

Review

Extended use of the intrauterine device: a literature review and recommendations for clinical practice^{☆,☆☆}

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Abstract

There are multiple advantages to “extended use” of the intrauterine device (IUD) use beyond the manufacturer-approved time period, including prolongation of contraceptive and non-contraceptive benefits. We performed a literature review of studies that have reported pregnancy outcomes associated with extended use of IUDs, including copper IUDs and the levonorgestrel intrauterine system (LNG-IUS). Among parous women who are at least 25 years old at the time of IUD insertion, there is good evidence to support extended use of the following devices: the TCu380A and the TCu220 for 12 years, the Multiload Cu-375 for 10 years, the frameless GyneFix[®] (330 mm²) for 9 years, the levonorgestrel intrauterine system 52 mg (Mirena[®]) for 7 years and the Multiload Cu-250 for 4 years. Women who are at least 35 years old at the time of insertion of a TCu380A IUD can continue use until menopause with a negligible risk of pregnancy. We found no data to support use of the LNG-IUS 13.5 mg (Skyla[®]) beyond 3 years. When counseling about extended IUD use, clinicians should consider patient characteristics and preferences, as well as country- and community-specific factors. Future research is necessary to determine the risk of pregnancy associated with extended use of the copper IUD and the LNG-IUS among nulliparous women and women less than 25 years old at the time of IUD insertion. More data are needed on the potential effect of overweight and obesity on the long-term efficacy of the LNG-IUS. © 2014 Elsevier Inc. All rights reserved.

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1. Introduction

The intrauterine device (IUD) is the most widely used reversible form of contraception in the world [1], although it remains underutilized in North America, South Asia, Oceania and sub-Saharan Africa [2]. Given its long-acting properties and excellent efficacy, the IUD is also the most cost-effective reversible contraceptive method [3]. Widespread use of the IUD beyond the manufacturer-approved time period could have a significant public health impact by decreasing the rate of unintended pregnancy at a population level. Other advantages of extended IUD use include patient convenience, cost-savings, extension of non-contraceptive benefits and avoidance of potential complications associated with re-insertion of another IUD including pelvic inflammatory disease in the immediate post-insertion period [4] and

the rare but real risk of uterine perforation [5]. We conducted a literature review of currently published studies regarding “extended IUD use”, that is, continuous use of an IUD beyond the manufacturer-approved time period. The focus of this review is *not* to recommend one IUD type over another; IUD selection must be based upon patient characteristics and preferences, provider skills and IUD types available. When possible, we encourage selection of IUDs associated with the highest contraceptive efficacies (the TCu380A, the Gynefix[®], the LNG-IUS) [6–8].

We focus our discussion on the copper IUD and the levonorgestrel intrauterine system (LNG-IUS) to address the following questions:

1. Based upon prior studies, what is the risk of pregnancy associated with extended IUD use?
2. How do the pharmacokinetic properties of the LNG-IUS and the copper IUD contribute to our understanding of the potential lifetimes of these IUDs?
3. What are current gaps in the literature regarding extended IUD use?

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4. *What research initiatives are necessary to address these gaps?*
5. *What recommendations should be made to women regarding extended IUD use based upon the current literature?*

2. Materials and methods

We searched PubMed and Medline for articles in all languages using the following MeSH terms and combination of terms: (1) “intrauterine device”, “IUD”, “IUCD”, “copper IUD”, “copper T IUD”, “copper release”, “levonorgestrel IUD”, “Mirena IUD”, “levonorgestrel IUS”, “Skyla”, “LNG-IUS; and/or (2) “extended use” or “prolonged use”. We retrieved 762 citations. The authors (J.W. and S.P.) independently reviewed each abstract and when necessary, the entire paper itself, to identify studies that reported the following: (1) pregnancy outcomes for any copper IUD or LNG-IUS in current use worldwide; and (2) pregnancy outcomes beyond the manufacturer approved time period for that IUD. Using this strategy, we identified seven manuscripts (all published in English) that met eligibility criteria and were reviewed in entirety. To ensure we did not miss articles relevant to IUDs less widely used than the TCu380A and the LNG-IUS (e.g., frameless IUDs and other copper IUD types), we repeated the same search strategy using the following MeSH terms and combinations of terms: (1) “frameless intrauterine device”, “GyneFix”, “FlexiGard”, “Cu-Fix”, “Multiload intrauterine device”, “Fibropland LNG-IUS”, “Nova-T”; and/or (2) “extended use” or “prolonged use”. Using this strategy, we retrieved 593 citations, from which we identified an additional five papers (all published in English) that met our eligibility criteria. Each article’s reference section was reviewed for citations that may have been missed initially. We also reviewed the bibliographies of all currently published Cochrane reviews containing the word “IUD” or “intrauterine device” in the title (13 in total) and did not retrieve any additional articles of relevance. When necessary, we contacted authors via email for clarification regarding data findings and interpretations. In total, we identified eight papers regarding copper IUDs and four papers regarding the LNG-IUS. When possible, we abstracted data regarding the total period of observation (in woman-years) and the period of observation considered to be “extended use” for that device. Pregnancy outcomes are reported by pregnancy rates per 100 women and/or gross numbers of pregnancies that occurred during a period of observation.

3. Results

3.1. *Based upon prior studies, what is the risk of pregnancy associated with extended IUD use?*

Table 1 summarizes eight papers that describe extended use of copper IUDs. Nulliparous women were excluded from

all studies. Collectively, the mean age of subjects in the copper IUD studies ranged from 26.7–38.8 years at the time of IUD insertion. The first two studies, a Brazilian study [9] and a multi-center, international randomized controlled trial (RCT) conducted by the World Health Organization/United Nations (WHO/UN) [10], collectively provide the largest body of evidence regarding extended use of the TCu380A (Paragard®). There were no pregnancies reported among parous women who used the TCu380A for 11–16 years; the number of women who were followed from Years 12–16 was small ($n=39$) [10]. A smaller Population Council Study also reported no pregnancies among parous women who used the TCu380Ag up to 20 years [11].

While not as widely used as the TCu380A, we included data regarding extended use of the TCu220, a “first generation” copper IUD [6]. Given the smaller amount of copper surface area, the efficacy of the TCu220 is inferior to that of the TCu380A (cumulative pregnancy rates of 7.2/100 versus 2.2 pregnancies/100 women at 10 years, respectively) [10]. Nevertheless, the TCu220 has been used by millions of women worldwide, most prevalently in China where the cost of the TCu220 is half the cost of the TCu380A [12]. The same WHO/UN RCT mentioned previously included a study arm of women who used the TCu220 for 12 years; three pregnancies (two intrauterine, one ectopic) occurred during Years 10–12 [10]. The majority of pregnancies that occurred during the entire 12-year period occurred prior to Year 8, and the three pregnancies that occurred during Years 10–12 minimally affected the cumulative pregnancy rate (7.2/100 at Year 10, 7.6/100 at Year 12) [10].

We identified two articles regarding extended use of the frameless GyneFix® IUD (330 mm² of copper), which is approved for 5 years of use [13]. Both papers describe RCTs comparing the GyneFix® with the TCu380A. Based upon data among 521 women who used the GyneFix® up to 8 years in a multi-center RCT, Meirik et al. reported a negligible increase in the pregnancy rate from Year 6 (2.4/100 women) to Year 7 (2.5/100 women) without any subsequent pregnancies occurring during Years 7–8 [14]. In a Chinese-based RCT, Cao et al. reported no pregnancies among 139 parous women who used the GyneFix® up to nine years; only 1 woman was lost to follow-up (0.64%) [15].

The Multiload is a horseshoe shaped copper IUD with serrated “fins” designed to minimize the risk of expulsion [16]; the Multiload Cu-375 (MLCu-375) is approved for 5 years of use and the Multiload Cu-250 (MLCu-250) is approved for 3 years of use [17]. A WHO sponsored RCT observed 352 parous women who used the MLCu-375 up to 10 years [18]; data isolated to Years 5–10 (the period that would be considered “extended”) were not available. Based upon data from Years 3 and 10, there was a small increase in the cumulative pregnancy rate (2.9/100 in Year 3→5.3/100 in Year 10) [18,19]. Similar to the MLCu-375, the MLCu-250 has demonstrated contraceptive efficacy beyond its approved time period; a Singapore based RCT (with only 5.2% lost to follow-up) reported no additional pregnancies

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