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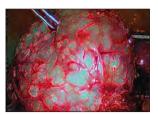
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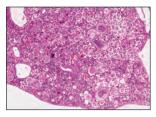
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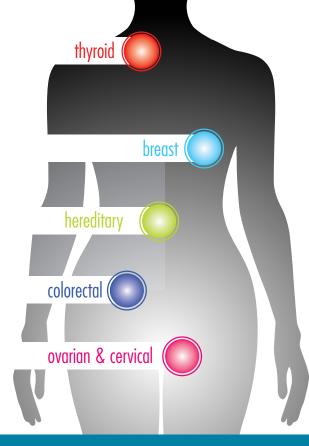
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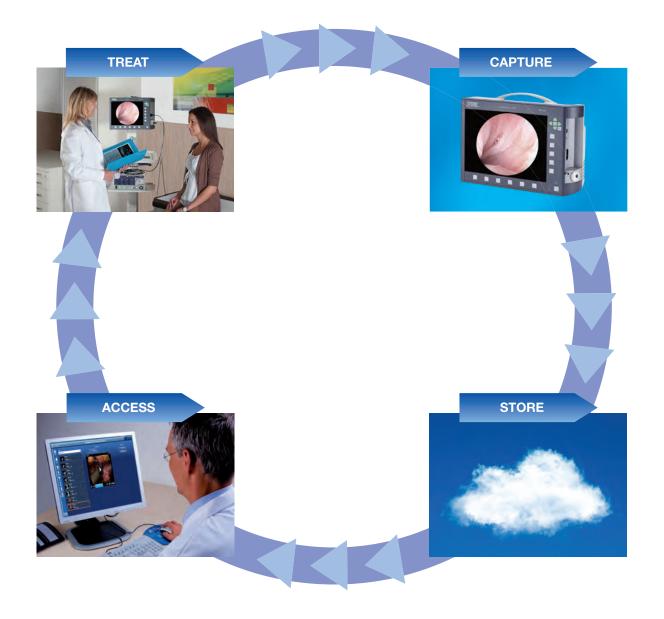
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**FIGURE** Twelve or more follicles on this ovary indicate that polycystic ovary syndrome is likely. The diagnosis is confirmed if the patient has anovulation or oligo-ovulation or hyperandrogenism (hirsutism or elevated androstenedione and/or dehydroepiandrosterone sulfate levels).

## Editorial

## Treating polycystic ovary syndrome: Start using dual medical therapy

Solution Many clinicians treat polycystic ovary syndrome with oral estrogen– progestin (OEP) monotherapy. Dual therapy with OEP plus metformin or OEP plus spironolactone is more effective.



#### Robert L. Barbieri, MD

Editor in Chief, OBG MANAGEMENT Chair, Obstetrics and Gynecology Brigham and Women's Hospital, Boston, Massachusetts Kate Macy Ladd Professor of Obstetrics, Gynecology and Reproductive Biology Harvard Medical School, Boston

sing the Rotterdam criteria, the diagnosis of polycystic ovary syndrome (PCOS) is made in the presence of 2 of the following 3 criteria<sup>1</sup>:

- 1. oligo-ovulation or anovulation
- hyperandrogenism manifested by the presence of either hirsutism or elevated hormone levels (including serum testosterone androstenedione and/or dehydroepiandrosterone sulfate)
- 3. ultrasonography evidence of multifollicular ovaries (≥12 follicles with a diameter of 2 mm to 9 mm in one or both ovaries; **FIGURE**) or ovarian stromal volume of 10 mL or more.

Among reproductive-age women, the prevalence of PCOS has been reported to range from 8% to 13% for different populations.<sup>2</sup> Most clinicians initiate treatment for PCOS with oral estrogen–progestin (OEP) monotherapy. OEP treatment has many beneficial hormonal effects, including:

- a resulting decrease in pituitary luteinizing hormone (LH) secretion, which decreases ovarian androgen production
- an increase in liver production of

sex hormone–binding globulin (SHBG), which decreases free testosterone levels

- protection against the development of endometrial hyperplasia
- induction of regular uterine withdrawal bleeding.

However, OEP therapy neither improves metabolic indices (insulin sensitivity and visceral fat secretion of adipokines) nor blocks androgen action in the skin.

Dual medical treatment for PCOS can address the issues that monotherapy cannot and, along with providing guidance on improving diet and exercise, many experts support the initial therapy of PCOS with dual medical therapy (OEP plus metformin or spironolactone).

## Advantages of OEP plus metformin

For many women with PCOS, the syndrome is characterized by abnormalities in both the reproductive (increase in LH secretion) and metabolic (insulin resistance and increased adipokines) systems. OEP monotherapy does not improve the metabolic abnormalities of PCOS. Combination treatment with both OEP plus metformin, along with diet and exercise, can best treat these combined abnormalities.

**Data support dual therapy with metformin.** In one small, randomized trial in women with PCOS, OEP plus metformin (1,500 mg daily) resulted in a greater reduction in serum androstenedione and a greater increase in SHBG than OEP monotherapy.<sup>3</sup> In addition, weight loss and a reduction in waist-to-hip ratio only occurred in the OEP plus metformin group.<sup>3</sup> In another small randomized study in women with PCOS, OEP plus metformin (1,500 mg daily) resulted in a greater decrease in free androgen index than OEP monotherapy.<sup>4</sup>

**In my clinical opinion,** women who may best benefit from OEP plus metformin therapy have one of the following factors indicating the presence of insulin resistance<sup>5</sup>:

- body mass index >30 kg/m<sup>2</sup>
- waist-to-hip ratio ≥0.85
- waist circumference >35 in (89 cm)
- acanthosis nigricans
- personal history of gestational diabetes

CONTINUED ON PAGE 10

- family history of type 2 diabetes mellitus (T2DM) in a first-degree relative
- diagnosis of the metabolic syndrome.

## My preferred treatment approach

Metformin is a low cost and safe treatment for metabolic dysfunction due to insulin resistance and excess adipokines. I often start PCOS treatment for my patients with an OEP plus metformin extended release (XR) 750 mg with dinner. If the patient tolerates this dose, I increase the dose to metformin XR 1,500 mg with dinner.

Adverse effects. The most common side effects of metformin are gastrointestinal, including abdominal discomfort, flatulence, borborygmi, diarrhea, and nausea. Metformin reduces serum vitamin B12 levels by 5% to 10%; therefore, ensuring adequate vitamin B12 intake (2.6  $\mu$ g daily) is helpful.<sup>6</sup> Although metformin does reduce vitamin B12 levels, there is no strong relationship between metformin and anemia or peripheral neuropathy.<sup>7</sup> Lactic acidosis is a rare complication of metformin.

**Beneficial effects.** In the treatment of PCOS, metformin may have many beneficial effects, including<sup>8</sup>:

- decrease in insulin resistance
- · decrease in harmful adipokines
- reduction in visceral fat
- reduction in the incidence of T2DM.

#### **OEP** plus spironolactone

Many women with PCOS have increased LH secretion and increased androgen activity in the skin due to increased 5-alpha reductase enzyme activity, which catalyzes the conversion of testosterone

## Optimal dual therapy for PCOS when an OEP is contraindicated

An oral estrogen–progestin (OEP) may be contraindicated for the treatment of PCOS, for instance because of the presence of thrombophilia. In these cases, alternative dual therapy options include a progestin plus a second agent. Options for progestin dual therapy include:

- oral norethindrone acetate 5 mg daily (which can lower luteinizing hormone levels and block ovulation) plus metformin
- norethindrone acetate 5 mg plus spironolactone

 levonorgestrel-intrauterine device plus metformin or spironolactone. These progestin therapies reduce the risk of pregnancy and decrease the likelihood of endometrial hyperplasia development.

to the powerful intracellular androgen dihydrotestosterone.<sup>9</sup> Women with PCOS may present with a chief problem report of hirsutism, acne, or female androgenetic alopecia. OEP plus spironolactone may be an optimal initial treatment for women with a dominant dermatologic manifestation of PCOS. OEP treatment results in a decrease in pituitary LH secretion and ovarian androgen production. Spironolactone adds to this therapeutic effect by blocking androgen action in the skin.

The data on dual therapy with spironolactone. Many dermatologists recommend spironolactone in combination with cosmetic measures for the treatment of acne, but there are only a few randomized trials that demonstrate its efficacy.10 In one trial spironolactone was demonstrated to be superior to placebo for the treatment of inflammatory acne.10 Authors of multiple randomized trials report that the antiandrogens, spironolactone, or finasteride are superior to metformin to treat hirsutism.<sup>11</sup> In addition, a few small trials report that spironolactone plus OEP is superior to either OEP or metformin monotherapy for hirsutism.11 Clinical trials of spironolactone for hirsutism have been rated as "low quality" and additional controlled trials of OEP monotherapy versus OEP plus spironolactone are warranted.<sup>12</sup>

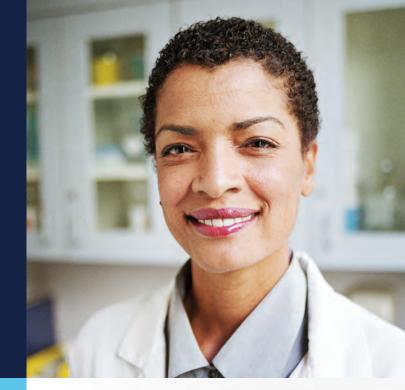
## My preferred treatment approach

Spironolactone is effective in the treatment of hirsutism at doses ranging from 50 mg to 200 mg daily. I routinely use a dose of spironolactone 100 mg daily because this dose is near of the top of the doseresponse curve and has few adverse effects (such as intermittent uterine bleeding or spotting). With spironolactone monotherapy at a dose of 200 mg, irregular uterine bleeding or spotting is common, but concomitant treatment with an OEP tends to minimize this side effect. In my practice I rarely have patients report irregular uterine bleeding or spotting with the combination treatment of an OEP and spironolactone 100 mg daily.

**Contraindications.** Spironolactone should not be given to women with renal insufficiency because it can cause hyperkalemia. However, it is not necessary to check potassium levels in young women taking spironolactone with normal creatinine levels.<sup>13</sup>

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2. Based on internal report #15003596, Preclinical test using analog tissue. 2016.

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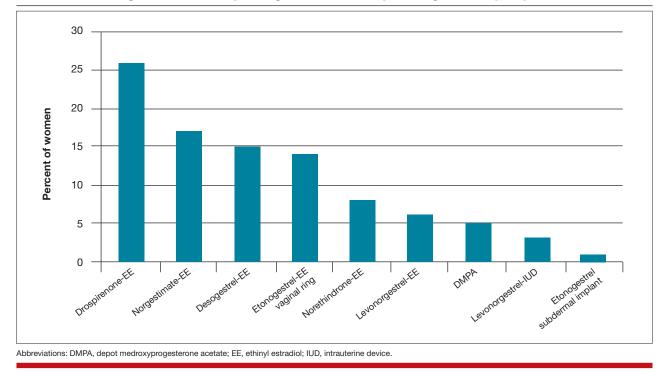
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## Editorial



#### FIGURE Percentage of women reporting their contraceptive significantly improved their acne<sup>16</sup>

#### Triple therapy: OEP plus metformin plus spironolactone

Some experts strongly recommend the initial treatment of PCOS in adolescents and young women with triple therapy: OEP plus an insulin sensitizer plus an antiandrogen.14 This recommendation is based in part on the observation that OEP monotherapy may be associated with an increase in circulating adipokines and visceral fat mass as determined by dual-energy x-ray absorptiometry.<sup>15</sup> By contrast, triple treatment with an OEP plus metformin plus an antiandrogen is associated with a decrease in circulating adipokines and visceral fat mass.

## What is the best progestin for PCOS?

Any OEP is better than no OEP, regardless of the progestin used to treat the PCOS because ethinyl estradiol plus any synthetic progestin suppresses pituitary secretion of LH and decreases ovarian androgen production. However, for the treatment of acne, using a progestin that is less androgenic may be beneficial.<sup>16</sup>

In one study, 2,147 consecutive women who were taking a contraceptive and presented for treatment of acne were asked if their contraceptive had a positive impact on their acne. The percentage of women reporting that their contraceptive significantly improved their acne ranged from 26% for those taking drospirenone-ethinyl estradiol (EE) to 1% for those taking the etonogestrel subdermal implant (**FIGURE**).<sup>16</sup> The US Food and Drug Administration has approved 4 OEP contraceptives for the treatment of acne (**TABLE**). The OEPs with drospirenone, norgestimate, desogestrel, or norethindrone acetate may be optimal choices for the treatment of acne caused by PCOS.

#### The bottom line

PCOS is a common endocrine disorder treated primarily by obstetricians-gynecologists. Among

## **TABLE FDA**-approved estrogen–progestin contraceptives for the treatment of acne

Brand name	Generic name		
Estrostep	Norethindrone acetate-ethinyl estradiol plus ferrous fumarate		
Ortho Tri-Cyclen	Norgestimate-ethinyl estradiol		
Yaz	Drospirenone-ethinyl estradiol		
BeYaz	Drospirenone-ethinyl estradiol plus levomefolate		

adolescents and young women with PCOS chief problem reports include irregular menses, hirsutism, obesity, acne, and infertility. Among mid-life women the presentation of PCOS often evolves into chronic medical problems, including obesity, metabolic syndrome, hyperlipidemia, hypertension, T2DM, cardiovascular disease, and endometrial cancer.<sup>17-19</sup> To optimally treat the multiple pathophysiologic disorders manifested in PCOS, I recommend initial dual medical therapy with an OEP plus metformin or an OEP plus spironolactone. **©** 

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#### COMING SOON....

- >> Managing urologic injury in gynecologic surgery Elizabeth Mueller, MD
- >> Update on cervical disease Mark Einstein, MD, MS
- >> LARCs and adolescents: Management pearls Ronald T. Burkman, MD
- >> Start using antenatal corticosteroids for women delivering between 34 0/7 and 36 6/7 weeks' gestation Robert L. Barbieri, MD
- >> Should the Ob be separated from the Gyn? Pro/con from Geoffrey Cundiff, MD, and Kimberly Kenton, MD





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## WHEN SIMPLE THINGS BECOME **VERY VERY AVENUE**

## It may be vulvar and vaginal atrophy (VVA), a chronic and progressive medical condition that affects many menopausal women.<sup>1-3</sup>

VVA, a component of genitourinary syndrome of menopause (GSM), is a common condition in menopausal women caused by a decrease in estrogen.<sup>1-4</sup> Approximately 1 in 2 menopausal women in the United States experience VVA symptoms.<sup>2,3</sup> The most common physical symptoms of VVA include dyspareunia (painful sex), vaginal dryness, burning, and irritation or soreness. Urinary symptoms such as dysuria (painful urination) and recurrent urinary tract infections are also associated with VVA.<sup>1-4</sup> These symptoms may negatively impact a woman's sense of self, relationships, and enjoyment of life.<sup>2,5</sup>

Unlike night sweats and hot flashes, VVA may not resolve without treatment,<sup>1</sup> putting many women in a prickly situation.

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#### "LONG-ACTING REVERSIBLE CONTRACEPTIVES AND ACNE IN ADOLESCENTS"

ROBERT L. BARBIERI, MD, AND ANDREA H. ROE, MD (EDITORIAL; JANUARY 2017)

#### Manage acne with spironolactone for women on LARC

Dr. Barbieri's editorial with Dr. Roe addressed the very important theme of proactively talking about acne before a patient starts long-acting reversible contraception (LARC), especially when switching from a birth control pill that had controlled the acne to a levonorgestrel intrauterine device (LNG-IUD). It missed the mark, however, in not mentioning a very important presenting feature of adolescent polycystic ovary syndrome (PCOS)-cystic acne. I highly recommend obtaining baseline testosterone levels and using spironolactone, 50 to 200 mg daily, to treat acne while on LARC, especially an LNG-IUD. I learned this trick a few years ago from a Canadian endocrinologist.

> John Lewis, MD Waterbury, Connecticut

#### >> Dr. Barbieri responds

I thank Dr. Lewis for the important clinical pearl to use spironolactone to prevent and treat acne when inserting a progestin-releasing LARC in an adolescent or young woman. Spironolactone blocks testosterone action in the pilosebaceous unit, thereby decreasing sebum production and reducing acne activity. I frequently use spironolactone in my practice, especially for women with PCOS who have hirsutism and acne (see my editorial on page 8 of this issue). However, authors of a recent systematic review reported that there is minimal evidence from clinical trials to support the use of spironolactone to treat acne vulgaris.1

#### Reference

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#### "TRUST: HOW TO BUILD A SUPPORT NET FOR OBGYNS AFFECTED BY A MEDICAL ERROR"

PATRICE M. WEISS, MD (JANUARY 2017)

#### Support for ObGyn versus "evidence" for attorney

While every clinician recognizes the need to support the practitioner involved in a significant medical error, I found it puzzling that Dr. Weiss' article did not mention our constant after-the-event associate, the personal injury attorney. How are we to provide the needed relief for the practitioner's emotional distress without handing ammunition to the plaintiff's lawyer?

> **E. Darryl Barnes, MD** Mechanicsville, Virginia

## Experienced being the second victim

As Dr. Weiss states in her article. patients and their families, the first victims, are not the only ones affected by medical errors. I was involved in a medication error on a labor and delivery unit more than 20 years ago, and I was the second victim. There were also countless others. You are correct when you state that physicians, and others in medicine, do not support colleagues who have experienced a medical error. I agree with Dr. Wu's observation that lack of empathy by peers is distressing. Symptoms of depression, burnout, decreased quality of life, and feelings of distress, guilt, and shame can occur in the second victim. I hope more people will get on board to use The Joint Commission toolkit to assist health care organizations in developing a second-victim program.

> Carol Permiceo, RN Long Island, New York

#### >> Dr. Weiss responds

I thank Dr. Barnes for his comments. The purpose of this article was mainly to assist people in establishing institutional support systems for providers when medical errors occur. Often we are not aware of litigation until some time well after the event. The TRUST second-victim support program and other programs are for immediate first aid for the provider and the team. Concerning the plaintiff's ammunition, please remember that the purpose of these support systems, whether immediate or ongoing, is to discuss the emotional impact of the case on the provider, not the clinical details of the case.

I appreciate Ms. Permiceo sharing her story. As you probably have figured out, my interest in this area stems from my own experiences with medical errors (one in particular) and unanticipated outcomes. I hope by talking about it and validating our feelings (we are only human, after all) others will suffer less and come forward.

#### "MANAGEMENT OF WOUND COMPLICATIONS FOLLOWING OBSTETRIC ANAL SPHINCTER INJURY (OASIS)"

ROBERT L. BARBIERI, MD, AND JEANNINE M. MIRANNE, MD, MS (EDITORIAL; DECEMBER 2016)

## Delivering clinician should be seated

Indeed, obstetric anal sphincter injuries (OASIS),<sup>1</sup> with their shortand long-term consequences, merit clinical attention, as spotlighted in

CONTINUED ON PAGE 18

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#### Comment & Controversy

CONTINUED FROM PAGE 16

Dr. Barbieri and Dr. Miranne's article. An issue not discussed is the position of the obstetrician.

In our practice, we sit down to perform a vaginal delivery, as taught by Soranus of Ephesus.<sup>2</sup> We strive to be at the bedside sooner than when the nurse calls "she is crowning." This allows communication with the woman, attending nurse, and support person(s), as well as for a brief review of recent estimated fetal weight, length of the second stage, position of the presenting part, degree of flexion, presence of caput, and other last-minute details. Sitting down in front of the outlet permits uninterrupted visual evaluation of the distention of the soft perineal tissues. All traditional maneuvers are performed comfortably from the sitting position: the vertex is controlled by hands-on, and a quick reach with the nonpredominant hand searches for a loop of cord or a small part procidentia to resolve it. The patient is coached either for the next bearing-down effort or to not push to allow for gradual, controlled delivery of the fetal shoulder girdle. We avoid use of the fetal head for traction and move to facilitate "shrugging" with reduction of the bisacromial to facilitate delivery.

In our experience, the sitting position is ideal to observe uninterruptedly the tension of the perineal body during vertex and shoulders delivery, without having to flex and rotate our back and neck in repeatedly nonergonomic positions.

If an obstetrician of aboveaverage height stands for the delivery, the obstetric bed should be elevated to fit her or his reach. Should shoulder dystocia occur, an assistant will stand on a chair and hover over the maternal abdomen to provide suprapubic pressure (indeed, an indelible memory for any parturient and her family). From the sitting position, exploration of the birth canal and repair of any injury, if necessary, can be conducted without technical impediments.

These simple steps have provided our patients and ourselves with clinical and professional satisfaction with minimal OASIS events as shown by others.<sup>3</sup> Ironically, if we successfully avoid perineal injuries, our young trainees may require simulation training to learn this tedious repair procedure. In our geographic practice area, a new "collaborative" expects the frequency of episiotomy to be less than 4.6%. Thirdand 4th-degree spontaneous or procedure-related perineal injuries still are used to measure quality of care despite demonstrated reasons for this parameter to be a noncredible metric.

> Federico G. Mariona, MD Dearborn, Michigan

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#### >> Dr. Barbieri responds

I agree with Dr. Mariona that in some cases the fetal head delivers without causing a 3rd- or 4th-degree laceration, but then the delivery of the posterior shoulder causes a severe perineal injury. Dr. Mariona's clinical pearl is that the delivering clinician should be seated, carefully observe the delivery of the shoulders, and facilitate fetal shrugging by gently reducing the bisacromial diameter as the posterior shoulder transitions over the perineal body.

#### "SHOULDER DYSTOCIA: TAKING THE FEAR OUT OF MANAGEMENT" JOHN T. REPKE, MD, AND RONALD T. BURKMAN, MD (WEB EXCLUSIVE: APRIL 2016)

## Montgomery maneuver for shoulder dystocia

In managing shoulder dystocia, my maneuver is to use my elbow to maximize mechanical advantage when applying suprapubic pressure to push the trapped shoulder down. It works well and is more efficient than having a nurse standing off to the side.

> J.S. Montgomery, MD Cypress, Texas



Photo courtesy of J.S. Montgomery, MD.

#### >> Dr. Barbieri responds

I thank Dr. Montgomery for sharing his maneuver for dislodging the trapped anterior shoulder by using his elbow to apply suprapubic pressure. There is vast knowledge and experience in our clinical community, and sharing insights is helpful to all our readers.

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# Which treatments for pelvic floor disorders are backed by evidence?

#### **Recent studies support stepwise treatment of pelvic floor disorders. Pelvic floor muscle**

**training** (PFMT) produced a small but important reduction in pelvic organ prolapse (POP) symptoms in a randomized controlled trial of women with stage 1 to 3 prolapse. **Surgical repairs with native tissue or mesh** 

expand treatment choices for POP as well as urinary incontinence, but reoperation for these disorders often is necessary, and mesh should be used with caution, according to data from 2 randomized trials and a cohort study.

Hagen S, Glazener C, McClurg D, et al. Pelvic floor muscle training for secondary prevention of pelvic organ prolapse (PREVPROL): a multicentre randomised controlled trial. Lancet. 2017;389(10067):393–402.

Glazener CM, Breeman S, Elders A, et al; PROSPECT study group. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). Lancet. 2017;389(10067):381-392.

Morling JR, McAllister DA, Agur W, et al. Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997-2016: a population-based cohort study. Lancet. 2017;389(10069):629-640.

#### **EXPERT COMMENTARY**

**Meadow M. Good, DO,** is Assistant Professor and Chief, Division of Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics and Gynecology, University of Florida Health, Jacksonville.

Care of women with pelvic floor disorders, primarily urinary incontinence and POP, involves:

- assessing the patient's symptoms and determining how bothersome they are
- educating the patient about her condition and the options for treatment
- initiating treatment with the most conservative and least invasive therapies.

The author reports no financial relationships relevant to this article.

Safe treatments include PFMT and pessaries, and both can be effective. However, since approximately 25% of women experience one or more pelvic floor disorders during their life, surgical repair of these disorders is common. The lifetime risk of surgery for stress urinary incontinence (SUI) or POP is 20%,<sup>1</sup> and onethird of patients will undergo reoperation for the same condition. Midurethral mesh slings are the gold standard for surgical management of SUI.<sup>2</sup> Use of transvaginal mesh for primary prolapse repairs, however, is associated with challenging adverse effects, and its use should be reserved for carefully selected patients.

Data from 3 recent studies contribute to our evidence base on various treatments for pelvic floor disorders.

#### Details of the studies

**PFMT** for secondary prevention of POP. In a study conducted in the United Kingdom and New Zealand, Hagen and colleagues randomly assigned 414 women with POP, with or without symptoms, to an intervention group or a control group. The women had previously participated in a longitudinal study of postpartum pelvic floor function. Participants in the intervention group (n = 207) received 5 formal sessions of PFMT over 16 weeks,



The lifetime risk of surgery for SUI or POP is 20%, and one-third of women will have reoperation for the same condition followed by Pilates-based classes focused on pelvic floor exercises; those in the control group (n = 207) received an informational leaflet about prolapse and lifestyle. The primary outcome was self-reported prolapse symptoms, assessed with the POP Symptom Score (POP-SS) at 2 years.

At study end, the mean (SD) POP-SS score in the intervention group was 3.2 (3.4), compared with a mean (SD) score of 4.2 (4.4) in the control group (adjusted mean difference, -1.01; 95% confidence interval [CI], -1.70 to -0.33; P = .004).

**Investigators' interpretation.** The researchers concluded that the participants in the PFMT group had a small but significant—and clinically important—decrease in prolapse symptoms.

The PROSPECT study: Standard versus augmented surgical repair. In a multicenter trial in the United Kingdom by Glazener and associates, 1,352 women with symptomatic POP were randomly allocated to surgical repair with native tissue alone (standard repair) or to standard surgical repair augmented either with polypropylene mesh or with biological graft. The primary outcomes were participant-reported prolapse symptoms (assessed with POP-SS) and prolapse-related quality of life scores; these were measured at 1 year and at 2 years.

One year after surgery, failure rates (defined as prolapse beyond the hymen) were similar in all groups (range, 14%–18%); serious adverse events were also similar in all surgical groups (range, 6%–10%). Overall, 6% of women underwent reoperation for recurrent symptoms. Among women randomly assigned to repair with mesh, 12% to 14% experienced mesh-related adverse events; three-quarters of these women ultimately required surgical excision of the mesh.

**Study takeaway.** Thus, in terms of effectiveness, quality of life, and adverse effects, augmentation of a vaginal surgical repair with

#### WHAT THIS EVIDENCE MEANS FOR PRACTICE

These studies highlight the prevalence of pelvic floor disorders and underscore the need for evidence-based treatment strategies. Women with symptomatic pelvic floor disorders initially should be offered conservative options and education. Although mesh grafts certainly have expanded the surgical options for managing pelvic floor disorders, they should be used with caution transvaginally for primary prolapse repairs. Because of the complexity of POP and its treatment, it is reasonable to refer patients with the condition to a specialist experienced in female pelvic medicine and reconstructive surgery.

>> MEADOW M. GOOD, DO

either mesh or graft material did not improve the outcomes of women with POP. Adverse events after surgical procedures for pelvic floor disorders. In Scotland, Mor-

ling and colleagues performed a retrospective observational cohort study of first-time surgeries for SUI (mesh or colposuspension; 16,660 procedures) and prolapse (mesh or native tissue; 18,986 procedures).

After 5 years of follow-up, women who underwent midurethral mesh sling placement or colposuspension had similar rates of repeat surgery for recurrent SUI (adjusted incidence rate ratio, 0.90; 95% CI, 0.73–1.11). Use of mesh slings was associated with fewer immediate complications (adjusted relative risk, 0.44; 95% CI, 0.36–0.55) compared with nonmesh surgery.

Among women who underwent surgery for prolapse, those who had anterior and posterior repair with mesh experienced higher late complication rates than those who underwent native tissue repair. Risk for subsequent prolapse repair was similar with mesh and native-tissue procedures.

Authors' commentary. The researchers noted that their data support the use of mesh procedures for incontinence but additional research on longer-term outcomes would be useful. However, for prolapse repair, the study results do not decidedly favor any one vault repair procedure. <sup>(2)</sup>



In the PROSPECT trial, outcomes for effectiveness, quality of life, and adverse effects were not improved in women who had augmention of a vaginal surgical repair for POP with either mesh or graft material

Position statement on mesh midurethral slings for stress urinary incontinence. Female Pelvic Med Reconstr Surg. 2014;20(3):123-125.

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<sup>2.</sup> Nager C, Tulikangas P, Miller D, Rovner E, Goldman H.



#### **PART 2 OF 3**



## **Abdominal myomectomy: Patient and surgical technique** considerations

Solution With the second secon whether or not they wish to preserve their childbearing potential. An expert provides guidance on abdominal myomectomy, including intraoperative technique, controlling blood loss, and postoperative care.

#### William H. Parker, MD



#### Abdominal incision technique

page 23 

Managing blood loss page 24

**Postoperative** care page 27



**Three surgical** videos from Dr. Parker at obgmanagement.com

#### **CASE** Woman with fibroids seeks alternative to hysterectomy

A 42-year-old woman (G2P2) presents to the office for evaluation of heavy menstrual bleeding and known uterine fibroids. Physical examination reveals a 16-week-sized uterus, and ultrasonography shows at least 6 fibroids, 2 of which impinge on the uterine cavity. She does not want to have any more children, but she wishes to avoid a hysterectomy.

#### **Abdominal myomectomy:** A good option for many women

Abdominal myomectomy is an underutilized procedure. With fibroids as the indication for surgery, 197,000 hysterectomies were performed in the United States in 2010, compared with approximately 40,000 myomectomies.<sup>1,2</sup> Moreover, the rates of both



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The author reports no financial relationships relevant to this article.

laparoscopic and abdominal myomectomy have decreased following the controversial morcellation advisory issued by the US Food and Drug Administration.<sup>3</sup>

The differences in the hysterectomy and myomectomy rates might be explained by the many myths ascribed to myomectomy. Such myths include the beliefs that myomectomy, when compared with hysterectomy, is associated with greater risk of visceral injury, more blood loss, poor uterine healing, and high risk of fibroid recurrence, and that myomectomy is unlikely to improve patient symptoms.

Studies show, however, that these beliefs are wrong. The risk of needing treatment for new fibroid growth following myomectomy is low.4 Hysterectomy, compared with myomectomy for similar size uteri, is actually associated with a greater risk of injury to the bowel, bladder, and ureters and with a greater risk of operative hemorrhage. Furthermore, hysterectomy (without oophorectomy) can be associated with early menopause in approximately 10% of women, while myomectomy does not alter ovarian hormones. (See "7 Myomectomy myths debunked," which appeared in the February 2017 issue of OBG MANAGEMENT.) Another myth debunked: Fibroids do not "degenerate" into leiomyosarcomas, and the risk of leiomyosarcoma in premenopausal women with presumed uterine fibroids is extremely low.<sup>5,6</sup>

For women who have serious medical problems (severe anemia, ureteral obstruction) due to uterine fibroids, surgery usually is necessary. In addition, women may request surgery for fibroid-associated quality-of-life concerns, such as heavy menstrual bleeding, infertility, pelvic pressure, urinary frequency, or incontinence. In one prospective study, the authors found that when women were assessed 6 months after undergoing myomectomy, 75% reported experiencing a significant decrease in bothersome symptoms.<sup>7</sup>

Myomectomy may be considered even for women with large uterine fibroids who desire uterine conservation. In a systematic review of the perioperative morbidity associated with abdominal myomectomy compared with abdominal hysterectomy for fibroids, which included 1,520 women with uterine size up to 16 to 18 weeks, no difference was found in major morbidity rates.<sup>8</sup> Investigators who studied 91 women with uterine size ranging from 16 to 36 weeks who underwent abdominal myomectomy reported 1 bowel injury, 1 bladder injury, and 1 reoperation for bowel obstruction; no women had conversion to hysterectomy.<sup>9</sup>

Since ObGyn residency training emphasizes hysterectomy techniques, many residents receive only limited exposure to myomectomy procedures. Increased exposure to and comfort with myomectomy surgical technique would encourage more gynecologists to offer this option to their patients who desire uterine conservation, including those who do not desire future childbearing.

## Imaging techniques are essential in the preoperative evaluation

For women with fibroid-related symptoms who desire surgery with uterine preservation, determining the myomectomy approach (abdominal, laparoscopic/robotic, hysteroscopic) depends on accurate assessment of the size, number, and position of the fibroids. If abdominal myomectomy is planned because of uterine size, the presence of numerous fibroids, or patient choice, transvaginal/transabdominal ultrasonography usually is adequate for anticipating what will be found during surgery. Sonography is readily available and is the least costly imaging technique that can help differentiate fibroids from other pelvic pathology. Although small fibroids may not be seen on sonography, they can be palpated and removed at the time of open surgery.

If submucous fibroids need to be better defined, saline-infusion sonography can be performed. However, if laparoscopic/robotic myomectomy (which precludes accurate palpation during surgery) is being considered, magnetic resonance imaging (MRI) allows the best assessment of the size, number, and position of the fibroids.<sup>10</sup> When adenomyosis is considered in the differential diagnosis, MRI is an accurate way to determine its presence and helps in planning the best surgical procedure and approach.

#### Correct anemia before surgery

Women with fibroids may have anemia requiring correction before surgery to reduce the need for intraoperative or postoperative blood transfusion. Mild iron deficiency anemia can be treated prior to surgery with oral elemental iron 150 to 200 mg per day. Vitamin C 1,000 mg per day helps to increase intestinal iron absorption. Three weeks of treatment with oral iron can increase hemoglobin concentration by 2 g/dL.

For more severe anemia or rapid correction of anemia, intravenous (IV) iron sucrose infusions, 200 mg infused over 2 hours and given 3 times per week for 3 weeks, can increase hemoglobin by 3 g/dL.<sup>11</sup> In our ObGyn practice, hematologists manage iron infusions.

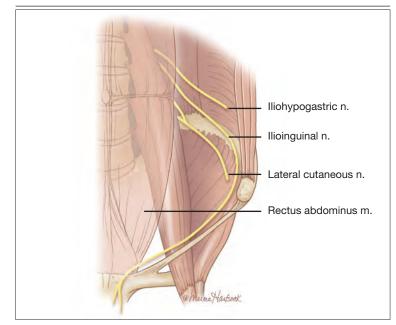
#### Abdominal incision technique

Even a large uterus with multiple fibroids usually can be managed through use of a transverse lower abdominal incision. Prior to reaching the lateral borders of the rectus abdominis, curve the fascial incision



Hysterectomy, compared with myomectomy for similar size uteri, is actually associated with a greater risk of injury to the bowel, bladder, and ureters and with a greater risk of operative hemorrhage abdominal myomectomy

## FIGURE 1 Ilioinguinal nerve at the lateral border of the rectus muscle





We employ 4 approaches to reduce intraoperative blood loss: misoprostol, tranexamic acid, vasopressin, and a uterine and ovarian vessel tourniquet cephalad to avoid injury to the ileoinguinal nerves (**FIGURE 1**). Detaching the midline rectus fascia (linea alba) from the anterior abdominal wall, starting at the pubic symphysis and continuing up to the umbilicus, frees the rectus muscles and allows them to be easily separated (see **VIDEO 1**). Since fascia is not elastic, these 2 steps are important to allow more room to deliver the uterus through the incision.

Delivery of the uterus through the incision isolates the surgical field from the bowel, bladder, ureters, and pelvic nerves. Once the uterus is delivered, inspect and palpate it for fibroids. Identify the fundus and the position of the uterine cavity by locating both uterine cornua and imagining a straight line between them. It may be necessary to explore the endometrial cavity to look for and remove submucous fibroids. Then plan the necessary uterine incisions for removing all fibroids (see VIDEO 2).

## 4 approaches to managing intraoperative blood loss

In my practice, we employ misoprostol, tranexamic acid, vasopressin, and a uterine

and ovarian vessel tourniquet to manage intraoperative blood loss.<sup>12</sup> Although no data exist to show that using these methods together is advantageous, they have different mechanisms of action and no negative interactions.

**Misoprostol** 400 µg inserted vaginally 2 hours before surgery induces myometrial contraction and compression of the uterine vessels. This agent can reduce blood loss by 98 mL per case.<sup>12</sup>

**Tranexamic acid,** an antifibrinolytic, is given IV piggyback at the start of surgery at a dose of 10 mg/kg; it can reduce blood loss by 243 mL per case.<sup>12</sup>

**Vasopressin** 20 U in 100 mL normal saline, injected below the vascular pseudocapsule, causes vasoconstriction of capillaries and small arterioles and venules and can reduce blood loss by 246 mL per case.<sup>12</sup> Intravascular injection should be avoided because rare cases of bradycardia and cardiovascular collapse have been reported.<sup>13</sup> Using vasopressin to decrease blood loss during myomectomy is an off-label use of this drug.

**Place a tourniquet** around the lower uterine segment, including the infundibular pelvic ligaments. Tourniquet use is the most effective way to decrease blood loss during myomectomy, since it can reduce blood loss by 1,870 mL.<sup>12</sup> For women who wish to preserve fertility, take care to ensure that the tourniquet does not compromise the tubes. For women who are certain they do not want to preserve fertility, discuss the possibility of performing bilateral salpingectomy to decrease the risk of subsequent tubal ("ovarian") cancer.

Some surgeons incise the broad ligaments bilaterally and pass the tourniquet through the broad ligaments to avoid compromising blood flow to the ovaries. Occluding the uteroovarian ligaments with bulldog clamps to control collateral blood flow from the ovarian artery has been described, but the clamps can tear these often enlarged and fragile uterine veins during manipulation of the uterus. Release the tourniquet every 15 to 30 minutes to allow reperfusion of the ovaries. In women with ovarian torsion lasting hours to days, the ovary has been found to resist hypoxia and

CONTINUED ON PAGE 26

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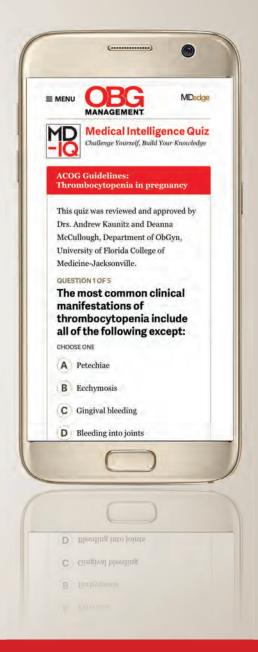
#### Andrew M. Kaunitz, MD, FACOG, NCMP

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**SURGICAL**Techniques



abdominal myomectomy CONTINUED FROM PAGE 24

#### FIGURE 2 A salvage-type autologous blood transfusion device reduces the need for transfusion



Pictured, Cell Saver 5+ Autologous Blood Recovery System, Haemonetics Used with permission.

recover function.<sup>14</sup> Antral follicle counts of detorsed and contralateral normal ovaries following a mean of 13 hours of hypoxia are similar 3 months following detorsion.<sup>15</sup>

Consider blood salvage. For women with multiple or very large fibroids, consider using a salvage-type autologous blood transfusion device, which has been shown to reduce the need for heterologous blood transfusion.16 This device suctions blood from the operative field, mixes it with heparinized saline, and stores the blood in a canister (FIGURE 2). If the patient requires blood reinfusion, the stored blood is washed with saline, filtered, centrifuged, and given back to the patient intravenously. Blood salvage, or cell salvage, avoids the risks of infection and transfusion reaction, and the oxygen transport capacity of salvaged red blood cells is equal to or better than that of stored allogeneic red cells.

## Additional surgical considerations

Previous teaching suggested that proper placement of the uterine incisions was an important factor in limiting blood loss. Some authors suggested that vertical uterine incisions would avoid injury to the ascending uterine vessels should inadvertent extension of the incision occur. Other authors proposed horizontal uterine incisions to avoid severing the arcuate vessels that branch off from the ascending uterine arteries and run transversely across the uterus. However, since fibroids distort the normal vascular architecture, it is not possible to entirely avoid severing vessels in the myometrium (FIGURE 3).<sup>17</sup> Uterine incisions can therefore be made as needed based on the position of the fibroids and the need to avoid inadvertent extension to the ascending uterine vessels or cornua.17

Fibroid anatomy and vascularity. Fibroids are entirely encased within the dense blood supply of a pseudocapsule (FIGURE 4),<sup>18</sup> and no distinct "vascular pedicle" exists at the base of the fibroid.<sup>19</sup> It is therefore important to extend the uterine incisions down through the entire pseudocapsule until the fibroid is clearly visible. This will identify a less vascular surgical plane, which is deeper than commonly recognized. Once the fibroid is reached, the pseudocapsule can be "wiped away" using a dry laparotomy sponge (see **VIDEO 3**). Staying under the pseudocapsule reduces bleeding and may preserve the tissue growth factors and neurotransmitters that are thought to promote wound healing.<sup>20</sup> Adhesion prevention. Limiting the number of uterine incisions has been suggested as a way to reduce the risk of postoperative pelvic adhesions. To extract fibroids that are distant from an incision, however, tunnels must be created within the myometrium, and this makes hemostasis within these defects difficult. In that blood increases the risk of adhesion formation, tunneling may be counterproductive. If tunneling incisions are avoided and hemostasis is secured immediately, the risk of adhesion formation should be lessened.

Therefore, make incisions directly over



Preserving the pseudocapsule reduces bleeding and may maintain tissue growth factors and neurotransmitters that are thought to promote wound healing the fibroids. Remove only easily accessed fibroids and promptly close the defects to secure hemostasis. Multiple uterine incisions may be needed; adhesion barriers may help limit adhesion formation.<sup>21</sup>

On final removal of the tourniquet, carefully inspect for bleeding and perform any necessary re-suturing. We place a pain pump (ON-Q\* Pain Relief System, Halyard Health, Inc) for pain management and close the abdominal incision in the standard manner.

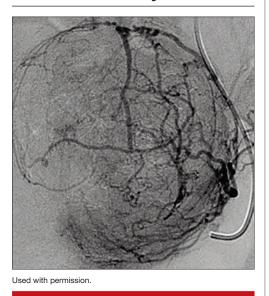
## Postoperative care: Manage pain, restore function

The pain pump infuser, attached to one soaker catheter above and one below the fascia, provides continuous infusion of bupivacaine to the incision at 4 mL per hour for 4 days. The pain pump greatly reduces the need for postoperative opioids.<sup>22</sup> Use of a patient-controlled analgesia pump, with its associated adverse effects (sedation, need for oxygen saturation monitoring, slowing of bowel function) can thus be avoided. The patient's residual pain is controlled with oral oxycodone or hydrocodone and scheduled nonsteroidal anti-inflammatory drugs.

In my practice, we use an enhanced recovery after surgery (ERAS) protocol designed to reduce postoperative surgical stress and expedite a return to baseline physiologic body functions.<sup>23</sup> Excellent well-researched, evidence-based studies support the effectiveness of ERAS in gynecologic and general surgery procedures.<sup>24</sup>

Pre-emptive, preoperative analgesia (gabapentin and celecoxib) and end-of-case IV acetaminophen are given to reduce the inflammatory response and the need for postoperative opioids. Once it is confirmed that the patient is hemodynamically stable, add ketorolac 30 mg IV every 6 hours on postoperative day 1. Nausea and vomiting prophylaxis includes ondansetron and dexamethasone at the end of surgery, avoidance of bowel edema with restriction of intraoperative and postoperative fluids (euvolemia), early oral feeding, and gum chewing. On the evening of surgery, the urinary catheter is

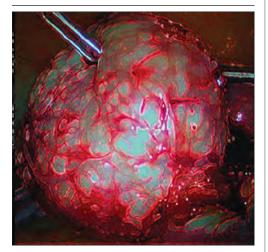
## FIGURE 3 Distortion of normal uterine vessels by fibroids<sup>17</sup>



removed to reduce the risk of bladder infection and facilitate ambulation. Encourage sitting at the bedside and early ambulation starting the evening of surgery to reduce risk of thromboembolism and to avoid skeletal muscle weakness and postoperative fatigue.

Most women are able to be discharged on postoperative day 2. They return to the

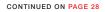
#### FIGURE 4 A pseudocapsule with a rich vascular network surrounds the fibroid<sup>18</sup>



Used with permission.



Evidence-based studies support the effectiveness of ERAS in gynecologic and general surgery procedures





#### **SURGICAL**Techniques

abdominal myomectomy



#### Linea alba incision



#### **Deliver uterus**



#### Pseudocapsule



office on postoperative day 5 for removal of the pain pump.

### CASE Continued: Fibroids removed via abdominal myomectomy

We performed an abdominal myomectomy through a Pfannenstiel incision. Nine fibroids-3 of which were not seen on MRI-ranging in size from 1 to 7 cm were removed. Intravaginal misoprostol, IV tranexamic acid, subserosal vasopressin, and a uterine vessel tourniquet limited the intraoperative blood loss to 225 mL. After surgery, a pain pump and ERAS protocol allowed the patient to be discharged on postoperative day 2, and she returned to the office on day 5 for removal of the pain pump. Oral pain medication was continued on an asneeded basis.

**WATCH FOR** part 3 of this 3-part series, in which Dr. Parker provides pearls for laparoscopic myomectomy technique. **©** 

#### Acknowledgment

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**SPECIAL SECTION** 

## THE ROLE OF MOISTURIZERS AND LUBRICANS IN GENITOURINARY SYNDROME OF MENOPAUSE AND BEYOND



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PHOTO: CNRI / SCIENCE SOURCE

#### Lisa Larkin, MD

President, Lisa Larkin, MD, & Associates Cincinnati, Ohio ROUNDTABLE

## THE ROLE OF MOISTURIZERS AND LUBRICANTS IN GENITOURINARY SYNDROME OF MENOPAUSE AND BEYOND

What role do moisturizers and lubricants play for women across patient populations? By openly talking to patients, we can individualize treatment choices and pave the way to sexual health.

#### Michael L. Krychman, MD; Alyssa Dweck, MD; Sheryl Kingsberg, PhD; and Lisa Larkin, MD

aginal/vulvar dryness and atrophy, along with painful sexual intercourse, are frequent problem reports among postmenopausal women. So frequent, in fact, that the term "genitourinary syndrome of menopause," or GSM, recently was adopted, largely in an effort to develop an accurate and more inclusive term that would improve and ease conversations about the subject between postmenopausal women and their health care professionals.<sup>1,2</sup> But postmenopausal women are not the only ones affected: vaginal dryness and sexual discomfort can affect women of any age.<sup>3</sup> The American College of Obstetricians and Gynecologists reports that nearly 3 of every 4 women

Dr. Larkin reports being a consultant and speaker for Valeant Pharmaceuticals.

**OBG MANAGEMENT** and the roundtable faculty do not endorse any specific product mentioned over another in this roundtable discussion. experience painful intercourse at some point during their lifetime, stemming from a variety of causes.<sup>4</sup>

Although reduced levels of estrogen, such as those that occur with menopause, childbirth, and breastfeeding, are the chief culprits, a host of other factors can lead to vaginal dryness and dyspareunia. These factors include cancer treatments; certain medications, such as antihistamines and aromatase inhibitors; and medical conditions including diabetes and immune dysfunction. Left untreated, vaginal dryness and atrophy and painful sexual intercourse are chronic and progressive medical conditions that can last a lifetime, profoundly affecting a woman's quality of life and sexual health.<sup>3,5</sup>

In recent years, there has been a veritable explosion of safe and effective treatments that have come to market, both prescription and over the counter (OTC), for vaginal/vulvar dryness and painful intercourse. Yet study data suggest the issues remain underreported and undertreated,<sup>5</sup> and this highlights the importance of having open discussions with patients and, if feasible, their partners to normalize the need for moisturizers and lubricants across a variety of diverse patient populations. With this backdrop, OBG MANAGEMENT assembled a panel of experts in gynecology and sexual health to discuss available agents, treatment choices, and strategies for effectively opening a dialogue with patients.

Dr. Krychman reports receiving research support from New England Research Institutes (NERI) and being a consultant for Palatin, Shionogi, Inc, Sylk USA, TherapeuticsMD, and Valeant Pharmaceuticals; a speaker for Shionogi and Valeant; and an advisor for Uniderm.

Dr. Dweck reports being a consultant to Uniderm and a speaker for Bayer Pharmaceuticals.

Dr. Kingsberg reports receiving grant or research support from Palatin; being a consultant to Acerus, AMAG, Emotional Brain, EndoCeutics, Materna, NovoNordisk, Nuelle, Palatin, Pfizer, Scientific Strategic Solutions, Shionogi, TherapeticsMD, and Valeant Pharmaceuticals; and being a speaker for Valeant.



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#### Meet the panel

**Michael L. Krychman, MD, Moderator:** I am from the Southern California Center for Sexual Health and Survivorship Medicine in Newport Beach. With the recent explosion of OTC moisturizers and lubricants, the consumer is left with much confusion regarding product selection and utilization. Misinformation exists concerning ingredients and additives as well as efficacy of use and the US Food and Drug Administration is now looking toward research to ensure that no false claims are misleading the consumer. Some products have obtained 510K clearance as a medical device. See the **TABLE** of select products.<sup>6,7</sup>

Here to help me set the record straight is my esteemed panel of sexual health and gynecologic experts: Dr. Alyssa Dweck from CareMount Medical in Mt. Kisco, New York, Dr. Sheryl Kingsberg from Case Western Reserve in Cleveland, Ohio, and Dr. Lisa Larkin from Cincinnati, Ohio.

#### Patient selection: Postmenopausal women and beyond

**Dr. Krychman:** When we think of moisturizers for adequate tissue hydration and lubricants for love-making, we often think of the older woman reporting symptoms of GSM. Who is the patient that can benefit from moisturizers or lubricants for overall sexual health? Let's define her.

It is important that we normalize for women that lubricant use is common and does not necessarily reflect any inadequacy or dysfunction on their part.

**Sheryl Kingsberg, PhD:** First, this discussion should not be limited to older women and postmenopausal women. We know that in women of all ages, lubricants are particularly helpful during sexual activity regardless of gender or partner. It is important that we normalize for women that lubricant use is common and does not necessarily reflect any inadequacy or dysfunction on their part. Although effective lubrication and pain-free sexual activity is an important issue for women of any age, we must certainly educate our patients to the fact that, as they age, they may want to use lubricants and moisturizers.

Further, we need help to differentiate between lubricants and moisturizers. That is, that lubricants should be used during sexual activity and are short acting, whereas moisturizers are used daily (similar to facial and body moisturizers). With postmenopausal women, we want to be very clear about the limitations of lubricants and moisturizers with regard to GSM. Lubricants and moisturizers will be not be effective in treating the underlying cause of GSM, which is best addressed with prescription therapies including estrogens and such topical preparations as creams, rings, and tablets, and the newly approved prasterone (topical dehydroepiandrosterone [DHEA]).

**Dr. Krychman:** I agree. In my clinical practice, I sometimes treat women who are taking a variety of medications, like antihistamines, or even young women taking oral contraceptives, who report vaginal dryness or painful intercourse and who may benefit from using moisturizers and lubricants. Some patients are not well versed with arousal, or they may have partners who have delayed ejaculation, so they may have longer duration of intercourse that may impact comfort.

#### **Special populations**

Alyssa Dweck, MD: Another group of women who are hit with a double whammy are the lactating and postpartum women. First of all, they may not have returned to ovulation and menstruation; therefore, their estrogen levels remain low and their vaginas are drier and more delicate. In addition, many of these women have taken a break from sexual relations, so less lubrication and lack of use creates this double whammy. I recommend lubricants as a quintessential element in their return to sexual intercourse, and I reassure them that the vagina will return to a natural lubricating state once ovulation and menstrual cycles resume. Lisa Larkin, MD: Also overlooked are cancer survivors-specifically, survivors of breast and other gynecologic cancers-women who have undergone chemotherapy and have chemotherapy-induced menopause and are taking medications that result in significant vaginal atrophy and

Treatment	Comments	Available products	
Lubricants			
Water-based	Ingredients: deionized water, glycerin, propylene glycol; latex safe; rare irritation; dry out with extended sexual activity	Astroglide, Good Clean Love, K-Y Jelly, Natural, Organic, Pink, Sliquid, Sylk, Yes	
Oil-based	Ingredients: avocado, olive, peanut, corn; latex safe; can be used with silicone products; stain- ing; safe (unless peanut allergy); nonirritating	Coconut oil, vegetable oil, vitamin E oil	
Silicone-based	Ingredients: silicone polymers; staining; typically nonirritating; long lasting; waterproof; should not be used with silicone dilators, sexual toys, or gynecologic products	Astroglide X, Oceanus Ultra Pure, Pink Silicone, Pjur Eros, Replens Silky Smooth Silicone Premium JO, SKYN, Überlube, Wet Premium	
Petroleum-based	Staining; ingredients: mineral oil, petroleum jelly, baby oil; irritating; not latex safe and not for use with cervical caps or intravaginal diaphragms	Rarely recommended	
Fertility friendly	Minimize harm to sperm motility; designed for couples trying to conceive	Astroglide TTC, Conceive Plus, Pre-Seed, Yes Baby	
Moisturizers			
Vaginal moisturizers	For maintenance use 1 to 3 times weekly; can benefit women with dryness, chafing with ADL, and recurrent vaginal infections irrespective of sexual activity timing	Balance Active Menopause Vaginal Moisturizing Lubricant, Canesintima Intimate Moisturizer, Replens, Rephresh, Sylk Natural Intimate Moisturizer, Yes Vaginal Moisturizer	
Hybrids	Properties of both water- and silicone-based products (combination of a vaginal lubricant and moisturizer); nonirritating; good option for women with allergies and sensitivities	Lubrigyn, Luvena	

#### TABLE Lubricants and moisturizers for treating GSM and VVA\*,6,7

\*Before using or recommending a product patients and their providers should check a product's pH, ingredients, and additives, and ensure the product is 510K FDA cleared.

Abbreviations: ADL, activities of daily living; FDA, US Food and Drug Administration; GSM, genitourinary syndrome of menopause; VVA, vulvovaginal atrophy.

dryness and often pain with intercourse. This is a patient population that often needs very aggressive treatment with moisturizers and lubricants and a lot of education about how these can be helpful to manage their symptoms.

**Dr. Krychman:** Education is especially important for patients during active treatment, such as during chemotherapy or radiation. Regardless of whether patients are undergoing intravaginal radiation or systemic chemotherapy, they often have been advised not to use local hormones or other medications that may interfere with treatment, but they still have problematic symptoms—not only intravaginally but also externally.

#### **Counseling approaches**

**Dr. Krychman:** What are your recommendations for talking with patients about lubricants and moisturizers, and how do you broach the topic? **Dr. Larkin:** I think the most important thing to do is open the dialogue with patients, who often are very reluctant to bring up their symptomatology. I start with the basics—the difference between moisturizers and lubricants—and then expand into water-based versus silicone-based lubricants. I have a handout that I provide with a few products in each category.

I also discuss "kitchen pantry" solutions. Today's patients are often very interested in natural and holistic approaches to managing their symptoms, so some women will use olive or peanut oil or other things that they find in their bathroom, such as mineral oil, baby oil, and petroleum jelly. I talk about why those products are probably not the best options and that there are others that would be more beneficial. There are some concerns about those agents promoting bacterial infection, <sup>8,9</sup> and many of them stain when they are being used.

#### Ingredients matter

**Dr. Krychman:** How do you differentiate between agents, and under what circumstances would you recommend one used over another?

It is best to avoid products with parabens if a patient is particularly sensitive or has a history of a hormonesensitive cancer.

Dr. Dweck: The amount of choices can be overwhelming for women. I typically make very specific recommendations, usually beginning with an over-the-counter water-based lubricant, such as K-Y Jelly or Astroglide. I explain to my patients that they are easy to find, cost-effective, compatible with condoms, and do not stain bedding. Some women report that water-based lubricants are sticky and require frequent reapplication, particularly with long sexual sessions. In that case, I recommend a silicone lubricant. Silicone lubricants are very slick, last longer, and are compatible with condoms. They are so slick, in fact, that just a little bit needs to be used with each sexual act. I advise exercising extreme caution when using silicone lubricants during water play, such as in the shower or bath, because they are so slick that they can cause slipping.

**Dr. Kingsberg:** We always think about lubricants and moisturizers with regard to vaginal penetration, but we should think about anal sex as well. There are gels specifically designed to be used as anal lubrication that are thicker and last longer, although they tend to be stickier. Some contain a bit

of antiseptic to reduce sensitivity, and that can be a good thing. It also can be a bad thing, because it is important for there to be sensation to warn if the sex is causing problems or injury.

#### Counsel to empower

**Dr. Krychman:** I think counseling is very important, especially regarding which products patients are using and what sexual activity they are engaging in. It is very important to empower women to start reading labels, not only to see what is included but also to see what is excluded from the product. Osmolality, pH, and additives remain important. We are so focused on reading food labels, we often do not think about reading the labels on over-the-counter products.

## Individualize choices for different patient populations

**Dr. Kingsberg:** I agree. Couples trying to conceive should read the labels. There is a lot of controversy over whether there is a difference between lubricants and what is going to help or interfere with couples conceiving.<sup>10</sup>

**Dr. Krychman:** Infertile couples or those trying to conceive are often under pressure to perform and the time scheduling may impact natural lubrications, so we often recommend they use adjunctive products. One of my favorites is Pre-Seed. It is marketed specifically for the couple trying to conceive and does not harm sperm or the vagina.

**Dr. Kingsberg:** You are absolutely right. Couples who are trying hardest to conceive often have difficulty getting aroused under pressure and are likely to benefit from lubricants. However, lubricants do tend to affect sperm motility. It is really about the vaginal pH levels—some lubricants change the level in a way that is negative toward sperm motility. Fertility-friendly lubricants are designed to minimize this. In addition to Pre-Seed, there is Conceive Plus, Yes Baby, and Astroglide TTC. We do not have clear evidence about which lubricants are better than others, but couples often have so much anxiety about trying to conceive that if you can promote the so-called fertility-friendly products to them, I think it will reduce some anxiety.

**Dr. Dweck:** The 2 ingredients that are talked about most in my patient population are glycerin and parabens. Glycerin is the main ingredient in many water-based lubricants. Some studies suggest that



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Cranberry Extract	🖌 YES	NØ	NØ
Natural Enzyme Protection	🖌 YES	NØ	NØ
Paraben Free	🖌 YES	NØ	NØ
Glycerin Free	VES	NØ	NØ

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glycerin might increase the risk of yeast infections, especially in those who are particularly prone to yeast.<sup>7</sup> For those patients, I recommend a lubricant that does not contain glycerin. Parabens are used as preservatives to increase shelf-life and are often ingredients in various lubricants; they also have been considered possible hormone disruptors, with estrogen-like qualities.<sup>7</sup> Although the jury is still out on them, I think it is best to avoid products with parabens if a patient is particularly sensitive or has a history of a hormone-sensitive cancer.

**Dr. Krychman:** The American Cancer Society and other organizations have stated that, in such low quantities, these chemicals are not causative agents of cancer.<sup>7</sup> However, if you have an option to avoid them, it might be prudent to read the labels and avoid them.

An ideal water-based lubricant or moisturizer should have an osmolality of not greater than 1,200 mOsm/kg, and this is an important feature to consider when choosing a product to recommend.

There are emerging data indicating that some of these products cause microabrasions, not only in the vaginal mucosa but also in the anal mucosa,<sup>7</sup> and that they may actually increase the risk of sexually transmitted infections or HIV. We have to be very cautious about some additives.

## Consider plasma osmolality and hyaluronic acid

**Dr. Larkin:** Another important topic is plasma osmolality. We have known for a long time that when cells are exposed to hypertonic fluid, it causes fluid shifts and this can cause cellular disruption and cellular compromise. The same is true in the vagina. Normal plasma osmolality is somewhere between 285 and 295 mOsm/kg; human semen is a little bit higher, 250 to 380 mOsm/kg. We have learned that most water-based lubricants on the market have a very high osmolality, somewhere in the range of 2,000 to 6,000 mOsm/kg, so they are very hypertonic. This can cause fluid shifts in the vaginal cells, and cellular compromise can be one of the factors that contributes to vaginal irritation and worsening symptoms. According to the World Health Organization, an ideal water-based lubricant or moisturizer should have an osmolality of not greater than 1,200 mOsm/kg, and this is an important feature to consider when choosing a product to recommend.<sup>11</sup>

**Dr. Dweck:** Hyaluronic acid is naturally found in the body and is "all the rage" right now as an antiaging and smoothing ingredient. The dermatologic and ophthalmologic communities have been using it for a while in their products. As a vaginal gel, hyaluronic acid has been shown to improve vaginal itching, painful intercourse, and vaginal burning related to aging,<sup>7</sup> so we are seeing this ingredient in more and more products, including vulvar and vaginal washes. Lubrigyn cream and lotion come to mind, which are from Italy. In addition, many of the compounding pharmacies are making compounded moisturizers for vaginal use that contain hyaluronic acid with good result.

#### Let's discuss recommendations

**Dr. Krychman:** I recommend Lubrigyn Cream, with hyaluronic acid (a little goes a long way). It is a high-quality product and is not very expensive. Cost is always an issue; it is not necessarily the more you pay, the better the product.

I also have recommended Lubrigyn as a vulvar wash. Many women use a douche, which may contain caustic ingredients like sodium lauryl sulfate that may actually strip away the natural protective barrier of the vulvar skin. The vagina, the vulva, the clitoris, and the whole genital pelvic area can be sensitive with estrogen decline, so vulvar washes are becoming more common.

I like several water-based lubricants, like Good Clean Love, which also has very good osmolality; the K-Y products, which are tried, tested, and true; and Sylk, which is all natural, too. I also recommend Überlube, which is silicone and a little vitamin E, as well as the Wet products, which seem to be very well tolerated and affordable.

**Dr. Kingsberg:** I like products that offer a variety of choices, such as a sensitive skin gel, a thicker formula gel, a silicone option, a water-based liquid, and paraben-free. It is about patient preference, and the good clinician is going to have several samples in his or her office. I suggest having a water-based

and a silicone-based option so that patients can see the difference for themselves. I think letting patients sample products is very helpful because some of preference is related to sensation—the tackiness, the slipperiness, perhaps the scent. Women who are prone to irritation, particularly postmenopausal women with thinning tissue, might find warming lubricants more problematic than beneficial. Patients appreciate having all the options listed in a handout, and having lots of samples.

**Dr. Krychman:** For academic centers or other institutions that are not allowed to have samples, a good referral is the MiddlesexMD website, which has a lubricant sampler for a small cost. Patients can then fill out a card after and send it back to receive a full bottle of their favorite lubricant. The site also has downloadable patient education materials about moisturizers and lubricants.

**Dr. Larkin:** MiddlesexMD.com is a terrific website. Their sampler package is a great way for patients to try different products. Breast cancer patients and survivors taking aromatase inhibitors often have vaginal concerns and report painful intercourse the tissue is very fragile in that population. I have seen that vulvar washes can be very helpful in this setting; I like Lubrigyn. As for the water-based lubricants, Good Clean Love is certainly popular in my practice. For a silicone-based product, I frequently recommend Pjur. In terms of vaginal moisturizers, I like Yes VM—it has an appropriate pH and low osmolality. Among the hybrid products, I do like Lubrigyn and Luvena very much, and patient feedback has been positive for both.

**Dr. Dweck:** The products mentioned are favorites of mine as well. I also give patients a handout that differentiates moisturizers from lubricants because I find that is a very confusing issue for people and that patients get overwhelmed by the amount and number of products available over the counter. I try to give them one example each of a water-based and silicone-based. For my more naturally inclined patient I recommend coconut oil—the best oil for moisturizing and lubricating the area. I also like to mention that silicone lubricants and silicone toys are often not compatible, so it is important to exercise caution.

Lubrigyn is definitely my "go to" for my menopausal population. I often rely on the compounded hyaluronic acid formulas for my breast cancer survivor population. I find they are very hesitant to use anything over the counter that might contain a concerning ingredient, so the one that I use contains hyaluronic acid, vitamin E, and aloe. It can be compounded at any compounding pharmacy, and I get a very good result from it.

**Dr. Krychman:** I will add that Luvena is a hybrid; it acts as a moisturizer and lubricant. Replens and RepHresh also can be helpful for many patients.

As you can see, there are several products. Just in our small group, we have a variety of recommendations and suggestions for selection.

If you do not want to spend a lot of time talking about it, be sure to have a handout that differentiates lubricants from moisturizers and from treating the GSM with local estrogen, an oral tablet, or DHEA.

As clinicians, we need to individualize product choices. I believe many of the companies that produce the products mentioned would be happy to send the readership samples and information, so clinicians can begin gathering samples to share with their patients.

**Dr. Kingsberg:** I would urge readers to take into account how important it is to have this conversation with patients—to let them know that there are products available OTC that can be very safe and have a huge impact on quality of life. If you do not want to spend a lot of time talking about it, be sure to have a handout that differentiates lubricants from moisturizers and from treating the GSM with local estrogen, an oral tablet, or DHEA. Normalize the use of lubricants and moisturizers for women of all ages and populations. Simply talking about these issues validates patients' sexuality, and I think that increases patient satisfaction with you and their overall life.

**Dr. Krychman:** Thank you, panel members, for joining me for this OBG MANAGEMENT program. Moisturizers and lubricants are not just for postmenopausal women with GSM. Thank you for your insights.

#### CONTINUED FROM PAGE SS9

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- >> GYN Imaging Quiz: 2-week left-sided pelvic pain



## ABNORMAL UTERINE BLEEDING

As we move toward a value-based health care model, study data indicate that we consider obesity over age as a risk factor for endometrial hyperplasia, the LNG-IUD for treatment of heavy bleeding in obese patients, and diagnostic hysteroscopy in the office versus the operating room



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The authors report no financial relationships relevant to this article.

IN THIS ARTICLE

Obesity vs age as hyperplasia risk This page

LNG-IUD as AUB treatment in obese women page 32

Office hysteroscopy page 34 Two issues of emerging importance are being addressed in the literature: caring for patients with obesity and the concept of delivering value-based care. Value-based care does not mean providing the cheapest care; "value" places importance on quality as well as cost. In this Update, we present 3 practices that the evidence says will deliver value:

• endometrial biopsy in all obese women. Although performing more endometrial biopsies in younger women with a body mass index (BMI) in the obese range will not be less expensive initially, the procedure's value likely will be in early diagnosis, which hopefully will translate to eventual health care system savings.

- use of the levonorgestrel-releasing intrauterine device (LNG-IUD) in obese patients experiencing abnormal uterine bleeding (AUB). This practice appears to add value in the context of AUB.
- performance of routine diagnostic hysteroscopy in the office setting. We should reconsider our current habits and traditions of performing routine diagnostic hysteroscopy in the operating room (OR) as we move toward providing value-based care.

## Endometrial sampling and obesity: Forget the "age 45" rule

Wise MR, Gill P, Lensen S, Thompson JM, Farquhar CM. Body mass index trumps age in decision for endometrial biopsy: cohort study of symptomatic premenopausal women. Am J Obstet Gynecol. 2016;215(5):598.e1-e8. How do we bring more value to our patients with AUB? We are well aware that heavy menstrual bleeding places a burden on many women; AUB affects 30% of those of

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What lies ahead for women's health as ACOG and US leadership transition?

How to offer counseling for hysteroscopic tubal occlusion

## 7 MYOMECTOMY MYTHS DEBUNKED

William H. Parker, MD

9 women's health recommendations I intend to follow in my pratice Robert L. Barbleri, MD

Fertility Update Management considerations for Zika, obesity, and subclinical hypothyroidism

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Infection prevention: Evidence-based guidance Kathyn E. Patrick, MD; Sara L. Deatsman, MD; Patrick Daff, MD

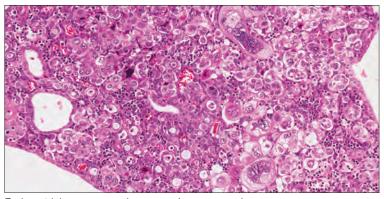
Should you use vasopressin? Robert L. Barbieri, MD

Is one technique better than another? John M. Thorp Ir, MD

Fostering surgical innovation: The path forward An expert roundtable See page \$\$1

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Endometrial cancer sample seen on low-power microscopy.

reproductive age. The condition often results in lost workdays and diminished quality of life. It also is associated with significant cost expenditures for hygiene products. It is important not only to bring value to women with heavy menstrual bleeding but also to consider our increasingly expensive health care system.

Obesity is a significant problem that likely will increase the number of women presenting with AUB to ObGyns. Recent studies from New Zealand—which has 33% of its population classified as obese—have provided valuable information.<sup>1</sup>

#### Obesity is a risk factor for endometrial hyperplasia

In a large retrospective cohort study, Wise and colleagues analyzed data from 916 premenopausal women referred for AUB who had an endometrial biopsy from 2008 to 2014. The setting was a single large urban secondary women's health service in New Zealand. This study challenges the concept of age-related biopsy guidelines.

Of the 916 women, half were obese. Almost 5% of the women had complex endometrial hyperplasia with atypia or cancer. This incidence had risen from 3% in the years 1995 to 1997, likely due to the rising incidence of obesity. Women with a BMI  $\geq$ 30 kg/m<sup>2</sup> were 4 times more likely to develop complex hyperplasia or cancer than normalweight women.

Other factors associated with an increased risk for complex hyperplasia or cancer were nulliparity (odds ratio [OR], 2.51; 95% confidence interval [CI], 1.25-5.05), anemia (OR, 2.38; 95% CI, 1.25-4.56), and a thickened endometrium on ultrasonography (defined as >12 mm; OR, 4.04; 95% CI, 1.69-9.65). Age was not a significant risk factor in this group.

#### WHAT THIS EVIDENCE MEANS FOR PRACTICE

Although guidelines suggest that age 45, or age 40 with obesity, should be used as an indication for endometrial sampling in women with AUB, results from this study suggest that obesity (BMI  $\geq$ 30 kg/m<sup>2</sup>) should be considered a more important risk factor than age. We will adjust our practice according to these findings, as the risk is fairly significant.

## Small study shows LNG-IUD is effective for treating heavy menstrual bleeding in obese patients

Shaw V, Vandal AC, Coomarasamy C, Ekeroma AJ. The effectiveness of the levonorgestrel intrauterine system in obese women with heavy menstrual bleeding. Aust N Z J Obstet Gynaecol. 2016;56(6):619–623.

In another recent study from New Zealand, researchers set out to assess the efficacy of the LNG-IUD for the treatment of heavy menstrual bleeding in obese women. This

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In women with AUB, obesity (BMI ≥30 kg/m<sup>2</sup>) rather than age should be used as an indicator for endometrial sampling IN COLLABORATION WITH



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An LNG-IUD reduced heaving bleeding in obese women, with an actual efficacy rate of 67%.

study is important because there are very few studies of the LNG-IUD in the obese population, and none that have studied quality-of-life measures.

Shaw and colleagues conducted the prospective observational study at a tertiary teaching hospital. Twenty obese (BMI  $>30 \text{ kg/m}^2$ ) women with heavy menstrual bleeding agreed to treatment with an LNG-IUD, and 14 completed the study (2 had a device expulsion, 1 had a device removed for pain, and 1 had a device removed for infection; 2 were lost to follow-up). The women were aged 27 to 52 years (median, 40.5 years), and their BMI ranged from 30 to 68 kg/m<sup>2</sup> (median, 40.6 kg/m<sup>2</sup>). At recruitment, 6 months, and 12 months, participants completed the Menstrual Impact Questionnaire and the Pictorial Bleeding Assessment Chart—2 validated tools.

Compared with baseline Pictorial Bleeding Assessment scores, the authors found the LNG-IUD to be effective in 73.2% (95% CI, 55.3%–83.9%) of women at 6 months and in 92.8% (95% CI, 80.0%–97.4%) of women at 12 months. Taking into consideration device failures, including removed and expelled LNG-IUDs (which occurred in 4 women, or 20%, in the intent-to-treat analysis), the actual efficacy rate was 67%. Similarly, there was significant improvement at 6 and 12 months in Menstrual Impact Questionnaire scores for social activities, work performance, tiredness, productivity, hygiene, and depression.

#### WHAT THIS EVIDENCE MEANS FOR PRACTICE

Obese women with heavy menstrual bleeding treated with the LNG-IUD experienced an overall 67% efficacy in treatment for bleeding and significant improvement in quality-of-life measures at 6 and 12 months. We will offer obese women with heavy bleeding this treatment as it is a low-risk and low-cost option compared with surgical management in this population.

# Is it time to abandon diagnostic hysteroscopy in the OR?

Leung S, Leyland N, Murji A. Decreasing diagnostic hysteroscopy performed in the operating room: a quality improvement initiative. J Obstet Gynaecol Can. 2016;38(4):351–356.

Diagnostic hysteroscopy: Are we stuck in the 1990s? Why are we still performing so many diagnostic hysteroscopies in the OR, thus subjecting our patients to general anesthesia and using our precious OR time? That is the question asked by a group of researchers in Canada.

According to data from the Ontario Ministry of Health and Long Term Care, diagnostic hysteroscopy was performed 10,027 times in the 2013–2014 fiscal year. Ontario researchers designed and implemented a quality improvement initiative at their institution and successfully

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Obese women with heavy menstrual bleeding treated with an LNG-IUD experienced significant improvements in social activities, work performance, productivity, tiredness, hygiene, and depression

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decreased the number of diagnostic hysteroscopies performed in their hospital by 70% from their baseline 12-month period. The improvements resulted in a savings of 78 hours of case costing, or \$126,984. When these data are extrapolated to the Ontario population (in which more than 10,000 diagnostic hysteroscopies were performed), potentially 7,000 women could avoid the risk of general anesthesia and the health care system could save \$11 million.

## Re-education protocol was key to reducing OR procedures

How did the researchers accomplish their results? The multifaceted intervention had 3 key components:

**Staff education and review.** Many surgeons were performing diagnostic hysteroscopy in the OR because that is how they were trained, and they were unaware of less invasive options. An awareness campaign was conducted by e-mail, during staff meetings, and at rounds.

#### WHAT THIS EVIDENCE MEANS FOR PRACTICE

Although some patients may need to have diagnostic hysteroscopy performed in the OR because of difficulty accessing the endometrial cavity, the vast majority of cases can be done in the office with no anesthesia or with local anesthesia. Habit and tradition will not continue to win the day as we head toward providing value-based health care.

Accessible sonohysterography. This diagnostic modality was made more accessible to referring physicians in a timely manner. Initiation of an operative hysteroscopy education program. To allow more surgeons greater comfort with office hysteroscopy, the authors instituted didactic sessions, dry and wet lab simulations, and mentorship. <sup>(9)</sup>

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## Two free, comprehensive drug reference apps for your practice

The Epocrates and Medscape apps could allow for rapid decision making

#### Katherine T. Chen, MD, MPH

understand that you as an ObGyn do not have the time or bandwidth to "vet" the available mobile apps for your practice. However, that does not mean you need to forgo using apps that could make your clinical life a little easier if possible. In this continuation of my "APP review" series, I focus on drug reference apps, which generally include the names of drugs, their indications, dosages, pharmacology, drug-drug interactions, contraindications, cost, and identifying characteristics.<sup>1</sup> Drug reference apps, along with medical calculator and disease diagnosis apps, are reported as most useful by health care professionals and medical or nursing students.1 Drug reference apps are particularly popular among residents and medical students as the apps allow for rapid decision making.2

I have selected 2 drug reference apps-Epocrates and Medscape-to report here



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Dr. Chen is an OBG MANAGEMENT Contributing Editor.

The author reports no financial relationships relevant to this article.

as both of these apps are free and are the only apps that appear in independent comprehensive studies.<sup>1,3</sup> I particularly like Epocrates' pill identification function for those patients who have forgotten the name of the medication they use but have the actual pill with them. I find Medscape's additional information on diseases, conditions, and medical procedures especially useful for the times I have forgotten the condition that the medication is indicated for.

The recommended apps are listed in the TABLE on page 38 alphabetically and are detailed with a shortened version of the APPLICATIONS scoring system, APPLI (app comprehensiveness, price, platform, literature use, and important special features).<sup>4</sup> Visit the OBG MANAGEMENT website to download the apps featured.

Watch for my next column in which I will recommend, according to APPLI, the top apps for patients to use to track their menstrual cycles.

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**Epocrates and** Medscape app details page 38



apps for drug reference CONTINUED FROM PAGE 37

#### TABLE Top 2 recommended apps: Drug reference applications

Арр	App comprehensiveness	Price	Platform	Literature used	Important special features
Epocrates iTunes Preview: https:// itunes.apple.com/us /app/epocrates -reference-tools /id281935788?mt=8 Google Play: https://play .google.com/store/apps /details?id=com .epocrates&hl=en	For most drugs, information is provided for: • adult and pediatric dosing • formulary • alternatives • contraindications/cautions • adverse reactions • drug interactions • safety/monitoring • pregnancy/lactation • pharmacology • manufacturer/pricing • pill pictures	Free	iTunes and Google Play stores	Not reported	<ul> <li>Drug interaction checker</li> <li>Pill identifier</li> <li>Medical calculators</li> </ul>
Medscape iTunes Preview: https:// itunes.apple.com /us/app/medscape /id321367289?mt=8 Google Play: https://play .google.com/store/apps /details?id=com .medscape.android&hl=en	For most drugs, information is provided for: • dosages and indications • adverse effects • warnings • pregnancy • pharmacology • administration • images • formulary	Free	iTunes and Google Play stores	References provided in diseases, conditions, medical procedures, and medical news sections	<ul> <li>Information on diseases, conditions, and medical procedures with tables, images, and videos covering pathophysiology, epidemiology, differential diagnosis, and treatment options</li> <li>Drug interaction checker</li> <li>Pill identifier</li> <li>Medical calculators</li> <li>Medical news</li> </ul>

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## Advanced techniques in cystectomy for mature cystic teratomas

#### ELISA M. JORGENSEN, MD, AND MASOUD AZODI, MD



In this video, the surgeons offer 3 techniques to improve the efficiency and safety of laparoscopic ovarian cystectomy. They suggest manipulating the cyst entirely with a specimen removal bag. A rolling technique is used to dissect the ovarian tissue off the cyst in a more controlled manner than simple traction/countertraction. With very large cysts, a trocar is inserted into the cyst to allow for fluid removal, insufflation, and visualization of the inside of the cyst with a camera. Two case studies illustrate these techniques.

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## Medical Verdicts

NOTABLE JUDGMENTS AND SETTLEMENTS



## Forceful use of forceps, infant dies: \$10.2M verdict

A WOMAN IN HER MID-20S went to the hospital in labor. After several hours, fetal heart-rate (FHR) monitor results became nonreassuring. The ObGyn and the nurse in charge disagreed on the interpretation of the FHR monitor strips. The

nurse went to her supervisor, who confronted the ObGyn 2 hours later, saying that fetal distress was a serious concern and necessitated the cessation of oxytocin. The ObGyn disagreed and ordered another nurse to increase the oxytocin dose.

Three hours later, when the FHR monitoring strips showed severe distress, the ObGyn decided to undertake an operative vaginal delivery. During a 17-minute period, the ObGyn unsuccessfully used forceps 3 times. On the second attempt, a cracking noise was heard. Then a cesarean delivery was ordered; the baby was born limp, lifeless, and unresponsive. She was found to have hypoxic ischemic encephalopathy, was removed from life support, and died.

▶ PARENTS' CLAIM: Oxytocin should not have been continued when the baby was clearly in distress. The supervising nurse should have contacted her supervisor and continued up the chain of command until the ObGyn was forced to stop the oxytocin.

Physicians are prohibited from using their leg muscles when applying forceps; gentle action is critical. During one attempt, the ObGyn had his leg on the bed to increase the force with which he pulled on the forceps. The ObGyn's reckless use of forceps caused a skull fracture to depress into the brain. The ObGyn also tried to turn the baby using forceps, which is outside the standard of care because of the risk of rotational injury. A mother's pushing rarely causes such severe damage to the baby.

DEFENDANTS' DEFENSE: There was no negligence. The hypoxia was due to a hemorrhage. Natural forces of a long delivery caused the skull injury.
 VERDICT: A \$10,200,575 Texas verdict was returned.

## After long labor, baby has CP: \$8.4M settlement

PHOTO: SHUTTERSTOCK

EARLY ON MARCH 20, a 30-year-old woman who weighed 300 lbs was admitted for delivery at 40 weeks' gestation. Labor was induced with oxytocin. Within 30 minutes, FHR monitoring showed that the baby's baseline began to climb, accelerations ceased, and late decelerations commenced. The oxytocin dose was steadily increased throughout the day. A nurse decided that the baby was not tolerating the contractions and discontinued oxytocin. The attending ObGyn ordered oxytocin be restarted after giving the baby a chance to recover. The mother requested a cesarean delivery, but the ObGyn refused, saying that he was concerned with the risk due to her excessive weight and prior heart surgery. When his shift ended, his partner took over.

On March 21, a nurse reported that the FHR had climbed to 160 bpm although labor had not progressed. The ObGyn ordered terbutaline to slow contractions but he did not examine the mother. An hour after terbutaline administration, the FHR showed a deceleration. An emergency cesarean delivery was performed. The baby, born severely depressed, was resuscitated. Magnetic resonance imaging performed at 23 days of life showed that the child had a hypoxic ischemic injury. She has cerebral palsy and is nonambulatory with significant cognitive deficits.

▶ PARENTS' CLAIM: The care provided by 2 ObGyns, nursing staff, and hospital was negligent. A cesarean delivery should have been performed on March 20 when the nurse identified fetal distress. The nurses should have been more assertive in recommending cesarean delivery. The injury occurred 30 minutes prior to delivery and could have been prevented by an earlier cesarean delivery.

• DEFENDANTS' DEFENSE: FHR strips on March 20 were not as nonreassuring as claimed and did not warrant cesarean delivery, which was performed when needed.

**VERDICT:** An \$8.4 million Wisconsin settlement was reached by mediation.

## Eclamptic seizure, twins stillborn: \$4.25M

A 29-YEAR-OLD WOMAN pregnant with twins had an eclamptic seizure at 33 4/7 weeks' gestation. The babies were stillborn.

CONTINUED ON PAGE 40

## Medical Verdicts

CONTINUED FROM PAGE 39

▶ PARENT'S CLAIM: The ObGyn failed to properly treat the patient's preeclampsia for more than 11 weeks. The seizure caused hypovolemic shock, tachycardia, and massive hemorrhaging and required an emergency hysterectomy and bilateral salpingo-oophorectomy. The patient has no children and has been rendered unable to conceive. She sought to apportion 60% of the settlement proceeds to her distress claim and 20% each to wrongfuldeath and survival claims. She also sought to bar the twins' biological father from sharing in the recovery due to abandonment.

► HOSPITAL'S DEFENSE: The case was settled during the trial.

▶ VERDICT: The mother agreed to receive 65% of the wrongful-death and survival funds, with 35% going to the father. A Pennsylvania settlement of \$4.25 million was reached.

## Brachial plexus injury: \$4.8M verdict

A WOMAN GAVE BIRTH with assistance from a midwife. During delivery, shoulder dystocia was encountered. The baby has a permanent brachial plexus injury.

▶ PARENTS' CLAIM: The midwife mismanaged shoulder dystocia by applying excessive traction to the baby's head. The ObGyn in charge of the mother's care did not provide adequate supervision.

• DEFENDANTS' DEFENSE: The hospital settled prior to trial. The midwife and ObGyn denied negligence during delivery and contended that the child's injury occurred as a result of the natural forces of labor.

**VERDICT:** The jury found the midwife 60% negligent and the ObGyn 40% negligent. A \$4.82 million Florida verdict was returned.

## What caused infant's death?

**DURING PRENATAL CARE, a woman** underwent weekly nonstress tests due to excessive amniotic fluid until the level returned to normal. Near the end of her pregnancy, the patient noticed a decrease in fetal movement and called her ObGyn group. She was told to perform a fetal kick count and go to the emergency department (ED) if the count was abnormal, but she fell asleep. In the morning, she presented to the ObGyns' office and was sent to the hospital for emergency cesarean delivery, which was performed 2.5 hrs after her arrival. The infant was born in distress and died 8 hours later.

▶ PARENTS' CLAIM: The ObGyns should have continued weekly tests even after the amniotic fluid level returned to normal. She should have been sent to the ED when she initially reported decreased fetal movement. Cesarean delivery should have been performed immediately upon her arrival at the hospital.

> PHYSICIANS' DEFENSE: Further prenatal testing for amniotic fluid levels was unwarranted. Telephone advice to count fetal kicks was appropriate. The delay in performing a cesarean delivery was beyond the ObGyns' control. The outcome would have been the same regardless of their actions.

**VERDICT:** A Michigan defense verdict was returned.

## Perineal laceration during vaginal delivery

**DURING VAGINAL DELIVERY**, a 27-yearold woman suffered a 4th-degree perineal laceration. She developed a retrovaginal fistula and has permanent fecal incontinence. ▶ PATIENT'S CLAIM: The ObGyn's care was negligent. She failed to perform a rectal examination to assess the severity of the perineal laceration. The laceration was improperly repaired, and, as a result, the patient developed a retrovaginal fistula that persisted for 6 months until it was surgically repaired. A divot in her anal canal causes fecal incontinence.

▶ PHYSICIAN'S DEFENSE: The ObGyn contended she correctly diagnosed and repaired a 3rd-degree laceration. The wound later broke down for unknown reasons.

▶ **VERDICT**: An Arizona defense verdict was returned. ♥

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.

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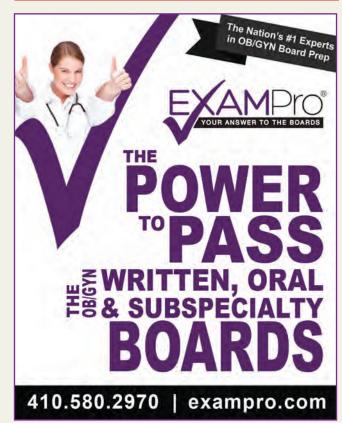
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## **Robot-assisted laparoscopic excision** of a rectovaginal endometriotic nodule

A review of key anatomy and a stepwise demonstration of technique

Obianuju Sandra Madueke-Laveaux, MD, MPH; Khara M. Simpson, MD; and Arnold P. Advincula, MD

A rectovaginal endometriosis (RVE) is the most severe form of endometriosis. The gold standard for diagnosis is laparoscopy with histologic confirmation. A review of the literature suggests that surgery improves up to 70% of symptoms with generally favorable outcomes.

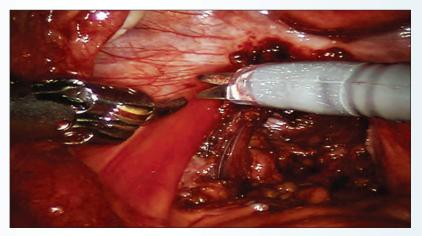
In this video, we provide a general introduction to endometriosis and a discussion of disease treatment options, ranging from hormonal suppression to radical

Dr. Madueke-Laveaux is Assistant Attending, Department of Obstetrics & Gynecology, Columbia University Medical Center, New York, New York.

Dr. Simpson is Assistant Professor, Minimally Invasive Gynecology, Johns Hopkins Hospital, Baltimore, Maryland.

Dr. Advincula is the Levine Family Professor of Women's Health and Vice Chair, Department of Obstetrics & Gynecology, Columbia University Medical Center and Chief of Gynecology, Sloane Hospital for Women at New York-Presbyterian Hospital/ Columbia University. He serves on the OBG MANAGEMENT Board of Editors.

Dr. Advincula reports being a consultant to Intuitive Surgical and Titan Medical and having additional financial relationships with Applied Medical, ConMed, and CooperSurgical. The other authors report no financial relationships relevant to this video.



## To view the video

Visit Arnold Advincula's Surgical Techniques Video Channel, found in the MENU at **obgmanagement.com** or use the QR code at right **>>>>** 



bowel resections. We also illustrate the steps in robot-assisted laparoscopic excision of an RVE nodule:

- 1. identify the borders of the rectosigmoid
- 2. dissect the pararectal spaces
- 3. release the rectosigmoid from its attachment to the RVE nodule
- 4. identify and isolate the ureter(s)
- 5. determine the margins of the nodule

6. ensure complete resection.

Excision of an RVE nodule is a technically challenging surgical procedure. Use of the robot for resection is safe and feasible when performed by a trained and experienced surgeon.

I am pleased to bring you this video, and I hope that it is helpful to your practice.

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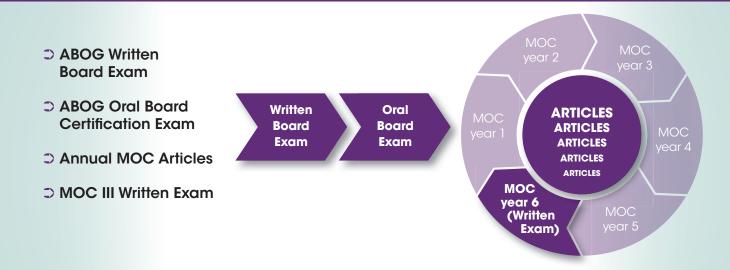
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