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Robert L. Barbieri, MD

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References:

1. Fourquet J, Gao X, Zavala D, et al. Patients' report on how endometriosis affects health, work, and daily life. *Fertil Steril*. 2010;93(7):2424-2428.
2. De Graaff AA, D'Hooghe TM, Dunselman GAJ, Dirksen CD, Hummelshoj L; WERF EndoCost Consortium, Simoens S. The significant effect of endometriosis on physical, mental and social wellbeing: results from an international cross-sectional survey. *Hum Reprod*. 2013;28(10):2677-2685.

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Important Safety Information

INTRAROSA is contraindicated in women with undiagnosed abnormal genital bleeding. Estrogen is a metabolite of prasterone. Use of exogenous estrogen is contraindicated in women with a known or suspected history of breast cancer. INTRAROSA has not been studied in women with a history of breast cancer.

In four 12-week randomized, placebo-controlled clinical trials, the most common adverse reaction with an incidence ≥2 percent was vaginal discharge. In one 52-week open-label clinical trial, the most common adverse reactions with an incidence ≥2 percent were vaginal discharge and abnormal Pap smear.

Brief Summary: Consult full Prescribing Information for complete product information.

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Undiagnosed abnormal genital bleeding: Any postmenopausal woman with undiagnosed, persistent or recurring genital bleeding should be evaluated to determine the cause of the bleeding before consideration of treatment with INTRAROSA.

WARNINGS AND PRECAUTIONS Current or Past History of Breast Cancer

Estrogen is a metabolite of prasterone. Use of exogenous estrogen is contraindicated in women with a known or suspected history of breast cancer. INTRAROSA has not been studied in women with a history of breast cancer.

ADVERSE REACTIONS Clinical Trials Experience

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

In four (4) placebo-controlled, 12-week clinical trials [91% - White Caucasian non-Hispanic women, 7% - Black or African American women, and 2% - "Other" women, average age 58.8 years of age (range 40 to 80 years of age)], vaginal discharge is the most frequently reported treatment-emergent adverse reaction in the INTRAROSA treatment group with an incidence of ≥2 percent and greater than reported in the placebo treatment group. There were 38 cases in 665 participating postmenopausal women (5.71 percent) in the INTRAROSA treatment group compared to 17 cases in 464 participating postmenopausal women (3.66 percent) in the placebo treatment group.

In a 52-week non-comparative clinical trial [92% - White Caucasian non-Hispanic women, 6% - Black or African American women, and 2% - "Other" women, average age 57.9 years of age (range 43 to 75 years of age)], vaginal discharge and abnormal Pap smear at 52 weeks were the most frequently reported treatment-emergent adverse reactions in women receiving INTRAROSA with an incidence of ≥2 percent. There were 74 cases of vaginal discharge (14.2 percent) and 11 cases of abnormal Pap smear (2.1 percent) in 521 participating postmenopausal women. The eleven (11) cases of abnormal Pap smear at 52 weeks include one (1) case of low-grade squamous intraepithelial lesion (LSIL), and ten (10) cases of atypical squamous cells of undetermined significance (ASCUS).

References: 1. Intrarosa [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; 2017. **2.** Archer DF, Labrie F, Bouchard C, et al; VVA Prasterone Group. *Menopause*. 2015;22(9):950-963. **3.** Labrie F, Archer DF, Koltun W, et al; VVA Prasterone Research Group. *Menopause*. 2016;23(3):243-256.

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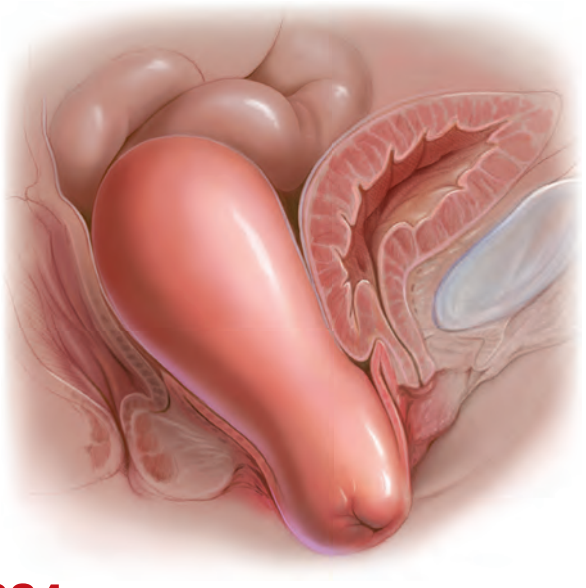

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What the evidence and the experts say about the various approaches for prolapse repair

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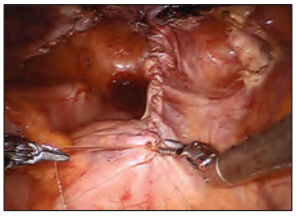

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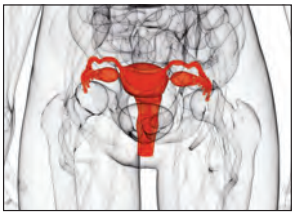

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*A hysteroscopic study has shown that narrow instrument diameter correlates with less patient discomfort during the post-procedure recovery phase.
†Based on internal bench testing that measured perceived ease of insertion through a simulated cervix of both the 6-mm and 8-mm devices. N=16 surgeon users.

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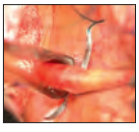

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Tactics for reducing the rate of surgical site infection following cesarean delivery

Consider these practices in your approach to preventing surgical site infection

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

CASE **Trusted nurse midwife asks you to consult on her patient**

The 25-year-old patient (G1P0) is at 41 weeks' gestation. She has been fully dilated and pushing for 3.5 hours, at station 0, with regular strong contractions, no descent and a Category II fetal heart-rate tracing. The estimated fetal weight is 8 lb. Membranes have been ruptured for 10 hours. Maternal temperature is 99° F and her prepregnancy body mass index (BMI) was 32 kg/m^2. After examining the patient and reviewing the labor progress, you recommend a cesarean delivery. As you prepare for the delivery, you identify the patient as high risk for surgical site infection and begin to recall all the interventions that might reduce postoperative infection for a patient at high risk for infection.

Halsted's surgical principles

Dr. William Steward Halsted, the first chief of surgery at Johns Hopkins Hospital, articulated a set of surgical principles that included strict aseptic technique, gentle tissue handling, meticulous hemostasis, minimum tension on tissue, accurate tissue apposition, preservation of blood supply, and obliteration of dead space where appropriate. These principles of "safe surgery" are believed to improve surgical outcomes and reduce the risk of surgical site infection.[1]

Preoperative antibiotics

All obstetricians who perform cesarean delivery know the importance of administering a narrow-spectrum antibiotic, such as cefazolin or ampicillin, prior to the skin incision, but not more than 60 minutes before the incision, to help reduce the risk of wound infection and endometritis. In a meta-analysis of 82 studies involving more than 13,000 women the administration of a preoperative antibiotic compared with placebo reduced the risk of wound infection (relative risk [RR], 0.40; 95% confidence interval [CI], 0.35–0.46) and endometritis (RR, 0.38; 95% CI, 0.34–0.42).[2]

Cefazolin 3 g versus 2 g for obese patients

There are no data from randomized trials of cesarean delivery that directly compare the efficacy of preoperative cefazolin at doses of 2 g and 3 g to reduce the risk of infection. However, based on the observation that, for any given dose of cefazolin, circulating levels are reduced in obese patients, many authorities recommend that if the patient weighs ≥120 kg that 3 g of cefazolin should be administered.[3]

Extended-spectrum preoperative antibiotics

Some experts recommend that, for women in labor and for women with more than 4 hours of ruptured membranes, IV azithromycin 500 mg be added to the standard narrow-spectrum cefazolin regimen to reduce the rate of postoperative infection. In one trial, 2,013 women who were in labor or had more than 4 hours of ruptured membranes were randomly assigned to IV cefazolin

Instant Poll

What is your advice for reducing the risk of surgical site complications following cesarean delivery?

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Please include your name and city and state.

alone or IV cefazolin plus azithromycin 500 mg prior to cesarean delivery.[4] The cefazolin dose was reported to be weight-based utilizing the BMI at the time of delivery. The rates of endometritis (3.8% vs 6.1%) and wound infection (2.4% vs 6.6%) were lower in the women receiving extended-spectrum antibiotics versus cefazolin monotherapy.

Concerns have been raised about the impact of extended-spectrum antibiotics on the newborn microbiome and risk of accelerating the emergence of bacteria resistant to available antibiotics. Limiting the use of azithromycin to those cesarean delivery cases in which the patient is immunosuppressed, diabetic, obese, in labor and/or with prolonged ruptured membranes would reduce the number of women and newborns exposed to the drug and achieve the immediate health goal of reducing surgical infection.

Preoperative vaginal preparation

Many authorities recommend the use of a preoperative povidone-iodine vaginal scrub for 30 seconds prior to cesarean delivery for women in labor and women with ruptured membranes. In a meta-analysis of 16 trials involving 4,837 women, the women who received vaginal cleansing before cesarean delivery had a significantly lower incidence of endometritis (4.5% vs 8.8%) and postoperative fever (9.4% vs 14.9%) compared with those who did not have vaginal cleansing.[5] Most of the benefit in reducing the risk of endometritis was confined to women in labor before the cesarean delivery (8.1% vs 13.8%) and women with ruptured membranes (4.3% vs 20.1%).[5]

Metronidazole gel 5 g also has been reported to be effective in reducing the rate of endometritis associated with cesarean delivery. In one study, 224 women having a cesarean delivery for various indications were randomly assigned to preoperative treatment with vaginally administered metronidazole gel 5 g or placebo gel. All women also received one dose of preoperative intravenous antibiotics. The rates of endometritis were 7% and 17% in the metronidazole and placebo groups, respectively.[6]

Povidone-iodine is approved for vaginal surgical site cleansing. For women with allergies to iodine or povidone-iodine, the options for vaginal cleansing are limited. The American College of Obstetricians and Gynecologists has noted the chlorhexidine gluconate solutions with a high concentration of alcohol should not be used for vaginal cleansing because the alcohol can irritate the mucosal epithelium. However, although not US Food and Drug Administration–approved for vaginal cleansing, solutions of chlorhexidine with a low alcohol content (Hibiclens, chlorhexidine with 4% alcohol concentration) are thought to be safe and may be considered for off-label use in vaginal cleansing.[7]

Preoperative abdominal preparation with chlorhexidine

Some authorities recommend skin preparation with chlorhexidine rather than povidone-iodine prior to cesarean delivery. Two recent randomized trials in women undergoing cesarean delivery[8,9] and one trial in patients undergoing general surgery operations[10] reported a reduction in surgical site infection with chlorhexidine. However, other trials have reported no difference in the rate of surgical site infection with these two skin preparation methods.[11,12]

Changing gloves and equipment after delivery of the newborn

Currently there is no high-quality evidence that changing gloves after delivery of the newborn or using new surgical instruments for closure reduces the risk of postcesarean infection. Two small clinical trials reported that changing gloves after delivery of the newborn did not reduce the rate of postcesarean infection.[13,14]

Postoperative antibiotics (a heretical challenge to the central dogma of antibiotic prophylaxis in surgery)

The central dogma of antibiotic prevention of postoperative infection is that antibiotics administered just before skin incision are effective, and postoperative antibiotics to prevent surgical infection generally are not useful. For the case of cesarean delivery, where the rate of postcesarean infection is very high, that dogma is being questioned. In a recent clinical trial, 403 women with a prepregnancy BMI ≥30 kg/m^2 were randomly assigned to postcesarean treatment with oral cephalexin plus metronidazole (500 mg of each medication every 8 hours for 6 doses) or placebo pills.[15] All women received preoperative IV cefazolin 2 g, indicating that the dosing was probably not weight-based. The surgical site infection rates in the cephalexin plus metronidazole and placebo groups were 6.4% and 15.4%, respectively (RR, 0.41; 95% CI, 0.22–0.77; $P = .01$). In a subgroup analysis based on the presence or absence of ruptured membranes, postoperative oral cephalexin plus metronidazole was most beneficial for the women with ruptured membranes. Among women with ruptured membranes the surgical site infection rates in the

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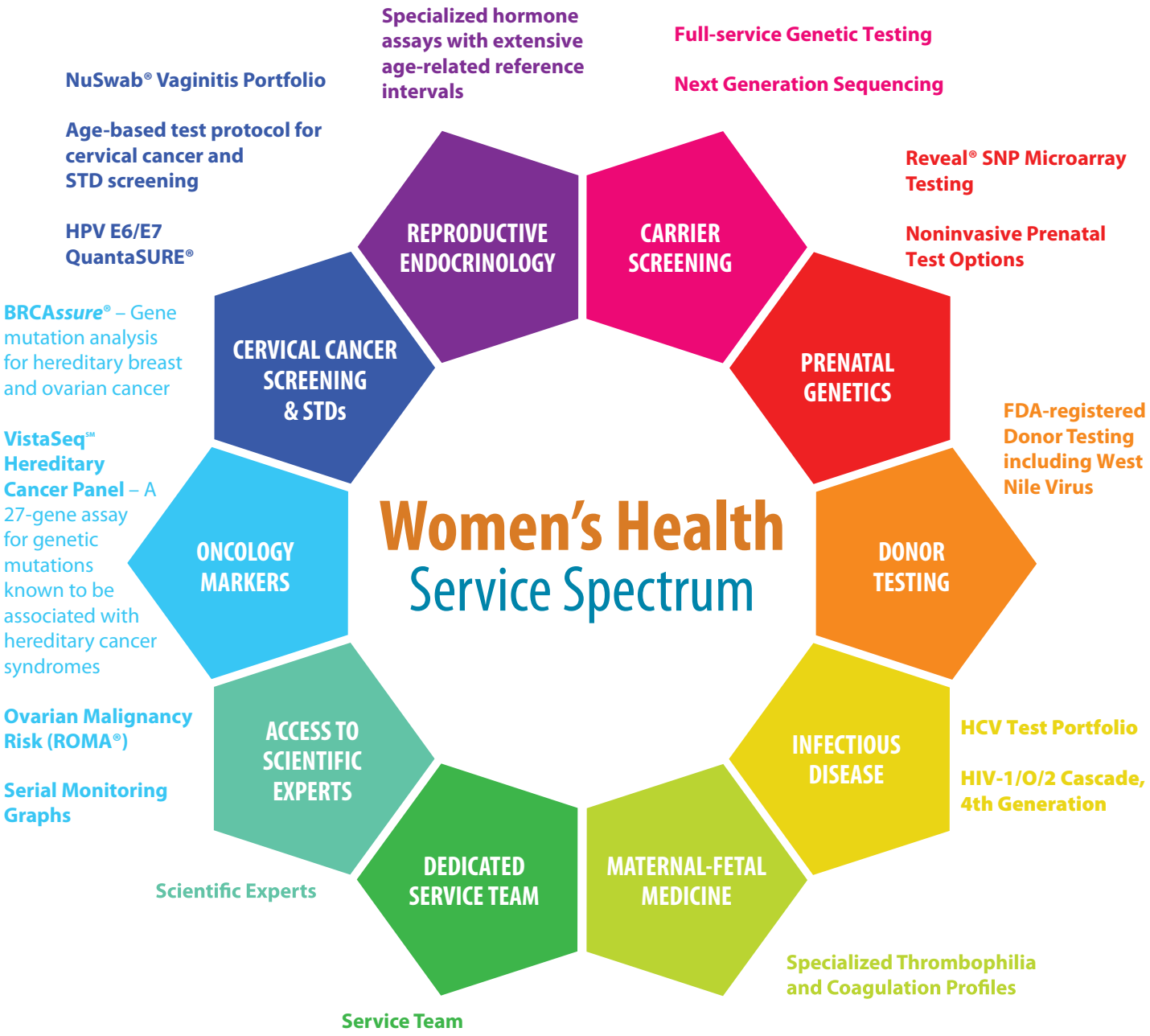

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CONTINUED FROM PAGE 8

cephalexin plus metronidazole and placebo groups were 9.5% and 30.2%, respectively. Among women with intact membranes the surgical site infection rates in the cephalexin plus metronidazole and placebo groups were 5% and 8.7%, respectively.

Given that these findings are not consistent with current dogma, clinicians should be cautious about using postcesarean antibiotics and await confirmation in additional trials. Of relevance, a randomized study of women with chorioamnionitis who were treated precesarean delivery with ampicillin, gentamicin, and clindamycin did not benefit from the administration of additional postoperative antibiotics (one additional dose of gentamicin and clindamycin) compared with no postdelivery antibiotics.[16]

Does suture selection matter?

In one randomized trial comparing two suture types, 550 women undergoing nonemergent cesarean delivery were randomly assigned to subcuticular skin closure with polyglactin 910 (Vicryl) or poliglecaprone 25 (Monocryl) suture. The poliglecaprone 25 suture was associated with a lower rate of wound complications (8.8% vs 14.4%; 95% CI, 0.37–99; $P = .04$).[17] However, a post-hoc analysis of a randomized trial of skin preparation did not observe a difference in wound complications between the use of polyglactin or poliglecaprone suture for skin closure.[18]

Prophylactic negative-pressure wound therapy: An evolving best practice?

A meta-analysis of 6 randomized trials and 3 cohort studies reported that in high-risk obese women the use of prophylactic negative-pressure wound therapy compared with standard wound dressing resulted in a decrease in surgical site infection (RR, 0.45; 95% CI, 0.31–0.66).[19] The number needed to treat was 17. In one recent study, the wound outcomes following cesarean delivery among women with a BMI ≥40 kg/m^2 were compared in 234 women who received and 233 women who did not receive negative-pressure wound therapy.[20] Wound infection was observed in 5.6% and 9.9% of the treated and untreated women, respectively.[20] However, another meta-analysis of prophylactic negative-pressure wound therapy for obese women undergoing cesarean delivery did not report any benefit.[21]

Let's work on continuous improvement

Cesarean delivery is a common major operation and is associated with wound infections and endometritis at rates much greater than those observed after vaginal delivery or other major intra-abdominal operations. As obstetricians, we can do more to guide practice toward continuous improvement in surgical outcomes. Systematically using a bundle of evidence-based interventions, including proper antibiotic selection, timing, and dosing; use of hair removal with clippers; use of chlorhexidine abdominal prep; removal of the placenta with gentle traction; and closure of the subcutaneous layer if tissue depth is ≥2 cm, will reduce the rate of postcesarean infection.[22] Although aspirational, we may, someday, achieve a postcesarean infection rate less than 1%!

CASE Conclusion

The patient was noted to be at high risk for postcesarean infection because she had both an elevated BMI and ruptured membranes. The surgeon astutely decided to administer cefazolin 3 g and azithromycin 500 mg, cleanse the vagina with povidone-iodine, use chlorhexidine for the abdominal prep, use poliglecaprone 25 subcuticular skin closure, and did not use postoperative antibiotics or prophylactic wound vacuum. Following an uneventful cesarean delivery, the patient was discharged without an infection on postoperative day 4. ●

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

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UPDATE Prenatal carrier screening

Mary E. Norton, MD
Dr. Norton is Professor of Obstetrics, Gynecology, and Reproductive Sciences at the University of California, San Francisco.

The author reports receiving grant or research support from Natera and being a consultant to Invitae.

The benefit of expanded carrier screening over standard testing is not clear. Recent data shed light on advantages and drawbacks of expanded panel testing.

Prenatal care has long included carrier screening for genetic diseases, such as cystic fibrosis and Tay-Sachs disease. Recently, advances in genetics technologies led to the development of multiplex panels that can be used to test for hundreds of genetic disorders simultaneously, and can be used to assess carrier status for expectant couples or those planning a pregnancy. Although such screening covers many more conditions than those recommended in traditional guidelines, the benefit of expanded carrier screening (ECS) over standard gene-by-gene testing is not clear.

In this Update, I review recent ECS research that can be helpful to those who practice reproductive endocrinology and infertility medicine, maternal–fetal medicine, and general ObGyn. This research considered some of the many complexities of ECS:

- number and type of severe autosomal recessive conditions identified by an ECS panel, or by panethnic screening for 3 common conditions (cystic fibrosis, fragile X syndrome, spinal muscular atrophy)
- whether the disorders covered by ECS panels meet recommended criteria regarding severity, prevalence, and test accuracy
- women's thoughts and perspectives on ECS
- whether the marketing materials disseminated by commercial providers of ECS are accurate and balanced.

IN THIS ARTICLE

Genetic diseases identified by expanded carrier screening

Haque IS, Lazarin GA, Kang HP, Evans EA, Goldberg JD, Wapner RJ. Modeled fetal risk of genetic diseases identified by expanded carrier screening. JAMA. 2016;316(7):734–742.

Screening during pregnancy to determine if one or both parents are carriers of genetic disorders historically has involved testing for a limited number of conditions, such as cystic fibrosis, hemoglobinopathies, and Tay-Sachs disease. Patients usually are offered testing for 1 or 2 disorders, with test choices primarily based on patient race and ethnicity. Unfortunately, ancestry-based screening may result in inequitable distribution of genetic testing and resources, as it has significant limitations in our increasingly multicultural society, which includes many people of uncertain or mixed race and ethnicity.

CONTINUED ON PAGE 15

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INDICATIONS

- SUPRAX® (cefixime) is a cephalosporin antibacterial drug indicated in the treatment of adults and pediatric patients six months of age and older with the following infections when caused by susceptible isolates of the designated bacteria: Uncomplicated Urinary Tract Infections; Otitis Media; Pharyngitis and Tonsillitis; Acute Exacerbations of Chronic Bronchitis; Uncomplicated Gonorrhea (cervical/urethral).

IMPORTANT SAFETY INFORMATION

SUPRAX should only be used to treat infections that are proven or strongly suspected to be caused by bacteria.

CONTRAINDICATIONS

- SUPRAX (cefixime) is contraindicated in patients with known allergyto cefixime or other cephalosporins.

WARNINGS & PRECAUTIONS

- Hypersensitivity reactions: Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. Before therapy with SUPRAX is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins, or other drugs. Discontinue use if a reaction occurs.
- *Clostridium difficile* associated diarrhea: Evaluate if diarrhea occurs.
- Dose Adjustment in Renal Impairment: The dose of SUPRAX should be adjusted in patients with renal impairment and those undergoing continuous ambulatory peritoneal dialysis and hemodialysis.
- Coagulation Effects: Cephalosporins, including SUPRAX, may be associated with a fall in prothrombin activity. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.
- Phenylketonurics: SUPRAX Chewable Tablets contain aspartame, a source of phenylalanine.

ADVERSE REACTIONS

- Most common adverse reactions are gastrointestinal such as diarrhea (16%), loose or frequent stools (6%), abdominal pain (3%), nausea (7%), dyspepsia (3%), and flatulence (4%).
- Adverse reactions during postmarketing experience occurred at rates of less than 2%. Some serious adverse reactions included: pseudomembranous colitis, hypersensitivity reactions including Stevens-Johnson syndrome and serum sickness, acute renal failure, seizures, agranulocytosis, and toxic epidermal necrolysis.

DRUG INTERACTIONS

- Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly.
- Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly with warfarin and anticoagulants.
- A false positive reaction for ketones and glucose in urine may occur with certain test kits. A false positive direct Coombs test has also been reported.

USE IN SPECIAL POPULATIONS

- Efficacy and safety in infants aged less than six months have not been established.
- Cefixime should be used during pregnancy only if clearly needed.
- Consideration should be given to discontinuing nursing temporarily during treatment with cefixime.

Please note this information is not comprehensive. Please see Brief Summary of Prescribing Information on the following page.

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

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LUPIN
PHARMACEUTICALS, INC.

111 South Calvert Street, Baltimore, MD 21202. PP-SPX-0062

SUPRAX® (cefixime)

BRIEF SUMMARY: This summary does not include all the information needed to use SUPRAX safely and effectively. Consult Full Prescribing Information for complete product information.

SUPRAX should only be used to treat infections that are proven or strongly suspected to be caused by bacteria.

INDICATIONS AND USAGE

SUPRAX (cefixime) is a cephalosporin antibacterial drug indicated in the treatment of adults and pediatric patients six months of age or older with the following infections when caused by susceptible isolates of the designated bacteria:

Uncomplicated Urinary Tract Infections caused by Escherichia coli and Proteus mirabilis.

Otitis Media caused by Haemophilus influenzae, Moraxella catarrhalis, and Streptococcus pyogenes. (Note: For patients with otitis media caused by Streptococcus pneumoniae, overall response was approximately 10% lower for cefixime than the competitor. Efficacy for Streptococcus pyogenes in this organ system was studied in fewer than 10 infections.)

Pharyngitis and Tonsillitis caused by Streptococcus pyogenes. (Note: Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* infections. SUPRAX is generally effective in the eradication of Streptococcus pyogenes from the nasopharynx; however, data establishing the efficacy of SUPRAX in the subsequent prevention of rheumatic fever is not available.)

Acute Exacerbations of Chronic Bronchitis caused by Streptococcus pneumoniae and Haemophilus influenzae.

Uncomplicated Gonorrhea (cervical/urethral) caused by Neisseria gonorrhoeae (penicillinase-and non-penicillinase-producing isolates).

CONTRAINDICATIONS

SUPRAX (cefixime) is contraindicated in patients with known allergy to cefixime or other cephalosporins.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. Erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have also been reported. Before therapy with SUPRAX is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins, or other drugs. Discontinue SUPRAX if an allergic reaction occurs.

Clostridium difficile-Associated Diarrhea: Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including SUPRAX.

Dose Adjustment in Renal Impairment: The dose of SUPRAX should be adjusted in patients with renal impairment.

Coagulation Effects: Cephalosporins, including SUPRAX, may be associated with a fall in prothrombin activity. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

Phenylketonurics: SUPRAX (cefixime) Chewable Tablets contain aspartame, a source of phenylalanine. 100 mg, 150 mg and 200 mg strength contains 3.3 mg, 5 mg and 6.7 mg of phenylalanine, respectively.

ADVERSE REACTIONS

The most commonly seen adverse reactions were gastrointestinal events, which were reported in 30% of adult patients on either the twice daily or the once daily regimen. Five percent (5%) of patients in the U.S. clinical trials discontinued therapy because of drug-related adverse reactions.

Individual adverse reactions included diarrhea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%. The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension was comparable to the incidence seen in adult patients receiving tablets.

DRUG INTERACTIONS

Carbamazepine: Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

Warfarin and Anticoagulants: Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.

Drug/Laboratory Test Interactions: A false-positive direct Coombs test has been reported during treatment with other cephalosporins; therefore, it should be recognized that a positive Coombs test may be due to the drug.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category B. Reproduction studies in mice have revealed no evidence of harm to the fetus due to cefixime. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: Cefixime has not been studied for use during labor and delivery and should only be given if clearly needed.

Nursing Mothers: It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

Pediatric Use: Safety and effectiveness of cefixime in children aged less than six months old have not been established.

Geriatric Use: Clinical studies did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in response between the elderly and younger patients. A pharmacokinetic study in the elderly detected differences in pharmacokinetic parameters, but they were small and do not indicate a need for dose adjustment.

Renal Impairment: Dose adjustment is advised in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully.

DOSAGE AND ADMINISTRATION

Adults: The recommended dose of cefixime is 400 mg daily. This may be given as a 400 mg tablet or capsule daily or the 400 mg tablet may be split and given as one half tablet every 12 hours. The capsule and tablet may be administered without regard to food.

Pediatric Patients (6 months or older): The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours. Children weighing more than 45 kg or older than 12 years should be treated with the recommended adult dose. SUPRAX (cefixime) Chewable Tablets must be chewed or crushed before swallowing.

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

Please note that this information is not comprehensive. Please visit www.supraxrx.com for Full Prescribing Information.

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Advantages of expanded carrier screening

Several commercial laboratories now offer ECS. Haque and colleagues used data from one of these laboratories and modeled the predicted number of potentially affected fetuses that would be identified with traditional, ethnicity-based screening as compared with ECS. In one of their hypothetical cohorts, of Northern European couples, traditional screening would identify 55 affected fetuses per 100,000 (1 in 1,800), and ECS would identify 159 per 100,000 (almost 3 times more). The numbers identified with ECS varied with race or ethnicity and ranged from 94 per 100,000 (about 1 in 1,000) for Hispanic couples to 392 per 100,000 (about 1 in 250) for Ashkenazi Jewish couples.

In Australia, Archibald and colleagues conducted a similar study, of panethnic screening of 12,000 women for cystic fibrosis, fragile X syndrome, and spinal muscular atrophy.[1] The number of affected fetuses identified was about 1 per 1,000 screened couples—not much different from the ECS number, though comparison is difficult given the likely very different racial and ethnic backgrounds of the 2 cohorts.

Although these data suggest ECS increases detection of genetic disorders, and it seems almost self-evident that more screening is better, there are concerns about ECS.[2] Traditional carrier screening methods focus on conditions that significantly affect quality of life—owing to cognitive or physical disabilities or required lifelong medical therapies—and that have a fetal, neonatal, or early-childhood onset and well-defined phenotype. In ECS panels, additional conditions may vary significantly in severity or age of onset. Although some genetic variants on ECS panels have a consistent phenotype, the natural history of others is less well understood. Panels often include conditions for which carrier screening of the general population is not recommended by current guidelines—for example, hemochromatosis and factor V Leiden. Moreover, almost by definition, ECS panels include rare conditions for which the natural history may not be well understood, and the carrier frequency as well as the proportion of condition-causing variants that can be detected may be unclear, leaving the residual risk unknown.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

This study provides additional information on the number and type of conditions that can be detected with ECS in different populations. Although ever larger panels can detect more conditions, the veracity of the results and the types of conditions detected are important considerations as providers and patients weigh the risks and benefits of this screening.

FAST TRACK

Although expanded carrier screening was found to detect almost 3 times more affected fetuses, additional conditions screened for may vary in natural history and current understanding

The ideal expanded carrier screening panel

Stevens B, Krstic N, Jones M, Murphy L, Hoskovec J. Finding middle ground in constructing a clinically useful expanded carrier screening panel. Obstet Gynecol. 2017;130(2):279–284.

Both the American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics and Genomics (ACMG) have proposed criteria for including specific disorders on ECS panels.[3,4] These criteria consider disorder characteristics, such as carrier prevalence, which should be at least 1 in 100; severity; early-childhood onset; and complete penetrance. In addition, they consider test characteristics, such as sensitivity, which should be at least 70%.

Details of the study

Stevens and colleagues evaluated the ECS panels offered by 6 commercial laboratories

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WHAT THIS EVIDENCE MEANS FOR PRACTICE

For practices that want to offer ECS, it is important to consider the type of conditions on a given laboratory's panel. Panels that include more conditions will detect at least one condition in more patients. As each positive test requires follow-up (typically partner testing), careful consideration should be given up-front to which test is used.

in the United States. They found that only 27% of included conditions met the recommended criteria, and concluded that these panels are putting patients at risk for undue anxiety, and that time and money are being spent on follow-up testing for rare and mild conditions for which the benefits of testing are unclear or unlikely. The potential benefits of the extra screening should be weighed against the significant resulting harms.

Across the 6 ECS panels, 96 conditions met the criteria. As some laboratories allow providers to customize their panels, members of my practice, after reviewing this thought-provoking article, agreed we should create a custom panel that includes only these 96 conditions. Unfortunately, no commercial laboratory includes all 96 conditions, so it is not feasible to create an "ideal" panel at this time.

Arguments favoring ECS include its low cost and the efficiency of screening with multigene panels. In a 2013 study, however, 24% of patients were identified as carriers, and in most cases this finding led to screening for the reproductive partner as well.[5] If the rate of detection of the disorder is low, the utility of screening with the same panel may be limited, and couples may require more extensive testing, such as gene sequencing, which is far more expensive. These findings and the additional testing also will increase the need for genetic counseling, and may lead to invasive prenatal diagnostic testing with further increases in costs. If counseling and prenatal testing yield improved outcomes—increased detection of important findings—the benefit will justify the higher costs. However, if the increased costs are largely generated chasing down and explaining findings that are not important to patients or providers, the costs may be incurred without benefit.

FAST TRACK

Only 27% of included conditions on 6 commercially offered ECS panels met the criteria outset by ACOG and the American College of Genetics and Genomics as appropriate for inclusion on ECS panels

Pregnant women's perspectives on expanded carrier screening

Propst L, Connor G, Hinton M, Poorvu T, Dungan J. Pregnant women's perspectives on expanded carrier screening [published online February 23, 2018]. J Genet Couns. doi:10.1007/s10897-018-0232-x.

Although several authors have discussed ECS detection rates, less has been reported on how women perceive ECS or how they elect or decline screening. Studies have found that the decision to undergo screening for cystic fibrosis is influenced by factors that include age, sex, ethnicity, socioeconomic status, lack of family history, cost, fear of a blood test, lack of knowledge about the condition, already having children, wanting to avoid having a disabled child, abortion preferences, and feeling pressured by health care providers.[6,7]

Propst and colleagues asked women for their perspectives on ECS, on electing or declining screening, and on any anxiety associated with their decision.

Details of the study

Women who declined ECS said they did so because they:

- had no family history
- knew there was a very small chance their partner carried the same condition
- would not change the course of their pregnancy on the basis of the test results.

Women who elected ECS said they did so because they wanted to:

- know their risk of having a child with a genetic condition

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- have all available information about their genetic risks
- be able to make decisions about continuing or terminating their pregnancy.

Women also were asked what they would do if they discovered their fetus had a genetic disorder. About 42% said they were unsure what they would do, 34% said they would continue their pregnancy and prepare for the birth of an affected child, and 24% said they likely would terminate their pregnancy.

The most common reason women gave for declining ECS was that they had no family history. However, ECS is not a good option for women with a positive family history, as they need genetic counseling and specific consideration of their own risks and what testing should be done. The majority of couples who have a child with a genetic disease have no other family history of the disorder. In a study of reproductive carrier screening in Australia, 88% of carriers had no family history.[1] Careful pretest counseling is needed to explain the distinction between, on one hand, genetic counseling and testing for those with a family history of genetic disease and, on the other hand, population screening performed to identify unsuspecting individuals who are healthy carriers of genetic disorders.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Different pregnant women may have very different preferences regarding genetic testing. Although many are unsure how they would proceed following the diagnosis of a fetal genetic disorder, it is important to carefully explain their options before any testing is done.

Another crucial point about carrier screening is the need to consider how its results will be used, and what options the carrier couple will have. For women who are pregnant when a risk is identified, options include expectant management, with diagnosis after birth, or prenatal diagnosis with termination of an affected fetus, out-adoption of an affected fetus, or expectant management with preparation for caring for an affected child. For women who are not pregnant when they have ECS, additional options include use of a gamete (ovum or sperm) donor to achieve pregnancy, or preimplantation genetic diagnosis with implantation of only unaffected embryos.

FAST TRACK

Women most commonly declined ECS because they had no family history; however, up to 88% of carriers have no family history. Therefore, careful pretest counseling is needed.

Marketing of expanded carrier screening

Chokoshvili D, Borry P, Vears DF. A systematic analysis of online marketing materials used by providers of expanded carrier screening [published online December 14, 2017]. Genet Med. doi:10.1038/gim.2017.222.

Prenatal carrier screening can be helpful to women and their families, but it is also a high-volume, lucrative business, with many commercial laboratories competing for the growing ECS market. Professional medical societies recommend making all screening candidates aware of the purpose, characteristics, and limitations of the tests, and of the potential significance of their results. As becoming familiar and comfortable with the tests and explaining them to each patient can be time-consuming, and daunting, many busy clinicians have started relying on marketing materials and other information from the commercial laboratories. Therefore analysis of the accuracy of such materials is in order.

Details of the study

Chokoshvili and colleagues performed a systematic analysis of the quality and accuracy of online marketing materials for ECS. They identified 18 providers: 16 commercial laboratories and 2 medical services providers. All described

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Visit **#SGS2018** and OBG Management on Twitter **@obgmanagement** and at **facebook.com/obgmanagement** for Dr. Tierney's coverage of the

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Ideally, carrier screening should be done prior to pregnancy

Determining that a woman carries a genetic disorder in the preconception period allows more time to evaluate her reproductive partner. If both partners in the couple carry the same genetic disorder, there are more options available to avoid an affected pregnancy. These options include the use of an ovum or sperm donor, or use of preimplantation genetic diagnosis on embryos conceived through in vitro fertilization. While obstetric providers commonly offer carrier screening, and most women are only screened during pregnancy, such genetic testing should be part of pregnancy planning. When gyn providers see patients who are considering a pregnancy, he or she should discuss the options of expanded carrier screening, or ethnicity-based screening.

ECS as a useful tool for family planning, and some were very directive in stating that this testing is "one of the most important steps in preparing for parenthood." In their materials, most of the companies cover some limitations, such as residual risk, but none of the commercial laboratories indicate that ECS can overestimate risk (many variants have incomplete penetrance, meaning that some individuals with a positive test result may in fact be asymptomatic throughout their lifetime).

In addition, whereas a large amount of the marketing materials implies the test was developed in line with professional recommendations, none in fact complies with ACOG and ACMG guidance. Finally, though some of the online information provided by laboratories can be helpful, it is important for clinicians to remember that reproductive genetic counseling should be nondirective and balanced. Carrier testing should be based on patient (not provider) values regarding reproductive autonomy.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Laboratories' educational materials can be useful, but clinicians must carefully assess them before recommending them to patients. Some commercial laboratory information is helpful and balanced; other information is directive or even coercive. Nonbiased information on prenatal genetic testing, for both patients and clinicians, is available in the Genetic Education Modules offered by the Perinatal Quality Foundation (https://www.perinatalquality.org).

Summary

ECS increasingly is being adopted into clinical practice. According to ACOG, traditional ethnicity-based screening, panethnic screening (the same limited panel of tests for all patients), and ECS are all acceptable alternatives for prenatal carrier screening.[3] For providers who offer ECS, it is important to have a good understanding of each selected test and its limitations. Providers should have a plan for following up patients who have positive test results; this plan may include having genetic counseling and prenatal genetic diagnostic testing in place. Although treatment is available for a few genetic conditions, for the large majority, prenatal screening has not been proved to lead to improved therapeutic options. Providers should try to make sure that patients do not have unrealistic expectations of the outcomes of carrier screening. ●

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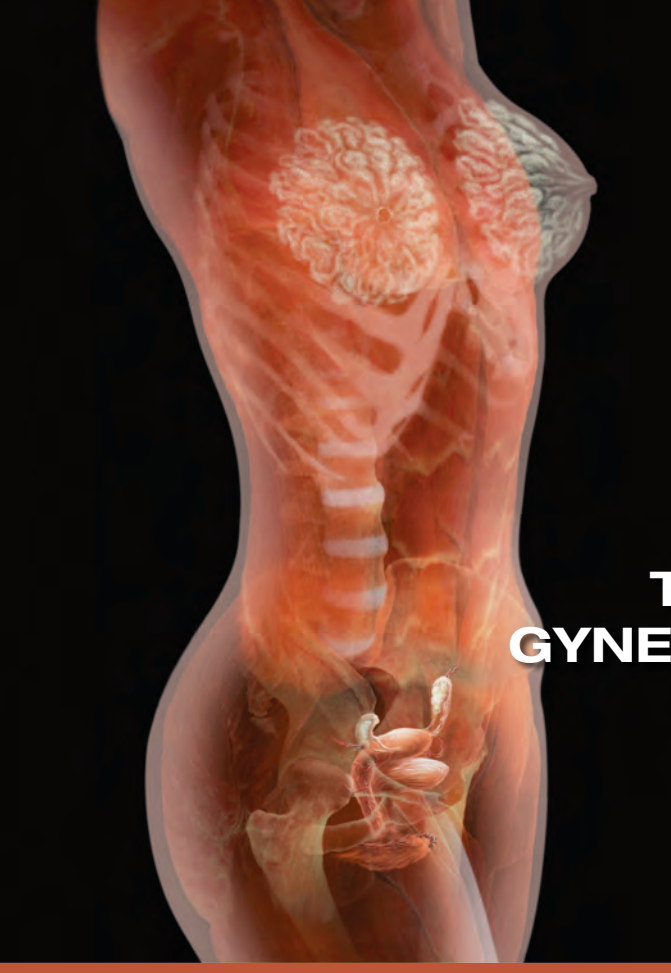

OBG MANAGEMENT

SPECIAL SECTION

HIGHLIGHTS FROM THE 2018 SOCIETY OF GYNECOLOGIC SURGEONS SCIENTIFIC MEETING PART 1

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PHOTO: SCIENCE SOURCE IMAGES / ANATOMICAL TRAVELOGUE

Leading best gynecologic surgical care into the next decade

Leadership was the theme at the annual meeting of the Society of Gynecologic Surgeons (SGS). We begin this special section with leading features on managing pelvic organ prolapse and patient experience.

Andrew Cassidenti, MD

With today's rapid health care transformation from fee for service to fee for value, it is imperative that gynecologic surgeons understand, engage in, and lead this transformation. The value equation is defined as patient experience times clinical outcome divided by cost. This 2-part special issue highlights some of the key content shared at the 2018 SGS annual meeting, held in Orlando, Florida, to help you engage and lead.

The keynote address was "Patient Experience: It is not about making people happy" and was presented by James Merlino, MD (author of *Service Fanatics: How to Build Superior Patient Experience the Cleveland Clinic Way*), who is former Chief Experience Officer and colorectal surgeon at the Cleveland Clinic and currently President and Chief Medical Officer, Strategic Consulting at Press Ganey. Dr. Merlino clearly defines that the patient experience is really about patient safety and quality. He shares practical tips to help physicians improve communication with patients, which not only increases patient satisfaction but also physician satisfaction. His wife Amy Merlino, MD, an ObGyn, coauthored the piece with him and shares their journey to implement programs that were impactful and designed to create greater personal appreciation and mindfulness of physicians' clinical work.

Optimal surgical outcomes delivered at lowest cost are the other key components of value health care. Endometriosis and the management of stage 3 and 4 pelvic organ prolapse remain challenging clinical scenarios that we face often. Rosanne Kho, MD, and colleagues taught a postgraduate course on contemporary management of deep infiltrating endometriosis and, in part 2 of this special section, share key highlights and pearls from that course. A highpoint of the meeting was a debate on the optimal management of stage 3 and 4 pelvic organ prolapse. Peter Rosenblatt, MD, moderated a lively discussion involving Rebecca Rogers, MD, who advocated for native tissue repair; Patrick Culligan, MD, who promoted abdominal sacrocolpopexy; and Vincent Lucente, MD, backing transvaginal mesh. They summarize their arguments beginning on page SS4 for you to decide.

Lastly, with increasing demand for minimally invasive hysterectomy, many surgeons could benefit from simulation training to enhance their practice, hone up on skills, and provide warm-up to sharpen technical skills prior to the day in the operating room. Simulation training improves patient safety and outcomes and lowers cost. Simulation training is also key in training residents and fellows. Christine Vaccaro, MD, and colleagues taught a postgraduate course on what is new in simulation training for hysterectomy and summarize important technologies in part 2 of this special section.

I hope you enjoy the content of this special section and find it impactful to your practice and future. ■

The author reports that he has served as a consultant and proctor for Astora Women's Health and as an expert witness for Boston Scientific in the mesh litigation.

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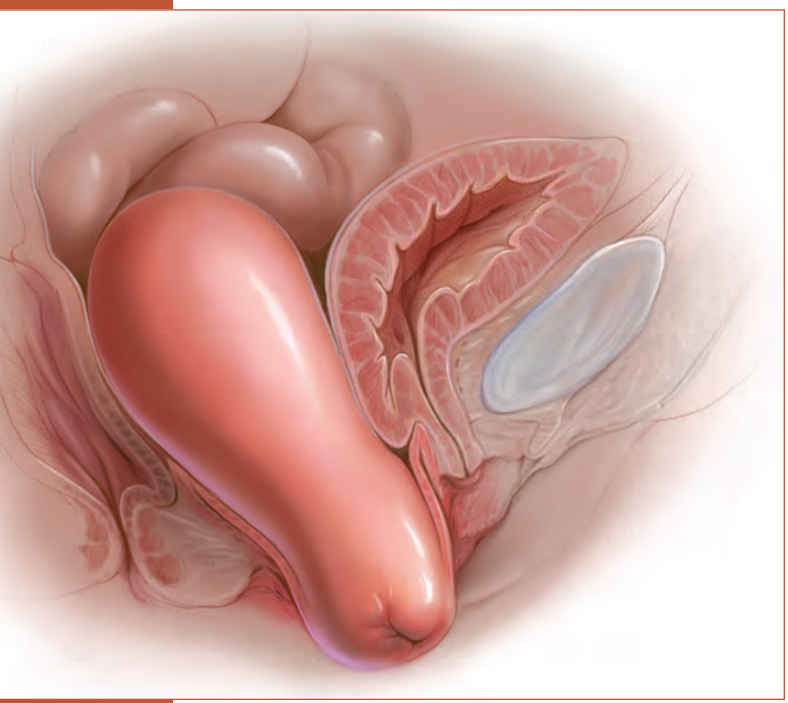
DEBATE

Optimal surgical management of stage 3 and 4 pelvic organ prolapse

What the evidence and the experts say about the various approaches for prolapse repair



Effective surgical management of advanced pelvic organ prolapse (POP) depends on prolapse location and stage, presence of urinary incontinence, need for hysterectomy, the patient's desire to maintain sexual function, type of surgery, and the surgeon's skill and experience, among other factors. For these reasons, POP repair is not a one-size-fits all procedure.

In this article, experts in minimally invasive prolapse repair offer their perspectives on 3 surgical approaches: use of native tissue (Drs. White, Aguilar, and Rogers), abdominal sacrocolpopexy (Drs. Huber and Culligan), and transvaginal mesh (Drs. Lucente and Ton). They evaluate the evidence on these procedures and provide recommendations based on their experience of best practices for achieving surgical success and minimizing adverse events.

Bonus: See instructive videos of several surgical techniques described in the article online at **www.mdedge.com/obgmanagement**.

ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT

Using native tissue for vaginal anatomy repair

Amanda White, MD; Vivian Aguilar, MD; and Rebecca G. Rogers, MD

Surgical therapy is the mainstay of treatment for POP, and 20% of US women will undergo prolapse and/or stress incontinence surgery by age 80.[1] Prolapse surgery either restores the vaginal anatomy (reconstructive surgery) or obliterates the vaginal canal (obliterative surgery). Vaginal reconstruction can be performed using the patient's native tissue or mesh. Because of concerns associated with mesh use, native tissue repairs continue to be commonly performed.

Unfortunately, not all prolapse surgeries result in prolapse cure, and recurrent prolapse that necessitates repeat operation is not rare, regardless of whether or not mesh is used.[2,3] Native tissue repairs are most commonly performed through the vaginal route, the first minimally invasive approach to

Dr. Rogers reports that she receives royalties from UpToDate. Drs. White and Aguilar report no financial relationships relevant to this article.

prolapse surgery. Restoration of the vaginal apex has been identified as critically important in these surgeries. Apical native tissue repairs include reconstructive procedures, such as sacrospinous ligament suspension (SSLS) or uterosacral ligament suspension (USLS), and obliterative procedures, such as colpocleisis.

In this discussion, we present 2 case vignettes that highlight surgical decision making for repair of stage 3 or 4 pelvic organ prolapse utilizing these techniques.

Take-home points

- Native tissue repair offers a minimally invasive approach to prolapse repair.
- Sacrospinous and uterosacral ligament suspensions have equivalent success rates.
- Prophylactic midurethral slings reduce postoperative incontinence at the time of transvaginal native tissue repair.
- Hysterectomy at the time of colpocleisis should not be performed routinely.

CASE 1 Active woman with prolapse

A 65-year-old woman (G2P2) presents with stage 3 prolapse, with the anterior compartment at +3 and the cervix at the hymen with straining. She is sexually active and desires to retain coital function. A trial of pessary has failed.

What surgical options can be considered for this patient?

Reconstruction procedures for prolapse

This patient presents with a typical configuration of prolapse; the anterior and apical compartments are the most likely to prolapse.[4] Importantly, conservative management of her prolapse has failed. While it is not required that women have a trial with pessary prior to undergoing surgery, all women should be offered conservative management of prolapse, according to the American Urogynecologic Society (AUGS) and the American College of Obstetricians and Gynecologists (ACOG).[4,5]

Apical suspension

Since this patient desires to retain coital function, her gynecologist recommends a reconstructive procedure. The combination of apical and anterior vaginal wall prolapse will require an apical suspension procedure (**FIGURES 1** and **2,** page SS6). If suspension of the apex does not correct the anterior wall prolapse, the patient also may require anterior compartment reconstruction.

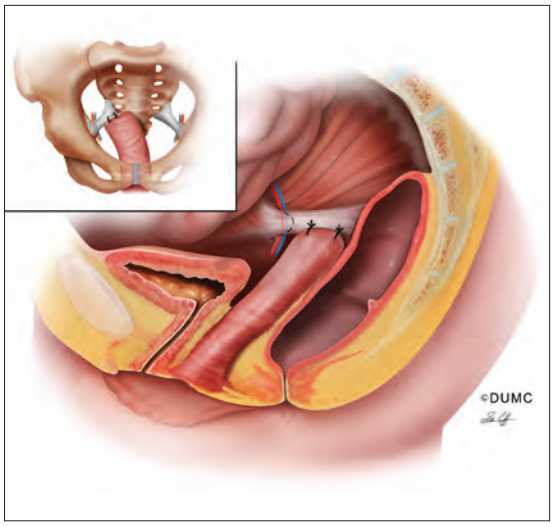
The 2 most commonly performed native tissue apical suspension procedures, SSLS and USLS, have equivalent outcomes at 2 years, according to a multicenter randomized trial.[6] Therefore, the choice of procedure is at the surgeon's discretion. USLS is most commonly performed at the time of hysterectomy via an intraperitoneal approach, while SSLS is often selected for posthysterectomy vault prolapse, given its extraperitoneal location.

Suture type. Whether to use permanent suture at the time of SSLS or USLS is controversial. Some data suggest that permanent suture provides greater long-term success compared with delayed absorbable suture.[7] However, permanent suture has been reported to be associated with higher rates of suture complications—up to 44% in USLS and 36% in SSLS—compared with a 3.5% complication rate in a USLS cohort treated with absorbable suture.[8–10]

Hysterectomy versus hysteropexy. Considerable debate exists regarding whether a patient requires hysterectomy at the time of prolapse repair. In a randomized trial at 12 months' follow-up, uterine preservation by sacrospinous hysteropexy was noninferior to vaginal hysterectomy with suspension of the uterosacral ligaments for surgical failure of the apical compartment.[11] A recent meta-analysis found that apical failure rates after sacrospinous hysteropexy versus vaginal hysterectomy were not different.[12] Repeat surgery rates for prolapse also were not different between groups. The most significant disadvantage of uterine-preservation prolapse surgery, when compared with hysterectomy, is the lack of prevention and diagnosis of uterine malignancy.[12] From 2002 to 2012, rates of hysteropexy significantly increased in the United States, although rates remain low.[13]

Sling procedure pros and cons. This case patient did not report urinary incontinence, but she may develop incontinence with reduction of the anterior wall prolapse. A large randomized controlled trial that included 337 women compared sling with no sling procedures among women with prolapse undergoing transvaginal prolapse

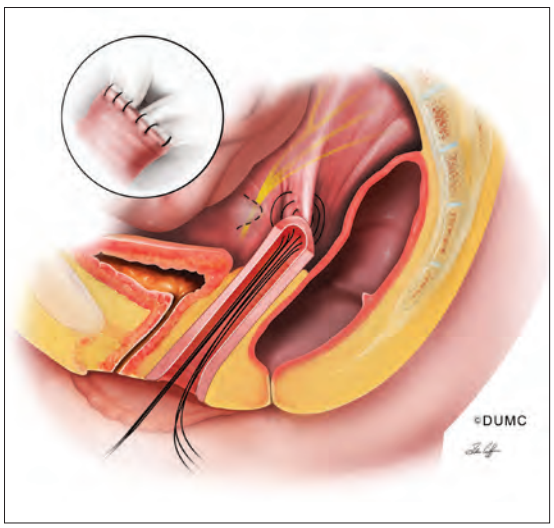
FIGURE 1 Prolapse repair with sacrospinous ligament fixation



Sacrospinous ligament fixation attaches the vaginal apex to the unilateral or bilateral sacrospinous ligament(s) using absorbable or nonabsorbable suture. Care must be taken to avoid the pudendal nerve, artery, and vein.

SOURCE: Siddiqui NY, Edenfield AL. Clinical challenges in the management of vaginal prolapse. Int J Womens Health. 2014;6:83–94. Used with permission.

FIGURE 2 Prolapse repair with uterosacral ligament suspension



Uterosacral ligament suspension attaches the vaginal apex to the bilateral uterosacral ligaments above the level of the ischial spine using absorbable or nonabsorbable suture.

SOURCE: Siddiqui NY, Edenfield AL. Clinical challenges in the management of vaginal prolapse. Int J Womens Health. 2014;6:83–94. Used with permission.

repair.[14] Management with a prophylactic sling resulted in less incontinence (27.3% and 43.0%, respectively, at 12 months postoperatively) but higher rates of urinary tract infection (31.0% vs 18.3%), major bleeding complications (3.1% vs 0%), and incomplete bladder emptying 6 weeks after surgery (3.7% vs 0%) ($P \leq .05$ for all).[14]

CASE 1 Recommendations for this patient

For this case, we would offer the patient a transvaginal hysterectomy and USLS. At the time of repair, we would assess whether she needed an anterior repair as well. We would offer a prophylactic sling procedure and also would discuss the risks and benefits of concomitant versus interval incontinence procedures.

CASE 2 Elderly woman with severe prolapse

An 85-year-old woman (G3P3) presents with procidentia, or complete eversion of the vagina, with the cervix 10 cm outside of the hymen. She has difficulty voiding, and the prolapse is uncomfortable when walking. A trial of pessary has failed. The patient denies vaginal bleeding. She is not sexually active and does not desire to retain coital function.

What treatment options would be appropriate for this patient?

Obliterative surgery

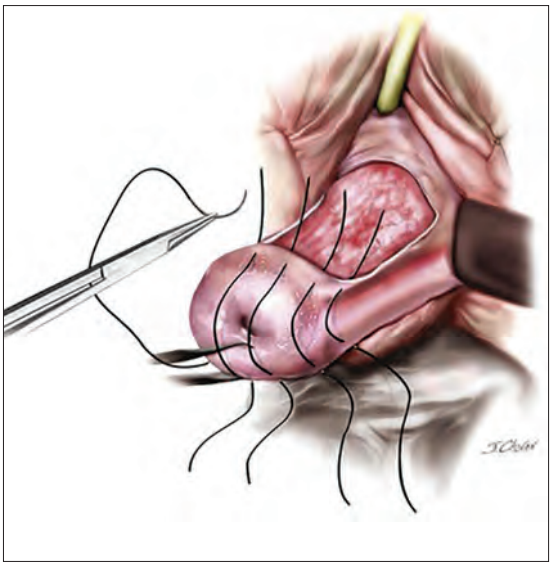
This elderly patient presents with advanced pelvic organ prolapse, and conservative management has failed. She is not sexually active and does not desire coital function in the future, so an obliterative procedure is indicated. Colpocleisis is a minimally invasive procedure that has cure rates ranging from 91% to 100%.[15] It is likely that this patient's voiding dysfunction will improve after surgery and that she will be highly satisfied with the surgery.[16]

The question of hysterectomy with colpocleisis

The role of hysterectomy at the time of colpocleisis is controversial. LeFort colpocleisis preserves the uterus, with the anterior and posterior vaginal walls sutured together (**FIGURE 3**). Hysterectomy at the time of vaginal closure increases the operative time and blood loss.[15] On the other hand, closure without hysterectomy prohibits future endometrial or cervical cancer screening.

In a recent review using the American College of Surgeons National Surgical Quality Improvement Program database, investigators compared

FIGURE 3 LeFort colpocleisis for prolapse repair



Rectangular shaped areas of prolapsed vaginal epithelium are removed prior to imbrication and perineorrhaphy in the obliterative procedure LeFort colpocleisis.

SOURCE: Baggish MS, Karram MM. Atlas of pelvic anatomy and gynecologic surgery. 3rd ed. St Louis, MO: Elsevier Saunders; 2011. Used with permission.

women who underwent colopocleisis alone with those who underwent colpocleisis with hysterectomy.[17] They found that the incidence of major complications was greater among women who underwent concomitant hysterectomy, and they concluded that hysterectomy should not be performed routinely at the time of colpocleisis.[17]

Among 322 urogynecologists who responded to a web-based survey, only 18% routinely performed hysterectomy at the time of colpocleisis.[18] Further, in a decision analysis model, the utility for colpocleisis without hysterectomy was higher in women older than age 40, suggesting that hysterectomy should be performed only in special circumstances.[19]

Evaluating the endometrium. If the uterus remains in situ, should endometrial evaluation be performed? If so, should ultrasonography or endometrial biopsy be used? Authors of a decision analysis model found that among women at low risk for cancer and without abnormal uterine bleeding, endometrial biopsy was not favored until the probability of cancer reached 64%.[20] Specifically, no evaluation or evaluation by transvaginal ultrasonography is adequate in the majority of cases.[20] When screened by transvaginal ultrasonography, the high, 99% negative predictive value for endometrial disease, using a cutoff value of 5 mm for endometrial stripe width, will allow most patients to avoid unnecessary tissue sampling.

Stress incontinence. It is likely that this patient's voiding dysfunction will resolve with reduction of the prolapse, and she may develop stress incontinence symptoms. In up to 68% of women, occult stress incontinence will be revealed with reduction of stage 3 or stage 4 prolapse.[21] If the patient demonstrates stress incontinence, a midurethral sling is likely to treat her incontinence effectively, with little added risk from the procedure.[22] Even among women who have an elevated postvoid residual urine volume, the incidence of sling revision is low.[15]

CASE 2 Procedure recommendation for this patient

For this case, we would perform a LeFort colpocleisis and discuss whether or not the patient would prefer a midurethral sling if stress incontinence was demonstrated on examination. We would not perform endometrial evaluation in this patient, as she has not been bleeding and her risk for endometrial cancer is low.

Weighing the benefits of native tissue repair

Native tissue repair when performed transvaginally is a minimally invasive approach to prolapse repair. In a multicenter randomized trial, anatomic success was reported to be 64.5% at 2 years.[6] Long-term follow up of patients undergoing mesh sacrocolpopexy shows a similar anatomic failure rate, with up to one-third of patients meeting the definition of composite failure.[3] Unlike mesh-augmented repairs, however, adverse events, including bowel obstruction, mesh exposure, and thromboembolism, are more likely to occur in the mesh sacrocolpopexy group.[23]

Obliterative procedures have the highest success rates of all prolapse repairs and carry with them low morbidity. However, women must forego the ability for coitus in the future. For all native tissue vaginal repairs, the surgeon and patient must weigh the risks and benefits of concomitant anti-incontinence procedures.

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Abdominal sacrocolpopexy: A tried-and-true approach for apical prolapse repair

Sarah Huber, MD, and Patrick Culligan, MD

CASE Woman with advanced prolapse desires surgical repair

A 55-year-old woman (G2P2) presents to her gynecologist's office reporting a vaginal bulge and pressure that has been worsening for the past year. She describes a nontender ball of tissue the size of an orange protruding past the introitus that worsens with ambulating and lifting heavy objects. She reports some urinary urgency and increased frequency and at times feels as though her bladder does not empty completely with voiding. She denies any urinary incontinence. The patient has regular bowel movements but does report some difficulty with stool evacuation. She has a history of 2 vaginal deliveries and is sexually active. She is postmenopausal, with the last menses about 4 years ago. She is active and exercises regularly.

The patient's Pap smears, mammograms, and colonoscopy are up to date and test results have been normal. She has no significant medical or surgical history and no significant family history of cancer. On examination, her body mass index is normal, as is the cardiopulmonary exam. Her pelvic organ prolapse quantification system (POP-Q) score is Aa +3, Ba +3, C +4, GH 3, PB 3, TVL 10, Ap +2, Bp +2, and D +2. The patient is interested in surgical management.

What urodynamic tests would be appropriate for this patient, and what treatment options would you recommend?

Take-home points

- Robot-assisted laparoscopic sacrocolpopexy is a safe, effective, and durable treatment for advanced-stage pelvic organ prolapse.
- This procedure can completely correct stage 3 or 4 prolapse when the dissection of the anterior vaginal wall extends to the bladder neck and the dissection of the posterior vaginal wall extends to the perineal body.
- One can avoid the need for concomitant vaginal prolapse repair by gathering up stretched out vaginal epithelium while suturing to the mesh arms.
- Sacral attachment sutures should be placed in the anterior longitudinal ligament distal to the sacral promontory to avoid the L5-S1 disc.
- Unless contraindicated, lightweight macroporous polypropylene mesh is the current implant of choice.

Additional tests needed

Patients with advanced-stage pelvic organ prolapse are at an increased risk for stress urinary incontinence that may be masked by urethral "kinking" due to anatomic distortion of the periurethral support mechanism. Based on recommendations from the American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), we routinely perform a postvoid residual urine volume measurement, urinalysis, urine culture, and a prolapse reduction stress test.[24] If the urinalysis is positive for blood, then a preoperative cystoscopy would be indicated.

If stress incontinence is confirmed by reduction stress testing, the patient should be offered an anti-incontinence procedure, such as a mesh midurethral sling.

This patient's overactive bladder symptoms warrant investigation via complex urodynamic testing to allow for comprehensive counseling about her postoperative expectations.

Counseling the patient on the sacrocolpopexy option

Abdominal sacrocolpopexy initially was described in 1962 by Lane as a technique to affix the vaginal apex to the sacral promontory using a graft. Although the procedure has been modified over the years, the principles of using an implanted strengthening material to permanently attach the apex to the anterior longitudinal ligament at the sacrum has proven to be a highly effective and safe treatment, establishing it as the gold standard for apical prolapse repair.[25,26]

Dr. Culligan reports that he is a shareholder in Oragami Surgical LLC and a consultant and speaker for Coloplast and Intuitive Surgical Inc. Dr. Huber reports no financial relationships relevant to this article.

Compared with other methods of apical prolapse repair, sacrocolpopexy via any approach is superior to vaginal surgery in terms of subjective and objective outcomes. In a recent systematic review comparing apical prolapse repairs, patients who underwent a vaginal approach were more likely to report awareness of their prolapse after surgery, undergo repeat surgery, have objective recurrent prolapse, and were at increased risk for postoperative stress urinary incontinence and dyspareunia.[26] Prospective studies within our practice have shown 1-year composite subjective and objective cure rates of 94% to 95%.[27,28]

Selecting a route for sacrocolpopexy

Although sacrocolpopexy can be approached via laparotomy or conventional laparoscopy, we routinely use a robot-assisted approach, as it has been shown to be especially beneficial for complex situations, such as in patients with prior pelvic surgery, a foreshortened vagina, or obesity.[29,30]

Potential complications

Sacrocolpopexy complications are rare, especially when a minimally invasive approach is used.[31] Reported complications of minimally invasive sacrocolpopexy include gastrointestinal or genitourinary injury, bowel obstruction or ileus, incisional hernia, vascular injury, discitis or osteomyelitis, conversion to open procedure, and mesh exposure.

Vaginal mesh exposure is rare following sacrocolpopexy, but it can occur at any time following surgery.[31] Some risk factors include mesh material selection (specifically polytetrafluoroethylene [PTFE] mesh), concurrent total hysterectomy, vaginal atrophy, and smoking.[32,33] As a result, recent recommendations have advised the use of polypropylene mesh with uterine preservation or supracervical hysterectomy at the time of sacrocolpopexy.[34] In fact, supracervical hysterectomy alone appears to cut down or eliminate the risk of mesh exposure in laparoscopic sacrocolpopexy.[35]

In our practice, avoiding split-thickness vaginal dissection, employing supracervical hysterectomy techniques, and using ultralightweight mesh has resulted in mesh exposure rates approaching zero.[28]

For atrophic vaginal tissue, one can consider prescribing preoperative vaginal estrogen for 4 to 6 weeks, but this is not essential and should not routinely delay pelvic reconstructive surgery.

What type of implant material is best?

While various materials have been used as the fixation media in sacrocolpopexy, loosely knitted synthetic type I macroporous polypropylene mesh is the best choice due to its efficacy, availability, and low adverse effect profile. We recommend a lightweight mesh with a maximum weight of 25 g/m^2. Two such products currently available are the UPsylon Y-Mesh (Boston Scientific, Marlborough, Massachusetts) and Restorelle Y mesh (Coloplast, Minneapolis, Minnesota). Lightweight mesh has been proven to maintain integrity, guaranteeing a successful outcome, while reducing the "mesh load" on the attached tissue.[27,28]

Comparative studies with fascia lata or cross-linked porcine dermal grafts demonstrated inferior outcomes versus synthetic mesh, and currently the only biologic material on the market indicated for prolapse repair augmentation, ACell Pelvic Floor Matrix (ACell, Columbia, Maryland), has not been extensively tested in sacrocolpopexy.[36–38]

Vaginal anatomy restored by sacrocolpopexy

Abdominal sacrocolpopexy, specifically via a minimally invasive approach, is an effective and long-lasting treatment that should be offered to women with advanced-stage prolapse.

Using the surgical techniques described below, including attachment of the mesh along the lengths of the anterior and posterior vaginal walls and gathering up excess tissue with mesh attachment, can provide women with adequate support for the entire vagina with restoration of normal vaginal anatomy and caliber.

ON THE WEB: Ten surgical videos from Drs. Huber and Culligan at **mdedge.com/obgmanagement**

Step-by-step tips for surgical efficiency

Robotic port placement

- Place the trocars in a "W" layout for the da Vinci Si Surgical System (**FIGURE 4,** page SS10; **VIDEO 1**)

FIGURE 4 Standard trocar placement for urogynecologic procedures using the da Vinci Si Surgical System

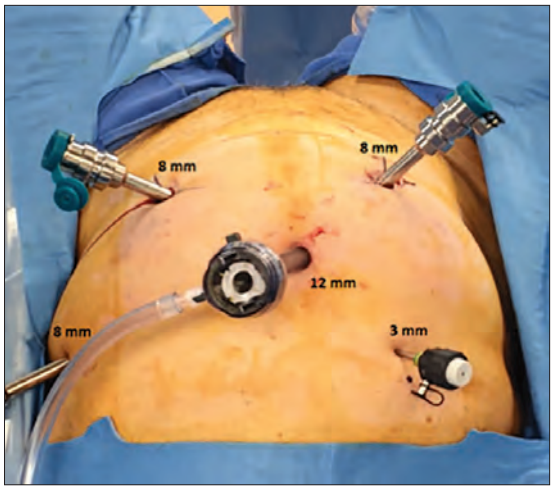
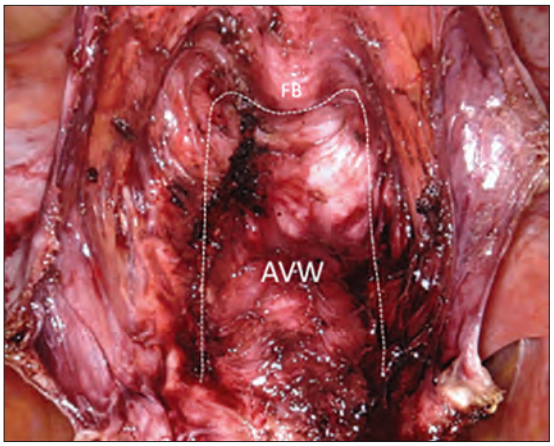


FIGURE 5 Completion of anterior vaginal wall dissection in robot-assisted laparoscopic sacrocolpopexy



Abbreviations: FB, outline of Foley bulb; AVW, anterior vaginal wall.

or in a linear layout for the da Vinci Xi Surgical System (Intuitive Surgical, Sunnyvale, California). Both Si and Xi port placement includes a 3- to 5-mm assistant port in the right upper quadrant of the abdomen.

Supracervical hysterectomy, if indicated

- Maneuver the uterus with the robotic tenaculum, which obviates the need for a uterine manipulator during the hysterectomy (**VIDEO 2**).
- Create the bladder flap just above the upper edge of the bladder to facilitate the upcoming anterior wall dissection. This helps to prevent the development of a split-thickness dissection plane.
- 1.5 to 2 cm of cervix should be left in place, and conization should be avoided.

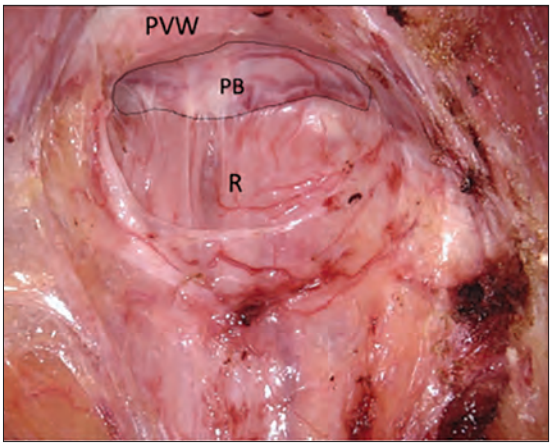
Anterior vaginal wall dissection

- The key to a good full-thickness dissection is sustained tissue traction and countertraction. The bedside assistant pulls the anterior peritoneal cut edge anteriorly for "gross" traction, and further "fine" traction can be created by pulling the areolar tissue with robotic forceps. The cervix is grasped with the tenaculum, which applies a constant midline cephalad countertraction (**VIDEO 3**).
- Sharp dissection with cold scissors allows for creation of the dissection plane, while cautery is judiciously applied only for hemostasis. If bleeding is encountered, this usually indicates that a split thickness of the vaginal wall has been created, and the surgeon should correct to the proper dissection plane.
- Dissection is made easier by taking down the bladder pillars before advancing down toward the bladder neck.
- The anterior dissection is always carried down to level of the trigone, confirmed by visualization of the Foley bulb (**FIGURE 5**).

Posterior vaginal wall dissection

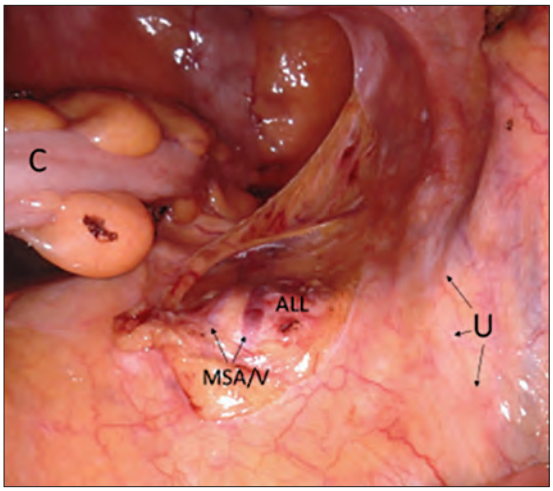
- Begin dissection just above the rectal reflection, leaving peritoneum on the posterior cervix (**VIDEO 4**).
- Extend the incision bilaterally to the uterosacral ligaments only after the correct dissection plane is confirmed by visualization of the areolar tissue.
- Apply cervical traction using the tenaculum in a cephalad midline direction, and place traction on the cut edge of the posterior peritoneum using the bipolar forceps. The tenaculum wrist must be turned away from the working instruments to avoid internal clashing.
- Completely transect the right uterosacral ligament to better facilitate the creation of a

FIGURE 6 Completion of posterior vaginal wall dissection in robot-assisted laparoscopic sacrocolpopexy



Abbreviations: PB, perineal body; PVW, posterior vaginal wall; R, rectum.

FIGURE 7 Dissection of the anterior longitudinal ligament



Abbreviations: ALL, anterior longitudinal ligament; C, colon swept medially; MSA/V, middle sacral artery and vein; U, right ureter.

contiguous peritoneal opening for burying the mesh. The remainder of the opening will be created later.

- While it is important to avoid split-thickness dissection, the vaginal plane must be "clean" (that is, without fat or adventitia) to allow for robust suturing.
- Dissection at least halfway down the posterior vaginal wall is recommended but proceeding down to the perineal body provides the most optimal support (**FIGURE 6**).

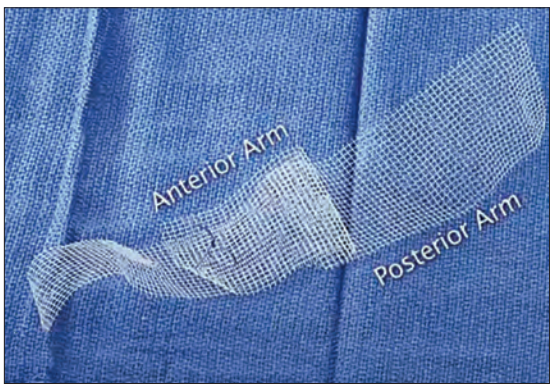
Sacral dissection

- Use a noncrushing instrument to laterally sweep the bowel to the left side, effectively "plastering" the peritoneum over the sacral promontory (**FIGURE 7; VIDEO 5**).
- Extend the superficial peritoneal incision down the right paracolic gutter halfway between the ureter and colon until it communicates with the incised posterior peritoneal edge created during the posterior dissection.
- Identify the middle sacral artery to avoid vascular injury, but there is no need to prophylactically coagulate it.

Vaginal mesh attachment

- Cut a lightweight Y-mesh to a length of 6 to 8 cm anteriorly and 8 to 11 cm posteriorly and place it into the surgical field (**FIGURE 8; VIDEO 6**). The length is determined based on the preoperative office examination and examination under anesthesia prior to starting the procedure.
- Attach the mesh securely and evenly to the anterior and posterior vaginal walls using multiple interrupted monofilament sutures. We aim to place sutures that provide mesh stability without excess vaginal wall incorporation to avoid "through-and-through" suturing.

FIGURE 8 Ultralightweight Y-mesh with the anterior arm cut to 6 cm and the posterior arm cut to 10 cm. A loose knot is placed through the anterior arm and sacral arm



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- The posterior wall suturing is performed first, starting at the perineal body and continuing cephalad (**VIDEO 7**). We find it easiest to tie the knots between the mesh and the vagina in this space.
- Suture the crotch of the Y-mesh to the cervix so that no gap exists between tissue and mesh.
- For advanced-stage prolapse with significant anterior prolapse, the stretched out vaginal epithelium can be systematically gathered up to reconfigure the tissue to conform to the desired mesh dimensions (**VIDEO 8**). This tissue remodeling is evident even at the 2- to 4-week postoperative visit.

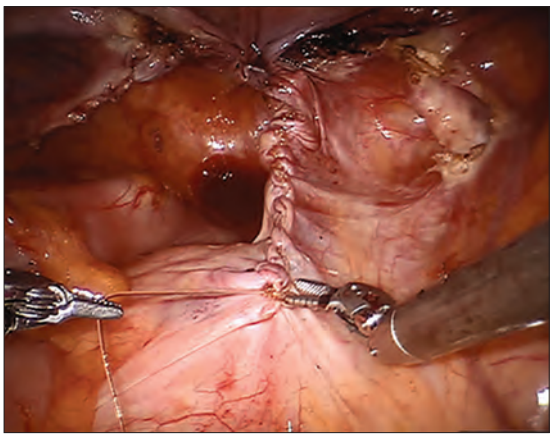
Peritoneal closure: Step 1

- Reapproximate the cut edges of peritoneum surrounding the vagina and cervix using a continuous purse-string suture of 0 Monocryl (poliglecaprone 25) on an SH needle (Ethicon, Somerville, New Jersey) with a fisherman's knot tied at the end (**VIDEO 9**). The needle passes are placed close together and close to the incised edge of the cut peritoneum.
- We typically start our peritoneal suture at the 5 o'clock position of the posterior peritoneum, extending in a clockwise direction and ultimately jumping anteriorly around the sacral arm of the mesh.
- Place the mesh within the paracolic peritoneal canal, and secure the needle for later use.

Sacral mesh attachment

- The mesh is tensioned so that a vaginal examination confirms adequate support of all the walls without excess tension or tissue banding. Some laxity of the anterior vaginal wall consistent with a mild cystocele is appropriate.
- Place 2 permanent PTFE sutures along the slope of the sacral promontory into the anterior longitudinal ligament (**VIDEO 10**). This avoids injury to the disc space that sits at the edge of the promontory. We do not advise the use of bone anchors as they increase the risk for discitis and osteomyelitis.
- Secure the mesh to the anterior longitudinal ligament without any tension. This is facilitated by creating mesh slack via cephalad pressure from a vaginal probe.

FIGURE 9 Completed robot-assisted laparoscopic sacrocolpopexy with peritoneal closure



Peritoneal closure: Step 2

- Close the remaining paracolic peritoneal incision, completely burying the mesh within the created canal (**FIGURE 9**).
- At the end of the procedure, perform a repeat vaginal exam, rectal exam, and cystoscopy.

Technique with prior total hysterectomy

- In patients with a prior total hysterectomy, place a 13 x 3.5 cm Breisky vaginal retractor and/or coated nonconductive stent (Marina Medical, Sunrise, Florida) into the vagina to delineate the anterior and posterior walls at the vaginal apex during dissection.
- Some surgeons may opt to retrograde fill the bladder to better identify its location.
- We routinely leave a segment of peritoneum attached to the dome of the vaginal apex for added tissue integrity to prevent erosion.

Transvaginal mesh: An effective, durable option for POP repair

Vincent R. Lucente, MD, MBA, and Jessica B. Ton, MD

As baseline health in the elderly population continues to improve, the number of women in the United States with symptomatic POP will increase by approximately 50% by 2050.[39] Unfortunately, after native tissue repair (NTR) the rate of prolapse recurrence is extremely high: approximately 40% regardless of approach, as demonstrated in the OPTIMAL (Operations and Pelvic Muscle Training in the Management of Apical Support Loss) trial by Barber and colleagues.[6] The authors of that clinical trial recently revealed that at the 5-year follow-up, these failure rates progressed to 70% for sacrospinous ligament fixation and 61% for uterosacral ligament suspension (data presented at the Society of Gynecologic Surgeons Annual Scientific Meeting 2018, Orlando, Florida). This establishes that NTR is not durable enough to meet the increasing physical demands of this age group and that mesh augmentation must be considered.

For patients at increased risk of prolapse recurrence, using transvaginal mesh (TVM) is the most minimally invasive approach and is an excellent option for mesh augmentation. Avoiding adverse events during placement of TVM depends largely on optimal surgical technique.[40]

The evidence on TVM versus NTR

Several studies have examined whether TVM has a measurable benefit over NTR.

A 2016 Cochrane review by Maher and colleagues included 37 randomized trials (4,023 women) that compared TVM and biologic grafts with NTR.[41] Three primary outcomes were defined: awareness of prolapse, recurrence, and repeat surgery. Compared with women treated with NTR, those treated with synthetic nonabsorbable TVM exhibited a greater reduction in awareness of prolapse (risk ratio [RR], 0.66; 95% confidence interval [CI], 0.54–0.81), decreased recurrence in the anterior compartment (RR, 0.33; 95% CI, 0.26–0.40), and decreased reoperation for prolapse (RR, 0.53; 95% CI, 0.31–0.88). The overall calculated exposure rate was 12%, with a range of 3.2% to 20.8%.[41] As we will discuss, this wide range most likely is attributed to a suboptimal, split-thickness dissection. There were no differences in other key secondary outcomes, including dyspareunia, operating time, and estimated blood loss.[41]

ON THE WEB: Surgical video from Drs. Lucente and Ton at **mdedge.com/obgmanagement**

Longitudinal studies are emerging as almost 2 decades have passed since TVM was introduced. In a study of 5-year follow-up after TVM placement, Meyer and colleagues reported that patients had continued significant improvements in both subjective and objective outcomes.[42] The mesh exposure rate was 6%, attributed to severe vaginal atrophy.[42] A 10-year observational study by Weintraub and colleagues demonstrated a recurrence rate of only 2.6% in the anterior compartment, 7.6% in the posterior (nonaugmented) compartment, and no exposures or extrusions after anterior TVM placement.[43]

Take-home points

- Active advanced age requires a durable reconstructive pelvic surgery for pelvic organ prolapse, and native tissue repair does not meet that demand.
- Mesh augmentation reduces the risk of prolapse recurrence, and vaginal placement of mesh is the most minimally invasive approach.
- Rates of exposure with transvaginal mesh would be minimized with use of a full-thickness vaginal wall dissection.
- Optimal surgical technique could be highly reproducible with better surgical training.

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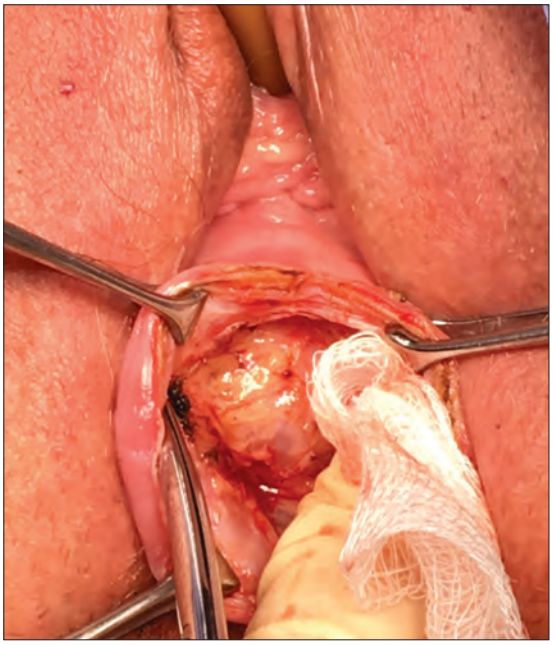
FIGURE 10 Demonstration of a full-thickness anterior vaginal wall dissection. The presence of fat denotes the true vesicovaginal space



In contrast to the Cochrane review, in the 2017 multicenter PROSPECT (Prolapse surgery: Pragmatic evaluation and randomized controlled trials) trial, Glazener and colleagues found no difference in desired outcomes with TVM compared with NTR.[44] There was an overall 6% to 7% exposure rate over 2 years.[44] To reflect "real-world" practice, however, this study was intentionally designed without rigorous standardization of surgical technique. The authors reported that "appropriately experienced surgeons" performed the procedure, but it is unclear how experience was determined given that 20% of the cases were performed by "registrars," the equivalent of US residents or fellows.[45]

The PROSPECT study protocol described the TVM procedure as "a standard repair with a nonabsorbable mesh inlay to support the stitches," implying that there was no apical attachment of the mesh to the sacrospinous ligament.[45] This is a suboptimal use of TVM because it does not address a detachment-type defect common in advanced prolapse. The PROSPECT study reinforces the need for better surgical training and standardization of the TVM procedure.[44]

How TVM compares with sacrocolpopexy

When comparing the use of TVM with sacrocolpopexy, our experience has been that TVM yields similar outcomes to sacrocolpopexy with additional benefits. We completed a 1-year retrospective cohort study comparing robot-assisted laparoscopic sacrocolpopexy (RALS) with TVM in a total of 86 patients, with both approaches performed by the same surgeon. Both treatment groups showed statistically significant improvements in nearly all functional and quality-of-life measures, including urinary symptoms, sexual function, and POP-Q scores.[40] In particular, points Aa and Ba on the POP-Q score were significantly improved with TVM as compared to RALS. This suggests that TVM can achieve both lateral and apical support, where sacrocolpopexy addresses only the apex.[40] This has clinical significance when considering DeLancey and colleagues' dynamic magnetic resonance imaging study, which demonstrated advanced prolapse results from both lateral and apical detachment.[46] In addition, TVM placement also was considerably faster than RALS by approximately 96 minutes and could be performed using regional anesthesia. Only 1 mesh exposure in each study arm was reported.[40]

Finally, as with other vaginal procedures, patients who undergo TVM placement require minimal to no pain medication postoperatively and report faster return to daily activities. Almost none of our patients require narcotics, which is a significant benefit in the face of the ongoing national opioid crisis.

Gutman and colleagues compared laparoscopic mesh hysteropexy with TVM; they demonstrated comparable cure rates and, again, significantly longer operative times for the laparoscopic approach (174 vs 64 minutes; $P<.0001$).[47] This multicenter study reported mesh exposure rates of 2.7% for laparoscopy and 6.6% for TVM,[47] again likely due to a split-thickness dissection.

Safety of TVM depends on the surgeon factor

Because of the reported complications associated with TVM, in 2011 the US Food and Drug Administration (FDA) issued an update on the safety and efficacy of TVM augmentation and mandated

postmarket studies.[48] While we do not dispute that the mesh exposure rates were accurate at the time the FDA document was issued, we recognize that exposure has been erroneously attributed to inherent properties of the mesh.

Mesh exposure rates reported in the literature vary widely, ranging from 0% to 30%, even when surgeons used identical mesh products.[49] This clearly establishes that the main contributing variable is surgical technique. It is critically important to recognize the "surgeon factor" as a confounder in trials that compare surgical procedures.[50] Studies on TVM have shown that low-volume surgeons had significantly higher reoperation rates, while high-volume surgeons achieved a 41% reduction in reoperations.[51,52] When TVM is performed by expert surgeons, the reported mesh exposure rates for TVM are noticeably lower.[40,42,43,53,54]

Decreasing mesh exposure rates would reduce the most common adverse event associated with TVM, thus improving its safety. The critical step to successful TVM placement is the initial dissection. Gynecologists traditionally have performed a split-thickness, colporrhaphy-style dissection to place the mesh within the layers of the vaginal wall.[55] Placement within these planes, however, is too superficial and increases the risk of exposure. By contrast, by consistently performing a full-thickness vaginal wall dissection (**FIGURE 10**) and placing the mesh in the true vesicovaginal space,[56] we have achieved a TVM exposure rate as low as 0% to 3%.[40,54] If we can standardize the dissection component across our subspecialty, the rate of mesh exposure undoubtedly will decrease.

The PROSPECT investigators readily admitted what the study was not: a trial conducted "exclusively by the most experienced surgeons in the highest volume centres…with a highly protocolised technique."[44] In reality, that is the kind of rigorous study on TVM that our subspecialty demands. We must hold ourselves accountable and ensure that only the most qualified surgeons are placing TVM.

Keep the mesh option available

We support the position of the American Urogynecologic Society in opposing an outright ban of TVM because such a restriction would deny our patients access to an effective, durable, and minimally invasive approach for prolapse repair.[57] ■

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Patient experience: It's not about satisfaction

What happens when an ObGyn is married to the chief experience officer?

James I. Merlino, MD, and Amy A. Merlino, MD

My pager went off 20 minutes into my case. The circulating nurse announced that it was the chief of staff's office, and as I migrated over to the phone, everyone was wondering what I had done to warrant a call from the boss. The nurse held the phone to my ear and Dr. Joe Hahn, a neurosurgeon and second-in-command at Cleveland Clinic, congratulated me: "You're it," he said. I thanked him and went back to work. My scrub tech wanted to know what happened. I told him I was just appointed chief experience officer at Cleveland Clinic. With a befuddled look, he asked what that meant. I said I wasn't sure.

Jim gets a fast lesson on how to lead patient experience

Patient experience was a signature issue for Dr. Toby Cosgrove, our then president and chief executive officer. Although the Clinic was revered for its high-quality care, patients did not always like going there. Dr. Cosgrove passionately believed that providing a high-quality experience was as important as the best medical care, and that the experience at the Clinic needed to be improved. Another physician had held the role of chief experience officer before me, but she came from outside the system and was not practicing, which proved to be a challenge in the Clinic's physician-dominated culture. Dr. Cosgrove wanted a physician who "grew up" in the organization to lead this initiative.

When I left my initial interview with Dr. Cosgrove, I could not define patient experience, did not know what HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) was—at the time were in the 10th percentile—and frankly had no idea how I would move a culture of 45,000 people, including 3,000 employed physicians, to embrace patient-centricity. By the time I left the Clinic in 2015, however, we had pushed our experience scores to the top quartile, realigned our culture, and had become world renown for patient experience.[1]

I knew intuitively that improving the patient experience was the right thing to do. In 2004, my father had died at the Clinic from surgical complications; his experience had been terrible. At that time, we did not use the term *experience,* but based on the items that hospitals are graded on today, my father would have failed us on all of them.

What *is* patient experience?

Patient experience is not about making people happy. Fundamentally, it is about delivering safe, high-quality, patient-centric care. A 2017 Press Ganey analysis of publicly reported data from the Centers for Medicaid and Medicare demonstrated that when performance on experience measures is high, safety and quality also are high.[2] Similarly, in 2015, *JAMA* published an article using data from the National Surgical Quality Improvement Project demonstrating a significant association between patient experience scores and several objective measures of surgical quality, including mortality and complications.[3]

In my new role, I mercilessly told my father's story, changed the narrative to include safety and quality, and asked my physician colleagues for their help to improve patient experience. People in health care pay very close attention to what physicians do and say, and I needed the doctors to "own it" if we were going to implement the desired change.

I also had to convince them to see themselves on the "other side." It was not just a matter of "treating patients the way you would want to be treated." It was about putting yourself in your patients' shoes—having empathy for what they are

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experiencing and recognizing that you or a family member could be sitting in that bed. Before my father was ill, I had never been on the other side so intimately, and it was an eye-opening experience.

Retooling communication competency

For the physicians, we zeroed in on helping them improve how they communicate with patients. Communication is a high-value target for experience improvement, and it directly influences safety and quality. We produced a physician-centric communication guide that provided useful tips (see "Practical tips to help physicians improve communication with patients"). We made communication scores transparent. In addition, working with the American Academy on Communication in Healthcare (AACH), we developed a program specifically designed to help physicians improve their communication skills and practice management.[4] The outcome was not only better scores but also higher physician engagement and lower burnout.[5]

Keeping it real

Being married to another member of the medical staff—a strong-willed and opinionated one at that—ensured that my strategic approach to improving patient experience was grounded. It gave me a safe place to test ideas and concepts, which in turn allowed me to keep my instincts framed and relevant to the needs of key stakeholders, particularly the physicians.

The ObGyn wife tells her side

When my husband was appointed chief experience officer, I naturally was happy for his accomplishment but admitted that I was not sure exactly what it meant. What was he going to be doing? Would he give up surgery, which he loved?

The experience "thing" always had been fuzzy to me. I equated experience with satisfaction, and I saw my primary role as taking care of patients, not making them happy. I believed that I had great patient relationships, so what else did I need to know to contribute to this work? The connection to safety and quality did resonate with me, though, and it made talking about patient experience more tangible.

When Jim started teasing apart what steps needed to be taken, improving the culture seemed like an obvious focus. One thing was clear: He would need to get the physicians on board by helping them to see the practical importance of this work. It could not be gimmicky or too touchy-feely. The work had to be relevant and tangible to their everyday practice. One thing he said struck a chord: "Everyone comes to health care to help people, and we all believe we are the best we can be, but clearly there are opportunities to improve, and evolve our skills." I started to consider specific circumstances in which that made sense.

Practical tips to help physicians improve communication with patients

- Introduce yourself and your role
- Address the patient by name and use common courtesy
- Make nursing your partner
- Ensure that the patient knows and understands the plan of care
- Explain what the patient can expect (tests, procedures, consultations)
- Address questions
- Understand that house staff, care partners, and consultants impact your communication scores
- Respect the patient's privacy
- Be aware of what you do and say in front of patients
- Include the patient's family when appropriate
- Ask patients and visitors how they are being treated and if they need anything
- Discuss pain management and set expectations
- When necessary, apologize—try to right a wrong
- Role model good behavior and address bad behavior

Practice to be a better communicator

Improving physician communication was a top priority. I believed that I was a very good communicator, so I was not sure I would learn much from participating in a required day-long session designed by the AACH.

For this program we convened in small groups of 8 to 10 physicians, and each person paired with a partner. The course provided an important framework that would help us to better organize the patient encounter, an approach that no one had ever taught me. It showed me how to leverage the patient's chief

complaint to empower her to set the agenda. This would avoid unnecessary and inefficient conversational tangents, such as the doorknob question—when the patient brings up the real reason for the visit as you are leaving the exam room.

The course also taught me that while I was a good communicator, I was not efficient. I learned how to listen more effectively. Notably, how we manage patients and how we communicate are learned skills, just like mastering a new surgical procedure. High performance requires thoughtful review and practice.

Work on relationship skills

I had professional colleagues who were difficult to work with or, as I knew from covering for them, had terrible relationships with patients. These interactions made my job harder and directly influenced patient care. I always found it distasteful to hear, "Dr. X treats people very poorly, but he or she is such a great doctor." Should not doctors be both excellent at their work and excel at the human relationship side of the business? Maybe we did need to work on certain things.

An early Cleveland Clinic initiative was to immerse every employee, including physicians, in a half-day appreciative-inquiry exercise. This entailed sitting around a table with other randomly selected caregivers—a nurse, valet, environmental service worker, administrator—and discussing various topics, such as our role in the organization, teamwork, and the servant-leader philosophy. Going into this exercise, I was skeptical. But going through it fostered a deeper understanding of how we all need to work better together to drive safe, high-quality patient care. It made me reflect on what patients go through every day and the critical contribution each team member makes. The program made me think about what we do and created greater appreciation and mindfulness of our work.

Think empathy

One of the most impactful efforts was getting people to understand and appreciate being on the other side of health care. The patient experience team crafted an empathy video that showcased people—patients, families, caregivers, physicians—and their thoughts as they experienced the other side of health care. The video frames what they are thinking about in the moment and is a powerful reminder that each person has something happening in their life that affects their daily experiences. The empathy video has been viewed by millions around the world. (See "Empathy: The human connection to patient care," at https://www.youtube.com/watch?v=cDDWvj_q-o8.)

Together we embraced the work

Amy and I shared a unique perspective on this work as the leader of the experience improvement initiative, married to a person experiencing it. We both came to realize that we did not know all there is to know about how to deliver high-quality patient care. Improving experience is both complex and highly nuanced, and it is a vital component of what we do as physicians. The Clinic's efforts moved the organization to high performance, and everyone played a role. However, we would not have succeeded without the engagement of physician leaders.

Making patients and families happy was never part of the equation. It is about reducing patient suffering and delivering safe, high-quality care in an environment where people feel cared for. That is what the people we serve desire, and it is what we want for ourselves. Although there will always be doubters, especially among physicians, of the importance of patient experience, we must never lose sight that this is the right thing to do for our patients, our families, and ourselves. ■

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VALUE-BASED MEDICINE: PART 4

It costs what?! How we can educate residents and students on how much things cost

In resident education, understanding the business of medicine in a value-based health care system is imperative

K. Nathan Parthasarathy, MD, and Mark B. Woodland, MS, MD

"Why are you ordering a CBC on the patient when her white blood cell count, hemoglobin, and platelets have been stable for the past 3 days?" sternly inquired the attending gynecologic oncologist. "Don't order tests without any clinical indication. If she is infected or bleeding, there will be signs and thus an indication to order a CBC. The physical exam is your test." There was an authoritative pause before he invoked the "value-based care" maxim.

For many residents who graduated in the past decade, education in value-based care and alternative payment models (APMs) was cobbled together from experience, demonstrated by attendings who labeled it as such, and from rare didactic education classroom sessions and inpatient environments.

In today's health care environment, professional survival requires the ability to successfully deliver high-value care to patients. Attendings often illustrate and champion how to do this by using patient care to highlight the definition: Value = Quality ÷ Cost.

For residency education programs to create the ObGyns of the future, they must teach trainees what they will be evaluated on and held accountable for.[1] Today's clinicians will have to take responsibility for reigning in health care costs from the fee-for-service era, which in the United States have snowballed into one of the unhealthiest cost-to-outcomes ratios worldwide. Residents will be required to understand not only value but also areas in which they can influence the cost of care and how their outcome metrics are valued.

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Modifiable factors in value-based care

As mentioned, value is defined by the equation, Value = Quality ÷ Cost. The granularity of these terms helps clarify the depth and the multitude of levels that clinicians can modify and influence to achieve the highest value.

IN THIS ARTICLE

Quality, as defined by the National Academy of Medicine, includes[2]:

- effectiveness: providing care processes and achieving outcomes as supported by scientific evidence
- efficiency: maximizing the quality of a comparable unit of health care delivered or unit of health benefit achieved for a given unit of health care resources used
- equity: providing health care of equal quality to those who may differ in personal characteristics other than their clinical condition or preferences for care
- patient-centeredness: meeting patient needs and preferences and providing education and support
- safety: actual or potential bodily harm
- timeliness: obtaining needed care while minimizing delays.

From electronic health records, which were mandated in the Patient Protection and Affordable Care Act of 2010, offices, hospitals, and medical systems have gained robust databases of mineable information. Even data abstraction from paper records has been made easier, allowing better reflection of practitioner-based delivery of care.

FAST TRACK

When broadly explored, cost can be broken down into cost to the patient, the health care system, and society

Understanding cost breakdown in the overall value equation

With regard to value-based care, cost is generally related to money. When broadly explored, however, cost can be broken down into cost to the patient, the health care system, and society this way:

- patient: time spent receiving evaluation and management from a clinician; money spent for family care needs while undergoing management; money spent for procedures and tests; wages lost due to appointments
- health system: preventive services versus costly emergency room visit; community-based interventions to improve population health
- society: cost to tax payers; equitable distribution of vital resources (for example, vaccines); prevention of iatrogenic antibiotic resistance.

To understand how physicians are paid, it is important to see how payers value our services. The Centers for Medicare and Medicaid Services states that it is "promoting value-based care as part of its larger quality strategy to reform how health care is delivered and paid for." In 2018, the US Department of Health and Human Services is striving to have half of Medicare payments in APMs.[3]

It is the physician's responsibility to recognize that costs to the patient, payer, health system, and society can compete with and directly influence the outcome of each other. For example, because the patient pays an insurance premium to participate in a risk pool where cost-sharing is the primary cost-containment strategy, poor-value interventions can directly translate into increased premiums, copayments, or deductibles for the entire pool.[4]

By clearly identifying the different variables involved in the value-based care equation, residents can better understand their responsibility in their day-to-day work in medicine to address value, not just quality or cost. Clarifying the tenets of value-based care will help guide educators in identifying "teaching moments" and organizing didactic sessions focused on practical implementation of value.

Less is more

In our opening anecdote, the attending shows how curbing overuse of resources can increase the value of care delivered. But that example illustrates only one of the many levels on which educators can help residents understand their impact on value. A multidisciplinary education that incorporates outpatient and inpatient pharmacists, social workers, occupational therapists, pelvic floor physiotherapists, office staff, billing specialists, operating room (OR) technologists, and others can be beneficial in learning how to deliver high-value care.

Value-based interventions at work

In the discussion that follows, we illustrate how residents can identify, evaluate, and put

into practice value-based interventions that can occur at multiple levels.

Antibiotic selection. Resident choices for outpatient antibiotics can severely affect patient adherence. Subtle differences in the formulation of certain antibiotics affect the price and thus pose a significant potential obstacle. Judicious use of inexpensive drug formulations with fewer dosing frequencies can help patients engage in their own care.

Knowing the pharmacologic difference between doxycycline hyclate and doxycycline monohydrate, for example, is to know the difference between esoteric salts—undeniably worthless information with regard to successfully treating a patient's infection. Knowing that one formula is on the bargain formulary at the patient's local pharmacy, or that one drug requires twice-daily dosing versus 4-times-daily dosing, however, can mean the difference between the patient's adherence or nonadherence to your expert recommendation.

Contraception options. Contraceptives pose a challenge with respect to value because of the myriad delivery systems, doses, and generic formulations available. There are dozens of oral contraceptive pills (OCPs) on the market that vary in their dosing, phasic nature (monophasic, multiphasic), iron content in the hormone-free week, and different progestogens for different conditions (such as drospirenone for androgen excess).

When weighing contraceptive options, the clinician must look at value not only from a cost perspective but also from an effectiveness perspective. The desired outcome in this scenario is preventing unwanted pregnancy with ideal or typical contraceptive use at the most inexpensive price point. When working within the value equation, the clinician must individualize the prescribed contraceptive to one that is most acceptable to the patient and that optimizes the various costs and quality measures. "Cost" can mean the cost of OCPs, menstrual control products, backup contraception, failed or unwanted pregnancy management, or suffering lost wages from

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missed days of work from, for example, dysmenorrhea. "Quality" can mean a low contraceptive failure rate, predictable cyclicality, the need for patient administration and the risk of forgetting, and the need for backup contraceptives.

In comparing the subdermal contraceptive implant (which can cost up to $1,300 every 3 years, equivalent to $36.11 per month) with OCPs (which can cost as low as $324 for 3 years for an ethinyl estradiol and norgestimate combination, or $9 per month), the OCPs significantly outweigh the implant in terms of cost. When comparing failure rates, the degree of patient intervention, and decreased use of menstrual control products due to amenorrhea, the subdermal contraceptive wins. As we know, long-acting reversible contraception (LARC), including the intrauterine device (IUD) and subdermal implant, is the most effective but often the most expensive contraceptive option.[5] When cost is evaluated from a global perspective, as highlighted by the adage "an IUD is cheaper than a baby," the LARC's value is derived from its overall high effectiveness and low cost.

If the patient elects to choose OCPs, the clinician should direct the prescription to a pharmacy that has discounted generic pills on its formulary. Generic OCPs have a low-cost burden without loss of efficacy, thus providing maximal value.[6] This requires an intimate knowledge of the local pharmacies and what their formularies provide. Sometimes the patient will need to drive out of her way to access cost-effective, quality medications, or the high-value option.

Surgery considerations. Judicious instrument selection in the OR can decrease overall operative costs. While most advanced sealing and cutting instrumentation is for single use, for example, it also can be reprocessed for reuse. Although the cost of reprocessed, single-use instruments is lower, studies evaluating the quality of these instruments "found a significant rate of physical defects, performance issues, or improper decontamination."[7]

Marketing largely has driven physician choice in the use of certain vessel sealing and cutting devices, but there has yet to be evidence that using any one device actually improves performance or outcomes, such as length of surgery, blood loss, or postoperative complications. Technology companies that create these instruments likely will have to start designing studies to test performance and outcomes as they relate to their devices to persuade hospital systems that using their products improves outcomes and reduces costs.

While learning laparoscopic hysterectomy, residents may see that some attending surgeons can complete the entire procedure with monopolar scissors, bipolar forceps, and laparoscopic needle drivers, while other surgeons use those instruments plus others, such as a LigaSure instrument or a Harmonic scalpel. With outcomes being the same between these surgeons, it is reasonable for hospitals to audit each surgeon using the Value = Quality ÷ Cost equation and to seek data to describe why the latter surgeon requires additional instrumentation.

Residency training poses a unique opportunity for physicians to learn numerous ways to perform the same procedure so they can fill their armamentarium with various effective techniques. Residency also should be a time in which proficiency with basic surgical instrumentation is emphasized. Attending physicians can help residents improve their skills, for example, by having them use only one advanced sealing and cutting device, or no device at all. This practice will make the trainee better able to adapt to situations in which an advanced device may fail or be unavailable. Future performance metrics may evaluate the physician's cost effectiveness with regard to single-use instruments during routine surgical procedures.

Standardized order sets. Evidence-based order sets help in the management of pneumonia, sepsis, deep vein thrombosis prophylaxis, and numerous other conditions. In the era of computerized physician order entry systems (CPOEs), a resident needs to enter just a few clicks to order all necessary tests, interventions, and imaging studies for a condition. In one fell swoop, orders are placed not only for admission but also for the

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Residency training poses a unique opportunity for physicians to learn numerous ways to perform the same procedure and thus fill their armamentarium with various effective techniques

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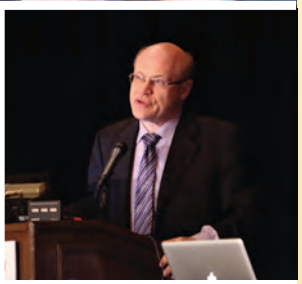

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patient's entire hospitalization. The paradox of the order set is that it uses a template to deliver individualized patient-centered care.

In the age of enhanced recovery pathways after surgery, we see patients who undergo a hysterectomy being discharged home directly from the postoperative anesthesia care unit (PACU). Generally, follow-up laboratory testing is not ordered on an outpatient basis. If, however, the patient needs to remain in the hospital for social reasons (such as delayed PACU transfer, transportation, weather), she receives the standardized orders from the post hysterectomy order set: a morning complete blood count ($55) with a basic metabolic panel ($45). As an academic exercise, the order set may help residents learn which orders they must consider when admitting a postoperative hysterectomy patient, but overuse of order sets can be a setback for a value-based care system.

Evaluating competence in value-based care

Research is an integral component of all residency programs accredited by the Accreditation Council for Graduate Medical Education (ACGME). The implementation of value-based care—with all its nuances, quality metrics, and cost parameters—creates a space for resident-led studies to contribute to peer education. The ACGME's Obstetrics and Gynecology Milestones project was developed to assess the development of ObGyn residents' competence as they progress through training. Despite national laws tying reimbursements to value-based care, there is no mention of value as it relates to the basic formula, Value = Quality ÷ Cost, in the project.

With the nuances that value-based care offers, it would behoove the Council on Resident Education in Obstetrics and Gynecology of the American College of Obstetricians and Gynecologists to incorporate a method of evaluation to determine competence in this evolving field.

Care also must be individualized

Academic ObGyns and instructors should focus their pedagogy not only on value-based care but also on individualized care that will maximize desired outcomes for each patient. Incorporating multidisciplinary didactics, focused research, and a 360-degree evaluation in the residency curriculum will create new ObGyns who are known for successfully delivering high-value care. ●

FAST TRACK

Academic ObGyns and instructors should focus their pedagogy not only on value-based care but also on individualized care that will maximize desired outcomes for each patient

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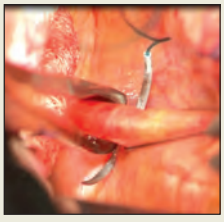
Uterosacral ligament colpopexy: The way we do it

TONYA N. THOMAS, MD; LAUREN N. SIFF, MD; AND MARK D. WALTERS, MD



In this video, the authors demonstrate their technique for performing uterosacral ligament colpopexy including visualization and isolation of the uterosacral ligaments, identification of important surrounding anatomic structures, suture placement through the uterosacral ligaments, suture anchoring to the vaginal cuff, and suspension of the apex. Also described are techniques to avoid ureteral kinking and strategies for management, and concomitant procedures for prolapse and urinary incontinence to restore normal anatomy and function.

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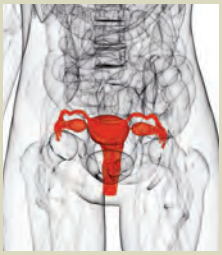

Failure to find cancer earlier; patient dies: $4.69M verdict

ON JULY 19, a 26-year-old woman presented to the emergency department (ED) with abnormal vaginal bleeding 3 months after giving birth. She was found to have endometrial thickening and an elevated ß human chorionic gonadotropin level. An ObGyn (Dr. A) assumed that the patient was having a miscarriage and sent her home.

On July 30, when the patient returned to the ED with continued bleeding, lesions on her cervix and urethra were discovered. A second ObGyn, Dr. B, addressed the bleeding, removed the lesion, and ordered testing. On August 17, the patient saw a third ObGyn (Dr. C), who did not conduct an examination.

Days later, the patient suffered a brain hemorrhage that was suspicious for hemorrhagic metastasis. After that, stage IV choriocarcinoma was identified. Although she underwent chemotherapy, the patient died 18 months later.

ESTATE'S CLAIM: All 3 ObGyns failed to take a proper history, conduct adequate examinations, and order appropriate testing. Even at stage IV, 75% of patients with choriocarcinoma survive past 5 years. The stroke rendered chemotherapy less effective and substantially contributed to the patient's death. Failure to diagnose the cancer before the stroke allowed the disease to progress beyond the point at which the patient's life could be saved.

DEFENDANTS' DEFENSE: The ObGyns and hospital claimed that appropriate care was provided and that they were not negligent in failing to consider the diagnosis of a very rare form of cancer.

VERDICT: A $4.69 million New Jersey verdict was returned, with all 3 physicians held partially liable.

When should delivery have occurred? $4M verdict

CONCERNED THAT HER FETUS had stopped moving, a mother presented to the ED. Results of fetal heart-rate (FHR) monitoring ordered by the attending ObGyn (Dr. A) were nonreassuring. A second ObGyn (Dr. B) ordered a fetal biophysical profile (BPP); the score was 2 points. Although a low score usually results in immediate delivery, Dr. B consulted a maternal-fetal medicine (MFM) specialist. After another fetal BPP scored 8 points, the mother was discharged.

The next day, the mother called her ObGyn (Dr. C), who told her to immediately come to his office. A fetal BPP scored 4 points, with nonreassuring fetal heart sounds.

The mother was transported to the hospital for emergency cesarean delivery. At birth, the baby was blue, not breathing, and had meconium in his lungs. After 6 minutes' resuscitation, he began breathing. The child has an hypoxic brain injury.

PARENTS' CLAIM: Based on the nonreassuring FHR readings when the mother first reported lack of fetal movement, and a BPP of 2 points, an immediate cesarean delivery should have been performed. If the child had been delivered in a timely manner, he would have escaped a brain injury. At the very least, the mother should have been kept in the hospital for monitoring.

DEFENDANTS' DEFENSE: Drs. A and B and the hospital claimed that the child did not have a hypoxic injury; he had gastroschisis.

VERDICT: A $4,098,266 New York verdict was returned.

Hot speculum burns patient: $547,090 award

A 54-YEAR-OLD WOMAN underwent a hysterectomy performed at a government-operated hospital. After she was anesthetized and unconscious, a second-year resident took a speculum that had been placed in the sterile field by a nurse, and inserted it in the patient's vagina.

When the patient awoke from surgery, she discovered significant burns to her vaginal area, perineum, anus, and buttocks.

PATIENT'S CLAIM: The speculum had just been removed from the autoclave and was very hot. The patient incurred substantial medical bills to treat her injuries and was unable to work for several months. She sued the hospital and resident, alleging

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

PHOTO: SHUTTERSTOCK

error by the nurse in placing the hot speculum in the sterile field without cooling it or advising the resident that it was still hot. The resident was blamed for using the speculum without confirming that it was hot.

DEFENDANTS' DEFENSE: The resident claimed that she reasonably relied on the nurse to not place a hot instrument in the surgical field without first cooling it. The hospital, representing the nurse, denied fault, blaming the resident for not checking the speculum.

VERDICT: A $547,090 Louisiana verdict was awarded by a judge against the resident and the hospital, but it was halved by comparative fault to $273,545.

Second twin's birth delayed; brain damage: $1.5M settlement

A 35-YEAR-OLD WOMAN was 30 weeks' pregnant with twins when she was admitted to a hospital at high risk. At 36 weeks' gestation, she went into labor. A resident called the ObGyn to report that the patient was ready to deliver and waiting to push. The ObGyn advised that he was tied up in another procedure and for the mother to wait until he could get there.

Forty minutes later, the ObGyn arrived and the mother was allowed to push. A first-year resident delivered the first twin without incident. The second twin shifted from a cephalic presentation to a double footling breech presentation and his FHR reflected severe bradycardia. Under the supervision of the ObGyn, a fourth-year resident managed the delivery, which took 28 minutes. The second twin's Apgar scores were low. He was intubated and transferred to a children's hospital for brain cooling.

PARENT'S CLAIM: Although excellent care following the birth reduced the degree of brain damage, the delay caused by the ObGyn's late arrival was responsible for the child's injuries.

PHYSICIAN'S DEFENSE: In pretrial findings, a panel of physicians reported that the child did not have a qualifying injury. However, the case settled before the trial began.

VERDICT: A $1.5 million Virginia settlement was reached. ●

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ParaGard® should not be placed when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy
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3. Acute pelvic inflammatory disease, or current behavior suggesting a high risk for pelvic inflammatory disease
4. Postpartum endometritis or postabortal endometritis in the past 3 months
5. Known or suspected uterine or cervical malignancy
6. Genital bleeding of unknown etiology
7. Mucopurulent cervicitis
8. Wilson's disease
9. Allergy to any component of ParaGard®
10. A previously placed IUD that has not been removed

WARNINGS

1. Intrauterine Pregnancy

If intrauterine pregnancy occurs with ParaGard® in place and the string is visible, ParaGard® should be removed because of the risk of spontaneous abortion, premature delivery, sepsis, septic shock, and, rarely, death. Removal may be followed by pregnancy loss.

If the string is not visible, and the woman decides to continue her pregnancy, check if the ParaGard® is in her uterus (for example, by ultrasound). If ParaGard® is in her uterus, warn her that there is an increased risk of spontaneous abortion and sepsis, septic shock, and rarely, death. In addition, the risk of premature labor and delivery is increased.

Human data about risk of birth defects from copper exposure are limited. However, studies have not detected a pattern of abnormalities, and published reports do not suggest a risk that is higher than the baseline risk for birth defects.

2. Ectopic Pregnancy

Women who become pregnant while using ParaGard® should be evaluated for ectopic pregnancy. A pregnancy that occurs with ParaGard® in place is more likely to be ectopic than a pregnancy in the general population. However, because ParaGard® prevents most pregnancies, women who use ParaGard® have a lower risk of an ectopic pregnancy than sexually active women who do not use any contraception.

3. Pelvic Infection

Although pelvic inflammatory disease (PID) in women using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs within 20 days following insertion. Therefore, the visit following the first post-insertion menstrual period is an opportunity to assess the patient for infection, as well as to check that the IUD is in place. Since pelvic infection is most frequently associated with sexually transmitted organisms, IUDs are not recommended for women at high risk for sexual infection. Prophylactic antibiotics at the time of insertion do not appear to lower the incidence of PID.

PID can have serious consequences, such as tubal damage (leading to ectopic pregnancy or infertility), hysterectomy, sepsis, and, rarely, death. It is therefore important to promptly assess and treat any woman who develops signs or symptoms of PID.

Guidelines for treatment of PID are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia at www.cdc.gov or 1-800-311-3435. Antibiotics are the mainstay of therapy. Most healthcare professionals also remove the IUD.

The significance of actinomyces-like organisms on Papanicolaou smear in an asymptomatic IUD user is unknown, and so this finding alone does not always require IUD removal and treatment. However, because pelvic actinomycosis is a serious infection, a woman who has *symptoms* of pelvic infection possibly due to actinomyces should be treated and have her IUD removed.

4. Immunocompromise

Women with AIDS should not have IUDs inserted unless they are clinically stable on antiretroviral therapy. Limited data suggest that asymptomatic women infected with human immunodeficiency virus may use intrauterine devices. Little is known about the use of IUDs in women who have illnesses causing serious immunocompromise. Therefore these women should be carefully monitored for infection if they choose to use an IUD. The risk of pregnancy should be weighed against the theoretical risk of infection.

5. Embedment

Partial penetration or embedment of ParaGard® in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.

6. Perforation

Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove ParaGard® promptly, since the copper can lead to intraperitoneal adhesions. Intestinal penetration, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

7. Expulsion

Expulsion can occur, usually during the menses and usually in the first few months after insertion. There is an increased risk of expulsion in the nulliparous patient. If unnoticed, an unintended pregnancy could occur.

8. Wilson's Disease

Theoretically, ParaGard® can exacerbate Wilson's disease, a rare genetic disease affecting copper excretion.

PRECAUTIONS

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

1. Information for patients

Before inserting ParaGard® discuss the Patient Package Insert with the patient, and give her time to read the information. Discuss any questions she may have concerning ParaGard® as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

2. Insertion precautions, continuing care, and removal.

3. Vaginal bleeding

In the 2 largest clinical trials with ParaGard®, menstrual changes were the most common medical reason for discontinuation of ParaGard®. Discontinuation rates for pain and bleeding combined are highest in the first year of use and diminish thereafter. The percentage of women who discontinued ParaGard® because of bleeding problems or pain during these studies ranged from 11.9% in the first year to 2.2 % in year 9. Women complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue ParaGard®.

4. Vasovagal reactions, including fainting

Some women have vasovagal reactions immediately after insertion. Hence, patients should remain supine until feeling well and should be cautious when getting up.

5. Expulsion following placement after a birth or abortion

ParaGard® has been placed immediately after delivery, although risk of expulsion may be higher than when ParaGard® is placed at times unrelated to delivery. However, unless done immediately postpartum, insertion should be delayed to the second postpartum month because insertion during the first postpartum month (except for immediately after delivery) has been associated with increased risk of perforation.

ParaGard® can be placed immediately after abortion, although immediate placement has a slightly higher risk of expulsion than placement at other times. Placement after second trimester abortion is associated with a higher risk of expulsion than placement after the first trimester abortion.

6. Magnetic resonance imaging (MRI)

Limited data suggest that MRI at the level of 1.5 Tesla is acceptable in women using ParaGard®. One study examined the effect of MRI on the CU-7® Intrauterine Copper Contraceptive and Lippes Loop™ intrauterine devices. Neither device moved under the influence of the magnetic field or heated during the spin-echo sequences usually employed for pelvic imaging. An in vitro study did not detect movement or temperature change when ParaGard® was subjected to MRI.

7. Medical diathermy

Theoretically, medical (non-surgical) diathermy (short-wave and microwave heat therapy) in a patient with a metal-containing IUD may cause heat injury to the surrounding tissue. However, a small study of eight women did not detect a significant elevation of intrauterine temperature when diathermy was performed in the presence of a copper IUD.

8. Pregnancy

ParaGard® is contraindicated during pregnancy.

9. Nursing mothers

Nursing mothers may use ParaGard®. No difference has been detected in concentration of copper in human milk before and after insertion of copper IUDs. The literature is conflicting, but limited data suggest that there may be an increased risk of perforation and expulsion if a woman is lactating.

10. Pediatric use

ParaGard® is not indicated before menarche. Safety and efficacy have been established in women over 16 years old.

ADVERSE REACTIONS

The most serious adverse events associated with intrauterine contraception are discussed in **WARNINGS** and **PRECAUTIONS**. These include:

Intrauterine pregnancy	Pelvic infection
Septic abortion	Perforation
Ectopic pregnancy	Embedment

The following adverse events have also been observed. These are listed alphabetically and not by order of frequency or severity.

Anemia	Menstrual flow, prolonged
Backache	Menstrual spotting
Dysmenorrhea	Pain and cramping
Dyspareunia	Urticarial allergic skin reaction
Expulsion, complete or partial	Vaginitis
Leukorrhea	

CooperSurgical

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This brief summary is based on the ParaGard full prescribing information dated September 2014.

PAR-41287 01/18

ASK HER IF SHE WANTS A birth control that's HORMONE FREE

PARAGARD®
(intrauterine copper contraceptive)—
the only highly effective, reversible birth control that is *completely hormone free*[1]

- **100% hormone free**
- **94% patient satisfaction*[2]**
- **Removable whenever she decides†**
- **>99% effective for up to 10 years**

56% of women reported that they had **concerns with hormones** in their birth control‡[3]

Tell her she has a hormone-free choice—tell her about PARAGARD.

INDICATION

PARAGARD is indicated for intrauterine contraception for up to 10 years.

IMPORTANT SAFETY INFORMATION

- **PARAGARD does not protect against HIV/AIDS or other sexually transmitted infections (STI).**
- PARAGARD must not be used by women who are pregnant or may be pregnant as this can be life threatening and may result in loss of pregnancy or fertility.
- PARAGARD must not be used by women who have acute pelvic inflammatory disease (PID) or current behavior suggesting a high risk of PID; have had a postpregnancy or postabortion uterine infection in the past 3 months; have cancer of the uterus or cervix; have an infection of the cervix; have an allergy to any component; or have Wilson's disease.
- The most common side effects of PARAGARD are heavier and longer periods and spotting between periods; for most women, these typically subside after 2 to 3 months.
- If a woman misses her period, she must be promptly evaluated for pregnancy.
- Some possible serious complications that have been associated with intrauterine contraceptives, including PARAGARD, are PID, embedment, perforation of the uterus, and expulsion.

Please see the following page for a brief summary of full Prescribing Information.

*Data are from the Contraceptive CHOICE Project. The study evaluated 3- and 6-month self-reported bleeding and cramping patterns in 5011 long-acting reversible contraceptive (LARC) users (n=826, PARAGARD), and the association of these symptoms with method satisfaction. Study participants rated satisfaction with their LARC method as "very satisfied," "somewhat satisfied," or "not satisfied." For the data analyses, "satisfied" and "very satisfied" were grouped together as "satisfied."[2]

†PARAGARD must be removed by a healthcare professional.

‡Based on a September 2017 web-based survey of US women aged 18-45 years (N=300), where participants were asked about their attitudes about birth control that contains hormones. Respondents were required to be currently using birth control or have plans to use birth control in the next year. Repeat respondents within the previous 6 months were not permitted.

References: 1. Kaneshiro B, Aeby T. Long-term safety, efficacy, and patient acceptability of the intrauterine Copper T-380A contraceptive device. *Int J Womens Health*. 2010;2:211-220. **2.** Diedrich JT, Desai S, Zhao Q, Secura G, Madden T, Peipert JF. Association of short-term bleeding and cramping patterns with long-acting reversible contraceptive method satisfaction. *Am J Obstet Gynecol*. 2015;212(1):50.e1- 50.e8. **3.** Data on File. CooperSurgical, Inc., September 2017.

PARAGARD® T380A
intrauterine copper contraceptive
Life on *Her* Terms.

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