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Patients' experiences and providers' observations on pain during Intrauterine device insertion

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ABSTRACT

Objective

To determine women's (patients') experiences of intrauterine device (IUD) insertion under our current practice and the extent to which these agreed with the observations of the health professionals (providers) who had performed the IUD insertion procedures.

Method

Questionnaires were used to collect information on women's experiences of the IUD insertion procedure from both patients and providers in a sexual and reproductive health service.

Results

Overall response rates were high (77%, 284 responses in total). Seventy-three percent of patients were nulliparous and over half nulligravid. The providers predominantly used local anaesthesia for IUD insertions (93%). Most patients reported being anxious before their procedure (86%). Patients mainly described the overall experience of their IUD insertion procedure as being associated with 'minimal discomfort/nothing' (42%) or 'uncomfortable' (41%). 'Minimal discomfort/nothing' (56%) and 'uncomfortable' (33%) were the main observations of providers. When responses of patients and their providers were compared, agreement was slight for reported pain levels ($k = 0.167$ CI [0.13 – 0.24]). Patients' reported pain levels were significantly higher than those reported to have been observed by their providers ($P < 0.001$).

Conclusion

Patients' and providers' responses suggested that the IUD insertion procedure under our current practice appeared acceptable to most patients. However, providers were not usually accurate in their observations and tended to underestimate the degree of pain experienced by their patients during IUD insertion procedures.

KEYWORDS Intrauterine device; Insertion; Pain; Experience

INTRODUCTION

Contraception is provided free of charge to women in the UK under the National Health Service (NHS). However, up to a third of pregnancies in the UK are unplanned and abortion rates are high at over 185,000 per year¹. Expert opinion suggests that increased use of long-acting reversible contraception (LARC) could lower unintended pregnancy rates². Intrauterine contraception is one such LARC, but its uptake in the UK is still low³ despite being the most commonly used LARC worldwide⁴ and associated with high continuation rates⁵⁻⁷.

Current recommendations are that women wishing to use intrauterine contraception should be given information, counselled and offered available pain relief for the insertion procedure.^{8,9} More information on the experiences of women undergoing intrauterine device insertions (patients) and observations of health professionals (providers) regarding the degree of pain or discomfort women experience will be useful. Exploring patients' experiences and providers' observations under current practice will facilitate further understanding of women's experiences, provide information for prospective intrauterine contraception users and potentially stimulate more research. Such information may also guide providers who contend that they can accurately predict women's sensitivity to pain and requirement of pain relief for intrauterine device (IUD) insertion procedures.

We carried out a study to determine the pain or discomfort, if any, experienced by women having an IUD (either a T-shaped copper or levonorgestrel impregnated intrauterine device) inserted under our current practice and the extent to which this agreed with estimates of the women's pain or discomfort by the health professionals inserting the device. We also examined whether any pain or discomfort experienced was related to or influenced by the age, gravidity, or parity of the woman.

METHODS

A survey was performed of both patients and providers to measure the extent of anxiety before and degree of pain during IUD insertion as recalled by the women and as perceived by their health professionals respectively. Women aged 16 or older, literate in English and seeking intrauterine contraception and who gave consent to complete a questionnaire concerning their experience at insertion, were eligible.

Because no standardised questionnaires are available for determining pain or discomfort with IUD, specific questionnaires were developed for this study which were validated and pre-tested before commencement of the study. These questionnaires were designed for (1) health professionals who had inserted IUDs at our health service during the study period, and (2) those women who had IUD insertions at our service during the study period. Questionnaires, designated as 1 and 2, were printed on papers of different colours for easy identification. Each questionnaire was numbered so as to enable them to be paired subsequently after completion. Both health professionals and women were asked to rate the woman's anxiety before the procedure with the following scores: 1 representing very anxious, 2 a little anxious and 3 not anxious at all. A woman's overall experience of the IUD insertion procedure was scaled from 1 to 3 with 1 representing painful, 2 uncomfortable and 3 minimal or no discomfort or nothing. How painful a woman found the procedure was scored on a numerical

rating scale of 0 to 10, where 0 represented no pain at all and ranged up to 10, the worst pain imaginable. Additionally, health professionals documented the use of local anaesthesia while women provided demographic details and obstetric history. No participant identifiable data was recorded or collected on any of the questionnaires. The setting for this study was a London sexual and reproductive health (SRH) service which performed about a hundred IUD insertions per month and had an established practice of routinely offering patients local anaesthesia for IUD insertions. Local anaesthesia available in this service consisted of 2% Lidocaine gel (11 ml, Instillagel[®]) used topically and/or 3% Plain Mepivacaine (2.2 ml, Scandonest[®]) by intracervical injection. Ethical approval for this study was granted following review by the County Durham and Tees Valley Research Ethics Committee, UK. Local NHS Research and Development approval was obtained from the North Central London Research Consortium. Cardiff University acted as sponsor for this study. Health professionals who performed IUD insertions at the service were informed about the study by email and at a staff meeting prior to the study start date. The SRH service staff placed attached copies of Questionnaire 1 and 2 and their respective information sheets in the patient folders of each woman who attended for IUD insertion. Upon completion of the insertion procedure and consultation, the health professional informed each woman of the survey, detached Questionnaire 2 with its information sheet and handed it to her. The women were assured that the completed questionnaire could not be identified with any individual. Women interested in the study read the participant information sheet and completed Questionnaire 2 in a waiting area outside the consultation room. Health professionals willing to participate in the study completed Questionnaire 1 while still in the consultation room but after the woman had left. Persons who declined participation were not required to return the questionnaire, or could return it blank. Questionnaires were returned to a labelled box in the patient waiting area.

DATA ANALYSIS

All women who responded were included in the pertinent analyses. The variables collected from patients were age, previous pregnancy and previous vaginal delivery. The outcome variables were anxiety, overall experience and pain scores obtained from both patients and providers. Anxiety and overall experience were rated using an ordinal scale. Pain level was rated using an 11-point (0 to 10) numerical rating scale (NRS). Reported pain scores were further grouped into categories of mild (0 – 3), moderate (4 – 6) and severe pain (7 – 10) for easier communication of the results. To compare reported pain scores of patients and providers overall and by women's age, gravidity and parity, and to compare patients' and providers' reported anxiety levels before insertion and overall experience of the IUD insertion procedure, the Wilcoxon test for matched-pairs was applied. In order to probe the relationship between each age group, previous pregnancy and previous vaginal delivery; and each patient's pain score and their provider's perceived pain score, Kruskal-Wallis equality-of-populations rank test or Mann-Whitney test was employed as appropriate.

To evaluate agreement between patients' and providers' reported anxiety before insertion, overall experience of the IUD insertion procedure and pain scores, chi-squared kappa statistics were used. A *kappa coefficient* is a statistical measure of agreement between two independent observers. A *kappa* of 1 indicates total agreement, a *kappa* of 0 indicates agreement equivalent to that obtainable purely by chance while a *kappa* of -1 indicates total disagreement. *Kappa* values ranging from 0.01 – 0.20 and 0.21 – 0.40 were considered as 'slight agreement' or 'fair agreement' respectively¹⁰. All analyses were performed using StataSE 12, with a significance level of $\leq 5\%$.

RESULTS

A total of 284 questionnaires were returned. Partially completed questionnaires were included for the questions that had been answered. Seven paired responses (14 questionnaires) were excluded because they were found to be still attached (if the woman questionnaire was not separated from the health professional questionnaire, then they may not have been completed confidentially). This gave a response rate of 77% respectively in both women ($n = 135$) and health professionals ($n = 135$). Each questionnaire from a woman (patient) was subsequently paired with its counterpart health professional (provider) questionnaire where available. For comparisons of responses obtained from patients and their providers, 129 paired responses were obtained for anxiety and overall experience respectively and 126 for reported pain scores. Women in the 25 – 34 age group formed the majority (54%), with no participants in the age range 16 – 19; 73% had never had a vaginal delivery and 54% had never been pregnant (Table 1). The preponderance of women reported feeling a little anxious before their IUD insertion procedure (65%). A total of 41% described their insertion as being associated with ‘minimal discomfort/nothing’. The same percentage, 41 (but with one less woman), described the insertion as ‘uncomfortable’. Health professionals considered that most (56%) of the women felt a little anxious before the procedure and perceived ‘minimal discomfort/nothing’ during the insertion. The providers also reported that 33% of the women had been ‘uncomfortable’ during the insertion. Reported pain score distribution of patients and their providers was not similar (Figure 1). Most pain scores reported by patients were higher (median [interquartile range, IQR]: 4 [2 – 6]) than the pain scores reported by their providers (3 [2 – 4]), and irrespective of whether the woman had been previously pregnant or had had a vaginal delivery in the past. The differences in patients’ and providers’ reported pain scores were found to be statistically significant ($p < 0.001$; Table 2).

When pain score responses were grouped into categories of mild (0 – 3), moderate (4 – 6) and severe pain (7 – 10), 43% ($n = 58$) of women reported experiencing mild pain, 40% ($n = 54$) moderate pain and the remainder severe pain (17%, $n = 22$). These ratios were similar to the descriptions of their overall experience of the IUD insertion procedure. Patients’ descriptions of their overall experience of the IUD insertion procedure were significantly different when the comparison was based on previous pregnancy ($p < 0.002$) and previous vaginal delivery ($p = 0.007$), but they were not found to be related to their reported anxiety level before the procedure ($p = 0.601$). Providers’ perception of women’s overall experiences on the other hand was only significantly different when the comparison was based on previous vaginal delivery ($p < 0.01$).

Patients’ anxiety, overall experiences and pain scores were further compared with those as perceived by their providers for agreement. There was slight to fair agreement on anxiety levels ($k = 0.194$ [0.06 – 0.35]) and reported pain scores ($k = 0.167$ [0.13 – 0.24]) and fair to slight agreement ($k = 0.251$ [0.13 – 0.37]) on overall experiences of the IUD insertion procedure (Table 3).

Local anaesthesia was used for 93% of the IUD insertions with the majority (80%) of patient participants having received injectable local anaesthetic alone and very few (3%) having had both topical gel and injectable local anaesthetic administered. In the case of those patients who received topical gel alone (10%) the mean topical gel contact time before insertion was 2 minutes. The pain experienced by the 10 patients (7%) who did not have local anaesthesia

with their IUD insertion was reported by these patients as mainly minimal or nothing ($n = 5$), with their pain scores ranging from 0 to 8. Most of these women had been pregnant before ($n = 8$) and half of them had had a previous vaginal delivery ($n = 5$).

DISCUSSION

Findings and interpretation

This study indicated that where local anaesthesia was used routinely, most women reported mild pain with IUD insertion, and described the procedure overall as being associated with minimal or no discomfort. Women who experienced moderate pain according to their pain scores, mainly described their procedure as being ‘uncomfortable’, rather than ‘painful’. This suggested that the IUD insertion procedure was tolerated by the majority of these women irrespective of age, gravidity or parity. Health professionals’ perceptions were similar to the women’s reports of pain, though there was disparity in their assessments in approximately half of the cases. This suggests that although the providers were sensitive to the patients’ experience during the procedure, they were not consistently accurate in their assessment of the severity of patients’ pain.

Strengths and weaknesses

The present investigation had the following strengths. Pain score responses were grouped into the categories of mild (0 – 3), moderate (4 – 6) or severe (7 – 10) pain. These are readily understandable labels of pain severity used in clinical settings. It was also for the reason of clarity that words like ‘painful’ and ‘uncomfortable’ were options to describe any pain experienced, since these terms are also commonly used by patients and providers in the study setting. An 11-point (0 – 10) numerical rating scale (NRS) was used in the questionnaires administered after the IUD insertion procedure rather than employing a visual analogue scale (VAS) administered upon IUD placement. This was to ensure minimal interference with the consultation routine as well as maximising the objectivity and confidentiality of patients’ responses since provider explanation of a VAS might introduce bias. Previous comparisons have found fewer practical difficulties with NRS than VAS, and NRS has proved just as sensitive as VAS in assessing pain in gynaecology.^{11–14}

The present investigation took place in an SRH service with women and health professionals who consented to take part. While systematic differences between those who consented to take part and those who did not cannot be ruled out, the response rate was relatively high which favours the generalisability of its findings for similar populations. A potential study weakness is asking questions about anxiety experienced before the IUD insertion immediately after the procedure, as this introduces the possibility of recall bias. Although the relevant time period was short (typically ten minutes or less between IUD placement and completion of the questionnaire), the overall insertion experience could have affected women’s perception of their anxiety level before the procedure. This time lapse could possibly have also affected women’s reported overall experience and pain scores. As only four insertions did not use local anaesthesia, meaningful comparison of overall IUD insertion pain with use and non-use of local anaesthesia was not possible.

The prevalence of injectable local anaesthesia use here may not be applicable to most providers of intrauterine contraception. Furthermore, by the design of this study it cannot be ascertained if the pain experienced by patient participants was influenced by the use of local anaesthesia, or that a similar pain score distribution would be obtained if local anaesthesia

was not used for most of the IUD insertions. This study did not take the opportunity to examine how characteristics of providers may have affected the anxiety, overall experience or pain scores of the patients. This is because the questionnaires for providers were also anonymous.

Differences in results in relation to other studies

This study and its findings appear similar to a recently published secondary analysis of pain reported in a trial of intracervical lidocaine gel for IUD insertion by Maguire *et al.*¹⁵. Their providers' assessment of maximum pain during IUD insertion was found to be significantly lower than the maximum reported to have been experienced by the patients ($p < 0.001$) with a moderately positive correlation (Spearman's rho 0.53, $p < 0.001$). Their trial also involved both copper and levonorgestrel-impregnated intrauterine devices, use of local anaesthesia and pain assessment on a numerical rating scale. In another study of 93 nulliparous women over 10 months, Berger *et al.* (1976)¹⁶ found an even greater disparity between the percentage of patients (6.5%) who the health professionals identified as having experienced severe pain with IUD insertion and those patients (41.2%) who actually reported severe pain. However their result may have been biased by: the insertion of larger devices in 55 of the participants (Lippes loops A or B were inserted in 27 women, and the Dalkon shield in 28 women); all participants having been nulliparous; as well as patients' reporting of total pain experienced with IUD insertion after they had left the clinic while the health professionals on the other hand had assessed pain with the IUD insertion procedure only¹⁶. We avoided this last possible bias by asking both patients and providers for overall experience and pain, and to complete their questionnaires just after the consultation in the clinic and at the same time.

Our study findings may be more applicable to routine practice than those of other studies. There were no exclusion criteria based on age or recent delivery and most patients were either nulligravid or nulliparous. Also, confidential reporting and anonymity of patients was ensured by using a self-explanatory numerical rating scale for pain measurement, rather than using a visual analogue scale that will have required an assistant. Nulligravidity and nulliparity were identified as pain predictors similar to previous large randomized and case control studies^{17,18} but pain scores obtained here were higher than in these previous studies despite the use of local anaesthesia for the majority of IUD insertions. Cultural background may be a factor influencing outcomes. Lower levels of pain have been observed in Chile¹⁷, Denmark¹⁹ and developing countries^{20,21} in comparison to the United Kingdom²² and Sweden²³.

Relevance of findings: Implications for clinicians and policymakers

Despite the finding that severity of pain experienced by women in this study was not related to their anxiety, there is evidence to show that the psyche has a role to play²⁴. Less anxious and better informed patients suffer less pain than their more anxious counterparts^{22,25,26}. Therapies including analgesia, lavender and 'verbal anaesthesia' have been used and recommended respectively to reduce anxiety and pain perceived by patients during IUD insertion^{22,27,28}.

Though pain may be a valid reason for some women not to embrace a very effective method of contraception, the provision of intrauterine contraception appears to be acceptable to most women when performed according to recommended practice^{8,9}. This involves reducing pain by a holistic approach that includes the option of local anaesthesia, as depicted in this study. Use of local anaesthesia should be considered by health professionals who perform IUD

insertions and discussed with women who choose to use intrauterine contraception until more efficacious means of pain relief are identified.

Unanswered questions and future research

Further study of how providers can better predict and manage patients' pain with IUD insertion is required, especially for nulligravid and nulliparous women who have been identified as likely to experience more pain than their counterparts. Also, there are no published studies on the use of 3% Plain Mepivacaine (2.2 ml, Scandonest[®]) as a local anaesthetic for IUD insertion and this study was not designed to evaluate its ability to reduce pain with the insertion procedure. This product could be further investigated as the search for effective analgesia for insertion of intrauterine contraception continues.

CONCLUSION

This study on the pain and/or discomfort experienced by women having the insertion of an intrauterine method of contraception, most of whom had local anaesthesia, suggests that most women and their health professionals found the procedure acceptable. However, health professionals should be aware that women may experience a greater degree of pain during the procedure than providers may perceive, a difference which health professionals should consider in their management of these women.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Table 1 Characteristics of women who participated in the study of pain at IUD insertion.

<i>Characteristic</i>	<i>Groups</i>	<i>n</i>	<i>%</i>
Age*	20–24 years	27	20
	25–34 years	73	54
	≥ 35 years	35	26
Previous pregnancy [†]	No	72	54
	Yes	62	46
Previous vaginal delivery [‡]	No	97	73
	Yes	36	27

*135 women reported their age

[†]134 women reported on ever being pregnant or not

[‡]133 women reported on ever having a vaginal delivery or not

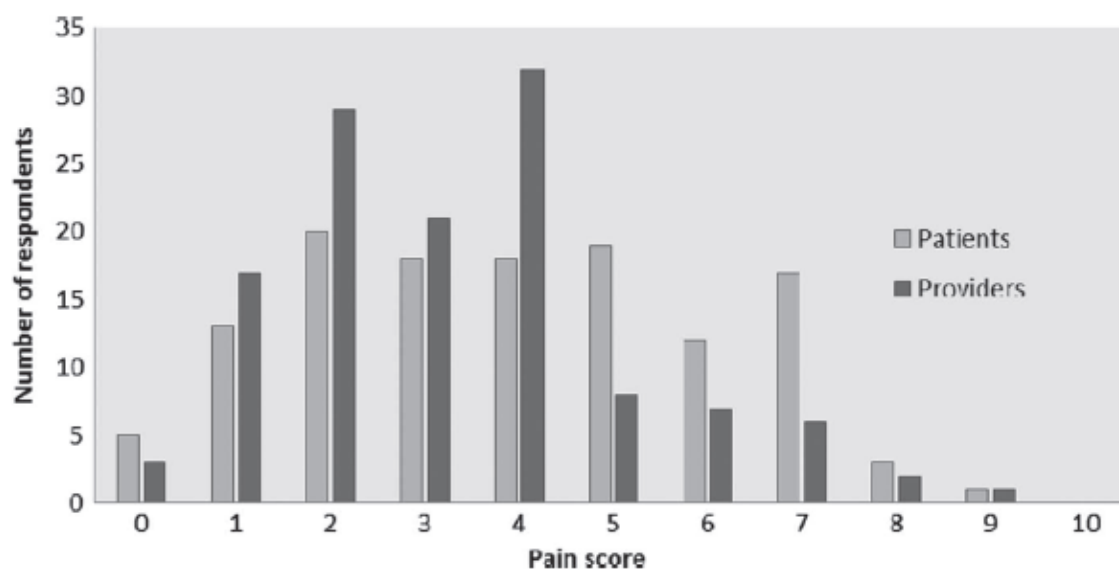


Figure 1 Distribution of pain scores reported by patients and providers.

Table 2 Reported anxiety, overall experiences of pain, and pain scores by patients and providers.

<i>Experience</i>	<i>Scores</i>	<i>Patients</i>		<i>Providers</i>		<i>p-value*</i>
		<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	
Anxiety before IUD insertion (3 score levels)	Very anxious	25	19	21	16	p = 0.003
	Little anxious	85	66	70	54	
	Not anxious at all	19	15	38	30	
	Total	129	100	129	100	
Overall experience of pain during IUD insertion (3 score levels)	Painful	23	18	14	11	p = 0.003
	Uncomfortable	51	39	43	33	
	Minimal discomfort or nothing	55	43	72	56	
	Total	129	100	129	100	
Pain level during IUD insertion (11 score levels)	0	5	4	3	4	p < 0.001
	1	13	10	17	10	
	2	20	16	29	16	
	3	18	14	21	14	
	4	18	14	32	14	
	5	19	15	8	15	
	6	12	10	7	10	
	7	17	13	6	13	
	8	3	2	2	2	
	9	1	1	1	1	
	10	0	-	0	-	
Total	126	100	126	100		

*p-values derived from Wilcoxon's test for matched pairs

Table 3 Agreement between patients' and providers' reports of anxiety, overall experience of pain and pain scores before and during IUD insertion.

<i>Experience</i>	<i>Relationship of paired scores</i>	<i>Number in groups*</i>		<i>Agreement between groups†</i>
		<i>n</i>	<i>%</i>	
Anxiety before insertion (3 score Levels)	Patient's score > Provider's score	18	14	k = 0.194 CI (0.06–0.35)
	Patient's score = Provider's score	70	54	
	Patient's score < Provider's score	41	32	
	All groups	129	100	
Overall experience of IUD insertion (3 score levels)	Patient's score > Provider's score	18	14	k = 0.251 CI (0.13–0.37)
	Patient's score = Provider's score	70	54	
	Patient's score < Provider's score	41	32	
	All groups	129	100	
Pain level during IUD insertion (11 score levels)	Patient's score > Provider's score	64	51	k = 0.167 CI (0.13–0.24)
	Patient's score = Provider's score	35	28	
	Patient's score < Provider's score	27	21	
	All groups	126	100	

*The values for Anxiety before insertion (first row) and Overall experience of IUD insertion (second row) have been checked to be accurate at several levels of review and found to be coincidentally the same.

†Chi-squared kappa statistics