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Clinical Guidelines

Use of the Mirena™ LNG-IUS and Paragard™ CuT380A intrauterine devices in nulliparous women

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Abstract

Two intrauterine devices (IUDs) are available in the United States, the levonorgestrel-bearing intrauterine system (Mirena™) and the copper-bearing T380A (Paragard™). These devices have very low typical-use failure rates but are used by only a minority of women. In particular, there is concern about their use in nulliparous women. We review the available data to address common concerns about using IUDs in this population and show that nulliparous women desiring effective contraception should be considered candidates for IUDs.

Keywords: Intrauterine device; Intrauterine contraception; Intrauterine system; IUD; IUS; Nulliparity

Background

Intrauterine devices (IUDs) are highly effective, safe and well-tolerated contraceptives with typical-use failure rates (TUFRs) similar to surgical sterilization [1,2]. Two IUDs are available for use in the United States, the CuT380A, a T-shaped copper-bearing device marketed in the United States as Paragard™, and the T-shaped Mirena™ LNG-IUS (levonorgestrel intrauterine system). Despite their low failure rates, both of these devices remain relatively underused in the United States [3]. According to the 2002 National Survey of Family Growth, only 1.3% of women using contraception reported use of an IUD, while approximately one third use the combined hormonal contraceptive pill, which is significantly less effective for the typical user [1,4].

One reason for this low usage rate is a continued perception among many clinicians that there are strict eligibility criteria that need to be fulfilled for women to use IUDs, such as a history of having had at least one child [5,6]. In a survey of 400 fellows of the American College of Obstetrics and Gynecology, 68% of respondents reported that parity status had a strong affect on their selection of candidates for an IUD [5]. A recently published survey in the United Kingdom found that less than 2% of clinicians said they would recommend an IUD to a 19-year-old nulliparous woman [7]. Particular concerns relate to IUD's effect on the incidence of pelvic inflammatory disease (PID) and infertility, increased complication rates and difficulty with insertion [6–9]. Eligibility criteria for IUD use typically reflected these concerns, which arose from the use of earlier intrauterine contraceptives, such as the Dalkon Shield. When the Paragard™ copper-releasing IUD was first marketed in the United States in 1988, the prescribing information contained a "recommended patient profile," which included a history of childbearing. In 2005, this labeling was amended; the package insert no longer contains language-discouraging use by nulliparous women [10]. However, prescribing information for the Mirena™ LNG-IUS continues to recommend use in women who have had at least one child [11]. In its Medical Eligibility Criteria for Contraceptive Use, the World Health Organization (WHO) designates nulliparity as Category 2 for intrauterine contraception (advantages generally outweigh risks), while for parous women, it is Category 1 (no restriction) [12]. Use of IUDs in nulliparous women is therefore commonly discouraged. Compounding this, many studies of IUDs have excluded nulliparous women, resulting in a limited amount of data to support their use in this specific population. This article will address some of the common concerns raised by use of the Mirena™ LNG-IUS and the Paragard™ IUD in nulliparous women, using data from studies of these and other devices.

Clinical questions and recommendations

1. Does intrauterine contraception maintain its low failure rate in nulliparous women?

Intrauterine devices are highly effective methods of contraception, with TUFRs of 0.2% for the Mirena™

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LNG-IUS and 0.8% for the Paragard™ CuT380A in the first year of use [1,4]. There are limited data on the failure rates of Mirena™ and Paragard™ stratified by parity. In a prospective study comparing the Mirena™ LNG-IUS with oral contraceptive pills by Suhonen et al. [13], no pregnancies occurred in 94 nulliparous women using the LNG-IUS over 1 year. In another more recent prospective pilot study by Brockmeyer et al. [14], there were no pregnancies among a cohort of nulliparous women using either the LNG-IUS (n=9) or copper-based devices (n=104) at 1 year. A study that evaluated the failure rate of a "frameless" levonorgestrel-releasing IUD designed for nulliparous women also reported no pregnancies in 92 women at 1 year [15]. A study of the Femilis™ IUD (a T-shaped levonorgestrel-releasing device similar to Mirena™) from Belgium included 112 nulliparous women and reported no pregnancies in this group over the 5-year study period [16]. Data from studies of other devices that have been stratified by parity have not shown a difference in failure rate [17,18]. These data suggest that IUDs have a similarly low failure rate in nulliparous and parous women.

2. Is intrauterine contraception acceptable to nulliparous women?

Acceptability of a contraceptive method can be inferred from its continuation rate. Both of the available IUDs have high continuation rates at 1 year [1,4]. In the study of Suhonen et al. [13] comparing the Mirena™ LNG-IUS with oral contraceptive pills, 80% of 94 women using the LNG-IUS chose to continue use after 1 year. In another study comparing LNG-IUS use in nulliparous and parous women, 90% of 92 nulliparous women continued using the method at 1 year [15]. Brockmeyer et al [14] found high continuation rates among 113 nulliparous women using either copper-based devices or the Mirena™ LNG-IUS for 1 year — 65 of 86 women available for follow-up were continuing to use their IUD. Patients in this study also reported high levels of satisfaction with IUDs. While it is easier to discontinue pills than intrauterine contraceptives, continuation rates are a useful surrogate indicator of method acceptability. If continuation rate is considered an accurate reflection of acceptability, IUDs are highly acceptable to women regardless of parity status.

3. Is the rate of expulsion increased in nulliparous women?

The rate of IUD expulsion in parous women, outside the setting of an abortion or delivery, has been reported at 4.2% [19]. A retrospective cohort study of 461 women using IUDs, which included 129 nulliparous women, found no difference in rates of expulsion in nulliparous compared to parous women [20]. One study examining different copper-based devices designed for use by nulliparous women also found no difference in rates of expulsion by parity [21]. Brockmeyer's study reported six expulsions out of 113 women over 1 year, giving an expulsion rate of less than 5% [15]. However, in a review of studies examining the performance of a variety of copper-based IUDs in nulliparous women, Hubacher [21] found that 13 of 20 studies demonstrated an increased expulsion rate in this group. Only one of these studies examined the currently available CuT380A (Paragard™) device. Therefore, while the available data are limited, the expulsion rate for the Mirena™ LNG-IUS appears to be comparable between nulliparous and parous women but may be slightly increased for copper-based devices in nulliparous users compared to parous users.

4. Are side effects increased in nulliparous women?

Common side effects of the CuT380A include increased menstrual bleeding and pain [22]. Levonorgestrel-releasing IUDs have a tendency to lighter, but unpredictable, bleeding and amenorrhea. There are no published studies comparing the side effects experienced by nulliparous and parous users of the Mirena™ LNG-IUS. Hubacher's [21] review investigating copper-based devices found that in 15 of 20 studies, removals for pain and bleeding were slightly increased in nulliparous users compared to parous women. As mentioned previously, only one of these studies looked at the Paragard™ CuT380A specifically, and the increase in removals for bleeding and pain was slight for nulliparous users of this particular device compared with multiparous women.

5. Is the risk of perforation at insertion increased in nulliparous women?

The risk of uterine perforation with insertion of IUDs in all women is between 0% and 1.3% [18]. This risk could theoretically be increased in nulliparous women due to a smaller uterine cavity and greater cervical resistance to dilation. There are no studies directly comparing the rate of perforation at the time of IUD insertion in nulliparous and parous women. In the study of Brockmeyer et al. [14], no perforations were reported during 117 insertions in nulliparous women. One prospective follow-up study did find that increasing parity reduced the risk of perforation with insertion of the CuT380A but included only two nulliparous patients out of a total of 8343 women [23]. It is therefore not possible to make a statement regarding whether or not perforation risk is increased in nulliparous women.

6. Is the risk of PID increased in nulliparous users of intrauterine contraception?

There is no evidence that nulliparous users of IUDs have any greater risk of developing PID than parous users [17]. The Dalkon Shield, an IUD that is no longer available, increased users' risk of PID by a wicking effect of its multifilament string that allowed microbes to ascend into the upper genital tract from the vagina [24]. A large study by the WHO and the Women's Health Study have demonstrated that modern devices, all of which have