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Can intrauterine contraceptive devices lead to VulvoVaginal Candidiasis (VVC) andanemia in Iranian new users?

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A B S T R A C T

Objectives: To assess the prevalence of anemia and VulvoVaginal Candidiasis (VVC) in women before and 3 months after copper Intra Uterine Device (IUD) insertion.
Methods: Longitudinal prospective study was performed with 101 women aged 15–45 year who wanted to use the IUD at six health centers in Tehran, Iran from November 2011 to August 2012. The pattern of bleeding, Hemoglobin and Hematocirt levels, and Candida colony count/cultures in the women were assessed before and after 3 months of IUD insertion. Data analysis was performed by descriptive and analytical statistics using the SPSS software for Windows.
Results: At the end of 3 months, a significant increase in menstrual blood loss and a significant decrease of Hb and HCT ($P = 0.047$ and 0.001, respectively) were reported. Moreover, no difference in the prevalence of anemia before and after IUD insertion was observed. The mean ± SD Candida colony counts significantly increased ($P = 0.001$), but positive Candida cultures were not significantly different before and 3 months after IUD insertion. Also, no clinical VVC was reported 3 months after IUD insertion. While BMI ≥ 29 had a positive relationship with Candida colony counts, the results remained unchanged after adjusting for potential risk factors.
Conclusions: Despite an increase in bleeding and Candida colony counts in copper IUD users in this study, clinical VVC or anemia cases were not increased, which indicates relative safety of this contraception method. The study findings can be helpful to healthcare professionals and midwives to counsel women who want to start using IUD and also current users who are contemplating IUD removal due to its complications.

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Introduction

Copper intrauterine devices (IUD) were first marketed in the early 1970s and represented an important contraceptive option for 150 million women worldwide. This is a safe, rapidly reversible, inexpensive, highly effective, long-acting, and non-hormonal method that has no interference with sexual intercourse [1]. It is considered to be one of the most effective methods with less than 1% failure rate and about 10 years effectiveness [2], which makes it unique and desirable for many users. However, menstrual blood loss and irregular bleeding are important and intolerable side effects that cause early removal of the device in up to 15% of users [2]. World Health

Organization (WHO) reported that menstrual blood loss is increased 20–50% after insertion of a copper-bearing IUD. It also can lead to iron deficiency anemia or exacerbate existing anemia [3], which is one of the most important medical indications for IUD removal [4]. A few studies have reported the presence of a link between the IUD use and Candida colonization that may lead to Vulvovaginal candidiasis (VVC) [5]. Chassot et al. (2008) stated that intrauterine contraceptive devices can be Candida Albicans reservoirs [6]. They confirmed that all parts of the IUD allow the adherence of yeasts. The adherence of C. Albicans to the different parts of IUD and formation of Biofilm are important attributes influencing the occurrence of VVC and recurrent VVC. However, anecdotal information accumulated from clinicians and some published information suggests that side effects of the copper IUD decrease over time [7]. For instance, a large study with 2700 copper IUD users in India showed that bleeding complaints by women decreased over time [8]. Similarly, Milsom et al. reported an increase in menstrual blood loss between 3 and 12 months post insertion

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of IUD remained largely unchanged [9]. By the way, existing anemia is not listed among contraindications of IUD insertion by WHO [3]. Iron deficiency anemia and VVC as prevalent concerns of Iranian women during reproductive age can affect sexual and health related quality of life [10–12]. Although IUD has been offered freely by the Iranian healthcare system, less than 6% of all contraceptive users have welcomed its use due to their concern about iron deficiency anemia and VVC [13]. It has also resulted in a high prevalence of IUD removal among the users [13].

In Iran as a developing country with a relatively high prevalence of anemia and VVC in women who have inserted IUD, 50% of users discontinue their contraceptive method in the first 6 months due to increased menstrual bleeding and switch it to a less effective method. In order to improve the women adherence to this contraceptive method, the aim of the present study was to determine the prevalence of anemia and VVC before and 3 months after IUD insertion.

Material and methods

Ethical approval for this study was obtained from the Ethics Committee of Tarbiat Modares University, Tehran, Iran, which corroborated its ethical considerations throughout the study process. The purpose of the study was explained to all participants, and informed consent was obtained from them. This study was a longitudinal prospective research performed with 101 women clients attending six health centers in Tehran, Iran during 9 months from November 2011 to August 2012. The sample size of the study was determined based on information obtained on alternation of hemoglobin and hematocrit levels from a pilot study of 30 women using IUDs. Considering 95% confidence, 80% power and an effect size of 0.3 and using the formulae of Pockock [14] the required sample size was calculated at least 90 cases and considering some loss during follow-up, 101 subjects were invited to enter the study.

The study participants were healthy women aged 15–45 years who wanted to use the IUD copper T 380 (manufactured by Pregna International Ltd., Mumbai, India). Women with absolute or relative contraindications for IUD insertion, medical treatments or intake of nutritional supplements (e.g., vitamins), prior removal of an IUD due to its complications such as severe anemia or clinical symptom of anemia [15] or VVC-related clinical symptoms including vaginal burning, itching, soreness, vaginal malodor or abnormal colored discharge, dyspareunia and pelvic pain [16] were excluded from the study.

All women were scheduled to two traditional visits: before and 3 months after copper IUD insertion. A baseline interview to collect data about socio-demographic status, reproductive history, history of sexually transmitted infections and abnormal vaginal symptoms was conducted. At the pre-insertion visit, a pelvic examination was performed, an unlubricated speculum was inserted and specimens from the vagina and endocervix were collected using dry cotton-tipped swabs for laboratory examination. The procedure was repeated at the second visit. For fungus culture, Sabouraud's dextrose agar-65 of the media (by Shimi-Azma Company, Tehran, Iran) was suspended in distilled water. It was mixed well until a uniform suspension was obtained. It was heated with frequent agitation and boiled and then sterilized at 118–121 °C for 15 min. To prepare a selective culture medium aseptically, Streptomycin was added for every milliliter of medium before use.

Also, colony counting was done according to Clinical and Laboratory Standards Institute [17].

In both visits, a whole blood sample was obtained from the cubital vein to determine hemoglobin and hematocrit levels. Blood samples were transferred to a single laboratory. Hemoglobin and hematocrit were measured by Sysmex K-21 cell counter and micro hematocrit centrifuge.

Table 1
Participant's demographics.

	Baseline
Age, mean ± SD	27.8 ± 6.1
Educational level, *n* (%)	
>High school	68 (67.3)
Diploma	31 (30.6)
College degree	2 (1.9)
Current main activity, *n* (%)	
Employed	1 (0.9)
Non-employed	100 (99)
BMI (kg/m2), mean ± SD	
>19.8	13 ± 12.8
19.8–26	49 ± 48.5
26–29	24 ± 23.7
>29	15 ± 14.8
History of IUD usage, *n* (%)	
Yes	32 (31.6)
No	69 (68.3)
Parity, *n* (%)	
Nulliparous	0
≥2	96 (95)
<2	5 (4.9)
Smoking, *n* (%)	
Never	71 (70.2)
Past	2 (1.9)
Current	3 (2.9)
Passive smoking[a]	25 (24.7)

[a] Passive smoking was defined as involuntary inhalation of smoke from cigarettes smoked by other people.

Laboratory diagnosis of anemia was according to the definition of WHO, as blood hemoglobin values of less than 12 g/dl in non pregnant women [18] and hemoglobin levels less than 10.5 g/dl were defined as severe anemia.

Statistical analysis

Data were analyzed using the SPSS software version 11.5 for Windows (SPSS, Inc., Chicago, IL). The results were expressed as mean (standard deviation). The normality of distribution of the data was evaluated and confirmed using Kolmogorov–Smirnov (K-S test). Comparisons between the data collected before and after IUD insertion were performed using paired samples *t* test, McNemar test and Wilcoxon signed-rank test. Regression models were used for adjusting potential confounders. Statistical significance was set at $P < 0.05$.

Results

A total of 101 women were recruited for the study. The demographic and baseline characteristics of the participants in the study are summarized in Table 1. The mean ± SD age of the participants were 27.8 ± 6.1 years. Comparisons between culture, colony count of Candida in cervicovaginal secretions, blood loss, HB and HCT are presented in Table 2.

Anemia evaluation

At the end of 3 months after IUD insertion, the women experienced a significant increase in the mean number of days of menstrual blood loss from 5.3 ± 3.4 to 6.6 ± 3.7 days ($P = 0.042$). The menstrual interval significantly decreased from 31.3 ± 5.4 to 28.7 ± 5.2 days ($P = 0.032$) as shown in Table 2. Also, intra-menstrual bleeding occurred in 16.8% of the participants. In this respect, there was a significant decrease of HB, and HCT levels at the end of 3 months ($P = 0.047$ and 0.001, respectively), but the prevalence of anemia did not differ before and after IUD insertion. There was no case with severe anemia after IUD insertion. From 7 participants who