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The use of a menstrual cup as a risk factor for displacement of intrauterine devices: a case-control study

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Abstract

Background Menstrual cups (MC) are being increasingly used for menstruation management as an alternative to tampons and sanitary pads. Intrauterine devices (IUD) are commonly and increasingly used for birth control. Displacement of an IUD from the uterine fundus can reduce its efficiency, potentially leading to unwanted pregnancies. Recently, concerns have been raised regarding a possible increase in the risk of IUD displacement, associated to the use of MC. This study measures the association between MC use and IUD displacement, taking into account the already known risk factors of IUD displacement.

Methods and findings Women consulting for follow-up of an IUD in two primary care facilities in Paris were enrolled in the study between March 2020 and May 2021. IUD position was assessed by transvaginal ultrasound. Use of MC and exposition to known risk factors for IUD displacement were assessed by a standardized investigator-administered questionnaire. Frequency of MC use was compared between patients with well-positioned IUD and patients with displaced IUD. A linear regression model looked for an independent association between MC use and IUD displacement, with respect to known risk factors for IUD displacement. 747 patients were included, out of which 6.8% had a displaced IUD. MC use was reported by 17.0% of patients with a well-positioned IUD versus. 41.2% of patients with a displaced IUD. After adjustment for known risk factors of IUD displacement, MC use appeared to be significantly and independently associated with IUD displacement (aOR [95CI]: 3.09 [1.56–6.05]).

Conclusions The use of a menstrual cup seems to be an independent risk factor for intrauterine device displacement. Clinical trial registration: NCT04782583.

Keywords Intrauterine device, General practice, Menstrual cup, Transvaginal ultrasound, Case-control study

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Introduction

In France, about 26% of contracepting women had chosen intrauterine devices (IUD) as a birth control method, and since the contraceptive pill crisis, more and more young nulliparous women choose IUD as a birth control method [1]. This crisis built upon earlier debates from 2012 to 2013 when several lawsuits against pharmaceutical companies highlighted risks of venous thromboembolism associated with newer-generation pills and lead to many women seeking alternative contraceptive methods [2]. Contraceptive failures with IUDs are mainly related to displacement or expulsion [3]. Young age (<25 years) [3–6], menorrhagia, dysmenorrhoea [3, 7, 8], use of a copper IUD rather than a levonorgestrel releasing one [6, 9, 10], history of IUD expulsion or uterine abnormality (fibroid, adenomyosis) [3, 7, 11–13], obesity, and higher parity have been identified as risk factors for IUD displacement or expulsion [14-19]. There is no consensus in the literature regarding other potential risk factors such IUD insertion within 6 weeks of an abortion [5, 20-22].

Menstrual cups (MC) are being increasingly used worldwide as an alternative to tampons and sanitary pads and are a safe option for menstruation management, especially in younger generations of women [23]. Recently, concerns have been raised regarding possible IUD displacement linked to MC use [24-26]. A metaanalysis published in 2019 pointed out dislodgement of IUD in 13 women who used MC (8 in case reports, and 5 in a study) within 1 week to 13 months after insertion of the IUD [24, 25]. A possible mechanism underlying MC-induced IUD displacement would be a suction effect when removing the MC, another mechanism is that strings are pulled [25]. To date, only 3 studies were published addressing the risk of IUD displacement associated to MC use. A 2012 Canadian retrospective chart survey on 743 women reported that IUD displacement rate was not different between women using tampons, pads or MC [27]. A 2018 French cohort study identified an association between declared IUD expulsion and MC use, the risk being higher for MC use inferior to 3 menstrual cycles [28, 29]. A 2019 American Internet-based survey identified positive association between MC use and IUD expulsion (OR: 2.75, 95% CI: 1.40–5.42, *p*=0.002) [28, 29]. None of these studies adjusted for risk factors. Moreover, focus was on IUD expulsion but intrauterine displacement of the IUD, which is associated to a loss in contraceptive efficiency, was not addressed.

The objective of the present study was to measure the association between IUD displacement (as diagnosed by ultrasound measure of IUD position) and MC use in patients consulting for IUD follow-up. The study was designed to consider potential risk factors.

Methods

Study and patients

From March 2020 to May 2021, we conducted a casecontrol study (IUD in adequate position vs. displaced) tracing MC exposure since IUD insertion. Participation in the study was systematically offered to women who consulted for systematic follow-up of their IUD, or pain/symptoms related to IUD, pregnancy on IUD or IUD expulsion in two primary care medical facilities in Paris. General practitioners and midwives recruited the patients. Patients with abnormal uterine cavity such as a fibroid or adenomyosis and patients with pregnancy on displaced IUD were excluded.

Data collection

IUD position was assessed by standard, 2D, transvaginal ultrasound (TVU) for all patients except for the one reporting an IUD expulsion. There is no specific recommendation on the ultrasound criteria for a well-positioned IUD. In this context, results were classified as "IUD in adequate position in the uterine cavity" (including pregnancy on an IUD seemingly in proper position i.e. non-cervically displaced) versus "IUD in a non-adequate position" (including expelled IUD and IUD in the lower uterine segment or cervix).

Data were collected by the investigators, by interviewing the patient, regarding known and potential risk factors of IUD displacement: age, parity, past pregnancies, BMI, type of IUD, menorrhagia, dysmenorrhea, history of IUD expulsion and surgical abortion within 6 weeks before IUD insertion.

MC use and exposure was collected using a standardized investigator-administered questionnaire. The use of MC was defined by the answer "yes" to the question: "Has the patient used a MC since IUD insertion?". To describe the different uses of MC that women could have, its utilization was classified as "always" (no use of other menstrual protection than the cup), "almost daily" (almost every day of menstruation but can occasionally have used other protections), "regularly" (at least 1 day/cycle or not every cycle but several days), "occasionally" (e.g.: for an activity), "anecdotally" (e.g.: try once) or "never". The type of use could vary with time, so women could describe their type of use for several periods of time. For each period of time, the type of use, the number of cycles, and the approximate number of MC withdrawal per cycle were collected. An exposure score was calculated by multiplying the number of cycles since the IUD insertion by the type of exposure for each MC period of use, semiquantitatively estimated as follows: "Always" worth 5 pts, "almost daily" 4 pts, "regularly" 3 pts, "occasionally" 2 pts, "anecdotally" 1 pts and "never" 0 pts. All periods scores were summed up to get a final score.

Statistics

Assuming an IUD displacement of 15% among MC users and 5% among non-users and, a MC use by at least 10% of women, the required sample size was estimated at 740 to obtain a power of 80% and an alpha risk of 5%. Statistical analyses were performed by the Clinical Research Department of the Adolphe de Rothschild Foundation. Wilcoxon tests and Chi2 tests (or Fisher exact tests) were used for univariate comparisons of continuous parameters and qualitative parameters, respectively. Univariate logistic regressions were performed to assess the association between IUD position (adequate or not) and the other variables. For multivariate analysis, regression was adjusted for factors selected with a stepwise variable selection. Odds Ratios were calculated with a 95% confidence interval. Analysis was performed on available data. All statistical analyses were performed using R software version 4.0.3. (www.r-project.org).

Results

IUD follow-up consultations flow-chart

Data from 769 consultations were collected for this study (Fig. 1). Among them, 38 were not included in the analysis: 13 because of abnormal uterine cavity, 3 for pregnancy on displaced IUD, 2 for absence of TVU realisation, 1 for missing data regarding US result, 1 for presence of two IUDs in the uterine cavity, 2 for missing data regarding MC use and 16 for consultations checking for the same IUD and for which only data of the most recent

consultation were kept for the analysis. Thus, the analysis included 731 IUD follow-up consultations.

Characteristics of the study population

Table 1 provides the main characteristics of the study population. Median age was 27 years old, nulliparity was reported in 89.9% of the cases and never having been pregnant in 81.4%. Copper IUDs were in the vast majority in our population (76.6%). The most frequent copper IUD was the UT 380° Short (Mona Lisa NT Cu 380 mini, CCD UT 380 short, 7 MED USHA, EUROMEDIAL 380 CU mini, GYNEAS T 380 CU Plus mini): (93% of copper IUDs). Hormonal IUDs were Kyleena° (levonorgestrel 19,5 mg) for 47%, Jaydess° (levonorgestrel 13,5 mg) for 43% and Mirena° (levonorgestrel 52 mg) for 9%. The median time since IUD insertion was 7.7 months, with a wide range of situations as the minimum was 6 days and the maximum 5 years and 8 months.

On the 731 consultations, 18.6% of women had used a MC. Women using a MC had been using their IUD for a longer time (median of 15.4 months vs. 5.5 months for women not using a MC, p < 0.001), were more likely to have never been pregnant (88.2% vs. 79.8%, p = 0.023), were more often using a copper IUD (94.1% vs. 72.6%, p < 0.001) and were more likely to report heavy menstrual bleeding since IUD insertion (47% vs. 35.7%, p = 0.016).

IUD position in the uterus cavity on TVU was adequate in 93.6% of cases. Adequate position without pregnancy (n = 680, 93%) was the most common but 4 (0.5%)

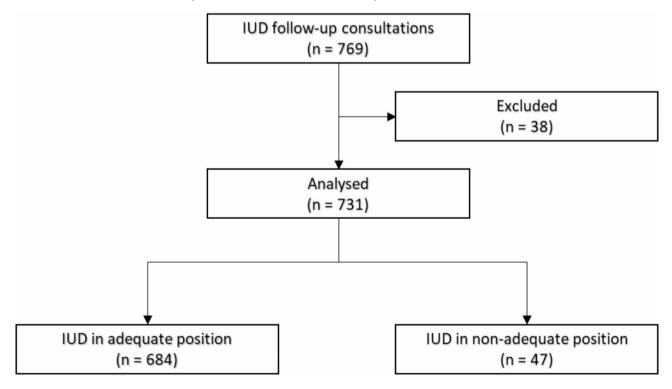


Fig. 1 IUD follow-up consultations inclusion flowchart

Table 1 Characteristics of the study population

Median (IQR) or N (%)	Total sample (N=731)	Use of MC (<i>N</i> = 136)	No use of MC (<i>N</i> =595)	<i>p</i> value
Age (years)	27 (25–29)	27 (25–30)	27 (25–29)	0.108
BMI (kg/m²)	21.3 (19.8–23.4)	21.3 [20.0-23.3]	21.2 [19.7–23.4]	0.915
NA	6	0	6	
Nulliparity	657 (89.9%)	124 (91.2%)	533 (89.6%)	0.578
Never been pregnant	595 (81.4%)	120 (88.2%)	475 (79.8%)	0.023
Surgical abortion within 6 weeks of IUD insertion	26 (3.6%)	5 (3.7%)	21 (3.5%)	0.933
History of IUD expulsion	56 (7.7%)	15 (11.0%)	41 (6.9%)	0.102
IUD type :				
Hormonal	171 (23.4%)	8 (5.9%)	163 (27.4%)	< 0.001
Copper	560 (76.6%)	128 (94.1%)	432 (72.6%)	
Time since IUD insertion (months)	7.7 (2.6–23.5)	15.4 (4.2–29.8)	5.2 (2.5-20.9)	< 0.001
Dysmenorrhea since IUD insertion	254 (34.9%)	51 (37.5%)	203 (34.3%)	0.479
NA	3	0	3	
Heavy menstruation since IUD insertion:	270 (37.8%)	62 (47.0%)	208 (35.7%)	0.016

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16

NA

 Table 2
 IUD displacement and associated risk factors

Median (IQR) or <i>N</i> (%)	Adequate IUD position (<i>N</i> = 684)	Non-adequate IUD position (N=47)	Crude OR [95CI]	Adjusted* OR [95Cl] (<i>N</i> =709)
Age (years)	27 (25–29)	27 (25-29.5)	0.99 [0.92–1.06]	-
BMI (kg/m ²)	21.3 (19.8–23.4)	21.3 (19.9–23.7)	1.06 [0.97–1.14]	1.06 [0.96–1.16]
NA	6	0		-
Nulliparity	614 (89.8%)	43 (91.5%)	1.23 [0.48-4.16]	2.14 [0.70–9.40]
Never been pregnant	556 (81.3%)	39 (83%)	1.12 [0.54–2.64]	-
Surgical abortion within 6 weeks of IUD insertion	26 (3.8%)	0 (0%)	-	-
History of IUD expulsion	42 (6.1%)	14 (29.8%)	6.48 [3.15–12.86]	6.57 [3.01–14.00]
IUD type:				
Copper	516 (75.4%)	44 (93.6%)	4.78 [1.72–19.87]	3.06 [1.00–13.29]
Hormonal	168 (24.6%)	3 (6.4%)		
Time since IUD insertion (months)	7,7 (2,6–23,6)	7.3 (2,7–17)	0.98 [0.96–1.01]	0.97 [0.94–0.99]
Dysmenorrhea since IUD insertion	235 (34.5%)	19 (40.4%)	1.29 [0.69–2.34]	1.27 [0.63–2.50]
NA	3	0		
Heavy menstruations since IUD insertion	248 (37%)	22 (48.9%)	1.63 [0.88–2.99]	0.98 [0.49–1.95]
NA	14	2		
Use of a MC since IUD insertion	117 (17.1%)	19 (40.4%)	3.29 [1.75–6.05]	3.13 [1.55–6.25]

MC: menstrual cup; IUD: Intrauterine device; BMI: Body mass index

* Variables not mentioned for adjusted OR were not included in the model after stepwise variable selection

pregnancies with IUD in seemingly proper position i.e. non-cervically displaced were observed. We noted 37 (5%) displaced IUD including 4 with pregnancies. IUD expulsion accounted for 13 cases (1.8%).

Impact of menstrual cup use on IUD displacement

The proportion of MC use in the adequate IUD position group was 17.1% compared to 40.4% in the non-adequate IUD position group (p < 0.001) which corresponds to a proportion of displaced IUDs of 4.7% in patients not using MC and of 13.9% in patients using it (p < 0.001). After adjustment, the use of MC appeared independently associated with IUD displacement (aOR [95CI] = 3.13 [1.55–6.25]). Among other risk factors, only previous IUD expulsion was independently associated with IUD displacement (aOR [95CI] = 6.57 [3.01–14.00]). Details are presented in Table 2. Regarding IUD expulsion, it was up to 5.9% in MC users and 0.5% in non-users (p < 0.01).

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The type of IUD being associated to IUD displacement and MC use, and copper IUDs representing the vast majority (>75%) in our population, subgroup analyses were made regarding the type of IUD. In the copper IUD group, the association between MC use and IUD displacement was still significant (aOR [95CI] = 3.20

Median (IQR) or <i>N</i> (%)	MC use sample (N=136)	Adequate IUD position (N=117)	Non-adequate IUD position (N=19)	Crude OR [95Cl]
Estimated number of menstrual cycles with MC use	8.5 (2–19)	9 (2-21.5)	3 (1.5–15.5)	0.96 [0.91–1.01]
NA	14	14	0	
Estimated number of MC withdrawals since IUD insertion	49 (11.2-160.5)	50 (15–156)	32 (1-180)	1.00 [1.00-1.00]
NA	62	56	6	
Type of MC:				
With stem	115 (84%)	99 (85%)	16 (84%)	ref
Without stem	16(12%)	13 (11%)	3 (16%)	1.43 [0.30–5.06]
Unkown	5 (4%)	5 (4%)	0 (0%)	-
Break of the MC suction before removal	115 (85%)	99 (85%)	16 (84%)	0.97 [0.29–4.47]
MC as main menstrual protection	94 (72%)	78 (70%)	16 (84%)	2.26 [0.69–10.16]
NA	6	6	0	
MC exposition score	35 (6.5–76.5)	35 (7–75)	15 (7-67.5)	0.99 [0.98-1.00]
NA	14	14	0	

Table 3 Details of MC utilisation

MC: menstrual cup; IUD: Intrauterine device

[1.57–6.44]), but it was not in the hormonal IUD group (OR could not be calculated as only 3 hormonal IUDs were in non-adequate position, none of them in women using MC).

Description of MC utilisation and association with IUD displacement

In 136 consultations, patients declared having used MC at least once since IUD insertion (details can be found in Table 3). Among them, regarding the last period of utilisation, 56 (43%) used it always, 38 (29%) used it almost daily, 16 (12%) used it regularly, 3 (2%) used it occasionally and 17 (13%) had used it anecdotally. We can consider that 94 (72%) were using the MC as main menstrual protection (always or almost daily). Regarding the evolution of MC utilisation, the great majority of patients (N=115, 85%) reported that they had not changed their frequency of use of MC since they started using it (= one period of use).

Among MC users 117 (86%) had an IUD in adequate position and 19 (14%) a displaced IUD.

Removing suction before withdrawal, MC exposition score or estimated number of withdrawal were not significantly associated to IUD displacement in univariate analysis (Table 3).

Discussion

We conducted a case-control study enrolling 731 IUD follow-up consultations, addressing IUD displacement with respect to MC use and other known or suspected displacement factors. We found that the use of MC appears to be an independent risk factor for IUD displacement (aOR 3.13). However, this conclusion can only be drawn for the patients with copper IUD, representing the vast majority of our population. In the MC users,

neither the level of exposure to MC since IUD insertion (combining frequency and length of use) the number of MC withdrawals since IUD insertion, nor the fact that the patient broke the MC suction or not before removal, appeared to be predictive of IUD displacement. The lack of significance of the latter results is probably related to a lack of power, the number of women using MC in our population being small (only 11 women in the displaced IUD group).

Our study was limited by a memory bias as the patients had to remember how they had been using the MC since IUD insertion. Another limitation is the way the questionnaire was completed regarding MC use. Indeed, the questionnaire was not filled by the patient herself but by the practitioner who interviewed her. This method may have influenced the patients' answers, especially those concerning the proper use of MC. It is recommended in France for all women with IUD to have an annual followup or in case of experiencing any symptoms so we hope to have a limited selection bias.

Our young and urban population of patients, mainly nulliparous and with copper IUDs might not be representative of how MC can be used in other populations. Regarding the high proportion of nulliparous women in pour IUD population, the more recent French data on IUD use are from 2016, yet at that time IUD use in 25–29 years old had increased since 2010 from 6.9–19% [1]. It is likely that this increase has been maintained since 2016, as more and more gynaecologists are agreeing to insert IUDs in nulliparous women, as the discourse of health professionals has changed, particularly in connection with the crisis of the contraceptive pill, which has led to a shift in use to other contraceptive methods.

Our results corroborate those of the D-COUPE study [28] conducted on 207 patients, which found a

displacement 4 times more frequent in MC users than in non-users, as well as the results of a survey of 638 responses [29] showing a 2.75-fold increase in the risk of IUD displacement in patients using MC. However, our results differ from those of Wiebe et al., investigating 743 women, in whom the risk of IUD displacement did not differ with respect to their menstrual protections. This study did not adjust the results for other IUD displacement risk factors and the lack of homogeneity between the groups compared, especially in terms of age, was described as a major limitation of the study by the authors [27]. However, a literature review in 2023 on 7 studies concluded that there is a possible association between menstrual cup use despite scarce evidence [30].

We chose to assess IUD displacements and not only expulsions, as the majority of our patients were using copper IUDs. Indeed, literature data do not show a significant difference between patients with a hormonal IUD in place or not for the risk of pregnancy. However, there is a significant difference in the risk of pregnancy in patients with a copper-bearing IUD [26, 31, 32].

There is no specific recommendation on the ultrasound criteria for a well-positioned IUD and this subject is controversial. Some studies use the IUD - uterine fundus distance (from 4 to 30 mm) [11, 33–36], others the IUD - endometrium distance (from 5 to 10 mm) [9, 35-39], rarer studies suggest that the IUD - myometrium distance(<10 mm) is more reliable than the IUD - endometrium distance because the endometrium thickness varies according to the cycle [34, 36, 38], and finally, many studies do not use a measurement criterion but note whether the IUD is in place, in the lower part of the uterus, partially or entirely in the cervix [6, 12, 18, 33, 40]. Regarding the lack of recommendations and consistency among studies, we decided to use the latter method and that each investigator would judge the proper position of the IUD as in his usual practice.

Conclusion

Our results show that regardless of other known risk factors for displacement, MC use was an independent risk factor for IUD displacement. Clinicians should be aware of this risk to offer patients the opportunity to choose the most appropriate menstrual protection when using an IUD. The mechanisms behind MC-induced IUD displacement remains to be explored. Further studies will be needed to determine whether it is indeed related to a suction effect and whether this effect could be reversed by therapeutic education sessions on MC use.

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Author contributions

JC, SM, AY, CC, HP contributed to the conception and the design of the work. JC, ID and RL contributed to the acquisition of the data. HP, CC, SM contributed to the analysis and interpretation of data. HP, JC and RL wrote the manuscript text. All authors reviewed the manuscript. All authors contributed equally to the work.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethical approval and consent to participate

All participants signed an informed consent for study participation. The study obtained approval from the "Comité de Protection des Personnes Sud Méditerranée V" in February 2020 (IDRCB: 2019-A02870-57).

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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