Clinical Perspectives in Intrauterine Contraception and Postmenopausal Hormone Therapy

HIGHLIGHTS OF SYMPOSIA

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TOPIC HIGHLIGHTS

Hormone Therapy Today:
Perception, Attitudes, and Evidence

Intrauterine Contraception:
The Evidence Refutes the Myths

The Role and Appropriate Use of the Modern IUD

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Clinical Perspectives in Intrauterine

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TARGET AUDIENCE
This educational activity has been prepared for obstetrician/gynecologists and other health care professionals who counsel and treat women of childbearing age who desire contraception and postmenopausal women who may be candidates for hormone therapy.

EDUCATIONAL NEEDS
Women’s health practitioners must be prepared to provide counseling and treatment for women of childbearing age who desire reversible contraception and for older women who require treatment for postmenopausal symptoms.

In the United States today, the most commonly used contraceptive methods are oral contraceptives and surgical sterilization. However, clinicians should be knowledgeable about—and women should be advised about the availability of—longer-term, reversible methods that are safe, convenient, and highly effective, namely, intrauterine contraception (IUC). In this supplement, clinicians receive updated information about the two devices that are currently available to American women: the copper IUD (copper T) and the levonorgestrel-releasing intrauterine system (LNG-IUS), including which women are suitable candidates for this method, the mechanisms of action of the two IUC types, and the noncontraceptive benefits associated with the hormone-releasing system.

Regarding women beyond childbearing years—that is, postmenopausal women—concerns that arose from the publication of data from large-scale epidemiologic studies such as the Women’s Health Initiative caused many women to avoid beginning, or to stop taking, postmenopausal hormone therapy (HT). Since that time, further research and analysis of the previously available data allow clinicians to view all of the evidence in context. This supplement provides an overview of both the risks of HT and the established benefits regarding modulation of vasomotor symptoms and overall improvement in quality of life in at-risk women. Specifically covered are current misconceptions about HT use and risks for breast cancer and cardiovascular disease, scientific data that address lingering concerns about side effects, and therapeutic strategies that are in line with current U.S. Food and Drug Administration guidelines for using lower-dose estrogen alternatives.
LEARNING OBJECTIVES
After reading and studying this educational activity, participants should be able to:

• Determine which women may be appropriate candidates for intrauterine contraception
• Describe the mechanisms of action, duration of use, and advantages and disadvantages associated with the copper T and the levonorgestrel-releasing intrauterine system
• Name the noncontraceptive benefits associated with intrauterine contraception
• Critique clinical trial data that examine perceived links between hormone replacement therapy and increased risks of breast cancer and cardiovascular disease
• Discuss the efficacy and safety of low-dose estrogen in managing vasomotor symptoms
• Evaluate strategies for balancing the risks and benefits of HT in women with moderate-to-severe vasomotor symptoms

REFERENCES

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Dr Darney has received honoraria for speakers’ bureau meetings from Bayer Healthcare Pharmaceuticals. He intends to reference unlabeled/unapproved uses of levonorgestrel-releasing intrauterine system (LNG-IUS) in his article. Dr Jensen has received funding for clinical grants from Bayer, Novartis Pharmaceuticals Corporation, Warner Chilcott, and Wyeth Pharmaceuticals. He is a consultant to Bayer, Novartis, and Wyeth and has received honoraria from Bayer and Wyeth. He intends to reference unlabeled/unapproved uses of LNG-IUS in his article. Dr Miller has nothing to disclose. Dr Shulman has received funding for clinical grants from Barr-Duramed Pharmaceuticals, National Institutes of Health (NIH), and Wyeth. He is a consultant to and has received honoraria for speakers’ meetings and advisory boards from Barr-Duramed, Bayer, GlaxoSmithKline, Hoffmann-LaRoche Ltd., Organon, Ortho-McNeil Inc. Dr Simon is a consultant to Abbott Laboratories, Ascend Therapeutics, Barr Pharmaceuticals, Inc., Berlex/Bayer Healthcare Pharmaceuticals, BioSante Pharmaceuticals, Depomed Inc., Duramed Pharmaceuticals, Inc., Esprit Pharma, Inc., GlaxoSmithKline, Hoffmann-LaRoche, Johnson & Johnson Family of Companies, KV Pharmaceuticals, Co., Medtrina Pharmaceuticals, Inc., Merck & Co., Inc., Nana/Tripharma, Noven Pharmaceutical, Inc., Organon, Pfizer Inc., Procter & Gamble Pharmaceuticals, Inc., QuatRx Pharmaceuticals Company, Solvay Pharmaceuticals Inc., TAP Pharmaceuticals, Inc., Trinity Marketing, VIVUS, Inc., Warner Chilcott, and Wyeth. He has received funding for clinical grants from Amgen, Inc., Barr, Berlex/Bayer, Besins Pharma GmbH, BioSante, Boehringer Ingelheim Corporation, Duramed, Endozeichnet, GlaxoSmithKline, Ortho-McNeil, Nana/Tripharma, Novartis, Pfizer, Procter & Gamble, Trinity Marketing, VIVUS, and Wyeth. In addition, he has received honoraria for speakers’ meetings and advisory boards from Abbott, Ascend, sanofi-aventis, U.S. LLC, Berlex/Bayer, Duramed, Esprit Pharma, GlaxoSmithKline, Hoffmann-LaRoche, Merck, Novogyne Pharmaceutical Inc., Ortho-McNeil Pharmaceutical Inc., Pfizer, Solvay, Warner Chilcott, and Wyeth.

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Please see Dr Darney, Dr Jensen, and Dr Simon’s faculty disclosures in column 2. Jennifer DiBenedetto of the Elsevier Office of Continuing Medical Education has nothing to disclose regarding conflicts of interest.

SPECIAL NEEDS
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Introduction

Two important issues that affect women’s health today are contraception and postmenopausal hormone therapy (HT). Although the former affects women of childbearing age and the latter concerns those beyond the reproductive years, contraception and HT both present a common problem in clinical practice—that is, misinformation, misperceptions, and myths that patients have been exposed to and believe to be true must be identified and corrected through counseling and education.

In this supplement, a faculty of three distinguished experts address these issues in articles based on their presentations at a continuing medical education satellite symposia held during OB/GYN. NEWS’ Perspectives in Women’s Health Conference (November 30-December 1, 2007) in San Diego, California.

Dr James Simon, Clinical Professor of Obstetrics and Gynecology at George Washington University School of Medicine in Washington, DC, reviews the risks and benefits of HT in light of the most recent research findings and further analysis of the data from the Women’s Health Initiative.

Intrauterine contraception is the focus of articles by Dr Philip D. Darney, Professor and Chief of Obstetrics and Gynecology at San Francisco General Hospital, University of California, San Francisco, and Dr Jeffrey T. Jensen, Leon Speroff Professor of Obstetrics and Gynecology, Oregon Health and Science University, Portland. This method of contraception is comparable in efficacy to sterilization, yet is also easily reversible. Unfortunately, this intrauterine contraception often is not even considered when options for contraception are discussed.

The goal of this supplement is to provide a succinct and evidence-based overview of these two areas in women’s health that will be of practical clinical value.

Hormone Therapy Today: Perception, Attitudes, and Evidence

James A. Simon, MD, CCD, FACOG

It has been well established that estrogen deficiency has an adverse impact on quality of life. As many as 90% of hypoestrogenic women experience vasomotor symptoms (hot flashes, night sweats) and as many as 50% complain of vaginal dryness and dyspareunia. Sexual dysfunction can result from vaginal dryness, dyspareunia, and postcoital burning. Sleep disturbances, which commonly begin even before the last menstrual period, can lead to mood disturbances and fatigue.

Vasomotor symptoms also have major psychosocial and socioeconomic consequences. These include decreased productivity at work and at home and increased costs for hygiene-related personal products, physician visits, prescription drugs, and over-the-counter remedies for menopausal symptoms.

Brief History of Hormone Therapy

In 1896, the first description of hormone therapy (HT) for severe menopausal symptoms was published. At the time, the source of hormones for such treatment was animal glands, usually gonads. In 1927, the first commercial preparations of estrogen became available. In 1932, clinicians began to consider estrogen as a viable treatment for “climacteric syndrome,” and, in the late 1940s, conjugated estrogen was introduced. In 1966, Robert A. Wilson published Feminine Forever, a book in which hormones were touted as a panacea for a wide range of ailments, including aging. In the 1970s, it was recognized that progestin should be added to estrogen regimens to protect the endometrium from hyper trophy and the risk for uterine cancer.

For a number of decades prior to 2002, the use of hormone replacement therapy (HRT)—either estrogen alone or estrogen plus a progesterational agent—became increasingly common as a treatment to alleviate vasomotor and other signs and symptoms of menopausal estrogen deficiency. (Note that HRT is now referred to as hormone therapy, or HT.) The results of epidemiologic and observational studies over the past 30+ years also demonstrated that estrogen deficiency was associated with an increased risk for osteoporosis and cardiovascular disease and that estrogen replacement mitigated the effects of hormonal deficiency.

In 2002, the lay media widely publicized (and sensationalized) early reports from the Women’s Health Initiative (WHI) purportedly demonstrating the “dangers” of HT, particularly a “markedly” increased risk for breast cancer and cardiovascular disease. These conclusions were premature, but, nevertheless, resulted in the widespread discontinuation of HT and, not surprisingly, a return of vasomotor symptoms in most women who stopped treatment.

In the intervening 5 years, the data have been reanalyzed, and the risks and benefits of HT have been clarified. Unfortunately, it will take much more time for this information to reach the
signed observational studies have found that postmenopausal estrogen use was cardioprotective, but the evidence was variable. Within the last 15 years, several observational studies of estrogen or combination HT suggested a statistically significant reduction in the risk for coronary heart disease, demonstrated by a lower number of heart attacks and strokes with both estrogen alone and combination HT. However, even the largest and most carefully designed observational studies have inherent biases that cannot be eliminated (Table 2). For example, individuals who volunteer for observational studies are most likely to be literate, have the discretionary time in their daily schedules to participate, and receive some services from the health care system. The WHI investigators intended to gather data in a prospective, placebo-controlled manner that would not be affected by these types of bias.

The first data from the WHI became available to the public in July 2002. At that point, the estrogen-progestin arm of the study was halted prior to its anticipated conclusion, and the responses and reactions to this news included sensational attention by the media, widespread alarm among HT users, immediate changes in treatment recommendations by the medical community, and precipitous changes in the labeling of all HT, including the incorporation of a black box warning.

During that same time frame and to further complicate the situation—the World Health Organization (WHO) issued a statement characterizing estrogens as carcinogens. This statement was issued against the advice of many women’s health organizations, including the North American Menopause Society, and despite the fact that the clinical relevance of the carcinogenicity was deemed to be exceedingly small. Other examples of WHO-categorized carcinogens with little or no clinical importance are aflatoxin, present in peanut butter, and caffeic acid, which is found in salad greens, pears, celery, carrots, and potatoes. Regardless of these facts, which were not publicized, the statement from the WHO added to an already unfortunate constellation of erroneous and exaggerated conclusions concerning hormones.

The distortions of the WHI data began when findings from that study (Table 3 on page 6) were initially publicized in 2002 in a press conference. While the investigators may have clearly spoken about the results, clinicians and patients alike heard on the radio and television and read in newspapers that HT was associated with dramatic increases in cardiovascular events and, even worse, according to public perception, with a 26% increase in breast cancer. Few noticed the findings of a 33% decrease in hip fracture, a 37% decrease in colorectal cancer, a 24% decrease in total fractures, and no difference in all-cause mortality, nor were any of the results put into a context that the average user of hormone therapy at the time could understand. The resulting media attention was a sensationalized series of print and broadcast stories about the risks of HT. The press carried articles with startling headlines, among them, from July 22, 2002, “Study Dismissed HRT as Clinically Useless” (Financial Times) and “The End of the Age of Estrogen” (Newsweek).

The total number of these mentions was extraordinary—more than 400 newspaper stories and 2,500 television and radio stories. The media attention was a phenomenon that prompted at least one article to be written and published in the medical literature, not about the WHI or the announced results, but about the media coverage itself. Clinicians were

### TABLE 1. Estrogens: Plausible Mechanisms of Cardioprotection

- Lipid effects: lower LDL cholesterol and Lp(a); increased HDL cholesterol
- Antioxidant effects: decreased lipid oxidation
- Vascular effects: eNOS upregulation; vasodilation
- Inhibition of platelet aggregation
- Increased prostacyclin: COX-2 activity
- Decreases in cell adhesion molecules
- Decreases in inflammatory factors: TNF, IL-6, MCP-1, fibrinogen

LDL=low-density lipoprotein; Lp(a)=lipoprotein(a); HDL=high-density lipoprotein; eNOS=endothelial nitrous oxide synthetase; COX=cyclooxygenase; TNF=tumor necrosis factor; IL=interleukin; MCP=monocyte chemoattractant protein.

### TABLE 2. Inherent Biases in Observational Studies of HT

- Selection bias: healthier women were prescribed HT
- Prevention bias: monitoring and treatment more intensive in women who were prescribed HT
- Compliance bias: patients with greater adherence—even to placebo—have better outcomes
- Survivor bias: HT may be stopped due to illness
- Prevalence-incidence bias: early adverse effects of HT not observed if user dies before becoming part of cohort

HT=hormone therapy.
inundated with telephone calls and requests for office visits from patients on HT who were concerned about whether their hormone treatment was giving them breast cancer.

In 2004, the estrogen-only arm of the WHI also was terminated prematurely, not because of risk, but because no additional time was necessary to fully appreciate the findings already at hand; however, this fact was not announced in any press conference and the media coverage was far less than it had been in 2002. This was unfortunate because the findings from the estrogen-only cohort were somewhat different and much more reassuring for the many women who undergo surgical menopause.

**Reviewing the Data: A Reality Check**

The review of some WHI data here is not intended to be exhaustive, but to point out some important issues that should be considered in evaluating both reports in the lay media and papers in the medical literature.

The WHI was designed with four randomized interventions plus a separate observational cohort. The four interventions were estrogen plus progesterin vs placebo (WHI-E+P), conjugated equine estrogen vs placebo, involving only women with a prior hysterectomy (WHI-CEE), low-fat dietary pattern, and calcium plus vitamin D combination vs placebo.

The two interventional arms that involved hormone therapy—WHI-E+P and WHI-CEE—together constituted the topic of attention in July 2002 with the primary focus on the WHI-E+P arm. But important details were left out of the stories that would have helped give the data a rational perspective.

In the WHI, the mean age at enrollment was 63 years, with a range of 50 to 79 years of age—not a population that is typical for a “menopause study,” as the mean age of onset of menopause in the United States is about 51 years. In addition, women with night sweats and other vasomotor symptoms—which, as noted above, are the most common symptoms of menopause—were largely excluded from participating. This exclusion was necessary in the WHI because it was a trial of long-term treatment effects and thus required that enough subjects in both active treatment and placebo groups continue on their blinded therapy. If women with severe hot flashes had been enrolled, it would have been obvious early on—based on decrease or resolution of symptoms or lack thereof—to which group they had been assigned, and the integrity of the double-blind design would have been affected. In addition, those whose symptoms resolved would have been more likely to remain in the study long term, and the others would have been more likely to drop out.

In the WHI, the mean body mass index (BMI) was 28.5 kg/m²; 34.1% of the subjects had a BMI of 30 kg/m² or greater. In addition, 49.9% of WHI subjects were current or past smokers.17 Because the WHI population constituted a group that was far beyond the age of menopause onset, had a tendency toward overweight and obesity, had a history of smoking or were current smokers, the likelihood of age-related risks for cardiovascular disease and cancer were inherently increased. Although many women in the United States are overweight and are or were smokers, such confounding variables are often eliminated in randomized studies in which the focus is a particular treatment.

**WHI Observational Study**

The results of the observational study (WHI-OS) appeared in the literature without media fanfare. This part of the WHI enlisted 93,676 women ages 50-79; therefore, a cohort of women young enough to experience menopausal symptoms was also included.19,20

This population is closer in baseline characteristics to those seen in the Nurses’ Health Study (NHS), which was a prospective, observational cohort study involving 121,700 nurses followed for 30 years (1976-2005).21 The NHS tracked HT for 20 years, starting in 1976, by means of a biennial questionnaire about details of HT use, including duration and types of hormones. Although the study designs were different, a comparison of the WHI and NHS is revealing.

The average woman in the NHS began HT between 30 and 55 years of age, predominantly for hot flashes and night sweats. The mean BMI in the NHS was 25.1 kg/m². Only 6.9% of the women in the NHS were past or current smokers, and a total of 43.9% of participants in the NHS used aspirin regularly, compared to 19.1% in the WHI.17,21

The data from WHI-OS yielded results that were similar to those seen in the NHS and provided further evidence that observational studies on younger women with symptoms are different than clinical trials on older women in which the end points are cardiovascular.17,21

**Cardiovascular Disease Risk**

Many women, and even some health care practitioners, incorrectly believe that breast cancer is the most common cause of death among women. In fact, breast cancer accounts for about 4% of deaths in women, and all cancers combined account for less than 22%. The number one cause of death in women is heart disease, which car-
ries a mortality rate of 45%; together, heart disease and stroke account for more deaths in women than do all other causes of mortality combined.22

The epidemiologic/observational data from a number of studies7-13 suggested that HT is cardioprotective, whereas, the WHI hormone intervention data show that HT actually presents an increased cardiovascular risk. To examine this discrepancy, Grodstein and colleagues27 reanalyzed the cohort from the NHS using the baseline characteristics of the women in the WHI E+P study. The researchers found that women who started on either estrogen or estrogen-progestin replacement therapy late had no reduction in the risk of cardiovascular disease; those who started early on either estrogen alone or combination HT did have a reduction. The NHS investigators also found that timing of the start of HT was important among the subgroup of women who did not have existing heart disease: the benefit was greater for early starters than for the late starters in this subgroup as well.

Clarkson’s24 classic studies in monkey models have explored the issue of timing of HRT as it affects cardiovascular benefits. It is his hypothesis that starting HT early, near the onset of menopause, stabilizes cardiovascular plaque development, whereas, starting HT later can trigger a series of inflammatory and thrombotic processes, which, in turn, trigger a cardiovascular event that would otherwise have occurred at a later time.

There is another important point about the validity of the conclusions drawn from the initial analyses of WHI data released in 2002: although the WHI was intended to be a primary prevention trial, the investigators purportedly excluded from enrollment women with prevalent cardiovascular disease, defined as acute myocardial infarction (MI) or transient ischemic attacks, as well as pulmonary embolism or deep-vein thrombosis that was nontraumatic or that had occurred within the previous 6 months. However, the investigators did not exclude 2% to 3% of the participants who reported having had a previous MI and/or coronary revascularization procedures, and study applicants were not actually prescreened for the existence of coronary heart disease. Thus, for some patients, the trial was one of secondary prevention, not primary prevention. This would not have been significant had the number of cardiovascular events not been relatively small.

Breast Cancer Risk

There was no statistically significant increase in breast cancer risk in the WHI-CEE cohort; the reported 26% increase in breast cancer occurred in the combination HT arm (WHI-E+P). However, when the data on the combination HT group were broken down by years of prior hormone use (Table 4), it became clear that duration of use was a crucial factor in breast cancer risk.17

There was no increase in breast cancer risk among the 12,304 women who had no prior hormone use at baseline and who took hormones continuously during the study for 5.3 years. All of the risk in the WHI-E+P arm was driven by women who had used hormones before, particularly those who had been on HT for more than 5 years. Thus, the 26% increase in breast cancer in WHI-E+P really represented an increase of only 8 women in 10,000, or less than one extra woman per 1,000 women/year.

This distinction is important because very few women use hormones for 5 years or longer. Pilon and colleagues29 showed that among a group of 3,395 women, about 40% were still taking HT after 1 year, and more than 90% had discontinued HT by year 5; this duration of use was found before the results of the WHI were so widely publicized. One would assume that duration for use is even shorter now.

Just over 1 year ago, another series of news stories appeared reporting that the number of breast cancer cases in the United States had dropped dramatically in 2003 and asserting that this decrease was linked to a reduction in HT use, which, in turn, had resulted from the news from the WHI about the high risk of using hormones. What was not reported was the fact that there are a number of obvious—and not-so-obvious—alternative explanations for these statistical changes.29

One is that breast cancer rates have been declining since 1999—that is, since 3 years prior to the announcement of the first WHI data. Another is that many of the women who had discontinued using hormones following the 2002 news reports had been using HT for its reported benefits in protecting against osteoporotic bone loss and cardiovascular disease; a substantial number of these women began or increased their use of calcium supplements, vitamin D, raloxifene, and nonsteroidal anti-inflammatory drugs (including aspirin), all of which have been associated with a reduction in breast cancer risk. Also, during the period from 2002 to 2004, there was a 3.2% decrease in screening mammograms among women 50 to 64 years of age, resulting in a decrease in breast cancer detection. A third possibility concerns the fact that there is a difference between cancer initiation (mutagenesis) and cancer growth promotion (mitogenesis). Estrogen is a potent growth factor, which accounts for its activity in the growth of bone, repair of

| TABLE 4. Women’s Health Initiative Breast Cancer Risk by Years of Prior Use |
|------------------|----------|-----------------|--------|------|
| Years            | N        | HT vs Placebo   | HR     | 95% CI |
| None             | 12,304   | 114 vs 102      | 1.06   | 0.81-1.38 |
| <5               | 3,005    | 32 vs 15        | 2.13   | 1.15-3.94 |
| 5-10             | 703      | 11 vs 2         | 4.61   | 1.01-21.02 |
| >10              | 515      | 9 vs 5          | 1.81   | 0.60-5.43 |

HT= hormone therapy; HR=hazard ratio; CI=confidence interval.

Source: Writing Group for Women’s Health Initiative Investigators.17
the vaginal epithelium, and wound healing, among other effects. However, this does not mean that estrogen causes cancer. Further study is needed to clarify this.

Furthermore, the greatest number of discontinuations of HT occurred in the group of women between 45 and 50 years of age, but there was no decrease in breast cancer incidence in this group. However, there was an 11% decrease in the risk of breast cancer in the subjects more than 70 years of age, although only a small absolute number in this group had been taking hormones.23

Finally, regarding its Cancer Facts & Figures 2003 publication of the Surveillance, Epidemiology, and End Results program data, the American Cancer Society issued the following statement: “It is very important to note that the incidence and mortality data in the 2003 report will be age-adjusted to the 2000 population standard of the United States. This change in method will affect the comparability of the new report’s data with that of previous years. The new approach will result in some dramatic changes in the rates of cancer incidence and mortality, rates at different ages, magnitude of improvement in cancer, and racial and ethnic differences.”24

The Future of HT in the US

A great deal of research effort is now being expended on establishing the lowest dose of estradiol that will treat hot flashes. One study of an estradiol gel demonstrated that serum estradiol levels as low as 20 pg/mL reduced the severity and frequency of hot flashes.25 Studies of other preparations have yielded similar results.

The issue of progestins in HT also is being examined to determine the possible effects of various oral systemic progestins on breast cancer risk.

Conclusion

Based on the accumulated evidence on the risks and benefits of HT to date, symptomatic patients—that is, those who have vasomotor symptoms, vulvovaginal atrophy, etc.—should be treated with estrogen or combination estrogen-progestin hormone therapy, as appropriate, after considering each patient’s individual risk factors. For all patients, thrombosis is the most important risk factor to consider; this is an important contributor to the risk for stroke and MI.

Systemic therapy for vasomotor symptom amelioration should be prescribed only as long as symptoms persist. In addition, using the lowest effective dosage of treatment will reduce the risk for thrombosis. Also consider routes of administration other than oral: patches, creams, lotions, gels, and vaginal rings have been shown also to reduce the risk for thrombosis. Patients with no systemic symptoms should receive local therapy and consider alternatives to hormones for osteoporosis prevention.

References

Intrauterine Contraception: The Evidence Refutes the Myths

Philip D. Darney, MD, MSc

Intrauterine contraception is a reversible method with efficacy rates rivaling those of surgical sterilization. Despite the efficacy and demonstrated safety of today’s intrauterine devices (IUDs), the use of intrauterine contraception in the United States is lower than that in any other developed country.1

The low rate of IUD use in the United States is largely the result of myths, misperceptions, and unfounded fears that are the legacy of poorly controlled studies and well-publicized liability issues of the past, as well as misperceptions about how today’s IUDs work. Some case-controlled studies published in the 1960s and 1970s helped perpetuate the idea that intrauterine contraception is unsafe.

Furthermore, ongoing inconsistencies in the labeling of IUDs reflect this misinformation—for example, the patient selection labeling for one IUD is substantially different from that of the other, and the contraindications that are delineated in some protocols used by American clinicians are not found in good evidence.

Addressing the Myths About IUDs

Four prevailing myths, in particular, have contributed to the low use of IUDs in the United States—three that concern associated risks2 and one related to mechanism of action.

**Myth #1: IUDs increase the risk for pelvic inflammatory disease (PID).** Several studies have demonstrated that any increased PID risk associated with IUDs relates mainly to the time of placement.3,4 A study from the World Health Organization (WHO) of 23,000 IUD insertions showed that the risk of PID increased in the first 30 days after insertion, but after this time—and for up to 12 years of follow-up—the PID risk was below the baseline of about two cases per 1,000 woman-years of exposure.3

Even in situations of high prevalence of sexually transmitted infections (STIs), the estimated risk for PID with IUD use is quite low: 0.15%, or just over one case per 1,000 insertions.5 In a Medline search of all peer-reviewed literature published between 1966 and 2006 on IUDs and PID risk, Mohllajee and colleagues6 found that the absolute risk for IUD-associated PID in women with such infections ranges from 0% to 5%. In contrast, the risk in women without STIs is 0% to 2%. In a randomized clinical trial, Scandinavian researchers studied the infection risk associated with either a copper IUD or a levonorgestrel-releasing device in women immediately postabortion.7

They found no increase in PID rates over baseline with either device and actually found evidence of protection from PID in users of the levonorgestrel system.

Screening for chlamydial and gonorrheal infections is not necessary prior to IUD insertion, and administration of antibiotic prophylaxis is not recommended. A large study by Walsh and colleagues8 in Los Angeles showed no decrease in infection risk when prophylaxis was used prior to IUD insertion.

**Myth #2: IUDs increase the risk for tubal infertility.** The notion that intrauterine contraception can cause infertility because it compromises tubal function has been shown to be false. Hubacher and colleagues9 of Family Health International conducted a study to explore this issue in a population of women with infertility. The study was done in Mexico, where, in contrast to the United States, intrauterine contraception is routinely offered to nulliparous women. Hysterosalpingograms were performed to identify a group of women with infertility secondary to tubal obstruction. Once selected for the study, the patients were evaluated for serologic evidence of chlamydial infection, and their medical records were reviewed for a history of IUD use. No increased risk for tubal obstruction was found to be associated with past use of IUDs, but such an association was found in patients whose blood tests were positive for chlamydia.

**Myth #3: IUDs increase the risk for ectopic pregnancy.** Although some clinicians and patients believe that IUD use increases the risk for ectopic pregnancy, the opposite is true: both of the IUDs available in the United States actually decrease the risk for ectopic pregnancy. Women who use hormonal and copper IUDs have, respectively, 0.20 and 0.34 ectopic pregnancies per 1,000 woman-years. The two IUDs confer a much lower risk than does no contraception at all, which is associated with 1.20 to 1.60 ectopic pregnancies per 1,000 woman-years.10–12

**Myth #4: IUDs work as abortifacients.** Some patients and clinicians object to the idea of IUDs because of the mistaken belief that the mechanism of action of IUDs is abortifacient, preventing implantation of a fertilized ovum. This notion arose from studies examining inert plastic IUDs (no longer used anywhere in the world), which showed that use of these devices produced a profound inflammatory response. It was believed that this hostile endometrium led to destruction of a blastocyst after it came to rest in the uterus. IUDs used around the world today are active, releasing either copper or levonorgestrel from a plastic or stainless steel frame.

The primary contraceptive action of the two devices currently approved...
for use in the United States—the copper T380A IUD (copper T) and the levonorgestrel-releasing intrauterine system (LNG-IUS)—is prevention of fertilization, not prevention of implantation. The copper IUDs release copper ions, which are highly spermicidal and also interfere with sperm migration, capacitation, and ovum transport.12 The LNG-IUS produces the same cervical mucus changes as those that are seen with all progestin-only contraceptive methods. This thickened cervical mucus is an effective barrier to sperm, providing a mechanism of contraceptive efficacy in addition to changes in tubal function and occasional suppression of ovulation.

Alvarez and colleagues14 conducted a study in which women who had copper IUDs in place and who were scheduled for laparoscopic sterilization procedures were asked to have intercourse during the midcycle prior to their surgery. Then, during surgery, the investigators washed the oviducts and peritoneal cavity to harvest any sperm or fertilized ova. Few viable sperm were found, fertilized ova were rare, and normal blastocysts were very unusual.

In cases in which ova are fertilized and reach the endometrium, human chorionic gonadotropin (HCG) levels begin to rise as soon as implantation occurs. In an early study of IUD mechanism of action, Segal and colleagues8 used highly sensitive assays for β-HCG levels to detect increases in this hormone in women with IUDs. These investigators failed to detect increases in HCG levels that would signal implantation.

In summary, fertilization rarely happens with IUD use; even when it does happen, blastocyst implantation does not occur. These two lines of evidence provide compelling arguments refuting the idea that IUDs are abortifacients.

IUD Product Labeling and Use Guidelines

Standardization of labeling for IUDs is lacking, and the product labels for the copper T and LNG-IUS devices are different. In addition, the guidelines provided by the national and international organizations that provide authoritative information and recommendations on contraception—that is, American College of Obstetricians and Gynecologists (ACOG) in the United States and the WHO worldwide—conflict on certain points.

Labeling Issues

Labeling and package inserts for drugs and devices often are obsolete. Mullen and colleagues16 studied a collection of product labels published in the Physicians' Desk Reference and concluded that more than 50% were inaccurate or outdated, presenting, in some cases, ineffective or even harmful information. Another problem with labeling is that there is a gap between approved package inserts and ongoing research findings. Clinicians should, of course, be familiar with the approved labeling for the products used in patient care. However, practice guidelines are a crucial element in decision making for therapy because labeling may not reflect current practice.

Several selected contraindications listed in the current label for the copper T are shown in Table 1 along with three outmoded contraindications that were removed when the label was revised in 1995 (history of PID, patient or partner with multiple partners, and conditions increasing susceptibility to infection, such as acquired immune deficiency syndrome [AIDS] or diabetes).

The three outmoded contraindications were removed after studies were presented to the US Food and Drug Administration demonstrating that revisions were warranted. After the package insert was first approved for the copper T, strong evidence had emerged showing that an IUD can be used safely if PID is no longer active. The second contraindication was deleted because patients or partners with multiple partners should be using condoms to protect each other, regardless of the method of contraception used; multiple partners, alone, is not a rationale for a contraindication for any contraceptive method.

Finally, there is no evidence that an individual’s compromised immunity from AIDS or diabetes has any effect on the safety or efficacy of IUD use—either the copper T or the LNG-IUS device. In fact, an IUD is an excellent choice for women, like those with diabetes or AIDS, who want to use the most effective contraceptive available, and intrauterine contraception meets this need. IUDs also provide highly effective contraception without altering carbohydrate metabolism.

The contraindications for the LNG-IUS device (Table 2 on page 11) are different from those in the copper T label, despite little to no evidence to suggest any actual differences. Still pre-

<table>
<thead>
<tr>
<th>TABLE 1. Copper T Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selected Current Labeling Contraindications</strong></td>
</tr>
<tr>
<td>◆ Acute PID or current behavior suggesting high risk of PID</td>
</tr>
<tr>
<td>◆ Postpartum/postabortal endometritis in the past 3 months</td>
</tr>
<tr>
<td>◆ Known/suspected uterine/cervical malignancy</td>
</tr>
<tr>
<td>◆ Genital bleeding of unknown etiology</td>
</tr>
<tr>
<td>◆ Mucopurulent cervicitis</td>
</tr>
<tr>
<td>◆ Wilson’s disease</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Former Contraindications (Removed in 1995)</th>
</tr>
</thead>
<tbody>
<tr>
<td>◆ History of PID</td>
</tr>
<tr>
<td>◆ Patient or partner with multiple partners</td>
</tr>
<tr>
<td>◆ Conditions increasing susceptibility to infection (eg, AIDS)</td>
</tr>
</tbody>
</table>

AIDS = acquired immunodeficiency syndrome; PID = pelvic inflammatory disease.
cluded in labeling is LNG-IUS use in patients with a history of PID, conditions—such as AIDS—that affect the integrity of the immune system, and patients or partners with multiple sex partners—conditions that no longer contraindicate use of the copper T, according to the recent label changes.

A history of ectopic pregnancy still is listed as a contraindication to LNG-IUS use, but not to the use of the copper T. As noted above, both IUDs actually prevent ectopic pregnancy.10-12 Other contraindications that are still included in the LNG-IUS package insert and are not supported by scientific evidence are postpartum endometritis or infected abortion in the past 3 months, uterine or cervical neoplasia or unresolved abnormal Pap smear, and known or suspected breast cancer.

Risk of breast cancer is the most alarming of these contraindications, but, in a Finnish study of a large number of users (N=17,360) of the LNG-IUS device,17 investigators reported that women who had used the device for up to 12 years were at no greater risk for breast cancer than were women who had not. Furthermore, the current ACOG practice guidelines do not include known or suspected breast cancer as a contraindication.18

The labels for the copper T and LNG-IUS devices also differ with respect to parity and uterine size. There is a contraindication for use of the LNG-IUS but not for the copper T in nulliparous women. In fact, the hormone-releasing IUD may be better tolerated in some nulliparous women because it is associated with less cramping and bleeding. The issue of uterine size is spurious; there are no data to support the idea that the uterus must be a certain size to accommodate an IUD.

### Practice Guidelines for IUDs

The ACOG practice guidelines list seven key contraindications to IUD insertion16: PID within the previous 3 months, current STI, puerperal or postabortion sepsis within 3 months, purulent cervicitis, undiagnosed abnormal vaginal bleeding, genital tract malignancy, and uterine anomalies or fibroids that distort the cavity in a way that is incompatible with IUD placement. These guidelines are less restrictive than those in either the copper T or the LNG-IUS package insert.

The WHO’s medical eligibility criteria for intrauterine contraception19 have only one absolute contraindication: current PID. Generally, women with a history of PID without subsequent pregnancy and nulliparous women are considered eligible for IUD use. Women who are postpartum/lactating for more than 4 weeks or who are obese, as well as those who have mood disorders, uterine fibroids (without uterine cavity distortion), or a history of PID with subsequent pregnancy, are listed as eligible for IUD use “in any circumstance.”

Listed in Table 3 are the contraindications that I consider to be reasonable, given the evidence to date.

### Professional Practice Issues

There is good evidence from several studies that practitioners are burdened by unreasonable protocols and by lack of knowledge of the counseling that should be provided to patients regarding intrauterine contraception.10,21 An analysis of survey data about intrauterine contraception provision in California’s 1.6 million-patient Family Planning Access, Care, and Treatment (Family PACT) program22 yielded results similar to those reported by Vos and colleagues20 in the Netherlands and Bianchi-Demicheli and coworkers21 in Switzerland.

In the Family PACT program in fiscal year 2004-2005, despite the fact that the state spends nearly $400 million a year for services and covers IUDs, only 1.3% of reproductive-age women were given intrauterine contraception, more than 40% of clinicians inserted no IUDs at all, and only 23% of practitioners provided IUDs to more than 20 women.

To try to determine why IUD use was so low, our group conducted a survey of Family PACT providers randomly selected from those who billed the program for providing contraception to at least 100 patients each year.22

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**Table 2. LNG-IUS Selected Current Labeling Contraindications**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute PID or history of PID (unless subsequent intrauterine pregnancy)</td>
<td></td>
</tr>
<tr>
<td>Conditions associated with increased susceptibility to infection (eg, AIDS, IV drug abuse)</td>
<td></td>
</tr>
<tr>
<td>Patient or partner has multiple sex partners</td>
<td></td>
</tr>
<tr>
<td>History of ectopic pregnancy or condition predisposing to ectopic pregnancy</td>
<td></td>
</tr>
</tbody>
</table>

AIDS = acquired immune deficiency syndrome; LNG-IUS = levonorgestrel-releasing intrauterine system; PID = pelvic inflammatory disease.

**Table 3. Reasonable Contraindications to IUD Use**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy</td>
<td>No benefit, distinct harm</td>
</tr>
<tr>
<td>Cervical stenosis, uterine distortion</td>
<td>Unable to insert</td>
</tr>
<tr>
<td>Uterine cavity too small</td>
<td>Expulsion rates high?</td>
</tr>
<tr>
<td>Uterine cavity too large</td>
<td>Decreases efficacy?</td>
</tr>
<tr>
<td>Uterus infected</td>
<td>Complicates infection</td>
</tr>
<tr>
<td>Uterine cancer</td>
<td>Complicates treatment?</td>
</tr>
<tr>
<td>Unexplained abnormal bleeding</td>
<td>Delay of diagnosis</td>
</tr>
<tr>
<td>Wilson’s disease</td>
<td>Copper content (applies to copper IUD only)</td>
</tr>
</tbody>
</table>

IUD = intrauterine device.
eight-page survey was mailed to 1,246 physicians, nurse practitioners, and physician assistants in June and July of 2006; 816 surveys were completed and returned for a response rate of 65%. The survey questions covered demographics, professional practice, attitudes about intrauterine contraception, patient counseling, IUD candidates, IUD insertions and removals, and IUD referrals.

The results showed that many of these clinicians provided inappropriate counseling for intrauterine contraception, confused the indications and contraindications for the copper T and LNG-IUS (as noted in the section on labeling issues above), the package inserts for these devices are not the same, and confused the side effects. For example, in counseling patients about the copper T, one in four respondents emphasized the device’s “hormonal” side effects (headaches, mood disturbances, breast tenderness, and nausea), although the copper T contains no hormones and is not associated with any of these side effects. Thirty-eight percent of respondents emphasized amenorrhea when counseling patients about the copper T, although menstrual bleeding actually may increase with this device; with the LNG-IUS, one in five women experience amenorrhea by the end of the first year of use.

When counseling about the LNG-IUS, 69% of respondents said they emphasized dysmenorrhea, 66% emphasized menorrhagia, and 49% emphasized amenorrhea; in fact, the LNG-IUS is associated with decreased menstrual pain, decreased excessive bleeding, and increased hemoglobin levels.

Although clinicians’ attitudes toward intrauterine contraception as a method was favorable, the survey showed that many providers do not have sufficient knowledge to provide IUDs, and many of those who do provide IUDs follow cumbersome protocols (Table 4).

**Conclusion**

Intrauterine contraception is a highly effective method that can be considered by women throughout their reproductive years and is appropriate for young women, women who are nulliparous, and those who are perimenopausal. It is important for clinicians to keep abreast of the most current and accurate information regarding intrauterine contraception and to be prepared to address the common myths and misperceptions that many patients hold about IUDs.

**References**


**Table 4. Family PACT Survey: Respondents Follow Cumbersome Medical Protocols**

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Respondents Follow Cumbersome Medical Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exclude nulliparous and/or younger women (49%)</td>
<td>☑</td>
</tr>
<tr>
<td>Require three or more visits for IUD insertion (18%)</td>
<td>☑</td>
</tr>
<tr>
<td>Require Hemoglobin test within past 3 months (51%)</td>
<td>☑</td>
</tr>
<tr>
<td>Require Papanicolau test within past year (92%)</td>
<td>☑</td>
</tr>
<tr>
<td>Exclude chlamydia test within past 3 months</td>
<td>☑</td>
</tr>
<tr>
<td>— Women &lt;25 years old (94%)</td>
<td>☑</td>
</tr>
<tr>
<td>— Women &gt;25 years old (85%)</td>
<td>☑</td>
</tr>
</tbody>
</table>

ACOG = American College of Obstetrics and Gynecology; Family PACT = Family Planning Access, Care, and Treatment; IUD = intrauterine device.

Source: Harper et al.21
The Role and Appropriate Use of the Modern IUD

Jeffrey T. Jensen, MD, MPH

Each year in the United States, about 6.5 million pregnancies occur, about half of which are unintended. Approximately one in 20 women of reproductive age experience an unintended pregnancy annually, and this risk doubles to one in 10 in the subset of younger than 25.¹

Over seven percent of sexually active couples not seeking pregnancy do not use contraception and risk a probability of pregnancy of about 85% in one year.²⁻³ This group of non-users contributes about half of the roughly 3.2 million unintended pregnancies that occur each year.⁴ The much larger 93% of sexually active couples in the United States currently reporting use of some method of contraception contribute the remaining half of unintended pregnancies through method or user failure.⁴ Therefore, to reduce the number of unintended pregnancies efforts must focus both on reducing non-use and on increasing the use of highly effective methods.

Efficacy of Contraception and Patterns of Use

Data published from the National Survey of Family Growth, a national representative directed-interview survey of more than 9,000 households, demonstrate trends in contraception use and unintended pregnancies. Finer and Henshaw¹ compared data from the most recent survey (conducted in 2002) with those from the immediately previous survey (conducted in 1995), and found that the use of more effective contraceptive methods increased from the earlier survey to the latter. Although the number of unintended pregnancies decreased between 1995 and 2002, the decrease was less than would be expected, given the increase in use of the more effective methods. One explanation may be that nonuse of contraception among women who reported being sexually active, at risk for pregnancy, and not desiring pregnancy increased by 2.2% (from 5.2% to 7.4%) during the same time interval,⁵ and this additional non-use may have resulted in 500,000 unintended pregnancies in 2002.

In terms of levels of contraceptive efficacy, according to first-year typical failure rates (Table 1),⁶ the least effective are barrier-contraceptive, behavioral, and over-the-counter methods, all of which require couples to be compliant with contraception around the time of intercourse. Combined hormonal methods are more effective; they require daily, weekly, or monthly use, and their contraceptive efficacy is not associated with the timing of coitus. The most effective methods of contraception have a long duration of use—3 months for injectable contraception, 3 years for etonogestrel implants, 5 to 10 years for intrauterine contraception, and indefinitely for surgical sterilization.

Perhaps surprisingly, the most effective methods of contraception available are not necessarily those in widest use in the United States. In the United States, surgical sterilization and oral contraceptives (OCs) are the most frequently used: 30.6% of American women who use contraception use the Pill, and 36.2% of contraception users choose sterilization (tubal sterilization, 27.0%, and vasectomy, 9.2%). Only 2.0% of American women choose intrauterine devices (IUDs).⁷

In other regions around the world, IUD usage acceptance rates are much higher than they are in North America. According to a 2005 United Nations report, the United States has the lowest rate of intrauterine contraception use among developed countries—0.7%, compared with 2.9% in Canada, 6% in the United Kingdom, 14.1% in Mexico, 19.9% in France, 24.1% in Norway, and 36.4% in China.⁷ Clearly, the challenge in reducing the rate of unintended pregnancy in the United States is twofold: to determine which methods are acceptable to individuals who currently are not using contraception and to encourage all sex-

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Percentage of Women Experiencing an Unintended Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonorgestrel intrauterine system</td>
<td>0.1%</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>0.5%</td>
</tr>
<tr>
<td>Copper T IUD</td>
<td>0.8%</td>
</tr>
<tr>
<td>Injection</td>
<td>3%</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>8%</td>
</tr>
<tr>
<td>Vaginal ring</td>
<td>8%</td>
</tr>
<tr>
<td>Patch</td>
<td>8%</td>
</tr>
<tr>
<td>Condom</td>
<td>15%</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>16%</td>
</tr>
<tr>
<td>Fertility awareness</td>
<td>25%</td>
</tr>
<tr>
<td>Spermicide</td>
<td>29%</td>
</tr>
<tr>
<td>No method of contraception</td>
<td>85%</td>
</tr>
</tbody>
</table>

Source: Trussel J.¹
ually active couples to choose (or consider changing to using) contraceptive methods with the greatest efficacy.

**Long-Acting Contraceptive Methods: Advantages and Disadvantages**

Sterilization is an important method of contraception, one that is considered first when a woman desires permanent contraception. This choice is typically based on the assumption that sterilization is the only foolproof way to prevent unintended pregnancy; and that fallopian tubes can be “untied” if a pregnancy is desired in the future. Even some clinicians who recognize that even sterilization does not guarantee 100% contraceptive efficacy in all cases commonly quote overly optimistic efficacy rates. Data from the landmark US Collaborative Review of Sterilization (CREST) —an observational study in which 10,685 women were followed from 1978 to 1987—showed a sterilization failure rate of 1.85% over 10 years. (Of course, given the time period of this study, the CREST data do not take into account the development of improved technology and techniques for female sterilization; nevertheless, this is the best study on this issue done to date.)

In addition, patients who are considering this method also should understand that sterilization is associated with the same surgical complications that exist with any operative procedure. Furthermore, the issue of “sterilization regret” must be considered, particularly by younger women. Approximately 20% of women who undergo sterilization before 30 years of age later regret having had the procedure.

The advantages of longer-acting, nonpermanent methods are that they are characterized by essentially convergent perfect- and typical-use efficacy rates. There is little to no opportunity for incorrect use, and additional acts of compliance are not required. Separating contraception from sexual activity eliminates some of the behavioral issues that can lead to contraceptive failure. Although the initial cost for these longer-acting methods is high compared with that of other reversible contraceptive methods, the total cost over time (duration of use) is low.

**IUD Efficacy**

Intrauterine contraception is a highly effective method, and it is reversible yet comparable in efficacy to that reported for surgical sterilization. Insertion of an IUD is an office-based, noninvasive procedure that is easy for a practitioner to learn and is well tolerated by patients. Once the device is in place, no maintenance is required over the useful life of the IUD—10 years in the case of the copper T380A IUD (copper T) device and 5 years for the levonorgestrel-releasing intrauterine system (LNG-IUS). (These are the two devices currently approved for use in the United States by the US Food and Drug Administration [FDA].)

The LNG-IUS releases 20 μg/day of levonorgestrel directly into the uterine cavity, resulting in serum levels 20 to 50 times lower than those seen with low-dose OCs. The first-year failure rate with the LNG-IUS is 0.2%. The copper T device releases copper ions into the uterus and is associated with a first-year failure rate of 0.7%.

**IUDs and Bleeding Patterns**

Both the LNG-IUS and the copper T affect menstrual bleeding patterns (Table 2). Most women tolerate these symptoms well, but this should be thoroughly discussed prior to choosing an IUD as a contraception method and in determining which device is most appropriate for an individual patient.

The copper T tends to cause heavier menstrual bleeding and also may cause more uterine cramping than does the LNG-IUS. Women who have used hormonal contraception previously—such as an OC—will likely have experienced lighter menstrual bleeding or amenorrhea while using these methods. Such patients should anticipate that, after switching to a copper T device, a normal menstrual cycle will resume and, in addition, bleeding may become heavier, perhaps accompanied by cramping. These symptoms generally improve within the first 3 to 6 months of use.

With the LNG-IUS, bleeding and spotting are initially unpredictable. Typically, the incidence of irregular bleeding and spotting decreases after the first 3 to 4 months of use, with one in five women experiencing amenorrhea by the end of the first year of use.

**Noncontraceptive Benefits of IUD Use**

Noncontraceptive benefits are seen with both IUDs. Both the copper T and the LNG-IUS are associated with a reduced risk for endometrial cancer.

**TABLE 2. Intrauterine Contraception: Bleeding Patterns**

<table>
<thead>
<tr>
<th>Levonorgestrel Intrauterine System (LNG-IUS)</th>
<th>Copper T</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Initially unpredictable bleeding/spotting</td>
<td>♦ Increased bleeding in first 3-6 months</td>
</tr>
<tr>
<td>♦ Bleeding decreases over time</td>
<td>♦ Overall, may increase menstrual blood loss and cramping</td>
</tr>
<tr>
<td>♦ Long-term reduction in menstrual blood loss</td>
<td></td>
</tr>
</tbody>
</table>
The most recent evidence supporting this protective association comes from a population-based, case-controlled study in China, in which Tao and colleagues⁵ found a reduction in risk (odds ratio, 0.53; 95% confidence interval, 0.43-0.65), regardless of the duration of use or age at first and last use.

Other noncontraceptive benefits of the LNG-IUS include a reduction in excessive menstrual blood loss and dysmenorrhea. Additional benefits include prevention of endometrial hyperplasia in women using postmenopausal estrogen replacement or tamoxifen therapy, treatment of endometrial hyperplasia, and improvement of pain associated with endometriosis.¹⁴ None of these is an FDA-approved indication for the LNG-IUS, although the device is approved in 106 countries as a treatment for idiopathic menorrhagia and in 97 countries to provide the progestin component in postmenopausal hormone replacement regimens.

The LNG-IUS has been studied as a treatment for idiopathic menorrhagia and an alternative to hysterectomy. Hurskainen and coworkers¹⁵ studied 236 women with idiopathic menorrhagia who were referred for hysterectomy. The patients were randomized to receive either LNG-IUS or surgery and were followed for 5 years. At the end of that time, 42% of those in the LNG-IUS group chose to undergo hysterectomy; 58% chose to cancel their plans for surgery and continue with the levonorgestrel system.

Summary

Increasing the acceptability of longer-acting methods of contraception, such as intrauterine devices, will reduce the burden of unintended pregnancy and bring our society much closer to our social goal of having every baby planned and strongly desired. Clinicians have a responsibility to make all available forms of contraception accessible to patients, a goal that is achieved only when clinicians and patients are informed about the advantages, risks, and benefits of all contraceptive methods. Improvements should be made in the usage rates of the highly effective but underused method of intrauterine contraception; educational and informational efforts that result in higher usage rates are also likely to result in a decrease in the rate of unintended pregnancies in the United States.

References

Clinical Perspectives in Intrauterine Contraception and Postmenopausal Hormone Therapy
HIGHLIGHTS OF SYMPOSIA

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INSTRUCTIONS: For each question or incomplete statement, choose the answer or completion that is correct. Circle the most appropriate.
Seven out of ten responses are required for credit.

1. Which one of the following statements about intrauterine devices (IUDs) and pelvic inflammatory disease (PID) is true?
   a. The risk for PID is greatest at the time of placement.
   b. IUDs substantially increase the risk for PID only in the presence of a sexually transmitted disease.
   c. The risk for PID increases gradually over time.
   d. To reduce the risk for PID, women should be screened for chlamydia and gonorrhea prior to IUD placement.

2. Women who use copper-releasing or hormone-releasing IUDs:
   a. Have an increased risk for ectopic pregnancies
   b. Have an increased risk for tubal infertility
   c. Have an increased risk for tubal infertility only if they are nulliparous
   d. Have a lower risk for ectopic pregnancies than if they used no contraception at all

3. The main mechanism of action of copper-releasing and hormone-releasing IUDs is:
   a. Abortifacient
   b. The destruction of blastocysts
   c. Prevention of fertilization
   d. Prevention of implantation of fertilized ova in the endometrium

4. The efficacy of the copper-releasing and hormone-releasing IUDs is comparable to that of:
   a. Abstinence
   b. Condoms with spermicide
   c. Oral contraception
   d. Surgical sterilization

5. The useful life of the copper IUD (copper T) is ___ years, and the useful life of the levonorgestrel-releasing intrauterine system (LNG-IUS) is ___ years.
   a. 12; 5
   b. 12; 3
   c. 10; 5
   d. 10; 3

6. The copper T tends to cause:
   a. Amenorrhea
   b. Endometrosis
   c. Heavier menstrual bleeding
   d. Lighter menstrual bleeding

7. Although not approved as indications for the LNG-IUS, observed non-contraceptive benefits of the LNG-IUS include all but one of the following. The exception is:
   a. Complete elimination of pain associated with endometriosis
   b. Reduction in excessive menstrual blood loss and dysmenorrhea
   c. Prevention of endometrial hyperplasia in women using postmenopausal estrogen replacement or tamoxifen therapy
   d. Treatment of endometrial hyperplasia

8. The purpose of the Women’s Health Initiative was to examine the effects of hormonal therapy on:
   a. Breast cancer risk
   b. Cardiovascular disease risk
   c. Osteoporosis
   d. Women older than 65 years of age

9. Among the results of the Women’s Health Initiative announced in 2002 was an increase in all of the following except:
   a. All-cause mortality
   b. Cardiovascular disease
   c. Strokes
   d. Venous thromboembolism

10. The Women’s Health Initiative data showed that the cardiovascular benefits of hormone therapy are affected by:
    a. The dosage of estrogen: the higher, the better
    b. The timing of onset of therapy: the earlier, the better
    c. The type of progestin used
    d. Whether a progestin is used: combination therapy is better than estrogen alone

EVALUATION FORM: We would appreciate your answering the following questions in order to help us plan for other activities of this type.

1. How do you rate the overall quality of the activity? 12345
2. How do you rate the educational content of the activity? 12345
3. Would you be willing to participate in a phone, e-mail, or in-person discussion exploring ways to improve our CME activities? __Y es __ No
4. Was the presented information fair, objective, balanced, and free of bias in the discussion of any commercial product or service? __Y es __ No
5. Suggested topics for future activities:
6. Suggested authors for future activities:
7. Would you be willing to participate in postactivity follow-up surveys? __Y es __ No
8. Would you be willing to participate in a phone, e-mail, or in-person discussion exploring ways to improve our CME activities? __Y es __ No

The EO CME thanks you for your participation in this CME activity. All information provided improves the scope and purpose of our programs and your patients’ care.

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