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Chorionicity in twin gestations

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EDITORIAL BY CHARLES J. LOCKWOOD, MD, MHCM

One of this nation’s greatest public health successes resulted from the decision to cheaply supplement table salt with iodine. Since iodine supplementation of our diets began in the 1920s, we in the United States have almost eliminated severe iodine deficiency. Before then, endemic iodine deficiency was prevalent in the so-called goiter belt—the Great Lakes, Appalachian, and Northwestern regions—where 26% to 70% of children had clinically apparent goiter.1

Iodine deficiency is still a major global health problem; approximately 2 billion people are currently at risk. It remains a leading cause of preventable mental retardation in children worldwide.2 In the past, the stigmata of iodine deficiency and the ensuing hypothyroid states could not be ignored. In addition to large goiters, affected women had pregnancy complications and their offspring had severe developmental delays. Fortunately, such overt clinical manifestations are vanishingly rare in this country today, but more subtle forms of iodine deficiency are on the rise and pose a potential risk to pregnant women and their fetuses. Thus, US obstetricians need to once again be concerned about maternal iodine deficiency.

Thyroid hormone homeostasis in pregnancy
Iodine is crucial to maintaining a euthyroid state because it forms the elemental backbone of both thyroxine (T4) and triiodothyronine (T3). Normal thyroid function is critical to energy homeostasis and metabolism as well as normal cognition and neurological functioning in adults and children. Pregnant women are particularly vulnerable to iodine deficiency because early pregnancy is characterized by a rapid surge in thyroid hormone production (and iodine requirements).3 Late pregnancy also stresses maternal iodine stores because of increased renal clearance. Normally this enhanced iodine demand is easily overcome by adequate iodine intake, but these changes can easily overwhelm a woman who begins pregnancy with borderline or low iodine stores.

The increasing prevalence of iodine deficiency in pregnancy
The World Health Organization recommends 250 µg of iodine daily for pregnant and lactating women while...
the Institute of Medicine recommends 220 µg daily during pregnancy and 290 µg daily during lactation. While achieving such intake levels was easily accomplished in the past, contemporary dietary trends are making it harder for US mothers to meet these recommendations. Currently, the major sources of dietary iodine are iodized salt/table salt, breads/grains, and dairy products. However, the current push to reduce salt intake in order to lower risks of hypertension and cardiovascular disease as well as increasing intake of noniodized salt from processed foods and sea salts or kosher salts have measurably reduced US dietary iodine intake. Seafood is also an excellent source of iodine but reduced seafood consumption during pregnancy, caused by concerns about excess mercury ingestion, has further exacerbated reduced iodine intake in pregnant women. As a consequence of these cumulative trends, US iodine stores have dropped by 50% from 1970s levels when assessed by urinary iodine concentration (UIC), the most common method of evaluating iodine status in populations. From 1971 to 1974, the median UIC was 320 µg/L, but by 2005 to 2008, the median UIC level had fallen to 164 µg/L. National survey data also suggest that among women of childbearing age, the median UIC decreased from 294 µg/L to 128 µg/L, and the most recent National Health and Nutrition Examination Survey (2003–2004) reported that 37.2% of women of childbearing age had UIC values below 100 µg/L, which suggests mild iodine deficiency.

**Does mild iodine deficiency matter?**

Severe maternal iodine depletion causes severe fetal hypothyroidism, which impairs myelination of the central nervous system, causing developmental delays and—at the extreme—cretinism. Maternal sequelae include infertility, spontaneous abortion, stillbirth, preterm birth, and preeclampsia. There is no contro-
versy concerning the importance of identifying and managing severe iodine deficiency to prevent these complications. But the evidence is less clear regarding whether or not mild-to-moderate iodine deficiency in pregnancy is harmful. There does appear to be some evidence for developmental concerns with milder forms of iodine deficiency and uncontrolled trials have noted modest benefits of maternal supplementation on childhood neurologic development.\textsuperscript{5,10} However, available randomized trials of iodine supplementation have yielded discordant results and none has been designed to demonstrate improved neurodevelopment in the offspring. There are, however, at least 2 ongoing trials seeking to assess such neurodevelopmental outcomes.\textsuperscript{11}

Prenatal vitamin supplementation would seem to be a simple expedient to eliminate any such risk. It would also be a reasonable alternative to pregnant women dramatically increasing their intake of iodized table salt or seafood! Unfortunately, only 28% (27 of 96) prescription prenatal vitamins tested by Leung, et al contained any iodine, and what is listed on the label may not reflect bioavailable iodine, especially when derived from seaweed sources rather than from potassium iodide.\textsuperscript{2}

**Take-home message**

For every public health action there is a reaction—usually in the form of unintended consequences. Pregnant women are now told not to consume excess salt or eat too much seafood, and this has caused an increase in mild iodine deficiency. But what are the real consequences of such deficiency? We need randomized trials examining the benefits of iodine supplementation on neonatal and childhood neurodevelopment in mildly deficient pregnant women. In the interim, I agree with Stagnaro-Green and associates.\textsuperscript{12}

They call for professional organizations such as the American College of Obstetricians and Gynecologists to "work collaboratively with pharmaceutical and vitamin manufacturers to ensure that all prenatal multivitamins contain 150 µg of potassium iodide." They state that "in the interim, clinicians should recommend only those prenatal vitamins that contain iodine. The path seems clear. It is time for all prenatal vitamins to contain iodine."\textsuperscript{33}

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**Dr Lockwood,** editor in chief, is Dean of the College of Medicine and Vice President for Health Sciences at The Ohio State University, Columbus, Ohio.

**REFERENCES**


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Noninvasive testing for fetal chromosomal abnormalities has long been the "holy grail" in obstetrics. It now appears practical to achieve prenatal diagnosis using cell-free fetal DNA in maternal blood.

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8 Make single-embryo transfer standard policy at IVF clinics
7 Find causes of fibroids & identify ways to prevent them
6 Understand causes of endometriosis and find noninvasive biomarkers & better therapies
5 Give all women access to expert reproductive healthcare & contraception
4 Eliminate deaths due to cervical cancer worldwide
3 Find methods to predict risk of ovarian & endometrial cancers
2 Find effective ways to prevent preterm birth
1 Eliminate preventable deaths during childbirth worldwide

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ES186678_obgyn0213_007.pgs 01.29.2013 23:08 ADV
Experts recommend selective use of cystoscopy

Although many researchers have recommended cystoscopy as a universal screening tool to detect injury at the time of hysterectomy, new research recommends selective use of cystoscopy based on the low absolute risk of urinary tract injury.

A retrospective cohort study of 1982 patients at Brigham and Women’s Hospital in Boston, Massachusetts, who underwent a hysterectomy for any indication (excluding obstetric) between January 2009 and December 2010 was the basis for the researchers’ conclusions. The study appeared in the December 2012 issue of Obstetrics & Gynecology.

Two hundred fifty-one women (12.66%, 95% confidence interval [CI] 11.23–14.21%) underwent a cystoscopy at the time of hysterectomy with no reported complications resulting from cystoscopy. The procedure was most frequently used by low-volume surgeons and in cases involving prolapse or vaginal mode of access.

Fourteen patients (0.71%, 95% CI 0.39–1.19%) experienced bladder injury and 5 patients (0.25%, 95% CI 0.08–0.58%) sustained ureteral injury. None of these complications was detected by cystoscopy; cystoscopy was either normal at the time of hysterectomy or was omitted. The presence of adhesions was significantly associated with bladder injury at the time of hysterectomy ($P = .006$). Low-volume surgeon and laparoscopic or robotic mode of access were both significantly associated with ureteral injury ($P = .023$ and $P = .042$, respectively).

These data support selective rather than universal cystoscopy at the time of hysterectomy, stated the researchers. They also wrote “... in cases involving low-volume surgeons, significant pelvic pathology, or both, cystoscopy should be performed liberally. Surgeons should also be aware that a normal cystoscopy does not negate the possibility of urinary tract injury and maintain vigilance during the postoperative period.”

Binge drinking common among US teen girls

Sobering statistics from the Centers for Disease Control and Prevention (CDC) reveal that in 2011, 54.6% of high-school girls who consumed alcohol reported binge drinking. The prevalence was highest for high-school seniors: 61.7% of 12th-grade girls who used alcohol reported binging.
Pharmacology

mirabegron on the pharmacokinetics of co-administered drugs (e.g., ketoconazole,
Drug interaction studies were conducted to investigate the effect of co-
Urologic

worldwide postmarketing experience:

The following events have been reported in association with mirabegron use in
postmarketing experience, from a population of uncertain size, the frequency of
Because these spontaneously reported events are from the worldwide

Postmarketing Experience

Johnson syndrome with increased serum ALT, AST and bilirubin in a patient
In a separate clinical study in Japan, a single case was reported as Stevens-

In Study 4, in patients treated with Myrbetriq 50 mg once daily, adverse reactions

Cystitis 2.1 2.3
Arthralgia 2.1 2.0
Influenza 2.6 3.4
Sinusitis 2.7 1.5
Dizziness 2.7 2.6
Back Pain 2.8 1.6
Nasopharyngitis 3.9 3.1
Headache 4.1 2.5
Hypertension 9.2 9.6

90 mg CYP2D6

Digoxin

When given in combination, mirabegron increased mean digoxin C

Digoxin

AUC by approximately 9% when administered as a single dose of 25 mg after

Digoxin

Control once daily, respectively. Neoplasms reported by 2 patients treated with

Myrbetriq 50 mg, Myrbetriq 100 mg and active

(0.4%) and osteoarthritis (0.2%). Serum ALT/AST increased from baseline by

(0.5%), hypertension (0.5%), dry eyes (0.4%), nausea (0.4%), vision blurred

(0.5%) of patients treated with Myrbetriq 50 mg, Myrbetriq 100 mg and active

[see Clinical Pharmacology].

Warfarin

However, the effect of mirabegron on multiple doses of warfarin and on warfarin

[see Clinical Pharmacology].

Pediatric Use

The safety and effectiveness of Myrbetriq in pediatric patients have not been

Pending access to full information, decisions should be made whether to discontinue nursing or to discontinue the drug, taking into

Potential for serious adverse reactions in nursing infants, a decision should be

Nursing Mothers

Because Myrbetriq is predicted to be excreted in human milk and because of the

humans, its presence in human breast milk, or its effects on the breast-fed child.

have been conducted to assess the impact of Myrbetriq on milk production in

It is not known whether Myrbetriq is excreted in human milk. Mirabegron was

cardiomegaly were reported in rabbits.

fetal weights were observed in rats and rabbits, and fetal death, dilated aorta, and

recommended human dose (MRHD). At maternally toxic exposures decreased

exposures greater than or equal to 22 and 14 times, respectively, the maximal

Reversible adverse developmental findings consisting of delayed ossification and

Based on animal data, mirabegron is predicted to have a low probability of

pregnant during Myrbetriq treatment are encouraged to contact their physician.

There are no adequate and well-controlled studies using Myrbetriq in pregnant

Pregnancy Category C

No dose adjustment is necessary for the elderly. The pharmacokinetics of

Geriatric Use

The safety and effectiveness of Myrbetriq in the elderly were evaluated in two
different clinical trials. A total of 298 patients, 65 years of age or older, were

The pharmacokinetics of Myrbetriq were similar in young (18 to 65 years of age) and

elderly patients (65 years of age and older) in the two clinical trials. No

elderly patients (65 years of age and older) were evaluated by age group in the

elderly population. No dose adjustment is recommended based on age.

No dose adjustment is recommended when these drugs are co-

[see Warnings and Precautions]

[see Warnings and Precautions]

[see Warnings and Precautions]

[see Clinical Pharmacology]
In a study of 352 healthy subjects assessing the effect of multiple daily doses of Myrbetriq on blood pressure, the study showed that Myrbetriq also increased blood pressure in a dose-dependent manner. The maximum mean increase in supine SBP/DBP at the maximum recommended dose was approximately 2.5, 4.5, and 6.0 mmHg for 50 mg, 100 mg, and 200 mg, respectively. Morning DBP increased by at least 10 mmHg in 4.6%, 4.1%, and 6.6% of placebo, Myrbetriq 25 mg, and Myrbetriq 50 mg patients, respectively. Both SBP and DBP increases were reversible upon discontinuation of treatment.

In another study in 96 healthy subjects to assess the impact of age on pharmacokinetics of multiple daily doses of 50 mg, 100 mg, 200 mg, and 300 mg of Myrbetriq for 10 days, SBP also increased in a dose-dependent manner. The mean maximum increases in SBP were approximately 2.5, 4.5, and 6.0 mmHg for 50 mg, 100 mg, and 200 mg, respectively. Morning DBP increased by at least 10 mmHg in 4.6%, 4.1%, and 6.6% of placebo, Myrbetriq 25 mg, and Myrbetriq 50 mg patients, respectively. Both SBP and DBP increases were reversible upon discontinuation of treatment.

In a study with demonstrated ability to detect small changes in QTc, the change from baseline in mean pulse rate for the 50 mg, 100 mg, and 200 mg dose groups compared to placebo were 0.8 bpm, 1.5 bpm, and 2.0 bpm, respectively. In this thorough QT study, Myrbetriq increased heart rate on ECG in a dose-dependent manner. Maximum mean increases from baseline in heart rate for the 50 mg, 100 mg, and 200 mg dose groups compared to placebo were 13.4 bpm, 10.4 bpm, and 9.8 bpm, respectively.

Gender differences were observed in the QTc interval at 4-5 hours post-dose. The mean difference from placebo on QTcI interval was evaluated in a randomized, placebo- and active-controlled study. The largest placebo adjusted, baseline-corrected QTc based on individual correction factors was 6.1 msec (upper bound of the 95% CI 5.1 msec) for males and 8.1 msec (upper bound of the 95% CI 9.8 msec) for females.

The effect of multiple doses of Myrbetriq 50 mg, 100 mg and 200 mg once daily on QTc interval was evaluated in a randomized, placebo- and active-controlled study. The mean difference from placebo on QTcI interval was 3.7 msec (upper bound of the 95% CI 5.1 msec) for males and 7.6 msec (upper bound of the 95% CI 13.4 msec) for females.

Cardiac Electrophysiology

7.1.2.1.1.2 Cardiac Electrophysiology

Pharmacodynamics

Urodynamics

Nonclinical Toxicology

Mutagenesis

Human systemic exposure at the 50 mg dose was estimated to be 38 to 45-fold higher in rats and 21 to 38-fold higher in mice than the anticipated maximum blood levels at 50 mg. Mirabegron was not mutagenic in the Ames bacterial reverse mutation assay, did not induce chromosome aberrations in vitro, did not induce sister chromatid exchanges in CHO cells, and did not induce chromosomal aberrations in vivo. Mirabegron showed no carcinogenic potential at systemic exposures of 4.8-6.0 mg/kg bw/day in male rats, 1.5-2.0 mg/kg bw/day in female rats, and 0.3-0.5 mg/kg bw/day in male and female mice. The systemic exposure in female rats was estimated to be 11 times the MRHD in men, and the systemic exposure in female mice was estimated to be 22 times the MRHD in men.
The CDC analyzed data from the 2011 Behavioral Risk Factor Surveillance System to describe the prevalence, frequency, and intensity of binge drinking (4 or more drinks on an occasion in the last 30 days) among US women aged ≥18 years. Data were also analyzed from the 2011 national Youth Risk Behavior Survey on the prevalence of current alcohol use (1 or more drinks during the past 30 days) and binge drinking (5 or more drinks in a row during the past 30 days) among US high school girls in grades 9-12.

Binge drinking was most prevalent among women aged 18 to 24 years (24.2%) and 25 to 34 years (19.9%), and among those from households with annual incomes ≥$75,000 (16.0%).

Women metabolize alcohol differently and reach higher blood alcohol levels compared with men when consuming the same amount of alcohol, even after accounting for body size, food consumption, and other factors, the report notes. Binge drinking increases a woman’s risk of unintended pregnancy and adverse outcomes such as miscarriage or birth defects, as well as of acquiring HIV, sexually transmitted infections, heart disease, and breast cancer, the researchers caution.

Underage girls are “overexposed” to the marketing of flavored alcoholic beverages, the researchers say, increasing the risk that girls will begin drinking alcohol at a young age and consume more alcohol when they drink.

Binge drinking accounted for more than half of the estimated 23,000 deaths and 633,000 years of potential life lost among women and girls in the United States from 2001 to 2005 that were attributed to excessive alcohol consumption.


The LNG-IUS group had significantly greater improvements in 7 of 8 QOL domains.

LNG-IUS better than medical therapy for menorrhagia

A randomized UK study of menorrhagia shows that the levonorgestrel intrauterine system (LNG-IUS) is more effective than standard medical treatment in reducing the adverse effect of the menstrual problem on women’s quality of life.

The multicenter ECLIPSE (Effectiveness and Cost-Effectiveness of Levonorgestrel-Containing Intrauterine System in Primary Care against Standard Treatment for Menorrhagia) trial enrolled 571 women aged 25 to 50 years. All the participants presented to primary care physicians with complaints of menorrhagia during at least 3 consecutive menstrual cycles. Randomization was to the LNG-IUS or standard therapy for menorrhagia (tranexamic acid, mefenamic acid, combined estrogen-progestogen, or progesterone alone).

The goal of the research was to assess, over a 2-year period, patient-reported scores on the Menorrhagia Multi-Attribute Scale (MMAS), which measures the effect of menorrhagia on practical difficulties, social life, psychological health, physical health, work and daily routine, and family life and relationships. MMAS scores were assessed at 6, 12, and 24 months on a scale from 0 (severely affected) to 100 (not affected). The study had 90% power (P <0.05) to detect 0.3 SD differences in primary outcome at any given time.

From baseline to 6 months, MMAS scores in both groups improved, with mean increase of 32.7 points in the LNG-IUS group versus 21.4 in the usual-treatment group. The trend continued at 12 and 24 months, with more significant increases in the LNG-IUS group than the usual-treatment group (mean between-group difference, 13.4 points; 95% CI, 9.9 to 16.9; P <0.001). The LNG-IUS group had significantly greater improvements in all MMAS domains and in 7 of 8 quality-of-life domains. More women in the LNG-IUS group than in the group receiving usual treatment also were continuing their therapy at 2 years (64% vs 38%, P <0.001). No significant differences between groups were reported for rates of surgical intervention, sexual-activity scores, or serious adverse events.

The strengths of the trial, according to the researchers, included its large size, multicenter design, relatively low rates of loss to follow-up, 2-year assessment period, and focus on burden of menorrhagia.
More money spent on breast Ca screening may not lead to better outcomes

Medicare spending on breast cancer screening exceeds $1 billion annually in the fee-for-service program, according to a recent study. Despite this, the researchers who conducted the study concluded that it is unclear whether higher screening expenditures are achieving better breast cancer outcomes.

The goal of the study, which appeared in the January 2013 issue of JAMA Internal Medicine, was to determine whether regional-level screening expenditures are associated with cancer stage at diagnosis or treatment costs, particularly because newer breast cancer screening technologies, like digital mammography and computer-aided detection (CAD), are now commonly used in the care of older women.

The researchers used the linked Surveillance, Epidemiology, and End Results–Medicare database to identify 137,274 women aged 66 to 100 years who had not had breast cancer and assessed the costs to fee-for-service Medicare of breast cancer screening and workup during 2006 to 2007. For women who developed cancer, the researchers calculated initial treatment costs. They then assessed screening-related costs at the hospital referral region (HRR) level and evaluated the association between regional expenditures and workup test utilization, cancer incidence, and treatment costs.

The researchers found that in the United States, the annual costs to fee-for-service Medicare for breast cancer screening-related procedures (comprising screening plus workup) and treatment expenditures were $1.08 billion and $1.36 billion, respectively. For women 75 years or older, annual screening-related expenditures exceeded $410 million.

In a commentary that accompanied the article, Jeanne S. Mandelblatt, MD, MPH; Anna N.A. Tosteson, ScD; and Nicolien T van Ravesteyn, MSc, cautioned that the study “focused on the period early in the adoption of digital screening (2006-2007), when costs related to false-positive readings may be highest because of the learning curve in reading the images.”

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Ruptured uterus results in lengthy malpractice case

A TENNESSEE WOMAN became pregnant in the summer of 1999 and received prenatal care from an obstetrician. She went into labor at term and was admitted to a hospital. At 1:30 PM, sudden fetal heart rate (FHR) decelerations were noted and the physician began an emergency cesarean delivery. The infant was delivered at 1:58 PM, and a ruptured uterus was diagnosed. The infant sustained an ischemic insult and profound brain injury.

A lawsuit was filed, claiming that there was a delay in delivering the infant and alleging that if the delivery had occurred even minutes earlier, the injuries would have been mild. The patient contended that the hospital nurses delayed calling the obstetrician for 15 minutes to report the FHR deceleration and that the physician should have delivered the baby sooner.

The hospital claimed that the obstetrician was notified as soon as the FHR tracing was concerning and that the delivery occurred within 30 minutes from decision to incision, although they faulted the doctor for any delay.

The obstetrician settled with the patient before trial and the hospital received a defense verdict in 2007.

Legal Perspective

After the 2007 trial, the patient filed a motion for a new trial, which was granted. The new trial was held in 2009 and ended in a directed verdict against the doctor. The jury was then asked to assign the amount of liability and found the physician to be 96.25% liable and the hospital to be 3.75% at fault. The award to the patient was for $4,528,454, which was reduced to $164,273.

The patient again moved for a new trial, citing error in directing a verdict against the physician and claiming that during deliberations, a juror had contacted her nurse mother regarding issues in the case and alleging that a quotient verdict had been reached. (A quotient verdict is an award based on each juror’s written opinion of what the amount should be. These amounts are totaled and then divided by the number of jurors. This is improper and grounds for setting aside the judgment.) Nevertheless, this new trial motion was denied, and the plaintiff appealed. An appellate court reversed both the denial—after finding several juror affidavits provided evidence of a quotient verdict—and the directed verdict against the obstetrician. A third trial was then held, and this jury found fault at 60% to the doctor and the remainder to the hospital. The award was for $13,623,000, which was reduced to $7,974,505 after allocation of fault. A posttrial motion by the hospital was still pending at time of publication.

Failure to promptly diagnose placental abruption

A PREGNANT MISSISSIPPI WOMAN went to a hospital emergency department at 26 weeks’ gestation with a complaint of abdominal pain. An obstetrician examined her at 4 AM, diagnosed premature labor, and arranged for transfer to a facility with a higher level of care. The patient was transferred at 6:48 AM, and a placental abruption was suspected on arrival. A cesarean delivery was performed 28 minutes after her arrival. The infant suffered profound brain damage.
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Changing expectations
The woman sued the first obstetrician who saw her in the emergency department, alleging negligence in failing to diagnose the placental abruption promptly and to immediately deliver the infant.

The physician claimed that the patient's presentation was initially consistent with preterm labor and that stabilization before transfer was appropriate. He also claimed that even with an earlier delivery, the outcome would have been poor, because the injuries were related to the prematurity, not the abruption. He also suggested that the child would not have survived if delivery had taken place at the first hospital. A defense verdict was returned.

Failure to timely diagnose uterine cancer

A MASSACHUSETTS WOMAN in her 50s went to a gynecologist in 2004 with complaints of vaginal spotting. She returned to the doctor’s office several months later complaining of daily bleeding. An ultrasound (U/S) showed a 4-cm mass in the endometrial cavity that was consistent with a large polyp. A hysteroscopy was performed by the gynecologist 2 months later, and a biopsy revealed that the assumed polyp was actually uterine cancer. The patient underwent a hysterectomy and radiation therapy, but metastases were found in her lungs 8 months later, and she died 10 months after that.

A lawsuit was filed by her estate, claiming that the physician was negligent in failing to diagnose the uterine cancer in a timely manner.

The gynecologist claimed that the cancer was aggressive and that earlier diagnosis would not have changed the outcome. An $820,000 settlement was reached.

Claim of brachial plexus injury caused by excessive force during delivery

A MISSISSIPPI WOMAN who was pregnant in 2001 was cared for by her obstetrician. An U/S in the fifth month of pregnancy showed that the fetus measured slightly large for gestational age. The infant was born at term, and the delivery required use of the McRoberts maneuver. The infant suffered a brachial plexus injury. Her left arm is shorter than the right, she cannot make a fist, and her fingers are not fully developed. She has scars from operative attempts to repair the injury.

The mother sued the delivering obstetrician, alleging use of excessive force during delivery and maintaining that she had symptoms of gestational diabetes, and therefore, a planned cesarean delivery should have been performed.

The physician maintained that the fetus was not large enough to be considered macrosomic and that the McRoberts maneuver was properly used without excessive force. A defense verdict was returned.

Uterine perforation and iliac artery injury during D&C

A 47-YEAR-OLD WISCONSIN WOMAN underwent a dilation and curettage (D&C) performed by her gynecologist at a hospital. She subsequently sued the physician, claiming that her uterus was perforated, her iliac artery was punctured, and the artery injury caused her to suffer a heart attack. She argued that the doctor had failed to open the cervix with the appropriate dilators to gain access to the cervical and endometrial cavity and then failed to use the proper instrumentation in the uterus. She also maintained that the doctor had failed to correctly assess the shape of the uterus. She maintained that she suffered cognitive and emotional damages and that she would require surgery in the future. A $350,000 settlement was reached.

Failure to provide adequate fetal monitoring during labor

A PREGNANT WOMAN at 32 and 4/7 weeks’ gestation was admitted to a Massachusetts hospital with preterm premature rupture of membranes (PPROM). She was managed for 10 days with a plan to induce labor at 34 weeks. She began to have cramping and contractions on the morning of the scheduled induction. FHR monitoring showed a normal tracing, and the patient had no fever. The fetus was noted to be a compound presentation, with the chin presenting first. The patient progressed to 6-cm dilation by 1 pm. The FHR began to show some recurrent mild variable decelerations that became increasingly deeper. The patient later claimed that the technical quality of the external FHR tracing was poor, but no internal monitor was placed, and that the interpretable tracing showed severe variable decelerations.

At 4 pm the patient was fully dilated, the baby’s head was at +1 to +2 station, and the patient began push-
Endometrial Ablation: The Facts
A Whitepaper

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Endometrial Ablation: The Facts

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Introduction

Nonresectoscopic endometrial ablation has become an increasingly popular treatment for selected patients suffering from heavy menstrual bleeding (HMB) since it is minimally invasive and, if successful, avoids both hysterectomy and the chronic use of medical therapy. In the United States, five endometrial ablation devices have been approved: four utilizing techniques that increase the temperature of tissue (NovaSure, ThermaChoice, Hydro ThermAblator, Microwave Endometrial Ablation) and one that uses hypothermic technology (Her Option).

Although endometrial ablation has been available for a number of years, questions remain that may influence technique selection based on patient characteristics and procedure location. Continued interest in these issues was illustrated by recent discussion in the literature concerning postablation synechiae or adhesions in the endometrial cavity.¹ ² ³ The purpose of this paper is to further explore the fundamental differences between the two approaches to endometrial ablation (hyperthermic and hypothermic) with respect to patient outcomes, including postprocedure cavity integrity, procedural tolerability, and the successful resolution of the symptom of HMB.

Tissue effects: heat versus cold

Hyperthermia is a common method used to achieve destruction of the endometrium to the level of the basal layer, thereby effecting a decrease in or elimination of menstrual flow. After heat-based ablation, the endometrium undergoes necrosis with variable degrees of acute inflammation that can last up to three months. “This is followed by a chronic repair and regeneration phase with foreign body and granulomatous reaction, which in most cases results in striking endometrial scarring.”⁴ This phenomenon is illustrated in the following four studies:

% Colgan et al evaluated 19 women after heat-based (rollerball) endometrial ablation for the symptom of HMB. The 6 specimens that were examined at less than three months postprocedure exhibited necrotic myometrium and a “florid” foreign-body reaction. Specimens obtained after three months were found to contain granulomatous and foreign-body reactions as well as “striking endometrial scarring” in the majority of cases.⁵

% Davis et al examined 207 women after electrothermal ablation and noted “necrosis dominated the first month, and a chronic repair-regeneration
phase followed. Foreign-body giant cells reacted with necrotic eschar, remnants of which were present to 47 months.8

Luo et al evaluated 53 women following microwave ablation. One year after ablation, hysteroscopy revealed a fibrotic cavity with myofibrinous scars. Two years or more following ablation, a second hysteroscopy demonstrated the presence of intrauterine adhesions in over 50% of patients.8

In contrast, cryoablation is an ablative technique designed to freeze the tissue, resulting in hypothermic stress and cellular death. Ice crystals form in the extracellular space and sequester free water, which increases the toxicity of extracellular space. Osmotic tension draws free intracellular water from cells, dehydrating them. Additionally, if cooling is rapid, free water is trapped within cells during the freezing process and results in intracellular ice crystal formation, a harbinger of immediate cell death. Resultant tissue effects have been studied within gynecologic applications:

Bruno et al reported on a cohort of 75 women who underwent cryoablation of the endometrium for treatment of the symptom of HMB (menorrhagia). Hysteroscopy was subsequently performed 3 to 12 months postprocedure. In all cases after cryoablation, minimal scarring of the endometrial cavity was noted, and in the majority of cases the ostia of the fallopian tubes remained visible. The authors concluded that cryoablation of the endometrium maintains the contour and depth of the endometrial cavity with minimal scarring or intrauterine synechiae.9

In a pilot study performed by Goldstein,1 four of five patients treated with the Her Option cryoablation device had a shortened but normal uterine cavity with one patient having a thickened band of tissue.

In addition to gynecologic application, multiple specialties utilize cryoablation to destroy targeted tissue because of the uniform reduction in scar tissue. By example:

Kaufman et al utilized cryotherapy for the treatment of breast fibroadenomas. Thirty-seven fibroadenomas were treated, with 99% of patients satisfied with the results; the authors noted that the treatment incurred minimal discomfort and little to no scarring.10

Har-Shai et al evaluated cryotherapy for treatment of keloids. Histomorphometric examination of keloids after intralesional cryotherapy treatment revealed a significant tendency toward normalization of the collagen structure as well as the presence of normal young collagen fibers. The authors postulated that cryotherapy might inhibit keloid recurrence by reducing infiltration of activated fibroblasts toward the affected areas.11

With regard to the endometrium, Ahonkallio et al investigated the ability to evaluate the uterine cavity after heat-based endometrial ablation. Results revealed endometrial sampling failed in 23% of patients because “there was no access to the uterine cavity.” Even in the patients with successful biopsy, 63% of
the time “it was either difficult or painful.” Importantly, endometrial thickness on sonography was non-predictive of biopsy failure, implying failure was not due to atrophy or postablative elimination of the endometrium. Sonohysterography faced the same challenge in these patients, with only 16% of the cavities distending normally.12

As Drs. Lukes and Evantash3 correctly note, endometrial ablation does not appear to increase the risk of endometrial carcinoma and proper patient selection is vital to identify patients with risk factors for neoplasia. The main risk factor for endometrioid endometrial carcinoma is an excess of endogenous or exogenous estrogen without adequate opposition by a progestin — other and potentially related risk factors include Tamoxifen therapy, nulliparity, diabetes mellitus, and hypertension. Since women in the United States have a 2.6% lifetime risk of developing uterine (generally endometrial) cancer at an average age of 6113 and a number of these risk factors may not become apparent until after the decision to perform an endometrial ablation, consideration of using a device that has the best chance of maintaining cavity integrity is reasonable. Based on the biologic response of tissue to hyper-and hypo-thermic injury, as well as the small case series of Dr. Goldstein and data collected by Bruno et al, it is within reason that cryoablation is the most likely of the endometrial ablation technologies to allow uninhibited access to uterine cavity postprocedure.

**Efficacy of endometrial ablation**

Since all endometrial ablation devices are designed with the primary purpose of reducing menstrual flow, it seems obvious that procedure efficacy is of paramount importance. It is interesting to note that Drs. Lukes and Evantash imply that success in treating the symptom of HMB is directly correlated with scarring. While this Asherman-like phenomenon appears to correlate well with hyperthermic devices, it is the destruction of the regenerative basal endometrial cell that ultimately provides bleeding reduction with cryoablation. It should be also noted that extensive scarring following hyperthermic ablation does not ensure destruction of endometrial cells. Hence, Fadare et al reported that following hyperthermic ablation and despite deep tissue damage and formation of a “hyalinized, subendometrial band-like zone” that was apparent throughout the uterus, scattered aggregates of stromal cells in the endometrium remained relatively viable.14

In evaluating device performance, clinicians must also screen for population bias when examining reports on postablation amenorrhea rates. By example, the 2010 study of Penninx et al15 compared outcomes of radiofrequency endometrial ablation with hydrothermablaltion for HMB reporting one-year amenorrhea rates of 47% and 24%, respectively. Careful review shows that patients who underwent subsequent hysterectomy (5% and 11%, respectively) were included as meeting the endpoint of amenorrhea. While these patients clearly had amenorrhea, it is unlikely they would consider the endometrial ablation procedure a success. In a subsequently published study, the same group also examined outcomes at five years postprocedure.16 The results from this analysis did remove patients who underwent a hysterectomy from the amenorrhea-success category; however, they did not correct for the 20% increase in amenorrhea rates based purely on the aging of the study population (both groups had an average age of >49 years at study conclusion). By comparison, the “intent to treat” analysis done for FDA approval of these two devices illustrates a
failure to achieve amenorrhea in 64% of NovaSure patients and 65% of the Hydro ThermAblator devices.17

As espoused by the American College of Obstetricians and Gynecologists, the goal of endometrial ablation is to restore menses to normal or less.18 All of the currently available endometrial ablation devices have met this FDA threshold in randomized control comparison with monopolar resectoscopic ablation techniques, usually with a rollerball coagulating electrode. For example, at 24 months 94% of evaluable patients treated with the Her Option cryoablation device were free of abnormal uterine bleeding and 91% were very or extremely satisfied with treatment results.19 Outcome remained durable, with 91% of the 108 patients followed for three years after the Her Option cryoablation procedure reporting satisfaction in treatment of heavy menstrual bleeding.20 Further, in a review of 1,169 women who underwent various types of endometrial ablations, Shavell et al noted that the rate of subsequent hysterectomy was significantly associated with the type of ablation performed: 33.0% for rollerball vs 16.5% for thermal balloon (p = .003), 11.0% for radiofrequency (p < .001), and 9.8% for cryoablation (p < .001).21

Pain control in an office setting

Although each device is efficacious in treating selected patients with the symptom of HMB, unique characteristics may lead a practitioner to choose a certain technology based on an individual patient’s situation or the proposed procedure setting. One such difference is the perception of pain during and after an endometrial ablation procedure. Individual steps that may cause pain during such procedures include cervical dilation, uterine distention, and activation of the hyperthermic or hypothermic technique.

In a randomized controlled study performed by Clark et al, bipolar radiofrequency ablation (RFA — NovaSure) was compared to thermal balloon ablation (TBA — Thermal Balloon Ablation). Preprocedure opioids were used in conjunction with “vocal local” to facilitate ablation completion in this office-based study. Pain was measured using Visual Analogue Scores (VAS) both during the procedure (RFA-7.7 +/- 2; TBA 6.5 +/- 2.9) and one hour postprocedure (RFA-5.1 +/- 3.1 and TBA 6.7 +/- 3.1). “Just more than one-third of women would have preferred general anesthesia with hindsight.”22 Similar results have also been reported, with the Hydro ThermAblator device with patients reporting a pain visual analogue score of 6.4.23

In contrast, the Her Option endometrial cryoablation system was evaluated in 82 subjects for pain tolerance in an operating room (17 patients) and office setting (65 patients). Office procedures did not provide any IV sedation and protocols were considered “minimal anesthesia” per the providers. Results revealed that pain scores were not statistically different between the office-based procedures (VAS 1.1) as compared with the surgical center (VAS 1.0). As part of the conclusion, the authors noted: “Some degree of cryoanalgesia caused by low temperatures used during the procedure may contribute to Her Option tolerability.”24 In another review, Erinjeri and Clark noted “because the cooling of tissues and nerves provides an anesthetic effect, cryoablation tends to be less painful than the heat-based thermal ablation techniques like microwave or radiofrequency ablation.”25 This phenomenon also appears to be consistent with the gynecologic endometrial ablation literature.
Conclusion

It is clear that endometrial ablation devices represent a valuable group of technologies for treating selected women with the symptom of HMB. Currently there are five technologies approved by the FDA in the United States. Only the Her Option system utilizes cryoablation, with all others relying on hyperthermic destruction of the endometrium. Biologic plausibility indicates that cryoablation is less likely to stimulate the process of scar formation when compared with hyperthermic ablation. Based on current clinical evidence, it also appears likely that cavity integrity is best maintained with hyperthermic technology. Although uterine cancer is rare after endometrial ablation, should unexpected bleeding occur, necessitating subsequent evaluations such as endometrial biopsy or sonohysterography, heating technologies result in significant challenges in accessing the uterine cavity. All of the technologies produce excellent reduction in the volume of menstrual flow and high degrees of patient satisfaction. Clinicians must be aware of bias inherent in published studies, especially if they illustrate significantly higher rates of amenorrhea compared with the FDA pivotal approval trial outcomes. Each technology does have unique characteristics that may influence use with a particular group of patients or procedure setting. Although no direct comparison studies exist, based on cryoanalgesic properties resulting in very low VAS scores, the Her Option cryoablation device appears to be an excellent alternative for patients requesting an office-based procedure with minimal analgesia/anesthesia.

Disclosures

Dr. Duleba and Dr. Whiteside are consultants for CooperSurgical, Inc. Dr. Auerbach is employed by CooperSurgical, Inc.

1 Goldstein SR. It takes a big man to admit he’s wrong. Contemp OB/GYN. April 2012;51-52.
11 Har-Shai Y, et al. Intralesional cryosurgery for the treatment of hypertrophic scars and keloids following aesthetic surgery: the


ing. The interpretable part of the FHR showed minimal variability with significant decelerations and tachycardia at 190 bpm. The residents and nurses noted the FHR, but the attending physician was not present until the last half hour of labor. Meconium was noted, and the infant was delivered at 6:47 pm. The Apgar scores were 1 at 1 minute, 5 at 5 minutes, and 7 at 10 minutes, and the arterial cord pH was 6.85. An initial head U/S was normal, but subsequent magnetic resonance imaging showed subdural and intraventricular hemorrhage and evolving profound hypoxic ischemic injury. At just over 1 year of age the child had a seizure disorder, cortical blindness, and severe developmental delays.

After this delivery the patient’s attorney contacted the hospital and alleged negligence in the failure to respond to the FHR abnormalities, failure to insert an internal lead to obtain a better tracing, and failure to expedite delivery in the face of significant and worsening FHR abnormalities.

The hospital’s insurance carrier began settlement discussions when the infant was about 8 months old, which resulted in a $4.2 million settlement before filing a lawsuit.

**Complications after cystocele-rectocele repair**

A 51-YEAR-OLD VIRGINIA WOMAN went to her gynecologist after noticing a bulging in her vagina. The doctor diagnosed a cystocele and rectocele. An anterior and posterior colporrhaphy repair using tension-free vaginal tape obturator (TVT-O) was recommended. The physician stated that a urologist would be on hand during the procedure because a bladder lift was involved. The surgery was performed in 2008. The patient awoke after the procedure in excruciating pain and was told that she had lost a lot of blood and that “sometimes you can do everything right but things can still go wrong.” At the first postoperative visit the doctor told her that the stitches had not yet been absorbed and were causing an abrasion and that she would need to use a lot of lubricant for sexual intercourse because more vaginal tissue was cut than had been planned.

About 2 weeks later the patient could not see a vaginal opening because of severe stenosis. She continued to have severe groin pain and muscle spasms, and the physician found that the TVT-O was creating a ridge of tissue in the anterior portion of the vagina. Dilators were required to expand the vagina, and it was determined that there was entrapment of the dorsal clitoral nerve from the TVT-O. The woman continued to have dyspareunia and pain in her groin from nerve entrapment.

The patient sued the gynecologist, claiming that he failed to inform her that 2 months earlier the FDA had issued a public health notification regarding complications associated with transvaginal placement of surgical mesh during repair of prolapse and urinary incontinence. She also claimed that she was not informed that the doctor had just completed training in TVT-O surgery, was not fully credentialed to perform the procedure, and was being proctored on the procedure. A $390,000 settlement was reached.

**CP following failure to prevent premature delivery after PPROM**

IN 1995 A NEW YORK WOMAN who was pregnant with twins was admitted to the hospital with PPROM at 25 weeks’ gestation. Eight days later she reported pain. Although medication was administered for several hours, it was determined that she was in labor, which was allowed to progress and resulted in a vaginal delivery. One child was subsequently diagnosed with cerebral palsy (CP) and requires assistance with many daily activities, although her cognitive function is not impaired.

The woman sued those involved with the management of the pregnancy and claimed that the CP was caused by a failure to prevent the child’s premature delivery. She alleged negligence in the failure to recognize that she was in labor. She argued that timely recognition of contractions would have allowed for administration of a drug that would have delayed delivery. She maintained that contractions had been successfully stopped twice before. The patient also claimed that the infant suffered trauma during passage through the vagina that could have been prevented by an episiotomy or a cesarean delivery.

The physicians denied any negligence, and the hospital contended that monitors did not suggest any contractions initially. The jury found fault only as to the hospital, with the physicians being found not liable, and awarded $103,075,617.82 to the child.
Are hormones the answer to low libido?
Individualizing hormone therapy for low libido in midlife women

More than half of postmenopausal women report low sexual desire. Hormonal and nonhormonal treatments vary in efficacy and continued studies are needed.

BY LISA GROSSMAN, MD, AND MARY LAKE POLAN, MD, PHD, MPH

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Up to 43% of women report having sexual dysfunction, with decreased desire being the most common complaint.1 Although the incidence varies among the studies, low sexual desire is reported by more than half of postmenopausal women compared with one-quarter of premenopausal women.2 Hypoactive sexual desire disorder (HSDD) is defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) as a lack of desire that is persistent and leads to personal or interpersonal distress. Sexual dysfunction is multifactorial, including a variety of psychosocial components; however, this discussion will be about treatment options for low libido, focusing primarily on postmenopausal women.

TAKE-HOME MESSAGES

❯ Use testosterone therapy with caution and consider other options as well.
❯ Studies showing an impressive placebo effect point to a need for further research on low libido.

Physiology of libido
The ovaries and adrenal glands produce about 50% of circulating testosterone, whereas the other 50% comes from peripheral conversion of precursor steroids from the ovaries and adrenals. Most circulating testosterone is bound to sex hormone-binding globulin
(SHBG) and albumin, which leaves only 1% to 2% as active free testosterone.

Testosterone production is lower in menopause and can lead to decreased libido. In surgically menopausal patients, the ovarian androgen component as well as estrogen production is lost, which can affect sexual function in areas such as libido and vaginal dryness. Administering oral estrogen may be counterproductive because SHBG is increased and will further decrease the available testosterone.

**Testosterone**

A 2005 position statement from the North American Menopause Society, based on a thorough review of the literature on the use of testosterone therapy in postmenopausal women, concluded that testosterone therapy (preferably administered via transdermal or gel/cream) is an option for postmenopausal women with decreased sexual desire (Table 1). At the time of the position statement, testosterone therapy was not recommended without concomitant estrogen therapy, given a lack of evidence.

Since then, results of the APHRODITE study (A Phase 3 Research Study of Female Sexual Dysfunction in Women on Testosterone Patch Without Estrogen), which included 814 postmenopausal women with HSDD, were published and reported that treatment with a patch delivering 300 µg of testosterone per day led to a modest but meaningful improvement in sexual dysfunction without the addition of estrogen replacement.

Current options for testosterone treatment include a patch, cream, and oral therapies; transdermal methods are preferred because there is no first-pass effect. Additionally, unwanted androgen adverse effects and a negative effect on lipids may be reduced with transdermal application, although unwanted hair growth remains an issue.

There is specific dosing for each type of transdermal testosterone product (Table 2). These products are used off-label in women, and the recommended dose and use for men are inappropriate and dosage must be decreased for women. Some products (ie, the Intrinsa patch) are currently not available in the United States. For other products, the specific formulation must be compounded by a specialist pharmacy. Because these products and doses can vary, physicians and patients should talk directly to the pharmacist. These products often are not covered by insurance because they are being used off-label.

Despite studies showing a significant benefit of testosterone therapies in treating low libido and increasing sexual satisfaction, the US Food and Drug Administration (FDA) has not approved such regimens because of concerns about their safety. Some studies have shown a slightly increased risk of breast cancer in women using testosterone therapy. Additionally, concerns about its effect on cardiovascular health remain. Positive effects of testosterone treatment can include increased muscle mass, bone retention, and increased overall well-being.

**Other androgens**

The androgen dehydroepiandrosterone (DHEA; prasterone) has been used in the treatment of sexual dysfunction. Studies have shown no signifi-

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**TABLE 1**

Role of testosterone therapy in postmenopausal women

- Postmenopausal women with decreased desire associated with personal distress with no other identified cause may be candidates for testosterone therapy.
- Laboratory testing of testosterone should be used only to monitor for supraphysiologic levels, not to diagnose insufficiency.
- Transdermal patches and topical creams/gels are preferred to oral formulations because there is no first-pass effect.
- Custom-compounded products should be used with caution because dosing may be inconsistent.
- Testosterone products for men should be used with caution and in lower doses to avoid excessive dosing.
- Testosterone therapy is contraindicated in women with breast cancer, uterine cancer, cardiovascular disease, and liver disease.
- Counseling regarding risks and benefits must be done before initiating treatment.

Adapted from North American Menopause Society recommendations.

**TABLE 2**

Testosterone treatments

<table>
<thead>
<tr>
<th>Patch</th>
<th>Change q 3-4 d</th>
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<tbody>
<tr>
<td>Intrinsa (300 µg)</td>
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<table>
<thead>
<tr>
<th>Cream</th>
<th>1 fingertip-sized dab/d, rub into thigh/shoulder</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Gel</th>
<th>1 fingertip-sized dab/d, rub into thigh/shoulder</th>
</tr>
</thead>
</table>

- Androgein 1.62%
- Testim 1%

Source: Product manufacturer websites. Specific doses and instructions should be verified for the product a patient is using.
Hormones for low libido

Despite studies showing a significant benefit of testosterone therapies... the FDA has not approved such regimens because of concerns about their safety.

Although estrogen may not directly affect libido, estrogen deficiency causes vaginal atrophy and dryness, with associated pain on intercourse that can lead to sexual dysfunction. Estrogen therapy (ET) is commonly accepted as the most effective treatment of moderate to severe vaginal and vulvar atrophy.³,⁴ Local therapy (oral, patch, vaginal ring) is preferred to systemic because of fewer adverse effects. Local therapy includes vaginal conjugated estrogen and estradiol in the forms of creams or tablets. Both therapies can be managed by the patient at the lowest dose possible while still providing comfort.³ There are various options for local estrogen therapy, with recommended long-term dosing (Table 3); the patient may use the product more frequently when first starting treatment. The addition of progesterone is not indicated if estrogen is only used locally; however, postmenopausal bleeding would warrant evaluation.

Synthetic hormones

Tibolone is a synthetic steroid with metabolites that have androgenic, estrogenic, and progestogenic effects. It decreases SHBG, leading to increased free testosterone and estradiol. In some well-designed trials comparing tibolone to estrogen/progestin therapy, tibolone was similar or superior in the treatment of sexual dysfunction.¹⁴,¹⁵ However, a recent Cochrane review concluded that tibolone was less effective than hormone replacement therapy but noted that it decreased the incidence of vaginal bleeding.¹⁶ There have not been trials directly comparing tibolone to testosterone. Tibolone is commonly used by postmenopausal women in Europe but is not approved or available in the United States because of concerns for risk of breast cancer and stroke.

Nonhormonal options

There are a variety of nonhormonal options available to treat low libido, although they vary in results and adverse effects. Bupropion has been shown to improve sexual function in both premenopausal nondepressed women with HSDD⁶ and those with selective serotonin reuptake inhibitor (SSRI)-associated sexual dysfunction.¹⁸ Flibanserin, which has central effects on serotonin, dopamine, and...
norepinephrine, has improved sexual function in premenopausal women with HSDD but was not approved by the FDA because of concerns about adverse effects. Apomorphine, a dopamine agonist, has shown positive effects on sexual function but has numerous adverse effects, limiting its long-term use. Studies with buspirone have shown conflicting outcomes. Phosphodiesterase inhibitors have not been successful in the general population of women; however, they could be helpful in certain subsets, such as those with diabetes and certain neurologic disorders, and to treat SSRI-associated sexual dysfunction.

Over-the-counter treatments

There are numerous over-the-counter (OTC) treatments for low libido, including topical therapies, that have some clinical data supporting their use. Zestra is a botanical cream that has been shown in trials to significantly increase desire and arousal in women with generalized sexual difficulties. ArginMax is a nutritional supplement shown to increase satisfaction with sex life, desire, and frequency of intercourse, and to reduce vaginal dryness.

Additionally, there are a plethora of herbal preparations that have marginal information on safety and efficacy. Women should be cautioned about the unknown safety, efficacy, and concentration of active ingredients in these supplements. For example, some with estrogenic components may be associated with the same risks as unopposed estrogen treatment. Patients should feel free to review the use of such products with their physicians. Beyond treatment for low libido, a wide variety of OTC lubricants and moisturizers for vaginal dryness are available at drugstore pharmacies.

Oral contraceptives and libido

Although more postmenopausal women report decreased sexual interest, a significant number of premenopausal women also complain of low libido. Thus, there has been a long debate about the effect of oral contraceptive pills (OCPs) on libido.

Physiologically, OCPs lead to an increase in SHBG and a decrease in ovarian androgen production. In theory, this decrease in free testosterone may lead to a lower libido. There have been numerous studies with varying results. Schaffir addresses the multifactorial nature of libido and suggests that one must look beyond solely the biologic effects of OCPs. For example, a patient may have increased libido on an OCP if she is less worried about an unwanted pregnancy.

In a retrospective study of 124 premenopausal women with sexual health complaints, SHBG levels in the “discontinued user” group did not decrease to the values of “never users.” Clearly, prospective studies are needed to determine whether prolonged use of OCPs leads to increased gene expression of SHBG and how this affects long-term libido.

Placebo effect

Beyond the various hormones, drugs, and supplements, just taking a medication may actually help libido. Studies have shown an impressive placebo effect that can approach 40%, mandating placebo-controlled studies to evaluate therapies for sexual dysfunction. In a review of data from 16 studies, it was noted that placebo recipients reported significant improvements on 1 or more major sexual dysfunction outcomes compared with baseline. Although the responses varied among the studies, the within-group effect sizes were often in the moderate range, thus making a case for the positive effect of the attention and care that accompanies the administration of the placebo.

Summary

Sexual dysfunction, including low libido, is a problem for many women, especially in the postmenopausal years. For women with HSDD, transdermal testosterone can be used with appropriate counseling. Other androgen therapy, including DHEA cream, can be considered. Vaginal estrogen may be used to decrease vaginal dryness and discomfort with intercourse, which can lead to increased sexual satisfaction. If a woman cannot or does not want to take hor-

TABLE 3 Local estrogen treatment

<table>
<thead>
<tr>
<th>Vaginal cream:</th>
<th>1 g used 2-3 times/wk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjugated estrogens (Premarin)</td>
<td></td>
</tr>
<tr>
<td>Estradiol (Estrace)</td>
<td></td>
</tr>
<tr>
<td>Vaginal tablet:</td>
<td>2 times/wk</td>
</tr>
<tr>
<td>Estradiol (Vagifem)</td>
<td></td>
</tr>
</tbody>
</table>

Source: Product manufacturer websites. Specific doses and instructions should be verified for the product a patient is using.
Hormones for Low Libido

In addition to the use of hormones, she should be careful about using herbal remedies for which the actual dose and absorption of the compounded product are unknown. However, OTC remedies are reasonable options if there are good, published clinical data on efficacy and safety. There are a variety of nonhormonal medications that may be helpful in certain subsets of women.

Continued studies are needed to identify further treatment of low libido. Additionally, sexual dysfunction can be caused by a variety of factors, so although medical treatment is important, counseling and further psychosocial evaluation may also be needed.

REFERENCES
Increased Visibility

Kii®
Advanced Fixation

SCAN for more information
appliedmedical.com/kii_visibility

or VISIT

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Preventing urinary tract injury at the time of hysterectomy
Four strategies for success

First know the anatomy and the risk factors, but don’t forget to screen for and recognize injury as well.

BY JANELLE K. MOULDER, MD, AND SARAH L. COHEN, MD, MPH

Hysterectomy remains the most common gynecologic procedure in the United States; approximately 600,000 hysterectomies are performed each year, the majority of which are for benign disease. Minimally invasive approaches to hysterectomy have well-documented advantages, yet abdominal hysterectomy remains the most common mode of access, accounting for more than 60% of all hysterectomies performed in the United States as of 2005.

Despite the frequency with which hysterectomy is performed, urinary tract injury is not uncommon given the intimate relationship between the genital and urinary tracts. The various approaches to hysterectomy are accompanied by differing rates of urinary tract injury, but the combined incidence of such events during procedures for benign disease is as high as 4.3% to 4.8%.

With regard to mode of hysterectomy, vaginal hysterectomy is reported to have a lower incidence of ureteral injury when compared with abdominal hysterectomy (0.9% vs 1.7%, although the differences did not reach statistical significance). Notably, the rate of ureteral injury did increase to 2.6% when vaginal hysterectomy was performed concomitant with pelvic floor reconstruction.

**TAKE-HOME MESSAGES**

- Increased proficiency with laparoscopic hysterectomy will lead to decreased rates of urinary tract injury.
- Strategies to minimize risk of injury apply to all operative approaches.

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Neither author has a conflict of interest to disclose with respect to the contents of this article.
More data have also become available on rates of urinary tract injury with laparoscopy as this approach has gained wider acceptance. In one of the first studies comparing incidence of ureteral injury in a Finnish cohort, incidence of injury was as high as 13.9 in 1000 for laparoscopic hysterectomy, versus 0.4 in 1000 for abdominal and 0.2 in 1000 for vaginal hysterectomies. However, in a follow-up study, incidence of ureteral injuries was 3.4 in 1000, a significant decrease that may be attributable to the learning curve associated with laparoscopic hysterectomy.

Recent data do support a higher rate of recognized ureteral injury during total laparoscopic hysterectomy compared with other methods, including laparoscopic supracervical hysterectomy.

In the same initial Finnish cohort, incidence of bladder injury was higher in the abdominal hysterectomy group than in the vaginal or supracervical hysterectomy groups (1.3 vs 0.2 and 0.3 in 1000), but incidence of injury was highest with the laparoscopic approach (8.9 in 1000). The follow-up to this initial study also demonstrated a higher incidence of bladder injury with laparoscopic hysterectomy (3.4 in 1000). Notably, no significant difference has been shown with regard to incidence of bladder injuries for total versus subtotal laparoscopic hysterectomy.

The eVALuate study was a 2-part, randomized controlled trial that examined outcomes with laparoscopic hysterectomy versus abdominal hysterectomy and laparoscopic hysterectomy versus vaginal hysterectomy. In both arms of the trial, bladder injuries were encountered in all forms of hysterectomy, though ureteral injuries were noted only in laparoscopic hysterectomy cases. Laparoscopic hysterectomy was associated with a significantly higher rate of all major complications (including urinary tract injuries) than was abdominal hysterectomy. Although this difference was not detected in the vaginal hysterectomy arm of the trial, it was underpowered to detect such a difference.

In terms of mode of access for hysterectomy, gynecologic surgeons’ familiarity with vaginal and abdominal approaches may explain the favorable rates of urinary tract injury associated with these procedures. Laparoscopic hysterectomy, however, is being performed more frequently due to advantages in minimizing blood loss, reducing length of hospital stay and decreasing postoperative pain and time to recovery.

As surgeons progress on the learning curve and gain increased proficiency with laparoscopic hysterectomy, it is likely that rates of urinary tract injury will decrease. This article outlines strategies for successfully minimizing risk of urinary tract injury during hysterectomy, regardless of the operative approach.
STRATEGY 1: Possess knowledge of the anatomy

Detailed knowledge of pelvic anatomy is essential to avoid injury to the ureter or bladder during hysterectomy. With regard to bladder injury, the dome of the bladder is commonly involved in injury during total hysterectomy. The bladder neck is at most risk during vaginal hysterectomy or reconstructive surgeries of the anterior vaginal wall. The most common sites of ureteral injury are at the pelvic brim, near the infundibulopelvic ligament (Figure 1), and deeper in the pelvis, as it courses by the uterosacral ligament under the uterine artery approaching the cardinal ligaments (Figure 2).

When considering the course of the ureter, division into abdominal and pelvic portions allows for ease of identification of neighboring structures. The ureter is 25 cm to 30 cm long, and its sources of perfusion vary as it passes from the abdomen into the pelvis. Notably, the right ureter is approximately 1 cm longer than the left ureter, but whether that has clinical significance for operative planning remains unclear.

In the abdomen, the ureter overlies the psoas muscle, receiving its perfusion in part from the renal vessels and common iliac. Mobilization of the colon and its mesentery allows access to the retroperitoneum and visualization of the ureter. Before entering the true pelvis, the gonadal vessels cross the ureter anteriorly and provide a perfusing branch. Given the close proximity to the gonadal vessels, isolation and identification of the ureter is imperative to minimize risk of transection during adnexal surgery. At the pelvic brim, the ureter passes over the bifurcation of the common iliac arteries and is ensheathed in connective tissue.

The ureter continues to course in the medial leaf of the broad ligament, and remains medial to the internal iliac arteries on the posterolateral pelvic sidewall. It then passes under the uterine artery through the cardinal ligament, before proceeding anterolaterally, approximately 1 cm to 1.5 cm from the cervix. There, the ureter lies along the anterior vaginal wall, separated from the wall of the bladder by 1.5 cm, before opening into the bladder trigone.

This course in the deep pelvis necessitates isolation and lateralization of the ureter in cases of total or radical hysterectomy in order to avoid injury. Nearly 80% of ureteral injuries occur in close proximity to the uterine artery. The bladder trigone and bladder base are also at risk of injury in the deep pelvis. The trigone rests over the anterior bladder fornix and the bladder base rests on the lower uterine segment and cervix (Figure 3).

STRATEGY 2: Address patient-specific risk factors

In addition to knowledge of the anatomy and meticulous dissection, preoperative planning is essential to minimize risk of urinary tract injury. Half of all patients who sustain a ureteral injury have no identifiable risk factors, but if patient-specific issues are identified, additional imaging
studies or alterations in the surgical plan can be considered to mitigate risk.\textsuperscript{14}

Risk of injury to the urinary tract is higher in procedures for invasive cancer or urogynecologic surgery.\textsuperscript{14} Ten percent of patients undergoing hysterectomy for known cervical pathology (such as a mass or tumor) will have a ureter within 5 mm of the cervical tissue.\textsuperscript{17} In these individuals, preoperative imaging may be helpful for surgical planning in an attempt to minimize risk of ureteral injury.

Pelvic anatomy also may be distorted in association with particular clinical scenarios. For example, pelvic adhesive disease may be the initial barrier to visualizing and isolating pertinent anatomy in patients with a history of abdominopelvic surgery, pelvic radiation, pelvic infections or advanced endometriosis. In such cases, sharp dissection is preferable to blunt dissection or use of thermal instruments to minimize risk of injury in the setting of compromised anatomic planes.

Multiple cesarean deliveries are also associated with an increased risk of pelvic adhesive disease,\textsuperscript{18} and difficulty with bladder dissection during subsequent gynecologic surgery can be expected. The bladder dome, adhered to the lower uterine segment, requires meticulous dissection to avoid injury; cystotomy occurs in greater than 20\% of women with more than 3 prior cesarean deliveries.\textsuperscript{19} Specific to endometriosis, fibrosis of the uterosacral ligament can draw the ureter medially at this location, placing the ureter at high risk of injury during dissection in the posterior cul-de-sac.\textsuperscript{20}

Patients undergoing hysterectomy for large uteri or who require resection of adnexal masses are also at increased risk of ureteral injury.\textsuperscript{21} This may be related to anatomic distortion and engorgement of the vasculature, which can make identification of the anatomic course of the ureter challenging. Less commonly, ectopic insertion of the ureter or duplication in the renal system puts a patient at increased risk of ureteral injury.\textsuperscript{21} Although preoperative imaging would aid in surgical planning, such anomalies are often identified intraoperatively and the surgeon should have a high degree of suspicion when dissection reveals an anatomic variant.

Ureteral catheterization prior to hysterectomy has been proposed in high-risk populations and has also been investigated as universal preoperative prophylaxis. In both a retrospective study and randomized trial, use of catheterization resulted in no significant difference in incidence of ureteral injury.\textsuperscript{22,23} In Kuno’s retrospective study,\textsuperscript{22} all injuries occurred in patients undergoing laparotomy for malignancy or leiomyomata (although uterine size was not disclosed).

A separate retrospective study found a decreased incidence of ureteral injury with preoperative stent placement, in addition to a cost savings in terms of operative time related to identification of the ureter.\textsuperscript{24} This cost savings may be attributable to decreased operative time if anatomic deviations were corrected by straightening the ureter’s course.\textsuperscript{23} Based on these findings, we suggest that prophylactic ureteral catheterization should not be a substitute for meticulous dissection, but in an appropriately selected patient it may improve the ability to identify the ureter either visually or by palpation. The deci-
Gynecologic surgeons’ familiarity with vaginal and abdominal approaches may explain the lower rates of injury associated with these procedures.

Situation about use of catheterization should be left to the surgeon’s discretion.

**STRATEGY 3: Screen for injury**
Minimizing the risk of intraoperative injury requires maintaining visual identification of the ureters and bladder in relation to the operative target. This also allows early recognition of injury, should it occur. Confirmatory measures for further reorientation include palpation of the ureters and bladder, bladder back-filling, administration of intravenous (IV) dye, cystoscopy, and retrograde pyelography.

During abdominal and vaginal hysterectomy, the ureter can be palpated and elevated to confirm its course. During vaginal hysterectomy, the ureter can be palpated between the infundibular and hypogastric artery pulses. This may not always be possible, however, if a surgeon cannot readily appreciate this subtle anatomic landmark intraoperatively.

During abdominal and laparoscopic hysterectomy, when the retroperitoneum is opened with division of the round ligament, the ureter can be visually identified on the medial leaf of the broad ligament. Observation of ureteral peristalsis allows for visual identification of the ureter’s course through the deep pelvis, although this alone should not be viewed as confirmation of ureteral integrity as peristalsis may occur despite injury.

In patients with extensive pelvic adhesive disease (i.e. advanced-stage endometriosis, history of prior pelvic procedures, history of pelvic radiation), visual identification or palpation of the ureter may be impossible even after careful dissection; in these cases a full ureterolysis may be necessary. If oophorectomy is undertaken alone or at the time of hysterectomy, opening the retroperitoneum surrounding the infundibulopelvic (IP) ligament on the pelvic sidewall allows the surgeon to “peel” the retroperitoneum and IP ligament medially so that the ureter can be seen coursing inferio-posteriorly to this dissection.

Many surgeons place a uterine manipulator at the start of laparoscopic hysterectomy. Although a variety of manipulators are available, many have a cervical cup or ring. With cephalad pressure, the cup or ring should be well applied to the vaginal fornices, which provides an important intraoperative landmark. The cephalad pressure allows for palpation of the ring intra-abdominally, identifying the level at which the colpotomy should be performed. When cephalad pressure is applied during colpotomy, the previously ligated uterine vascular pedicle and ureter fall away from the colpotomy incision and remain lateral to the vaginal cuff during closure (Figure 4).

Intraoperatively, limiting blunt dissection of the tissue planes surrounding the bladder is paramount to minimize risk of bladder injury. In cases where suspicion is high for a bladder injury, backfilling the bladder with saline or dilute indigo carmine solution can help assess integrity of the lower urinary tract by revealing leakage at the site of damage. Intravenous administration of indigo carmine with subsequent efflux of blue fluid from the site of injury can reveal occult ureteral transection. In addition, during a laparoscopic procedure, the Foley catheter bag may fill with gas in cases of cystotomy.

Regardless of the surgical approach, careful closure of the vaginal cuff is warranted in cases of total hysterectomy. Anchoring the vaginal cuff to the uterosacral ligament pedicle is commonly practiced as a mode to support the vaginal apex, but the surgeon must take care to avoid an anchoring...
stitch lateral to the cuff margins so as not to run the risk of incorporating the ureter into the closure.

Immediately following the procedure, cystoscopy can be used as a surveillance technique to assess both bladder and ureter integrity. In a study based on universal cystoscopy at the time of hysterectomy, rate of detection of urinary tract injury pre-cystoscopy was found to be approximately 25.6%, with improvement to 97.4% detection once cystoscopy was employed. Importantly, 75% of injuries detected on cystoscopy were previously unsuspected.5

It should be noted that visualization of bilateral ureteral jets immediately post-hysterectomy does not guarantee ureteral integrity as this may not reveal thermal injuries, kinking, or stricture of the ureters. Despite these limitations, the American Association of Gynecologic Laparoscopists currently recommends that routine cystoscopy be considered at the time of total laparoscopic hysterectomy, although data are insufficient to extend the recommendation to laparoscopic subtotal hysterectomy.4

At the start of cystoscopy, information about bladder integrity is obtained, as inability to adequately distend the bladder often indicates that cystotomy has occurred. A full bladder survey is then performed, with special attention to areas near the surgical dissection, such as the bladder dome or base. Intravenous administration of dye (indigo carmine is preferred, given the small but appreciable risk of methemoglobinemia with use of methylene blue) aids in visualization of the efflux of urine from the ureteral orifices. Sluggish or absent efflux of urine from the ureteral orifices is often a sign of ureteral injury.

Cystoscopy is a useful screening tool, but does have its limitations. A recent retrospective study from our institution based on selective (rather than universal) cystoscopy found that no intraoperative bladder injuries were diagnosed using cystoscopy. Additionally, cystoscopy was normal in 50% of patients who had a postoperative diagnosis of cystotomy.25 These limitations are particularly important in the case of laparoscopic hysterectomy, which commonly involves dissection and vessel sealing with electrosurgical devices. Damage due to thermal injury may be delayed in onset by 10 to 14 days, and as such is generally not detected on intraoperative cystoscopy or immediate postoperative imaging.25,26 As mentioned above, normal ureteral efflux is also not a guarantee of ureteral integrity in cases of partial obstruction. Although cystoscopy may be a useful adjunct to aid in detection of bladder or ureteral injury, it should not be considered a substitute for proper surgical technique and intraoperative visualization and isolation of these structures.

**STRATEGY 4: Recognize the injury**

Delayed identification of urinary tract injury can result in poor outcomes with long-standing sequelae such as compromised or lost renal function. Intraoperative or postoperative consultation with a urologist is recommended and may be necessary in complex cases, even when the gynecologic surgeon is capable of ureteric or bladder repair. The approach to immediate repair is dependent on the type of injury, with crush or thermal injuries requiring resection of the damaged segment. In cases of delayed diagnosis, placement of a nephrostomy tube may be required as a temporizing measure prior to definitive repair.

Postoperatively, a high degree of suspicion is required to identify patients with urinary tract injuries unrecognized at the time of surgery. Patients may present with a wide range of complaints, depending on the time since the primary surgery. Symptoms may include flank pain or costovertebral angle tenderness, fever, ileus, peritonitis, anuria,27 or frank fistula.28,29 Computed tomography imaging aids in postoperative diagnosis of urinary tract injury by its ability to detect intra-abdominal extravasation of urine.28 Fluoroscopic retrograde

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**FIGURE 4**

**Elevation of colpotomy ring at time of ligation, with lateralization of vessels**

White arrow demonstrates elevation of colpotomy ring; black arrow shows lateralization of uterine vessels.
Urinary tract injury is a known complication of hysterectomy, regardless of route of procedure. Surgeon familiarity and comfort with complex anatomy, as well as preoperative risk stratification, is essential to minimizing risk of urinary tract injury. Intraoperative assessment of ureter and bladder integrity is the first step in preventing delayed diagnosis of injury. Although a useful adjunct, cystoscopy does not identify all injuries. A high index of suspicion postoperatively with appropriate imaging will promote early diagnosis of intraoperative injuries. Consultation with an advanced gynecologic surgeon and/or urologist is recommended when definitive repair intraoperatively is possible. Postoperative repair of injury may require additional interventions prior to corrective surgery.

REFERENCES
The importance of determining chorionicity in twin gestations

A 32-year-old G2P1001 was diagnosed with twins at her initial ultrasound (U/S) examination in her obstetrician’s office at 12 weeks’ gestation. At her next U/S examination, scheduled at 20 weeks to evaluate fetal anatomy, a dividing membrane was not visualized between the twins, and a monoamniotic gestation was suspected. Maternal-fetal medicine consultation was requested, and a monochorionic-diamniotic gestation was subsequently diagnosed—complicated by severe twin-twin transfusion syndrome (TTTS).

How common are twin pregnancies, and how do monochorionic and dichorionic twins arise?

Based on data from the Centers for Disease Control and Prevention, the number of twins almost doubled between 1980 and 2009, increasing from 18.9 to 33.2 per 1000 births. Since 2005, the increase has slowed to less than 1% per year. As a result, however, twins accounted for fewer than 1 in 53 pregnancies delivered in the United States in 1980 but now make up 1 in 30. Approximately one-third of the increase is due to increasing maternal age at conception, and the remainder is thought to be secondary to the widespread availability and use of assisted reproductive technology.

In a dizygotic twin gestation, fertilization of 2 oocytes by 2 sperm results in a pregnancy that is dichorionic (DC) and diamniotic (DA). In about 25% of monozygotic twin gestations, cleavage of the morula within 4 days of conception will result in “identical twins” that are also DC and DA, with separate placental masses (Figure 1). In most of the remaining 75% of monozygotic twin gestations, cleavage of the more advanced blastocyst between 4 and 8 days after conception results in monochorionic, diamniotic (MC, DA) membranes and a single placental mass (Figure 1).

Cleavage between 8 and 12 days after conception occurs in less than 1% of twins and results in a monochorionic monoamniotic (MC, MA) gestation. Cleavage beyond 12 days after conception, which is fortunately rare, may result in conjoined twins.

Why is it important to determine chorionicity?

MC twins are associated with increased risks compared with DC twins, and these risks necessitate closer surveillance. In one large twin cohort study, the perinatal mortality rate was found to be more than two-fold increased in MC compared with DC twins. This was predominately influenced by the marked increase in fetal demise in MC twins, 7.6% versus 1.6%. Overall neonatal morbidity was also increased in MC twins compared with their DC counterparts. Several unique complications of MC twins contribute to these differences:

1. Twin-twin transfusion syndrome

Inter-twin vascular anastomoses are present in virtually all MC placentas. An imbalance in flow across the transplacental connections in MC twins can lead to volume and endocrine changes that result in a polyhydramnios/oligohydramnios sequence known as TTTS. This condition complicates 8% to 10% of MC twin gestations and usually presents in the second trimester.

1. TTTS

Breakdown of zygoty and chorionicity in twin gestations

* percentage in each block represents the fraction of all twin gestations.
accounts for more than one-third of all perinatal deaths in MC pregnancies. In severe cases, the perinatal mortality without treatment is 70% to 100%. Most experts consider fetoscopic laser photocoagulation of placental anastomoses to be the best available approach to treat severe TTTS in continuing pregnancies less than 26 weeks. This procedure has been associated with an overall perinatal survival of 50% to 70% in those with severe disease. Early detection of disease can lead to appropriate treatment and improve perinatal outcomes.

2. Intrauterine growth restriction

The prevalence of intrauterine growth restriction (IUGR) has been reported to be 26% in DC twins and as high as 46% in MC twins. Monochorionicity increases the overall risk of IUGR in twin pregnancies due to disproportionate placental sharing. In one prospective series, selective IUGR, defined as a birthweight discordance of at least 25% in the absence of TTTS, was reported to complicate about 15% of MC pregnancies and was associated with perinatal mortality of 5% to 10%. Management options range from selective termination to strict antepartum surveillance and consideration of early delivery, depending on the gestational age at diagnosis, severity of growth impairment, and patient preference.

It is particularly important to establish chorionicity prior to consideration of selective termination. Selective termination can be performed using intracardiac potassium chloride injection if the pregnancy is DC. However, if the pregnancy is MC, selective termination must be done either with radiofrequency ablation or umbilical cord occlusion.

3. Co-twin demise and neurodevelopmental morbidity after single fetal death

With the death of one of the fetuses in a MC twin gestation, vascular intra-placental connections may place the co-twin at significant perinatal risk. In a recent meta-analysis, death of 1 twin was associated with co-twin demise in 15% of MC gestations and 3% of DC gestations. Similarly, the incidence of neurologic morbidity following death of a co-twin was 26% in MC gestations, compared with 2% in DC gestations. Previously thought to be related to the passage of thromboplastin-like substances after the death of the twin, the more widely accepted theory is that acute hypotension in the initial dying fetus results in a “sink” phenomenon. Acute exsanguination of the normal co-twin results in its death or survival with neurologic sequelae. Thus, immediate or emergent delivery confers no advantage to the surviving fetus after the death of its co-twin in a MC twin gestation.

4. Monoamniotic twins

Although MA twins comprise only 0.3% of twin pregnancies (Figure 1), they are at particularly high risk. Historically, MA twins have been associated with perinatal mortality in up to 80% of cases, primarily related to umbilical cord entanglement. Even in recent series, the perinatal mortality rate is approximately 15%. In an effort to avoid fetal demise, a number of authors have discussed the role of inpatient management as early as 24 to 28 weeks, with steroid administration for fetal lung maturity, daily fetal surveillance, serial assessment of fetal growth, and delivery between 32 and 34 weeks. However, the optimal management of these pregnancies remains to be delineated definitively, and co-management with a maternal-fetal medicine specialist is recommended.

5. Twin anemia-polycythemia sequence

A form of chronic fetofetal transfusion known as twin anemia-polycythemia sequence (TAPS) may occur spontaneously in up to 5% of MC twin pregnancies and is also a recognized complication of incomplete laser treatment for TTTS. Significant hemoglobin differences in the fetuses can be identified by finding an elevated middle cerebral artery peak systolic velocity, indicating severe fetal anemia in 1 twin, or by the presence of fetal hydrops in the absence of oligohydramnios-polyhydramnios sequence.

Extreme cases of TAPS can progress to fetal death. Suggested treatment options include laser photocoagulation, intrauterine blood transfusion, selective termination, and early delivery, but there is inadequate literature to guide the optimal approach.

These complications highlight the need to properly establish chorionicity so that management of the pregnancy and antenatal surveillance can be planned appropriately. The American Institute of Ultrasound in Medicine in conjunction with the American College of Radiology and the American College of Obstetricians and Gynecologists recommend that amnioncisis and chorionicity should be documented for all multiple gestations when possible. The British, Australian and New Zealand, Canadian, and French Colleges of Obstetrics and Gynecology have made similar recommendations.

How is chorionicity determined sonographically?

Chorionicity is most reliably established sonographically early in gestation.

Before 14 weeks

Evidence of 2 distinct gestational sacs on transvaginal ultrasound (TVU) performed before 10 weeks’ gestation suggests dichorionicity (Figure 2). Determination of amnionicity is thought to be less accurate before 10 weeks, due to a delay in the sonographic
Hypertrophic cardiomegaly
In women with pre-existing hypertrophic cardiomegaly, estrogen therapy may be associated with elevations of plasma triglycerides leading to paracarditis. Consider discontinuation of treatment if paracarditis occurs.

Hepatic Impairment and/or History of Cholestatic Jaundice
Estrogens may be poorly metabolized in patients with impaired liver function. For women with a history of cholestatic jaundice associated with past estrogen use or with pregnancy, caution should be exercised and in the case of recurrence, medication should be discontinued.

Hypothyroidism
Estrogen administration leads to increased thyroid-binding globulin (TBG) levels. Women with normal thyroid function can compensate for the increased TBG by making more thyroid hormone, thus maintaining free T₄ and T₃ serum concentrations in the normal range. Women dependent on thyroid hormone replacement therapy who are also receiving estrogens may require increased doses of their thyroid replacement therapy. These women should have their thyroid function monitored in order to maintain their free thyroid hormone levels in an acceptable range.

Fluid Retention
Estrogens may cause some degree of fluid retention. Women with conditions that might be influenced by this factor, such as cardiac or renal dysfunction, warrant careful observation when estrogen is prescribed.

Hypocalcemia
Estrogen therapy should be used with caution in women with hyperparathyroidism as estrogen-induced hypercalcemia may occur.

Exacerbation of Endometriosis
A few cases of malignant transformation of residual endometrial implants have been reported in women treated post-hysterectomy with estrogen-alone therapy. For women known to have residual endometriosis post-hysterectomy, the addition of progesterin should be considered.

Hereditary Angioedema
Exogenous estrogens may exacerbate symptoms of angioedema in women with hereditary angioedema.

Exacerbation of Other Conditions
Estrogen therapy may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraines, porphyria, systemic lupus erythematous, and hepatic hemangiomata and should be used with caution in women with these conditions.

Laboratory Tests
Serum follicle stimulating hormone (FSH) and estradiol levels have not been shown to be useful in the management of moderate to severe vasomotor symptoms.

Drug-Drug Interaction Tests
Increased prolactin and decreased LH levels have been reported in some studies of postmenopausal women treated with estrogen therapy, yet no significant changes were seen in other studies.

Clinical Studies
There were no clinical trials conducted with IVELLE™ (estradiol transdermal system). IVELLE™ is bioequivalent to Vivelle® (estradiol transdermal system). The following adverse reactions have been reported with Vivelle®.

Table 1: Summary of Most Frequently Reported Adverse Reactions (Vivelle® versus Placebo) Regardless of Relationship Reported at a Frequency > 5%

<table>
<thead>
<tr>
<th>Condition</th>
<th>Vivelle 0.025 mg/day† (N=47)</th>
<th>Vivelle 0.05 mg/day† (N=120)</th>
<th>Vivelle 0.1 mg/day (N=103)</th>
<th>Vivelle 0.175 mg/day (N=90)</th>
<th>Placebo (N=157)</th>
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</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
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</tr>
<tr>
<td>Constipation</td>
<td>3 (6.4)</td>
<td>6 (4.9)</td>
<td>5 (5.8)</td>
<td>0</td>
<td>3 (3.2)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>4 (8.5)</td>
<td>12 (9.2)</td>
<td>3 (2.9)</td>
<td>2 (4.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Nausea</td>
<td>2 (4.3)</td>
<td>8 (6.2)</td>
<td>7 (5.0)</td>
<td>0</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>General disorders and administration site complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza-like illness</td>
<td>3 (6.4)</td>
<td>6 (4.9)</td>
<td>8 (7.6)</td>
<td>0</td>
<td>3 (2.3)</td>
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<tr>
<td>Pain NOS</td>
<td>8 (6.2)</td>
<td>9 (6.8)</td>
<td>7 (5.5)</td>
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<td>7 (5.6)</td>
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<td>Infections and infestations</td>
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<tr>
<td>Influenza</td>
<td>4 (8.5)</td>
<td>10 (8.3)</td>
<td>10 (9.7)</td>
<td>9 (19.6)</td>
<td>11 (7.0)</td>
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<td>Meningitis</td>
<td>3 (6.0)</td>
<td>15 (12.5)</td>
<td>10 (9.7)</td>
<td>19 (39.6)</td>
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<td>Sinusitis NOS</td>
<td>4 (8.0)</td>
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<td>Upper respiratory tract infection NOS</td>
<td>3 (6.0)</td>
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<td>6 (4.5)</td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight gain</td>
<td>4 (8.5)</td>
<td>5 (4.0)</td>
<td>2 (1.9)</td>
<td>2 (4.3)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

† Represents milligrams of estradiol delivered daily by each system.

If NOS represents not otherwise specified.

* NEC represents not otherwise classified.

** Application site erythema and application site irritation were observed in 0.2% or less of patients across treatment groups.

During the clinical pharmacology studies with IVELLE™, 35 percent or less of subjects experienced barely perceptible erythema. No transdermal systems were removed due to irritation. Three subjects (2.2 percent) reported mild discomfort while wearing IVELLE™ (N=136).

DRUG INTERACTIONS
No drug interaction studies have been conducted for IVELLE™.

Metabolic Interactions
In vitro and in vivo studies have shown that estrogens are metabolized partially by cytochrome P450 3A4 (CYP3A4). Therefore, inducers or inhibitors of CYP3A4 may affect estrogen drug metabolism. Inducers of CYP3A4 such as St. john’s wort (Hypericum perforatum) preparations, phenobarbital, carbamazepine and rifampicin may reduce plasma concentrations of estrogens, possibly resulting in a decrease in therapeutic effects and/or changes in the uterine bleeding profile. Inhibitors of CYP3A4 such as erythromycin, clarithromycin, ketocazole, itraconazole, ritonavir, and grapefruit juice may increase plasma concentrations of estrogens and may result in side effects.

USE IN SPECIFIC POPULATIONS

Pregnancy
MINILEVÉ™ should not be used during pregnancy (see Contraindications (4)). There appears to be little or no increased risk of birth defects in children born to women who have used estrogens and progestins as an oral contraceptive inadvertently during early pregnancy.

Nursing Mothers
MINILEVÉ™ should not be used during lactation. Estrogen administration to nursing women has been shown to decrease the quantity and quality of the breast milk. Detectable amounts of estrogens have been identified in the breast milk of women receiving estrogen therapy. Caution should be exercised when MINILEVÉ™ is administered to a nursing woman.

Pediatric Use
MINILEVÉ™ is not indicated in children. Clinical studies have not been conducted in the pediatric population.

Geriatric Use
There have not been sufficient numbers of geriatric women involved in clinical studies utilizing MINILEVÉ™ to determine whether those over 65 years of age differ from younger subjects in their response to MINILEVÉ™.

The Women’s Health Initiative Studies
In the WHI estrogen-alone substudy (daily CE 0.625 mg-alone versus placebo), there was a higher relative risk of stroke in women greater than 65 years of age (see Clinical Studies (14.2)).

In the WHI estrogen plus progestin substudy (daily CE 0.625 mg plus MPA 2.5 mg versus placebo), there was a higher relative risk of nonfatal stroke and invasive breast cancer in women greater than 65 years of age (see Clinical Studies (14.2)). The Women’s Health Initiative Memory Study

In the WHIMS, ancillary studies of postmenopausal women 65 to 79 years of age, there was an increased risk of probable dementia in women receiving estrogen-alone or estrogen plus progestin when compared to placebo (see Warnings and Precautions (5.3), and Clinical Studies (14.3)). Since both ancillary studies were conducted in women 65 to 79 years of age, it is unknown whether these findings apply to younger postmenopausal women (see Warnings and Precautions (5.3), and Clinical Studies (14.3)).

OVERDOSAGE
Excess dosage of estrogen may cause nausea, vomiting, breast tenderness, abdominal pain, droveness and fatigue, and withdrawal bleeding may occur in women. Treatment of overdose consists of discontinuation of MINILEVÉ™ therapy with institution of appropriate supportive measures.

PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Patient Information and Instructions for use)
appearance of the thin diamniotic membrane that is often not appreciated in the monochorionic gestation. In such cases, confirmation of the presence of an intervening membrane should be undertaken at a later U/S to exclude a MA twin gestation.

Between 10 and 14 weeks, visualization of the interface between the placenta and the intervening twin membrane is an important determination of chorionicity (Figure 3). A lambda sign (also known as a twin peak sign) is the triangular projection of placental tissue into the base of the intertwin membrane. It represents the chorionic villi between the 2 layers of chorion at its origins from the placenta. The presence of either a lambda sign or 2 separate placental masses can also be used to confirm dichorionicity; however, this finding is usually present in only about one-third of twin gestations. Both the presence of a thin bridge of placental tissue between 2 dominant placental masses and the presence of a succenturiate placental lobe can be seen in a MC gestation thereby limiting this parameter as a useful diagnostic tool.

Infrequently, the thickness of the intertwin membrane may be helpful in the determination of chorionicity. In a recent study, a threshold of 2 mm had 90% sensitivity and 76% specificity for determining MCDA membranes using standard 2-dimensional sonography, and sensitivity was further improved using 3-dimensional sonography.

How does knowledge of chorionicity affect U/S surveillance in twin gestations?

Although evidence for the optimal surveillance of twin gestations is limited, it is prudent to develop a management plan based on risk assessment related to chorionicity. All women with a twin pregnancy should be offered U/S examination at 10 to 13 weeks’ gestation to assess chorionicity, viability, crown-rump length, and nuchal translucency. Regardless of chorionicity, an anatomical assessment should be performed at 18 to 20 weeks’ gestation. Fundal height is not expected to reliably detect growth abnormalities in multiple gestations, and for this reason, serial sonographic assessment is recommended. DC twins should undergo sonography approximately every 4 weeks to assess fetal growth.

In MC, DA twins, sonography as often as every 2 weeks has been proposed to monitor for the development of discordance of fetal gender by U/S has a positive predictive value that approaches 100% for predicting dichorionicity. However, only 55% of all twins are discordant for gender. On rare occasions, post-zygotic disjunction in MC twins can result in a female fetus with 45XO karyotype and a normal male co-twin. Visualization of 2 separate placental masses can also be used to confirm dichorionicity; however, this finding is usually present in only about one-third of twin gestations.

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of TTTS. The serial sonographic evaluations should include at least the maximal vertical pocket of amniotic fluid in each sac, and the presence of the bladder in each fetus. Limited sonography may be alternated every 2 weeks with serial growth assessments. In addition, the prevalence of cardiac anomalies is increased in MC twins, and screening for congenital heart disease is warranted. If the estimated fetal weight is below the tenth percentile, umbilical artery Doppler studies should be considered.

In 2 retrospective series of MC twins, U/S examinations performed every 2 weeks were more likely to result in the early detection of TTTS as compared with traditional monthly assessment.

**Conclusions**

- Chorionicity should be routinely assessed in twin gestations, as early as possible in pregnancy, and ideally by 10 to 13 weeks.
- MC twins are at increased risk of specific complications, including TTTS, selective IUGR, severe perinatal morbidity and mortality after the death of a co-twin, monoamniotic and subsequent cord entanglement, and TAPS.
- In DC twins, U/S examinations approximately every 4 weeks should be considered to assess fetal growth.
- In MC twins, limited U/S examinations every 2 weeks should be considered, beginning at 16 weeks, with evaluation of fetal growth at about 4-week intervals.

This opinion was developed by the Publications Committee of the Society for Maternal-Fetal Medicine with the assistance of Kenneth J. Moise, MD, and Pedro S. Argoti, MD, and was approved by the Executive Committee of the Society on November 20, 2012. Neither Dr. Moise, Dr. Argoti, nor any member of the Publications Committee (see the list of 2013 members at www.smfm.org) has a conflict of interest to disclose with regard to the content of this article.

**DISCLAIMER:** The practice of medicine continues to evolve and individual circumstances will vary. Clinical practice also may vary. This opinion reflects information available at the time of acceptance for publication and is not designed nor intended to establish an exclusive standard of perinatal care. This publication is not expected to reflect the opinions of all members of the Society for Maternal-Fetal Medicine.

**REFERENCES**

Endometrial ablation
Let’s look at all the data

BY VANCE MCCAUSSLAND, MD AND ARTHUR MCCAUSSLAND, MD

Determining the best ablation technique is essential in the effort to minimize post-ablation intrauterine scarring.

Andrea S. Lukes, MD, MHSc, a consultant for Hologic, and Edward G. Evantash, MD, Medical Director and Vice President, Medical Affairs for Hologic, recently authored a paper titled The issue of scarring post-ablation: The data. [Editor’s note: This paper appeared as a promotional supplement to the November 2012 issue of Contemporary OB/GYN.] It is critical that data are presented accurately. We feel that in this paper not only were some important medical data excluded, but also that many of the conclusions were inaccurate.

Partial endometrial ablation

In the section “Endometrial Ablation and Uterine Scarring,” the supplement authors state, “No studies to date have demonstrated that one ablation technique is more or less likely to cause endometrial scarring.” This is true for total or global endometrial ablation (GEA) but the authors did not mention the 1 study that specifically addressed this issue: Partial rollerball endometrial ablation: A modification of total ablation to treat menorrhagia without causing complications from intrauterine adhesions. 2 A partial endometrial ablation (PEA) is defined as ablating or resecting only the anterior or posterior endometrial wall. When only 1 wall is injured, it heals in juxtaposition to a normal, uninjured endometrial surface on the opposite wall. Consequently, the injured and uninjured surfaces do not grow together. Intrauterine contracture and adhesions are therefore avoided, leaving the cavity open for easy future access and evaluation.

The goal is to cause hypomenorrhea or eumenorrhea, not amenorrhea, and to prevent intrauterine adhesions. Interestingly, although GEA manufacturers often define success with post-ablation amenorrhea rates, most women prefer not to have amenorrhea. Niles surveyed 400 women with abnormal uterine bleeding and found that 80% defined a “successful outcome” as hypomenorrhea or eumenorrhea, not amenorrhea. 3 At this year’s American Association of Gynecologic Laparoscopists (AAGL) meeting, we presented a long-term follow-up study of PEA that demonstrated a significant improvement in quality of life and avoidance of all obstructive problems. 4

As a disclosure, we are involved with a patent for an in-office partial endometrial ablation device and are consultants to Omnitech Systems, Inc., a medical device company developing this instrument.

Incidence of re-intervention

In the section “Incidence of Re-Intervention After GEA,” the supplement authors present “data” that the incidence of re-intervention after NovaSure is lower than that following the use of other GEA devices. Unfortunately, they did not include the largest long-term study to date addressing this issue. Longinotte et al followed 3681 women for up to 8 years who had either a first- or second-generation procedure. 5 The GEAs they studied included Thermacheoice, Hydro-ThermAblator, and NovaSure. They found no difference in long-term re-intervention rates among the different endometrial modalities.

Hysterectomy was subsequently performed in 774 women (21%), whereas 143 women (3.9%) had uterine-conserving procedures. Hysterectomy risk increased with each decreasing
stratum of age and exceeded 40% in women aged 40 or younger. Although Drs. Lukes and Evantash state in their conclusions that “the vast majority of patients undergoing NovaSure endometrial ablation will not require re-intervention,” larger long-term studies have found a different outcome. The long-term incidence for re-intervention is significant and is similar for all GEA devices, including NovaSure.

Post-ablation evaluation

In the section “Evaluation of the Post-Ablation Cavity,” the authors refer to a paper by Ahonkallio et al and state that this study “reported successful endometrial biopsy with Pipelle in 77% of women an average of 6 years after ablation.” This is factual but leaves the reader with the impression that post-ablation endometrial biopsies are also reliable, which we feel is inaccurate.

Drs. Lukes and Evantash did not include the discussion by Ahonkallio et al regarding the work of Turnbull et al. They showed in their MRI study of the uterus that after endometrial resection/ablation, more than 90% of patients had residual endometrium, which was most commonly present in the uterine fundus, close to the tubal ostia. Ahonkallio et al state that “this leads to the conclusion that endometrial biopsies do not always represent the entire endometrium, but there may be areas that are not accessible.”

Further, they state that “the detection of malignancy in women who have undergone endometrial ablation may pose a problem, especially as typical early presentation of endometrial cancer with postmenopausal bleeding may not occur.” In their conclusion they say that endometrial ablation “significantly complicates endometrial assessment later on.” We agree that the majority of endometrial biopsies after an ablation are unreliable unless cancer is found.

Drs. Lukes and Evantash refer to the outstanding work of Dr. Wortman et al and correctly state that in all cases, “the uterine cavity could be identified” and include pictures of his technique. This leaves the impression that post-ablation intrauterine evaluation is not problematic. We are very familiar with Dr. Wortman’s work. Unfortunately, he was unable to attend this year’s AAGL meeting in Las Vegas and asked one of us (AMc) to present his paper. He made it clear that to safely access a post-ablation intrauterine cavity, you must not only be an expert resectoscopic surgeon, but also have a dedicated ultrasound team to guide you. Even with these requirements, uterine perforations have occurred.

Post-ablation intrauterine evaluation is turning out to be a major clinical problem. The vast majority of ob/gyns are not expert resectoscopic surgeons and most do not have access to dedicated ultrasound technicians. Dr. Wortman has told us that most of his re-interventions are from obstructed bleeding caused by post-ablation intrauterine scarring. Consequently, he is now considering partial endomyometrial resections in younger women to avoid these complications.

In the “Conclusions” section of the supplement, Drs. Lukes and Evantash state, “For those patients who do require re-intervention for symptoms of bleeding and/or pain, the data show that visualization of the uterine cavity is not limited, and that endometrial sampling is feasible and often of high yield.” This is an attempt to leave the impression that post-ablation intrauterine evaluation is not problematic. Again, we feel that this is an inaccurate conclusion.

Drs. Lukes and Evantash write that they agree with Dr. Goldstein, who originally was against GEA but now recognizes that there is a benefit to GEA in carefully selected patients. However, the authors did not mention that Dr. Goldstein’s original concern was post-ablation intrauterine evaluation.

He eventually studied 10 satisfied post-ablation patients with saline infusion sonograms (SIS). He was encouraged after finding that 4 of the 5 patients treated with HerOption had extremely small and shortened endometrial cavities that were easily evaluated with SIS. However, of the 5 patients treated with NovaSure, 4 had multiple adhesive bands, making endometrial evaluation inadequate. This is problematic and Dr. Goldstein feels that a larger study is needed to determine which GEA technique allows for adequate endometrial cavity assessment post-procedure. He hopes that these data would help clinicians choose which GEA techniques to use.

Scarring and complications

Also in the “Conclusions” section of the supplement, Drs. Lukes and Evantash state “it is within reason that higher rates of GEA success … may be associated with increased scarring of the uterine cavity.” This may be true, but every post-ablation long-term compli-
Since patient satisfaction rates are fairly similar after first- and second-generation ablation techniques, determining the ones that cause the least amount of scarring and contracture is important.

Since patient satisfaction rates are fairly similar after first- and second-generation ablation techniques, determining the ones that cause the least amount of scarring and contracture is important. We agree with Dr. Goldstein that a multicenter prospective trial is needed to determine which ablation techniques accomplish this goal.

Summary
When discussing the subject of post-ablation intrauterine scarring, it is important to include all pertinent medical data. We feel that some of these data were excluded and that many of Drs. Lukes and Evantash’s conclusions were inaccurate. This can confuse the reader and make it difficult for physicians to provide enough information for patients to give valid informed consent.

This is a significant women’s health issue, because without accurate informed consent, patients are unable to know which surgical procedure is best for them in the long term.

References
1. Lukes AS, Evantash EG. The issue of scarring post-ablation: The data. A promotional supplement to Contemporary OB/GYN. 2012;57(11).


The very good news about preterm deliveries in the United States is that for the fifth year in a row, the preterm birth (PTB) rate has fallen. In 2011, prematurity complicated 11.7% of all US births, down from the peak of 12.8% in 2006. The largest drop has been in the late preterm (34 to 36 weeks) group, which has fallen from 9.15% in 2006 to 8.28% in 2011. Although these trends are going in the right direction, it is clear that work still needs to be done to better understand both predictors and prevention of PTB. So what is new in the October 2012 Practice Bulletin: Prediction and Prevention of Preterm Birth? To be succinct: progesterone is back, cervical length is hot, and cerclage is still unclear.

Clinical predictors of PTB in 2012 are similar to those mentioned in the 2001 practice bulletin: prior PTB, smoking, vaginal bleeding during index pregnancy, and short cervix. However, in the intervening 11 years, the efficacy of potential interventions aimed at these risk factors has been refined. Screening for salivary estriol, fetal fibronectin, and bacterial vaginosis (BV) and use of home uterine activity monitoring were questioned in 2001. In the current practice bulletin, estriol is not even mentioned and we now know that there is no utility in home uterine monitoring, BV, or fetal fibronectin screening for PTB in low-risk women. Prior PTB continues to remain one of the strongest risk factors for subsequent PTB. Although we have known for years that a short cervix is associated with PTB, very important new data have refined this association and identified a treatment strategy to reduce PTB in these women.

The only screening tools that identify women who are at risk of spontaneous PTB and for whom we have an intervention that reduces that risk are obtaining a history of previous spontaneous PTB and second-trimester cervical length screening. If a patient’s prior delivery was a spontaneous PTB (delivery initiated by spontaneous rupture of membranes or preterm labor) and her current pregnancy is singleton, then she should be offered progesterone supplementation from 16 to 24 weeks until 34 to 37 weeks’ gestation. Administering progesterone has been shown to be effective in reducing PTB in such women. This intervention has been given a level A recommendation by the American College of Obstetricians and Gynecologists.
ACOG GUIDELINES AT A GLANCE

“Inaccurate measurement of cervical length or measurement at the wrong gestational ages has the potential to result in many false-positive results.”

Screening for cervical length

Now we come to the short cervix. There are at least 2 randomized trials of women with singleton pregnancies with a demonstrated short cervix in the second trimester who, when randomized to vaginal progesterone supplementation, had a significantly lower risk of PTB. One trial used a cervical length <15 mm at 20 to 25 weeks, and the other trial used a cervical length of 10 mm to 20 mm at 19 to 23 weeks. These findings are compelling but several details should be noted. Both studies screened more than 24,000 women and identified only a small percentage (approximately 2%) who met the criteria for a short cervix. Cervical length measurements were all performed with transvaginal ultrasound in the second trimester. Measuring cervical lengths after 25 weeks has not been shown to be useful.

So the obvious next question is: Should second-trimester cervical length screening become universal? Two decision and economic analyses have concluded that cervical length screening and subsequent treatment with progesterone in appropriate women are cost-effective. ACOG recommended treating women with progesterone who had an “incidentally” identified short cervix in the second trimester and gave this a level A recommendation. However, they did not mandate universal cervical length screening but said it can be considered and gave that statement a level B recommendation.

Placement of cerclage

Now what about cerclage? Does it have any role now that we are more commonly measuring cervical length? In women with no prior PTB but a current short cervix, cerclage placement did not significantly reduce PTB. In women with a prior PTB and a short cervix, the utility of cerclage is complex. In such women with a cervical length <25 mm there was no benefit of cerclage placement in reducing PTB <35 weeks. However, there was a significant reduction in births <24 weeks. If the cervix was <15 mm, cerclage placement demonstrated a significant decrease in PTB <35 weeks.

Based on these data and several other studies, ACOG suggests that cerclage use is associated with reduction in PTB in women with prior PTB and short cervix. However, this becomes confusing because there are not yet data indicating that cerclage adds additional benefit to progesterone treatment in these women (ie, those with a prior PTB and a short cervix). ACOG offers a diagram to direct management of the woman with a prior PTB and a short cervix that recommends giving progesterone and considering a cerclage. However, one of their recommendations also states: “Insufficient evidence exists to assess if progesterone and cerclage together have an additive effect in reducing the risk of preterm birth in women at high risk for preterm birth.”

Finally, neither progesterone supplementation nor cerclage use has been shown to be efficacious in multiple gestations. In fact, cerclage may worsen outcome and increase PTB in multiple gestations.

Summary

Inaccurate measurement of cervical length or measurement at the wrong gestational ages has the potential to result in many false-positive results, which will lead to mistreatment and overtreatment of women. We do not want to have another clinical scenario similar to the rollout of fetal heart rate monitoring in which our testing has resulted only in increased maternal morbidity (ie, increased cesarean delivery) without a dem-
Observation: Improvement in neonatal outcome. Hence, pay good heed to the technique and timing of cervical length measurement.

Moving ahead, to prevent PTB, we should:
1. Give progesterone to women with a singleton gestation and a history of spontaneous PTB;
2. Give vaginal progesterone to women with a singleton gestation and current short cervix in the second trimester;
3. Consider offering cerclage to women with a singleton gestation and a history of a prior spontaneous PTB and a current short cervix, particularly if the length is <15 mm;
4. Perhaps screen all women for short cervix in the second trimester; and
5. Avoid the use of cerclage or progesterone in women with multiple gestations.

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Florence, Italy
CONTACT: www2.kenes.com/diabetes-pregnancy/symposium/Pages/General_Information.aspx

APRIL
8-10: 99th Annual SGS Scientific Meeting—Society of Gynecologic Surgeons
Charleston, South Carolina
CONTACT: http://www.sgsonline.org/futuremeetings.php

18-20: 27th Annual Clinical and Research Meeting of the North American Society for Pediatric and Adolescent Gynecology (NASPAG)
San Diego, California
CONTACT: http://www.naspag.org/

27-28: Interactive & Comprehensive Retreat for Chronic Pelvic Pain
Bethlehem, Pennsylvania
CONTACT: http://www.allianceforpelvicpain.com

MAY
4-8: 61st Annual Clinical Meeting of the American Congress of Obstetricians and Gynecologists (ACOG)
New Orleans, Louisiana
CONTACT: http://classic.acog.org/acm/

MAY/JUNE
MAY 31-JUNE 4: American Society of Clinical Oncology (ASCO)
Annual Meeting
Chicago, Illinois
CONTACT: http://chicago2013.asco.org

MAY 15-JUNE 4: American Society of Clinical Oncology (ASCO)
Annual Meeting
Chicago, Illinois
CONTACT: http://chicago2013.asco.org

JUNE
15-18: ENDO 2013
95th Annual Meeting and Expo of the Endocrine Society
San Francisco, California

SEPTEMBER
19-21: Reproductive Health 2013
Denver, Colorado
CONTACT: www.arhp.org/RH13

19-21: 3rd Annual Meeting of the Society of OB/GYN Hospitals
Denver, Colorado
CONTACT: http://societyofobgynhospitalists.com

OCTOBER
2-5: International Society for the Study of Vulvovaginal Disease
International Postgraduate Course
Dan Panorama Hotel
Tel Aviv, Israel
CONTACT: www.issvd.org/wordpress

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