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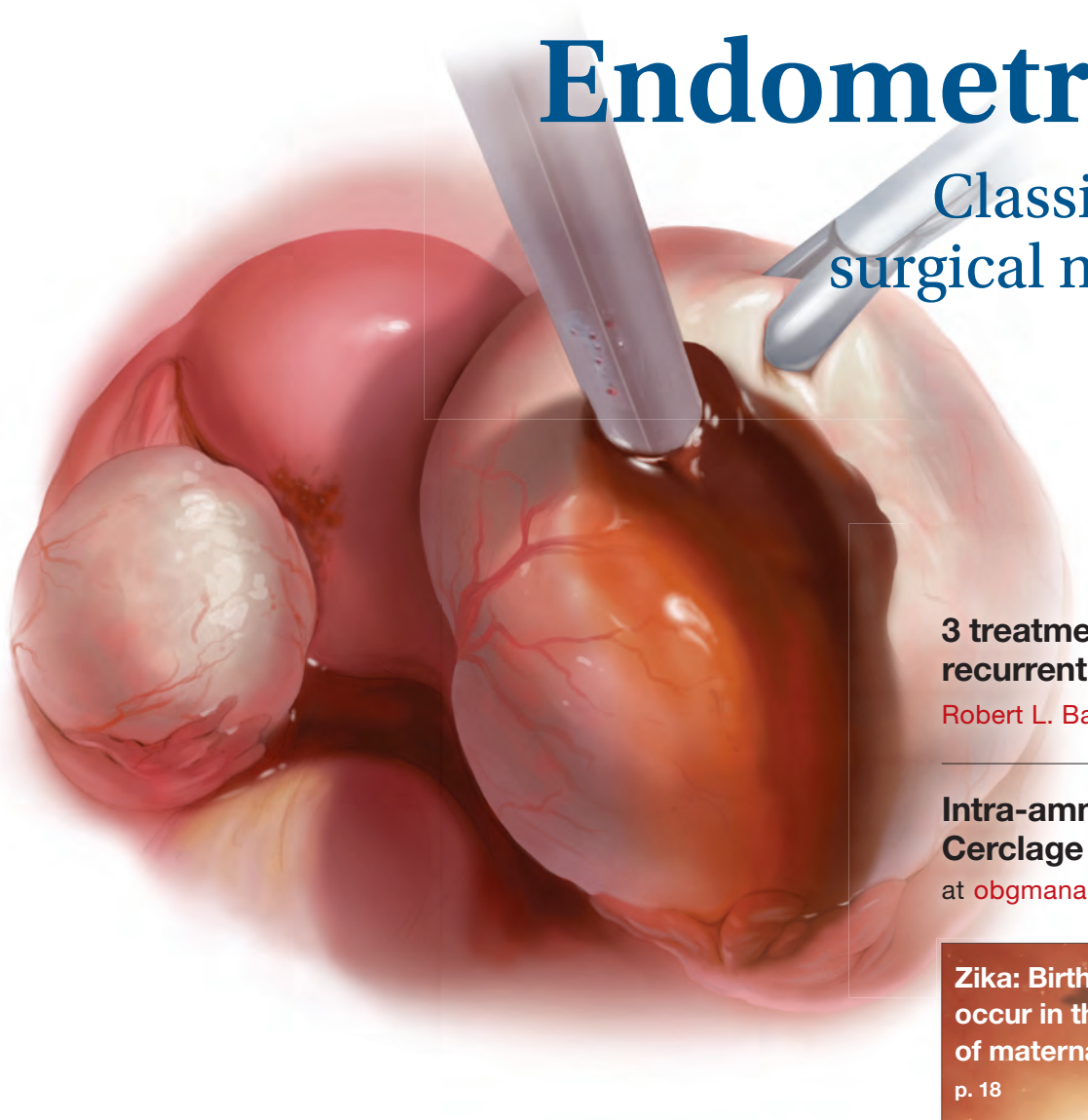

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Robert L. Barbieri, MD

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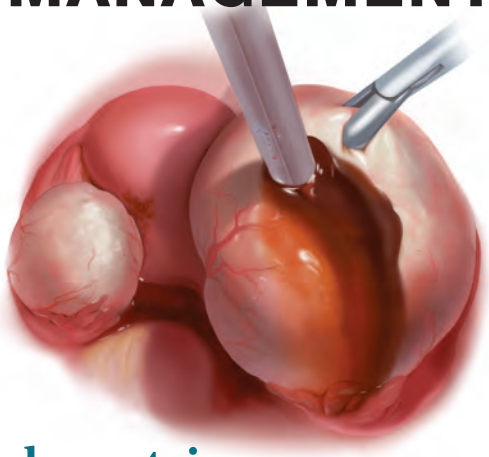

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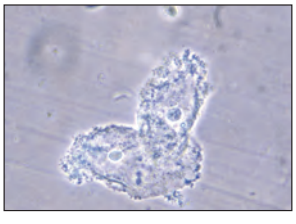
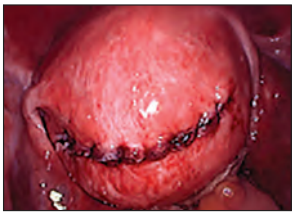


Bacterial vaginosis **7**



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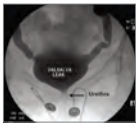

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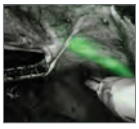

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Effective treatment of recurrent bacterial vaginosis

The 3 treatment options presented herein may help to suppress the rate of bacterial vaginosis recurrence and improve patients' symptoms as well as quality of life

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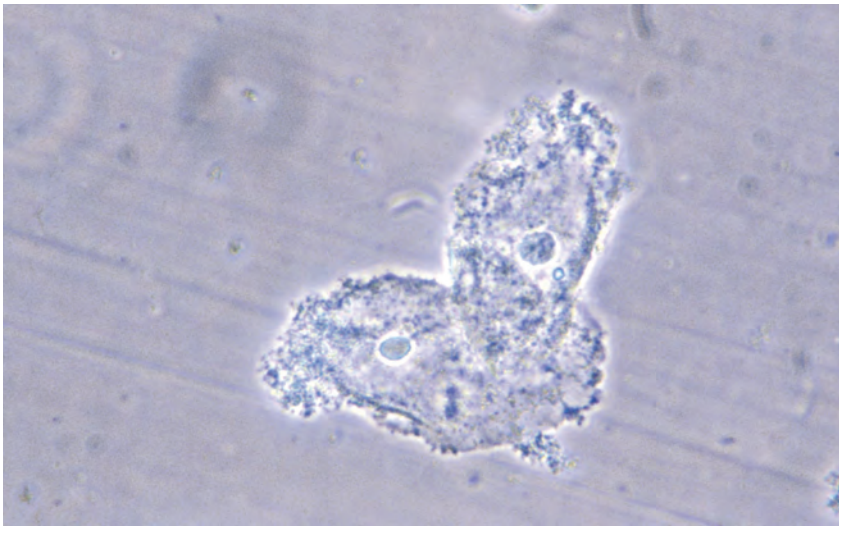
Bacterial vaginosis (BV) is caused by a complex change in vaginal bacterial flora, with a reduction in lactobacilli (which help maintain an acidic environment) and an increase in anaerobic gram-negative organisms including *Gardnerella vaginalis* species and *Bacteroides, Prevotella,* and *Mobiluncus* genera. Infection with *G vaginalis* is thought to trigger a cascade of changes in vaginal flora that leads to BV.[1]

BV is present in 30% to 50% of sexually active women, and of these women 50% to 75% have an abnormal vaginal discharge, which is gray, thin, and homogeneous and may have a fishy odor.[2] In addition to causing an abnormal vaginal discharge, BV is a cause of postpartum fever, posthysterectomy vaginal cuff cellulitis, and postabortion infection, and it increases the risk of acquiring HIV, herpes simplex type 2, gonorrhea, chlamydia, and trichomoniasis infection.[3]

When using microscopy and the Amsel criteria, the diagnosis of BV is made when at least 3 of the following 4 criteria are present:

1. homogeneous, thin, gray discharge
2. vaginal pH >4.5
3. positive whiff-amine test when applying a drop of 10% KOH to a sample of the vaginal discharge
4. clue cells detected with microscopy on a saline wet mount.



Photomicrograph revealing clue cells (epithelial cells that have had bacteria adhere to their surface). Clue cell presence on a saline wet mount is a sign of bacterial vaginosis.

PHOTO: CDC/ M. REIN

If microscopy is not available, the Affirm VPIII test (BD Diagnostic Systems, Franklin Lakes, New Jersey) for DNA sequences of *G vaginalis* has high sensitivity and specificity.[4] The OSOM BVBlue test (Sekisui Diagnostics, Lexington, Massachusetts), a Clinical Laboratory Improvement Amendments–waived point of service test, measures vaginal sialidase, which is produced by *Gardnerella* and other pathogens associated with BV.[5] BV may be detected in routine cervical cytology testing and, if the patient is symptomatic, treatment is recommended.

Initial treatment of BV. The Centers for Disease Control and Prevention

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(CDC) has recommended 3 treatment regimens for BV and 4 alternative treatment options (**TABLE**, page 11).[6] In addition to antimicrobial treatment, the CDC recommends that women with BV use condoms with sexual intercourse. The CDC also advises that clinicians should consider testing women with BV for HIV and other sexually transmitted infections.

Treatment of recurrent BV

A major problem with BV is that, although initial treatment is successful in about 80% of cases, up to 50% of women will have a recurrence of BV within 12 months of initial treatment.[2] Preliminary studies suggest that for women with 3 or more episodes of BV, the regimens below may be effective.

Regimen 1

Following the completion of a CDC-recommended treatment regimen (see TABLE), prescribe metronidazole vaginal gel 0.75%, one full applicator, twice weekly for 6 months.[7]

In a prospective randomized trial examining this regimen, following initial treatment with a 10-day metronidazole vaginal gel regimen 112 women were randomly assigned to chronic suppressive therapy with metronidazole vaginal gel 0.75%, one full applicator, twice weekly for 16 weeks or a placebo. During the treatment period, recurrent BV was diagnosed in 26% of the women taking metronidazole gel and 59% of the women taking placebo.[7] This regimen may be complicated by secondary vaginal candidiasis, which may be treated with a vaginal or oral antifungal agent.

Regimen 2

Initiate a 21-day course of vaginal boric acid capsules 600 mg once daily at bedtime and simultaneously prescribe a standard CDC treatment regimen (see TABLE). At the completion of the vaginal boric acid treatment initiate metronidazole vaginal gel 0.75% twice weekly for 6 months.[8] NOTE: Boric acid can cause death if consumed orally.[9] Boric acid capsules should be stored securely to ensure that they are not accidentally taken orally. Boric acid poisoning may present with vomiting, fever, skin rash, neutropenia, thrombocytopenia, metabolic acidosis, and renal failure.[10] Boric acid should not be used by pregnant women because it is a teratogen.[11]

The bacterial organisms responsible for BV reside in a self-produced matrix, referred to as a biofilm, that protect the organisms from antimicrobial agents.[12] Boric acid may prevent the formation of a biofilm and increase the effectiveness of antimicrobial treatment.

Regimen 3

Following the completion of a standard treatment regimen (see TABLE), prescribe oral metronidazole 2 g and fluconazole 150 mg administered once every month.[13]

In a randomized clinical trial, 310 female sex workers were randomly assigned to monthly treatment with oral metronidazole 2 g plus fluconazole 150 mg or

CONTINUED ON PAGE 11

Instant Poll

In your practice do you prefer 1 of the following options for the treatment of recurrent BV?

A) Regimen 1: Intermittent vaginal metronidazole treatment. Following the completion of a CDC-recommended treatment regimen prescribe metronidazole vaginal gel 0.75%, one full applicator, twice weekly for 6 months.

B) Regimen 2: Boric acid followed by intermittent vaginal metronidazole treatment. Initiate a 21-day course of vaginal boric acid capsules 600 mg once daily at bedtime and simultaneously prescribe a standard CDC treatment regimen. At the completion of the vaginal boric acid treatment initiate metronidazole vaginal gel 0.75% twice weekly for 6 months.

C) Regimen 3: Monthly single-dose oral metronidazole plus fluconazole treatment. Following the completion of a standard treatment regimen, prescribe oral metronidazole 2 g and fluconazole 150 mg administered once every month.

D) Other regimen not listed above.

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INDICATIONS AND USAGES

Methylergonovine Maleate is a semi-synthetic ergot alkaloid used for the prevention and control of postpartum hemorrhage. It is used following delivery of placenta, for routine management of uterine atony, hemorrhage, and subinvolution of the uterus as well as for control of uterine hemorrhage in the second stage of labor following delivery of the anterior shoulder.

CONTRAINDICATIONS

Hypertension, toxemia, pregnancy, and hypersensitivity are contraindications to Methylergonovine Maleate Tablets.

WARNINGS

General: This drug should not be administered intravenously routinely because of the possibility of inducing sudden hypertensive and cerebrovascular accidents. If intravenous administration is considered essential as a lifesaving measure, methylergonovine maleate should be given slowly over a period of no less than 60 seconds with careful monitoring of blood pressure. Intra-arterial or periarterial injection should be strictly avoided. Caution should be exercised in presence of impaired hepatic or renal function.

Breast-Feeding: Mothers should not breast-feed during treatment with Methylergonovine Maleate Tablets, USP. Milk secreted during this period should be discarded. Methylergonovine Maleate Tablets, USP may produce adverse effects in the breast-feeding infant. Methylergonovine Maleate Tablets, USP may also reduce the yield of breast milk. Mothers should wait at least 12 hours after administration of the last dose of Methylergonovine Maleate Tablets, USP before initiating or resuming breast-feeding.

Coronary Artery Disease: Patients with coronary artery disease or risk factors for coronary artery disease (e.g., smoking, obesity, diabetes, high cholesterol) may be more susceptible to developing myocardial ischemia and infarction associated with methylergonovine-induced vasospasm.

Medication Errors: Inadvertent administration of Methylergonovine Maleate Tablets, USP to newborn infants has been reported. In these cases of inadvertent neonatal exposure, symptoms such as respiratory depression, convulsions, cyanosis, and oliguria have been reported. Usual treatment is symptomatic. However, in severe cases, respiratory and cardiovascular support is required. Methylergonovine Maleate Tablets, USP has been administered instead of vitamin K and Hepatitis B vaccine, medications which are routinely administered to the newborn. Due to the potential for accidental neonatal exposure, methylergonovine maleate should be stored separately from medications intended for neonatal administration.

PRECAUTIONS

General: Caution should be exercised in the presence of sepsis, obliterative vascular disease. Also use with caution during the second stage of labor. The necessity for manual removal of a retained placenta should occur only rarely with proper technique and adequate allowance of time for its spontaneous separation.

Drug Interactions

CYP3A4 Inhibitors (e.g., Macrolide Antibiotics and Protease Inhibitors): There have been rare reports of serious adverse events in connection with the coadministration of certain ergot alkaloid drugs (e.g., dihydroergotamine and ergotamine) and potent CYP3A4 inhibitors, resulting in vasospasm leading to cerebral ischemia and/or ischemia of the extremities. Although there have been no reports of such interactions with methylergonovine alone, potent CYP3A4 inhibitors should not be coadministered with methylergonovine. Examples of some of the more potent CYP3A4 inhibitors include macrolide antibiotics (e.g., erythromycin, troleandomycin, clarithromycin), HIV protease or reverse transcriptase inhibitors (e.g., ritonavir, indinavir, nelfinavir, delavirdine) or azole antifungals (e.g., ketoconazole, itraconazole, voriconazole). Less potent CYP3A4 inhibitors should be administered with caution. Less potent inhibitors include saquinavir, nefazodone, fluconazole, grapefruit juice, fluoxetine, fluvoxamine, zileuton, and clotrimazole. These lists are not exhaustive, and the prescriber should consider the effects on CYP3A4 of other agents being considered for concomitant use with methylergonovine.

CYP3A4 Inducers: Drugs (e.g. nevirapine, rifampicin) that are strong inducers of CYP3A4 are likely to decrease the pharmacological action of Methylergonovine Maleate Tablets, USP.

Beta-Blockers: Caution should be exercised when Methylergonovine Maleate Tablets, USP is used concurrently with beta-blockers. Concomitant administration with beta-blockers may enhance the vasoconstrictive action of ergot alkaloids.

Anesthetics: Anesthetics like halothan and methoxyfluran may reduce the oxytocic potency of Methylergonovine Maleate Tablets, USP.

Glyceryl Trinitrate and Other Antianginal Drugs: Methylergonovine maleate produces vasoconstriction and can be expected to reduce the effect of glyceryl trinitrate and other antianginal drugs. No pharmacokinetic interactions involving other cytochrome P450 isoenzymes are known. Caution should be exercised when methylergonovine maleate is used concurrently with other vasoconstrictors, ergot alkaloids, or prostaglandins.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies have been performed in animals to evaluate carcinogenic potential. The effect of the drug on mutagenesis or fertility has not been determined.

Pregnancy: Category C: Animal reproductive studies have not been conducted with methylergonovine maleate. It is also not known whether methylergonovine maleate can cause fetal harm or can affect reproductive capacity. Use of methylergonovine maleate is contraindicated during pregnancy because of its uterotonic effects. (See INDICATIONS AND USAGE).

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Clinical studies of methylergonovine maleate did not include sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

The most common adverse reaction is hypertension associated in several cases with seizure and/or headache. Hypotension has also been reported. Abdominal pain (caused by uterine contractions), nausea and vomiting have occurred occasionally. Rarely observed reactions have included: acute myocardial infarction, transient chest pains, vasoconstriction, vasospasm, coronary arterial spasm, bradycardia, tachycardia, dyspnea, hematuria, thrombophlebitis, water intoxication, hallucinations, leg cramps, dizziness, tinnitus, nasal congestion, diarrhea, diaphoresis, palpitation, rash, and foul taste. There have been rare isolated reports of anaphylaxis, without a proven causal relationship to the drug product.

Nervous System Disorders: Cerebrovascular accident, paraesthesia.

Cardiac Disorders: Ventricular fibrillation, ventricular tachycardia, angina pectoris, atrioventricular block.

DRUG ABUSE AND DEPENDENCE

Methylergonovine maleate has not been associated with drug abuse or dependence of either a physical or psychological nature.

OVERDOSAGE

Symptoms of acute overdose may include: nausea, vomiting, abdominal pain, numbness, tingling of the extremities, rise in blood pressure, in severe cases followed by hypotension, respiratory depression, hypothermia, convulsions, and coma.

Because reports of overdosage with methylergonovine maleate are infrequent, the lethal dose in humans has not been established. The oral LD50 (in mg/kg) for the mouse is 187, the rat 93, and the rabbit 4.5. Several cases of accidental methylergonovine maleate injection in newborn infants have been reported, and in such cases 0.2 mg represents an overdose of great magnitude. However, recovery occurred in all but one case following a period of respiratory depression, hypothermia, hypertonicity with jerking movements, and convulsions.

Also, several children 1-3 years of age have accidentally ingested up to 10 tablets (2 mg) with no apparent ill effects. A postpartum patient took 4 tablets at one time in error and reported paresthesias and clamminess as her only symptoms.

Treatment of acute overdosage is symptomatic and includes the usual procedures of: 1. Removal of offending drug by inducing emesis, gastric lavage, catharsis, and supportive diuresis. 2. Maintenance of adequate pulmonary ventilation, especially if convulsions or coma develop. 3. Correction of hypotension with pressor drugs as needed. 4. Control of convulsions with standard anticonvulsant agents. 5. Control of peripheral vasospasm with warmth to the extremities if needed.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088, or call Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

Please note that this information is not comprehensive. Please see the full prescribing information at www.methergine.com.

Reference: 1. Creanga AA, Berg CJ, Ko JY, et al. Maternal mortality and morbidity in the United States: Where are we now? *J Women's Health*. 2014; 23(1):3-9.

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TABLE Centers for Disease Control and Prevention (CDC) recommended and alternative treatments for bacterial vaginosis.[6,a] Prices are calculated based on average cost of generic medications listed on the Internet sites GoodRx.com or Drugs.com.

CDC recommended treatments

Medication	Regimen	Approximate price
Metronidazole tablets[b]	500 mg orally twice daily for 7 days	$14
Metronidazole 0.75% vaginal gel[b]	One full applicator (5 g) intravaginally once per day for 5 days	$39
Clindamycin 2% vaginal cream[c]	One full applicator (5 g) intravaginally at bedtime for 7 days	$36

CDC alternative treatments

Medication	Regimen	Price
Tinidazole tablets[b]	2 g orally once daily for 2 days	$81
Tinidazole tablets[b]	1 g orally once daily for 5 days	$102
Clindamycin capsule	300 mg orally twice daily for 7 days	$14
Clindamycin vaginal suppository	100 mg intravaginally once at bedtime for 3 days	$161

[a]Women should refrain from sexual activity or use condoms during the treatment regimen.

[b]Alcohol consumption should be avoided during treatment with metronidazole and tinidazole, including for 24 hours after the last dose of metronidazole and 72 hours after the last dose of tinidazole.

[c]Clindamycin cream is oil-based and may weaken latex condoms and diaphragms for up to 5 days after use.

placebo for up to 12 months.[13] In the treatment and placebo groups episodes of BV were 199 and 326 per 100 person-years, respectively (hazard ratio, 0.55; 95% confidence interval, 0.49–0.63; *P*<.001). In Canada, a vaginal ovule containing both a high dose of metronidazole (500 mg) and nystatin (10,000 IU) is available and could be used intermittently to prevent recurrence.[14]

Treatment of partners

The CDC does not recommend treatment of the partners of women with BV because there are no definitive data to support such a recommendation. However, the 6 published clinical trials testing the utility of treating sex partners of women with BV have significant methodologic flaws, including underpowered studies and suboptimal antibiotic treatment regimens.[15] Hence, whether partners should be treated remains an open question. **Many experts believe that, in most cases, BV is a sexually transmitted disease.**[16,17] For women who have sex with women, the rate of BV concordance among partners is high. If one woman has diagnosed BV and symptoms are present in her partner, treatment of the partner is reasonable. For women with BV who have sex with men, sexual intercourse influences disease activity, and consistent use of condoms may reduce the rate of recurrence.[18] Male circumcision may reduce the risk of BV in female partners.[19]

Over-the-counter treatments

In women with BV it is thought that the vaginal administration of lactic acid can help restore the normal acidic pH of the vagina, encourage the growth of lactobacilli, and suppress the growth of the bacteria that cause BV.[20] Many products containing lactic acid in a formulation for vaginal use are available (among them Luvena and Gynofit gel).

Lactobacilli play an important role in maintaining vaginal health. *Lactobacillus rhamnosus* and *Lactobacillus reuteri* are available for purchase as supplements for oral administration. It is thought that oral administration of lactobacilli can help improve the vaginal microbiome. In one clinical trial, 125 women with BV were randomly assigned to receive the combination of 1 week of metronidazole plus oral *Lactobacillus* twice daily for 30 days or metronidazole plus placebo.[21] Resolution of symptoms was reported as 88% and 40% in the metronidazole-lactobacilli and metronidazole-placebo groups, respectively.[21] By contrast, one systematic review of probiotic treatment of BV concluded that there is insufficient evidence to recommend for or against probiotic treatment of BV.[22] Patients with

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recurrent BV commonly report that they believe a probiotic was helpful in resolving their symptoms.

On the horizon

In one trial, a single 2-g oral dose of secnidazole was as effective as a 7-day course of oral metronidazole 500 mg twice daily.[23] In a small dose-finding study, a single dose of either secnidazole 1 g or 2 g was equally effective in treating BV.[24] An effective single-dose treatment of BV would likely improve patient adherence with therapy. Symbionix is preparing for FDA review of this medication (secnidazole, Solosec) for use in the United States.

BV is a prevalent problem and often adversely impacts a woman's quality of life and love relationships. BV recurrence is very common. Many women report that their BV was resistant to intermittet treatment and recurred, repetitively over many years. The 3 treatment options presented in this editorial may help to suppress the recurrence rate and improve symptoms.

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Dr. Barbieri reports no financial relationships relevant to this article.

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DON'T MISS...

›› Dr. Barbieri's editorial next month on the labor management guidelines from ACOG and SMFM.

2017

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COURSE CHAIRS

Tommaso Falcone, MD
Cleveland Clinic

Mickey M. Karram, MD
The Christ Hospital

SPECIAL KEYNOTE SPEAKER

Bahaeddine M. Sibai, MD
University of Texas Medical School

Faculty

Michael S. Baggish, MD
St. Helena Hospital

Linda D. Bradley, MD
Cleveland Clinic

Andrew I. Brill, MD
California Pacific Medical Center

Amanda Nickles Fader, MD
Johns Hopkins Hospital

John Gebhart, MD
Mayo Clinic

Rosanne M. Kho, MD
Cleveland Clinic

Javier F. Magrina, MD
Mayo Clinic Phoenix

Mark D. Walters, MD
Cleveland Clinic

OPTIONAL PRE-CONFERENCE HANDS-ON WORKSHOPS

- Tissue Extraction Techniques *NEW!*
- Laparoscopic Suturing - The "Vertical Zone" (Simulation Lab)
- Hysteroscopy
- Ultrasound
- Technical Aspects of Vaginal Hysterectomy & Cystourethroscopy for the Gynecologist

SPECIAL KEYNOTES

- Avoiding and Managing Postpartum Perineal Disorders
- Management of Obstetric Hemorrhage

PLUS

- Hysterectomy Techniques
  Vaginal • Single Port • Robotic • Total Laparoscopic • Morcellation • Preserving Level 1 Support • Which Approach is Best?
- Incontinence and Prolapse Surgery
- Avoiding and Managing Complications
- Gynecologic Oncology for the Generalist
- Medical Legal Cases
- Fibroid Management & Principles of Electrosurgery
- Surgical Tips for Successful Pelvic Surgery Video Session

PLUS Optional Post-Conference
P.E.P. Practice Management Workshop

To register and for complete information please see our website: **PAGS-cme.org**.

PAGS SCIENTIFIC PROGRAM AGENDA

Agenda and faculty is subject to change. Please see website for updates.

WEDNESDAY, DECEMBER 13, 2017

Pre-Conference Workshops
(Optional, Separate fee required)

8:30 AM **Hands-On Tissue Extraction Techniques** (New workshop)
Led by: Roseanne M. Kho, MD

8:30 AM **Hands-On Laparoscopic Suturing - The "Vertical Zone"** (Simulation Lab)
Led by: Charles H. Koh, MD

1:30 PM **Hands-On Hysteroscopy Workshop**
Led by: Andrew I. Brill, MD

1:30 PM **Hands-On Ultrasound Workshop**
Led by: James M. Shwayder, MD, JD

1:30 PM **Technical Aspects of Vaginal Hysterectomy & Cystourethroscopy for the Gynecologist**
Led by: Mickey Karram, MD

THURSDAY, DECEMBER 14, 2017

6:30 AM **Registration/Breakfast/Exhibits**

7:30 AM **Course Overview**
Mickey Karram, MD

Pelvic Anatomy

7:35 AM **Pelvic and Abdominal Anatomy from the Laparoscopic Surgeon's View**
Tommaso Falcone, MD

8:15 AM **Anatomic Considerations: Facilitating Vaginal Procedures Safely and Effectively**
Mickey Karram, MD

Incontinence and Prolapse Surgery

8:45 AM **Case Discussions: How Best to Evaluate a Variety of Female Pelvic Floor Disorders**
John Gebhart, MD
Mickey Karram, MD

9:30 AM **Question and Answer Session**

10:00 AM **Break/Exhibits**

10:45 AM **Surgery for Stress Incontinence: Does One Sling Fit All?**
Mark D. Walters, MD

11:15 AM **Surgery for Pelvic Organ Prolapse: Getting Back to Basics - Native Tissue Suture Repairs**
John Gebhart, MD

11:45 AM **Mesh Augmented Prolapse Repair; Vaginal Mesh vs. Sacrocolpopexy**
Roseanne M. Kho, MD

12:15 PM **Question and Answer Session**

12:45 PM **Luncheon Symposium**

1:45 PM **Dessert Break/ Exhibits**

Thursday's Keynote Lecture

2:15 PM **Avoiding and Managing Postpartum Perineal Disorders**
Bahaeddine M.Sibai, MD

Fibroid Management & Principles of Electrosurgery

3:00 PM **Myomectomy: Open to Robotic Approaches**
Tommaso Falcone, MD

3:30PM **The Hysteroscopic Treatment of Submucosal Fibroids and Polyps**
Linda D. Bradley, MD

4:00 PM **Break/Exhibits**

4:30 PM **Safe Use of Electrosurgical Devices for Gynecologic Surgery**
Andrew I. Brill, MD

5:00 PM **Question and Answer Session**

FRIDAY, DECEMBER 15, 2017

7:00 AM **Breakfast/Exhibits**

7:10 AM **Breakfast Symposium**

Hysterectomy - Technique

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

8:50 AM **Single Port Approaches to Hysterectomy**
Amanda Nickles Fader, MD

9:25 AM **Total Laparoscopic Hysterectomy**
Andrew I. Brill, MD

10:00 AM **Break /Exhibits**

10:45 AM **Robotic Hysterectomy**
Javier F. Magrina, MD

11:15 AM **Tissue Extraction Techniques (Morcellation)**
Tommaso Falcone, MD

11:45 AM **Techniques to Preserve Level 1 Support at the Time of Vaginal Laparoscopic and Robotic Hysterectomy**
Mark D. Walters, MD

12:15 PM **Which Hysterectomy Approach is Best?**
Case Presentation and Audience Participation

12:45 PM **Question and Answer Session**

1:00 PM **Luncheon Symposium**

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

Friday's Keynote Lecture

2:30 PM **Management of Obstetric Hemorrhage**
Bahaeddine M. Sibai, 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 16, 2017

6:30 AM **Breakfast**

7:30 AM **Management of Endometriosis**
Tommaso Falcone, MD

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

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

10:30 AM **Break**

10:45 AM **Medical Legal Cases**
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 Karram, MD

1:00 PM **PAGS Scientific Program Adjournment**

P.E.P. PRACTICE MANAGEMENT WORKSHOP AGENDA

(Optional. Separate fee required)
3.25 CME Credits Available

Director
Neil H. Baum, MD
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 16, 2017

2:00 PM **Course Overview**

2:10-3:00 PM
Looking at the 4 Pillars of a Successful Practice in the Current Healthcare Environment
- Keeping patients already in your practice
- Attracting new patients to your practice (social media techniques to add 3-5 new patients a day to your practice)
- Communicating with your professional colleagues
- Enhancing staff morale

3:00-3:30 PM
Moving from Volume to Value- The New Metric of Healthcare
- Fee for Service and volume of work performed will no longer be the method of reimbursement in the near future
- Will define quality (outcomes\costs)
- Provide the 7 steps to measure cost-of-care

3:30-3:45 PM **Break**

3:45-4:15 PM
Online Reputation Management
- The importance of a physician's reputation
- How it can be ruined with the click of a mouse
- How to obtain positive reviews
- Management of negative reviews

4:15-4:45 PM
Patient Satisfaction
- Discuss why patient satisfaction is important
- What are the needs and wants of today's primary care patient
- How we measure patient satisfaction
- Practical suggestions for enhancing patient satisfaction

4:45-5:00 PM
Numbers you Need to Know
- Obstetricians and gynecologists need to know and monitor just a few numbers
- Without understanding these concepts, you will not understand the value of the services that you provide
- Will review 5 numbers that need to be monitored (charges\receipts, RVUs, ARs\days in AR, charge lag, denials)

5:00-5:15 PM **Q and A**

5:15-5:30 PM
The Future of Medical Practice and Conclusion
- What is the current situation
- What happens if ACA is repealed
- What can primary care providers do pro-actively to enhance their practices in the near future

PAGS Scientific Faculty

Course Chairs

Tommaso Falcone, MD
Professor and Chair
Department of Obstetrics-Gynecology
Cleveland Clinic
Cleveland, Ohio

Mickey M. Karram, MD
Director of Fellowship Program
Female Pelvic Medicine and Reconstructive Surgery
The Christ Hospital
Professor of Ob/Gyn & Urology
University of Cincinnati
Cincinnati, Ohio

Special Keynote Speaker

Bahaeddine M. Sibai, MD
Professor
Department of Obstetrics, Gynecology and Reproductive Sciences
University of Texas Health Science Center
Houston, Texas

Faculty

Michael S. Baggish, MD
Professor of Obstetrics and Gynecology
University of California San Francisco
St. Helena Hospital
St. Helena, California

Linda D. Bradley, MD
Vice Chair Obstetrics, Gynecology, and Women's Health Institute
Director, Fibroid and Menstrual Disorders Center
Director, Hysteroscopic Services
Cleveland Clinic
Cleveland, Ohio

Andrew I. Brill, MD
Director, Minimally Invasive Gynecology
California Pacific Medical Center
Mill Valley, California

Amanda Nickles Fader, MD
Associate Professor and Director
Kelly Gynecologic Oncology Service
Director of Minimally Invasive Surgery
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Baltimore, Maryland

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Director, Female Pelvic Medicine & Reconstructive Surgery Fellowship
Mayo Clinic
Rochester, Minnesota

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Cleveland, Ohio

Javier F. Magrina, MD
Professor of Obstetrics and Gynecology
Co-Director Minimally Invasive Fellowship in Gynecologic Surgery
Director, Gynecologic Oncology
Department of Gynecologic Surgery
Mayo Clinic
Phoenix, Arizona

Mark D. Walters, MD
Professor and Vice Chair of Gynecology
Center for Urogynecology and Reconstructive Pelvic Surgery
Department of Obstetrics-Gynecology
Cleveland Clinic
Cleveland, Ohio

Pre-Conference Workshops

(Optional. Separate fee required)
Please note: PAGS workshops have limited space available and do sell out. First come. First served!

Wednesday, December 13, 2017 The Cosmopolitan of Las Vegas

HANDS-ON TISSUE EXTRACTION TECHNIQUES WORKSHOP NEW!
4 CME Credits Available
8:00 AM - 12:30 PM
Director: Rosanne M. Kho, MD
Faculty: Andrew I. Brill, MD; Tommaso Falcone, MD; Keith B. Isaacson, MD

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

HANDS-ON HYSTEROSCOPY WORKSHOP
4 CME Credits Available
1:30-PM - 5:30 PM
Led by: Andrew I. Brill, MD
Faculty: Linda D. Bradley, MD; Tommaso Falcone, MD; Keith B. Isaacson, MD

HANDS-ON ULTRASOUND WORKSHOP
4 CME Credits Available
1:30 PM - 5:30 PM
Led by: James M. Shwayder, MD, JD
Faculty: William W. Brown, III, MD, FACOG, FAIUM; Todd Deutch, MD; Tommaso Falcone, MD

HANDS-ON TECHNICAL ASPECTS OF VAGINAL HYSTERECTOMY & CYSTOURETHROSCOPY FOR THE GYNECOLOGIST
4 CME Credits Available
1:30 PM - 5:30 PM
Led by: Mickey Karram, MD
Faculty: Rosanne M. Kho, MD and Douglas 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.

PAGS 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, Inc. The University of Cincinnati is accredited by the ACCME to provide continuing medical education for physicians.

The University of Cincinnati Continuing Medical Education Office has reviewed this activity and has approved it for 20 *AMA PRA CME Category 1 credits*™ for the conference scientific program, the pre-conference workshops at 4.0 *AMA PRA CME Category 1 credits*™ each, and the post workshop at 3.25 *AMA PRA CME Category 1 credits*™.

2017

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  - Laparoscopic Suturing
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  - Technical Aspects of Vaginal Hysterectomy & Cystourethroscopy for the Gynecologist
- **Incontinence and Prolapse Surgery**
- **Gynecologic Oncology for the Generalist**
- **Hysterectomy Techniques**
  - Vaginal
  - Single-port
  - Total Lap
  - Robotic
  - Morcellation
  - Preserving Level 1 Support
  - Which Approach is Best?
- **Avoiding and Managing Complications**
- **Fibroid Management & Principles of Electrosurgery**
- **Surgical Tips for Successful Pelvic Surgery**

SPECIAL KEYNOTES: Bahaeddine M. Sibai, MD

- **Avoiding and Managing Postpartum Perineal Disorders**
- **Management of Obstetric Hemorrhage**

Plus! "PEP" Practice Management Workshop*

*(*Optional, separate fee required)*

SCIENTIFIC SESSIONS **20 CME Credits Available**
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Optional **"PEP" PRACTICE MANAGEMENT PROGRAM**
3.25 CME Credits Available
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About Our Venue
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The 2017 Pelvic Anatomy and Gynecologic Surgery Symposium will take place at the ultra-modern Cosmopolitan of Las Vegas, where we have arranged for a discount room rate of just $179* a night for PAGS participants. To make your reservation call-855.435.0005 (domestic toll free) or 855.455.1055 (international toll free) and reference the code SGAME7.

The discount rate expires November 14, but we urge you to make your arrangements now, as our room block will sell out.

*Plus $25 amenity fee.

How to Register for PAGS

Online: www.PAGS-CME.org

Mail: PAGS 2017
c/o Global Academy for Medical Education
7 Century Drive, Suite 301
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Inquiries: PAGS@globalacademycme.com

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■ **Hands on Workshop (each)**	$195	$205	$255	$350

Cancellation Policy: 2017 PAGS will offer a full refund less a $50 administrative fee as follows: requests for refunds must be made in writing, postmarked, e-mailed, or faxed prior to November 14, 2017. After November 14, 2017, no refunds will be granted. Substitutions are welcomed in lieu of cancellations.
Refunds will not be issued to no-shows.

To register and for complete information please see our website: PAGS-cme.org.

"2017 UPDATE ON ABNORMAL UTERINE BLEEDING"
HOWARD T. SHARP, MD, AND MARISSA ADELMAN, MD (APRIL 2017)

Hysteroscopy equipment too expensive for employed or small-group practitioners

I could not agree more with Drs. Sharp and Adelman that diagnostic hysteroscopy should be performed in the office whenever possible. However, as a solo gynecologist in private practice, I could not afford or justify the cost of purchasing the equipment as well as its care and maintenance. Sometimes I was able to bring a third-party vendor to provide the equipment and a technician so that I could perform a diagnostic hysteroscopy in my office when I did an ablation with my own Thermachoice equipment and balloon system.

The hysteroscopy was bundled/required for the Current Procedural Terminology (CPT) code to work in the office. Most of these patients already had undergone an ultrasonography, endometrial biopsy, and some had an outpatient hysteroscopic dilation and curettage under general anesthesia, which did not resolve their bleeding. All of this adds to the cost and increased patient discomfort and inconvenience. Reimbursement for the office procedure was better than when performed at the hospital, and patients avoided $500 to $1,000 copays to the hospital and anesthesiologist.

When I closed my private practice and became employed by the hospital, I proposed that they purchase office hysteroscopy equipment for the other gynecologist and me to share. I continued to perform uterine ablations with my own equipment. Together we performed more than 100 outpatient diagnostic hysteroscopies per year, some with global endometrial ablation. Since there were only 2 gyns, the 2 new hysteroscopy sets they purchased sat in the closet most of the time.

I suggested they "lease" the equipment back to us on a case-by-case basis for office use since they owned and managed our practices. The hospital administration basically saw office procedures as taking away revenue from the hospital and decreasing operating room volume. The patients I treated in the office setting did well, preferred to avoid general anesthesia, and enjoyed the cost savings.

Large ObGyn groups with multiple providers and high volumes can justify the expenses of the equipment, but for those in solo practice or employed by a hospital, it may not be feasible. I sincerely hope that articles focusing on in-office hysteroscopy will open up the discussion to enable and encourage more physicians and hospital administrators to see the advantages of office-based procedures.

Steven R. Moffett, MD
Knoxville, Tennessee

"TREATING POLYCYSTIC OVARY SYNDROME: START USING DUAL MEDICAL THERAPY"
ROBERT L. BARBIERI, MD (EDITORIAL; APRIL 2017)

Why extended release metformin?

I read with interest Dr. Barbieri's editorial on polycystic ovary syndrome. It left me wondering: Is there a metabolic or pharmacologic reason why you give metformin XR 1,500 mg with dinner instead of 750 mg orally twice per day?

Marcelo Andreoli, MD
Vienna, Virginia

›› Dr. Barbieri responds

I thank Dr. Andreoli for the important clinical question about one-time or multiple dosing of metformin. To improve patient adherence with metformin treatment, I think once-daily dosing at dinner with an extended-release formulation is more convenient than twice-daily dosing with immediate-release metformin. Following ingestion of immediate- or extended-release metformin, peak metformin blood concentrations are achieved after 2 and 7 hours, respectively.[1] There is some evidence that extended-release metformin has fewer gastrointestinal (GI) adverse effects than immediate-release metformin.[2] In one study, the reported rates of GI adverse effects were 29% versus 39% with extended-release and immediate-release formulations, respectively.[2]

References

1. Ali S, Fonseca V. Overview of metformin: special focus on metformin extended release. Expert Opin Pharmacother. 2012;13(12):1797–1805.
2. Fujioka K, Pans M, Joyal S. Glycemic control in patients with type 2 diabetes mellitus switched from twice-daily immediate-release metformin to a once-daily extended-release formulation. Clin Ther. 2003;25(2):515–529.

"WHY ARE THERE DELAYS IN THE DIAGNOSIS OF ENDOMETRIOSIS?"
ROBERT L. BARBIERI, MD (EDITORIAL; MARCH 2017)

Look for symptoms of IBS, PCOS, and PMS

I practiced reproductive endocrinology for 40 years and saw too many patients whose endometriosis had been ignored or undertreated. I found that the initial suspicion for the disease could be discovered by looking for symptoms of 3 comorbidities: irritable bowel syndrome, polycystic ovary syndrome, and premenstrual syndrome.

Wilbur (Dub) Howard, MD
Dallas, Texas

CONTINUED ON PAGE 14

CONTINUED FROM PAGE 13

"ROBOT-ASSISTED LAPAROSCOPIC RESECTION OF A NONCOMMUNICATING CAVITARY RUDIMENTARY HORN"
OBIANUJU SANDRA MADUEKE-LAVEAUX, MD, MPH; BETH W. RACKOW, MD; AND ARNOLD P. ADVINCULA, MD
(VIDEO; JANUARY 2017)

The fallopian tube should have been removed

I watched the video by Dr. Advincula and colleagues and as always was impressed with the surgical skills demonstrated. While the robot-assisted approach is quite nice, this case could have been accomplished with only three 5-mm lower abdominal port sites and traditional straight-stick laparoscopic methods. The cosmetic benefit to a 15-year-old patient of this alternative should have been considered.

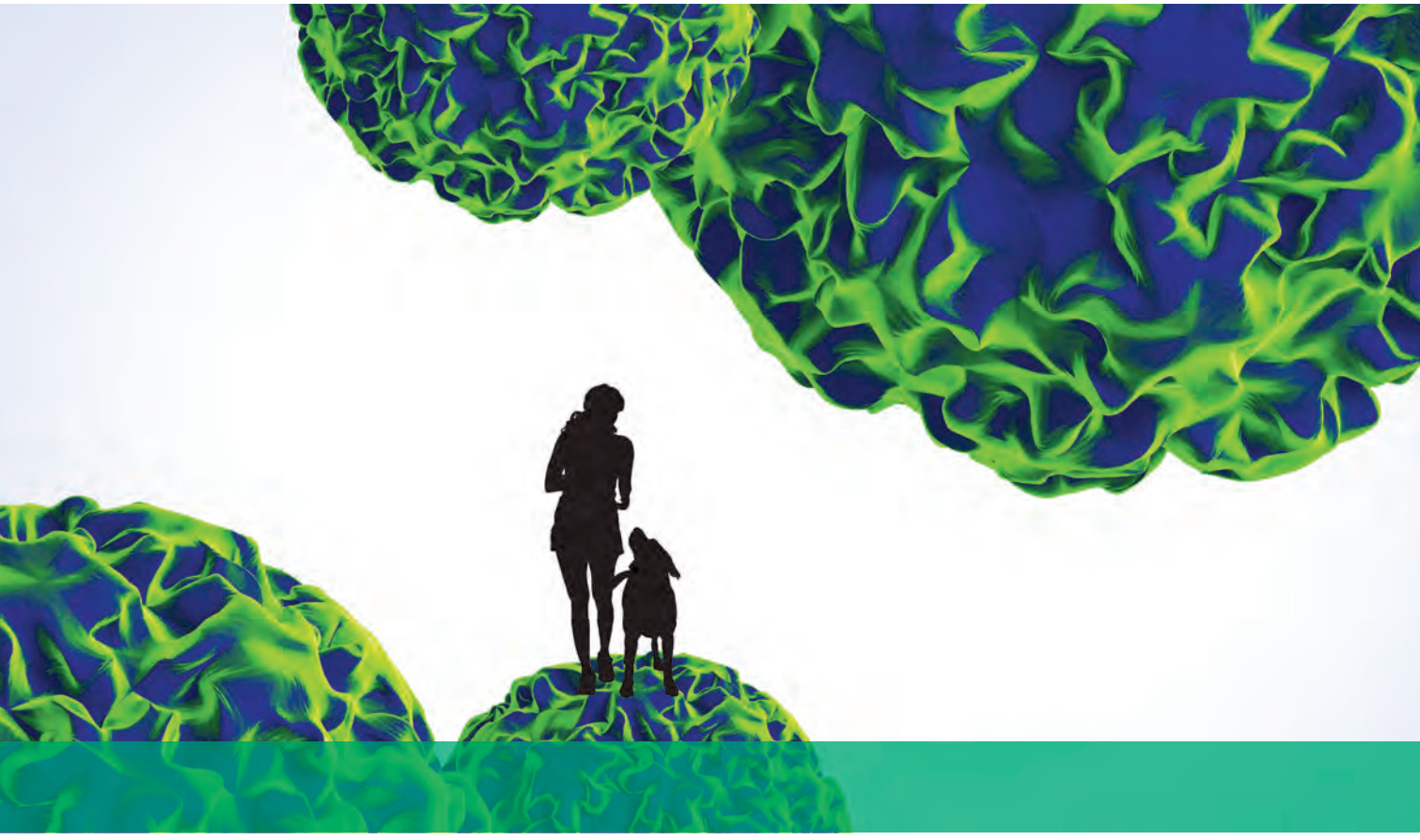
More importantly, the fallopian tube separated from the rudimentary horn should have been removed. Leaving the right tube in situ exposes the patient to the possibility of a future ectopic pregnancy in that tube and provides no benefit to the patient.

David L. Zisow, MD
Baltimore, Maryland

›› Dr. Advincula and team respond

We appreciate Dr. Zisow's perspective. As is known, tool selection is based on surgeon preference. Inherent to this point, a discussion about route of surgery, and any implications it would have, such as cosmesis, was had. Cosmesis was not an issue with this patient, and she was quite pleased with her cosmetic outcome.

We also discussed preoperatively, among our team and with the patient, the right fallopian tube. Although removal would have been optimal, there was concern intraoperatively of possible compromise to the ovary. Hence, a decision was made to forego removal particularly in light of the extremely rare risk of transperitoneal migration of spermatozoa weighed against the risk of compromising a perfectly healthy ovary in a 15-year-old woman.



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KNOW THE RISK

Is sentinel lymph node mapping associated with acceptable performance characteristics for the detection of nodal metastases in women with endometrial cancer?

Yes. Sentinel lymph node (SLN) biopsy will accurately identify nodal metastases in 97% of women with nodal disease. Negative SLNs are accurate in 99% of cases.

Rossi EC, Kowalski LD, Scalici J, et al. A comparison of sentinel lymph node biopsy to lymphadenectomy for endometrial cancer staging (FIRES trial): a multicenter, prospective, cohort study. Lancet Oncol. 2017;18(3):384–392.

EXPERT COMMENTARY

›› **Jason D. Wright, MD,** is Sol Goldman Associate Professor, Chief of the Division of Gynecologic Oncology, and Vice Chair of the Department of Obstetrics and Gynecology, Columbia University College of Physicians and Surgeons, New York, New York.

FAST TRACK

Of women with SLNs identified, 35 of 36 nodal metastases were identified—a 97% sensitivity. Negative SLNs correctly predicted the absence of metastases in 99.6% of patients.

The role of lymphadenectomy for endometrial cancer has evolved considerably over the last 30 years. While pathologic assessment of the nodes provides important information to tailor adjuvant therapy, 2 randomized trials both reported no survival benefit in women who underwent lymphadenectomy compared with hysterectomy alone.[1,2] Further, these trials revealed that lymphadenectomy was associated with significant short- and long-term sequelae.

SLN biopsy, a procedure in which a small number of nodes that represent the first drainage basins of a primary tumor are removed, has been proposed as an alternative to traditional lymphadenectomy. Although SLN biopsy is commonly used for other solid tumors, few large, multicenter studies have been conducted to evaluate the technique's safety in endometrial cancer.

The author reports that he is a consultant for Clovis and Tesaro.

Details of the study

The Fluorescence Imaging for Robotic Endometrial Sentinel lymph node biopsy (FIRES) trial was a prospective trial evaluating the performance characteristics of SLN biopsy in women with clinical stage 1 endometrial cancer at 10 sites in the United States. After cervical injection of indocyanine green, patients underwent robot-assisted hysterectomy with SLN biopsy followed by pelvic lymphadenectomy. Para-aortic lymphadenectomy was performed at the discretion of the attending surgeon. The study's primary end point was sensitivity of SLN biopsy for detecting metastatic disease in women who had mapping.

Over approximately 3 years, 385 patients were enrolled. Overall, 86% of patients had mapping of at least 1 SLN and 52% had bilateral mapping. Positive nodes were found in 12% of the study population. Among women who had SLNs identified, 35 of 36 nodal metastases were identified (97% sensitivity). Negative SLNs correctly predicted the absence of metastases (negative predictive value) in 99.6% of patients.

Overall, the procedure was well tolerated. Adverse events were noted in 9% of patients, and approximately two-thirds were considered serious adverse events. The most common adverse events were neurologic complications, respiratory distress, nausea and vomiting, and bowel injury in

3 patients. One ureteral injury occurred during SLN biopsy.

Study strengths and weaknesses

The FIRES study provides strong evidence for the effectiveness of SLN biopsy in women with apparent early stage endometrial cancer. The procedure not only was highly accurate in identifying nodal disease but it also had acceptable adverse events. Further, many of the benefits of SLN biopsy, such as a reduction in lymphedema, will require long-term follow-up.

Consider study results in context. As oncologists consider the role of SLN biopsy in practice, this work should be interpreted in the context of the study design. The study was performed by only 18 surgeons at 10 centers. Prior to study initiation, each site and surgeon underwent formal training and observation to ensure that the technique for SLN biopsy was adequate. Clearly, there will be a learning curve for SLN biopsy, and this study's results may not immediately be generalizable.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

While the role of lymph node assessment for endometrial cancer will remain controversial, for women who undergo nodal evaluation, SLN biopsy is associated with excellent performance characteristics and is a reasonable option.

›› JASON D. WRIGHT, MD

Despite rigorous quality control procedures, there was no nodal mapping in 48% of the hemi-pelvises. In practice, these patients require lymph node dissection. The authors estimated that 50% of patients would still require lymphadenectomy (40% unilateral, 10% bilateral) if SLN mapping was used in routine practice. In addition, while the FIRES trial included women with high-risk histologies, the majority of patients had low-risk, endometrioid tumors. Further study will help to define performance of SLN biopsy in populations at higher risk for nodal metastases.

FAST TRACK

SLN biopsy not only was highly accurate in identifying nodal disease but it also had acceptable adverse events

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INFECTIOUS DISEASE

Four recent studies provide new data—with potential global impact—regarding birth defect rates in symptomatic and asymptomatic maternal Zika virus infection, dual-agent prophylaxis for postcesarean infection, tenofovir treatment of hepatitis B in pregnant women, and HIV transmission rates in patients receiving ART

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The authors report no financial relationships relevant to this article.

IN THIS ARTICLE

In this Update we review the results of 4 recent investigations that have important implications:

- the first analysis of the US Zika Virus Infection in Pregnancy Registry
- a study revealing an improved antibiotic regimen to prevent postcesarean infection
- an important new methodology for reducing the rate of perinatal transmission of hepatitis B virus (HBV) infection
- the risks and benefits of combination antiretroviral therapy (ART) in pregnancy.

Zika virus–associated birth defect rates similar regardless of symptom presence; first-trimester exposure has highest rate of anomalies

Honein MA, Dawson AL, Petersen EE, et al; US Zika Pregnancy Registry Collaboration. Birth defects among fetuses and infants of US women with evidence of possible Zika virus infection during pregnancy. JAMA. 2017;317(1):59–68.

Honein and colleagues provide a summary of the data from the US Zika Virus in Pregnancy Registry (a collaboration between the Centers for Disease Control and Prevention and state and local health departments), estimating the proportion of fetuses and infants with birth defects based on maternal symptoms of Zika virus infection and trimester of possible infection.

Details of the study

The authors evaluated the outcomes of 442 women who had laboratory evidence of a possible Zika virus infection during pregnancy. Overall, 26 infants (6%; 95% confidence interval (CI), 4%–8%) had evidence of birth defects related to the Zika virus. Of note, abnormalities were detected in 16 of the 271 children (6%; 95% CI, 4%–9%) born to women who were asymptomatic and 10 of 167 (6%; 95% CI, 3%–11%) children delivered to women with symptomatic infections.

The most common birth defect was microcephaly, although other serious central nervous system abnormalities were noted as well. Nine of 85 women (11%; 95% CI, 6%–19%) who had exposure only during the first trimester had infants with birth defects. There were no documented abnormalities in infants born to mothers who developed Zika virus infection only in the second or third trimester.

Key study findings

This article is important for several reasons. First, the authors describe the largest series of pregnant women in the United States with Zika virus infection. All of these patients developed Zika virus infection as a result of foreign travel or exposure to sexual partners who had traveled to Zika virus endemic areas. Second, the authors confirmed findings that previously had been based only on mathematical models rather than on actual case series. Specifically, they demonstrated that the risk of a serious birth defect following first-trimester exposure to Zika virus infection was approximately 11%, with a 95% CI that extended from 6% to 19%. Finally, Honein and colleagues

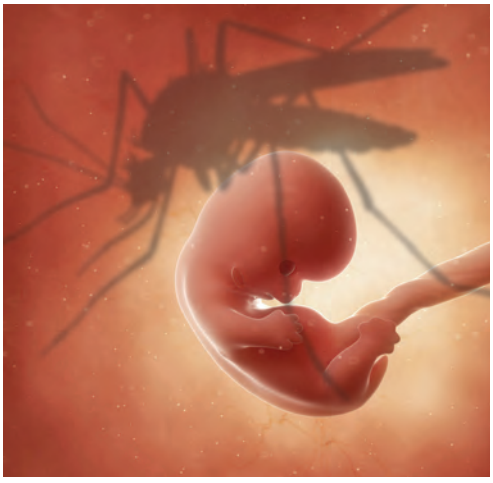

ILLUSTRATION: SHUTTERSTOCK

highlighted the key fact that the risk of a serious birth defect was comparable in mothers who had either an asymptomatic or a symptomatic infection, a finding that seems somewhat counterintuitive.

CONTINUED ON PAGE 20

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This study's critical observations are a "call to action" for clinicians who provide prenatal care.[1,2] Proactive steps include:

- For patients considering pregnancy, strongly advise against travel to any area of the world where Zika virus is endemic until an effective vaccine is available to protect against this infection.
- For any woman with a newly diagnosed pregnancy, ask about travel to an endemic area.
- Inquire also about a pregnant woman's exposure to partners who live in, or who have traveled to, areas of the world where Zika virus infection is endemic.
- Be aware that both asymptomatic and symptomatic infection in the first trimester of pregnancy pose a grave risk to the fetus.
- Recognize that, although microcephaly is the principal abnormality associated with Zika virus infection, other central nervous system anomalies also may occur in these children. These include ventriculomegaly, subcortical calcifications, abnormalities of the corpus callosum, cerebral atrophy, and cerebellar abnormalities. In addition, infected infants may have arthrogryposis.
- Finally, as Honein and colleagues noted, laboratory testing for Zika virus infection is imperfect. In the early stages of infection or exposure, testing for Zika virus infection by polymerase chain reaction (PCR) in both serum and urine is the preferred test. After a period of 2 weeks, the preferred laboratory test is an immunoglobulin M (IgM) assay. Positive tests on the IgM assay must be confirmed by the plaque neutralization reduction test—a very important test for differentiating Zika virus infection from infection caused by other arboviruses, such as those that cause dengue fever and chikungunya.

CONTINUED FROM PAGE 19

Two antibiotics before cesarean delivery reduce infection rates further than one agent

Tita AT, Szychowski JM, Boggess K, et al; for the C/SOAP Trial Consortium. Adjunctive azithromycin prophylaxis for cesarean delivery. N Engl J Med. 2016;375(13):1231–1241.

FAST TRACK

Previous studies showed that adding azithromycin to a usual antibiotic regimen reduced the rates of postcesarean endometritis and wound infection

Tita and colleagues reported the results of a multicenter trial that was designed to assess whether a combination of 2 antibiotics, including one that specifically targets ureaplasma species, provided more effective prophylaxis against postcesarean infection than single-agent prophylaxis.

Details of the study

The Cesarean Section Optimal Antibiotic Prophylaxis (C/SOAP) trial was conducted at 14 centers in the United States and included 2,013 women who were at least at 24 weeks' gestation and who had a cesarean delivery during labor or after membrane rupture.

The authors randomly assigned 1,019 women to receive 500 mg of intravenous azithromycin plus conventional single-agent prophylaxis (usually cefazolin) and 994 women to receive a placebo plus conventional prophylaxis. The primary outcome was the composite of endometritis, wound infection, or other infection occurring within 6 weeks.

The authors observed that the primary outcome occurred in 62 women (6.1%) who received azithromycin plus conventional prophylaxis and in 119 women (12%) who received only single-agent prophylaxis. The relative risk of developing a postoperative infection was 0.51 in women who received the combined therapy. There were significant differences between the 2 groups in both the rates of endometritis (3.8% vs 6.1%, $P = .02$) and wound infection (2.4% vs 6.6%, $P<.001$). There were no differences between the groups in the frequency of the secondary neonatal composite outcome, which included neonatal death and serious neonatal complications.

Efficacy of dual-agent prophylaxis

At present, the standard of care is to administer prophylactic antibiotics to all women having cesarean delivery, including women having a scheduled cesarean in the absence of labor or ruptured membranes. Multiple studies have shown clearly that prophylaxis reduces the frequency of endometritis and, in high–risk patient populations, wound infection, and that prophylaxis is most beneficial when administered prior to the time the surgical incision is made. The most commonly used drug for prophylaxis is cefazolin, a first-generation cephalosporin. The usual recommended dose is 2 g, administered immediately prior to surgery.[3,4]

Although most centers in the United States traditionally have used just a single antibiotic for prophylaxis, selected recent reports indicate that expanding the spectrum of activity of prophylactic antibiotics can result in additional beneficial effects. Specifically, Tita and colleagues evaluated an indigent patient population with an inherently high rate of postoperative infection.[5] They showed that adding azithromycin 500 mg to cefazolin significantly reduced the rate of postcesarean endometritis. In a follow–up report from the same institution, Tita and colleagues demonstrated that adding azithromycin also significantly reduced the frequency of wound infection.[6] Of note, in both these investigations, the antibiotics were administered after cord clamping. In a subsequent report, Ward and Duff showed

that the combination of azithromycin plus cefazolin administered preoperatively resulted in a combined rate of endometritis and wound infection that was less than 3%.[7]

C/SOAP trial confirmed lower infection rates with combined regimen

Results of the present study confirm the findings of these 3 investigations. The trial included a large sample size. The study was carefully designed, and the end points were clearly defined. It included only patients at increased risk for postoperative infection by virtue of being in labor or having ruptured membranes at the time of cesarean delivery. Patients who received standard prophylaxis, usually cefazolin, *plus* azithromycin had a significantly lower risk of postcesarean endometritis and wound infection compared with patients who received a single antibiotic. The overall risk of infection was reduced by an impressive 50%.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Based on the results of the C/SOAP trial, considered in conjunction with the 3 previously cited investigations,[5–7] we believe that the standard approach to antibiotic prophylaxis should be to administer both cefazolin, in a dose of 2 g, plus azithromycin, in a dose of 500 mg, prior to surgery. Cefazolin can be administered as an intravenous bolus; azithromycin should be administered as a continuous infusion over a 60–minute period prior to surgery. Clinicians may anticipate very low rates of both endometritis and wound infection with this regimen.

Tenofovir treatment in pregnant women with HBV reduces vertical transmission

Pan CQ, Duan Z, Dai E, et al; China Study Group for the Mother-to-Child Transmission of Hepatitis B. Tenofovir to prevent hepatitis B transmission in mothers with high viral load. N Engl J Med. 2016;374(24):2324–2334.

A multicenter, open-label, randomized, parallel-group investigation was conducted from March 2012 to June 2013 at academic tertiary care centers in 5 geographic regions of China. Two hundred mothers, who were positive for both hepatitis B surface antigen (HBsAg) and hepatitis B e antigen (HBeAg) and who had HBV DNA concentrations of 200,000 IU/mL or greater, were randomly assigned in a 1:1 ratio to either tenofovir or to usual treatment. Exclusion criteria were coexistent viral infections or medical conditions, renal failure, laboratory abnormalities, fetal deformities, and use of many medications.

Details of the study

Women in the active treatment group received tenofovir 300 mg by mouth daily from 30 to 32 weeks' gestation until postpartum week 4. Patients were monitored every 4 weeks in the antepartum period for adverse events and laboratory abnormalities. In the postpartum period, mother-infant dyads were evaluated at weeks 4, 12, 24, and 28.

Primary outcomes were the rates of mother-to-child transmission and birth defects with, or without, tenofovir exposure. Secondary outcomes were the percentage of mothers who had an HBV DNA serum concentration of less than 200,000 IU/mL at delivery and the percentage of mothers with HBeAg or HBsAg loss or seroconversion at postpartum week 28. Safety outcomes included the adverse event profile of tenofovir in mothers and safety events in the mother-infant dyads. These outcomes encompassed

FAST TRACK

We believe that the standard approach to antibiotic prophylaxis for cesarean delivery should be to administer cefazolin 2 g plus azithromycin 500 mg before surgery

all adverse events and drug discontinuations in patients who received at least one dose of tenofovir.

Sixty-eight percent of mothers in the tenofovir group, compared with 2% of mothers in the control group, had HBV levels less than 200,000 IU/mL at delivery ($P<.001$). The rate of mother-to-child HBV transmission at postpartum week 28 was lower in the tenofovir group. In the intention-to-treat analysis, the rate was 5% (95% CI, 1–10; 5 of 97 infants) in the tenofovir group versus 18% (95% CI, 10–26; 18 of 100 infants) in the control group ($P = .007$). In the per-protocol analysis, the rate was 0% (95% CI, 0–3; 0 of 92 infants) in the tenofovir group versus 7% (95% CI, 2–12; 6 of 88 infants) in the control group ($P = .01$). Maternal and infant safety profiles were similar between the 2 groups, with the exception of elevated creatinine kinase and alanine aminotransferase levels in mothers treated with tenofovir. Maternal HBV serologic titers did not differ significantly between the 2 groups.

FAST TRACK

In the intention-to-treat analysis, the rate of mother-to-child HBV transmission was 5% in the tenofovir-treated group versus 18% in the control group ($P = .007$)

Study strengths and limitations

This study's strengths include a multicenter, randomized controlled design, with strict inclusion and exclusion criteria. The results are clinically relevant and of global impact, with potential to decrease morbidity and mortality from HBV infection in children born to infected mothers.

A limitation, however, is that the study was probably underpowered to detect small differences in the rate of birth defects between the tenofovir and usual-care treatment groups. Additionally, some patients ceased taking tenofovir in the postpartum time period. Abrupt cessation may be associated with acute, severe HBV exacerbation.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

HBV is a serious infection that can lead to liver failure and cirrhosis. HBV infection is most likely to have long-term sequelae if acquired in the perinatal period. If untreated, chronic HBV infection will develop in 80% to 90% of infants born to mothers positive for HBeAg. Current immunoprophylaxis for at-risk neonates is postnatal HBV vaccine in combination with hepatitis B immune globulin. Unfortunately, this immunoprophylaxis fails in 10% to 30% of infants born to mothers with an HBV DNA level of greater than 6 log 10 copies/mL. Thus, the observations of Pan and colleagues are welcome findings.

Based on the results of this study, we recommend the use of tenofovir to decrease HBV transmission during pregnancy for women with high viral loads.

Benefits of ART for reducing mother-to-baby HIV transmission outweigh higher risk of adverse outcomes

Fowler MG, Qin M, Fiscus SA, et al; IMPAACT 1077BF/1077FF PROMISE Study Team. Benefits and risks of antiretroviral therapy for perinatal HIV prevention. N Engl J Med. 2016;375(18):1726–1737.

Part of the larger PROMISE (Promoting Maternal and Infant Survival Everywhere) trial, a study by Fowler and colleagues compared the relative efficacy and safety of various proven ART strategies for

prevention of mother-to-child transmission of HIV infection in women with relatively high CD4 counts.

Details of the study

The trial was conducted at 14 sites in 7 countries. Patients were stratified according to HBV coinfection status and country of origin. The primary efficacy outcome was frequency of early infant HIV infection.

Women were randomly assigned to 1 of 3 treatment categories:

- zidovudine alone (zidovudine plus a single intrapartum dose of nevirapine, followed by 6 to 14 days of tenofovir plus emtricitabine postpartum)
- zidovudine-based ART (zidovudine in combination with lamivudine and lopinavir-ritonavir)
- tenofovir-based ART (tenofovir in combination with emtricitabine and lopinavir-ritonavir).

All regimens were continued through 6 to 14 days postpartum. All infants received nevirapine at birth and in the immediate postpartum period.

Two trial periods. During period 1 (April 2011–September 2012), safety data on tenofovir in pregnancy were limited. Women without HBV coinfection were assigned only to zidovudine alone or zidovudine-based ART. During period 2 (October 2012–October 2014), since more information about tenofovir use in pregnancy was available, the study protocol was modified to allow women to be assigned to any of the 3 regimens, regardless of their HBV status.

Inclusion criteria were as follows: CD4 count of at least 350 cells/mm^3 (or country-specific threshold for initiating triple-drug ART, if that threshold was higher), gestation of at least 14 weeks and not in labor, no previous use of triple-drug ART, no clinical or immune-related indication for triple-drug ART, hemoglobin level of at least 6.5 g/dL, an absolute neutrophil count of at least 750 cells/mm^3, an alanine aminotransferase level of less than 2.5 times the upper limit of normal range, an estimated creatinine clearance of greater than 60 mL/min, and no serious pregnancy complications. Patients were excluded if they had active tuberculosis, HBV infection requiring treatment, a structural or conduction heart defect, or a fetus with a serious congenital malformation.

Primary outcomes. The primary efficacy outcome was early infant HIV infection, defined as a positive infant HIV nucleic acid test result at birth or at 1 week postpartum. The primary safety outcome was a composite of adverse events.

Adverse events in mothers were defined as hematologic abnormalities, abnormal blood chemical values, or abnormal signs/symptoms during pregnancy through 1 week postpartum. Severe pregnancy composite outcomes were low birth weight (<2,500 g), preterm delivery before 37 weeks' gestation, spontaneous abortion (<20 weeks), stillbirth (≥20 weeks), or congenital anomaly. Adverse events in infants were defined as death from any cause, hematologic abnormalities or abnormal blood chemical values, and abnormal signs/symptoms through 1 week postpartum.

A total of 3,490 mother-infant sets were included in the analysis (2,261 during trial period 1 and 1,229 during trial period 2). Baseline maternal characteristics were well balanced between groups. Most women were African, young (median age, 26 years), and asymptomatic.

Study results

The combined maternal ART-treated groups had significantly lower rates of early transmission of HIV infection compared with the zidovudine-alone group (0.5% vs 1.8%, –1.3 percentage points; CI, –2.1 to –0.4). The zidovudine-based ART-treated group had a significantly higher rate of infant HIV-free survival through postpartum week 1 than did the zidovudine-alone group (P = .001) or the tenofovir-based ART group (P = .002).

When examining trial periods 1 and 2 combined, the zidovudine-based ART group experienced significantly higher rates of any adverse event than those receiving

FAST TRACK

Significantly lower rates of early transmission of HIV infection were found in the combined maternal ART-treated groups compared with the mothers treated with zidovudine alone (0.5% vs 1.8%)

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Although antenatal ART was associated with a higher risk of adverse maternal and neonatal outcomes when compared with zidovudine alone, these risks are outweighed by the benefit of significantly lower rates of early HIV transmission. Therefore, women who meet the World Health Organization's (WHO) eligibility criteria should be treated with combination ART during pregnancy. The WHO major eligibility criteria for ART during pregnancy are:

1. CD4 count of ≤350 cells/mm^3, irrespective of clinical staging
2. clinical stage 3 or stage 4 disease, irrespective of CD4 cell count.

The WHO recommends starting ART at 14 weeks' gestation.[8]

FAST TRACK

The benefit of significantly lower rates of early HIV transmission with antenatal ART compared with zidovudine alone outweigh the higher risk of adverse maternal and neonatal outcomes

zidovudine alone (21.1% vs 17.3%, P = .008) and higher rates of abnormal blood chemical values (5.8% vs 1.3%, P<.001). During period 2 alone, the tenofovir-based ART group had significantly higher rates of abnormal blood chemical values than did the zidovudine-alone group (2.9% vs 0.8%, P = .03). There were no significant differences between the 2 ART treatment groups. No maternal deaths occurred during the study, and the trial-drug discontinuation rate was low (2%–5%) and did not vary among the 3 groups.

During trial periods 1 and 2, the zidovudine-based ART group had significantly higher rates of adverse pregnancy outcomes than did the zidovudine-alone group (40% vs 27.5%, P<.001). These included low birth weight less than 2,500 g (23% vs 12%) and preterm delivery before 37 weeks (20.5% vs 13.1%). During trial period 2, the tenofovir-based ART group had significantly higher rates of adverse pregnancy outcomes than did the zidovudine-alone group (34.7% vs 27.2%, P = .04). There were no significant differences for any outcome between the 2 ART-treated groups, and there were no significant differences in stillbirth or spontaneous abortion and congenital anomalies among the 3 groups.

Regarding severe pregnancy outcomes, there were no significant differences (composite or individual) between the zidovudine-based ART group and the zidovudine-alone group. The tenofovir-based ART group experienced significantly higher rates of composite severe adverse pregnancy outcomes compared with the zidovudine-based ART group (9.2% vs 4.3%, P = .02), and very preterm birth before 34 weeks (6.0% vs 2.6%, P = .04).

Infant safety outcomes were also examined. There were no significant differences for composite or individual adverse neonatal outcomes other than death. The tenofovir-based ART group experienced a significantly higher rate of infant death than did the zidovudine-based ART group (4.4% vs 0.6%, P<.001). However, a post hoc analysis suggested that extreme prematurity contributed to the infant mortality.

Limitations of the study

This study had minor limitations. It divided patients into only 2 major categories with respect to gestational age—more than or less than 34 weeks. Some maternal medical conditions, such as malaria, were not controlled for. In addition, breastfeeding and formula feeding were combined for analysis, and we know that breastfeeding would inherently confer a higher risk of HIV transmission.

Nevertheless, this study was thoughtfully designed and carefully conducted, and the results are of significant global impact.

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In-office hysteroscopy procedures: Reimbursement jumps 237%

Plus other Relative Value Unit changes that affect your income

Melanie Witt, RN, MA

IN THIS ARTICLE

As it does annually, the Centers for Medicare & Medicaid Services (CMS) has announced changes to the resource-based relative value scale (RBRVS) physician payment system. This system is not static, and each year the CMS identifies codes to review that appear to be either overvalued or undervalued. While the CMS leads this process, the American Medical Association (AMA), working in conjunction with national medical specialty societies, provides annual recommended updates and changes to the CMS via its AMA/Specialty Society RVS Update Committee (RUC).

RVUs defined

Relative value units (RVUs), assigned to most codes found in the AMA's *Current Procedural Terminology* (CPT) book, are calculated based on 3 elements: physician work, practice expense, and malpractice cost. For Medicare reimbursement purposes, these elements are adjusted by the current geographic index, and this adjusted RVU is then multiplied by the Medicare calculated annual conversion factor (in fiscal year 2017, that amount is $35.8887) to determine the final allowable for any given provider.

Commercial payers who use the RBRVS system for reimbursement usually calculate their own conversion factors, which they may or may not publish. Such calculation can be based on a percentage increase over the Medicare rate or other factors.

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The author reports no financial relationships relevant to this article.

In-office hysteroscopy procedure reimbursement increases

This year, some notable increases and decreases in the practice expense element will impact payment to ObGyn practices. The best news is that for practices in which clinicians have been removing polyps or performing endometrial sampling or a full dilation and curettage (D & C) using a hysteroscope in the office, practice expense reimbursement now will improve dramatically. The practice expense RVU for CPT code **58558**, *Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C*, has been increased more than 450% in this setting, with an increase from 6.11 in 2016 to 33.82 as of January 2, 2017,

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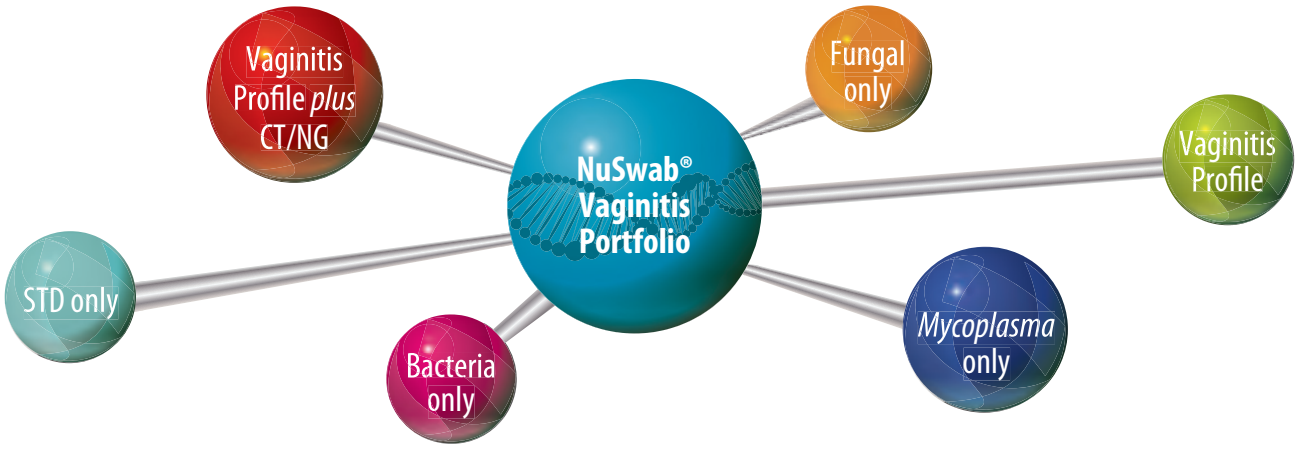

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Vaginitis accounts for approximately 10 million office visits each year.[1] Most women will experience vaginitis symptoms.[2] Recurrence is common.[3] This condition commands a great deal of your daily patient care time. You need a test with diagnostic accuracy to help treat patients properly on the first visit and help reduce recurrence.

Tests **She** Needs - Bacterial

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- uses 3 quantitative organisms: *Atopobium vaginae*, BVAB-2, *Megasphaera-1*
- distinguishes normal flora from BV
- is 97% sensitive and 92% specific according to a published clinical study[4]

Tests **She** Needs - Fungal

The NuSwab C *albicans* and C *glabrata* test:

- targets the 2 most common *Candida* species
- helps guide treatment – C *glabrata* is often resistant to fluconazole[5]
- six species test options and add-on testing of 4 additional *Candida* species in refractory or recurrent cases

Tests **She** Needs - Parasitic

The NuSwab *Trichomonas vaginalis* (Tv) test:

- is 100% sensitive and 99% specific for Tv diagnosis[6]
- shown to be more sensitive than culture, microscopy, and Affirm™ VPIII[7]
- can be used as a follow-up test to confirm negative wet mounts[8]

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TABLE 1 Reimbursement adjustments in total RVUs for services provided in an office setting

CPT code	Description	2016 total RVUs	2017 total RVUs	% change
51700	Bladder irrigation, simple, lavage and/or instillation	2.36	2.07	-12%
51701	Insertion of non-indwelling bladder catheter (eg, straight catheterization for residual urine)	1.55	1.35	-13%
51702	Insertion of temporary indwelling bladder catheter; simple (eg, Foley)	1.99	1.79	-10%
51784	Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique	5.44	1.97	-64%
51784-TC	• Technical component	3.24	0.89	-73%
51784-26	• Professional component	2.20	1.08	-51%
52000	Cystourethroscopy (separate procedure)	5.80	4.68	-19%
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy	12.25	10.38	-15%
58555	Hysteroscopy, diagnostic (separate procedure)	8.80	7.60	-14%
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C	11.44	38.51	+237%
58562	Hysteroscopy, surgical; with removal of impacted foreign body	11.83	9.64	-19%
76948-26	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation: Professional component	0.86	0.96	+11%

Abbreviations: D & C, dilation and curettage; RVUs, relative value units.

which reduces to a 237% increase when the change to the total RVU is calculated.

More new-found income. The only other procedure showing at least a 10% increase in reimbursement in the office setting is the professional component for the ultrasonic guidance for aspiration of ova.

When your reimbursements will decrease

Unfortunately, reimbursement has also been decreased for some CPT code procedures. The urodynamic study code **51784**, *Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique*, has decreased in RVU value by about 64%. This is due to cutting by half the physician work, practice expense, and malpractice cost RVU elements. Although hit with a somewhat smaller decrease, code **58562**, *Hysteroscopy, surgical; with removal of impacted foreign body*, also suffered a decrease in all 3 RVU elements in the office setting, amounting to about a 19% decrease.

In the facility setting, the RVU for the code for vaginoplasty has been increased by 10%, but 11 procedures have lost between 11% and 19% of their previous RVU levels in this setting, and more than half are for hysteroscopic procedures. The complete list of codes that have incurred at least a 10% RVU change in 2017 are listed in **TABLES 1 AND 2** according to place of service.

What's up next for review and possible adjustment

Finally, as a reminder to all providers, the CMS has identified 3 procedure codes that are potentially misvalued due to their being reported more than 50% of the time with an evaluation and management (E/M) service. These codes represent 0-day procedures and will be evaluated during 2017:

- **57150**, *Irrigation of vagina and/or application of medicament for treatment of bacterial, parasitic, or fungoid disease*
- **57160**, *Fitting and insertion of pessary or other intravaginal support device*
- **58100**, *Endometrial sampling (biopsy) with or without endocervical sampling*

TABLE 2 Reimbursement adjustments in total RVUs for services provided in a facility setting

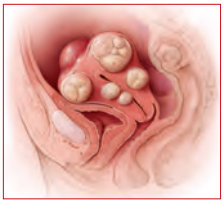
CPT code	Description	2016 total RVUs	2017 total RVUs	% change
51700	Bladder irrigation, simple, lavage and/or instillation	1.29	1.04	-19%
51702	Insertion of temporary indwelling bladder catheter; simple (eg, Foley)	0.87	0.74	-15%
52000	Cystourethroscopy (separate procedure)	3.63	2.94	-19%
57291	Construction of artificial vagina; without graft	17.45	15.01	-14%
57335	Vaginoplasty for intersex state	32.31	35.65	+10%
58555	Hysteroscopy, diagnostic (separate procedure)	5.37	4.40	-18%
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C	7.56	6.72	-11%
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)	9.68	8.28	-14%
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)	19.13	9.07	-17%
58561	Hysteroscopy, surgical; with removal of leiomyomata	18.47	12.52	-19%
58562	Hysteroscopy, surgical; with removal of impacted foreign body	20.14	6.64	-19%
58563	Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)	9.67	7.82	-19%

Abbreviations: D & C, dilation and curettage; RVUs, relative value units.

(biopsy), without cervical dilation, any method (separate procedure).

The CMS has made it clear that all 0-day procedure codes include evaluation services on the date of service, including the decision to do the procedure. If the CMS examination of data finds that the documentation does not support a separate and significant E/M service at the time of the procedure, the agency will consider adjusting the physician work component. All providers should therefore examine their reporting of an E/M service with 0-day procedures to ensure that the documentation clearly supports doing so.

PART 3 OF 3



Laparoscopic myomectomy: Tips for patient selection and technique

Some women who want fibroids removed but the uterus preserved are candidates for laparoscopic myomectomy. This article explains patient selection and provides tips for addressing issues before, during, and after the procedure.

William H. Parker, MD

IN THIS ARTICLE

CASE Patient wants minimally invasive surgery for her fibroids, and no hysterectomy

A 44-year-old G1P1 woman comes to the office to discuss her uterine fibroids, heavy menstrual bleeding, and urinary frequency. Treatment with oral contraceptives has not been effective in reducing the bleeding. She now wants surgical treatment without a hysterectomy (the hysterectomy was recommended by her previous gynecologist). On examination, a 14-week-size irregular uterus is felt. Myomectomy is discussed, and the patient asks if minimally invasive surgery (MIS) is possible. Complete blood cell count testing shows a hemoglobin level of 9.4 g/dL. Pelvic magnetic resonance imaging (MRI) shows a 6-cm type 2 posterior fundal fibroid and a 6-cm type 5 posterior lower-uterine-segment fibroid (**FIGURE 1**). These 2 fibroids have regular contours, and enhancement is not increased with contrast, consistent with benign fibroids.

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The author reports no financial relationships relevant to this article.

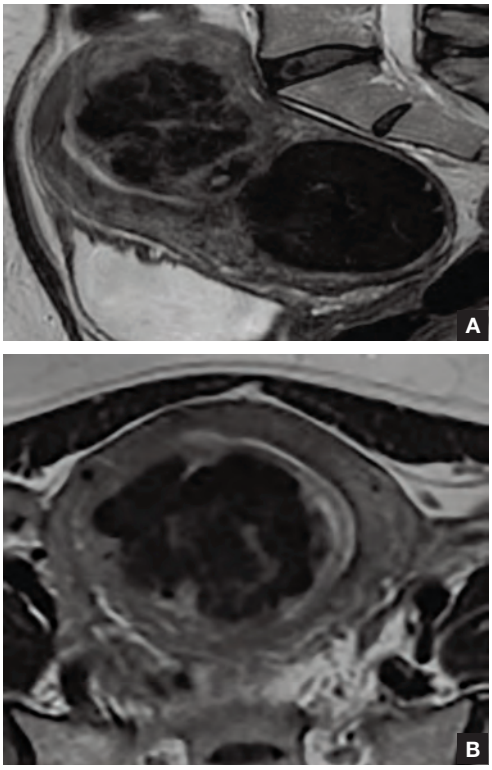
Determining that laparoscopic myomectomy is a good option

Fibroids may affect quality of life—they may cause heavy menstrual bleeding, pelvic pain or pressure, or urinary frequency or incontinence. For many women who want large or numerous fibroids removed but the uterus preserved, abdominal myomectomy is required. Smaller and less numerous fibroids usually can be managed laparoscopically or with robotic assistance.

A systematic review of 6 randomized, controlled trials comparing laparoscopic and open myomectomy in 576 patients found that, although laparoscopic myomectomy was associated with longer operative time (approximately 13 minutes), it was also linked to less operative blood loss, fewer overall complications, reduced postoperative pain, and faster recovery.[1] However, wide application of the laparoscopic approach may be limited by the size and number of fibroids that can be reasonably removed and by the surgical skill needed for fibroid excision and laparoscopic suturing.

ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT

FIGURE 1 Pelvic MRI scans of uterine fibroids



Pelvic magnetic resonance imaging (MRI) scans show a 6-cm type 2 posterior fundal fibroid (**A**) and a 6-cm type 5 posterior lower-uterine-segment fibroid (**B**) in a 44-year-old woman.

Use imaging to assess fibroid size, location, and number

Four imaging modalities can be used for fibroids: transvaginal sonography (TVS), saline-infusion sonography (SIS), hysteroscopy, and MRI. TVS is the most readily available and least costly modality used to differentiate fibroids from other pelvic pathology; SIS provides contrast for the endometrial cavity and better defines submucous fibroids; and hysteroscopy detects visually apparent distortion of the cavity. MRI, however, provides the most complete evaluation of size, position, and number of fibroids.

A study comparing TVS, SIS, hysteroscopy, and MRI found that number and position of fibroids were best identified with MRI.[2] In addition, with MRI, the proximity of the fibroids and uterus to the bladder, rectum, and iliac bones can be evaluated. As tactility in laparoscopic and robot-assisted surgery is very limited, surgeons who use MRI to accurately assess fibroids preoperatively may be able to avoid missing them during the procedure.[3] MRI also can be used reliably to diagnose adenomyosis and may be able to help identify uterine sarcoma.

Tip. For all women considering laparoscopic or robot-assisted myomectomy, I order pelvic MRI with and without contrast. Having the radiologist limit the number of MRI sequences may reduce the cost and make it comparable to that of other imaging modalities. I request T2-weighted MRI scans in the coronal, sagittal, and axial planes; in addition, to determine distortion of the uterine cavity by submucous fibroids, I request scans in the planes parallel with and perpendicular to the uterine axis. One gadolinium-enhanced T1-weighted MRI scan is needed to evaluate perfusion.

Although radiologists are experts in image interpretation, they are unfamiliar with the treatments and surgical issues that gynecologists must consider. Reading MRI scans for fibroids is straightforward, and gynecologists who regularly treat women with fibroids should consider viewing images with a radiologist until they become proficient.

Surgeon and patient factors

Surgeons who have the experience and skill and know the size, number, and position of fibroids are able to select the appropriate candidates for laparoscopic myomectomy. Authors of a study of 2,050 laparoscopic myomectomies found that fibroids larger than 5 cm, removal of more than 3 fibroids, and broad ligament fibroids were more likely to be associated with major complications, including visceral injury, conversion to laparotomy, and bleeding requiring blood transfusion.[4]

In laparoscopic myomectomy, uterus reconstruction requires laparoscopic suturing. Although robot-assisted myomectomy may make laparoscopic suturing easier, the added cost, longer operative time, and unimproved outcomes must be considered too.

FAST TRACK

Fibroids larger than 5 cm, removal of more than 3 fibroids, and broad ligament fibroids were more likely to be associated with major complications

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Preoperative considerations for patients undergoing laparoscopic myomectomy

Condition	Management
Anemia	• Before surgery, increase hemoglobin levels with use of 1 of 3 treatments: – Intravenous iron[a,1] – Gonadotropin-releasing hormone agonist[b,2] – Ulipristal[c,3]
Postoperative nausea and vomiting	• The night before surgery, have the patient place a scopolamine patch behind her ear – Reduces risk
Surgical blood loss	• 2 hours before surgery, have the patient insert misoprostol 400 µg intravaginally – Induces myometrial contraction and compression of uterine vessels – Reduces surgical blood loss • On entry to operating room, piggyback IV tranexamic acid 10 mg/kg – Reduces bleeding
Pain and inflammatory reaction	• 30 minutes before surgery, give celecoxib 400 mg and gabapentin 1,200 mg orally, with sip of water – Provides preemptive pain relief – Celecoxib also decreases inflammatory reaction to surgery
Venous thromboembolism	• Use sequential compression devices in all cases – Risk is low to moderate
Surgical site infection	• Antibiotic prophylaxis typically not administered – Risk is low in laparoscopic procedures in which neither vagina nor bowel is entered

[a]Intravenous iron can increase hemoglobin levels by 1 to 2 g/dL within 1 week.

[b]According to a *Cochrane Review*, hemoglobin levels rose by 1.3 g/dL in women who had fibroids treated with a gonadotropin-releasing hormone agonist for 3 to 4 months.

[c]Taking ulipristal 5 mg/day for 13 weeks increased hemoglobin levels by 4 g/dL in women with heavy bleeding caused by uterine fibroids.

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FAST TRACK

Laparoscopic suturing is more ergonomic with 2 ports placed on one side of the patient

Trocar placement

Place the patient in the dorsal lithotomy position.

Tip. For most women, I do not use a uterine manipulator, as my assistant can manipulate the uterus with laparoscopic graspers.

Port placement should be based on the position and size of the fibroids to be removed. Laparoscopic suturing is more ergonomic with 2 ports placed on one side of the patient (**FIGURE 2**). For suture access, a 12-mm port is placed about 2 cm medial to the iliac crest and a 5-mm port is placed medial to the 12-mm port, near the level of the umbilicus. Lateral trocars should be placed high, above the superior aspect of the uterus, to make it easier to access the fibroids, and lateral to the inferior epigastric vessels, to avoid injuring those vessels. If the uterus is near or above the umbilicus, a left upper quadrant approach may be used, with the access ports placed above the umbilicus.

Managing intraoperative blood loss

I use a combination of 3 agents to reduce intraoperative blood loss during laparoscopic

FIGURE 2 Port placement for laparoscopic myomectomy, based on position and size of the fibroids to be removed

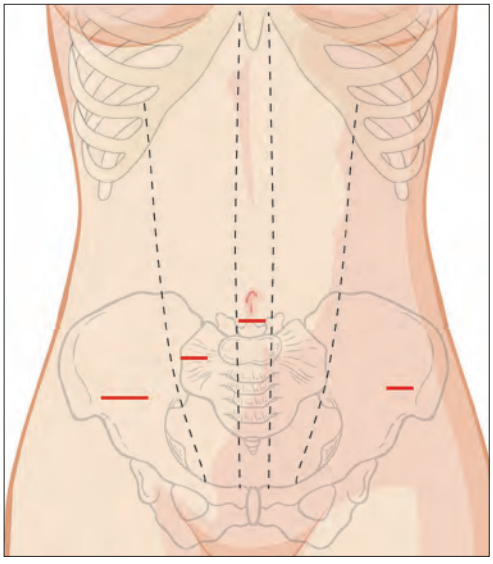


Illustration shows 2 ports placed on one side of the patient for suturing; a 12-mm port placed approximately 2 cm medial to the iliac crest for suture access; and a 5-mm port placed medial to the 12-mm port, near the level of the umbilicus, for fibroid removal.

myomectomy: preoperative misoprostol and tranexamic acid and intraoperative vasopressin. Although there are no data showing an advantage in using these drugs together, the agents have different mechanisms of action and no negative interactions.

Injected below the vascular pseudocapsule, 20 units of vasopressin in 100 mL of normal saline causes vasoconstriction of capillaries, small arterioles, and venules. Avoid intravascular injection given that bradycardia and cardiovascular collapse have been reported (rare cases). Loss of peripheral pulses, bradycardia, unmeasurable blood pressure, and cardiac complications have been reported after myometrial injection of ≥5 units of vasopressin.[5]

Although vasopressin is a powerful vasoconstrictor, these clinical findings are often interpreted as severe hypotension. However, evaluation of peripheral arterial blood flow by Doppler ultrasonography has revealed severe vasospasm and increased proximal blood pressure.[5] Keep this potential reaction in mind to avoid misinterpreting findings and treating a patient with vasopressors. Presence of palpable carotid pulses and maintenance of normal partial pressure of end-tidal carbon dioxide can help differentiate peripheral vasospasm from global hypotension.

Use of vasopressin to reduce blood loss during myomectomy is off-label. On occasion, I apply a tourniquet around the lower uterine segment, including the infundibular pelvic ligaments. I use a red Robinson catheter, throw 1 tie in front of the uterus, pull with graspers on both ends until it is tight, and then clamp the half-knot with a locking grasper.

Tip. Although a salvage-type autologous blood transfusion device may be used during laparoscopic or robot-assisted myomectomy, cases in which this device is considered for very large or multiple fibroids might be better managed with abdominal myomectomy.

Surgical technique

After injecting vasopressin, I use a high-frequency mechanical vibration scalpel to incise the myometrium directly over a prominent fibroid and carry the incision deeply until fibroid tissue is definite. Alternatively, a monopolar laparoscopic needle can be used in cut mode—which also limits damage to the myometrium.

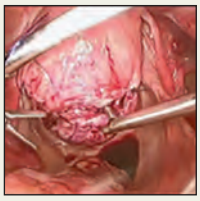
Tip. The course of vessels over a fibroid is unpredictable, and we cannot be certain that any uterine incision will avoid bleeding. Therefore, I make transverse incisions, which allow more ergonomic laparoscopic suturing.

It is important to incise completely through the myometrium and through the pink-red pseudocapsule containing the vascular network surrounding the fibroid. This plane is often deeper than usually recognized and can be identified just over the white fibroid.

The fibroid is grasped with a tenaculum for traction, and countertraction is applied with a grasper on the myometrial edges. Once the fibroid is reached, graspers and the mechanical vibration scalpel are used

Find the video that accompanies this article at obgmanagement.com:

Laparoscopic myomectomy technique



FAST TRACK

Incise completely through the myometrium and through the pink-red pseudocapsule containing the vascular network surrounding the fibroid

to tease the pseudocapsule away from the fibroid (**VIDEO**).

Tip. Staying under the pseudocapsule reduces bleeding and may preserve the tissue's growth factors and neurotransmitters, which are thought to promote wound healing.[6]

Dissection with the mechanical vibration scalpel (or monopolar needle) should be performed under visual control to identify the tissue adhering to the fibroid, which is desiccated and then divided. The fibroid is dissected until free of the myometrium and is placed in the right lower abdomen. Small fibroids can be strung together on a long suture so none will be lost. Using bipolar paddles, desiccate large bleeding vessels in the myometrial defect sparingly, with care taken to avoid devascularizing the myometrium, which might compromise wound healing. Myometrial repair should be performed in accordance with the accepted surgical technique used in laparotomy.

Place delayed absorbable sutures in 2 or 3 layers, as needed, to reapproximate the myometrium and secure hemostasis.

Tip: I use 0 polydioxanone interrupted figure-of-8 sutures, but continuous running sutures with or without barbs also can be used. For the serosa, I use a continuous barbed suture in a baseball stitch, which buries both the raw edges of the serosa and the barbs for smooth closure (**FIGURE 3**). These closure methods have not been compared to see which provides superior wound healing or subsequent wound strength.

FAST TRACK

During laparoscopic myomectomy, the pelvis and abdomen are irrigated with about 3 L of normal saline and suctioned multiple times

Morcellating the fibroid

The fibroid can be morcellated with an electromechanical morcellator or a scalpel (hand morcellation). Either instrument can be used in contained or uncontained fashion. I insert an electromechanical morcellator through the right lower quadrant incision and morcellate tissue in the anterior midpelvis. Safety requires careful control of the rotating blade and scrutiny of the bowel, bladder, and major vessels. Our operating room has **4 rules for morcellator use:**

1. The blade is activated only under direct visualization.
2. Both the surgeon and the assistant must say "ready" before the blade is activated.
3. The hand holding the morcellator must remain still while tissue is being drawn into the device.
4. Any undue resistance from the tissue is cause to stop the blade. This precaution is taken because there is a tendency to drop the blade in an attempt to overcome the resistance.

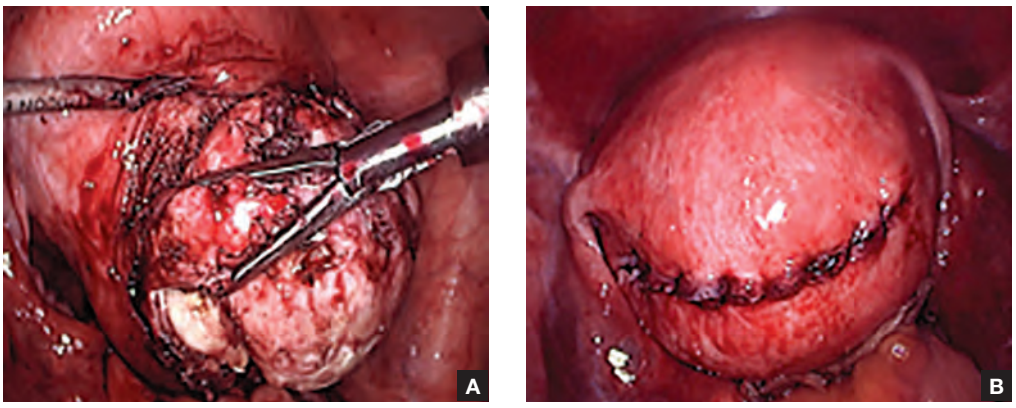
Tip: I limit rotational forces and scattering of tissue by "pulsing" the blade on and off when morcellating softer tissue.

Various methods of *contained morcellation* (morcellation in a containment bag) have been described.[7] In one method, tissue is placed in a bag, the neck of the bag is brought through an enlarged umbilical incision, and the tissue is cut into small pieces until it is entirely removed. Another method is to use an electromechanical morcellator with a specially designed containment bag inside the abdomen. The bag is introduced through a 12-mm port and unfurled inside the abdomen; the specimen is placed in the bag; the neck of the bag is brought out through the port; the bag is insufflated with carbon dioxide; the laparoscope, a 5-mm grasper, and the morcellator tip are passed into the bag; and morcellation is performed. Early studies of contained morcellation reported longer operating times, leaking bags, and visceral injuries. In 2016, the US Food and Drug Administration (FDA) cleared the PneumoLiner containment system but required that its manufacturer (Advanced Surgical Concepts) warn patients and health care providers that its bag has not been proved to reduce the risk of spreading cancer during morcellation procedures.[8]

Irrigation is important

During laparoscopic myomectomy, fibroid removal by myometrial dissection disperses tissue fragments, and the unprotected fibroid is usually stored in the abdomen until hemostasis is secured and suturing completed. Limiting the rotational forces that lead to further dispersement and irrigating copiously to remove tissue fragments help eliminate residual tissue.

FIGURE 3 Laparoscopic removal of a fibroid



Laparoscopic removal of a fibroid with a mechanical vibration scalpel and tenaculum (**A**) and closure of the incision site with continuous barbed suture in a baseball stich (**B**).

The pelvis and the abdomen are irrigated with normal saline (approximately 3 L) and suctioned multiple times.

Tip. Alternating between the Trendelenburg and reverse Trendelenburg positions allows fluid to wash tissue down to the pelvis, where it is more easily seen and removed.

Careful inspection for tissue fragments and copious irrigation and suctioning are important in reducing the risk that tissue fragments will remain in the peritoneal cavity and parasitic fibroids will develop. In cases of occult leiomyosarcoma (LMS), this step may be particularly important.

Final steps

I place a knitted fabric of modified cellulose over the hysterotomy suture lines to reduce the incidence of adhesion formation. Once the procedure is complete, the local anesthetic bupivicaine is injected deep into the incision sites. Injecting anesthetic before making the incisions does not provide better pain relief; injecting after the procedure provides pain relief for 6 hours.[9]

Morcellation and risk of leiomyosarcoma

Given the need to prevent laparoscopic morcellators from inadvertently spreading tissue within the peritoneal cavity of women with occult LMS, the FDA issued a safety communication in 2014 warning against their use in the majority of women who undergo myomectomy or hysterectomy for fibroids.[10] However, Pritts and colleagues estimated the prevalence of LMS in women who had surgery for presumed uterine fibroids at about 1 in 2,000 (0.05%), significantly lower than the FDA's estimate of 1 in 350.[10,11] In 2015, a large population-based prospective registry study found 2 cases of occult LMS in 8,720 fibroid surgery patients (0.02%).[12]

Since LMS metastasizes through the bloodstream, there is no reliable evidence that morcellation influences survival or that electromechanical morcellation is inferior to vaginal or mini-laparotomy morcellation with a scalpel. According to recent publications, compared with MIS, open abdominal surgery is associated with more morbidity and mortality in women.[13] Since the FDA advisory was issued, the number of abdominal surgeries has increased, as has the number of related complications.[13]

I use electromechanical morcellation techniques for women who want MIS. All surgical procedures have potential risks, and patients' and physicians' understanding of risks forms the foundation of medical decision making. The possibility of occult LMS should be considered by women and their gynecologists, and proper informed consent, noting both the LMS risk and the increased risks of abdominal surgery, should be obtained.

FAST TRACK

Since the FDA safety communication on power morcellation in 2014, the number of abdominal surgeries has increased, as has the number of related complications

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Risk of uterine rupture after laparoscopic myomectomy

After abdominal myomectomy, uterine rupture during pregnancy or delivery is rare, according to reviews of delivery records of many thousands of women.[14] Operative techniques, instruments, and energy sources used during laparoscopic or robot-assisted myomectomy may differ from those used during laparotomy, and anecdotal communications suggest that uterine rupture may be more common after laparoscopic or robot-assisted myomectomy. A meta-analysis of 56 articles (3,685 pregnancies) published between 1970 and 2013 found 29 cases of uterine rupture after myomectomy, with no statistical difference in rupture risk between laparoscopic and abdominal myomectomy.[15] As most reports are case studies or small case series, the incidence of rupture cannot be reliably calculated.

There is no consensus regarding the factors that may increase the risk of uterine rupture after laparoscopic myomectomy. Three factors are postulated to interfere with myometrial wound healing and increase uterine rupture risk: failure to adequately suture myometrial defects, excessive use of monopolar or bipolar electrosurgery with devascularization of the myometrium, and lack of hemostasis with subsequent hematoma formation.[16] It seems prudent that surgeons should adhere to time-tested techniques for abdominal myomectomy. Even with use of ideal surgical techniques, however, individual wound-healing characteristics may predispose to uterine rupture.

CASE Resolved

After giving proper informed consent, the patient underwent laparoscopic myomectomy and electromechanical morcellation. Her 2 fibroids were removed, with a blood loss of 200 mL, and that afternoon she was discharged from the surgery center with written postoperative instructions and oral pain medication. A telephone call the next day found her comfortable, with no nausea or vomiting, and happy to be fibroid free. Pathologic inspection of the morcellated tissue confirmed that the fibroids were benign. At 2-week follow-up, the patient was no longer taking pain medication and was ready to return to work and normal activity. Her fatigue persisted, though, and she arranged to take time to rest during the day.

FAST TRACK

Failure to adequately suture myometrial defects, excessive use of monopolar or bipolar electrosurgery with devascularization of the myometrium, and lack of hemostasis with subsequent hematoma formation are postulated to interfere with wound healing and increase the risk of uterine rupture

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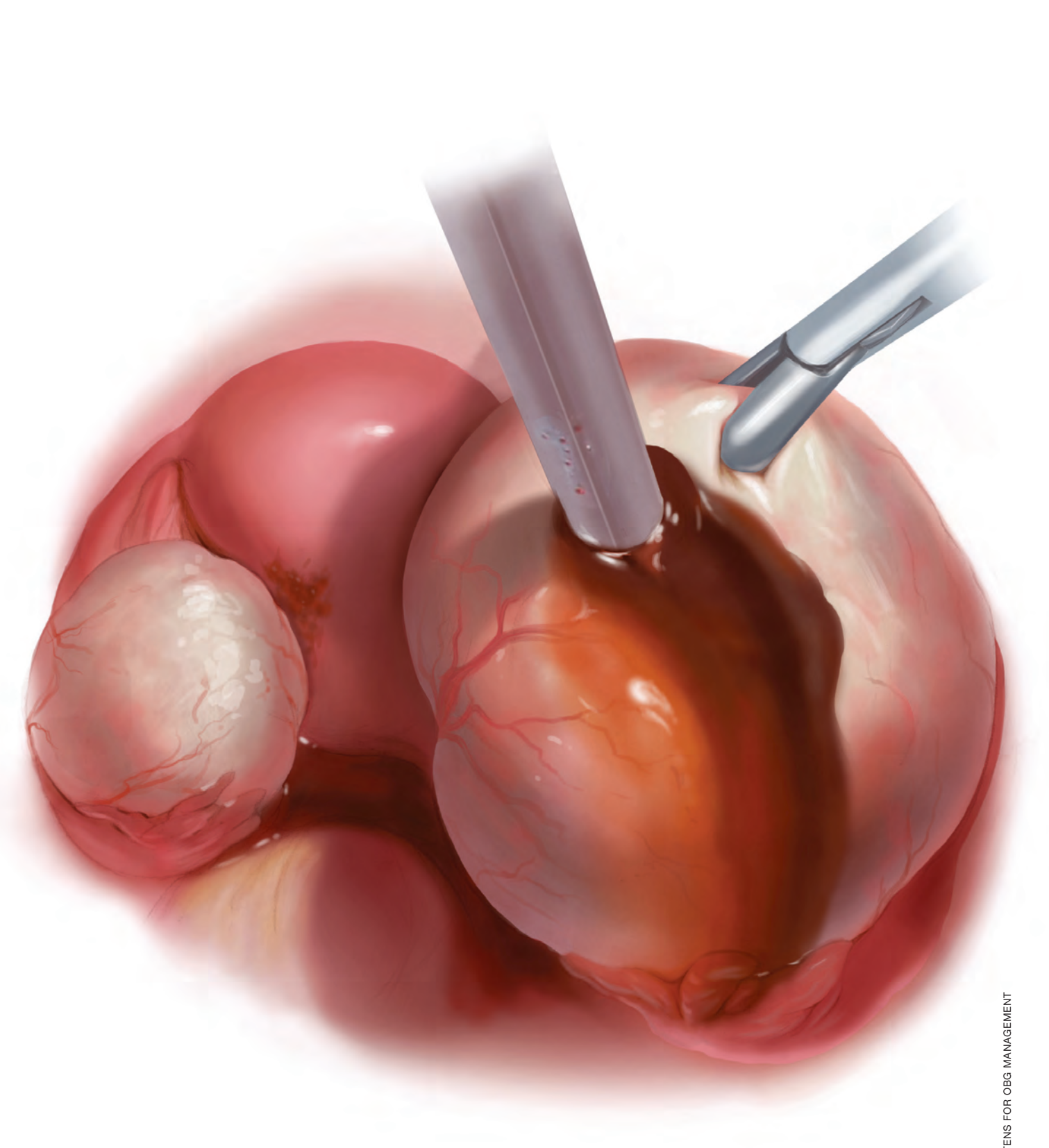

Endometriomas are called chocolate cysts due to the dark brown color of the fluid they contain. When possible, endometriomas should be aspirated and irrigated prior to cystectomy to avoid seeding the pelvis with spilled endometriotic contents.

ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT

Endometriomas: Classification and surgical management

Understanding the etiology of endometriomas and implementing a more nuanced classification system can aid in the successful management of this common condition

Rebecca C. Falik, MD, MST; Anjie Li, MD; Frances Farrimond, MD; Gity Meshkat Razavi, MD; Ceana Nezhat, MD; and Farr Nezhat, MD

Endometriosis, a disorder in which tissue resembling endometrium develops outside the uterine cavity, is a common cause of pelvic pain and infertility, affecting 6% to 10% of women.[1] Although endometriosis occurs in almost all organs and anatomic locations, it most often affects the pelvic organs.[2] An ovarian endometrioma, an ovarian cystic mass generally consisting of endometrial glands and stroma, is seen in 17% to 44% of women with endometriosis.[3] Endometriomas are sometimes called *chocolate cysts* for the dark brown, thick, and tarry concentrated hemosiderin-laden fluid they contain, but histology shows that not all chocolate cysts have endometriosis within their walls.[4] Understanding the etiology of endometriomas and implementing a more nuanced classification system can aid in the successful management of this common condition.

Etiology

Endometriomas are extensively described in the literature, and their origin is the subject of several theories. In 1921, Sampson noted luteal membrane and ovarian epithelial tissues within endometriomas and was the first to indicate that endometriomas may result from the invasion of functional cysts by endometrial tissue.[2,4,5] In 1979, Czernobilsky and Morris[6] found endometrial and oviduct-like epithelium in ovarian endometriosis and concluded that ovarian tissue may be a common histologic precursor. Several other

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CONTINUED FROM PAGE 39

authors subsequently have reported finding different types of tissue within ovarian endometriomas, and not all of these chocolate cysts showed histologic evidence of endometriosis.[4,7,8]

Disease classification

Our classification system identifies 2 types of endometriomas on the basis of their etiologies and characteristics. Type I, which arise from endometrial tissue implanted on the ovarian surface, are also called *true endometriomas*. Invagination of cortex and subsequent hemorrhage from endometrial tissue result in cyst formation. Endometrial tissue (endometrial stroma and glands) is histologically present in all type I endometriomas.[1,4,9] These endometriomas usually are small (<5 cm in diameter) and have a densely adherent fibrous capsule.[4] Often, there is no clear plane between cyst wall and ovarian stroma.[3]

Type II endometriomas arise from functional cysts involved in or invaded by cortical or pelvic side-wall endometrial implants or by type I endometriomas. Type II endometriomas are subclassified by the extent of endometrial implant involvement in the cyst wall. Type IIA endometriomas are hemorrhagic cysts with less than 10% of endometrial tissue within the cyst wall. Similar to the functional cysts from which they originate, type IIA endometriomas have a cyst wall that is separated easily from ovarian tissue during surgery.[4,7,9] Although type II endometriomas tend to be larger than their type I counterparts, in some cases they are identified at an early stage of 2 to 5 cm. Endometriomas larger than 5 cm are almost always type II.[4]

Type IIB and IIC endometriomas have endometrial implants and fibrosis within their cyst walls, with progressively more endometrial invasion in type IIC endometriomas (>50%) than in type IIB (10% to 50%). Consequently, type IIB cysts are relatively easy to dissect from ovarian tissue, except adjacent to an endometriotic area where the cyst densely adheres to the ovarian stroma. In type IIC, endometrial tissue more extensively penetrates the capsule, making dissection of diseased tissue from the ovarian stroma more difficult; in fact, separating type IIC cyst wall from ovarian stroma can be as challenging as excising a type I endometrioma.[7] In most cases, a type IIC cyst is attached by adhesions and fibrosis to the pelvic side wall or uterus and ruptures during mobilization (**TABLE**).

FAST TRACK

Endometriomas classified as type I arise from endometrial tissue implanted on the ovarian surface; type II form from functional cysts invaded by type I endometriomas or endometrial implants

TABLE Characteristics of type I and type II endometriomas[1,3,4,7,9]

Type	Characteristics
I	• Arise from endometrial tissue implanted on ovarian surface • Endometrial tissue histologically present • Typically <5 cm in size • Capsule is densely adherent • Often no clear plane between cyst wall and ovarian stroma
II	• Form from functional cysts invaded by type I endometriomas or endometrial implants • Can be sized 2–5 cm but often >5 cm in size
IIA	• Hemorrhagic cysts with <10% endometrial tissue within cyst wall • Cyst wall easily separated from ovarian tissue at surgery
IIB	• 10% to 50% invasion of cyst walls with endometrial implants and fibrosis • Typically easily dissected from ovarian tissue
IIC	• >50% invasion of cyst walls with endometrial implants and fibrosis • Difficult dissection from ovarian tissue

Presentation and diagnosis

Almost all patients with an endometrioma concurrently have peritoneal endometriosis, which is characterized by dysmenorrhea, dyspareunia, chronic pelvic pain, infertility, and, in some cases, gastrointestinal or genitourinary dysfunction.[1] Pelvic examination may reveal an adnexal mass that is an endometrioma, or an endometrioma may appear on imaging obtained in a pelvic pain or infertility work-up. Given its 73% sensitivity, 94% specificity, safety, and low cost, transvaginal ultrasonography is the preferred imaging modality for endometrioma.[3] The characteristic ultrasonographic appearance is that of a round, homogeneous, fluid-filled mass with low-level echoes.[1] Magnetic resonance imaging is appropriate when a more sensitive imaging modality is indicated, as for a patient with risk factors for malignancy.[3,10–12]

Surgical management

Clinical indications

Indications for surgical excision of endometriomas include pelvic pain, infertility, and prevention and diagnosis of malignancy. Endometriomas may be excised prior to use of assisted reproductive technology.[13–15] Medical therapy, such as oral contraceptives, can be used to reduce the size of endometriomas but does not improve fertility.[3] Certain ovarian cancers are more common in women with endometriosis, and ovarian tumors are thought to develop in about 1% of ovarian endometriosis cases.[1,12] Therefore, endometrioma excision may reduce the risk of malignancy. As with other ovarian cysts, large endometriomas may be excised to reduce the risks of rupture and torsion.

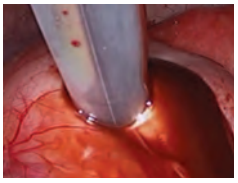
Approach

Laparoscopy is the preferred approach for endometrioma excision. Controversy exists regarding the ideal procedure: complete excision (with stripping of the cyst capsule) or drainage and ablation of the cyst wall. Compared with drainage and ablation, excision reduces recurrence of endometriomas; relieves dysmenorrhea, dyspareunia, pelvic pain, and other symptoms; and improves fertility.[13,16] The recurrence rate may be as low as 5.8% with complete excision but is 90% with simple transvaginal aspiration.[17,18] If not performed properly, however, cyst capsule stripping may damage nearby ovarian stroma and decrease the ovarian reserve.[14] Some authors have advocated combining excision and ablation—performing cystectomy until there is no longer a clear plane between capsule and ovarian stroma and then ablating any remaining endometrial tissue.[8]

With type I and IIC endometriomas, we have seen the endometrial cyst wall infiltrating the ovarian stroma so deeply there is not always a definable plane. By contrast, type IIA and IIB endometriomas typically have a plane between the cyst wall and the ovarian cortex. In type II endometriomas, endometrial implants on the ovarian cortex infiltrate the plane of the cyst wall such that the juxtaposing lipomatous follicular cyst detaches with minimal intraoperative traction. Portions of type II endometriomas containing fibrosis and adhesions may become more difficult to peel off the cyst wall. For most endometriomas, at least 1 spot is difficult to peel off the ovary, and extra care must be taken at the hilum of ovary to avoid excising healthy ovarian cortex.[4,5,7,8]

Our surgical approach accounts for the described variations in type I and II endometriomas. Endometrial contents often spill as the endometrioma is dissected off neighboring structures. When possible, endometriomas should be aspirated and irrigated prior to cystectomy to avoid seeding the pelvis and abdomen with spilled endometriotic

Don't miss the video that accompanies this article!



Watch the authors perform laparoscopic excision of type I and type II endometriomas, at obgmanagement.com

FAST TRACK

Type IIA, and to some extent type IIB, endometriomas have a clear plane between cyst wall and ovarian cortex, which allows for minimal surgical intervention for removal

Key takeaways

- Endometriomas are common adnexal masses in women affected by endometriosis and may exacerbate pelvic pain and impair fertility. Classification of endometriomas into type I and type II, depending on their etiology and characteristics, can guide minimally invasive surgical management.
- Type I endometriomas arise from invagination of endometrial implants on the ovarian cortex, resulting in dense fibrosis and adhesions. These lesions typically require piecemeal excision in order to completely remove the cyst capsule.
- Type II endometriomas result from invasion of endometrial tissue into preexisting functional cysts and are further subclassified by the proportion of cyst capsule containing endometrial tissue (IIA <10%, IIB 10% to 50%, IIC >50%).
- The difficulty of excising type II endometriomas correlates with the degree of endometrial invasion, with type IIA being relatively straightforward and type IIC being as challenging and piecemeal as type I.
- We generally favor complete excision rather than ablation of the cyst capsule, except for when excision would result in an unacceptable loss of healthy ovarian tissue.

FAST TRACK

A piecemeal excision approach is often necessary for type I and IIC endometriomas, and excision can be difficult for IIB endometriomas

contents. We use hydrodissection, the injection of dilute vasopressin with a laparoscopic needle, to create a plane between cyst wall and ovarian stroma and strip the cyst capsule with laparoscopic graspers. Type I endometriomas adhere densely to the ovary. Given the presence of fibrosis and adhesions, the cyst is excised in a piecemeal fashion. Care is taken to remove any endometrial implants from the ovary while preserving as much of the ovarian tissue as possible.[1]

Type II endometriomas are larger cysts originating from the invasion of endometrial implants or type I endometrioma into functional cysts. The difficulty of capsule excision varies according to the extent of endometrial invasion. Type IIA endometriomas contain less than 10% endometrial tissue within the cyst capsule. Thus, the standard ovarian cystectomy stripping technique is successful in removing more than 90% of the cyst capsule. Special care is taken in stripping the residual small portion that involves the endometrial glands and stroma and adheres densely to the ovary.

The larger proportion of endometrial tissue present in type IIB and IIC endometriomas degrades the plane between the cyst capsule and the ovarian stroma, making excision more difficult. Similar to the type I excision, a piecemeal approach is often necessary. If complete stripping of the cyst capsule would result in extensive loss of healthy ovarian tissue, then electrocautery, plasma energy, or laser ablation can be selectively used to destroy focal areas of endometrial invasion. Complete ablation may be difficult, as the endometrioma wall can be up to 5 mm thick.[19] For these thick-walled endometriomas, we recommend excision (vs ablation), which lowers the risk of endometrioma recurrence.

Conclusion

Endometriomas, common adnexal masses in women affected by endometriosis, may exacerbate pelvic pain and impair fertility. Gynecologists should be prepared to excise endometriomas completely and exercise care in preserving as much of the ovarian stroma as possible. We classify endometriomas into 2 types: type I, which develop from invagination of endometrial implants in the ovarian cortex, and type II, which stem from invasion of functional cysts by endometrial implants or type I endometrioma. This distinction guides surgical management. We hope this article and its accompanying video will be helpful in guiding laparoscopic excision of type I and II endometriomas.

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Top free menstrual cycle tracking apps for your patients

Clue, Glow, and Pink Pad Period Tracker Pro are popular because of their accuracy and special features

Katherine T. Chen, MD, MPH

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Menstrual cycle tracking apps
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App overload is a challenge for both providers and patients. As of September 2015, the number of health apps in the US Apple iTunes and Google Play stores exceeded 165,000, with approximately 7% focused on women's health and pregnancy.[1] Clinicians express interest in promoting the use of health apps with their patients and seek guidance about making app recommendations.[2] In my prior articles in this "App review" series, I have recommended due date calculator and drug reference apps.

One area in which an app may enhance your patient care is in menstrual cycle tracking. Patients may be more honest with their phones than with their health care professionals, and the results are more accurate than paper questionnaires and calendars.[3] Of note, menstrual cycle tracking apps are the fourth most popular health app among adults and likely even more popular if limited to adult women.[4]

Dr. Paula Castano and her team systematically identified and evaluated free menstrual cycle tracking apps.[5] The accuracy of each app was determined by menstrual cycle predictions based on average cycle lengths of at least 3 previous cycles, ovulation predicted at 13 to 15 days prior to the start of the next cycle, and qualification that the application contained no misinformation.[5]

The top 3 recommended menstrual cycle tracking apps from Dr. Castano and colleagues' study are listed in the **TABLE** alphabetically and are detailed with a shortened version of the APPLICATIONS scoring system, APPLI (app comprehensiveness, price, platform, literature use, and important special features).[6] I hope this column will allow you to feel more comfortable recommending these "vetted" apps to your patients.

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TABLE Top 3 recommended menstrual cycle tracking applications

App	App comprehensiveness	Price	Platform	Literature used	Important special features
 **Clue** iTunes: https://itunes.apple.com/us/app/clue-period-tracker-period-ovulation-tracker/id657189652?mt=8 Google Play: https://play.google.com/store/apps/details?id=com.clue.android&hl=en	• Allows fertility tracking for women trying to conceive • Contains information on contraception or pregnancy	Free	iTunes and Google Play store	References provided for science information section	• Password protection • Medical disclaimer • Health education • Data back-up • Email/export • Spanish language • Custom reminder • Track flow • Track symptoms • Track intercourse • Alert next menses • Alert for fertility • Average cycle length
 **Glow** iTunes: https://itunes.apple.com/us/app/glow-fertility-period-and-ovulation-tracker-app/id638021335?mt=8 Google Play: https://play.google.com/store/apps/details?id=com.glow.android&hl=en	• Allows fertility tracking for women trying to conceive • Contains information on contraception or pregnancy • Includes tracking of fertility medications	Free	iTunes and Google Play store	None reported	• Password protection • Social media • Medical disclaimer • Health education • Data back-up • Email/export • Custom reminder • Pregnancy mode • Track flow • Track symptoms • Track intercourse • Alert next menses • Alert for fertility • Average cycle length
 **Pink Pad Period Tracker Pro** Google Play: https://play.google.com/store/apps/details?id=com.alt12.pinkpadpro&hl=en	• Allows fertility tracking for women trying to conceive	Free	Google Play store	None reported	• Password protection • Social media • Medical disclaimer • Health education • Data back-up • Email/export • Spanish language • Custom reminder • Pregnancy mode • Track flow • Track symptoms • Track intercourse • Alert next menses • Alert for fertility • Average cycle length

NONESTROGEN PRODUCT FOR DYSPAREUNIA

Intrarosa (prasterone 6.5 mg), from **AMAG Pharmaceuticals** and **Endoceutics, Inc,** is announced as the only FDA-approved, locally administered, daily, nonestrogen steroid for the treatment of moderate-to-severe dyspareunia, a common symptom of vulvovaginal atrophy due to menopause (also known as genitourinary syndrome of menopause). The two companies have recently entered into an agreement providing **AMAG** with the US commercial rights to **Intrarosa.** Prasterone, also known as dehydroepiandrosterone (DHEA), is an inactive endrogenous steroid that is converted locally into androgens and estrogens to help restore vaginal tissue, according to the manufacturer. The usual dose of **Intrarosa** is one insert placed into the vagina every day at bedtime.

FOR MORE INFORMATION, VISIT: http://www.amagpharma.com

ORAL MAINTENANCE TX FOR RECURRENT CANCER

ZEJULA (niraparib 100 mg) from **TESARO,** is a recently FDA-approved and available once-daily oral maintenance treatment for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Niraparib is a poly (ADP-ribose) polymerase (PARP) inhibitor. PARP is a family of proteins involved in many functions in a cell, says **TESARO,** including DNA repair, gene expression, cell cycle control, intracellular trafficking, and energy metabolism. According to the manufacturer, PARP inhibitors have shown activity as a monotherapy against tumors with existing DNA repair defects, such as *BRCA1* and *BRCA2* mutations, and as combination therapy with anticancer agents that induce DNA damage. The recommended dose of **ZEJULA** is 300 mg taken once daily with or without food.

FOR MORE INFORMATION, VISIT: http://www.zejula.com

MIGS STAPLING SYSTEM WITH REAL-TIME FEEDBACK

Medtronic reports that its new **Signia Stapling System** offers surgeons real-time feedback and automated responses to real-time data, one-handed staple firing, and Adaptive Firing technology that measures the firing force and adjusts the stapler's speed based on tissue variability, allowing for consistent staple lines. **Medtronic** says the device chooses 1 of 3 firing speeds based on the clamped tissue's variability and thickness and tells the surgeon, with audible and visual feedback on the handle's LED screen, how it is adapting to tissue variability, before firing. The reposable handle is designed to provide the surgeon fully powered rotation, articulation, and firing with one hand. The **Signia** system has applications in open and minimally invasive gynecologic surgery.

FOR MORE INFORMATION, VISIT: http://www.medtronic.com

BONE BUILDING AGENT

Radius Health announces recent FDA approval for **TYMLOS** (abaloparatide) injection, a bone-building agent for the treatment of postmenopausal women with osteoporosis who are at high risk for fracture. Those at high risk for fracture, says **Radius**, include women with a history of osteoporotic fracture, multiple risk factors for fracture, or have failed on or are intolerant to other available osteoporosis therapy. Results of the ACTIVE trial demonstrated that **TYMLOS** showed significant reductions in the relative risk of new vertebral (86%) and nonvertebral (43%) fractures compared with placebo (absolute risk reduction, 3.6% and 2.0%, respectively). The injection provides 3,120 µg/1.56 mL (2,000 µg/mL) in a single-patient-use prefilled pen. The pen delivers 30 daily doses of 80 µg abaloparatide in 40 µL of sterile, clear, colorless solution. **Radius** is also developing a transdermal application of abaloparatide based on 3M's patented Microstructured Transdermal System technology.

FOR MORE INFORMATION, VISIT: http://www.radiuspharm.com

PROTEOMIC BREAST CANCER ASSAY

Using advanced proteomic technology, **Provista Diagnostics** has developed **Videssa Breast**, the first blood test of its kind that detects and analyzes multiple types of tumor protein biomarkers for improved cancer detection when mammography results are abnormal. Unlike other liquid biopsy techniques, breast cancer proteins are more abundant in the blood, according to the manufacturer; **Videssa Breast** uses proprietary technology to examine multiple serum protein biomarkers (SPBs) secreted by breast tumors and tumor-associated autoantibodies (TAAbs). Evaluating these biomarkers with patient clinical data generates a unique protein signature that detects breast cancer in the body. Through research and clinical trials, the top 11 SPBs known to provide the highest sensitivity and the top 28 TAAbs for early breast cancer detection have been identified. **Videssa Breast** incorporates 11 SPBs and 13 TAAbs in its assay.

FOR MORE INFORMATION, VISIT: http://www. provistadx.com

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Audiocasts from ACOG 2017

Breast cancer screening: My practices and response to the USPSTF guidelines

In a debate with George Sawaya, MD, regarding the 2016 US Preventive Services Task Force breast cancer screening guidelines, **Dr. Mark Pearlman** argued that the C recommendation for screening mammography in the age group of 40 to 49 years leaves out younger women who develop aggressive breast cancers. He also disagreed with the Task Force's recommendation for biannual vs annual screening. In this audiocast, Dr. Pearlman expands on his reasoning and explains his own practice decisions.

Bacterial vaginosis: Meet patients' needs with effective diagnosis and treatment

In this audiocast, **Dr. Steven Chavoustie** offers steps for diagnosis and his recommended treatment for first-time and recurrent disease.

Obesity medicine: How to incorporate it into your practice

Dr. Robert M. Huster discusses how obesity medicine can enhance your practice. In this audiocast, he reviews the need to address the obesity epidemic in the US, defines obesity medicine, and provides tips and resources for obtaining the necessary certifications.

News for your practice from ACOG 2017

Educate patients about dense breasts and cancer risks

Approximately one-third of cancers in dense breasts have a delayed diagnosis on mammography, and 70% of cancers occur in dense breasts, emphasizes **Dr. Monica Saini**, a radiologist, and **JoAnn Pushkin**, executive director of the nonprofit educational website DenseBreast-info.org.

Medical treatments for uterine fibroids show promise in efficacy and safety studies

Two agents in the pipeline promise nonsurgical (and thus less costly) relief to women with uterine fibroids.

Los Angeles County encourages LARC use to decrease Zika cases

Almost half of births in LA County are unplanned. Educating providers to place long-acting reversible contraceptives can decrease neonatal Zika complications by preventing unplanned pregnancies.

Labor and delivery mismanaged, child has CP: $30.5M award

WHEN A 34-YEAR-OLD WOMAN saw her ObGyn at 35 weeks' gestation, she was found to have gestational diabetes mellitus (GDM). No additional testing was ordered.

Two days later, the mother reported decreased fetal movement; she was admitted to the hospital for continuous fetal heart-rate (FHR) monitoring, and a maternal-fetal medicine (MFM) specialist was consulted. The mother was not placed on FHR monitoring until 2 hours after admission. Three hours after admission, the MFM, by phone, recommended further testing and later, cesarean delivery.

The child was found to have spastic quadriplegic cerebral palsy, profound developmental delays, a seizure disorder, and cortical blindness.

PARENT'S CLAIM: The child's injuries were due to mismanagement of labor and delivery. The MFM prescribed ultrasonographic biophysical profiles, but they were not performed until 2 hours after ordered. There were 3 ultrasonography (US) technicians at the hospital when the mother was admitted: 1 was on break, another was performing other tests, and the third was not notified because the hospital's computer system was down. When test results were unfavorable, the MFM recommended emergency cesarean delivery. An earlier delivery could have prevented the child's injuries.

DEFENDANTS' DEFENSE: The infant's injuries were a result of her mother's failure to keep her GDM under control.

VERDICT: A $30,545,655 Georgia verdict was returned.

Blood vessels injured during trocar insertion: $8.7M verdict

A 26-YEAR-OLD WOMAN went to the emergency department with periodic pelvic pain. The attending ObGyn ordered exploratory laparoscopic surgery. When a resident physician inserted the trocar, the right common iliac artery and vein were injured. The patient started hemorrhaging and required a laparotomy to repair the injury. Postsurgery, the patient's bowel began to swell; the wound was kept open for drainage, requiring an additional procedure for closure. She remained in the intensive care unit for several weeks. She has a large abdominal scar and reports chronic abdominal pain. She is at risk for further complications, including bowel obstruction, because of abdominal adhesive disease. She lost her job and struggles to maintain her daily life.

PATIENT'S CLAIM: The resident was negligent in performing trocar insertion during laparoscopic surgery by inserting the trocar too far into the abdomen. The attending ObGyn did not supervise the resident properly. There is nothing in the patient's medical records to indicate that she had abnormal anatomy. The woman's life is in turmoil after what was supposed to be a routine procedure.

DEFENDANTS' DEFENSE: There was no negligence. The patient's anatomy was abnormal, making the risk of surgery higher. The injury is a known complication of laparoscopic surgery.

VERDICT: An $8,718,848 Illinois verdict was returned.

Did oxytocin cause child's spastic CP? $14.4M verdict

WHEN A WOMAN went to the hospital in labor, her ObGyn ordered oxytocin to enhance delivery. The FHR monitor showed repetitive decelerations for the next hour, dropping to 60 bpm by 8:00 PM, when the ObGyn expedited delivery but did not stop the oxytocin. By 8:20 PM, the baby's head was crowning, but the ObGyn waited another 10 minutes before performing an episiotomy and delivering the baby.

The child, intubated 5 minutes after birth, was found to have spastic tetraparesis cerebral palsy (CP) with impaired cognition, seizures, and global aphasia.

PARENTS' CLAIM: The ObGyn and nurses failed to properly monitor labor and delivery. The ObGyn should not have started oxytocin because the patient's labor was progressing normally. He should have taken the mother off oxytocin at 8:00 PM when the FHR dropped to 60 bpm. He should have performed an operative

These cases were selected by the editors of OBG MANAGEMENT *from* Medical Malpractice Verdicts, Settlements, & Experts, *with permission of the editor, Lewis Laska (www.verdictslaska.com). The information available to the editors about the cases presented here is sometimes incomplete. Moreover, the cases may or may not have merit. Nevertheless, these cases represent the types of clinical situations that typically result in litigation and are meant to illustrate nationwide variation in jury verdicts and awards.*

PHOTO: SHUTTERSTOCK

delivery at 8:20 PM when the baby's head crowned. An earlier delivery would have prevented injury.

DEFENDANTS' DEFENSE: The ObGyn's treatment was within the standard of care. He properly determined that vaginal delivery would be the quickest. It is his practice to stop oxytocin when the FHR slows, though he had no memory of halting oxytocin administration in this case. The baby's CP stemmed from insufficiencies in the placenta, seizures, and meconium aspiration syndrome.

VERDICT: A $14.4 million Pennsylvania verdict was returned. The ObGyn was found 60% liable for the baby's injuries and the hospital 40% responsible.

Wrong fallopian tube transected: $1.8M award

A 28-YEAR-OLD WOMAN UNDERWENT an appendectomy. During the operation, the surgeon saw an abscess on the patient's right fallopian tube and called in an ObGyn to remove the abscess. While doing so, the ObGyn transected the left fallopian tube. Both fallopian tubes were removed.

PATIENT'S CLAIM: The surgeon did not tell the ObGyn which fallopian tube was abscessed and therefore the ObGyn operated on the wrong tube. In addition, the surgeon failed to obtain informed consent for bilateral salpingectomy. The patient is now unable to conceive without assisted reproductive treatment.

PHYSICIAN'S DEFENSE: The surgeon admitted his mistakes but disputed the informed consent claim. The patient probably would not have been able to conceive naturally due to the infection.

VERDICT: A $1.8 million Connecticut verdict was returned.

Woman with preeclampsia dies: $6M verdict

A 34-YEAR-OLD WOMAN had been a patient of her family practitioner (FP) for many years. Her blood pressure (BP) averaged 105/63 mm Hg over that time. At a regular prenatal visit on February 26, the patient reported a headache and cough. Her BP was 130/90 mm Hg and she had gained 8.6 lb since her last visit 4 weeks earlier. She was told to return in 2 weeks.

She contacted her FP 2 days later to report acute vaginal bleeding and a severe headache. The FP sent her to the hospital, where potential placental abruption was considered. Two US studies demonstrated oligohydramnios, intrauterine growth restriction, and a grade II placenta. She continued to have repeated high BP readings, headaches, variable and late decelerations, and a dropping platelet count.

She was discharged on the morning of March 3 and sent to another hospital for a specialized US. The FP spoke to the physician who was to perform the US, advising him by phone and in writing to evaluate the oligohydramnios and intrauterine growth restriction. No other information was provided.

At 6:00 PM on March 3, the patient's husband called the FP to report that his wife was vomiting, reporting abdominal pain and intense headache. He was advised to call back in 1 hour, and when he did, he was told to take his wife to the hospital. At the hospital at 8:50 PM on March 3, her BP was 128/103 mm Hg. She reported throbbing headache, vomiting, and facial edema. She was admitted for observation.

At 9:30 PM, when the patient's BP was 155/100 mm Hg, a nurse contacted the FP to report the patient's continued throbbing headache and elevated, labile BP. The FP neither requested a consultation with an attending ObGyn nor went to the hospital until 4:31 AM on March 4.

At 3:15 AM on March 4, a nurse found the patient with her head hanging over the side of the bed in an obtunded state, having vomited. The rapid response team and an attending ObGyn were called. The ObGyn diagnosed eclampsia, ordered magnesium sulfate and hydralazine and immediately transported her to the operating room for an emergency cesarean delivery. Although the baby was healthy, the mother remained unresponsive. A computed tomography (CT) scan confirmed a massive intracranial hemorrhage. She was pronounced dead at 5:10 PM.

ESTATE'S CLAIM: The FP negligently deviated from the standard of care, leading to the mother's death. The FP fraudulently misrepresented her experience and training for obstetric conditions. She was negligent for failing to adequately diagnose and react to the patient's condition or refer her to an ObGyn, per hospital policy.

DEFENDANTS' DEFENSE: The patient's treatment met the standard of care. The FP was credentialed to practice obstetrics at the hospital. The patient's BP never reached or sustained a level that would require the FP to consult an ObGyn until 3:15 AM on March 4. When the patient first presented with a headache, the FP had consulted a board-certified ObGyn and an MFM, who suggested continued antepartum testing and induction at 39 weeks. The patient's death was unforeseeable because her BP values were inconsistent; the FP had no knowledge of a family history of stroke. The autopsy reported that a ruptured aneurysm was the cause of death.

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VERDICT: A $6,067,830 Ohio verdict was returned. The award was reduced to $900,000 due to a high/low agreement.

Fetal abnormalities not diagnosed: Baby has Down syndrome

ON SEPTEMBER 6, at 10 weeks' gestation, a woman began prenatal care at a clinic with Dr. A, an ObGyn. The mother participated in the California Prenatal Screening Program and received test results on October 23 that showed normal risk for birth defects. On November 1, she saw Dr. B, another ObGyn, who confirmed the negative prenatal screening and ordered an US. A radiologist reported to Dr. B that the fetal anatomy was not well visualized. When the mother was at 23 2/7 weeks' gestation (December 6), Dr. B told the parents that the US results were normal.

On January 2, the parents saw Dr. A, who disclosed that the US radiology report indicated an incomplete fetal anatomy scan and ordered a repeat US. The US performed on January 17 showed a cardiac defect. Further testing confirmed that the fetus had Down syndrome. The parents scheduled but did not appear for a late-term abortion because they feared that the procedure was illegal.

PARENTS' CLAIM: The parents told both ObGyns that they wanted extensive prenatal testing because of a family history of birth defects and that they would terminate the pregnancy if birth defects were discovered. Because Dr. B did not discuss prenatal testing, the parents did not know their child had Down syndrome until it was too late to legally terminate the pregnancy. The mother testified that she had never heard of amniocentesis until mid-January, when a perinatologist confirmed that the baby had Down syndrome.

DEFENDANTS' DEFENSE: The ObGyns denied having any discussions with the parents about their request for extensive prenatal tests or desire for termination. Difficulty in visualizing the fetus is common in second trimester US, and therefore Dr. B routinely performs another US later in the pregnancy. He also denied responsibility for discussing prenatal testing with the parents, stating that such discussions should happen in the first trimester. Since the parents saw Dr. A during that time, Dr. B believed that those conversations had already taken place. The prenatal screening pamphlet that the mother signed on September 6 discussed amniocentesis. The child's grandmother testified that she had discussed amniocentesis with the parents early in the pregnancy. A clinic employee testified that in January she asked the mother why she had not chosen amniocentesis earlier in the pregnancy; the mother replied that she had decided against it because her prenatal screening test was normal.

VERDICT: A California defense verdict was returned.

Complications after vaginal hysterectomy

A WOMAN UNDERWENT laparoscopic vaginal hysterectomy and bilateral salpingo-oophorectomy with anterior and posterior repair using mesh in August 2010. Shortly after surgery, the patient reported vaginal discharge with pain and bleeding. She was treated with antibiotics. Results of a CT scan identified the cause of her symptoms as vaginal cuff granulations.

Her pain continued and in June 2011, she underwent vaginal tissue biopsy. After testing revealed the presence of fecal matter, a small-bowel vaginal fistula was identified. She underwent laparoscopic enterectomy, urethral lysis, an omental pedicle flap, and cystoscopy. The mesh had perforated several loops of the small bowel.

In August 2011, the patient reported spinal pain. Magnetic resonance imaging (MRI) revealed a new fluid abscess in a disc extending through the tract anterior to the soft tissue of the pelvis. She underwent intensive antibiotic therapy.

PATIENT'S CLAIM: The gynecologic surgeon fell below the standard of care in his treatment of her conditions.

PHYSICIAN'S DEFENSE: The surgeon denied allegations.

VERDICT: A Nevada defense verdict was returned.

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- a pro/con on whether the Ob should be separated from the Gyn
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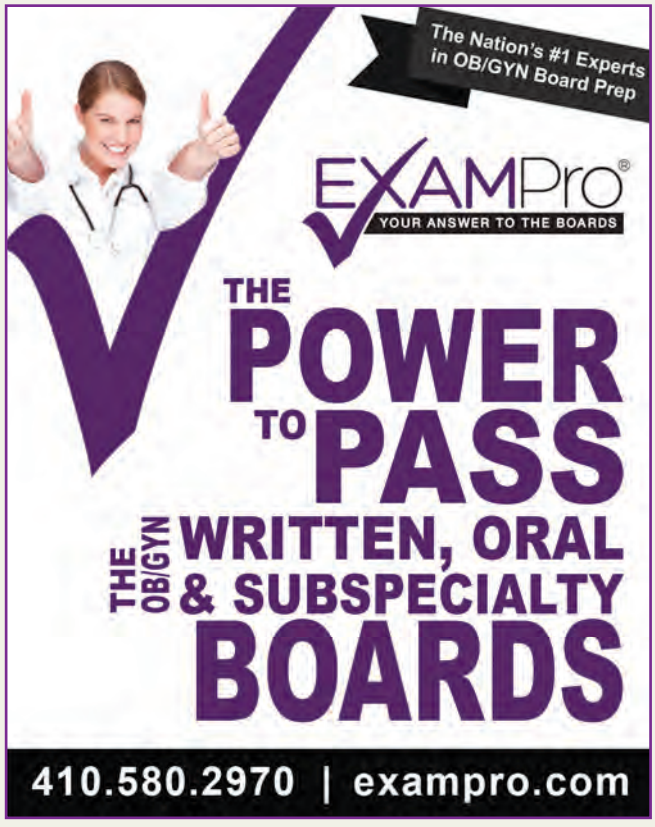

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*Data are from the Contraceptive CHOICE Project. The study evaluated 3- and 6-month self-reported bleeding and cramping patterns in 5011 long-acting reversible contraceptive (LARC) users (n=826, PARAGARD), and the association of these symptoms with method satisfaction. Study participants rated satisfaction with their LARC method as "very satisfied," "somewhat satisfied," or "not satisfied." For the data analyses, "satisfied" and "very satisfied" were grouped together as "satisfied."[3]

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References: 1. PARAGARD® T 380A [Prescribing Information]. North Wales, PA: Teva Women's Health, Inc.; September 2014. **2.** Kaneshiro B, Aeby T. Long-term safety, efficacy, and patient acceptability of the intrauterine Copper T-380A contraceptive device. *Int J Womens Health*. 2010;2:211-220. **3.** Diedrich JT, Desai S, Zhao Q, Secura G, Madden T, Peipert JF. Association of short-term bleeding and cramping patterns with long-acting reversible contraceptive method satisfaction. *Am J Obstet Gynecol*. 2015;212(1):50.e1-50.e8.

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