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Contraception

Contraception xx (2016) xxx-xxx

Review article

The safety of intrauterine devices in breastfeeding women: a systematic review^{☆,☆☆,★}

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Abstract

Objectives: To investigate levonorgestrel (LNG)-releasing and copper-bearing (Cu) intrauterine device (IUD) safety among breastfeeding women and, for Cu-IUD use, breastfeeding performance and infant health.

Study design: Systematic review.

Methods: We searched PubMed, Embase, Cochrane Library and clinicaltrials.gov for articles through January 2016. We included studies of Cu-IUD or LNG-IUD users comparing IUD-specific (perforation, expulsion) and other contraceptive-related (infection, removal/cessation due to bleeding/pain and other adverse events) outcomes for breastfeeding vs. non-breastfeeding women. We also included studies of breastfeeding women comparing contraceptive-related outcome for IUD-users vs. other contraceptive-method users. Finally, we included studies comparing breastfeeding outcomes among Cu-IUD users to users of other nonhormonal contraceptives or no contraception.

Results: Of 548 articles identified, 23 (16 studies) met the inclusion criteria. Two studies suggested that the risk of IUD perforation was 6-10 times higher among breastfeeding vs. non-breastfeeding women. Seven studies suggested that risks for other adverse events were similar or lower among breastfeeding vs. non-breastfeeding women. Three studies among breastfeeding women found no increased risk of adverse events in IUD users vs. nonusers. Breastfeeding performance and infant growth were similar for Cu-IUD users and users of other nonhormonal methods or no contraception.

Conclusion: Overall, risks for adverse events among IUD users, including expulsion, pain and removals, were similar or lower for breastfeeding women vs. non-breastfeeding women. Uterine perforation with IUDs, while rare, appeared more frequent among breastfeeding women. No evidence indicated that Cu-IUD use in breastfeeding women influences breastfeeding performance or infant growth. © 2016 Elsevier Inc. All rights reserved.

Keywords: IUD; Intrauterine device; breastfeeding; uterine perforation

1. Introduction

The American Academy of Pediatrics and the Institute of Medicine recommend breastfeeding through the first 12 months of life, and the World Health Organization (WHO)

Financial support: None.

recommends breastfeeding for up to 2 years, or beyond [1-3]. The Lactational Amenorrhea Method (LAM) is an effective form of contraception for 6 months postpartum among exclusively or nearly exclusively breastfeeding women. However, many women who are breastfeeding may want to use additional forms of contraception, may not choose LAM or may not qualify for LAM [4]. Intrauterine devices (IUDs), including nonhormonal copper IUDs (Cu-IUDs) and levonorgestrel-releasing IUDs (LNG-IUDs), are highly effective and convenient methods of contraception often used by breastfeeding women [5,6]. Women who are in the postpartum period, as compared to those who are not, may have different risk associated with IUD use, such as higher risk of IUD expulsion [7]. The hormonal changes experienced in the postpartum period and during

And Conflicts of interest: None.

[★] Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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breastfeeding, including low estrogen and elevated oxytocin have been associated with changes to the uterus and endometrium that may impact the performance of an IUD [8,9]. Prior systematic reviews have examined the safety of IUD insertion in the postpartum period but have not looked specifically at the safety of IUD insertion or use among breastfeeding women compared with non-breastfeeding women [10,11].

Our primary objective in this systematic review was to examine the published evidence for the safety of IUD use in breastfeeding women with respect to IUD-related complications (e.g., perforation, expulsion or infection). Another recent systematic review from the WHO examined the safety of progestin-only contraception (including the LNG-IUD) among breastfeeding women with regard to breastfeeding and infant health outcomes; however, that review did not address the Cu-IUD [12]. Thus, our secondary objective was to examine the safety of Cu-IUD use among breastfeeding women with respect to breastfeeding performance and infant health.

We conducted this systematic review in preparation for a meeting held at the Centers for Disease Control and Prevention in August 2015 with the purpose of updating the *U.S. Medical Eligibility Criteria for Contraceptive Use*, 2010 [13].

2. Methods

2.1. Search strategy

We conducted a systematic review according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [14]. We searched PubMed, Embase, Cochrane Library and clinicaltrials.gov databases from database inception through February 10, 2016. The search terms used for each database were generated with assistance from a reference librarian (Appendix 1).

2.2. Selection criteria

We sought studies that examined any of the following three research questions: (1) among IUD users, do women who breastfeed as compared with those who do not have an increased risk of adverse events (perforation, expulsion, infection, pain or other adverse events)? (2) Among breastfeeding women, does IUD use, as compared with use of other contraceptive methods, increase the risk of adverse events (bleeding, infection, pain or other adverse events)? and (3) Among breastfeeding women, does Cu-IUD use, as compared with use of other nonhormonal methods or no method, increase the risk of adverse breastfeeding or infant outcomes (breastfeeding continuation and exclusivity, use of supplementation, infant growth or infant health)? We included randomized controlled trials (RCTs), prospective or retrospective cohort studies and case-control studies published in any language and excluded unpublished data,

conference abstracts, dissertations, case reports and case series. For research questions #1 and #2, we included articles that studied Cu-IUDs that are or have been available in the US (Cu 7, TCu200 and TCu380A) and LNG-IUDs currently available in the US. However, for articles that contained multiple IUD types, we included articles if at least 25% of the IUDs in the study met the above criteria (Cu 7, TCu200, TCu380A or LNG-IUDs). If studies included one or more of the qualifying IUDs plus other (excluded) IUD types, then we included the study only if it reported outcomes by IUD type. For breastfeeding assessment, we included articles that reported on women fully or partially breastfeeding by self-report at the time of IUD insertion. We use the term "immediate insertion" for IUD insertion within 10 min after delivery of the placenta, "early postpartum" for insertion greater than 10 min after the placenta but less than 4 weeks postpartum, and "interval insertion" for insertion at least 4 weeks postpartum. For women with immediate postpartum insertion, we included articles that examined outcomes by women who then went on to breastfeed after IUD insertion compared to women who did not breastfeed.

Several included articles used the term lactation infertility to describe the contraceptive method chosen by a study participant who chose no method other than the decreased fertility associated with lactation. In this review, the term lactational infertility is defined as women who were exclusively breastfeeding and amenorrheic. Some or all articles may have been referring to what is now know as LAM, but as they did not provide specific details, we did not use the term LAM.

We included articles that defined outcomes of interest in the following ways: bleeding — removals for bleeding or comparative hemoglobin/hematocrit measures; expulsion — patient report, provider diagnosis or chart review, either complete or partial expulsion; infection — endometritis or pelvic inflammatory disease, with diagnosis criteria reported; pain — removals for pain or pain (visual analog scale scores) at insertion; and perforation — patient report, provider diagnosis by imaging or surgery or chart review. We included studies with at least 4 weeks of follow-up for all outcomes except pain at insertion.

2.3. Study selection, data synthesis and quality rating

One author (E.B.B.) performed the search and reviewed the titles and abstracts of each article to determine the papers requiring full-text review. Two authors (E.B.B. and N.T.) identified the included articles by reviewing the full text and applying the inclusion and exclusion criteria. For articles reporting on the same study containing duplicate results, we only included the article that was most complete.

We analyzed and summarized the data using standard abstraction tables. For each study, two authors (E.B.B. and N.T., T.J. or M.W.) independently used the US Preventative Services Task Force rating system to assess methodological features and assign a quality rating [15].

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