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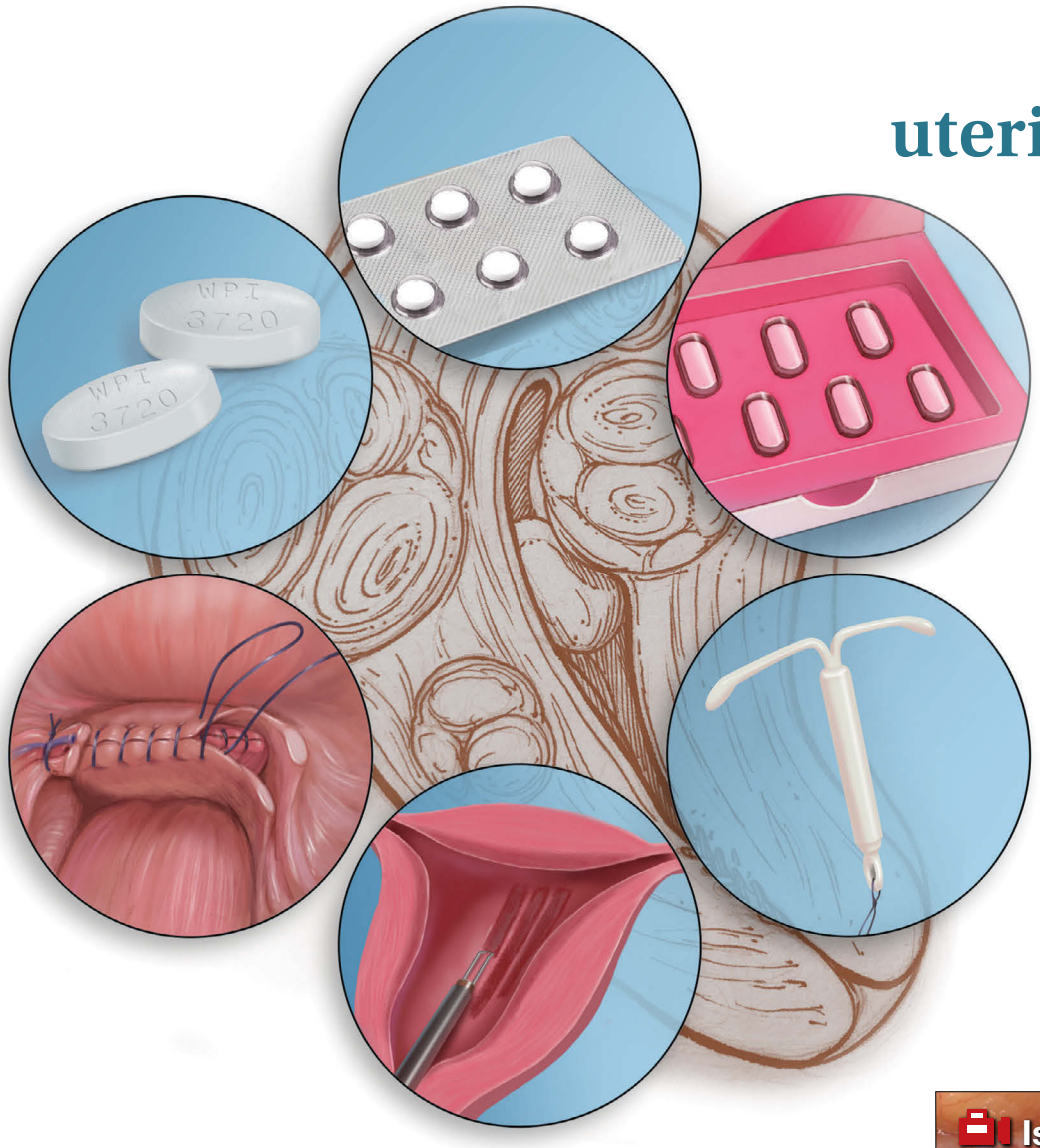

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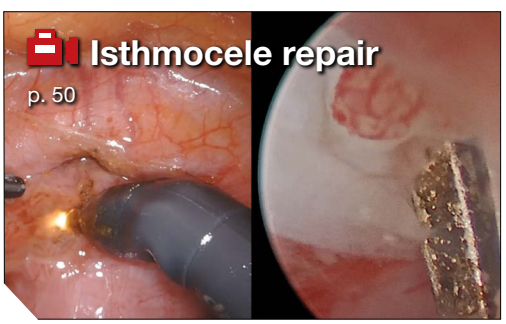

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Meet the innovative contraception designed to empower women

Created for her control: Long-lasting, reversible, and procedure-free[1]

Created for her comfort: Soft and flexible for easy insertion and removal[1,2]

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*ANNOVERA is inserted for 21 continuous days and removed for 7 days for 13 cycles.

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IMPORTANT SAFETY INFORMATION

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS
See full prescribing information for complete boxed warning.

- **Females over 35 years old who smoke should not use ANNOVERA.**
- **Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive use.**

CONTRAINDICATIONS

ANNOVERA is contraindicated and should not be used in women with a high risk of arterial or venous thrombotic diseases; current or history of breast cancer or other estrogen- or progestin-sensitive cancer; liver tumors, acute hepatitis, or severe (decompensated) cirrhosis; undiagnosed abnormal uterine bleeding; hypersensitivity to any of the components of ANNOVERA; and use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.

WARNINGS AND PRECAUTIONS

- Stop ANNOVERA if a thrombotic or thromboembolic event occurs, and at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery, in females who are not breastfeeding. Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years.
- Discontinue if jaundice occurs.
- Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir. ANNOVERA can be restarted 2 weeks following completion of this regimen.
- Do not prescribe ANNOVERA for females with uncontrolled hypertension or hypertension with vascular disease. Monitor blood pressure and stop use if blood pressure rises significantly in females with well-controlled hypertension.
- Monitor glucose in pre-diabetic or diabetic females taking ANNOVERA. Consider an alternate contraceptive method for females with uncontrolled dyslipidemias.
- Patients using ANNOVERA who have a significant change in headaches or irregular bleeding or amenorrhea should be evaluated. ANNOVERA should be discontinued if indicated.

- Other warnings include: gallbladder disease; depression; cervical cancer; increased serum concentrations of binding globulins; hereditary angioedema; chloasma (females who tend to develop chloasma should avoid exposure to the sun or UV radiation while using ANNOVERA); toxic shock syndrome (TSS) (if a patient exhibits symptoms of TSS, remove ANNOVERA, and initiate appropriate medical treatment); vaginal use (ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration).

ADVERSE REACTIONS

The most common adverse reactions reported in at least 5% of women who received ANNOVERA were: headache/migraine, nausea/vomiting, vulvovaginal mycotic infection/candidiasis, lower/upper abdominal pain, dysmenorrhea, vaginal discharge, urinary tract infection, breast pain/tenderness/discomfort, bleeding irregularities including metrorrhagia, diarrhea, and genital pruritus.

DRUG INTERACTIONS

Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with ANNOVERA.

INDICATION

ANNOVERA is a progestin/estrogen combination hormonal contraceptive indicated for use by females of reproductive potential to prevent pregnancy.

Limitation of Use: ANNOVERA has not been adequately studied in females with a body mass index of >29 kg/m^2.

Please note this information is not comprehensive. Please see Brief Summary of the Full Prescribing Information on the next page, including BOXED WARNING, or visit www.Annovera.com/pi.pdf.

References: 1. Annovera® [Full Prescribing Information]. Boca Raton, FL: TherapeuticsMD, Inc; 2019. **2.** Merkatz RB, Plagianos M, Hoskin E, et al. Acceptability of the Nestorone®/ethinyl estradiol contraceptive vaginal ring: development of a model; implications for introduction. *Contraception*. 2014;90(5):514–521. doi:10.1016/j.contraception.2014.05.015. **3.** Kumar N, Koide SS, Tsong YY, Sundaram K. Nestorone®: a progestin with a unique pharmacological profile. *Steroids*. 2000;65:629–636.

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For Her. For Life.

ANVA-20142 02/2020

ANNOVERA® (segesterone acetate and ethinyl estradiol vaginal system)

BRIEF SUMMARY OF PRESCRIBING INFORMATION
This Brief Summary does not include all the information needed to use ANNOVERA safely and effectively. Please visit **ANNOVERA.com/pi.pdf** for Full Prescribing Information (PI).

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive (CHC) use. This risk increases with age, particularly in females over 35 years of age, and with the number of cigarettes smoked. For this reason, CHCs should not be used by females who are over 35 years of age and smoke.

INDICATIONS AND USAGE
ANNOVERA is indicated for use by females of reproductive potential to prevent pregnancy.
Limitations of Use: ANNOVERA has not been adequately studied in females with a BMI >29 kg/m^2.

DOSAGE AND ADMINISTRATION
One ANNOVERA is inserted in the vagina. The vaginal system must remain in place continuously for 3 weeks (21 days) followed by a 1-week (7-day) vaginal system-free interval. One vaginal system provides contraception for thirteen 28-day cycles (1 year). Follow instructions for starting ANNOVERA, including switching from other contraceptive methods, and use after abortion, miscarriage, or childbirth *[see How to Start ANNOVERA (2.2) in PI]*.
Contraceptive efficacy of ANNOVERA may be reduced if a woman deviates from the recommended use. If ANNOVERA is out of the vagina for more than 2 continuous hours or more than 2 cumulative hours during the 21 days of continuous use, then back-up contraception, such as male condoms or spermicide, should be used until the vaginal system has been in the vagina for 7 consecutive days.

CONTRAINDICATIONS
ANNOVERA is contraindicated in females who are known to have the following conditions: • A high risk of arterial or venous thrombotic diseases. Examples include females who are known to: smoke, if over age 35; have current or history of deep vein thrombosis or pulmonary embolism; have cerebrovascular disease; have coronary artery disease; have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation); have inherited or acquired hypercoagulopathies; have uncontrolled hypertension or hypertension with vascular disease; have diabetes mellitus and are over age 35, diabetes mellitus with hypertension or vascular disease, or other end-organ damage, or diabetes mellitus of >20 years duration; have headaches with focal neurological symptoms, migraine headaches with aura, or are over age 35 with any migraine headaches. • Current or history of breast cancer or other estrogen- or progestin-sensitive cancer. • Liver tumors, acute hepatitis, or severe (decompensated) cirrhosis. • Undiagnosed abnormal uterine bleeding. • Hypersensitivity to any of the components of ANNOVERA. Hypersensitivity reactions reported include: throat constriction, facial edema, urticaria, hives, and wheezing. • Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for alanine transaminase (ALT) elevations.

WARNINGS AND PRECAUTIONS
Thromboembolic Disorders and Other Vascular Conditions
Females are at increased risk for a venous thrombotic event (VTE) when using ANNOVERA.
Stop ANNOVERA if a thrombotic or thromboembolic event occurs, or unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions and evaluate for retinal vein thrombosis immediately. Stop ANNOVERA at least 4 weeks before and through 2 weeks after major surgery. Start ANNOVERA no earlier than 4 weeks after delivery in females who are not breastfeeding. Before starting ANNOVERA, consider history and risk factors of thrombotic or thromboembolic disorders. ANNOVERA is contraindicated in females with a high risk of arterial or venous thrombotic/thromboembolic diseases.
Arterial Events
Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years. CHCs increase the risk of cardiovascular events and cerebrovascular events, such as stroke and myocardial infarction. The risk is greater among older females (>35 years of age), smokers, and females with hypertension, dyslipidemia, diabetes, or obesity.
Venous Events
The use of CHCs increases the risk of VTE, such as deep vein thrombosis and pulmonary embolism. Risk factors for VTEs include smoking, obesity, and family history of VTE, in addition to other factors that contraindicate use of CHCs. The rates of VTE are even greater during pregnancy, and especially during the postpartum period. The risk of VTE is highest during the first year of CHC use and when restarting hormonal contraception following a break of 4 weeks or longer. The risk of VTE due to CHCs gradually disappears after use is discontinued.
Liver Disease
Impaired Liver Function
ANNOVERA is contraindicated in females with acute hepatitis or severe (decompensated) cirrhosis of the liver. Discontinue ANNOVERA if jaundice develops. Acute liver test abnormalities may necessitate the discontinuation of ANNOVERA use until the liver tests return to normal and ANNOVERA causation has been excluded.
Liver Tumors
ANNOVERA is contraindicated in females with benign or malignant liver tumors. Hepatic adenomas are associated with CHC use (estimated 3.3 cases/100,000 CHC users). Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.
Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment
Stop ANNOVERA prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir. ANNOVERA can be restarted 2 weeks following completion of treatment with the Hepatitis C combination drug regimen.
Hypertension
ANNOVERA is contraindicated in females with uncontrolled hypertension or hypertension with vascular disease. For all females, including those with well-controlled hypertension, monitor blood pressure at routine visits and stop ANNOVERA if blood pressure rises significantly.
Age-Related Considerations
The risk for cardiovascular disease and prevalence of risk factors for cardiovascular disease increase with age. Certain conditions, such as smoking and migraine headache without aura, that do not contraindicate CHC use in younger females, are contraindications to use in women over 35 years of age. Consider the presence of underlying risk factors that may increase the risk of cardiovascular disease or VTE, particularly before initiating ANNOVERA for women over 35 years, such as hypertension, diabetes, dyslipidemia, and obesity.
Gallbladder Disease
Studies suggest a small increased relative risk of developing gallbladder disease among CHC users. Use of CHCs may also worsen existing gallbladder disease. A past history of CHC-related cholestasis predicts an increased risk with subsequent CHC use. Females with a history of pregnancy-related cholestasis may be at an increased risk for CHC-related cholestasis.
Adverse Carbohydrate and Lipid Metabolic Effects
Hyperglycemia
ANNOVERA is contraindicated in diabetic females over age 35, or females who have diabetes with hypertension, nephropathy, retinopathy, neuropathy, other vascular disease, or females with diabetes of >20 years duration. ANNOVERA may decrease glucose tolerance. Carefully monitor prediabetic and diabetic females who are taking ANNOVERA.
Dyslipidemia
Consider alternative contraception for females with uncontrolled dyslipidemia. ANNOVERA may cause adverse lipid changes. Females with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using ANNOVERA.
Headache
ANNOVERA is contraindicated in females with certain headaches. Evaluate new or significant changes in headaches, including migraines, and discontinue ANNOVERA if indicated.
Bleeding Irregularities and Amenorrhea
Females using ANNOVERA may experience unscheduled (breakthrough) bleeding and spotting, especially during the first month of use. If unscheduled bleeding occurs or persists, check for causes such as pregnancy or malignancy.
Based on subject diaries from the two clinical efficacy trials of ANNOVERA, 5–10% of females experienced unscheduled bleeding per 28-day cycle. A total of 41 subjects (1.7%) discontinued use due to menstrual disorders including metrorrhagia, menorrhagia, and abnormal withdrawal bleeding. Females who are not pregnant and use ANNOVERA may experience amenorrhea. Based on subject diary data from two clinical trials for up to 13 cycles, amenorrhea occurred in 3–5% of females per cycle using ANNOVERA and in 0.9% of females in all 13 cycles. If scheduled bleeding does not occur, consider the possibility of pregnancy.
Depression
Carefully observe females with a history of depression and discontinue ANNOVERA if depression recurs to a serious degree.
Cervical Cancer
Some studies suggest that CHCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia.
Effect on Binding Globulins
The estrogen component of ANNOVERA may raise the serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. The dose of replacement thyroid hormone or cortisol therapy may need to be increased.
Hereditary Angioedema
In females with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms of angioedema.
Chloasma
Chloasma may occur with ANNOVERA use, especially in females with a history of chloasma gravidarum. Advise females who tend to develop chloasma to avoid exposure to the sun or ultraviolet radiation while using ANNOVERA.
Toxic Shock Syndrome (TSS)
If a patient exhibits signs/symptoms of TSS, consider the possibility of this diagnosis, remove ANNOVERA, and initiate appropriate medical evaluation and treatment.
Vaginal Use
Some females are aware of the vaginal system on occasion during the 21 days of use or during coitus, and partners may feel the vaginal system during coitus. ANNOVERA may not be suitable for females with conditions that make the vagina more susceptible to vaginal irritation or ulceration. Vaginal and cervical erosion and/or ulceration has been reported in females using other contraceptive vaginal devices. In some cases, the ring adhered to vaginal tissue, which necessitated removal by a healthcare provider.

ADVERSE REACTIONS
Clinical Trial Experience
Most Common Adverse Reactions
In clinical trials, adverse reactions reported in by ≥5% of ANNOVERA-treated subjects include: headache, including migraine (38.6%); nausea/vomiting (25.0%); vulvovaginal mycotic infection/vaginal candidiasis (14.5%); abdominal pain/lower/upper (13.3%); dysmenorrhea (12.5%); vaginal discharge (11.8%); UTI/cystitis/pyelonephritis/genitourinary tract infection (10.0%); breast pain/tenderness/discomfort (9.5%); metrorrhagia/menstrual disorder (7.5%); diarrhea (7.2%); and genital pruritus (5.5%).
Adverse Reactions Leading to Discontinuation
Among subjects using ANNOVERA for contraception, 12% discontinued from the clinical trials due to an adverse reaction. Adverse reactions leading to discontinuation by ≥1% of ANNOVERA-treated subjects, include: metrorrhagia/menorrhagia (1.7%); headache, including migraine (1.3%), vaginal discharge/vulvovaginal mycotic infections (1.3%); nausea/vomiting (1.2%). In addition, 1.4% of subjects discontinued ANNOVERA use due to vaginal system expulsions.
Serious Adverse Reactions
Serious adverse reactions occurring in ≥2 subjects were: VTEs (deep venous thrombosis, cerebral vein thrombosis, pulmonary embolism); psychiatric events; drug hypersensitivity reactions; and spontaneous abortions.

DRUG INTERACTIONS
Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of ANNOVERA or increase breakthrough bleeding. Counsel patients to use a backup or alternative method of contraception when enzyme inducers are used with ANNOVERA. Do not co-administer ANNOVERA with HCV drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to potential for ALT elevations.

USE IN SPECIFIC POPULATIONS
Pregnancy
Discontinue ANNOVERA if pregnancy occurs.
Lactation
Not recommended for nursing mothers; can decrease milk production.
Pediatric Use
Safety and efficacy of ANNOVERA have been established in women of reproductive age. Efficacy is expected to be the same for postpubertal adolescents under the age of 18 as for users 18 years and older. Use of ANNOVERA before menarche is not indicated.
Geriatric Use
ANNOVERA has not been studied in females who have reached menopause and is not indicated in this population.
Hepatic Impairment
No studies have been conducted to evaluate the effect of hepatic impairment on the disposition of ANNOVERA. Acute or chronic disturbances of liver function may necessitate the discontinuation of CHC use until markers of liver function return to normal and CHC causation has been excluded.
Renal Impairment
No studies were conducted in subjects with renal impairment; ANNOVERA is not recommended in patients with renal impairment.
Body Mass Index (BMI)/Body Weight
The safety and efficacy of ANNOVERA in females with a BMI >29 kg/m^2 have not been adequately evaluated because this subpopulation was excluded from the clinical trials after 2 VTEs occurred in females with a BMI > 29 kg/m^2. Higher body weight is associated with lower systemic exposure of SA and EE.

Manufactured for: TherapeuticsMD, Inc.
Boca Raton, FL 33431
Based on ANVA-LAB-20001.2 01/2020

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Enhancing the quality of women's health care and the professional development of ObGyns and all women's health care clinicians†

*Source: Kantar Media, Medical Surgical Study December 2019, Obstetrics/Gynecology Combined Office & Hospital Readers.
†OBG MANAGEMENT recognizes the importance of addressing the reproductive health of gender-diverse individuals.

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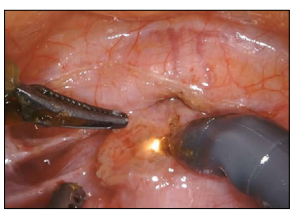

Isthmocele repair
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BIFTU MENGESHA, MD, MAS;
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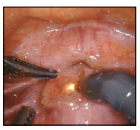
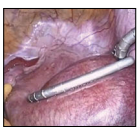


Isthmocele repair: Simultaneous hysteroscopy and robotic-assisted laparoscopy

SIERRA J. SEAMAN, MD;
CHETNA ARORA, MD;
AND ARNOLD P. ADVINCULA, MD



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- Guidance on infection prevention for health care personnel
- Cortisol levels on COVID-19 admission may be a marker of severity
- Experts publish imaging recommendations for pediatric COVID-19
- Where does dexamethasone fit in with diabetic ketoacidosis in COVID-19?
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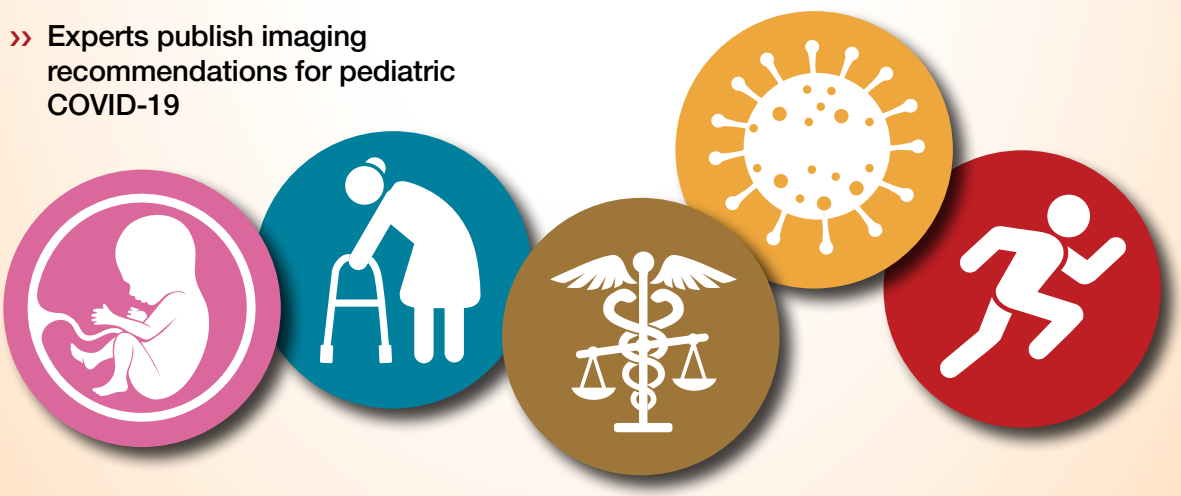

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EDITORIAL

The Fetal Pillow: A new option for delivering the deeply impacted fetal head

For laboring women with a prolonged second stage who require a cesarean delivery, use of the Fetal Pillow will decrease traumatic extensions of the uterine incision and facilitate delivery of the fetal head

Robert L. Barbieri, MD
Editor in Chief, OBG Management
Chair, Obstetrics and Gynecology
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Obstetricians know that a cesarean delivery (CD) for a woman with a prolonged second stage and a fetal head deeply impacted in the pelvis is challenging. In this situation, extensions of the uterine incision commonly occur, resulting in prolonged operative time and increased blood loss. Even more harrowing is the inability to deliver the fetal head, necessitating emergency assistance from other clinicians. In this situation, interventions that may be helpful include:

- extend or T the uterine incision
- enlist the aid of a clinician to push up on the fetal head with a vaginal hand (**FIGURE 1**)
- reverse breech extraction (**FIGURE 2**), and
- vaginal insertion of a Fetal Pillow prior to starting the delivery.

Evidence from clinical trials indicates that reverse breech extraction or insertion of a Fetal Pillow result in the best clinical outcomes.

Reverse breech extraction vs the push technique

Although the data are limited, most studies report that compared with pushing up with a vaginal hand (as shown in Figure 1), the reverse breech extraction technique (as shown in Figure 2) is associated with a reduction in extensions of the uterine incision, reduced blood loss, and reduced operative time.[1] In a randomized trial, 108 women with obstructed labor undergoing CD in the second stage were randomly assigned to reverse breech extraction or pushing up with a vaginal hand.[2] Following the uterine incision, the reverse breech extraction technique is performed by immediately reaching into the upper uterus and grasping the lower portion of the fetal leg and applying gentle traction on the leg until the second leg appeared. The lower legs are then pulled out of the uterus. Standard breech delivery maneuvers are used to deliver the shoulders and head. In the trial, compared with the push technique, reverse breech extraction was associated with fewer extensions of the uterine incision (30% vs 11%; $P<.05$), less blood loss (899 mL vs 1,257 mL; $P<.001$), and shorter operative time (56 min vs 89 min, $P<.001$). Fetal injury was similar with the push and breech extraction techniques (6% and 7%).

In another randomized trial, 192 women undergoing CD for obstructed labor were randomly assigned to reverse breech extraction or pushing the head up with a hand in the vagina.[3] Compared with the vaginal push technique, reverse breech extraction was associated with fewer extensions of the uterine incision (19% vs 48%; $P = .003$), fewer cases of wound infection (2% vs 13%; $P = .007$), and fewer blood transfusions (2 vs 11; $P = .012$).

Additional options and adjuvants

FIGURE 1 Pushing up the fetal head with a vaginal hand

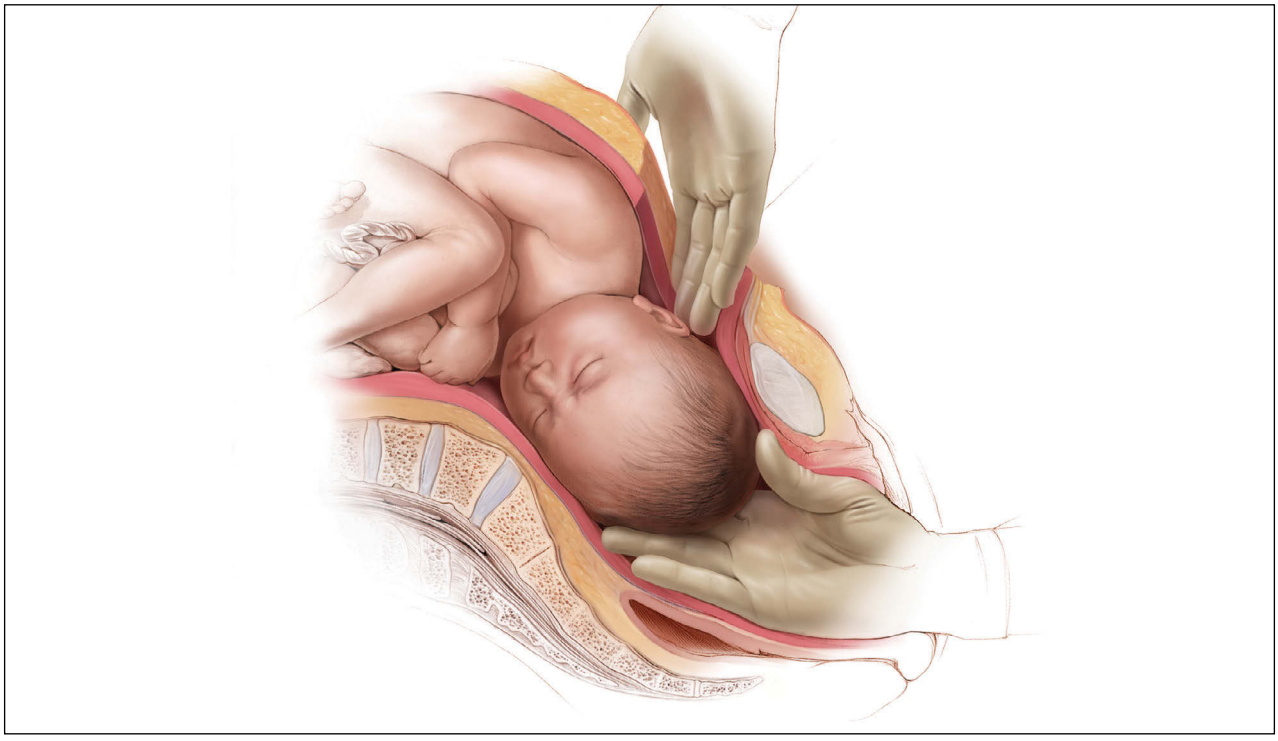

FIGURE 2 Reverse breech extraction

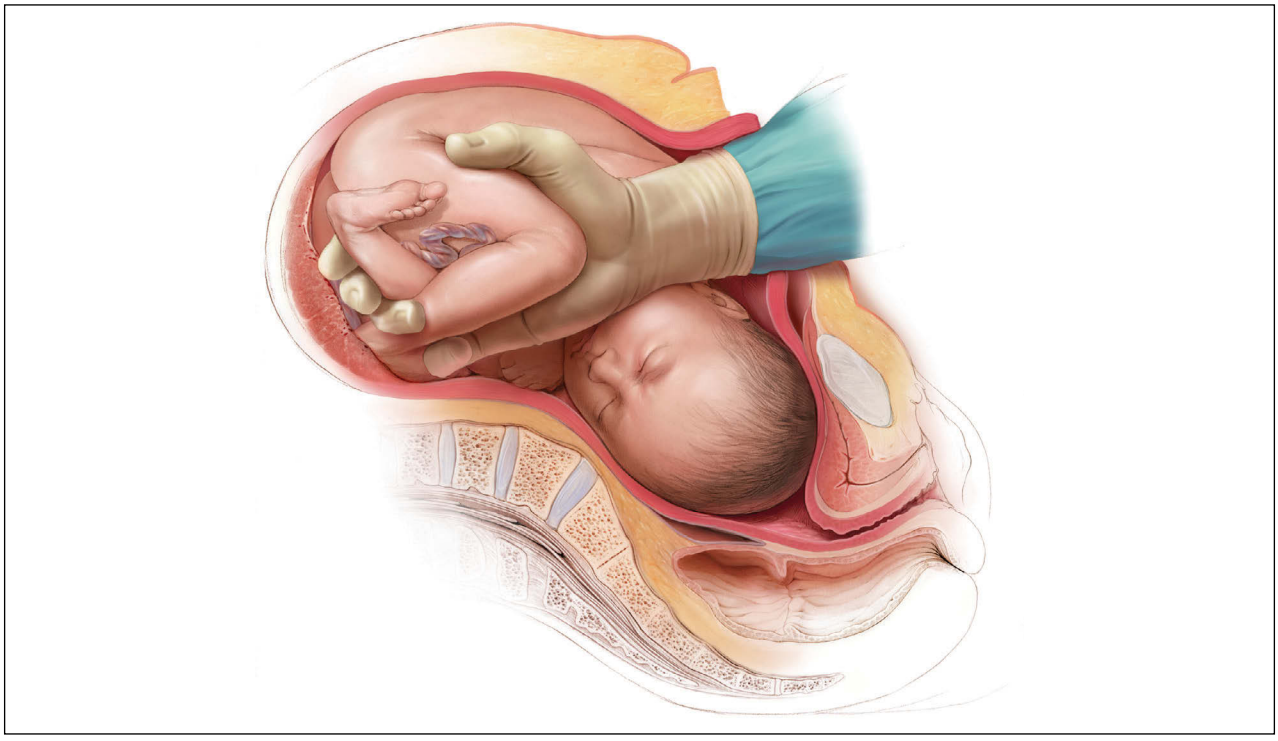

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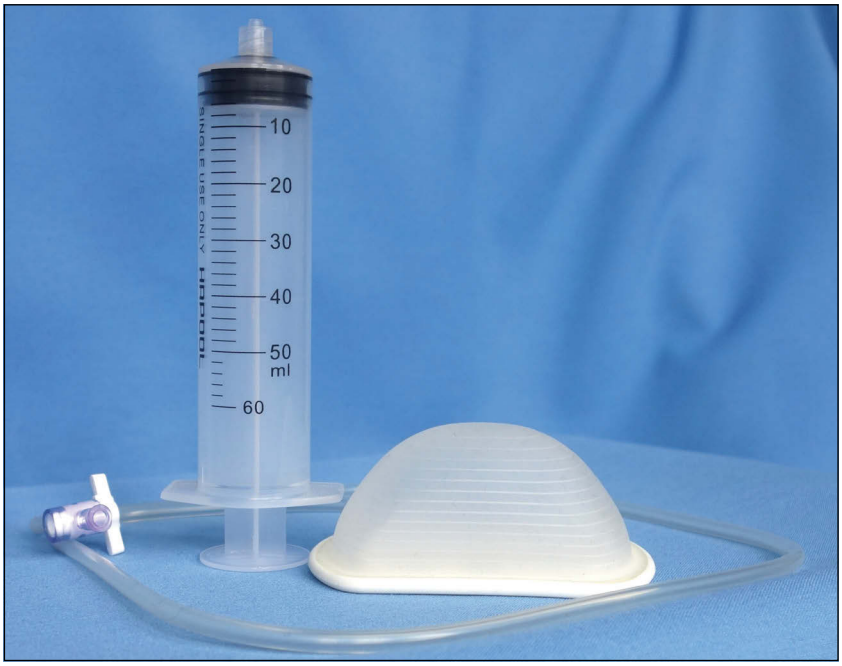
FIGURE 3 Fetal Pillow



for facilitating delivery of a fetal head deeply impacted in the pelvis include: using a Coyne spoon, using nitroglycerine or terbutaline to relax the myometrium, breaking the vaginal suction on the fetal head before attempting delivery, keeping the wrist of the delivering hand as straight as possible to reduce uterine incision extensions, and incising the ring (if a Bandl's ring is detected).

The Fetal Pillow

The Fetal Pillow (Safe Obstetric Systems, New York, New York) is a single-use fetal cephalic elevation device for managing the deeply impacted fetal head (**FIGURE 3**). The Fetal Pillow has a firm plastic base upon which is attached a soft silicon balloon. The Fetal Pillow is inserted into the vagina prior to initiating CD and the balloon is filled with 180 mL of saline, causing the fetal head to be pushed to a higher station (**FIGURE 4**). Use of the Fetal Pillow may be indicated prior to CD in the following situations:

- second stage labor with a deeply impacted head
- second stage labor and failed operative delivery
- occiput posterior position or deep transverse arrest
- absent progress in the first stage between 8 cm and 10 cm with a deeply impacted fetal head or excessive caput of the fetal head.

The Fetal Pillow is inserted after completing vaginal preparation for CD and before initiating skin preparation and abdominal draping. The steps for inserting the Fetal Pillow include:

1. Use the 60 mL syringe to fully deflate the Fetal Pillow and leave the cock-stop open.
2. Fold the Fetal Pillow by squeezing the firm plastic base, and with the patient's legs in a frog-leg position, place the device in the vagina.
3. Allow the firm plastic base to open to a flat position with the base against the posterior vaginal wall and the soft silicon balloon against the fetal head.
4. Using pressure on the plastic base, gently push the Fetal Pillow posteriorly toward the sacrum of the mother.
5. Use the 60 mL syringe to inflate the balloon with 180 mL of normal saline and close the valve.
6. Straighten the patient's legs and proceed with skin preparation and abdominal draping (**FIGURE 4**).

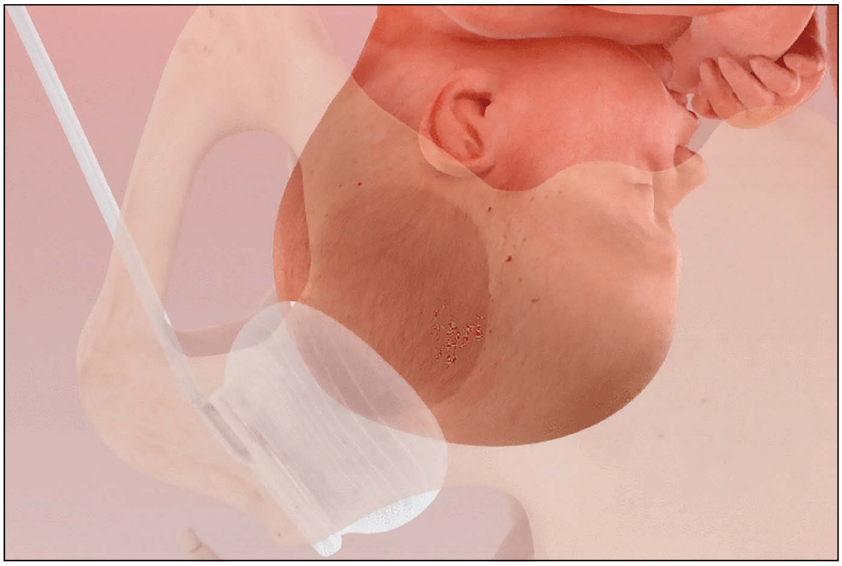
When the CD is completed, deflate the balloon by drawing out the saline with the 60 mL syringe and remove the device by hooking a finger around the firm plastic base. The Fetal Pillow is surprisingly easy to use.

Effectiveness of the Fetal Pillow

In one randomized trial, 240 women undergoing CD were randomly allocated to a group in which the Fetal Pillow was placed in the vagina and inflated prior to the cesarean and a control group in which the Fetal Pillow was not used. In this study the mean length of the second stage averaged 1.9 hours.[4] Compared with no Fetal Pillow, use of the Fetal Pillow was associated with a reduction in grade 3 extension of the uterine incision (extension into the uterine artery, vagina, or bladder) (2.5% vs 23%), a reduction in blood loss > 1,000 mL (4% vs 22%), and fewer difficult plus very difficult deliveries of the fetal head as reported by the surgeon (6% vs 39%).

In another randomized trial, 60 nulliparous women undergoing CD in the second stage of labor had a Fetal Pillow inserted in the vagina and were randomly allocated to inflation of the pillow (Fetal Pillow group) or noninflation of the pillow

FIGURE 4 Placement of the Fetal Pillow



(control group).[5] In this study the mean length of the second stage was 4 hours. Compared with noninflation of the Fetal Pillow, use of the inflated Fetal Pillow was associated with a reduction in grade 3 extension of the uterine incision (extensions into the uterine artery, vagina, or bladder) (0% for inflation vs 13% for noninflation) and fewer difficult plus very difficult deliveries of the fetal head as reported by the surgeon (0% for inflation vs 37% for noninflation). There was no significant difference in blood loss between the two groups (800 mL vs 900 mL). These two randomized studies both reported that the use of the Fetal Pillow was associated with a reduction in grade 3 extensions of the uterine incision and a decrease in the difficulty of delivering the fetal head.

Consider trialing the Fetal Pillow

When a CD is performed after a prolonged second stage of labor, surgical complications are common, including extensions of the uterine incision and difficulty delivering the fetal head. When a grade 3 extension occurs—with tearing of a uterine artery, deep extension into the vagina, or damage to the bladder—the surgical repair can be extraordinarily challenging. Clinical trials report that both reverse breech extraction and the Fetal Pillow can facilitate CD in the setting of a prolonged second stage. For many obstetricians reverse breech extraction is a challenging obstetric maneuver. The insertion and inflation of a Fetal Pillow is a simple procedure. Obstetrician-gynecologists learn by doing. If you have never used the Fetal Pillow, I suggest you consider trialing it in your practice. ●

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

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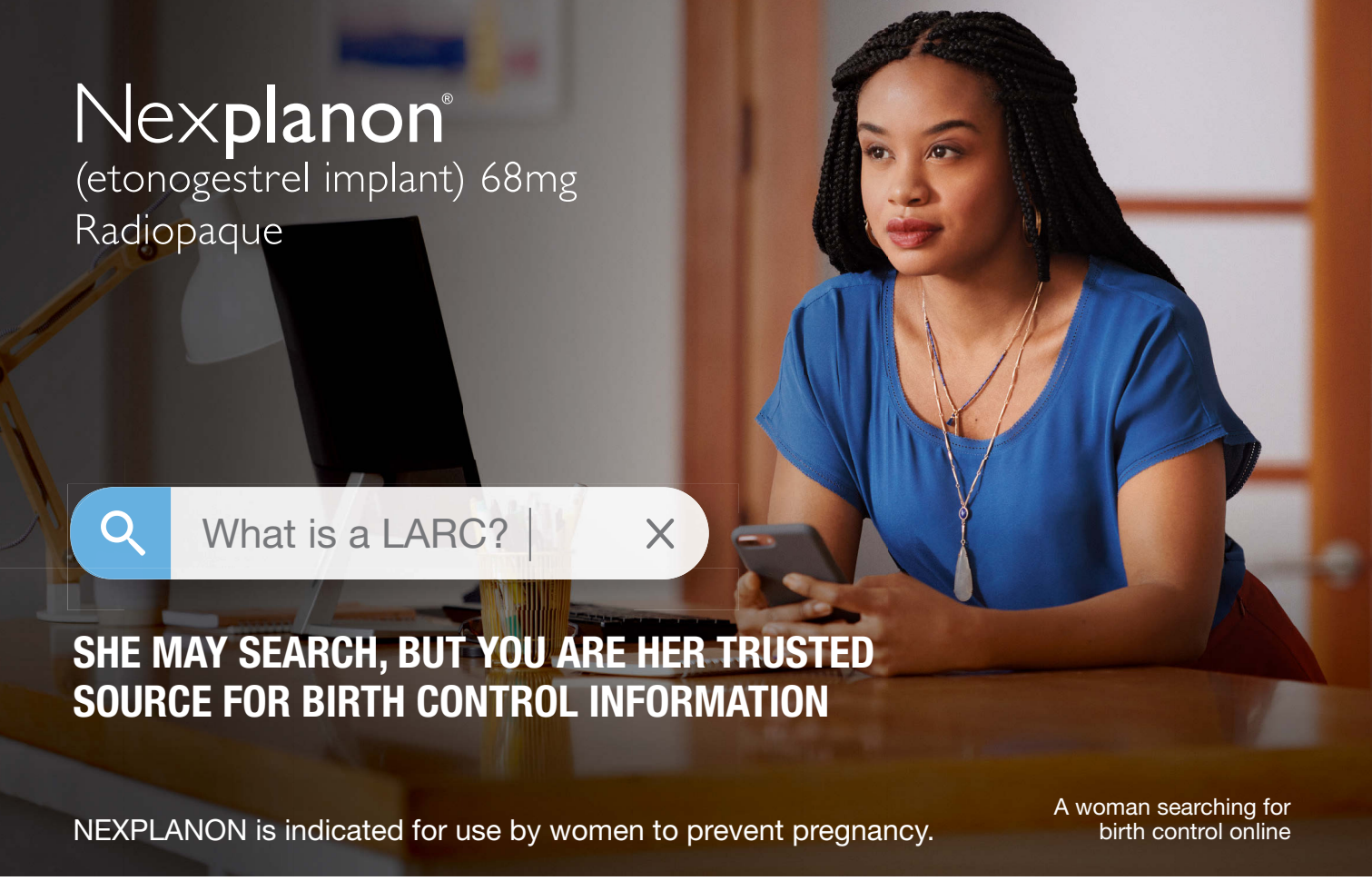
Nexplanon®
(etonogestrel implant) 68mg
Radiopaque



SHE MAY SEARCH, BUT YOU ARE HER TRUSTED SOURCE FOR BIRTH CONTROL INFORMATION

NEXPLANON is indicated for use by women to prevent pregnancy.

A woman searching for birth control online

SELECTED SAFETY INFORMATION

Who is not appropriate for NEXPLANON

- NEXPLANON should not be used in women who have known or suspected pregnancy; current or past history of thrombosis or thromboembolic disorders; liver tumors, benign or malignant, or active liver disease; undiagnosed abnormal genital bleeding; known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past; and/or allergic reaction to any of the components of NEXPLANON.

Complications of insertion and removal

- NEXPLANON should be inserted subdermally and be palpable after insertion. Palpate immediately after insertion to ensure proper placement. Undetected failure to insert the implant may lead to unintended pregnancy. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.
- Insertion and removal-related complications may include pain, paresthesias, bleeding, hematoma, scarring, or infection. If NEXPLANON is inserted too deeply (intramuscular or in the fascia), neural or vascular injury may occur. Implant removal may be difficult or impossible if the implant is not inserted correctly, inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. If at any time the implant cannot be palpated, it should be localized and removal is recommended.
- There have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. Endovascular or surgical procedures may be needed for removal.

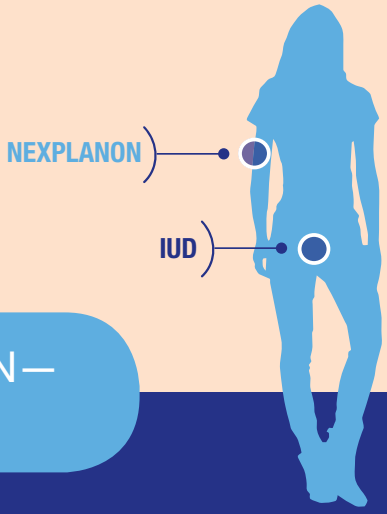
NEXPLANON and pregnancy

- Be alert to the possibility of an ectopic pregnancy in women using NEXPLANON who become pregnant or complain of lower abdominal pain.
- **Rule out pregnancy before inserting NEXPLANON.**

Educate her about the risk of serious vascular events

- The use of combination hormonal contraceptives increases the risk of vascular events, including arterial events [stroke and myocardial infarction (MI)] or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis (DVT), retinal vein thrombosis, and pulmonary embolism). Women with risk factors known to increase the risk of these events should be carefully assessed. Postmarketing reports in women using etonogestrel implants have included pulmonary emboli (some fatal), DVT, MI, and stroke. NEXPLANON should be removed if thrombosis occurs.
- Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum.
- Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Consider removing the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

Help your patients understand both LARC location options



Talk to your patients about NEXPLANON— **the only non-uterine LARC option**

Up to **3** years of pregnancy prevention*

>99% effective†

Reversible if plans change

LARC = long-acting reversible contraceptive.
*NEXPLANON must be removed by the end of the third year and may be replaced by another NEXPLANON at the time of removal, if continued contraceptive protection is desired.
†Less than 1 pregnancy per 100 women who used NEXPLANON for 1 year.

SELECTED SAFETY INFORMATION *(continued)*

Counsel her about changes in bleeding patterns

- Women are likely to have changes in their menstrual bleeding pattern with NEXPLANON, including changes in frequency, intensity, or duration. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy. In clinical studies of the non-radiopaque etonogestrel implant, changes in bleeding pattern were the most common reason reported for stopping treatment (11.1%). Counsel women regarding potential changes they may experience.

Be aware of other serious complications, adverse reactions, and drug interactions

- Remove NEXPLANON if jaundice occurs.
- Remove NEXPLANON if blood pressure rises significantly and becomes uncontrolled.
- Prediabetic and diabetic women using NEXPLANON should be carefully monitored.
- Carefully observe women with a history of depressed mood. Consider removing NEXPLANON in patients who become significantly depressed.
- The most common adverse reactions (≥10%) reported in clinical trials were headache (24.9%), vaginitis (14.5%), weight increase (13.7%), acne (13.5%), breast pain (12.8%), abdominal pain (10.9%), and pharyngitis (10.5%).
- Drugs or herbal products that induce enzymes, including CYP3A4, may decrease the effectiveness of NEXPLANON or increase breakthrough bleeding.
- The efficacy of NEXPLANON in women weighing more than 130% of their ideal body weight has not been studied. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. Therefore, NEXPLANON may be less effective in overweight women.
- Counsel women to contact their health care provider immediately if, at any time, they are unable to palpate the implant.
- NEXPLANON does not protect against HIV or other STDs.

Please read the adjacent Brief Summary of the Prescribing Information.

MERCK
INVENTING FOR LIFE

Nexplanon®
(etonogestrel implant) 68mg
Radiopaque

Nexplanon®
(etonogestrel implant) 68mg

BRIEF SUMMARY (For full Prescribing Information, see package insert.)

Women should be informed that this product does not protect against HIV infection (the virus that causes AIDS) or other sexually transmitted diseases.

INDICATION AND USAGE

NEXPLANON is indicated for use by women to prevent pregnancy.

DOSAGE AND ADMINISTRATION

The efficacy of NEXPLANON does not depend on daily, weekly or monthly administration. All healthcare providers should receive instruction and training prior to performing insertion and/or removal of NEXPLANON. A single NEXPLANON implant is inserted subdermally just under the skin at the inner side of the non-dominant upper arm. The insertion site is overlying the triceps muscle about 8-10 cm (3-4 inches) from the medial epicondyle of the humerus and 3-5 cm (1.25-2 inches) posterior to the sulcus (groove) between the biceps and triceps muscles. This location is intended to avoid the large blood vessels and nerves lying within and surrounding the sulcus. An implant inserted more deeply than subdermally (deep insertion) may not be palpable and the localization and/or removal can be difficult or impossible *[see Dosage and Administration and Warnings and Precautions]*. NEXPLANON must be inserted by the expiration date stated on the packaging. NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive method. The implant must be removed by the end of the third year and may be replaced by a new implant at the time of removal, if continued contraceptive protection is desired.

CONTRAINDICATIONS

NEXPLANON should not be used in women who have

- Known or suspected pregnancy
- Current or past history of thrombosis or thromboembolic disorders
- Liver tumors, benign or malignant, or active liver disease
- Undiagnosed abnormal genital bleeding
- Known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past
- Allergic reaction to any of the components of NEXPLANON *[see Adverse Reactions]*

WARNINGS AND PRECAUTIONS

The following information is based on experience with the etonogestrel implants (IMPLANON® [etonogestrel implant] and/or NEXPLANON), other progestin-only contraceptives, or experience with combination (estrogen plus progestin) oral contraceptives.

Complications of Insertion and Removal

NEXPLANON should be inserted subdermally so that it will be palpable after insertion, and this should be confirmed by palpation immediately after insertion. Failure to insert NEXPLANON properly may go unnoticed unless it is palpated immediately after insertion. Undetected failure to insert the implant may lead to an unintended pregnancy. Complications related to insertion and removal procedures, such as pain, paresthesias, bleeding, hematoma, scarring or infection, may occur.

If NEXPLANON is inserted deeply (intramuscular or in the fascia), neural or vascular injury may occur. To help reduce the risk of neural or vascular injury, NEXPLANON should be inserted subdermally just under the skin at the inner side of the non-dominant upper arm overlying the triceps muscle about 8-10 cm (3-4 inches) from the medial epicondyle of the humerus and 3-5 cm (1.25-2 inches) posterior to the sulcus (groove) between the biceps and triceps muscles. This location is intended to avoid the large blood vessels and nerves lying within and surrounding the sulcus. Deep insertions of NEXPLANON have been associated with paraesthesia (due to neural injury), migration of the implant (due to intramuscular or fascial insertion), and intravascular insertion. If infection develops at the insertion site, start suitable treatment. If the infection persists, the implant should be removed. Incomplete insertions or infections may lead to expulsion.

Implant removal may be difficult or impossible if the implant is not inserted correctly, is inserted too deeply, not palpable, encased in fibrous tissue, or has migrated.

There have been reports of migration of the implant within the arm from the insertion site, which may be related to deep insertion. There also have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. In cases where the implant has migrated to the pulmonary artery, endovascular or surgical procedures may be needed for removal.

If at any time the implant cannot be palpated, it should be localized and removal is recommended.

Exploratory surgery without knowledge of the exact location of the implant is strongly discouraged. Removal of deeply inserted implants should be conducted with caution in order to prevent injury to deeper neural or vascular structures in the arm and be performed by healthcare providers familiar with the anatomy of the arm. If the implant is located in the chest, healthcare providers familiar with the anatomy of the chest should be consulted. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.

Changes in Menstrual Bleeding Patterns

After starting NEXPLANON, women are likely to have a change from their normal menstrual bleeding pattern. These may include changes in bleeding frequency (absent, less, more frequent or continuous), intensity (reduced or increased) or duration. In clinical trials of the non-radiopaque etonogestrel implant (IMPLANON), bleeding patterns ranged from amenorrhea (1 in 5 women) to frequent and/or prolonged bleeding (1 in 5 women). The bleeding pattern experienced during the first three months of NEXPLANON use is broadly predictive of the future bleeding pattern for many women. Women should be counseled regarding the bleeding pattern changes they may experience so that they know what to expect. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy.

In clinical studies of the non-radiopaque etonogestrel implant, reports of changes in bleeding pattern were the most common reason for stopping treatment (11.1%). Irregular bleeding (10.8%) was the single most common reason women stopped treatment, while amenorrhea (0.3%) was cited less frequently. In these studies, women had an average of 17.7 days of bleeding or spotting every 90 days (based on 3,315 intervals of 90 days recorded by 780 patients). The percentages of patients having 0, 1-7, 8-21, or >21 days of spotting or bleeding over a 90-day interval while using the non-radiopaque etonogestrel implant are shown in Table 1.

Table 1: Percentages of Patients With 0, 1-7, 8-21, or >21 Days of Spotting or Bleeding Over a 90-Day Interval While Using the Non-Radiopaque Etonogestrel Implant (IMPLANON)

Total Days of Spotting or Bleeding	Percentage of Patients		
	Treatment Days 91-180 (N = 745)	Treatment Days 271-360 (N = 657)	Treatment Days 631-720 (N = 547)
0 Days	19%	24%	17%
1-7 Days	15%	13%	12%
8-21 Days	30%	30%	37%
>21 Days	35%	33%	35%

Bleeding patterns observed with use of the non-radiopaque etonogestrel implant for up to 2 years, and the proportion of 90-day intervals with these bleeding patterns, are summarized in Table 2.

Table 2: Bleeding Patterns Using the Non-Radiopaque Etonogestrel Implant (IMPLANON) During the First 2 Years of Use*

Bleeding Patterns	Definitions	%†
Infrequent	Less than three bleeding and/or spotting episodes in 90 days (excluding amenorrhea)	33.6
Amenorrhea	No bleeding and/or spotting in 90 days	22.2
Prolonged	Any bleeding and/or spotting episode lasting more than 14 days in 90 days	17.7
Frequent	More than 5 bleeding and/or spotting episodes in 90 days	6.7

* Based on 3315 recording periods of 90 days duration in 780 women, excluding the first 90 days after implant insertion

† % = Percentage of 90-day intervals with this pattern

In case of undiagnosed, persistent, or recurrent abnormal vaginal bleeding, appropriate measures should be conducted to rule out malignancy.

Ectopic Pregnancies

As with all progestin-only contraceptive products, be alert to the possibility of an ectopic pregnancy among women using NEXPLANON who become pregnant or complain of lower abdominal pain. Although ectopic pregnancies are uncommon among women using NEXPLANON, a pregnancy that occurs in a woman using NEXPLANON may be more likely to be ectopic than a pregnancy occurring in a woman using no contraception.

Thrombotic and Other Vascular Events

The use of combination hormonal contraceptives (progestin plus estrogen) increases the risk of vascular events, including arterial events (strokes and myocardial infarctions) or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis, retinal vein thrombosis, and pulmonary embolism). NEXPLANON is a progestin-only contraceptive. It is unknown whether this increased risk is applicable to etonogestrel alone. It is recommended, however, that women with risk factors known to increase the risk of venous and arterial thromboembolism be carefully assessed. There have been postmarketing reports of serious arterial and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using etonogestrel implants. NEXPLANON should be removed in the event of a thrombosis.

Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum. Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Evaluate for retinal vein thrombosis immediately if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions. Consider removal of the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

Ovarian Cysts

If follicular development occurs, atresia of the follicle is sometimes delayed, and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally, these enlarged follicles disappear spontaneously. On rare occasion, surgery may be required.

Carcinoma of the Breast and Reproductive Organs

Women who currently have or have had breast cancer should not use hormonal contraception because breast cancer may be hormonally sensitive *[see Contraindications]*. Some studies suggest that the use of combination hormonal contraceptives might increase the incidence of breast cancer; however, other studies have not confirmed such findings. Some studies suggest that the use of combination hormonal contraceptives is associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings are due to differences in sexual behavior and other factors. Women with a family history of breast cancer or who develop breast nodules should be carefully monitored.

Liver Disease

Disturbances of liver function may necessitate the discontinuation of hormonal contraceptive use until markers of liver function return to normal. Remove NEXPLANON if jaundice develops. Hepatic adenomas are associated with combination hormonal contraceptives use. An estimate of the attributable risk is 3.3 cases per 100,000 for combination hormonal contraceptives users. It is not known whether a similar risk exists with progestin-only methods like NEXPLANON. The progestin in NEXPLANON may be poorly metabolized in women with liver impairment. Use of NEXPLANON in women with active liver disease or liver cancer is contraindicated *[see Contraindications]*.

Weight Gain

In clinical studies, mean weight gain in U.S. non-radiopaque etonogestrel implant (IMPLANON) users was 2.8 pounds after one year and 3.7 pounds after two years. How much of the weight gain was related to the non-radiopaque etonogestrel implant is unknown. In studies, 2.3% of the users reported weight gain as the reason for having the non-radiopaque etonogestrel implant removed.

Elevated Blood Pressure

Women with a history of hypertension-related diseases or renal disease should be discouraged from using hormonal contraception. For women with well-controlled hypertension, use of NEXPLANON can be considered. Women with hypertension using NEXPLANON should be closely monitored. If sustained hypertension develops during the use of NEXPLANON, or if a significant increase in blood pressure does not respond adequately to antihypertensive therapy, NEXPLANON should be removed.

Gallbladder Disease

Studies suggest a small increased relative risk of developing gallbladder disease among combination hormonal contraceptive users. It is not known whether a similar risk exists with progestin-only methods like NEXPLANON.

Carbohydrate and Lipid Metabolic Effects

Use of NEXPLANON may induce mild insulin resistance and small changes in glucose concentrations of unknown clinical significance. Carefully monitor prediabetic and diabetic women using NEXPLANON. Women who are being treated for hyperlipidemia should be followed closely if they elect to use NEXPLANON. Some progestins may elevate LDL levels and may render the control of hyperlipidemia more difficult.

Depressed Mood

Women with a history of depressed mood should be carefully observed. Consideration should be given to removing NEXPLANON in patients who become significantly depressed.

Return to Ovulation

In clinical trials with the non-radiopaque etonogestrel implant (IMPLANON), the etonogestrel levels in blood decreased below sensitivity of the assay by one week after removal of the implant. In addition, pregnancies were observed to occur as early as 7 to 14 days after removal. Therefore, a woman should re-start contraception immediately after removal of the implant if continued contraceptive protection is desired.

Fluid Retention
Hormonal contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention. It is unknown if NEXPLANON causes fluid retention.

Contact Lenses
Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

***In Situ* Broken or Bent Implant**
There have been reports of broken or bent implants while in the patient's arm. Based on *in vitro* data, when an implant is broken or bent, the release rate of etonogestrel may be slightly increased. When an implant is removed, it is important to remove it in its entirety *[see Dosage and Administration]*.

Monitoring
A woman who is using NEXPLANON should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated health care.

Drug-Laboratory Test Interactions
Sex hormone-binding globulin concentrations may be decreased for the first six months after NEXPLANON insertion followed by gradual recovery. Thyroxine concentrations may initially be slightly decreased followed by gradual recovery to baseline.

ADVERSE REACTIONS
In clinical trials involving 942 women who were evaluated for safety, change in menstrual bleeding patterns (irregular menses) was the most common adverse reaction causing discontinuation of use of the non-radiopaque etonogestrel implant (IMPLANON® [etonogestrel implant]) (11.1% of women).

Adverse reactions that resulted in a rate of discontinuation of ≥1% are shown in Table 3.

Table 3: Adverse Reactions Leading to Discontinuation of Treatment in 1% or More of Subjects in Clinical Trials of the Non-Radiopaque Etonogestrel Implant (IMPLANON)

Adverse Reactions	All Studies N = 942
Bleeding Irregularities*	11.1%
Emotional Lability†	2.3%
Weight Increase	2.3%
Headache	1.6%
Acne	1.3%
Depression‡	1.0%

*Includes "frequent", "heavy", "prolonged", "spotting", and other patterns of bleeding irregularity.
† Among US subjects (N=330), 6.1% experienced emotional lability that led to discontinuation.
‡ Among US subjects (N=330), 2.4% experienced depression that led to discontinuation.

Other adverse reactions that were reported by at least 5% of subjects in the non-radiopaque etonogestrel implant clinical trials are listed in Table 4.

Table 4: Common Adverse Reactions Reported by ≥5% of Subjects in Clinical Trials With the Non-Radiopaque Etonogestrel Implant (IMPLANON)

Adverse Reactions	All Studies N = 942
Headache	24.9%
Vaginitis	14.5%
Weight increase	13.7%
Acne	13.5%
Breast pain	12.8%
Abdominal pain	10.9%
Pharyngitis	10.5%
Leukorrhea	9.6%
Influenza-like symptoms	7.6%
Dizziness	7.2%
Dysmenorrhea	7.2%
Back pain	6.8%
Emotional lability	6.5%
Nausea	6.4%
Pain	5.6%
Nervousness	5.6%
Depression	5.5%
Hypersensitivity	5.4%
Insertion site pain	5.2%

In a clinical trial of NEXPLANON, in which investigators were asked to examine the implant site after insertion, implant site reactions were reported in 8.6% of women. Erythema was the most frequent implant site complication, reported during and/or shortly after insertion, occurring in 3.3% of subjects. Additionally, hematoma (3.0%), bruising (2.0%), pain (1.0%), and swelling (0.7%) were reported.

Effects of Other Drugs on Hormonal Contraceptives
Substances decreasing the plasma concentrations of hormonal contraceptives (HCs) and potentially diminishing the efficacy of HCs: Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the plasma concentrations of HCs and potentially diminish the effectiveness of HCs or increase breakthrough bleeding.

Some drugs or herbal products that may decrease the effectiveness of HCs include efavirenz, phenytoin, barbiturates, carbamazepine, bosentan, felbamate, griseofulvin, oxcarbazepine, rifampicin, topiramate, rifabutin, rufinamide, aprepitant, and products containing St. John's wort. Interactions between HCs and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when enzyme inducers are used with HCs, and to continue back-up non-hormonal contraception for 28 days after discontinuing the enzyme inducer to ensure contraceptive reliability.

Substances increasing the plasma concentrations of HCs: Co-administration of certain HCs and strong or moderate CYP3A4 inhibitors such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase the serum concentrations of progestins, including etonogestrel.

Human Immunodeficiency Virus (HIV)/Hepatitis C Virus (HCV) protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma concentrations of progestin have been noted in cases of co-administration with HIV protease inhibitors (decrease [e.g., nelfinavir, ritonavir, darunavir/ritonavir, (fos)amprenavir/ritonavir, lopinavir/ritonavir, and tipranavir/ritonavir] or increase [e.g., indinavir and atazanavir/ritonavir])/HCV protease inhibitors (decrease [e.g., boceprevir and telaprevir]) or with non-nucleoside reverse transcriptase inhibitors (decrease [e.g., nevirapine, efavirenz] or increase [e.g., etravirene]). These changes may be clinically relevant in some cases. Consult the prescribing information of anti-viral and anti-retroviral concomitant medications to identify potential interactions.

Effects of Hormonal Contraceptives on Other Drugs
Hormonal contraceptives may affect the metabolism of other drugs. Consequently, plasma concentrations may either increase (for example, cyclosporine) or decrease (for example, lamotrigine). Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

USE IN SPECIFIC POPULATIONS

Pregnancy
Risk Summary
NEXPLANON is contraindicated during pregnancy because there is no need for pregnancy prevention in a woman who is already pregnant *[see Contraindications]*. Epidemiologic studies and meta-analyses have not shown an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb-reduction defects) following maternal exposure to low dose CHCs prior to conception or during early pregnancy. No adverse development outcomes were observed in pregnant rats and rabbits with the administration of etonogestrel during organogenesis at doses of 315 or 781 times the anticipated human dose (60 µg/day). NEXPLANON should be removed if maintaining a pregnancy.

Lactation
Risk Summary
Small amounts of contraceptive steroids and/or metabolites, including etonogestrel are present in human milk. No significant adverse effects have been observed in the production or quality of breast milk, or on the physical and psychomotor development of breastfed infants. Hormonal contraceptives, including etonogestrel, can reduce milk production in breastfeeding mothers. This is less likely to occur once breastfeeding is well-established; however, it can occur at any time in some women. When possible, advise the nursing mother about both hormonal and non-hormonal contraceptive options, as steroids may not be the initial choice for these patients. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NEXPLANON and any potential adverse effects on the breastfed child from NEXPLANON or from the underlying maternal condition.

Pediatric Use
Safety and efficacy of NEXPLANON have been established in women of reproductive age. Safety and efficacy of NEXPLANON are expected to be the same for postpubertal adolescents. However, no clinical studies have been conducted in women less than 18 years of age. Use of this product before menarche is not indicated.

Geriatric Use
This product has not been studied in women over 65 years of age and is not indicated in this population.

Hepatic Impairment
No studies were conducted to evaluate the effect of hepatic disease on the disposition of NEXPLANON. The use of NEXPLANON in women with active liver disease is contraindicated *[see Contraindications]*.

Overweight Women
The effectiveness of the etonogestrel implant in women who weighed more than 130% of their ideal body weight has not been defined because such women were not studied in clinical trials. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. It is therefore possible that NEXPLANON may be less effective in overweight women, especially in the presence of other factors that decrease serum etonogestrel concentrations such as concomitant use of hepatic enzyme inducers.

OVERDOSAGE
Overdosage may result if more than one implant is inserted. In case of suspected overdose, the implant should be removed.

NONCLINICAL TOXICOLOGY
In a 24-month carcinogenicity study in rats with subdermal implants releasing 10 and 20 mcg etonogestrel per day (equal to approximately 1.8-3.6 times the systemic steady state exposure in women using NEXPLANON), no drug-related carcinogenic potential was observed. Etonogestrel was not genotoxic in the *in vitro* Ames/Salmonella reverse mutation assay, the chromosomal aberration assay in Chinese hamster ovary cells or in the *in vivo* mouse micronucleus test. Fertility in rats returned after withdrawal from treatment.

PATIENT COUNSELING INFORMATION *See FDA-Approved Patient Labeling.*
- Counsel women about the insertion and removal procedure of the NEXPLANON implant. Provide the woman with a copy of the Patient Labeling and ensure that she understands the information in the Patient Labeling before insertion and removal. A USER CARD and consent form are included in the packaging. Have the woman complete a consent form and retain it in your records. The USER CARD should be filled out and given to the woman after insertion of the NEXPLANON implant so that she will have a record of the location of the implant in the upper arm and when it should be removed.
- Counsel women to contact their healthcare provider immediately if, at any time, they are unable to palpate the implant.
- Counsel women that NEXPLANON does not protect against HIV infection (AIDS) or other STDs.
- Counsel women that the use of NEXPLANON may be associated with changes in their normal menstrual bleeding patterns so that they know what to expect.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA.

For more detailed information, please read the Prescribing Information.
USPI-MK8415-IPTX-1810r020
Revised: 10/2018

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Should all women with a history of OASI have a mediolateral episiotomy at their subsequent delivery?

No, this should not be a universal recommendation. Women with a history of obstetric anal sphincter injury (OASI) should be counseled regarding the risks of recurrence, potential risk factors such as macrosomia and increased length of the second stage of labor, and potential mediating factors such as mediolateral episiotomy (MLE) and cesarean delivery. The risks of both episiotomy and cesarean delivery need to be considered, as well as how the existing literature on this topic applies to the specific clinician and patient population involved.

FAST TRACK

For women with a history of OASI, standardized recommendations for mode of delivery and use of MLE currently are not available

Van Bavel J, Ravelli AC, Abu-Hanna A, et al. Risk factors for the recurrence of obstetrical anal sphincter injury and the role of a mediolateral episiotomy: an analysis of a national registry. BJOG. 2020;127:951-956.

EXPERT COMMENTARY
Jaimey M. Pauli, MD, is Associate Professor, Pennsylvania State College of Medicine, Chief, Division of Maternal-Fetal Medicine, Milton S. Hershey Medical Center, Hershey, Pennsylvania. She serves on the OBG MANAGEMENT Board of Editors.

Women with a history of OASI are at increased risk for recurrence in a subsequent delivery. Higher rates of anal and fecal incontinence are reported in women with recurrent OASI (rOASI) compared with women who had an OASI only in their first delivery. Previous studies have reported recurrence rates of 5% to 7%,[1] and some suggested that MLE may be protective, but standardized recommendations for mode of delivery and use of MLE currently are not available.

The author reports no financial relationships relevant to this article.

Recently, van Bavel and colleagues sought to determine the rate of rOASI in their population as well as the factors that increase and decrease the risk of this complication.

Details of the study

This cohort study used data from the Dutch Perinatal Registry (Perined) that included 268,607 women who had their first and second deliveries (singleton, term, vertex, < 43 weeks) vaginally in 2000–2009. The study's primary objective was to determine the rate of rOASI in women who had OASI in their first delivery. The secondary objectives were to identify risk factors for rOASI and to assess the effect of MLE. For the purposes of this study, OASI was defined as subtotal and total rupture of the perineum, or grades 3A-4 as defined by the Royal College of Obstetricians and Gynaecologists.[2]

Within this cohort, 9,943 women had an OASI in their first delivery (4%), and the rate of rOASI was 5.8% (579 of 9,943). After multivariate analysis, the risk factors for rOASI were birth weight of 4,000 g or greater (odds ratio [OR], 2.1; 95% confidence

interval [CI], 1.6–2.6) and duration of the second stage of labor of 30 minutes or longer (OR, 1.8; 95% CI, 1.4–2.3).

The MLE rate was 40.8% (4,054 of 9,943) and was associated with a lower rate of rOASI (OR, 0.3; 95% CI, 0.3–0.4). This association persisted when delivery type was separated into spontaneous and operative vaginal deliveries, with the number of MLEs needed to prevent one rOASI of 22 and 8, respectively. Birth weight of less than 3,000 g also was noted to be protective against rOASI (OR, 0.5; 95% CI, 0.3–0.9).

Based on these findings, as well as comparisons to previous studies, the authors concluded that MLE could be considered for routine use or at least discussed with all women with a prior OASI for prevention of rOASI.

Study strengths and limitations

A strength of this study was the large number of deliveries and the wide variation of practice included in the registry database, which promotes the generalizability of the results and reduces bias. This also provides an adequate base on which to determine an accurate rate of rOASI in the Dutch population.

One study limitation is that information is not available regarding how the episiotomies were performed (specifically, angle of incision), delivery techniques ("hands on" vs "hands off"), and indication for the episiotomy. Additional limitations suggested are that clinicians who perform an episiotomy may have an inherent bias regarding the protective nature of the procedure and may miss a rOASI due to inadequate examination postprocedure, overestimating its protective effect.

Finally, the relatively high rate of MLE and low rate of cesarean delivery (6.9%) in this study are specific to the Netherlands and do not reflect the obstetric practices used in many other countries. Generalizability of these results in the context of much lower MLE and higher cesarean delivery rates (as in the United States) would therefore be in question. ●

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Prevention of rOASI is important, as fecal incontinence is debilitating and difficult to treat. While this study provides evidence that MLE may protect against this complication, its results may not be generalizable to all patient or clinician populations. Differences in baseline rate of MLE and cesarean delivery, technique, indication, and comfort with repair—all not evaluated in this study—must be taken into account when counseling OASI patients about their options for delivery and the use of MLE in a subsequent pregnancy.

JAIMEY M. PAULI, MD

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PART 3 OF 3

Telemedicine: Navigating legal issues

Some legal concerns and caveats of using telemedicine, as well as a prediction for the future of virtual health care

Mickey Karram, MD; Anjali Dooley, MBA, JD; Nadia de la Houssaye, JD; and Neil Baum, MD

IN THIS ARTICLE

In the first 2 articles of this series, "Telemedicine: A primer for today's ObGyn" and "Telemedicine: Common hurdles and proper coding for ObGyns," which appeared in the May and June issues of OBG MANAGEMENT, we discussed caring for patients without face-to-face visits and that virtual visits are an opportunity to provide good care in a world such as that created by COVID-19. We also discussed which patients are the most appropriate candidates for telemedicine, as well as how to properly code virtual visits so that you are paid for your time and service. This third article addresses the legal concerns and caveats of using telemedicine and makes a prediction for the future of virtual health care.

Legal issues surrounding telemedicine

There are numerous legal, regulatory, and compliance issues that existed before the pandemic that likely will continue to be of concern postpandemic. Although the recent 1135 waiver (allowing Medicare to pay for office, hospital, and other visits furnished via telehealth)[1] and other regulations are now in place for almost every aspect of telemedicine, virtual medicine is not a free-for-all (even though it may seem like it). Practicing ethical telemedicine entails abiding by numerous federal and state-specific laws and requirements. It is important to be aware of the laws in each state in which your patients are located and to practice according to the requirements of these laws. This often requires consultation with an experienced health care attorney who is knowledgeable about the use of telemedicine and who can help you with issues surrounding:

- **Malpractice insurance.** It is an important first step to contact your practice's malpractice insurance carrier and confirm coverage for telemedicine visits. Telemedicine visits are considered the same as in-person visits when determining scope of practice and malpractice liability. Nevertheless, a best practice is to have written verification from your malpractice carrier about the types of telemedicine services and claims for which your ObGyn practice is covered. Additionally, if you care for patients virtually who live in a state in which you are not licensed, check with your carrier to determine if potential claims will be covered.

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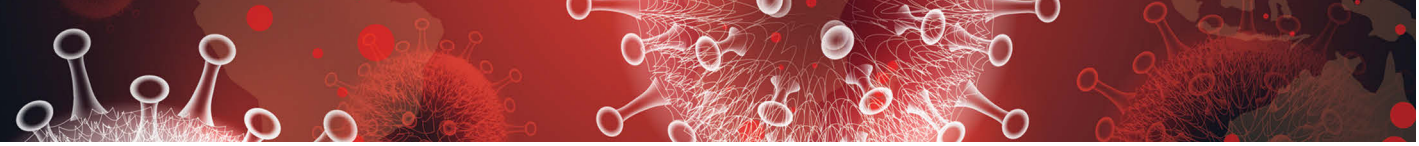
The authors report no financial relationships relevant to this article.



- **Corporate practice laws.** These laws require that your practice be governed by a health care professional and not someone with a nonmedical background. This becomes important if you are looking to create a virtual practice in another state. States that prohibit the corporate practice of medicine have state-specific mandates that require strict adherence. Consult with a health care attorney before entering into a business arrangement with a nonphysician or corporate entity.
- **Delegation agreement requirements.** These laws require physician collaboration and/or supervision of allied health care workers such as nurse practitioners (NPs) and physician assistants (PAs) and may limit the number of allied health care providers that a physician may supervise. Many states are allowing allied health care workers to practice at the top of their license, but this is still state specific. Thus, it is an important issue to consider, especially for practices that rely heavily on the services of advanced practice registered nurses (APRNs), for example, who have a broad scope of practice and who may be qualified to care for many common ObGyn problems.
- **Informed consent requirements.** Some states have no requirements regarding consent for a virtual visit. Others require either written or verbal consent. In states that do not require informed consent, it is best practice to nevertheless obtain either written or oral consent and to document in the patient's record that consent was obtained before initiating a virtual visit. The consent should follow state-mandated disclosures, as well as the practice's policies regarding billing, scheduling, and cancellations of telemedicine visits.
- **Interstate licensing laws.** Because of the COVID-19 pandemic, federal and state licensure waivers are in place to allow physicians to care for patients outside the physician's home state, but these waivers likely will be lifted postpandemic. Once waivers are lifted, physicians will need to be licensed not only in the state in which they practice but also in the state where the patient is located at the time of treatment. Even physicians who practice in states that belong to the Interstate Medical Licensure Compact[2] must apply for and obtain a license to practice within Compact member states. Membership in the Interstate Medical Licensure Compact expedites the licensure process, but does not alleviate the need to obtain a license to practice in each member state. To ensure compliance with interstate licensure laws, seek advice from a health care attorney specializing in telemedicine.
- **Drug monitoring laws.** The Ryan Haight Online Pharmacy Consumer Protection Act of 2008[3] implemented a requirement that physicians have at least one in-person, face-to-face visit with patients *before* prescribing a controlled substance for the first time. Because state laws may vary, we suggest consulting with a health care attorney to understand your state's requirements for prescribing controlled substances to new patients and when using telemedicine (see "Prescription drugs" at https://www.cdc.gov/phlp/publications/topic/prescription.html for more information).
- **Data privacy and security.** From a content perspective, health care data and personally identifiable information are extremely rich, which makes electronic health records (EHRs), or the digital form of patients' medical histories and other data, particularly tempting targets for hackers and cyber criminals. We caution that services such as Facetime and Skype are not encrypted; they have been granted waivers for telemedicine use, but these waivers are probably not going to be permanent once the COVID-19 crisis passes.
- **HIPAA compliance.** Generally—and certainly under normal circumstances—telemedicine is subject to the same rules governing protected health information (PHI) as any other technology and process used in physician practices. The Health Insurance Portability and Accountability Act (HIPAA) Security Rule includes guidelines on telemedicine and stipulates that only authorized users should have

FAST TRACK

It is best practice to obtain and document informed consent before initiating a virtual visit

access to ePHI, that a system of secure communication must be established to protect the security of ePHI, and that a system to monitor communications must be maintained, among other requirements.[4] Third parties that provide telemedicine, data storage, and other services, with a few exceptions, must have a business associate agreement (BAA) with a covered entity. Covered entities include health care providers, health plans, and health and health care clearinghouses. Such an agreement should include specific language that ensures that HIPAA requirements will be met and that governs permitted and required uses of PHI, strictly limits other uses of PHI, and establishes appropriate safeguards and steps that must be taken in the event of a breach or disallowed disclosure of PHI. Best practice requires that providers establish robust protocols, policies, and processes for handling sensitive information.

During the COVID-19 pandemic, however, certain HIPAA restrictions relating to telemedicine have been temporarily waived by the US Department of Health and Human Services (HHS). More specifically, HHS Secretary Alex Azar has exercised his authority to waive sanctions against covered hospitals for noncompliance with requirements: to obtain a patient's consent to speak with family members or friends involved in the patient's care, to distribute a notice of privacy practices, to request privacy restrictions, to request confidential communications, and the use of nonpublic facing audio and video communications products, among others.[5] These are temporary measures only; once the national public health emergency has passed or at the HHS Secretary's discretion based on new developments, this position on discretionary nonenforcement may end.

FAST TRACK

Services such as Facetime and Skype have been granted waivers for telemedicine use, but these waivers will probably end after the COVID-19 crisis

Crisis creates opportunity: The future of telemedicine

It was just a few years ago when the use of telemedicine was relegated to treating patients in only rural areas or those located a great distance from brick and mortar practices. But the pandemic, along with the coincident relaxation of the Centers for Medicare and Medicaid Services' (CMS) requirements for conducting telemedicine visits has made the technology highly attractive to ObGyns who can now treat many patients 24/7 from their homes using laptops and even mobile devices. In addition, the pandemic has prompted an expansion of current procedural terminology (CPT) codes that makes it possible to bill patients for telemedicine services and be appropriately compensated.

Thus, as awful as COVID-19 is, we can conclude that it has provided us with opportunities. We predict that when the crisis has abated, although the current relaxation of HIPAA guidelines will probably be rescinded, restrictions will not likely return to precoronavirus status; changes will certainly be made, and telemedicine will likely become part and parcel of caring for ObGyn patients.

Telemedicine has been used successfully for years to improve patient access to medical care while reducing health care costs. In 2016, an estimated 61% of US health care institutions and 40% to 50% of US hospitals used telemedicine.[6] And according to the results of a survey of America's physicians conducted in April 2020, almost half (48%) are treating patients through telemedicine, which is up from just 18% 2 years ago.[7]

Letting loose the genie in the bottle

Widespread use of telemedicine traditionally has been limited by low reimbursement rates and interstate licensing and practice issues, but we predict that the use of telemedicine is going to significantly increase in the future. Here's why:[8] Disruptive innovation was defined by Professor Clayton Christensen of the Harvard Business School in 1997.[9] Disruptive innovation explains the process by which a disruptive force spurs the development of simple, convenient, and affordable solutions that then replace processes that are expensive and complicated. According to Christensen, a critical element of the process is a technology that makes a product or

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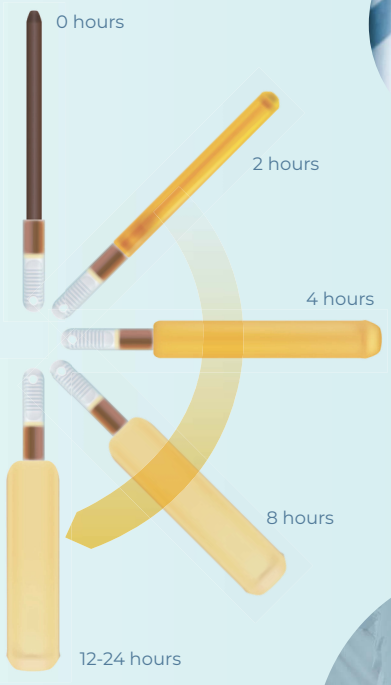

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References: 1. DILAPAN-S® Instructions for Use. DSPIenus-Rev018/2020-04. **2.** Saad AF et al. *Am J Obstet Gynecol.* 2019;220(3):275.e1-275.e9.

medicem

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A look at one company's use of telemedicine: CVS Pharmacy

CVS is using telemedicine to complement the company's retail "Minute Clinic," which offers routine preventive and clinical services, such as vaccine administration, disease screenings, treatment for minor illnesses and injuries, and monitoring of chronic conditions—services that traditionally were provided in physician's offices only. These clinics are open 7 days per week, providing services on a walk-in basis at an affordable price—about $60 per visit compared with an average of $150 for an uninsured patient to see a primary care physician in his/her office.[1] While this seems to be fulfilling an unmet need for patients, the service may prove disruptive to traditional health care delivery by removing a lucrative source of income from physicians.

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FAST TRACK

Telemedicine can help to address physician shortages in rural and urban areas alike

service more accessible to a larger number of people while reducing cost and increasing ease of use. For example, innovations making equipment for dialysis cheaper and simpler helped make it possible to administer the treatment in neighborhood clinics, rather than in centralized hospitals, thus disrupting the hospital's share of the dialysis business.

The concept of telemedicine and the technology for its implementation have been available for more than 15 years. However, it was the coronavirus that released the genie from the bottle, serving as the disruptive force to release the innovation. Telemedicine has demonstrated that the technology offers solutions that address patients' urgent, unmet needs for access to care at an affordable price and that enhances the productivity of the ObGyn. The result is simple, convenient, and affordable; patients can readily access the medical care they need to effectively maintain their health or manage conditions that arise.

Telemedicine has reached a level of critical mass. Data suggest that patients, especially younger ones, have accepted and appreciate the use of this technology.[10] It gives patients more opportunities to receive health care in their homes or at work where they feel more comfortable and less anxious than they do in physicians' offices.

Several other health care issues may be altered by telemedicine.

The physician shortage. If the data are to be believed, there will be a significant shortage of physicians—and perhaps ObGyns—in the near future.[11] Telemedicine can help the problem by making it possible to provide medical care not only in rural areas where there are no ObGyns but also in urban areas where a shortage may be looming.

Continuing medical education (CME). CME is moving from large, expensive, in-person conferences to virtual conferences and online learning.

The American health care budget is bloated with expenses exceeding $3 trillion.[12] Telemedicine can help reduce health care costs by facilitating patient appointments that do not require office staff or many of the overhead expenses associated with brick and mortar operations. Telemedicine reduces the financial impact of patient no-shows. Because patients are keen on participating, the use of telemedicine likely will improve patient engagement and clinical outcomes. Telemedicine already has a reputation of reducing unnecessary office and emergency room visits and hospital admissions.[13]

Clinical trials. One of the obstacles to overcome in the early stages of a clinical trial is finding participants. Telemedicine will make patient recruitment more straightforward. And because telemedicine makes distance from the office a nonissue, recruiters will be less restricted by geographic boundaries.

In addition, telemedicine allows for the participants of the trial to stay in their homes most of the time while wearing remote moni-

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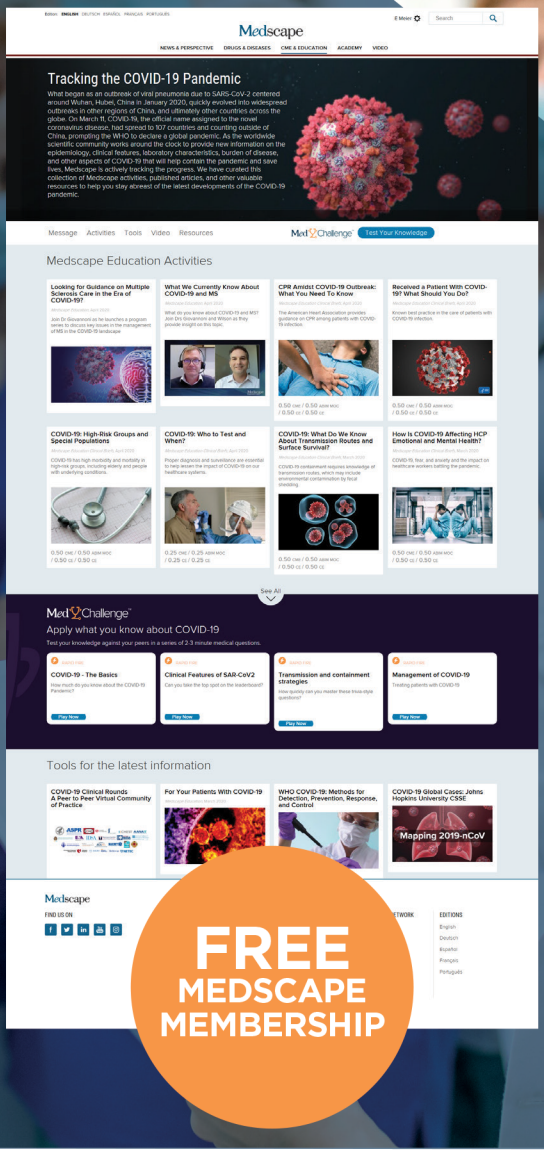

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toring devices. Such devices would enable trial researchers to spot deviations from patients' baseline readings.

The bottom line

COVID-19 has provided the opportunity for us to see how telemedicine can contribute to reducing the spread of infectious diseases by protecting physicians, their staff, and patients themselves. Once the COVID-19 crisis has passed, it is likely that telemedicine will continue to move health care delivery from the hospital or clinic into the home. The growth and integration of information and communication technologies into health care delivery holds great potential for patients, providers, and payers in health systems of the future. ●

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Lyndsey S. Benson, MD, MS, and Sarah W. Prager, MD, MAS

IN THIS ARTICLE

The American College of Obstetricians and Gynecologists (ACOG) defines early pregnancy loss (EPL) as a nonviable, intrauterine pregnancy up to 12 6/7 weeks' gestation.[1] The term EPL has been used interchangeably with miscarriage, spontaneous abortion, and early pregnancy failure; the preferred terms among US women who experience pregnancy loss are EPL and miscarriage.[2] EPL is the most common complication of early pregnancy and accounts for up to 15% to 20% of clinically recognized pregnancies.[3]

The most common cause of EPL is a chromosomal abnormality (**TABLE 1**). Other common etiologies include structural abnormalities, such as uterine fibroids or polyps. Risk factors for EPL include maternal age, prior pregnancy loss, and various maternal conditions and medication and substance use (**TABLE 2**).

Definitive diagnosis of EPL often requires more than 1 ultrasonography scan

TABLE 1 Etiology of EPL

Chromosomal abnormalities (50%-70%)
Trisomies
Polyploidies
Monosomy X
Other
Maternal anatomic abnormalities
Uterine leiomyomas (fibroids)
Uterine polyps
Intrauterine adhesions
Uterine septa
Trauma
Violence (for example, gunshot wound)
Iatrogenic (for example, chorionic villus sampling)
Unexplained

Abbreviation: EPL, early pregnancy loss.

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or other examination to determine whether a pregnancy is nonviable versus too early to confirm viability. The consensus guidelines from the Society of Radiologists in Ultrasound provide transvaginal ultrasonographic criteria to diagnose EPL (**TABLE 3**).[4] Two of the diagnostic criteria require only 1 ultrasonography scan while the others require repeat ultrasonography.

Note that a definitive diagnosis may be more important to some patients than others due to differing pregnancy intent and/or desirableness. Patients may choose to take action in terms of medication or uterine aspiration based on suspicion of EPL, or they may wish to end the pregnancy regardless of EPL diagnosis.

TABLE 2 Risk factors for EPL

Increasing maternal age
Race/ethnicity[a]
Prior pregnancy loss
Maternal medical conditions
Infection
Diabetes
Obesity
Thyroid disease
Stress
Inherited thrombophilia
Intrauterine device in situ
Subchorionic hemorrhage
Medication and substance use
Smoking
Caffeine (> 200 mg daily)
Alcohol
Cocaine
Methamphetamines
Environmental exposures
Ionizing radiation
Excessive air pollution
Toxin exposure (for example, lead, arsenic)

Abbreviation: EPL, early pregnancy loss.

[a]Studies have shown increased rates of EPL among women of color, likely resulting from cumulative stressors of racism, social determinants of health, and increased environmental and occupational exposures.

TABLE 3 Society of Radiologists in Ultrasound guidelines for transvaginal ultrasonographic diagnosis of EPL[a,4]

Findings diagnostic of EPL[b]	Findings suggestive, but not diagnostic, of EPL[c]
Crown-rump length of 7 mm or greater and no heartbeat	Crown-rump length of less than 7 mm and no heartbeat
Mean sac diameter of 25 mm or greater and no embryo	Mean sac diameter of 16-24 mm and no embryo
Absence of embryo with heartbeat 2 weeks or more after a scan that showed a gestational sac without a yolk sac	Absence of embryo with heartbeat 7-13 days after an ultrasound scan that showed a gestational sac without a yolk sac
Absence of embryo with heartbeat 11 days or more after a scan that showed a gestational sac with a yolk sac	Absence of embryo with heartbeat 7-10 days after an ultrasound scan that showed a gestational sac with a yolk sac
	Absence of embryo for 6 weeks or longer after last menstrual period
	Empty amnion (amnion seen adjacent to yolk sac, with no viable embryo)
	Enlarged yolk sac (greater than 7 mm)
	Small gestational sac in relation to the size of the embryo (less than 5 mm difference between mean sac diameter and crown-rump length)

Abbreviation: EPL, early pregnancy loss.

[a]Criteria are from the Society of Radiologists in Ultrasound Multispecialty Consensus Conference on Early First Trimester Diagnosis of Miscarriage and Exclusion of a Viable Intrauterine Pregnancy, October 2012.

[b]These are the radiologic criteria only and do not replace clinical judgment.

[c]When there are findings suspicious for EPL, follow-up ultrasonography at 7-10 days to assess the pregnancy for viability is generally appropriate.

Used with permission.[4]

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Ordering mifepristone

- There are 2 distributors of mifepristone in the United States. Danco (www.earlyoptionpill.com) distributes the branded Mifeprex and GenBioPro (www.genbiopro.com) distributes generic mifepristone.
- To order mifepristone, 1 health care provider from your clinic or facility must read and sign the distributor's prescriber agreement and account setup form. These forms and instructions can be found on each distributor's website. Future orders can be made by calling the distributor directly (Danco: 1-877-432-7596; GenBioPro: 1-855-643-3463).
- The shelf life of mifepristone is 18 months.
- Each patient who receives mifepristone needs to read and sign a patient agreement (available on distributor websites), as required by the US Food and Drug Administration–approved Risk Evaluation and Mitigation Strategy (REMS) program.

FAST TRACK

EPL can be managed expectantly, with medication, or with uterine aspiration

Management options for EPL

EPL can be managed expectantly, with medication, or with uterine aspiration. These methods have different risks and benefits, and in most cases all should be made available to women who experience EPL.[5-7]

Expectant management

Expectant management involves waiting for the body to spontaneously expel the nonviable pregnancy. In the absence of any signs of infection, hemodynamic instability, or other medical instability, it is safe and reasonable to wait a month or more before intervening, according to patient choice. Expectant management is up to 80% effective.[8]

Medication management

Medication management entails using mifepristone and misoprostol, or misoprostol alone, to cause uterine contractions to expel the pregnancy. A landmark study demonstrated that medication management of EPL with the combination of mifepristone and misoprostol is significantly more effective than misoprostol alone.[9] While the mean cost of mifepristone is approximately $90 per dose, its addition is cost-effective given the increased efficacy.[10]

The evidence-based combination regimen is to provide mifepristone 200 mg orally, followed 24 hours later by misoprostol 800 µg vaginally, for a success rate of 87.8% by 8 days, and 91.2% by 30 days posttreatment. Success rates can be increased further by adding a second dose of misoprostol to take as needed.[5]

We strongly recommend using the combination regimen if you have access to mifepristone. If you do not have access to mifepristone in your clinical setting, perhaps this indication for use can help facilitate getting it onto your formulary. (See "Ordering mifepristone" on this page.)

Without access to mifepristone, medication abortion still should be offered after discussing the decreased efficacy with patients. The first-trimester misoprostol-only regimen for EPL is to give misoprostol 800 µg buccally, vaginally, or sublingually, with a second dose if there is no effect (**TABLE 4**).[1,5] For losses after 9 weeks, some data suggest adding additional doses of misoprostol 400 µg every 3 hours until expulsion.[11]

TABLE 4 Evidence-based regimens for EPL management[1,5]

Drug	Dose
Mifepristone plus misoprostol	• Mifepristone 200 mg orally • Misoprostol 800 µg buccally, vaginally, or sublingually 24 hours after mifepristone pretreatment • Repeat misoprostol dose in 12-24 hours if no effect
Misoprostol alone	• Misoprostol 800 µg buccally, vaginally, or sublingually • Repeat misoprostol dose in 12-24 hours if no effect

Abbreviation: EPL, early pregnancy loss.

Uterine aspiration

Uterine aspiration is the third management option for EPL and is virtually 100% successful. Although aspiration is used when expectant or medication management fails, it is also a first-line option based on patient choice or contraindications to the other 2 management options.

We recommend either manual vacuum aspiration (MVA) or electric vacuum aspiration (EVA); sharp curettage almost never should be used. Uterine aspiration can be performed safely in a clinic, emergency department, or operating room (OR) setting, depending on patient characteristics and desires.[12-14] For various reasons, many patients prefer outpatient management. These reasons may include avoiding the costs and delays associated with OR management, wanting more control over who performs the procedure, or avoiding more significant/general anesthesia. MVA in the outpatient setting is the most cost-effective approach to uterine aspiration.[15]

Choosing a management approach

There are virtually no contraindications for uterine aspiration. Expectant and medication management are contraindicated (and uterine aspiration is recommended) in the setting of bleeding disorders, anticoagulation, suspected intrauterine infection, suspected molar pregnancy, significant cardiopulmonary disease, or any condition for which heavy, unsupervised bleeding might be dangerous.[1] Uterine aspiration offers immediate resolution, with a procedure usually lasting 3 to 10 minutes. By contrast, expectant and medication management offer a less predictable time to resolution and, often, a more prolonged period of active pregnancy expulsion.

In the absence of a contraindication, patient choice should determine which management option is used. All 3 options are similarly safe and effective, and the differences that do exist are acceptable to patients as long as they are allowed to access their preferred EPL management method.[5,6,16] Patient satisfaction is associated directly with the ability to choose the method of preference.

Managing pain

Pain management should be offered to all women diagnosed with EPL. Those who choose expectant or medication management likely will require only oral nonsteroidal anti-inflammatory drugs (NSAIDs). A minority may require the addition of a small number of narcotic pain pills.[17]

Women who choose uterine aspiration also should be offered pain management. All patients should be given a paracervical block; other medications can include NSAIDs, an oral benzodiazepine, intravenous (IV) sedation, or even general anesthesia/monitored airway care.[17]

Patients' expectations about pain management should be addressed directly during initial counseling. This may help patients decide what type of management and treatment location they might prefer.

Checking blood type: Is it necessary?

The ACOG practice bulletin for EPL states, "administration of Rh D immune globulin should be considered in cases of early pregnancy loss, especially those that are later in the first trimester."[1] A growing body of evidence indicates that Rho(D) immune globulin likely is unnecessary in early pregnancy.

A recent prospective cohort study of 42 women who were at 5 to 12 weeks' gestation found that the fetal red blood cell concentration was below the calculated threshold for Rh sensitization.[18] In light of recent evidence, the National Abortion Federation now recommends foregoing Rh testing and provision of Rh immune globulin at less than 8 weeks' gestation for uterine aspiration and at less than 10 weeks' gestation for medication abortion.[19]

We feel there is sufficient evidence to forego Rh testing in EPL at similar gestational ages, although this is not yet reflected in US societal guidelines. (It is already standard practice in some countries.) Although the risk of Rh alloimmunization is low, the risk of significant consequences in the event of Rh alloimmunization is high. Currently, it also is reasonable to continue giving Rho(D) immune globulin to Rh-negative patients

FAST TRACK

Uterine aspiration offers immediate resolution of EPL, while expectant and medication management offer a less predictable time to resolution and, often, a prolonged period of active pregnancy expulsion

who experience EPL at any gestational age. A lower dose (50 µg) is sufficient for EPL; the standard 300-µg dose also is acceptable.[20]

We anticipate that society and ACOG guidelines will change in the next few years as the body of evidence increases, and practice should change to reflect new guidance.

Prophylactic antibiotics

The risk of infection with EPL is low overall regardless of the management approach.[1] Prophylactic antibiotics are recommended for patients undergoing uterine aspiration but are not necessary in the setting of expectant or medication management. We recommend prophylaxis with 1 dose of oral doxycycline 200 mg or oral azithromycin 500 mg approximately 30 minutes to 1 hour prior to uterine aspiration.[21] Alternatives include 1 dose of oral metronidazole 500 mg or, if the patient is unable to take oral medications, IV cefazolin 2 g.

A multisite international randomized controlled trial concluded that antibiotic prophylaxis before uterine aspiration for EPL did not significantly reduce the risk of infection.[22] However, there was a significant reduction in pelvic infection with antibiotic administration for the subgroup of women who underwent MVA, which is our recommended approach (along with EVA, and opposed to sharp curettage) for outpatient EPL management.

FAST TRACK

Prophylactic antibiotics are recommended for patients undergoing uterine aspiration but are not necessary for expectant or medication management

Follow-up after EPL

In-person follow-up after treatment of EPL is not medically necessary. A repeat ultrasonography 1 to 2 weeks after expectant or medication management can be helpful to confirm completion of the process, and clinicians should focus on presence or absence of a gestational sac to determine if further management is needed.[1]

Follow-up by telemedicine or phone also is an option and may be preferred in the following situations:

- the patient lives far from the clinic
- travel to the clinic is difficult or expensive
- the patient has child-care issues
- there is a global pandemic necessitating physical distancing.

If the patient's reported history and symptoms are consistent with a completed process, no further intervention is indicated.

If ongoing EPL is a concern, ask the patient to come in for an evaluation and ultrasonography. If visiting the clinic is still a challenge, following with urine or serum human chorionic gonadotropin (HCG) levels also is acceptable. Experts recommend waiting 4 weeks before expecting a negative urine HCG measurement, although up to 25% of women with a completed EPL will still have a positive test at 4 weeks.[23,24]

A postprocedure serum HCG is more helpful if a preprocedure HCG level already is known. Numerous studies have evaluated phone follow-up after medication abortion and it is reasonable to translate these practices to follow-up after EPL, recognizing that direct data looking at alternative EPL follow-up are much more limited.[23,25-30]

The benefit of HCG follow-up at a scheduled time (such as 1 week) is less clear for EPL than for medication abortion, as HCG trends are less predictable in the setting of EPL. However, if the pregnancy has passed, a significant drop in the HCG level would be expected. It is important to take into account the patient's history and clinical symptoms and consider in-person evaluation with possible ultrasonography if there is concern that the pregnancy tissue has not passed.

Pay attention to mental health

It is critical to assess the patient's mental and emotional health. This should be done both at the time of EPL diagnosis and management and again at follow-up. Both patients and their partners can struggle after experiencing EPL, and they may suffer from prolonged posttraumatic stress.[31]

Often, EPL occurs before people have shared the news about their pregnancy. This can amplify the sense of isolation and sadness many women report. Equally critical is recognizing that not all women who experience EPL grieve, and clinicians should normalize patient experiences and feelings. Provider

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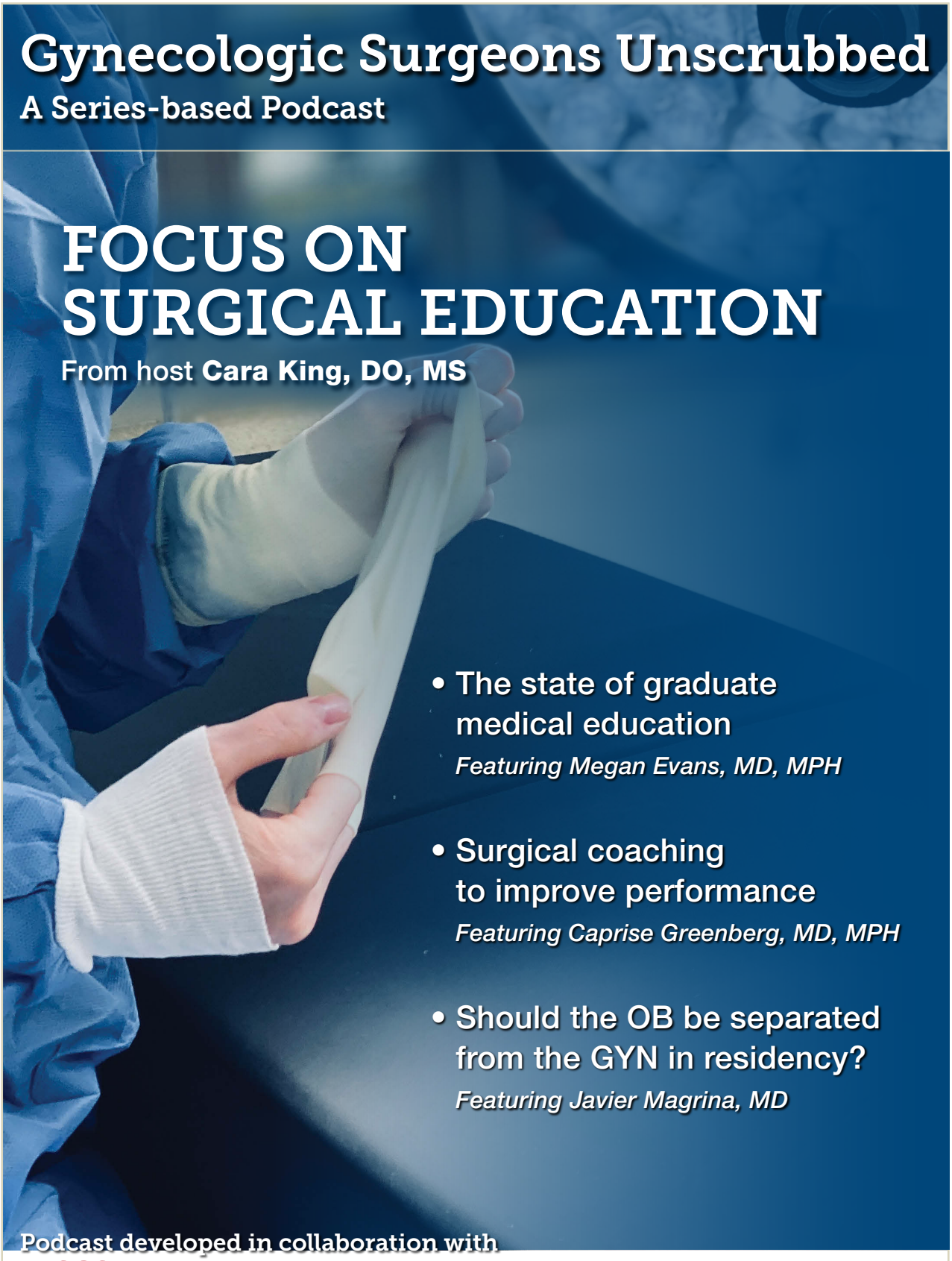
Gynecologic Surgeons Unscrubbed

A Series-based Podcast



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Key takeaways

- Early pregnancy loss (EPL) is common, occurring in up to 15% to 20% of clinically recognized pregnancies.
- EPL can be managed expectantly, with medication, or by uterine aspiration.
- There are virtually no contraindications to uterine aspiration.
- Contraindications to expectant or medication management include any situation in which heavy, unsupervised bleeding might be dangerous.
- In the absence of contraindications, patient preference should dictate the management approach.
- Mifepristone-misoprostol is more effective than misoprostol alone.
- Manual uterine aspiration in the outpatient setting is the most cost-effective approach to uterine evacuation.
- Rh testing is not necessary at less than 8 weeks' gestation if choosing uterine aspiration, or at less than 10 weeks' gestation if choosing expectant or medication management.
- Antibiotic prophylaxis is indicated for uterine aspiration, but not for expectant or medication management.
- Ultrasonography follow-up should focus on presence or absence of gestational sac.
- There are viable telemedicine and phone follow-up options that do not require repeat ultrasonography or in-person evaluation.
- There is no need to delay future conception once EPL management is confirmed to be complete.
- It is okay to initiate any contraceptive method immediately on completed management of EPL.
- Feelings toward EPL can be complex and varied; it is helpful to normalize your patients' experiences, ask open-ended questions, and provide support as needed.

FAST TRACK

After EPL, discuss plans for future conception as well as needs for immediate contraception and counseling

language is important. We recommend use of these questions and phrases:

- I'm so sorry for your loss.
- How are you feeling?
- How have you been doing since I saw you last?
- Your friends/family/partner may be grieving differently or at a different pace than you—this is normal.
- Just because the EPL process is complete doesn't necessarily mean your processing and/or grieving is over.
- Whatever you're feeling is okay.

Address desire for future pregnancy or contraception

No additional workup is necessary after EPL unless a patient is experiencing recurrent pregnancy loss. We do recommend discussing plans for future conception. If a patient wants to conceive again as soon as possible, she can start trying when she feels emotionally ready (even before her next menstrual period). One study found that the ability to conceive and those pregnancy outcomes were the same when patients were randomly assigned to start trying immediately versus waiting 3 months after EPL.[32]

Alternatively, a patient may want to prevent pregnancy after EPL, and this information should be explicitly elicited and addressed with comprehensive contraception counseling as needed. All forms of contraception can be initiated immediately on successful management of EPL. All contraceptive methods, including an intrauterine device, can be initiated immediately following uterine aspiration.[1,33,34]

Patients should be reminded that if they delay contraception initiation by more than

7 days, they are potentially at risk for pregnancy.[35] Most importantly, clinicians should not make assumptions about future pregnancy desires and should ask open-ended questions to provide appropriate patient counseling.

Finally, patients may feel additional anxiety in a subsequent pregnancy. It is helpful to acknowledge this and perhaps even offer earlier and more frequent visits in early pregnancy to help reduce anxiety. EPL is commonly experienced, and unfortunately it is sometimes poorly addressed by clinicians.

We hope this guidance will help you provide excellent, evidence-based, and sensitive care that will not only manage your patient's EPL but also make the experience as positive as possible. ●

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UPDATE Abnormal uterine bleeding

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The evidence base on management strategies for AUB continues to grow, and recent studies suggest that therapy can be tailored based on certain factors, such as patient age and fertility goals and surgeon skill

IN THIS ARTICLE

Abnormal uterine bleeding (AUB) continues to be a top reason that women present for gynecologic care. In general, our approach to the management of AUB is to diagnose causes before we prescribe therapy and to offer conservative therapies initially and progress to more invasive measures if indicated.

In this Update, we highlight several new studies that provide evidence for preferential use of certain medical and surgical therapies. In considering conservative therapy for the treatment of AUB, we take a closer look at the efficacy of cyclic progestogens. Another important issue, as more types of endometrial ablation (EA) are being developed and are coming into the market, is the need for additional guidance regarding decisions about EA versus progestin-releasing intrauterine devices (IUDs). Lastly, an unintended consequence of an increased cesarean delivery rate is the development of isthmocele, also known as cesarean scar defect or uterine niche. These defects, which can be bothersome and cause abnormal bleeding, are treated with various techniques. Within the last year, 2 systematic reviews that compare the efficacy of several different approaches and provide guidance have been published.

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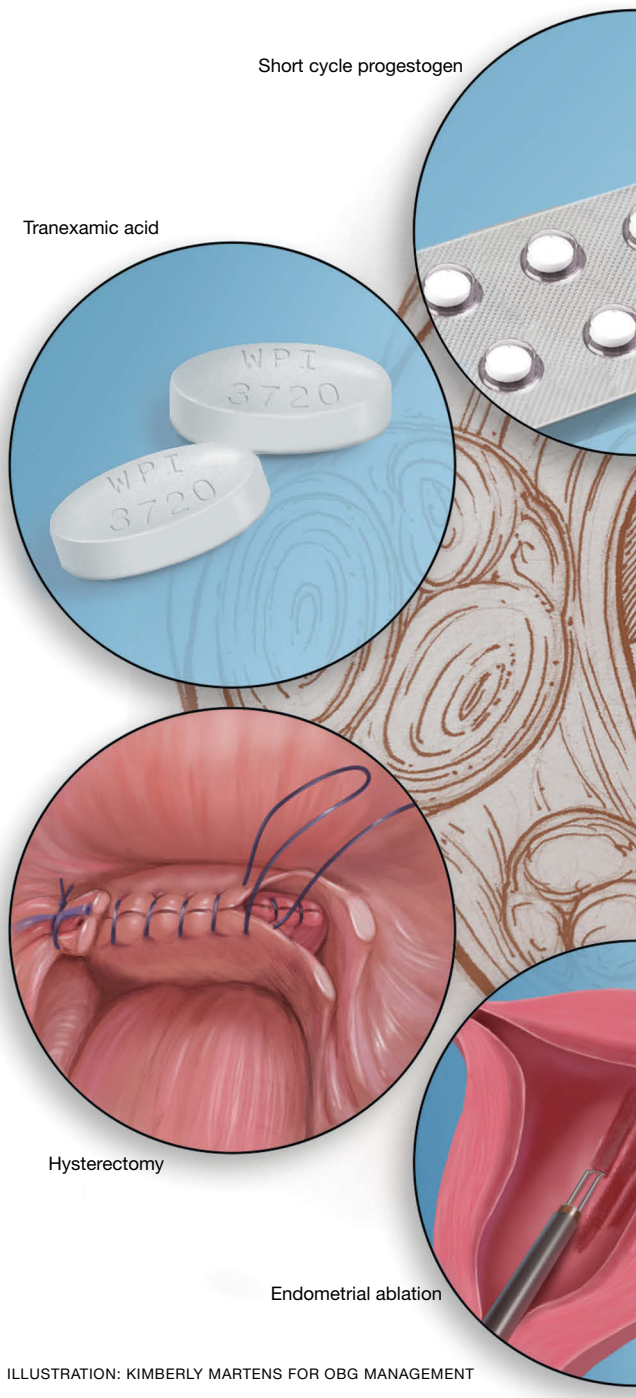
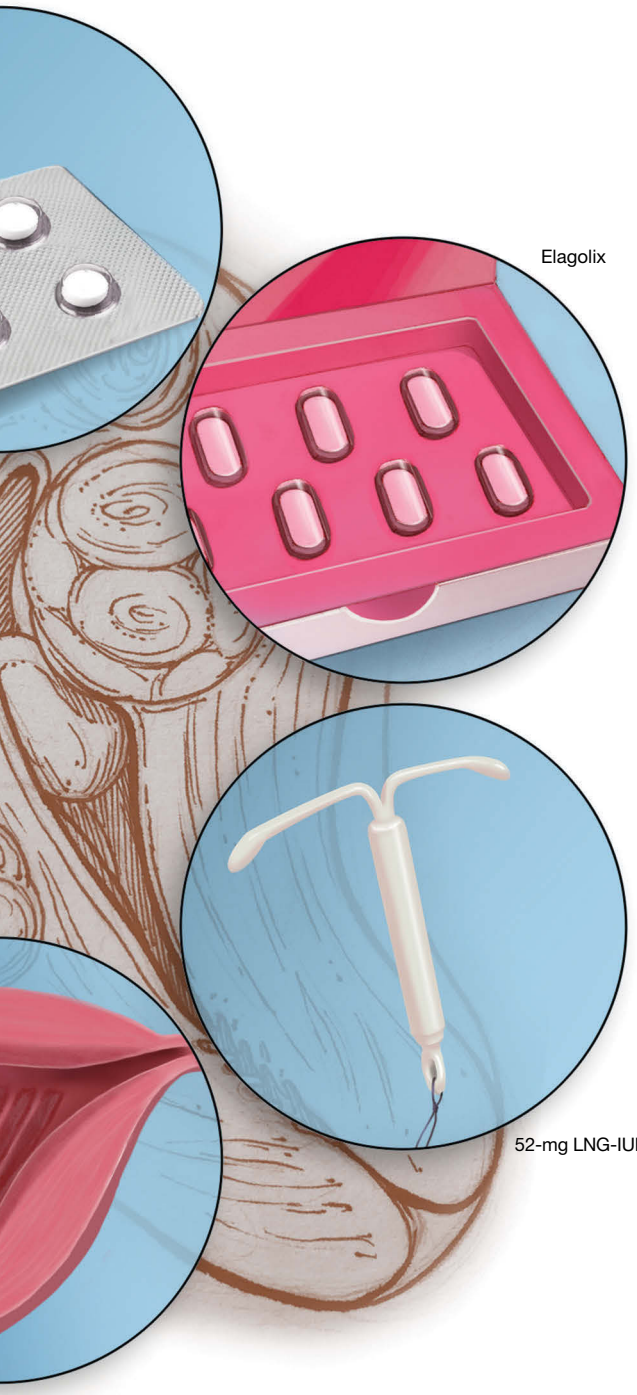


ILLUSTRATION: KIMBERLY MARTENS FOR OBG MANAGEMENT

How effective is elagolix treatment in women with fibroids and HMB?

Elagolix with hormonal add-back therapy (estradiol/norethindrone) was effective: 87.9% of participants who received combination therapy met both primary endpoints:

1) percentage of women with less than 80 mL menstrual blood loss during the final month, and 2) a 50% or greater reduction in menstrual blood loss from baseline to final month. Treatment was for up to 12 months as an extension of 1 of 2 randomized, double-blinded, placebo-controlled studies using elagolix.



Simon JA, Al-Hendy A, Archer DF, et al. Elagolix treatment for up to 12 months in women with heavy menstrual bleeding and uterine leiomyomas. Obstet Gynecol. 2020;135:1313-1326.

EXPERT COMMENTARY
Andrea S. Lukes, MD, MHSc, is Founder, Carolina Women's Research and Wellness Center, and Chief Medical Officer, Health Decisions Inc., Durham, North Carolina.

Uterine fibroids are common (occurring in up to 80% of reproductive-age women),[1,2] and often associated with heavy menstrual bleeding (HMB). There are surgical and medical options, but typically medical options are used for short periods of time. Elagolix with hormonal add-back therapy was recently approved (May 29, 2020) by the US Food and Drug Administration (FDA) for treatment of HMB in women with uterine fibroids for up to 24 months.

Dr. Lukes reports being the Principal Investigator for Abbvie, Myovant, and Obseva; a consultant for Abbvie, Myovant, and Antev; a speaker for Abbvie; a member of the Liberty Steering Committee for Myovant; and an investigator for Abbvie, Myovant, Obseva, Merck, Bayer, Sequoia, Ferring, and Sebela.

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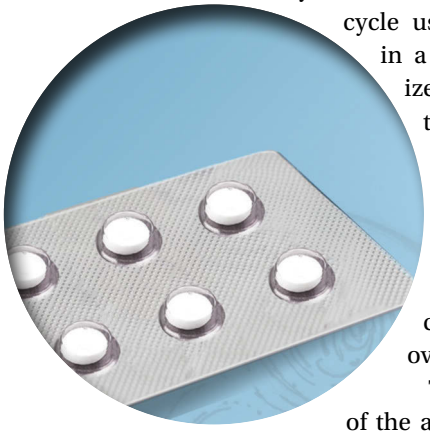
Is it time to retire cyclic progestogens for the treatment of heavy menstrual bleeding?

Bofill Rodriguez M, Lethaby A, Low C, et al. Cyclical progestogens for heavy menstrual bleeding. Cochrane Database Syst Rev. 2019;(8):CD001016.

In a recent *Cochrane Database Systematic Review,* Bofill Rodriguez and colleagues looked at the efficacy, safety, and tolerability of oral progestogen therapy for heavy menstrual bleeding.[1] They considered progestogen (medroxyprogesterone acetate or norethisterone) in short-cycle use (7 to 10 days in the luteal phase) and long-cycle use (21 days per cycle) in a review of 15 randomized clinical trials (RCTs) that included a total of 1,071 women. As this topic had not been updated in 12 years, this review was essential in demonstrating changes that occurred over the past decade.



The primary outcomes of the analysis were menstrual blood loss and treatment satisfaction. Secondary outcomes included the number of days of bleeding, quality of life, adherence and acceptability of treatment, adverse events, and costs.

Classic progestogens fall short compared with newer approaches

Analysis of the data revealed that short-cycle progestogen was inferior to treatment with tranexamic acid, danazol, and the 65-µg progesterone-releasing IUD (Pg-IUD). Of note, the 65-µg Pg-IUD has been off the market since 2001, and danazol is rarely used in current practice. Furthermore, based on 2 trials, cyclic progestogens demonstrated no clear benefit over nonsteroidal anti-inflammatory drugs. Additionally, long-cycle progestogen therapy was found to be inferior to the 52-mg levonorgestrel-releasing IUD (LNG-IUD), tranexamic acid, and ormeloxifene.

It should be noted that the quality of evidence is still lacking for progestogen therapy, and this study's main limitation is bias, as the women and the researchers were aware of the treatments that were given. This review is helpful, however, for emphasizing the advantage of tranexamic acid and LNG-IUD use in clinical care.

The takeaway. Although it may not necessarily be time to retire the use of cyclic oral progestogens, the 52-mg LNG-IUD or tranexamic acid may be more successful for treating AUB in women who are appropriate candidates.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Cyclic progestogen therapy appears to be less effective for the treatment of AUB when compared with tranexamic acid and the LNG-IUD. It does not appear to be more helpful than nonsteroidal anti-inflammatory drugs. We frequently offer and prescribe tranexamic acid, 1,300 mg 3 times daily, as a medical alternative to hormonal therapy for up to 5 days monthly for women without thromboembolism risk. Lukes and colleagues published an RCT in 2010 that demonstrated a 40% reduction of bleeding in tranexamic acid–treated women compared with an 8.2% reduction in the placebo group.[2]

Endometrial ablation: New evidence informs when it could (and could not) be the best option

Bergeron C, Laberge PY, Boutin A, et al. Endometrial ablation or resection versus levonorgestrel intra-uterine system for the treatment of women with heavy menstrual bleeding and a normal uterine cavity: a systematic review with meta-analysis. Hum Reprod Update. 2020;26:302-311.

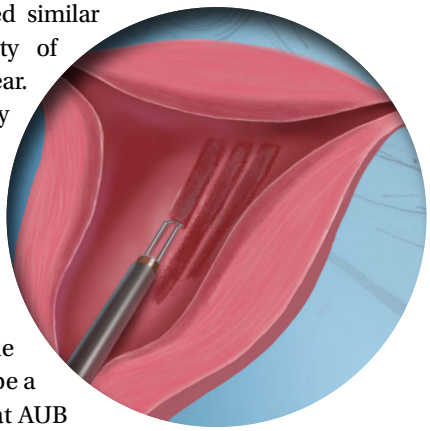
Vitale SG, Ferrero S, Ciebiera M, et al. Hysteroscopic endometrial resection vs hysterectomy for abnormal uterine bleeding: impact on quality of life and sexuality. Evidence from a systematic review of randomized controlled trials. Curr Opin Obstet Gynecol. 2020;32:159-165.

Two systematic reviews evaluated the efficacy of EA in women with abnormal uterine bleeding. One compared EA with the LNG-IUD and reported on safety and efficacy, while the other compared EA with hysterectomy and reported on quality of life.

Bergeron and colleagues reviewed 13 studies that included 884 women to compare the efficacy and safety of EA or resection with the LNG-IUD for the treatment of premenopausal women with AUB.[3] They found no significant differences between EA and the LNG-IUD in terms of subsequent hysterectomy (risk ratio [RR] = 1.3; 95% confidence interval [CI], 0.60–2.11). It was not surprising that, when looking at age, EA was associated with a higher risk for hysterectomy in women younger than age 42 (RR = 5.26; 95% CI, 1.21–22.91). Conversely, subsequent hysterectomy was less likely with EA compared to LNG-IUD use in women older than 42 years. However, statistical significance was not reached in the older group (RR = 0.51; 95% CI, 0.21–1.24).

In the systematic review by Vitale and colleagues, 9 studies met inclusion criteria for a comparison of EA and hysterectomy, with the objective of ascertaining improvement in quality of life and several other measures.[4]

Although there was significant heterogeneity between assessment tools, both treatment groups experienced similar improvements in quality of life during the first year. However, hysterectomy was more advantageous in terms of improving uterine bleeding and satisfaction in the long term when compared with EA.[4]



The takeaway. The LNG-IUD continues to be a very good option to treat AUB in patients who would be candidates for EA, especially in younger patients, who have a high failure rate with EA. Hysterectomy may have greater durability for improving quality of life and bleeding compared with EA.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

As EA is considered, it is important to continue to counsel about the efficacy of the LNG-IUD, as well as its decreased associated morbidity. Additionally, EA is particularly less effective in younger women.

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Laparoscopy is best approach for isthomocele management, with caveats

He Y, Zhong J, Zhou W, et al. Four surgical strategies for the treatment of cesarean scar defect: a systematic review and network meta-analysis. J Minim Invasive Gynecol. 2020;27:593-602.

Vitale SG, Ludwin A, Vilos GA, et al. From hysteroscopy to laparoendoscopic surgery: what is the best surgical approach for symptomatic isthmocele? A systematic review and meta-analysis. Arch Gynecol Obstet. 2020;301:33-52.

FAST TRACK

In terms of reducing abnormal bleeding and scar depth, laparoscopy for isthmocele performed better than hysteroscopy, laparoscopy combined with hysteroscopy, and vaginal repair

The isthmocele (cesarean scar defect, uterine niche), a known complication of cesarean delivery, represents a myometrial defect in the anterior uterine wall that often presents as abnormal uterine bleeding. It also can be a site for pregnancy-related complications, such as invasive placentation, placenta previa, and uterine rupture.

Two systematic reviews compared surgical strategies for treating isthmocele, including laparoscopy, hysteroscopy, combined laparoscopy and hysteroscopy, laparotomy, and vaginal repair.

Laparoscopy reduced isthmocele-associated AUB better than other techniques

A review by He and colleagues analyzed data from 10 pertinent studies (4 RCTs and 6 observational studies) that included 858 patients in total.[5] Treatments compared were laparoscopy, hysteroscopy, combined laparoscopy with hysteroscopy, and vaginal repair for reduction of AUB and isthmocele and diverticulum depth.

The authors found no difference in intraoperative bleeding between the 4 surgical methods (laparotomy was not included in this review). Hysteroscopic surgery was associated with the shortest operative time, while laparoscopy was the longest surgery. In terms of reducing intermittent abnormal bleeding and scar depth, laparoscopic surgery performed better than the other 3 methods.

Approach considerations in isthmocele repair

Vitale and colleagues conducted a systematic review that included 33 publications (28 focused on a single surgical technique, 5 compared different techniques) to examine the effectiveness and risks of various surgical approaches for isthmocele in women with AUB, infertility, or for prevention of obstetric complications.[6]

Results of their analysis in general favored a laparoscopic approach for patients who desired future fertility, with an improvement rate of 92.7%. Hysteroscopic correction had an 85% improvement rate, and vaginal correction had an 82.5% improvement rate.

Although there were no high-level data to suggest a threshold for myometrial thickness in recommending a surgical approach, the authors provided a helpful algorithm for choosing a route based on a patient's fertility desires. For the asymptomatic patient, they suggest no treatment. In symptomatic patients, the laparoscopic approach is the gold standard but requires significant laparoscopic surgical skill, and a hysteroscopic approach may be considered as an alternative route if the residual myometrial defect is greater than 2.5 to 3.5 mm. For patients who are not considering future reproduction, hysteroscopy is the gold standard as long as the residual myometrial thickness is greater than 2.5 to 3.5 mm.

The takeaway. Of the several methods used for surgical isthmocele management, the laparoscopic approach reduced

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CONTINUED FROM PAGE 35

Elagolix is an oral, nonpeptide gonadotropin-releasing hormone antagonist that results in a dose-dependent reduction of gonadotropins and ovarian sex hormones. There are now 2 approved products containing elagolix, with different indications:

- **Orilissa.** Elagolix was approved in 2018 by the FDA for moderate to severe pain associated with endometriosis. For that indication there are 2 dose options of elagolix (150 mg for up to 2 years and 200 mg for up to 6 months) and *there is no hormonal add-back therapy*.
- **Oriahnn.** Elagolix and hormonal add-back therapy was approved in 2020 for HMB associated with uterine fibroids for up to 24 months. The total daily dose of elagolix is 600 mg (elagolix 300 mg in the morning with estradiol 1 mg/norethindrone acetate 0.5 mg and then in the evening elagolix 300 mg and no hormonal add-back).

This new class of drug, GnRH antagonist, is an important one for women's health, and emerging science will continue to expand its potential uses, such as in reproductive health, as well as long-term efficacy and safety. The difference in daily dose of elagolix for endometriosis (150 mg for 24 months) compared with HMB associated with fibroids (600 mg for 24 months) is why the hormonal add-back therapy is important and allows for protection of bone density.

This is an important manuscript because it highlights a medical option for women with HMB associated with fibroids, which can be used for a long period of time. Further, the improvement in bleeding is both impressive and maintained in the extension study. Approximately 90% of women show improvement in their menstrual bleeding associated with fibroids.

The question of what to do after 24 months of therapy with elagolix and hormonal add-back therapy is an important one, but providers should recognize that the limiting factor with this elagolix and hormonal add-back therapy is bone mineral density (BMD). We will only learn more and more moving forward if this is a clinically meaningful reason for stopping treatment at 24 months. The FDA takes a strict view of safety, and providers must weigh this with the benefit of therapy.

One other highlight between the 2 approved medications is that Orilissa does not have a black box warning, given that there is no hormonal add-back therapy. Oriahnn does have a warning, regarding thromboembolic disorders and vascular events:

- Estrogen and progestin combinations, including Oriahnn, increase the risk of thrombotic or thromboembolic disorders, especially in women at increased risk for these events.
- Oriahnn is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events, including women over 35 years of age who smoke or women with uncontrolled hypertension.

Details about the study

The study by Simon et al is an extension study (UF-EXTEND), in that women could participate if they had completed 1 of the 2 pivotal studies on elagolix. The pivotal studies (Elaris UF1 and UF2) were both randomized, double-blinded, placebo-controlled studies with up to 6 months of therapy; for UF-EXTEND, however, participants were randomly assigned to either combined elagolix and hormone replacement therapy or elagolix alone for an additional 6 months of therapy. Although it was known that all participants would receive elagolix in UF-EXTEND, those who received hormonal add-back therapy were blinded. All women were then followed up for an additional 12 months after treatment ended.

The efficacy of elagolix was measured by the objective alkaline hematin method for menstrual blood loss with the a priori coprimary endpoints. The elagolix and hormonal add-back therapy group showed objective improvement in menstrual blood loss at 12 months in 87.9% of women in the extension study (89.4% in the elagolix alone group). This compares with 72.2% improvement at 6 months of treatment in the UF1 and UF2 studies for those taking elagolix and hormonal add-back therapy. These findings

FAST TRACK

For those women who experienced a decrease in bone density, the reduction was less than 5% for the lumbar spine

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Elagolix and hormonal add-back therapy offer a long-term medical option for women with HMB associated with fibroids that is both effective and safe.

ANDREA S. LUKES, MD, MHSc

illustrate maintenance of the efficacy seen within the 6-month pivotal studies using elagolix over an extended amount of time.

The safety of elagolix also was demonstrated in UF-EXTEND. The 3 most common adverse events were similar to those found in Elaris UF1 and UF2 and included hot flushes, headache, and nausea. In the elagolix and hormonal add-back therapy group during the extension study, the percentage with hot flushes was 7%, headache 6%, and nausea 4%. These are small percentages, which is encouraging for providers and women with HMB associated with fibroids.

Effects on bone density

Bone density was evaluated at baseline in the UF1 and UF2 studies, through treatment, and then 12 months after the extended treatment was stopped. The hormonal add-back therapy of estradiol 1 mg/norethindrone acetate 0.5 mg significantly protected bone density. Some women did not have a decrease in bone density, but for those who did the average was less than 5% for the lumbar spine. The lumbar spine is considered the most reactive, so this illustrates the safety that combined therapy offers women with HMB and fibroids.

The lumbar spine is considered the most reactive, so this site is often used as the main focus with BMD studies. As Simon et al show, the lumbar spine mean BMD percent change from baseline for the elagolix with add-back therapy was -1.5% (95% confidence interval [CI], -1.9 to -1.0) in women who received up to 12 months of treatment at month 6 in the extension study. After stopping elagolix with add-back therapy, at 6 months the elagolix with add-back therapy had a Z-score of -0.6% (95% CI, -1.1 to -0.1). This shows a trend toward baseline, or a recovery within a short time from stopping medication.

Study strengths and limitations

Strengths of this study include its overall design; efficacy endpoints, which were all established a priori; the fact that measurement of menstrual blood loss was done with the objective alkaline hematin method; and the statistical analysis, which is thorough and well presented. This extension study allowed further evaluation of efficacy and safety for elagolix. Although the authors point out that there may be some selection bias in an extension study, the fact that so many women elected to continue into the extended study is a positive reflection of the treatment.

As providers learn of new therapies for management of HMB associated with fibroids, it is important to consider who will benefit the most. In my opinion, any woman with heavy periods associated with fibroids could be a candidate for elagolix with add-back therapy. This treatment is highly effective, well tolerated, and safe. My approach to management includes educating a woman on all potential therapies and this new option of elagolix and add-back therapy is an important one. The decision for an individual woman on how to manage heavy periods associated with fibroids should consider her contraceptive needs, medical issues, and the risk and benefit of individual therapies. ●

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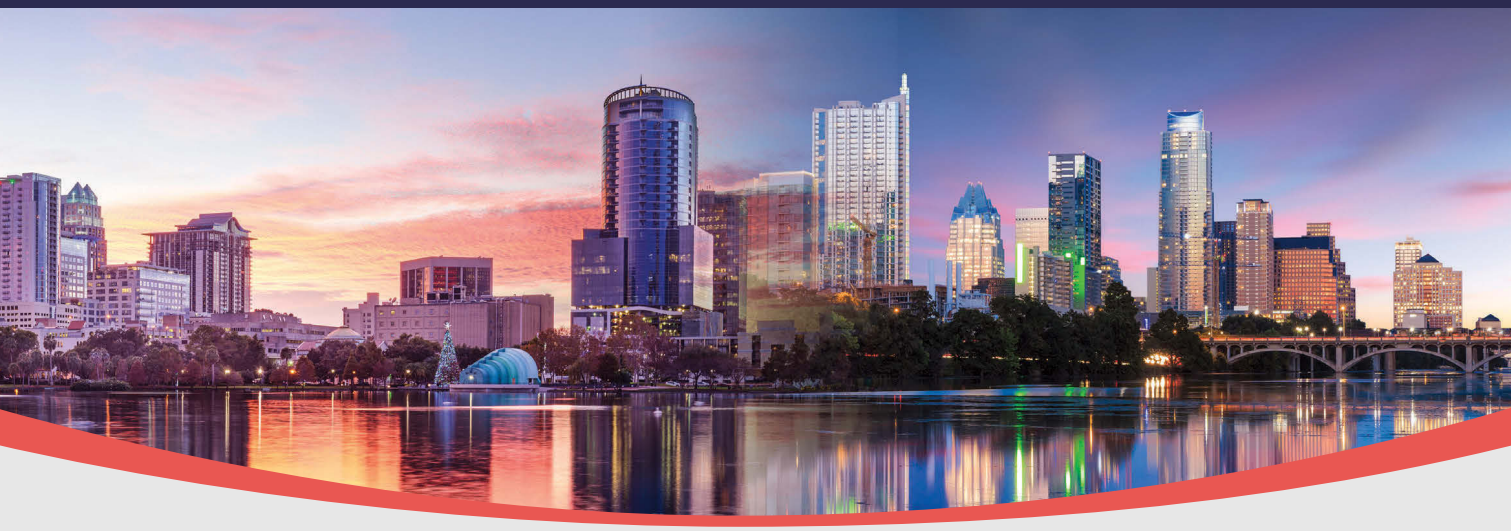

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BREAK THIS PRACTICE HABIT

The in-person postpartum blood pressure check: For whose benefit?

While society guidelines continue to recommend the in-person postpartum blood pressure check, this practice is often both unachievable and insufficient for providing the best care for women at risk for adverse outcomes in the postpartum period

Melissa S. Wong, MD, MHDS, and Lauren D. Demosthenes, MD

IN THIS ARTICLE

CASE Patient questions need for postpartum BP check

Ms. P presents at 28 weeks' gestation with superimposed preeclampsia. She receives antenatal corticosteroids and titration of her nifedipine, but she is delivered at 29 weeks because of worsening fetal status. Her physician recommends a blood pressure (BP) visit in the office at 7 days postpartum.

She asks, *"But can't I just call you with the BP reading? And what do I do in the meantime?"*

Hypertensive disorders of pregnancy and chronic hypertension remain among the leading causes of maternal morbidity and mortality in the United States and worldwide.[1] The postpartum period remains a particularly high-risk time since up to 40% of maternal mortality can occur after delivery. To that end, the 2013 American College of Obstetricians and Gynecologists Hypertension in Pregnancy Task Force recommends postpartum follow-up 7 to 10 days after delivery in women with a hypertensive disorder of pregnancy.[2]

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The authors report no financial relationships relevant to this article.

Why we need to find an alternative approach

Unfortunately, these guidelines are both cumbersome and insufficient. Up to one-third of patients do not attend their postpartum visit, particularly those who are young, uninsured, and nonwhite, a list uncomfortably similar to that for women most at risk for adverse outcomes after a high-risk pregnancy. In addition, the 7- to 10-day visit still represents only a single snapshot of the patient's BP values rather than an ongoing assessment of symptoms or BP elevation over time. Moreover, studies also have shown that BP in both normotensive and hypertensive women often rises by the fifth day postpartum, suggesting that leaving this large window of time without surveillance may miss an opportunity to detect elevated BP in a more timely manner.[3]

It is time to break the habit of the in-office postpartum BP check and to evaluate the patient where she is and when she needs it. Research in the last 2 years shows that there are several solutions to our case patient's question.

Solution 1: The provider-driven system

"Of course. Text us your numbers, and you will hear from the doctor if you need to do anything differently."

One method that addresses both the communication and safety issues inherent in the 7- to 10-day routine in-office BP check is to have the patient send in her BP measurements for direct clinician review.

Researchers at the University of Pennsylvania developed a robust program using their Way to Health platform.[4] Participating patients text their BP values twice daily, and they receive automated feedback for all values, with additional human feedback in real time from a clinician for severe-range values (>160 mm Hg systolic or >110 mm Hg diastolic). As an added safety measure, a physician reviews all inputted BPs daily and assesses the need for antihypertensive medication for BPs in the high mild range. Using this protocol, the researchers achieved a significant increase in adherence with the recommendation for reporting a BP value in the first 10 days after discharge (from 44% to 92%) as well as having fewer readmissions in the text-messaging arm (4% vs 0%).

Perhaps most impressive, though, is that the technology use eliminated pre-existing racial disparities in adherence. Black participants were as likely as nonblack participants to report a postpartum BP in the text-messaging system (93% vs 91%) despite being less than half as likely to keep a BP check visit (33% vs 70%).[5]

A similar solution is in place at the University of Pittsburgh, where a text message system on the Vivify platform is used to deliver patient BP measurements to a centralized monitoring team.[6] This program is unique in that, rather than relying on a single physician, it is run through a nurse "call center" that allowed them to expand to 3 hospitals with the use of a single centralized monitoring team. To date, the program has enrolled more than 2,000 patients and achieved patient satisfaction rates greater than 94%.

A final program to consider was developed and piloted at the University of Wisconsin with an added technological advance: the use of a Bluetooth-enabled BP cuff that permits values to be automatically transmitted to a tablet that then uploads the information to a centralized database.[7] This database was in turn monitored by trained nurses for safety and initiation or titration of antihypertensive medication as needed. Similar to the experience at the University of Pennsylvania, the researchers found improved adherence with monitoring and a notable reduction in readmissions (3.7% in controls vs 0.5% in the intervention arm). Of note, among those who did receive the ongoing monitoring, severe hypertension occurred in 56 (26.2%) of those patients and did so a mean of 6 days after discharge (that is, *prior* to when they typically would have seen a provider.)

The promise of such provider-driven systems is that they represent a true chronicle of a

FAST TRACK

The promise of provider-driven systems is that they represent a true chronicle of a patient's ongoing clinical course rather than a single snapshot of her BP in an artificial environment

patient's ongoing clinical course rather than a single snapshot of her BP in an artificial environment (and often after the highest risk time period!). In addition, direct monitoring by clinicians ensures an optimal safety profile.

Such systems, however, are also extremely resource intense in terms of both upfront information technology investment and ongoing provider surveillance. The systems above also relied on giving the patients a BP cuff, so it is unclear whether it was the technology support or this simple intervention that yielded the benefits. Nonetheless, the benefits were undeniable, and the financial costs saved by reducing even 1 hospital admission as well as the costs of outpatient surveillance may in the end justify these upfront expenditures.

Solution 2: The algorithm-driven system

"Sure. Plug your numbers into our system, and you'll receive an automated response as to what to do next."

One way to alleviate both the financial and opportunity cost of constant clinician surveillance would be to offload some tasks to algorithmic support. This approach—home BP monitoring accompanied by self-titration of antihypertensive medication—has been validated in outpatient primary care hypertension management in nonpregnant adults and more recently for postpartum patients as well.

In the SNAP-HT trial, investigators randomly assigned women to either usual care or algorithm-driven outpatient BP management.[8] While both groups had serial visits (for safety monitoring), those in the experimental arm were advised only by the algorithm for any ongoing titration of medication. At 6 weeks, the investigators found that BPs were lower in the intervention group, and diastolic BPs remained lower at 6 months.

This methodology emphasizes the potential utility of true self-management of hypertension in the postpartum period. It relies, however, on having a highly developed system in place that can receive the data,

FAST TRACK

Offloading some tasks to algorithmic support is one way to alleviate the financial and opportunity cost of constant clinician surveillance

Do-it-yourself options for remote blood pressure monitoring

Electronic health record (EHR) messaging

Most EHR systems have some form of patient messaging built in. Consider asking your patient to:

- message her blood pressure measurements every 1 to 2 days
- send a photo of handwritten blood pressure measurements

Vendor text messaging platforms

The year 2020 has seen the entire telehealth space grow tremendously, and platforms such as Doxy.me (https://doxy.me) and Updox (https://www.updox.com) allow secure text messaging with patients.

All-in-one connected vendor solutions

Third-party solutions are available that give the patient a connected blood pressure cuff, scale, and personalized app. For the clinician, these data then can be accessed either independently through a portal or can be integrated into the EHR. Examples of 2 companies include:

- Babyscripts (https://www.getbabyscripts.com)
- Wildflower Health (https://www.wildflowerhealth.com)

Telehealth visits

Scheduling weekly telephone or video visits (while not near the frequency of the above) would still yield greater engagement, and many payors currently reimburse for these visits at rates on par with in-person visits.

respond with recommendations, and safely monitor for any aberrations in the feed. Still, this hybrid method may represent the sweet spot: a combination that ensures adequate surveillance while not overburdening the clinician with the simpler, initial steps in postpartum antihypertensive management.

Solution 3: The DIY system

"That's a good point. I want to hear about your blood pressure readings in the meantime. Here's what we can do."

What about the 99% of practicing ObGyns who do not have an entire connected system for remote hypertension monitoring? A number of options can be put in place today with little cost and even less tech know-how (see "Do-it-yourself options for remote blood pressure monitoring," on page 44). Note that since many of these options would not be monitored in "real time" like the connected systems discussed above, the patient should be given strict parameters for contacting her clinician directly. These do-it-yourself, or DIY, methods are instead best for the purpose of chronic monitoring and medication titration but are still an improvement in communication over the single-serve BP check.

The bottom line

Pregnant women represent one of the most connected, Internet-savvy demographic groups of any patient population: More than three-quarters of pregnant women turn to the Internet for advice during their pregnancy.[9,10] In addition, unlike most social determinants of health, such as housing, food access, and health care coverage, access to connected electronic devices differs little across racial lines, suggesting the potential for targeting

health care inequities by implementing more—not less—technology into prenatal and postpartum care.

For this generation of new mothers, the in-office postpartum BP check is insufficient, artificial, and simply a waste of everyone's time. While there is no one-size-fits-all approach, there are many options, and it is up to us as health care providers to facilitate the right care, in the right place, at the right time for our patients. ●

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The "Break This Practice Habit" series is spearheaded by Dr. Lauren Demosthenes, who makes overarching high value cost decisions in her role as Medical Director of High Value Care and Innovation, Department of ObGyn at Greenville Health System in Greenville, South Carolina. Watch for case presentations of low value, low evidence practices that should be questioned in current day, followed by reasons why that practice should be abandoned. If you would like to contribute to this series, please submit your query to Dr. Demosthenes at ldemosthenes@mdedge.com.

Free videoconferencing apps for the ObGyn

These apps are designed to help clinicians with the transition to a virtual setting

Kimia Menhaji, MD, and Katherine T. Chen, MD, MPH

IN THIS ARTICLE

Details on recommended apps
page 48

The COVID-19 pandemic has created a metamorphosis in human interactions. One way we have adapted is our increased use of virtual platforms for tasks such as lectures, meetings, interviews, conferences, and patient care via telemedicine.[1] Virtual platforms have allowed for the continuation of existing programs and facilitated new collaborations ranging from international webinars on patient care to national lectures for residents and fellows in ObGyn. New virtual platforms continue to emerge. We present here a review of free virtual communication apps available to the ObGyn care provider.

We used the term "videoconference" to search the Apple and Google Play app stores between May 29, 2020, and June 1, 2020. A total of 25 apps that offered both audio and videoconferencing were identified. All were free for download, but the majority required an ongoing paid subscription fee for the service. Thirteen programs were either completely free or offered a free version of their services. Based on our review and a systematic analysis, we selected 5 apps to feature here: Cisco Webex Meetings, Free Conference Call, Jitsi Meet, Microsoft Teams, and Zoom.

Featured videoconferencing apps

Cisco Webex Meetings and Free Conference Call offer an easy video meeting setup from

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Dr. Chen reports being an advisory board member and receiving royalties from UpToDate, Inc. Dr. Menhaji reports no financial relationships relevant to this article.

TABLE Five free videoconference apps and included features

	Cisco Webex Meetings	Free Conference Call	Jitsi Meet	Microsoft Teams	Zoom
Devices: iOS and Android	✓	✓	✓	✓	✓
Mac, Windows			✓	✓	✓
Free format	Personal	PWYC	N/A	Free	Basic
Registration required	✓	✓	X	✓	✓
Maximum number of participants	100	1,000	75	500K	100
Number of meetings	Unlimited	Unlimited	Unlimited	Unlimited	Unlimited
Length of 1:1 meeting	Unlimited				Unlimited
Length of group meeting	50 min				40 min
HD video and/or audio	✓				✓
Voice over Internet Protocol	✓	✓			
Active speaker view	✓	✓			✓
Full screen and/or gallery view	✓	✓	✓		✓
Screen sharing	✓	✓	✓	✓	✓
Multi-share		✓			✓
Whiteboard	✓				✓
Co-annotation on shared screen		✓			✓
File sharing	✓	✓		✓	
Keyboard/mouse control					✓
Virtual background/background blur				✓	✓
Instant meetings	✓		✓	✓	✓
Scheduled meetings	✓	✓			✓
Calendar compatibility	✓		✓		✓
Chrome and/or Outlook plug-ins		✓			✓
Web app—no downloads or plug-ins	✓		✓		
Custom/unique meeting links	✓		✓		✓
Polling	✓				
Recording	✓	✓	✓		✓
Private chat/messaging		✓			✓
Group chat/messaging	✓	✓	✓	✓	✓
Host controls	✓				✓
Raise hand	✓		✓		✓
Breakout rooms		✓			✓
Secure socket layer (SSL) encryption					✓
Personal room locking and unlocking	✓	✓	✓		
Additional features		Integrate with other apps: Slack, Evernote, Dropbox	Available for Slack	Real time collaboration: Word, Excel, PowerPoint, and OneNote	Closed captioning

Abbreviations: min, minutes; N/A, not applicable; PWYC, pay what you can; U, unlimited.

both a smartphone and a desktop app. They provide seamless access to functions on the virtual main page, including chat with other participants in the meeting and screen sharing. These apps both require screen recording in order to share screens.

Jitsi Meet is a web app usable on an iPhone or Android as well as on a desktop through the meet.jit.si website. No account is required. On the app or website, the user creates a meeting name and shares the unique URL or meeting name with invitees to join the videoconference. The mobile app and website both offer a "raise your hand" feature, full screen and/or gallery (tile) view, group chat, and live streaming. In both settings, users may lock the meeting and require a password. Additional features through the website include screen sharing, recording the meeting, blurred background, muting all participants, and sharing YouTube videos.

The Microsoft Teams app asks you the purpose of signing up on the website—"use for school," "with friends and family," or "for work." If you choose "with friends and family," the app directs you to Skype. Choosing the "for work" function directs you to complete your free registration. Microsoft Teams requires participants to create teams; thus, others participating in the videoconference need to have their own account. However, "guest access" also is available.

On the Zoom platform, immediate and scheduled meetings can be set up on the app as well as on the website, or directly on Microsoft Outlook and Google Calendar if the plug-in has been established. The desktop and smartphone apps are similar in function and provide access to personalized settings.

For patient care, since HIPAA (Health Insurance Portability and Accountability Act) protection is a concern, we recommend following guidelines at the user's institution regarding use of apps such as Epic Haiku for telehealth visits. For teaching and interacting with colleagues, we recommend Cisco Webex, Free Conference Call, Microsoft Teams, and Zoom, keeping in mind the time limitations of each app for the free account.

Overall, these 5 apps are easy to set up and user-friendly. Deciding which program to choose will depend on the number of participants allowed for a meeting and the duration of the meeting, as these two factors seem to be the most constraining among the free videoconferencing apps. ●

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OBG MANAGEMENT

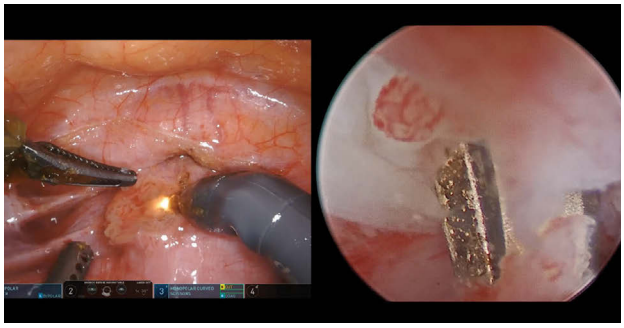
Isthmocele repair: Simultaneous hysteroscopy and robotic-assisted laparoscopy

Sierra J. Seaman, MD; Chetna Arora, MD; and Arnold P. Advincula, MD

An isthmocele is a pouch-like anterior uterine wall defect at the site of a previous cesarean scar. The incidence is not well known, but it is estimated in the literature to be between 19% and 88%.[1] Issues arising from an isthmocele may include abnormal uterine bleeding; abdominal pain; diminished fertility; ectopic pregnancy; or obstetric complications, such as uterine rupture. Repair of an isthmocele may be indicated for symptomatic relief and preservation of fertility. Multiple surgical approaches have been described in the literature, including laparoscopic, hysteroscopic, and vaginal approaches.

The objective of this video is to illustrate the use of robotic-assisted laparoscopy with simultaneous hysteroscopy as a feasible and safe approach for the repair of an isthmocele. Here we illustrate the key surgical steps of this approach, including:

1. presurgical planning with magnetic resonance imaging
2. diagnostic hysteroscopy for confirmation of isthmocele
3. simultaneous laparoscopy for identification of borders
4. strategic hysterotomy
5. excision of scar tissue
6. imbricated, tension-free closure.



Exploration of the isthmocele with simultaneous robotic-assisted laparoscopy (left) and hysteroscopy (right).

To view the video

Visit Arnold Advincula's Surgical Techniques Video Channel in the Multimedia Library at **mdedge.com/obgyn**

We hope that you find this video useful to your clinical practice.

›› **DR. ARNOLD P. ADVINCULA AND COLLEAGUES**

Reference

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Dr. Arora is Fellow, Division of Gynecologic Specialty Surgery, Department of Obstetrics and Gynecology, Columbia University Irving Medical Center/New York-Presbyterian Hospital.

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

Dr. Advincula reports being a consultant to Abbvie, Baxter, ConMed, CooperSurgical, Eximis Surgical, Intuitive Surgical, and Titan Medical and receiving royalties from CooperSurgical. The other authors report no financial relationships relevant to this video.

UPDATE abnormal uterine bleeding

CONTINUED FROM PAGE 38

intermittent abnormal bleeding and scar depth better than other methods. It also was associated with the longest surgical duration. Hysteroscopic surgery was the quickest procedure to perform and is effective in removing the upper valve to promote the elimination of the hematocele and symptoms of abnormal bleeding; however, it does not change the anatomic aspects of the isthmocele in terms of myometrial thickness. Some authors suggested that deciding on the surgical route should be based on fertility desires and the residual thickness of the myometrium. ●

WHAT THIS EVIDENCE MEANS FOR PRACTICE

In terms of isthmocele repair, the laparoscopic approach is preferred in patients who desire fertility, as long as the surgeon possesses the skill set to perform this difficult surgery, and as long as the residual myometrium is thicker than 2.5 to 3.5 mm.

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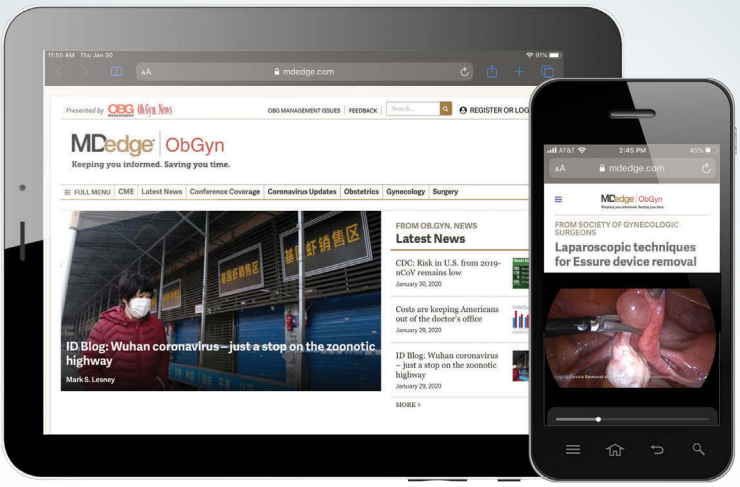

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