OBSTETRICS

Forceps

21st century tips for utilizing a classic obstetric tool

Melissa S. Wong, MD
Wrapping up 2019

In the 1980s, most of the instrumental vaginal deliveries performed in the United States utilized forceps. Operative vaginal deliveries in general have decreased for a lot of reasons, but in some instances, a pair of forceps may still be the right tool to affect a safe delivery.

In this month’s cover article, Dr. Melissa Wong examines forceps from a 21st century perspective and provides practical information on their use. Be sure to also check out the links to her instructive videos on the anatomy of forceps and their safe application and handling.

The use of hormonal therapy to treat menopausal symptoms has come into and fallen out of favor over the past half century: from its first use in the 1950s and ’60s, to concerns about safety, to revised treatment recommendations in response to studies appearing to link therapy to endometrial cancer, coronary heart disease, and breast cancer … to today.

Hormonal therapy has come full circle and is now, once again, the treatment of choice for symptomatic women. Dr. Nanette Santoro and her associates describe the latest studies and most up-to-date indications for which patients are most likely to benefit from treatment, along with the different regimens available.

Finally, for the fans of our Legally Speaking column, you may notice that it isn’t in its usual place: at the back of the magazine. It’s an online exclusive this month and delves into whether a delay in assessing decreased fetal movement resulted in brain injury. You can find Legally Speaking at contemporaryobgyn.net.

From our family to yours, we wish you a safe and happy holiday season. See you next year!

Mike Hennessy, Sr.
Chairman and Founder, MJH Life Sciences
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MELISSA S. WONG, MD
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CORRECTION
In the article “Practical approach to sonographic evaluation and management of placenta previa” which appeared in the November 2019 issue, several lines of text on pages 13 and 14 were inadvertently hidden from view. An updated version of the article with the restored text may be viewed at contemporaryobgyn.net/PlacentaPrevia. The editors apologize for the omissions.
Managing endometriosis pain with cannabis

by BEN SCHWARTZ

Women with endometriosis seeking pain relief may want to consider cannabis or cannabidiol (CBD), according to a recent study presented at the 2019 American Association of Gynecologic Laparoscopists (AAGL) Global Congress in Vancouver, Canada. The survey aimed to identify the prevalence of medical cannabis among endometriosis patients as well as the effectiveness of both cannabis and cannabidiol in their pain management.

The online REDCap survey invited participants through email and contained 50 to 75 questions based on branching logic. The questions focused on pelvic pain history, demographics, and experience with cannabis and CBD for management of pelvic pain. Participants were identified through an ICD-10 code for endometriosis diagnosis at a clinic or from the mailing list of the Endometriosis Association.

Anna Reinert, MD, the presenting author noted “Our participation was very different between our two groups. The invitation stressed that this was an anonymous survey, but I think there’s still a lot of taboo around this topic. For the Endometriosis Association, only 1.4% of participants replied, which is much lower than the participation rates for other surveys that were being sent out around the same time frame. From our clinic population, we had about 16%.”

Of the 240 respondents from the Endometriosis Association, 77 (32.1%) reported having tried cannabis, with the majority of these participants (52 of 77, 67.5%) reporting cannabis to be very or moderately effective. Of the 124 clinic respondents, 58 (46.8%) reported having tried marijuana, with the majority of patients (44 of 58, 75.9%) reporting cannabis to be very or moderately effective.

Sixty-seven respondents from the Endometriosis Association reported having tried CBD, with 50% (34 of 67) reporting CBD to be very or moderately effective. Fifty-seven clinic respondents reported having tried CBD, with 64.9% (37 of 57) reporting that CBD was very or moderately effective in pain reduction.

In terms of effectiveness, participants from both groups were more likely to report cannabis as very effective (40.2% of Endometriosis Association participants, 53.4% of clinic participants) on a Likert scale. CBD was more likely to be reported on a Likert scale as moderately effective in both groups (31.4% of Endometriosis Association participants, 36.8% of clinic participants).

Looking ahead, Dr. Reinert said, “Further research is needed to explore the potential benefits and clarify the limitations and risks of the use of cannabis for the management of chronic pelvic pain and endometriosis.”

Ben Schwartz is the associate editor for Contemporary OB/GYN.

SOURCE
Reinert AE, Hibner ME. Self-reported efficacy of cannabis for endometriosis pain. Oral presentation at: AAGL 48th Congress on MIGS; November 12, 2019; Vancouver, Canada.
OCS and concurrent depressive symptoms

by BOB KRONEMYER

Scores for depression were higher in 16-year-olds who used oral contraceptives (OCS) than those who did not, according to a prospective cohort study of depressive symptoms among women aged 16 to 25. However, the study in JAMA Psychiatry found no connection between OC use and depressive symptoms when all age groups were combined.

“We started this study because data on depressive symptom severity of women currently using oral contraceptives are needed to provide information on the immediate associated risks,” said senior author Anouk de Wit, a MD and PhD candidate in psychiatry at the University Medical Centre Groningen in the Netherlands.

Data were collected from the third to sixth wave of the prospective cohort study Tracking Adolescents’ Individual Lives Survey (TRAILS), conducted from 2005 onwards among children from the Netherlands. For this study, data from 1,010 females were analyzed, ranging from 743 to 903 females per wave. Study participants were assessed in waves every 2 to 3 years, with questionnaires, interviews, tests, and/or physical measurements. They filled out between one to four assessments of OC exposure at ages 16, 19, 22, and/or 25.

At age 16, nonusers of oral contraceptive had a higher mean socioeconomic status than users: 0.17 vs. -0.15. Nonusers were also more likely to be virgins: 79% vs. 24.4%, respectively.

Depressive symptoms were assessed by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-4)-oriented affective problems scale of the Youth Self-Report for the study’s 16 year olds and by the Adult Self-Report for the latter years.

“On average, depression scores were 21.2% higher among 16-year-old females using oral contraceptives,” compared to nonusers de Wit told Contemporary OB/GYN. “This difference persisted after adjustment for age, socioeconomic status and ethnicity.”

The youngest contraceptive users particularly reported more crying (odds ratio [OR] 1.89; 95% confidence interval [CI]: 1.38 to 2.58; P < .001), more hypersomnia (OR 1.68; 95% CI: 1.14 to 2.48; P = 0.006) and more eating problems (OR 1.54; 95% CI: 1.13 to 2.10; P = 0.009) than nonusers.

“However, the two core symptoms for the diagnosis of depression—anhedonia and sadness—were rarely noted,” de Wit said. “The more common self-reported symptoms mirror the symptom profiles of adolescent depression, where there is an emphasis on vegetative or physical disturbances, such as loss of energy and changes in weight, appetite and sleep, rather than on anhedonia.”

Two study limitations are that its observational data precludes any causal inference and the longitudinal analysis did not provide any information about specific oral contraceptive pills.

In addition, based on study results, “we cannot say that oral contraceptives cause mood changes,” de Wit said. “But we have evidence that suggests that the relationship between oral contraceptive use and depressive symptoms is going in both directions.”

de Wit recommends that if an adolescent or young woman is experiencing depressive symptoms, whether caused by OCS or not, she should contact her healthcare provider to review the options for improving mood.

She also said that monitoring depressive symptoms in adolescents who are using OC is important because the hormones may affect their quality of life and place them at risk of noncompliance.

Anouk de Wit reports no relevant financial disclosures.

Bob Kronemyer is a freelance writer for Contemporary OB/GYN.

SOURCE

How common are volatile organic compounds in feminine hygiene products?

by BEN SCHWARTZ

Volatile organic compounds (VOCs) have been associated with several toxic effects and a recent study appearing in the Journal of Women’s Health suggests that douching may contribute to higher VOC exposure in women. VOCs are used to retain fragrances, and since douches often contain fragrances, these materials may be unrecognized sources of exposures.

The study included data from the National Health and Nutrition Examination Survey (NHANES) between 2001 and 2004. Participants were restricted to women aged 20 to 49 years with self-reported data on feminine hygiene product (FHP) use (n = 2432). Information about usage of feminine products (tampons, sanitary napkins, vaginal douches, sprays, powders, wipes/towelettes, and other products) was self-reported. Blood samples were collected from a subsample of participants (approximately one-third of the population). Reproductive health survey data were collected via interviews on the day of the health examination. Demographic information was also collected, including race/ethnicity, and participants were classified into white, black, Mexican American, other Hispanic, and other racial/ethnic group.

Considering use of FHPs in the past month, non-Hispanic white women reported significantly higher use of tampons, whereas non-Hispanic black women had significantly higher use of vaginal douche, feminine spray, feminine powder, wipes/towelettes, and other products. Non-Hispanic black women also used vaginal douching more frequently than other racial/ethnic groups.

The authors found that women who reported more frequent douching tended to be older than never users ($P = 0.03$) and were more likely to have significantly higher body mass index (BMI) with a mean of $30.0$ (SE $= 0.7$) kg/m$^2$ ($P = 0.0002$). Women reported using douching as a type of vaginal cleansing during pregnancy, but pregnant women reported less frequent douching ($P = 0.003$). Women who reached menopause due to hysterectomy and/or oophorectomy were more likely to douche in the 6 months following their surgery when compared to premenopausal women and women who reached natural menopause ($P < 0.0001$).

Black and Mexican women had significantly higher concentrations ($P < 0.0001$) of 1,4-dichlorobenzene (DCB), a VOC and noted carcinogen. Adjusting for confounders illustrated a dose-response relationship between the frequency of vaginal douching in the past 6 months and 1,4-DCB concentrations. Compared with never users, women with occasional use ($\leq 1$ time/month) of vaginal douching had $18\%$ (95% CI $-12\%$ to $59\%$) higher concentrations and those with frequent use ($\geq 2$ times/month) had $81\%$ (95% CI $2\%$ to $221\%$) higher concentrations. Feminine powder was also associated with $36\%$ (95% CI: $0.4\%$ to $83\%$ higher concentrations of ethylbenzene.

The authors recommend following the recommendations from the American College of Obstetricians and Gynecologists and US Department of Health and Human Services Office and suggest that douching or use of feminine deodorant powder be discouraged, especially during pregnancy. They also called on manufacturers to disclose all ingredients and urged that screening tests to evaluate chemicals in FHPs be considered.

Ben Schwartz is the associate editor for Contemporary OB/GYN.

SOURCE
Operative vaginal delivery remains an important skill for obstetricians to provide the full spectrum of care for pregnant patients. It can reduce the need for cesarean deliveries, an important goal of both our specialty nationwide and of individual providers and patients. Notably, 2017 was the first year the cesarean delivery rate increased since 2009, suggesting an even greater urgency in focusing on tools to reduce it.1 The top two reasons for cesarean delivery – labor dystocia and abnormal or indeterminate fetal heart rate tracings – can both potentially be resolved by operative vaginal delivery.2 Despite this, the overall trend for operative deliveries has shown a dramatic decline. While approximately 10% of deliveries were performed via operative delivery in the 1990s, the most recent National Vital Statistics Survey shows a 2.58% rate for vacuum deliveries and 0.56% for forceps deliveries. It is these latter deliveries – forceps-assisted vaginal deliveries – which will be the focus of this article.3

History
The history of the obstetric forceps is one of the more theatrical tales in medical literature. Invented by the two Chamberlen brothers (Peter the Elder and Peter the Younger) in the 1600s, the timing was particularly fortuitous because malnourishment, rickets and thus pelvic dystocia were on the rise. The two male midwives were so maligned, however, and so obsessed with the secrecy of their invention that before employing the forceps they would make all attendees leave the room and blindfold the laboring woman before applying them. The secret method ultimately remained with the family for another century and the instruments unseen until their discovery under the floorboards of Peter’s son’s house in 1813. And though some modifications were made in the following years, the two most commonly used forceps designs of today – Simpson and Elliot-type forceps – were each invented about a century and a half ago.3

by MELISSA S. WONG, MD.

**ANATOMY OF THE FORCEPS** Visit our website to view Dr. Wong’s discussion on the parts of the forceps and differences between various types.
ccontemporaryobgyn.net/ForcepsAnatomy

**FORCEPS DELIVERY TECHNIQUE.** Dr. Wong demonstrates a forceps delivery from beginning to end and provides step-by-step instructions.
ccontemporaryobgyn.net/ForcepsDelivery

DR. WONG is a physician in Maternal-Fetal Medicine in the Department of Obstetrics and Gynecology at Cedars-Sinai Medical Center, Los Angeles, Calif.
Indications and contraindications for forceps deliveries

Indications and prerequisites for proceeding with a forceps delivery mirror those for a vacuum delivery and include prolonged second stage of labor, suspicion of fetal compromise, and shortening of the second stage for maternal benefit. Prerequisites include the cervix being fully dilated, membranes ruptured, and the head being fully engaged. An estimation of fetal weight, fetal position, and pelvic adequacy should also have been previously performed. Regarding the patient, adequate anesthesia should be in place, the bladder empty, and consent obtained. At a system level, there should be a willingness and ability to have a back-up plan in place in case of failure to deliver. A helpful mnemonic for recalling these may be to remember A-B-Cs.

Contraindications for both forceps and vacuum include a strong suspicion for a fetal bone demineralizing or bleeding disorder. But while vacuum delivery has been discouraged for the fetus less than 34 weeks, there is no lower limit for gestational age for forceps delivery.

Assessment of fetal position

Knowledge of the fetal head position is particularly critical for forceps deliveries, since it determines the type of forceps delivery being performed (Table 2) and incorrect assessment of position can make forceps placement both less effective and more prone to cause fetal injury. Provider determination of fetal head position is fraught with error with studies showing accuracy ranging from 27% to 80% by digital palpation even by experienced providers. However, ultrasound assessment, on the other hand, has consistently proven more accurate than digital palpation, including in a large, multicenter randomized trial where the accuracy of ultrasound assessment was found to be 98.4%. Given the importance of correct determination of fetal position, it is reasonable to consider a bedside ultrasound in patients for whom a forceps delivery is being considered; an excellent expert review was published on the topic by Bellussi, et al and includes an accompanying video demonstrating the technique.

Forceps 101

ANATOMY OF THE FORCEPS

The basic anatomy of the forceps is described in the video, “Anatomy of the forceps,” which can be viewed at contemporaryobgyn.net/ForcepsAnatomy.

TYPES OF FORCEPS

The two most commonly used types of forceps for the cephalic presenting fetus are Simpson type and Elliot or Tucker-McLane forceps. The main differences between the two are that the Simpson forceps have shanks that are separated (remember “Simpson shanks separated”) whereas those of the Elliot/Tucker-McLane type are overlapping (remember “Tucker tucked in”). The separated shanks as well as the longer tapering cephalic curve allow for the Simpson type forceps to be used on longer, more molded heads whereas the Elliot or Tucker-
McLane types are narrower and might be chosen for the easier pull in a multiparous patient, for example.

The other two commonly used forceps are for special indications. Kielland forceps are used for rotational maneuvers (you “turn a key”) owing to their very slight reverse pelvic curve and sliding lock which allows for correction of asynclitism. The Piper forceps, with their long backward curving shanks and reverse pelvic curve, are designed specifically for stabilization and delivery of the aftercoming head in a breech presentation.

**Choosing the Candidate**

While we will never be able to perfectly choose only those candidates in whom an operative delivery will be successful, certain characteristics can make success less likely. Macrosomia has been associated with an increased likelihood of failure in an operative delivery. This association holds for both vacuum and forceps deliveries; one study found increased odds of failure of 14% for every 100 g increase in estimated fetal weight. In addition, macrosomia and operative delivery are independent risk factors for shoulder dystocia. A study performed reviewing 175,000 births in California noted a synergistic effect particularly in diabetic mothers, suggesting additional concerns when considering a forceps delivery in a macrosomic fetus.

Other factors that have been associated with failure of operative delivery include station at application (low is more likely to fail than outlet), arrest as the indication for operative delivery, prolonged second stage, and occiput posterior presentation. When possible, occiput posterior presentation can be resolved either by digital rotation or by Scanzoni maneuver (instrumental rotation ideally using Kielland forceps). It is preferable to resolve it since while it is possible to deliver directly OP (as described below in Technique), it is often more difficult, more prone to higher-order lacerations, and was thus discouraged by Dennen in his original forceps textbook.

**Technique**

We have created a simulation video of a forceps-assisted vaginal delivery for a cephalic presenting fetus in an occiput anterior position (See “Forceps delivery technique” at contemporaryobgyn.net/forceps) delivery and the steps listed in Table 3.

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**TABLE 3**

<table>
<thead>
<tr>
<th>Steps in performing a forceps-assisted vaginal delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ghost application.</td>
</tr>
<tr>
<td>2. Identify the posterior blade. For example, in a LOA presentation, this is the left blade (used for the rest of this example).</td>
</tr>
<tr>
<td>3. Hold the handle of the left blade with the fingertips of your left hand, dangling directly perpendicular to the ground. Concurrently, advance your right fingers 1-3 into the left side of the vagina to make space between the walls and the fetus’ left parietal bone. Position the cephalic curve or “palm side” of the forceps blade directly apposing the fetal scalp.</td>
</tr>
<tr>
<td>4. Guide the handle in a straight arc until the maternal thigh is reached then drop the handle medially to begin advancing the toe inwards using only the pressure of your right thumb on the heel of the blade.</td>
</tr>
<tr>
<td>5. Repeat 3-4 with the opposite blade.</td>
</tr>
<tr>
<td>6. Confirm placement in three dimensions:</td>
</tr>
<tr>
<td>- The line formed by the handles is in line with the sagittal suture.</td>
</tr>
<tr>
<td>- A plane bisecting the shanks is 1-2 fingerbreadths anterior to the posterior fontanelle</td>
</tr>
<tr>
<td>- No more than 1 finger can be inserted into the fenestration on each side.</td>
</tr>
<tr>
<td>7. Traction in the axis of the pelvis</td>
</tr>
<tr>
<td>8. Either delivery with forceps or Ritgen maneuver then disarticulation and delivery</td>
</tr>
</tbody>
</table>

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Assisted vaginal delivery found that failure was 35% less likely with forceps compared to vacuum delivery (9% vs 14% of those attempted). It is important, however, to only attempt an operative delivery when it is likely to be successful. A study by Towner, et al found that the likelihood of injury was greatest when sequential interventions were required whether that was an operative attempt then cesarean or sequential operative attempts compared to when a single intervention was successful (i.e., a successful operative delivery or cesarean delivery). Improving the likelihood of success in performing a forceps delivery can be achieved by choosing the appropriate candidates, utilizing optimal technique, and avoiding pitfalls that can contribute to failure.
**COMMON PITFALLS IN TECHNIQUE**

Common pitfalls gathered from both performing and teaching learners to perform forceps deliveries are reviewed in Table 4. The most frequent struggles are usually encountered in initial placement – particularly of the second blade – and less commonly during traction. It is important that the cephalic curve (or “palm side” of the blade) is as closely apposed to the fetal scalp as possible, or if the fetal scalp is not visible, then to the maternal introitus. Importantly, as the forceps begins its motion, there can be no movement forward or backward of the handle until the maternal thigh is reached. Doing so starts the blade of the forceps down the sacrum/face (in an OA fetus) rather than along the more hollow space between parietal bone and vagina. A forceps blade on the correct trajectory should require almost no force, and I remind learners of this by encouraging them to hold the handle with only their fingertips.

As the forceps lock, if the left blade was placed first, this allows the English lock to come together easily. If, however, the right blade was placed first (as would be the case in a ROA or LOP presentation placing the posterior blade first), then they will appear to come together and be unable to lock. This is easily resolved by moving the left handle so that it falls under the right and the English lock will come together correctly. Last, the correct direction of traction is best achieved by visualizing the presenting part and cardinal movements necessary for delivery. For an OA presentation, this requires direct downward (axis) traction. Only after the occiput clears the symphysis is this then transitioned to outward then upward to minimize perineal injury. For OP presentations, the biparietal diameter is typically much higher than anticipated and Dennen recommends depressing the shanks against the perineum before locking (effectively inching them higher and more anterior on the parietal bone).

We have found also that there is typically a much greater need for downward traction initially before then turning outward and upward to take the fetus into flexion for delivery.

**Ensuring a future for forceps deliveries**

Perhaps the greatest potential threat to forceps deliveries is the dwindling provider base. This has resulted in a subsequent trickle-down effect with fewer providers able to teach the skills, less comfort in offering the method to patients, and then fewer opportunities to demonstrate or involve trainees in these deliveries.

The decline in utilization of obstetrical forceps is, however, a reversible trend. Training programs today have more resources at their disposal for simulation than ever before, and high-fidelity forceps simulations (as demonstrated in the video, “Forceps delivery technique”) offer realistic approximations of the procedure. In addition, attendings should be encouraged to allow trainees to attempt placement because – unlike the cut-clamp that occurs when transecting a uterine artery at hysterectomy – a misguided forceps blade is an easily remedied misstep. Similarly, traction can be performed hand-over-hand so that direct manual supervision for optimal safety is readily achievable.

Finally, a junior attending who has completed training with a handful of forceps deliveries under her belt should be encouraged to continue to identify patients for whom a forceps delivery is appropriate and perfect her craft. One study comparing 118 attending physicians at varying levels of training in fact showed no difference in lacerations or adverse neonatal outcomes between experience levels.17

**DISCLOSURES**

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

**FOR REFERENCES VISIT**

contemporaryobgyn.net/ForcepsDelivery

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**TABLE 4**

<table>
<thead>
<tr>
<th>Common pitfalls in technique while performing forceps deliveries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The cephalic curve is not apposed to the fetal scalp.</td>
</tr>
<tr>
<td>2. The handle is not perpendicular to the floor (usually too caudad).</td>
</tr>
<tr>
<td>3. The handle is moved medially or dropped caudad too soon.</td>
</tr>
<tr>
<td>4. Excessive pressure is applied with the non-vaginal hand.</td>
</tr>
<tr>
<td>5. Right over left blade is interpreted as a mistake when using the English lock.</td>
</tr>
<tr>
<td>6. Trajectory does not consider the fetal station, i.e. first downward then horizontal.</td>
</tr>
</tbody>
</table>

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**READ MORE**

Get a handle on the Scanzoni maneuver Tips on rotating a posterior presentation to anterior and affecting delivery using Luikart forceps. contemporaryobgyn.net/scanzoni
How often do patients turn to social media for STD second opinions?

Study of crowd-sourced ‘diagnoses’ via Reddit

by Ben Schwartz

Social media is ubiquitous today, but one area that has not been fully investigated is its effect on medical diagnoses. A recent research letter in *JAMA* looked at crowd-diagnoses via social media to determine whether they were for a second opinion after seeing a health care professional.

The authors focused their study on Reddit, a social media website with 330 million monthly active users that hosts more than 232 health forums. The research focused exclusively on the subreddit, (r/STD), which allows users to publicly share “stories, concerns, and questions” about “anything and everything STD [sexually transmitted disease]-related.”

The authors obtained all posts from the inception of the subreddit in November 2010 through February 2019. They then drew a random sample of 500 posts and independently coded whether each post requested a crowd-diagnosis, and if so, whether that request was made to obtain a second opinion after seeing a health-care professional.

The r/STD subreddit included 16,979 total posts. There was an 80% agreement among all coders on crowd-diagnoses (Cohen κ = 0.73) and 88% agreement on whether the crowd-diagnoses were requests for a second opinion (Cohen κ = 0.53) among an overlapping sample of 50 posts.

The authors found that:

- **58%** (95% CI, 54%-63%) of posts requested a crowd-diagnosis and
- **31%** (95% CI, 26%-36%) of posts included an image of the physical signs.
- **20%** of those requesting a crowd-diagnosis posted to receive a second opinion after their initial diagnosis by a healthcare professional.
- **87%** (95% CI, 83%-91%) of all posts requesting a crowd-diagnosis received a reply. Median time for the first response was 3.04 hours (range, 59 seconds to 8.8 weeks), but 79% of requests (95% CI, 74%-84%) were answered in less than 1 day.

The authors admit that there are a few limitations to this study. It was limited to one social media platform and a single medical condition. Perhaps more importantly, the accuracy of the diagnoses and whether individuals acted on the provided advice were not investigated.

The authors suggest that health care professionals could “partner with social media outlets to promote the potential benefits of crowd-diagnosis while suppressing potential harms, for example by having trained professionals respond to posts to better diagnose and make referrals to health care centers.”

Ben Schwartz is the associate editor for Contemporary OB/GYN.

**SOURCE**


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**READ MORE** App reveals data about menstrual cycles**

Research shows that common assumptions about ovulation may differ from what happens to women in the real world. contemporaryobgyn.net/OvulationApp
Practical approach to managing menopause

Hormonal therapy is not without controversy but it is still one of the most effective treatments for patients with symptoms.

by NANETTE SANTORO, MD, FRED GONZALES, MD, AND THANH-HA LUU, MD.

Most women who traverse menopause experience significant symptoms and many require at least temporary pharmacological treatment for maintenance of quality of life. Despite the controversy surrounding it, hormone therapy (HT) with either estrogen alone (E) or estrogen plus progestin (E+P) remains the most effective treatment for menopausal symptoms. This article provides a brief history of menopausal hormone therapy (HT) and discusses practical aspects of treatment and discontinuation.

HT from the 1950s to WHI

HT has had a cyclical history of high acceptance and uptake, followed by reduced use related to emergence of risk. Its efficacy for symptoms was recognized in the 1950s and 1960s. Shortly thereafter, increased risk of endometrial cancer associated with E preparations was followed by the addition of progestin to regimens for women with a uterus, and a transient reduction in enthusiasm for HT.

In the 1980s, the strong observational association between hormone use and reduced risk of coronary heart disease (CHD) led to exploration of systemic benefits of HT beyond symptom relief, which triggered another surge in use. However, when the effectiveness of HT as a preventive medication was tested in a randomized clinical trial, the Women’s Health Initiative (WHI), there was no observed reduction in CHD in women with or without a uterus, and a small signal for initial harm emerged, with differential risks depending upon whether a woman had a uterus and was randomized to E+P or had a hysterectomy and therefore took E Alone (Table 1). Differences in treatment with E+P compared to E alone reveal an elevated risk of CHD, venous thromboembolism (VTE), breast cancer in the E+P arm and no risk for breast cancer in the E-only arm (Table 1). The association between breast cancer in the E+P arm was further corroborated by an 11-year follow-up study among participants of the WHI study, which demonstrated a small increase in breast cancer incidence (HR, 1.25 [95%CI 1.07-1.46; P = 0.004]) and mortality (HR, 1.96 [95%CI: 1.00-4.04, P = 0.49]). After publication of these findings, HT prescriptions dropped by 32% overall with a >60% drop in prescriptions for conjugated equine estrogen (CEE)/medroxyprogesterone acetate (MPA).
Based upon these findings, HT is not recommended for preventive use by the American College of Obstetricians and Gynecologists, the Endocrine Society, or the North American Menopause Society (Table 2).8-10 Despite its rigor, the WHI was designed in the late 1980s and was constructed to test the hypothesis that CHD would be prevented by the then-commonly-used preparation of CEE plus MPA (in women with a uterus) or CEE alone in women without a uterus. Subclinical coronary disease was not considered in participant recruitment, and women were stratified into 10-year age bins that included many women who would otherwise not be taking HT for current indications (i.e., symptom relief). This makes some of the endpoints difficult to interpret when advising a current patient in her early 50s who requires symptom control.

### TABLE 2
Considerations for starting hormonal therapy in postmenopausal women

<table>
<thead>
<tr>
<th>Relative contraindications</th>
<th>FDA-approved indications</th>
<th>Other common indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes, hypertriglyceridemia</td>
<td>Vasomotor symptoms</td>
<td>Sleep disturbance</td>
</tr>
<tr>
<td>&gt; 400 mg/dl*</td>
<td>Prevention of bone loss</td>
<td>Mood disorders: anxiety/depression</td>
</tr>
<tr>
<td>Active gallbladder disease</td>
<td>Genitourinary symptoms (including sexual function)</td>
<td>Joint pain, sarcopenia</td>
</tr>
<tr>
<td>Hypoparathyroidism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benign meningoima</td>
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<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Event</th>
<th>E + P</th>
<th>E-Alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD</td>
<td>+6</td>
<td>-3</td>
</tr>
<tr>
<td>Stroke</td>
<td>+7</td>
<td>+12</td>
</tr>
<tr>
<td>VTE</td>
<td>+18</td>
<td>+8</td>
</tr>
<tr>
<td>Breast Ca</td>
<td>+8</td>
<td>+6</td>
</tr>
<tr>
<td>Hip Fracture</td>
<td>-5</td>
<td>-6</td>
</tr>
<tr>
<td>Colon Ca</td>
<td>-6</td>
<td>+1</td>
</tr>
<tr>
<td>Ovarian Ca</td>
<td>+1.5</td>
<td>--</td>
</tr>
<tr>
<td>Lung Ca</td>
<td>+2.5</td>
<td>+2</td>
</tr>
</tbody>
</table>

Numbers in the columns are additional (red) or avoided (green) events per 10,000 women-years of exposure. For example: the green -6 under the E + P column for colon cancer indicates that there would be 6 fewer cases of colon cancer in a group of 10,000 women who used E + P HT for 1 year. Note that the increased risk of CHD in the E + P study was no longer statistically significant upon further follow-up.

### Current evidence from WHI and other trials

More recent follow-up of women who participated in the WHI, now 17 years after its original outcome publication, provide a very reassuring perspective on the long-term harms and benefits of exposure to HT for women in different age groups, and can be helpful for clinicians in guiding their recommendations.11,12 Studies subsequent to the WHI have examined a series of intermediate endpoints to help explain the discrepancy between the WHI and observational studies, specifically the Nurses’ Health Study,7 with respect to the outcome of CHD. When the WHI data are limited to women in the youngest age group (50-59), there is no increased risk of CHD associated with HT. Follow-up studies such as the Kronos Early Estrogen Prevention Study (KEEPS) provided similar reassurance about the safety of “early initiation” of HT with respect to carotid intimal medical thickness (CIMT) and coronary calcium scores. The Late Intervention Trial with Estradiol (ELITE) study demonstrated reduced CIMT accrual with early initiation of HT following menopause and minimal cardiovascular effects with later treatment initiation compared to placebo.13,14 Taken together, these findings support the notion that use of HT in women who are in the early postmenopause does not confer CHD risk, and may be of some benefit.

### Indications for HT

Because of its unmatched effectiveness,
## TABLE 3
Estrogen and progestin preparations for treatment of menopausal symptoms

<table>
<thead>
<tr>
<th>Hormones</th>
<th>Generic name</th>
<th>Brand name</th>
<th>Dose (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Estrogens</strong>*</td>
<td>Conjugated estrogens</td>
<td>Premarin</td>
<td>0.3, 0.45, 0.625, 0.9, 1.25</td>
</tr>
<tr>
<td>Oral</td>
<td>17β-estradiol</td>
<td>Estrace/generics</td>
<td>0.5, 1.0, 2.0</td>
</tr>
<tr>
<td>Transdermal</td>
<td>17β-estradiol</td>
<td>Alora patch†</td>
<td>0.025, 0.05, 0.075, 0.1</td>
</tr>
<tr>
<td></td>
<td>Climara patch‡</td>
<td>0.025, 0.0375, 0.05, 0.075, 0.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Menostar patch‡</td>
<td>0.014</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evamist spray</td>
<td>1.53/spray</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Elestrin gel</td>
<td>0.025/pump</td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>Silastic estradiol</td>
<td>Estradiol vaginal ring*</td>
<td>0.075</td>
</tr>
<tr>
<td></td>
<td>Estradiol vaginal tablet</td>
<td>Vagifem®</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>Estradiol vaginal inserts</td>
<td>Imvexxy®</td>
<td>0.004, 0.01</td>
</tr>
<tr>
<td></td>
<td>Prasterone (DHEA)</td>
<td>Intrarosa®</td>
<td>6.5</td>
</tr>
<tr>
<td></td>
<td>Estradiol vaginal cream</td>
<td>Estrace®</td>
<td>0.1/1g cream</td>
</tr>
<tr>
<td></td>
<td>Conjugated estrogen vaginal cream</td>
<td>Premarin®</td>
<td>0.3125/0.5g cream</td>
</tr>
<tr>
<td></td>
<td>Estradiol acetate</td>
<td>Femring vaginal ring§</td>
<td>0.05, 0.10</td>
</tr>
<tr>
<td><strong>Progestins</strong></td>
<td>Medroxyprogesterone acetate</td>
<td>Provera/generics</td>
<td>2.5, 5.0, 10.0</td>
</tr>
<tr>
<td>Oral</td>
<td>Micronized progesterone</td>
<td>Prometrium</td>
<td>100, 200 (in peanut oil)</td>
</tr>
<tr>
<td>Vaginal</td>
<td>Progesterone</td>
<td>Prochieve 4%</td>
<td>45 every other day</td>
</tr>
<tr>
<td><strong>Combination preparations</strong></td>
<td>Conjugated estrogens and medroxyprogesterone acetate</td>
<td>Premphase</td>
<td>0.625 + 5.0</td>
</tr>
<tr>
<td>Oral sequential†</td>
<td>Conjugated estrogens and medroxyprogesterone acetate</td>
<td>Prempro</td>
<td>0.625 + 2.5 or 5.0; 0.45 + 2.5 or 1.5; 0.3 + 1.5</td>
</tr>
<tr>
<td>Oral continuous¶</td>
<td>Conjugated estrogens and medroxyprogesterone acetate</td>
<td>Activella</td>
<td>1.0 + 0.5; 0.5 + 0.1</td>
</tr>
<tr>
<td></td>
<td>17β-Estradiol and norethindrone acetate</td>
<td>Duavee</td>
<td>0.45 + 20</td>
</tr>
<tr>
<td></td>
<td>17β-Estradiol and micronized progesterone</td>
<td>Bijuva</td>
<td>0.5 + 100; 1 + 100</td>
</tr>
<tr>
<td>Transdermal continuous§</td>
<td>17β-Estradiol and levonorgestrel</td>
<td>Climara Pro‡</td>
<td>0.045 + 0.015</td>
</tr>
<tr>
<td></td>
<td>17β-Estradiol and norethindrone acetate</td>
<td>CombiPatch†</td>
<td>0.05 + 0.14 or 0.25</td>
</tr>
</tbody>
</table>

*Approximately equivalent doses of estrogens are shown in bold.
†Patch applied twice per week.
‡Patch applied once per week.
§Vaginal ring inserted every 90 days
¶Each pill contains estrogen days 1 to 14 and estrogen with progestin days 15 to 28.
‖Each pill or patch contains estrogen and progestin.
HT is the treatment of choice for many symptomatic women, and more recent review of clinical guidelines indicates situations in which extended use for more than just a few years can be considered (as opposed to the “lowest possible dose for the shortest possible time”) after informed, shared decision-making.

While hot flashes and night sweats are the most prevalent symptoms of menopause, vaginal dryness or genitourinary syndrome of menopause (GSM), adverse mood (depression and/or anxiety), and poor sleep are additional clinical complaints that are attributable to menopause and likely to be relieved by HT. This is not an all-encompassing list of symptoms, however, and clinicians may consider a 3- to 6-month empiric trial of HT for atypical symptoms that appear strongly related to menopause. If HT is ineffective, it should be stopped, and other causes and treatments will need to be considered.

Common indications for initiating hormonal therapy in women include vasomotor symptoms (VMS) and genitourinary dysfunction. While the mechanism for VMS is not fully understood and is likely multifactorial, symptoms can be severe and affect quality of life. Average duration of vasomotor symptoms is 7.4 years but durations up to 10 years have been reported. HT has been shown to reduce hot flash frequency and severity by about 75%. Genitourinary symptoms include vaginal or vulvar dryness, discharge, itching, and dyspareunia as a result of vaginal atrophy from hypoestrogenism—GSM. These symptoms can cause sexual dysfunction and detrimental effects on quality of life, self-esteem, and sexual intimacy. With local therapy for atrophic vaginitis, the addition of progesterone is usually not indicated due to no evidence of increased risk of endometrial cancer although very-long-term data are lacking. HT has also been shown to reduce the rate of postmenopausal osteoporotic fractures, with some studies showing a reduction in hip fracture of as much as 33%. While prevention of osteoporosis is not usually an indication for HT, it is an additional benefit that will accrue to women who take it for symptom control. Some studies have shown HT to be effective in postmenopausal women with chronic insomnia although it should not be used as a first-line agent for chronic insomnia, and should only be considered in the presence of other comorbid conditions and if the benefits outweigh the risks of HT. The benefit of HT for reducing joint pain is controversial with preclinical studies showing positive effects that have not been consistently seen with follow-up clinical studies. In the WHI, women randomized to HT were less likely to have joint stiffness compared to placebo. Estrogen therapy, when combined with exercise, has shown efficacy in maintaining and increasing muscle mass, strength, and performance.

Hormone therapy regimens

There are many options when it comes to HT, so the best treatment regimen for each patient can be optimized given the patient’s specific goals and risk factors. Women who have a uterus should take a progestin or a selective estrogen receptor modulator (SERM) in combination with estrogen to avoid the effects of unopposed E on the endometrial lining. For women with prior hysterectomy, if hormone therapy is indicated, E alone should be used as there is no benefit and potential harm to adding P. Various US Food and Drug Administration (FDA)-approved formulations of E are available (Table 3). E can be delivered orally, transdermally, or vaginally. Retrospective studies and meta-analyses have shown that the transdermal mode of delivery carries less risk of VTE, presumably due to bypass of the liver. However, there are no RCTs that have compared oral and transdermal routes directly. A recent observational study of oral estradiol use indicated that its VTE risks were similar to transdermal and less than oral CEE.

Application of transdermal estrogen can be done via patches, gels or sprays. Although there is high acceptability of transdermal routes, complaints from patients with patches include skin irritation and lack of adhesion. There are many blogs and reviews of patches online that may discourage women from trying this effective option. It may be useful to give patients a set of steps to troubleshoot issues with patches when initiating therapy (Table 4). CEE has similar efficacy for vasomotor and genitourinary symptoms when compared to transdermal estradiol.

If GSM is a patient’s primary concern, then vaginal E can be provided in a low dose that improves local symptoms without having systemic effects. It can take the form of a low-dose vaginal ring, cream, tablet or insert. Note that high-dose vaginal creams and rings have systemic effects and may require P for endometrial protection. Table 3 lists vaginal E formulations.

The treatment goal for HT is symptom relief using the lowest effective dose. For this reason, it is most often appropriate to start with lower doses of E and titrate up on a biweekly to monthly basis until symptom relief is optimally balanced.
against side effects. Starting dose varies by compound and route: oral CEE can be started at 0.45 mg/daily, oral estradiol 0.5 mg/daily, and transdermal estradiol 0.025 mg/daily. Patients with surgical menopause may require higher doses for symptomatic relief. Common side effects of E include breast tenderness, vaginal bleeding, bloating, and headaches, which occur less frequently at lower doses. Higher starting doses may be needed for women with severe vasomotor symptoms and significant distress.

Progestins have the same routes of administration as E, as well as delivery via an intrauterine device. However, progesterone is not available in a transdermal formulation. Progestins can be combined with E in a pill or a patch or given separately. Whether treatment is E only or E+P, continuous (daily) use is advised. Exceptions in which cycling E+P is indicated may be for women in their first years of menopause, as they are more prone to breakthrough bleeding, and women with premature menopause who want to have a monthly bleed. For women who do not tolerate E therapy, P can be given alone for treatment of vasomotor symptoms. Oral synthetic progestins and micronized progesterone have been shown to be effective in the treatment of hot flashes. However, micronized progesterone has a less negative effect on serum lipoproteins compared to MPA, reduces postprandial increases in glucose, and can also induce a soporific effect when taken at bedtime. For these reasons, it may be the preferred progestin by many women.

Bioidentical hormones refer to plant-based hormones such as phytoestrogens that share the same chemical or structural composition as hormones produced by the body. In addition, the idea of bioidentical hormones has often been conflated with a product that is more “natural” and therefore safer than conventional pharmaceuticals. Although there are FDA-approved bioidentical hormones such as micronized progesterone and estradiol in numerous forms including the pill, patch, gel, and ring, compounded formulations are readily available but are not under the scrutiny of the FDA approval process. Due to concerns regarding reliability of dosage, purity, lack of evidence regarding superior effectiveness over FDA-approved hormonal formulations and lack of FDA oversight, use of compounded hormonal therapy is not recommended.

Innovations in menopause symptom treatment have led to creation of symptom-specific medications (Table 4). Patients on HT should be monitored every 1 to 2 months once treatment is optimized. Age-appropriate breast cancer screening should be maintained. Any vaginal bleeding that arises after the first 6 months of HT should be investigated further for endometrial hyperplasia and cancer, unless the patient is clearly not yet menopausal.

### TABLE 4

**Symptom-specific recommendations for HT**

- An FDA-approved combination of E and P can be used to treat moderate-to-severe vasomotor symptoms of menopause. It is available in two doses: 0.5 mg/100 mg and 1 mg/100 mg.

- Combination CEE and bazedoxifene (a SERM) (0.45 mg/20 mg) is indicated for treatment of vasomotor symptoms in menopause, as well as osteoporosis prevention, in women with an intact uterus. The SERM acts as an antagonist to estrogen receptors on the endometrium, eliminating the need for P. This type of combination is known as a tissue selective estrogen complex (TSEC). TSEC’s action is highly dependent on the ratio of estrogen to SERM with consideration of balancing between agonist and antagonist effects to improve safety and efficacy. Currently the combination of CEE/bazedoxifene is the only FDA-approved TSEC and is only available in one set ratio.

- Another SERM, ospemifene, can be used for treatment of moderate-to-severe dyspareunia associated with GSM. Ospemifene does not appear to have agonistic activity on the endometrium. Studies have shown no significant changes to the endometrium on vaginal ultrasound at 52-weeks use of this medication. Although it does have agonistic activity in breast tissue, ospemifene is contraindicated in women with a history of breast cancer.

- Dehydroepiandrosterone (DHEA; prasterone) is also FDA-approved for GSM symptoms, specifically vaginal pain. DHEA is an abundant steroid hormone that does not have a cognate receptor; rather, it is metabolized into androgens and estrogens in the periphery. When given vaginally, it appears to cause minimal change in circulating estradiol levels and may be locally metabolized primarily to androgens, which provide its therapeutic effect.
Perimenopause’s negative impact on sexual function

by JUDITH M. ORVOS, ELS

A new study by Italian investigators points to a link between perimenopause and sharp decline in sexual function. The results, published in *Menopause*, show that vaginal atrophy—a treatable condition—is the factor that has the most impact on the negative trend.

The cross-sectional study enrolled 518 women aged 40 to 55 years at 30 centers across Italy. The authors analyzed relationships between vaginal atrophy and symptoms associated with it and the Female Sexual Function Index (FSFI) score, which is composed of 19 questions around the domains of desire, arousal, orgasm, dyspareunia, lubrication, and sexual satisfaction.

Vaginal atrophy was defined as presence of a pH > 5, subjective vaginal dryness, and an objective sign, as assessed by a medical doctor. Mucosal pallor and dryness, thinning of vaginal rugae, mucosal fragility, and presence of petechiae were the signs considered.

Overall, 70.6% of participants had sexual dysfunction, as defined by a FSFI score < 26.55. It was seen in 55% of those aged 40 to 45, compared with 82.8% of those aged 52 to 55 (*P* < 0.01). From 48 to 51 versus 46 to 48 years, mean FSFI score and sexual dysfunction increased: 23.13 ± 9.76 vs. 19.49 ± 9.88; *P* < 0.05). A similar trend was seen from ages 48 to 51 vs. 52 to 55: 21.3 ± 8.06 to 17.59 ± 9.11; *P* < 0.01).

Age, weight, ex-smoking status, sedentary lifestyle, menopausal status, subjective vaginal dryness, dyspareunia, and vaginal atrophy were all inversely related to a woman’s FSFI score. Age, vaginal atrophy, and presence of vaginal dryness were all independent determinants of FSFI (R2 0.08; *P* = 0.011). The score was independently correlated (R2 0.116) with weight (CR -0.067; 95% confidence interval [CI] -0.126, -0.006; *P* < 0.032), menopausal status (CR -2.406; 95% CI -4.180, -0.63; *P* < 0.008), and vaginal dryness (CR -5.647; 95% CI -7.677, -3.618; *P* < 0.0001).

The only variable that correlated independently with each FSFI domain—

including desire, arousal, lubrication, orgasm, satisfaction, and dyspareunia—was vaginal atrophy. The authors concluded that it is the symptom most closely related to all domains of female sexuality. They believe that prospective studies are needed to determine whether selective treatment of vaginal dryness improves female sexual function in perimenopausal women.

Said North American Menopause Society Medical Director Dr. Stephanie Faubion in a press release, “Given the high prevalence of sexual dysfunction in women, identifying an eminently treatable contributing factor such as vaginal dryness may allow women to maintain their sexual function during the menopause transition.”

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

**SOURCE**

HAVE YOUR SAY ONLINE
How often do you refer patients with symptoms associated with menopause to a menopause specialist? Let us know by taking our poll at contemporaryobgyn.net/MenopauseSpecialist.
JOIN our large, multi-disciplinary team of OB/GYNs, CNMs, Fam Med Providers, and CNPs as a specialist/consultant at Erie Family Health Centers in Chicago. Erie performed >2,600 deliveries last year, ranking #1 in IL and top 10 in the country for births by a Federally Qualified Health Center. Work with OB/GYN and Family Medicine residents and medical students at our partner hospitals. Participate in a full spectrum practice where you function as a consultant, not a primary care physician. All Erie sites qualify for NHSC with a HPSA score of 19.

AAGL study links cystoscopy post-robotic hysterectomy with UTI

by LINDA MARIE WETZEL, RN

Young women who undergo longer-more complex hysterectomies done robotically may have an increased incidence of UTI, according to new research discussed at the 2019 American Association of Gynecologic Laparoscopists (AAGL) Congress. Further, these patients were also noted to have a higher incidence of a malignant postoperative diagnosis.

The results were presented at the 2019 American Association of Gynecologic Laparoscopists (AAGL) Congress in Vancouver by Katherine Kleinberg, a medical student from Burrell College of Osteopathic Medicine, Las Cruces, NM. Ms. Kleinberg was invited by the AAGL Scientific Committee to present her study findings at the Congress.

“The objectives of this study were to evaluate incidence of UTI status post-robotic-assisted hysterectomy and routine cystoscopy, to compare instances from malignant and benign surgical cases, and justify routine cystoscopy in robotic assisted hysterectomy,” Ms. Kleinberg stated.

The 151 cases that made up this study were obtained from the database of a single gynecologic oncologist. In these cases, minimally invasive robotic total hysterectomy was performed for treatment of both benign and malignant disease, and patients who did not meet the standard of minimally invasive surgery were excluded. In all cases, routine cystoscopy was performed to detect any intraoperative injury to the ureters and bladder. No detectable urinary tract injury was reported in any of these patients.

In those cases where routine cystoscopy was performed, dysuria was the most common urinary tract complaint in postoperative clinic visits. Postoperative UTIs were found in 21 (13.9%) of patients within 30 days of the procedure, with 2% to 9% of benign cases and 4% to 31% of malignant cases presenting with UTI. Patients with postoperative UTIs were noted to have had longer operating room times, more complex surgeries, higher estimated blood loss, and were younger. The only statistically significant variable reported between the malignant and benign cohorts was presence of postoperative complications, with incision cellulitis being the most common complication seen in patients with malignant disease.

The results demonstrate that, although UTIs are common in women undergoing gynecologic surgery, rates of infection appeared to be higher in this cohort composed of patients in whom routine cystoscopy was performed. Ms. Kleinberg noted that a similar study consisting of a larger sample size should be considered.

Linda Marie Wetzel, RN, is the executive editor of Contemporary OB/GYN.

SOURCE
Kleinberg KA, Saldivar, JS. Incidence of post-op urinary tract infections after routine cystoscopy in minimally invasive robotic gynecologic surgery. Oral presentation at: AAGL 48th Congress on MIGS; November 12, 2019; Vancouver, Canada.
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