

ECHO

A CME SELF-STUDY ACTIVITY

FALL 2008



Protecting Your Patients

Oral Contraceptives: This is Not Your Mother's Pill

PATRICIA J. SULAK, MD

Genital Herpes: Diagnosis, Treatment and Counseling

DEBRA L. HILL-BUSSELLE, MD, FACOG

Pelvic Adhesions: Pathophysiology and Prevention

KAYLEN M. SILVERBERG, MD

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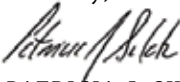
DEAR HEALTHCARE PROFESSIONAL,

Welcome to the fall issue of ECHO, an educational publication that is available to all healthcare providers who attend Omnia Education's live Continuing Medical Education (CME) activities. ECHO's goal is to reinforce key educational highlights from our live symposia in an abbreviated format.

This issue of ECHO focuses on patient protection in three different areas. What you can do to safeguard them from unintended pregnancy and unwanted symptoms of menstruation, and the prevention of the transmission of genital herpes and protection from pelvic adhesions through barriers.

I hope this self-study activity will serve as a refresher and help enhance the level of retention from the live event you attended. Educating women's healthcare professionals is what Omnia Education does—all day, every day and I hope you'll take advantage of obtaining additional CME credits by completing this activity. Please enjoy this complimentary issue and look for the next issue coming this winter.

Sincerely,



PATRICIA J. SULAK, MD

Omnia Education, Medical Advisory Board

Instructions for Credit Read the three articles attached and complete the self-assessment and activity evaluation on page 11. Fax or mail the completed form as indicated on the form instructions. Your CME certificate will be sent via email. If an email address is not provided, your certificate will be sent via mail.

Course Description Three distinct clinical conditions are discussed in this issue of ECHO that collectively deal with prevention, protection and the physician's role in providing counseling.

The contraception focused article will discuss the availability of new and developing technologies which have been presenting themselves to the medical community. Unintended pregnancies account for about half of all pregnancies in the country and many women are still not consistent in compliance with birth control regimens.

The second article discusses genital herpes prevention, counseling to reduce transmission and the difficulty of diagnosis, type specific serology, and the recommended guidelines for treatment.

The article discussing pelvic adhesions focuses on the benefits, use and implementation of adhesion barriers and provides information on appropriate counseling of patients regarding adhesion prevention.

Target Audience This course is designed to meet the Continuing Medical Education needs of the practicing obstetrician and gynecologist, primary care physician, clinical nurse practitioner and physician assistant.

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Oral Contraceptives: This Is Not Your Mother's Pill

LEARNING OBJECTIVE

AT THE CONCLUSION OF THIS ACTIVITY, PARTICIPANTS SHOULD BE ABLE TO:

- Discuss the efficacy and side effects of optional contraceptive methods to counsel and improve the quality of life for patients of reproductive age and beyond

Until the last five years, the same basic oral contraceptive (OC) design of 21 combination estrogen plus progestin pills followed by seven placebo pills persisted. Numerous studies now confirm that the 21/7 regimen needs to be modified. The seven-day hormone-free interval (HFI) in today's OCs is associated with reduced pituitary-ovarian suppression and hormone withdrawal symptoms. Modifications in OC regimens are now appearing on the market secondary to the accumulated scientific data on the disadvantages of today's 21/7 pills.

DRAWBACKS OF THE 21/7 REGIMEN

The original decision to use a 21/7-day pill regimen was not based on a physiologic need for 13 cycles per year. Rather, to make the pill socially acceptable and to provide monthly reassurance she was not pregnant, an HFI was instituted to create a hormone withdrawal bleed. While 21/7 OCs have been the mainstay over the 45-year history of the pill, reductions in dosage of hormones have led to a need to redesign the standard regimen.

Lack of Pituitary-Ovarian Suppression

Although today's low-dose 21/7 OCs are very effective in preventing pregnancy if taken consistently, studies have confirmed incomplete inhibition of pituitary-ovarian function with follicular growth and resultant endogenous hormone production and potential for follicular cysts and ovulation.¹⁻⁵ With a standard seven-day HFI, FSH begins to increase on day three to four of the HFI, allowing follicular

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recruitment and estradiol production.⁵ Pregnancy can occur because of escape ovulation, even in perfect users. Low dose OCs have also been shown to provide little to no protection from the development of functional ovarian cysts because of the seven-day HFI.⁶ Unfortunately, most of our patients do not take their pills perfectly, increasing the chance of ovarian cysts and pregnancy.

Hormone Withdrawal Symptoms Today's standard low dose 21/7-day OCs have also been responsible for the occurrence of nuisance side effects. Published data docu-

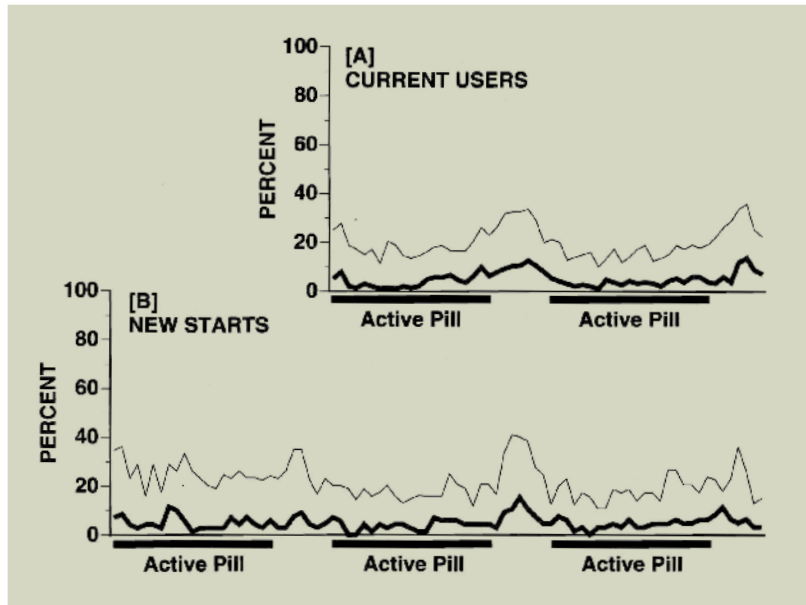


Oral contraceptives are the most common method of reversible contraception and provide women with many non-contraceptive benefits.

ment an increased incidence of menstrual-related symptoms during the seven-day HFI.⁷ In a prospective observational study of 262 women taking 21/7 OCs, each of the menstrual symptoms recorded (headache, pelvic cramps or pain, bloating or swelling, and breast tenderness) was found to occur significantly more frequently ($P < 0.001$) during the HFI than during the three active pill weeks. [TABLE 1] Symptomatology during the HFI also led to significantly increased use of pain medication ($P = 0.001$). Many women may be discontinuing their OCs because of hormone withdrawal symptoms induced by the seven-day HFI.

FIGURE 1

Frequency of Headaches Reported by Women Utilizing Combined OCs



Source: Sulak P, et al. *Obstet Gynecol.* 2000;95:261-266.

[A] CURRENT USERS – patients with a history of prior OC use
 [B] NEW STARTS – patients with no prior history of OC use starting OC therapy for the first time
 UPPER LINE – all headaches LOWER LINE – severe headaches

Unnecessary Withdrawal Bleeding Both spontaneous menstrual bleeding associated with ovulatory cycles and iatrogenically induced scheduled bleeding associated with 21/7 OCs are due to endogenous or exogenous hormone withdrawal. However, menstrual bleeding associated with an ovulatory cycle fulfills a physiologic need to slough the secretory endometrium in preparation for a new cycle and possible pregnancy. In contrast, there is no health-related reason to bleed while taking OCs. All OCs today are progestin dominant and prevent endometrial proliferation, creating a decidualized, attenuated endometrium. For many women, this artificially induced bleeding on 21/7 OCs is undesired.

MODIFYING THE 21/7 OC REGIMEN

OC regimens that extend the active pill interval beyond the conventional 21 days have been used for decades in clinical practice. Prior to the introduction of the

first extended regimen in 2003, use of an extended regimen required creative prescribing with instructions on eliminating the seven-day HFI and going immediately into the next package of pills.⁸ Newer FDA approved OC regimens have centered around modifications of the seven-day HFI by:

- Shortening to less than seven days
- Decreasing the frequency
- Adding low dose estrogen
- Eliminating it entirely

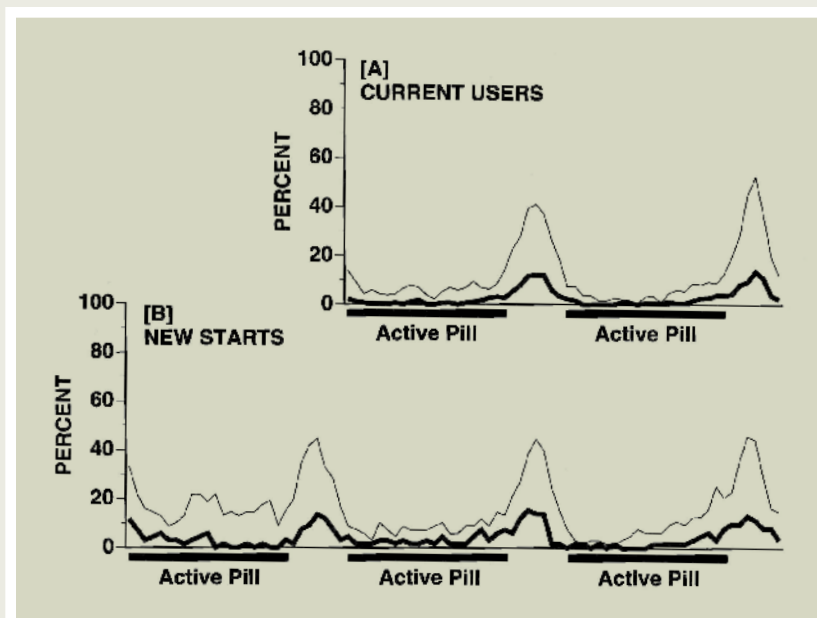
Shortening the Seven-day HFI Shortening the HFI has been documented to provide greater pituitary ovarian suppression.⁵ Randomized controlled trials have evaluated regimens containing 24 days of active combined therapy and a shortened (four-day) HFI.⁹⁻¹⁰ These FDA approved regimens contain either 20 mcg ethinyl estradiol (EE)/3 mg drospirenone or norethindrone acetate (NETA) 1 mg/EE 20 mcg. Shortening the HFI to four days may provide a reduction in premenstrual

symptoms. The effect of the 24/4 regimen containing 3 mg drospirenone/20 mcg EE on reducing symptoms of premenstrual dysphoric disorder (PMDD) was assessed in a double-blind, randomized placebo controlled trial confirming significant improvements in premenstrual symptoms compared to placebo.¹¹ ($P < .001$)

Reducing the Frequency of the Seven-day HFI It has been common practice for practitioners to allow patients to extend the number of active pills beyond the standard three weeks of active pills to 6, 9, 12, or greater weeks followed by a seven-day HFI.^{8,12} The first approved extended regimen became available in the United States in 2003 with a regimen that consisted of a 91-day cycle with 84 days of levonorgestrel (LNG) 150 mcg/EE 30 mcg followed by a seven-day HFI.¹³

Adding Estrogen to the Seven-day HFI A new OC approved in the United States

FIGURE 2

Frequency of Pelvic Pain and Cramps Reported by Women Using Combined OCs

Source: Sulak P, et al. *Obstet Gynecol.* 2000;95:261-266.

- [A] **CURRENT USERS** – patients with a history of prior OC use
 [B] **NEW STARTS** – patients with no prior history of OC use starting OC therapy for the first time
UPPER LINE – all pelvic pain and cramps **LOWER LINE** – severe pelvic pain and cramps

in May, 2006, both extends combination active therapy to 84 days and adds low-dose estrogen to the usual seven-day HFI. The safety and efficacy of a 91-day regimen utilizing LNG 150 mcg/EE 30 mcg with 10 mcg EE during the final week was evaluated in an open-label, multi-center trial involving 1006 women 18-40 years (mean 27.4 years).¹⁴ Bleeding occurs during the seven-day EE monotherapy interval due to progestin withdrawal. Addition of low dose EE to the typical seven-day HFI of the 84-day extended regimen has been shown to provide greater pituitary ovarian suppression and less follicular cysts than a typical seven-day HFI.¹⁵ In addition, there was a tendency towards less headaches during the EE-supplemented seven-day interval compared to a standard seven-day HFI.

Eliminating the Seven-day HFI

Continuous OC administration without an HFI has been commonly employed in clinical practices for treatment of endome-



Many women may be discontinuing their oral contraceptives because of hormone withdrawal symptoms induced by the seven-day hormone free interval.

triosis and prevention of numerous menstrual-associated problems.^{8,12} Prospective studies have confirmed reductions in premenstrual symptoms, bleeding, and menstrual-associated migraines compared to baseline 21/7 regimens.¹⁶⁻¹⁸ The impact of eliminating the seven-day HFI on incidence of self-reported headaches was assessed in an open label study of a 168-day extended regimen containing 3 mg drospirenone and 30 mcg EE.¹⁸ Significant reductions in daily headache scores were detected compared to the baseline 21/7 cycle ($P < .001$) with significant improvement in impact of headache on work, family and social functions ($P < 0.05$). In this same study, the incidence and severity of premenstrual-type symptoms was evaluated.¹⁶ PMS-type symptoms decreased significantly in all segments of the extended regimen compared with the baseline 21/7 cycle ($P < .001$). A continuous daily regimen of LNG 90 mcg/EE 20 mcg administered daily for 12 months has been approved by the FDA.

Extended/continuous OC regimens can be associated with nuisance breakthrough bleeding/spotting that can lead to frustration and discontinuation. In an extended OC study, patients experiencing a minimum of seven consecutive days of spotting and/or bleeding were randomized to either a three-day break from the extended regimen and then immediately resuming the extended regimen versus continuing their extended regimen to see if the breakthrough bleeding would resolve.³⁷ Institution of a three-day break was significantly more effective in resolving the bleeding than continuing active pills ($P < .0001$). This shortened HFI can only be instituted after a minimum of three weeks of active pills.

SUMMARY

OCs are the most common method of reversible contraception and provide women with many non-contraceptive benefits. With the reduction in hormone content over the past few decades, the standard

Newer oral contraceptive regimens offer the option of an induced withdrawal bleed every month, every three months, or no forced withdrawal bleed.

greater contraceptive efficacy and reduction in menstrual-associated symptoms. Today, women have many options if they elect to initiate OCs. Newer OC regimens offer the option of an induced withdrawal bleed every month, every three months, or no forced withdrawal bleed. Determining desired menstrual frequency is important to match the pill with the patient.

TABLE 1
Hormone Withdrawal Symptoms in Oral Contraceptive Users

N = 262	21-day Active Pill Period	7-day Hormone Free Interval	p value
Pelvic pain	21%	70%	<.001
Headaches	53%	70%	<.001
Breast tenderness	19%	58%	<.001
Bloating/swelling	16%	38%	<.001
Use of pain meds	43%	69%	<.001

Source: Sulak P, et al. *Obstet Gynecol*. 2000;95:261-266.

seven-day HFI has been shown to lead to unacceptable pituitary-ovarian escape leading to follicular development, endogenous estradiol production, and possible ovarian cyst formation and ovulation. Hormone withdrawal symptoms as a result of the seven-day HFI can lead to discontinuation and unintended pregnancy. Modifications in the 21/7 design have the potential for

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Genital Herpes: Diagnosis, Treatment and Counseling

Genital Herpes (GH) is a common viral sexually transmitted infection (STI) caused by Herpes Simplex Virus HSV 1 or HSV 2. The clinical diagnosis can be difficult and genital herpes is often undiagnosed or misdiagnosed by both patients and clinicians. Understanding the types of testing available can help clinicians accurately diagnose genital herpes. Counseling is an essential part of management and should include a discussion of treatment options and how to reduce transmission.

PREVALENCE

Genital herpes is the most prevalent sexually transmitted infection in the United States. More than 60 million Americans (19% of the U.S. adult population) are infected with genital HSV, 50 million with genital HSV-2 and 10-15 million with genital HSV-1. Seroprevalence varies by race and gender. African-Americans have the highest seroprevalence rate (52%), followed by Hispanics (26%), Caucasians (18%) and then Asians (10%). These racial disparities are largely unexplained. Additionally, females are twice as likely to be infected than males (23.1% vs. 11.2%). Anatomy and immunology may explain this difference.¹ 80-90% of genital HSV infections have not been diagnosed.² Genital herpes is more common in primary care and ob/gyn practices than most clinicians believe. This lack of awareness is a major contributing factor to the under-diagnosis of genital HSV. In a study that targeted middle and upper middle class patients in the suburbs of six large U.S. cities, 5452 patients aged 18 to 59 years underwent serologic testing: 25.5% tested positive for HSV-2. 88% of these patients had not previously been diagnosed.³

SYMPTOMS

Genital HSV infection causes a wide spectrum of disease. Classic HSV (painful genital vesicles or ulcers) presents in only about 20% of cases.^{2,4} Most HSV out-

LEARNING OBJECTIVES

AT THE CONCLUSION OF THIS ACTIVITY, PARTICIPANTS SHOULD BE ABLE TO:

- Discuss the prevalence of genital herpes and how to improve diagnosis
- Apply current guidelines for screening and testing, treatment and counseling of patients with genital herpes
- Discuss current recommendations for genital herpes in pregnancy (reducing vertical transmission)

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breaks are more subtle, and characterized by recurrent symptoms of vulvar erythema, vulvar/rectal itching and burning, dysuria, pain, cervical/vaginal discharge, and excoriations or fissures. Recurrent herpetic lesions are not limited to the genitalia. These viruses establish latency in the nerves of the sacral ganglia, and, with reactivation, herpetic lesions and symptoms can occur anywhere in the "boxer shorts" area.⁴

Genital HSV is often misdiagnosed by both physicians and patients. Common



It is important to remember that up to 70% of initial genital herpes infections are asymptomatic or unrecognized acquisitions.

misdiagnoses include vulvar yeast infection, vulvar contact dermatitis, hemorrhoids, urethritis/urethral syndrome, urinary tract infection, shingles or vaginitis. First-episode infections, when symptomatic, are usually the most severe, causing multiple, painful lesions,

inguinal adenopathy, systemic symptoms and fever. Recurrent outbreaks are typically milder and of shorter duration (average six to eight days).⁵ It is important to remember that up to 70% of initial genital herpes infections are asymptomatic or unrecognized

70% for crusted or recurrent lesions.^{5,7} PCR testing (amplified DNA swab testing), is three to four times more sensitive than HSV viral culture, can detect smaller amounts of virus, is less dependent on sampling and transport since live virus is not necessary, and results are available

antibody tests are available, but are not accurate, are not type-specific and cannot determine when infection occurred. The IgM tests should not be used in making a GH diagnosis.⁸

Candidates for serologic testing include patients with: recurrent genitourinary symptoms, a culture-negative lesion, clinical diagnosis only, requesting STD screening or herpes testing, an STD diagnosis, a current or past partner with genital herpes, or HIV-infection.⁷

HOW DO YOU EVALUATE A PATIENT WITH A SUSPICIOUS GENITAL LESION?

Swab the lesion and send it for either viral culture or PCR testing. If the test is positive for HSV-1 or HSV-2, you have your diagnosis. Without serology, you do not know if this is a newly acquired infection or a first-recognized clinical outbreak. Negative serology would indicate newly acquired infection, whereas a positive serology test means the patient has been infected for an indeterminate amount of time.

If the swab test is negative, you should do serologic testing to rule out a false negative test. Test for both HSV-1 and HSV-2 with glycoprotein G-based type-specific tests. The various results and interpretations are listed in Table 2.

COUNSELING

The goals of counseling are twofold: to help the patient cope with the disease and to educate the patient on the natural history of genital herpes, including outbreaks, asymptomatic shedding, transmission and options for therapy. Episodic antiviral therapy reduces the duration and severity of each outbreak but will not decrease number of outbreaks nor days of asymptomatic shedding.⁷ Daily antiviral therapy reduces outbreaks and asymptomatic shedding by 70-80%.^{4,7} In discordant couples, daily suppressive therapy reduces transmission by approximately 50%.⁹ The CDC and ACOG recommend daily suppressive therapy for the infected partner in a discordant relationship, along with safer

The goals of counseling are twofold: to help the patient cope with the disease and to educate the patient on the natural history of genital herpes, including outbreaks, asymptomatic shedding, transmission and options for therapy.

acquisitions. Thus, patients can be infected for years and not have been diagnosed. Serologic studies show that up to 50% of first clinical episodes are, in reality, first-recognized recurrences, not newly-acquired infection.⁶

DIAGNOSIS AND TESTING

In the past, clinicians have relied on the appearance of genital lesions to make a diagnosis of genital herpes. The CDC states that “the clinical diagnosis of genital herpes is both insensitive and nonspecific. Therefore, the diagnosis of genital herpes should be confirmed by laboratory testing with type-specific virologic or serologic testing.”⁷ There are two options for lesion testing: viral culture or polymerase chain reaction (PCR). Per CDC Guidelines, lesion culture is the preferred virologic test for patients with genital ulcers or other mucocutaneous lesions. Culture can differentiate HSV-1 from HSV-2.⁷ Viral culture requires careful sampling to ensure that a live virus is obtained and requires special and rapid transport to the lab to ensure viability of the virus. Results can take up to 14 days. Culture has a high specificity (true positive results) but a low sensitivity (high rate of false negatives).¹³ A negative culture does not mean viral infection is not present. The false negative rate is 20% for primary infection in the vesicle stage, 50% for ulcerative stage and

in one to two days. PCR testing is more expensive, available at national labs, and used by many clinicians, but not yet FDA-approved for genital lesions.^{5,7}

Both type-specific and non-type-specific antibodies to HSV develop during the first several weeks post-infection and persist indefinitely. Antibodies are present in 50% at three weeks, 70% at six weeks, and 95% at 12 to 16 weeks. Accurate type-specific, glycoprotein G-based IgG antibody tests have been available since 2000. They can accurately detect and differentiate between HSV-1 and HSV-2 (see Table 1). Older, non-type-specific testing is available, but confers a 40-50% chance of cross reactivity between HSV-1 and HSV-2.⁸ IgM

**TABLE 1
FDA-approved Assays**

Biokit-HSV (a point of care test) and the newer HerpeSelect® Direct kit FDA-cleared assays
HerpeSelect®-1 ELISA and HerpeSelect™-2 ELISA
HerpeSelect® 1 and 2 Immunoblot
Captia™ ELISA 1 and 2

Centers for Disease Control and Prevention, Workowski KA, Berman SM, Sexually Transmitted diseases treatment guidelines, 2006. MMWR Recomm Rep. 2006;55(RR-11):1-94.

TABLE 2

HSV-1 Serology	HSV-2 Serology	Interpretation
–	+	Genital HSV-2 infection
+	–	HSV-1 infection; site unknown. Repeat HSV-2 serology in 8 to 12 weeks. Reswab subsequent lesions.
+	+	Genital HSV-2 infection; probable orolabial HSV-1 infection
–	–	Repeat HSV-1 and HSV-2 serology in 8 to 12 weeks. Reswab subsequent lesions.

Ashley R, Wald A. Genital Herpes: review of the epidemic and potential use of type-specific serology. *Clin Microbiol Rev.* 1999;12(1):1-8.

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sex practices including condom usage and avoidance of sexual activity during outbreaks to reduce transmission.^{5,7}

CHARACTERISTICS OF GENITAL HSV-2 VS HSV-1

Genital HSV-2 is usually acquired from penile-vaginal or penile-anal intercourse. HSV-2 causes more frequent recurrences (average four to six per year) and higher rates of asymptomatic shedding (three to ten days per month). Asymptomatic shedding persists indefinitely. Genital HSV-1 is usually acquired via oral-genital sex, has less frequent recurrences (less than one per year), less asymptomatic shedding (<one day per month), and is increasingly responsible for new cases of genital herpes in college students. Frequent, recurrent genital herpes outbreaks are usually caused by HSV-2.^{4,5,10,11,13}

HOW DO YOU COUNSEL A PATIENT WHO IS HSV-2 SEROPOSITIVE, BUT ASYMPTOMATIC?

The CDC states that seropositive asymptomatic persons should receive the same counseling as those who are seropositive and symptomatic.⁷ Asymptomatic patients shed virus asymptotically and can transmit infection.¹² Most patients who state they are asymptomatic actually do have unrecognized symptomatic disease. With education, up to 87% of patients who

were HSV-2 seropositive and asymptomatic could recognize genital symptoms consistent with genital herpes within three months of diagnosis.¹²

GENITAL HERPES IN PREGNANCY

The incidence of neonatal herpes is estimated at 1/3200 live births.¹⁴ Most cases of neonatal herpes occur when maternal acquisition of HSV occurs near delivery. Most mothers of infants with neonatal herpes do not have a history of genital herpes. Routine screening of pregnant women has not been advocated by the CDC nor ACOG.^{7,15} However, both organizations state that there may be "high risk" populations who would benefit from screening. ACOG recommends asking all pregnant women if they have genital herpes or have symptoms consistent with genital herpes. Women who have active recurrent genital herpes should be offered suppressive therapy at or beyond 36 weeks gestation. Cesarean delivery is indicated in women with active genital lesions or prodromal symptoms, such as vulvar pain or burning at delivery, because these symptoms may indicate an impending outbreak. Cesarean delivery is not recommended for women with a history of HSV infection but no active genital disease during labor.¹⁵ Genital HSV-1 is more efficiently transmitted to the neonate than HSV-2.¹⁴

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Pelvic Adhesions: Pathophysiology and Prevention

LEARNING OBJECTIVE

AT THE CONCLUSION OF THIS ACTIVITY, PARTICIPANTS SHOULD BE ABLE TO:

- Analyze the medical impact, as well as the pathophysiology, of pelvic adhesions and assess the use of barriers to lessen the incidence of adhesions

Pelvic adhesions present a significant problem following gynecologic and obstetric surgery. Over 400,000 surgical procedures are performed annually for lysis of adhesions, with the resulting economic impact exceeding \$1.3 billion.^{1,2} Approximately 40,000 of these operations are performed for tubal and/or ovarian adhesions. In addition, 30-35% of bowel obstructions are thought to result from these adhesions.

INCIDENCE

Many gynecologic and obstetric procedures are associated with an increased risk for development of pelvic adhesions. These include:

- Myomectomy
- Hysterectomy
- Resection/ablation of endometriosis
- Lysis of adhesions
- Cesarean section

The incidence of pelvic adhesions at second look laparoscopy ranges from 55%-100% following exploratory laparotomy.³ Following myomectomy, de novo adnexal adhesions develop in up to 94% of patients who had posterior uterine incisions compared to 56% of patients who had anterior or fundal incisions.

Pelvic adhesions are also a significant problem following Cesarean section, especially when the peritoneum is not closed. A recent prospective study demonstrated a 52% incidence of adhesions if the parietal peritoneum was closed at primary Cesarean section, compared with a 73% incidence if the parietal peritoneum was not closed ($P < 0.01$).⁴

Peritoneal closure at primary Cesarean section was associated with a five-fold protective effect against adhesion development.

ADHESION PREVENTION: MECHANISMS

The pathologic process of adhesion formation mimics the physiologic process of wound healing. Data suggest that no new adhesions form more than seven days following surgery.⁵ Therefore, tissues must ideally be separated for at least five, if not seven, days in order to minimize adhesion formation. Most investigators believe that the best way to prevent adhesion formation is to minimize tissue damage, which can be accomplished by following some basic tenets of microsurgery:

- Minimize tissue manipulation
- Use continuous irrigation to prevent tissue desiccation
- Limit the use of cautery and locking sutures
- Use the smallest gage of least reactive suture
- Strive for absolute hemostasis
- Use prophylactic antibiotics
- Close the parietal peritoneum

SURGICAL ADJUNCTS: CRYSTALLOID SOLUTIONS

Crystalloid solutions are commonly used as intraoperative surgical irrigants. Many surgeons leave some crystalloid in the pelvis upon completion of a procedure, believing that this will allow the tissues to float away from each other and

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minimize adhesion formation. Unfortunately, the intraperitoneal residence time for crystalloid is less than 20 hours — i.e. far less than the requisite seven days necessary to have a significant effect.⁶ Wiseman’s meta analysis of 259 total reports from 1966-1996 demonstrated that the adhesion-free outcome was enhanced when crystalloid was not left in the pelvis following either laparoscopy or laparotomy.⁶ Their conclusion was that crystalloid “does not reduce adhesion formation; its use is not warranted”.

ADHESION BARRIERS: THE PERFECT ADHESION BARRIER

The perfect adhesion barrier would be non-reactive, supplied in a formulation that would be easily administered at laparoscopy or laparotomy, and have an adequate residence time of at least five to seven days in order to maximize efficacy and minimize adverse effects. Following that time, it should be absorbed or metabolized without initiating a tissue response, and the metabolic products must be inert and easily excreted.

Gynecare Interceed Adhesion Barrier Interceed is made of oxidized regenerated cellulose⁷ and it adheres without suturing. It turns into a gel within eight hours, forming a gelatinous “cocoon” overlying the tissue within 20 hours. Within three days, Interceed degrades into glucose and glucuronic acid, and it is completely excreted within 10 days of application.

Interceed is easy to apply at laparotomy, and although laparoscopic use is feasible, there is an FDA “black box” warning regarding the laparoscopic use of Interceed, indicating that neither safety nor efficacy have been demonstrated.

Multiple surgical trials have demonstrated clinically significant efficacy of Interceed. Other surgical trials and

communications have suggested that, in the absence of absolute hemostasis, Interceed is less effective and potentially adhesiogenic.^{8,9} Upon contact with blood, Interceed often turns black. This led to the recommendation that black Interceed should be replaced after achieving better hemostasis.

Wiseman’s meta analysis demonstrated a 24.2% reduction in adhesions on the side treated with Interceed, compared with the control side ($P < 0.001$), suggesting that the barrier was 1.5 to 2.5 times more effective than good surgical technique alone.⁹



Surgical procedures associated with a significant incidence of pelvic adhesions include myomectomy, resection/vaporization of endometriosis, lysis of adhesions, tuboplasty, ovarian cystectomy, hysterectomy, and Cesarean section.

The authors corroborated several earlier reports suggesting that Interceed might be ineffective in the presence of bleeding, and questioned its residence time.

Gore-Tex Made of polytetrafluoroethylene, Gore-Tex prevents cellular growth.¹⁰ It is non-inflammatory and non-absorbable, which led to the recommendation that it be removed at second look laparoscopy. Gore-Tex does not adhere to tissue and has to be sutured in place. Although only a few trials have been published, they do suggest clinical efficacy.¹¹ A single long-term observational study evaluated the safety of Gore-Tex ($N = 146$).¹² In this trial, 58 patients had Gore-Tex placed laparoscopically, while 88 underwent laparotomy. Twenty-four patients underwent a second look laparoscopy. There was a single postoperative infection that did not necessitate removal of the membrane, suggesting that the membrane can remain in place indefinitely.

Seprafilm Adhesion Barrier Seprafilm is a sheet of sodium hyaluronate and carboxymethylcellulose. It is non-antigenic, biocompatible, and non-hemolytic. Seprafilm does not promote bacterial growth, even in the presence of infected bowel, and several studies have demonstrated no inhibition of wound healing.

Seprafilm adheres to tissue without suturing, turns into a gel within 24-48 hours, and remains in place for up to seven days. There is no evidence that Seprafilm is adhesiogenic in the presence of blood, although tissues should be dry prior to application so that the film will lay flat and adhere. The two most commonly cited concerns regarding Seprafilm include the learning curve required to place it adequately and the fact that it cannot be applied laparoscopically.

Seprafilm is the most widely studied adhesion barrier, with more than 20 published studies demonstrating efficacy

in over 4,600 patients. A general surgical trial evaluating placement of Seprafilm in patients undergoing colectomy for ulcerative colitis found that fifty-one percent of study patients were adhesion-free, compared to 6% of control patients.³³ A recent multinational, prospective, randomized study demonstrated that not only did Seprafilm reduce the formation of postoperative adhesions, it also reduced the incidence of subsequent small bowel obstruction.³⁴ A prospective, randomized gynecologic myomectomy trial demonstrated that Seprafilm significantly reduced the incidence of postoperative adhesion formation regardless of the location of the uterine incision(s).³⁵

Despite the demonstrated efficacy of adhesion barriers, many surgeons are concerned about their cost. In an attempt to address this issue, Bristow and colleagues recently evaluated the cost effectiveness of Seprafilm in a radical hysterectomy model.³⁶ Based on their analysis, the authors concluded that the routine use of Seprafilm was associated with significant cost savings.

Adept Adhesion Reduction Solution (4% Icodextrin)

Adept is a 4% icodextrin solution made of an alpha 1, 4 linked glucose polymer. It is nonviscous, colorless, and odorless. In the peritoneal cavity, it is metabolized by amylase to maltose and glucose. The relative absence of amylase in peritoneal fluid affords the product increased residence time. Published data suggest that icodextrin provides prolonged hydroflotation, as approximately 60% of Adept was still present in the abdomen four days following instillation.³⁷

Adept's prospective, randomized double blinded pivotal study employed lactated ringers as the control.³⁸ Significantly more study patients had a decrease in adhesions at second look laparoscopy of at least three sites or 30% of the sites initially lysed ($P < 0.05$). In addition, study patients demonstrated a 23% reduction in the number of sites with adhesions at second look laparoscopy compared to the first surgery ($P < 0.001$).

CONCLUSION

Pelvic adhesions represent a significant cause of both morbidity and mortality following intra-abdominal and/or pelvic surgery. Surgical procedures associated with a significant incidence of pelvic adhesions include myomectomy, resection/vaporization of endometriosis, lysis of adhesions, tuboplasty, ovarian cystectomy, and

To minimize the potential morbidity and mortality associated with adhesion formation following surgical procedures, it is incumbent on the surgeon to take all possible measures to lessen the likelihood of inducing the formation of adhesions.

hysterectomy. Recent data also suggest that Cesarean section causes significant adhesion formation. In order to minimize the potential morbidity and mortality associated with adhesion formation following these procedures, it is incumbent on the surgeon to take all possible measures to lessen the likelihood of inducing the formation of adhesions. Such measures include optimizing surgical technique to decrease the occurrence of tissue damage, and consideration of the use of intraoperative barriers.

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SELF-ASSESSMENT

Please complete this self-assessment and the activity evaluation on the following page. To receive CME credit and a certificate, fax or mail the completed form to the information at the bottom of page 12.

Article 1 Contraception

1. Having an occasional hormone withdrawal period is necessary on continuous oral contraceptives to prevent endometrial hyperplasia/cancer. True False

2. Continuous oral contraceptives are associated with an increased incidence of thromboembolic events when compared with 21/7 pills. True False

3. Studies have documented that an effective way to manage breakthrough bleeding on continuous oral contraceptive is to:
 Double up on pills for 3 to 4 days
 Triple up on pills for 3 to 4 days
 Add supplemental estrogen
 Take a 3 to 4 day break from the pills

4. New oral contraceptive regimens include:
 Adding 20mcg of ethinyl estradiol only to the typical 7 day hormone free interval
 Adding more than 7 days to the hormone free interval
 Shortening the hormone free interval to 3 days only
 Eliminating the hormone free interval

5. Based on this article, what two new patient care strategies do you plan to use that you have not used before?

6. What challenges or barriers might you face as you work to implement these strategies?

Article 2 Genital Herpes

1. What percentage of people infected with genital herpes have been diagnosed?
 20% 50% 80% 100%

2. Compared to viral culture, using PCR to detect the presence of HSV DNA in genital lesions: (CHECK ONE)

- Is more dependent on careful sampling and transport
- Has higher sensitivity
- Requires a longer time for results to be available
- Is less expensive

3. Which of the following statements is CORRECT regarding interpretation of type-specific serology results in non-pregnant female patients with a suspicious lesion who are culture-negative or PCR-negative? (CHECK ONE)

- Results indicating seropositivity for HSV-1 denotes definite genital HSV-1 infection
- Results indicating seropositivity for HSV-2 denotes definite genital HSV-2 infection
- Results indicating seronegativity for HSV-2 denotes that infection is orolabial, not genital
- Results indicating seronegativity for both HSV-1 and HSV-2 denotes that there is no need to swab subsequent lesions

4. Daily antiviral therapy

- Can reduce asymptomatic shedding by 70%-80%
- Can reduce symptomatic outbreaks by 70%-80%
- Can reduce transmission to an uninfected sex partner by 50%
- All of the above

5. Based on your participation in this CME activity, do you plan to INCREASE the frequency with which you do the following? (3=Yes, 2=No, 1=Unsure, N=N/A)

- A. Include type-specific serology as part of routine STD testing: 3 2 1 N
- B. Offer antiviral suppressive therapy to patients newly-diagnosed with genital HSV-2: 3 2 1 N
- C. Cesarean delivery if symptomatic herpes is present, to reduce the chance of neonatal herpes: 3 2 1 N
- D. For women with a history of recurrent genital herpes, prescribe antiviral therapy from 36 weeks gestation to delivery: 3 2 1 N

please continue on back

SELF-ASSESSMENT *continued*

6. How confident do you feel counseling patients with genital herpes on strategies that can reduce their risk of sexually transmitting HSV to their partners? (5 = Extremely confident, 1 = Not at all confident, N = N/A) 5 4 3 2 1 N

7. Based on this article, what two new patient care strategies do you plan to use that you have not used before?

8. What challenges or barriers might you face as you work to implement these strategies?

Article 3
Pelvic Adhesions

1. Pelvic adhesions are more likely to occur following a myomectomy when the incisions are made on the anterior aspect of the uterus. True False

2. Pelvic adhesions are less likely to occur following closure of the peritoneum at Cesarean section. True False

3. After a pelvic adhesion barrier is used, how many days until a confluent layer of

mesothelial cells provide a natural adhesion-resistant surface preventing the formation of new adhesions? (CHECK ONE)

3-5 days 5-7 days 7-9 days

4. After participating in this CME activity, how often do you now plan to use an adhesion barrier for each of the following procedures? (5 = Always, 1 = Never, N = N/A)

Myomectomy: 5 4 3 2 1 N

Endometriosis: 5 4 3 2 1 N

Lysis of adhesions: 5 4 3 2 1 N

Tuboplasty: 5 4 3 2 1 N

Ovarian cystectomy: 5 4 3 2 1 N

Pelvic inflammatory disease:

5 4 3 2 1 N

Cesarean section: 5 4 3 2 1 N

Post-hysterectomy (bowel obstruction prevention): 5 4 3 2 1 N

5. Based on this article, what two new patient care strategies do you plan to use that you have not used before?

6. What challenges or barriers might you face as you work to implement these strategies?

ACTIVITY
EVALUATION

Answer the first two questions using a scale of 1-5 (5 = Strongly Agree, 3 = Agree and 1 = Strongly Disagree)

1. The articles met the stated objectives. 1 2 3 4 5

2. The articles are relevant to my current clinical practice needs. 1 2 3 4 5

3. Disclosure of faculty relationships with commercial organizations was made available before the articles. True False

4. The commercial supporters were acknowledged in print. True False

5. The articles were balanced and free of commercial bias. True False

6. If trade names were used, all product trade names were discussed. True False

7. Any off-label drug use, and/or investigational drug use not yet approved by the FDA was disclosed before or during the activity. True False

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