Journal of Gynecology Obstetrics and Human Reproduction 48 (2019) 719–725

Available online at
ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com/en

Original Article

A prospective, randomized study evaluating the pain felt during intrauterine device insertion by the direct technique vs conventional technique

Djazia Rahou Aissat[a], Delphine Veillard[a], Tiphaine Raia Barjat[b,c], Manuela Munoz[b], Sébastien Bruel[a], Beatrice Trombert[d], Céline Chauleur[b,c,*]

[a] General Medicine Department, Jacques Lisfranc Faculty of Medicine, University of Saint-Etienne, 10 rue de Marandière, 42270 Saint-Priest en Jarez, France
[b] Gynecology and Obstetrics Department, Saint-Etienne University Hospital Center, North Hospital, avenue Albert Raimond, 42270 Saint Priest en Jarez, France
[c] INSERM, SAINBIOSE, U1059, Vascular Dysfunction and Hemostasis, Jean-Monnet University of Saint-Etienne, CIC1408, 42055 Saint-Etienne, France
[d] Public Health Department, Saint Etienne University Hospital Center, North Hospital, avenue Albert Raimond, 42270 Saint Priest en Jarez, France

ARTICLE INFO

Article history:
Received 31 January 2019
Received in revised form 2 May 2019
Accepted 7 May 2019
Available online 9 May 2019

Keywords:
Intrauterine device
IUD insertion
Pain
Direct technique
Conventional technique

ABSTRACT

Objective: To assess the value of the direct insertion technique compared to the conventional insertion technique in reducing the pain experienced during placement of an intrauterine device (IUD).
Methods: A prospective, controlled, randomized, single-blind trial was conducted in women eligible for IUD insertion. Participants were randomized into two groups: "conventional placement" and "direct placement". The primary endpoint was the percentage of women reporting pain scored as ≥ 4 on the Numerical Verbal Rating Scale (NVRS) at IUD release. Secondary endpoints comprised the number of immediate incidents (insertion failure, vasovagal reaction, and IUD expulsion), the correct positioning of the IUD, checked by ultrasound, the occurrence of incidents within the week following IUD insertion, and the operators' evaluation of the procedure.
Results: A total of 60 patients were enrolled. During IUD insertion, 27 women (45.8%) reported an NVRS score ≥ 4, 32.1% in the "direct placement" group and 58.1% in the "conventional placement" group ($p = 0.07$). The median NVRS pain scores in the "direct placement" and "classic placement" groups were 2 and 4, respectively ($p = 0.01$). No statistically significant between-group differences were found with regard to the secondary endpoints.
Conclusion: Use of the direct technique reduced the pain experienced during IUD placement. We observed a trend towards a decreased proportion of patients reporting an NVRS pain score ≥ 4 at IUD release with use of the direct technique and the median pain intensity scored on the NVRS was significantly lower in this group. The two techniques did not differ with respect to complications.
© 2019 Elsevier Masson SAS. All rights reserved.

Introduction

Use of an intrauterine device (IUD) is one of the most effective methods of contraception (Pearl index between 0.2 and 0.8%), with a long-lasting action and few contraindications [1]. The most recent data published by Santé Public France in September 2017 revealed its use by 4.7% of women aged 20–24 years, this method gradually supplanting use of an oral contraceptive. The proportion of women using an IUD increased with age and was higher among women who had already given birth. Among women aged 25–29 years, only 7.6% of nulliparous women used an IUD, compared to 31.8% of women having had children [2].

Numerous factors discourage the use of an IUD, in particular the pain experienced during insertion of the device [3,4]. A systematic Cochrane review published in 2015 analyzed 33 clinical trials, including a total of 5710 patients, of which 29 were recent (reported between 2010 and 2015). This review clearly showed that fear of pain during IUD insertion is a barrier to use of this method [5].

Pain control during insertion of an IUD is therefore important to avoid discouraging the use of this method of contraception by certain women.

Abbreviations: CI, confidence interval; IUD, intrauterine device; LNG, levonogestrel; NVRS, numerical verbal rating scale; RR, relative risk; SD, standard deviation.

* Corresponding author at: Département de Gynécologie-Obstétrique, CHU de Saint Etienne, Hôpital NORD, Avenue Albert Raimond, 42270 Saint Priest en Jarez, France.
E-mail address: celine.chauleur@chu-st-etienne.fr (C. Chauleur).

http://dx.doi.org/10.1016/j.jogoh.2019.05.010
2468-7847/© 2019 Elsevier Masson SAS. All rights reserved.

In general, published studies have shown only a moderate effect of analgesic treatments or procedures in either preventing pain during IUD insertion or in relieving pain after this procedure. The authors conclude that lidocaine gel, misoprostol and most nonsteroidal anti-inflammatory drugs (NSAID) did not significantly decrease pain either during IUD insertion or during the first 6 h after this. In contrast, certain other treatments may be of value, such as lidocaine administered by paracervical injection, naproxen and tramadol, but the counterbalancing risk of adverse events and the increased costs associated with their use for IUD placement should be fully taken into account [5–7].

The direct insertion technique, known as the “torpedo” technique, or the Cristalli-Bonneau method (referring to the first authors to have described this approach in 2006) appears to be appreciated by its users for being more reliable and, above all, less painful for patients [8–11].

However, up to now, no randomized study has evaluated the superiority of the direct insertion technique in diminishing pain.

The primary objective of our prospective, randomized study was therefore to compare the level of pain experienced during IUD placement with use of the direct and conventional techniques in terms of the percentages of women reporting pain scored as ≥ 4 on the NVRS at IUD release.

Material and methods

Study design and patients

This randomized, controlled, single-blind, clinical trial compared pain during IUD insertion using the direct and conventional placement techniques (ClinicalTrials.gov identifier: NCT02595125; date of registration 3 November 2015). The study was approved by the Institutional Review Board, in accordance with the Declaration of Helsinki, and by the National Commission on Computerization and Freedom (*Commission Nationale de l’Informatique et des Libertés* [CNIL]).

Written informed consent was obtained from all patients before their randomization. The study was conducted in Saint-Etienne University Hospital from February 2016 to September 2017 and compared two different techniques for placement of a T-shaped IUD (hormonal or copper-coated).

For each group, patients were in a gynecological position, a two-hand touch was performed to better understand the position of the uterus (anterior or retroverted), the speculum was placed and then the cervix was disinfected with BETADINE®,

The first technique, known as "classical", was generally carried out in the following stages (Fig. 1):

- The anterior part of the cervix was pulled and held with the Pozzi forceps,
- Hysterometry with CCD® device, the insertion tube was inserted to the uterine fundus and then removed to leave the IUD in place.

The second technique, known as "direct", was performed without hysterometry and the Pozzi forceps were only used in the second intention in case of a retroverted uterus. Its basic principle was that only the IUD (or SIU) entered the uterine cavity, the insertion tube was stoped at the internal cervical os (Fig. 1) [11].

- The strings were cut 2–3 cm centimeters after the cervix, the Pozzi forceps and the speculum removed.

Patients were randomized in a 1:1 ratio to the two study groups: patients assigned to group A undergoing IUD placement using the conventional technique, those in group B undergoing IUD placement using the direct technique. Both procedures were implemented with the use of REDCap electronic data capture tools hosted at the University Hospital Center of Saint-Etienne (France). Patients were randomized using a computer-generated randomization sequence. Randomization was balanced by the use of blocks of variable size and stratified according to the type of IUD envisaged: copper-coated or hormonal.

The patients were unaware of the group to which they had been assigned.

All types of T-shaped IUD, whether copper-coated or coated with levonorgestrel (LNG), were acceptable for the study, irrespective of the placement technique employed. The IUDs used

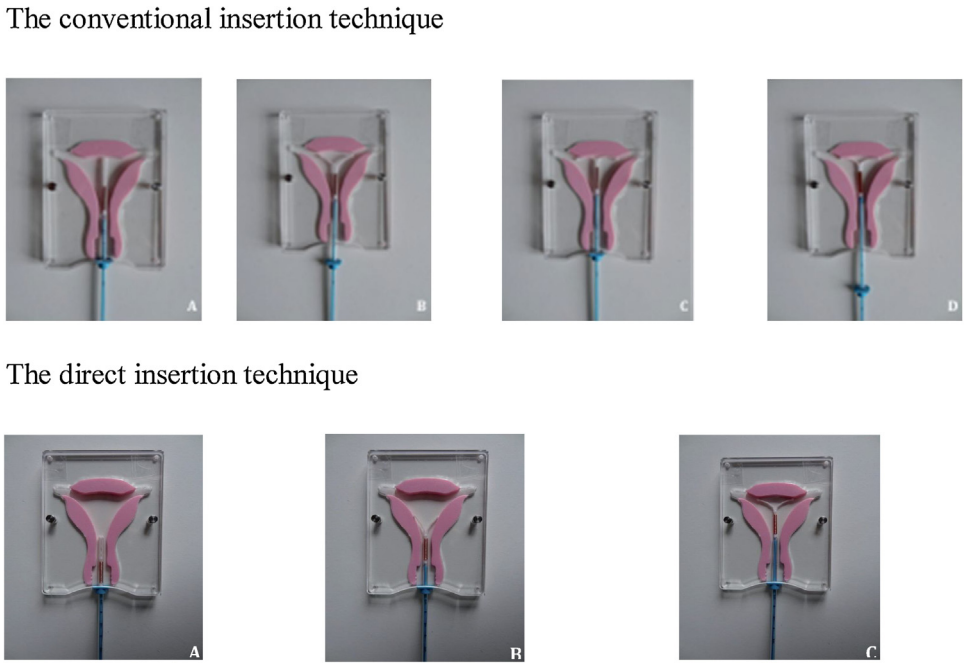

Fig. 1. The conventional insertion technique.

The direct insertion technique.

were: copper IUDs with copper as the active ingredient and hormonal IUSs with levonorgestrel as the active ingredient.

These different devices are characterized by their size and shape. The size can be standard if the uterine height is greater than or equal to 7 cm or smaller ("short" or "mini" models). In clinical practice, size selection is often made on the basis of parity, with the "short" IUDs being preferred for nulliparous patients [1].

After the operators had been trained in the two techniques (Mannequin training and 3 verified successful poses for both techniques on patients not included in this study), the IUDs were inserted according to the group to which each patient had been allocated.

In both groups, pain experienced was recorded by the operator according to the score on the NVRS scale (from 0 to 10) attributed by the patient just after release of the IUD.

On completion of IUD placement, the operator performed a control pelvic ultrasound examination to check the position of the device. Before their discharge, the patients were instructed to record the occurrence of any incident in their study diary, every day for 7 days, and also to note the levels of pain experienced at D1 and D7 expressed as NVRS scores.

One week after IUD insertion, each patient was contacted by telephone to determine the occurrence and nature of any incidents during the past week, as well as the NVRS pain scores attributed at D1 and D7. This telephone call at D7 corresponded to the end of the study.

The interviewer collecting this information by telephone was unaware of the group to which each patient had been allocated.

Study endpoints

Primary endpoint

The primary endpoint was the percentage of women reporting pain scored as ≥ 4 on the NVRS on completion of IUD placement, i.e. at IUD release. According to published data, pain scored as ≥ 4 on the NVRS is recorded in 79% of IUD placements [11].

Secondary endpoints

These endpoints comprised:

- Failure to insert the IUD, vasovagal reaction and/or immediate or delayed expulsion of the IUD, medical consultation for a reason related to IUD insertion, need for analgesics, and NVRS pain score at D1 and D7.
- Correct positioning of the IUD, checked by a pelvic ultrasound examination performed after IUD placement. The distance of the IUD from the uterine fundus had to be no more than 2 cm [12].
- The operator's evaluation of the IUD placement procedure was recorded by means of a questionnaire to determine the difficulty of IUD insertion and the occurrence of any placement failures.

Statistical analysis

All study data were collected prospectively and anonymously, using REDCap for data collection and processing. Statistical analyses were performed using SAS-Windows® software, version 9.4.

The sample size calculation was based on the results of previous studies. These data revealed that 79% of patients experienced pain scored as ≥ 4 on the NVRS during IUD placement using the conventional technique [11]. We postulated that use of the direct technique would lead to a 50% decrease in the incidence of pain scored as ≥ 4 on the NVRS.

For a power of 90% and a bilateral type I error (α) of 5%, we calculated that 27 patients would be needed in each group. However, after incorporation of a 5% drop-out rate, the target study population was increased to 30 patients per group, i.e. 60 patients in total, to avoid any data insufficiency or statistical problems.

Statistical analyses were performed according to the intention-to-treat principle.

Quantitative variables were presented as the number, median, mean and standard deviation (SD) and qualitative variables as the number of cases and percentages. Fisher's exact test was used to compare qualitative variables. The relative risk (RR) and its 95% confidence interval (95% CI) were also estimated. The threshold of statistical significance was set at $P < 0.05$.

With regard to quantitative variables, the two groups were compared using Student's *t*-test for variables with a normal distribution, and a rank sum test (comparing median values) for variables with a non-normal distribution. The normality of each variable was checked before statistical analysis using the Shapiro-Wilk test. The difference between means with its 95% CI was also presented.

Results

The study was conducted from February 2016 to September 2017. Sixty patients were included, randomized and analyzed, 32 in the group undergoing IUD placement according to the conventional technique (group A) and 28 in the group undergoing IUD placement using the direct technique (group B). The patients ranged in age from 19 to 51 years. Five patients were nulliparous. Of the 60 IUD inserted, 32 were hormonal and 28 copper-coated; (Fig. 2 Flow chart). There was no imbalance in patient characteristics between the two groups at inclusion (Tables 1 and 2). Nine operators participated, 4 doctors, 1 midwife, 4 residents used both techniques.

A total of 27 (45.8%) patients reported pain scored as ≥ 4 on the NVRS at the time of IUD release (Table 3). The patients having undergone IUD placement using the direct technique showed a trend towards a lower incidence of pain scored as ≥ 4 on the NVRS compared to those in whom the conventional technique was used (32.1% and 58.1%, respectively), but this difference was not statistically significant (RR = 0.55 (95% CI: 0.30–1.03), $P = 0.07$) (Table 2). The two groups differed to a statistically significant extent with regard to median NVRS pain score ($P = 0.01$). At the time of IUD release, patients in group A as a whole reported more intense pain than those in group B, the median NVRS pain score being 4 *versus* 2, respectively.

One patient randomized to group A (conventional technique) was not evaluable for this endpoint: after placement failure using the conventional technique (according to the randomization schedule), placement also failed after use of the direct technique. As this patient experienced placement failure with use of both techniques, the IUD was not released and consequently the NVRS pain score at IUD release could not be determined.

Immediately after IUD insertion, 6.7% of patients experienced at least one incident (Table 4). Two IUD placement failures were noted in each group. A change in technique resulted in successful IUD placement in three of these four patients experiencing initial placement failure. In one patient in group A (conventional technique) the IUD was expelled. No vasovagal reaction was observed. Overall, there was no statistically significant difference between the two groups with regard to the number of incidents occurring immediately after IUD insertion.

The IUD was properly positioned in 91.4% of cases, 90.3% in group A (conventional technique) and 92.6% in group B (direct technique), the difference between the two groups not being statistically significant. At one week after IUD placement, all patients could be contacted, no patient being lost to follow-up. At least one incident during the week following IUD placement was

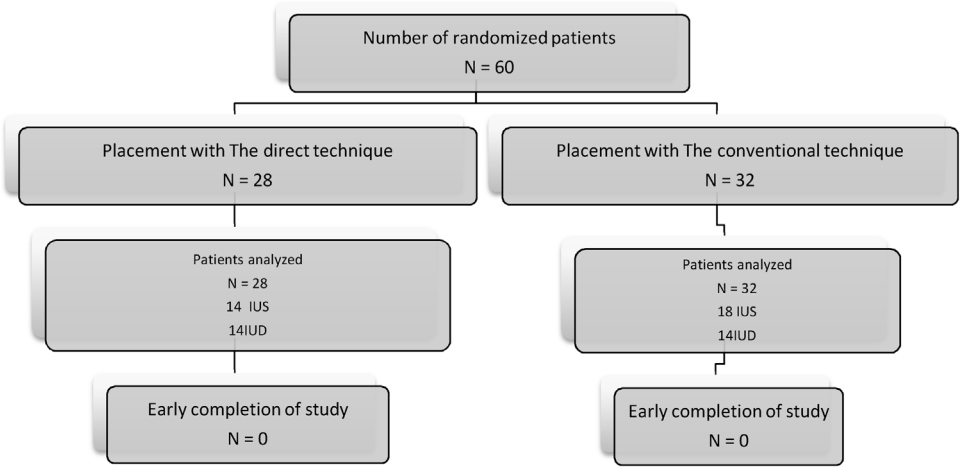

Fig. 2. Flow chart.

Table 1
Patient characteristics at inclusion.

	Direct technique (n = 28)	Conventional technique (n = 32)	Total (n = 60)	*P*
Stratum				
IUD UT 380 std UT 380 short NT 380 TT 380	14(50%)10220	14 (43.8%)642	28 (46.7%)	0.80
IUS Levo 52 mg Levo 13.5 mg	14(50%)131	18 (56.25%)171	32 (53.3%)	
Age, years				
Mean (SD)	34.1(7.8)	32.9 (7.2)	33.5 (7.4)	0.55
BMI (kg/m^2)				
Mean (SD)	25.3(5.2)	25.6 (5.3)	25.5 (5.2)	0.87
Median	24.5	24.8	24.6	
Gravidity				
number	25	31	56	0.58
1	5(20.0%)	11 (35.5%)	16 (28.6%)	
2	8(32.0%)	10 (32.3%)	18 (32.1%)	
3	6(24.0%)	3 (9.7%)	9 (16.1%)	
4	2 (8.0%)	2 (6.5%)	4 (7.1%)	
≥5	4(16.0%)	5 (16.1%)	9 (16.1%)	
Parity				
number	28	31	59	0.40
0	4(14.3%)	1 (3.2%)	5 (8.5%)	
1	6(21.4%)	11 (35.5%)	17 (28.8%)	
2	11(39.3%)	9 (29.0%)	20 (33.9 %)	
3	6 (21.4%)	7 (22.6%)	13 (22.0%)	
≥ 4	1 (3.6%)	3 (9.7%)	4 (6.8%)	
Insertion				
Senior Junior midwife	10(35.7%) 10 (35.7%) 8 (28.5%)	11 (34.3%)7 (21.8%)14 (43.7%)	21 (35%)17 (28,3%)22 (36,6%)	0.38

BMI: body mass index; IUD: intrauterine device; IUS: intrauterine system.
UT 380 CCD® or Monalisa® std: standard ; UT 380 CCD® short; TT 380 CCD®; NT 380 CCD® or Monalisa® ; Levo 52 mg: lévonorgestrel 52 mg Mirena Bayer ®; lévo 13.5 mg: lévonorgestrel 13.5 mg Jaydess Bayer®.

reported by 50% of the patients included. One IUD expulsion was reported in each group (Table 4). In group A (conventional technique) three consultations with a physician for a complication related to the IUD or to its placement were recorded, compared to no consultation in group B (direct technique). Analgesics were taken by 50% of patients in group A (conventional technique) *versus* 42.9% of those in group B (direct technique). None of these differences was statistically significant.

Evaluation of pain at D1 showed a statistically significant difference between the two groups (P = 0.007). The patients in group A (conventional insertion technique) recorded more intense pain than those in group B (direct technique) based on all NVRS pain scores combined. An NVRS pain score ≥ 4 was recorded for 62.5% of patients in group A (conventional technique) *versus* 32.1% of patients in group B (direct technique) (P = 0.02). At D7, only one patient in each group still recorded an NVRS pain score ≥ 4.

No patient presented a serious adverse event as defined in the protocol. During the week following IUD placement, 33 patients (55%) reported at least one non-serious adverse event (NSAE): 20 (62.5%) in group A (conventional insertion technique) *versus* 13 (46.4%) in group B (direct technique) (P = 0.21). In group A (conventional technique), one patient presented moderate truncated sciatica, one patient experienced back pain judged to be severe, three patients reported abdominal pain and the other 15 patients reported mild to moderate metrorrhagia. In group B (direct technique), one patient experienced IUD expulsion, one reported mild abdominal pain and the other 11 patients reported mild to moderate metrorrhagia.

The operators considered that IUD placement was difficult in 18.8% of cases using the conventional technique as opposed to 10.7% of cases with use of the direct insertion technique. The type of insertion technique used had no impact on failure of IUD placement.

Discussion

Our prospective, randomized, single-blind, quantitative clinical trial was the first study to assess the value of the direct technique for IUD placement in reducing pain experienced during device insertion, compared to the conventional technique. It was also the first study to evaluate the effects of IUD placement in both nulliparous and multiparous women with use of the various types of IUD approved in France. The results showed that use of the direct technique led to a trend towards decrease in the number of women experiencing pain scored as ≥ 4 on the NVRS at IUD release compared to use of the conventional technique. However, this difference did not reach statistical significance. In contrast, the median pain intensity recorded immediately after IUD release was statistically significantly lower in women whose IUD was inserted using the direct technique. Use of this technique resulted in a clinically relevant decrease of 50% in median pain intensity compared to use of the conventional technique, with median pain scores of 2 *versus* 4, respectively.

No statistically significant difference was seen between the two groups with regard to IUD placement failures or incidents occurring immediately after IUD insertion. Published data indicate

Table 2
Patient medical and surgical history.

	Direct technique (n=28)	Conventional technique (n=32)	Total *P* (n=60)
Medical history	3 (10.7%)	2 (6.3%)	5 (8.3%)0.66
Surgical history	5 (17.9%)	4 (12.5 %)	9 (15.0%)
Conization	2 (7.1%)	2 (6.3%)	4 (6.7%)
Other relevant surgical history	3 (10.7%)	2 (6.3%)	5 (8.3%)
Obstetrical history	12 (42.9%)	10 (31.3%)	22 (36.7%) 0.43
Spontaneous miscarriages	11 (39.3%)	8 (25.0%)	19 (31.7%)
1	7 (63.6%)	3 (37.5%)	10 (52.6%)
2	1 (9.1%)	3 (37.5%)	4 (21.1%)
≥ 3	3 (27.3%)	2 (25.0%)	5 (26.3%)
History of cervical lesion	3 (10.7%)	2 (6.3%)	5 (8.3%)0.66
Surgery	0 (0.0%)	1 (3.1%)	1 (1.7%)
Laser treatment	1 (3.6%)	0 (0.0%)	1 (1.7%)
Conization	2 (7.1%)	2 (6,3%)	4 (6.7%)
Time since conization (months)			
Mean (SD)	78.4 (87.4)	43.5 (25.2)	61.0 (56.3)
Median	78.4	43.5	43.5
History of IUD placement	13 (46.4 %)	8 (25.0%)	21 (35.0%) 0.11
1	9 (69.2%)	4 (50.0%)	13 (61.9%)
2	2 (15.4%)	1 (12.5%)	3 (14.3%)
≥ 3	2 (15.4%)	3 (37.5%)	5 (23.8%)
Time since last placement (years)	13	8	21
Mean (SD)	4.0 (1.8)	6.8 (6.9)	5.1 (4.5)
Median	4.7	5.1	5.0
Q1 – Q3	2.8 – 5.1	4.1 – 5.5	3.1 – 5.2
Difficulties in IUD placement	3 (10.7%)	2 (6.3%)	5 (8.3%)
Uterus position Anterior position Retroverted uterus	25 (89.2%) 3 (11.8%)	27 (84.3%) 5 (16.7%)	52 (86.6%) 0.718 (14.4%)

SD: standard deviation.

Table 3
Primary endpoint: number of women reporting pain scored as ≥4 on the NVRS at IUD release.

		Direct technique (n=28)	Conventional technique (n=32)	Total (n=60)	p
Women with pain scored as ≥ 4 on the NVRS at IUD release	N	28	31	59	
	No. (%)	9 (32.1%)	18 (58.1%)	27 (45.8%)	0.07
	RR (95% CI)		0.55 (0.30; 1.03)		

rates of IUD placement failure ranging from 1% to 18% [13–15]. In our study, we observed a rate of 6.7% which is within the range reported in the literature. In France, the practice of systematically checking the position of the inserted IUD by ultrasound is not recommended, but is nevertheless frequent [16].

With use of the direct technique, medical practitioners might be concerned about the position of the IUD within the uterine cavity as the device is not introduced up to the uterine fundus. However, our study showed correct positioning of the IUD in 92.6% of insertions accomplished using the direct technique compared to 90.3% in the conventional technique group, this difference not being statistically significant. The rate of malpositioned IUD (8.6%) was below that reported in the literature.

Many malpositioned IUD spontaneously adopt a correct position in the uterine cavity within the first few weeks following their placement [17,18]. A real-time video of an ultrasound performed immediately after IUD insertion using the direct technique was posted for the first time on the BlueGyn site by Dr JC Hald. This video shows the spontaneous ascension of the IUD up to the uterine fundus by an “active swimming” maneuvre (or by uterine peristalsis) [19].

Some authors have pointed out that there is no established guideline concerning the procedure to follow if an IUD is found to be malpositioned [12], and that in this situation the risk of pregnancy is greater if the IUD is removed than if it is left in place [20]. Furthermore, according to the study by De Kroon et al. (2003), clinical evaluation of proper IUD positioning was as reliable as ultrasound in the absence of any pain or difficulties encountered in device placement [21].

One IUD expulsion was reported in each group, corresponding to a rate of 3.3%, consistent with the published rate of 4.2% irrespective of the parity of the patient for LNG-releasing IUD [22], being somewhat higher for nulliparous patients receiving a copper-coated IUD [23].

Reports of studies conducted in countries other than France evaluating the efficacity and adverse effects of IUD, and recourse to analgesics during their placement, never specify the insertion technique employed. No study focusing on the direct technique was identified in the scientific literature. In contrast, this technique has been evaluated in two French studies.

In a qualitative study published in 2015, operators using the direct technique declared that they had chosen this technique because it was less painful for patients, notably because it does not involve gripping of the cervix followed by traction of the uterus or passage through the internal orifice of any object other than the IUD [24]. In early 2018, a prospective, observational study of the direct insertion technique was reported in the context of a thesis in general medicine [25]. Its objective was to compare pain experienced during IUD placement in groups of women undergoing device insertion by the direct technique and by the conventional technique, respectively, and to observe the complications arising during the 6 months following IUD insertion. The results obtained in this study were similar to ours concerning the statistically significant decrease in pain experienced during IUD insertion using the direct technique, compared to that associated with use of the conventional technique, but these data have not been published.

Our study was underpowered to reveal a statistically significant difference between the two techniques evaluated in terms of the number of women experiencing pain scored as ≥ 4 on the NVRS during IUD placement. It showed a treatment effect quite close to that expected, namely a 50% reduction in pain with use of the direct technique compared to the conventional technique, the observed reduction being 45%. However, the frequency of women experiencing pain scored as ≥ 4 on the NVRS with use of the conventional technique (group A) was lower than expected, 58% of patients reporting pain of this intensity in contrast to the expected 79% incorporated in the sample size calculation on the basis of the literature [11]. This discrepancy led to a lack of power to reveal a difference between the two techniques. It might be explained by the smaller proportion of nulliparous women enrolled in our study (8.3%) compared to that in the published study (31.1%) given that nulliparous women are more likely to experience pain scored as ≥ 4 on the NVRS during IUD placement [26].

Our study did not show any statistically significant difference between the two IUD placement techniques concerning the operators’ evaluation of the procedures implemented. The wide range of professional experience of the operators in terms of specialty and level of training (advanced medical students, junior

Table 4
Secondary endpoints.IUD : intrauterine device ; NVRS: numerical verbal scale.

		Direct technique (n=28)	Conventional technique (n=32)	Total (n=60)		*P*
1 – At least one incident immediately post-insertion	No. (%)	2 (7.1%)	2 (6.3%)	4 (6.7%)		0.89
Placement failure	No. (%)	2 (7.1%)	2 (6.3%)	4 (6.7%)		0.89
Result of repeat placement	Success	2	1	3		
	Failure	0	1	1		
Incidents related to IUD placement	No. (%)	0 (0.0%)	1 (3.1%)	1 (1.7%)		
Vaso-vagal reaction	No. (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
IUD expulsion	No. %)	0 (0.0%)	1 (3.1%)	1 (1.7%)		
Insertion technique	Direct	0	1	1		
	Conventional	0	0	0		
2 – Proper positioning of IUD (distance from uterine fundus $\leq$ 2 cm)	N	27	31	58		
	No. (%)	25 (92.6%)	28 (90.3%)	53 (91.4%)		0.76
Distance from uterine fundus (cm)	N	27	31	58		
	Median	1.4	1.6	1.5		0.48
3 – At least one incident during the week following IUD placement	No. (%)	13 (46.4%)		17 (53.1%)	30 (50.0%)	0.60
IUD expulsion	No. (%)		1 (3.1%)	1 (3.3%)	2 (3.3%)	0.96
Emergency consultation for an IUD-related complication	No. (%)		0 (0.0%)	1 (3.1%)	1 (1.7%)	0.35
Consultation of a health care professional for an IUD-related complication	No. (%)	0 (0.0%)		2 (6.3%)	2 (3.3%)	0.18
Need for analgesics	No. (%)	12 (42.9%)		16 (50.0%)	28 (46.7%)	0.58
NVRS score at IUD release	N	28		31	59	
	Median	2.0		4.0	3.0	0.01
NVRS score at D1	N	28		32	60	
	Median	1.0		4.5	3.0	0.007
NVRS score $\geq$ 4	No. (%)	9 (32.1%)		20 (62.5%)	29 (48.3%)	0.02
NVRS at D7	N	28	32		60	
	Median	0.0	0.0		0.0	0.08
NVRS score $\geq$ 4	No. (%)	1 (3.6%)	1 (3.1%)		2 (3.3%)	0.92
4 – Operator evaluation						
Difficulty in placement	No. (%)	3 (10.7%)	6 (18.8%)		9 (15.0%)	0.38
Placement failure	No. (%)	2 (7.1%)	2 (6.3%)		4 (6.7%)	0.89
Recourse to conventional technique	No. (%)	2 (7.1%)	–		–	

physicians in general medicine, junior physicians specializing in gynecology and obstetrics, fully qualified gynecologists and obstetricians, and midwives), as well as the heterogeneity of the women randomized in our study, reinforce the external validity of our study and the possibility of extrapolating its results.

The direct technique of IUD insertion is very simple, requiring very few steps. It is easy to master and involves no risk of forgetting steps or inversing their order, as described with use of the conventional technique [3,27]. The complexity of the latter technique has often been described and does not encourage its use. In contrast, the direct placement technique is very easily reproducible. Use of this technique, besides being simple, permits more rapid placement of IUD, a particular advantage in that lack of time is often an obstacle to the implementation of technical procedures by general practitioners [28]. The results of this study should reassure medical practitioners and ultimately encourage them to prescribe and insert IUD, a mode of contraception that should be systematically proposed to women in view of its high efficacy, its ease of use, its reversible nature, and the absence of any major contraindications.

In conclusion, this study represents the first prospective, controlled, randomized and blinded clinical trial assessing the value of the direct technique of IUD insertion in terms of reducing the pain experienced during IUD insertion compared to the conventional placement technique.

Even though use of the direct technique did not reduce to a statistically significant extent the proportion of women experiencing pain scored as $\geq$4 on the NVRS) at IUD release, in comparison to use of the conventional technique, it significantly decreased median pain intensity at this time. The direct technique is simple, rapid, effective and reliable, and its use should be encouraged in order to overcome the principle obstacles to IUD placement cited by medical practitioners.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of interest

The authors declare that there is no conflict of interest. The author has no substantial direct or indirect commercial or financial incentive associated with publishing the article.

Acknowledgements

We are grateful to Paula Harry for English revision and editorial assistance

References

[1] Autorité de Santé Haute. Méthodes contraceptives : Focus sur les méthodes les plus efficaces. 2017. https://www.has-sante.fr/portail/jcms/c_1369314/fr/methodes-contraceptives-focus-sur-les-methodes-les-plus-efficaces-disponibles.
[2] INPES-Santé publique France. Baromètre santé. Contraception. Quatre ans après la crise de la pilule, les évolutions se poursuivent. 2016. http://inpes.santepubliquefrance.fr/CFESBases/catalogue/detaildoc.asp?numfiche=1806.
[3] Autorité de Santé Haute. État des lieux des pratiques contraceptives et des freins à l'accès et au choix d'une contraception adaptée. 2013. https://www.has-sante.fr/portail/jcms/c_1545927/fr/etat-des-lieux-des-pratiques-contraceptives-et-des-freins-a-l-acces-et-au-choix-d-une-contraception-adaptee.
[4] Driat D. Freins et réticences à l'utilisation du dispositif intra-utérin chez les nullipares en médecine générale [Thèse de doctorat en médecine] Paris Ile-de-France-Ouest. 2012.
[5] Lopez LM, Bernholc A, Zeng Y, Allen RH, Bartz D, O'Brien PA, et al. Interventions for pain with intrauterine device insertion. Cochrane Database Syst Rev 2015;29:CD007373, doi:http://dx.doi.org/10.1002/14651858.CD007373.pub3 juill.

[6] Pergialiotis V, Vlachos DG, Protopappas A, Vlachos GD. Analgesic options for placement of an intrauterine contraceptive: a meta-analysis. Eur J Contracept Reprod Health Care Off J Eur Soc Contracept 2014;19:149–60, doi:http://dx.doi.org/10.3109/13625187.2014.903238.
[7] Karasu Y, Cömert DK, Karadağ B, Ergün Y. Lidocaine for pain control during intrauterine device insertion. J Obstet Gynaecol Res 2017;43:1061–6, doi:http://dx.doi.org/10.1111/jog.13308.
[8] BlueGEEK Journal [consulté le 27 janvier 2018].Technique de la torpille de Cristalli- Bonneau, [En ligne]. http://bluegyn.com/spip/spip.php?page=article&id_article=79. http://archive.bu.univ-nantes.fr/pollux/show.action?id=d5791624-175d-427b-bc21-e636b701420d.
[9] Perez G. Pose atypique de DIU en consultation: l'experience du groupe FORMAGYN [Thèse de doctorat en médecine]. Université de Nante; 2017 http://archive.bu.univ-nantes.fr/pollux/show.action?id=d5791624-175d427b-bc21-e636b701420d.
[10] Savignac-Krikorian L, Benedini E, Bezanson E, Ruelle Y. Insérer un dispositif intra-utérin : méthode classique et méthode directe. Exercer 2015;(121):229–34.
[11] Santos ARG, Bahamondes MV, Hidalgo MM, Atti A, Bahamondes L, Monteiro I. Pain at insertion of the levonorgestrel-releasing intrauterine system in nulligravida and parous women with and without cesarean section. Contraception 2013;88:164, doi:http://dx.doi.org/10.1016/j.contraception.2012.10.015 <8.
[12] Clinical guidance: intrauterine contraception. Faculty of Sexual and Reproductive Healthcare; 2015. https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/.
[13] Dermish AI, Turok DK, Jacobson JC, Flores MES, McFadden M, Burke K. Failed IUD insertions in community practice: an under-recognized problem? Contraception. févr 2013;87:182–6, doi:http://dx.doi.org/10.1016/j.contraception.2012.06.015.
[14] de Santé Haute Autorité. Contraception chez l'homme et chez la femme. Rapport d'élaboration. 2017. https://www.has-sante.fr/portail/upload/docs/application/pdf/2015-02/contraception_fiches_memo_rapport_delaboration.pdf.
[15] Golightly E, Gebbie AE. Low-lying or malpositioned intrauterine devices and systems. J Fam Plann Reprod Health Care 2014;40:108–12, doi:http://dx.doi.org/10.1136/jfprhc-2013-100684.
[16] Bluegyn. Torpille direct [en ligne] 2017; vidéo: 1.44 min, https://www.youtube.com/watch?time_continue=2&v=OEFQzHRp7W8.
[17] Braaten KP, Benson CB, Maurer R, Goldberg AB. Malpositioned intrauterine contraceptive devices: risk factors, outcomes, and future pregnancies. Obstet Gynecol 2011;118:1014–20, doi:http://dx.doi.org/10.1097/AOG.0b013e3182316308.
[18] Lyus R, Lohr P, Prager S. Board of the society of family planning. Use of the mirena LNG- IUS and paragard CuT380A intrauterine devices in nulliparous women. Contraception 2010;81:367–71, doi:http://dx.doi.org/10.1016/j.contraception.2010.01.010.
[19] Mansour D. The benefits and risks of using a levonorgestrel-releasing intrauterine system for contraception. Contraception 2012;85:224–34, doi:http://dx.doi.org/10.1016/j.contraception.2011.08.003.
[20] Lori SK. Méthode de pose directe des dispositifs intra-utérins [Memoire DIU regulation des naissances]. Université Paris Descartes Faculté de Médecine; 2015. http://www.docteurmilie.fr/wordpress/wp-content/uploads/2015/06/DIUposedirecte-memoire.pdf.
[21] Bastin A. Méthode de pose directe des dispositifs intra-utérins et système intra-utérins hormonaux : efficacité sur la réduction de la douleur liée à l'insertion et tolérance à 6 mois : étude prospective observationnelle [Thèse de doctorat en médecine]. Rennes: Université Bretagne Loire Faculté de médecine; 2018.
[22] Bednarek PH, Creinin MD, Reeves MF, Cwiak C, Espey E, Jensen JT, et al. Prophylactic ibuprofen does not improve pain with IUD insertion: a randomized trial. Contraception 2015;91:193–7, doi:http://dx.doi.org/10.1016/j.contraception.2014.11.012.
[23] Salmon O. Le dispositif intra-utérin et l'implant : analyse des facteurs déterminant la pratique des médecins généralistes du Loir-et-Cher [Thèse de doctorat en médecine]. Tours: Université François Rabelais Faculté de médecine; 2013. http://www.applis.univ-tours.fr/scd/Medecine/Theses/2013_Medecine_SalmonOlivine.pdf.
[24] Guidi RB. Quels sont les freins à la pose du stérilet par les médecins généralistes? Etude qualitative dans l'Arrageois. [Thèse de doctorat en médecine]. Lile 2: Faculté de médecine Henri; 2019.
[25] Warembourg; 2016, https://pepite-depot.univ-lille2.fr/nuxeo/site/esupversions/6f83f17a-3b92-4d05-aa4f-83cf63adbd8f.