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Factors associated with low-lying intrauterine devices: a crosssectional ultrasound study in a cohort of African-American women

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Abstract

Objective: The object of this study is to examine factors and symptoms associated with low-lying IUDs as defined by ultrasound.

Study Design: This is a cross-sectional sub-study of participants in the Study of Environment, Life-style, and Fibroids (SELF). SELF participants had screening ultrasounds for fibroids at study enrollment; those with an IUD in place are included in this sub-study. Low-lying IUDs were identified and localized. Logistic regression was used to identify factors and symptoms associated with low-lying IUDs.

Results: Among 168 women with IUDs at ultrasound, 28 (17%) had a low-lying IUD. Having a low-lying IUD was associated with low education level (high school: aOR 3.1 95% CI 1.14-8.55) and with increased BMI (p=0.002). Women with a low-lying IUD were more likely to report a "big problem" with dysmenorrhea (the highest option of the Likert scale) as compared to women with a normally-positioned IUD (OR 3.2 95% CI 1.07-9.54).

Conclusion: Our study found that women with a low-lying IUD are more likely to be of lower education and higher BMI, and to report more dysmenorrhea.

Conflict of interest

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All authors declare no conflict of interest.

Implications: Women who are obese may benefit from additional counseling and closer followup after IUD placement. Future research is warranted to investigate IUD placement and possible IUD migration among women who are obese.

Keywords

Intrauterine contraception device; Low-lying; malposition; dysmenorrhea; obesity; expulsion

1. Introduction

The use of long acting reversible contraception (LARC) has steadily risen from 8.5% in 2009 to 11.6% in 2012 in the U.S.; this has been largely due to the increasing popularity of the intrauterine device (IUD) [1, 2]. IUDs provide highly effective contraception, and levonorgestrel IUDs also treat heavy menstrual bleeding [3-5]. However, some women will experience IUD expulsion or IUD displacement [6-9] even if the IUD was positioned appropriately in the fundus at the time of insertion [10]. There have been prior studies on risk factors for IUD malposition [7, 9, 11-17]. However, the types of malposition varied; they included expulsions, low-lying or partially expelled IUDs, IUD perforations, and/or embedded/rotated IUDs and often unspecified combinations of these. While some research suggests that many low-lying and/or abnormally-located IUDs may resolve spontaneously [10, 18, 19], other studies have observed an increased risk of expulsions [8, 20]. Data also suggest that low-lying IUDs may contribute to pelvic pain [6, 8, 21] and reduced contraceptive efficacy has been reported for copper IUDs [22, 23]. In the current study, we examined factors associated with well-defined, low-lying IUDs as diagnosed by ultrasound.

We identified low-lying IUDs, defined as IUDs located in the lower uterine segment and/or cervix, during a screening ultrasound examination systematically conducted at study enrollment for a large prospective study of uterine fibroid development [24]. Study participants using IUDs constitute the sample for this current, cross-sectional study. Because participants in the parent study underwent ultrasound examination regardless of symptoms, this study has the unique advantage of allowing us to assess pelvic pain symptoms associated with low-lying IUDs without bias from selective referral for follow-up of IUD position.

2. Materials and Methods

2.1 Participants

The parent study, the Study of Environment, Lifestyle & Fibroids (SELF), is designed to investigate risk factors for fibroid development including fibroid incidence and fibroid growth. Women were eligible for enrollment in SELF if they were between the ages of 23-34 self-identified as African-American or black, had an intact uterus, resided in the U.S., and were willing to complete study activities over a five-year period [24]. Women who had a prior diagnosis of uterine fibroids, radiation or chemotherapy for cancer, or a diagnosis of lupus, Grave's disease, Sjogren's syndrome, scleroderma, or multiple sclerosis that required medication were not eligible for SELF. Institutional Review Boards at the National Institute of Environmental Health Sciences and Henry Ford Health System, the collaborating group in

Detroit, approved the parent study. The current analysis includes all SELF participants with IUDs in place at the time of enrollment.

2.2 Data Collection

We published details of the SELF protocol elsewhere [24]. Participants usually completed a telephone interview and self-administered questionnaires prior to attending a clinic visit. Participants who had not completed the questionnaires prior to the clinic visit did so at their clinic visit. Trained interviewers conducted the computer-assisted telephone interviews to provide uniformly-collected data on reproductive and contraceptive history. Data included number of prior IUDs, type, age at insertion(s), and reasons for use. A webbased questionnaire elicited demographic and medical history data including dysmenorrhea over the past 12 months. Women reported how much of a problem they had with menstrual cramps or discomfort using the following Likert scale: not a problem, small problem, medium problem, big problem. Women also reported if their menstrual cramps or discomfort interfered with daily activities: not at all, a little, some, a lot.

At the clinic visit study staff measured weight and height. Experienced gynecologic sonographers who were trained on the study protocol conducted a 2-D transvaginal ultrasound examination. They recorded uterine position as anteverted or retroverted, and uterine size as measured in duplicate (sagittal, longitudinal, and transverse measures). Uterine volume was calculated for each duplicate set of measures with the ellipsoid formula, and averaged. The sonographer noted the presence of any low-lying IUDs, those located in the lower segment and/or cervix (Figure 1, for example), and study staff informed the participant. Two study authors (MM, ED) used the stored images to confirm the position of the low-lying IUDs and to document lower uterine segment versus cervical location. They also independently measured the distances from the fundus to the IUD for all low-lying IUDs.

2.3 Data Analysis

We calculated the prevalence odds ratio (OR) for low-lying IUDs associated with each participant characteristic using univariate logistic regression. The factors of interest for which we had data were age, education, body mass index (BMI), parity, retroverted uterus, uterine volume, fibroid status, and type of IUD. Data on insurance status was also available for a subset of the participants, but since it was highly correlated with education, only education level was examined. Age, BMI, and uterine volume were analyzed as continuous variables as well as categorically. When possible, we categorized variables for analysis so that each category had at least 5 low-lying IUDs. Exceptions due to small numbers (categories of parity, fibroid status in Table 2, and BMI in Figure 2) are noted with the results. We dichotomized the education variable to high school vs > high schoolbecause we were particularly interested in the effect of low education. To examine BMI categorically, we initially dichotomized it (<35/35). Then, to further assess any doseresponse relationship between BMI and low-lying IUDs, we examined BMI using Centers for Disease Control obesity guidelines [25]. However, due to low frequencies of women with a low-lying IUD among non-obese women, we evaluated BMI using the categories of <30, 30-<35, 35-<40, and 40. We used multivariable logistic regression models to

simultaneously examine all variables that were significantly associated with low-lying IUDs, and kept variables that changed the association for another significant factor by at least 10%. We repeated the analysis looking at the association between significant factors after excluding the 3 participants whose IUD was low-lying but not in the cervix.

We examined the association between having a low-lying IUD and dysmenorrhea based on two dichotomized menstrual-pain variables: 1) menstrual pain reported to be a big problem vs. not a big problem and 2) menstrual pain that interfered with daily activities some or a lot vs. none or a little. We used logistic regression to calculate the odds ratio for the association between a low-lying IUD and dysmenorrhea. To evaluate possible bias that could arise if women with a low-lying IUD were more likely to use an IUD as a possible way of reducing dysmenorrhea, we examined reported reasons for using the IUD.

Analyses were performed using SAS software version 9.3 [26].

3. Results

3.1 Low-lying IUDs: prevalence and risk factors.

Of the 1693 women enrolled in SELF, 168 (10%) had an IUD currently in place. These current IUD users were mostly first-time users (89%). The average length of use at the time of enrollment was 2.2 years (range <1 to 8), as estimated by subtracting age at insertion from age at enrollment. Twenty-eight of the 168 women (17%) had a low-lying IUD; those with and without a low-lying IUD had their IUD inserted at similar ages (26.1 years vs 26.8 years). Twenty-five of the low-lying IUDs were located at least partially in the cervix, and all of the low-lying IUDs were greater than 2 cm from the fundus, a distance which would have been considered low enough for removal for many studies assessing IUD malposition [15, 20, 21].

Table 1 shows descriptive characteristics of participants as a group and by IUD position. The majority of participants were educated beyond high school, had BMIs in the overweight or obese categories, and were parous. Nearly three quarters were using the Mirena IUD. The sample of women with a low-lying IUD had a higher proportion of women who were young, less educated, in higher BMI categories, and with larger uteri compared with normally-positioned IUD users. The two groups were similar in proportions of parity, retroverted uterine position, fibroids status, and IUD type. The two statistically important factors associated with low-lying IUD position were lower education and higher BMI (Table 2). Women with no more than a high school education had an adjusted odds ratio of having a low-lying IUD of 3.1 (95% CI 1.14-8.55). As BMI increased (using the continuous measure of BMI), so did the odds of having a low-lying IUD (p=0.002). We observed a dose-response pattern using the following BMI categories (<30_{reference}, 30-<35, 35-<40, 40). The aOR increased from 4.1 (95% CI 0.94-17.78) to 6.6 (1.71-25.24) (Figure 2). The analysis excluding participants whose IUDs were low-lying but not in the cervix (n=3) showed essentially the same results (data not shown).

3.2 Low-lying IUDs and dysmenorrhea

Women with a low-lying IUD were more likely to report a "big problem" with dysmenorrhea in the past 12 months than women with a normally-positioned IUD (OR 3.2 95% CI 1.07-9.54) (Table 3). Although proportionately more women with a low-lying IUD reported dysmenorrhea that interfered with activities of daily living, the association was not statistically significant (Table 3). We found that women with a low-lying IUD were not more likely than those with normally-positioned IUDs to report choosing the IUD to alleviate menstrual pain symptoms (7.1% versus 8.6%, P=0.79, based on chi-square test), suggesting that the increased dysmenorrhea in the group with low-lying IUDs was not due to problems with dysmenorrhea prior to IUD insertion.

3. Discussion

In our study of young African-American women, increased BMI was strongly associated with having a low-lying IUD and showed a dose-response pattern. One fourth of IUD users with a BMI 35 had a low-lying IUD. This BMI category is no longer rare. Based on National Health and Nutrition Examination Survey data, 15% of all reproductive-age women 20-39 and 31% of African-American women of these ages have BMIs 35 [27]. When we examined the association with finer categories of BMI, an increased risk appeared to begin with level 1 obesity (BMI=30-<35). However, our small sample size precluded looking at overweight women as a separate category.

To our knowledge, BMI has been examined in three other IUD malposition/expulsion studies. In a U.S. study Madden et al. [9] studied risk factors associated with complete and partial expulsions among 5,403 reproductive-age women. The IUD position data were based on women's self-report gathered during phone interviews or clinic contact during a 2-year follow-up. Complete and partial expulsions were combined in their analysis. The authors reported increased expulsion rates associated with BMI 30. A study conducted in Finland, which identified only complete expulsions, reported a significantly-elevated relative odds of expulsion for BMI >30 [14]. Additionally, Saito-Tom et al. [28] found that Hawaiian women with a BMI over 40 were 3 times more likely to expel their LNG-IUD compared to women with a BMI of <35. The mechanism(s) by which obesity might increase risk of a low-lying IUD is unknown and is worthy of further research. Obesity could make initial placement more difficult. It is also possible that factors associated with obesity, such as differing hormone levels, might influence migration. We are not aware of any studies that have examined BMI-related factors as potential risk factors for IUD migration.

The other factor significantly associated with a low-lying IUD was having no more than a high school education. This association is consistent with prior studies evaluating factors that reflect socioeconomic status and IUD expulsion/malposition [7, 9]. Education level may be a surrogate for less access to care, or care by less experienced providers, an observed risk factor for adverse events during and after IUD insertion in some studies [11, 29], but not all [21].

We also examined age, parity, retroverted uterine position, uterine volume, fibroid status, and IUD type. None were significantly associated with low-lying IUD position. However,

given the narrow age-range of participants and our sample size of only 12 nulliparous women, our ability to investigate these factors was limited.

The primary strength of our study is the systematic ultrasound screening for detection of the low-lying IUDs. This allowed us to fill an important research gap in the data on possible dysmenorrhea associated with abnormally-positioned IUDs. Our data from women who were screened regardless of symptoms, demonstrates that the link between abnormal IUD position and pelvic pain that has previously been reported [6, 8, 21], is unlikely to be an artifact of selective self-referral among symptomatic women. Also, future studies of risk factors may benefit from more precise definitions of IUD position that can be done with ultrasound data, because partial IUD expulsions and complete expulsions may differ in their risk factors.

The primary limitation of our study was the small number of cases. We could not investigate IUD type when looking at BMI given that our sample included only 8 copper IUD users with low-lying IUDs. Nor could we adjust for potential confounding in the dysmenorrhea analysis. In addition, some IUDs that are low-lying in the uterus may spontaneously migrate to a normal fundal position [10, 18, 19], but we only had a single measure of IUD position.

3.1 Conclusion

Our study adds to the evidence that high BMI is a risk factor for low-lying IUDs [9, 14, 28]. The American College of Obstetricians and Gynecologists (ACOG) states that LARC is the most effective reversible contraception, and can be offered to the majority of women regardless of BMI [30, 31]. Our findings should not be considered as a contraindication for IUD use among women with high BMI. However, women with high BMIs may benefit from additional counseling and follow-up regarding risk of dysmenorrhea and expulsion.

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Figure 1: Example of a low-lying IUD from a SELF participant.



Figure 2:

Dose-response relationship between body mass index and having a low-lying IUD (n = 168, adjusted for education, reference category sample is limited (only 3 low-lying IUDs).

Table 1:

Characteristics of participants by position of IUD (N=168)

	Analysis Population N=168		Low-lying IUD N=28		Normally positioned IUD N=140	
	N	%	Ν	(%)	Ν	(%)
Age at IUD insertion (years)						
20-26	81	48	16	57	65	46
27-34	87	52	12	43	75	54
Education						
High school or GED	143	85	8	29	17	12
>High school or GED	25	15	20	71	123	88
Body mass index (kg/m ²)						
<25	22	13	2	7	20	14
25-<30	37	22	1	4	36	26
30-<35	33	20	6	21	27	19
35-<40	30	18	7	25	23	16
40+	46	27	12	43	34	24
Parity						
0	12	7	3	11	9	6
1	156	93	25	89	131	94
Retroverted uterus						
No	139	83	23	82	116	83
Yes	29	17	5	18	24	17
Uterine volume (cc, quartiles)						
41-82	42	25	5	18	37	26
83-107	42	25	8	29	34	24
108-136	42	25	5	18	37	26
137-401	42	25	10	36	32	23
Fibroids at enrollment						
No	140	83	25	89	115	82
Yes	28	17	3	11	25	18
Type IUD						
Mirena®	123	73	20	71	103	74
Paragard®	45	27	8	29	37	26

Table 2:

Associations between baseline characteristics and low-lying IUD position (N=168)

	OR (95% CI) N=28	aOR (95% CI) N=140	P-value ^a
Age at IUD insertion			
Continuous (years)	0.9 (0.83, 1.07)	1.0 (0.86, 1.12)	0.75
Categorical			
20-26	1.0 (ref)	1.0 (ref) 0.7 (0.30, 1.70)	0.45
27-34	0.7 (0.29, 1.47)		
Education			
High school or GED	2.9 (1.10, 7.59)	3.1 (1.14, 8.55)	0.03
>High school or GED	1.0 (ref)	1.0 (ref)	
Body mass index (kg/m2)			
Continuous (1 unit)	1.1 (1.03, 1.13)	1.1 (1.03, 1.14)	0.002
Categorical			
<35	1.0 (ref)	1.0 (ref) 3.0 (1.26, 7.20)	0.01
35	3.1 (1.30, 7.28)		
Parity ^b			
0	1.0 (ref)	1.0 (ref)	0.34
1	0.6 (0.15, 2.26)	0.5 (0.12, 2.29)	
Retroverted uterus			
No	1.0 (ref)	1.0 (ref)	0.76
Yes	1.1 (0.36, 3.04)	1.2 (0.39, 3.69)	
Uterine volume (cc)			
Continuous (1cc)	1.0 (1.00, 1.01)	1.0 (1.00, 1.01)	0.15
Categorical (quartiles)			
41-82	1.0 (ref)	1.0 (ref)	0.31
83-107	1.7 (0.52, 5.84)	2.6 (0.72, 9.56)	
108-136	1.0 (0.27, 3.75)	1.0 (0.26, 4.20)	
	2.3 (0.72, 7.47)	2.3 (0.67, 7.93)	
137-401			
Fibroids at enrollmen b			
No	1.0 (ref)	1.0 (ref) 0.6 (0.15, 2.10)	0.39
Yes	0.6 (0.16, 2.00)		
Type of current IUD			
Mirena®	1.0 (ref)	1.0 (ref) 1.1 (0.41, 2.79)	0.88
Paragard®	1.1 (0.45, 2.74)		

OR: Odds Ratio, 95% CI: 95% Confidence Interval, aOR: Odds Ratio adjusted for continuous BMI and education, except BMI variables were only adjusted for education and education was only adjusted for continuous BMI.

^a p-value for overall effect of variable;

 $b_{\mbox{Results}}$ based on limited sample size (one of the categories had only 3 low-lying IUDs).

Table 3:

Dysmenorrhea among participants with a low-lying IUD compared to normally positioned IUD at time of enrollment (N=168)

IUD position	Dysmenorrhea in past 12 months						
	None or Medium	Big Problem N=17		OR (95% CI)			
	Ν	%	Ν	%			
Normally positioned	129	85	11	65	1.0 (ref)		
Low-lying	22	15	6	35	3.2 (1.07, 9.54)		
IUD position	Dysmenorrh	ea interferes with	a daily activ	vities in pas	at 12 months		
	None or A Little N=142		Some or A Lot N=26		OR (95% CI)		
	Ν	%	Ν	%			
Normally positioned	120	85	20	77	1.0 (ref)		
Low-lying	22	16	6	23	1.6 (0.59, 4.54)		