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Another option? Contraceptive patches are now under research

Transdermal systems may boost compliance, lower unintended pregnancy

Think about your patients who have problems remembering to take their daily birth control pill, and images of the forgetful teen, the busy mother, and the pressed-for-time working woman immediately come to mind. What if a transdermal contraceptive patch could provide them with safe, effective birth control, thus eliminating the need for a daily pill?

Several such patches are now in the research pipeline. While their safety and efficacy profiles are yet to be fully established in large-scale trials, contraceptive transdermal systems represent yet another potential option with a built-in convenience factor.

Interest in contraceptive patches was heightened this summer when news broke about Evra, a transdermal system under development by Ortho-McNeil Pharmaceuticals of Raritan, NJ. Preliminary information on Evra and other products under development was reviewed during a meeting of financial analysts hosted by Johnson & Johnson of New Brunswick, NJ, the parent company of Ortho-McNeil.

Company comments about Evra are limited because the company has yet to submit regulatory filings on the product, says **Linda Fedow**,

EXECUTIVE SUMMARY

Contraceptive transdermal patches now under research may represent an option for women who have trouble sticking with a daily pill regimen.

- Evra, a contraceptive patch under development by Ortho-McNeil Pharmaceuticals, relies on the estrogen ethinyl estradiol and the progestin norgestimate for birth control efficacy. Scientists at the Population Council are looking at a contraceptive transdermal system using Nestorone, a progestin developed by the council.
- While no contraceptive patches are on the market, women use transdermal patches for management of menopausal symptoms. Scientists say the steady, slow release of hormones might eliminate some of the side effects associated with oral administration of such drugs.

director of public affairs for Ortho-McNeil. The company is in Phase III clinical trials, but Fedow declines to discuss its findings.

"What I can tell you is that we believe that this product is highly innovative, and its contraceptive efficacy is comparable to the most popular and some of the best oral contraceptives," she says. "Other than that, we really can't speak to [risks and benefits] because it is so early."

Evra will contain the estrogen ethinyl estradiol and an active metabolite of norgestimate, which family planners will recognize as the progestin used in Ortho-Cyclen and Ortho Tri-Cyclen, two of the company's most popular oral contraceptive brands. The technology for the transdermal system is being supplied by outside partner Cygnus, a company in Redwood City, CA, that focuses on the development and manufacture of diagnostic and drug delivery systems.

The patch is being developed so it can be used on any one of four areas of a woman's body: the abdomen, the buttocks, the upper outer arm, and the upper torso, Fedow reports.

"We believe this will be a very novel system for women," she says. "We believe it does have a convenience factor and that it will adhere well to a woman's skin, allowing her to perform all different types of routine daily activities, whether it be bathing, swimming, or exercise."

Women are looking for long-term birth control methods that offer the efficacy of the Pill but are easily reversible, says Fedow. Evra is squarely aimed at those potential users.

The Population Council in New York City also is researching a contraceptive patch, confirms **Sandra Waldman**, director of public information. The transdermal system uses Nestorone, a progestin developed by the council. [***Contraceptive Technology Update*** **reviewed the council's partnership with Miramar, FL-based Sano Corp. in developing transdermal patches for both contraception and hormone replacement therapy (HRT) in its October 1997 issue, p. 121.** Under a December 1997 stock acquisition by Elan Corp. in Dublin, Ireland, Sano now operates as a business unit of Elan Pharmaceutical Technologies, Elan's drug delivery division.[1]] "The Population Council is looking at patches that potentially can be used for contraception, including emergency contraception, and hormone replacement therapy," reports Waldman. "The primary hormone we are using is Nestorone, a versatile progestin that is readily absorbed through the skin into the bloodstream."

The council's work is in a preliminary stage, she notes. Scientists also are looking at use of Nestorone for use in contraceptive vaginal rings. One version of such a ring contains a combination of the estrogen ethinyl estradiol and Nestorone, while the other contains Nestorone alone. **(For more information on those research developments, see *CTU,* May 1998, p. 57.)**

HRT patches on market

While the Evra patch may be the first contraceptive transdermal system to come under federal Food and Drug Administration (FDA) review, it won't be the first patch developed specifically for women. American women already are becoming familiar with transdermal technology with the advent of systems used to deliver HRT.

There are at least six estradiol patches now on the U.S. market:

- Alora from Proctor & Gamble Pharmaceuticals of Cincinnati;
- Climara from Berlex Laboratories of Wayne, NJ;
- Esclim from Groupe Fournier of Dijon, France;
- Estraderm and Vivelle, both of Novartis Pharmaceuticals Corp. of East Hanover, NJ;
- FemPatch from Parke-Davis of Morris Plains, NJ.

CombiPatch received FDA approval in August 1998 as the first U.S.-approved HRT patch to combine estrogen and progestin. The system, which delivers the estrogen 17-beta-estradiol and the progestin norethindrone acetate, is marketed by Rhône-Poulenc Rorer of Collegeville, PA.

By delivering a steady flow of drugs over an extended period of time, transdermal patches

COMING IN FUTURE MONTHS

- Review research data on once-a-month injectable
- Who is responsible for patient education?
- Adolescent reproductive health care and the law
- Questions you need to ask OC users on follow-up visits
- Children in the clinic: How do you cope?

avoid the "peak and valley" hormone effect of pills or injections, thereby reducing associated side effects.[2]

"The advantage of the transdermal system is the consistent blood levels," observes **David Archer**, MD, professor of obstetrics and gynecology at the Jones Institute for Reproductive Medicine in the Eastern Virginia Medical School in Norfolk. "The rapid absorption and high blood levels with oral administration are felt to be the cause of nausea [sometimes associated with pill use]; transdermals may reduce this effect."

While there is no comparable contraceptive patch yet on the market, research comparing women's experiences with HRT patches vs. pills shows mixed acceptance of transdermal technology. In one 1997 presentation, researchers reported that more women seem to prefer transdermal therapy to oral HRT, because transdermal therapy ensures more constant estradiol levels.[3] However, a study published in 1998 indicated that among women starting HRT, those using a semiweekly transdermal estradiol regimen have a lower rate of continuation than do those using daily oral estrogen therapy.[4]

"Transdermal HRT systems have not found large acceptance from the consumer," Archer says. "I believe it is due to local [skin] irritation and lack of a good adhesive."

Users must remember to change transdermal patches once or twice a week, which differs from daily dosing, he notes. This may be seen as a benefit by a large part of the population. Contraceptive patches may be embraced by those women who want to try something new, Archer says. By developing a stylish backing for a contraceptive patch, marketers may tie into the recent increase in interest in tattoos and body art, he suggests.

The true test of contraceptive transdermal patches will be the release of full safety and efficacy data. If the patches don't provide effective birth control or are linked to unacceptable side effects, they will not be accepted by women.

"No data on bleeding or other related issues that can influence compliance is yet available," Archer says. "This information will be needed to determine utilization."

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No link between OC use and heart attack

Good news to share with your patients: According to the latest published research, there is no significantly increased risk of acute myocardial infarction (AMI/heart attack) in women who use oral contraceptives (OCs).[1] Even more important, scientists were unable to find evidence of a difference between second- and third-generation OCs when it comes to heart attack risk.

These results come from a retrospective community-based, case-controlled study, conducted in England, Scotland, and Wales, in which researchers examined the association between OC use and heart attack in women under age 45.

A total of 448 women ages 16 to 44 who had suffered a heart attack were matched with 1,728 women in the control group. Main outcome measures were odds ratios for heart attack in current users of all combined OCs stratified by their progestin content compared with non-users, as well as a comparison of current users of third-generation vs. second-generation pills.

"There is no association between any type of modern low-estrogen dose OC and myocardial infarction," says **Nicholas Dunn**, MA, DM, MSc,

EXECUTIVE SUMMARY

Just-released research indicates there is no significant increase in risk of acute myocardial infarction in women who use oral contraceptives (OCs).

- Scientists did not find evidence of a difference between second- and third-generation OCs and heart attack risk.
- For women under age 45 who had had a heart attack, 87% were not taking any birth control pill.
- Of women who had had a heart attack, 88% had one or more known cardiovascular risk factors.
- Young women who want to preserve their cardiovascular health should be counseled to stop smoking.

MRCGP, senior research fellow at the Drug Safety Research Unit at Bursledon Hall in Southampton, UK, and lead author of the study. "Women who have any of the classical risk factors for AMI, most notably smoking, should be warned that it is these risk factors that are of importance — not the OC that they may be taking."

Researchers for the current investigation were involved as a collaborating center in the "transnational study," a multinational case-control study on thrombotic effects of OCs. This study was ended prematurely in 1995, due to what has been dubbed "the pill scare" in the United Kingdom. **(See *Contraceptive Technology Update*, October 1996, p. 126, for more information on research affected by concerns surrounding third-generation pills containing gestodene and desogestrel.)**

"This left unfinished business on the AMI question, and for this reason, we designed the study to have sufficient power to answer the question as to whether there was a difference between second- and third-generation OCs," notes Dunn.

The present study could not confirm a differential effect on the risk of AMI between oral contraceptives with second- and third-generation progestins, says **Øjvind Lidegaard**, MD, assistant professor of obstetrics and gynecology at Herlev Hospital, University of Copenhagen in Denmark. He wrote a commentary on the study, and both were published in the *British Medical Journal*.[2] This study offers different results from a 1997 case-controlled investigation conducted in 16 centers in Germany, the United Kingdom, France, Austria, and Switzerland.[3] In that study, a significantly lower risk of heart attack was found when comparing use of third-generation OCs with use of second-generation OCs.

Researchers involved in the UK study found that of those women under age 45 who suffered a heart attack, 87% were not taking any oral contraceptive. The majority of women who had a heart attack had at least one or more known cardiovascular risk factors.

While the risk for heart attack among women under 45 is rare, young women who wish to preserve their cardiovascular risk should be advised to stop smoking above all other actions, note the researchers. Smoking was strongly associated with heart attack, results showed. "Three out of four AMIs in young women would be prevented if all women stopped smoking," Lidegaard advises.

Dunn sees the results from the current study as "fairly conclusive" on the OC / AMI question. "However, our data has thrown up interesting questions regarding regional variation in incidence and case fatality of AMI among this age group of women in the UK," he notes. "We shall be looking into this further."

Many older studies have demonstrated a significantly increased risk of thrombotic diseases, including AMI, in current users of oral contraceptives, notes Lidegaard. This increased risk seems to apply primarily to older high-dose oral contraceptives. "Generally, studies demonstrating risks in users of oral contraceptives are the object of more attention than reassuring studies like this one," says Lidegaard of the UK study. "In order to ensure a balanced impression of oral contraceptives, it is important also to focus on the good news, so that some of the concern, which many people might have had, can be eliminated."

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Young age a factor in sterilization regret

While most women don't regret their decision to undergo tubal sterilization, new research indicates that one in five women sterilized at a young age do.[1]

These results come from the largest and longest prospective study of women undergoing tubal sterilization in the United States, which was conducted by researchers at the Centers for Disease Control and Prevention (CDC) in Atlanta and the U.S. Collaborative Review of Sterilization (CREST) Work Group, with support from the National Institutes of Health in Bethesda, MD. **(*Contraceptive Technology Update* has covered other findings from this multicenter research project. See the August 1996 issue, pp. 93 and 99, for information on sterilization failure rates, and the June 1997 issue, p. 67, for an overview of ectopic pregnancies following tubal sterilization.)**

EXECUTIVE SUMMARY

Young age at the time of tubal sterilization is a significant factor in predicting future regret, according to the latest data from the largest and longest prospective study of U.S. women undergoing sterilization.

- Some 20% of women who underwent a tubal sterilization at 30 or younger expressed regret within 14 years afterward, researchers found. About 6% sterilized after 30 expressed regret.
- Nearly half of the young women expressing regret also requested information about reversing their sterilization procedure.
- While most women who choose sterilization will not have regrets, presterilization counseling can help identify those who may have doubts after such a procedure.

"Young age at the time of tubal sterilization is the most important risk factor for subsequent regret," reports **Susan Hillis**, PhD, reproductive health epidemiologist at the CDC and lead author of the current study.

Previous studies have indicated young age as the principal determinant of regret following sterilization,[2,3] notes **Amy Pollack**, MD, MPH, president of AVSC International in New York City. This study confirms that data and reinforces the need to ensure adequate counseling at the time of decision making, she states.

Sterilization is the most popular form of birth control among American women,[4] a fact that prompted researchers to undertake the CREST study. More than 11,000 women ages 18 to 44 years who underwent sterilization between 1978 and 1987 were included in the overall study. More than 65% were married at the time of sterilization, and more than 95% chose the method for contraceptive rather than health reasons.

At follow-up interviews, women were considered to have expressed regret if they responded negatively to the question, "Do you still think tubal sterilization as a permanent method of birth control was a good choice for you?" Some 20% of women who underwent a tubal sterilization at 30 or younger expressed regret within 14 years after the procedure, researchers found. In contrast, about 6% of women who underwent sterilization after 30 expressed regret.

Regret is hard to quantify because its definition differs from person to person, and it is difficult to gauge its intensity and impact on an individual's life, says **Herbert Peterson**, MD, chief of the CDC's women's health and fertility branch and a co-author of the paper. Despite these challenges, researchers say the issue should be examined because sterilization is intended to be a permanent form of birth control.

The study's results show that if sterilization of young women occurred within a year of the birth of their youngest child, regret was similar to that for women undergoing postpartum sterilization — more than 20% in both cases — and was substantially higher than that for the 8.3% of women sterilized eight or more years after the birth of their youngest child. The probability of regret was lowest among women with no previous births.

A change in the desired family size was the most common reason for regret among young women. Since almost half of all U.S. marriages end in divorce, young women who choose sterilization are more likely to be of child-bearing age upon remarriage — and prone to regret their contraceptive choice, Peterson says. Almost half of young women expressing regret also requested information about reversing their sterilization procedure, study results show. Researchers plan to examine the link between requests for reversals with actual reversal procedures in a future paper, he says.

While most women do not express regret, even many years after sterilization, family planning clinicians now can predict who will be in the highest risk category, says Peterson. The CREST study confirms that age is a key determinant, he says.

With these findings in hand, clinicians can use presterilization counseling to help identify those women who may experience doubts later on and reassure others that most sterilized women are comfortable with their decision, Peterson says.

"It is also reassuring to note that rates of regret are so much lower in older women and indicates the need to assure that this contraceptive method continues to be widely available to all women," says Pollack.

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Keep condom use high, retain no-charge status

In today's climate of budget cuts, reproductive health facility administrators may be tempted to eye free distribution of condoms as a potential source for belt-tightening. However, a recently published study indicates that when condom distribution programs switch from a no-charge to even a minimal-charge status, use of such protection drops.[1]

Any budget savings is not worth the risk of potential HIV infection, contends **Thomas Farley**, MD, MPH, medical director of the HIV/STD prevention program in the Louisiana Office of Public Health's Department of Health and Hospitals in New Orleans. "The calculation we use here is that if you assume that an HIV infection in one person indebts you to $100,000 in future medical costs, then if you distribute 2 million condoms and prevent only one HIV infection, then it is cost-effective," notes Farley, a co-author of the study.

As a response to the epidemic of HIV and the high rates of other sexually transmitted diseases (STDs), the Louisiana Department of Health and Hospitals developed Operation Protect in 1993.

A statewide social marketing campaign, Operation Protect was designed to increase accessibility of condoms by providing them in a targeted fashion at 93 public health clinics, 39 community mental health centers, 29 substance abuse treatment sites, and more than 1,000 small businesses in neighborhoods with high rates of STD and HIV, says **Deborah Cohen**, MD, MPH, associate professor in the department of public health and preventive medicine at Louisiana State University Medical Center in New Orleans. Cohen served as lead author for the two evaluations addressing the Operation Protect program.

From 1994 to 1996, more than 33 million condoms were distributed for free in the state.[2] Self-reported condom use increased, especially among African-American men and African-American women with two or more sex partners, research shows. The demand for free condoms eventually outstripped the purchasing budget, Cohen says.

"The problem we had was that we were victims of our own success. The condoms were so popular that we ran into budget problems," Farley says.

EXECUTIVE SUMMARY

Cost can be a barrier to condom use, according to research from a Louisiana public health condom distribution program. When the program moved from a free- to a minimal-charge status, a decrease in reported condom use was noted.

- In 1993, Louisiana began offering free condoms at 93 public health clinics, 39 community mental health centers, 29 substance abuse treatment sites, and more than 1,000 small businesses in neighborhoods with high rates of STD and HIV.
- The state began charging a small fee to cope with budgetary constraints due to the popularity of the free program. The state has reverted to free distribution again, citing the role condoms play in protection against HIV and other sexually transmitted diseases.

State acted as condom broker

To address the budget situation, the state then experimented with developing a private-label brand of condoms, says Farley. The state acted as a broker by obtaining a guaranteed price from Ansell Personal Products of Eatontown, NJ, the condom manufacturing company, then directing participating retail outlets to communicate directly with the manufacturer on orders. Retail outlets then were able to purchase condoms at the negotiated 8 cents per condom bulk rate and sell them at a discounted rate of up to 25 cents each. A number of retail sites switched from free distribution to for-sale distribution.

The state evaluated the impact of the transition on reported condom use among persons with two or more sex partners with pretest and post-test surveys. At pretest, 57% of respondents had obtained free condoms, and 77% had used a condom during their most recent sexual encounter. When the price was raised to 25 cents, the respective percentages decreased to 30% and 64%.

"We saw the number of condoms distributed go down dramatically, and condom use went down as well," observes Farley.

Based on the surveys' results, the state terminated the low-cost condom program and returned to the free distribution method, Farley reports.

"We are trying to re-establish the free condom distribution in small businesses in neighborhoods with a high incidence of STD/HIV," says Cohen. "We are continuing to encourage free distribution in public sites as well."

The commitment to the statewide condom program is not lightly taken, Farley observes. "Using state funds, [the condom budget] runs $600,000 a

year," he says. "In very rough terms, it costs us 5 cents per condom, and we distribute 12 million condoms a year."

State public health officials say the cost is worth the commitment, given the fact that Louisiana is one of the top 10 states in the nation in syphilis, gonorrhea, and other STD rates and is experiencing rapid increases in heterosexually transmitted HIV. Given the spread of HIV and the acknowledgement of the protective role condoms play in averting disease transmission, more emphasis should be put on a national condom distribution program, Farley and Cohen contend. The two served as co-authors of a paper calling for such a policy.[3]

"People frequently list purchase of condoms as sort of the last item on their budget, when I think it perhaps ought to be the first," says Farley. "At the bare minimum, we ought to have an adequate supply of condoms for everyone out there, and to the extent that we can afford it, we also should have people who can provide counseling and other services."

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Late-night hours draw busy patients

The challenge: How do you get women to come in for reproductive health care when their days are filled with multiple roles as student, mother, employee, or two-job employee? The solution: Offer a late-night clinic at your facility.

Planned Parenthood of Houston and Southeast Texas kicked off a test night clinic at the beginning of the year. Results of an informal survey among Planned Parenthood affiliates indicate that the Houston facility is the first to offer such a service, according to Planned Parenthood-Houston spokeswoman **Susan Nenney**.

The test program is in the process of review as of *Contraceptive Technology Update* press time, but clinic director and clinician **Marie Tekle**, RNC, WHC, CNP, hopes it will get the green light from administration to continue its twice-a-month schedule. "I think times have changed," says Tekle, a 25-year Planned Parenthood veteran. "We have to meet the needs of the consumer now."

The Houston Planned Parenthood program already offers a wide variety of operating hours. It opens every day at 7 a.m. during the week and even offers Saturday service. Still, many women would tell Tekle, "you just don't have hours for me," when she asked them about their care.

Whether they were college students with after-class jobs, women holding down two jobs, or women with night-shift employment, all shared a common problem: an inability to get to the clinic during daytime hours. Tekle drew up the plans for the pilot night clinic, received administration clearance, and began the first one Jan. 15.

Tekle says Friday nights work best because most people who work are off on Saturdays. The night clinic, under its test formation, is held twice a month on Friday. It began with hours of 10:30 p.m. to 7 a.m. but has operated the last two months from 7:30 p.m. to 3:30 a.m.

By modifying the hours during the test phase of the clinic, program administrators have been able to see what works best for the patients. Initial findings show that most women prefer to come in from 7:30 p.m. to 1:30 a.m.

The night clinic offers the identical services

EXECUTIVE SUMMARY

Planned Parenthood of Houston and Southeast Texas is finding a new way to meet the needs of today's busy women: a reproductive health care clinic with nighttime hours.

- The pilot program, now under review, operates twice a month on Fridays. It began with hours from 10:30 p.m. to 7 a.m. but now operates from 7:30 p.m. to 3:30 a.m.
- The service is staffed by one clinician and two clinic assistants. There have been no security problems since its January inception, but a security guard is on duty as a safety precaution.
- Women who use the clinic's services say they don't have to wait as long for care. Staff report fewer "no-shows" on the clinic schedule.

that are available during the daytime, reports Tekle. "We have inserted IUDs, we have done pregnancy confirmations, we have supplied birth control — just whatever we do during the day."

Publicizing the clinic has been very low-key: Other than an announcement on the facility's recorded telephone greeting and a few scattered posters around the building, news of the night clinic has been mainly by word of mouth. This has allowed the clinic to evolve without fear of protest, since reproductive health facilities are often the site of anti-abortion picketers. While there have been no problems since the service has been in operation, a security guard is on staff, says Tekle. If the night clinic receives approval as a ongoing venture, it will be marketed more aggressively, she notes.

Patients, providers win

The night clinic is staffed by one clinician and two clinician assistants. A night's schedule may include around 25 patients, with an average of 17 to 22 coming in for their appointments.

The clinic offers benefits for both patients and providers. Patients tend to keep their appointments better at night, and those who work in the clinic say patients are much calmer. Women who use the clinic's services say they don't have to wait as long, and the night hours cut the number of children who often have to accompany women during the daytime due to lack of childcare. Parking, which can be a problem during the daytime, is more easily accessed at night.

Staff who work the night clinic like the scheduling flexibility afforded by the service, since they trade a day shift for a night shift. The convenience of having an off-day during the week is an attractive option, reports Tekle.

The night clinic costs the same to run as a day clinic; in fact, the service has shown a profit, she notes. Perhaps the most important benefit is the fact that patients' needs are being met at a time when time constraints are pulling women in many different directions.

"Many of the patients, especially those who are working two jobs or have problems with transportation, say 'Please keep this up — don't stop it,'" says Tekle.

Nenney agrees. "The night clinic is meeting a huge need," she says. "Access is critical, especially when it comes to women's health care." ■

SOURCE

- **Marie Tekle**, RNC, WHC, CNP, Clinic Director, Planned Parenthood of Houston and Southeast Texas, 6121 Hillcroft, Suite 0, Houston, TX 77081. Telephone: (713) 541-9753.

ASK THE EXPERTS

Answering questions on when to use pills

Providing oral contraceptives (OCs) to a young, healthy nonsmoker is an uncomplicated clinical decision, but what is your approach when dealing with patients with common conditions such as borderline high blood pressure?

Eileen Swanson, RN, women's clinic coordinator for Kansas State University's Lafene Health Center in Manhattan, poses such questions to *Contraceptive Technology Update*'s panel of experts.

Comments are from **Andrew Kaunitz**, MD, professor and assistant chair of obstetrics and gynecology at the University of Florida Health Sciences Center in Jacksonville; **Michael Rosenberg**, MD, MPH, clinical professor of obstetrics and gynecology and epidemiology at the University of North Carolina at Chapel Hill and president of Health Decisions, a private research firm; and **Susan Wysocki**, RNC, BSN, NP, president of the National Association of Nurse Practitioners in Women's Health in Washington, DC.

Question: Which OCs are the best suited for a woman with a strong history of hypercholesterolemia? Should pills using norgestrel or levonorgestrel be avoided?

Kaunitz: Given the family history of lipid disorder, it would be appropriate to check a fasting lipid profile. If it returns normal, the choice of OC formulation is not necessarily of importance from a lipid perspective. However, if the patient is found to have elevated LDL and / or low HDL, an OC formulated with less androgenic progestins (norgestimate or desogestrel) would be appropriate. Specifically, norgestimate OCs and the 30 mcg estrogen / desogestrel formulation increase HDL and decrease LDL levels. If the sole abnormality is an increased triglyceride level, use of an OC with a

more androgenic progestin (e.g., levonorgestrel) may lower the triglyceride level. However, if the baseline fasting triglyceride level is >300, avoid all estrogen-containing (combination) OCs and instead use progestin-only methods, which will not increase triglyceride levels, or an IUD.

Wysocki: While some studies have shown differences in laboratory parameters in HDL, LDL, and total cholesterol with various progestins, animal studies indicate that regardless of those laboratory parameters, low-dose combination OCs actually decrease the formation of atherosclerotic plaque. In a study using macaque monkeys that were given high atherosclerotic diets, those on an OC formulation had fewer plaques than projected given the diet regimen.[1] I am not aware of evidence that supports avoiding norgestrel or levonorgestrel.

Question: Should OC use be discontinued in patients with blood pressure (BP) elevations of 140/90? Is depot medroxyprogesterone acetate (Depo-Provera or DMPA) recommended for these patients? Also, please address your recommendations regarding a patient with a mild or moderately elevated BP who has a BMI of >30.0.

Kaunitz: All combination OCs raise ambulatory blood pressure to some degree. Therefore, clinicians should be very cautious recommending any combination OC to hypertensive women. I would only prescribe combination OCs to hypertensive women in the following circumstances:

- highly compliant woman with well-controlled hypertension;
- nonsmoking patient under age 35;
- communication with and support from clinician treating hypertension;
- close follow-up with frequent blood pressure monitoring is appropriate if OCs are prescribed in this setting.

Rosenberg: The literature linking OCs with increased blood pressure is both scanty and rather dated by today's standards. In addition, elevated BP is easy to overdiagnose in obese subjects if the appropriate cuff is not used. In both cases, I believe that low-dose OCs — preferably 20 mcg, but also 30 mcg — should be instituted and then the BP carefully monitored. If the BP is elevated, then control with appropriate drugs or other measures is probably more significant than the contribution of OCs. In the end, each patient represents a mixture of risk that must be individually gauged and accordingly adjusted.

Wysocki: If this person's blood pressure was normally 140/90, a trial of OCs could be initiated. Monitor — as you would even if not on OCs — the blood pressure to ensure that it doesn't become elevated. DMPA is also an appropriate choice. The [Geneva, Switzerland-based] World Health Organization Medical Eligibility Criteria specifies category 2 precaution for DMPA [can use method; advantages general outweigh theoretical or proven risks].[2]

Moreover, the issue with patients with mild hypertension and high BMI is to focus on helping them with lifestyle changes, such as diet and exercise. There is more chance of success with these strategies when a woman doesn't experience an unintended pregnancy.

Question: Which OCs are best suited for a woman with a history of tension or migraine headaches?

Kaunitz: Traditionally, contraception experts have suggested that OCs can be prescribed to women with migraines provided:

- they were nonsmokers;
- migraines were without aura;
- no focal neurologic signs accompanied migraine;
- with close follow-up, migraine frequency and/or intensity did not increase after initiating combination OCs.

Recent U.S. and European epidemiologic studies, however, may suggest an even more conservative approach in this setting. In a U.S. study, use of combination OCs by women with a history of migraines was associated with an increased risk of stroke.[3] A European study also found an increased risk of stroke in OC users with a history of migraine, whether or not the migraines were associated with aura.[4]

With or without OC use, strokes are fortunately very rare (but devastating) in reproductive age women. My perspective is that combination OCs do not represent an optimum contraceptive choice in any woman with a bona-fide history of migraine headaches. Progestin-only or intrauterine contraceptives are preferable in this setting. If a woman with migraines refuses to use these latter methods, combination OC use can be considered if the following criteria are met:

- nonsmoker, under age 35, with no history of diabetes or hypertension;
- close clinical monitoring, discontinuing OCs if frequency or intensity of migraines increases.

Rosenberg: There is little objective information, but anecdotal reports that Mircette [Organon, West Orange, NJ], which contains five days of 10 mcg of ethinyl estradiol during what would

normally be a seven-day hormone-free interval, seems to work well.

Wysocki: There is no evidence to support claims that one OC is better than the next for tension headaches and menstrual (not neurological) migraines. However, since menstrual migraines are a result of decreased estrogen, those women may benefit from maintaining their estrogen level by decreasing or eliminating the hormone pill-free interval. One OC on the market [Mircette] offers 10 mcg of estrogen for five days during the week that is normally hormone-free.

The first consideration for choosing an OC for a woman with any special health circumstances, or any woman for that matter, is that the formulation is low-dose: less than 50 mcg. The second consideration is that the pill choice is covered under her insurance formulary.

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Mid-Years WOMEN'S HEALTH

Contraceptive options for perimenopausal women

By **Ivy M. Alexander**, MS, C-ANP
Adult Nurse Practitioner, Assistant Professor
Yale University School of Nursing
Adult and Family Nurse Practitioner Programs
New Haven, CT

Perimenopause is the time period preceding menopause. It lasts four years on average and can range from a few months to several years.[1-3] Symptoms may begin as early as the mid-30s but are more common in the later 30s and early 40s. Characteristic symptoms are multiple and affect each woman differently. Symptoms can include changes in menstrual patterns, vasomotor instability, psychological and cognitive changes, sleep disturbances, vulvovaginal problems, somatic symptoms, and sexual problems.[1-3]

Contraception during perimenopause continues to be an important issue. Although fertility is reduced,[1,2] pregnancy remains a real possibility for about 50% of patients.[1] Perimenopausal women experience a high rate of unintended pregnancies (77%) — second only to adolescents 13 to 14[4] — and thus experience a higher proportion of abortion.[2,4] Pregnancy after age 35 also carries risks, such as higher rates of spontaneous abortion and miscarriage, increased maternal mortality, and greater incidence of chromosomal abnormalities.[1] Careful evaluation for appropriate contraception is important. Consider these options:

• **Combined OCs.** Hormonal contraceptives include combined oral contraceptive pills (COC) and progestin-only pills, implants, and injections. With recent data demonstrating that age is not a contraindication to COC use, COCs provide a good contraceptive option for perimenopausal women who do not smoke or have hypertension, diabetes, or cardiovascular risks. Current low-dose COCs are safer than older, higher-dose preparations and do not significantly impact the lipid profile.[1] In healthy nonsmokers, the risks for myocardial infarction, stroke, or thromboembolism are low.[1,2] Recent studies suggest that COC use may not impact breast cancer incidence.[1,5]

Noncontraceptive benefits include reduced perimenopausal symptoms, decreased endometrial and ovarian cancer risk, increased bone density, reduction in benign breast disease, improved cycle control, and potential reduction of menorrhagia and fibroid size and pain.[1,2,5,6]

Because women taking COCs continue to cycle, diagnosing menopause can be difficult. Some recommend that women cease COC use after age 50 to evaluate follicle-stimulating hormone (FSH) levels. These women must be cautioned about the

remaining possibility of pregnancy and need for alternate contraception.[1,2] If regular cycling resumes, or FSH levels remain low, COC use can be restarted. Alternately, a woman can continue on COCs and have FSH levels evaluated annually at the end of the pill-free week.[7] Although FSH levels may not fully increase by the end of the pill-free week, remaining on COCs does not pose a risk for a healthy woman. When a single elevated FSH is seen, future ovulation is still a possibility and appropriate contraceptive counseling is needed.[1,2]

• **Progestin-only methods.** Progestin-only pills, injections, and implants offer an alternative for perimenopausal women who smoke or have cardiovascular risks.[1,2] While they afford some protection against ovarian and endometrial cancer and bone loss, these methods do not offer the benefits of estrogen replacement and can increase menstrual irregularity, already a problem among many perimenopausal women. Specific recommendations for identifying menopause when using these formulations are not widely available.[2] With injections, the long and unpredictable return to regular menstruation can make identification difficult. **(See *Contraceptive Technology Update,* December 1998, p. 160, for details on use of injections during perimenopause.)** In women using implants, evaluating for menopause after scheduled removal is reasonable.[2] Due to the long duration of action, injections and implants are not recommended for women interested in future pregnancy.[2]

• **Barrier methods and IUDs.** Barrier methods have lower overall efficacy than COCs but have the added benefit of greater protection against sexually transmitted diseases (STDs).[1,2] Because perimenopausal women have reduced fertility, the failure rate for these methods is slightly lower than among younger women.[1,2] Even so, barrier methods often are not recommended for women who have not used them previously. If they are used, the addition of spermicidal preparations can enhance effectiveness and help women with vaginal dryness.

Intrauterine devices (IUDs) represent another birth control option; in fact, the Copper T-380 offers contraceptive effectiveness equal to that of surgical sterilization.[2] Menopause is easily identified since the IUD does not mask menstrual cessation.[2] The most notable problem associated with the IUD is the possibility of heavier or longer bleeding. Hormone-containing IUDs can reduce bleeding through a local suppressive effect on the endometrium.[1,2] While the Progestasert IUD (Alza, Palo Alto, CA) needs to be replaced annually, it represents a good option for women with menorrhagia who are not COC candidates.

• **Periodic abstinence.** Periodic abstinence becomes less effective due to perimenopausal cycle irregularity. However, using additional indicators of ovulation (mucous changes and basal body temperature) can improve effectiveness. Education regarding cycle changes, reduced days when intercourse is permitted, and the decreased reliability of this method during perimenopause is important.[1,2] Women who have used this method may continue to find it effective; however, it is generally not recommended as a new method due to low efficacy, perimenopause cycle irregularity, and lack of STD protection.

• **Surgical sterilization.** Surgical sterilization, available for both women and men, is used by about 50% of women over age 30 and about 15% of partners.[2] Regret is less common with increasing age, but potentially reversible methods are always preferable.[1,2] Although extremely effective, sterilization is generally not easy to reverse

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Editor: **Rebecca Bowers**.
Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Executive Editor: **Park Morgan**, (404) 262-5460, (park.morgan@medec.com).
Managing Editor: **Joy Daughtery Dickinson**, (912) 377-8044, (joy.dickinson@medec.com).
Production Editor: **Terri McIntosh**.

Editorial Questions

Questions or comments?
Call **Joy Daughtery Dickinson** (912) 377-8044.

and does not afford protection against STDs.

Counseling about options, potential benefits, and side effects for each choice is necessary for women to select a safe and effective method. Careful attention to personal and family health history, individual preferences, previous experiences, and any wishes for future fertility should guide the selection process.

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After reading *Contraceptive Technology Update*, the participant will be able to:

- Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. **(See "Another option? Contraceptive patches are now under research,"p. 113.)**
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.
- Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts.**(See "Young age a factor in sterilization regret," p. 116, and "Answering questions on when to use pills," p. 120.)** ■

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