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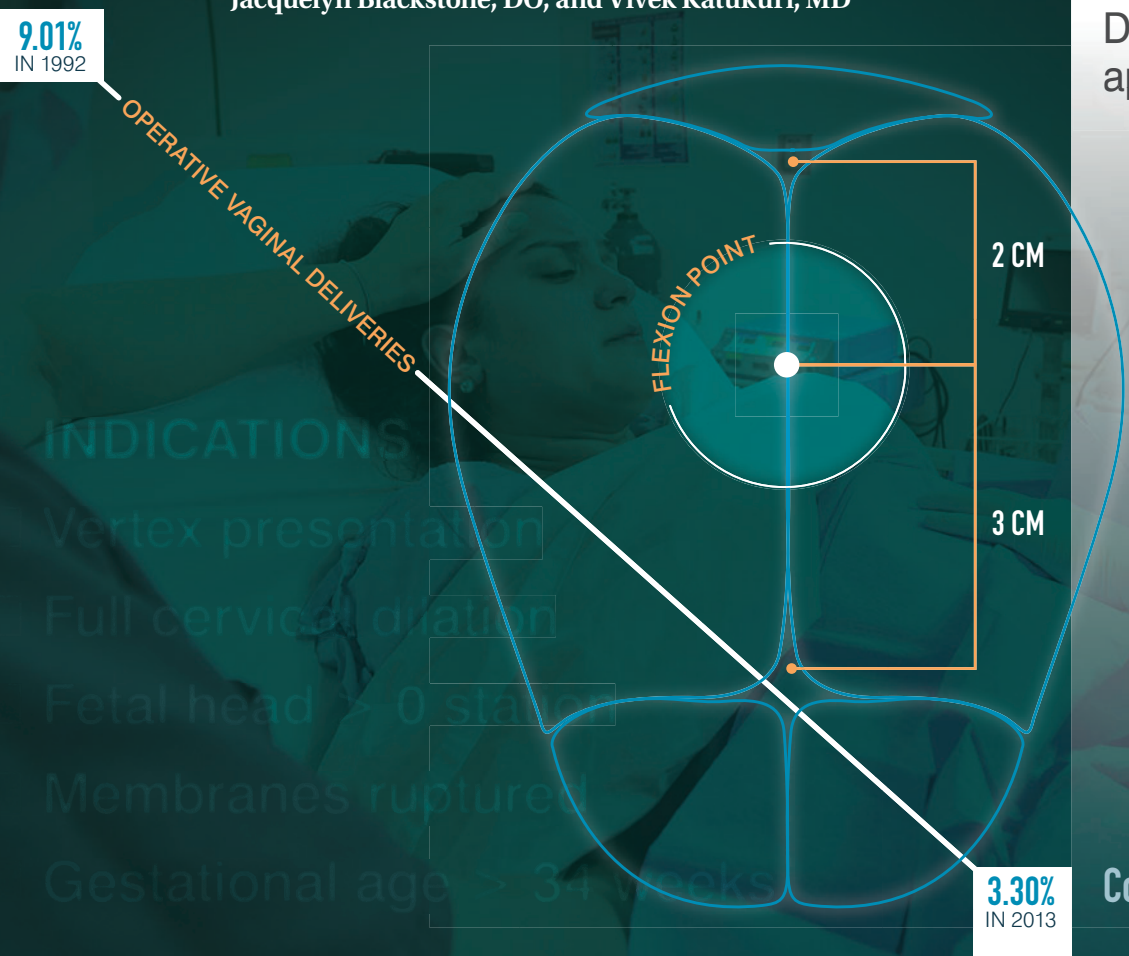
Expert Advice for Today's Ob/Gyn For Doctors by Doctors

Vacuum extraction

Revisiting operative delivery

Jacquelyn Blackstone, DO, and Vivek Katukuri, MD



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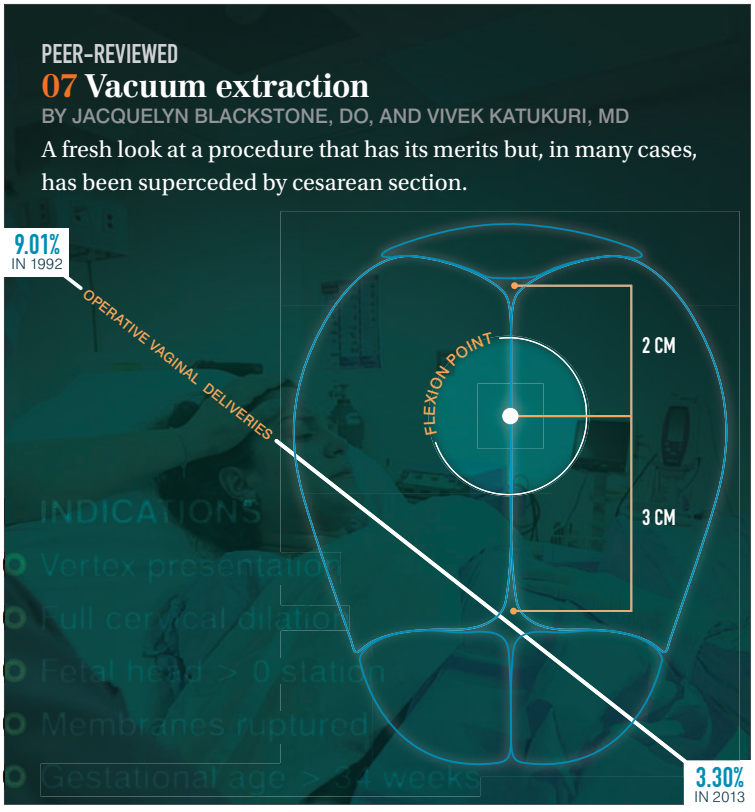

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by CHARLES J LOCKWOOD, MD, MHCM

Ensuring medications are more affordable without stifling innovation (Part 2)

In the second part of this series, potential solutions to fix the rising drug cost problem are examined.

In my prior editorial on this topic, I reviewed the principal reasons why prescription medications in this country are so costly. I pointed out that the "market" in prescription drugs is grossly distorted by opaque pricing, costly intermediaries, price inelasticity and a lack of consumer control as well as manufacturer rebates, direct-to-consumer advertising and co-pay coupons. I also noted that brand drug makers are free to set their own prices, which in the case of specialty drugs can be astronomical (e.g., spending on just Humira exceeded $10 billion in 2015).[1]

To make matters worse, when patents expire, manufacturers can delay conversion of their costly brand drugs to less expensive generics through "product hopping" and "ever-greening." But even after generic transitions occur, limited competition frequently permits generic manufacturers to achieve effective monopolies, sustaining high prices. Well-intentioned government regulations (e.g., Orphan Drug Act) designed to promote innovation have had disastrous unintended consequences for drug prices. Medicare's inability to negotiate drug prices or import inexpensive foreign drugs also drive up costs. And then there are the financial incentives that drug companies dangle in front of physicians to prescribe high-cost medications. While the sheer complexity of the problem is daunting, there are simple steps that the Federal government could take to restrain prescription drug costs without restraining the extraordinary innovation that is the hallmark of the US pharmaceutical industry (Table 1).

Increase drug pricing transparency

Many stakeholders from the National Academy of Medicine (NAM) to the Trump Administration have advocated for greater transparency in the various financial flows and profit margins within the drug supply chain (e.g., manufacturers, pharmacy benefit managers [PBMs], and retail, wholesale and 340 B-eligible hospital pharmacies).[2,3] For example, a patient goes to her pharmacy to pick up a prescription drug and, if the drug is covered by an insurer, likely has a co-pay. Subsequently the manufacturer sends a rebate to the PBM hired by the patient's insurer to negotiate prices. The PBM, after retaining some of the rebate, passes the remainder on to the insurer, which often uses it to offset premium costs to retain customers. This incentivizes higher drug costs since patients will potentially pay exorbitant sums for a drug their physician says they need but manufacturers' rebates go to intermediaries and not to the

READ PART 1

In the first part of this series, Dr. Lockwood examined the challenges posed by the high cost of brand-name drugs and why prescription medications are so expensive in Amerca. Government regulations, suppression of generic competition, and direct payment to physicians all play a large role. Read Part 1 from last month's issue: **contemporaryobgyn.net/DrugCostsPart1**

TABLE 1 **Steps to ensure that medications are more affordable without stifling innovation in the US pharmaceutical industry.**

Increase drug pricing transparency

- Department of Health and Human Services (HHS) should obtain, curate and publicly report data on drug pricing.
- HHS should require manufacturers to pass discounts directly to Medicare patients rather than offer rebates to intermediaries like Pharmacy Benefit Managers and insurers.
- Congress should eliminate the Medicaid drug rebate program, which discourages drug makers from discounting drug costs to any payer.

Reform Federal regulations that are driving up drug prices

- Encourage the Trump Administration to continue to accelerate generic drug approval and strengthen generic drug competition.
- Reform the Orphan Drug act so that it cannot be extended to widely sold generic drugs and is triggered by a lower number of affected patients (e.g., 30,000 vs. 200,000).
- End the 2006 FDA Unapproved Drug Initiative, which has made long-used, safe, inexpensive agents expensive and in short supply.
- Require the FDA to permit reduced-dose medication vial sizes, encourage multi-dose vial use, and extend shelf lives of medications to decrease wastage.
- Enact Tort reform so that drug companies are liable only for known or predictable harms not disclosed during an FDA review, and not for rare, unpredictable harms.

Allow select drug importation

- When market distortions exist leading to drug shortages or high prices, the FDA should use its authority to support importation

Control unscrupulous manufacturing practices

- Congress should eliminate the tax deductibility of direct-to-consumer (DTC) advertising.
- A strict industry code of conduct should be adopted for such DTC marketing.
- Congress should require mandatory disclosure of industry support of not-for-profit patient advocacy groups subsidized by drug makers to promote their products.
- State and federal governments should tighten restrictions on drug detailing visits and inducements to MDs.

Institute value-based payment for medications

- Brand drugs should be priced based on value (outcome over cost). Outcome should include effects of a drug on survival, function, and quality of life years added. Cost estimates should consider a drug's net impact on reducing other health costs (e.g., hospitalization, surgery, need for multiple medications, rehabilitation, nursing home care)

patient. Worse, all these transactions are cloaked in secrecy in the name of market competition.

Requiring drug makers to publish their prices and rebates would expose the true costs of intermediaries and likely exert downward pressure on pricing due to improved market efficiency. The NAM has proposed that the Department of Health and Human Services (HHS) obtain, curate, and publicly report drug pricing data (e.g., list prices, rebates, discounts, net prices) on a quarterly basis, conduct analyses of these data, and inform the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) of possible abuses.[2] Beyond the "dog shaming" impact of such reporting on drug pricing, this would likely fuel meaningful antitrust actions to enhance market efficiency.

In a more radical disintermediation step, this January, HHS proposed modifying Medicare Part D rules to require manufacturers to pass discounts directly to Medicare patients at the pharmacy counter rather than indirectly, through rebates to intermediaries like PBMs.[4] Currently Medicare patients are not eligible for manufacturers' patient assistance plans because of federal kick-back restrictions but perversely, rebates to intermediaries are allowed. While this proposal holds great promise for reducing individual patient drug costs and seems inherently more just, it does risk increasing Part D premiums and reducing pressure to switch to generic or biosimilar specialty drugs.[4] Similarly, Congress should eliminate the Medicaid drug rebate program, which discourages drug

makers from discounting drug costs to any payer since it would increase the cost of their rebate to Medicaid.

Reform Federal regulations that are driving up drug prices

The Trump administration has accelerated FDA approval of generic drugs with over 1000 new approvals in 2017 potentially saving $9 billion.[3] Moreover, it is seeking to close loopholes used by brand drug makers to restrain generic competition. More importantly, HHS is seeking authority to increase Medicare's ability to negotiate drug prices. These actions deserve robust bipartisan support. I believe strongly that there is an urgent need to apply the full weight of US government drug purchasing power to negotiate drug prices for both Medicare and Medicaid and create a national formulary like those used by most other industrialized nations.

There is need to reform the Orphan Drug Act of 1983.[2] First, financial incentives for prevention and treatment of rare diseases should not be extended to widely sold generic drugs (e.g., 17-hydroxyprogesterone caproate). Second, reducing the patient number threshold defining an "orphan" disease from less than 200,000 to a more reasonable number (e.g., 30,000) would have an immediate beneficial effect on costs. I would also advocate ending the 2006 FDA Unapproved Drug Initiative, which was designed to bring grandfathered medications under stricter control but has resulted in substantially higher prices, on average 37% higher, and frequent drug shortages.[5]

Other simple regulatory actions with potentially major economic benefits include having the FDA permit reduced-dose medication vial size, encourage utilization of multiuse vials, and significantly extend the recommended shelf lives of medications to decrease wastage. The latter is particularly egregious as the designated shelf life of drugs is often not evidence-based and frequently grossly underestimated.[6]

Congress should eliminate the tax deductibility of DTC advertising and an industry code of conduct should be adopted.

Finally, we need Tort reform. Drug companies should be liable only for known or predictable harms purposefully not disclosed during an FDA review, and not for rare harms undetectable during Phase 1 to 3 clinical trials. Reducing such liability costs could have a demonstrable effect on drug pricing.[2]

Allow select drug importation

Because foreign governments effectively negotiate with US drug makers for lower prices and many of the components of U.S. medications are manufactured abroad, there is an inherent logic to allowing drug importation. The FDA has pointed out drugs manufactured in a foreign country for the US market are produced in FDA-registered plants that also make drugs sold (at far lower prices) in other countries, an implicit indicator of drug safety.[7] However, there are risks to unrestrained importation. A substantial number of drugs imported via the Internet have been reported to be less effective or ineffective and/or to contain impurities or toxins.[8] Thus, FDA oversight would be needed for any such program, which would add costs. Califf and Slavitt have argued that when market distortions exist leading to drug shortages or high prices, the FDA should use its authority to support importation.[9] This seems like a very reasonable middle ground.

Control unscrupulous manufacturing practices

There is no doubt that direct-to-consumer (DTC) advertising works or we would not be flooded with the vast number of ads we see on television touting high-cost specialty drugs that clear skin, prevent clots, or permit quicker recovery from chemotherapy. Most come with the offer of a manufacturers' patient assistance plan or co-pay coupons (if commercially insured) which reduces patient out-of-pocket expenses for costly brand drugs but also reduces use of inexpensive generic drugs by 60%.[2] While First Amendment protections likely make it impossible to ban such advertising, Congress should eliminate the tax deductibility of DTC advertising and an industry code of conduct should be adopted for such marketing. Similarly, Congress should require mandatory disclosure of industry support for not-for-profit patient advocacy groups, which are often heavily subsidized by drug makers to promote their products.[2] Finally, it should tighten restrictions on drug detailing visits and inducements to MDs.

Institute value-based payment for medications

Health care financing is evolving from a fee-for-service system that incents

volume to a value-based payment (VBP) system that rewards better outcome for lower costs. Prescription drug pricing should also be based on a VBP paradigm.[9] Pricing of brand medications should consider the high development costs and substantial financial risks manufacturers incur to bring new drugs to market (e.g., 90% of new drugs fail to reach market approval). Indeed, patent protections permit exclusivity to sell novel drugs as a hedge against such development risks, but such exclusivity should not be a license for unrestrained pricing. Rather, brand drug pricing should also be based on value—effects of a drug on actual outcomes (e.g., survival, improved function, and quality of life years added) over cost. A drug's impact on aggregate health costs (e.g., need for hospitalizations, surgery, multiple medications, rehabilitation, and nursing home care) should also be considered in price determinations. While these measurements are complex and require time to calculate, the 21st Century Cures Act of 2016 should help fund federal agencies that can make such calculations. In the end, VBP for drugs is likely the most effective way of restraining medication costs without restraining innovation.

Take-home message

America should be justifiably proud of the incredible discoveries and innovative therapies that its pharmaceutical industry has produced, often in concert with medical school researchers. However, prescription drug costs in this country are far too high and rising at many multiples of the rate of inflation. These costs threaten the financial viability of Medicare, Medicaid and indeed, our entire health system. Our system also burdens American families with high out-of-pocket costs. There are many causes of this crisis, including an opaque and distorted pharmaceutical market, perverse government regulations, unscrupulous marketing techniques, and a failure to leverage the federal government's vast negotiating leverage. Fortunately, there are some very straightforward steps that can be taken to lower costs without impeding innovation. These include measures to increase price transparency to restore market forces, reform of well-meaning Federal regulations whose unintended consequences are paradoxically inflating drug prices, eliminating or at least restraining unscrupulous marketing practices, and ultimately transitioning to a VBP system for medications. ■

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FOR REFERENCES VISIT
contemporaryobgyn.net/DrugCostsPart2

Will vacuum delivery go the way of vaginal breech delivery?

Rising cesarean delivery rates along with inadequate training has largely sidelined vacuum deliveries, even though the procedure has its benefits.

by JACQUELYN BLACKSTONE, DO, AND VIVEK KATUKURI, MD

Operative vaginal delivery is an important management option for patients in the second stage of labor whose clinical situation requires expedited delivery. There has been a decreasing trend of using either vacuum or forceps during delivery, which coincides with the increasing rates of cesarean delivery during the past 3 decades.[1] Operative vaginal delivery decreases maternal risk of infection and hemorrhage, shortens maternal recovery and length of hospitalization postpartum[2] and preserves a woman's reproductive options by eliminating risks of both vaginal birth after cesarean delivery (VBAC) and abnormal placentation in future pregnancies but operative vaginal delivery also involves risks for both neonatal and maternal complications which includes a two- to six-fold increase in third- and fourth-degree perineal tears depending on the type of operative vaginal delivery.[3]

The desire to minimize pelvic floor trauma during delivery has resulted in a shift in recent obstetric practice away from use of forceps toward vacuum-assisted vaginal delivery, possibly due to the purported higher rates of obstetric anal sphincter and pelvic floor injury associated with forceps-assisted delivery (8%-23%), compared to vacuum-assisted delivery (6%-9%).[4]

The decrease in operative delivery rates seen in conjunction with the continued increase in cesarean delivery rates is not likely to reverse unless there is a concerted effort to teach vacuum extraction to residents in training. In addition, many ob/gyns are reluctant to use vacuum extraction because of concerns about anal sphincter and pelvic floor injuries and neonatal complications with their associated risk of litigation.[3,5]

History

The history of using vacuum to aid vaginal delivery has been described in multiple texts, most notably by J.A. Chalmers in his book "The Ventouse" published in 1971.[6] By most accounts, the technique was first attempted unsuccessfully by Dr. James Yonge in 1706.[7] In 1849, J.Y. Simpson invented the Air Tractor, which by several ac-

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TABLE 1 Indications for operative vaginal delivery

Indication	Examples
Prolonged second stage of labor[14,15]	> 3-4 hours in nulliparous women > 2 hours in multiparous women
Suspicious for immediate or potential fetal compromise[8]	Non-reassuring fetal heart patterns in second stage of labor and need for expedited delivery for fetal wellbeing.
Maternal condition precluding active second stage[8,9]	• Cardiovascular conditions such as Marfan syndrome, systemic ventricular dysfunction, severe aortic stenosis, and dilated cardiomyopathy • Cerebrovascular conditions such as arteriovenous malformations • Pulmonary conditions such as pulmonary fibrosis • Neurological conditions such as neuromuscular disease and spinal injury

TABLE 2 Selected contraindications

- Suspected fetal bleeding disorder such as hemophilia
- Inability to place cup at flexion point
- Suspected fetal skeletal condition such as OI or other demineralizing bone disease
- Gestational age < 34 weeks or < 2500 g*
- Known malpresentation such as breech, transverse lie or brow presentation
- Cervix not fully dilated
- Unengaged fetal head
- Fetal macrosomia

*See the section on controversies about vacuum extraction in low birthweight neonates for further information.
Abbreviation: OI = osteogenesis imperfecta

counts could be the first time that a device similar to the modern vacuum was used successfully but it unfortunately failed to gain favor with the medical community.[8] More than a century later, a Swedish professor, Tage Malmstrom, developed the Malmstrom extractor and published a series of studies.[9] This led to more widespread adoption of the vacuum extractor to aid childbirth. Its adoption in Northern European countries increased in 1970 followed by adoption in the United States.

Indications and contraindications

The first American College of Obstetricians and Gynecologists (ACOG) document on operative vaginal delivery was published in 1991. The document, previously called the Technical Bulletin, has undergone multiple revisions and replacements and was finally replaced by Practice Bulletin Number 154, published in November 2015 and reaffirmed in 2018.[10] Since then, indications and contraindications for vacuum delivery have been enumerated in several publications. They are summarized here in Tables 1 and 2.[10-13] Table 3 offers tips for ensuring a successful vacuum delivery. Of note, none of these indications is absolute and a cesarean delivery can be offered in all these circumstances.

There is no consensus regarding what is considered adequate analgesia for vacuum delivery. Epidural anesthesia is preferable but absence of an epidural is not a contraindication for vacuum delivery.

Controversies

Vacuum vs forceps

One advantage of forceps over vacuum extraction is its higher success rate in achieving a vaginal birth.[16] However, forceps deliveries are more likely to result in neonatal facial laceration, instrument marks and bruising, facial nerve palsy, corneal abrasions and external ocular trauma, skull fracture, and intracranial hemorrhage[5,10,] Maternal complications associated with forceps deliveries include major perineal and vaginal tears, third- and fourth-degree perineal lacerations associated long term with pelvic organ prolapse.[8,14,15] Conversely, vacuum extraction can result in fetal scalp laceration, cephalohematoma formation, and subgaleal or intracranial hemorrhage (Table 4).[10] Retinal hemorrhages and increased rates of hyperbilirubinemia have also been reported.[10]

In a 2016 systematic review, Tahtinen et al. found no difference in long-term prevalence of stress urinary incontinence (SUI) between vacuum delivery and spontaneous vaginal delivery.[17] A follow-up study of 13,694 women who had experienced a vaginal birth in Norway found that among women aged < 50 years, there was a statistically significant difference in risk of SUI with forceps delivery (odds ratio [OR] 1.42, 95% CI, 1.09-1.86), but not with vacuum delivery (OR 0.80, 95% CI, 0.59-

1.09) when compared with spontaneous vaginal delivery. Among women aged < 50 years, forceps deliveries were associated with a higher rate of SUI (OR 1.76, 95% CI 1.20-2.60) when compared to vacuum deliveries. These results supported those of Handa et al.[18] who reported, in a retrospective cohort study, that forceps delivery increased odds of all pelvic floor disorders considered, especially overactive bladder (OR 2.92, 95%CI 1.44,5.93) and prolapse (OR 1.95, 95% CI 1.03,3.70). These results may have had an impact on the decreasing numbers of forceps-assisted births seen in low- and middle-income countries.[19]

In contrast, a recent retrospective cohort study that included all singleton, term, cephalic vaginal deliveries in Kaiser Permanente Northern California between 2013 and 2014 found that women with vacuum-assisted vaginal deliveries had four times the odds of obstetric anal sphincter injury (OR 4.23,95% CI 3.59-4.98) compared to those who did not. In this study, the predominant choice of instrument for operative vaginal delivery was vacuum extraction at 6.2% compared to forceps, which was only 0.4%. Hence, the authors eliminated forceps deliveries from the study. The primary outcome studied was third- or fourth- degree perineal lacerations. This group also noted that women whose second-stage labor lasted 180 minutes vs less than 60 minutes had three times the odds of obstetric anal sphincter injury (OR 3.20, 95% CI 2.62-3.89).[5]

Pelvic floor disorders

Nygaard et al[20] found that approximately 25% of women in the United States had at least one pelvic floor disorder, with the rate almost double in women older than age 80.[20] Because the US population aged 65 and older is expected to double between 2010 and 2050,[21] this statistic underscores the potential cost to the health care system and the likelihood that a significant part of the population will suffer from such a condition, which will seriously impact quality of life. Blomquist et al followed women annually from their first delivery for up to 9 years looking for evidence of pelvic floor disorders.[20] They found that cumulative incidence of each pelvic floor disorder was significantly associated with mode of delivery. Compared with spontaneous vaginal delivery, cesarean delivery was associated with a significantly lower hazard of SUI, overactive bladder (OAB), and pelvic organ prolapse (POP). Indeed, vaginal delivery is associated with an almost two-fold increase in risk of developing SUI, compared with cesarean delivery, with a smaller effect on urgency urinary incontinence (UUI).[22] In contrast, operative vaginal delivery was significantly associated with a higher hazard of anal incontinence and POP. There is evidence that 10% to 20% of vaginal deliveries result in levator ani damage that is undetected at the time of delivery,[23] the effect of which evolves over decades, resulting in a long latency

VACUUM CUP PLACEMENT

The diagram shows the flexion point in relation to fetal skull landmarks such as the anterior and posterior fontanelles

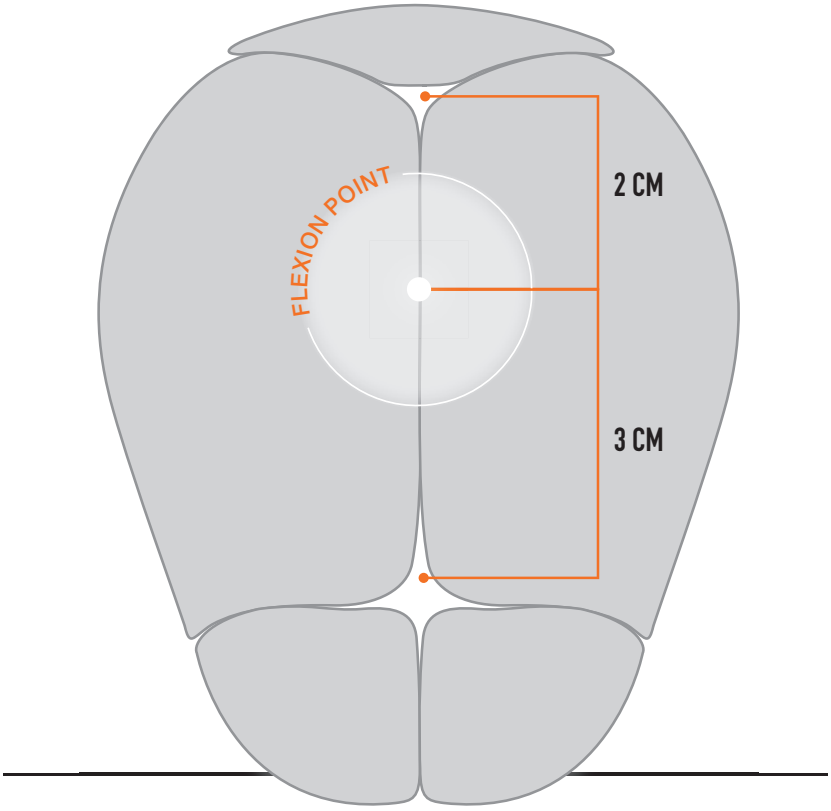

TABLE 3 Essentials and tips for ensuring successful vacuum delivery

Prerequisites

Operator experience: Do not attempt if not confident or lacking adequate experience

Patient selection: Vertex, engaged fetal head, at least '0' station

Consent: Written consent whenever possible. If oral, discuss potential fetal and maternal risks (see Table 4) of the vacuum delivery including but not limited to scalp injuries, cephalohematoma, subgaleal hemorrhage, intracranial hemorrhage and retinal hemorrhage in the fetus and urinary tract as well as anal sphincter injuries and risk of incontinence in the mother

Types of vacuum

- Soft bell-shaped cup
- Rigid mushroom cup (also called the M cup)

Application

- Drain bladder
- Remember "flexion point" (imaginary point on the sagittal suture which is 2 cm anterior to posterior fontanelle or 3 cm posterior to the anterior fontanelle)
- Check for vaginal or cervical tissue
- Apply 450-600 mm Hg pressure
- Synchronize pull with contractions
- Avoid jerking or rocking movements
- Releasing and maintaining pressure between pulls are both acceptable
- No more than 3 pop offs, 3 sets of pulls with no descent, and no more than 30 minutes of total application time

for symptomatic POP. Damage to the urethral sphincter occurring at vaginal delivery is the etiology of relatively early onset of incontinence disorders after delivery.[24]

Ramm et al. found that nearly one-fourth (24%) of the women in their study who had undergone a vacuum-assisted delivery incurred obstetric anal sphincter injury (OASIS).[5] That is a substantial increase over historically quoted 6% to 9% OASIS rates with vacuum-assisted vaginal delivery and at least equal to the 8% to 23% rates quoted with forceps-assisted vaginal deliveries.[5,25] This raises the question of whether the rate of maternal complications is as low with this procedure as previously believed. However, these investigators also noted that duration of second-stage labor was independently associated with obstetric anal sphincter injury, even after controlling for vacuum-assisted vaginal delivery and VBAC.[5] Because a longer second stage has become the norm in an effort by the obstetrical community to prevent primary cesarean deliveries, we may find that it has become a risk factor for OASIS.[26]

Adequacy of resident training

As long ago as 1996, when operative vaginal deliveries were much more common, a study that surveyed a random sample of 1600 trainees in the United States about their experience of operative vaginal delivery training established that 25% of trainees with < 10 years of experience had not received training on vacuum extraction during their residency. Despite this, 88% of the same group carried out the procedure regularly.[27] Given current use of this modality, we can only surmise how much less experience a recent graduate can be expected to have today, and how much less skill at performing an operative vaginal delivery would be anticipated, possibly resulting in worse maternal and neonatal outcomes than have been reported in the past.

The impact of changes in work hours, attending presence, and involvement in deliveries, and simulation training for these relatively rare obstetrical procedures is unknown. A 2017 survey of Irish and Canadian trainees demonstrated that trainee comfort levels with operative vaginal delivery are positively correlated with numbers performed.[28] This did not hold true with trainee self-confidence, suggesting that other factors are involved. (Trainee confidence was assessed based upon their last few forceps deliveries using a modified version of a six-item five-point tool (maximum score out of 30) previously validated for gynecology trainees to measure self-confidence. Measures of trainee comfort were assessed across 13 variables of second-stage assessment, measured on a 5-point Likert scale (1 not very comfortable, 2 not comfortable, 3 neutral, 4 comfortable, 5 very comfortable). A 2007 US survey found that > 90% of residents reported confidence in performing vacuum ex-

traction with 57% reporting confidence in performing a forceps delivery.[29] Because the rate of vacuum deliveries peaked at 5.9% of all deliveries in 1995 with a steady decline since then,[1] one can only infer that confidence levels would currently be considerably lower than those in 2007, given the actual opportunities available to trainees today to hone their operative delivery skills.

Because the United States has one of the lowest rates of operative vaginal deliveries of all developed countries,[1,30] many training programs are developing simulation training as part of their core curriculum to teach residents operative delivery skills. There is some evidence to suggest that local "in-house" simulation training is the most effective.[31]

Episiotomy with vacuum extraction?

None of the accepted national guidelines, including those from ACOG, the Council of the Society of Obstetricians and Gynaecologists of Canada (SOGC), and the UK's Royal College of Obstetricians and Gynaecologists (RCOG), have included episiotomy as a mandatory step in vacuum delivery. Rather, the guidelines recommend restrictive use of episiotomy, using the operator's individual judgement.[8,32,33] Unfortunately, indications for this selective procedure are not clearly defined. Numerous studies have noted that episiotomy use is related to increased rates of several obstetric complications, including urinary and anal incontinence, postpartum hemorrhage, and pain.[10] This procedure can also be related to a higher, rather than lower, incidence of advanced perineal tears.[34] A meta-analysis of episiotomy in vacuum delivery performed by Sagi-Dain and Sagi in 2015 concluded that median episiotomy was related to a higher risk of OASIS in vacuum delivery in nulliparous women (OR 5.11, 95% CI 3.23-8.08) as well as parous women (OR 89.4, 95% CI 11.8-677.1).[32] Their findings suggest that midline and mediolateral episiotomy in parous women may increase risk of advanced perineal tears at vacuum delivery, but that lateral episiotomy in nulliparous women appears to be associated with a decreased risk of OASIS. Mediolateral episiotomy may increase risk of postpartum hemorrhage and pain.

TABLE 4 Vacuum delivery complications

Neonatal	Maternal
■ Intracranial hemorrhage	■ Vulvar hematomas
■ Intraventricular hemorrhage	■ Vaginal hematomas
■ Subgaleal hemorrhage	■ Urinary tract injuries
■ Retinal hemorrhage	■ Anal sphincter injuries
■ Cephalohematoma	
■ Scalp lacerations	
■ Brachial plexus injury secondary to shoulder dystocia	

Vacuum extraction in LBW neonates

That the patient should be over 34 weeks and the estimated fetal weight should be over 2500 g for vacuum extraction is generally accepted.[10] However, in the mid-1990s, both Morales et al and Thomas and associates showed no significant differences in neonatal outcomes in vacuum extractions among preterm infants with weights below 2500 g and 2000 g, respectively.[35,36] In 2017, Aviram et al. again studied this group of neonates and found no increase in birth injury in neonates.[37]

Long-term neonatal complications

Known complications of operative vaginal deliveries may be related to the complicated labor, rather than the procedure used to effect the delivery. Fetal size greater than 4000 g can play a part,[38] as can a prolonged second stage.[5]

Operative vaginal delivery was associated with a rate of neonatal encephalopathy of 4.2 per 1000 term neonates compared with 3.9 per 1000 delivered by cesarean section.[39] Another study that compared vacuum extractions, cesarean deliveries and spontaneous vaginal deliveries showed that the rate of intracranial hemorrhages (both traumatic and non-traumatic) was more than six times greater among newborns delivered by vacuum extractions (19.0 per 10,000) and more than double that for those born by cesarean (7.3 per 10,000) compared with infants born by spontaneous vaginal delivery (2.8 per 10,000). Even after adjusting for indication for operative delivery and other covariates, these newborns had a 10-fold risk for traumatic hemorrhages and more than double the risk for non-traumatic hemorrhages.[40] However, long-term outcomes in children in Sweden

CONTINUED ON PAGE 28

Making chronic pelvic pain a little less painful

This review discusses the etiologies, evaluations and management strategies for what can often be a frustrating condition for patients.

by NICHOLAS ANDREWS, MD, PHD, AND CHARLOTTE PICKETT, MD

Chronic pelvic pain is a common chief complaint, accounting for approximately 10% of referrals to a gynecologist, 20% of hysterectomies and 40% of diagnostic laparoscopies.[1] The complex and often multifactorial nature of the disorder makes management challenging for patients and providers alike, which can frequently lead to both provider and patient dissatisfaction.[2] This straightforward review of the most common etiologies, evaluation, and opioid-sparing management strategies is intended to demystify the disorder and empower providers to improve women's quality of life through practical, evidence-based strategies.

Defining 'chronic' pelvic pain

Chronic pelvic pain has traditionally been defined as noncyclic pain of 6 months duration that localizes to the anatomic pelvis, anterior abdominal wall at or below the umbilicus, the lumbosacral back or the buttocks, and is of sufficient severity to cause functional disability or lead to medical care.[3] This broadly defined anatomic region necessitates an equally broad differential diagnosis, with potential sources of pain not limited to the genitourinary system. Gastrointestinal, neurological, and musculoskeletal sources of pain, with which the general ob/gyn may be less familiar, must also be considered. Adding to this complexity, chronic pain syndromes usually have a central nervous system (CNS) component: input from peripheral sources is more readily passed along through the spinal cord to higher cortical centers, leading to perceived pain that can appear disproportionate to the peripheral stimulus. This combination of multiple anatomic structures over which no individual medical specialty has comprehensive knowledge, and alterations in central pain processing belie the need for a multidisciplinary approach.

Neuropsychobiology of chronic pelvic pain

Historically, the severity of chronic pelvic pain was felt to be directly proportional to the extent of pathology. However, studies using diagnostic laparoscopy have shown that the extent of pelvic pain does not correlate well with the extent of endometriosis or adhesions present in the pelvis.[4] This observation is consistent with current thinking about chronic pain syndromes in that, unlike acute pain, chronic pain involves both CNS and peripheral nervous system pathways. Alterations in central pathways are highly dependent on psychosocial influences, with anxiety and stress suspected to amplify the experience of pain, independent of the

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magnitude of the peripheral stimulus.[5,6] In addition, there is a strong association between a history of physical or sexual abuse and development of chronic pelvic pain. This relationship could be causal, related to sensitization via alterations in central processing, or coincidental. Regardless of the relationship, concurrent treatment of these psychosocial comorbidities plays a key role in treatment success.[7,8]

Establishing a treatment relationship

Given the prevalence of comorbid anxiety, depression, and sexual abuse with chronic pelvic pain, successful treatment relies heavily upon establishing a trusting, therapeutic relationship with these patients. A small qualitative study of the attitudes of patients with chronic pelvic pain toward their care revealed four main themes, which can be reframed as a useful guide for establishing a productive treatment relationship[9]:

1. Provide a sense of personalized care
2. Help the patient to feel understood and taken seriously
3. Emphasize potential explanation(s) for the pain, as much as "curing" it
4. Provide reassurance

Providing a sense of personalized care and helping patients to feel understood and taken seriously often translates to a significant amount of face-to-face time, which can be challenging to accommodate in a busy office practice. However, the additional time spent at the initial visit can often be recouped because future visits are shorter and less frequent. In fact, a patient's favorable impression of the initial visit has been shown to be associated with a higher likelihood of complete resolution of pain.[10] Helping patients suffering from chronic pain to feel they are being taken seriously requires special attention, as patients are often sensitized to even subtle messages from providers that their pain is "all in their head." It is therefore helpful to provide tangible examples to patients of how both central and peripheral pathways are involved in our pain experience, such as the common experience of noting a laceration only long after the injury may have occurred, or times in which a stubbed toe resulted in a surprisingly intense experience of pain.

TABLE 1 Characteristics and structures involved in two physiologic pathways of pelvic pain[11]

	Visceral pain	Somatic pain
Characteristics	Poorly localized. Associated with nausea, vomiting, diaphoresis	Discrete and localized
Structures involved	Sympathetic - ovaries, fundus, upper cervix Parasympathetic - lower cervix, vulva	Pelvic bone, ligaments, muscles and fascia

Etiologies

As is true with most other conditions, the etiology of chronic pelvic pain can be consistently identified through a detailed history and physical exam, provided the starting point is a reasonable list of potential diagnoses. The broad anatomic area that falls under the definition of pelvic pain requires an equally broad list of potential conditions, which can often be overwhelming. Therefore, it may be useful to organize the differential diagnosis anatomically into the uterus, cervix, fallopian tubes, ovaries, vagina, bladder, ureters, rectum, intestines, pelvic bones, pelvic musculature, and pelvic nerves. The character of a patient's pain may help to further narrow the differential diagnosis, given the two different physiologic pathways that can be involved in pelvic pain: visceral and somatic (Table 1).[11]

While an exhaustive list of etiologies of pelvic pain is too expansive to fully itemize,[12] only a handful of conditions account for the majority of chronic pelvic pain, with multiple causes often present concurrently (Table 2).[12-15] For the general ob/gyn, the ability to diagnose and appropriately treat or refer these conditions would make a tremendous impact for most women who suffer from chronic pelvic pain.

> Additional time spent at the initial visit can often be recouped because future visits are shorter and less frequent.

The aforementioned extended time at the initial visit may best be used to collect a detailed history, going back to our training roots and eliciting the seven dimensions of the symptom (Table 3) and to perform a detailed exam. In addition, it is paramount to ask the patient what she thinks her pain may represent. Patients often fear that their

TABLE 2 Common causes of chronic pelvic pain[12-15]

	Incidence*
Endometriosis	33%
IC /painful bladder syndrome	38% to 85%
IBS	50% to 80%
Musculoskeletal disorders	75%

*Column totals more than 100% because often multiple conditions co-exist
Abbreviations: IBS = irritable bowel syndrome; IC = interstitial cystitis

pain is due to malignancy or some as-yet-undiscovered and potentially lethal condition. Often, these anxieties can be readily assuaged at the initial assessment by taking the time to explain the rationale for the most likely diagnosis. Failure to identify these concerns can significantly impair further treatment.

Screening for interstitial cystitis quickly identifies a subset of patients who suffer from a non-gynecologic condition that frequently presents with chronic pelvic pain. Urinary frequency is often the first symptom. Evaluating for pain that improves with defecation or onset of symptoms associated with changes in frequency or form of stool will screen for irritable bowel syndrome. Evaluation should also include assessment of the patient's psychosocial situation, including sexual function, presence of depression, post-traumatic stress disorder, and any history of physical or sexual abuse. The International Pelvic Pain Society (IPPS) has a detailed history and physical examination form available for download in multiple languages (https://www.pelvicpain.org/IPPS/Professional/Documents-Forms/IPPS/Content/Professional/Documents_and_Forms.aspx).

A careful abdominal exam, which includes light and deep palpation, will identify neuralgias. Single-digit palpation with both flexion and relaxation of the rectus abdominus muscles will distinguish abdominal wall pathology from intra-abdominal sources: focal pain that worsens with engagement of the abdominal muscles is highly likely to be related to the abdominal wall, whereas pain that improves when the rectus abdominus muscles are flexed may suggest a visceral source. Evaluation of spinous processes and paraspinal muscle tenderness along with lower extremity strength, sensation, and range of motion can elucidate additional musculoskeletal sources of pain.[15]

Before starting the pelvic exam, the providers should empower the patient to request a break or ask that the exam be concluded at any time. Provided adequate trust is established between provider and patient, in our experience, very rarely is it impossible to complete pelvic exams in patients with chronic pelvic pain, despite the high prevalence of sexual abuse and trauma in these women.

Begin the exam with external inspection and test for provoked and unprovoked vulvodynia through light palpation with a Q-tip. A single-digit internal exam with palpation of the urethra, obturator internus, bladder base, rectum, levator ani, anterior and posterior cul-de-sac and uterosacral ligaments, in addition to palpation of the uterus and adnexa is essential to identify the many possible sources of pain. With palpation of each area, it is also important to clarify with the patient if what she is feeling is the same pain she wanted evaluated because pain produced on pelvic exam often is not experienced in daily life.

TABLE 3 Seven dimensions of a symptom

- Onset/duration
- Location
- Radiation
- Intensity
- Quality/character
- Aggravating/alleviating factors
- Associated symptoms

Pelvic ultrasound is not indicated for all patients but should be considered in the presence of uterine or adnexal tenderness, or if the pelvic exam is limited secondary to patient habitus. Laboratory evaluation is rarely indicated, except to address specific symptoms or exam findings. Diagnostic laparoscopy is common for evaluation of chronic pelvic pain, despite limited data supporting its use. Given the relatively poor correlation between intraabdominal findings at time of laparoscopy and the extent of symptoms, diagnostic laparoscopy should be reserved for patients with known pathology by ultrasound, or in patients in whom endometriosis is suspected, but who do not respond to or cannot tolerate a trial of hormonal therapy.

Management

Multiple studies have demonstrated the efficacy of a multidisciplinary approach to treatment of chronic pelvic pain.[7,16,17] The decision to refer for care by another provider should be based on local resources and provider ex-

perience. While general ob/gyns are well trained to manage endometriosis, treatment of the other three most common diagnoses—interstitial cystitis/painful bladder syndrome, irritable bowel syndrome, and musculoskeletal disorders—may be outside their purview. In addition, for the subset of patients with other, less common etiologies of chronic pelvic pain, referral to a chronic pelvic pain specialist should be considered. The IPPS maintains a directory of pelvic pain specialists, searchable by zip-code (https://www.pelvicpain.org/IPPS/Patients/Find_A_Provider/IPPS/Content/Professional/Find_A_Provider.aspx).

For endometriosis, continuous combined or progesterone-only oral contraceptives (OCs) remain first-line treatment. Setting clear expectations about possible side effects is important, as is counseling patients that it make take 2 to 3 months of treatment for their pain to improve. Patients whose pain doesn't respond or responds inadequately to initial therapy should be evaluated further with laparoscopy to confirm the diagnosis and potentially relieve symptoms. Once the diagnosis is confirmed, treatment for endometriosis should be primarily medical with either ongoing continuous OCs, or one of several evidence based second-line therapies (Table 4).[18-23]

Suspected interstitial cystitis should prompt a urinalysis and culture to rule out urinary tract infection and then, if feasible, the patient should be referred to a urogynecologist. These subspecialists are well-equipped to not only make this diagnosis, but also to evaluate and treat commonly related diagnoses, such as overactive bladder syndrome, urinary incontinence, and pelvic organ prolapse. Patients can be given a list of common bladder irritants and asked to sequentially eliminate each from their diet and maintain a symptom diary in preparation for their consultation. A helpful patient handout is available from the American Urogynecologic Society (https://www.augs.org/assets/2/6/IC.pdf). A treatment guide from the American Urological Association may be helpful in cases where referral to a urogynecologist is not possible.[24]

TABLE 4 Second-line treatments for endometriosis[18-23]

Therapy	Dosing	Source
Leuprolide with add-back therapy	Conjugated equine estrogen 0.625 mg and norethindrone 5 mg daily	Hornstein et al
LNG-IUS	20 μcg daily	Tanmahasamut et al
Etonogestrel implant	25-70 μcg daily	Carvalho et al
Letrozole with norethindrone	Letrozole 2.5 mg daily, Norethindrone 2.5 mg daily	Ferrero et al
Elagolix, an oral GnRH agonist	150 or 200 mg daily	Taylor et al
Danazol	200-400 mg daily	Brown et al

Abbreviations: GnRH = gonadotrophin; LNG-IUS = levonorgestrel intrauterine system.

The decision to refer for care by another provider should be based on local resources and provider experience.

Irritable bowel syndrome is highly likely in patients with chronic pelvic pain who have bowel symptoms. However, as with painful bladder syndrome, it is important to rule out other more serious conditions prior to settling on this diagnosis. "Red flag" symptoms (Table 5) should prompt consideration of alternative diagnoses or referral to a gastroenterologist. In the absence of these concerning symptoms, the ROME II criteria[25] can be used to make the diagnosis. A practical treatment guide, including a patient handout, is available from the American Academy of Family Physicians (https://www.aafp.org/afp/2002/1115/p1867.html).

Musculoskeletal etiologies of pelvic pain are exceedingly common and can be readily elicited by careful exam, as described. While levator ani or obturator internus myalgia can be a primary cause of chronic pelvic pain, pelvic myalgia is more often due to chronic muscle contraction and subsequent injury in response to other painful stimuli. In addition to treating the other source(s) of pain, pelvic physical therapy is highly effective, with one study suggesting that about two-thirds of patients can expect mod-

TABLE 5 Red flag symptoms in evaluation of IBS

- Anemia
- Family history of IBS or colon cancer
- Fever
- Heme-positive stools
- New onset of symptoms over age 50
- Nocturnal symptoms
- Palpable abdominal or rectal mass
- Recent antibiotic use
- Weight loss

Abbreviation: IBS = irritable bowel syndrome

erate or marked improvement in pain symptoms[26] and another demonstrating that patients rated the treatment efficacy as 8/10.[27] The American Physical Therapy Association maintains a registry of physical therapists that is searchable by zip code and area of expertise (aptaapps.apta.org/findapt/SearchResults.aspx).

A significant proportion of patients who report chronic pelvic pain will have physical exam findings in the abdominal wall consistent with a trigger point, which has been defined as a focus of hyperirritability in a tissue that, when compressed, is locally tender and, if sufficiently hypersensitive, gives rise to referred pain and tenderness, and sometimes to referred autonomic phenomena and distortion of proprioception.[28] While much controversy continues to surround this phenomenon, a trial of self-massage to the point of moderate discomfort has been proposed as a low-risk, potentially effective intervention. For patients in whom 2 to 3 weeks of self-massage has proven to be ineffective, a trial of trigger point injections could be considered.[29,30] There are many variations in technique, though one example can be found here: https://emedicine.medscape.com/article/1997731-technique. In our clinic, a weekly series of three to four injections of 3 to 5 mL of 0.25% bupivacaine into the area of tenderness in the abdominal wall, low back, or pelvic floor muscles often provides significant relief. If there is no response after the third or fourth injection, consider alternative treatments.

Given the known role of psychosocial factors in modulating central pain processing, these comorbidities should be treated concurrently with evaluation and treatment of peripheral sources of pain. Delaying management of anxiety, depression, and social stressors until after a trial of treatment of peripheral sources of pain is likely to result in decreased treatment efficacy and can often lead to the patient feeling dismissed. Any plan for referral should be a shared decision with the patient, with the discussion focusing on the role of both peripheral and central pain processing in the patient's overall pain experience. Developing a referral network of providers with expertise in pharmacologic management of depression, anxiety, and PTSD, as well as provision of counseling services will greatly bolster treatment efficacy and likely provider and patient satisfaction.

What about opioids?

In 2015, there were 20,101 overdose deaths related to prescription pain medications; nearly double the deaths related to heroin.[31] We cannot take the opioid epidemic lightly. However, we should not overlook careful prescription of opioids as an option for pain management. Multiple studies have demonstrated that opioids decrease acute pain by about 30%.[32,33] Their lasting effect on chronic pain is much more controversial. Because most

CONTINUED ON PAGE 28

RESPONSIBLE PRESCRIBING PRACTICES INCLUDE:

- Prescribing only in situations where the pain is very likely to improve with time and additional treatments
- Counseling patients as to risks and signs of tolerance, dependence, and opioid-induced hyperalgesia
- Counseling regarding safe use, such as avoiding taking during any activity in which sedation would cause risk of harm to self or others and storing safely and securely
- Clearly defining and documenting the prescribing relationship (opioid contract)
- Utilizing a prescription monitoring program database
- Closely monitoring for abuse/diversion (dosing adjustments without discussion, lost prescriptions, additional substance use)
- Considering suboxone in cases of comorbid depression/concern for overdose
- Concurrently consulting with a pain specialist

How likely are adolescents to fill antibiotic prescriptions for STIs?

by **BEN SCHWARTZ**

Adolescents are disproportionately affected by sexually transmitted infections (STIs), but whether they actually fill antibiotic prescriptions provided in the emergency department (ED) setting is largely unknown. Researchers from Washington, DC, recently attempted to answer that question, as reported in *JAMA Pediatrics*.

For the retrospective cohort study, described in a researcher letter, visits to two EDs by adolescents aged 13 to 19 were analyzed. The focus was on encounters associated with a diagnosis of pelvic inflammatory disease (PID) for which outpatient antimicrobial treatment was prescribed between January 1, 2016 and December 31, 2017.

The primary outcome of the study was prescription filling of STI-related antimicrobial treatment and secondary outcomes included patient-level and visit-level factors associated with prescription filling. Filling data were acquired through a program in the hospital's electronic health record that collects data from participating pharmacies and insurance plans.

During the study period, 696 ED visits resulted in an STI diagnosis. Outpatient prescriptions for antimicrobial treatment were given to 208 patients with such diagnoses (cervicitis/urethritis n=65; 31.2%) or (PID n=143; 68.8%). Of the prescriptions, 57.7% (95% CI 50.9%-64.5%) were

EXPERT PERSPECTIVE *This study, which found that fewer than 60% of adolescents who were diagnosed with STIs, including PID, filled their prescriptions for outpatient antibiotics is not a huge surprise to me. There are many possible explanations, including one of the authors' findings—that hospitalized patients were more likely to fill their outpatient prescriptions, possibly correlating with more severe symptoms. Other possible factors leading to lack of adherence, or inability to adhere to the recommendations include adolescents' desires for confidentiality, difficulties in navigating the healthcare system, problems in paying for prescriptions while keeping their sexual activity private, or lack of understanding of the importance or potential sequelae of their infections. Perhaps the clinicians didn't spend sufficient time explaining the need for antibiotics or the potential risks to future fertility. At any rate, we as clinicians and our healthcare system need to do a better job of facilitating healthy outcomes for teens with STIs.*

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filled. Using multivariable analysis, the only factor associated with prescription filling was hospital admission (73.7% vs 54.1%; AOR 2.3; 95% CI 1.0-5.0). The authors noted that patients admitted likely had more severe symptoms, and as a result, they may have been more motivated to fill a prescription for symptom relief.

The authors believe their findings indicate that more novel intervention needs to be explored to ensure that prescriptions given to adolescents for STIs are being filled. In-depth conversations about the necessity of antibiotic treatment for STIs could be beneficial, as could a consultation with an adolescent medicine specialist. Future studies should focus on understanding the barriers that underlie prescription filling for adolescents to promote STI-related treatment adherence. ■

Ben Schwartz is the associate editor of *Contemporary OB/GYN*.

SOURCE

Lieberman A, Badolato GM, Tran J, et al. Frequency of prescription filling among adolescents prescribed treatment for sexually Transmitted Infections in the Emergency Department. JAMA Pediatrics. 2019. doi:10.1001/jamapediatrics.2019.1263.

Study supports noninvasive testing for Down syndrome in twins

by JUDITH M. ORVOS, ELS

Results of a prospective study combined with a meta-analysis suggest that cell-free DNA (cfDNA) testing for trisomy 21 (Down syndrome) may be just as effective in twin pregnancies as in singletons. The research also showed that in twin pregnancies, the noninvasive testing is superior to use of combined testing in the first trimester or second-trimester biochemical testing.

Published in *Ultrasound in Obstetrics and Gynecology*, the findings are from a prospective study and meta-analysis by European authors. They sought to assess performance of cfDNA testing for trisomies 21, 18 and 13 in twin pregnancy.

The data for the prospective study were from screening at 10 +0 and 14 +1 weeks in 997 twin gestations in two groups. The first group were women who self-referred for screening to institutions in London or Brussels. The second group were women selected for cfDNA testing after routine first-trimester combined testing at one of two National Health Service hospitals in England.

The authors also performed a meta-analysis of peer-reviewed publications on clinical validation or implementation of cfDNA testing for trisomies 21, 18 and 13 in twin pregnancy. Assessment of the literature and results from the prospective study were combined to determine cfDNA test performance.

In the prospective study, the researchers found that cfDNA testing correctly classified 16 of the 17 cases of trisomy 21 (94.1%), nine of 10 cases of trisomy 18 (90.0%), and 962 of 968 cases without any trisomy (99.4%). Combining data from seven relevant studies, the pooled weighted detection rate (DR) and false-positive rate (FPR) for trisomy 21 were 98.2% and 0.05%, respectively. For trisomy 18, the DR and FPR were 88.9% and 0.03%, respectively, and for trisomy 13, they were 66.7% and 0.19%, respectively.

There were too few cases of trisomies 18 and 13, the authors said, to accurately assess the predictive performance of cfDNA testing. For trisomy 21, they concluded that their results show that "performance of the cfDNA test is superior, both in terms of higher DR and substantially lower FPR, to that of the first-trimester combined test or second-trimester biochemical test" in twin pregnancy. Clinically, the authors said, the results are "particularly important in the case of dichorionic twins in which both the incidence of aneuploidy and the invasive procedure-related risk of pregnancy loss are increased compared to in singletons." ■

Judith M. Orvos, ELS, is an editorial consultant for *Contemporary OB/GYN*.

SOURCE

Gil MM, Galeva S, Jani J, et al. Screening for trisomies by cfDNA testing of maternal blood in twin pregnancy: update of The Fetal Medicine Foundation results and meta analysis. *Ultrasound Obstet Gynecol*. 2019; 53:734-742.

Which factors predict likelihood of mesh revision?

by **BEN SCHWARTZ**

Rates of revision surgery for mesh midurethral sling placement drop dramatically once a surgeon has reached a certain threshold of annual cases, according to results of a new study. The research, which appears in *Obstetrics & Gynecology*, looked at how health system factors (surgeons' annual surgical volume, specialty, and hospital type) affect risk of revision.

For the retrospective population-based cohort, de-identified administrative health data on all hospital visits between 2004 and 2017 from Alberta Health Services in Canada were examined. Using Canadian Classification of Health Intervention codes, the researchers identified women who underwent mesh midurethral sling placement and tracked whether they needed revision surgery, which was the primary outcome of the study. They also recorded exposure including the annual number of midurethral sling procedures performed by a surgeon, surgeon specialty, facility type, patient age, and concomitant prolapse repair.

Of the 21,028 women who received a midurethral sling for urinary incontinence during the 13-year study period, 1,517 underwent a concomitant mesh procedure for pelvic organ prolapse (POP). Those cases were censored from the final dataset, resulting in a sample size of 19,511 women. Mean follow-up for participants was 6.78 ± 3.59 years.

Cumulative rates of revision surgery were 3.84% (95% CI 3.54-4.17) at 5 years and at 10 years the rate increased to 5.26% (95% CI 4.82-5.74). The most vulnerable window for revision was the first year after placement, with 0.40% (95% CI 0.31-0.49) undergoing revision within 30 days and 2.15% (95% CI 1.95-3.52) within 1 year.

Surgeon experience was associated with revision, as was concomitant prolapse surgery. However, after 50 cases per year, odds of revision declined with each additional case (OR 0.99/case, 95% CI 0.98-0.99; OR 0.91/10 cases, 95% CI 0.84-0.98). This decline plateaued at 110 cases per year. Surgeon specialty, hospital type, and patient age were not associated with outcome.

Revision surgery occurs in just a small proportion of women undergoing midurethral sling placement but each surgery comes with risk. The authors believe that this study is important because it can help identify ways to reduce risk and patients who might be at increased risk. Because the data point to a period of time when most repair surgeries occur, physicians may want to pay closer attention to their patients during the first year after sling placement. ■

Ben Schwartz is the associate editor of *Contemporary OB/GYN*.

SOURCE

Brennand EA, Quan, H. Evaluation of the Effect of Surgeon's Operative Volume and Specialty on Likelihood of Revision After Mesh Midurethral Sling Placement. *Obstet Gynecol*. 2019 June; 133(6):1099-1108.

EXPERT PERSPECTIVE *The midurethral sling procedure has become the standard of care for treatment of stress urinary incontinence, in part due to it being a fairly simple procedure with low risk of complications, but also because of excellent long-term outcomes. This study demonstrates that cumulative rates of revision surgery are 5.26% at 10 years after surgery, with most revisions occurring after the first year of placement. Perhaps not surprisingly, high physician surgical volumes were associated with a significantly decreased risk of revision in this study. Surgeon volume and surgeon skill have been repeatedly demonstrated to influence patient outcomes, with an inverse relationship between volume and complications. However, surgical volume is not the only factor that influences complication rates, and although it seems like a logical step, it is not always clear that setting volume criteria improves outcomes. This is a complicated issue and many have advocated for objective evaluation of surgical skills to establish a minimum skill level that surgeons have to obtain to operate on patients. The FLS test is one example, and passing it will be a requirement in order to graduate from ob/gyn residency as of 2020. More objective testing methods are being developed and may be available soon.*

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Reproductive issues in sickle cell disease

Three cases illustrate the unique challenges ob/gyns face while caring for SCD patients at various life stages.

by ANDRA H. JAMES MD, MPH

Sickle cell disease (SCD) is a devastating blood disorder with particular implications for women. In the 1970s, the life expectancy for a person with SCD in the United States was approximately 10 years.[1] Now, the life expectancy is approximately 50 years.[1] Girls born with SCD in this century can expect to live to and through their childbearing years. Their blood disorder, however, presents unique challenges at every life stage that ob/gyns need to know how to manage.

Etiology of SCD

SCD is an autosomal-recessive disease characterized by presence of sickled red blood cells (RBCs). Sickled RBCs form in an individual who is homozygous for the sickle hemoglobin (HbS) gene (SS genotype) or is heterozygous for HbS and has another abnormal hemoglobin such as hemoglobin C (SC genotype), beta thalassemia (S-beta thal+ or S-beta thal^0 genotype), or some other rare hemoglobin. HbS has a single amino acid substitution of valine for a glutamic acid in the beta chain of the hemoglobin molecule, which prevents hemoglobin from forming neat tetramers. Instead the hemoglobin forms long, fibrous polymers that distort RBC membranes. These distorted RBCs are readily destroyed by the reticuloendothelial system. The normal life span of sickled RBCs is approximately 15 days compared to the 120 days of normal RBCs.[2] Consequently, individuals with SCD suffer from moderate to severe anemia. Table 1 lists the prevalence of various genotypes derived from California newborn screening data[2] and the severity of the various genotypes.[3] The SS genotype (which accounts for more than half of the affected individuals in the United States) and the S-beta thal^0 genotype generally result in a more severe phenotype described as "sickle cell anemia." The other genotypes do not usually result in severe disease.

Anemia is not the only mechanism of the disease. Lysed RBCs release free hemoglobin, which consumes nitric oxide and leads to endothelial damage and possibly thrombosis. Membrane receptors become rearranged on the distorted RBC surface, altering its adhesive properties. These altered RBCs interact with the endothelium, white blood cells, and platelets, and contribute to intravascular congestion, thrombosis, and downstream ischemia, resulting in both acute and chronic tissue damage.

Epidemiology of SCD

SCD affects approximately 1 million individuals worldwide, two-thirds of whom live in West Africa. Unfortunately, mortality for children with SCD in low-

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TABLE 1 Sickle cell genotypes identified through newborn screening in California[3]

Genotype	% of Newborns	Phenotype
SS	56%	Severe = sickle cell anemia
SC	29%	Not severe
S-beta thal^{+}	9%	Not severe
S-beta thal^{0}	5%	Severe = sickle cell anemia
SD, SE, SO	Rare	Varies

and middle-income countries is 50% to 90%. In the United States, approximately 100,000 Americans are affected with SCD, mostly individuals of African descent, but also Mediterranean, Middle Eastern, and Indian descent.[1] Forty years ago, 50% of children in the United States born with SCD also died before adulthood and 30% died before their fifth birthday,[3] but since the 1970s, newborn screening programs, institution of penicillin prophylaxis, vaccinations against encapsulated organisms, and disease-modifying therapy with hydroxyurea have led to a dramatic decline in childhood mortality. SCD is no longer a life-threatening disease of childhood, but now a chronic disease of adults.[3]

Consequences of SCD

SCD affects almost every organ and organ system, as shown in Table 2. Acute complications of the disease are listed in Table 3.[4-7] The cost of care, estimated from a study of Florida Medicaid claims from 2001-2005, averaged $1389 per month per patient.[8]

Of particular concern to ob/gyns are the maternal and fetal consequences of SCD. Pregnancy complications are summarized in Table 4. During normal pregnancy, there is a demand for increased erythropoiesis. Because women with SCD are already anemic, 30% to 40% require transfusion during pregnancy.[4,5,9] During normal pregnancy, women have an increased susceptibility to certain infections. The risk of infection is compounded in women with SCD. Compared to women without SCD, infectious morbidity is increased 2- to 13-fold. During normal pregnancy, women have an increase in glomerular filtration. Pregnancy has the potential to further impair renal function in women with sickle cell nephropathy. Normal pregnancy results in an increase in cardiac output. In a woman with SCD, the increased cardiopulmonary demands of pregnancy are potentially life-threatening, especially in women with SCD-induced pulmonary hypertension. Pregnancy results in an increased risk of thrombosis. In women with SCD who are already at high risk of VTE and stroke, pregnancy increases the risk of thrombosis 2- to 5-fold compared to women without the disease. Preeclampsia is increased 6- to 8-fold in women with SCD and maternal mortality is increased 6-fold, compared to women without SCD.[6,10] Fetal growth appears to start out normally, then lags after 25 weeks' gestation.[7] Fetal consequences of SCD include a 2-fold increased risk of preterm birth,[6] a 3-fold risk of small-for-gestational age,[6] and a 4-fold increased risk of stillbirth.[6]

Diagnosis

Diagnosis of SCD within the first 3 months of life allows for early treatment. Since 2006, every state in the United States has had a newborn screening program for the disease. A study conducted in California found that overall mortality for children who were diagnosed after they presented with symptoms was 8%, compared to 1.8% after early identification of SCD through screening and accompanying education of providers.[3,11]

Treatment

Treatment for SCD consists of preventing complications, managing pain, modifying the disease, or attempting a cure. Prevention of complications includes prophylactic penicillin for children to prevent sepsis and meningitis from encapsulated bacteria, and vaccinations against *Streptococcus pneumoniae* (pneumococcus) and *Haemophilus influenza*.[3] Individuals with SCD are particularly vulnerable to these encapsulated bacteria due to functional or surgical asplenia. Chil-

TABLE 2 Organs and organ systems affected by SCD

- Eyes
- Brain
- Heart
- Lungs
- Kidneys
- Liver
- Spleen → "autosplectomy"
- Bones
- Placenta

TABLE 3 SCD Acute complications

- Vaso-occlusive (pain) crises
- Acute chest syndrome (which most closely resembles pneumonia) and the most common cause of death in SCD
- Stroke (11% by age 20, 24% by age 25)
- Splenic sequestration
- Acute renal failure
- Acute cholecystitis
- VTE (10%-25% by age 30 to 40)

Abbreviation: VTE = venous thromboembolism

dren with SCD are also particularly vulnerable to stroke. Children with abnormal transcranial Doppler velocities are prescribed long-term transfusion therapy, which has been shown to dramatically reduce incidence of stroke.[12]

Managing the acute and chronic pain of SCD is challenging. The mainstay of pain management has been opioids, but nonsteroidal anti-inflammatory drugs (NSAIDs) have also been used. Particularly for management of chronic pain, amitriptyline, gabapentin, selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), and complementary therapies have also been helpful. Disease-modifying therapy includes hydroxyurea, which raises fetal hemoglobin levels and reduces incidence of vaso-occlusive crises and episodes of acute chest syndrome. Hydroxyurea has been found to cause birth defects in animals, but has not been found to increase risk of birth defects in humans.[13] Nonetheless, hydroxyurea has generally been avoided during pregnancy. L-glutamine has recently been approved for prevention of vaso-occlusive crises, but there is little experience with this medication.[13] Other disease-modifying therapies are currently in development, but have not been approved for use.[10]

Cures of SCD have been accomplished with hematopoietic stem cell transplantation (HSCT) and now with gene therapy.[14] For HSCT, the donor may be related (e.g. a sibling) or unrelated. Related donors can be human leukocyte antigen (HLA) histocompatibility-matched (typically at 8/8 HLA loci) or haploidentical (matched at half of HLA loci). Originally only matched donors were considered, but now successful transplants have occurred with haploidentical donors as well. In preparation for HSCT, recipients receive chemotherapy or radiation. HCST offers a cure, but can result in death, graft rejection, graft versus host disease, and sterility.[3,13] After HSCT, a high proportion of young women do become amenorrheic and are presumed infertile. Gene therapy for SCD[15] is still experimental but there are three clinical trials underway. Subjects receive their own genetically modified hematopoietic stem cells. In preparation, however, they still require gonadotoxic chemotherapy with the same potential risks to fertility as those with HSCT.

CASE 1 Menstruation and contraception in young women with SCD

Typical case: A 16-year-old gravida 0 with SCD is referred by her pediatric hematologist because of heavy, painful periods since she started having periods 1 year ago. She reports that the menstrual pain is distinct from the pain of vaso-occlusive crises. Her disease is otherwise adequately managed. She has no history of stroke or venous thromboembolism (VTE). Her Hb is 9 g/dL. A transabdominal ultrasound of the pelvis was normal.

Delay in menarche is not uncommon in girls with SCD. Several studies have reported on delayed menarche among girls with the disease.[16] A longitudinal cohort study of girls from infancy to young adulthood in Jamaica found that compared to controls, girls with SC genotype had a delay in mean age at menarche of 0.5 years and girls with SS genotype had a delay in mean age at menarche of 2.4.[17] This patient's ability to distinguish menstrual pain from the pain with vaso-occlusive crises is also not uncommon. Women with SCD do report distinct differences in the pain of menstruation compared to the pain with vaso-occlusive crises.[18]

Management of primary dysmenorrhea includes hormonal contraceptives and NSAIDs. In SCD, NSAIDs may increase vascular, bleeding, and renal risks, which may be compounded in patients with end-organ co-morbidities. For patients with SCD without a contraindication, however, NSAIDs are acceptable.[12] Hormonal therapy can reduce blood loss and pain with periods (a potential benefit in SCD), but combined hormonal contraceptives increase risk of VTE and stroke[19] (a potential hazard in SCD). Depot medroxyprogesterone acetate (DMPA) injections have also been shown to increase risk of VTE,[16] but other progestin-only contraceptives do not.[16] In women with SCD, a systematic review of four studies showed no increased risk of VTE among those who used

hormonal contraceptives, but there were only 118 total subjects.[20] Obviously, no combined hormonal contraceptives should be prescribed to a young woman with a history of stroke or VTE. Common sense further dictates progestin-only contraceptives be prescribed to a woman with SCD over combined hormonal contraceptives whenever possible.

Anticipation of HSCT

The first published case[14] of a young woman referred for HSCT describes a scenario that has become more frequent. This patient was a 19-year-old young gravida 0 with SS genotype. She had a history of multiple episodes of vaso-occlusive pain crises and acute chest syndrome. Fortunately, her sister was an HLA match. She was referred to a reproductive endocrinologist who counseled her and her family regarding the options for cryopreservation of:

- embryos (created with donor sperm), which allows for preimplantation genetic testing (PGT)
- oocytes, and
- ovarian tissue – still experimental, but the only option for prepubescent girls.

A low-dose ovarian stimulation protocol was used. Enoxaparin 30 mg subcutaneous every 12 hours was administered during stimulation and held 24 hours before egg retrieval. Eight mature oocytes were vitrified (rapidly cooled to prevent formation of crystals). No reports exist about whether this patient has pursued a pregnancy successfully, but thousands of women without SCD have had successful pregnancies after oocyte preservation.[21] Also, while ovarian tissue preservation is considered experimental, more than 87 subsequent pregnancies have been reported, including two in women with SCD (one using her own ovarian tissue and another using her sister's).[3]

CASE 2 Preconception counseling

A typical case: A 28-year-old gravida 0 with SCD with SS genotype is referred by her hematologist because she will be married soon and is planning a pregnancy. She is currently taking hydroxyurea. Her partner does not think he has sickle trait or beta thalassemia minor, but he is not certain.

This patient's partner should be referred for testing. If he has abnormal Hb, the couple should be referred for genetic counseling and they should be aware of the option of PGT with in vitro fertilization. A type and screen should be reviewed or obtained. If antibodies are present that are known to cause hemolytic disease, the partner should be tested for the corresponding antigen(s). The patient should be counseled regarding the maternal and fetal risks of SCD in pregnancy. Although the risk of maternal mortality is increased, the absolute risk of maternal mortality is about 1%,[22] which does not discourage most women and their families from pursuing a pregnancy. The patient's medications should be reviewed and before a prenatal vitamin is prescribed, her ferritin should be checked. If the level is elevated, which is very likely if the patient has received transfusions, she should receive a prenatal vitamin WITHOUT iron (such as prenatal gummies). In addition, the American College of Obstetricians and Gynecologists recommends 4 mg of folate per day for women with SCD.[23] With respect to hydroxyurea, the patient should have a consultation with a maternal-fetal medicine specialist. After consultation

TABLE 4 SCD pregnancy complications

Complications	Risks compared to those without SCD
Maternal	
Severe anemia with need for transfusion	
Infection	2- to 13-fold
Thrombosis	2- to 5-fold
Preeclampsia	6- to 8-fold
Mortality	6-fold
Fetal	
Alloimmunization	Depends on maternal RBC antibody and paternal RBC antigen status
Preterm birth	2-fold
Small-for-gestational-age at delivery	3-fold
Stillbirth	4-fold
Neonatal	
Neonatal abstinence syndrome	Depends on fetal exposure to opioids
Sickle cell disease	Depends on paternal sickle/thalassemia status

Abbreviations: RBC = red blood cell; SCD = sickle cell disease

with that specialist and a hematologist regarding risks and benefits, some patients may elect to continue hydroxyurea during pregnancy or at least until conception, stop for the duration of pregnancy, or stop it temporarily and restart it after the first trimester.

CASE 3 Pregnancy

A typical case: A 32-year-old gravida 3 para 1011 (one term pregnancy and one miscarriage) with SCD (SS genotype) at 36 weeks' gestation has worsening fetal growth restriction (FGR), which is now at the fourth percentile. Amniotic fluid volume is low normal and the umbilical artery Doppler S/D ratio is normal. The patient has been hospitalized almost monthly since conception for vaso-occlusive crises and was recently discharged from the medical intensive care unit after an admission for acute chest syndrome. She has received multiple transfusions in the past. Her antibody screen was positive for anti-C antibodies in this pregnancy, but her titer never exceeded 4. She took hydroxyurea in the past but stopped prior to her first pregnancy. The patient's family history is significant for a sister who also had SCD with SS genotype and died in the second trimester of her first pregnancy. Her partner's sickle cell status is unknown. The patient's current medications include prenatal gummies, low-dose aspirin for preeclampsia prevention, and oxycodone for pain. Her only complaint is near constant, severe pain in her bones. Her vital signs are normal, and her exam is unremarkable. Her Hb is 7.6 g/dL, hemoglobin 22%, creatinine 0.6, and lactate dehydrogenase is normal.

Once pregnancy is established, a patient with SCD should be cared for with the help of specialists in maternal-fetal medicine and hematology who have expertise in SCD. In early pregnancy, this patient's partner should have been offered testing. If he had abnormal Hb, the couple should have been referred for genetic counseling and made aware of the options for prenatal diagnosis. He also could have been tested for the C red cell antigen. Anti-C antibodies are a rare but documented cause of hemolytic disease of the newborn.[24] If the partner were negative, the fetus would not have been at any risk for alloimmunization.

Because of the increased risk of preeclampsia, low-dose aspirin was started at 12 weeks' gestation. Because of the increased risk of infection, monthly urine cultures were ordered. The patient's hemoglobin was monitored. A Hb of 8 g/dL was targeted and a Hb of > 7 g/dL was maintained for most of the pregnancy. There is no good-quality evidence that a strategy of prophylactic blood transfusion does or does not benefit the mother or fetus when compared to selective transfusion.[25] Whatever the transfusion strategy, the benefits of transfusion need to be balanced against the risks of alloimmunization and delayed hemolytic transfusion reactions, which can be life-threatening.[26]

Because of the high risk of FGR, fetal growth was monitored with serial ultrasounds.[23] Our practice is to start at 24 to 28 weeks' gestation. Due to the increased risk of stillbirth, a plan for fetal surveillance was also in place. Our practice is to start antepartum testing at 32 weeks' gestation. If all is going well, we plan to deliver women with sickle cell anemia (SS and S-beta thal^0 genotypes) at 37 weeks' gestation and women with other genotypes at 39 weeks. For the patient on opioid medication, the nursery needs to be prepared for neonatal withdrawal syndrome. During hospitalization, there should be a plan for VTE prophylaxis. It is our practice to prescribe prophylactic doses of low-molecular-weight heparin for 6 weeks postpartum.

Case 3 continued

This patient was transfused with 2 units of RBCs prior to induction of labor. She delivered a 2400-g infant vaginally. Postpartum, she received thromboprophylaxis with enoxaparin. She planned to use a long-acting reversible contraceptive and restart hydroxyurea postpartum.

Menopause

For a variety of reasons, women with SCD may be at risk of early menopause or even premature ovarian failure, but there are essentially no data about menopause in these patients.[13] With a life expectancy of 50 years, however, women with SCD will need the help of gynecologists to manage menopausal symptoms.

Conclusion

Increasing therapeutic options for women with SCD and a longer life span are changing how ob/gyns care for women with SCD. For more information please visit the website for the Foundation for Women and Girls with Blood Disorders at www.FWGBD.org. ■

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FOR REFERENCES VISIT
contemporaryobgyn.net/SickleCellDisease

What to consider when discussing Essure removal

When a patient is interested in having the device removed, her physician needs to examine several factors before deciding on a surgical approach.

by CHARISSE M. LODER, MD, MSC, AND SHEILA FLAUM, DO

The recent removal of Essure from the US market has created concern among patients with the device about the reason for the manufacturer's action. Many women also may have questions about whether to have the device removed. This article reviews the history, literature, and symptoms related to Essure as well as removal techniques to guide physicians through the counseling process.

Essure background

Essure is a hysteroscopic sterilization technique involving placement of nickel-titanium microinserts in the fallopian tubes. Over the course of 12 weeks, the microinserts cause fibrosis and occlusion of the fallopian tubes. Essure was approved by the US Food and Drug Administration (FDA) in 2002.[1] Benefits of the technique were that it was a minimally invasive procedure that could be conveniently performed in the office without requiring general anesthesia or abdominal incisions and hormone-free sterilization. It was a safe option for women who had contraindications to general anesthesia or hormonal contraception or who wanted to avoid abdominal surgery.

Concerns about Essure

Increasing patient reports about Essure-related symptoms led to a growing number of safety concerns about the device. Patient concerns have ranged widely from hair loss to physical and mental disabilities.[2] One retrospective cohort study found that the most commonly reported symptoms following Essure placement were abdominal pain, back pain, fatigue, leg and hip pain, dysmenorrhea, and heavy menstrual bleeding.[3] Another retrospective case series revealed that pelvic pain, abnormal uterine bleeding (AUB), and a reported allergic reaction were the symptoms most commonly reported by women prior to undergoing Essure removal.[4] Patients who reported allergic reactions prior to sterilization were at higher risk of developing an allergic reaction with hysteroscopic sterilization when compared to laparoscopic sterilization.[5]

Websites and Facebook groups run by women with Essure who had symptoms, led to a public outcry against the device, specifically in regards to the polyethylene terephthalate (PET) fibers in the microinserts.[6,7] In response, in 2015, the FDA appointed a special panel to investigate these claims, added a "black box" warning, and created stricter guidelines for placement.[1] Continued complaints and stricter guidelines caused a significant decrease in the number of devices placed.[8] Bayer removed Essure from the European market in September 2017[3] and from the US market in December 2018 due to the decrease in sales.[1] In its announcement, Bayer stated that preventative removal for those without symptoms was unnecessary.[1]

Device-related symptoms

Gynecologists may see patients who have multiple concerns about the Essure device, including a variety of symptoms and questions raised by recent media coverage. When a woman presents with an Essure-related complaint, it's important to take a detailed

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history. Patients may report multiple symptoms that may or may not be associated with the device and each should be documented and assessed. For each symptom, we recommend determining whether it is localized or generalized and identifying the timing of onset, severity, aggravators, or relievers. Patients may experience symptom onset from immediately to several years after Essure placement. We recommend documenting treatment attempts, including non-pharmacologic and pharmacologic treatments. In addition, because patients may also seek care from other consulting providers—such as allergists, rheumatologists, gastroenterologists or neurologists—it may be beneficial to collaborate with these consultants to determine a care plan.

TABLE 1 Differential diagnosis for abdominopelvic pain in patients with Essure

Perforation of device through fallopian tube or myometrium	Pelvic floor tension myalgia
Device misplacement (migration of multiple devices in one fallopian tube)	Pelvic congestion syndrome
Endometriosis	Vulvodynia
Adenomyosis	Adnexal masses
Irritable bowel syndrome	Uterine fibroids
Myofascial pain syndrome	

Office exam and work-up

For symptomatic patients, we recommend a detailed physical exam with a pelvic exam. It is particularly important to use a systematic approach to an abdominopelvic exam in cases of pain-related symptoms prior to surgery to eliminate other causes of pelvic pain. This type of exam includes an abdominal exam and may start with assessment of sensation with light touch or a pinprick. Next, lightly palpate to help identify any trigger points related to myofascial pelvic pain syndrome. Next, deep palpation can assess for any masses or hernias. Finally, assess for Carnett's sign, which if positive, suggests an abdominal wall etiology. Pelvic exam should first include a Q-tip test along the external genitalia to evaluate for vulvodynia and assess sensation. Next, proceed with internal palpation of the obturator internus and levator ani to evaluate for pelvic floor myofascial pain. A bimanual exam can assess uterine size and adnexa. Finally, perform a speculum exam to observe for anatomic abnormalities or evaluate for infectious etiologies.[9]

Additional laboratory studies may be helpful in some patients. We recommend a work-up for AUB, which may include a complete blood count, thyroid screening, Pap test, and assessment of the endometrium with an endometrial biopsy. Transvaginal ultrasound (US) is helpful for diagnosis and surgical planning to evaluate uterine size, uterine structural abnormalities, or any adnexal masses.

In asymptomatic patients who present with concerns about safety of Essure following removal from the market, conversation and detailed education is necessary. A pelvic exam may or may not be indicated.

A range of imaging techniques can be used to evaluate microinsert placement, including ultrasonography, hysterosalpingography (HSG), and abdominal pelvic x-ray. Imaging can confirm placement of the device and may inform counseling regarding device removal or surgical technique. We recommend ultrasonography, as it may elucidate other causes of symptoms such as fibroids, endometrial polyps, or ovarian cysts such as endometriomas. In addition, ultrasonography may also show perforation of the device through the uterus or fallopian tubes. HSG and x-ray imaging can confirm tubal occlusion and evaluate the implants, with the possibility of revealing fractured implants.[10]

Surgical techniques

Several techniques for removal of Essure have been documented, including use of hysteroscopy, laparoscopic salpingectomy, cornuectomy, and total hysterectomy.[5,11-13] The type of removal chosen may depend on a patient's symptoms and comorbidities, and the surgeon's skill and experience. When discussing surgery with a patient, it is important to elicit her concerns, including preference for an approach, recovery time, and desire for en bloc removal. Because most patients with Essure want permanent sterilization, we do not discuss fertility-preserving techniques here.

Hysteroscopic Essure removal can be an option up to 6 weeks after placement, before tubal occlusion has occurred.[14] This method of removal can be performed in situations of acute postprocedural pain and may help avoid abdominal surgery. Hysteroscopic removal also can be performed in conjunction with a laparoscopic salpingectomy to ensure removal of all filaments.

Laparoscopic bilateral salpingectomy has been well-documented as a removal method; however, there is a theoretical risk of incomplete removal.[13] This approach can often be performed with three 5-mm laparoscopic ports. The surgeon makes an incision in the fallopian tube with electrocautery approximately 1 cm from the cornua. The Essure device is then grasped and gentle traction is used to remove both the outer and inner coils from the cornua. Next, electrocautery is used along the mesosalpinx to remove the fallopian tube.[15] Postoperative recovery time is usually 2 to 4 weeks. Benefits of this approach include the ability to diagnose and remove any pelvic pathology, that could also be contributing to the patient's symptoms. This technique, however, has the potential to leave fragments of the microinsert device, PET fibers, in the pelvis or in the uterus as the microinsert is pulled from the cornua. In addition, we counsel patients that they may require another surgery if their symptoms continue postoperatively.

Laparoscopic cornuectomy with bilateral salpingectomy, an approach used to remove the microinsert and fallopian tubes en bloc, requires a laparoscopic surgeon trained in cornual wedge resection. It may require a 10-mm and two 5-mm laparoscopic ports, vasopressin for hemostasis, and suturing of the cornua in multiple layers. Although this technique has increased risks, including blood loss,[34] patients may benefit from complete removal of the device. It may also be helpful in patients with symptoms concerning for allergic reaction. Patients may require 4 to 6 weeks for recovery.

Hysterectomy with bilateral salpingectomy will also remove the Essure inserts and can be done vaginally, laparoscopically or abdominally. This technique may be desirable for patients who also have symptoms of AUB and/or adenomyosis. Hysterectomy has the greatest surgical risk of all Essure removal techniques, including infection, hemorrhage, and ureteral injury. Recovery time for this method is the longest, at 6 to 8 weeks.[4] In one study of women who underwent gynecologic surgery following Essure placement, hysterectomy was the most commonly performed surgery.[12] This may be because it is the most likely to treat multiple symptoms, including Essure-related allergy, pelvic pain, and AUB.

> Hysterectomy has the greatest risk of all Essure removal techniques.

Discussing postoperative outcomes

Several case studies and prospective and retrospective research have looked at symptom relief after Essure removal. Studies have reported that 40% of patients have complete resolution of symptoms when followed up to 3 years after removal via hysteroscopic, laparoscopic and laparotomy removal.[3] This unfortunately means that most patients do not have complete resolution of symptoms after removal. In addition, 10% to 15% reported no change in symptoms, with abdominopelvic pain being the most commonly experienced symptom prior to and following the surgeries previously mentioned.[3] Another study showed 75% improvement in quality-of-life following surgery, which was similar for patients undergoing laparoscopic bilateral salpingectomy or hysterectomy for removal.[4] A number of case series have proven that patients with previous nickel allergy or who develop allergy after Essure placement have improved outcomes after laparoscopic or hysteroscopic removal.[16] In a follow-up study of medical outcomes after sterilization, there was no difference in risk of developing an autoimmune disease with hysteroscopic versus laparoscopic sterilization.

One difficulty in assessing surgical success is that it may also be hard to distinguish between resolution due to removal due to placebo effect.

Patient-centered care

Patients with the Essure device may present with or without symptoms related to the microinsert. Women without symptoms should be counseled that they do not need to have their coils removed and that removal could cause increased risk of injury. Symptomatic patients who want counseling about Essure removal should be worked up for the most common differential diagnoses for their symptoms. A thorough history and physical exam is crucial to identifying possible causes. Specific labs, imaging, and consultation with multidisciplinary consultants may also assist with diagnoses unrelated to Essure. Counseling regarding methods of removal and outcomes associated with them are necessary for shared patient decision-making to achieve a patient's desired outcomes. ■

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FOR REFERENCES VISIT
contemporaryobgyn.net/EssureCounseling

Vacuum delivery CONTINUED FROM PAGE 11

delivered by vacuum extraction suggest that cognitive outcomes in this group are about equal to those delivered by unplanned cesarean delivery. In Australia, children were evaluated at age 8 and Hsieh et al. found that in singleton children born at term, instrumental delivery did not appear to have an adverse effect on neurodevelopment.[41]

Discussion

In the future, if women decide to have fewer children, tend to live longer, and expect a higher quality of life in older age, long-term consequences of vaginal and cesarean deliveries will have to be considered. Shared decision-making should become the norm. The physician–patient discussion in a problematic second stage will include discussion of immediate and long-term surgical risks due to cesarean section, balanced against risks of short- and long-term sequelae of anal sphincter and pelvic floor injuries related to an operative vaginal delivery. These conversations are complicated at any time and might better be addressed prior to the onset of labor.

If we are to continue to offer vacuum deliveries as an alternative to cesarean deliveries for maternal or fetal complications in the second stage, we must be assured that our residents are adequately trained in the technique. At a time when experienced attending physicians skilled in forceps deliveries are rare, "on-the-job" training from these individuals may no longer be an option. Because use of vacuum extraction has had greater acceptance than forceps delivery due to the belief that less damage to the perineum is involved, and is perceived as an easier skill to acquire, there are still some opportunities for a resident to practice under the guidance of an experienced practitioner. However, simulation systems designed to practice vacuum extractions will increasingly need to be utilized to compensate for currently low numbers of this type of delivery.[42]

We need to consider the possibility that operative delivery in general, rather than the instrument itself, is associated with OASIS and other pelvic floor injuries.[3] It may be that a prolonged second stage, which is increasingly common in modern obstetric management, is also implicated in increased incidence of these complications as noted by Ramm et al.[3]

It is possible that whenever a procedure is necessary to effect prompt delivery, whether operative or cesarean delivery, in the second stage, there will often be some sequelae that may affect the mother, the neonate or both simply due to the fact that the labor is abnormal. Therefore, an appropriate discussion with the patient about the likelihood of success and potential risks involved in the recommended procedure is imperative. ■

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FOR REFERENCES VISIT
contemporaryobgyn.net/VacuumDelivery

Chronic pelvic pain CONTINUED FROM PAGE 16

placebo-controlled randomized clinical trials evaluating opioids for pain management are ≤6 weeks in duration, there is insufficient evidence to guide opioid prescribing for chronic pain. (For more information, see Responsible prescribing practices sidebar on page 16).

Conclusion

Chronic pelvic pain is a complex, often multifactorial condition that afflicts many women and poses a significant challenge to our healthcare system. Evaluation should include a comprehensive history and physical with consideration for gynecologic and nongynecologic sources of pain. Practical, non-opioid-based treatments exist for the most common causes of chronic pelvic pain, which should be provided in concert with therapy for any co-existing psychosocial stressors. Opioids should be prescribed only after careful consideration and with patient safety in mind. While challenging, treatment of chronic pelvic pain can be rewarding and have a lasting impact on our patients' quality of life. ■

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Building bridges

When a resident's promise to appreciate nurses is challenged, a conversation with one illustrates how both roles play an integral part in patient care.

by **LUKE BURNS, MD**

There are no doctors in my family, and only a single nurse, my Aunt Frances. When I was accepted to medical school, she took me aside and made me promise to do one thing: Never take the nurses for granted.

I have always found the culturally accepted animosity between doctors and nurses baffling. Medical TV shows would have us believe the two groups are like animals from different species, insisting we are preternaturally destined not to get along, that we come from different worlds.

Frustrated with this concept and determined to heed my aunt's advice, I committed to do my utmost to buck this trend. At first, it was easy. Throughout my clinical rotations in medical school, I had no trouble befriending nurses and doctors alike; each group was as likely to cheer or chastise me. I hung out at the nurses' station almost as much as the residents' workroom. But during my first month as an intern, I noticed something had changed.

A patient came in to the labor and delivery ward at term with decreased fetal movement. Her elevated labs and pressures in triage were consistent with preeclampsia with severe features. Her induction was started but, dulled by a magnesium drip, proceeded slowly. Eventually, though, she dilated to 6 cm and, expecting her to make some change in active labor, I dutifully reported to the nursing station to reexamine the patient. But the nurse was reluctant to accompany me to the patient's room.

> Wasn't I trying to advocate for the patient [too]? And wasn't she our patient?

"She's been up all night, she's so upset, she feels awful on the magnesium, and it's only been a couple hours since you last checked. Can't you just give her a little longer?"

I was confused. The patient's variability on fetal heart rate (FHR) monitoring was minimal, and she was in active labor. Her category 2 tracing was not dire, but it wasn't exactly reassuring given her preeclampsia. The American College of Obstetricians and Gynecologists Practice Bulletin I had stayed up the night before memorizing clearly stated she needed to be checked every 2 hours. And after all, this was hardly my decision. My attending and senior resident had instructed me to go assess the patient's labor. I was just doing what I was told.

With my aunt's words echoing in my ears, I pleaded my case as gently as I could to the nurse. She pleaded with me, too, insisting the patient needed rest. Eventually the charge nurse overheard our conversation and told her colleague she had to stick with protocol. As the nurse stood up to join me, she said quietly, "I'm just trying to advocate for my patient."

I was shocked. Wasn't I trying to advocate for the patient? And wasn't she "our" patient? I didn't want her to have an eclamptic seizure or a stroke, I didn't want her baby to spend his first 24 hours of life in the neonatal intensive care unit. By the nurse presenting

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This nurse and I had fundamentally different definitions of the word "care." The level of deep, committed, responsive care she was expected to provide was entirely different from the clinical medical care I was offering.

herself as the patient's advocate, I instantly felt categorized as an antagonist.

We arrived in the room and I did a cervical exam. The patient's condition remained unchanged. After placement of an intrauterine pressure catheter, and another hour of waiting, the patient was taken to the operating room for a cesarean delivery for arrest of dilation.

I was still upset about the nurse's words. By accepting the narrative that she and I had different agendas for our patients, she only reestablished the supposedly natural, eternal conflict between doctor and nurse I had been trying so hard to defy.

After that, I grew cynical. I stopped spending time in the nurses' station and instead retreated as often as I could to the physicians' workroom. I was cordial and friendly with the nurses, but I didn't go out of my way to make friends.

And then one day, a different nurse stopped me in the hall of the labor and delivery floor to ask a question about a patient. "I have the patient in room 9," she said. "Are you taking care of her?"

"Yes, of course," I said. "I'm taking care of everybody." She looked confused. How could I be taking care of a dozen laboring patients at once?

This short conversation brought home two conclusions for me. First of all, this nurse and I had fundamentally different definitions of the word "care." The level of deep, committed, responsive care she was expected to provide was entirely different from the clinical medical care I was offering. I am hardly an automaton and endeavor to spend time getting to know my patients beyond their medical diagnoses. But it would be impossible for me, managing an entire labor floor, to have the same intimate relationship with every patient that the nurse could offer.

Second, I realized that neither of us really understood the other's job. I thought back to my conversation with the nurse who told me she was advocating for her patient. I had not realized then just how much time she had spent taking care of this patient, one-on-one, and how she had been this patient's source of comfort and reassurance. How could she not see herself as an advocate and a defender, especially against possibly unnecessary interventions from a doctor who was only able to visit this patient every few hours?

I decided to quit holing myself up with the other physicians. Whenever I had a free moment, or a question about a patient, I resolved to go sit in the nurses' station and have an actual interaction. I began asking questions about the nurses' jobs, about the hundreds of varied tasks they were responsible for, things I had always taken for granted. While sitting there, I saw just how often they got up to check on their patients and how closely they monitored the FHR tracings in front of them. Likewise, they saw just how often my pager went off, summoning me to one of the many patients I was taking care of concurrently.

To be honest, expending that level of emotional effort can be exhausting. Unsurprisingly, it turns out that building bridges with colleagues can be as tiring as the work itself. Ultimately, however, I believe it is a valuable practice. By knowing one another as people, by fully understanding not only how alike we can be but just how vastly different—and equally important—our jobs are, we begin to better understand how our roles complement each other.

And that is an important truth: the jobs are vastly different. How else would we both be able to "advocate" for a patient and yet suggest completely different management plans? But that is why doctors and nurses have been a part of the Western model of medicine since the nineteenth century: they both play roles on the spectrum of medical care. One could not function without the other.

In the "animal kingdom" of modern medicine, perhaps we're not so different after all. ■

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Is it possible to make OB coding less complicated?

The sheer number of code options can be intimidating, but mastering a few concepts can alleviate some of the stress.

by MIKE ENOS, CPC, CPMA, CPC-I, CEMC

Just like our patients, proper coding and billing for obstetric patients can be...complicated. As a coding instructor and compliance auditor, I field a lot of questions from new students and experienced billers alike. In this article, I'll break down a few of the most important concepts you need to understand to master obstetric coding.

The global period

Billing codes for maternity care and delivery are used to report antepartum care, vaginal or cesarean delivery, and postpartum care in uncomplicated pregnancies. Antepartum care includes the initial prenatal history and examination, subsequent prenatal history and examinations, recording of weight, blood pressures, fetal heart tones, routine chemical urinalysis, and monthly visits up to 28 weeks' gestation; biweekly visits to 36 weeks' gestation; and weekly visits until delivery. Delivery services include the hospital admission, management of uncomplicated labor, and cesarean or vaginal delivery (including episiotomy and repair if needed). Postpartum care includes visits in the hospital and a 6-week follow-up in the office following

EXAMPLE CODING SCENARIOS:

EXAMPLE: **A patient comes in for a routine prenatal visit at 28 weeks. An H&P is done along with a recording of weight, blood pressures, fetal heart tones, and routine chemical urinalysis.** This is a global service and is not separately billable.

EXAMPLE: **A patient in labor in her 39th week is seen in the maternity ward. The fetus is in a breech presentation. The provider performs an external cephalic version, turning the fetus into a head first position.** This is not part of the global OB package, and may be billed separately with CPT code **59412**. The diagnoses for the service would be **O32.1XX0** *Maternal care for breech presentation* and **Z3A.39 39** *weeks gestation of pregnancy*.

EXAMPLE: **A pregnant patient presents to her obstetrician with a fever and nausea at 18 weeks. Lab results confirm a UTI.** This is not part of the global OB package, and may be billed separately as an evaluation and management service (**99211-99215**) with a diagnosis of **O23.92** *Unspecified genitourinary tract infection in pregnancy, second trimester* and **Z3A.18** *18 weeks gestation of pregnancy*.

EXAMPLE: **A patient returns to her ob/gyn 4 weeks after delivery complaining of fever and breast tenderness. She is diagnosed with mastitis associated with lactation.** This is not part of the global OB package, and may be billed separately as an evaluation and management service (**99211-99215**) with a diagnosis of **O91.23** *Nonpurulent mastitis associated with lactation.*

EXAMPLE: **A patient vaginally delivers a single liveborn infant in the hospital. Following the delivery, the patient develops elevated blood pressure and swelling of the hands and feet. She is diagnosed with Eclampsia and is followed-up closely in the hospital.**
The delivery was uncomplicated, and would be billed as **59400** with a diagnosis of **O80** *Encounter for full-term uncomplicated delivery* and **Z37.0** *Single live birth.* The eclampsia and associated follow-up are not part of the global OB package, and may be billed separately as an evaluation and management service (**99221-99233**) with a diagnosis of **O15.2** *Eclampsia complicating the puerperium.*

CPT CODES DISCUSSED IN THIS ARTICLE:

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VAGINAL DELIVERY, ANTEPARTUM AND POSTPARTUM CARE PROCEDURES

- **59400** Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
- **59409** Vaginal delivery only (with or without episiotomy and/or forceps)
- **59410** Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care
- **59412** External cephalic version, with or without tocolysis
- **59414** Delivery of placenta (separate procedure)
- **59425** Antepartum care only; 4-6 visits
- **59426** Antepartum care only; 7 or more visits
- **59430** Postpartum care only (separate procedure)

CESAREAN DELIVERY PROCEDURES

- **59510** Routine obstetric care including antepartum care, cesarean delivery, and postpartum care
- **59514** Cesarean delivery only
- **59515** Cesarean delivery only; including postpartum care
- **59525** Subtotal or total hysterectomy after cesarean delivery (List separately in addition to code for primary procedure)

DELIVERY PROCEDURES AFTER PREVIOUS CESAREAN DELIVERY

- **59610** Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
- **59612** Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps)
- **59614** Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care
- **59618** Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
- **59620** Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery
- **59622** Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care

delivery. It may also include services related to a cesarean delivery, such as an incision check.

When billing for maternity care and delivery, codes exist to bill the global package (antepartum care, delivery, and postpartum care) or for specific components in the event you are billing for a provider who performed the antepartum care only, delivery only, or postpartum care only.

Note that pregnancy confirmation during a problem-oriented or preventive visit is not considered part of antepartum care and should be reported separately using the appropriate E/M code (for example an Outpatient Office Visit Code, 99201-99215). Also, remember that medical complications of pregnancy (eg, cardiac problems, neurological problems, diabetes, hypertension) and medical problems complicating labor and delivery management may require additional resources and should be billed separately – they are not included in the "global OB package."

Delivery coding

When it comes to billing for maternity care and delivery, the number of code options can be confusing. Simply put, there are codes to report the global package, or components of it (as discussed above) depending on the method of delivery. For example, 59400 is used to report Routine OB care including antepartum care, *vaginal delivery*, and postpartum care. Codes immediately following 59400 report individual components of the global package. Code 59510 reports Routine OB care including antepartum care, *cesarean delivery*, and postpartum care.

However, there's one more wrinkle that confuses some coders: Patients who have had a previous cesarean delivery and now present with an expectation of vaginal delivery have their own set of delivery codes, depending on the outcome. 59610 reports routine OB care including antepartum care, vaginal delivery, and postpartum care *after* a previous cesarean delivery. 58618 is used when the same patient with a previous cesarean attempts a vaginal delivery but *delivers again via cesarean section*.

ICD-10 concepts

With ICD-10 OB coding came a new set of billing guidelines that can be complicated, especially for newer coders trying to get acclimated to coding. The first important consideration when selecting a diagnosis code is to read the

CONTINUED ON PAGE 34

Managing information overload

Practitioners are awash in volumes of research and information; good strategies help manage the deluge.

by COREY DEAN, MD, FACP, FAAP, CAQSM

It's no secret that doctor burnout is a real and growing issue. I've seen it time and again in fellow internal medicine physicians, as well as colleagues in other specialties. But there's something contributing to this phenomenon that doesn't get as much attention as electronic health records, increased administrative duties, and reduced time with patients.

That something is information overload.

To get a sense of sheer volume, as of March 2019, there were 679,747 articles on PubMed labeled "clinical trial." The number of medical sources continues to climb, and the reality is that new clinical research is coming out so fast doctors simply can't keep up.

And it's not that they don't want to. They just don't have the time. In a recent survey by Univadis of 550 physicians across four specialties—general medicine, cardiology, endocrinology, and oncology—64% said the time they spend keeping up to date in their field is insufficient. That number was higher for cardiologists (68%) and general practice (65%) doctors.

To peel the onion back one more layer, doctors are often finding limited value in investing their time in reviewing clinical research. According to the survey, 82% overall said that fewer than half of the studies they do read actually have an impact on how they practice medicine. Cardiologists (76%) felt the information they review was slightly more useful, and general practitioners (84%) felt it was less useful, but that makes sense given the breadth they have to keep up

WHAT CAN DOCTORS DO to stay up to date and manage the changing doctor/patient relationship?

- **Figure out your learning style:** There are many ways to access information. Knowing whether you like to consume information through reading, listening to a podcast, experiencing it in person in a venue like a conference, or joining an online physician community will help you seek and retain information in the way that's best for you.
- **Choose your top sources:** Given the volume and variety of sources, try to figure out three to four go-to sources and consult those first. Trying to keep up with it all is a sure-fire way to burn out.
- **Be humble:** Doctors can't know everything, and in today's interconnected world, we don't have to. If a patient does present you with something you hadn't heard of—which happens to all doctors—thank them, let them know you'll look into it, and then follow through. You'll be approaching the information they brought up based on all your medical knowledge and can then let them know whether the source is reliable and explain your recommendation accordingly.
- **Build alliances and collaborations:** Interacting with fellow physicians, both at their institution and elsewhere, can generate knowledge and healthy debate on current medical research. There are many online physician communities ripe with insights about which research is actually impacting their practice of medicine.
- **Seek curated content:** Doctors can also look to subscribe to a credible service that summarizes the latest research that is relevant to their field of medicine.

on. This begs the question that, in a profession with so many competing priorities, why would a doctor invest valuable time in something that won't ultimately elevate the level of care they bring to their patients?

While the volume of research increases, patients are changing as well. They are web-savvy and spending time researching their condition. They're showing up at their appointment more informed than ever, sometimes even surprising their doctors with new information.

In fact, 52% of doctors in the Univadis survey admitted that they've had patients present them with credible, relevant medical information they were unaware of. That's no surprise given the Internet and the speed at which new information is released. The fact is that in some cases, a patient with a specific diagnosis probably has more time to uncover every option than their doctor.

If nothing else, the Univadis survey demonstrates that the rise in the volume of clinical medical information is impacting the relationships doctors have with their patients and shifting the dynamic. But it will remain important for doctors to remain informed.

Information is certainly not going to slow down, so doctors should come up with a plan to keep up so they are ready to have informed conversations with patients. ■

Corey Dean, MD, FACP, FAAP, CAQSM is the associate program director of ambulatory education at St. Joseph Internal Medicine Residency Program in Ann Arbor, Mich. He is board certified in internal medicine, pediatrics, and sports medicine. He has been a clinician-educator for the past 15 years and practices primary care at the Neighborhood Family Health Center. He is the team physician for Concordia University and Saline and Ypsilanti-Lincoln High Schools in the Ann Arbor area.

DISCLOSURE The author reports no potential conflicts of interest with regard to this article.

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Coding for obstetrics CONTINUED FROM PAGE 32

guidelines for each section. The ICD-10 guidelines state that codes for chapter 15 (Complications of Pregnancy, Childbirth, and the Puerperium) have sequencing priority over other codes from other chapters and are to be listed first unless the pregnancy is completely incidental and has nothing to do with the reason for the visit.

Another important consideration is the fact that in ICD-10, most of the diagnoses in chapter 15 include the concept of trimester. The guidelines state that not only should you select the code with the appropriate trimester for the current encounter, but a separate code (Z3A.--) should be used to report the weeks gestation for the encounter. For example, a patient in her 16th week of pregnancy should be assigned a code from chapter 15, followed by the code Z3A.16 to indicate 16 weeks' gestation.

Routine vs problem visits

For a routine outpatient prenatal visit when no complications are present, select a diagnosis code from range Z34, Encounter for Supervision of Normal Pregnancy, as the primary diagnosis. Remember that on average, the global OB package encompasses 13 routine visits during pregnancy, which includes routine visits in uncomplicated cases, and 6 weeks postpartum care. This may include H&Ps, routine measurements, and educational services such as breastfeeding or basic newborn care. Services that are not part of the global OB package may be billed separately, such as an initial evaluation and management service to diagnose pregnancy, amniocentesis, cephalic version, additional E&M services for unrelated reasons (e.g., asthma or urinary tract infection) or greater frequency of visits due to a high-risk pregnancy. Sometimes coders get confused and either miss out on billing a service that isn't included in the global OB package or they mistakenly try to bill for a visit that is included in the package.

Sometimes our patients (and our coding) can be routine, but other times things can get complicated. Having a good understanding of what is included can help you be prepared so that when you encounter a situation that isn't included, you don't forget to bill for it. It always helps to have your (*heavily marked up and highlighted*) coding manuals and/or cheat sheets nearby, and reimbursement policies from your office's biggest payers on your computer. ■

DISCLOSURE The author reports no potential conflicts of interest with regard to this article.

Avoiding ultrasound errors

CONTINUED FROM PAGE 41

the fundal height and the estimated gestational age. The plaintiff's expert witness testified that the ultrasound report erroneously reported the estimated date of delivery, the primary obstetrician should have recognized this discrepancy and the persistent discrepancy in the fundal height and gestational age and ordered a repeat ultrasound.

THE VERDICT
The case settled for $980,000 prior to trial.

LEARNING POINTS

Imaging specialists must construct their report to alert referring physicians to significant sonographic findings or notify the referring physician of them personally or through their appropriate delegate, such as that physician's nurse. Recommendations for further studies are integral to a complete report. For example, in the referenced case, a preferred report follows:

> *The estimated gestational age by ultrasound is 9w4d. This is not consistent with the estimated age by dates. ACOG recommends adjusting the EDD if the discrepancy is more than 7 days when the gestational age is between 9w0d and 13w6d. Thus,* ***the EGA should be adjusted to 9w4d, with an EDD = 6/03/XX.*** *The adjusted EDD should be confirmed on subsequent ultrasound studies. Consider a nuchal translucency at 11-14 weeks. An anatomic survey is recommended at 18-20 weeks EGA.*

The final written report is considered the definitive means of communicating the results of an imaging study or procedure.

LEARNING POINTS

The final written report is considered the definitive means of communicating the results of an imaging study or procedure. Direct or personal communication must occur in certain circumstances, such as major fetal anomalies or findings that immediately impact management of the pregnancy. The primary obstetrician must read the entire report and correlate the ultrasound findings with the clinical findings. Inconsistencies require further investigation or imaging.

CASE 3 Be careful about what you DO NOT document.

A 33 year-old G3P2002 underwent an ultrasound at 19 and 1/7 weeks' gestation. The ultrasound reported stated, "Normal ultrasound with fetus at 19 1/7 weeks of gestation." No further ultrasounds were performed. At 39 weeks' gestation, the patient delivered a baby with Down syndrome. An expert review of the ultrasound revealed mild pyelectasis with calyceal dilatation of 4.3 and 4.4 mm. In addition, an echogenic intracardiac focus was identified. At trial, the radiologist testified that the practice rounds to the nearest whole number. Thus, the calyceal dilation would have been 4 mm and within normal limits. Further, an echogenic intracardiac focus is a worthless marker and of no consequence. Thus, the ultrasound was normal.

It is the obstetrician's duty to recommend further testing to the patient. The obstetrician testified that the ultrasound was reported as normal and he had no reason to recommend amniocentesis or further ultrasound studies. The plaintiff's expert testified that calyceal dilatation > 4 mm at 19 and 1/7 weeks' gestation warrants a repeat ultrasound at 32 weeks to evaluate for persistence of the calyceal dilatation. As an isolated finding, an echogenic focus is poor marker for Down syndrome. However, when multiple soft markers for Down syndrome are identified, they should be noted in the report and recommendations made to recalculate the patient's risk with amniocentesis, if indicated. A repeat ultrasound should have been recommended.

THE VERDICT
The jury found as follows:
Obstetrician: Defense verdict
Radiologist: Plaintiff verdict. The radiologist had a duty to report the findings to the obstetrician. If he had done so, the duty for further counseling, evaluation, and treatment would have transferred to the obstetrician.

LEARNING POINTS

Imaging specialists, regardless of their specialty, should report all visualized abnormal findings, recommending clinical correlation and further studies as indicated. Significant or concerning findings may require direct communication with the referring physician or his or her delegate. Further, this case demonstrated a rather common error made during trial: One defendant criticizes the care or blames the outcome on another defendant. Such actions render a case virtually indefensible. Defendants should not act as experts for the plaintiff. At trial, a defendant should confine his or her testimony to their actions and rationale, while avoiding criticizing the care of others.

CASE 4 Be careful what you bill and how you document

A radiology group routinely performs and bills for transabdominal and transvaginal ultrasound (TVUS) studies in all patients referred for a pelvic ultrasound. They came under scrutiny for billing fraud, for inappropriately billing for both studies in all patients, particularly as they could not identify an order requesting both studies from referring physicians.

THE VERDICT

The Department of Justice fined the group $10 million for performing "unnecessary procedures."

LEARNING POINTS

Many ultrasonographers opine that the standard of care requires the performance of both an abdominal and a vaginal sonogram at the time of pelvic ultrasound. This is not the standard of care. Certainly, if all relevant anatomy cannot be identified with one approach, appropriate evaluation requires the additional approach. Whether a specific order is required is controversial. If a practice performs its own ultrasound studies, this is a minor issue, as the providers are readily available to confirm the need for additional study. However, imaging specialists who see many referred patients face greater obstacles, particularly in the era of electronic health records and electronic orders.

Several recommendations can be made for ordering, reporting, and billing. (See Sidebar: **Options for overcoming the issue of performing studies without appropriate orders**)

Incorporating language like what is shown in the sidebar into the electronic

Options for overcoming the issue of performing studies without appropriate orders include:

1. Encouraging referring physicians to order both TVUS and transabdominal ultrasound studies as indicated.
2. Developing a protocol that allows performance of an abdominal ultrasound if complete evaluation of pelvic anatomy is not possible with TVUS. Similar protocols have been developed for mammography and breast evaluation, which allow more detailed imaging studies and even ultrasound, if clinically indicated. This concept works best in an integrated health system with established protocol committees. Outside of an integrated system, referring physicians can be notified of such protocols and their ongoing approval for use of such protocols in their referred patients obtained.
3. Contacting the referring physician to obtain an order for the additional study. This is the most cumbersome and time-consuming solution.

There are a number of ways to use language in the report to justify the need for additional imaging, such as by saying:

1. An abdominal ultrasound was required due to the inability to adequately visualize one or both ovaries on the vaginal study.
2. An abdominal ultrasound was required due to the inability to adequately visualize the uterus on the vaginal study.
3. An abdominal ultrasound was required due to the inability to adequately evaluate the pregnancy on the vaginal study.
4. A vaginal ultrasound was performed to evaluate cervical length.

reporting system can facilitate its inclusion in an ultrasound report.

Billing for both studies must be appropriate. For example, if an ovary not seen on TVUS could be visualized on abdominal ultrasound, it would be appropriate to bill CPT 76830 (Complete evaluation of the female pelvic anatomy-vaginal study) and CPT 76857 (Ultrasound, pelvic [non-obstetric], real-time with image documentation; limited or follow-up).[1] Billing for CPT 76856 (Complete evaluation of the female pelvic anatomy-abdominal study) should not be done unless all elements of the abdominal ultrasound are performed.

These elements include:

- Description and measurements of uterus and adnexal structures
- Measurement of the endometrium
- Measurement of the bladder (when applicable)
- Description of any pelvic pathology

In general, the code for a limited study, whether transabdominal or transvaginal, is the more common second code. It documents that the study did not include all elements of a complete study.

Inaccurate or inappropriate billing may present greater financial risk than medical liability. The physician is ultimately responsible for submitting the correct bill. Delegating coding for procedures increases the risk of error, for which the provider is liable. Electronic health records highlight another risk of possible fraudulent billing. Including the documentation for a management consult in the ultrasound report is not adequate for the purpose of billing an evaluation and management (E&M) code. Documentation in a separate progress note should be performed when billing an E&M code, in addition to the CPT code(s) for an ultrasound study.

The physician is ultimately responsible for submitting the correct bill. Delegating coding for procedures increases the risk for error, for which the provider is liable.

Summary

These cases illustrate common errors leading to litigation when performing obstetric and gynecologic ultrasound. Underlying each scenario is proper documentation of the ultrasound findings. Findings should be recorded and results communicated consistent with the AIUM Practice Parameter for Documentation of an Ultrasound Examination.[2] Applying the discussed recommendations is no guarantee that a physician will not be held liable for such errors. Applying these best practices, however, will enhance the defensibility of such cases. ■

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LEGALLY SPEAKING

by JAMES M. SHWAYDER, MD, JD

Ultrasound errors to avoid: How important is the report?

Four cases illustrate common errors that can lead to litigation.

CASE 1 Look at the images

A patient underwent four ultrasounds during her pregnancy. The sonographer remarked that in three of the studies, there were, "Structural irregularities that require further evaluation." The physician notified the patient that the ultrasounds were normal. The baby was born with a midline facial defect, cleft palate, club foot, and lower-limb anomalies. The child has limited cognitive and communication skills. During litigation, the physician admitted that he had not reviewed the images from the studies or the sonographer's handwritten report about the findings.

THE VERDICT
A $1.9 million settlement was reached prior to trial.

LEARNING POINTS

Unfortunately, it is not uncommon for physicians to rely on the sonographer's "report" and fail to personally review the images. Although sonographers are responsible for obtaining appropriate images, interpreting ultrasounds is beyond the scope of their professional practice. Interpretation of studies and associated recommendations are the responsibility of the physician. Physicians should review study images and either scan the patient themselves or refer the patient to an imaging specialist for further evaluation and diagnosis.

CASE 2 Documenting and reading the report carefully

A 28-year-old G3P2002 presented to her physician at 16 weeks, 4 days with a history of oligomenorrhea and two prior cesarean deliveries. Her estimated date of delivery (EDD) was 4/10/XX. Because of the woman's body habitus, the physician was unable to palpate the uterine fundus. Fetal heart tones were documented at 160 beats per minute. The patient was referred for an ultrasound, which was performed at 17 weeks' gestation by dates and consistent with 9 weeks, 4 days' gestation. The report stated, "Live, intrauterine pregnancy with a gestational age of 9 weeks 4 days + 6 days. The EDD is 4/10/XX. No abnormalities visualized." The EDD should have been 6/2/XX but the report showed the original EDD, rather than the new one. No further ultrasounds were performed during the pregnancy.

On 4/05/XX, the patient delivered a 1710-g male infant via cesarean, who had Apgar scores of 9 and 9 at 1 and 5 minutes, respectively. The baby's Ballard score was consistent with 31 weeks. He suffered unusually severe complications of prematurity with severe respiratory distress syndrome, bronchopulmonary dysplasia, and necrotizing enterocolitis requiring surgery.

Deposition of the defendant obstetrician revealed repeated exam inconsistencies and poor documentation. For example, the patient was seen for abdominal pain at 23 and 2/7 weeks by dates and 15 and 5/7 weeks by ultrasound. The only documentation of the examination was "Uterus is normal." There were repeated discrepancies between

FOR MORE LEGALLY SPEAKING TURN TO PAGE 35

Dr. Shwayder is professor of obstetrics and gynecology and former chair at the University of Mississippi Medical Center. He is a graduate of the University of Denver College of Law and is a nationally and internationally recognized expert in gynecology ultrasound and minimally invasive surgery. He actively consults on legal matters in medicine, including liability in ultrasound and gynecologic surgery, as well as issues surrounding privileging and insurance fraud.

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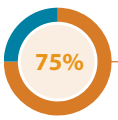
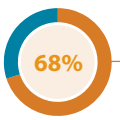


~75% of women infected with **chlamydia** are asymptomatic[1]



~68% of women infected with **gonorrhea** are asymptomatic[1]

Chlamydia and gonorrhea are two of the most common reportable sexually transmitted infections (STIs) and rates of infection are on the rise.

A universal screening CT/NG strategy would focus on women within the high-risk age group covered by guidelines from USPSTF and CDC guidelines (women 15-24 years old) without regard to the sexual activity they report.

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- Decrease infertility due to undiagnosed infections
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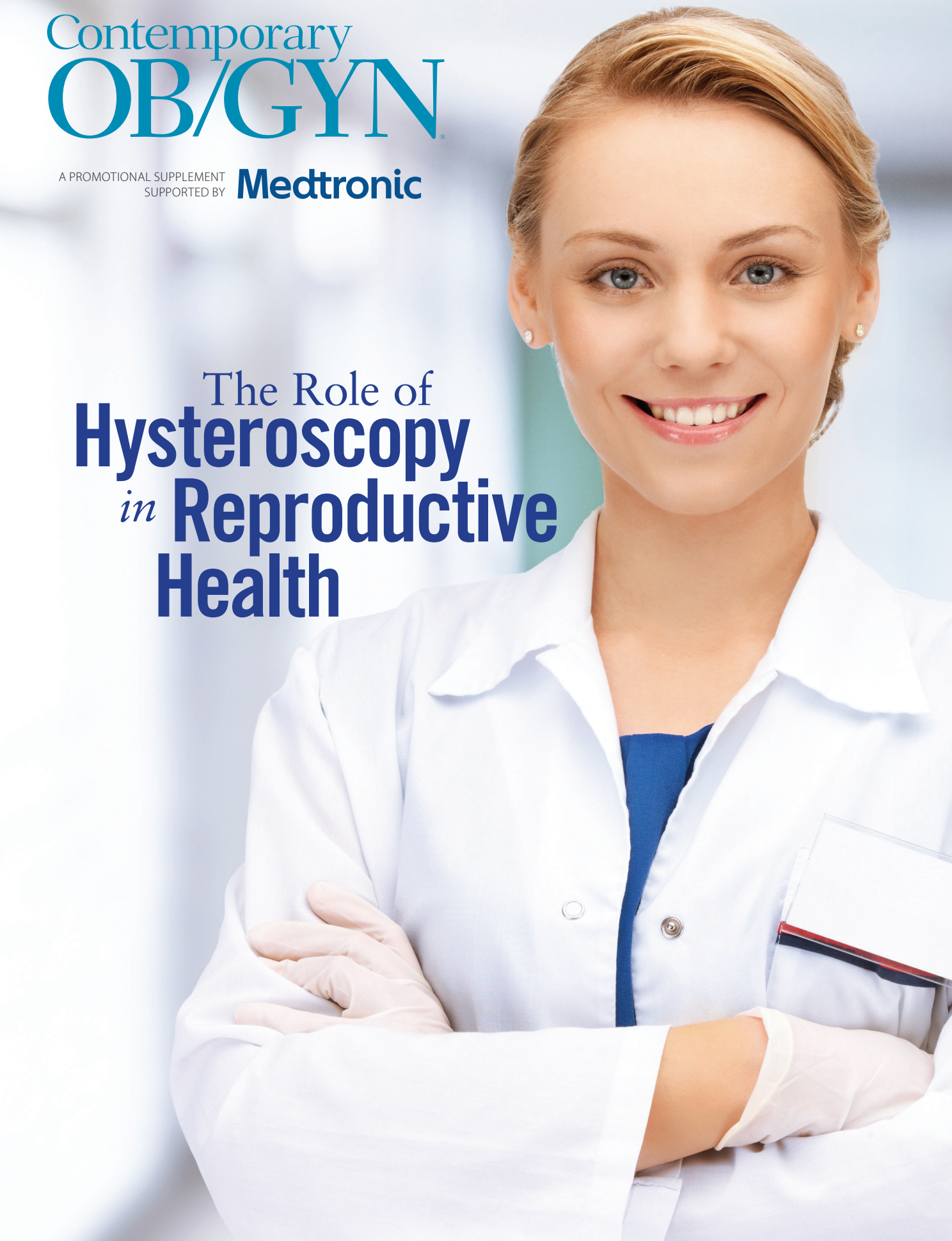
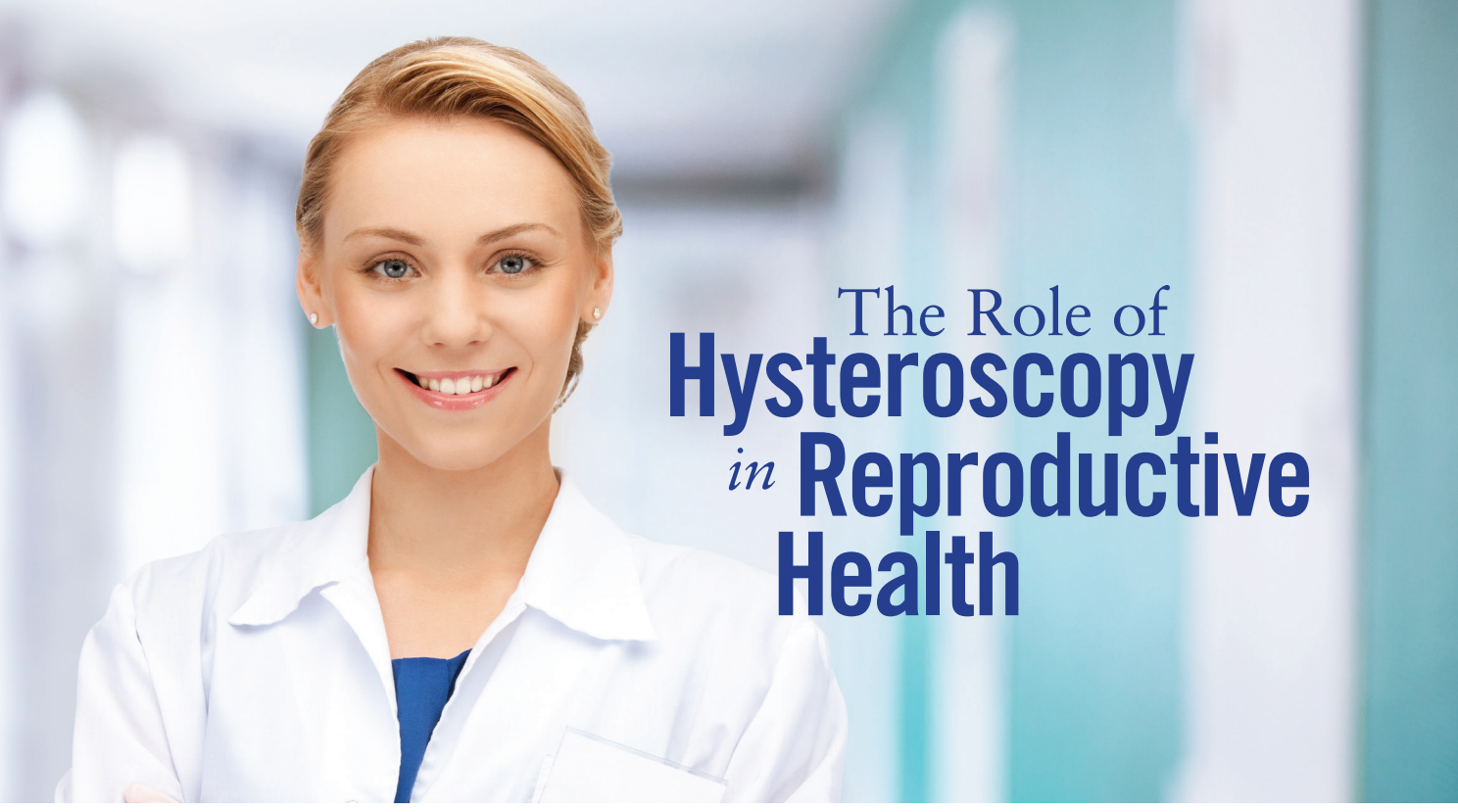
The Role of Hysteroscopy *in* Reproductive Health





The Role of Hysteroscopy *in* Reproductive Health

Panelists

Dorette Noorhasan, MD, is medical director and cofounder of CCRM Dallas–Fort Worth, TX. She is board certified as a reproductive endocrinologist and infertility specialist. Dr. Noorhasan graduated summa cum laude from the University of the Virgin Islands and attended medical school at Boston University School of Medicine. After medical school, she completed her obstetrics and gynecology residency at the University of Texas in Houston and a reproductive endocrinology and infertility fellowship at New Jersey Medical School in Newark. She has published in numerous journals, including *Fertility & Sterility*, *Human Reproduction*, *Women's Health Issues*, *Journal of Pediatrics*, and *Obstetrics and Gynecology International*.

Charles Miller, MD, FACOG, is founder, president, and medical director of the Advanced IVF Institute and the Advanced Gynecologic Surgery Institute, Charles E. Miller, MD & Associates, in metropolitan Chicago, IL. He specializes in the treatment of infertile couples and minimally invasive gynecologic surgery. A graduate of the honors program in medical education at Northwestern University, Dr. Miller completed his residency in obstetrics and gynecology at the University of Texas Southwestern Medical School, Parkland Memorial Hospital. Dr. Miller later earned his fellowship in reproductive endocrinology and infertility at the Hospital of the University of Pennsylvania. He is a past president of the International Society for Gynecologic Endoscopy and the AAGL.

Disclosures

All faculty, planning committee members, editors, managers, and other individuals who are in a position to control content are required to disclose any relevant relationships with any commercial interests related to this activity. The existence of these interests or relationships is not viewed as implying bias or decreasing the value of this publication.

Disclosures are as follows:

DORETTE NOORHASAN, MD, has disclosed that she has no relevant financial relationships specific to the subject matter within the last 12 months.

CHARLES MILLER, MD, FACOG, has the following affiliations – Abbvie (speakers' bureau, consultant, grant/research/studies); Espiner Medical (consultant, grant/research/studies, royalties); Gynesonics (consultant, grant/research/studies, stock option agreement); Medtronic (consultant); Richard Wolf (consultant); Allergan (grant/research/studies) and Karl Storz (grant/resrach/studies).

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DUE TO A VARIETY OF FACTORS, the number of women with infertility issues in the United States is on the rise. According to the latest data from the Centers for Disease Control and Prevention, approximately 12.1% of women between the ages of 15 and 44 years have fertility problems and 7.3 million have used an infertility service. These percentages increase as women age, with approximately 16.2% of women between the ages of 40 and 44 years experiencing fertility issues. These percentages skyrocket in women who have not had a previous successful childbirth.[1]

In this supplement, two infertility experts discuss the importance of diagnosing and treating abnormal uterine pathology during infertility work-ups. They also discuss the tools that are available to providers to help accomplish that goal.

Infertility in today's patients

***Moderator:* Your practices both focus significantly on managing and treating infertility issues. How do the majority of your current patients end up in your practice?**

Dorette Noorhasan, MD: There are several ways that patients typically find me. The first is a direct referral from their ob/gyn. The second is a simple Internet search. The third is word of mouth from my prior patients who have had a good experience. Social media is also very important. There are insurance plans as well that direct patients to Centers of Excellence for infertility. Fortunately, at CCRM Dallas–Fort Worth, we are lucky enough to be a Center of Excellence.

Charles Miller, MD: When I was a younger man, it was virtually all via physician referral. Nowadays, while there are still a lot of physician referrals, many of my current patients come through referrals from their family or friends or through personal links to patient advocacy groups.

***Moderator:* In today's healthcare environment, do you find that the majority of general ob/gyns will attempt to manage their patient's infertility issues on their own initially, or do most of them refer patients to specialists such as yourselves right from the start? Do you have a preference?**

Dr. Noorhasan: I'm OK with either approach. There are several physicians in my area who will refer patients directly to me, particularly patients with advanced reproductive age (≥35 years), abnormal fallopian tubes (tubal factor), or abnormal semen parameter (male factor). Some ob/gyns will try to manage infertility initially in younger patients and in those without abnormal testing, only sending these patients to me after they have failed approximately 3 cycles of ovulation induction with oral medications such as clomiphene citrate or letrozole.

***Moderator:* What are currently the most common causes of infertility you see in your practice?**

Dr. Miller: Successful fertility comes down to the sperm traveling to meet and fertilize the egg, and then the fertilized egg successfully implanting into the uterus. Thus, the causes of infertility are secondary to the following:

- Male factors, including sperm count and function
- Cervical factors, namely the ability to create a conducive environment within the cervix to allow transport of the sperm from the vagina into the uterus
- Egg factors, including folliculogenesis, ovulation, and luteinization
- Pelvic factors, which allow ovum pick up, fertilization in the fallopian tubes, and implantation in the uterus

In addition to these factors, endometrial polyps, submucosal fibroids, intrauterine adhesions, uterine malformation, and retained products of conception can also all lead to implantation issues affecting fertility.

Dr. Noorhasan: The most common cause of infertility that I see today is age-related. We're all waiting until later in life to have children—traveling the world, starting our careers, those types of things—and starting a family is often put on the backburner. And then, by the time it becomes a priority, there is a heightened risk of infertility issues.

There are also a lot of people I see in their late 30s or 40s who are on their second or maybe even third marriages, who have children from a previous marriage and thought they were done building a family. Maybe they had a vasectomy or had their tubes tied, but now they've met someone new and want to have another child. Infertility issues are common in that population as well.

Hysteroscopy: the basics

***Moderator:* In general, what is the value of using a hysteroscope in an ob/gyn practice?**

Dr. Miller: In an ob/gyn practice, hysteroscopes give you the ability to not only diagnose but also often treat conditions related to abnormal uterine bleeding and some causes of pelvic pain. In a practice that focuses on infertility issues, a hysteroscope is an invaluable tool that allows providers to treat conditions related to abnormal uterine structures that may affect fertility.

Dr. Noorhasan: When patients come in to see me with infertility, I tell them that there are four things I initially evaluate: their eggs, their reproductive tract, their male partner's sperm, and my "other" category, where I look for thyroid problems, diabetes, and other issues that can impact infertility.

The hysteroscope is the gold standard for allowing providers to look directly into the uterus and determine if problems are related to fibroids, polyps, and/or scar tissue. In addition to being a diagnostic tool, hysteroscopy allows you to treat these problems rather easily.

***Moderator:* How do you determine when hysteroscopy is going to be appropriate in a given patient?**

Dr. Miller: My initial screening tool in women with fertility issues is a saline-infused sonogram, which allows me to evaluate the uterus, uterine conditions, and—with the use of saline and air—tubal patency. The saline-infused sonogram gives me the ability to look at the myometrium, which an examination of the uterine cavity does not allow. If the saline sonogram shows the presence of polyps, fibroids, or intrauterine adhesions, I will use the hysteroscope as my operative tool.

There are other infertility specialists as well as ob/gyns who will use a hysteroscope as their primary diagnostic tool, especially those who often deal with infertility issues, as direct visualization is considered the gold standard. That is certainly an option, although I tend to reserve hysteroscopy as an operative tool in patients I suspect to have endometrial pathology, submucosal fibroids, or uterine malformations that will need to be treated.

Diagnosing and treating retained products of conception

***Moderator:* How does the presence of retained products of conception affect fertility?**

Dr. Miller: Retained products of conception are essentially foreign material inside the endometrial cavity, which can cause problems with the endometrial lining and negatively impact implantation of the embryo. There can also be scarring that occurs with retained products of conception, which results in issues impacting proper endometrial lining development and fluid collection within the endometrial cavity, both of which can disrupt implantation.

***Moderator:* What can be done in women with retained products of conception?**

Dr. Miller: Without question, the treatment of choice in women with retained products of conception is direct visualization and treatment via mechanical hysteroscopic tissue removal. That approach allows you to shave those products back to the level of the endometrium. Hysteroscopy allows you to hone in on the pathology that needs to be treated and see the endpoint so that you are not affecting normal, healthy tissue. I have been utilizing this technique for more than a decade. It is associated with low rates of adhesion formation.

Diagnosing and treating uterine adhesions

***Moderator:* How does the development of uterine adhesions result in infertility?**

Dr. Noorhasan: Scar tissue is avascular, which makes implantation and development of an embryo difficult. During natural conception, once the egg is fertilized with the sperm in the fallopian tube, the embryo migrates down from the fallopian tube and finds a cozy spot in the uterus to implant and grow. Because scar tissue is avascular, it is difficult for an embryo to implant or grow on it. Embryos need to establish maternal vascular supply during the implantation process, and if one cannot do so optimally, it makes implantation and growth difficult, resulting in either infertility or miscarriage.

Dr. Miller: There is one further way that an intrauterine adhesion can be problematic for women trying to get pregnant. Adhesions may be associated with fluid buildup in the endometrial cavity that prevents embryo implantation.

***Moderator:* What are the risk factors for the development of intrauterine adhesions?**

Dr. Miller: Adhesions can be caused by endometritis post-instrumentation, particularly as a result of termination of pregnancy or miscarriage. Adhesions can also occur secondary to retained products of conception or postsurgical cases such as polypectomy, myomectomy, lysis of adhesions, and transection of uterine septum. There is also a cesarean scar defect called uterine isthmocele that can lead to adhesions.

***Moderator:* Do previous episodes of failed in vitro fertilization (IVF) commonly result in intrauterine adhesions?**

Dr. Noorhasan: It's very unlikely for a failed IVF cycle to result in an intrauterine adhesion. Now, if you implanted an embryo and the patient later had a miscarriage that required surgical removal of retained products of conception, that's a different story. But a typical failed IVF is unlikely to result in intrauterine adhesions.

***Moderator:* What are the benefits of a hysteroscopic approach in the diagnosis of intrauterine adhesions?**

Dr. Miller: The hysteroscopic approach allows you to "peek and treat," in other words, to directly evaluate the severity of the adhesions and immediately treat under direct visualization. In the past, most ob/gyns would perform a blind dilation and curettage (D&C), which was really challenging because you couldn't assess the extent of adhesive disease or know if adhesiolysis was complete. By the same token, there was a risk of traumatizing areas of the uterine cavity where there was normal tissue. Using a hysteroscopic approach that allows you to see what is being treated is a tremendous improvement.

***Moderator:* What can be done in women with intrauterine adhesions?**

Dr. Noorhasan: In women with mild intrauterine adhesions, you can perform operative hysteroscopy and take down the scar tissue fairly well without any additional assistance. With moderate-to-severe adhesions, many times we will do the hysteroscopy at the same time we are doing either an abdominal ultrasound or a laparoscopy to help guide the hysteroscopy. Sometimes, the scar tissue is so severe that you don't know where the anatomy ends, which mandates use of laparoscopy or ultrasound guidance to avoid a uterine perforation.

In our clinic, we typically have a second physician perform the laparoscopy or abdominal ultrasound and watch to make sure we are not going too far out in any direction as we are taking down the scar tissue, so that we stop once we have reached normal uterine tissue.

Dr. Miller: A patient who develops intrauterine adhesions once is at significant risk of recurrent adhesions, so it's important that you develop a clear strategy before the start of the procedure. The two edges of the uterus are juxtaposed, so that if you simply remove adhesions between the two walls—say from the anterior to the posterior wall—after you take out your instrument and the fluid leaves, those walls are once again juxtaposed and thus may fuse, causing adhesions. When there are significant adhesions involving two edges of the uterus, we will often use a uterine stent to separate the edges for 5 to 14 days, as well as estrogen for 1 month to prevent those edges from fusing.

When removing intrauterine adhesions, it is important to minimize the use of energy applied during the procedure. The concern is that the excessive use of energy in the uterus can spread laterally and cause tissue necrosis. We treat our severe cases of lysis of intrauterine adhesions utilizing laparoscopy or ultrasound guidance.

Dr. Noorhasan: I will also insert an intrauterine stent or balloon and leave it in for 4 to 7 days after surgery to keep the uterus distended and prevent scar tissue from re-forming. Additionally, I will prescribe estrogen pills following surgery to help rebuild the endometrium. That's the area that is usually most significantly scarred, so estrogen can help rebuild the endometrial lining.

In most patients with intrauterine adhesions, we are able to remove the scar tissue during hysteroscopy.

Use of hysteroscopy in women with failed IVF

***Moderator:* What are the benefits of diagnosing and/or treating pathology prior to each IVF cycle? And what is the potential role of hysteroscopy in that process?**

Dr. Noorhasan: I perform a saline-infused sonogram as the initial screening test and follow up with a hysteroscopy if anything is abnormal, but hysteroscopy is generally considered the gold standard.[2,3]

In 95% to 99% of all cases, my experience is that a saline-infused sonogram is comparable to a diagnostic hysteroscopy, especially if it's a three-dimensional sonogram. You can see a lot of details with that. If the saline-infused sonogram demonstrates an abnormality, I will then perform an operative hysteroscopy for treatment. If I have a patient who fails two IVF cycles and has only had normal results on a saline-infused sonogram, I will typically perform a hysteroscopy and sometimes a laparoscopy to make sure there is not anything we are missing. We rarely will find anything because we are so attentive to making sure the uterus is normal prior to IVF, but it will happen occasionally.

Dr. Miller: I take a similar approach and will also typically wait until two failed IVF cycles before following up a saline-infused sonogram with hysteroscopy, although it depends in part on the age of the patient and their insurance coverage. In a woman who is older, there is more urgency to accomplish your goal. We are fortunate that Illinois is a state that mandates fertility coverage as part of health insurance, but for patients who do not have that coverage, each IVF cycle can be a significant financial burden. It's therefore vital to perform appropriate diagnostic testing so that you are absolutely sure of the patient's pathology. In those cases, I would likely only wait until one failed cycle or even add hysteroscopy to a saline-infused sonogram upfront. I would also be more likely to use mechanical hysteroscopic tissue removal to biopsy tissue and look for any plasma cells in the sample to rule out a possible occult endometritis.

Choosing the right hysteroscope for your practice

***Moderator:* Which hysteroscope do you currently use in your practice? Why was that your technology of choice?**

Dr. Noorhasan: I use the TruClear™ hysteroscopic tissue removal system by Medtronic. What I like about the TruClear™ system is that it has a passive outflow channel, which allows fluid to leave the uterine cavity. In a patient in whom there is significant bleeding or debris obstructing my visual field, I can turn on the outflow channel to drain the fluid in the uterus and the inflow channel simultaneously pumps clean fluid back in. In a hysteroscopic system without an outflow channel, the only way to clear your visual field is to pump in more fluid, which can increase your fluid deficit.

Dr. Miller: I also use the TruClear™ hysteroscopic tissue removal system. In the office setting, it allows me to deal easily with endometrial polyps, retained products of conception, and even small fibroids. In the outpatient, operating room setting, I also have the ability to utilize the TruClear™ Dense Tissue Shaver Plus for type 0, type 1, and some type 2 fibroids, as well as when dealing with retained products of conception immediately post-delivery when the uterus is still enlarged.

Key Takeaways

- A healthy uterus is key to successful conception and pregnancy. Therefore, a thorough evaluation of any woman with infertility issues with a saline-infused sonogram and hysteroscope is always recommended.
- Any abnormalities found during the initial evaluation of the uterus should be further examined and treated with a hysteroscope.
- Hysteroscopy is the treatment of choice for the removal of small fibroids, polyps, and retained products of conception.
- Many hysteroscopic procedures can be performed in an office environment, although more significant procedures may require use of an outpatient surgical facility.

***Moderator:* What are some of the other key features of the TruClear™ system that make it clinically efficient?**

Dr. Miller: It's an instrument you can use to both look at the uterus and treat any abnormalities at the same time. While the TruClear™ system doesn't have its own instrumentation to transect uterine septum and intrauterine adhesions, we have been able to find scissors that are adaptable to the platform so that I can use the TruClear™ hysteroscopes."

The beveled scope and the small overall size of the TruClear™ hysteroscopes allows me to enter the endometrial cavity easily. I'm able to use a vaginoscopy technique with no dilation, so that I can go from the vagina to the cervix to the uterine cavity without having to place a tenaculum. That is very conducive to procedures in the office setting. Moreover, the integrated continuous inflow and outflow offers excellent visualization even with activation of the shaver.

In my outpatient surgical suite where I'm treating larger fibroids and more significant pathology, I have a family of instruments that we have adapted to use with the TruClear™ Elite hysteroscopes. I can perform just about any procedure I need to with the TruClear™ system at this point.

Dr. Noorhasan: They have improved a lot of the optics and the operating channel with the TruClear™ hysteroscopes recently. In previous iterations of the TruClear™ hysteroscopes, you had to lock and then unlock it to insert instruments through. Now, there is a dedicated area where you can put instruments through without having to lock and unlock the device.

Back when I was in my medical training, when you had a woman with large fibroids in her uterus, you had to switch from a tiny 3-mm hysteroscope that allowed you to only look at the uterus to a much larger 10-mm hysteroscope (called a resectoscope) for treatment. There was no size in between to rely on.

Now, with the TruClear™ system you can go from smaller 3- to 4-mm diagnostic scopes to 5- to 7-mm scopes for treatment. Not having to use a larger 10-mm scope can make a big difference, because at a certain point, a woman's cervix simply will not dilate to accommodate the larger size.

Also, in the past, you had to pull out the entire scope every time you resected a portion of the fibroid using a resectoscope. But with the TruClear™ system, it can stay inside the uterus the whole time. It cuts and suctions simultaneously, so you don't need to pull the scope out, take the specimen off the resecting device, and then reinsert the scope. That was a big advance.

My operating time to remove polyps and small fibroids used to be 45 minutes to an hour. Now, the procedure takes only a few minutes. Not only does that save me time as a surgeon but it also means that the patient is under anesthesia for a shorter time. It's a win-win for everyone.

***Moderator:* This has been a terrific discussion. We want to thank both of you for your insights. I hope that our audience is able to take away some helpful information from our discussion to inform their practice's approach to the use of hysteroscopy.**

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