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Postmenopausal Hormone Therapy and Primary Prevention of Cardiovascular Disease—Nurses' Health Study 20-Year Follow-Up

ABSTRACT & COMMENTARY

The 20-year follow-up from the nurses' health study reports a reduced risk of coronary heart disease in current users of postmenopausal hormone therapy, but a slight increase in the risk for nonfatal stroke.

Grodstein and colleagues from the Nurses' Health Study report the effect of postmenopausal hormone therapy on cardiovascular disease, based upon follow-up from 70,533 postmenopausal women. This prospective, cohort study recorded 953 myocardial infarctions, 305 coronary deaths, and 767 strokes from 1976-1996. The major observations are presented in the following tables:

Table 1
Coronary Heart Disease

	Cases	Adjusted RR (Confidence Interval)
Current users	259	0.61 (0.52-0.71)
0.3 mg	19	0.58 (0.37-0.92)
0.625 mg	9	0.54 (0.44-0.67)
1.25 mg	41	0.70 (0.51-0.97)
Estrogen alone	?	0.55 (0.45-0.68)
E + P*	?	0.64 (0.49-0.85)

Table 2
Stroke

	Cases	Adjusted RR (Confidence Interval)
Current users	238	1.13 (0.94-1.35)
0.3 mg	9	0.54 (0.28-1.06)
0.625 mg	124	1.35 (1.08-1.68)
1.25 mg	46	1.63 (1.18-2.26)
Estrogen alone	?	1.18 (0.95-1.46)
E + P*	?	1.45 (1.10-1.92)

* Estrogen and Progestin together

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Table 3

Fatal Stroke

	Adjusted RR (Confidence Interval)
0.625 mg	1.01 (0.59-1.71)
1.25 mg	1.25 (0.57-2.77)
Estrogen alone	0.81 (0.49-1.34)
E + P	1.22 (0.65-2.28)

These numbers indicate that current users of postmenopausal hormone therapy have a significant reduction in the risk of coronary heart disease with estrogen alone or with a combination of estrogen and progestin (although not reported, this is most likely nearly all sequential regimens). The results were adjusted for body mass index, diabetes, hypertension, elevated cholesterol, smoking, and age of menopause. Further analysis of diet, physical activity, and use of aspirin and vitamin supplements did not significantly change the results. Overall, there was no significant effect of hormone therapy on the risk of nonfatal and fatal stroke. However, there was a suggestion that higher doses of estrogen and estrogen combined with progestin modestly increased the risk of nonfatal stroke (a statistically significant effect was present only with ischemic stroke, not with hemorrhagic stroke), but no significant increase in the risk of fatal stroke. (Grodstein F, et al. *Ann Intern Med* 2000; 133:933-941)

COMMENT BY LEON SPEROFF, MD

This latest update from the Nurses' Health Study on the effect of postmenopausal hormone therapy on the primary prevention of cardiovascular disease provides no major changes from the 16-year report, about a 40% reduced risk for coronary heart disease, but it allows a better assessment of the effect of dose and duration of use.[1] Overall, this report from the Nurses' Health Study provides support for the belief that postmenopausal hormone therapy provides primary prevention against coronary heart disease, and that the doses of 0.3 mg and 0.625 mg of conjugated estrogens produce comparable effects.

Unfortunately, the report does not provide the case numbers for the relative risks associated with estrogen alone compared with a combination of estrogen and progestin, and for the analysis of fatal stroke. The tight confidence intervals suggest that the estimates of risk are precise, usually a result of adequate case numbers. However, notice that the stroke risk associated with 0.3 mg conjugated estrogens is based on only nine cases. Thus, one appropriate concern is whether the conclusions regarding combined estrogen and progestin are limited by small case numbers. It would also be of great interest to know whether the stroke results in the Nurses' Health Study are influenced by the ages of the women. An obvious concern is whether the dose of estrogen should be decreased with increasing age.

In contrast to the uniform results from observational studies of the association between postmenopausal hormone therapy and coronary heart disease, epidemiologic data over the last 20 years regarding estrogen use and stroke have not been consistent. Many studies have indicated either no effect of postmenopausal hormone therapy on the risk of stroke or a reduction in risk associated with estrogen or estrogen-progestin use.[1-12]

In a large Danish case-control study, no affect could be detected of either estrogen or combined estrogen and progestin on the risk of nonfatal stroke, both thromboembolic and hemorrhagic.[11] A case-control study from Seattle found about a 50% reduced risk of subarachnoid hemorrhage with the use of postmenopausal hormone therapy, and the effect was even

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greater among smokers.[10] In the prospective study of the Leisure World cohort, estrogen therapy was associated with a 46% overall reduction in the risk of death from stroke, with a 79% reduction in recent users.[5] The population-based cohort study in Uppsala, Sweden, documented a 30% reduced incidence of stroke in postmenopausal users of estrogen, and, importantly, women prescribed an estrogen-progestin combination, containing a significant dose of the potent androgenic agent levonorgestrel, also experienced a reduced incidence of stroke.[9] A reduced risk for mortality from stroke in this Swedish study was confined to intracerebral hemorrhage.[13]

Within this confusing mixture of results, there has been one consistent observation. The cohort studies (with a sufficient number of cases) that have assessed the effect of hormone use on the risk of death from stroke have all indicated a beneficial effect (except for the Nurses' Health Study). For example, the National Health and Nutrition Examination Survey (NHANES) recruited a large cohort of women from 1971-1975 for epidemiologic analysis. The follow-up longitudinal study of this cohort yielded a U.S. national sample of 1910 white, postmenopausal women. Postmenopausal hormone use in this cohort provided a 31% reduction in stroke incidence and a strongly significant 63% reduction in stroke mortality.[8]

One emphasis in the discussion in the current report from the Nurses' Health Study was especially disturbing to me. Grodstein et al twice refer to their examination of women with previous coronary disease in the Nurses' Health Study, concluding that short-term hormone use increased the rate of recurrent cardiac events, supporting the HERS Trial. Grodstein et al conveniently do not provide their numbers, but they have been presented in abstract form[14] (*See Table 4*).

Table 4

	Cases	Risk of Recurrent Cardiac Event
Current Use	?	0.65 (0.45-0.95)
< 1 year	6	2.1 (0.88-4.97)
1-1.9 yrs	3	1.01 (0.31-3.27)
2+ yrs	33	0.56 (0.37-0.85)

These numbers do not indicate a statistically significant increase with less than two years of hormone use in women with coronary heart disease, and citing the results with short-term use, based on only six cases, is yet another example of selective reporting by the Nurses' Health Study authors. Indeed, where there is some strength of numbers, these data support the idea that with increasing duration of exposure there is secondary prevention of recurrent events (as also noted in the HERS Trial)!

The editorial accompanying the report from the Nurses' Health Study concludes that the disappointing results from the HERS Trial, the ERA Trial, and the recent report from the Women's Health Initiative (WHI) indicate that clinicians should not use hormone therapy for the prevention of coronary disease until we have final data from randomized trials.[15] I disagree with this conclusion. This latest report from the Nurses' Health Study continues to provide support for the belief that postmenopausal hormone therapy provides protection against coronary heart disease in current users. It also suggests that we should begin to consider the use of lower doses of estrogen in older women (after age 65). The HERS Trial and the WHI report indicated a growing benefit with increasing duration of use, not a totally null or adverse effect. Randomized trial data will not emerge until 2006-2008. Until then, the current state of knowledge is sufficient, in my view, to support hormone therapy for primary prevention of coronary heart disease. ❖

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Can we Reduce the Cesarean Section Rate Through Pulse Oximetry?

ABSTRACT & COMMENTARY

Synopsis: *The pulse oximeter more reliably predicted which patients really needed a cesarean section for true fetal distress.*

Source: Garite TJ, et al. *Am J Obstet Gynecol* 2000; 183(5):1049-1058.

For the past 15 years, there has been an attempt to decrease the high cesarean section rate (CSR) in this country. Three of the most common reasons for performing cesarean section are dystocia, a previous cesarean operation, and fetal distress diagnosed by fetal heart rate patterns suggestive of hypoxia. Since 1990, the national CSR has dropped a few percentage points because of loosening definitions of "failure to progress" in labor, increased emphasis on vaginal birth after cesarean (VBAC), and, in some hospitals, heightened peer review. Recently, a technique has emerged which, hopefully, will allow clinicians to do fewer cesarean deliveries for fetal distress.

Garite and colleagues have reported on the results of a multi-center, randomized trial to evaluate a fetal pulse oximeter in labor. One thousand ten patients were recruited from nine centers. Entry was predicated upon an abnormal fetal heart rate pattern in labor. Five hundred eight patients were randomized to have a pulse oximeter placed through the vagina against their fetus' cheeks. The 502 control patients were managed by fetal heart rate monitoring alone. The continuous oxygen saturation values were available to the managing clinicians in the study group. The CSR for fetal distress in the pulse oximeter group was less than half of the control group (4.5% vs 10.2%). Although there was no difference in major neonatal morbidity between groups, the neonates in the pulse oximeter groups whose mothers were sectioned for fetal distress had more legitimate evidence of metabolic acidemia than those in the control group where sections were done for the same diagnosis. Garite et al concluded that the pulse oximeter more reliably predicted which patients really needed a cesarean for true "fetal distress."

A surprising finding in the study was that the total CSR in both groups was similar (26% vs 29%) because of a statistically significant increase in cesarean sections done for dystocia in the pulse oximetry group. When Garite et al attempted to weed out confounding variables including clinician bias, predisposing factors to dystocia, labor augmentation, etc., they found the only difference between groups was a higher rate of arrest of labor in the pulse oximeter group.

COMMENT BY JOHN C. HOBBINS, MD

The function of fetal heart rate monitoring has been to identify fetuses that are tolerating labor poorly because of hypoxia secondary to the nebulous term "uteroplacental insufficiency." Randomized trials, especially in low-risk patients, have failed to show an improvement in most perinatal outcomes when continuous fetal heart rate monitoring was compared with intermittent auscultation. However, no study yet has shown that a reassuring fetal heart rate pattern is an imprecise predictor of normal fetal oxygenation. In fact, electronic fetal monitoring (EFM) is a reliable predictor of fetal well being, but an imperfect predictor of fetal ill being. This is where the pulse oximeter can be of great value. External EFM can be used as a screening tool to pick out the fetuses at risk for hypoxia whose oxygenation can then be assessed accurately with the pulse oximeter. As Garite et al point out, this should halve the amount of cesarean sections performed for fetal distress.

Another spinoff benefit from the study, not discussed in this paper, was the anecdotal finding that variable decelerations, including deep, "scary" variables, were rarely associated with a decrease in fetal oxygen saturation levels. Hopefully, since even severe variables represent a baroreceptor response to umbilical cord impingement rather than a chemoreceptor response to hypoxia, this should put an end to applying an oxygen mask to every patient having the slightest deflection on the fetal heart rate monitor. This practice, which not only confines the patient, but also frightens the wits out of her, should be abandoned unless there is solid evidence of fetal hypoxia through pulse oximetry.

The finding of a higher number of cesarean sections being performed for dystocia in the pulse oximetry group is puzzling and concerning, especially when the CSR in this group was 29%, a figure that is much higher than the average CSR in the United States. As stated before, Garite et al tried to explain in various ways the higher rate of dystocia in the pulse oximetry group, but could not. One interesting finding was a higher rate of nonreassuring fetal heart rate patterns (mostly variables) in those sectioned for dystocia.

Why should fetuses of mothers displaying sluggish progress in labor have a higher rate of fetal heart rate abnormalities? Is this some sort of heralding sign of an

imperfect fetal/pelvic fit, or are we dealing with a maternal response (stress) to having a gadget placed in her because her caregivers think her baby may not be getting enough oxygen? Obviously, this finding needs more investigation. ❖

Five-year Incidence and Remission Rates of Urinary Incontinence in a Population Younger Than 65

ABSTRACT & COMMENTARY

Synopsis: *In a population-based cohort of women younger than 65 years of age with urinary incontinence, on average, 6% will experience spontaneous remission each year.*

Source: Samuelsson EC, et al. *Am J Obstet Gynecol* 2000;183:568-574.

Urinary incontinence is an extremely common condition in the adult female population. Symptoms vary greatly from minor disturbances to complete incontinence. The prevalence of the condition increases with age. The purpose of this study was to determine both the incidence and the spontaneous remission rates of urinary incontinence in a population of women 20-59 years of age.

This study was carried out in Sweden where all women are eligible for routine gynecologic examinations on a regular basis. Those women scheduled for an examination during 1993 in the population district chosen to serve as the basis for this study were potential participants. Pregnant and lactating women, and those with mental retardation, were excluded. In addition, a small number of women with severe incontinence who required immediate treatment were also excluded.

Incontinence was broadly defined and all women who reported any degree of incontinence were included as being affected. Samuelsson and colleagues then subdivided this group into those who experienced symptoms monthly, weekly, or daily. Four hundred ninety-one women answered the questionnaire, and 487 were examined and represented the starting point of this study. Five years later a similar questionnaire was administered and 382 women responded (88% participation rate).

The average age of the study group was 42.5 years at follow-up. Sixty-two percent had given birth at least once. Of those women 45 years old or older, 30% were receiving estrogens.

Of the 383 women who participated throughout the study, 23.6% were incontinent at baseline, and 27.5% were incontinent at the time of the follow-up questionnaire. However, considerable crossover had occurred. Specifically, 40 of the women who were originally continent became incontinent at follow-up, while 25 of the 90 women who were originally incontinent became continent at follow-up. Thus, the remission rate was approximately 6% and the incidence rate was approximately 3%.

In an effort to determine which variable might be responsible for the occurrence of incontinence, a multivariant logistic regression analysis was performed. Only estrogen treatment was found to be significant. However, the effect of the estrogen treatment was interesting. Those women who were receiving estrogen were more likely to be incontinent than those who were not. Samuelsson et al were unable to determine whether women with more severe symptoms had been given estrogen, or whether estrogen therapy itself might be a predictor of incontinence. The duration of incontinence prior to the study did not predict whether the disease would remit during the follow-up period.

COMMENT BY KENNETH L. NOLLER, MD

Urinary incontinence is an almost unbelievably complex condition. The more it is studied, the more obvious it is that some of our long-held beliefs have been in error. For example, when I was in training it was common to suggest to women who were experiencing incontinence of a mild-to-moderate degree that they should have surgical correction while they were still "young" as the condition only worsened with age. A number of previously published articles using elderly populations as study participants have shown that incontinence is not always irreversible or progressive. This article from Sweden now demonstrates that the same facts are true for younger women. Specifically, women 20-65 years of age who have incontinence, and who are followed for five years, have approximately a one-in-four chance of the incontinence disappearing.

The observations concerning exogenous estrogen therapy in this study are certainly worthy of some thought. For many years it has been suggested that estrogen therapy can decrease the frequency of urinary incontinence among women who have no or low levels of endogenous estrogen. While the studies supporting this "fact" have not always been well conceived or executed, I think most of us have believed that estrogen could help

reduce incontinence. This article found exactly the opposite effect; and namely, that women on exogenous estrogen had more incontinence than those not on estrogen. Because the reason for estrogen therapy was not known in this study it is likely that Samuelsson et al's observation was due to the "fact" that the women with more significant incontinence were placed on estrogen, whereas those with minor difficulties were not. However, it must be recognized that it is at least possible that estrogen therapy does not help and may even hinder the remission of incontinence. The subject certainly deserves further study. ❖

Serum Creatine Phosphokinase to Evaluate Suspected Ectopic Pregnancy

ABSTRACT & COMMENTARY

Synopsis: *This investigation was designed to evaluate the use of maternal creatine phosphokinase in predicting the presence of an ectopic pregnancy in an emergency department setting.*

Source: Birkhahn RH, et al. *Am J Emerg Med* 2000; 18(6):695-697.

Biochemical markers of early normal and abnormal pregnancy have been investigated to enhance diagnosis of ectopic pregnancy (EP) sufficiently early to increase maternal safety and decrease maternal morbidity. Birkhahn and colleagues measured serum creatine phosphokinase (CPK) levels in women presenting to an urban emergency room (ER) with a diagnosis of first-trimester pregnancy and bleeding and/or abdominal pain. A case-control design matched women with a diagnosis of EP through randomization to a cohort of women with nonEP. The mean serum CPK was 118 mIU/dL in the EP group and 64 mIU/dL in the non-EP group. A CPK more than 70 mIU/dL was 100% sensitive for detection of EP, with a specificity of 61.9%, positive predictive value of 72.4%, and negative predictive value of 100%.

Lavie and colleagues first introduced CPK as a potential marker for EP in 1993, theorizing that the invasion of tubal smooth muscle by trophoblastic tissue would produce a rise in CPK.[1] CPK is elevated in the presence of damage to skeletal muscle, heart, smooth muscle, and brain; and serum levels are lower than normal or normal in pregnancy until patients enter labor. Other investigations of CPK for diagnosis of EP have used different study designs and produced variable results, with some studies finding CPK to be useful in differentiating ectopic and non-ectopic pregnancy, and others finding no difference.[2-5]

The use of CPK for determination of EP is limited in several clinical situations. Birkhahn et al excluded women with a recent history of chest pain, trauma, myositis, cocaine use, known renal disease, or intramuscular injection. EPs in locations where the developing trophoblast does not invade muscle will not develop CPK elevation. Birkhahn et al note that the positive predictive value obtained in this study is falsely elevated due to the case control study design with an "artificial" pretest probability of 50% for EP. In an urban ED population with a 10% prevalence of EP, the positive predictive value would be reduced to 23%, while the negative predictive value would remain 100%.

COMMENT BY ELLEN L. SAKORNBUT, MD

EP presents as a diagnostic concern to physicians from multiple disciplines in office or clinic settings and urgent and emergency care centers. While diagnostic goals are similar for all clinicians, resources to make the diagnosis are not. In any setting where transvaginal ultrasound is readily available, findings of normal or abnormal intrauterine pregnancy, indeterminate findings, or findings suspicious or confirmatory for EP may be obtained in a brief period of time. The use of laboratory testing in this context is greatest for patients with indeterminate findings, although quantitative HCG levels and progesterone levels may be used for patients diagnosed with EP as prognostic indicators for success of medical treatment such as methotrexate.

Birkhahn et al recommend the use of CPK when ultrasound is nondiagnostic or not immediately available and in patients with HCG levels below 1500 mIU/mL, using a CPK measurement less than 70 mIU/dL as a means of "ruling out" EP. They also recommend a large prospective study to assess further the use of CPK for diagnosis of EP. At this time, the use of CPK in conjunction with other tests to "rule out" EP appears best suited to an ER setting with rapid availability of results. The high negative predictive value of CPK is similar to a serum progesterone level less than 22 ng/mL, but CPK levels are available "STAT" in almost all emergency settings, whereas progesterone levels are not.[6] ❖

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Special Feature

The Future of the Office Practice of Gynecology

By Kenneth L. Noller, MD

Several years ago, the special requirements for specialty training in obstetrics and gynecology were amended to increase exposure to preventive medicine and other primary care. Some pundits spoke out loudly against this change as it took time from other areas of training. The most cynical suggested that the reason behind the changes was purely financial (access to patients) and had nothing to do with providing high quality healthcare to women. Despite these opinions, the changes were enacted, and all residency programs in the United States now include such training. Nonetheless, naysayers still protest the changes and point to the fact that most states now have enacted legislation that preserves the access by women to their OB/GYNs. I believe that there is an important and different way to view the emphasis on primary care training in Obstetrics and Gynecology that is unemotional and pragmatic.

What will the practicing OB/GYN be doing 10 years from now? I think there is no doubt that the vast majority of the approximately 4 million deliveries which occur in the United States each year will continue to be attended by OB/GYNs. Although other specialties and some nonphysician practitioners have obstetrical practices, at the present time they account for only a small proportion of deliveries, and I see no reason to expect it to grow significantly in the next 10 years. In fact, I strongly suspect that the best way for an OB/GYN to maintain a busy practice is to continue to provide prenatal services throughout her/his career.

The practice of gynecology, in the past, was largely devoted to the evaluation of women with gynecologic problems. Indeed, the preventive care aspects of gynecology (annual visits) did not become a major reason for a woman to see a gynecologist in the United States until approximately 1960. The development of the oral form of contraception, as well as the widespread recognition of the usefulness of regular cytology screening, led to more and more annual visits. There were few medical solutions to common gynecologic problems and, thus, the practicing OB/GYN spent a considerable amount of time in the operating room.

As everyone knows who is actively practicing gynecology, fewer and fewer surgical procedures are now indicated, as many gynecologic abnormalities are amenable to medical therapy. In the future, it is likely that even more conditions will be treated with medications. Because gynecologic problems will continue to occur, practitioners can expect a steady stream of patients with gynecologic complaints in their offices. However, it is likely that less and less surgery will be performed by the general practitioner of obstetrics and gynecology.

Thus, in order to stay busy, the practicing OB/GYN will need to spend an ever-greater proportion of her/his time practicing preventive medicine. But we must be prepared to change our approach to the "annual visit." In the past the annual gynecologic visit was comprised of a gynecologic interim health history, and breast and pelvic examinations including a pap smear. Some offices even included routine hematology testing and urine analysis. I believe that this approach to preventive care will need to change dramatically if we wish to maintain our patient base.

What is wrong with the annual visit as described above? Let's examine the four components: interval gynecologic history, breast examination, pelvic examination, and cervical cytology.

The interim gynecologic history should be negative for all women who are having a screening visit. Indeed, if it is otherwise the visit becomes "problem oriented." The screening gynecologic history takes only a few seconds to perform.

Many practitioners routinely perform breast examinations; the gynecologist has no particular advantage.

The pelvic examination has long been the backbone of the office practice of gynecology. Many other specialists refuse to perform these examinations. Unfortunately, the practice of screening pelvic examinations is coming into more and more dispute. Despite the fact that all of us perform these examinations day in and day out, there has never been a study which has shown any benefit to screening pelvic examinations (i.e., pelvic examination in a woman without a gynecologic complaint). I strongly suspect that there will be greater and greater pressure from third-party carriers to eliminate this as an annual procedure.

That leaves cervical cytology. Many other specialists perform this procedure. In addition, there has been recent emphasis in the medical literature on the lack of demonstrated need for annual cytology in women who are at low risk for the development of cervical neoplasia. The additional financial burden of the costs of some of the new pap smear technologies has led some payers to reexamine their payment for annual cytology. Several recent documents (and several that will be published in the near future) have emphasized the lack of support for cytology screening in women who have undergone hysterectomy for benign changes.

Therefore, overall, the gynecologist has no advantage over other specialists for routine annual screening visits. In my opinion, the way to overcome this problem is for us to incorporate a full range of preventive services in our annual visits. For example, an internist may tell her/his patient that, "There is no reason to see your gynecologist. I can perform all the procedures that would be done at that visit." We also should be prepared to tell our patients, "There is no reason for you to see an internist this year as I can provide all of the services you need." Of course, this requires that we become familiar with recommended screening procedures at all ages, vaccinations and other active preventive measures, and perform significant in-office counseling. We can use as our guide the excellent documents prepared by ACOG, those which are available from other specialties, and the U.S. Public Health Service guidelines.

The future of gynecology in the United States is not surgery, and it is not annual well-woman pelvic examinations. Rather, it is preventive care which starts at the top of the head and ends at the soles of the feet. Thus, the emphasis on primary care in our residency training programs is both appropriate and expedient. ❖

CME Questions

5. **The following statements are true regarding postmenopausal hormone therapy and the prevention of cardiovascular disease *except*:**
   a. Case-control and cohort studies uniformly indicate that postmenopausal hormone therapy reduces the risk of coronary heart disease by about 40-50%.
   b. Case-control and cohort studies uniformly indicate that unopposed estrogen and combined estrogen-progestin treatment have similar cardiovascular benefits.
   c. Case-control and cohort studies uniformly indicate that postmenopausal hormone therapy reduces the risk of stroke.
   d. Case-control and cohort studies are not uniformly accepted by clinicians and epidemiologists.

6. **In the study by Samuelsson et al, which one of the following statements concerning urinary incontinence is true?**
   a. Once established, urinary incontinence persists and progresses.
   b. Urinary incontinence is a dynamic condition with spontaneous remissions.
   c. During a five-year study period, approximately one woman in four developed urinary incontinence.
   d. Treatment with exogenous estrogens decreases the incidence of urinary incontinence.

7. **Which one of the following statements is *not* true?**
   a. A progesterone level greater than 25 ng/mL is associated with normal intrauterine pregnancy.
   b. Maternal creatine phosphokinase less than 45 mIU/dL is indicative of a normal intrauterine pregnancy.
   c. Patients with a quantitative HCG level less than 1500 mIU/mL, no intrauterine gestational sac on transvaginal ultrasound, and CPK greater than 70 mIU/dL are at high risk for ectopic pregnancy.
   d. Creatine phosphokinase cannot be reliably used to "rule out" abdominal pregnancy.

Attention CME Subscribers

Due to an American Health Consultants error, a mistake has been made with the CME numbering. The numbering should have started over in your January 2001 issue. In the January 2001 issue, questions 29-32 should be questions 1-4. A reminder will also be sent with your CME Scantron. We regret any confusion this might have caused. ❖

Attention Readers

As a special supplement to our subscribers, *OB/GYN Clinical Alert* is inserting *Ob-Gyn Coding Alert*, a monthly advisor for ethically optimizing coding reimbursement published by The Coding Institute. The editorial team at *OB/GYN Clinical Alert* will continue to provide cutting-edge analyses and updates on developments in obstetrics and gynecology. Please tell us what you think about *Ob-Gyn Coding Alert*. Send your comments to Robin Mason, P.O. Box 740059, Atlanta, GA 30374 or by e-mail: robin.mason@ahcpub.com. ❖

In Future Issues:

Is Cesarean Section Safer for Breeches than Vaginal Delivery?

A supplement to OB/GYN Clinical Alert, February 2001

AAPC Approved

OB-GYN CODING ALERT

The practical monthly advisor for ethically optimizing coding reimbursement and efficiency in ob-gyn offices and clinics

Expert Answers to Your Most Vexing Ob-Gyn Coding Questions

Ectopic Pregnancy

Question: *I am looking for a CPT code for a packaged procedure for an ectopic pregnancy treatment. The physician is treating the patient in the office with methotrexate intramuscular to dissolve the ectopic growth. Is there one procedure code that includes the office visit and the injection?*

Cheryl Kuehne, CPC
Multicare Associates, Blaine, Minn.

Answer: A general rule with most third-party carriers is that if a therapeutic injection is given at the time of a visit, the administration (90782, *therapeutic or diagnostic injection; subcutaneous or intramuscular*) of the medication is bundled into the visit code. In this scenario, the provider would bill for the evaluation and management (E/M) visit (99201-99215) and the HCPCS code for the medication (J9260, *methotrexate sodium, 50 mg*). Note that the drug methotrexate is a chemotherapeutic agent and, as such, some payers may allow the physician to bill 96400 (*chemotherapy administration, subcutaneous or intramuscular, with or without local anesthesia*) in addition to the E/M service, even without a cancer diagnosis, but check with your payer before trying this method.

If the patient is receiving just the injection and there is not a separately identifiable E/M service rendered and documented, the administration code 90782 (or 96400 when allowed) is billed in addition to the HCPCS code for the medication.

*— Answered by **Emily Hill, PA-C,** president of Hill & Associates, a coding and compliance consulting firm based in Wilmington, NC.*

Established Patient or Well Visit?

Question: *A patient came to our office for her annual exam. She was on birth control pills and hormone replacement therapy and had no new complaints. Her prescription for birth control pills and hormones was renewed for the year. Is this an established patient visit or a well visit?*

Jenie Graham, RRA, CCS
Ob & Gyn Specialists, PC, Davenport, Iowa

Answer: When coding for any service, ask, "What is the reason for the patient's visit today?" Patients on birth control pills or hormone replacement therapy are usually given these medications for prophylactic or preventive reasons. Therefore, for annual checkups (established patient), you would use the preventive medicine codes representing the patient's age — commonly 99394-99397 (*periodic preventative medicine reevaluation and management of an individual including a comprehensive history, comprehensive examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of appropriate laboratory/diagnostic procedures, established patient*) for gynecological patients.

Also note that part of the description of the service is "risk factor reduction interventions." This is where birth control and hormone replacement therapy come into play. Remember that the intent of age-based codes clarify that not all examinations fall under the same type of history, exam, and other contributory factors for each age group. The ICD-9 code must correctly identify the reason for the visit as well. For instance, include V07.4 (*postmenopausal hormone replacement therapy*) if the patient presents for a routine gynecological exam and renewed prescription of hormone replacement therapy. A patient having problems with her medication — for instance, a menopausal patient comes to the office complaining of hot flashes while taking 0.5 mg of estradiol daily — would constitute a problem-oriented evaluation and management service (99211-99215). To indicate medical necessity, assign 627.2 (*menopausal or female climacteric states*).

*— Answered by **Laurie Castillo, MA, CPC,** president of Physician Coding and Compliance Consulting in Manassas, Va.*

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E/M Visit With OB Global

Question: *We charge an evaluation and management (E/M) visit for the first obstetric visit and then bill the global fee at delivery. Is it ever acceptable to bill separately for each subsequent OB visit and then bill the global at delivery? I am aware of the antepartum codes, and we use these only for OB patients who leave our practice. Many times, we will see our OB patients for more than the 13 visits usually considered part of global.*

Arizona Subscriber

Answer: According to guidelines published by the American College of Obstetricians and Gynecologists, the first visit included in the global OB package is the one in which the OB record is initiated, although you may want to check with individual insurers for their particular guidelines. If a patient is seen more than the typical number of times (13 antepartum visits) for other than a normal pregnancy (the patient is diabetic, for example), the total number of antepartum visits can be added together and any beyond the normal 13 can be billed at the end of the pregnancy.

The physician will need to document these extra visits very carefully so the coder will know exactly how many extra visits took place, the reason(s) for the visits, and the level of E/M service supported by the documentation.

*— Answered by **Melanie Witt, RN, CPC, MA,** an independent coding educator.*

Transvaginal Ultrasound

Question: *How can I code a transvaginal ultrasound of the ovaries to follow follicles in a gonadotropin-stimulated cycle? Generally, I perform one ultrasound when I see the patient initially and code 76856, then code 76857 for the follow-up transvaginal scans used to measure follicles. The corresponding diagnosis is usually an infertility code like 628.9 (*infertility, female, of unspecified origin*).*

Maryland Subscriber

Answer: There are two options for billing an initial ultrasound: 76830 (*echography, transvaginal*) or 76856 (*echography, pelvic [nonobstetric], B-scan and/or real time with image documentation; complete*). The only difference between the two is that the procedure described by 76830 uses a vaginal transducer, while 76856 is performed with an abdominal transducer. According to the American College of Obstetricians and Gynecologists' *Ob/Gyn Coding Manual: Components of Correct Procedural Coding*, the imaging for both procedures involves a study of the "uterus, tubes, ovaries and pelvic structures, as indicated." Therefore, the approach should determine which code to use.

Note: The Medicare fee schedule assigns the same number of RVUs for both 76830 and 76856 (2.62 RVUs in 2000, and 2.61 RVUs in 2001), so there is no financial advantage to using one code over the other.

For the follow-up to check for follicles, 76857 (*echography, pelvic [nonobstetric], B-scan and/or real time with image documentation; limited or follow-up [e.g., for follicles]*) clearly describes the procedure performed and may be reported. In this case, there is no need to differentiate between a transvaginal and abdominal approach.

*— Answered by **Melanie Witt, RN, CPC, MA,** an independent coding educator.* ❑

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