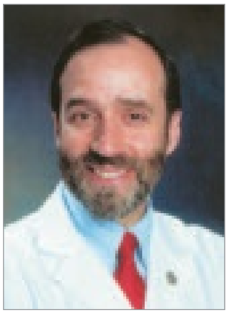
EDITORIAL



Robert L. Barbieri, MD
Editor-in-Chief

We should encourage more women to use the modern IUD

The catastrophe of the Dalkon Shield is a distant memory. So why is the IUD underutilized in the US?

Considering how common a clinical problem unplanned pregnancy is in the United States, widespread use of the highly effective intrauterine device (IUD) could help reduce the rate of unplanned pregnancy. In most developed countries of the world, use of the IUD is considerably greater than it is in the United States: Among women in Denmark and Germany who use contraception, for example, 24% and 17%, respectively, use an IUD.[1] In the United States, on the other hand, only 1% to 2% of women use an IUD.[2] In fact, few medical treatments have such a markedly different frequency of use between Europe and the United States.

The evidence strongly suggests that the IUD is underutilized in this country, owing to a combination of patient, clinician, and health-system factors.

***FAST** TRACK*

The IUD is:

- effective
- safe in nulligravid women
- a promising (but unapproved) treatment for other gyn problems

What's behind underutilization of the IUD?

Patient factors include a lack of knowledge about the device and a lack of understanding that it is safe and effective.[3]

Physician factors include

- a belief that an IUD may significantly increase the risk of pelvic infection
- a tendency to recommend an IUD only to monogamous women[4]
- reluctance to recommend an IUD, stemming from experience in the early 1970s with severe, often life-threatening clinical problems caused by the Dalkon Shield.[5]

A social factor is that the US health system and common practices of health insurance companies may guide women and their partners toward surgical sterilization, rather than the use of an IUD.

Safe in nulligravida

Recent studies indicate that the modern IUD is safe. Hubacher and colleagues recruited 1,311 nulligravid, infertile women 18 years of age and older to study the relationship between the IUD and infertility.[6] Hysterosalpingography demonstrated that 358 of the women had tubal disease and 953 did not. Among these infertile women with and without tubal disease, the odds ratio for tubal occlusion associated with prior use of a copper IUD was 1.0 (95% confidence interval, 0.5 to 1.9).

In addition, the long-term use of a copper IUD, removal of the IUD because of side effects, and a history of gynecologic symptoms during use of an IUD were not associated with an increased risk of tubal occlusion among the subjects. In contrast, the presence of antibodies to *Chlamydia trachomatis* among women who had not used an IUD was associated with an increased risk of tubal occlusion (odds ratio 2.4; 95% confidence interval, 1.7 to 3.2).

The Hubacher study demonstrates the safety of the IUD and suggests that *C. trachomatis* infection among non-IUD users is the main contributor to tubal factor infertility.

CONTINUED

Who's afraid of the IUD?

It is rare for a single product to cause such a furor or have such lasting effects, but that is what happened with the Dalkon Shield intrauterine device (IUD). The crisis over its health risks during the 1970s and early 80s drove the US market for the IUD to a standstill—and it still has not fully recovered. Although more than 90 million women worldwide use the IUD, fewer than 1% to 2% of contracepting American women choose this method.

A brief history of a fiasco

The Dalkon Shield was developed by Dr. Hugh J. Davis, a prominent gynecologist, and introduced in the United States in 1971. At the time, it was touted as "almost perfect," with practically no potential for adverse effects. Because many women and physicians were worried about the risks posed by oral contraceptives, the Dalkon Shield was widely prescribed. Within 4 years, more than 2 million women were using it.

The Dalkon Shield had 2 major design flaws, which quickly began causing problems. First, its shape: round, with 5 small "fins" along each side that may have caused the IUD to become embedded in the uterine wall in some women and certainly complicated removal. The second—and more serious—flaw was its tail string, which was composed of multiple filaments and open on each end. The open ends effectively made the string a wick, drawing organisms from the bacteria-laden vagina into the more pristine confines of the uterus and causing serious infection. By the time the medical community and general public caught on to the problems, the IUD had been linked to more than 200,000 infections and 18 deaths, and there was evidence that the A.H. Robins pharmaceutical company, which manufactured the device, had suppressed proof that it was less safe and effective than originally claimed.

Although the manufacturer stopped selling the IUD in 1974, the device was not removed from all users until the early 1980s. Shortly thereafter, a $2.5 billion fund was established to compensate women injured by the Dalkon Shield. Over its lifetime, the fund handled roughly 400,000 claims and paid out almost $3 billion.

If there was a silver lining…

The fiasco was largely responsible for a 1976 federal law requiring extensive testing of medical devices as a prerequisite to approval by the Food and Drug Administration.

—Janelle Yates, Senior Editor

***FAST* TRACK**

A levonorgestrel-releasing intrauterine system treats excessive menstrual bleeding and pelvic pain caused by endometriosis

More: The IUD can treat common gyn problems

IUDs are not approved by the FDA to treat gynecologic disease. Recently published data indicate, however, that a levonorgestrel-releasing intrauterine system (IUS) is effective for treating excessive menstrual bleeding and pelvic pain caused by endometriosis.

Menstrual bleeding. Randomized studies have reported that the levonorgestrel IUS reduces heavy menstrual bleeding. In head-to-head comparison of the levonorgestrel IUS with endometrial resection and with endometrial balloon ablation, for example, patient satisfaction was similar with all treatments, although endometrial resection and balloon ablation reduced self-reported blood loss more than the levonorgestrel IUS.[7]

In another randomized trial, treatment of heavy menstrual bleeding with the levonorgestrel-containing device was better accepted by patients than treatment with oral norethindrone.[8] Forty-four women with self-reported menorrhagia, measured menstrual blood loss of >80 mL/cycle, normal pelvic exam, and normal cervical cytology were randomized to a levonorgestrel IUS or norethindrone, 15 mg daily, for cycle days 5 through 26. The IUS and norethindrone reduced measured blood loss by 94% and 87%, respectively.

After 3 months of treatment, 76% of subjects treated with the levonorgestrel IUS requested that they be allowed to continue treatment. In contrast, only 22% of women treated with norethindrone requested to continue treatment with the oral progestin.

Why were women in the levonorgestrel IUS group more likely to elect to continue treatment? Specific reasons were not detailed in the report, but it is likely because the device greatly reduced menstrual bleeding and was associated with few side effects.

Pelvic pain. As mentioned, several trials have demonstrated that the levonorgestrel IUS is effective for treating pelvic pain caused by endometriosis.[9–11]

And other evidence. Additional reported uses of the levonorgestrel IUS include treatment of endometrial hyperplasia[12] and prevention of endometrial polyps in women who take tamoxifen.[13]

We can make the difference in boosting utilization

Many factors contribute to the low rate of IUD use in the United States. One obstacle, the crisis over the Dalkon Shield, is now decades old—a distant memory for older clinicians and beyond the experience of a new generation of women and clinicians. If physicians put greater emphasis on expanding the use of the modern IUD, we would likely help increase the number of American women who benefit from this device.

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INSTANT POLL

What would you do for this patient?

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"I want an IUD"

A 24-year-old G0 graduate student asks you to insert an intrauterine device for contraception. She reports having 3 sexual partners over the past 6 months; they have used a condom "occasionally," she tells you.

The physical examination is normal and a test for *Chlamydia trachomatis* is negative. She has received a first dose of the human papillomavirus vaccine.

How would you respond?

- ❑ Because she has multiple partners and a significant risk of sexually transmitted infection, I would not insert an IUD
- ❑ Because she has not had a prior delivery, I would be reluctant to insert an IUD and prefer that she use an oral contraceptive and condoms for her partners
- ❑ Because the IUD is so effective, I would insert one and counsel her to have her partners use a condom