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REVIEW

Is pain better tolerated with mini-hysteroscopy than with conventional device? A systematic review and meta-analysis

Hysteroscopy scope size and pain

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Abstract
Background Hysteroscopy is an indispensable approach in gynecology. Miniaturization may reduce pain allowing office procedures without anesthesia.
Objectives Our main objective is to determine if modifications in scope diameters have made office hysteroscopy less painful.
Search strategy Studies were sought with key words "hysteroscopy" and "pain" from available online sources. Time frame was from 2000 onward. Thirty-three articles were retrieved for detailed analysis.
Selection criteria Prospective randomized trials, studying pain as main outcome in office hysteroscopy expressed in means, confidence intervals and SD, comparing office mini-hysteroscopy to conventional hysteroscopy. Studies or arms within a study where conscientious sedation, anesthesia or non-steroidal drugs were used were excluded.
Data collection and analysis We analyzed data from eight studies (seven RCT) comparing mini-hysteroscopy with conventional scopes, involving a total of twenty-three hundred and twenty-two participants, of which nineteen hundred and eighty-six completed the intervention.
Main results A meta-analysis revealed a significant reduction pain score (MD: −3.64; 95 % CI −5.16 to −2.12; test for overall effect $p < 0.00001$) and available data support miniaturization decreases pain in outpatient hysteroscopy.
Conclusions Pain in office hysteroscopy is lower with mini-hysteroscopes.

Keywords Hysteroscopy · Scope size · Pain

Introduction

Hysteroscopy is a routine technique allowing direct visualization of unsuspected pathology: endometrial hyperplasia, cancer, and other conditions and is considered gold standard in uterine abnormal bleeding. It allows histological sampling cancer staging and foreign bodies can be retracted or inserted into cavity and tubes. Hysteroscopy is useful in infertile women.

Modern mini-hysteroscopes avoid cervical dilation, misoprostol facilitates operations [1, 2], either by vaginal or sublingual administration [3], and the vaginoscopic no-touch approach [4–8] improved tolerance as data in a 2010 systematic review by Cooper [8] demonstrate. Reduction in pain has led to performing examination and even operations without anesthesia [2, 9–11]. Ultrasonography and 3D sonohysterography are not as accurate in diagnosing intrauterine abnormalities [12], and hysteroscopy is generally needed to confirm diagnosis. It also plays an important role in fertility treatment workup [13]. Both rigid and flexible mini-hysteroscopes reduce pain and may be adequate for examination [14] but rigid scopes seem to have superior optical properties [15].

Distension media is important. Plain water can be harmful, glycine and sorbitol/mannitol are adequate for mono-polar electrosurgery, but can provoke fatal

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outcome. Gas embolization is common, even using normal saline as bipolar electrodes produce bubbles and can be life-threatening. Both CO_2 and normal saline are adequate for diagnostic outpatient hysteroscopy [16] as Cooper's 2010 systematic review on effect on pain concluded, but saline is more convenient if surgery is to be done [17].

Pain is responsible for vasovagal syndrome in 0.21–30 % and leads to halting of procedure. Various interventions [18, 19], medications [20, 21], para-cervical block cocktails, and conscious sedation have been suggested to control pain without convincing results [1, 22–26]. Cengiz [27] compared intrauterine lidocaine and paracervical block and concluded there was no significant difference, but lidocaine has a longer post-operative effect. Two recent systematic reviews in 2010, one by Cooper [24] and another by Ahmad [28] have, however, suggested a reduction of pain with local anesthetic, but "clinical significance of results is limited as the reduction in mean pain score is small" [28]. Success with outpatient technique without anesthesia is associated to very low cost of gynecological care and justifies its generalized use for some authors [5]. Pain perception may vary among population subgroups [29, 30].

A recent paper by Cicinelli [31] summarizes evidence gathered from various studies and sources.

Objectives

Our main objective is to determine if modifications in scope diameters has made office hysteroscopy less painful. While most studies agree that slender hysteroscopes reduce pain, one randomized controlled trial (RCT) from 2005 by Rullo [32] and one prospective cohort study by Torok in 2012 [33] failed to find statistical difference between scope diameters and pain scores. So the question remains: is reduction in hysteroscope diameter associated with lower pain perception?

Search strategy

Studies were sought with key words "hysteroscopy" and "pain" from the following sources: Pubmed/Medline (465), Portal de Pesquisa da BVS (214), LILACS (13) CINHAL, Embase and Cochrane database (82) Cochrane systematic reviews (3) DARE systematic reviews (4) IBECS (3) Scielo (8) Global Health Library (GHL), (20) Western Pacific region Health Index (WPRIM) (12) Index Medicus for the Eastern Mediterranean Region (IMEMR) (8), and Index Medicus for South-East Asia Region (IMSEAR) (1) giving a total 834 hits. Time frame was from 2000 onward. After reading titles and eliminating duplicates, 94 abstracts were independently assessed by three authors (A.P., M. S. and C.P.) and of theses, 33 articles retrieved for detailed analysis.

Methods

Ethical and regulatory compliance: This study was conducted in compliance with the protocol, the Declaration of Helsinki, the Good Epidemiological Practice, and all applicable laws and regulations.

Seven papers (including eight studies) were selected from literature sources. Flow chart of selection is specified in Fig. 1.

Using standard meta-analysis software (RevMan 5.0),[1] we computed mean differences (MD) also known as Cohen' d and 95 % confidence intervals (CI) for all studies. Because we expected considerable heterogeneity, we use a random-effects model taking into account both within and between-study variation to compute the overall effect estimate. However, we first tested the heterogeneity using the Q statistic and the I^2 statistic with values of 0.25, 0.50, and 0.75 indicating low, moderate, and high degrees of heterogeneity. Sensitivity analysis by excluding one study at each turn and pooling results from the remainder further confirms the robustness of our findings. To explore the heterogeneity across studies, we conducted subgroup meta-analyses (by assessing the difference between groups in trials with similar participant characteristics). Publication bias was assessed using funnel plot analysis. Visual inspection of a funnel plot can give an indication of publication bias; the studies can be expected to spread symmetrically about the pooled effect size when publication bias is absent.

Eligibility criteria

Seven RCT [1, 22, 32, 34–37] (giving a total of eight studies) comparing pain during mini-hysteroscopy versus conventional hysteroscopy, involving a total of twenty-three hundred and twenty-two patients were included and analyzed.

Other studies were rejected for the following reasons: De Iaco [38] was to our knowledge the first to publish data on pain and outpatient hysteroscopy, but his work was observational. For the same reason Siristatidis [9], Torok [33], and Cicinelli [30] were also excluded. Bettocchi's studies had different objectives or were operative hysteroscopy as was De Placido's paper [39], and authors judged they were not suitable for the purpose of this study.

[1] Review manager (RevMan) [Computer Program]. Version 5.0. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration (2008).

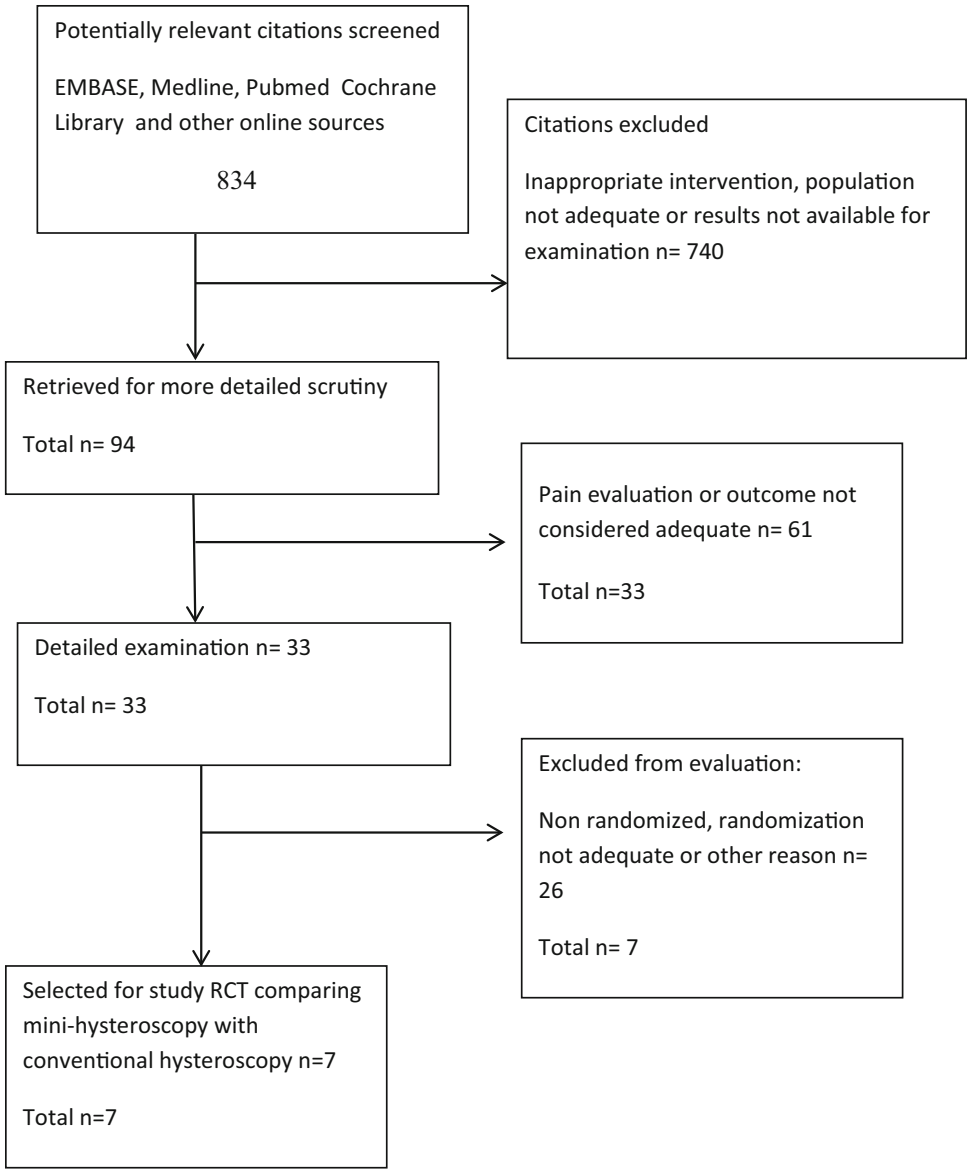

Fig. 1 Flow chart for selection process of studies for evaluation of pain in hysteroscopy

Bias assessment

Our eight studies were assessed for bias using the Cochrane tool for bias assessment. Revision authors judged blinding of personnel in such studies was very unlikely to be effective as operators always knew which hysteroscope is being used. Randomization was judged low risk in seven series and unclear in one, and so was concealment. Blinding of outcome assessors was attained in three and unclear in five. All studies account for missing cases and selective reporting was unclear in one study. Authors believe studies are high quality, having an overall low risk of bias. (Fig. 2).

Results

In order to allow comparison of means and SD results, input was in reference to a 10 cm scale. Other results were converted as described: for Cicinelli's 20 cm scale means variation has a $Y = X/2$ relation with adopted scale. So accordingly $E[Y] = E[Y]/2$ for *means* and $V[Y] = V[X]/4$ for *variance* were taken as comparative values; Kassem reported in absolute numbers and revision authors converted rank classes 1–4 into categories and adapted results to a 0–10 scale, calculating means, variance, and SD for each category.

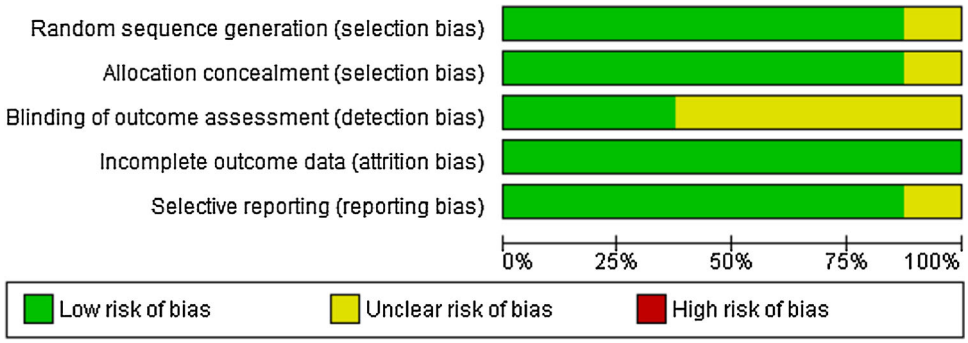

Fig. 2 Risk of bias graph using Cochrane tool for bias assessment: review authors' judgments

Giorda's and Campo's studies seem to have heterogeneity with all others; we doubled check our data extraction but found heterogeneity was high ($I^2 = 99.6$ %, p value <0.001). As a result, we conducted a subgroup meta-analysis (high and low effect studies) and the difference between subgroups effect sizes is significant (the correspondent confidence intervals have no overlapping). Meta-analysis of the eight studies showed a significant reduction in pain scores (MD: −3.64; 95 % CI −5.16 to −2.12; test for overall effect $p < 0.00001$). The implemented subgroup analysis dividing the studies according the effect size strength also showed, for both subgroups, a significant reduction in pain. Fig. 3.

For studies with high effect sizes, the meta-analysis presents MD: −11.26; 95 % CI −12.39 to −10.13 (test for overall effect $p < 0.00001$); for studies with low effect sizes the meta-analysis reveals MD: −1.15; 95 % CI −1.54 to −0.76 (test for overall effect $p < 0.00001$).

Results of sensitivity analysis excluding one by one each study in the analysis at a turn and pooling results from the remainder, further confirmed the robust findings of significant reduction in pain scores as shown in Table 1.

Furthermore, as was expected, Campo and Giorda studies show highest influence in the overall results. Inspection of the funnel plots (subgroup analysis) did not indicate possible publication bias as there seems to be a symmetrical distribution around the means (Fig. 4).

Discussion

Data from all studies suggest mini-hysteroscopy is less painful than conventional hysteroscopy in an office, anesthesia free setting. In the subgroup analysis results, although two studies seem outsiders in respect to others, they go in the same direction and favor reduction of pain with miniaturization. Furthermore, there seems to be no

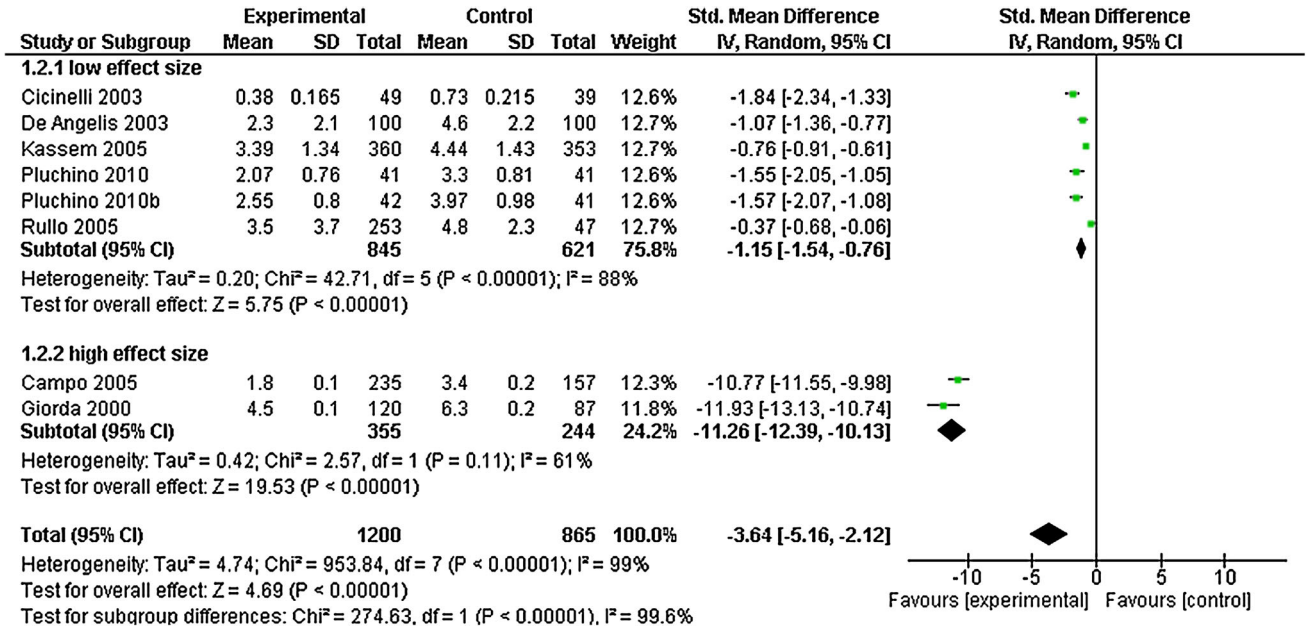

Fig. 3 Forest plot analysis including subgroup results

Table 1 Sensitivity analysis excluding one study at a time one by one each study in the analysis

Excluded study	Std. mean difference	LCI 95 %	HCI 95 %	I^2
Giorda et al. [36]	−2.51614	−3.85895	−1.17334	99.06196
Pluchino [34] saline	−3.95236	−5.66861	−2.2361	99.36957
Pluchino [34]	−3.94905	−5.66551	−2.23259	99.36937
De Angelis et al. [1]	−4.04133	−5.94324	−2.13943	99.37043
Campo et al. [22]	−2.52677	−3.5681	−1.48545	98.37323
Kassem et al. [37]	−4.10099	−6.2301	−1.97189	99.32171
Rullo et al. [32]	−4.13742	−5.97931	−2.29553	99.35012
Cicinelli et al. [35]	−3.91028	−5.61973	−2.20084	99.36656

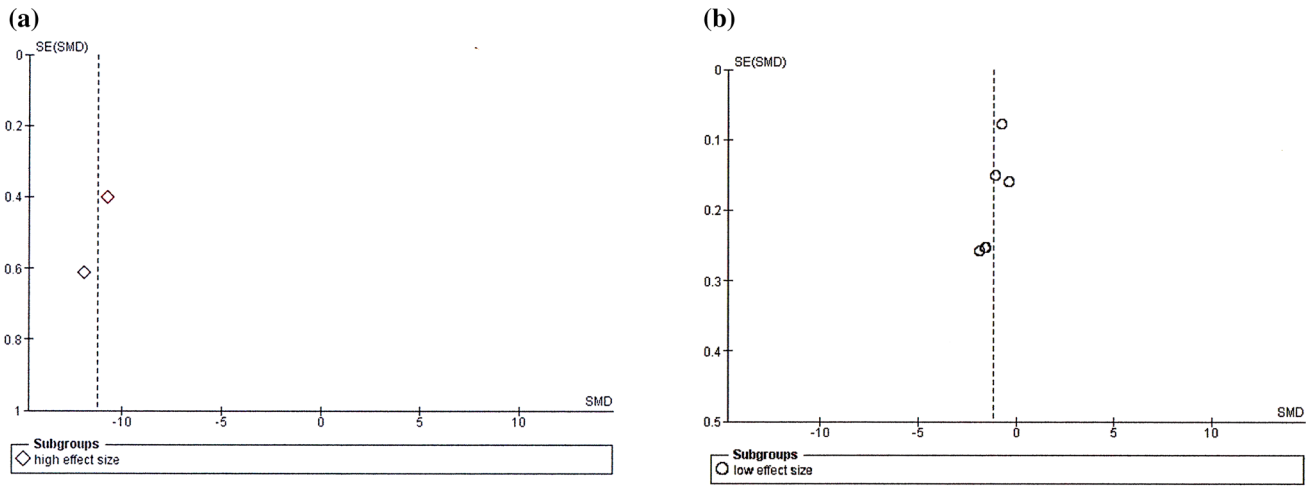

Fig. 4 Funnel plot comparing studies by size effect, **a** subgroup of high effect size values, **b** subgroup of low effect size values

significant differences in quality of vision or diagnostic accuracy with reduction in hysteroscope diameter [1, 11, 22, 32, 34–37].

Not all mini-hysteroscopes used were the same size: 3 mm (Rullo), 3.3 mm (Angelis) and 3.5 mm (Pluchino, Campo, Cicinelli, Giorda and Kassem). Our forest plot does not seem to reflect a difference in pain with these small changes in diameter: the high effect size include two 3.5 mm series (Campo and Giorda), while both smaller diameter hysteroscopy studies (Rullos' 3 mm and Angelis' 3.3 mm) are in line with the other 3.5 mm studies which showed low effect size. We could be tempted to speculate that further reduction in scope diameters might lead to lower pain perception; however, our analysis suggests there may be a cut off around 3.5 mm, below which reduction of scope size might not further reduce pain. Additional studies comparing slender instruments may be warranted to answer this question.

Regarding the inconsistencies found we offer the following possible explanations: Giorda's study was conducted exclusively on postmenopausal women, most likely giving rise to a selection bias; on the other hand in Campo's series, the 5 mm scope arm had to be changed to the mini-hysteroscope in eighty-three cases to complete examination (34 %).

Main findings

Miniaturization of scopes shifts pain levels down, compared to traditional hysteroscopy, allowing accurate gynecological care in an office, anesthetic free environment.

Strengths and limitations

Results showed overall results are very consistent and there seems to be no doubt of a significant reduction of VAS using mini-hysteroscopy. Authors believe that evidence is convincing, accurate, reproducible, and can be extrapolated to general population. For details please refer to Table 2.

Interpretation (findings in light of other evidence)

Miniaturization reduces pain scores and has made hysteroscopy tolerable for most patients.

Table 2 Strength and weakness

	Study type	*n*	Strengths	Weaknesses	Risk of bias
Pluchino et al. [34]	RCT	184	Multicentre randomized trial, several outcome measures including two VAS measures and relating results to medium distention method and operator experience. Patients having additional procedure were not considered in pain evaluation Results were expressed in mean and SE values with 95 % confidence intervals	Population exclusively referred for primary infertility; several outcome measures including two VAS measures and quality of visualization	Authors judged adequate to consider two groups (saline solution or CO2 as distention media), hence accepting two series for meta-analysis comparison. VAS1 score (immediately after hysteroscopy) was chosen. For this purpose study was considered having low risk of bias with adequate randomization and concealing
De Angelis et al. [1]	RCT	207	Randomized trial at a Obstetrics and Gynecology Department of a University Hospital. Population with various indications for hysteroscopy. Main outcome measure was VAS score Results were expressed in mean and SE values with 95 % confidence intervals	Outcome measures included two VAS scores (immediately after and five minutes after). All patients underwent hysteroscopy with speculum insertion, although no traction or cervical dilatation was allowed	Authors judged adequate to consider this study (using CO2 as distention media on both arms), accepting series for meta-analysis comparison. VAS score (immediately after hysteroscopy) was chosen. For this purpose study was considered having low risk of bias with adequate randomization and concealing
Campo et al. [22]	RCT	480	Multicentre randomized trial, with main outcome measures of VAS measure, relating results to vaginal delivery or no vaginal delivery and operator's experience. Population with various indications for hysteroscopy Results were expressed in mean and SE values with 95 % confidence intervals	Other outcome measures included quality of visualization. Interchangeability of scopes was allowed. All patients underwent hysteroscopy with speculum insertion, although no traction or cervical dilatation was allowed	Authors judged adequate to consider this study (using saline as distention media on both arms), accepting series for meta-analysis comparison. VAS score (immediately after hysteroscopy) was chosen. For this purpose study was considered *having unclear risk* of bias as interchangeability of scopes was significant and could affect results. Study had adequate randomization and concealing
Kassem et al. [37]	RCT	740	Randomized trial at a Obstetrics and Gynecology Department of a University Hospital. Significant number of participants	Results were expressed in four ranks of pain and in absolute numbers. Revision authors converted ranks into categories and calculated means, variance, SE and 95 % confidence intervals in reference to a 0 to 10 scale to allow comparison	Considering total number of patients involved, revision authors judged adequate to include this study, accepting series for meta-analysis comparison. Randomization was computer generated but concealment was probably not adequate. For purpose of this research study was considered having *unclear risk* of bias
Rullo et al. [32]	RCT	371	Randomized trial at a Obstetrics and Gynecology Department of a University Hospital. Population with various indications for hysteroscopy. Results were expressed in mean and SE values with 95 % confidence intervals	Non equal randomization: smaller number of patients in 5 mm arm Outcome included failure of procedure due to pain (ranging from 3.8 % to 15.4 %.), three evaluations of VAS score at different time (during, immediately after and 30 min after. Diagnostic accuracy and time consumed were also evaluated comparing parity, menopause and scope diameter. All patients underwent hysteroscopy with speculum insertion	Results were expressed in mean and SE values with 95 % confidence intervals (data collected from Cicinelli, E. in his review 2010). For this purpose study was considered *having unclear risk* of bias as neither randomization nor concealment seem to be adequate

Table 2 continued

	Study type	*n*	Strengths	Weaknesses	Risk of bias
Cicinelli et al. [35]	RCT	100	Randomized trial at a Obstetrics and Gynecology Department of a University Hospital. All patients were referred for abnormal uterine bleeding. The vaginoscopic "no touch" approach was used to minimize pain Results were expressed in mean and SE values with 95 % confidence intervals	Evaluation of pain used a 20 cm ruler and prior to examination a "pain expectancy" form was completed by each patient (could subjectively influence rating of actual pain experienced) Pain evaluation was done by placing a mark on the ruler	Authors judged adequate to consider this study (using saline as distention media on both arms), accepting series for meta-analysis comparison. VAS score (immediately after hysteroscopy) was chosen. For this purpose study was considered *low risk* of bias although it is not clear suggestion from prior expectancy rating could affect results. Study had adequate randomization and concealing
Giorda et al. [36]	RCT	240	Randomized trial at a Obstetrics and Gynecology Department of a University Hospital. 4 Results were expressed in mean and SE values with 95 % confidence intervals	Computer randomization, but not blind study. Included 3 groups: 3.5 mm scope, 5 mm scope and 5 mm scope with paracervical block Population referred was exclusively post-menopausal	Authors judged adequate to consider two study arms: 3.5 mm scope and 5 mm scope without paracervical block. N = 240 (using CO2 as distention media on both arms), accepting series for meta-analysis comparison. VAS score (immediately after hysteroscopy) was chosen Although not blind, authors were satisfied for the purpose of this study allocation was computer randomized and judged low risk for bias

Conclusions

From the evidence gathered, we must conclude that mini-hysteroscopy is the most acceptable and suitable for office in outpatients. Traditional hysteroscopy (5 mm scopes) may not be the most adequate for this purpose.

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Conflict of interest The authors have no conflict of interest with any institution private or public.

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