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Long-Term Reversible Contraception:

A dialogue among Andrew M. Kaunitz, MD, David A. Grimes, MD, and Anita L. Nelson, MD, held on October 29, 2006.

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Learning Objectives

- After reviewing this material, clinicians should be able to
 - Describe the problem of unintended pregnancy and the efficacy of available contraceptives
 - List current methods of long-term reversible contraception along with mechanisms of action, advantages, and disadvantages
 - Enumerate concerns about intrauterine contraceptive relative to evidence-based risks
 - Identify potential noncontraceptive benefits of intrauterine contraceptives for women with menstrual symptoms including those caused by fibroids, adenomyosis, and endometriosis
 - Describe practices that enhance the safety of intrauterine contraception
 - List the pros and cons of the single-rod contraceptive implant.

Sponsorship

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Target Audience

Obstetricians/gynecologists, nurse practitioners, and other advanced practice clinicians who focus on women's health.

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Reproductive-age women have varying contraceptive needs. For many women, long-term reversible contraception, defined as IUDs and implants for the purpose of this article, represents an excellent choice. Research shows that many women do not use oral contraceptives effectively: 1 million pregnancies each year result from the faulty use of oral contraceptives.¹ Additionally, unintended pregnancies remain common.

Clearly, the method of contraception must be tailored to meet the needs of the individual. Recent research has shown that women who choose contraceptive agents that do not require self-administration, periodic renewal, or daily pill-taking are better able to avoid unintended pregnancy than are women who use other contraceptive methods.^{2,3} Although available long-term agents are as effective as sterilization, they are also rapidly and completely reversible. Reports indicate that 20% of women who have elective sterilization at age 30 or younger subsequently express regrets.⁴

For women interested in long-term reversible contraception, several options are currently available: the copper T intrauterine device (IUD); the levonorgestrel-releasing intrauterine system (IUS); and the single-rod progestin-only implant (TABLE).⁵ Despite the safety and efficacy of these contraceptive

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The recommended use of specific contraceptive methods in this supplement reflects the opinions of the discussants; they are not attributable to the sponsor or the publishers. Clinical judgement must guide each clinician in weighing the risks and benefits of any contraceptive drug or device.

TABLE
IUDs and implants available in the United States

Contraceptive methods	First year failure rates in typical use (%)	FDA-approved duration of use (y)	Documented duration of use (y)
Copper T IUD (ParaGard® T 380A)	0.8	10	12
Levonorgestrel-releasing IUS (Mirena®)	0.1	5	7
Single-rod etonogestrel-releasing implant (Implanon™)	NA	3	16

IUD=intrauterine device; IUS=intrauterine system; NA=not available.

Adapted from Peterson HB, et al. *N Engl J Med.* 2005; 353:2169-2175.⁵

options, the most popular methods in the United States are oral contraceptives or sterilization. Health care providers need reliable information to counsel their patients effectively and work with them to make the most appropriate contraceptive selection.

In this dialogue, 3 highly recognized experts in the fields of gynecology and contraception specifically discuss intrauterine and implant devices as long-term reversible contraception strategies in the context of 3 case studies.

The landscape of reversible long-term contraception

Dr Kaunitz: In the United States, the contraceptive landscape is continuing to change. Recently, implantable contraception has returned to this country with FDA approval of the single-rod etonogestrel (progestin)-releasing implant. With the implant's availability, women have gained an effective, convenient, and long-acting method that provides "insert it and forget it" contraception for up to 3 years, rivaling the effectiveness of sterilization.

Regarding the copper T IUD, the FDA has recently liberalized its package labeling in several important ways. Old, restrictive labeling with respect to nulliparous women has been removed so that both nulliparous and multiparous women are now deemed appropriate candidates for the copper T IUD. Likewise, old and obsolete restrictive language regarding a history of pelvic inflammatory disease has been removed from labeling

for this effective, convenient IUD, which is approved for up to 10 years of use.

Regarding the levonorgestrel-releasing IUD or IUS, new reports related to off-label noncontraceptive applications of this device continue to be published. We now have a wealth of data documenting the effectiveness of this IUS in the treatment of heavy menstrual periods (menorrhagia), including that associated with fibroids.⁶⁻¹¹ Data also suggest efficacy in treating symptoms associated with uterine adenomyosis.¹² A randomized trial from Brazil demonstrated the levonorgestrel-releasing IUS had comparable efficacy to that of gonadotropin-releasing hormone agonist (GnRH-a) therapy for symptomatic pelvic endometriosis (BOX 1).¹³

What this means is that our patients have access to 3 efficacious, convenient, and long-acting methods of contraception (FIGURE 1). Having said that, these methods remain underutilized in practice. For that reason, I feel enthusiastic about the 3 cases that Drs Nelson, Grimes, and I will be discussing; they illustrate how the new contraceptive implant system, as well as both IUDs, can fit into today's clinical practice.

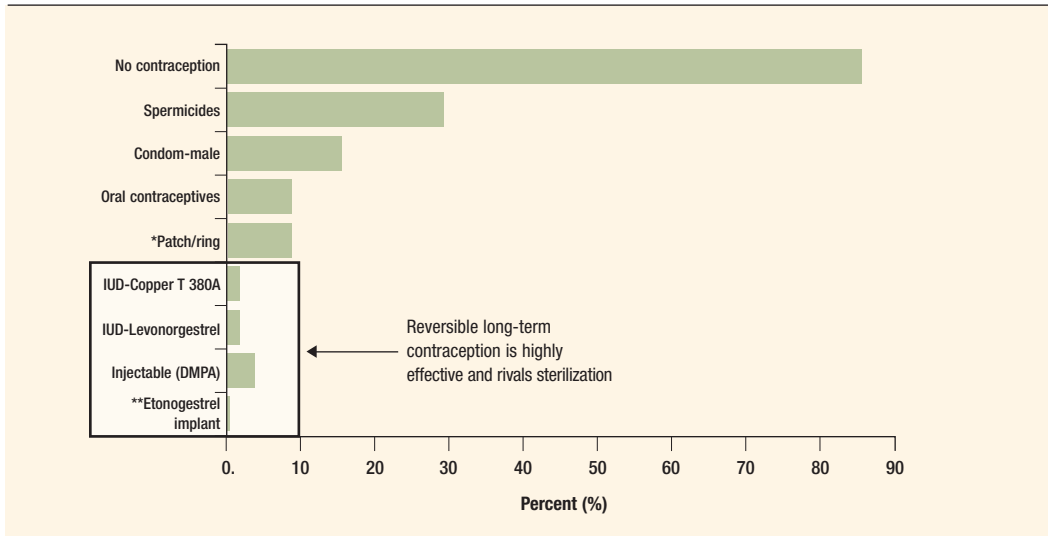
Dr Grimes: The problem with contraceptives today is not that the hormones aren't right. The problem is human nature. It's very difficult for people who feel well to take medicine on an ongoing basis. Compliance is the Achilles' heel of contraception that requires daily attention, so I think we need to move increasingly toward forgettable contraception for which the default option is protection. The beauty of the 3 methods we're talking about

KEY POINT

"All 3 methods (IUD, LNG-IUS, and the single-rod implant), because of their extreme efficacy and convenience, represent first-line choices."

-Andrew M. Kaunitz, MD

FIGURE 1
First year failure rates of contraceptives with typical use



DMPA=depot medroxyprogesterone acetate; IUD=intrauterine device; IUS=intrauterine system.
 *Estimate in lieu of actual data.
 Trussell J. *Contraception*. 2004;70:89-96.²
 **Funk S et al. *Contraception*. 2005;71:319-326.³

today is that they all provide contraception that's tantamount to surgical sterilization, without the attendant risks and irreversibility.

Dr Nelson: I think it's important that we have these 3 different devices that have totally different utilization profiles, because we need different options for different people. Each of these methods achieves high efficacy. Each of them is cost-effective.¹⁴ Most importantly, each has very few medical contraindications to its use. Women with histories of myocardial infarction, stroke, deep vein thrombosis (DVT), systemic lupus erythematosus, hypertension, and even older smokers can use each of these top-tier methods. These 3 methods are long-lasting and require minimal or no ongoing effort to use, which is a real plus for the convenience of a patient. But from the same standpoint, I think we should also recognize that sometimes this long-term "convenience" may be perceived as a negative by certain patients who may fear they are losing control over their contraception. We must explicitly communicate that we will remove these devices whenever the patient requests removal. Having promised that, I think even

BOX 1
Use of IUDs: Contraception and beyond

Dr Grimes: My impression is that much of the rapid growth in IUD use is being fueled by noncontraceptive benefits through off-label uses, not just for contraception itself.

Dr Kauntiz: Yes, in my practice, which does not include obstetrics and has a menopausal focus, the average age of my patients is older than in the general OB-GYN practice. A high percentage of the progestin-releasing IUDs in my patients are being placed specifically off-label for noncontraceptive benefits, particularly to treat menorrhagia, including that associated with uterine fibroids.

I think when patients recognize that they can achieve their goals, whether their goal is long-term, highly effective, convenient birth control or treatment of heavy bleeding without an invasive and irrevocable surgical procedure, many more women will choose these long-acting contraceptives.

more patients can embrace these IUDs and implant with as much confidence as we have when we offer them.

KEY POINT

"We need different options for different people."

-Anita L. Nelson, MD

BOX 2**Important tips when inserting an IUD**

Dr Kaunitz: Do not open the IUD package until you've confirmed your patient's desire to proceed with insertion, performed a bimanual exam, placed a speculum, placed antiseptic on the cervix and upper vagina, placed a cervical tenaculum, and sounded the uterus.

Dr Nelson: For women living in a resource-poor area, oftentimes full ultrasound evaluation can't be provided prior to insertion. If you gently sweep the uterine sound laterally at the fundus, you can ensure that the IUD is placed at the fundus where the IUD arms can open up comfortably and maintain correct IUD placement. You can do this quick, on-the-spot procedure to reassure yourself that the cavity is adequate for the device you are placing.

Case 1**Contraception and relief of menorrhagia**

A busy 29-year-old lawyer has a 6-month-old child. She's thinking of becoming pregnant again in several years, but pregnancy any sooner would pose career concerns. Because of heavy menstrual flow and an irregular but not grossly enlarged uterus on bimanual exam, an ultrasound was performed that revealed several small intramural fibroids.

Dr Kaunitz: This woman brings several issues into her discussion of birth control with her OB-GYN. She's interested in child spacing, she likely will want to conceive again but not for several years, and her life circumstances indicate that an unintended pregnancy in the near term would be a major problem for her. Oral contraceptives, and for that matter depot medroxyprogesterone acetate (DMPA), would reduce her menorrhagia. With oral contraceptives her periods would be shortened and more predictable, or with long-term injectables amenorrhea may possibly result.

Dr Nelson: We could use extended-cycle rings or birth control pills, but remembering to take these might be a bit difficult given her

busy lifestyle. Just to make sure that things are really easy for her, a progestin-only method would be even simpler. I would not use an implant but would suggest a progestin-only IUS. What do you think about using the levonorgestrel-releasing IUD for a woman who has intramural fibroids?

Dr Kaunitz: Let me comment first about the implant. The single-rod etonogestrel (progestin)-releasing implant would provide highly effective birth control for up to 3 years for this 29-year-old woman. However, erratic spotting and bleeding is characteristic, not only initially but throughout use. I'm not aware of any data that indicate what type of menstrual pattern might occur for an implant user with baseline menorrhagia. So I, too, would be hesitant to recommend the contraceptive implant because of her history of menorrhagia and uterine fibroids.

Dr Grimes: With regard to IUDs, in general, for women without pathology, the measured menstrual blood loss is increased by about 50% with copper devices and even more so with nonmedicated devices that were available in decades past.

Dr Kaunitz: We have data from reports on the use of a progestin-releasing IUD in women with fibroids and normal uterine cavities,^{6,9,10} but one report also showed promising results in reduction of menstrual blood loss for women with uterine cavities distorted by submucosal fibroids.⁸ I'd be most comfortable inserting an IUD in a woman with fibroids when I suspect from an unenhanced sonogram that her cavity is normal. The limited published data regarding use in women with cavities distorted by fibroids, however, suggest that there may be a role for use of the progestin-releasing IUS in selected patients with abnormal cavities (**BOX 2**).

Dr Nelson: A few intramural fibroids would not be a problem. The ones you're talking about, small ones, do not seem to be an issue.

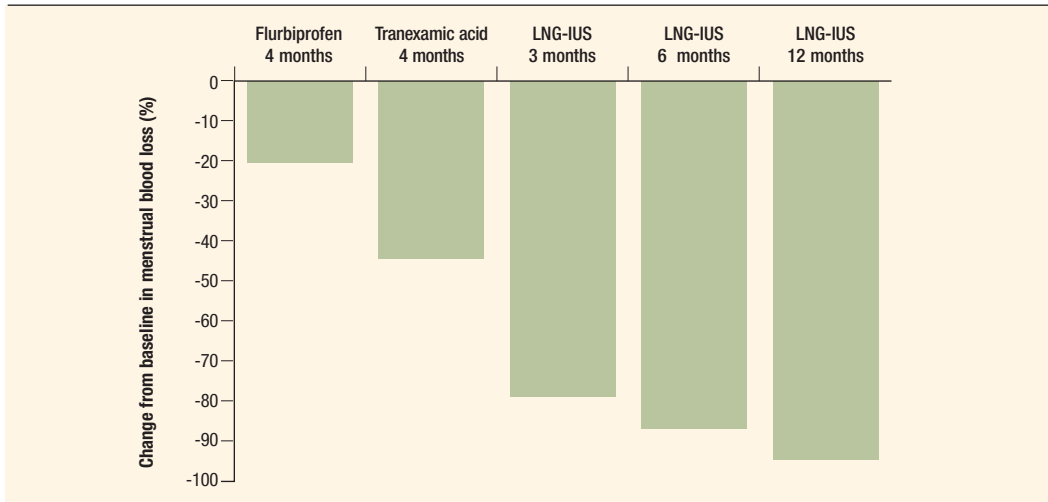
I think in this case we can go back to the patient with several options from which she can choose. Clearly we're very enthusiastic

KEY POINT

"A progestin-releasing IUD makes sense for a woman with baseline menorrhagia."

-Andrew M. Kaunitz, MD

FIGURE 2
Bleeding reduction with LNG-IUS vs NSAID vs tranexamic acid



LNG-IUS levonorgestrel-releasing intrauterine system; NSAID=nonsteroidal anti-inflammatory drug.
Milsom I, et al. *Am J Obstet Gynecol.* 1991;164:879-883.¹⁵

about the levonorgestrel-releasing IUD because it will accomplish so many of her goals, but you could also offer her DMPA, extended-cycle vaginal rings off label, or on-label extended-cycle birth control pills. I think she has some excellent choices.

Dr Kaunitz: Yes, this is a woman who will benefit from hormonal contraception. Part of the dialogue that needs to occur as she selects which one she’s going to try must relate to whether or not she’s comfortable and confident in her ability to consistently take oral contraceptives and her feelings about contraceptive rings, IUDs, and injections. She also needs to understand the erratic or unpredictable light bleeding and spotting that characteristically occur for women during their first 3 to 4 months of progestin IUD use. This erratic spotting and bleeding may be heavier or more irregular for women with baseline menorrhagia associated with fibroids.

Dr Grimes: I would also mention the use of a nonsteroidal anti-inflammatory drug (NSAID), which tends to reduce bleeding among women with and without organic pathology of the uterus. I would include an NSAID in the options for her to consider. It is not nearly as effective as a levonorgestrel-releasing IUS.

Indeed, the levonorgestrel system has been shown to be more effective to reduce bleeding than either an NSAID or tranexamic acid, an agent we don’t have here in the United States (FIGURE 2).¹⁵ A recent Cochrane review showed that NSAIDs are effective for treating both pain and bleeding related to IUD use¹⁶; however, in a large, well-designed study by Hubacher and colleagues,¹⁷ 2019 first-time IUD users in Santiago, Chile were randomized to receive either prophylactic ibuprofen or placebo. Prophylactic ibuprofen was found to have no effect on IUD removal rates due to pain or bleeding.

Case 1 Resolution

The patient chose to have the levonorgestrel-releasing IUS inserted. After approximately 4 months of some erratic spotting, she began to feel confident with her choice. It has now been 9 months since insertion of the IUS, and she reports that she no longer experiences any days of heavy bleeding. She also notes that menstrual cramps have decreased substantially. On many levels, she feels she made a good contraceptive decision (BOX 3).

KEY POINT

“We wouldn’t recommend NSAIDs as a prophylactic measure, but rather as a therapeutic measure after insertion.”

-David A. Grimes, MD

BOX 3**Comments on breast-feeding and hormonal contraception**

Dr Nelson: In case 1, the woman has a 6-month-old child. What if she were still breast-feeding? Would that have any effect on your selection of methods?

Dr Kaunitz: Probably not. Classically, in the United States OB-GYNs have been most comfortable recommending nonhormonal or progestin-only contraceptives to breast-feeding mothers and that tactic would be the standard in my practice here in Jacksonville as well. However, to my understanding, the quality of the data that suggest that quantity or quality of mother's milk may be diminished with combination estrogen-progestin methods such as birth control pills, patches, or rings is limited.

Dr Grimes: Sarah Truitt and colleagues¹ wrote the Cochrane review on that topic, and you're exactly right. The studies reviewed were from the early 1980s done by the World Health Organization (WHO). The important point is that in these studies, despite some minor effects on the quantity and quality of breast milk in women using combined oral contraceptives, no effect on infant growth was seen.

Dr Nelson: I think the point is that this 6-month-old infant is probably already receiving some supplements. The American Academy of Pediatrics is comfortable with offering women who are breast-feeding, but not exclusively breast-feeding, use of combined hormonal contraceptives.

Dr Grimes: Plus, during the early months of levonorgestrel system use, you have miniscule serum levels, much lower than with other progestin-only contraceptives.

Dr Nelson: So there's no problem, even if she were breast-feeding, with offering any of these methods.

1. Truitt ST, Fraser A, Gallo MF, Lopez LM, Grimes DA, Schulz KF. Combined hormonal versus nonhormonal versus progestin-only contraception in lactation. *Cochrane Database Syst Rev.* 2003;(2):CD003988.

Case 2**Birth control for the overweight woman**

A 38-year-old patient is referred for sterilization by her primary care physician. She is interested in an intervention that

offers long duration of use. This patient is 65 inches (5'5") tall, weighs 190 pounds, and has a body mass index (BMI) of 32.

Dr Nelson: The question I have is why are we talking about sterilization in this woman? Clearly she doesn't want more children, but we certainly have effective nonsurgical methods that can be used for her to prevent further pregnancies, don't we?

Dr Kaunitz: We do, and I'm glad we're talking about this particular case. Given the epidemic of obesity in the United States, OB-GYNs are frequently addressing the challenges associated with overweight status in terms of contraceptive decision making. Laparoscopic sterilization can be performed in women with thick abdominal walls, but with more technical difficulty, and anesthesia as well as surgical risks are greater than for women who are not overweight.

Dr Nelson: Many people today would recommend that she have a hysteroscopic procedure because of these challenges. Clearly many women are impressed with sterilization as one-stop shopping, but this method isn't reversible. Maybe at age 38 she's absolutely convinced she doesn't want any more children, but sterilization poses more immediate medical risks. The convenience of sterilization is appealing, but we have medical therapies today that are long acting and offer equal efficacy. I think those options need to be seriously explored with the patient before she makes this major decision.

Dr Kaunitz: I find that in my practice, many of the women who are referred for sterilization are focusing on surgical sterilization not because they've made a permanent decision never to have children again, but because they don't have confidence in their ability to use reversible methods effectively. Many of these women are surprised to hear that the 3 options we're talking about today—the copper IUD, the progestin-releasing IUD, and the contraceptive implant—provide efficacy absolutely comparable to that of sterilization.

KEY POINT

“Many women are impressed with sterilization as one-stop shopping.”

—Anita L. Nelson, MD

Dr Grimes: I do think tubal sterilization has some noncontraceptive benefits; a considerable amount of epidemiologic evidence points to a reduced risk of ovarian cancer after tubal sterilization. The mechanism isn't clear, but I think the data are fairly consistent.

Dr Kaunitz: I'd like to make another point regarding this patient's high BMI. She meets the criteria for obesity, and this fact changes the contraceptive options we'll be discussing with this particular woman. We've recognized for decades that the main risk associated with combination estrogen-progestin hormone contraception is an elevated risk of DVT. Fortunately, among our contraceptive patients overall, the baseline risk of DVT is low; however, obesity is itself an independent risk factor for DVT. For that matter, age is also an independent risk factor for DVT. Women who are older than 35, overweight, and using estrogen-progestin contraceptives, have a high absolute risk of DVT. In fact, the American College of Obstetricians and Gynecologists, in its recently updated guidelines for hormonal contraception for women with coexisting medical conditions,¹⁸ indicates that the presence of obesity in women older than 35 years should cause OB-GYNs to move toward progestin-only and intrauterine contraceptives and to discourage combination contraceptives for these women.

Dr Nelson: That puts obesity in the same category as the one we traditionally have thought about for cigarette smoking. You'd much rather have the patient lose weight than give up the benefits of combination hormonal contraception, but we do have excellent alternatives for her today.

Dr Kaunitz: The copper T might be a good option for this patient. She's 38 and if she were to have a copper IUD inserted, she could enjoy highly effective birth control for the 10 years as described in package labeling for this device, and perhaps longer based on the available data, which indicate ongoing efficacy for at least several years after the 10-year window endorsed by the FDA.^{19,20}

Case 2

Follow-up and resolution

The patient chose to have the copper T IUD inserted. She is now 48 years old and has been happy with her IUD for the past 10 years. She is not menopausal yet. Should the IUD be removed because the 10 years are up?

Dr Kaunitz: I have seen a few patients like this because the copper T IUD was first marketed in this country during the late 1980s. We now have studies both from the United Nations and Brazil indicating high efficacy of the copper T IUD persisting after the 10-year window.^{19,20} I have 1 or 2 patients in my practice who have elected to continue with their copper T IUD into years 11, 12, and beyond rather than have it pulled and have to reinstitute contraception.

Dr Grimes: I would agree. Another factor to consider is that spontaneous fertility beyond age 45 is exceedingly unlikely, so the IUD becomes effective as a method of contraception throughout a woman's 30s and 40s. The current copper T 380A IUD stands on the shoulders of the old copper T IUD. By placing that amount of copper high in the fundus, the device can do substantially better in terms of efficacy than its predecessor.

Case 3

A young woman seeking long-term contraception

An 18-year-old patient who had an unintended pregnancy and abortion 16 months ago after being prescribed oral contraceptives comes to your office wanting to find out about long-term contraception.

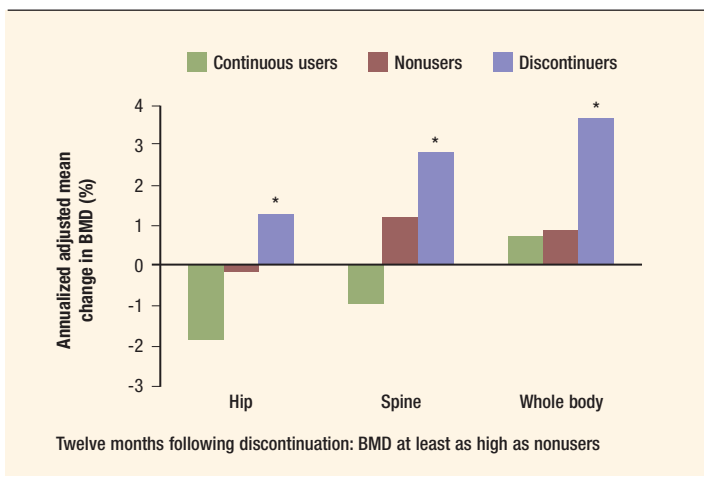
Dr Nelson: I think this case is interesting. You wonder if she ever started her birth control pills. Her history reminds us that we want to use same-day start protocols for sexually active women. Certainly exploring with

KEY POINT

"None of these methods are contraindicated for women who are overweight."

-Anita L. Nelson, MD

FIGURE 3
DMPA-IM 150: BMD in adolescent discontinuers



BMD=bone mineral density; DMPA-IM=depot medroxyprogesterone acetate-intramuscular.
 * $P < .005$ for discontinuers versus nonusers.
 Scholes D, et al. *Arch Pediatr Adolesc Med.* 2005;159:139-144.²⁴

her whether she thinks can take birth control pills now that she is 18 years old would be a good idea. Oral contraceptives have many benefits and we can tailor the way she takes them on a daily basis for a cyclic withdrawal bleeding or an extended cycle. She may also be a good candidate for a patch. The ring may be intriguing for her. I think, though, that we want to remember that a highly effective method of birth control is very important to her. The implant takes 1 minute to put in and maybe 2 minutes to take out if she changes her mind, but it's there protecting her for the next 3 critical years.

I think the thing that is new to us is the possibility that this young woman might be a good candidate for either of the IUDs. Some clinicians might shy away from this because we don't know whether she's in a mutually monogamous relationship, and she hasn't had a child before. Under the old rules she may not have even been considered as a candidate. However, today I think she deserves being offered either the copper IUD or the levonorgestrel IUS. We have a whole range of options to discuss with her.

Dr Grimes: I would agree with you concerning any 18-year-old or any adolescent,

but particularly an adolescent who's been through the unpleasant experience of an induced abortion. She may be motivated or enthusiastic about these highly effective methods we've been discussing, whether it be the contraceptive implant or an IUD.

Dr Kaunitz: We should also recognize that DMPA has provided effective contraception for hundreds of thousands of US teens, and increased use of DMPA among teens may be in part responsible for declines in pregnancy and abortions among adolescent women in the United States.²¹

Dr Nelson: What about bone density concerns associated with giving an 18-year-old DMPA?

Dr Grimes: The definitive word on that topic was from the World Health Organization (WHO). The WHO reviewed all the literature and determined there should be no time limitations with use of DMPA for women of any age.²² The FDA overreacted based on surrogate markers of no known validity and did a great deal of harm in the process.

I think the use of an IUD in a younger woman is fine, and if you're concerned about the issue of the patient's not being in a mutually monogamous, stable relationship, I would in general recommend a hormonal IUD because of the tantalizing prospect that this IUD may not be just neutral in terms of risk of infection but actually may be positively protective. A study by Toivonen and colleagues²³ showed a lower risk of removals of the IUD due to upper genital tract infection with the hormonal IUD than with the copper IUD. So for a woman of any age who may be at some increased risk of acquiring a sexually transmitted disease (STD), I would suggest a hormonal IUD as opposed to a copper device.

Dr Kaunitz: I'd like to pick up the point about DMPA and skeletal health. As you mentioned, the black box warning that the FDA added to DMPA package labeling in 2004 has had a chilling effect on initiation and continuation of this very effective birth

KEY POINT

“Women having abortions are often motivated to begin effective contraception.”

-David A. Grimes, MD

control method, and I agree that the FDA overreacted. In terms of case 3, this is an 18-year-old woman, and we have good-quality data from Scholes and colleagues²⁴ indicating that in teens who discontinue DMPA injections, bone mineral density (BMD) returns to baseline within 1 year after their last injection (FIGURE 3). There do not appear to be any long-term concerns about skeletal health with DMPA use in teens or adults.

Dr Grimes: To give you an idea how detrimental this FDA black box warning has been, there is at least one county in South Carolina where the health department no longer offers DMPA for contraception.

Dr Kaunitz: The tragedy of that policy is that health care providers in that area are likely to already be seeing rates of teen pregnancy and teen abortion increase, all because of an overreaction to observations about declines in BMD among current users of DMPA. Once clinicians and patients understand that decreases in BMD associated with hypoestrogenic states are transient, whether among DMPA users or among women who are breast-feeding, they will be much more comfortable that there don't appear to be any long-term adverse skeletal health effects with DMPA use.

Dr Nelson: I'd like to come back to the fact that she's 18 years old. In some ways it's sobering and discouraging how very low the continuation rates are for most methods of birth control among adolescents. With DMPA, young women tend to start and stop. They'll get an injection, try something else, and restart the injections again. I would never give up on DMPA with them, but part of the beauty of these longer-acting systems is that they give adolescents a chance to avoid pregnancy without having to take any further action. The characteristics of each of these methods that we've been talking about really lend them to long-term use. This is important because these methods are fairly expensive up front and we want to make sure that the investment is a good one for the patient.

Case 3 Resolution

The patient chose to insert the etonogestrel (progestin)-releasing implant. Although she experiences the unpredictable episodes of spotting and bleeding that she was counseled about, she has been happy with her decision. Sha has been told to use condoms to protect against STDs. Because the implant is effective for only 3 years, when she turns 21 she will have to make another decision regarding her birth control method.

Dr Kaunitz: I'd like to thank both of you, Anita and David, for a dynamic and engaging discussion regarding 3 cases that I think every reader will recognize as similar to women they see in their own practices. We've talked about new methods, we've talked about new data, we've talked about new package labeling, and how this all should or shouldn't affect how we counsel women and help them make good choices regarding birth control. I've learned a lot in this discussion, and I'm confident that our readers will as well.

References

1. Rosenberg MJ, Waugh MS, Long S. Unintended pregnancies and use, misuse and discontinuation of oral contraceptives. *J Reprod Med.* 1995;40:355-360.
2. Trussell J. Contraceptive failure in the United States. *Contraception.* 2004;70:89-96.
3. Funk S, Miller MM, Mishell DR Jr, et al; for the Implanon US Study Group. Safety and efficacy of Implanon, a single-rod implantable contraceptive containing etonogestrel. *Contraception.* 2005;71:319-326.
4. Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Poststerilization regret: findings from the United States Collaborative Review of Sterilization. *Obstet Gynecol.* 1999;93:889-895.
5. Peterson HB, Curtis KM. Long-acting methods of contraception. *N Engl J Med.* 2005;353:2169-2175.
6. Grigorieva V, Chen-Mok M, Tarasova M, Mikhailov A. Use of a levonorgestrel-releasing intrauterine system to treat bleeding related to uterine leiomyomas. *Fertil Steril.* 2003;79:1194-1198.
7. Marjoribanks J, Lethaby A, Farquhar C. Surgery versus medical therapy for heavy menstrual bleeding. *Cochrane Database Syst Rev.* 2003;2:CD003855.
8. Soysal S, Soysal ME. The efficacy of levonorgestrel-releasing intrauterine device in selected cases of myoma-related menorrhagia: a prospective controlled trial. *Gynecol Obstet Invest.* 2005;59:29-35.

KEY POINT

“The low continuation rates for most methods of birth control among adolescents are discouraging.”

-Anita L. Nelson, MD

9. Hurskainen R, Teperi J, Rissanen P, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up. *JAMA*. 2004;291:1456-1463.
10. Inki P, Hurskainen R, Palo P, et al. Comparison of ovarian cyst formation in women using the levonorgestrel-releasing intrauterine system vs. hysterectomy. *Ultrasound Obstet Gynecol*. 2002;20:381-385.
11. Reid PC, Virtanen-Kari S. Randomized comparative trial of the levonorgestrel intrauterine system and mefenamic acid for the treatment of idiopathic menorrhagia: a multiple analysis using total menstrual fluid loss, menstrual blood loss and pictorial blood loss assessment charts. *BJOG*. 2005;112:1121-1125.
12. Fedele L, Bianchi S, Raffaelli R, Portuese A, Dorta M. Treatment of adenomyosis-associated menorrhagia with a levonorgestrel-releasing intrauterine device. *Fertil Steril*. 1997;68:426-429.
13. de Sa Rosa e Silva AC, Rosa e Silva JC, Nogueira AA, Petta CA, Abrao MS, Ferriani RA. The levonorgestrel-releasing intrauterine device reduces CA-125 serum levels in patients with endometriosis. *Fertil Steril*. 2006;86:742-744.
14. Chiou CF, Trussell J, Reyes E, et al. Economic analysis of contraceptives for women. *Contraception*. 2003;68:3-10.
15. Milsom I, Andersson K, Andersch B, Rybo G. A comparison of flurbiprofen, tranexamic acid, and a levonorgestrel-releasing intrauterine contraceptive device in the treatment of idiopathic menorrhagia. *Am J Obstet Gynecol*. 1991;164:879-883.
16. Grimes DA, Hubacher D, Lopez LM, Schulz KF. Non-steroidal anti-inflammatory drugs for heavy bleeding or pain associated with intrauterine-device use. *Cochrane Database Syst Rev*. 2006;4:CD006034.
17. Hubacher D, Reyes V, Lillo S, et al. Preventing copper intrauterine device removals due to side effects among first-time users: randomized trial to study the effect of prophylactic ibuprofen. *Hum Reprod*. 2006;21:1467-1472.
18. American College of Obstetricians and Gynecologists (ACOG), Committee on Practice Bulletins—Gynecology. Use of hormonal contraception in women with coexisting medical conditions. ACOG Practice Bulletin No 73. *Obstet Gynecol*. 2006;107:1453-1472.
19. Bahamondes L, Faundes A, Sobreira-Lima B, Lui-Filho JF, Pecci P, Matera S. TCu 380A IUD: a reversible permanent contraceptive method in women over 35 years of age. *Contraception*. 2005;72:337-341.
20. United Nations (UN) Development Programme, UN Population Fund, World Health Organization (WHO) and World Bank, Special Programme of Research, Development and Research Training in Human Reproduction. Long-term reversible contraception: twelve years of experience with the TCu380A and TCu220C. *Contraception*. 1997;56:341-352.
21. Centers for Disease Control. Achievements in public health, 1990-1999: family planning. *MMWR Morb Mortal Wkly Rep*. 1999;48:1073-1080.
22. World Health Organization. WHO statement on hormonal contraception and bone health. July 2005. 2005;80:302-304. Available at: <http://www.who.int/wer/2005/wer8035.pdf>. Accessed November 14, 2006.
23. Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: three years' comparative experience of levonorgestrel- and copper-releasing intrauterine devices. *Obstet Gynecol*. 1991;77:261-264.
24. Scholes D, LaCroix AZ, Ichikawa LE, Barlow WE, Ott SM. Change in bone mineral density among adolescent women using and discontinuing depot medroxyprogesterone acetate contraception. *Arch Pediatr Adolesc Med*. 2005;159:139-144.

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1. **The FDA has recently revised the package labeling for the Copper T 380A intrauterine device (IUD). Which of the following statements is INCORRECT?**
 - A. Nulliparous women should not receive the copper T 380A IUD.
 - B. Both nulliparous and multiparous women are appropriate candidates for the copper T IUD.
 - C. Women with a history of pelvic inflammatory disease may receive the copper T 380A IUD.
 - D. The copper T 380A IUD is approved for up to 10 years of use.
2. **The recently approved single-rod etonogestrel-releasing implant provides contraceptive efficacy for up to:**
 - A. 1 year
 - B. 3 years
 - C. 7 years
 - D. 10 years
3. **Which of the following statements is INCORRECT regarding the levonorgestrel-releasing intrauterine system?**
 - A. It is effective for the treatment of women with heavy menstrual periods (menorrhagia).
 - B. It is not useful for the treatment of women with menorrhagia associated with fibroids.
 - C. It is a highly effective contraceptive that provides efficacy for up to 5 years.
 - D. It has been shown to have comparable efficacy to that of gonadotropin-releasing hormone agonist (GnRH-a) therapy for endometriosis.
4. **The most popular options for female birth control in the United States are:**
 - A. Oral contraceptives and IUDs
 - B. Sterilization and IUDs
 - C. Oral contraceptives and sterilization
 - D. IUDs and implants.
5. **When placing the levonorgestrel-releasing IUS for contraception and treatment of menorrhagia due to fibroids, which of the following statements is CORRECT?**
 - A. A few intramural fibroids would be a problem when placing the levonorgestrel-releasing IUS.
 - B. A sonogram is helpful to determine whether the uterine cavity is distorted.
 - C. Patients should be counselled that they may experience more persistent or heavier spotting/bleeding in the first 6 months than women without menorrhagia.
 - D. All are correct.
6. **Studies by the World Health Organization suggest that while combined oral contraceptives may have some minor effect on the quality and quantity of breast milk, no effect was seen on infant growth.**
 - A. True
 - B. False
7. **Counseling obese women who are seeking birth control presents unique challenges. Which of the following statements is INCORRECT?**
 - A. DMPA, the copper T IUD, the levonorgestrel-releasing IUS, and the single-rod implant are all contraindicated for obese women.
 - B. Obesity and age are independent risk factors for development of deep vein thrombosis.
 - C. The copper T IUD is an attractive option for obese women in their late 30s because it offers a safe and effective birth control for 10 years.
 - D. The American College of Obstetricians and Gynecologists recommends that obese women older than 35 years should receive progestin only and/or intrauterine contraceptives.
8. **Which of the following steps is NOT necessary when inserting an IUD?**
 - A. Confirm the patient's desire for the insertion of an IUD.
 - B. Carry out a bimanual examination and sound the uterus.
 - C. Perform a sweep of the uterine sound laterally at the fundus.
 - D. Place antiseptic on the cervix and upper vagina.
9. **When counseling young adolescent women with regard to long-term contraception, which of the following statements is INCORRECT?**
 - A. DMPA provides highly effective contraception for adolescents and research shows that any bone mineral density loss that might occur is recovered within about 1 year after discontinuation.
 - B. Because adolescents are unreliable patients, birth control pills or the patch are not good options.
 - C. A hormonal IUD is good option because it is an effective method of birth control and it may be positively protective in terms of risk of infection.
 - D. The single-rod etonogestrel-releasing implant is easy to insert, provides an easy option for the patient who changes her mind, and provides protection for 3 years.
10. **When a patient is identified who might be at risk for acquiring a sexually transmitted disease, you should recommend dual protection with a condom and an effective method of birth control.**
 - A. True
 - B. False

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