

Comparison of two cohorts of women who expelled either a copper-intrauterine device or a levonorgestrel-releasing intrauterine system

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Abstract

Aim: To assess if there is a difference in the characteristics of the women who expelled a copper-intrauterine device (TCu-IUD) or the levonorgestrel-releasing intrauterine system (LNG-IUS) and the frequency of expulsions over different periods of observation.

Methods: We retrospectively analyzed 19 697 medical charts of women consulting between January 1980 and December 2013 who requested a TCu-IUD or a LNG-IUS.

Results: The medical records of 17 644 Cu-IUD and 2053 LNG-IUS users returning to the clinic for a follow-up visit after insertion of an IUC were reviewed. Of these, 1532 Cu-IUD and 254 LNG-IUS parous users were found to have expelled the IUC for a first time. The mean age at insertion (\pm standard deviation) was 26.3 ± 6.6 years (range 16–49) for Cu-IUD users and 31.7 ± 7.6 years (range 18–48) for LNG-IUS users ($P < 0.001$). A total of 263 (13.4%) and 12 (4.3%) of the Cu-IUD and the LNG-IUS users were ≤ 19 years old, and 49.1% and 54.1% of the expulsions among the Cu-IUD and LNG-IUS users, respectively, were reported in the first six months after placement. A regression model showed that the variables significantly associated with an expulsion of either a Cu-IUD or LNG-IUS were age < 25 years, less than two deliveries and using a Cu-IUD.

Conclusion: Our findings showed that the characteristics associated with IUC expulsion were age under 25 years, having had less than two deliveries and being users of Cu-IUD.

Key words: copper IUD, expulsion, Intrauterine device, levonorgestrel-releasing intrauterine system.

Introduction

Intrauterine contraceptives (IUCs) include the copper intrauterine device (Cu-IUD) and the levonorgestrel-releasing intrauterine system (LNG-IUS). These contraceptive methods belong to a family of long-acting reversible contraceptives (LARCs), which are among the methods with the highest contraceptive effectiveness.^{1–3} The Cu-IUD is the most frequently used reversible contraceptive method worldwide.^{4–6}

Device-related complications, such as expulsion and uterine perforation, occur to a similar extent with the

Cu-IUD and the LNG-IUS.⁷ Proper insertion is the key to preventing complications that include bleeding, pain, expulsion and perforation. Approximately one in every 20 women fitted with an IUC expels the device, with expulsion being most common in the first three months after insertion, often during menstruation.⁸

Higher rates of IUC expulsion have been reported to be associated with previous expulsion of a device, young age and nulliparity.^{9–13} Nevertheless, there is some confusion in the scientific literature regarding the terms *nulligravida* and *nulliparous*, which were considered the same, although the first term refers to women who were

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never pregnant and the second to those who were pregnant and had an abortion.^{14–16} In a systematic review in which the authors assessed 20 studies conducted with nulliparous women, users of the Cu-IUD presented more expulsions in 13 out of 20 studies.⁴ Nevertheless, this is a controversial issue, as later studies have found no difference in the expulsion rate between nulligravidas and parous women fitted with a Cu-IUD or a LNG-IUS.^{14,17}

Furthermore, no association was found between number of children, mode of delivery and education level and the occurrence of spontaneous expulsions.^{13,18} However, most previous studies evaluated a limited number of women, with sample sizes generally consisting of no more than 500 IUC expulsion events.^{10,14,18} Consequently, with the objective of adding to the available data on IUC expulsion, this study was designed to assess if there is a difference in the characteristics of women who had a complete or partial expulsion of a TCu-IUD or LNG-IUS, the frequency of expulsions over different time periods of observation and what factors contributed to the expulsion of both IUCs.

Methods

This was a retrospective study carried out at the Human Reproduction Unit, Department of Obstetrics and Gynaecology, School of Medical Sciences, University of Campinas (UNICAMP), Campinas, São Paulo, Brazil. The Ethical Committee approved the study; however, informed consent was deemed unnecessary, as the study consisted of a review of medical records and the data were retrieved without identifying the women. Records of nulligravidas and parous women who had expelled an IUC for a first time (TCu380A Cu-IUD or an LNG-IUS) consulting between January 1980 and December 2013 from a database which was de-identified, used in a previously published study, and stored at the clinic, were identified and the characteristics of these women were evaluated.³ All of the IUCs were inserted within the first five days of the menstrual cycle. As routine practice at the clinic, women were excluded if they presented abnormal uterine bleeding without diagnosis, purulent cervicitis and abnormal endometrial cavity resulting from fibromas or malformation. Complete expulsion was defined when the IUC was not found in the uterine cavity and partial when the IUC was found on the cervical canal. We excluded all women who had had a new IUC inserted following expulsion and those who received a LNG-IUS for therapeutical purpose.

Nulligravidas were also excluded because they were only 65 women, representing 3.5% of the total sample. Because our center is located at a teaching university hospital, many of the IUC placements were performed by personnel in training and with less clinical experience.

Statistical Analysis

We estimated the power of our sample to show significant differences. For a power of 80%, 123 women in each group of users were necessary. Sociodemographic characteristics and the variables associated with an expulsion were presented as means and standard deviation (SD) for the continuous variables. The two IUCs were compared using the Mann–Whitney nonparametric test. In addition, the duration of use until expulsion was analyzed for both methods and the methods were compared using Pearson's χ^2 test. The Wilcoxon–Gehan test was used to compare the expulsions for the two IUCs (overall and every 6 months up to 60 months of use). Finally, a Cox multivariate regression analysis was performed for 10 possible covariables associated with the time until expulsion and according to the device used (the Cu-IUD or the LNG-IUS) with a statistical 'forward' selection of Wald with only variables of $P = 0.05$. The model included the time (months) between insertion and expulsion as a dependent variable. The independent variables were: use of Cu-IUD versus LNG-IUS; age (<25 vs ≥ 25 years old); previous pregnancies (1 vs ≥ 2); parity (≤ 1 vs ≥ 2); abortion (0 vs ≥ 1); living children (≤ 1 vs ≥ 2); cesarean section (0 vs ≥ 1); previous use of combined oral contraceptive (Yes/No); previous use of condom (Yes/No); and previous use of IUC (Yes/No). SPSS version 20 was used throughout the statistical analysis. Significance was established at $P < 0.05$.

Results

We reviewed the medical records of 17 644 Cu-IUD (TCu380A) users and 2053 LNG-IUS users who returned to the clinic for a follow-up visit after the insertion of an IUC. From these charts, 1532 TCu-IUD and 254 LNG-IUS users with an IUC expulsion after the first insertion were identified. The mean age of Cu-IUD users was significantly lower than LNG-IUS users (26.3 ± 6.6 vs 31.7 ± 7.6 years; $P < 0.001$) and the Cu-IUD users also had significantly fewer years of schooling and had had fewer cesarean sections compared with the LNG-IUS users (both $P < 0.001$; Table 1).

Table 1 Demographic characteristic of women who experienced expulsion of IUCs

Variable	Cu-IUD (<i>n</i> = 1532)	LNG-IUS (<i>n</i> = 254)	<i>P</i> value*
Age (years)	26.3 ± 6.6	31.7 ± 7.6	<0.001
Schooling (years)†	7.5 ± 3.3	10.4 ± 3.4	<0.001
Number of gravidity	2.0 ± 1.1	2.1 ± 1.1	0.034
Number of deliveries	1.7 ± 0.9	1.8 ± 1.0	0.079
Number of c-section	0.7 ± 0.8	0.9 ± 0.9	<0.001
Number of living children	1.7 ± 0.9	1.8 ± 0.9	0.135
Number of abortions	0.3 ± 0.1	0.2 ± 0.1	0.639

*Mann–Whitney' nonparametric test. †Missing information for one user of Cu-IUD. All values are mean ± standard deviation. Cu-IUD, copper intrauterine device; IUC, intrauterine contraceptive; LNG-IUS, levonorgestrel-releasing intrauterine system.

The number of women who had an IUC inserted in each period of evaluation and the number of expulsions registered during the same period is shown in Table 2. We identified that 49.1% and 54.1% of expulsions among the Cu-IUD and LNG-IUS users, respectively, occurred in the first six months after placement and 60.9% and 68.9% in the first 12 months after insertion, respectively. However, we found that expulsions occurred as long as

60 months or even later after insertion of a Cu-IUD (Table 3).

Expulsions were significantly higher for users of the LNG-IUS overall ($P < 0.001$), especially during the first two years of use. However, in the Cox multivariate regression analysis of the variables associated with the cumulative expulsion rate of the IUC, when prior use of both combined oral contraceptives and IUC, and the

Table 2 The relationship between the number of IUC insertions with different follow-up periods and number of expulsions

Years of insertion	Cu-IUD		LNG-IUS	
	Inserted at the period (<i>n</i> = 17 644)	Expulsed (<i>n</i> = 1532)	Inserted at the period (<i>n</i> = 2053)	Expulsed (<i>n</i> = 254)
1980–1984	479	26	24	10
1985–1989	1222	42	46	15
1990–1994	3060	172	29	17
1995–1999	5369	475	138	25
2000–2004	3938	416	118	14
2005–2009	2964	331	1052	63
2010–2012	612	70	646	110

Cu-IUD, copper intrauterine device; IUC, intrauterine contraceptive; LNG-IUS, levonorgestrel-releasing intrauterine system.

Table 3 Timing of IUC expulsion among women who experienced one expulsion

Month at expulsion (%)	Cu-IUD (<i>n</i> = 1532) †	LNG-IUS (<i>n</i> = 254) †	<i>P</i> value*
Within 1 month	63 (4.1)	15 (5.9)	<0.001
1 to 6	690 (45.0)	123 (48.4)	
7 to 12	180 (11.8)	37 (14.6)	
13 to 18	121 (7.9)	21 (8.3)	
19 to 24	67 (4.4)	17 (6.7)	
25 to 30	124 (8.1)	18 (7.1)	
31 to 36	61 (4.0)	5 (2.0)	
37 to 42	30 (1.9)	2 (0.8)	
43 to 48	29 (1.9)	6 (2.4)	
49 to 54	27 (1.8)	2 (0.8)	
54 to 60	32 (2.1)	8 (3.1)	
61 or more	108 (7.0)	—	

*Pearson χ^2 test; †percentage of women experiencing expulsion. Cu-IUD, copper intrauterine device; IUC, intrauterine contraceptive; LNG-IUS, levonorgestrel-releasing intrauterine system.

type of IUC was taken into account, the variables significantly and directly associated with an expulsion were age < 25 years, less than two vaginal deliveries (for both models of IUC evaluated) and having used a Cu-IUD (Table 4).

Discussion

Our study identified through bivariate analysis that when we compared the Cu-IUD with the LNG-IUS the women who used the LNG-IUS were more likely to expel the device, but only up to two years of use. However, after the logistic model the only variables directly associated with an expulsion of either a Cu-IUD or the LNG-IUS were age < 25 years, having had less than two deliveries and using a Cu-IUD.

Although there is information regarding IUC expulsion in the scientific literature, there is limited evidence about the causes associated with spontaneous IUC expulsion. Expulsion rates range from 2% to 10% in the different studies and also differ according to the type of IUC used. The factors that have been commonly associated with expulsion were adolescence, nulligravidas, dysmenorrhea, heavy menstrual bleeding (HMB) and insertion performed immediately following an abortion or delivery.^{4,14,19,20} Our results are consistent with those found in previous studies, which show that women younger than 20 years of age and those with less than two children are more likely to expel the device.^{20,21} However, a systematic review showed that the relationship between IUC expulsion and parity was weak and inconsistent.²²

Furthermore, it has been reported that the IUC expulsion rate was significantly lower in nulliparous women compared with parous women; however,

significantly higher in adolescents versus older women, regardless of parity or IUD type, and also higher among users of Cu-IUD when compared with those using a LNG-IUS.¹⁴

The initial finding from our study that expulsion was significantly more likely in LNG-IUS users contradicts the results reported by Madden *et al.*, but is in agreement with Sivin *et al.*^{14,19} It is reasonable to speculate that at the time of our study the healthcare professionals (HCPs) were unfamiliar with this new device compared to their experience with the Cu-IUD, thus explaining the greater number of expulsions. In the present study, as in a previous study, the HCPs were more familiar with the T-shaped Cu-IUD than with the LNG-IUS.¹⁹ In addition, because the present study was conducted in a teaching hospital, interns, residents in Obstetrics and Gynaecology and Family Medicine and fellows from other hospitals constantly undergo training in IUC placement, which can increase the expulsion rate. Unfortunately, data were not available in every case on the experience of the individual who inserted the IUC.

Furthermore, there has been a shift over the past five years in women attending the clinic and requesting an IUC to opt for an LNG-IUS rather than the Cu-IUD, a trend that has also been reported in other settings.²³ Our initial result of a higher expulsion rate observed with the LNG-IUS when compared with the Cu-IUD and the fact that almost half of the expulsions occurred during the first year of use could be attributed to the LNG-IUS being a treatment to control HMB and dysmenorrhea.²⁴ Consequently, it is possible that insertions during a HMB episode and cramping (especially in the first months of use) or non-diagnosed fibroids may be responsible for the initial higher expulsion rates observed with the LNG-IUS.^{25,26}

Table 4 Cox proportional hazards regression model for the variables associated with the cumulative expulsion rate of IUCs

Model/Variable	Coefficient	SE (coefficient)	P value
Model 1: [n = 1666]			
Number of deliveries (≥ 2)	-0.176	0.052	<0.002
Use of the LNG-IUS	-0.176	0.052	<0.002
Model 2: Only users of the Cu-IUD [n = 1467]			
Number of deliveries (≥ 2)	-0.160	0.058	0.006
Age (<25 years old)	-0.009	0.004	0.042
Model 3: Only users of the LNG-IUS [n = 248]			
Age (< 25 years old)	0.026	0.010	0.013

Dependent variable: Time between insertion and expulsion (months). Independent variables: [Model 1] copper-intrauterine device (Cu-IUD)/levonorgestrel intrauterine system (LNG-IUS); age (years; <25 vs ≥ 25); previous pregnancies (1 vs ≥ 2); parity (≤ 1 vs ≥ 2); abortion (0 vs ≥ 1); living children (≤ 1 vs ≥ 2); cesarean section (0 vs ≥ 1); previous use of combined oral contraceptive (Yes/No); previous use of condom (Yes/No); previous use of intrauterine contraceptive (IUC) (Yes/No); [Model 2 and 3] Cu-IUD/LNG-IUS; age (years; <25 vs ≥ 25); previous pregnancies (≤ 1 vs ≥ 2); parity (≤ 1 vs ≥ 2); abortion (0 vs ≥ 1); living children (≤ 1 vs ≥ 2); cesarean section (0 vs ≥ 1).

The results showed that almost 50% of the expulsions occurred in the first 12 months after insertion; one explanation for this could be that IUCs were inserted in a low position. There is evidence that in users of T-shaped IUDs who received the device in a low position, the IUD tends to move upward after insertion.²⁷ Additionally, previous studies have shown that growth and thinning of the endometrium, assessed by ultrasound, influenced the T-shaped IUD position in the uterine cavity and that during the first three months of IUD use the device accommodates in the uterine cavity.^{7,28,29}

As in other reports, the main limitation of the present study is the retrospective design, which does not allow estimation of the actual rate of IUC expulsions, as the figures presented represent the total number of expulsions and not a cumulative expulsion rate year by year.^{10,18} We could have underestimated the true rate of expulsion because women who received an IUC at the clinic and never returned to a control visit could have expelled the device and sought care elsewhere. Furthermore, there were a small number of adolescents in the study; therefore, it is not possible to evaluate whether this characteristic is a variable associated with expulsion. Nevertheless, age < 25 years was found to be associated with expulsion of both the Cu-IUD and LNG-IUS.

The strengths of this study are related to the large number of expulsions evaluated and the fact that we included the T-shaped Cu-IUD and the LNG-IUS. Additionally, an expulsion was considered only when complete or partial expulsion occurred and not when in a routine ultrasound exam an HCP considered that an IUC was positioned low in the uterine cavity. Another strength was the careful data collection and analysis process.³

Although the women receiving care at the clinic were socioeconomically and ethnically diverse, it may not be possible to extrapolate the present findings to other populations, because the data were collected at a single center. Notwithstanding, this study provides HCPs with additional information about the variables associated with IUC expulsions. More studies are needed with a large sample size, mainly with nulligravidas and adolescents to assess the rate of expulsion of both the Cu-IUD and the LNG-IUS in these two particular populations.

In conclusion, the factors contributing to the expulsion of both IUCs were age < 25 years and having had less than two deliveries. Cu-IUD users are more prone to expulsion. The frequency of expulsion was higher within the first year after insertion.

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Disclosure

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