Anticipated Pain as a Predictor of Discomfort with Intrauterine Device Placement

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Disclosures: Dr. Dina, Ms. Peipert, and Ms. Zhao report no conflicts of interest.
Dr. Peipert has served on advisory boards for Teva Pharmaceuticals and Perrigo, and has received research support from Merck, Bayer, and Teva.

Funding: This research was supported by an anonymous foundation.

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Word Count: Abstract: 411 Main text: 2,758

This is the author's manuscript of the article published in final edited form as:

Dina, B., Peipert, L. J., Zhao, Q., & Peipert, J. F. (2018). Anticipated pain as a predictor of discomfort with intrauterine device placement. American Journal of Obstetrics and Gynecology, 218(2), 236.e1-236.e9. https://doi.org/10.1016/j.ajog.2017.10.017

CONDENSATION

Higher anticipated pain is associated with increased discomfort during intrauterine device placement.

SHORT VERSION OF TITLE

Discomfort with Intrauterine Device Placement.

ABSTRACT

Background: Intrauterine Devices (IUDs) have been gaining popularity for the past 2 decades. Current data reports that more than 10% of women using contraception are using an IUD. With less than 1% failure rates, IUDs are one of the most effective forms of long acting reversible contraception, yet evidence shows that fear of pain during IUD placement deters women from choosing an IUD as their contraceptive method.

Objective(s): The objective of this analysis was to estimate the association between anticipated pain with IUD placement and experienced pain. We also assessed other factors associated with increased discomfort during IUD placement. We hypothesized that patients with higher levels of anticipated pain would report a higher level of discomfort during placement.

Study Design: We performed a secondary analysis of the Contraceptive CHOICE Project (CHOICE). 9,256 patients were enrolled in CHOICE from the St. Louis region between 2007 and 2011, of which 1,149 subjects presenting for their first placement of either the original 52mg LNG IUS or the copper IUD were analyzed in this study. Patients were asked to report their anticipated pain prior to IUD placement and experienced pain during placement on a 10-point visual analog scale. We assessed the association of anticipated pain as well as patient demographic and reproductive characteristics and IUD type with experienced pain with IUD placement.

Results: The mean age of CHOICE participants in this subanalysis was 26 years. Of these 1,149 study subjects, 44% were black and 53% were of low socioeconomic status. The median expected pain score was 5 for both the LNG-IUS and the copper IUD while the median experienced pain score was 5 for the LNG-IUS and 4 for the copper IUD. After controlling for

parity, history of dysmenorrhea, and type of IUD, patient anticipated pain was associated with increased experienced pain (adjusted relative risk for one unit increase in anticipated pain = 1.19, 95% confidence interval 1.14, 1.25). Nulliparity, history of dysmenorrhea, and the hormonal IUD (compared to copper) were also associated with increased pain with IUD placement.

Conclusion(s): High levels of anticipated pain correlated with high levels of experienced pain during IUD placement. Nulliparity and a history of dysmenorrhea were also associated with greater discomfort during placement. This information may help guide and treat patients as they consider IUD placement. Future research should focus on interventions to reduce pre-procedural anxiety and anticipated pain to potentially decrease discomfort with IUD placement.

Key Words: Intrauterine device insertion, placement, pain, discomfort, anticipated pain, nulliparity, dysmenorrhea

INTRODUCTION

Intrauterine devices (IUDs), including the copper (TCu830A) and the hormonal IUD (levonorgestrel intrauterine system or LNG-IUS), are two of the most effective forms of reversible contraception available; failure rates are less than 1% for both perfect and typical use.[1] Multiple studies have demonstrated high levels of acceptability of IUDs and continuation rates at 2-3 years are in the range of 67-77%.[2,3] In fact, continuation rates for IUDs are higher than those for shorter-acting reversible contraceptive methods, such as the pill, ring, contraceptive patch, or depo-medroxyprogesterone acetate (DMPA).[3] The rate of use of IUDs in the US has steadily increased in the last 2 decades. The most recently published data demonstrates 10.3% of contracepting women aged 15-44 are using an IUD.[4] Though highly effective and acceptable, qualitative and anecdotal evidence has suggested that perceived pain with placement may be a barrier to the use of intrauterine contraception.[5]

Few small studies have been published evaluating predictors of increased pain with IUD placement and results have been inconsistent. Factors that have been associated with more significant pain at the time of IUD placement include nulliparity[6-9] or no prior vaginal delivery,[10] age greater than 30 years,[8] a longer interval since last pregnancy or menses,[7,8] a history of dysmenorrhea,[6,11] absence of current breastfeeding,[7,8] and higher educational achievement.[7] Additionally, higher anxiety preceding the procedure, or higher expected pain with placement have been associated with greater pain at the time of placement.[10,12-14] Explaining the pros and cons of IUDs, guidance on what to expect during and after the procedure, and suggestion of coping mechanisms like distraction techniques prior to placement have been proposed as methods to decrease pain with placement.[15]

The purpose of this secondary analysis was to describe the pain or discomfort

experienced with IUD placement, and to assess whether anticipated or expected pain is associated with discomfort experienced with placement. We also sought to evaluate the association of demographic or psychological factors with increased pain with placement. Our specific hypothesis was that subjects with higher levels of anticipated pain with placement would score higher on our scale of reported discomfort with placement.

MATERIALS & METHODS

We performed a secondary analysis of the women undergoing IUD placement in the Contraceptive CHOICE Project (CHOICE). CHOICE was a prospective cohort study that educated all participants about contraceptive methods, including the most effective methods (IUDs and the contraceptive implant). CHOICE reduced access obstacles to contraception and provided all methods at no cost. The goal of the study was to reduce the unintended pregnancy rate in the St. Louis region.[3] The methods of CHOICE have been previously described in this journal;[16] we will briefly outline the substudy methods here.

CHOICE project participants were between the ages of 14 and 45 years, and were enrolled between August 2007 to September 2011. Inclusion criteria for CHOICE were as follows: 1) sexually active or planning to become sexually active with a male partner within the next six months; 2) willing to begin using or switch to a new reversible method of contraception; and 3) English or Spanish speaking. If individuals wanted to conceive in the next 12 months or had undergone a hysterectomy or sterilization procedure, they were not eligible to participate in CHOICE. Participants were eligible for this secondary analysis if they chose an IUD (the original 52mg LNG IUS (Bayer, Whippany, NJ) or copper) for their contraceptive method and had their expected and experienced pain assessed at the

placement visit (questions regarding pain with placement were added November, 2010). Our analysis included each participant once. If a woman had multiple IUD placements during her participation in CHOICE, only the first CHOICE placement was included in the dataset. We did not exclude women who had previously had an IUD prior to CHOICE enrollment. The Washington University in St. Louis institutional review board approved the study protocol and all participants provided written informed consent.

All subjects were asked to complete a baseline questionnaire. We collected comprehensive demographic and reproductive data as well as information regarding sexual activity, medical, and surgical history. At the baseline interview, women were asked "During the past 12 months, on average, how often did you have pain or cramping during your period?" Women were categorized as having a history of dysmenorrhea if they answered "often" or "always;" participants responding "sometimes" or "never" were considered our referent group. Patients were considered to have a history of depression and/or anxiety if they provided an affirmative response to the question, "have you ever had depression/anxiety?"

In CHOICE, many different providers (e.g. nurse practitioners, residents, fellows, and attending physicians) inserted IUDs; however, most (>80%) were done by nurse practitioners. In the few minutes prior to placement of their chosen IUD, women were asked to describe the pain they anticipated experiencing with the IUD placement on a 10-point visual analog scale (VAS). In the few minutes after placement, participants were asked to rate their actual experienced pain on the same scale. This information was collected by the same provider who placed the IUD and was recorded along with the type of IUD placed.

The primary outcome of this study was the patients' score of the level of actual pain experienced during the IUD placement. Pain experienced during the IUD placement was

analyzed two ways: 1) as a continuous variable; and 2) dichotomized into experienced pain less than 7 (low pain score) vs greater than or equal to 7 (high pain score). We chose a value of 7 on the pain scale as a clinically meaningful value that would be understandable to providers interpreting these data for clinical use.

We considered a participant to be of “low SES” if they answered "yes" to either of the following questions: “do you currently receive food stamps, WIC, Welfare, and/or unemployment?” or “during the past 12 months, have you had trouble paying for transportation, housing, health, medical care or medications, and/or food?” We did not use household income in our definition, as many adolescents were cohabitating with parents or guardians, and could not provide accurate household income data.

Patient characteristics were summarized using mean and standard deviation, median and range, or frequency and percentage depending on data type. Student t test or chi-square test were used to compare the patient characteristics between two IUD types. Our primary exposure variable in this analysis was anticipated pain with IUD placement. When experienced pain was treated as a continuous variable, linear regression models were used to estimate the change in experienced pain with placement. When experienced pain was treated as a dichotomized variable, Poisson regression models with robust variance were used to estimate the relative risk for high pain. Demographic and reproductive characteristics and IUD type were evaluated for potential confounding effect in the association between anticipated and experienced pain. Confounding was defined as a greater than 10% relative change in the association between anticipated and experienced pain with or without the potential confounding covariate in the model. Confounders were included in the final multivariable

model. All the statistical analyses were performed using Stata software, version 11 (StataCorp). The significance level (alpha) was set at 0.05.

RESULTS

Of the 9256 CHOICE participants, there were 4,302 IUD placements. Of these placements, we collected information regarding anticipated and experienced pain in 1,208 participants. Once we excluded multiple IUD placements, 1,149 IUD first placements remained in our dataset.

Table 1 provides the demographic, reproductive, and other patient characteristics of our study sample. The mean age was 26.1 years. Women choosing a LNG-IUS were significantly younger than women choosing the copper IUD (mean age 25.8 vs. 27.3 respectively; $p<0.01$). Black women were significantly more likely to choose LNG-IUS (46.4% vs. 34.8%; $p<0.01$) while white women were significantly more likely to choose the copper IUD (58.5% vs. 47.2%; $p<0.01$). There were no other patient demographics or characteristics associated with the type of IUD chosen. Notably, there was no significant difference in choice of IUD type in regards to a woman's history of dysmenorrhea or level of pain she anticipated with the procedure.

The median expected pain score on the VAS was 5 (range: 0-10, mean=5.2, standard deviation (s.d.)=2.5) and expected pain was similar for women undergoing placement of both IUD types (LNG-IUS: median=5, range: 0-10, mean=5.1, s.d.=2.5; copper IUD: median=5, range: 0-10, mean=5.2, s.d.=2.4). The median experienced pain with IUD placement on the VAS was also 5 (range: 0-10, mean=5.0, s.d.=2.5). For women who had the LNG-IUS placed, median experienced pain score was 5 (range: 0-10, mean=5.1, s.d.=2.5); for the copper IUD, median experienced pain score was 4 (range: 0-10, mean=4.71, s.d.=2.4).

Experienced pain with IUD placement by the participant demographics and characteristics is shown in Table 2. In our unadjusted analysis, the following factors were associated with increased risk of high pain score with IUD placement: young age (<20 years), non-black race, single and/or never married; normal body mass index (BMI); having private or no insurance; nulliparity; having no history of unintended pregnancy or termination of pregnancy; history of dysmenorrhea; and higher anticipated pain score.

Table 3 shows results of the multivariable model. Four characteristics were found to be significantly associated with the risk of a high pain score in our adjusted model: level of expected pain, parity, history of dysmenorrhea, and the type of IUD chosen. For each additional “point” of pain expected on the VAS, a woman was 19% more likely to experience high pain (score $\geq$ 7) during placement (relative risk (RR)=1.19). Increasing parity was associated with experiencing less pain with placement. Women who had the LNG-IUS placed were more likely to experience high pain as compared to women who had the copper IUD placed (RR=1.31, 95% CI: 1.05-1.63). Women who reported a history of dysmenorrhea were also more likely to experience high pain (RR=1.53, 95% CI: 1.28-1.83). The results from the linear regression lead to the same conclusions (data not shown).

COMMENT

In our analysis of over 1,000 IUD placements, we found that women with higher levels of anticipated pain were more likely to experience increased discomfort during placement, supporting our hypothesis. We also noted that nulliparity, history of dysmenorrhea, and placement of the LNG-IUS, compared to the copper IUD, were associated with higher pain scores.

Our finding that increased anticipated pain was associated with increased experienced pain with IUD placement is consistent with previous publications.[10,12-14] Though an explanation for this finding has not yet been noted in the literature, studies involving other procedures such as cystoscopy and urodynamic procedures provide greater detail.[17-19] Shaw conducted a qualitative study which focused on patients' feelings about urodynamics procedures to isolate reasons contributing to patients' emotional and physical discomfort throughout the procedures.[19] By recording unstructured interviews, researchers recognized anxiety and fear of embarrassment as key components correlated with increased discomfort during procedures. Several patients reported experiencing less anxiety after having friendly conversations with nurses and physicians, unrelated to the procedure. Simple conversations with healthcare professions can put patients at ease with the procedure at hand, reducing anxiety levels and in turn, decreasing discomfort at the procedure. On the other hand, conversing extensively about the procedure has not been shown to reduce experienced discomfort.[17]

Our finding that nulliparity is associated with increased risk of high pain during IUD placement, is also consistent with findings reported elsewhere.[6-10,14] In a case-control study of factors associated with severe pain with IUD placement, women with parity less than 3 were more likely to experience severe pain compared to women with higher parity.[7] Allen et al.

reported that women with no prior vaginal delivery were more likely to have increased pain with IUD placement, regardless of whether they were nulliparous or had only delivered via cesarean; this effect was still noted in women who had some degree of cervical dilation prior to cesarean.[10]

Other studies have found an increased risk for high pain score in women with a history of dysmenorrhea.[6,11] Dysmenorrhea may be associated with changes in uterine blood flow and hypercontractility.[11,20,21] Women with severe dysmenorrhea have altered CNS responses to pain, differences in steroid hormone levels, and differ from women without dysmenorrhea in several immunologic factors.[22-24] These same factors may predispose to pain with IUD placement.

We noted that women who had LNG-IUS placed were significantly more likely to report a high pain score than women who chose the copper IUD. The diameter of the original 52mg LNG IUS inserter tube (which was the only hormonal LNG-IUS used in CHOICE) was 4.8 mm at the time CHOICE IUD placements took place[25] while the copper IUD insertion tube was 4.39 mm +/- 0.1 mm.[26] In 2012, after CHOICE recruitment was complete, the original 52mg LNG IUD inserter became 4.4 mm. Studies of IUD type and discomfort with placement have been mixed. One 2015 study using the 4.8 mm inserter agreed with our findings.[14] Two other studies found no difference in pain with LNG-IUS versus copper IUD placement.[6,11] Of these two studies, Kaislasuo et al. compared the copper IUD inserter tube to both the 4.8 mm and 4.4 mm LNG-IUD inserter,[11] and Weibe reported on placements that took place in 2013 (after the new inserter had been introduced) but did not specify on the size of the tube used.[6]

One prior study found that women older than 30 years were more likely to experience high pain with IUD placement.[8] However, we found no relationship between age and

experienced pain, even when we analyzed age as a continuous or categorical variable. Similarly, we found no association between level of education and experienced pain, which differs from one other report.[7]

Several trials have attempted to identify methods for reducing pain with the IUD placement procedure. A Cochrane review published in 2015 and several subsequent trials have demonstrated some modest benefit in decreasing pain with lidocaine 4% topical gel in nulliparous women, lidocaine 10% spray in parous women, lidocaine 1% paracervical block, and a combined lidocaine-prilocaine cream.[27-32] Tramadol and naproxen, but not ibuprofen, have been shown to have a modest effect on reducing pain with placement in parous women or within a short time frame after placement for nulliparous women;[29,33] neither diclofenac nor ketorolac have shown clinical significance in pain reduction.[34,35]

Various studies have reported on misoprostol use prior to IUD placement. A meta-analysis of most published data on misoprostol indicates that misoprostol is associated with no improvement in pain, and occasionally in increased pain and unpleasant side effects.[29] Only one study has shown misoprostol to decrease pain with IUD placement.[36] Studies of nitric oxide donors, in the forms of nitroprusside gel, nitroglycerin ointment, and inhaled N_2O/O_2 have all shown no improvement in pain with placement.[37-39] Use of a vulsellum instead of a single-toothed tenaculum also does not appear to reduce pain experienced.[14]

One strength of the analysis presented here is the large sample size of IUD placements with prospective data collection of anticipated and experienced pain. As a prospective cohort study, CHOICE was able to reduce the possibility of recall bias as data regarding anticipated and actual pain were collected in real time. One limitation of the data presented here is the limited details regarding any interventions used by clinicians and CHOICE participants at the

time of IUD placement. Non-steroidal anti-inflammatory drugs (NSAIDS) were routinely offered to participants prior to IUD placement, and almost all women accepted this premedication. Lidocaine was rarely used for IUD placement in CHOICE, and was reserved for more difficult insertions. Unfortunately, information regarding NSAID and lidocaine use was not routinely collected. We do not believe this has an appreciable impact on our results, given routine use of NSAID and very rare use of lidocaine. Given the recruitment years of the CHOICE study (2007-11), we are not able to address pain with placement for other IUDs, such as LNG-IUS devices that are smaller or have a different dose of levonorgestrel or a different inserter. All participants were from a single, large midwestern city in the U.S., and this population may not be generalizable to the US population.

In summary, we found that higher anticipated pain was associated with discomfort experienced during IUD placement. In addition, nulliparity, a history of dysmenorrhea, and placement of the hormonal IUD (with a 4.8mm inserter) were associated with a higher placement pain scores. Our data may allow providers the opportunity to personalize their approach to IUD placement with appropriate, risk-factor based counseling prior to placement of an IUD. For example, a nulliparous patient with a history of dysmenorrhea and high anticipated pain or anxiety may benefit from additional patient-tailored counseling and offering evidence-based options for pain control. Researchers should focus future studies on interventions to reduce pre-procedural anxiety and anticipated pain, with a goal of decreasing discomfort with IUD placement.

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Table 1: Patient demographic and reproductive characteristics by type of intrauterine device.

	All (n=1149)		LNG-IUS (n=862)		Copper IUD (n=287)		
	Mean	SD	Mean	SD	Mean	SD	p-value
Age	26.1	5.9	25.8	5.6	27.3	6.4	<0.01
	N	%	N	%	N	%	
Age group							0.66
<20 years old	116	10.1	89	10.3	27	9.4	
>=20 years old	1033	89.9	773	89.7	260	90.6	
Race							<0.01
Black	500	43.5	400	46.4	100	34.8	
White	575	50.0	407	47.2	168	58.5	
Others	74	6.4	55	6.4	19	6.6	
Ethnicity							0.54
Hispanic	45	3.9	32	3.7	13	4.5	
Non-Hispanic	1104	96.1	830	96.3	274	95.5	
Education							0.25
<=HS	242	21.1	189	21.9	53	18.5	
Some College	528	46.0	399	46.3	129	44.9	
College/Grad	379	33.0	274	31.8	105	36.6	
Marital Status							0.33
Single/Never Married	648	56.4	494	57.3	154	53.8	
Married/Living with partner	395	34.4	295	34.2	100	35.0	
Separated/Divorced/Widowed	105	9.1	73	8.5	32	11.2	
BMI							0.61
Underweight	25	2.2	17	2.0	8	2.8	
Normal	480	41.8	353	41.0	127	44.3	
Overweight	269	23.4	206	23.9	63	22.0	
Obese	374	32.6	285	33.1	89	31.0	
Low SES							0.23
No	540	47.0	414	48.0	126	43.9	
Yes	609	53.0	448	52.0	161	56.1	
Insurance							0.48
None	383	33.5	279	32.6	104	36.2	
Private	608	53.1	460	53.7	148	51.6	
Public	153	13.4	118	13.8	35	12.2	
Parity							0.22
0	563	49.0	412	47.8	151	52.6	
1	253	22.0	200	23.2	53	18.5	
2	213	18.5	164	19.0	49	17.1	

3+	120	10.4	86	10.0	34	11.8	
Unintended Pregnancies							0.70
0	509	44.3	377	43.8	132	46.0	
1	280	24.4	214	24.9	66	23.0	
2	185	16.1	143	16.6	42	14.6	
3+	174	15.2	127	14.8	47	16.4	
History of abortion							0.09
No	814	70.8	622	72.2	192	66.9	
Yes	335	29.2	240	27.8	95	33.1	
History of STI							0.09
No	672	58.5	492	57.1	180	62.7	
Yes	477	41.5	370	42.9	107	37.3	
STI at time of baseline interview							0.27
No	1028	92.8	765	92.3	263	94.3	
Yes	80	7.2	64	7.7	16	5.7	
History of depression and/or anxiety							0.12
No	845	73.5	644	74.7	201	70.0	
Yes	304	26.5	218	25.3	86	30.0	
History of violence and/or abuse in lifetime							0.10
No	272	45.0	211	46.9	61	39.4	
Yes	333	55.0	239	53.1	94	60.6	
History of dysmenorrhea							0.12
Never or Sometimes	681	65.2	501	63.9	180	69.2	
Often or Always	363	34.8	283	36.1	80	30.8	

Table 2: Experienced Pain by Participant Characteristics: Unadjusted Relative Risks for Dichotomous Outcome (Pain Score ≥ 7)

	Mean Experienced Pain Score	Pain Score (≥ 7)	Unadjusted Relative Risk	95% CI	
Age group					
<20 years old	5.6	37.07	1.36	1.05	1.76
>=20 years old	4.9	27.3			
Race					
Black	4.5	22.8	0.70	0.58	0.86
White	5.3	32.35			
Others	5.5	33.78	1.04	0.74	1.47
Ethnicity					
Hispanic	5.7	40			
Non-Hispanic	4.9	27.81	0.70	0.48	1.01
Education					
<=HS	4.9	28.93			
Some College	4.9	26.89	0.93	0.73	1.18
College/Grad	5.1	29.82	1.03	0.80	1.32
Marital Status					
Single/Never Married	5.2	31.02			
Married/Living with partner	4.6	24.56	0.79	0.64	0.97
Separated/Divorced /Widowed	4.8	25.71	0.83	0.59	1.17
BMI					
Underweight	5.5	40	1.16	0.71	1.91
Normal	5.4	34.38			
Overweight	4.8	24.54	0.71	0.56	0.91
Obese	4.4	22.46	0.65	0.52	0.82
Low SES					
No	5.2	30.56			
Yes	4.7	26.27	0.86	0.72	1.03
Insurance					
None	5	27.42	0.89	0.73	1.09
Private	5.1	30.76			
Public	4.2	19.61	0.64	0.45	0.90
Parity					
0	5.8	39.08			
1	4.8	20.95	0.54	0.41	0.70
2	4.2	15.96	0.41	0.30	0.57

3+	3.6	15	0.38	0.25	0.60
Unintended Pregnancies					
0	5.6	36.15			
1	4.6	22.5	0.62	0.49	0.80
2	4.7	25.41	0.70	0.54	0.92
3+	4	17.82	0.49	0.35	0.69
History of abortion					
No	5.1	30.1			
Yes	4.7	23.88	0.79	0.64	0.99
History of STI					
No	5	28.42			
Yes	4.9	28.09	0.99	0.82	1.19
STI at time of baseline interview					
No	5	28.5			
Yes	4.7	27.5	0.96	0.67	1.40
History of depression and/or anxiety					
No	4.9	27.34			
Yes	5.2	30.92	1.13	0.93	1.38
History of violence and/or abuse in lifetime					
No	4.4	19.49			
Yes	4.5	24.62	1.26	0.93	1.72
History of dysmenorrhea					
No	4.7	22.61			
Yes	5.5	39.67	1.75	1.45	2.12
Expected pain*					
< median	4	15.15			
> median	5.5	35.19	2.32	1.80	2.99
Type of IUD					
LNG-IUS	5.1	29.58			
Copper	4.7	24.39	0.82	0.66	1.04

* Expected pain was analyzed as a continuous variable in the multivariable model.

Table 3: Adjusted Analysis for the Association of Patient Characteristics, IUD Type, Anticipated Pain and Experienced Pain

Characteristic		Adjusted Relative Risk	95% Confidence Interval
Parity	0	1.0 (referent)	
	1	0.61	0.47, 0.80
	2	0.48	0.35, 0.66
	3+	0.45	0.29, 0.71
History of Dysmenorrhea		1.53	1.28, 1.83
Copper IUD (compared to LNG-IUS)		0.76	0.61, 0.95
Anticipated Pain		1.19	1.14, 1.25

IUD = intrauterine device

LNG-IUS = levonorgestrel intrauterine system