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RESEARCH ARTICLE

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Insertion experience of women and health care professionals in the Kyleena® Satisfaction Study

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ABSTRACT

Purpose: The Kyleena® Satisfaction Study (KYSS) is a prospective, observational study conducted to assess satisfaction with LNG-IUS 12 (Kyleena®) in clinical practice and aims to provide adequate information for counselling women on what to expect regarding insertion and satisfaction.

Materials and methods: Women deciding to use LNG-IUS 12 during routine counselling were informed of the study and provided informed consent. A baseline analysis was conducted to evaluate demographics, ease of insertion assessed by investigators, pain at insertion rated by women, additional interventions for insertion, and adverse events.

Results: 1,110 women (536 parous, 574 nulliparous) had an insertion attempt and were included. Insertion was rated as easy in 494 (92.2%) parous and 516 (89.9%) nulliparous women. Pain was assessed as none or mild by 475 (88.6%) parous and 387 (67.4%) nulliparous women. Additional interventions were not required for most insertions (705; 63.6%). Overall 111 (10.0%) women reported adverse events at the time of baseline analysis.

Conclusions: This analysis demonstrates that LNG-IUS 12 insertion is easy and associated with no or mild pain in most women. Additional interventions for insertion are not required in most cases. After 3 months, the number of adverse events is low.

Implications: The present baseline analysis of the Kyleena® Satisfaction Study (KYSS) demonstrates that most women rate insertion pain of LNG-IUS 12 as none or mild and clinicians consider insertion easy in the majority of cases.

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Introduction

Intrauterine contraception (IUC) is highly effective and associated with low rates of unintended pregnancy [1,2]. However, this form of contraception is not widely used, despite being recommended in clinical guidelines [3–8]. This may be due to particular concerns around difficulty and pain relating to insertion of IUC in nulliparous women [9]. These fears are rarely evidence-based, and favourable safety and efficacy profiles have been demonstrated in nulliparous and young women as well as parous women [10–14]. Fear of pain during the insertion procedure is often perceived as a barrier by women considering IUC; providing information and reassurance on the insertion procedure can reduce anxiety and consequently the pain experienced during insertion [15–18].

Results from clinical trials of levonorgestrel intrauterine delivery system (LNG-IUS) 12 (Kyleena®) have shown that the majority of women report no or mild pain during insertion, and insertion is considered easy by most health care professionals (HCPs) [19,20]. It is important to supplement these data from clinical trials with real-world evidence from observational studies that reflect routine clinical practice [21].

The Kyleena® Satisfaction Study (KYSS) will deliver the first evidence on the use of LNG-IUS 12 in a real-world setting. The study has been designed to assess pain at insertion, ease of insertion and satisfaction with LNG-IUS 12 to inform women's expectations of the insertion procedure and satisfaction with the method. The study will also gather information that may help in counselling patients who wish to start contraception with a hormonal IUC or change their contraceptive method. While the study is ongoing, this planned baseline analysis reports demographics and subject characteristics as well as aspects of pain and ease of insertion.

Materials and methods

Study design

The KYSS (NCT03182140) is a prospective, multinational, single-arm, observational study to assess user satisfaction with LNG-IUS 12 in routine clinical practice. Participants were recruited from Belgium, Canada, Germany, Norway, Sweden, Spain and the USA from 2017 to 2018.

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Independent ethics committee/institutional review board approval was obtained for all participating centres.

Study objectives

The primary aim of the study is to evaluate overall satisfaction with LNG-IUS 12 in subgroups of women with different previously used contraceptive methods and different motivations for choice of LNG-IUS 12.

The present baseline analysis was conducted after the last woman completed her initial visit at first attempt of LNG-IUS 12 insertion and aimed to assess LNG-IUS 12 insertion characteristics (i.e., ease of insertion judged by investigators and pain at insertion rated by women) as well as present information on demographics, subject characteristics, motivation for change to/choice of LNG-IUS 12, and additional interventions used for insertion. Ease of insertion was assessed by investigators using the observed categories 'easy', 'slightly difficult', and 'very difficult' and pain at insertion assessed by women using the observed categories 'none', 'mild', 'moderate', or 'severe'. The analysis also evaluated adverse events (AEs) and removal of LNG-IUS 12 within the first 3 months after insertion as a proxy for early discontinuation.

Study population

Overall, 1114 women were enrolled in seven countries. The selection of countries and country-specific sample sizes were determined according to feasibility of recruiting. In order to avoid over-representation of any particular region, sites could enrol a maximum of 20 participants each. After informative discussion with their health care provider during a routine medical visit, women who independently decided to use LNG-IUS 12 were informed about the study. Women could have used any other contraceptive methods prior to inclusion (including no contraception, e.g., new users). We included no age restrictions, all women who were eligible for LNG-IUS 12 were able to participate. Written informed consent was obtained for all participants. For children/adolescents, additional consent was obtained and signed by their parent or legal guardian. Exclusion criteria were contraindications for LNG-IUS 12, mental incapacity to consent, and participating in a clinical trial with interventions outside routine clinical practice.

Data collection

Data for the baseline analysis were collected from participant questionnaires at the initial visit, medical records and interviews. Safety data including AEs, pregnancies and reasons for early discontinuation up to 3 months were collected from electronic case report forms completed by HCPs. The 12-month observation period is still ongoing therefore, at the cut-off point for the baseline analysis (i.e., last participant completing initial visit), women could have had different lengths of exposure to LNG-IUS 12 due to recruitment beginning in individual countries at different times.

Following attempted or successful insertion, the participant was asked to complete an initial visit questionnaire, which included questions on demography, gynaecological history, co-morbidities, reason for stopping previous contraceptive method, reasons for choosing LNG-IUS 12, as well as pain at insertion. HCPs were asked to record their rating of ease of insertion, as well as any additional interventions used at insertion (categorized as none, local medication, systemic medication, dilatation, and other) in an electronic case report form. Details of other medications used at insertion were also recorded. For women with an unsuccessful insertion attempt, assessment of pain at and ease of insertion attempt was documented but no follow-up was performed (end of observation).

At a routine follow-up visit at 4–12 weeks following LNG-IUS 12 insertion, a follow-up questionnaire was completed by participants. Follow-up visits at 4–12 weeks were not performed in Norway and Sweden, as these visits are not routine in those countries.

Data analysis

Statistical analyses are of an explorative and descriptive nature. The study is not designed to confirm or reject predefined hypotheses.

The baseline analysis includes data from all patients enrolled before the cut-off point for the data snap-shot in November 2018. Analysis of the overall satisfaction with LNG-IUS 12 after one year of use will be conducted after full end of the study. The endpoints of ease of insertion and pain at insertion were analysed descriptively from the safety analysis set (SAF) with relative frequencies based on the number of non-missing answers (denominator);the Spearman coefficient (r_s) for the correlation between ease of insertion and pain at insertion was also calculated. The SAF includes all women with an insertion attempt, irrespective of whether the attempt was successful. Data are summarized by country, parity and overall.

Early discontinuation rate (defined as within the first 3 months of LNG-IUS 12 use), and reasons for discontinuation are reported from the full analysis set (FAS).

AEs are categorized and summarized according to the relationship to LNG-IUS 12 and seriousness of the AE. The incidence of treatment-emergent AEs is summarized descriptively by Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class and MedDRA Preferred Term. An AE is considered treatment-emergent if it occurred from the day of the first insertion attempt until the end of observation.

Results

Overall 1,114 women were enrolled in the study between July 2017 and the cut-off point for the data snapshot in November 2018. Four women did not return for their insertion visit and therefore are not included in the SAF (n = 1,110). In three other women the first insertion attempt was not successful, leaving 1,107 women for FAS analysis.

Within the SAF, 574/1,110 (51.7%) women were nulliparous and 536 (48.3%) were parous (Table 1). Some form of birth control was used by 814 (73.3%) of women in the 3 months prior to enrolment, with the predominant methods being oral contraceptives (366; 33.0%), barrier methods (168; 15.1%) and IUS (167; 15.0%) (Figure 1).

Table 1. Baseline demographics (safety analysis set).

SAF *N* (%)	Belgium (*N* = 100)	Canada (*N* = 100)	Germany (*N* = 508)	Norway (*N* = 100)	Sweden (*N* = 100)	Spain (*N* = 102)	USA (*N* = 100)	Total (*N* = 1,110)
Age								
≤17	4 (4.0)	12 (12.0)	5 (1.0)	3 (3.0)	2 (2.0)	0 (0.0)	3 (3.0)	29 (2.6)
18–25	51 (51.0)	56 (56.0)	136 (26.8)	39 (39.0)	51 (51.0)	9 (8.8)	54 (54.0)	396 (35.7)
26–35	24 (24.0)	23 (23.0)	184 (36.2)	31 (31.0)	24 (24.0)	35 (34.3)	29 (29.0)	350 (31.5)
>35	21 (21.0)	9 (9.0)	183 (36.0)	27 (27.0)	23 (23.0)	58 (56.9)	14 (14.0)	335 (30.2)
BMI								
<20	11 (13.8)	8 (8.0)	41 (10.1)	8 (9.1)	15 (19.7)	5 (7.4)	7 (7.2)	95 (10.4)
≥20 – <25	49 (61.3)	63 (63.0)	225 (55.6)	52 (59.1)	40 (52.6)	47 (69.1)	37 (38.1)	513 (56.1)
≥25 – <30	16 (20.0)	20 (20.0)	100 (24.7)	21 (23.9)	17 (22.4)	12 (17.6)	33 (34.0)	219 (24.0)
≥30 – <35	4 (5.0)	6 (6.0)	22 (5.4)	2 (2.3)	3 (3.9)	3 (4.4)	9 (9.3)	49 (5.4)
≥35	0 (0.0)	3 (3.0)	17 (4.2)	5 (5.7)	1 (1.3)	1 (1.5)	11 (11.3)	38 (4.2)
Missing	20	0	103	12	24	34	3	196
Parity								
Parous	31 (31.0)	12 (12.0)	305 (60.0)	44 (44.0)	42 (42.0)	73 (71.6)	29 (29.0)	536 (48.3)
Nulliparous	69 (69.0)	88 (88.0)	203 (40.0)	56 (56.0)	58 (58.0)	29 (28.4)	71 (71.0)	574 (51.7)
Previous contraception during last 3 months								
Yes	82 (82.0)	86 (86.0)	383 (75.4)	65 (65.0)	53 (53.0)	78 (76.5)	67 (67.0)	814 (73.3)
No	18 (18.0)	14 (14.0)	125 (24.6)	35 (35.0)	47 (47.0)	24 (23.5)	33 (33.0)	296 (26.7)

BMI, body mass index; SAF, safety analysis set.

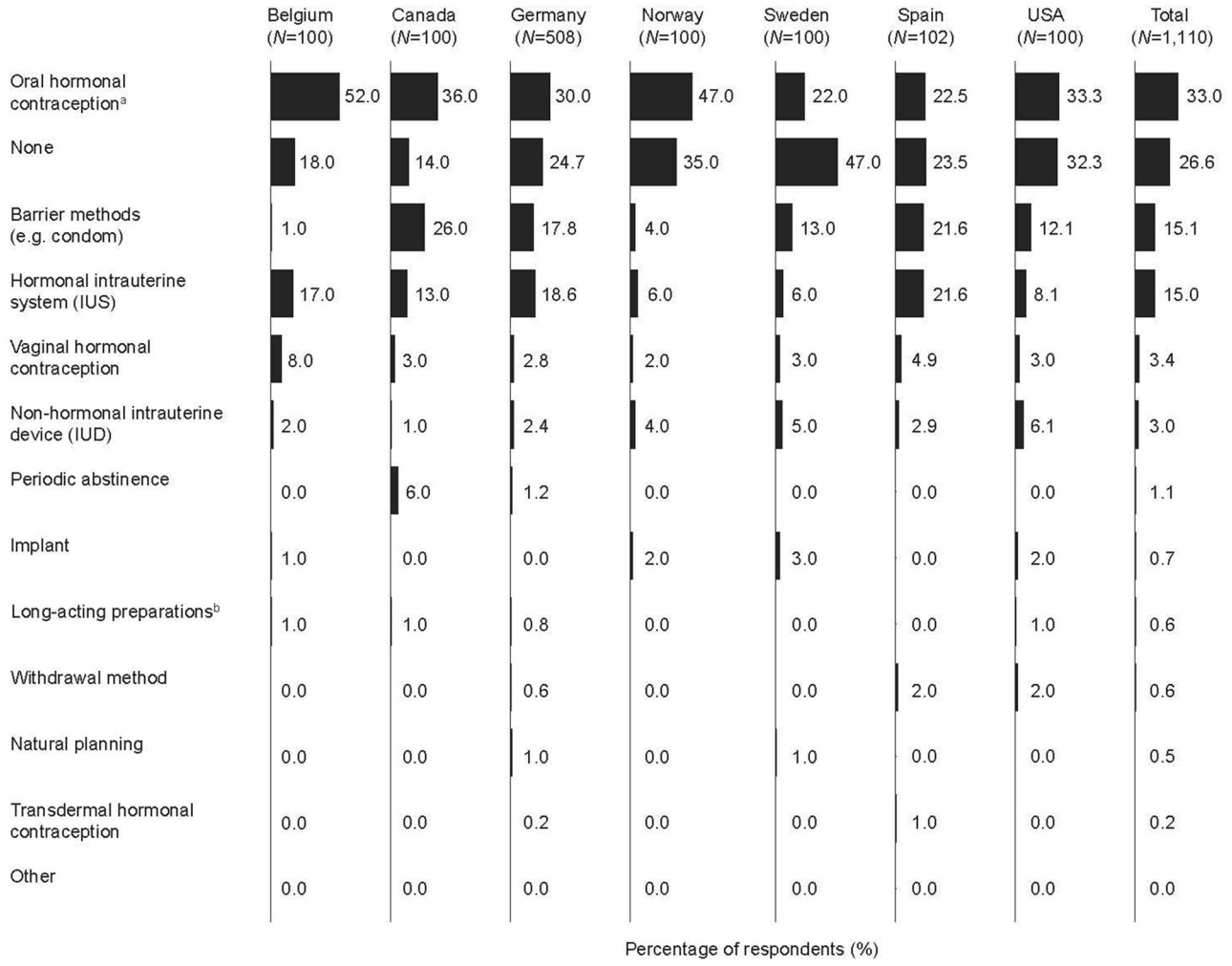

Figure 1. Previous contraceptive method during 3 months prior to insertion (safety analysis set).
[a]COC or POP. COC indicates combined oral contraceptive; POP, progestogen-only pill.
[b]Long acting preparations include methods (e.g., monthly contraceptive injection) other than hormonal or non-hormonal IUC.

Women's three most common reasons for choosing LNG-IUS 12 were: no daily, weekly or monthly contraceptive routine (377; 34.8%), high contraceptive reliability (299; 27.6%) and low hormone dose (288; 26.6%) (Table 2). No daily, weekly or monthly contraceptive routine was the most common reason for choosing LNG-IUS 12 in the majority of countries. In Canada and Sweden, high contraceptive reliability and low hormone dose were the most common reasons, respectively (Table 2).

Investigators rated the majority (n = 1,010; 91.0%) of LNG-IUS 12 insertions as easy (Table 3). Insertion was rated as easy in 516 (89.9%) nulliparous women and 494 (92.2%)

Table 2. Women's main reason for choosing LNG-IUS 12 overall and by country (safety analysis set).

SAF *n* (%)	Belgium (*N* = 100)	Canada (*N* = 100)	Germany (*N* = 508)	Norway (*N* = 100)	Sweden (*N* = 100)	Spain (*N* = 102)	USA (*N* = 100)	Total (*N* = 1,110)
High contraceptive reliability	17 (17.5)	34 (34.0)	157 (32.2)	15 (15.0)	25 (25.0)	28 (28.3)	23 (23.2)	299 (27.6)
No daily, weekly, or monthly contraceptive routine	43 (44.3)	32 (32.0)	169 (34.6)	31 (31.0)	19 (19.0)	33 (33.3)	50 (50.5)	377 (34.8)
Expectation of shorter, lighter, and less-frequent bleeding episodes	26 (26.8)	14 (14.0)	98 (20.1)	20 (20.0)	21 (21.0)	17 (17.2)	12 (12.1)	208 (19.2)
Acts mainly locally	8 (8.2)	6 (6.0)	70 (14.3)	11 (11.0)	5 (5.0)	5 (5.1)	3 (3.0)	108 (10.0)
Low hormone dose	20 (20.6)	21 (21.0)	157 (32.2)	21 (21.0)	39 (39.0)	19 (19.2)	11 (11.1)	288 (26.6)
Estrogen-free contraception	6 (6.2)	14 (14.0)	34 (7.0)	6 (6.0)	5 (5.0)	5 (5.1)	4 (4.0)	74 (6.8)
Small size	9 (9.3)	7 (7.0)	18 (3.7)	10 (10.0)	3 (3.0)	2 (2.0)	8 (8.1)	57 (5.3)
Minimal drug interactions	0 (0.0)	2 (2.0)	17 (3.5)	1 (1.0)	0 (0.0)	4 (4.0)	1 (1.0)	25 (2.3)
Other	10 (10.3)	8 (8.0)	22 (4.5)	4 (4.0)	6 (6.0)	13 (13.1)	4 (4.0)	67 (6.2)
Missing	3	0	20	0	0	3	1	27

LNG-IUS, levonorgestrel intrauterine delivery system; SAF, safety analysis set.

Table 3. Ease of and pain at LNG-IUS 12 insertion overall and by country (safety analysis set).

	Country							Parity		
SAF *N* (%)	Belgium (*N* = 100)	Canada (*N* = 100)	Germany (*N* = 508)	Norway (*N* = 100)	Sweden (*N* = 100)	Spain (*N* = 102)	USA (*N* = 100)	Parous (*N* = 536)	Nulliparous (*N* = 574)	Total (*N* = 1,110)
Ease of insertion assessed by investigator										
Easy	92 (92.0)	89 (89.0)	458 (90.2)	96 (96.0)	97 (97.0)	88 (86.3)	90 (90.0)	494 (92.2)	516 (89.9)	1010 (91.0)
Slightly difficult	8 (8.0)	9 (9.0)	45 (8.9)	3 (3.0)	3 (3.0)	12 (11.8)	7 (7.0)	38 (7.1)	49 (8.5)	87 (7.8)
Very difficult	0 (0.0)	2 (2.0)	5 (1.0)	1 (1.0)	0 (0.0)	2 (2.0)	3 (3.0)	4 (0.7)	9 (1.6)	13 (1.2)
Pain at insertion reported by women										
None	35 (35.0)	5 (5.0)	185 (36.4)	27 (27.0)	15 (15.0)	62 (60.8)	27 (27.0)	260 (48.5)	96 (16.7)	356 (32.1)
Mild	41 (42.0)	63 (63.0)	231 (45.5)	53 (53.0)	44 (44.0)	29 (28.4)	45 (45.0)	215 (40.1)	291 (50.7)	506 (45.6)
Moderate	19 (19.0)	29 (29.0)	72 (14.2)	13 (13.0)	32 (32.0)	10 (9.8)	26 (26.0)	49 (9.1)	152 (26.5)	201 (18.1)
Severe	5 (5.0)	3 (3.0)	20 (3.9)	7 (7.0)	9 (9.0)	1 (1.0)	2 (2.0)	12 (2.2)	35 (6.1)	47 (4.2)
Additional measures used to manage pain at insertion										
None	88 (88.0)	48 (48.0)	301 (59.3)	67 (67.0)	55 (55.0)	82 (80.4)	88 (88.0)	371 (69.3)	334 (58.2)	705 (63.6)
Medication – local	2 (2.0)	16 (16.0)	60 (11.8)	24 (24.0)	0 (0.0)	2 (2.0)	2 (2.0)	43 (8.0)	67 (11.7)	110 (9.9)
Medication – systemic	4 (4.0)	32 (32.0)	110 (21.7)	8 (8.0)	32 (32.0)	6 (5.9)	4 (4.0)	82 (15.3)	129 (22.5)	211 (19.0)
Dilatation	0 (0.0)	3 (3.0)	17 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (1.7)	18 (3.1)	27 (2.4)
Other	6 (6.0)	1 (1.0)	20 (3.9)	1 (1.0)	13 (13.0)	12 (11.8)	6 (6.0)	30 (5.6)	26 (4.5)	56 (5.0)
Missing	0	0	0	0	0	0	1	1	0	1

LNG-IUS, levonorgestrel intrauterine delivery system; SAF, safety analysis set.

parous women (Fig.2A). Additional interventions for insertion were not required in 63.6% (n = 705) women (Table 3). Supplementary systemic medication (e.g., non-steroidal anti-inflammatory drugs (NSAIDs)) was used in 211 (19.0%) women overall, while local medication was used in 110 (9.9%) and cervical dilatation prior to insertion in 27 (2.4%) of procedures. Local anaesthesia combined with systemic pain medication, or cervical dilatation in combination with systemic pain medication were used in 5.0% of women. No additional interventions were used in 371 (69.3%) of insertions in parous, versus in 334 (58.2%) in nulliparous women. Pharmacological interventions at or around the time of insertion such as cervical priming, cervical anaesthesia, analgesia or antibiotics for infection prophylaxis were applied in 104 (26.2%) parous and 201 (35.3%) nulliparous women.

Pain at insertion was rated as none or mild by 862 (77.7%), moderate by 201 (18.1%) and severe by 47 (4.2%) women (Table 3). Overall, 260 (48.5%) parous and 96 (16.7%) nulliparous women reported no pain at insertion, while 215 (40.1%) and 291 (50.7%) women reported mild pain, respectively (Fig.2B). Moderate pain was reported in 49 (9.1%) parous and 152 (26.5%) nulliparous women. When insertion was rated as easy by investigators, most women (823; 81.5%) reported pain as none or mild. Overall, 100 (9.0%) insertions were assessed as slightly or very difficult by investigators. Women reported more pain if the healthcare provider rated the insertion as slightly difficult or very difficult (r_s, 0.23; Fig.3). Use of systemic medication at insertion was reported more often among women with moderate or severe pain at insertion than among those with mild or no pain (Fig.4).

At the time of this baseline analysis, 111 (10.0%) women reported an AE, 84 (7.6%) of them having a study drug-related AE. No uterine perforation was recorded. Bleeding-related AEs such as excessive or abnormal uterine bleeding and uterine haemorrhage were reported in 34 (3.1%) women. A total of 4 (0.4%) women reported serious AEs – one woman with a long history of condyloma was diagnosed with cervical carcinoma *in situ* about 6.5 months after LNG-IUS 12 placement, a woman with chronic sinusitis underwent functional endoscopic sinus surgery, and one participant with a history of morbid obesity and diabetes suffered from hypertension and retinal detachment. These serious adverse events were assessed by investigators as unrelated to LNG-IUS 12. Another woman was diagnosed as 6-weeks pregnant about 6 months after LNG-IUS 12 placement. The pregnancy aborted spontaneously and was classified as a serious AE. The pregnancy and abortion were assessed by the investigator as being related to LNG-IUS 12.

Removal of the device within 3 months after insertion was considered as a proxy for 'early discontinuation' rate. This follow-up information was available for 1,101 women following successful LNG-IUS 12 insertion (99.5%). Twenty-four (2.2%) of them had the LNG-IUS 12 removed, 4 (0.36%) due to expulsion of the device, 1 (0.09%) due to a decision to switch to another contraceptive method, 1

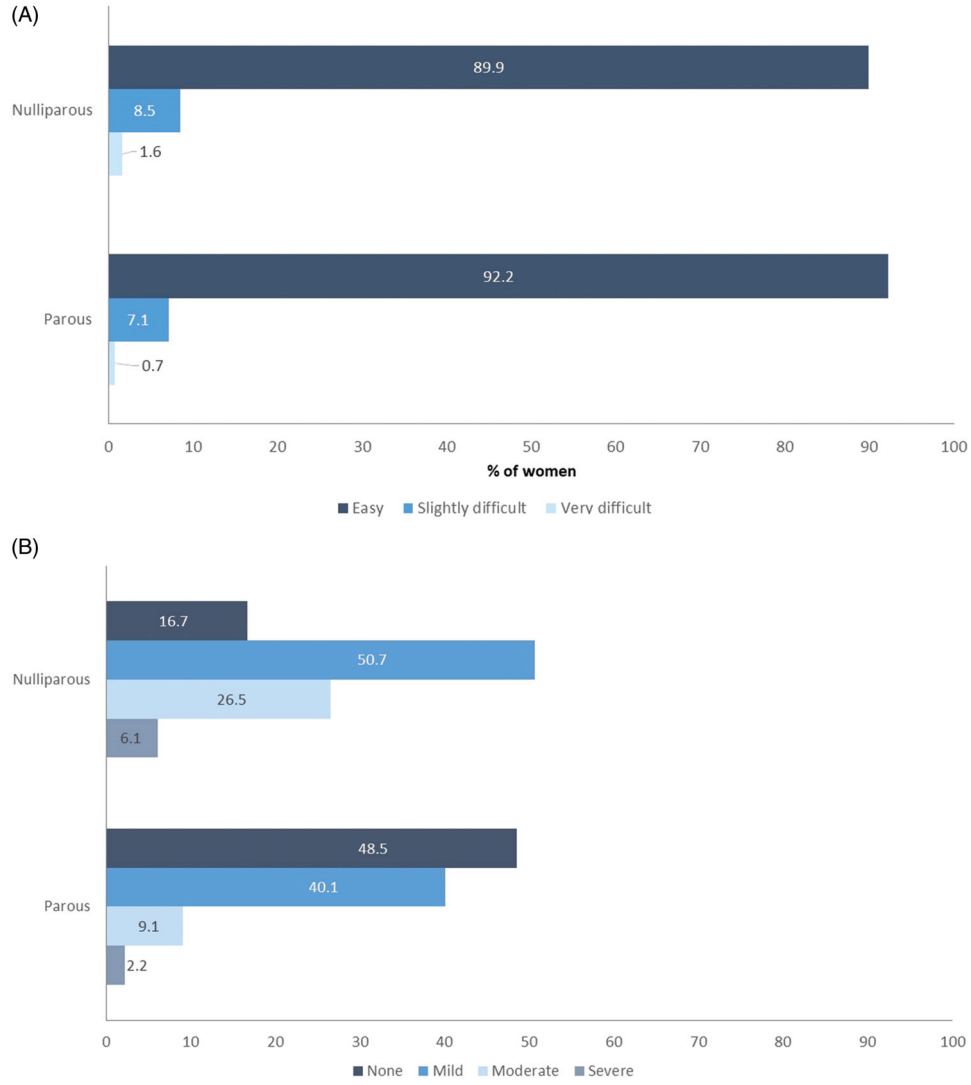

Figure 2. (A) Ease of insertion assessed by investigator, by parity (safety analysis set). (B) Pain at insertion assessed by women, by parity (safety analysis set).

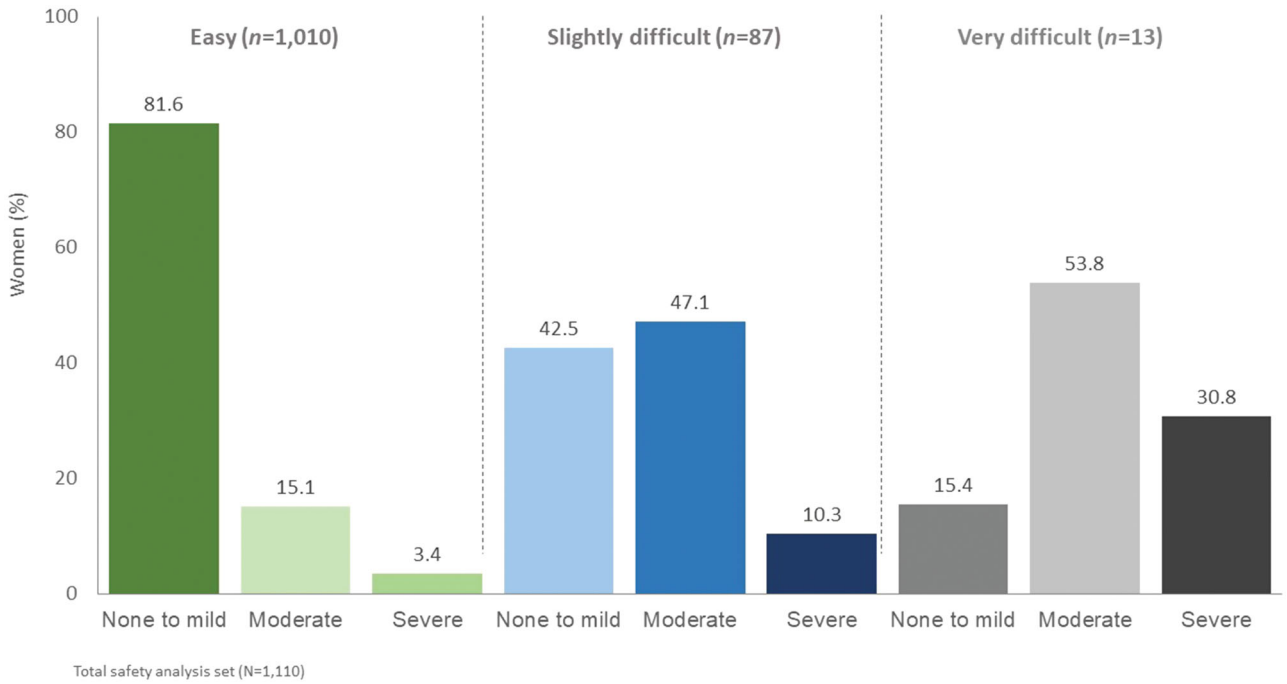

Figure 3. Women's rating of pain at insertion by ease of insertion (safety analysis set).

(0.09%) due to dissatisfaction with LNG-IUS 12 and 18 (1.6%) due to AEs. AEs leading to LNG-IUS 12 removal included pelvic pain (N = 3; 0.3% of women), uterine haemorrhage (N = 3; 0.3%), lower abdominal pain (N = 3; 0.3%), mood swings (N = 2; 0.2%), acne (N = 2; 0.2%), excessive or abnormal uterine bleeding (N = 2; 0.2), dysmenorrhea (N = 1; 0.09%), panic attack (N = 1; 0.09%), depression (N = 1; 0.09%), headache (N = 1; 0.09%) and nausea (N = 1; 0.09%). Nine women (0.8%) had LNG-IUS 12 removed due to multiple AEs.

Discussion

Findings and interpretation

The present analysis of baseline data from the KYSS provides the first real-world evidence on the use of LNG-IUS 12 in clinical practice. Insertions were rated as easy in the majority of women. Most women reported none or mild pain when the insertion was rated as easy by investigators, supporting findings from previous clinical trials which demonstrated insertion of LNG-IUS 12 is considered easy and associated with none or mild pain by most healthcare providers and women [19,20]. Intervention with systemic pain medication at the time of insertion occurred in just under 50% of women, and more frequently among those reporting moderate or severe pain than those with mild or no pain. Currently, there are no comparative studies of pain and systemic medication use at insertion between IUC of different sizes or insertion tube diameters. Data from one randomised controlled trial of LNG-IUS 12, LNG-IUS 8 and LNG-IUS 20 however, do indicate that insertions may be considered easier and less painful with the smaller LNG-IUS 12 and 8 devices, both of which have t-body frames and insertion tube diameters smaller than the LNG-IUS 20 [19]. Further studies designed to comparatively assess the relationship between device size, insertion tube diameter and the pain, ease and requirement for additional pain interventions at insertion may be useful.

Adverse events, including uterine bleeding-related adverse events, were uncommon. There was one pregnancy during the study that aborted spontaneously. A pregnancy test should be undertaken before LNG-IUS-12 is inserted [22], however the timing of this pregnancy (about 6 months after insertion) could suggest that the device may have been partially expelled.

Strengths and weaknesses

The results may not be generalizable to all populations in all countries, because this study was not designed to investigate the influence of age, race, ethnicity, education level or socioeconomic status on women's decision to initiate or change contraception or have the device removed. From observational studies we know that these factors may influence a woman's choices regarding contraception [23,24].

For women whose prior contraceptive method was an IUS, data on the timing of previous device removal and insertion of new LNG-IUS 12 was not collected and a subgroup analysis of insertion pain by previous contraceptive method was not performed. It would be interesting to collect this information in future studies as it may facilitate further assessment of the relationship between previous IUS insertion and pain experienced at next insertion, as well as the impact of combining removal and replacement of IUS in the same visit on the pain reported by women.

Similarities and differences in relation to other studies

Previously published data have indicated a significant association between ease of insertion assessed by the HCP and

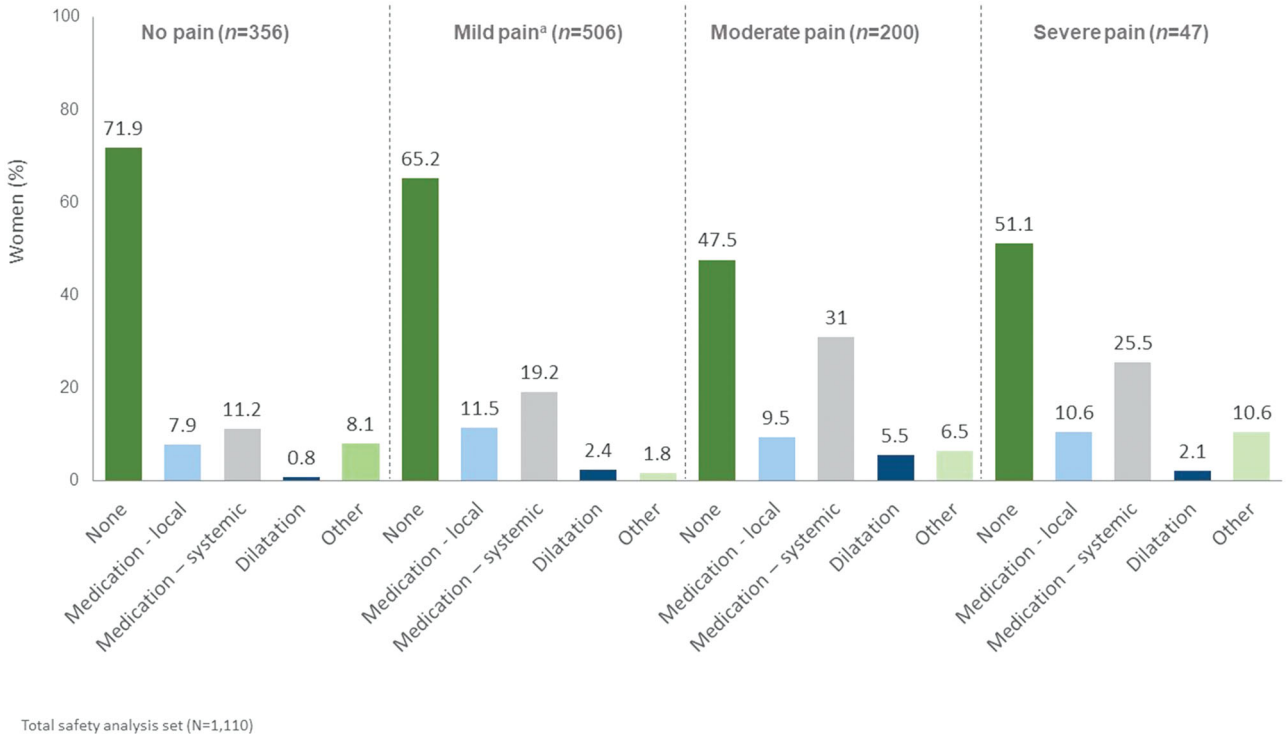

Figure 4. Additional methods used by health care professionals to manage pain at insertion, by pain at insertion (safety analysis set).
[a]One patient in the moderate pain category had missing information for additional interventions.

the pain experienced by the woman [25]. We observed that when insertion was rated as easy by the HCP, over 80% of women reported none or mild pain. This proportion decreased to 42.5% for insertions that were rated as slightly difficult and to less than 15% for insertions that were very difficult. Physician familiarity and confidence with the procedure may play important role, and appropriate training should be given to all healthcare providers who insert LNG-IUS 12 to ensure expertise.

To provide effective counselling it is important to have a thorough understanding not only of contraceptive methods, but also of an individual's perceptions and needs. Effectiveness is considered to be the most important factor when choosing a contraceptive method [26] and in the present analysis, high contraceptive reliability was among women's top three reasons for choosing LNG-IUS 12 alongside no daily, weekly or monthly contraceptive routine and low hormone dose. The efficacy of long-acting reversible contraception and particularly hormonal IUC is often underestimated however, and some HCPs may not include these methods in their counselling, especially for nulliparous women [9,14,26]. Training programs to increase HCPs' knowledge of IUC may be beneficial in encouraging more clinicians to discuss IUC with women [27]. Evidence from observational studies in routine clinical practice such as KYSS also demonstrate the acceptability of LNG-IUS 12 to young and nulliparous women and should further encourage clinicians to include these effective options in their contraceptive counselling.

In the majority of women in our study, no additional interventions for insertion were required and local or systemic medication (or a combination of the two) was used most often in insertions where pain was rated as moderate or severe by women, or the difficulty of insertion was rated as difficult by the physician. Despite the importance of proper management of pain during insertion, there are no universal guidelines on the appropriate dose, timing, and route of administration of various substances (analgesics or otherwise), nor their efficacy [28]. Additionally, the use of prophylactic analgesia to manage insertion pain is debated, though some studies have suggested a modest beneficial effect [25,29,30]. Anxiety regarding IUC insertion and anticipation of pain are associated with an increased pain perception and may partly explain the variable levels of pain at insertion experienced by individuals [15]. Prior to IUC insertion, HCPs should offer reassurance and information about what to expect and, during the procedure, be prepared to take measures to reduce pain and discomfort if required [15].

At 3 month post insertion, a low number of AEs, including uterine bleeding events, were reported. The AEs are consistent with the safety profile of LNG-IUS 12 and other LNG- containing IUS [12,19,20,31]. Changes in menstrual bleeding patterns are common in LNG-releasing IUS users and impact on method continuation, particularly within first 3 months [32,33].

Future research

This baseline analysis represents the first evidence on the use of LNG-IUS 12 in routine clinical practice, and shows high initial acceptability of LNG-IUS 12 insertion. This should help to give further confidence to HCPs when considering the insertion of LNG-IUS 12, particularly in young and nulliparous women.

Providing counselling around bleeding profile following insertion is important to set realistic expectations, improve user satisfaction and reduce the likelihood of early discontinuation [34]. In this study, women received informative counselling during their initial visit, and were encouraged to consult with their HCP if they had any questions or concerns. Future full analysis of our data will examine women's satisfaction with the menstrual bleeding profile of LNG-IUS 12 and enable more effective counselling on this aspect.

Further data from the main analysis of the KYSS will add to the understanding of factors influencing acceptability, satisfaction and continued use.

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Disclosure of interest

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