cases of excess blood loss, clinicians request assistance from colleagues, endeavor to identify the cause of the bleeding, utilize additional uterotonics (methylergonovine, carboprost, misoprostol), perform uterine massage, warm the uterus, repair lacerations and replace blood products. If blood loss continues after these initial measures, obstetricians may consider uterine artery embolization (UAE) or hysterectomy. While UAE is a highly effective measure to control postpartum hemorrhage, it is not available at all obstetric hospitals. Even when available, there may be a significant time

delay from the decision to consult an interventional radiologist to completion of the embolization procedure.

To avoid the permanent sterilization of a hysterectomy, or to obtain time for UAE or correction of coagulopathy, additional uterus-sparing surgical interventions should be considered. These include: 1) progressive uterine devascularization, 2) uterine compression sutures, and 3) intrauterine balloon tamponade. One caveat is that there is very little high-quality evidence from randomized trials to compare the efficacy or outcome of these uterus-sparing surgical interventions. Most of our evidence is based on limited case series and expert recommendations.

## Uterine devascularization

Many techniques have been described for performing progressive uterine devascularization. Most experts recommend first performing an O'Leary suture, ligating both ascending uterine arteries and accompanying veins at a point approximately 2 cm closer

to the cervix than the uterine incision (FIGURE 1). An absorbable suture is passed through the myometrium, being sure to remain medial to the ascending uterine vessels. Clear visualization of the vessels posteriorly is essential, usually necessitating exteriorization of the uterus. The needle is then driven through an avascular space in the broad ligament close to the uterine vessels, and the suture is tied down. Ureteral injury can be avoided by extending the bladder flap laterally to the level of the round ligament and mobilizing the vesicouterine peritoneum inferiorly, with the suture placed directly on endopelvic fascia. If necessary, the utero-ovarian ligament can be ligated in a second step, just below the uterine-tubal junction. The progressive devascularization intervention can be limited to the first or second steps if bleeding is well controlled.

In our experience, bilateral O'Leary sutures are highly effective at controlling ongoing uterine bleeding, particularly from the lower

*The authors report no financial relationships relevant to this article.*

uterine segment. In the event that they are not successful, placement does not preclude later use of UAE.

### Uterine compression sutures

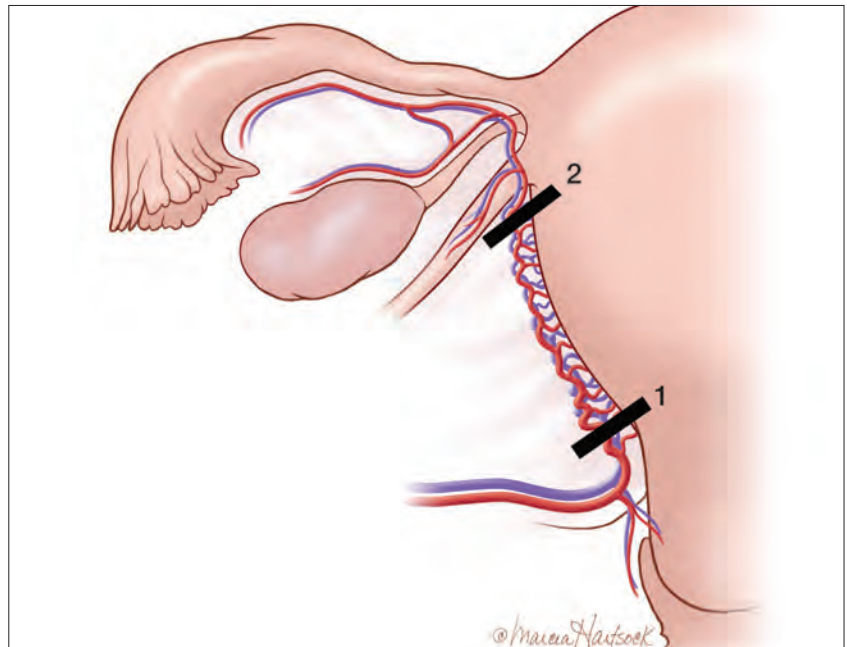
Compression sutures are most often used in the setting of refractory uterine atony. They also may be helpful for controlling focal atony or bleeding from a placental implantation site. More than a dozen different types of uterine compression sutures have been reported in the literature; the B-Lynch, Hyman, and Pereira sutures are most commonly performed.<sup>2</sup>

**The B-Lynch suture**<sup>3</sup> is performed with a long, rapidly absorbable suture on a large needle (FIGURE 2, page 6). We use a 60-inch #1 or #2 chromic suture on a TP-1 needle in the following steps:

1. Take bites on either side of the right edge of the hysterotomy incision (A and B). Place these bites approximately 3 cm from the edge of the hysterotomy incision.
2. Loop the suture around the fundus and reenter the uterus through the posterior uterine wall at point C, which is directly posterior to point B.
3. Exit the posterior wall of the uterus through point D.
4. Loop the suture over the uterine fundus.
5. Anchor the suture in the lower uterine segment by taking bites on either side of the left edge of the uterine hysterotomy incision (points E and F).
6. Pull the two ends of the suture tight while an assistant squeezes the uterus to aid compression.
7. Place a surgical knot to secure the suture.
8. Close the hysterotomy incision.

The B-Lynch suture was described with an open hysterotomy incision,<sup>3</sup> which avoids closing off the lower uterine segment. We have successfully performed a modifi-

**FIGURE 1** Sequential uterine devascularization sutures



Suture #1 is the O'Leary suture. Suture #2 reduces blood flow to the uterus from the vessels associated with the round and utero-ovarian ligaments.

tion on a closed uterus, taking care to not drive the lower uterine sutures through both the anterior and posterior walls.

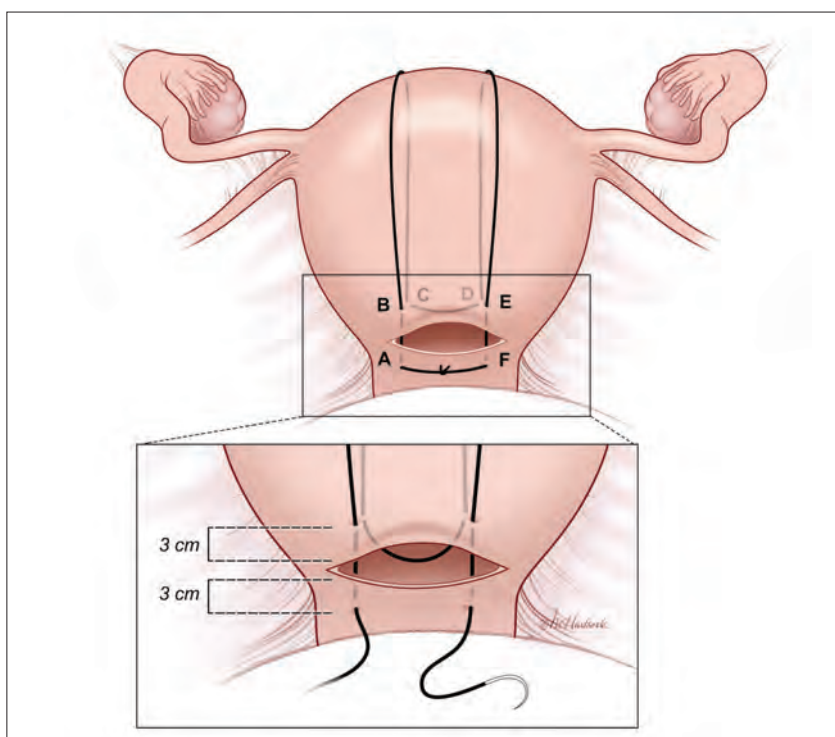
**The Hayman suture**<sup>4</sup> was proposed with two important modifications: The suture is placed through-and-through the lower uterine segment with a closed hysterotomy, and the suture can be fixed to the uterine fundus to avoid slippage. This vertical compression suture (FIGURE 3, page 7) is performed by placing two to four vertical #2 chromic sutures directly through the anterior to posterior uterine wall, tying the suture on the fundus using a 3-throw technique to minimize slippage of the first knot. In the original description, Hayman also described injecting carboprost into the uterine fundus to stimulate uterine contraction and regularly inspecting the vagina to evaluate the extent of continued bleeding.<sup>4</sup>

**The Pereira sutures**,<sup>5</sup> also described on a closed uterus, combine vertical and horizontal sutures placed as a series of bites into the submucosal myometrium using #1 polyglactin 910 (Vicryl) sutures (FIGURE 4, page 7). The sutures do not enter the uterine cavity. Two to three transverse sutures are initially placed followed by two vertical sutures. When placing the transverse sutures, it is important to cross the broad ligament in an avascular area and avoid trauma to blood vessels, ureters, gonadal vessels and fallopian tubes. The vertical sutures begin and end at the level of the transverse suture closest to the cervix.

### Intrauterine balloon tamponade

Many types of balloon tamponade devices have been developed, ranging from the humble condom tied to a Foley urinary catheter to the

**FIGURE 2 B-Lynch suture**



B-Lynch suture as seen from the anterior uterine wall.

sophisticated Bakri<sup>6,7</sup> and Belfort-Dildy<sup>8</sup> balloon tamponade devices. Intrauterine balloon tamponade is highly effective in controlling excess bleeding following vaginal delivery and less effective when used following a CD. In one study of 226 women with postpartum hemorrhage treated with a Bakri balloon the success rate was 89% and 66% following vaginal delivery and CD, respectively.<sup>9</sup>

When using balloon tamponade during a CD, some experts recommend partially closing the transverse hysterotomy incision by placing sutures to close edges of the hysterotomy, followed by insertion of the balloon into the uterus and the stem through the cervix into the vagina. Attachment of the stem to a collection bag should help to quickly assess the rate of blood

loss. The balloon is inflated after the hysterotomy is closed. Following inflation of an intrauterine balloon, blood loss should decrease almost immediately.<sup>10</sup> If excessive blood loss continues for more than 10 minutes, additional uterus-sparing interventions or hysterectomy may be required. Following successful balloon tamponade, the balloon may be deflated 12 to 24 hours postpartum when maternal stabilization and normal coagulation have been achieved. If bleeding resumes, the balloon may be reinflated and UAE should be considered.

**Combined interventions: Uterine devascularization plus uterine compression sutures**

There are no high-quality randomized trials comparing the devascularization plus compression sutures

versus a single intervention alone, and case series and case reports on this topic are lacking. If uterine devascularization alone does not sufficiently control bleeding, adding a uterine compression stitch might resolve the hemorrhage. Both procedures require only suture material, which is immediately available in all operating rooms. Hence, this combination of interventions can be executed quickly.

**Uterine sandwich: Intrauterine balloon tamponade plus uterine compression sutures**

CD for placenta previa is associated with an increased risk of postpartum hemorrhage, with bleeding from the lower uterine segment greatly contributing to total blood loss. While O’Leary sutures can stem the flow of bleeding in this area, the use of both an intrauterine balloon tamponade plus uterine compression sutures—a so-called uterine sandwich—may result in maximal reduction in blood loss.<sup>11,12</sup>

In one randomized trial, 106 women undergoing CD for a placenta previa were randomly assigned to uterine devascularization alone or double transverse compression suture plus intrauterine Foley catheter balloon. Compared with women receiving devascularization alone, the combination of compression suture plus intrauterine balloon significantly reduced blood loss (1,350 mL vs 750 mL, respectively;  $P = .0001$ ).<sup>13</sup>

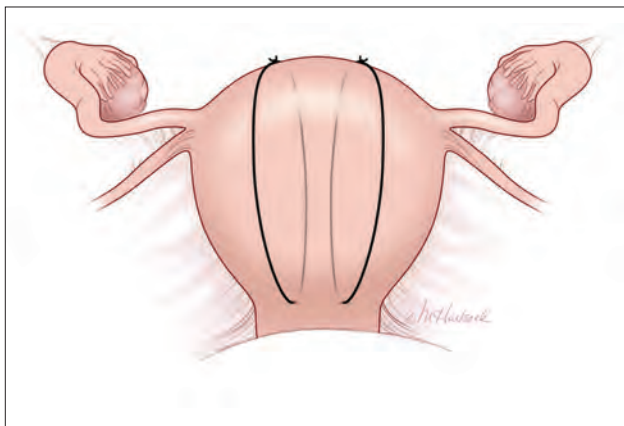
**Underutilization of uterine-sparing interventions**

In a nationwide study of 50 consecutive Danish peripartum hysterectomy cases, an audit committee concluded that 24% of the hysterec-

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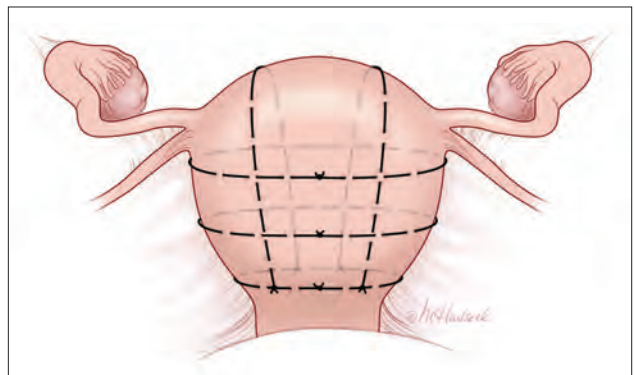


**FIGURE 3 Hayman suture**



The Hayman suture passes directly from the anterior uterine wall through the posterior uterine wall. Two to four longitudinal sutures can be placed. Two longitudinal sutures are pictured in this figure. A transverse cervicoisthmic suture also can be placed, if needed, to control bleeding from the lower uterine segment.

**FIGURE 4 Pereira sutures**



The Pereira sutures combine longitudinal and transverse sutures placed as a series of bites into the submucosal myometrium. The sutures do not enter the uterine cavity. The longitudinal sutures begin and end at the level of the transverse suture closest to the cervix. Avoid damage to blood vessels and the ureters when placing the transverse sutures. Two longitudinal sutures and three transverse sutures are pictured in this figure.

tomies could have been avoided, and an additional 30% of hysterectomies might have been avoided, if uterine-sparing surgical interventions had been utilized.<sup>14</sup> In a recent survey of senior ObGyn residents in France, greater than 70% of respondents reported that they had not mastered uterine-sparing techniques of uterine devascularization and compression sutures, nor peripartum hysterectomy.<sup>15</sup> Together, these studies suggest that uterine-sparing

interventions are underutilized and that with more training and practice clinicians would become facile with these interventions.

The cornerstones of uterine-sparing surgical interventions are simplicity, safety, and efficacy. If a combination of pharmacologic and **multiple** uterine-sparing surgical interventions do not control the bleeding, the patient may need an emergency hysterectomy or, if stable, a UAE. While devasculariza-

tion and compression sutures are described during CD, it is reasonable to use them after vaginal delivery if the next reasonable step would be a laparotomy. When you next face the clinical challenge of a postpartum hemorrhage, rapid recognition of excess blood loss, early identification of the cause, swift pharmacologic treatment, and timely escalation of surgical interventions will help you reduce the risk of hysterectomy and severe maternal morbidity. ●

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## WHAT IS YOUR APPROACH TO THE PERSISTENT OCCIPUT POSTERIOR MALPOSITION?

ROBERT L. BARBIERI, MD  
(EDITORIAL; MARCH 2019)

### A classic approach for managing fetal malposition

For those of us who trained and practiced obstetrics in the days of the 6% primary cesarean delivery (CD) rate, we never considered the management of the persistent occiput posterior (OP) position to be particularly difficult. I outline below a method that requires no unusual level of skill or dexterity.

1. The cervix must be fully dilated.
2. Dense regional anesthesia must be achieved.
3. The vertex must have reached +1 station.
4. The position must be clearly established, and this does not require anything other than the ability to palpate an ear, as it can be pointed only in one direction. If you feel ultrasonography is needed, be my guest.
5. Use an obstetric lubricant to reduce resistance and minimize lacerations.
6. While a trial of manual rotation is reasonable, it commonly will not succeed and requires that an operator's hand be inserted rather than a slender and less traumatic device (forceps).
7. Next, palpate the sagittal suture to determine whether the position is straight OP versus left OP or right OP. This should not be difficult unless the poor woman has gone through 2 or 3 hours of unproductive pushing, thereby creating caput.
8. After proper forceps application is confirmed, gently apply upward pressure. This will make rotation easier.
9. Dr. Irving's recommendations



MARCH 2019

notwithstanding, the forceps handles are not carried in a wide sweep. One should use Kielland's forceps, which do not have a pelvic curve and were invented for this precise indication. The forceps are simply rotated.

10. Try to avoid delivery as an OP, as this pulls a much larger diameter deflexed head through the pelvis and usually results in significant lacerations.
11. Episiotomy is not always required if rotation has succeeded.
12. Once descent to the outlet has been achieved, it is probably best to switch to a forceps with a pelvic curve to achieve easier extension.
13. This should complete the delivery, but as a general rule, if more than minimal resistance is met in any of the above steps, abandon the procedure and move to CD.
14. This process should result in at least a 70% success rate.

As is most likely understood by the current generation of obstetricians who appear to be satisfied with a 30% to 40% primary CD rate, the above reflects the views of a

long-retired ObGyn (whose CD rate never exceeded 10%) and may be inappropriate for those who are not adequately trained in or comfortable with vaginal obstetrics.

David M. Priver, MD  
San Diego, California

## HOW DO YOU FEEL ABOUT EXPECTANTLY MANAGING A WELL-DATED PREGNANCY PAST 41 WEEKS' GESTATION?

ROBERT L. BARBIERI, MD  
(EDITORIAL; FEBRUARY 2019)

### Membrane stripping can be problematic

The recent discussion on stripping membranes to facilitate the initiation of labor and delivery was intriguing. This practice was reviewed extensively during my training in the 1960s and abandoned when the results were disappointing or contradictory. Although the practice has been revitalized recently, I am concerned that potential risks and the absence of a recommended protocol of safeguards may allow new problems to develop.

In a metropolitan community where I provide consultative services, the only patients I see for evaluation of pregnancies beyond 40 to 41 weeks come from providers who are non-physicians. Apparently, they are concerned that they may have to turn their patients over to physician providers for interventions that they are not capable of doing. My advice to them is simply that nothing good happens after 40 to 41 weeks.

Well-grown babies may continue to grow if they are healthy, and they may incur greater risks of dystotic labor and delivery resulting in injury or the need for physician-administered surgical assistance. If, on the other hand, growth markedly diminishes or ceases, fetal harm or

neonatal complications may occur through asphyxia, meconium aspiration, or trauma. In either event, physician-based assistance is strongly encouraged, as long as due diligence in determining gestational age has been done.

Promoting membrane stripping without having a protocol for ascertainment of risk factors is worrisome to me. In my opinion, large population studies that fail to demonstrate increased risks of infection may fail to demonstrate that membrane stripping may induce a degree of perinatal infection comparable to that of prolonged labor with multiple internal examinations with or without ultimate cesarean birth. Prior to considering membrane stripping as a strategy, one should recognize certain important considerations, namely:

- Patients most in need of active

intervention may have the least favorable cervical findings, and as a result they are potentially at risk for the greatest discomfort.

- The frequency of group B streptococcal colonization of the vagina at term should be recognized, and a culture should be obtained immediately prior to intervention. When a culture is a positive, membrane stripping should be avoided, or at least a sober consideration of its use and appropriate antibiotic coverage should occur.
- Consider performing transvaginal ultrasonography prior to membrane stripping to exclude the possibility of a placental edge close enough to be encountered and compromised, with resultant hemorrhage in an outpatient venue ill equipped to provide adequate emergency support.
- The comparative effectiveness of

other direct cervical conditioning therapies, including use of a Foley catheter or regional prostaglandin medication, has been well explored and found effective. Also, if one takes seriously the need for any intervention, admission to the hospital for overnight cervical conditioning allows for surveillance and avoids the patient experience of being sent home cramping, bleeding, brooding infection, and questioning her trust in the provider.

I am concerned that the promotion of this potentially rather brutish practice by highly reputable advisors can result in its growing utilization by providers some of whom may be least qualified to apply proper judgment and sensitivity to its selection. In the most primitive of circumstances, it may have utility. Personally, however, I feel that medically based

## Appropriateness of performing in-office uterine aspiration

In their article, "Uterine aspiration: From OR to office" (February 2019), Lauren Thaxton, MD, MBA, and Bri Tristan, MD, made the case for why, in appropriate clinical situations, office-based uterine aspiration, compared with uterine aspiration in the OR, should be the standard surgical management of early pregnancy failure. Their reasons included an equivalent safety profile, reduced costs, and patient-centered characteristics.

OBG MANAGEMENT posed this query to readers in a website poll: "Should the standard location for uterine aspiration be in the office?" See how readers responded, below.

### Poll results

A total of 73 readers cast their vote:

- **86.3% (63 readers)** said yes, in appropriate clinical situations
- **13.7% (10 readers)** said no

### Reader comments

"Yes, in appropriate clinical situations."

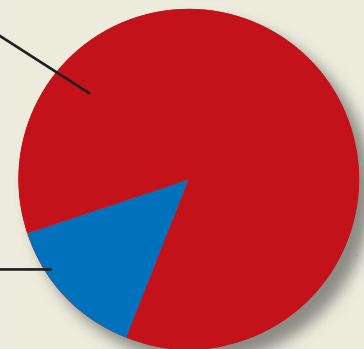
*-Yardlie Toussaint-Foster, DO, Downingtown, Pennsylvania*

"I have been doing it this way (in the office) for years, up to 11 to 12 weeks without complication."

*-John Lane, MD, Raleigh, North Carolina*

**Uterine aspiration should be done in the office in appropriate situations**  
**86.3%**

**Uterine aspiration should not be done in the office**  
**13.7%**



## COMMENT & CONTROVERSY

strategies initiated and monitored by professionals capable of dealing with any untoward departures from the expected results must be considered in the best traditions of what we do. The appeal of simplicity must not encourage the adoption of interventions that lack the proper application of thought and plan and whose

only appeal is that of simplicity.

**Richard P. Perkins, MD**

Fort Myers, Florida; Stockton, California

**Dr. Barbieri responds**

*I thank Dr. Priver for his excellent description of how to use forceps to resolve a persistent occiput posterior position. I also thank Dr. Perkins for*

*his valuable comments and agree with him that in the United States among the options available for outpatient cervical ripening, misoprostol or a balloon are more commonly used than membrane stripping. Membrane stripping is an outpatient cervical ripening technique that is commonly used in the United Kingdom.*

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## Ongoing maternal and neonatal health resources for your practice

### Did you read these recent news and clinical articles?

- » Diverse vaginal microbiome may signal risk for preterm birth
- » Obesity doesn't hamper flu vaccine response in pregnancy
- » One versus two uterotonics: Which is better for minimizing postpartum blood loss?
- » FIGO outlines global standards for preeclampsia screening
- » The benefits of first-trimester fetal heart evaluation
- » Rapid urine test could aid in preeclampsia diagnosis
- » Pregnancy mortality in the United States: Top causes of death and timing
- » Better screening needed to reduce pregnancy-related overdose, death
- » FDA: Vinpocetine associated with fetal harms, miscarriage
- » In women with preterm mild hypertensive disorders, does immediate delivery versus expectant management differ for neurodevelopmental outcomes?



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## Howard T. Sharp, MD

Dr. Sharp is Professor and Vice Chair for Clinical Activities, Department of Obstetrics and Gynecology, University of Utah Health Sciences Center, Salt Lake City.



## Marisa R. Adelman, MD

Dr. Adelman is Assistant Professor, Department of Obstetrics and Gynecology, University of Utah Health Sciences Center.

*The authors report no financial relationships relevant to this article.*

These experts discuss the factors that incur increased risk for malignant endometrial polyps, the relationship between chronic endometritis and endometrial polyps, whether the etonogestrel subdermal implant can treat EIN, and new endometrial ablation technology

**K**eeping current with causes of and treatments for abnormal uterine bleeding (AUB) is important. AUB can have a major impact on women's lives in terms of health care expenses, productivity, and quality of life. The focus of this Update is on information that has been published over the past year that is helpful for clinicians who counsel and treat women with AUB. First, we focus on new data on endometrial polyps, which are a common cause of AUB. For the first time, a

meta-analysis has examined polyp-associated cancer risk. In addition, does a causal relationship exist between endometrial polyps and chronic endometritis? We also address the first published report of successful treatment of endometrial intraepithelial neoplasia (EIN, formerly complex endometrial hyperplasia with atypia) using the etonogestrel subdermal implant. Last, we discuss efficacy data for a new device for endometrial ablation, which has new features to consider.

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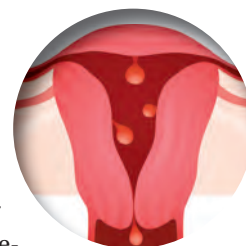
Endometrial ablation vapor system

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## What is the risk of malignancy with endometrial polyps?

*Sasaki LM, Andrade KR, Figueiredo AC, et al. Factors associated with malignancy in hysteroscopically resected endometrial polyps: a systematic review and meta-analysis. J Minim Invasive Gynecol. 2018;25:777-785.*

**I**n the past year, 2 studies have contributed to our understanding of endometrial polyps, with one published as



### WHAT THIS EVIDENCE MEANS FOR PRACTICE

The study takeaways regarding clinical and demographic risk factors suggest that menopausal status, age greater than 60 years, the presence of AUB, diabetes, hypertension, obesity, and tamoxifen use have an increased risk for premalignant and malignant lesions.

This study is important because its findings will better enable physicians to inform and counsel patients about the risks for malignancy associated with endometrial polyps, which will better foster discussion and joint decision-making about whether or not surgery should be performed.

the first ever meta-analysis on polyp risk of malignancy.

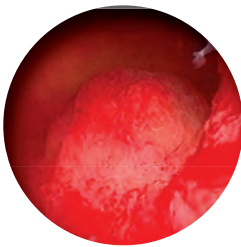
What can information from more than 21,000 patients with polyps teach us about the risk factors associated with endometrial malignancy? For instance, with concern over balancing health care costs with potential surgical risks, should all patients with endometrial polyps undergo routine surgical removal, or should we stratify risks and offer surgery to only selected patients? This is the first meta-analysis to evaluate the risk fac-

tors for endometrial cancer (such as obesity, parity, tamoxifen use, and hormonal therapy use) in patients with endometrial polyps.

### Risk factors for and prevalence of malignancy

Sasaki and colleagues found that about 3 of every 100 patients with recognized polyps will harbor a premalignant or malignant lesion (3.4%; 716 of 21,057 patients). The identified risk factors for a cancerous polyp included: menopausal status, age greater than 60 years, presence of AUB, diabetes mellitus, hypertension, obesity, and tamoxifen use. The risk for cancer was 2-fold greater in women older than 60 years compared with those younger than age 60 (prevalence ratio, 2.41). The authors found no risk association with use of combination hormone therapy, parity, breast cancer, or polyp size.

The investigators advised caution with using their conclusions, as there was high heterogeneity for some of the factors studied (including age, AUB, parity, and hypertension).



## New evidence associates endometrial polyps with chronic endometritis

Cicinelli E, Bettocchi S, de Ziegler D, et al.

*Chronic endometritis, a common disease hidden behind endometrial polyps in premenopausal women: first evidence from a case-control study. J Minim Invasive Gynecol. 2019. S1553-4550(19)30056-1. doi: 10.1016/j.jmig.2019.01.012.*

**T**he second important study published this year on polyps was conducted by Cicinelli and colleagues and suggests that inflammation may be part of the pathophysiology behind the common problem of polyps. The authors cite a recent study that showed that abnormal expression of “local” paracrine inflammatory mediators, such as

interferon-gamma, may enhance the proliferation of endometrial mucosa.<sup>1</sup> Building on this possibility further, they hypothesized that chronic endometrial inflammation may affect the pathogenesis of endometrial polyps.

### Details of the study

To investigate the possible correlation between polyps and chronic endometritis, Cicinelli and colleagues compared the endometrial biopsies of 240 women with AUB and hysteroscopically and histologically diagnosed endometrial polyps with 240 women with AUB and no polyp seen on hysteroscopy.

The tissue samples were evaluated with immunohistochemistry for CD-138 for plasma cell identification.

The study authors found a significantly higher prevalence of chronic endometritis in the group with endometrial polyps than in the group without polyps (61.7% vs 24.2%, respectively;  $P < .0001$ ). They suggest that this evidence supports the hypothesis that endometrial polyps may be a result of endometrial proliferation and vasculopathy triggered by chronic endometritis.

### WHAT THIS EVIDENCE MEANS FOR PRACTICE

The significance of this study is that there is a possible causal relationship between endometrial polyps and chronic endometritis, which may expand the options for endometrial polyp therapy beyond surgical management in the future.

## Can endometrial intraepithelial neoplasia be treated with the etonogestrel subdermal implant?



Wong S, Naresh A. Etonogestrel subdermal implant-associated regression of endometrial intraepithelial neoplasia. *Obstet Gynecol.* 2019;133:780-782.

**R**ecently, Wong and Naresh gave us the first case report of successful treatment of EIN using the etonogestrel subdermal implant. With so many other options available to treat EIN, some of which have been studied extensively, why should we take note of this study? First, the authors point out the risk of endometrial cancer development among patients with EIN, and they acknowledge the standard recommendation of hysterectomy in women with EIN who have finished childbearing and are appropriate candidates for a surgical approach. There is also concern about lower serum etonogestrel levels in obese patients. In this case, the patient (aged 36 with obesity) had been nonadherent with oral progestin therapy and stated that she would not adhere to daily oral therapy. She also declined hysterectomy, levonorgestrel-releasing intrauterine device therapy, and injectable progestin

therapy after being counseled about the risk of malignancy development. She consented to subdermal etonogestrel as an alternative to no therapy.

**EIN regressed.** Endometrial biopsies at 4 and 8 months showed regression of EIN, and at 16 months after implantation (as well as a dilation and curettage at 9 months) demonstrated an inactive endometrium with no sign of hyperplasia.

### FAST TRACK

*Although not appropriate for first-line therapy, the etonogestrel subdermal implant may be a reasonable option to manage EIN*

### WHAT THIS EVIDENCE MEANS FOR PRACTICE

The authors remain cautious about recommending the etonogestrel subdermal implant as a first-line therapy for EIN, but the implant was reported to be effective in this case that involved a patient with obesity. In cases in which surgery or other medical options for EIN are not feasible, the etonogestrel subdermal implant is reasonable to consider. Its routine use for EIN management warrants future study.

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## New endometrial ablation technology shows promising benefits

*Levie MD, Chudnoff SG. A prospective, multicenter, pivotal trial to evaluate the safety and effectiveness of the AEGEA vapor endometrial ablation system. J Minim Invasive Gynecol. 2019;26:679-687.*

**D**o we need another endometrial ablation device? Are there improvements that can be made to our existing technology? There already are several endometrial ablation devices, using varying technology, that currently are approved by the US Food and Drug Administration (FDA) for treatment of AUB. The devices use bipolar radiofrequency, cryotherapy, circulating hot fluid, and combined thermal and radiofrequency modalities. Additional devices, employing heated balloon and microwaves, are no longer used. Data on a new device, approved by the FDA in 2017 (the AEGEA Vapor System, called Mara), were recently published.

### Details of the study

Levie and colleagues conducted a prospective pivotal trial on Mara's safety and effectiveness. The benefits presented by the authors

include that the device 1) does not require that an intrauterine array be deployed up to and abutting the fundus and cornu, 2) does not necessitate cervical dilatation, 3) is a free-flowing vapor system that can navigate differences in uterine contour and sizes (up to 12 cm in length), and 4) accomplishes ablation in 2 minutes. So there are indeed some novel features of this device.

This pivotal study was a multicenter trial using objective performance criterion (OPC), which is based on using the average success rates across the 5 FDA-approved ablation devices as historic controls. In the study an OPC of 66% correlated to the lower bound of the 95% confidence intervals. The primary outcome of the study was effectiveness in the reduction of blood loss using a pictorial blood loss assessment score (PBLAS) of less than 75. Of note, a PBLAS of 150 was a study entry criterion. FIGO types 2 through 6 fibroids were included in the trial. Secondary endpoints were quality of life and patient satisfaction as assessed by the Menorrhagia Impact Questionnaire and the Aberdeen Menorrhagia Severity Score, as well as the need to intervene medically or surgically to treat AUB in the first 12 months after ablation.

### WHAT THIS EVIDENCE MEANS FOR PRACTICE

The takeaway is that the AEGEA device appears to be effective for endometrial ablation and offers the novel features of not relying on an intrauterine array to be deployed up to and abutting the fundus and cornu, not necessitating cervical dilatation in all cases, and offering a free-flowing vapor system that can navigate differences in uterine contour and sizes quickly (approximately 2 minutes).

The fact that new devices for endometrial ablation are still being developed is encouraging, and it suggests that endometrial ablation technology can be improved. Although AEGEA's Mara system is not yet commercially available, it is anticipated that it will be available at the start of 2020. The ability to treat large uteri (up to 12-cm cavities) with FIGO type 2 to 6 fibroids with less cervical dilatation makes the device attractive and perhaps well suited for office use.

### Efficacy, satisfaction, and quality of life results

At 12 months, the primary effectiveness endpoint was achieved in 78.7% of study participants. The satisfaction rate was 90.8% (satisfied or very satisfied), and 99% of participants showed improvement in quality of life scores. There were no reported serious adverse events. ●

#### Reference

1. Mollo A, Stile A, Alviggi C, et al. Endometrial polyps in infertile patients: do high concentrations of interferon-gamma play a role? *Fertil Steril*. 2011;96:1209-1212.



# The Affordable Care Act, closing in on a decade

ACOG continues to advocate for preexisting health care coverage protections and contraceptive coverage, despite setbacks to the ACA by the current Administration

Lucia DiVenere, MA

The Affordable Care Act (ACA) was enacted on March 23, 2010. Controversies, complaints, and detractors have and continue to abound. But the ACA's landmark women's health gains are unmistakable. Contraceptive coverage, maternity coverage, Medicaid coverage of low-income women, coverage for individuals with pre-existing conditions, and gender-neutral premiums are now a part of the fabric of our society. For most.

Many physicians and patients—many lawmakers, too—do not remember the serious problems people had with their insurance companies before the ACA. Maternity coverage was usually a free-standing rider to an insurance policy, making it very expensive. Insurance plans did not have to, and often did not, cover contraceptives, and none did without copays or deductibles. Women were routinely denied coverage if they had ever had a cesarean delivery, had once been the victim of domestic violence, or had any one of many common conditions, like diabetes. The many exclusionary conditions are so common, in fact, that one study estimated that around 52 million adults in the United

States (27% of those younger than age 65 years) have preexisting conditions that would potentially make them uninsurable without the ACA's protections.<sup>1</sup>

Before the ACA, it also was common for women with insurance policies to find their coverage rescinded, often with no explanation, even though they paid their premiums every month. And women with serious medical conditions often saw their coverage ended midway through their course of treatment. That placed their ObGyns in a terrible situation, too.

The insurance industry as a whole was running rough-shod over its customers, and making a lot of money by creatively and routinely denying coverage and payment for care. People were often insured, but not covered. The ACA halted many of these practices, and required insurers to meet high medical loss ratios, guaranteeing that 80% of the premiums' for individual and small market insurers (and 85% for large insurers) are returned to patients in care payments or even in checks. In fact, nearly \$4 billion in premiums have been rebated to insured individuals over the last 7 years under the ACA.<sup>2</sup>

The commitment of the American College of Obstetricians and Gynecologists (ACOG) to women's health and to our members' ability to provide the best care has centered on preserving the critical gains of the ACA for women, improving them when we can, and making sure politicians don't turn back the clock on women's health. We have been busy.



Ms. DiVenere is Officer, Government and Political Affairs, at the American College of Obstetricians and Gynecologists in Washington, DC. She is an OBG MANAGEMENT Contributing Editor.

The author reports no financial relationships relevant to this article.

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In this article, we will look at what has happened to these landmark gains and promises of improved women’s health, specifically preexisting condition protections and contraceptive coverage, under a new Administration. What happens when good health care policy and political enmity collide?

## **FAST TRACK**

*A judge declared the ACA unconstitutional in December 2018, although the decision has been limited in its practical effect so far*

### **Preexisting coverage protections**

The 1996 Health Insurance Portability and Accountability Act (HIPAA) defines a preexisting condition exclusion as a “limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date.” HIPAA prohibited employer-sponsored health plans from discriminating against individuals through denying them coverage or charging them more based on their or their family members’ health problems. The ACA expanded protections to prohibit the insurance practice of denying coverage altogether to an individual with a preexisting condition.<sup>3</sup>

### **Under Congress**

Republicans held the majority in both chambers of the 115th Congress (2017–2018), and

hoped to use their majority status to get an ACA repeal bill to the Republican President’s desk for speedy enactment. It was not easy, and they were not successful. Four major bills—the American Health Care Act, the Better Care Reconciliation Act, the Health Care Freedom Act, and the Graham-Cassidy Amendment—never made it over the finish line, with some not even making it to a vote. The Health Care Freedom Act was voted down in the Senate 51–49 when Senator John McCain came back from brain surgery to cast his famous thumbs-down vote.<sup>4</sup> These bills all would have repealed or hobbled guaranteed issue, community rating, and essential health benefits of the ACA. Of all the legislative attempts to undermine the ACA, only the 2017 Tax Cuts and Jobs Act (TCJA) was signed into law, repealing the ACA individual mandate.

### **Handling by the courts**

The TCJA gave ACA opponents their opening in court. Twenty Republican state attorneys general and governors brought suit in February 2018 (*Texas v Azar*), arguing that because the ACA relies on the mandate, and the mandate has been repealed, the rest of the ACA also should be struck down. A federal district judge agreed, on December 15, 2018, declaring the entire ACA unconstitutional.<sup>5</sup>

That decision has been limited in its practical effect so far, and maybe it was not altogether unexpected. What was unexpected was that the US Department of Justice (DOJ) refused to defend a federal law, in this case, the ACA. In June 2018, the DOJ declined to defend the individual mandate, as well as guaranteed issue, community rating, the ban on preexisting condition exclusions, and discrimination based on health status in the ACA. The DOJ at that time, however, did not agree with the plaintiffs that without the mandate the entire ACA should be struck down. It said, “There is no reason why the ACA’s particular expansion of Medicaid hinges on the individual mandate.” Later, after the December 15 ruling, the DOJ changed its position and agreed with the judge, in a two-sentence letter to the court, that the ACA should be stricken altogether—shortly after which 3

career DOJ attorneys resigned.<sup>6</sup>

A legal expert observed: “The DOJ’s decision not to defend the ACA breaks with the Department’s long-standing bipartisan commitment to defend federal laws if reasonable arguments can be made in their defense. Decisions not to defend federal law are exceedingly rare. It seems even rarer to change the government’s position mid-appeal in such a high-profile lawsuit that risks disrupting the entire health care system and health insurance coverage for millions of Americans.”<sup>7</sup>

### Regulatory tactics

What a policy maker cannot do by law, he or she can try to accomplish by regulation. The Administration is using 3 regulatory routes to undercut the ACA preexisting coverage protections and market stability.

**Route 1: Short-Term Limited Duration (STLD) plans.** These plans were created in the ACA to provide bridge coverage for up to 3 months for individuals in between health insurance plans. These plans do not have to comply with ACA patient protections, can deny coverage for preexisting conditions, and do not cover maternity care. In 2018, the Administration moved to allow these plans to be marketed broadly and renewed for up to 3 years. Because these plans provide less coverage and often come with high deductibles, they can be marketed with lower premiums, skimming off healthier younger people who do not expect to need much care, as well as lower-income families. This destabilizes the market and leaves people insured but not covered, exactly the situation before the ACA. Seven public health and medical groups sued to challenge the Administration’s STLD regulation; the lawsuit is presently pending.

**Route 2: Association Health Plans (AHPs).** The Administration also has allowed the sale of AHPs, marketed to small employers and self-employed individuals. These plans also do not have to comply with ACA consumer protections. They often do not cover maternity care or other essential benefits, and can charge women higher premiums for the same insurance. This regulation, too, resulted in litigation and a federal judge enjoined

the rule, but the case is now on appeal.

**Route 3: ACA Section 1332 waivers.** These waivers were created in the ACA to encourage state innovation to increase access to health coverage, under certain guardrails: states must ensure coverage is at least as comprehensive as the Essential Health Benefits; cost sharing protections must be at least as affordable as under the ACA; the plan must cover at least a comparable number of its residents; and the plan must not increase the federal deficit.

The Administration has come under fire for approving 1332 waiver plans that do not meet these guardrails, and allow insurers to exclude coverage for individuals with preexisting conditions, as well as skirt other important ACA patient protections. In response, Seema Verma, Administrator of the Centers for Medicare & Medicaid Services, promised as recently as April 23, that the Administration will not allow any weakening of the ACA preexisting coverage guarantee.<sup>8</sup> So far, however, we do not know what action this means, and not surprisingly, House Democrats, now in the majority, are waiting to see those assurances come true. Consistent polling shows that a large majority of Americans, across political parties, think preexisting coverage protections are very important.<sup>9</sup>

Already, the House passed HR986, to repeal the Administration’s changes to the 1332 waiver rules. The bill won only 4 Republican votes in the House and now waits a Senate vote.

The House is ready to vote on HR1010, which returns the STLD rules to the original ACA version. The Congressional Budget Office has determined that this bill will reduce the federal deficit by \$8.9 billion over 10 years, in part by reestablishing a large risk pool. Lower ACA premiums would mean lower federal subsidies and small federal outlays.

### Contraceptive coverage

Since 2012, the ACA has required non-grandfathered individual and group health plans to cover, with no copays or deductibles, women’s preventive services, as determined

## FAST TRACK

*The current Administration is using 3 regulatory routes to undercut the ACA’s preexisting coverage protections and market stability*

by the Health Resources and Services Administration (HRSA). HRSA asked the National Academy of Medicine (the Institute of Medicine [IOM] at the time) to develop these coverage guidelines based on clinical and scientific relevance. The IOM relied heavily on ACOG's testimony and women's health guidelines. The guidelines are updated every 5 years, based on extensive review by the Women's Preventive Services Initiative, led by ACOG. By law and regulation, covered services include:

- well-woman visits
- contraceptive methods and counseling, including all methods approved for women by the FDA
- breast and cervical cancer screening
- counseling for sexually transmitted infections
- counseling and screening for HIV
- screening for gestational diabetes
- breastfeeding support, supplies, and counseling
- screening and counseling for interpersonal and domestic violence.

The previous administration offered a narrow exemption—an accommodation—for churches, religious orders, and integrated auxiliaries (organizations with financial support primarily from churches). That accommodation was expanded in the Supreme Court's decision in *Hobby Lobby*, for closely held for-profit organizations that had religious objections to covering some or all contraceptives. Under the accommodation, the entity's insurer or third-party administrator was responsible for providing contraceptive services to the entity's plan participants and beneficiaries.

In October 2017, the Trump administration acted to greatly expand the ability of any employer, college or university, individual, or insurer to opt out of the ACA's contraceptive coverage requirement. You will read more about this later.

### **ACOG's business case for contraception**

Early in the Trump Administration, the White House released a statement saying,

"Ensuring affordable, accessible, and quality healthcare is critical to improving women's health and ensuring that it fits their priorities at any stage of life."<sup>10</sup> ACOG could not agree more, and we encouraged the President to accomplish this important goal by protecting the landmark women's health gains of the ACA. Our call to the President and the US Congress was: "Don't turn back the clock on women's health."

We made a business case for continued contraceptive coverage:

### **Contraception reduces unintended pregnancies and saves federal dollars.**

- Approximately 45% of US pregnancies are unintended.<sup>11</sup>
- No-copay coverage of contraception has contributed to a dramatic decline in the unintended pregnancy rate in the United States, now at a 30-year low.<sup>12</sup>
- When cost is not a barrier, women choose more effective forms of contraception, such as intrauterine devices and implants.<sup>13</sup>
- Unintended pregnancies cost approximately \$12.5 billion in government expenditures in 2008.<sup>14</sup>
- Private health plans spend as much as \$4.6 billion annually in costs related to unintended pregnancies.<sup>15</sup>

### **Contraception means healthier women and healthier families.**

- Under the ACA, the uninsured rate among women ages 18 to 64 almost halved, decreasing from 19.3% to 10.8%.<sup>16</sup>
- More than 55 million women gained access to preventive services, including contraception, without a copay or a deductible.<sup>16</sup>
- Women with unintended pregnancies are more likely to delay prenatal care. Infants are at greater risk of birth defects, low birth weight, and poor mental and physical functioning in early childhood.<sup>17</sup>

### **Increased access to contraception helps families and improves economic security.**

- Women saved \$1.4 billion in out-of-pocket costs for contraception in 1 year.<sup>18</sup>
- Before the ACA, women were spending between 30% and 44% of their total out-of-pocket health costs just on birth control.<sup>19</sup>
- The ability to plan a pregnancy increases

### **FAST TRACK**

*ACOG has argued for continued contraception coverage with evidence that contraception reduces unintended pregnancy, means healthier women and families, helps families build economic stability, and saves federal dollars*

engagement of women in the workforce and improves economic stability for women and their families.<sup>20</sup>

### **Administration expands religious exemptions to contraception coverage**

Still, on October 6, 2017, the Trump Administration moved to curtail women's access to and coverage of contraception with the Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act. In November 2018, the Administration published a revised rule, to take effect in January 2019.<sup>21</sup> The rule immediately was taken to court by more than a dozen states and, 1 month later, was subject to an injunction by the US Court of Appeals for the Ninth Circuit, blocking the rules from going into effect in those states.

The rule vastly expands the Obama Administration's religious accommodation to include "nonprofit organizations, small businesses, and individuals that have nonreligious moral convictions opposing services covered by the contraceptive mandate." The covered entities include<sup>21</sup>:

- churches, integrated auxiliaries, and religious orders with religious objections
- nonprofit organizations with religious or moral objections
- for-profit entities that are not publicly traded, with religious or moral objections
- for-profit entities that are publicly traded, with religious objections
- other nongovernmental employers with religious objections
- nongovernmental institutions of higher education with religious or moral objections
- individuals with religious or moral objections, with employer sponsored or individual market coverage, where the plan sponsor and/or issuer (as applicable) are willing to offer them a plan omitting contraceptive coverage to which they object
- issuers with religious or moral objections,

to the extent they provide coverage to a plan sponsor or individual that is also exempt.

The Administration says women losing coverage can get contraceptives through Title X clinics or other government programs. Of course, many women losing coverage are employed, and earn above the low income (100% of the federal poverty level) eligibility requirement for Title X assistance. To address that, the Administration, through its proposed Title X regulations, broadens the definition of "low income" in that program to include women who lose their contraceptive coverage through the employer-base health insurance plan. This move further limits the ability of the Title X program to adequately care for already-qualified individuals.

The Administration's rule also relied on major inaccuracies, which ACOG corrected.<sup>22</sup> First, ACOG pointed out that, in fact, FDA-approved contraceptive methods are not abortifacients, countering the Administration's contention that contraception is an abortifacient, and that contraceptives cause abortions or miscarriages. Every FDA-approved contraceptive acts before implantation, does not interfere with a pregnancy, and is not effective after a fertilized egg has implanted successfully in the uterus.<sup>23</sup> No credible research supports the false statement that birth control causes miscarriages.<sup>24</sup>

Second, ACOG offered data proving that increased access to contraception is not associated with increased unsafe sexual behavior or increased sexual activity.<sup>25,26</sup> The facts are that:

- The percentage of teens who are having sex has declined significantly, by 14% for female and 22% for male teenagers, over the past 25 years.<sup>27</sup>
- More women are using contraception the first time they have sex. Young women who do not use birth control at first sexual intercourse are twice as likely to become teen mothers.<sup>28</sup>
- Increased access to and use of contraception has contributed to a dramatic decline in rates of adolescent pregnancy.<sup>29</sup>
- School-based health centers that provide access to contraceptives are proven to

### **FAST TRACK**

*In November 2018, the Administration published a rule to vastly expand religious and moral exemptions to the ACA's contraceptive mandate*

increase use of contraceptives by already sexually active students, not to increase onset of sexual activity.<sup>30,31</sup>

Third, ACOG made clear the benefits to women's health from contraception. ACOG asserted: As with any medication, certain types of contraception may be contraindicated for patients with certain medical conditions, including high blood pressure, lupus, or a history of breast cancer.<sup>32,33</sup> For these and many other reasons, access to the full range of FDA-approved contraception, with no cost sharing or other barriers, is critical to women's health. Regarding VTE, the risk among oral contraceptive users is very low. In fact, it is much lower than the risk of VTE during pregnancy or in the immediate postpartum period.<sup>34</sup>

Regarding breast cancer: there is no proven increased risk of breast cancer among contraceptive users, particularly among those younger than age 40. For women older than 40, health care providers must consider both the risks of becoming pregnant at advanced reproductive age and the risks of continuing contraception use until menopause.<sup>35</sup>

### ACOG has 2 clear messages for politicians

ACOG has remained steadfast in its opposition to the Administration's proposals to block access to contraception. ACOG expressed its strong opposition to political interference in medical care, saying "Every woman, regardless of her insurer, employer, state of residence, or income, should have affordable, seamless access to the right form of contraception for her, free from interference from her employer or politicians."<sup>22</sup>

ACOG's voice has been joined by 5 other major medical associations—American Academy of Family Physicians, American Academy of Pediatrics, American Psychiatric Association, American Academy of Pediatrics, and American Osteopathic Association—together representing more than 560,000 physicians and medical students, in urging the Administration to immediately withdraw its proposals. This broad coalition unequivocally stated<sup>36</sup>:

Contraception is an integral part of preventive care and a medical necessity for women during approximately 30 years of their lives. Access to no-copay contraception leads to healthier women and families. Changes to our healthcare system come with very high stakes – impacting tens of millions of our patients. Access to contraception allows women to achieve, lead and reach their full potentials, becoming key drivers of our Nation's economic success. These rules would create a new standard whereby employers can deny their employees coverage, based on their own moral objections. This interferes in the personal health care decisions of our patients, and inappropriately inserts a patient's employer into the physician-patient relationship. In addition, these rules open the door to moral exemptions for other essential health care, including vaccinations.

These are challenging days for women's health policy and legislation federally, and in many states. ACOG has two clear messages for politicians: Don't turn back the clock on women's health, and stay out of our exam rooms. ●

## FAST TRACK

ACOG tells politicians: "Don't turn back the clock on women's health," and "Stay out of our exam rooms."

### References

1. Claxton G, Cox C, Damico A, et al. Pre-existing conditions and medical underwriting in the individual insurance market prior to the ACA. Kaiser Family Foundation website. <https://www.kff.org/health-reform/issue-brief/pre-existing-conditions-and-medical-underwriting-in-the-individual-insurance-market-prior-to-the-aca>. Published December 12, 2016. Accessed June 25, 2019.
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CONTINUED ON PAGE 34

2019

# PAGS PELVIC ANATOMY and GYNECOLOGIC SURGERY SYMPOSIUM

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OPTIONAL HANDS-ON WORKSHOPS  
December 11, 2019

**OPTIONAL HANDS-ON WORKSHOPS**

Limited Space Available. First come. First served!

- Energy-Based Devices for Hysterectomy and Tissue Extraction Techniques **NEW!**
- Laparoscopic Suturing
- Technical Aspects of Vaginal Hysterectomy & Cystourethroscopy for the Gynecologist
- Office-Based Gynecologic Procedures

**SCIENTIFIC SESSION TOPICS INCLUDE:**

- Hysterectomy Techniques
- Incontinence and Prolapse Surgery
- Avoiding and Managing Complications
- Gynecologic Oncology for the Generalist
- Medical Legal Cases
- Enhanced Recovery after Surgery
- Benign Gynecology
- Is there any Role for Vaginal Mesh?
- Surgical Tips for Successful Pelvic Surgery Video Session

**PLUS, SPECIAL KEYNOTES**

- The Evolution of Surgical Procedures Used to Correct Pelvic Organ Prolapse
- Techniques to Preserve Level 1 Support at the Time of Vaginal Laparoscopic and Robotic Hysterectomy

**AND,** Optional Post-Conference P.E.P. Practice Management Workshop



**COURSE CHAIRS**

**Tommaso Falcone, MD**  
Cleveland Clinic London

**Mickey M. Karram, MD**  
The Christ Hospital

**SPECIAL KEYNOTE SPEAKER**

**Mark D. Walters, MD**  
Cleveland Clinic

**Faculty**

**Sawsan As-Sanie, MD, MPH**  
University of Michigan

**Amanda Nickles Fader, MD**  
Johns Hopkins Hospital

**Michael S. Baggish, MD**  
St. Helena Hospital

**John B. Gebhart, MD, MS**  
Mayo Clinic

**Linda D. Bradley, MD**  
Cleveland Clinic

**Rosanne M. Kho, MD**  
Cleveland Clinic

**Andrew I. Brill, MD**  
California Pacific Medical Center

**Javier F. Magrina, MD**  
Mayo Clinic Phoenix

**Beri M. Ridgeway, MD**  
Cleveland Clinic

For complete information and to register please see our website: [PAGS-cme.org](http://PAGS-cme.org).

## WEDNESDAY, DECEMBER 11, 2019

### PRE-CONFERENCE WORKSHOPS

(Optional, Separate fee required)

**WORKSHOP A** 8:30 AM – 12:30 PM

**Energy-Based Devices for Hysterectomy and Tissue Extraction Techniques NEW!**

Led by: **Rosanne M. Kho, MD**  
4 CME Credits Available

**WORKSHOP B** 8:30 AM – 12:30 PM

**Hands-On Laparoscopic Suturing - The "Vertical Zone" (Simulation Lab)**

Led by: **Charles H. Koh, MD**  
4 CME Credits Available

**WORKSHOP C** 8:30 AM – 5:30 PM

**Office-Based Gynecologic Procedures**

All day workshop (Includes a morning lecture series and afternoon practicum.)

Led by: **Tommaso Falcone, MD**  
8 CME Credits Available

**WORKSHOP D** 1:30 PM – 5:30 PM

**Technical Aspects of Vaginal Hysterectomy & Cystourethroscopy for the Gynecologist**

Led by: **Mickey M. Karram, MD**  
4 CME Credits Available

### GENERAL SCIENTIFIC SESSIONS

## THURSDAY, DECEMBER 12, 2019

6:45 AM **Registration/Breakfast/Exhibits**

7:50 AM **Course Overview**  
**Mickey M. Karram, MD**

### PELVIC ANATOMY

8:00 AM **Pelvic and Abdominal Anatomy from the Laparoscopic Surgeon's View**  
**Tommaso Falcone, MD**

8:40 AM **Anatomic Considerations: Facilitating Vaginal Procedures Safely and Effectively**  
**Mickey M. Karram, MD**

### INCONTINENCE AND PROLAPSE SURGERY

9:10 AM **Panel Discussion: Evaluation and Non-Surgical Management of Female Pelvic Floor Disorders: What Every Generalist Should Know**  
**John B. Gebhart, MD, MS**  
**Mickey M. Karram, MD**  
**Beri M. Ridgeway, MD**

9:55 AM **Question and Answer Session**

10:25 AM **Break/Exhibits**

11:25 AM **Surgery for Stress Incontinence and the Future of Synthetic Slings**  
**Beri M. Ridgeway, MD**

12:05 PM **Surgery for Pelvic Organ Prolapse: Do We Need to Perform and Teach More Transvaginal Native Tissue Suture Repairs?**  
**John B. Gebhart, MD, MS**

12:25 PM **Mesh-Augmented Prolapse Repair: Is There Any Role for Vaginal Mesh: Indication and Technique of Sacral Colpopexy**  
**Beri M. Ridgeway, MD**

12:55 PM **Question and Answer Session**

1:10 PM **Lunch**

1:25 PM **Luncheon Symposium**

2:10 PM **Dessert Break/ Exhibits**

### THURSDAY'S KEYNOTE LECTURE

2:40 PM **The Evolution of Surgical Procedures Used to Correct Pelvic Organ Prolapse**  
**Mark D. Walters, MD**

### BENIGN GYNECOLOGY

3:25 PM **Safe Use of Energy-Based Devices for Gynecologic Surgery**  
**Andrew I. Brill, MD**

3:55 PM **Management of Endometriosis**  
**Tommaso Falcone, MD**

4:40 PM **The Hysteroscopic Treatment of Submucosal Fibroids and Polyps**  
**Linda D. Bradley, MD**

5:10 PM **Question and Answer Session**

## FRIDAY, DECEMBER 13, 2019

6:45 AM **Breakfast/Exhibits**

7:10 AM **Breakfast Symposium**

### HYSTERECTOMY - TECHNIQUE

8:15 AM **The Difficult Vaginal Hysterectomy**  
**Rosanne M. Kho, MD**

8:45 AM **When is it Appropriate to Remove Ovaries at Hysterectomy?**  
**Amanda Nickles Fader, MD**

9:15 AM **Total Laparoscopic Hysterectomy**  
**Andrew I. Brill, MD**

9:45 AM **Break /Exhibits**

10:30 AM **Robotic Hysterectomy**  
**Javier F. Magrina, MD**

11:00 AM **Tissue Extraction Techniques (Morcellation)**  
**Sawsan As-Sanie, MD, MPH**

11:30 AM **Uterine Preserving Procedures in Patients with Pelvic Organ Prolapse**  
**Mickey M. Karram, MD**  
**Beri M. Ridgeway, MD**

12:00 PM **Enhanced Recovery after Surgery**  
**Sawsan As-Sanie, MD, MPH**

12:30 PM **Question and Answer Session**

1:00 PM **Lunch**

1:15 PM **Luncheon Symposium**

2:00 PM **Dessert Break/Exhibits**

### FRIDAY'S KEYNOTE LECTURE

2:30 PM **Techniques to Preserve Level 1 Support at the Time of Vaginal Laparoscopic and Robotic Hysterectomy**  
**Mark D. Walters, MD**

### ONCOLOGY FOR THE GENERALIST

3:15 PM **Surgical Management of Pre-Cancer Vulvovaginal Lesions**  
**Amanda Nickles Fader, MD**

4:00 PM **Laparoscopic and Robotic Management of the Adnexal Mass**  
**Javier F. Magrina, MD**

4:45 PM **Spectrum of Vulvovaginal Disorders**  
**Michael S. Baggish, MD**

5:30 PM **Question and Answer Session**

## SATURDAY, DECEMBER 14, 2019

6:30 AM **Breakfast**

7:30 AM **Myomectomy: Open to Robotic Approaches**  
**Tommaso Falcone, MD**

8:30 AM **Avoiding and Managing Urogynecologic Complications**  
**John B. Gebhart, MD, MS**  
**Mickey M. Karram, MD**

9:30 AM **Avoiding and Managing Laparoscopic Complications**  
**Tommaso Falcone, MD**

10:30 AM **Break**

10:45 AM **Interesting Case Presentations in Medical Legal**  
**Michael S. Baggish, MD**  
**Tommaso Falcone, MD**

11:30 AM **Surgical Tips for Successful Pelvic Surgery: Video Session**  
**Surgical Management of Cornual Ectopic & Dermoid Cysts**  
**Tommaso Falcone, MD**

**Techniques to Suspend the Apex at the Time of Vaginal Surgery**  
**Mickey M. Karram, MD**

1:00 PM **Question and Answer Session**

1:15 PM **PAGS Scientific Program Adjournment**

## P.E.P. PRACTICE ENHANCEMENT PROGRAM AGENDA (Optional)

Open to Non-Attendees  
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### Director

**Neil H. Baum, MD**

Former Associate Clinical Professor of Urology  
Tulane Medical School and Louisiana State University  
New Orleans, Louisiana

Dr. Neil Baum is the author of *The Complete Business Guide to a Successful Medical Practice and 3-Stages of a Physician's Career*

## SATURDAY, DECEMBER 14, 2019 Encore at Wynn Las Vegas

2:00 PM **Course Overview**

2:10 PM • The 4 Pillars of a Successful Practice  
• How to Improve the Efficiency, Productivity, and Profitability of Your Practice  
• Online Reputation Management  
• Why Market and Promote Your ObGyn Practice

3:30 PM **Break**

3:45 PM • Using Social Media to Get to the Top of Google • Numbers You Need to Know  
• Moving from Volume to Value

5:00 PM **Q and A**

5:30 PM **P.E.P. Adjournment**



# PAGS Scientific Faculty

## Course Chairs



### Tommaso Falcone, MD

Chief of Staff  
Chief Academic Officer  
Medical Director  
Cleveland Clinic London  
Professor of Surgery  
Cleveland Clinic Lerner College of Medicine  
London, UK



### Mickey M. Karram, MD

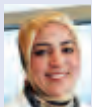
Director of Urogynecology  
The Christ Hospital  
Volunteer Professor of Ob/Gyn  
University of Cincinnati  
Cincinnati, Ohio

## Special Keynote Speaker



### Mark D. Walters, MD

Professor and Vice-Chair of Gynecology  
Department of Obstetrics and Gynecology  
Cleveland Clinic  
Cleveland, Ohio



## Faculty

### Sawsan As-Sanie, MD, MPH

Director  
Minimally Invasive Gyn Surgery and Chronic Pelvic Pain  
University of Michigan  
Ann Arbor, Michigan



### Michael S. Baggish, MD

Professor of Obstetrics and Gynecology  
University of California San Francisco  
St. Helena, California



### Linda D. Bradley, MD

Vice Chair  
Obstetrics, Gynecology, and Women's Health Institute  
Director  
Center for Menstrual Disorders  
Professor of Surgery  
Cleveland Clinic  
Cleveland, Ohio



### Andrew I. Brill, MD

Director  
Minimally Invasive Gynecology & Surgical Education  
California Pacific Medical Center  
San Francisco, California



### Amanda Nickles Fader, MD

Associate Professor and Director  
Kelly Gynecologic Oncology Service  
Director of Minimally Invasive Surgery  
Department of Gynecology/Obstetrics  
Johns Hopkins Hospital  
Baltimore, Maryland



### John B. Gebhart, MD, MS

Professor  
Obstetrics and Gynecology  
Mayo Clinic  
Rochester, Minnesota



### Rosanne M. Kho, MD

Head, Section Benign Gynecology  
Director  
Benign Gyn Surgery  
Women's Health Institute  
Cleveland Clinic  
Cleveland, Ohio



### Javier F. Magrina, MD

Professor of Obstetrics and Gynecology  
Barbara Woodward Lips Professor  
Mayo Clinic  
Phoenix, Arizona



### Beri M. Ridgeway, MD

Department Chair, Regional Ob/Gyn  
Cleveland Clinic  
Assistant Professor  
Cleveland Clinic Lerner College of Medicine  
Cleveland, Ohio

## Optional Workshops

For complete information please see [PAGS-CME.org](http://PAGS-CME.org).

Wednesday, December 11, 2019, Encore at Wynn Las Vegas

### Optional Hands-on Workshops

*PAGS hands-on workshops have limited space available and will sell out. First come. First served!*

**(See PAGS website for complete workshop details.)**

#### WORKSHOP A

### ENERGY-BASED DEVICES FOR HYSTERECTOMY AND TISSUE EXTRACTION TECHNIQUES NEW!

4 CME Credits Available

8:30 AM - 12:30 PM

Led by: Rosanne M. Kho, MD

Faculty: Andrew I. Brill, MD;  
Keith B. Isaacson, MD



#### WORKSHOP B

### HANDS-ON LAPAROSCOPIC SUTURING - THE "VERTICAL ZONE" (SIMULATION LAB)

4 CME Credits Available

8:30 AM - 12:30 PM

Led by: Charles H. Koh, MD



#### WORKSHOP C

### OFFICE-BASED GYNECOLOGIC PROCEDURES: THE GYNECOLOGIST OF THE FUTURE

FULL-DAY WORKSHOP

8 CME Credits Available

8:30 AM - 5:30 PM

Includes a morning lecture series and afternoon practicum on vulvar/vaginal injections and excisions, ultrasound and hysteroscopy



Led by: Tommaso Falcone, MD

Faculty: Andrew Brill, MD;  
Linda D. Bradley, MD; Mark Dassel, MD;  
Jeffrey R. Dell, MD; Laura Detti, MD;  
Oluwatosin Goje, MD; Keith Isaacson, MD;  
Mickey Karram, MD; James M. Shwayder, MD, JD

#### WORKSHOP D

### TECHNICAL ASPECTS OF VAGINAL HYSTERECTOMY & CYSTOURETHROSCOPY FOR THE GYNECOLOGIST

4 CME Credits Available

1:30 PM - 5:30 PM

Led by: Mickey M. Karram, MD

Faculty: Rosanne M. Kho, MD; Doug Miyazaki, MD

## Who Should Attend?

The PAGS conference is designed for obstetricians/gynecologists, second, third and fourth-year residents in Ob/Gyn, as well as sub-specialty fellows and advanced practice clinicians. Residents and advanced practice health clinicians are welcome at reduced rates.

### ACCREDITATION

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the University of Cincinnati and Global Academy for Medical Education, LLC. The University of Cincinnati is accredited by the ACCME to provide continuing medical education for physicians.

The University of Cincinnati designates this Live Activity for 20 *AMA PRA Category 1 credits™* for the conference and (1) 8-hour pre-conference workshops at 8.0 *AMA PRA Category 1 credits™*, (3) 4-hour pre-conference hands-on workshops at 4.0 *AMA PRA Category 1 credits™* each and (1) post workshop at 3.25 *AMA PRA Category 1 credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

2019

# PAGS PELVIC ANATOMY and GYNECOLOGIC SURGERY SYMPOSIUM

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"Continue with what you do and that is provide 2 1/2 days of excellent information to the average practicing Ob/Gyn."

"This is a fantastic conference year after year! I have travelled from Australia on three occasions to attend."

### Optional HANDS-ON WORKSHOPS

8 CME Credits Available

December 11, 2019

### SCIENTIFIC SESSIONS

20 CME Credits Available

December 12-14, 2019

### Optional "P.E.P." PRACTICE MANAGEMENT PROGRAM

3.25 CME Credits Available

December 14, 2019

### About Our Venue

#### Encore at Wynn Las Vegas

The 2019 Pelvic Anatomy and Gynecologic Surgery Symposium (PAGS) will take place at the Encore Wynn Las Vegas where we have arranged for a discount room rate of **just \$179\* a night for PAGS participants**. To make your reservation, please call (866) 770-7555. You must identify yourself as a Pelvic Anatomy and Gynecologic Surgery Symposium 2019 attendee or reference the block code: 6PAG1219 to receive the discounted rate.



**Discount room rate expires November 12, but we urge you to make your arrangements as soon as possible as our room block will sell out.**

\*Plus \$25 amenity fee

### How to Register for PAGS

Online: [www.PAGS-CME.org](http://www.PAGS-CME.org)

Inquiries: [PAGS@globalacademycme.com](mailto:PAGS@globalacademycme.com)

	Until Aug 2	Aug 3 - Sept 9	Sept 10 - Nov 8	After Nov 8
<b>PAGS Scientific Program</b>				
■ Physicians	\$775	\$795	\$895	\$995
■ Residents, Fellows, Allied Health	\$695	\$750	\$750	\$795
■ P.E.P. Program only Also open to non-attendees	\$575	\$595	\$695	\$495
■ <b>Best Buy!</b> PAGS + P.E.P. Discount Combination Package	\$975	\$995	\$1,195	\$1,395
■ <b>Office-Based Gynecologic Procedures: The Gynecologist of the Future All Day Workshop</b>	\$395	\$445	\$495	\$545
■ <b>Laparoscopic Suturing Morning Workshop</b>	\$225	\$245	\$275	\$345
■ <b>Energy-Based Devices for Hysterectomy and Tissue Extraction Techniques</b>	\$225	\$245	\$275	\$345
■ <b>Vaginal Hysterectomy &amp; Cystourethroscopy Afternoon Workshop</b>	\$295	\$325	\$350	\$395

**Cancellation Policy:** Full refund less a \$50 administrative fee as follows: Cancellations can be made using our online registration system until November 12, 2019. After November 12, 2019 no refunds will be granted. After the refund date, you have two options: you can send someone in your place, or we can mark a credit in the amount you paid minus \$50 administration fee, (plus additional \$35 administration fee per workshop) to be applied to your registration for next year's conference. Refunds will not be issued to no-shows.

To register and for complete information please see our website: [PAGS-cme.org](http://PAGS-cme.org).

**BREAK THIS PRACTICE HABIT**

# Feasibility—and safety—of reducing the traditional 14 prenatal visits to 8 or 10

The time has come to reconsider the number of in-office prenatal care visits needed for the woman at low risk. Technology-based communication and remote monitoring offer advantages for the patient and clinician.

**Erin Clark, MD; Yvonne Butler Tobah, MD; and Lauren D. Demosthenes, MD**

**CASE Low-risk maternity patient wants fewer prenatal visits**

A recently pregnant patient asks her obstetrician if she can schedule fewer prenatal visits given that she is at low risk, wants to minimize missing work, and lives an hour away from the clinic office. Her physician tells her that she needs the standard 13 to 15 visits to have a healthy pregnancy.



Dr. Clark is Associate Professor of Obstetrics and Gynecology and Chief of the Division of Maternal-Fetal Medicine, University of Utah Health Sciences Center, Salt Lake City.



Dr. Butler Tobah is an obstetrician-gynecologist at Mayo Clinic and an Instructor at Mayo Clinic Alix School of Medicine, Rochester, Minnesota.



Dr. Demosthenes is Medical Director, High Value Care and Innovation, Department of Obstetrics and Gynecology, Prisma Health Upstate, Greenville, South Carolina.

*The authors report no financial relationships relevant to this article.*

Obstetric care in the United States largely remains a “one-size fits all” approach despite compelling data that fewer visits for low-risk women are medically acceptable and may be more cost-effective.

## **Prenatal care: One size does not fit all**

With nearly 4 million births annually in the United States, prenatal care is one of the most widely used preventive health care strategies.<sup>1,2</sup> The ideal method for providing prenatal care, however, remains controversial. At the inception of early 20th century prenatal care in the United States, preventive strategies focused in part on eclampsia-related maternal morbidity and mortality, which in turn informed the content and frequency of prenatal visits.<sup>2</sup> Despite the dramatic changes in medical practice over the last 100 years, the basic timing and quantity of prenatal care has not changed substantively.

The lack of change is not because we have not explored other models of prenatal care and sought to introduce evidence-based change. Several studies have assessed the impact of reduced prenatal care visits for low-risk women.<sup>3-7</sup> Systematic reviews

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evaluated 7 randomized trials, with more than 60,000 women enrolled, of prenatal care models with a reduced number of planned antenatal visits (4 to 9 visits vs the traditional 13 to 15 visits).<sup>3,8</sup> There were no demonstrable differences in maternal or perinatal morbidity or mortality, particularly in higher resource settings.

Despite strong safety data and the potential cost-effectiveness of a reduced schedule of prenatal visits, US prenatal care practices generally continue to have a one-size-fits-all approach. Several organizations, however, have called for a change in practice.

Endorsing a reduced number of prenatal visits for low-risk women, the US Department of Health and Human Services Expert Panel on Prenatal Care issued a report in 1989 that stated “the specific content and timing of prenatal visits, contacts, and education should vary depending on the risk status of the pregnant woman and her fetus.”<sup>9</sup> Consistent with that recommendation, the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists (ACOG) jointly published guidelines that recommend a system of goal-oriented antenatal visits at specific gestational ages and that support a reduced schedule of prenatal visits, compared with traditional models, for low-risk, parous women.<sup>10</sup> The World Health Organization also published recommendations for an 8 “contact” prenatal care system to reduce perinatal mortality and improve women’s prenatal experience.<sup>11</sup>

### Is obstetric dogma the reason for lack of change?

Concerns about patient satisfaction may play a role in limiting the use of a reduced prenatal care visit model. In trials that evaluated a model of reduced prenatal care visits, women were less satisfied with a reduced visit schedule and the gap between provider contacts.<sup>3,8</sup> Anecdotally, providers have expressed concerns about perceived liability. Most compelling, perhaps, is the idea that the traditional prenatal schedule has become obstetric dogma.

Consciously or unconsciously, clinicians may feel uncomfortable diverging from a schedule of visits that is firmly entrenched in obstetric practice. Continuing the status quo is easier than restructuring prenatal care practice. Ultimately, a paradigm shift may be required to broadly adopt a model of fewer prenatal visits for low-risk pregnancies.<sup>12</sup> With these issues propelling the historic patterns of prenatal care, it is easy to see why we have not yet changed despite convincing reasons to do so.

In this article, we detail the reduced-visit prenatal care models developed at 3 institutions and how they incorporate use of today’s technology.

#### Approach #1: University of Utah Virtual Prenatal Care Program

The University of Utah Virtual Prenatal Care Program was conceived as a “baby step” toward developing a model of fewer total prenatal visits. Virtual visits were intended to reduce the number of prenatal face-to-face visits while maintaining the same total number of visits. Since large clinical trials had established the safety of reduced visits, the primary objectives were to retain patient satisfaction and to facilitate provider adoption.

**Would women be satisfied with remote prenatal care?** A prospective randomized controlled trial was designed in which 200 women were assigned to receive either a combination of telemedicine and 5 scheduled in-clinic prenatal visits (remote care group) or traditional in-clinic prenatal care (usual care group). Low-risk multigravida pregnant

### FAST TRACK

*The Virtual Prenatal Care Program included virtual prenatal visits intended to reduce the number of face-to-face visits while maintaining the same total number of visits*

## Instant Poll

Do you agree that the number of prenatal care visits for low-risk women should be reduced?

- Yes
- No

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women who were between 6 0/7 and 16 0/7 weeks' gestation were enrolled. The primary outcome was patient satisfaction.

The face-to-face visits were goal oriented, with scheduled physical examination, laboratory tests, or ultrasonography, and were conducted by the patient's established obstetric provider (physician or nurse midwife) to maintain continuity of care. The remote care group self-collected measurements for weight, blood pressure, and fetal heart rate by handheld Doppler device prior to each telemedicine visit and entered the information into the electronic medical record. The purpose of the self-collected data was patient engagement and satisfaction, as well as increased provider comfort with the change in prenatal care schedule, rather than medical necessity.

The primary outcome of overall patient satisfaction with prenatal care was ascertained by questionnaire after delivery. The sample size calculation of 200 patients was based on noninferiority testing, and analysis was by intent-to-treat. The details of the trial are pending publication.

As expected, the remote care group had significantly fewer in-clinic prenatal care visits compared with the usual care group (7.2 vs 11.3 visits); the total number of prenatal visits was not different between groups. Overall satisfaction with prenatal care was very high in both the remote care and the usual care group (100% vs 97%).

The virtual prenatal care model for low-risk pregnancies, consisting of a novel remote monitoring strategy and a reduced number of in-clinic visits, was not associated with lower patient satisfaction compared with traditional care.

**New care strategy gives patients a choice.** The success of this clinical trial has led to its programmatic adoption at the University of Utah, and low-risk women currently are offered a choice between participating in the Virtual Prenatal Care Program or receiving traditional prenatal care. The University of Utah is moving on from the one-size-fits-all approach to adopt new strategies that provide personalized evidence-based prenatal

care at the lowest cost, while retaining high patient satisfaction. Formal cost-effectiveness analyses are underway.

## Approach #2: Mayo Clinic OB Nest

In 2011, the Mayo Clinic Obstetric Division partnered with 2 other Mayo Clinic divisions, the Center for Innovation and the Center for the Science of Health Care Delivery, to redesign prenatal care for low-risk expectant mothers. Pregnant women and their obstetric health care teams (including obstetricians, certified nurse midwives, registered nurses, and clinical support staff) were convened to develop a novel model of prenatal care.<sup>4</sup> The goal of this collaboration centered on:

- creating an evidence-driven prenatal care model for low-risk expectant women designed by relevant stakeholders
- focusing on meeting the on-demand needs of expectant mothers
- integrating innovative 21st century technology, and
- reducing the burden of prescheduled, low-value office visits.

**Exploratory efforts to develop a novel care program.** Based on feedback from the collaboration and guided by these goals, 141 expectant mothers participated in 19 different experiments, enabling the health care team to understand the impact of changing various components of prenatal care.

The experiments included integration of home monitoring (home fetal Doppler devices, drop-in fetal Doppler stations, home blood pressure monitoring devices), technology-enhanced communication with obstetric team members (video chats, tummy photos, virtual prenatal clinic appointments, proactive calls), and social media engagement (secure online prenatal care community).

Recommendations for the final components of OB Nest were based on feasibility and the potential impact on care. The recommendations included decreasing scheduled clinic appointments from 14 to 8, providing home monitoring devices to measure maternal blood pressure and fetal heart rate, establishing OB Nest virtual connected care visits

## FAST TRACK

*OB Nest's program includes 8 clinic appointments, 6 virtual visits with a nurse, home monitoring of blood pressure and fetal heart rate, and access to a designated online prenatal care community*

with a registered nurse, and offering a secure online community of expectant mothers.

**Trial assessed program’s efficacy, safety, satisfaction.** A mixed-methods randomized controlled trial subsequently was conducted to evaluate the components of OB Nest.<sup>6</sup> The trial included 300 pregnant women who were randomly assigned to standard prenatal care as recommended by ACOG or to OB Nest care.

OB Nest care consisted of 8 scheduled clinic appointments, 6 planned virtual (phone or online) connected care visits with a registered nurse dedicated to OB Nest, home monitoring of blood pressure (with a home digital sphygmomanometer) and fetal heart rate, and access to an online prenatal care community designated for OB Nest participants.

While publication of the trial results currently is pending, the OB Nest program appears to safely and effectively decrease the number of scheduled prenatal care visits for low-risk expectant mothers while improving the overall patient experience. OB Nest care now is offered as one of several options for low-risk expectant mothers at Mayo Clinic.

**Additional avenues of study.** Studies evaluating the impact of OB Nest in various non-academic settings are now underway. Also under review is the potential cost savings of OB Nest as related to the productive lives of expectant mothers, while prenatal care safety is maintained.

The focus shift from a sick to a wellness perspective, stakeholder inclusion in the program design, and the integration of home monitoring tools are all major contributing factors to the success of OB Nest.

**Approach #3: Prisma Health utilizes mobile app technology**

A third approach to reducing unnecessary visits for routine maternity care is to employ mobile app technology. Technology companies have developed app platforms for providers to use to educate and connect with patients; such apps reduce the number of routine obstetric office visits while maintaining patient satisfaction.

**One group’s app experience.** In a pilot

study at a Prisma Health practice (South Carolina), 100 patients were placed on a reduced appointment schedule of 9 prenatal visits; the women self-monitored their weight gain and blood pressure using a remote monitoring system via an app called Babyscripts.<sup>7</sup> Patient feedback was collected, with 45 of 100 patients responding.

Ninety-five percent of patients were satisfied with the mobile app, 94% reported positivity around pregnancy readiness, 90% were satisfied with their health care team, and 89% were happy with remote monitoring. Patients visited the app 3 times per week on average, and the top categories of interest were travel, exercise, genetics, and eating right.

One patient using the Babyscripts mobile health app and schedule optimization platform commented, “I am on my second pregnancy and wish this had been available for the first! The app is easy to use and I love seeing my weight on a graph. And I very much like the quality of the cuff” (personal data generated from Babyscripts).

**In with the new**

As clinicians strive to provide more patient-centered care, offering expectant families more than one way to receive their prenatal care is appropriate. Beyond the traditional 14-visit care model, we should offer use of novel options like mobile health apps, which improve the patient experience while decreasing the cost of care by reducing unnecessary visits.<sup>12</sup> Note also that reducing visits for low-risk mothers opens space in the provider schedule for patients who need services more quickly.

**Benefits for postpartum care.** Traditionally, clinicians see the low-risk patient for a single follow-up appointment at 6 weeks postpartum. However, the World Health Organization recommends evaluating women at 3 days, 1 to 2 weeks, and 6 weeks postpartum.<sup>13</sup> Further, the National Institute for Health and Care Excellence guidance recommends screening all women for resolution of postpartum blues at 10 to 14 days.<sup>14</sup>

ACOG also has made recommendations

CONTINUED ON PAGE 46

**FAST TRACK**

*Of Prisma Health patients using the Babyscripts mobile app, 95% were satisfied with the app, 94% reported positivity around pregnancy readiness, 90% were satisfied with their health care team, and 89% were happy with remote monitoring*

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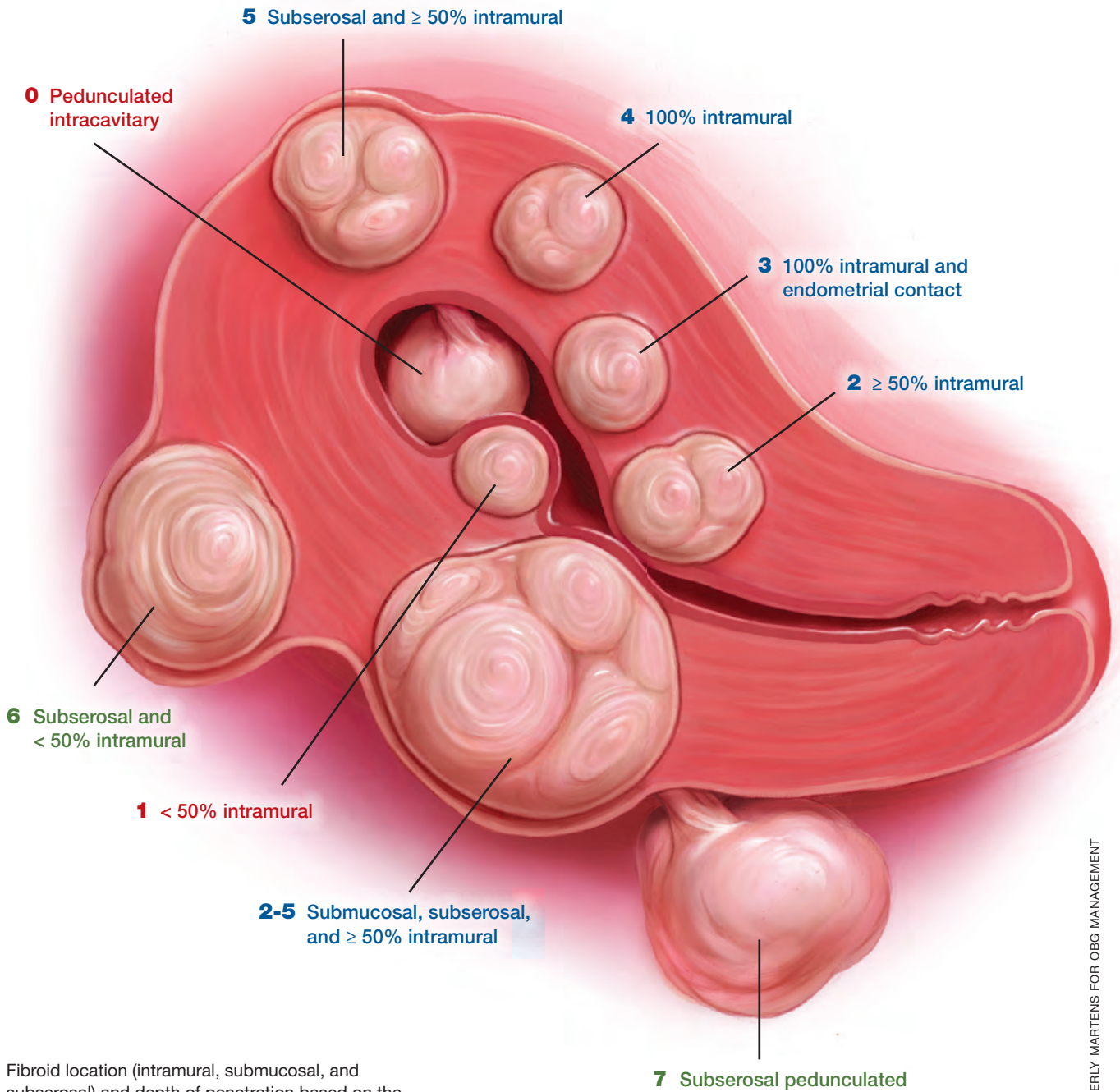
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■ Intramural

■ Submucosal

■ Subserosal



Fibroid location (intramural, submucosal, and subserosal) and depth of penetration based on the FIGO fibroid classification system

ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT



## ROUNDTABLE

# Fibroids: Patient considerations in medical and surgical management

Uterine fibroids can cause abnormal bleeding, pain, and infertility. ObGyns should be prepared to develop a treatment plan based on patient symptoms and goals. A panel offers guidance based on experience and expertise.

**Expert panel featuring Joseph S. Sanfilippo, MD, MBA; Linda D. Bradley, MD; and Ted L. Anderson, MD, PhD**

**U**terine fibroids (myomas or leiomyomas) are common and can cause considerable morbidity, including infertility, in reproductive-aged women. In this roundtable discussion, moderated by OBG MANAGEMENT Editorial Board member Joseph S. Sanfilippo, MD, MBA, 2 experts discuss imaging technologies and classification systems for assessing fibroids, various medical and surgical treatment options, and patient reproductive goals to consider when counseling women with fibroids.

### Perspectives on a pervasive problem

**Joseph S. Sanfilippo, MD, MBA:** First let's discuss the scope of the problem. How prevalent are uterine fibroids, and what are their effects on quality of life?

**Linda D. Bradley, MD:** Fibroids are extremely prevalent. Depending on age and race, between 60% and 80% of women have them.<sup>1</sup> About 50% of women with fibroids have no symptoms<sup>2</sup>; in symptomatic women, the symptoms may vary based on age. Fibroids are more common in women from the African diaspora, who have earlier onset of symptoms, very large or more numerous fibroids, and more symptomatic fibroids, according to some clinical studies.<sup>3</sup> While it

is a very common disease state, about half of women with fibroids may not have significant symptoms that warrant anything more than watchful waiting or some minimally invasive options.

**Ted L. Anderson, MD, PhD:** We probably underestimate the scope because we see people coming in with fibroids only when they have a specific problem. There probably are a lot of asymptomatic women out there that we do not know about.

### Case 1: Abnormal uterine bleeding in a young woman desiring pregnancy in the near future

**Dr. Sanfilippo:** Abnormal uterine bleeding is a common dilemma in my practice. Consider the following case example.

A 24-year-old woman (G1P1) presents with heavy, irregular menses over 6 months' duration. She is interested in pregnancy, not immediately but in several months. She passes clots, soaks a pad in an hour, and has dysmenorrhea and fatigue. She uses no birth control. She is very distraught, as this bleeding truly has changed her lifestyle.

What is your approach to counseling this patient?

**Dr. Bradley:** You described a woman whose

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## OBG MANAGEMENT Expert Panel



**Ted L. Anderson, MD, PhD**  
Vice Chair of Clinical Operations and Quality  
Betty and Lonnie S. Burnett Professor  
Obstetrics and Gynecology  
Director, Division of Gynecology  
Vanderbilt University Medical Center  
Nashville, Tennessee



**Linda D. Bradley, MD**  
Professor of Surgery and Vice Chairman  
Obstetrics, Gynecology, and  
Women's Health Institute  
Director, Center for Menstrual Disorders,  
Fibroids, and Hysteroscopic Services  
Cleveland Clinic  
Cleveland, Ohio



**Joseph S. Sanfilippo, MD, MBA**  
Professor, Department of Obstetrics, Gynecology,  
and Reproductive Sciences  
University of Pittsburgh  
Academic Division Director, Reproductive Endocrinology  
and Infertility  
Magee Womens Hospital  
Pittsburgh, Pennsylvania

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quality of life is very poor—frequent pad changes, clotting, pain. And she wants to have a child. A patient coming to me with those symptoms does not need to wait 4 to 6 months. I would immediately do some early evaluation.

**Dr. Anderson:** Sometimes a patient comes to us and already has had an ultrasonography exam. That is helpful, but I am driven by the fact that this patient is interested in pregnancy. I want to look at the uterine cavity and will probably do an office hysteroscopy to see if she has fibroids that distort the uterine cavity. Are there fibroids inside the cavity? To what degree does that possibly play a role? The presence of fibroids does not necessarily mean there is distortion of the cavity, and some evidence suggests that you do not need to do anything about those fibroids.<sup>4</sup> Fibroids actually may not be the source of bleeding.

We need to keep an open mind when we do the evaluation.

### Imaging technologies and classification aids

**Dr. Sanfilippo:** Apropos to your comment, is there a role for a sonohysterography in this population?

**Dr. Anderson:** That is a great technique. Some clinicians prefer to use sonohysterography while others prefer hysteroscopy. I tend to use hysteroscopy, and I have the equipment in the office. Both are great techniques and they answer the same question with respect to cavity evaluation.

**Dr. Bradley:** We once studied about 150 patients who, on the same day, with 2 separate examiners (one being me), would first undergo saline infusion sonohysterography (SIS) and then hysteroscopy, or vice versa. The sensitivity of identifying an intracavitary lesion is quite good with both. The additional benefit with SIS is that you can look at the adnexa.

In terms of the classification by the International Federation of Gynaecology and Obstetrics (FIGO), sometimes when we do a hysteroscopy, we are not sure how deep a fibroid is—whether it is a type 1 or type 2 or how close it is to the serosa (see illustration, page 26). Are we seeing just the tip of the iceberg? There is a role for imaging, and it is not always an “either/or” situation. There are times, for example, that hysteroscopy will show a type 0. Other times it may not show that, and you look for other things in terms of whether a fibroid abuts the endometrium. The take-home message is that physicians should abandon endometrial biopsy alone and, in this case, not offer a D&C.

In evaluating the endometrium, as gynecologists we should be facile in both technologies. In our workplaces we need to advocate to get trained, to be certified, and to be able to offer both technologies, because sometimes you need both to obtain the right answer.

**Dr. Sanfilippo:** Let's talk about the FIGO classification, because it is important to have a communication method not only between physicians but with the patient. If we deter-

mine that a fibroid is a type 0, and therefore totally intracavitary, management is different than if the fibroid is a type 1 (less than 50% into the myometrium) or type 2 (more than 50%). What is the role for a classification system such as the FIGO?

**Dr. Anderson:** I like the FIGO classification system. We can show the patient fibroid classification diagrammatically and she will be able to understand exactly what we are talking about. It's helpful for patient education and for surgical planning. The approach to a type 0 fibroid is a no-brainer, but with type 1 and more specifically with type 2, where the bulk of the fibroid is intramural and only a portion of that is intracavitary, fibroid size begins to matter a lot in terms of treatment approach.

Sometimes although a fibroid is intracavitary, a laparoscopic rather than hysteroscopic approach is preferred, as long as you can dissect the fibroid away from the endometrium. FIGO classification is very helpful, but I agree with Dr. Bradley that first you need to do a thorough evaluation to make your operative plan.

**Dr. Sanfilippo:** I encourage residents to go through an orderly sequence of assessment for evaluating abnormal uterine bleeding, including anatomic and endocrinologic factors. The PALM-COEIN classification system is a great mnemonic for use in evaluating abnormal uterine bleeding (TABLE).<sup>5</sup> Is there a role for an aid such as PALM-COEIN in your practice?

**Dr. Bradley:** I totally agree. In 2011, Malcolm Munro and colleagues in the FIGO Working Group on Menstrual Disorders helped us to have a reporting on outcomes by knowing the size, number, and location of fibroids.<sup>5</sup> This helps us to look for structural causes and then, to get to the answer, we often use imaging such as ultrasonography or saline infusion, sometimes magnetic resonance imaging (MRI), because other conditions can coexist—endometrial polyps, adenomyosis, and so on.

The PALM-COEIN system helps us to look at 2 things. One is that in addition to structural causes, there can be hematologic causes. While it is rare in a 24-year-old, we all

**TABLE Potential causes of abnormal uterine bleeding according to the PALM-COEIN classification<sup>5</sup>**

Polyp	Structural pathology measurable through imaging or histopathology
Adenomyosis	
Leiomyoma	
Malignancy & hyperplasia	
Coagulopathy	Bleeding unrelated to structural abnormalities
Ovulatory disorders	
Endometrial dysfunction	
Iatrogenic	
Not otherwise classified	

have had the anecdotal patient who came in 6 months ago, had a fibroid, but had a platelet count of 6,000. Second, we have to look at the patient as a whole. My residents, myself, and our fellows look at any bleeding. Does she have a bleeding diathesis, bruising, nose bleeds; has she been anemic, does she have pica? Has she had a blood transfusion, is she on certain medications? We do not want to create a “silo” and think that the patient can have only a fibroid, because then we may miss an opportunity to treat other disease states. She can have a fibroid coexisting with polycystic ovary syndrome (PCOS), for instance. I like to look at everything so we can offer appropriate treatment modalities.

**Dr. Sanfilippo:** You bring up a very important point. Coagulopathies are more common statistically at the earlier part of a woman's reproductive age group, soon after menarche, but they also occur toward menopause. We have to be cognizant that a woman can develop a coagulopathy throughout the reproductive years.

**Dr. Anderson:** You have to look at other medical causes. That is where the PALM-COEIN system can help. It helps you take the blinders off. If you focus on the fibroid and treat the fibroid and the patient still has bleeding, you missed something. You have to consider the whole patient and think of all the nonclassical or nonanatomical things, for example, thyroid disease. The PALM-COEIN helps us to evaluate the patient in a methodical way—every patient every time—so you do not miss something.

### FAST TRACK

*The PALM-COEIN system is a great mnemonic for use in evaluating abnormal uterine bleeding; it enables an orderly sequence of assessment, including anatomic and endocrinologic factors*

CONTINUED ON PAGE 30

## The value of MRI

**Dr. Sanfilippo:** What is the role for MRI, and when do you use it? Is it for only when you do a procedure—laparoscopically, robotically, open—so you have a detailed map of the fibroids?

**Dr. Anderson:** I love MRI, especially for hysteroscopy. I will print out the MRI image and trace the fibroid because there are things I want to know: exactly how much of the fibroid is inside or outside, where this fibroid is in the uterus, and how much of a normal buffer there is between the edge of that fibroid and the serosa. How aggressive can I be, or how cautious do I need to be, during the resection? Maybe this will be a planned 2-stage resection. MRIs are wonderful for fibroid disease, not only for diagnosis but also for surgical planning and patient counseling.

**Dr. Bradley:** SIS is also very useful. If the patient has an intracavitary fibroid that is larger than 4.5 to 5 cm and we insert the catheter, however, sometimes you cannot distend the cavity very well. Sometimes large intramural fibroids can compress the cavity, making the procedure difficult in an office setting. You cannot see the limits to help you as a surgical option. Although SIS generally is associated with little pain, some patients may have pain, and some patients cannot tolerate the test.

I would order an MRI for surgical planning when a hysteroscopy is equivocal and if I cannot do an SIS. Also, if a patient who had a hysteroscopic resection with incomplete removal comes to me and is still symptomatic, I want to know the depth of penetration.

Obtaining an MRI may sometimes be difficult at a particular institution, and some clinicians have to go through the hurdles of getting an ultrasound to get certified and approved. We have to be our patient's advocate and do the peer phone calls; any other specialty would require presurgical planning, and we are no different from other surgeons in that regard.

**Dr. Sanfilippo:** Yes, that can be a stumbling block. In the operating room, I like to have the images right in front of me, ideally an MRI or an ultrasound scan, as I know how to

proceed. Having that visual helps me understand how close the fibroid is to the lining of the uterus.

## Tapping into radiologists' expertise

**Dr. Bradley:** Every quarter we meet with our radiologists, who are very interested in our MRI and SIS reports. They will describe the count and say how many fibroids—that is very helpful instead of just saying she has a bunch of fibroids—but they also will tell us when there is a type 0, a type 2, a type 7 fibroid. The team looks for adenomyosis and for endometriosis that can coexist.

**Dr. Anderson:** One caution about reading radiology reports is that often someone will come in with a report from an outside hospital or from a small community hospital that may say, "There is a 2-cm submucosal fibroid." Some people might be tempted to take this person right to the OR, but you need to look at the images yourself, because in a radiologist's mind "submucosal" truly means under the mucosa, which in our liturgy would be "intramural." So we need to make sure that we are talking the same language. You should look at the images yourself.

**Dr. Sanfilippo:** I totally agree. It is also not unreasonable to speak with the radiologists and educate them about the FIGO classification.

**Dr. Bradley:** I prefer the word "intracavitary" for fibroids. When I see a typed report without the picture, "submucosal" can mean in the cavity or abutting the endometrium.

## Case 2: Woman with heavy bleeding and fibroids seeks nonsurgical treatment

**Dr. Sanfilippo:** A 39-year-old (G3P3) woman is referred for evaluation for heavy vaginal bleeding, soaking a pad in an hour, which has been going on for months. Her primary ObGyn obtained a pelvic sonogram and noted multiple intramural and subserosal fibroids. A sonohysterogram reveals a submucosal myoma.

The patient is not interested in a hysterectomy. She was treated with birth control

## FAST TRACK

*I would order an MRI for surgical planning when a hysteroscopy is equivocal and if I cannot do an SIS*

pills, with no improvement. She is interested in nonsurgical options. Dr. Bradley, what medical treatments might you offer this patient?

### Medical treatment options

**Dr. Bradley:** If oral contraceptives have not worked, a good option would be tranexamic acid. Years ago our hospital was involved with enrolling patients in the multicenter clinical trial of this drug. The classic patient enrolled had regular, predictable, heavy menstrual cycles with alkaline hematin assay of greater than 80. If the case patient described has regular and predictable heavy bleeding every month at the same time, for the same duration, I would consider the use of tranexamic acid. There are several contraindications for the drug, so those exclusion issues would need to be reviewed. Contraindications include subarachnoid hemorrhage. Cerebral edema and cerebral infarction may be caused by tranexamic acid in such patients. Other contraindications include active intravascular clotting and hypersensitivity.

Another option is to see if a progestin-releasing intrauterine system (IUS) like the levonorgestrel (LNG) IUS would fit into this patient's uterine cavity. Like Ted, I want to look into that cavity. I am not sure what "submucosal fibroid" means. If it has not distorted the cavity, or is totally within the uterine cavity, or abuts the endometrial cavity. The LNG-IUS cannot be placed into a uterine cavity that has intracavitary fibroids or sounds to greater than 12 cm. We are not going to put an LNG-IUS in somebody, at least in general, with a globally enlarged uterine cavity. I could ask, do you do that? You do a bimanual exam, and it is 18-weeks in size. I am not sure that I would put it in, but does it meet those criteria? The package insert for the LNG-IUS specifies upper and lower limits of uterine size for placement. I would start with those 2 options (tranexamic acid and LNG-IUS), and also get some more imaging.

**Dr. Anderson:** I agree with Linda. The submucosal fibroid could be contributing to this patient's bleeding, but it is not the total contribution. The other fibroids may be com-

pletely irrelevant as far as her bleeding is concerned. We may need to deal with that one surgically, which we can do without a hysterectomy, most of the time.

I am a big fan of the LNG-IUS, it has been great in my experience. There are some other treatments available as well, such as gonadotropin-releasing hormone (GnRH) agonists. I tell patients that, while GnRH does work, it is not designed to be long-term therapy. If I have, for example, a 49-year-old patient, I just need to get her to menopause. Longer-term GnRH agonists might be a good option in this case. Otherwise, we could use short-term a GnRH agonist to stop the bleeding for a while so that we can reset the clock and get her started on something like levonorgestrel, tranexamic acid, or one of the other medical therapies. That may be a 2-step combination therapy.

**Dr. Sanfilippo:** There is a whole category of agents available—selective progesterone receptor modulators (SPRMs), pure progesterone receptor antagonists, ulipristal comes to mind. Clinicians need to know that options are available beyond birth control pills.

**Dr. Anderson:** As I tell patients, there are also "bridge" options. These are interventional procedures that are not hysterectomy, such as uterine fibroid embolization or endometrial ablation if bleeding is really the problem. We might consider a variety of different approaches. Obviously, we do not typically use fibroid embolization for submucosal fibroids, but it depends on how much of the fibroid is intracavitary and how big it is. Other options are a little more aggressive than medical therapy but they do not involve a hysterectomy.

### Pros and cons of uterine artery embolization

**Dr. Sanfilippo:** If a woman desires future childbearing, is there a role for uterine artery embolization? How would you counsel her about the pros and cons?

**Dr. Bradley:** At the Cleveland Clinic, we generally do not offer uterine artery embolization if the patient wants a child. While it is an excellent method for treating heavy bleeding

### FAST TRACK

*If oral contraceptives have not worked, a good option would be tranexamic acid*

and bulk symptoms, the endometrium can be impacted. Patients can develop fistula, adhesions, or concentric narrowing, and changes in anti-Müllerian hormone levels, and there is potential for an Asherman-like syndrome and poor perfusion. I have many hysteroscopic images where the anterior wall of the uterus is nice and pink and the posterior wall is totally pale. The embolic microsphere particles can reach the endometrium—I have seen particles in the endometrium when doing a fibroid resection.

A good early study looked at 555 women for almost a year.<sup>6</sup> If women became pregnant, they had a higher rate of postpartum hemorrhage; placenta accreta, increta, and percreta; and emergent hysterectomy. It was recommended that these women deliver at a tertiary care center due to higher rates of pre-term labor and malposition.

If a patient wants a baby, she should find a gynecologic surgeon who does minimally invasive laparoscopic, robotic, or open surgery, because she is more likely to have a take-home baby with a surgical approach than with embolization. In my experience, there is always going to be a patient who wants to keep her uterus at age 49 and who has every comorbidity. I might offer her the embolization just knowing what the odds of pregnancy are.

**Dr. Anderson:** I agree with Linda but I take a more liberal approach. Sometimes we do a myomectomy because we are trying to enhance fertility, while other times we do a myomectomy to address fibroid-related symptoms. These patients are having specific symptoms, and we want to leave the embolization option open.

If I have a patient who is 39 and becoming pregnant is not necessarily her goal, but she does not want to have a hysterectomy and if she got pregnant it would be okay, I am going to treat her a little different with respect to fibroid embolization than I would treat someone who is actively trying to have a baby. This goes back to what you were saying, let's treat the patient, not just the fibroid.

**Dr. Bradley:** That is so important and sentinel. If she really does not want a hyster-

ectomy but does not want a baby, I will ask, "Would you go through in vitro fertilization? Would you take clomiphene?" If she answers no, then I feel more comfortable, like you, with referring the patient for uterine fibroid embolization. The point is to get the patient with the right team to get the best outcomes.

### Surgical approaches, intraoperative agents, and suture technique

**Dr. Sanfilippo:** Dr. Anderson, tell us about your surgical approaches to fibroids.

**Dr. Anderson:** At my institution we do have a fellowship in minimally invasive surgery, but I still do a lot of open myomectomies. I have a few guidelines to determine whether I am going to proceed laparoscopically, do a little minilaparotomy incision, or if a gigantic uterus is going to require a big incision. My mantra to my fellows has always been, "minimally invasive is the impact on the patient, not the size of the incision."

Sometimes, prolonged anesthesia and Trendelenburg create more morbidity than a minilaparotomy. If a patient has 4 or 5 fibroids and most of them are intramural and I cannot see them but I want to be able to feel them, and to get a really good closure of the myometrium, I might choose to do a minilaparotomy. But if it is a case of a solitary fibroid, I would be more inclined to operate laparoscopically.

**Dr. Bradley:** Our protocol is similar. We use MRI liberally. If patients have 4 or more fibroids and they are larger than 8 cm, most will have open surgery. I do not do robotic or laparoscopic procedures, so my referral source is for the larger myomas. We do not put retractors in; we can make incisions. Even if we do a huge Maylard incision, it is cosmetically wonderful. We use a loading dose of IV tranexamic acid with tranexamic acid throughout the surgery, and misoprostol intravaginally prior to surgery, to control uterine bleeding.

**Dr. Sanfilippo:** Dr. Anderson, is there a role for agents such as vasopressin, and what about routes of administration?

**Dr. Anderson:** When I do a laparoscopic or open procedure, I inject vasopressin (dilute

### FAST TRACK

*If a patient has 4 or 5 fibroids and most are intramural and I cannot see them but want to be able to feel them, and to get a good closure of the myometrium, I might choose to do a minilaparotomy*

20 U in 100 mL of saline) into the pseudo-capsule around the fibroid. I also administer rectal misoprostol (400 µg) just before the patient prep is done, which is amazing in reducing blood loss. There is also a role for a GnRH agonist, not necessarily to reduce the size of the uterus but to reduce blood flow in the pelvis and blood loss. Many different techniques are available. I do not use tourniquets, however. If bleeding does occur, I want to see it so I can fix it—not after I have sewn up the uterus and taken off a tourniquet.

**Dr. Bradley:** Do you use Floseal hemostatic matrix or any other agent to control bleeding?

**Dr. Anderson:** I do, for local hemostasis.

**Dr. Bradley:** Some surgeons will use barbed suture.

**Dr. Anderson:** I do like barbed sutures. In teaching residents to do myomectomy, it is very beneficial. But I am still a big fan of the good old figure-of-8 stitch because it is compressive and you get a good apposition of the tissue, good hemostasis, and strong closure.

**Dr. Sanfilippo:** We hope that this conversation will change your management of uterine fibroids. I thank Dr. Bradley and Dr. Anderson for a lively and very informative discussion. ●

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# The mesh mess, enmeshed in controversy

Beginning in the late 1990s, the US Food and Drug Administration cleared more than 150 devices using surgical mesh for urogynecologic indications. As of April 2019, there are no longer any FDA-approved surgical mesh products for transvaginal repair of pelvic organ prolapse. What happened?

Joseph S. Sanfilippo, MD, MBA, and Steven R. Smith, JD

## **CASE** Complications with mesh placement for SUI

A 47-year-old woman (G4 P3013) presents 5 months posthysterectomy with evidence of urinary tract infection (UTI). *Escherichia coli* is isolated, and she responds to antibiotic therapy.

Her surgical history includes a mini-sling procedure using a needleless device and mesh placement in order to correct progressive worsening of loss of urine when coughing and sneezing. She also reported slight pelvic pain, dysuria, and urgency upon urination at that time. After subsequent development of pelvic organ

prolapse (POP), she underwent the vaginal hysterectomy.

Following her UTI treatment, a host of problems occur for the patient, including pelvic pain and dyspareunia. Her male partner reports “feeling something during sex,” especially at the anterior vaginal wall. A plain radiograph of the abdomen identifies a 2 cm x 2 cm stone over the vaginal mesh. In consultation with female pelvic medicine and reconstructive surgery subspecialists, lithotripsy is performed, with the stone fragmented. The patient remains symptomatic, however.

The mesh is noted to be eroding through the vaginal wall. An attempt is made to excise the mesh, initially via transurethral resection, then through a laparoscopic approach. Due to the mesh being embedded in the tissue, however, an open approach is undertaken. Extensive excision of the mesh and stone fragments is performed. Postoperatively, the patient reports “dry vagina,” with no other genitourinary complaints.

The patient sues. She sues the mesh manufacturer. She also seeks to sue the gynecologist who placed the sling and vaginal mesh (as she says she was not informed of “all the risks” of vaginal mesh placement. She is part of a class action lawsuit, along with thousands of other women.



Dr. Sanfilippo is Professor, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburgh, and Academic Director, Reproductive Endocrinology and Infertility, at Magee-Womens Hospital, Pittsburgh, Pennsylvania. He also serves on the OBG MANAGEMENT Board of Editors.



Mr. Smith is Professor Emeritus and Dean Emeritus at California Western School of Law, San Diego, California.

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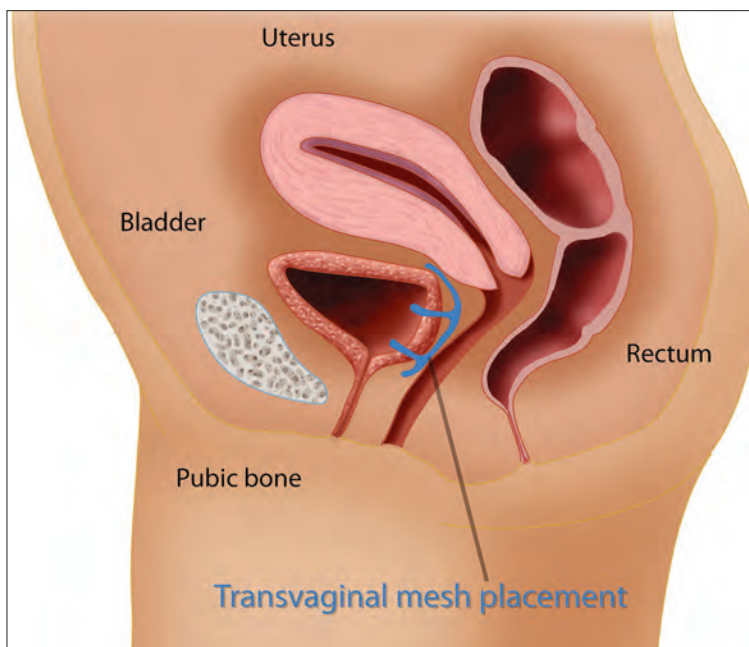
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**FIGURE** Transvaginal mesh placement



**FAST TRACK**

*Mesh erosion problems occur in up to 25% of transvaginal mesh POP implants*

**WHAT'S THE VERDICT?**

The device manufacturer settled out of court with the class action suit. (The gynecologist was never formally a defendant because the patient/plaintiff was advised to “drop the physician from the suit.”) The attorneys representing the class action received 40% of the award plus presented costs for the representation. The class as a whole received a little more than 50% of the negotiated award. The patient in this case received \$60,000.

**Medical background**

Stress urinary incontinence (SUI) is a prevalent condition; it affects 35% of women.<sup>1</sup> Overall, 80% of women aged 80 or younger will undergo some form of surgery for POP during their lifetime.<sup>2</sup> The pathophysiology of SUI includes urethral hypermobility and intrinsic sphincter deficiency.<sup>3</sup>

**Surgical correction for urinary incontinence: A timeline**

Use of the gracilis muscle flap to surgically correct urinary incontinence was introduced in 1907. This technique has been replaced by today’s more common Burch procedure,

which was first described in 1961. Surgical mesh use dates back to the 1950s, when it was primarily used for abdominal hernia repair. Tension-free tape was introduced in 1995.<sup>4-6</sup>

In the late 1990s the US Food and Drug Administration (FDA) permitted use of the first transvaginal meshes, which were designed to treat SUI—the midurethral sling. These mesh slings were so successful that similar meshes were developed to treat POP.<sup>7</sup> Almost immediately there were problems with the new POP devices, and 3 years later Boston Scientific recalled its device.<sup>8</sup> Nonetheless, the FDA cleared more than 150 devices using surgical mesh for urogynecologic indications (FIGURE).<sup>9</sup>

**Mesh complications**

Managing complications from intravesical mesh is a clinically challenging problem. Bladder perforation, stone formation, and penetration through the vagina can occur. Bladder-related complications can manifest as recurrent UTIs and obstructive urinary symptoms, especially in association with stone formation. From the gynecologic perspective, the more common complications with mesh utilization are pelvic pain, groin pain, dyspareunia, contracture and scarring of mesh, and narrowing of the vaginal canal.<sup>10</sup> Mesh erosion problems will occur in an estimated 10% to 25% of transvaginal mesh POP implants.<sup>11</sup>

In 2008, a comparison of transvaginal mesh to native tissue repair (suture-based) or other (biologic) grafts was published.<sup>12</sup> The bottom line: there is insufficient evidence to suggest that transvaginal mesh significantly improves outcomes for both posterior and apical defects.

**Legal background**

Mesh used for surgical purposes is a medical device, which legally is a product—a special product to be sure, but a product nonetheless. Products are subject to product liability rules. Mesh is also subject to an FDA regulatory system. We will briefly discuss products liability and the regulation of devices, both of

ILLUSTRATION: MONICA SCHROEDER/SCIENCE SOURCE IMAGES

which have played important roles in mesh-related injuries.

### Products liability

As a general matter, defective products subject their manufacturer and seller to liability. There are several legal theories regarding product liability: negligence (in which the defect was caused through carelessness), breach of warranty or guarantee (in addition to express warranties, there are a number of implied warranties for products, including that it is fit for its intended purpose), and strict liability (there was a defect in the product, but it may not have been because of negligence). The product may be defective in the way it was designed, manufactured, or packaged, or it may be defective because adequate instructions and warning were not given to consumers.

Of course, not every product involved in an injury is defective—most automobile accidents, for example, are not the result of any defect in the automobile. In medicine, almost no product (device or pharmaceutical) is entirely safe. In some ways they are unavoidably unsafe and bound to cause some injuries. But when injuries are caused by a defect in the product (design or manufacturing defect or failure to warn), then there may be products liability. Most products liability cases arise under state law.

### FDA's device regulations

Both drugs and medical devices are subject to FDA review and ordinarily require some form of FDA clearance before they may be marketed. In the case of devices, the FDA has 3 classes, with an increase in risk to the user from Class I to III. Various levels of FDA review are required before marketing of the device is permitted, again with the intensity of review increasing from I to III as follows:

- Class I devices pose the least risk, have the least regulation, and are subject to general controls (ie, manufacturing and marketing practices).
- Class II devices pose slightly higher risks and are subject to special controls in addition to the criteria for Class I.

- Class III devices pose the most risk to patients and require premarket approval (scientific review and studies are required to ensure efficacy and safety).<sup>13</sup>

There are a number of limits on manufacturer liability for defective devices. For Class III devices, the thorough FDA review of the safety of a device may limit the ability of an injured patient to sue based on the state product liability laws.<sup>14</sup> For the most part, this “preemption” of state law has not played a major role in mesh litigation because they were initially classified as Class II devices which did not require or include a detailed FDA review.<sup>15</sup>

The duty to warn of the dangers and risk of medical devices means that manufacturers (or sellers) of devices are obligated to inform health care providers and other medical personnel of the risks. Unlike other manufacturers, device manufacturers do not have to directly warn consumers—because physicians deal directly with patients and prescribe the devices. Therefore, the health care providers, rather than the manufacturers, are obligated to inform the patient.<sup>16</sup> This is known as the learned intermediary rule. Manufacturers may still be liable for failure to warn if they do not convey to health care providers proper warnings.

Manufacturers and sellers are not the only entities that may be subject to liability caused by medical devices. Hospitals or other entities that stock and care for devices are responsible for maintaining the safety and functionality of devices in their care.

Health care providers also may be responsible for injuries from medical devices. Generally, that liability is based on negligence. Negligence may relate to selecting an improper device, installing or using it incorrectly, or failing to give the patient adequate information (or informed consent) about the device and alternatives to it.<sup>17</sup>

### A look at the mesh mess

There are a lot of distressing problems and professional disappointments in dissecting the “mesh mess,” including a failure of the

### FAST TRACK

*Device manufacturers, physicians who prescribe devices, and hospitals that stock and care for devices all may be subject to liability caused by medical devices*

FDA to regulate effectively, the extended sale and promotion of intrinsic sphincter deficiency mesh products, the improper use of mesh by physicians even after the risks were known, and, in some instances, the taking advantage of injured patients by attorneys and businesses.<sup>18</sup> A lot of finger pointing also has occurred.<sup>19</sup> We will recount some of the lowlights of this unfortunate tale.

The FDA, in the 1990s, classified the first POP and SUI mesh as Class II after deciding these products were “substantially equivalent” to older surgical meshes. This, of course, proved not to be the case.<sup>20</sup> The FDA started receiving thousands of reports of adverse events and, in 2008, warned physicians to be vigilant for adverse events from the mesh. The FDA’s notification recommendations regarding mesh included the following<sup>13</sup>:

- Obtain specialized training for each mesh implantation technique, and be cognizant of risks.
- Be vigilant for potential adverse events from mesh, including erosion and infection.
- Be observant for complications associated with tools of transvaginal placement (ie, bowel, bladder, and vessel perforation).
- Inform patients that implantation of mesh is permanent and complications may require additional surgery for correction.
- Be aware that complications may affect quality of life—eg, pain with intercourse, scarring, and vaginal wall narrowing (POP repair).
- Provide patients with written copy of patient labeling from the surgical mesh manufacturer.

In 2011, the FDA issued a formal warning to providers that transvaginal mesh posed meaningful risks beyond nonmesh surgery. The FDA’s bulletin draws attention to how the mesh is placed more so than the material per se.<sup>19,21</sup> Mesh was a Class II device for sacrocolpopexy or midurethral sling and, similarly, the transvaginal kit was also a Class II device. Overall, use of mesh midurethral slings has been well received as treatment for SUI. The FDA also accepted it for POP, however, but with increasingly

strong warnings. The FDA’s 2011 communication stated, “This update is to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are not rare....Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk.”<sup>7,13</sup>

In 2014 the FDA proposed reclassifying mesh to a Class III device, which would require that manufacturers obtain approval, based on safety and effectiveness, before selling mesh. Not until 2016 did the FDA actually reclassify the mess as Class III. Of course, during this time, mesh manufacturers were well aware of the substantial problems the products were causing.<sup>13</sup>

After serious problems with mesh became well known, and especially after FDA warnings, the use of mesh other than as indicated by the FDA was increasingly risky from a legal (as well as a health) standpoint. As long as mesh was still on the market, of course, it was available for use. But use of mesh for POP procedures without good indications in a way that was contrary to the FDA warnings might well be negligent.

### Changes to informed consent

The FDA warnings also should have changed the informed consent for the use of mesh.<sup>22</sup> Informed consent commonly consists of the following:

1. informing the patient of the proposed procedure
2. describing risks (and benefits) of the proposed process
3. explaining reasonable alternatives
4. noting the risks of taking no action.

Information that is material to a decision should be disclosed. If mesh were going to be used, after the problems of mesh were known and identified by the FDA (other than midurethral slings as treatment of SUI), the risks should have been clearly identified for patients, with alternatives outlined. The American College of Obstetricians and Gynecologists Committee on Ethics has 8 fundamental concepts with regard to

### FAST TRACK

*After mesh problems were identified by the FDA, the risks of the product should have been clearly identified for patients, with alternatives outlined*

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## Take-away lessons

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- Maintain surgical skills and be open to new technology. Medical practice requires constant updating and use of new and improved technology as it comes along. By definition, new technology often requires new skills and understanding. A significant portion of surgeons using mesh indicated that they had not read the instructions for use, or had done so only once.<sup>1</sup> CME programs that include surgical education remain of particular value.
- Whether new technology or old, it is essential to keep up to date on all FDA bulletins pertinent to devices and pharmaceuticals that you use and prescribe. For example, in 2016 and 2018 the FDA warned that the use of a very old class of drugs (fluoroquinolones) should be limited. It advised “that the serious side effects associated with fluoroquinolones generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.”<sup>2</sup> Continued, unnecessary prescriptions for fluoroquinolones would put a physician at some legal risk whether or not the physician had paid any attention to the warning.
- Informed consent is a very important legal and medical process. Take it seriously, and make sure the patient has the information necessary to make informed decisions about treatment. Document the process and the information provided. In some cases consider directing patients to appropriate literature or websites of the manufacturers.
- As to the use of mesh, if not following FDA advice, it is important to document the reason for this and to document the informed consent especially carefully.
- Follow patients after mesh placement for a minimum of 1 year and emphasize to patients they should convey signs and symptoms of complications from initial placement.<sup>3</sup> High-risk patients should be of particular concern and be monitored very closely.

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informed consent that are worth keeping in mind<sup>23</sup>:

1. Obtaining informed consent for medical treatment and research is an ethical requirement.
2. The process expresses respect for the patient as a person.
3. It protects patients against unwanted treatment and allows patients’ active involvement in medical planning and care.
4. Communication is of paramount importance.
5. Informed consent is a process and not a signature on a form.
6. A commitment to informed consent and to provision of medical benefit to the patient are linked to provision of care.
7. If obtaining informed consent is impossible, a designated surrogate should be identified representing the patient’s best interests.
8. Knowledge on the part of the provider regarding state and federal requirements is necessary.

### Lawsuits line up

The widespread use of a product with a significant percentage of injuries and eventually with warnings about injuries from use sounds like the formula for a lot of lawsuits. This certainly has happened. A large number of suits—both class actions and individual actions—were filed as a result of mesh injuries.<sup>24</sup> These suits were overwhelmingly against the manufacturer, although some included physicians.<sup>7</sup> Device makers are more attractive defendants for several reasons. First, they have very deep pockets. In addition, jurors are generally much less sympathetic to large companies than to doctors. Large class actions meant that there were many different patients among the plaintiffs, and medical malpractice claims in most states have a number of trial difficulties not present in other product liability cases. Common defendants have included Johnson & Johnson, Boston Scientific, and Medtronic.

Some of the cases resulted in very large damage awards against manufacturers

based on various kinds of product(s) liability. Many other cases were settled or tried with relatively small damages. There were, in addition, a number of instances in which the manufacturers were not liable. Of the 32 plaintiffs who have gone to trial thus far, 24 have obtained verdicts totaling \$345 million (\$14 million average). The cases that have settled have been for much less—perhaps \$60,000 on average. A number of cases remain unresolved. To date, the estimate is that 100,000 women have received almost \$8 billion from 7 device manufacturers to resolve claims.<sup>25</sup>

Some state attorneys general have gotten into the process as well. Attorneys general from California, Kentucky, Mississippi, and Washington have filed lawsuits against Johnson & Johnson, claiming that they deceived doctors and patients about the risks of their pelvic mesh. The states claim that marketing and instructional literature should have contained more information about the risks. Some physicians in these states have expressed concern that these lawsuit risks may do more harm than good because the suits conflate mesh used to treat incontinence with the more risky mesh for POP.<sup>26</sup>

### The “ugly” of class action lawsuits

We have discussed both the sad (the injuries to patients) and the bad (the slow regulatory response and continuing injuries). (The ethics of the marketing by the manufacturers might also be raised as the bad.<sup>27</sup>) Next, let's look briefly at the ugly.

Some of the patients affected by mesh injuries have been victimized a second time by medical “lenders” and some of their attorneys. Press reports describe patients with modest awards paying 40% in attorney fees (on the high side for personal injury settlements) plus extravagant costs—leaving modest amounts of actual recovery.<sup>25</sup>

Worse still, a process of “medical lending” has arisen in mesh cases.<sup>28</sup> Medical lenders may contact mesh victims offering to pay up front for surgery to remove mesh, and then place a lien against the settlement for repayment at a much higher rate. They might pay the surgeon \$2,500 for the surgery, but place a lien on the settlement amount for \$60,000.<sup>29,30</sup> In addition, there are allegations that lawyers may recruit the doctors to overstate the injuries or do unnecessary removal surgery because that will likely up the award.<sup>31</sup> A quick Google search indicates dozens of offers of cash now for your mesh lawsuit (transvaginal and hernia repair).

The patient in our hypothetical case at the beginning had a fairly typical experience. She was a member of a class filing and received a modest settlement. The attorneys representing the class were allowed by the court to charge substantial attorneys' fees and costs. The patient had the good sense to avoid medical lenders, although other members of the class did use medical lenders and are now filing complaints about the way they were treated by these lenders. ●

### FAST TRACK

An estimated 100,000 women have received nearly \$8 billion to resolve claims against 7 device manufacturers

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# Is Routine 39-Week Induction of Labor in Healthy Pregnancy a Reasonable Course?

In this supplement to OBG MANAGEMENT, a panel of experts discuss the risks and benefits of routine induction of labor at 39 weeks. The panelists examine the findings from the ARRIVE trial and the potential impact on real-world practice, and describe their own approaches and what they see for the future.

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# Two cases of genital pruritus: What is the one diagnosis?

Genital itch can seriously impact a patient's quality of life. The right diagnosis and treatment can resolve symptoms and restore everyday functioning.

**Kerrie G. Satcher, MD; Stephanie J. Carstens, MD; and Andrew M. Kaunitz, MD**

**CASE 1 Vulvar pruritus affecting a woman's quality of life**

A 41-year-old premenopausal white woman presented to her gynecologist with intense vulvar pruritus for a 6-month duration, with a recent increase in severity (**FIGURE 1**). She tried treating it with topical antifungal cream, hydrocortisone ointment, and coconut oil, with no improvement. She noted that the intense itching was interfering with her sleep and marriage. The patient denied having an increase in urinary frequency or urgency, dysuria, hematochezia, or bowel changes.

**FIGURE 1** Pink to white excoriated plaque involving the superior labia majora in a 41-year-old woman



Dr. Satcher is Resident, Department of Dermatology, University of Florida College of Medicine, Gainesville.

Dr. Carstens is Assistant Professor, Department of Dermatology, University of Florida College of Medicine, Jacksonville.

Dr. Kaunitz is University of Florida Term Professor and Associate Chairman, Department of Obstetrics and Gynecology, University of Florida College of Medicine—Jacksonville; Medical Director and Director of Menopause and Gynecologic Ultrasound Services, UF Women's Health Specialists at Emerson, Jacksonville. Dr. Kaunitz serves on the OBG MANAGEMENT Board of Editors.

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**CASE 2 Older woman with long-term persistent genital pruritus**

An 83-year-old postmenopausal white woman presented to the dermatology clinic for a regular skin examination. The patient endorsed symptoms of vulvar and perianal pruritus that had persisted for more than 6 months (**FIGURE 2**). The genital itching occurred throughout most of the day. The patient previously treated her symptoms with an over-the-counter antifungal cream, which minimally improved the itching.

**FIGURE 2** Atrophic pruritic white plaque with inflammatory pink border involving the labia majora, labia minora, perineum in an 83-year-old woman



**What is the diagnosis?**

- Lichen simplex
- Lichen sclerosis
- Genitourinary syndrome of menopause

*Turn the page to see if you are correct.*

CONTINUED ON PAGE 44

**TABLE** Topical corticosteroids of varying potency that can be considered for treating lichen sclerosis

Potency	Corticosteroid ointment
Very high	Clobetasol propionate 0.05%
	Betamethasone dipropionate 0.05%
High	Mometasone furoate 0.1%
Moderate	Triamcinolone 0.1%
Low	Hydrocortisone 1%

### Lichen sclerosis

Lichen sclerosis is an inflammatory skin disease that primarily affects the genital and perianal skin of postmenopausal women. The mean age of onset is the mid- to late 50s; fewer than 15% of lichen sclerosis cases present in children.<sup>1,2</sup> Case 1 represents presentation of vulvar lichen sclerosis in a premenopausal woman, which is uncommon.

The classic presentation of lichen sclerosis is a well-defined white, atrophic plaque with a wrinkled surface appearance located on the vulva, perineum, and perianal skin. Less commonly, examination may reveal white papules and macules, pallor with overlying edema, or hyperpigmentation. Loss of labia minora tissue and phimosis of the clitoral hood also are often present in patients with untreated lichen sclerosis.

Additionally, secondary changes, such as erosions, fissuring, and blisters, can be seen on examination. The most frequent symptom associated with lichen sclerosis is intense itching of the affected area. Other symptoms include dyspareunia, dysuria, sexual dysfunction, and bleeding. Occasionally, lichen sclerosis is asymptomatic.<sup>1</sup> Like other autoimmune conditions, lichen sclerosis may persist indefinitely, highlighting the importance of effective treatment.

### How should we evaluate and treat patients with these symptoms?

Perform a skin biopsy and start treatment with very high-potency topical corticosteroid ointment daily for at least 6 weeks.

**Skin biopsy.** Definitive diagnosis of lichen sclerosis is made based on a skin biopsy. Because treatment can impact the interpretation of a skin biopsy, a biopsy is optimally performed prior to treatment initiation.

The patient in Case 1 underwent biopsy of the left labia majora. Results were consistent with early lichen

**FIGURE 3** Resolution of inflammatory skin changes following treatment with high-potency topical steroids



sclerosis. The patient in Case 2 was reluctant to proceed with vulvar biopsy.

A biopsy specimen should be taken from the affected area that is most white in appearance.<sup>1</sup>

**Topical treatment.** To induce remission, twice-daily application of very high-potency topical corticosteroid ointment to the affected area for at least 6 weeks is recommended. Once the skin color and texture have normalized, the topical corticosteroid strength (and frequency of application) can slowly be reduced to the lowest potency/frequency at which the patient remains in remission. Examples of very high-, high-, moderate-, and low-potency corticosteroid ointments are listed in the **TABLE**.

**Follow-up.** Evaluate the patient every 3 months until the topical steroid potency remains stable and the skin appearance is normal.

### Treat early, and aggressively, to prevent complications

Early diagnosis and aggressive intervention are important in managing this disease process. If diagnosis and treatment are delayed, significant scarring and deformation of the vulva can occur.<sup>1</sup>

Neoplastic transformation of lichen sclerosis into vulvar intraepithelial neoplasia and squamous cell carcinoma

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can occur (mean incidence, 2.8%). However, the literature reports significant variability in the incidence, ranging between 0% and 31%.<sup>3</sup> Published reports support decreased scarring and future development of malignancies in patients who adhere to treatment recommendations.<sup>4</sup>

### Symptoms resolved

In both cases described here, the patients were treated with clobetasol 0.05% ointment twice daily for 6 weeks.

Both women reported complete resolution of pruritus after treatment. As can be seen in the posttreatment photo of the patient described in Case 1, her vulvar inflammation resolved (**FIGURE 3**, page 44).

These cases represent the varied exam findings in patients experiencing vulvar pruritus with early (Case 1) versus more advanced (Case 2) lichen sclerosis. In addition, they underscore that appropriate evaluation and management of lichen sclerosis can produce excellent treatment results. ●

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## Feasibility—and safety—of reducing the traditional 14 prenatal visits to 8 or 10

CONTINUED FROM PAGE 24

on optimizing postpartum care. In a committee opinion, ACOG recommends that all women have contact with their provider within the first 3 weeks postpartum.<sup>15</sup> Recognizing that such an in-person visit may be difficult, ACOG has endorsed communication via text messaging, app-based support, and remote monitoring.<sup>15</sup> An app

such as Babyscripts would fill this need conveniently for both patient and provider.

In 2019, patients want choice. As maternity care providers, we should be open to considering novel, evidence-based options that may provide more cost-effective obstetric care. ●

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# Is the vaginal or buccal route more effective when administering prostaglandins for cervical ripening at term?

**Vaginal administration of misoprostol** (25 µg initial dose, 50 µg subsequent doses) **may be superior to the buccal route**, according to results of the IMPROVE trial, a prospective randomized placebo-controlled study of 300 women with a singleton vertex fetus requiring cervical ripening for induction of labor at term. Women treated with vaginal misoprostol (VM) had more rapid vaginal delivery, more vaginal deliveries within 24 hours, and fewer urgent cesarean deliveries for nonreassuring fetal testing (although the overall cesarean delivery rate was not significantly different) compared with those treated with buccal misoprostol (BM).

Haas DM, Dagg J, Flannery KM, et al. A comparison of vaginal versus buccal misoprostol for cervical ripening in women for labor induction at term (the IMPROVE trial): a triple masked randomized controlled trial. *Am J Obstet Gynecol.* 2019. doi:10.1016/j.ajog.2019.04.037.

## EXPERT COMMENTARY

**Errol R. Norwitz, MD, PhD, MBA**, is Louis E. Phaneuf Professor of Obstetrics and Gynecology, Tufts University School of Medicine, and Chief Scientific Officer and Chair, Department of Obstetrics and Gynecology, Tufts Medical Center, Boston, Massachusetts. He serves on the OBG MANAGEMENT Board of Editors. **Julie M. Stone, MD**, is Maternal Fetal Medicine Fellow, Tufts University School of Medicine, Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, Tufts Medical Center, Boston.

**C**ervical ripening is routine practice in women undergoing induction of labor who have an unfavorable

*The authors report no financial relationships relevant to this article.*

cervical examination.<sup>1</sup> This is because generating contractions against a long thick cervix is more likely to lead to failed induction and cesarean delivery. Cervical ripening can be achieved using mechanical or pharmacologic methods.

Misoprostol (a prostaglandin E<sub>1</sub> [PGE<sub>1</sub>] analog) is approved by the US Food and Drug Administration for the treatment of peptic ulcer disease, but it also is widely used off-label for cervical ripening, partly due to its low cost. Misoprostol's optimal dosing regimen and route of administration are not known. The IMPROVE trial was designed to address this knowledge gap, specifically to compare the efficacy and safety of VM versus BM in women undergoing labor induction at term.

## Details of the study

The IMPROVE trial was a prospective, randomized, noninferiority, triple-masked,

## FAST TRACK

*The IMPROVE trial was designed to address a knowledge gap: comparing the efficacy and safety of vaginal misoprostol versus buccal misoprostol for cervical ripening in women undergoing labor induction at term*

## Cervical ripening and risk of cesarean delivery among overweight patients

While a number of studies have evaluated the risk of cesarean delivery (CD) with the use of cervical ripening agents by different routes of administration, Handal-Orefice and colleagues studied this outcome specifically in a predominantly overweight population at a tertiary care center.<sup>1</sup>

The retrospective study included 276 women, of whom 91% had a body mass index (BMI) of 25 kg/m<sup>2</sup> or more and 61% had a BMI of 30 kg/m<sup>2</sup> or more at the time of delivery.

For cervical ripening, 138 women received vaginal misoprostol (25 µg) and 138 received oral misoprostol (50 µg). The frequency of CD (the primary study outcome) was significantly higher with oral compared with vaginal misoprostol use (32% vs 21%;  $P = .04$ ). When the analysis was adjusted for age, BMI, parity, indication for induction, and Foley catheter use, the risk of CD remained significantly higher for the oral misoprostol group (adjusted odds ratio [aOR], 2.01; 95% confidence interval [CI], 1.07–3.76).

Other key findings:

- frequency of CD among nulliparous women: 41% in the oral misoprostol group, 28% in the vaginal misoprostol group (aOR, 2.79; 95% CI, 1.26–6.19)
- time to vaginal delivery: 41 hours for the oral misoprostol group, 31 hours for the vaginal misoprostol group ( $P = .01$ )
- uterine tachysystole: 11% in the oral misoprostol group, 20% in the vaginal misoprostol group ( $P = .04$ ).

The authors noted that the strengths of the study, including the racial and ethnic diversity of the population (72% of women were of either black or Hispanic race or ethnicity), the commonly used doses of misoprostol, and the performance of inductions outside a research protocol, add to the generalizability of the results.

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### FAST TRACK

*The time to vaginal delivery from first dose was reduced in the VM versus BM group (20.1 vs 28.1 hours;  $P = .006$ ); urgent CD for nonreassuring fetal testing was similarly reduced in the VM patients (3.3% vs 9.5%;  $P = .33$ )*

placebo-controlled trial of 300 women with a singleton vertex fetus requiring cervical ripening for induction of labor at term.<sup>2</sup> Enrolled women were randomly assigned to VM or BM (same dosing regimen) and to a matching placebo administered via the opposite route.

Primary outcomes included time-to-vaginal-delivery from first dose, which was reduced in VM vs BM (20.1 vs 28.1 hours;  $P = .006$ ), and urgent cesarean delivery for nonreassuring fetal testing, which was similarly reduced in VM (3.3% vs 9.5%;  $P = .33$ ). These differences persisted after controlling for covariates. There was also a greater difference seen in multiparous versus nulliparous women.

Secondary outcomes also favored VM over BM, including more vaginal deliveries

within 24 hours, fewer doses to achieve active labor, and a lower maximum dose of oxytocin.

Overall cesarean delivery rates were similar in the 2 groups (VM, 15.8%; BM, 22.3%;  $P = .15$ ). There were no significant differences in other delivery characteristics or in maternal or fetal adverse events.

### Study strengths and limitations

The IMPROVE trial had a triple-blinded study design with an intention-to-treat paradigm and good follow-up. There was also standardization of PGE<sub>1</sub> administration criteria, which was consistent with the American College of Obstetricians and Gynecologists standards of care. Results were similar to those of prior studies regarding rates of tachysystole, urgent cesarean delivery, and vaginal delivery.

The study has good generalizability as it included both elective and medically indicated inductions; however, patients with ruptured membranes were excluded. Although there was no difference in the overall cesarean delivery rates, the study was underpowered to look at this outcome. The authors included a patient satisfaction survey, but this is hard to interpret since study participants all received tablets orally and vaginally. The study did not address efficacy of VM versus BM administration at different doses or time intervals.●

## WHAT THIS EVIDENCE MEANS FOR PRACTICE

Labor induction has doubled over the past 2 decades, with almost 25% of parturients currently undergoing induction in the United States.<sup>3</sup> This number is likely to increase given recent data suggesting that routine induction at 39 weeks may significantly decrease cesarean delivery rates.<sup>4</sup> It is critical, therefore, that we identify the optimal technique for cervical ripening, including the ideal dosing regimen and route of administration. Results of the IMPROVE trial suggest that vaginal administration of misoprostol (25 µg initial dose, 50 µg subsequent doses) may be superior to the buccal route, with more rapid vaginal delivery, more vaginal deliveries within 24 hours, and fewer urgent cesareans for nonreassuring fetal testing (although the overall cesarean delivery rate was not significantly different).

ERROL R. NORWITZ, MD, PHD, MBA; JULIE M. STONE, MD

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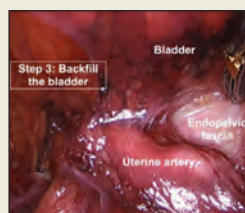
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### A stepwise approach to the difficult bladder flap to prevent urinary tract injury during laparoscopic hysterectomy

CHRISTINE FOLEY, MD, AND NICOLE DONNELLAN, MD



In this video, the authors demonstrate the surgical techniques necessary to develop a bladder flap during a total laparoscopic hysterectomy when scar tissue from prior surgeries exists. The video highlights key steps in identifying the endopelvic fascia laterally at the level of the uterine arteries to develop a virgin tissue plane, which can be dissected medially toward the scarred area. Utilization of this strategy helps the surgeon restore normal anatomy and prevent urinary tract injuries during total laparoscopic hysterectomy.

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## Opioids: Overprescribing, alternatives, and clinical guidance

### A Practice Essential from OBG MANAGEMENT and Ob.Gyn. News

How can ObGyns maximize postsurgical and postpartum pain relief without the use of opioids, and how can ObGyns best manage the care of pregnant women with opioid misuse? This interactive compilation for ObGyns and all women's health clinicians offers:

- A special introduction from Robert L. Barbieri, MD, Chair of ObGyn at Brigham and Women's Hospital and Kate Macy Ladd Professor of ObGyn and Reproductive Biology at Harvard
- Part 1: Optimal management of postpartum and postoperative pain
- Part 2: Optimal management of pregnant women with opioid misuse
- Pre/posttest questions to test your knowledge of the scope of the problem and specific management approaches.



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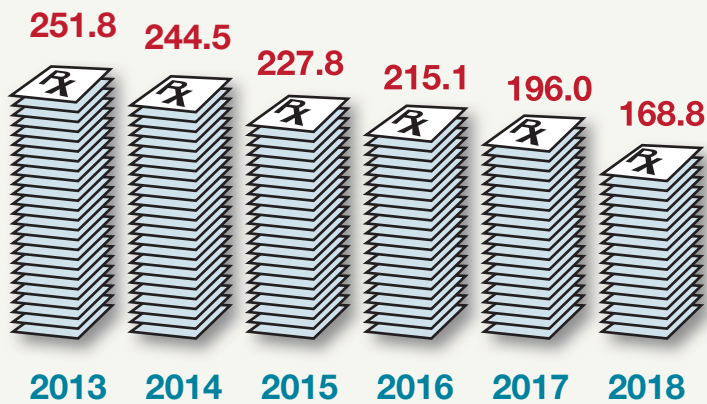
# Opioid prescriptions: 2019 snapshot

The American Medical Association (AMA)'s Opioid Task Force reports that the total number of opioid prescriptions written in the United States have

**decreased by more than 80 million**

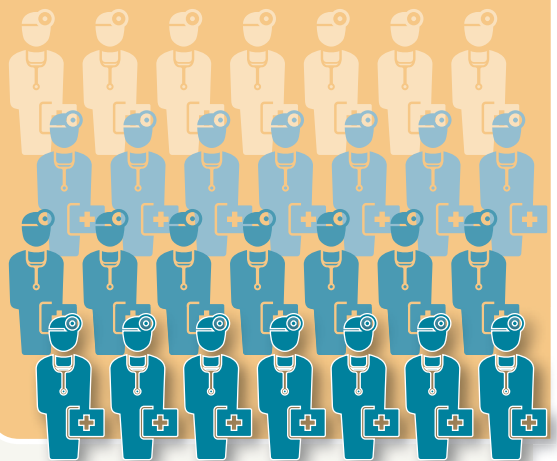
(a 33% decrease) since 2013.

Total opioid prescriptions  
(in millions)



**More than 66,000**

US health care professionals now can prescribe buprenorphine for the treatment of opioid use disorder.



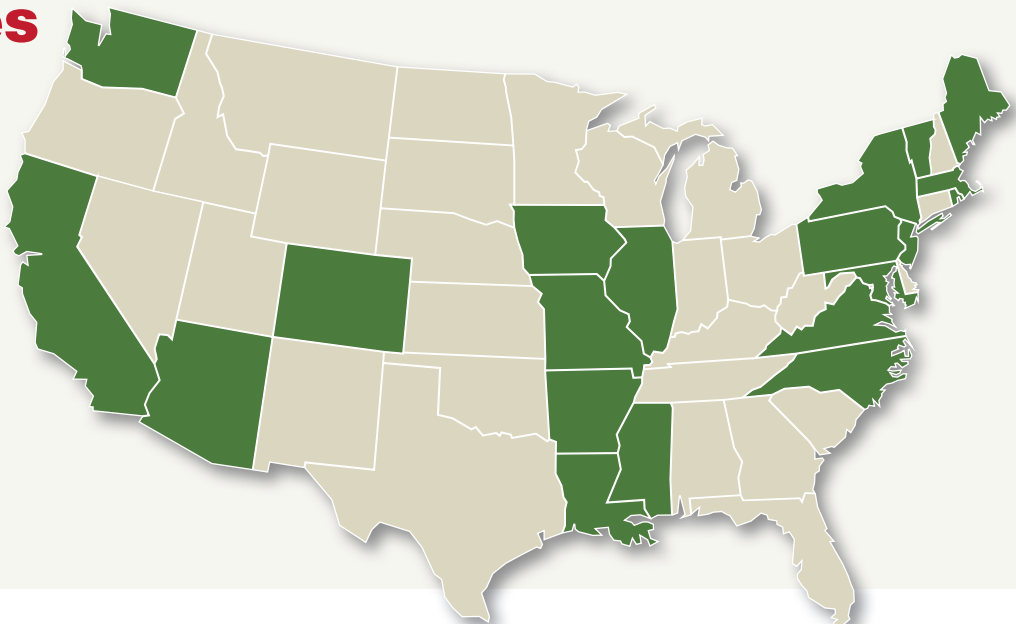
The AMA recommends that states

**remove administrative burdens**

or barriers that delay or deny care for FDA-approved medications used as part of medication-assisted treatment for opioid use disorder.

**20 states and DC**

have taken such action in the past 3 years.



Source: American Medical Association. Opioid task force 2019 progress report. <https://www.end-opioid-epidemic.org/wp-content/uploads/2019/06/AMA-Opioid-Task-Force-2019-Progress-Report-web.pdf>. Accessed June 25, 2019.

## BRIEF SUMMARY OF PRESCRIBING INFORMATION

### Rx Only

This Brief Summary does not include all the information needed to use SOLOSEC™ safely and effectively. See full Prescribing Information for SOLOSEC.

### SOLOSEC (secnidazole) 2g oral granules

#### Single oral dose

Initial U.S. approval: 2017

#### INDICATIONS AND USAGE

SOLOSEC is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in adult women.

#### DOSAGE AND ADMINISTRATION

Administer a single 2-gram packet of granules once orally, without regard to the timing of meals. Sprinkle entire contents of packet onto yogurt, applesauce, or pudding and consume all of the mixture within 30 minutes without chewing or crunching the granules. A glass of water may be taken after the administration of SOLOSEC to aid in swallowing. SOLOSEC is not intended to be dissolved in any liquid.

#### CONTRAINDICATIONS

**Hypersensitivity.** SOLOSEC is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.

#### WARNINGS AND PRECAUTIONS

**Vulvovaginal Candidiasis.** The use of SOLOSEC may result in vulvovaginal candidiasis and may require treatment with an antifungal agent.

**Potential Risk for Carcinogenicity.** Carcinogenicity has been seen in mice and rats treated chronically with nitroimidazole derivatives, which are structurally related to secnidazole. It is unclear if the positive tumor findings in lifetime rodent studies of these nitroimidazoles indicate a risk to patients taking a single dose of SOLOSEC to treat bacterial vaginosis. Avoid chronic use of SOLOSEC.

**Drug Resistance.** Prescribing SOLOSEC in the absence of proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

#### ADVERSE REACTIONS

**Clinical Trials Experience.** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety data described below reflect exposure to 589 patients, of whom 518 received a 2g dose of SOLOSEC. SOLOSEC was evaluated in 3 clinical trials of patients diagnosed with bacterial vaginosis: 2 placebo-controlled trials (Trial 1 n=215, Trial 2 n=189) and 1 uncontrolled safety trial (Trial 3 n=321).

All patients received a single oral dose of study medication or placebo. Trial 1 evaluated a 1g (this dose is not approved) dose (n=71) and a 2g dose (n=72) of SOLOSEC. Trial 2 evaluated a 2g dose (n=125). The population was female, aged 15 to 54 years. Patients in the placebo-controlled trials were primarily Black or African American (54%) or Caucasian (41%). There were no deaths in the trials. Two patients in Trial 3 discontinued due to vulvovaginal candidiasis in the SOLOSEC-treated arm.

#### Most Common Adverse Reactions

Among 197 patients treated with a single 2g dose of SOLOSEC in the 2 placebo-controlled trials, Trial 1 and 2, adverse reactions were reported by approximately 29% of patients. Table 1 displays the most common adverse reactions ( $\geq 2\%$  in SOLOSEC-treated patients) in these 2 trials.

Adverse Reaction	SOLOSEC N=197 n (%)	Placebo N=136 n (%)
Vulvovaginal candidiasis	19 (9.6)	4 (2.9)
Headache	7 (3.6)	2 (1.5)
Nausea	7 (3.6)	1 (0.7)
Diarrhea	5 (2.5)	1 (0.7)
Abdominal pain	4 (2.0)	2 (1.5)
Vulvovaginal pruritus	4 (2.0)	2 (1.5)

Among the 321 patients in an uncontrolled trial, Trial 3, adverse reactions were reported in 30% of patients. Vulvovaginal candidiasis (8.4%), nausea (5.3%), vomiting (2.5%) and dysgeusia (3.4%) were the most common adverse reactions reported in this trial.

**Postmarketing Experience.** The following adverse reactions have been reported during use of other formulations of secnidazole 2g outside of the United States. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Reported adverse reactions were nausea, dysgeusia, abdominal pain, headache, and vomiting.

#### DRUG INTERACTIONS

**Oral Contraceptives.** There was no clinically significant drug interaction between secnidazole and the combination oral contraceptive, ethinyl estradiol plus norethindrone. SOLOSEC can be co-administered with combination oral contraceptives (eg, ethinyl estradiol plus norethindrone).

#### USE IN SPECIFIC POPULATIONS

**Pregnancy.** Limited available data with SOLOSEC use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. In animal reproduction studies, there were no adverse developmental outcomes when secnidazole was administered orally to pregnant rats and rabbits during organogenesis at doses up to 4 times the clinical dose.

**Lactation.** Breastfeeding is not recommended. Discontinue breastfeeding for 96 hours after administration of SOLOSEC.

**Pediatric Use.** The safety and effectiveness of SOLOSEC in pediatric patients below the age of 18 years have not been established.

**Geriatric Use.** Clinical studies with secnidazole did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

#### NONCLINICAL TOXICOLOGY

**Carcinogenesis, Mutagenesis, Impairment of Fertility**  
Nitroimidazoles, which have similar chemical structures to secnidazole, have been associated with tumors affecting the liver, lungs, mammary, and lymphatic tissues in animals after lifetime exposures. It is unclear if these positive tumor findings in lifetime rodent studies of these nitroimidazoles indicate a risk to patients taking a single dose of secnidazole to treat bacterial vaginosis.

Secnidazole was positive in the bacterial reverse mutation assay, but was negative for the rat micronucleus test and mouse lymphoma test.

In a rat fertility study, females were dosed for 2 weeks prior to mating until Day 7 of gestation with males that were dosed for a minimum of 28 days before cohabitation. No parental toxicity or adverse effects on mating performance, estrous cycles, fertility or conception was observed at doses of up to the maximum tolerated dose (300 mg/kg/day, approximately 1.4 times the recommended dose based on AUC comparisons).

#### PATIENT COUNSELING INFORMATION


See FDA-Approved Patient Labeling (Patient Information).

Manufactured for and Distributed by:  
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Based on 7179660 Issued 10/2017

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# A full course of BV treatment in one oral dose<sup>1</sup>

Solosec™ (secnidazole) is the first and only bacterial vaginosis (BV) treatment designed to deliver a complete course of therapy in just one oral dose<sup>1,2</sup>

To learn how Solosec may make it easy for patients to complete treatment, visit [solosechcp.com/journal](http://solosechcp.com/journal).

**ONE PACKET.  
ONE DOSE.  
ONE TIME.**

## INDICATION

SOLOSEC™ (secnidazole) 2g oral granules is a 5-nitroimidazole antimicrobial agent indicated for the treatment of bacterial vaginosis in adult women.

## SELECT IMPORTANT SAFETY INFORMATION

- SOLOSEC is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.
- Vulvo-vaginal candidiasis may develop with SOLOSEC and require treatment with an antifungal agent.
- Potential risk of carcinogenicity in patients taking single-dose of SOLOSEC to treat bacterial vaginosis is unclear. Chronic use should be avoided.
- SOLOSEC is a single-dose therapy for oral use. The entire contents of SOLOSEC packet should be sprinkled onto applesauce, yogurt or pudding and consumed once within 30 minutes without chewing or crunching the granules. SOLOSEC is not intended to be dissolved in any liquid.
- In clinical studies, the most common adverse events occurring in (≥2%) of patients receiving SOLOSEC 2g oral granules were vulvovaginal candidiasis (9.6%), headache (3.6%), nausea (3.6%), dysgeusia (3.4%), vomiting (2.5%), diarrhea (2.5%), abdominal pain (2.0%), and vulvovaginal pruritus (2.0%).

Please see Brief Summary of Prescribing Information on adjacent page.

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-844-SOLOSEC (1-844-765-6732) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

References: 1. SOLOSEC [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; 2017.  
2. Broumas AG, Basara LA. Potential patient preference for 3-day treatment of bacterial vaginosis: responses to new suppository form of clindamycin. *Adv Ther.* 2000;17(3):159-166

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PP-SOL-0096

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