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THE WOMEN'S HEALTH ALLIANCE

The Myths and Facts of Intrauterine Contraception Bleeding Profiles

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Changes in bleeding patterns as a result of contraceptive use are a frequent cause of method discontinuation and unintended pregnancy. Because many contraceptive methods alter uterine bleeding, particularly during the critical early weeks and months of use, it is important that clinicians counsel patients on this topic. A roundtable of leading women's health experts convened to review the scientific evidence and provide clinical insight into bleeding profiles associated with intrauterine contraceptives (IUCs) and their impact on patient satisfaction. The findings summarized here provide the basis for effective patient counseling on the bleeding patterns associated with IUC use.

The Need for Effective Contraception

Nearly half of all pregnancies in the United States are unintended, even though long-acting, reversible methods, such as the IUC, injection, and implant, are available.[1] These methods are highly effective because they do not rely on user compliance or daily usage. However, their popularity does not compare to combination oral contraceptives (COCs), the most commonly used form of birth control in the United States.[2] For example, less than 2% of the US population uses IUCs,[3] although interest in the use of IUCs is increasing. Reasons for such low usage are varied but include limited access, cost, the reluctance of clinicians to use IUCs for nulliparous women and adolescents, clinicians untrained in insertion procedures, misperceptions regarding bleeding patterns and risks, and the lack of appropriate patient counseling.[4,5]

IUC Options

Two intrauterine contraceptives currently available in the United States are ParaGard® intrauterine copper contraceptive (T 380A, Duramed Pharmaceuticals, Inc, Pomona, NY) and Mirena® levonorgestrel (LNG)-releasing intrauterine system (Bayer HealthCare Pharmaceuticals, Inc, Wayne, NJ).[6,7] As noted in **TABLE 1** (page 2), these products differ not only in their length of contraceptive coverage and the presence and absence of hormones but also in their bleeding profiles.[6–9] The effect of IUCs on menstrual bleeding and

TABLE 1. Characteristics of Copper and Levonorgestrel Intrauterine Contraceptives[6–9]

	T 380A	LNG IUC
Components	T-shaped device containing copper	T-shaped device containing levonorgestrel
Indication and usage	Intrauterine contraception for up to 10 years	Intrauterine contraception for up to 5 years
Unique contraindications	Wilson disease, a rare genetic disease affecting copper excretion	Acute liver disease or liver tumor Known or suspected breast cancer
Effects on vaginal bleeding patterns	Discontinuations due to bleeding more common in first year Heavier periods and spotting generally diminish after 2 to 3 months	Irregular bleeding patterns and increased number of bleeding and spotting days in first 3 to 6 months Amenorrhea develops in 20% of users after 1 year of use

Abbreviations: LNG IUC, levonorgestrel intrauterine contraceptive; T 380A, intrauterine copper contraceptive.

discontinuation rates was the focus of the clinical studies reviewed and discussed by the roundtable panel of experts.

Bleeding Profiles—What Do the Studies Say?

The long-term effect of an IUC on menstrual bleeding depends primarily on whether or not it contains hormones. In several head-to-head studies of copper-releasing versus LNG-releasing IUCs, bleeding patterns and discontinuation rates were compared. It is important that the study results be evaluated since the data differ from perceptions widespread in clinical practice.

Discontinuation Due to Bleeding Disturbances

In an analysis of bleeding diaries of 1,905 IUC users enrolled in several multicenter contraceptive trials, Datey et al[8] found that 18% of women experienced prolonged/frequent bleeding for the first 3 months of use of either the copper or LNG IUC. For the copper IUC, bleeding patterns rapidly changed to "acceptable/normal" (defined as neither frequent/prolonged nor reduced/infrequent) in 80% of users within the first year. Conversely, users of the LNG IUC experienced a shift toward infrequent bleeding with only 37% of users experiencing acceptable/normal bleeding after the first 3 months, with little change throughout the first year. Acceptable bleeding patterns were fairly steady for COC users, with more than 80% experiencing an acceptable pattern during the first 3 months and throughout the first year (TABLE 2).[8,10]

"The myth is that **IUCs always cause menstrual bleeding to be heavier, longer, and more painful**. While that can be true in some cases, the vast majority of women—80%—will have **acceptable bleeding patterns** after insertion of a copper IUD and after the **initial adjustment period**—rates comparable to women using COCs."

—Miriam Zieman, MD, FACOG

Discontinuation rates due to bleeding irregularities after 1 year of use were higher for LNG-IUC users (13.8%) as compared to women using a copper IUC (5.7%); for COCs, the 1-year discontinuation rate was 2.6%. The panel noted the importance of counseling women who switch from a COC to an IUC that their bleeding patterns will change. Because the use of COCs often results in shorter and lighter periods,[11] bleeding with the nonhormonal copper IUC may seem prolonged in comparison.

"Tolerance of bleeding is highly individualized and often depends on the **woman's history** with other forms of contraception. Many women who used **injectable or implantable contraception** learned to tolerate menstrual changes for the first 3 to 9 months. On the other side of the spectrum are **most OC users** who are used to having really **light periods**."

—Suzy Reiter, WHNP-BC, MM, MSN, SANE-A, FAANP

TABLE 2. Bleeding Disturbances for Different Contraceptive Methods[8]

Method	Reference period (months)	Acceptable pattern	Infrequent bleeding	Frequent or prolonged bleeding	Total days bleeding*	Total days spotting*	Discontinuation rate for bleeding irregularities at 1 year
CuT-380Ag†	0-3	64.2%	17.7%	18.2%	12.4 ± 5.6	5.5 ± 5.2	N/A
	9-12	78.7%	15.3%	6.1%	10.8 ± 4.4	3.9 ± 3.8	N/A
CuT-200B†	0-3	63.8%	18.7%	17.4%	12.1 ± 5.4	4.9 ± 4.4	N/A
	9-12	81.8%	13.6%	4.6%	11.0 ± 4.7	3.7 ± 3.9	5.7%
LNG IUC	0-3	36.6%	45.8%	17.6%	8.9 ± 7.5	9.7 ± 9.3	N/A
	9-12	38.3%	60.6%	1.2%	5.2 ± 5.0	4.4 ± 4.7	13.8%
COC	0-3	80.2%	15.7%	4.0%	8.9 ± 2.9	3.3 ± 4.1	N/A
	9-12	89.1%	10.1%	0.8%	8.5 ± 2.5	3.5 ± 3.5	2.6%

N/A, not available.

*Mean ± standard deviations.

†Bleeding profiles similar and independent of copper surface area.[10]

Abbreviations: COC, combination oral contraceptive; CuT-200B and CuT-380Ag, nonhormonal copper T types of intrauterine devices; LNG IUC, levonorgestrel intrauterine contraceptive.

Adapted from Contraception, 51(3), Datey S, Gaur LN, Saxena BN, Vaginal bleeding patterns of women using different contraceptive methods (implants, injectables, IUDs, oral pills)—an Indian experience, 155–165, 1995, with permission from Elsevier.

> "I think that if we **educate** and get women through these **first 3 months,** and counsel them about **potential changes in bleeding,** then continuation and overall patient satisfaction is similar for both IUCs."
>
> *—Jay Cohen, MD, FACOG*

Impact of Amenorrhea Versus Menorrhagia

In a randomized, multicenter, prospective 7-year study of 2,226 women, Sivin and Stern compared efficacy and tolerance of a copper IUC versus LNG IUC (similar to ParaGard® and Mirena®).[12] Women maintained menstrual diaries detailing the days of bleeding and spotting from admission to end of study. Over the course of the study, the annual incidence of menstrual complaints decreased. Continuation rates over the course of 7 years were significantly higher for the copper IUC (27.2%) than for the LNG IUC (22.8%, $P<.001$), with significantly more "menstrual problems" among the users of the LNG IUC (5.9 vs 3.0 per 100 women-years, $P<.001$). Complaints of amenorrhea were more common in the LNG IUC users (4.4 vs 0.1 per 100 women-years, $P<.001$) and accounted for 72% of discontinuations. Menorrhagia was the main cause of discontinuation with the copper IUC.

Pedron evaluated actual menstrual blood loss for 365 Mexican women using 11 different types of IUCs, including 1 inert (Lippes Loop), 5 copper-bearing, and 5 progesterone-loaded devices.[13] The results showed that most copper IUCs produced moderately increased menstrual bleeding, while IUCs that release LNG or other progestins reduced the amount of actual bleeding. Although this study demonstrates that bleeding, when quantified, is indeed heavier than baseline with copper IUCs during the first months of use, what is clinically important is whether this leads to discontinuations. Discontinuations were not reported in this study, but the author comments that amenorrhea induced by LNG IUCs may lead to removal, because women do not have a means to determine if they are pregnant. Dr. Ramos noted that tolerance of bleeding alterations varies by cultural background. In her practice, Hispanic women prefer having a normal monthly period.

Hormonal Side Effects

In a large-scale, European, multicenter trial, 2,758 women were randomized to either a copper IUC (Nova-T® 200 mm^2; n=937) or an LNG IUC (n=1,821) and followed for 5 years.[9,14,15] Discontinuation rates at 12 months and at 5 years were 17% and 55% for Nova-T® and 20% and 53% for the LNG IUC, respectively.[9] At

TABLE 3. Menstrual Bleeding Patterns in a Comparative Trial of IUCs[9,14]

Net cumulative termination rates per 100 woman-years	Nova-T® IUC			LNG IUC		
Year	1	3	5	1	3	5
Bleeding problems	5.7	12.0	16.2	5.8	9.6	10.9
Amenorrhea	0.0	0.0	0.0	1.5	3.6	4.3
Pain	1.6	3.3	4.2	1.6	3.4	4.2
Hormonal*	0.1	0.6	1.1	2.3	6.4	8.4
Planning pregnancy	1.9	8.1	11.8	1.9	8.2	10.8
Continuation	83.0	59.4	44.5	79.9	56.7	46.9

*LNG IUC hormonal termination reasons included depression (2.9), acne (2.3), headache (1.9), weight change (1.5), breast tenderness (0.8), nausea (0.8), and hirsutism (0.7).

Abbreviations: IUC, intrauterine contraceptive; LNG, levonorgestrel.

Adapted from Contraception, 49(1), Andersson K, Odlind V, Rybo G, Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: A randomized comparative trial, 56–72, 1994, with permission from Elsevier.

12 months, discontinuation due to frequent irregular bleeding and amenorrhea was more common among the users of the LNG IUC compared to the Nova-T® (TABLE 3).[9,14] Hormonal side effects, such as acne, weight change, nausea, headache, mood changes, and breast tenderness, were cited as the reason for removal for 2.3/100 women-years in the LNG IUC group and only 0.1/100 women-years among users of the Nova-T® ($P<.001$).[9]

Preventing Discontinuation and Unintended Pregnancy

Although the overall discontinuation rates are similar for the copper and LNG IUCs, the reasons for discontinuation differ, with the main differentiators being the impact of IUCs on bleeding and spotting, and the systemic hormonal adverse effects of the LNG IUC (eg, headache, acne, mood changes).[16–18] The clinical evidence from large well-controlled studies is helpful when counseling patients on what to expect before and after method selection. Successful communication and careful counseling can prevent patient dissatisfaction and discontinuation.[19–21] By preventing discontinuation, the risk of an unintended pregnancy is reduced—half of women getting an abortion changed their contraceptive method in the 6 months preceding the abortion.[22]

Other Common Misperceptions About Intrauterine Contraception

Risk of Pelvic Inflammatory Disease

Many beliefs about the health risks associated with IUCs have been debunked (TABLE 4). Among them are the myths that IUC usage leads to sexually transmitted infections (STIs) and pelvic inflammatory disease (PID), which could impair future fertility. There is a risk of PID around the time of IUC insertion; however, this risk declines to normal rates within 20 days. In an analysis of 51,399 woman-years of follow-up among 22,908 IUC insertions, there were only 1.6 cases of PID per 1,000 woman-years of use.[23] The PID risk was 6-fold greater for the first 20 days postinsertion compared to later times; subsequent risk was low and remained low for up to 8 years of follow-up.[23]

Return to Fertility

Return to fertility after removal of an IUC is comparable to other methods of contraception.[24–26] The 12- and 24-month pregnancy rates of 82% and 89%, respectively, were comparable for the copper IUC, LNG IUC, and LNG implants (Norplant® or Norplant® II).[24] There was no delay in return to fertility, with 96% of pregnancies occurring within the first year after removal of the copper or LNG IUC.[26]

Appropriate Patient Selection

The misperception that IUCs should be used only in women who have already had children is common. The reluctance to offer IUCs to nulliparous patients was based upon a "Recommended Patient Profile" in the prescribing information for both IUCs that limited the use of the IUC to parous women. This section of the labeling was removed from ParaGard®.[6,27] Additionally, a past history of PID, once thought to be a contraindication, does not preclude IUC insertion. The World Health Organization points out that the IUC is contraindicated only with current PID or if a woman is at very

TABLE 4. Misperceptions About Intrauterine Contraception

Myth	Reality
IUCs increase the risk of STIs, PID, and ectopic pregnancy.	Other than a slightly increased risk of infection around the time of insertion, IUCs do not cause PID or other infections.
An IUC should be removed immediately if STI or PID develops.	Infections can be treated successfully with IUC in place. Close clinical follow-up is mandatory.
IUCs cause tubal infertility and impair a woman's future fertility.	Factors such as prior exposure to STIs are more likely to cause tubal infertility. Women using IUCs are as likely to achieve a pregnancy as they would be if they did not use an IUC.
IUCs are abortifacients.	The mechanism of action of IUCs is primarily spermicidal.
IUCs cannot be used by nulliparous women.	IUCs can be used by nulliparous women.*
IUCs cause either excessively heavy bleeding or amenorrhea.	The bleeding profiles for IUCs differ, but irregular or heavy bleeding patterns are generally transient.
A woman must use an IUC for 5 or 10 years.	IUCs can be used as contraception for 1, 2, or more years (up to 5 years for LNG IUC and up to 10 years for T 380A).

Abbreviations: IUC, intrauterine contraceptive; LNG, levonorgestrel; PID, pelvic inflammatory disease; STI, sexually transmitted infection.
*Not all IUCs are FDA approved for use in nulliparous women (eg, Mirena®).

high risk of recurrent STIs.[28] Dr. Cohen observed that women frequently are misdiagnosed with PID after being treated in the emergency department for a ruptured cyst or other gynecologic issue, which may cause them to falsely report a history of PID.

> "We also have **good evidence** that prior use of an IUC **does not impair later fertility,** and that's why the label for **ParaGard®** was expanded to say that it's **appropriate to insert in nulliparous patients.**"
>
> *—Miriam Zieman, MD, FACOG*

IUCs Are Not Abortifacients

Confusion about the mechanism of action of IUCs still persists in the minds of some clinicians and patients. Previous beliefs about endometrial alterations interfering with implantation, based upon animal research,[29] have given way to more current scientific evidence that has found interference with fertilization to be the primary means by which pregnancy is prevented. Alterations in sperm motility and integrity, interference with ova (ie, change in transport speed or number of ova recoverable from the fallopian tubes or uterus), and changes to the endometrial and tubal fluid all work to prevent fertilization of the ovum.[29–35]

Production and composition of cervical mucus are altered by both types of IUCs, making it more difficult for sperm to migrate and fertilize the ovum.[29] The LNG released by Mirena® is thought to thicken cervical mucus to prevent sperm passage and inhibit sperm capacitation,[7] while ParaGard® releases copper ions that inhibit the motility and viability of sperm.[29,34] Sensitive blood tests have failed to find chemical evidence of early pregnancy (prior to implantation), which supports that fertilization is prevented early among IUC users.[29,35] Also, studies that have evaluated the contents of the fallopian tubes and uterus at mid-cycle have found minimal evidence of viable fertilized eggs in IUC users.[29,31] Thus, scientific data do not support the belief that IUCs are abortifacients.[32]

Cost

Additional barriers to the use of the IUC may include economic factors. Women who think an IUC costs too much may be considering only short-term method costs rather than longer-term efficacy. A cost-effectiveness study that analyzed costs of the drug or device, physician services, method failures, and side effects found

Patient Experiences With IUCs Provided by Panel Participants*

IUC type	Patient example
Copper	A 27-year-old patient had significant PMS symptoms on Mirena® and headaches and blurry vision on COCs. She recently was found to be factor V positive and had numerous other conditions, making more pregnancies and hormonal contraceptives not recommended. She switched to ParaGard® and was happy, with no PMS, headaches, or other side effects.
	A 34-year-old patient was unable to tolerate COCs and refused any hormonal contraceptive. She desired 10 years of IUC and had a normal menstrual history. She was very satisfied with ParaGard®. She experienced menstrual spotting but no cramping.
	A 29-year-old patient had a history of sensitivity to hormones, depression, and poor compliance with COCs. She had 1 viable birth and 4 abortions. Her periods were very light. She was very satisfied with ParaGard®.
	A 20-year-old patient had 2 unintended pregnancies and postpartum depression. She was very satisfied with ParaGard®.
LNG	A 32-year-old nulliparous patient had wanted a tubal ligation but was turned down due to her obesity. She tried Mirena® but had significant cramps and switched to ParaGard®. She did not experience cramps with ParaGard® but did have menorrhagia. After about 1 year on ParaGard®, she switched back to Mirena®. After 6 months on Mirena®, she was satisfied because her periods were lighter and she was not experiencing any cramping.
	A 39-year-old patient unable to tolerate COCs had a long history of heavy menstrual bleeding and cramps. She experienced pain at insertion but overall was satisfied with Mirena®. She had not yet experienced any real change in bleeding pattern.
	A 46-year-old patient was starting to have heavy and irregular bleeding. She did not want COCs because she was a poor pill taker. She was very satisfied with Mirena®. She initially had some spotting that was resolved by her 6-week postinsertion visit.
	A 37-year-old patient with heavy bleeding wanted a birth control method to reduce the bleeding. She had some spotting with Mirena® but liked the method.

*All patients were counseled regarding the benefits of an IUC, along with the potential for pain at insertion, the potential for cramping after insertion and abnormal bleeding during the first few months, and the need to check the string monthly.

Abbreviations: COC, combination oral contraceptive; IUC, intrauterine contraceptive; LNG, levonorgestrel; PMS, premenstrual syndrome.

that the IUC and vasectomy were the least expensive methods.[36] The costs of unintended pregnancy and length of time the method can prevent it were influential factors in this analysis of the value of contraceptive methods. While health insurance is likely to cover contraceptive costs, instability in insurance coverage is a compelling factor that makes an IUC a logical choice for long-term contraception.

Clinical Pearls

Setting Patient Expectations

In their clinical practice, the experts felt that good counseling and reassurance are key factors to help their patients successfully handle any bleeding issues associated with IUC use. Menstrual diaries may be helpful in assisting patients to have a realistic view of their bleeding. Additionally, women switching from long-term use of COCs are used to light "pill periods" and should be told to expect a different bleeding pattern, particularly if switching to ParaGard®.

Ms. Reiter described working with her patients to help them continue use of their IUCs, sometimes prescribing nonsteroidal anti-inflammatory drugs, which may reduce bleeding or dysmenorrhea.[37] She also obtains a baseline hemoglobin level prior to insertion so that if the patient has bleeding concerns, a comparison level may reassure the patient and clinician if the hemoglobin remains within normal limits. The main point is that each contraceptive method, including both types of IUCs, requires an adjustment period, and making patients aware of this can eliminate follow-up phone calls or unnecessary early discontinuations.

> "Translate **changes in bleeding** to what it actually may mean for a patient—it may be **3 extra pads or tampons** a cycle. Often women will be **okay with that,** rather than telling them to expect heavier bleeding."
>
> *—Diana Ramos, MD, MPH, FACOG*

Patient Education

Dr. Cohen described how his patients are counseled in advance with handouts describing various contraceptive methods, including IUCs, before he sees them. His personal counseling includes a discussion of risks and benefits, insurance coverage, and what to expect during the insertion process. Drs. Zieman and Ramos also emphasized the importance of using patient literature as an aid in counseling and to help office staff deal with questions they may field.

Nonhormonal Option

The experts agreed that having ParaGard®, a nonhormonal option, was important when offering an IUC.

> "Some of my patients are concerned about **weight gain and hormones** and, in particular, have had trouble with other **hormonal birth control methods.** That's when it's important to discuss **nonhormonal methods.**"
>
> *—Henry Hess, MD, PhD*

Key Takeaway Points

Although some long-held beliefs indicate that discontinuation rates due to bleeding issues are higher for the copper IUC than the LNG IUC, the evidence does not support these views: Large head-to-head studies show similar discontinuation rates for both types of IUCs. What does differ is the reason behind the discontinuations. For the copper IUC, discontinuation is primarily due to heavier or longer bleeding, whereas irregular bleeding, spotting, and amenorrhea cause discontinuation with the LNG IUC. Intrauterine contraceptives are underutilized as a result of misinformation not only about bleeding profiles but also about how IUCs work, who should use them, and potential health risks. Dispelling such beliefs is an important step toward improving patients' and clinicians' comfort with IUCs.

Current IUCs in the United States offer women long-term, highly effective contraception with or without hormones and the attendant hormone-related side effects. Counseling strategies around these IUCs include dispelling myths and having a fact-filled discussion about the bleeding changes that may be expected after insertion. Approximately 20% to 40% of women will experience heavier bleeding upon insertion of an IUC. This bleeding typically subsides within 3 months and normalizes for the copper IUC while continuing to diminish for the LNG IUC. After this initial adjustment, acceptable bleeding rates with the copper IUC are comparable to those of COCs. Armed with knowledge, patients and clinicians will be better prepared to handle transitory changes in bleeding and achieve success with these reliable, reversible contraceptive methods. ■

Disclosures: Dr. Margolis is an employee of Teva Pharmaceuticals. Dr. Zieman reports that she is a consultant to Teva. Dr. Cohen reports that he is a speaker for Eli Lilly and Company, Teva, Novartis, Myriad Genetics, and Roche. Dr. Hess reports that he is a speaker for Teva. Dr. Ramos reports that she is a speaker for Teva and Bayer HealthCare Pharmaceuticals. Ms. Reiter reports that she is a consultant to Teva; a speaker for Teva, Ortho-McNeil-Janssen Pharmaceuticals, and Merck & Co; and an advisor to Bayer HealthCare Pharmaceuticals, Upsher-Smith Laboratories, and Novo Nordisk A/S.

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