Published in final edited form as:

Contraception. 2011 November ; 84(5): e5–e10. doi:10.1016/j.contraception.2011.05.010.

Duration of use of a levonorgestrel IUS amongst nulliparous and adolescent women

Tiffany Behringer¹, Matthew F. Reeves², Brianna Rossiter¹, Beatrice A. Chen³, and Eleanor Bimla Schwarz^{3,4}

¹University of Pittsburgh School of Medicine, Pittsburgh, PA, 15213

²WomanCare Global, Washington, DC 20015

³Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburgh School of Medicine, Pittsburgh, PA, 15213

⁴Division of General Internal Medicine, Center for Research on Health Care, University of Pittsburgh School of Medicine, Pittsburgh, PA, 15213

Abstract

Background—Intrauterine devices (IUDs) are cost-effective if used for two or more years. Early discontinuation may lead to reduced cost-effectiveness of this method and unintended pregnancy if other contraceptives are not used. This study sought to examine rates and reasons for discontinuation of IUS use in adolescents versus older women and nulliparous versus parous women, as these groups may be more likely to discontinue use.

Study Design—Retrospective cohort study of women receiving a levonorgestrel IUS between June 2005 and April 2008. Medical records were reviewed for all visits following placement of the IUS; rates and reasons for IUS discontinuation were calculated and categorized. Data were examined under two scenarios: (1) assuming that all women not seen for follow-up continued IUS use and (2) Only including women with follow-up visits. Cox regression was used to control for age, parity, race, and marital status in comparing rates of IUS discontinuation and expulsion in nulliparous versus parous women and adolescents versus older women.

Results—Of the 828 women included in this analysis, 104 (12.6%) were nulliparous, and 131 (15.8%) were ≤ 20 years of age. Nulliparous women were not more likely than parous women to have expelled their IUS [HR 1.40, 95% CI (0.57, 3.43)]. Adolescent women were more likely to experience expulsion than older women, although this did not reach statistical significance [HR 1.49 (0.76, 2.92)]. When we looked at reasons for IUS removal, we found that nulliparous women were not more likely than parous women to have their IUS removed because of dissatisfaction with the contraceptive method (6.7% vs. 11.5%, $p=0.15$) or desire to become pregnant (1.9% vs. 2.6%, $p=0.50$). Similarly, adolescents were not more likely than older women to have their IUS removed because of dissatisfaction with the contraceptive method (10.7% vs. 10.9%, $p=0.94$) or desire to become pregnant (3.1% vs. 2.4%, $p=0.43$).

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*Corresponding author: Tiffany Behringer 230 McKee Place, Suite 600, Pittsburgh, PA 15213 (412) 298-9687
behringer.tiffany@gmail.com.

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An abstract of this work was presented at the Reproductive Health 2010 conference in Atlanta, Georgia, on September 24, 2010.

Conclusions—Adolescents and nulliparous women are not more likely to prematurely discontinue use of their IUS than adult or parous women.

Keywords

IUS; discontinuation reasons; nulliparous; adolescents; dissatisfaction

1. Introduction

Fifty percent of pregnancies and 82% of teen pregnancies in the United States (US) are unintended [1, 2], highlighting a need for contraceptive methods that are highly effective and easy-to-use. The intrauterine device (IUD) is a reversible form of contraception with a failure rate comparable to tubal ligation [3]. While the upfront costs of IUDs are higher than other methods, IUDs are among the most cost-effective contraceptives available if used for two or more years [4]. With increasing duration of use, the IUD becomes even more cost-effective [5]. Despite these benefits, only 5.5% of US contraceptive users rely on an IUD to prevent pregnancy [6], and IUD use is even less common among adolescents and nulliparous women [6–8], who are at highest risk of unintended pregnancy [9].

The underutilization of IUDs in the US has been attributed to unfounded concerns that IUD use increases risk of pelvic inflammatory disease (PID) and infertility [10]. The Dalkon Shield, an IUD removed from the US market in the 1980s due to safety concerns, continues to affect the perceptions of some clinicians who worry about IUD complications and potential litigation [11, 12]. Despite evidence that the two IUDs currently available in the US are safe and do not increase the risk of PID or infertility, use of these devices remains low, particularly amongst nulliparous and adolescent women [13]. In a recent study examining clinician beliefs surrounding IUD provision, only 46% of clinicians felt that nulliparous women were appropriate candidates for IUD use and only 39% felt teenagers could safely use an IUD [14]. Even for those clinicians who recognize that IUD use is safe and appropriate for many adolescents and nulliparous women, concerns remain that younger and nulliparous women may more rapidly expel their IUD or experience more side effects from IUD use [13]. Premature discontinuation may reduce the cost-effectiveness of this method [4]. Because of these concerns about premature discontinuation in adolescents and nulliparous women and its effects, our objective was to quantify rates of and reasons for discontinuing use of a levonorgestrel IUS amongst adolescents and nulliparous women compared to parous and adult women.

2. Materials and methods

This retrospective cohort study included women aged 14–50 years who received a levonorgestrel IUS from an academic clinic in Pittsburgh, PA between June 2005 and April 2008. Our primary outcome was IUS discontinuation between nulliparous versus parous women and adolescents versus older women. We also explored IUS expulsion using the same comparisons. Women were identified using clinic billing data. We included insertions for women using the IUS for contraception, menorrhagia, or dysmenorrhea. Women were excluded if information on parity was not documented in their chart or if they were over 50 years of age. Medical records were reviewed for all clinical encounters following IUS insertion including clinic visits, emergency department visits, and hospitalizations at the same institution. Trained research assistants abstracted medical record data using a standardized data abstraction instrument after pilot testing of the instrument by the lead author. Data were collected on demographic characteristics; reproductive history including total number of pregnancies, deliveries, abortions, ectopic pregnancies, and miscarriages;

history of, testing for, and treatment for sexually transmitted infections; IUS expulsion; and reasons for IUS removal.

In our primary analysis, women who were not seen following IUS placement were assumed to have continued use of their IUS, as the best case scenario. In a secondary analysis, we examined only those women who made one or more follow-up visits. Cox proportional hazard models were constructed under both scenarios to control for age, race and marital status while examining the effects of nulliparity and adolescence on IUS discontinuation. This allowed us to use all data available for each subject despite differences in follow-up time. White, married parous women ages 21–30 were considered the reference group in all models. When considered as a covariate, age was analyzed as both a continuous variable and in categories (20 or less, 21–30, 31–40, and 41+ years). Because of the potential association between nulliparity and age, an interaction term was also included in the model to ensure that parity was not affecting the outcome coefficients differently for adolescents versus older women. Other potential interactions tested included race and age, race and parity, marital status and age, and marital status and parity. Kaplan Meier curves were created and log-rank tests were performed to test for equality of time to IUS removal and time to expulsion relative to total time of follow-up, between nulliparous versus parous women, and also between adolescents versus adult women. For the unadjusted results in Tables 1 and 2, chi-squared and Fisher's Exact tests were performed to test associations between categorical variables including race, marital status, indication for IUS placement, parity, follow-up, periods of IUS use, expulsion, and removal. T-tests were performed to examine associations with continuous variables including age, duration of follow-up, time to expulsion, and days between placement and removal. At the 0.05 significance level, we had 80% power to detect a 0.1675 difference in the hazards ratio of IUS discontinuation between nulliparous versus parous women. We had 80% power to detect a 0.2405 difference in the hazards ratio for IUS discontinuation between adolescents and older women. Adolescents were defined as women 20 years of age or younger. Statistical significance was assessed using $p < 0.05$. All analyses were conducted using STATA version 11 (StataCorp, College Station, TX). This study was approved by the University of Pittsburgh Institutional Review Board.

3. Results

Between June 2005 and April 2008, 867 women had an IUS placed at the study clinic (Table 1). Of these 867, three subjects were excluded from the study population because they were over 50 years of age and 36 subjects were excluded because their records lacked information on parity. Of the 828 subjects remaining, 104 (12.6%) were nulliparous and 131 (15.8%) were adolescents (less than 21 years of age). Demographic characteristics are provided in Table 1. The range in age was 14 to 50 years. Most (87%, $n=724$) were parous. There were statistically significant differences in race and marital status between nulliparous and parous women and adolescents versus older women (Table 1). There were also statistically significant differences in age between parous and nulliparous women and parity between adolescents and older women. To account for these differences we included each of these predictors in our model as well as an interaction term for parity and age. Of the adolescents, 107 (81.7%) were parous. During their last intercourse prior to IUS insertion, nulliparous women were more likely than parous women to have used condoms ($p=0.04$) and less likely to have used Depo Provera ($p=0.002$). There was no statistically significant difference between adolescent and adult women with regards to birth control method at last intercourse.

Of the 828 women included in this analysis, 573 (69.2%) made one or more follow-up visits (Table 2). There was no statistically significant difference in the occurrence of follow-up

based on parity or age, or in time from IUS placement to the last follow-up visit, by parity or age (Table 2).

Our primary outcome was comparing IUS discontinuation between nulliparous and parous women and adolescents and older women. In our primary model, cox regression with log-rank test comparing nulliparous to parous women showed no significant differences in time to IUS removal ($p=0.48$, Fig. 1) or time to IUS expulsion ($p=0.39$, Fig. 1). Our secondary model (including only those women with follow-up) was similarly not significant ($p=0.16$ for discontinuation, $p=0.82$ for expulsion). Amongst those women who had their IUSs removed, there was no difference in duration of use based on parity (Table 2). When looking at reasons for removal, nulliparous women were not more likely than parous women to have their IUS removed because of desiring pregnancy, experiencing an unintended pregnancy, pelvic infection, or because of dissatisfaction with their IUS (Table 2). The most common reasons for dissatisfaction that resulted in IUS removal were cramping, spotting, weight gain, and headaches.

Cox regression with log-rank test comparing adolescent to adult women also showed no significant differences in time to IUS removal ($p=0.53$, Fig. 1) or IUS expulsion ($p=0.12$, Fig. 1). Our secondary model (including only those women with follow-up) was similarly not significant ($p=0.84$ for discontinuation, $p=0.16$ for expulsion). In contrast to older women, adolescents were not more likely to experience expulsion at an earlier point (in days) but were more likely overall to expel, or perhaps self-remove, their IUS (Table 2). Three women (0.4%) experienced pregnancy with the IUS in place. Of those 3 pregnancies, 2 (0.2%) occurred within the first year of IUS use among parous adult women (Table 2). Adolescents and nulliparous women did not experience pregnancy during IUS use. Adolescent women were not more likely to have their IUS removed within 1 or 2 years than adult women. Amongst those women who had their IUSs removed by a clinician, there was no difference in duration of use for adolescents versus adult women. When looking at reasons for removal, adolescent women were also not more likely than adult women to have had their IUS removed because of desiring pregnancy, experiencing an unintended pregnancy, or dissatisfaction (Table 2). The most common reasons for dissatisfaction that resulted in IUS removal among adolescents were cramping and spotting. There was a trend towards increased removal of the IUS due to concern about PID in adolescents compared to adult women (2.3% versus 0.7% of adult women, $p=0.12$). However, they were not more likely to have been treated for PID following IUS insertion (3.1% versus 2.7%, $p=0.51$).

In Cox regression models predicting discontinuation of IUS use (Tables 3 and 4), adolescents were not more likely than women between 21 to 30 years of age to discontinue IUS use. There was no interaction between age as a continuous or categorical variable and parity for IUS removal, nor between race and parity, race and age, marital status and age, or marital status and parity.

4. Discussion

In this study of 828 women who had a levonorgestrel IUS placed, we found that nulliparous women and adolescents were not more likely than parous or adult women to have discontinued use of their IUS within 2 years of placement. Consistent with previous studies [15], we found that 5.8% of nulliparous women and 3.8% of adolescent women expelled their IUS within 2 years. We also found that 6.7% of nulliparous women and 9.9% of adolescents discontinue IUS use within 1 year and 11.5% of nulliparous women and 16.8% discontinue use within 2 years. Similarly, in a systematic review, Grimes found that continuation rates varied, ranging from 48% to 88% percent in adolescents at 12 months and 49% to 73% at 24 months [15]. In our study neither adolescents nor nulliparous women

were more likely to discontinue use because they desired pregnancy or because of dissatisfaction from side effects such as cramping or spotting. However, this study remains underpowered to detect smaller differences in rates of IUS discontinuation that some may feel are clinically relevant.

Another important finding of this study is that many women discontinue use of their IUS for reasons that may be amenable to clinician counseling. For instance, while evidence suggests that IUS use does not significantly impact body mass index [16], a number of women cited weight gain as a reason for desiring removal of their IUS. Additionally, while clinical guidelines do not recommend IUS removal in patients initially treated for PID [17], PID was cited as the reason for removal in 5% of cases. However, we do not have information available on whether or not removal occurred prior to treatment or after complications in PID treatment. Interestingly, although adolescent women were not more likely to have been treated for PID following IUS insertion, they were more likely to have had their IUSs removed because of concern of PID, indicating that clinicians may be less comfortable treating PID in younger women with an IUS in place.

Limitations of our study include the lack of information in the medical record on side effects experienced by women who did not have their IUSs removed. Further studies, which assess side effects experienced by both women who do and do not opt for IUS removal are needed to establish whether specific symptoms or concerns, such as weight gain, in fact predict early discontinuation of IUS use. A further limitation of this study is that follow-up information was not available for 31% of women who had IUSs placed. These women may have had their IUSs removed by other health care facilities, may have removed their IUSs themselves, or may have expelled their IUSs. For instance, Smith, et al found that expulsion rates may be even higher than those published for adolescents because they report self-removal [18]. Thus, the rate of IUS discontinuation and expulsion or self-removal may actually be higher than what was found in this study. These analyses are also limited by missing data on the date of expulsion for 24 women who had an IUS expulsion documented in their medical records. Finally, the relatively small number of adolescents and nulliparous women served by the study clinic limits the power of some comparisons.

In conclusion, the results of this study show that adolescents and nulliparous women are not more likely to prematurely discontinue use of their IUS than adult or parous women. Ongoing efforts are therefore needed to increase use of this underutilized but highly effective reversible method of contraception in the United States, particularly among adolescent and nulliparous women who frequently experience unintended pregnancy [9].

Acknowledgments

The authors appreciate the statistical guidance of Sara M. Parisi, MS, MPH.

This work was funded by The Doris Duke Charitable Foundation and Ms. Behringer's 5TL1RR024155-04. Dr. Schwarz is funded by K23HD051585. Dr. Reeves was funded by KL2 RR024154-03.

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Fig. 1.
IUD continuation and expulsion by parity and adolescents versus adult women.

Table 1

Subject characteristics by parity and age category

Variable*	All women	Nulliparous	Parous	p	Adolescents**	Adult women	p
N	828 (100.0%)	104 (12.6%)	724 (87.4%)		131 (15.8%)	697 (84.2%)	
Age (years)	26.8 (6.7)	25.2 (7.5)	27.0 (6.5)	0.01	19.1 (1.5)	28.2 (6.3)	NA***
≤20	131 (15.8%)	24 (22.7%)	107 (14.8%)		131 (100.0%)	0 (0.0%)	
21–30	503 (60.7%)	63 (60.6%)	440 (60.8%)		0 (0.0%)	503 (72.2%)	
31–40	146 (17.8%)	8 (7.7%)	138 (19.0%)		0 (0.0%)	146 (20.9%)	
≥ 41	48 (5.7%)	9 (8.7%)	39 (5.4%)		0 (0.0%)	48 (6.9%)	
Race							
Caucasian	428 (51.7%)	79 (76.0%)	349 (48.2%)	<0.001	56 (42.7%)	372 (53.4%)	0.03
Black	335 (40.5%)	13 (12.5%)	322 (44.5%)		67 (51.1%)	268 (38.5%)	
Other	23 (2.8%)	3 (2.9%)	20 (2.8%)		4 (3.1%)	19 (2.7%)	
Marital status				0.01			<0.001
Single	642 (77.5%)	85 (81.7%)	557 (76.9%)		122 (93.1%)	520 (74.6%)	
Married	131 (15.8%)	7 (6.7%)	124 (17.1%)		5 (3.8%)	126 (18.1%)	
Indication				0.22			0.28
Contraception	774 (93.5%)	95 (91.3%)	679 (93.8%)		126 (96.2%)	648 (93.0%)	
Menorrhagia	28 (3.4%)	5 (4.8%)	23 (3.2%)		2 (1.5%)	26 (3.7%)	
Dysmenorrhea	8 (1.0%)	2 (1.9%)	6 (0.8%)		0 (0.0%)	8 (1.1%)	
Parity							0.03
Nulliparous	104 (12.6%)	NA	NA	NA	24 (18.3%)	80 (11.5%)	
Parous	724 (87.4%)				107 (81.7%)	617 (88.5%)	
Prior contraception							
Condoms	262 (31.6%)	42 (40.4%)	220 (30.4%)	0.04	41 (31.3%)	221 (31.7%)	0.93
Oral	116 (14.0%)	21 (20.2%)	95 (13.1%)	0.05	20 (15.3%)	96 (13.8%)	0.65
Injectable	144 (17.4%)	7 (6.7%)	137 (18.9%)	0.002	27 (20.6%)	117 (16.8%)	0.29

Percentages do not add up to 100% in all cases, reflecting missing data.

* Mean (SD) or n(%).

** Age <21 years.

Not applicable.

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Table 2

Duration of follow-up and use and rates of removal and expulsion

Variable*	All women	Nulliparous	Parous	p	Adolescents**	Adult women	p
n	828 (100.0%)	104	724		131	697	
Returned to study clinic	573 (69.2%)	78 (75.0%)	495 (68.4%)	0.17	95 (72.5%)	478 (68.6%)	0.37
Time to last contact (days)	572 (348)	565 (352)	573 (348)	0.84	621 (331)	562 (351)	0.14
Length of follow-up (years)							
≤1	182 (22.0%)	29 (27.9%)	153 (21.1%)	0.12	24 (18.3%)	158 (22.7%)	0.27
1–2	172 (20.8%)	16 (15.4%)	156 (21.5%)	0.15	28 (21.4%)	144 (20.7%)	0.85
>2	219 (26.4%)	32 (30.8%)	187 (25.8%)	0.29	42 (32.1%)	177 (25.4%)	0.11
Duration of I US use (days)	397 (296)	435 (354)	393 (290)	0.60	388 (274)	399 (302)	0.87
IUS removal (years)							
within 1	76 (9.2%)	7 (6.7%)	69 (9.5%)	0.36	13 (9.9%)	63 (9.0%)	0.75
within 2	125 (15.1%)	12 (11.5%)	113 (15.6%)	0.28	22 (16.8%)	103 (14.8%)	0.55
within 3	146 (17.6%)	14 (13.5%)	132 (18.2%)	0.23	25 (19.1%)	121 (17.4%)	0.64
overall	155 (18.7%)	15 (14.4%)	140 (19.3%)	0.23	28 (21.4%)	127 (18.2%)	0.40
Time to expulsion (days)***	273 (246)	91 (37)	330 (257)	0.04	371 (285)	248 (238)	0.33
IUS expulsion (years)****							
within 1	19 (2.3%)	6 (5.8%)	13 (1.8%)	0.01	3 (2.3%)	16 (2.3%)	0.65
within 2	24 (2.9%)	6 (5.8%)	18 (2.5%)	0.06	5 (3.8%)	19 (2.7%)	0.33
within 3	25 (3.0%)	6 (5.8%)	19 (2.6%)	0.08	5 (3.8%)	20 (2.9%)	0.36
Overall	49 (5.9%)	7 (6.7%)	42 (5.8%)	0.71	13 (9.9%)	36 (5.2%)	0.03
Reason for removal Desired pregnancy	21 (2.5%)	2 (1.9%)	19 (2.6%)	0.50	4 (3.1%)	17 (2.4%)	0.43
Method failure (years)							
within 1	2 (0.2%)	0 (0.0%)	2 (0.2%)	0.76	0 (0.0%)	2 (0.2%)	0.71
within 2	2 (0.2%)	0 (0.0%)	2 (0.2%)	0.76	0 (0.0%)	2 (0.2%)	0.71
Overall	3 (0.4%)	0 (0.0%)	3 (0.4%)	0.67	0 (0.0%)	3 (0.4%)	0.60
Concern of pelvic infection	8 (1.0%)	1 (1.0%)	7 (1.0%)	0.73	3 (2.3%)	5 (0.7%)	0.12
Dissatisfaction	90 (10.9%)	7 (6.7%)	83 (11.5%)	0.15	14 (10.7%)	76 (10.9%)	0.94

* Mean (standard deviation) or n(%).

*** Age <21 years.

These analyses are limited by missing data on the date of expulsion for 24 women.

Table 3

Hazard of discontinuation and expulsion assuming continued use for women not seen for follow-up

Variable	HR* (95% CI) for discontinuation		HR (95% CI) for expulsion	
	Unadjusted	Adjusted**	Unadjusted	Adjusted**
Age (years)				
≤20	1.06 (0.70, 1.61)	1.01 (0.66, 1.55)	1.88 (0.97, 3.65)	1.49 (0.76, 2.92)
21–30	reference	reference	reference	reference
31–40	0.86 (0.55, 1.35)	0.84 (0.52, 1.35)	1.22 (0.57, 2.60)	1.17 (0.53, 2.59)
≥ 41	0.10 (0.01, 0.75)	0.12 (0.02, 0.83)	***	***
Race				
White	reference	reference	reference	reference
Black	1.26 (0.92, 1.75)	1.30 (0.93, 1.82)	2.38 (1.31, 4.31)	2.31 (1.25, 4.29)
Other	0.97 (0.35, 2.64)	1.04 (0.38, 2.90)	1.08 (0.14, 8.13)	1.40 (0.18, 10.70)
Parity				
Nulliparous	0.81 (0.48, 1.39)	1.02 (0.59, 1.78)	1.26 (0.57, 2.81)	1.40 (0.57, 3.43)
Parous	reference	reference	reference	reference
Marital status				
Married	reference	reference	reference	reference
Single	1.07 (0.70, 1.63)	0.94 (0.60, 1.46)	2.43 (0.87, 6.76)	1.82 (0.63, 5.25)

* Hazard Ratio.

** Adjusted for all variables shown in table and interaction terms.

*** There were no expulsions in this age group.

Table 4

Hazard of discontinuation and expulsion amongst women seen for follow-up

Variable	HR* (95% CI) for discontinuation		HR (95% CI) for expulsion	
	Unadjusted	Adjusted**	Unadjusted	Adjusted**
Age (years)				
≤20	1.09 (0.71, 1.65)	0.80 (0.48, 1.36)	0.64 (0.32, 1.27)	1.72 (0.61, 4.89)
21–30	reference	reference	reference	reference
31–40	1.28 (0.74, 2.21)	0.78 (0.33, 1.85)	0.82 (0.32, 2.10)	0.92 (0.26, 3.29)
≥ 41	0.12 (0.02, 0.85)	0.09 (0.01, 0.77)	***	***
Race				
White	reference	reference	reference	reference
Black	1.16 (0.84, 1.60)	0.66(0.36, 1.18)	2.36 (1.26, 4.41)	2.10 (0.69, 6.33)
Other	1.05 (0.38, 2.86)	0.27 (0.05, 1.53)	1.41 (0.19, 10.70)	1.22 (0.04, 35.80)
Parity				
Nulliparous	0.68 (0.40, 1.17)	1.03 (0.42, 2.73)	1.10 (0.49, 2.48)	0.24 (0.03, 2.00)
Parous	reference	reference	reference	reference
Marital status				
Married	reference	reference	reference	reference
Single	0.89 (0.58, 1.36)	0.92 (0.58, 1.44)	2.50 (0.77, 8.09)	2.25 (0.63, 8.00)

* Hazard Ratio.

** Adjusted for all variables shown in table and interaction terms.

*** There were no expulsions in this age group.