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Review

Efficacy and safety of topical anesthetics during intrauterine device insertion: A systematic review

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Introduction

Intrauterine devices (IUD) are highly effective long-acting reversible forms of contraception [1]. They are available as either hormonal or copper-based IUDs. Both types of IUDs have at least 99 % efficiency at preventing pregnancy and require no regular intervention following insertion [2]. The United Nation estimates a worldwide use of IUDs in 20 % of women of childbearing age who are in a relationship [3]. In 2019–2020 in Canada, 13.5 % of sexually active women reported the use of an IUD as a contraceptive method [4]. The low prevalence can be explained by barriers that limit their use, such as negative perception of the IUDs [5] and fear of pain during their insertion [6]. Several methods have been described to reduce pain during gynecological procedures including local anesthetic nerve block, topical anesthesia, oral sedation, non-steroidal anti-inflammatory drugs (NSAIDs) and cervical dilatation with a prostaglandin E1 [7–11]. With the aim of optimizing pain management during IUD placement, a recently published review provided guidance, including the assessment of certain risk factors associated with more painful procedures [12].

Topical anesthetics are a class of drugs that can be applied directly to the skin or mucosa to prevent and relieve pain mediated by local sensitive neurons [13]. The efficacy of topical anesthetics during IUD insertion has been evaluated in many randomized controlled trials (RCTs), but significant pain reduction has not consistently been established [14,15]. Furthermore, some side effects are also to be considered with the use of topical anesthetics such as allergic reaction, irritation or pruritus, nausea or vomiting, bradycardia, and convulsion [16].

Discrepancy in literature regarding efficacy of pain reducing strategies during IUD insertion procedures has prompted academic societies to highlight the need for more research regarding pain management in women health [17–19]. Recently, a statement released by the Society of Obstetricians and Gynaecologists of Canada (SOGC) suggested the use of some topical anesthetics as a pain reducing strategy during IUD insertion procedure [20]. This statement referred to few studies [21–25] and only one systematic review [11]. A clinical consensus from The American College of Obstetricians and Gynecologists recommends either lidocaine spray or lidocaine - prilocaine cream for IUD insertion, highlighting the fact that available evidence are conflicting among studies [26]. To our knowledge, some systematic reviews have addressed pain relief during IUD insertion [9,11,14,15,27]. However, most of them considered topical anesthesia among a lot of other interventions [9,11,15,27] and one focused specifically on cervical lidocaine [14]. The objective of this review was to consolidate all available data on the use of topical anesthetics in IUD insertion associated pain to gain a more accurate picture of the efficacy and safety of those products and help practitioners to improve gynecological pain management.

Methods

This systematic review and meta-analysis was conducted as per the PRISMA guidelines [28] and according to the Cochrane Handbook for Systematic Reviews of Interventions [29]. The protocol of the review was registered with the Centre for Reviews and Dissemination of the University of York (identification number, CRD42023384750).

In order to provide the most complete picture of the data available on the subject, all study designs comparing topical anesthetics with any comparator for women requiring IUD insertion procedure were included. The intervention of interest was the use of topical anesthetics to genital mucosa before and/or during IUD insertion. The primary outcome of this review was pain scores reported by patients on a 0 to 100 mm visual analog scale (VAS) at specific steps during IUD insertion procedure. Side effects related to topical anesthetics were also collected.

We searched literature from 2000 to April 14th, 2025 through MEDLINE, EMBASE, Center for Reviews and Dissemination, Cochrane library and Epistemonikos. We used a search strategy based on keywords related to topical anesthetics and IUD (available in Supp. 1). A detailed bibliography review of relevant articles was also conducted to identify additional references.

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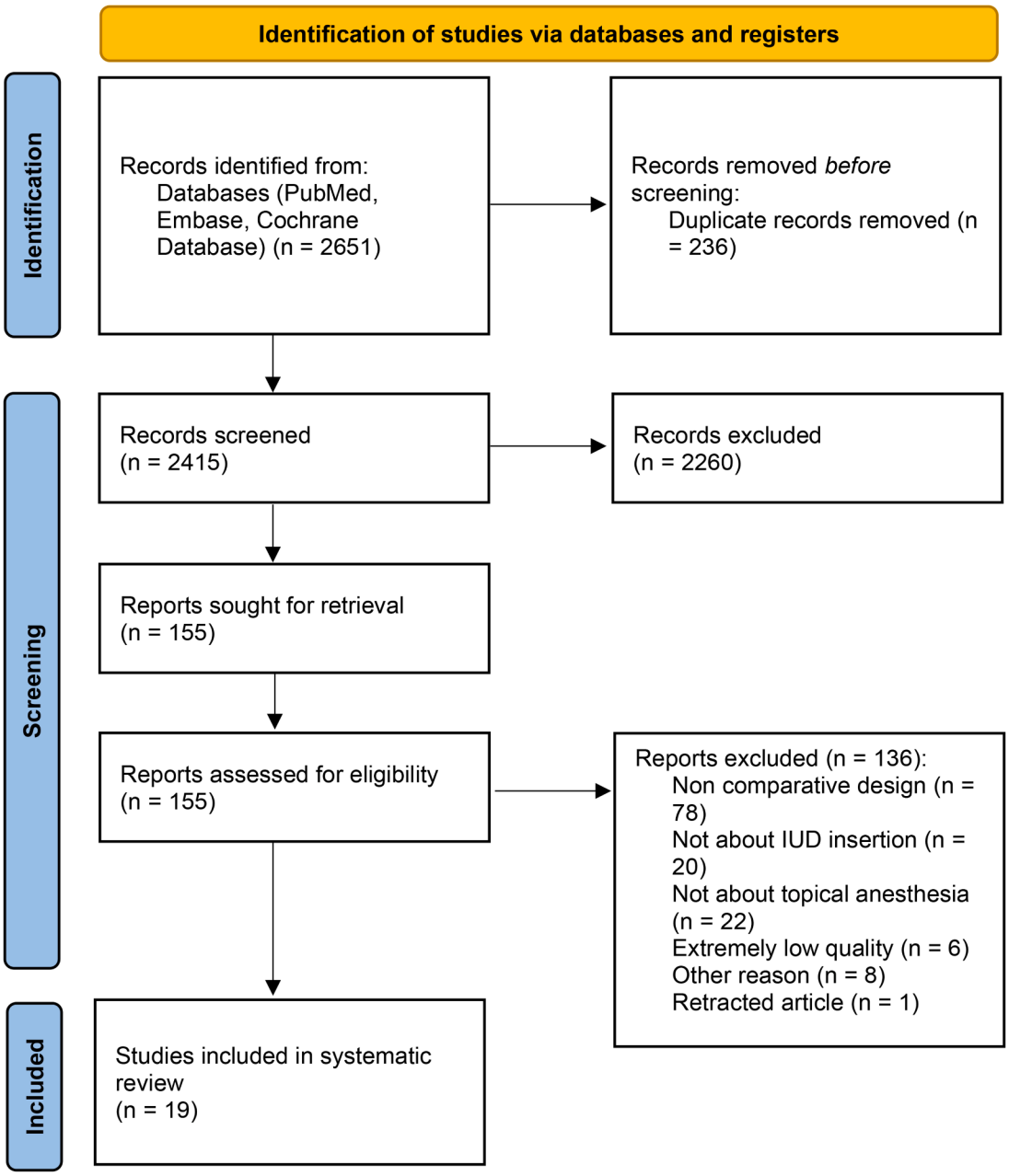


Fig. 1. PRISMA flow diagram.
PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analysis

Study screening and selection was performed in a two-stage process using Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org). First, two independent reviewers screened titles and abstracts of retrieved articles. Then, reviewers proceeded independently to the full text review of potentially eligible studies according to the predefined inclusion and exclusion criteria. Any disagreements were solved by a third reviewer. A list of the excluded studies is available on Supp. 2. The selection process for the analysis of studies is shown using a flow diagram following the PRISMA model (Fig. 1).

Two independent reviewers abstracted data from included studies using a standardized and pilot-tested data collection form. In case of discrepancy, consensus was reached with the involvement of a third reviewer. The data extraction form included study-related data (author, year of publication, country, study design and sample size), baseline demographics and clinical data of the included populations (age, parity, type of IUD inserted), details about the intervention (type of anesthetic molecule, dose, and site, time and mode of application), comparator (type of product) and primary and secondary outcomes data.

For included RCTs, the risk of bias was assessed independently by two reviewers using The Revised Cochrane Risk of bias tool for randomized trials (RoB 2) [30]. For non-randomized studies, the risk of bias was evaluated using the Cochrane tool Risk of Bias in Non-Randomized studies – of interventions (ROBINS-1) [31].

Mean differences between intervention and control groups with 95 % confidence intervals were calculated for continuous outcomes.

Results

Of the 2651 identified articles, 236 were duplicates and 2260 were excluded based on their titles or abstracts (Fig. 1). A total of 155 full-text articles underwent thorough evaluation and 135 of them did not meet

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Table 1
Characteristics of included studies.

Author, y [reference]	Study location	Setting; IUD	Sample size	Age (years) mean ± SD	Parity mean	Nulliparity (%)	Concentration (%); dose (mg)	Application site	Control group	Primary outcomes
Intervention: Lidocaine gel										
Mohammad-Alizadeh-Charandabi, 2010 [42]	Iran	Hospital Copper	IG : 31 CG1: 33 CG2 : 32	IG : 29 ± 7 CG1 : 27 ± 6 CG2 : 28 ± 6	IG : 1.8 CG1 : 1.4 CG2 : 1.7	NR	2 ; NR	Cervical canal	CG1 : Lubricant gel CG2 : no analgesia	Pain during IUD insertion
Maguire, 2012 [39]	USA	FPC Copper / LNG	IG : 100 CG : 100	IG : 28 ± 6 CG : 27 ± 6	NR	IG : 21 CG : 39	2 ; 20	Intracervical	Surgilube[MD]	Pain during sounding and IUD insertion
McNicholas, 2012 [40]	USA	NR Copper / LNG	IG : 100 CG : 99	NR	NR	IG : 50 CG : 51	2 ; 50 to 80	Ectocervix and cervical canal	Water-based lubricant	Pain during tenaculum placement and during IUD insertion
Allen, 2013 [35]	USA	Hospital Copper / LNG	IG : 72 CG : 73	IG : 26 ± 5 CG : 25 ± 5	IG : 2 CG : 1	IG : 4 CG : 7	2 ; 120	Anterior lip of the cervix and cervical canal	K-Y Jelly[MD]	Pain during IUD insertion
Tornblom-Paulander, 2015 [49]	Sweden	Hospital Copper / LNG	IG : 110 CG : 108	IG : 24 ± 5 CG : 23 ± 4	IG : 0 CG : 0	IG : 100 CG : 100	NR ; 340	Ectocervix, cervical canal and uterine cavity	Placebo gel	Pain 10 min after IUD insertion
Rapkin, 2016 [48]	USA	Hospital Copper / LNG	IG : 30 CG : 29	IG : 23 (19–25)[a] CG : 24 (21–28)[a]	NR	IG : 100 CG : 100	2 ; 80	Vagina	Placebo gel	Pain during IUD insertion
Conti, 2019 [36]	USA	Clinic Copper / LNG	IG : 108 CG : 107	IG : 29 (18–48)[b] CG : 27 (18–51)[b]	NR	IG : 77 CG : 74	2 ; 400	Vagina	Lubricant gel	Pain during IUD insertion
Goldthwaite, 2014 [38]	USA	Clinic NR	IG : 35 CG : 35	IG : 34 ± 7 CG : 35 ± 12	NR	IG : 29 CG : 37	2 ; 20	Uterine cavity	20 mg lidocain local injection	Pain during tenaculum placement
Intervention : Lidocaine gel + 100 mg oral dicolfenac										
Fouda, 2016 [44]	Egypt	Hospital Copper	IG : 45 CG : 45	IG : 33 ± 7 CG : 31 ± 8	IG : 2 CG : 2	-	2 ; 120	Anterior lip of the cervix and cervical canal	K-Y Jelly[MD]	Pain during IUD insertion
Intervention : Lidocaine gel (IG1) or Lidocaine spray (IG2)										
Torky, 2017[†] [34]	Egypt	Hospital Copper	IG1 : 140 IG2 : 140 CG : 140	IG1 : 29 ± 8 IG2 : 30 ± 7 CG : 26 ± 5	NR	-	NR ; NR	Cervical canal	No analgesia	Pain during IUD insertion
Intervention : Lidocaine spray										
Elsafty, 2015 [37]	Egypt	FPC NR	IG : 100 CG : 100	IG : 27 (23–32)[a] CG : 26 (23–30)[a]	NR	NR	10 ; 20	Cervix	Saline	Pain during IUD insertion
Aksoy, 2016 [22]	Türkiye	FPC Copper	IG : 100 CG : 100	IG : 30 ± 8 CG : 30 ± 7	IG : 2 CG : 2	-	10 ; 40	Cervical canal and uterine cavity	Saline	Pain during IUD insertion
Panichyawat, 2021 [23]	Thailand	FPC Copper	IG : 62 CG : 62	IG : 31 ± 7 CG : 31 ± 6	NR	IG : 7 CG : 3	10 ; 40	Cervix	Sterile water	Pain at various points during and after the procedure
Hajiesmaello, 2019 [45]	Iran	Research center Copper	IG : 40 CG : 40	IG : 29 ± 8 CG : 31 ± 7	IG : 1.9 CG : 1.8	-	10 ; 40	Cervical area	No analgesia	Pain at various points during and after the procedure
Intervention : Lidocaine solution										
Nelson, 2013 [43]	USA	FPC Copper / LNG	IG : 20 CG : 20	IG : 32 (20–43)[c] CG : 32 (19–46)[c]	IG : 1.7 CG : 1.3	NR	2 ; 24	Cervix	Saline	Pain at various points during and after the procedure
Intervention : Lidocaine solution + 375 mg oral naproxen or placebo										

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Table 1 (*continued*)

Author, y [reference]	Study location	Setting; IUD	Sample size	Age (years) mean ± SD	Parity mean	Nulliparity (%)	Concentration (%); dose (mg)	Application site	Control group	Primary outcomes
Miles, 2019 [41]	USA	Women health clinic Copper / LNG	IG1 : 39 IG2 : 39 CG1 : 40 CG2 : 39	IG1 : 31 ± 9 IG2 : 31 ± 7 CG1 : 31 ± 7 CG2 : 30 ± 7	NR	IG1 : 33 IG2 : 44 CG1 : 28 CG2 : 36	2 ; 100	Endocervix	CG1 : Saline + oral naproxen CG2 : Saline + oral placebo	Pain during IUD insertion
Intervention : Lidocaine – Prilocaine cream										
Tavakolian, 2015 [24]	Iran	Clinic NR	IG : 46 CG : 46	IG : 27 ± 4 CG : 26 ± 5	IG : 1.8 CG : 1.7	NR	2.5 ; 125 (each)	Anterior lip of the cervix	Placebo cream	Pain during tenaculum placement, during sounding and during IUD insertion
Abbas, 2017 [21]	Egypt	FPC Copper	IG : 60 CG : 60	IG : 31 ± 6 CG : 31 ± 7	IG : 3.2 CG : 3.3	-	2,5 ; 100 (each)	Anterior lip of the cervix and cervical canal	Placebo cream	Pain during tenaculum placement, during sounding, during and 5 min after IUD insertion
Hashem, 2022 [46]	Egypt	FPC LNG	IG : 70 CG1 : 70 CG2: 70	IG : 29 ± 6 CG1 : 29 ± 5 CG2 : 27 ± 5	IG : 2.6 CG1 : 2.9 CG2 : 2.8	-	2.5 ; 125 (each)	Cervix and cervical canal	CG1 : Placebo cream + oral placebo CG2 : Placebo cream + oral misoprostol	Pain during IUD insertion
Intervention : Mepivacaine solution										
Envall, 2019 [47]	Sweden	FPC et youth clinic Copper / LNG	IG : 41 CG : 40	IG : 22 (20–26)[a] CG : 22 (20–26)[a]	NR	IG : 100 CG : 100	1 ; 100	Uterine cavity	Saline	Pain during IUD insertion

CG: control group; FPC: familial planning clinic; IG: intervention group; IUD: intrauterine device; LNG: levonorgestrel containing IUD (i.e.: Mirena®), NR: not reported; USA: United States of America; y: year of publication;.

[a] Median (interquartile range).

[b] Median (range).

[c] Range.

eligibility criteria (Supplementary file 1), leaving 20 studies for inclusion. One of the articles retained at first was then retracted by the editor and therefore excluded from our analysis [32,33].

Characteristics of included studies are presented on Table 1. Among the included studies, one was an observational prospective study [34] and the 18 others were RCTs. Studies were conducted in Asia (Iran, Türkiye, Thailand) and in western countries (United States of America, Sweden) or Egypt. Sample sizes ranged from 40 to 420 women with mean or median age from 22 to 35 years. In half of the studies, both nulliparous and multiparous women were included [23,24,35–43] but nulliparous were excluded in six studies [21,22,34,44–46] and included exclusively in three studies [47–49]. In one RCT, only levonogestrel IUD were inserted [46] and copper-based IUD were the only IUD in seven studies [21–23,34,42,44,45]. Topical analgesia included lidocaine gel (20 to 400 mg) in 10 studies [34–36,38–40,42,44,48,49], lidocaine spray (20 to 40 mg) in 5 studies [22,23,34,37,45] and lidocaine solution (24 to 100 mg) in 2 studies [41,43]. Mepivacaine solution (100 mg) was studied in one RCT [47] and a cream combining lidocaine and prilocaine (100 to 125 mg) in three studies [21,24,46]. Lidocaine gel was administered in combination with diclofenac in one RCT [44] and lidocaine solution combined or not with naproxen was compared to naproxen only or a placebo in one study [41]. In two studies, the analgesia group was compared to no analgesia [34,45], to a lidocaine local injection in one study [38] and a placebo or no analgesia in one [42]. Concomitant analgesia was reported in two studies where women were taking ibuprofen [40] or nonsteroidal anti-inflammatory drugs (NSAIDs) [43] before the procedure.

The results of the assessment of the risk of bias of included RCTs are shown in Supplementary Figure 1. Most of the studies were at a low risk of bias except for three studies where the measurement of the outcome brought some concerns as the assessors were aware of the intervention [36,38,45] and two for which the randomization process was not clearly described [39,42].

Pain at tenaculum placement

Pain scores during tenaculum placement were evaluated in 14 RCTs [21,23,24,35–40,43–46,48]. The findings are depicted in Fig. 2 except for the results of Rapkin *et al.* (2016) who reported the median change in VAS between baseline and tenaculum placement [48]. Mean pain scores and mean differences are detailed in Supplementary Table 1. Mean pain levels reported with topical anesthesia varied between 7.5 and 40 mm on a 100 mm VAS, with the majority falling within the range of 20 to 40 mm. Conversely, in the control groups, reported pain ranged on average from 12.3 to 60 mm, predominantly clustered between 20 and 45 mm. Except for two studies where the comparator group reported less pain than the topical anesthetic group [38,39], and one study indicating no discernible difference between anesthetic and placebo [40], all other findings indicated a lower pain level when a topical anesthetic was administered, with mean differences ranging from 2 to 30 mm.

When compared to a placebo in a study with self-administered anesthetic, lidocaine gel induced a significant reduction in tenaculum-induced pain (median change in VAS [interquartile range, IQR]: 32 [18–54] for lidocaine and 56 [25 – 74] for placebo) [48]. However, no

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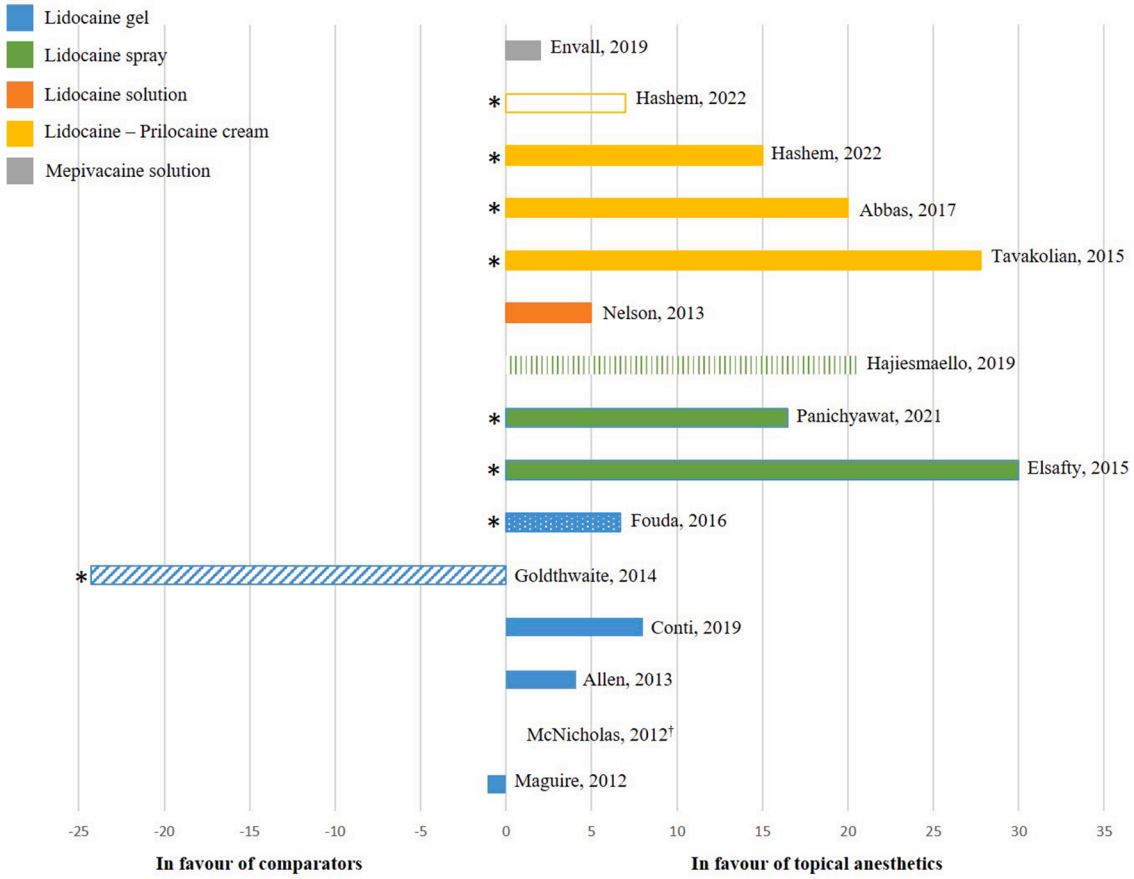


Fig. 2. Pain at tenaculum placement, The bar graph illustrates the difference between mean pain score with topical anesthesia and control during tenaculum placement. Each color represents a different anesthetic studied. The fill patterns within the bars denote the comparison groups: solid bars indicate placebo, hatched bars represent lidocaine paracervical block, vertically striped bars denote no intervention, dotted bar is for topical anesthetic and diclofenac compared to placebo and empty bars are for misoprostol.
* p value $< 0{,}05$ † Lidocaine gel vs placebo.

significant differences were shown in four other studies comparing lidocaine gel to placebo [35,36,39,40], two of which reported slightly lower pain scores with lidocaine (reduction ranging from 4.1 to 8 mm) [35,36]. Moreover, a significant reduction in pain during tenaculum placement was reported with lidocaine gel combined with diclofenac compared to placebo (16.6 versus 23.3; p value = 0.003) [44]. Nonetheless, lidocaine gel was associated with a lower degree of pain relief compared to paracervical lidocaine block, as reported by Goldthwaite *et al.* [38]. Lidocaine spray exhibited a significant reduction in pain during tenaculum placement compared to placebo (16.5 and 30 mm) [23,37] or no intervention (20.5 mm) [45].

Results from three studies suggest that lidocaine - prilocaine cream provided a significant pain relief compared to a placebo, with a mean difference ranging from 15 to 27.8 mm [21,24,46]. Although statistically significant, a smaller mean difference (7 mm) was reported compared with misoprostol use [46]. Lidocaine solution [43] or mepivacaine [47] showed no statistically significant effect on pain scores when compared to a placebo, with reductions of 5 and 2 mm on the 100 mm VAS, respectively.

Pain during uterine depth measurement

Pain assessment during uterine depth measurement using a hysterometer has been evaluated in nine RCTs [21,23,24,39,43,45–48] and one prospective comparative study [34]. The findings are illustrated in Fig. 3 and mean pain scores and mean differences are detailed in Supplementary Table 2. Except for the study by Maguire *et al.* [39], all other studies indicated lower mean pain scores with the use of a topical anesthetic, with differences ranging from 4 to 30 mm on a 100 mm VAS. The effects of lidocaine gel were inconsistent throughout the different studies. Maguire *et al.*, which reported less pain with a placebo, found no statistically significant difference between groups [39]. In Rapkin *et al.* (2016) no difference in pain was observed before the procedure versus pain during sounding either in the lidocaine group (median change in VAS [IQR]: 61 [51 – 71]) or the placebo one (median change in VAS [IQR]: 70 [62 – 83]) [48]. Conversely, an observational study comparing lidocaine gel or spray solution to no analgesia showed a significant reduction in pain with the topical anesthetic (15 and 20 mm) [34]. Other formulations (lidocaine spray, lidocaine - prilocaine cream) compared to placebo or no analgesia also resulted in significantly lower pain levels during uterine depth measurement (mean pain differences between 15 and 30 mm) [21,23,24,45,46]. Similarly, mepivacaine use was associated with a significant reduction in pain compared to placebo [47]. However, the infusion of lidocaine solution did not significantly reduce pain compared with placebo [43]. No significant difference was measured between misoprostol (30 mm) and a cream of lidocaine - prilocaine (26 mm) [46].

Pain during IUD insertion

Among the selected studies, 16 RCTs [21–24,35,36,39–46,48] and one observational study [34] focused on evaluating pain during IUD insertion. The results are presented in Fig. 4 and in more details in Supplementary Table 3. In most RCTs, the use of lidocaine gel was found

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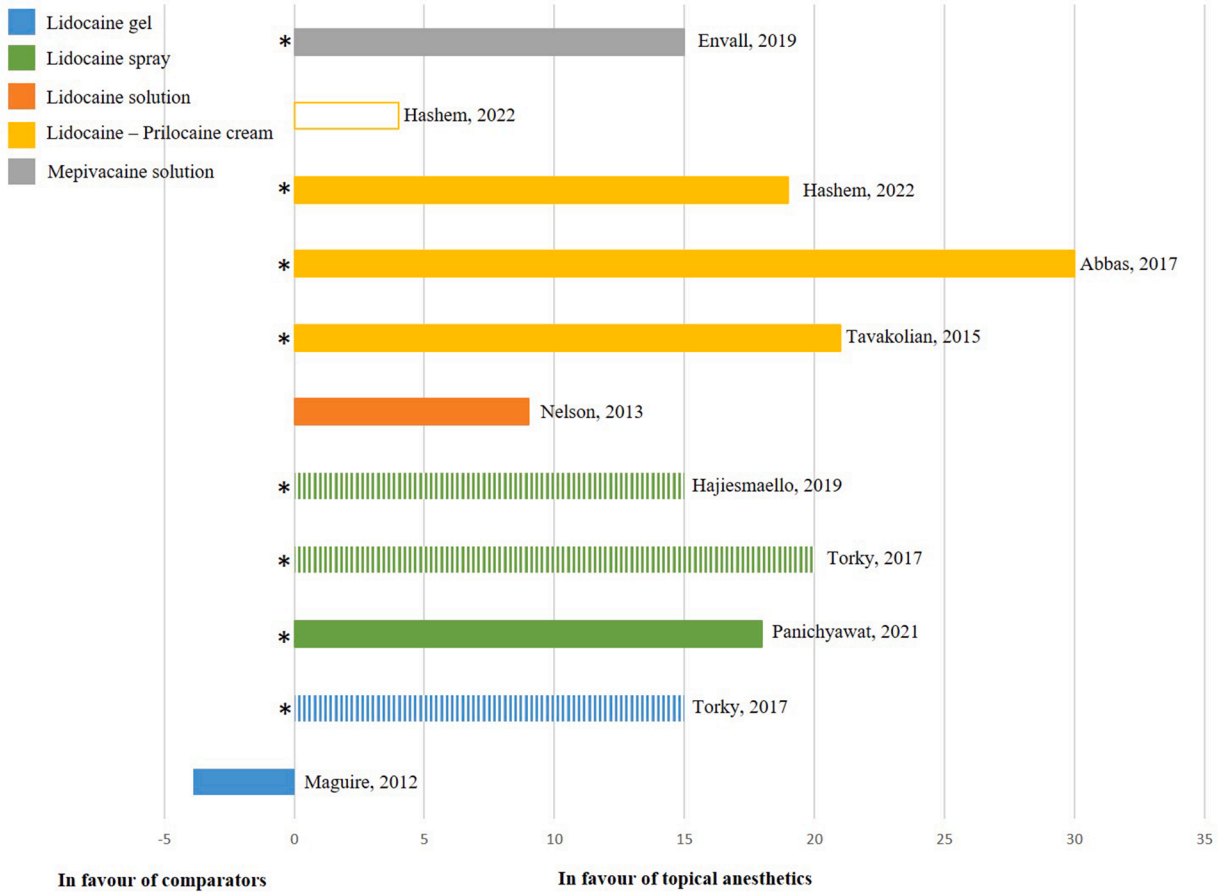


Fig. 3. Pain during uterine depth measurement The bar graph illustrates the difference between pain score with topical anesthesia and control during uterine depth measurement. Each color represents a different anesthetic studied. The fill patterns within the bars denote the comparison groups: solid bars indicate placebo, vertically striped bars denote no intervention, and empty bars is for misoprostol.
* p value < 0,05.

to have no significant effect on reducing pain levels compared to placebo [35,36,39,40,42,48]. In one study, adding diclofenac to lidocaine gel was associated with a significant but modest anesthetic effect compared to placebo (31.4 vs. 39.4 mm; p value = 0.001) [44]. Results from three RCTs suggest that the use of lidocaine spray reduced pain during IUD insertion, with women reporting 16.5 to 22.5 mm less pain than those receiving a placebo [22,23] or no analgesia [45]. However, in their observational study, Torky *et al.* (2017) found no significant reduction in pain with lidocaine gel or spray compared to no analgesia [34].

Authors of three RCTs also reported a statistically significant pain reduction associated with the use of lidocaine - prilocaine cream compared to placebo [21,24,46], although no significant difference was observed between the anesthetic cream and the use of misoprostol [46]. Lidocaine solution instillation showed no effect on pain levels compared to a placebo in two RCTs, whether used alone [43] or with naproxen [41]. Similar results were observed with a mepivacaine solution [47].

Pain after IUD insertion

Pain assessment immediately after the IUD insertion and up to 60 min afterward was conducted in nine RCTs [21,23,35,43,45–49]. The findings are summarized in Fig. 5 and detailed in Supplementary Table 4. In a study evaluating the effectiveness of lidocaine gel, the results indicated a statistically significant reduction in pain within 10 to 30 min post-procedure compared to placebo, whereas no difference was observed at the 60-minute measurement [49]. Results from two additional RCTs with the same lidocaine gel formulation (see Table 1) do not suggest disparity in pain levels at 5 [48] or 20 min [35] after IUD insertion compared to placebo. Regarding the use of lidocaine spray, no significant reduction in pain at 5 or 20 min post-procedure compared to placebo was reported in one RCT [23], while a statistically significant reduction 15 min after the procedure compared to no intervention was observed in another [45]. No discernible effect on pain scores post-procedure was noted with either lidocaine [43] or mepivacaine solution [47] compared to placebo. Statistically significant differences in mean pain levels at 5 [21] or 10 min [46] post-procedure compared to placebo [21,46] or misoprostol [46] were reported in two RCTs with lidocaine - prilocaine cream use.

Adverse events

In the studies included in this review, no cases of allergy to topical anesthetics were identified. Two patients who received 20 mg of lidocaine spray applied to the cervix experienced severe burning sensations, leading them to refuse IUD insertion [37]. No other adverse events were reported during or after the procedure, irrespective of the treatment group [37]. Panichyawat *et al.* (2021) noted a significantly higher incidence of vaginal irritations in patients treated with 40 mg of lidocaine spray compared to those who received a placebo (54.8 % vs. 1.6 %, $p < 0.001$) [23]. Cases of nausea during IUD insertion were reported with the use of lidocaine - prilocaine cream and in both comparison groups (placebo and misoprostol) in a RCT [46]. In the same study, two patients (2.9 %) reported a burning sensation after using lidocaine - prilocaine cream, whereas no such events were reported in the other two comparison groups (placebo and misoprostol) [46]. Several other adverse events, including abdominal cramps, vomiting, fever, chills,

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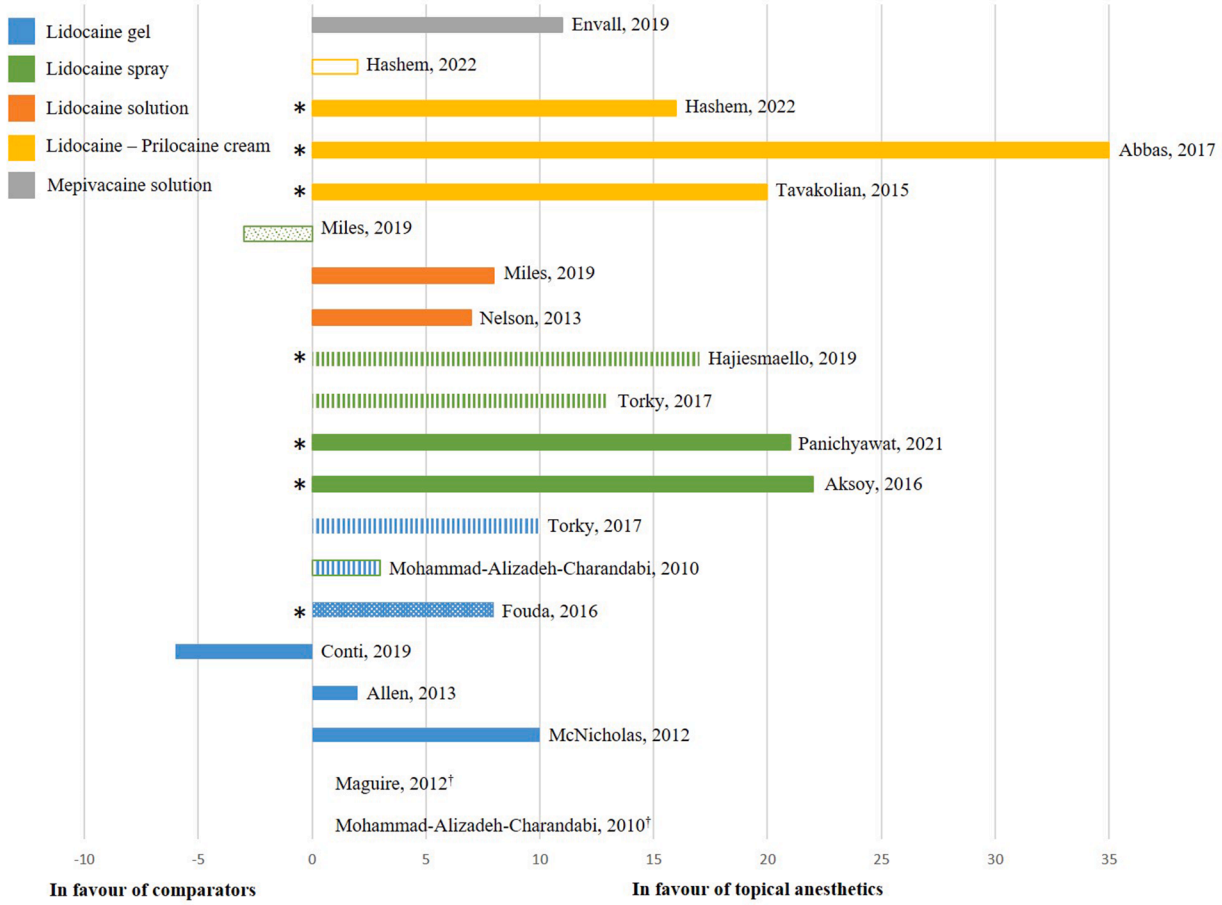


Fig. 4. Pain during intrauterine device insertion, The bar graph illustrates the difference between pain score with topical anesthesia and control during intrauterine device insertion. Each color represents a different anesthetic studied. The fill patterns within the bars denote the comparison groups: solid bars indicate placebo, vertically striped bars denote no intervention, white dotted bar is for topical anesthetic and diclofenac compared to placebo, green dotted bar is for topical anesthetic and naproxen compared to naproxen only and empty bars is for misoprostol.
* p value < 0,05, † Lidocaine gel vs placebo.

headache and diarrhea, were reported in both comparison groups in a study comparing lidocaine - prilocaine cream with misoprostol or placebo during IUD insertion [46]. Some cases of nausea were also reported in two patients (4.4 %) within 24 h in the group of lidocaine gel (120 mg) combined with oral diclofenac use before IUD insertion, while one patient (2.2 %) in the placebo gel group experienced the same event [44]. In a study by Fouda *et al.*, two patients (4.4 %) in each of the lidocaine gel with diclofenac and placebo groups reported heartburn, and one patient (2.2 %) in the treatment group complained of dizziness, while no such events were observed in the placebo group [44].

Discussion

The results of the studies suggest that some formulations of topical anesthetics could induce pain reduction, particularly lidocaine spray 10 % or cream of lidocaine - prilocaine 2.5 %, both during tenaculum placement, uterine depth measurement and IUD insertion. To our knowledge, this review is the only one to specifically address topical anesthetics at different stages of IUD insertion. Mean pain reductions of up to 35 mm on a 100 mm VAS were observed when a topical anesthetic was used compared to a placebo or no intervention. Several mean differences were found to be statistically significant, despite the heterogeneity of the doses used (lidocaine spray: 25 to 125 mg; lidocaine - prilocaine cream: 20 to 40 mg). No relationship was found either between the dose administered and the level of pain reduction or between the mode of administration (self-administered versus administered by a healthcare professional) and the effect on pain relief. Few adverse events were reported, with most studies detecting none. Serious adverse effects associated with the use of topical anesthetics, namely allergic reaction, toxicity on the central nervous system or cardiovascular collapse, have not been reported. Some cases of burning, itching or heat sensations were described in four RCTs involving few patients (2 to 10 % of patients) but the difference with the comparator was not statistically significant.

Our findings on the efficacy of lidocaine - prilocaine cream in alleviating pain during IUD insertion align with the results of a network meta-analysis by Samy *et al.* [11], which synthesized evidence on the most effective medications for pain relief during IUD insertion. These results suggest that lidocaine - prilocaine cream applied to the genital mucosa significantly reduced pain at tenaculum placement (standardized mean difference (MD): −2.38 mm; 95 % confidence interval (CI): −4.07 to −0.68) and at IUD insertion (MD: −2.76 mm; 95 % CI: −4.61 to −0.91) compared to placebo. Similar results were observed in a Cochrane review by Lopez *et al.*, where the mean pain score for IUD insertion was lower with lidocaine - prilocaine cream than with placebo (fixed MD: −1.96 mm; 95 % CI: −3.00 to −0.92) [9]. The efficacy of 10 % lidocaine spray in reducing IUD insertion-related pain was also described, specifically in parous women (median pain score: 1.00 vs. 3.00 in the placebo group) [9]. These findings are consistent with those presented in our review regarding the use of lidocaine spray. Our results are also in line with a review published recently suggesting practices in order to reduce pain for patients at IUD insertion [12]. The authors of

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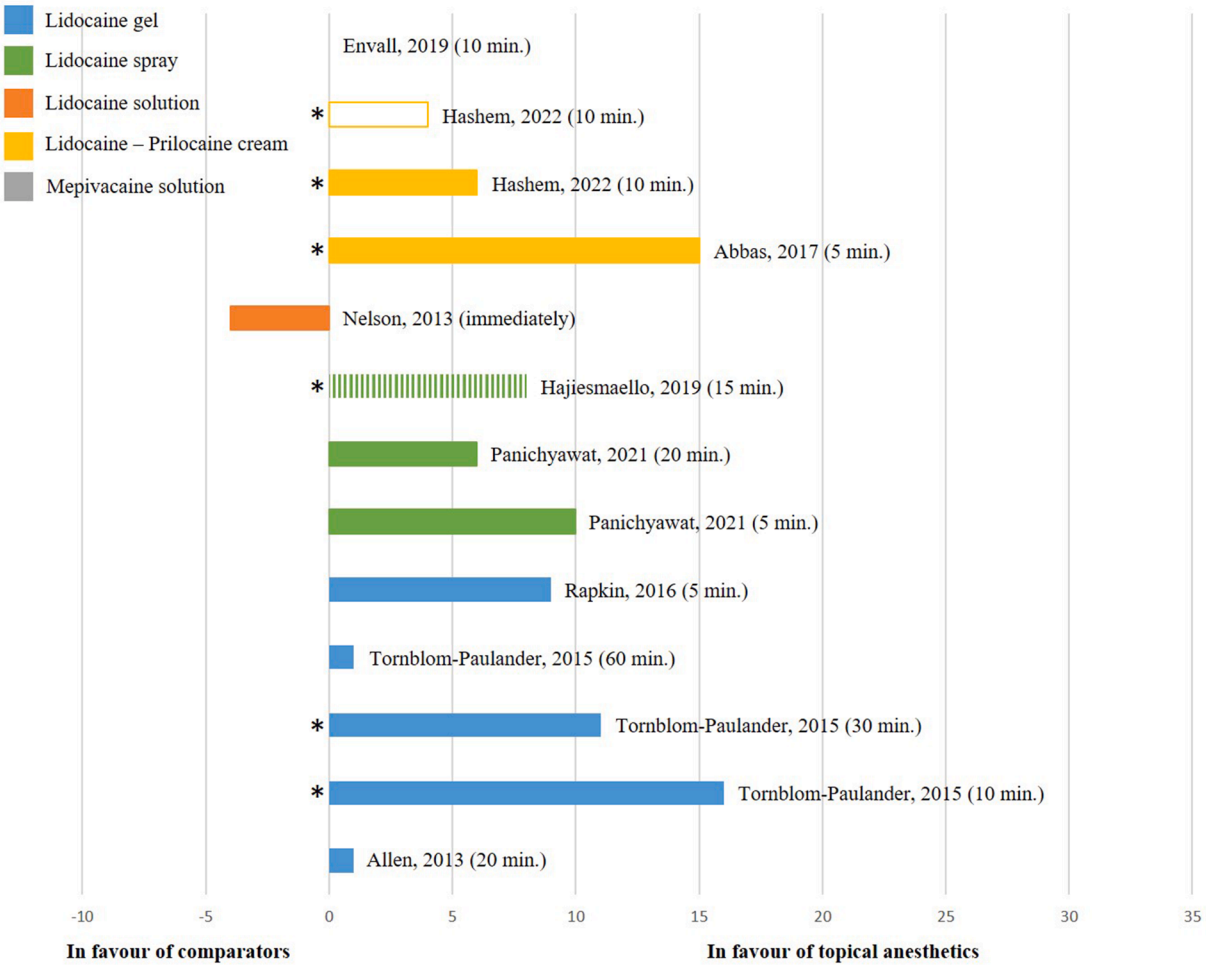


Fig. 5. Pain after intrauterine device insertion, The bar graph illustrates the difference between pain score with topical anesthesia and control after intrauterine device insertion. Each color represents a different anesthetic studied. The fill patterns within the bars denote the comparison groups: solid bars indicate placebo, vertically striped bars denote no intervention, and empty bars are for misoprostol. Time measurement is reported in minutes in parentheses.
* p value < 0,05.

this review recommended the use of topical anesthesia such as 5 mL lidocaine - prilocaine cream, 10 % lidocaine spray or 10 mL of 20 mg/mL mepivacaine. RCTs on lidocaine gel included in our review showed inconsistent results on pain reduction during uterine sounding, tenaculum placement, and IUD insertion, similar to findings by Lopez *et al.* Conflicting results with the use of 1 % lidocaine gel to reduce pain during IUD insertion were also reported in another systematic review [27].

There is no consensus on a threshold of clinical significance for the mean difference in pain reduction level during IUD insertion, as this can vary based on numerous factors, including the type of pain, the type of treatment, the population of interest, and the initial pain level [50]. Furthermore, none of the included RCT addressed this point. In other medical contexts, some authors consider a reduction of 30 % or 20 mm on a 100 mm VAS as a minimal clinically significant difference [51,52]. Based on this threshold, very few of the results reported in the studies included in our systematic review would be considered clinically significants. Pain levels observed in included studies using placebo or no intervention as comparators are mostly below 50 mm, indicating low [53,54] to moderate pain [55,56]. Some authors refer to this as discomfort [55,56]. However, pain prevention should be considered as a key component of interventions aimed at addressing gynecological violence. Increasingly, both healthcare professionals and the general public recognize that care approaches must account for the latent forms of gynecological violence embedded in clinical practices [57]. Therefore, a smaller reduction in pain may still be clinically significant for patients with initially low or moderate pain levels.

Some characteristics or factors appear to increase the likelihood of experiencing more pain during IUD insertion for subgroups of the population [12]. These groups include women who are nulliparous or have given birth only by cesarean section [53,58,59], those with a history of dysmenorrhea [7,59–61], those who have previously experienced painful gynecological or obstetrical procedures [5], or patients with anxiety, high anticipated pain, or a negative perception of the procedure [5,59,62]. It was not possible with the results of the selected studies to identify which patients would benefit more from the use of topical anesthetics, as very few or no subgroup analyses were performed by the authors. No difference in pain level according to parity was reported in one RCT [40], while another showed increased pain in patients with a history of dysmenorrhea and for nulliparous patients when the IUD is not inserted postpartum or post-termination of pregnancy [35]. Studies with larger sample sizes could enable subgroup analyzes to determine whether this intervention would be more beneficial for specific women populations, such as adolescents and nulliparous women.

The data of this review seem to indicate that the use of topical anesthetics for occasional use on the genital mucosa is generally a safe practice, although rare adverse events may occur. However, follow-up time and sample sizes in the included studies were generally too small to identify rare events such as allergic reaction (< 0,1 %), cardiovascular collapse or central nervous system toxicity (< 0,01 %) as described in

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the monography of some products [63,64].

The main limitation of this review is the heterogeneity of the included studies, which restricts the possibility of aggregating the results in a meta-analysis and adds difficulties in the clinical interpretation of the data. The variation across studies includes differences in formulations, doses, comparators, application sites, and methods of administration. Furthermore, this review did not consider the patients experience during IUD insertion as an outcome measurement. In the context of such a subjective outcome as pain assessment, it would have been interesting to include patient-reported experience measures in order to study how patients felt the procedure with or without topical anesthesia. Considering wide inclusion of comparative study designs and pain management comparators, this review provides the current evidence about the clinical impact of using topical anesthetics during IUD insertion. It also contributes a reflection on the clinical significance of the results and the potential adverse events. Moreover, focusing exclusively on topical anesthesia, our review offers a detailed analysis of their effects at each stage of IUD insertion. Furthermore, it updates the available evidence by including recent studies and innovative formulations (e.g. auto-administration).

Conclusion

Many gynecological procedures performed in outpatient clinics are associated with pain experience and it is of particularly importance to offer women solutions to prevent or alleviate this pain. Overall, the results of this review suggest a reduction in pain scores at tenaculum placement, uterine depth sounding, and intrauterine device insertion when topical anesthetics are applied. Despite the heterogeneity of the studies, a greater effect on pain reduction seems to emerge with the use of lidocaine spray or lidocaine - prilocaine cream. Although lidocaine gel is widely used in clinic to reduce pain during IUD insertion procedures, this review showed inconsistent results across studies. Generally, topical anesthetics are associated with safe use in gynecological procedures with few reported adverse events of low severity.

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Declaration of competing interest

The authors report no conflict of interest. This study was registered with the International Prospective Register of Systematic Reviews under identifier CRD42023384750 on March 25th 2023.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jogoh.2026.103104.

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