

# Reducing Postoperative Pain After Tubal Ligation With Rings or Clips

## A Systematic Review and Meta-analysis

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**OBJECTIVE:** To assess the effectiveness of using local anesthesia during interval laparoscopic tubal ligation to control postoperative pain.

**DATA SOURCES:** We searched MEDLINE, PubMed, and Cochrane databases and found additional articles from bibliographies of relevant studies.

**METHODS OF STUDY SELECTION:** We included only randomized, double-blind, placebo-controlled trials reporting postoperative pain after interval laparoscopic tubal ligation under general anesthesia (n=20). The trials compared the application of topical or injectable local anesthetic with placebo and used a visual analog scale (VAS) (scores 0–100) or the Modified McGill Pain Intensity Scale (subsequently converted to a VAS) to assess pain.

**TABULATION, INTEGRATION, AND RESULTS:** Pain scores were evaluated at the following times after extubation: 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, and 24 hours. The meta-analysis was based on random-effects methods for pooled data using RevMan. Postoperative pain decreased with the use of local anesthetic compared with placebo as follows (mean VAS decrease in millimeters, 95% confidence interval): 30 minutes 18.6 (11.7–25.5); 1 hour 16.6 (9.3–24.0); 2 hours 17.4 (9.6–25.2); 4 hours 12.5 (5.1–19.9); 8 hours 11.9 (6.7–17.1); and 24 hours 3.9 (–1.4 to 9.2). There was moderate heterogeneity in the

data across studies ( $I^2$  statistic ranging from 55% to 75%). The effect size was similar for the following subgroups: pain scores reported as means or medians and use of McGill compared with VAS pain scales. A stratified analysis of trials including ring tubal ligation compared with clip tubal ligation showed the use of local anesthetic decreased pain substantially for both. No eligible studies assessed tubal ligation with cautery.

**CONCLUSION:** Use of local anesthetic during laparoscopic tubal ligation substantially reduces postoperative pain up to 8 hours after surgery.

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In the United States and around the world, tubal ligation remains one of the most common forms of contraception. In 2006, approximately 643,000 women in the United States underwent tubal ligation with a rate of 12.2 procedures per 1,000 unsterilized women.<sup>1,2</sup> Nearly half of all sterilizations are performed outside the postpartum period, and laparoscopic tubal ligation is a prevalent method.<sup>1</sup> Women undergoing laparoscopic tubal ligation often have significant postoperative pain; laparoscopic procedures cause pain from stretching of somatic nerves during insufflation, irritation from the acidic environment created by carbon dioxide gas, and from residual intraperitoneal gas still present postoperatively.<sup>3</sup> Pain after a tubal ligation can also result from ischemia and necrosis of the tubes at the ligation site.<sup>4,5</sup>

Patients undergoing laparoscopic tubal ligation in the United States usually do so under general anesthesia.<sup>6</sup> Some gynecologists also administer local anesthetics to the sterilization site to reduce the intensity or duration of postoperative pain, and many trials have evaluated this practice. We undertook this systematic overview and meta-analysis to evaluate whether local anesthetics can decrease postoperative pain after laparoscopic tubal ligation under general anesthesia.

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### Financial Disclosure

Dr. Westhoff has served on the scientific advisory board for Agile Therapeutics. She has also served on the data safety monitoring board for several U.S. Food and Drug Administration (FDA)/European Medicines Agency (EMA)-mandated, phase 4 safety studies of newly marketed Merck contraceptive products as well as the data safety monitoring board of several FDA/EMA-mandated, phase 4 safety studies of novel Bayer contraceptive products. The other authors did not report any potential conflicts of interest.

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## SOURCES

For inclusion in this meta-analysis, a study needed the following characteristics: a double-blind, randomized, placebo-controlled trial; interval female sterilization performed by a laparoscopic approach under general anesthesia; use of topical or injectable local anesthetics (not intravenous or oral) as the intervention to reduce postoperative pain compared with placebo; use of a validated postoperative pain scale; and English language publication. We made no restrictions on publication year, country of origin, or journal of publication, but included only published articles.

We searched MEDLINE, PubMed, and Cochrane databases using the following search terms: tubal sterilization; pain, postoperative; surgery, laparoscopy; and randomized controlled trial. The bibliographies of identified articles were reviewed for additional sources. In our hand search of personal files, we did not identify any relevant articles beyond those identified through our search strategy.

## STUDY SELECTION

Our search strategy identified 271 published articles. Two reviewers (M.S.H., C.L.W.) independently reviewed the abstracts of all articles to identify which studies met or possibly met the inclusion criteria. The reviewers initially both selected 73 of the articles and after discussion, agreed to include two additional studies to read in full for possible inclusion in the study. Using an inclusion and exclusion checklist, reviewers agreed 21 of the 75 articles were suitable for analysis.

One author (M.S.H.) extracted necessary data from each of the 21 studies using a piloted form. Another author (C.L.W.) confirmed extracted data. We attempted to contact all authors by electronic mail to supply missing data and found contact information for 14 authors; nine responded. We subsequently excluded one paper as a result of our inability to calculate a variance estimate,<sup>7</sup> leaving 20 papers for the analysis (Table 1).<sup>8-27</sup> Only one author<sup>10</sup> provided useful additional information (regarding the timing of pain measurements).

We extracted the following variables: author, journal, year of publication, country of study origin, patients enrolled and final number analyzed, time points of pain ascertainment, pain scores at each time point, variance in pain scores, how pain levels were reported (means or medians), the scale used to assess pain level (visual analog scale<sup>28</sup> or Modified McGill Pain Intensity Scale<sup>29</sup>), type and dose of local anesthetic, site and method of anesthetic application, and

method of sterilization (clips or rings). When a paper did not report the means and standard deviations, we used other information provided in the paper to estimate these, including extrapolating data provided in figures to estimate means and using *P* values resulting from *t* tests to calculate the (unreported) pooled standard deviations. We estimated medians to equal the (unreported) means.<sup>30</sup>

Studies assessed postoperative pain at three to 17 time points after surgery. We selected the six most widely reported time points for inclusion in the meta-analysis. These were 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, and 24 hours after extubation. We mapped pain scores from each study onto these six time points. When studies reported pain scores at an event rather than at a time, we assigned the pain score to the nearest time point as follows: arrival to the postanesthesia care unit: 30 minutes postextubation<sup>14,18,25</sup>; discharge: 8 hours postextubation<sup>11,14,16-19,21,23,25,27</sup> except where specified to be earlier<sup>12</sup>; and postoperative day 1: 24 hours postextubation.<sup>12,25,27</sup> For studies that reported multiple pain scores, we used only the six that were closest to the times we defined and excluded additional pain scores. The 20 papers reported 92 pain scores. Seventy-six of these were between 30 minutes and 24 hours, and we included 69 of these (90.8%). One study had multiple measurements before 30 minutes and six studies had measurements after 24 hours; we did not consider those time points further.

Seven studies<sup>18,20-24,26</sup> reported results only as medians, and 13<sup>8-17,19,25,27</sup> reported results as means. For the purposes of the meta-analysis, we included all studies (means and medians), but we also examined them separately.

Seven studies<sup>8,11,15,18,20,22,25</sup> reported their results only in figures. To include these results in the meta-analysis, two authors (M.N.D., M.S.H.) independently extrapolated pain scores from the figures. The correlation coefficient ( $r^2$ ) of the two estimates ranged from 0.95 to 1.0. We included the mean of the two extrapolated scores in the primary meta-analysis.

Seventeen studies<sup>8-11,13-22,24-26</sup> reported results using visual analog scale (VAS), whereas three studies<sup>12,23,27</sup> used McGill. In brief, VAS quantifies pain intensity using a 10-cm line with ends anchored at 0 cm (no pain) and 10 cm (maximal pain). In the Modified McGill Pain Intensity Scale, patients rate pain from 0 (none) to 5 (excruciating). We converted McGill scores to VAS by multiplying by 20.

The site of local anesthetic application varied. To simplify, we assigned studies to one of three groups: topical tubal (dripping medication over the fallopian



**Table 1. Characteristics of Articles Included in the Meta-analysis**

Author	Year	Country	n <sub>i</sub> /n <sub>c</sub>	Mean or Median	Pain Scale Used	Type of TL	Local Anesthetic	Site of Local Anesthetic	Pain Scores Used*					
									30	1	2	4	8	24
Cook	1986	Australia	30/30	Mean	VAS	Clips	Bupivacaine	Topical	x				x	x
McKenzie	1986	U.S.	51/51	Mean	VAS	Rings	Etidocaine	Topical		x	x	x		
Alexander	1987	U.S.	25/25	Mean	VAS	Rings	Bupivacaine	Injection	x	x			x	x
Baram	1990	U.S.	46/41	Mean	VAS	Rings	Etidocaine	Topical				x	x	x
Kaplan	1990	U.S.	16/15	Mean	McGill	Rings	Bupivacaine	Topical	x	x			x	x
Smith	1991	U.K.	15/15	Mean	VAS	Rings	Bupivacaine	Injection		x			x	x
Barclay	1994	U.K.	33/29	Mean	VAS	Clips	Lidocaine	Topical	x		x		x	x
Benhamou	1994	France	25/25	Mean	VAS	Rings	Lidocaine	Injection	x		x		x	x
Wheatley	1994	U.K.	30/30	Mean	VAS	Clips	Bupivacaine	Topical		x			x	
Ezeh	1995	U.K.	37/37	Both	VAS	Clips	Lidocaine	Topical	x	x			x	
Eriksson	1996	Finland	29/30	Median	VAS	Clips	Lidocaine	Topical	x				x	
Fiddes	1996	New Zealand	30/30	Mean	Both	Clips	Lidocaine	Injection		x	x		x	x
Hunter	1996	U.K.	17/20	Median	VAS	Clips, rings	Bupivacaine	Peritoneal	x		x		x	
Kelly	1996	U.K.	27/30	Median	VAS	Clips	Bupivacaine	Peritoneal		x	x	x		x
Van Ee	1996	U.S.	20/17	Median	VAS	Rings	Bupivacaine	Injection		x	x	x	x	x
Tool	1997	U.S.	29/32	Median	McGill	Rings	Bupivacaine	Topical	x				x	x
Haldane	1998	U.K.	20/20	Median	VAS	Clips, rings	Lidocaine	Peritoneal	x					
Dreher	2000	Australia	10/9	Mean	VAS	Clips	Ropivacaine	Peritoneal	x	x	x		x	x
Schytte	2003	Denmark	35/35	Median	VAS	Clips	Bupivacaine	Peritoneal	x		x	x		
Brennan	2004	U.S.	20/29	Mean	McGill	Clips	Bupivacaine	Topical	x				x	x

n<sub>i</sub>, number in the intervention group; n<sub>c</sub>, number in the control group; TL, tubal ligation; VAS, visual analog scale.

\* Times reclassified where necessary as time elapsed since extubation.

tubes or coating of clips), injection (of mesosalpinx or cornual mesentery), or intraperitoneal (applied to pelvic peritoneum, pouch of Douglas, or through the uterine manipulator). One trial both injected the mesosalpinx and applied anesthetic topically over the right subdiaphragmatic area<sup>15</sup>; we included this study in the injection group.

All local anesthetic agents reported here are amide “-caines” and work by the same pharmacologic mechanism of action: inhibition of sodium ion channels, stabilizing neuronal cell membranes, and inhibiting nerve impulse initiation and conduction. We grouped studies by duration of anesthetic action: short-acting agents (lidocaine) and longer acting agents (bupivacaine, etidocaine, ropivacaine).<sup>31</sup> One study<sup>10</sup> assigned patients to four groups: bupivacaine, lidocaine, saline, or no infiltration; in this analysis, we compared only the bupivacaine group with the saline group.

We also grouped trials according to type of tubal ligation performed. We classified studies using Filshie or Hulka clips in the “clip” group and Falope rings, Yoon rings, and Silastic bands in the “ring” group. Two trials used both clips and rings in the study; rings were used in 83% of patients in one study,<sup>24</sup> whereas

the distribution of clips and rings was not recorded in the other.<sup>20</sup> We analyzed both trials with the ring group in the meta-analysis. No study that met eligibility criteria used cautery for tubal ligation.

To assess the risk of bias for each study, we used the quality grading scheme of the Cochrane handbook.<sup>32</sup> Each trial was evaluated based on its approach to randomization, allocation concealment, blinding of the operator, blinding of the patient, and percent missing outcomes.

The principal summary measure was mean difference in VAS between the placebo group and the group that received local anesthetic. We used Review Manager 5.2<sup>33</sup> to perform the meta-analysis. We performed subanalyses to compare studies that recorded mean or median pain scores, studies that reported McGill or VAS pain scales, and geographic location where the study was conducted (United States, Europe, Australia or New Zealand). We also compared effect size for different local anesthetic agents (short- or long-acting), different sites of application of local anesthetic (topical on tubes, injection, or intraperitoneal), and clip or ring method of tubal occlusion. We prespecified all subanalyses.



$I^2$  measure of consistency<sup>34</sup> showed moderate heterogeneity of the included studies, ranging from 55% to 75% across the six time points. A single study<sup>22</sup> contributed 4% of the data in the analysis and much of the heterogeneity. That study included 40 patients who all received intravenous ketorolac along with local anesthesia; it is the only study that included this additional intervention. Removing that study from the analysis reduced the heterogeneity but did not change the overall effect size; thus, we did not exclude it from the analysis. To further examine sources of heterogeneity across studies, we also performed stratified analyses as described previously.

## RESULTS

The flowchart demonstrating study selection is shown in Figure 1. Twenty randomized, double-blind, placebo-controlled trials of local anesthesia for women undergoing laparoscopic tubal ligation under general anesthesia published from 1986 to 2003 constitute this meta-analysis (Table 1). The individual studies included 19 to 102 participants, comprising a total of 1,144 women. Across all studies, authors reported results for 1,095 of 1,144 participants (95.7%). The study with the most missing data<sup>27</sup> reported results for 49 of 63, or 77.8% participants. All studies had a one-to-one allocation ratio. Studies assessed postoperative pain at three to 17 time points (median four) after surgery.

The studies originated in eight countries. The local anesthetics used included lidocaine (short-acting) or bupivacaine, etidocaine, and ropivacaine (longer acting). The intervention groups received local anesthetic applied to one of the following sites: fallopian tubes, onto the surgical clips, subdiaphragmatic area, mesosalpinx, cornua mesentery, port sites, pelvic peritoneum, pouch of Douglas, and through the uterine manipulator. The methods of tubal ligation

included Filshie clips, Hulka clips, Falope rings, Yoon rings, and Silastic bands.

We rated four studies as low,<sup>11,18,23,25</sup> eight as intermediate,<sup>16,17,20–22,24,26,27</sup> and eight as high-risk<sup>8–10,12–15,19</sup> of bias. Analyzed separately, the eight studies we considered to have a higher risk of bias had an effect size similar to the 12 studies that had a low to moderate risk of bias.

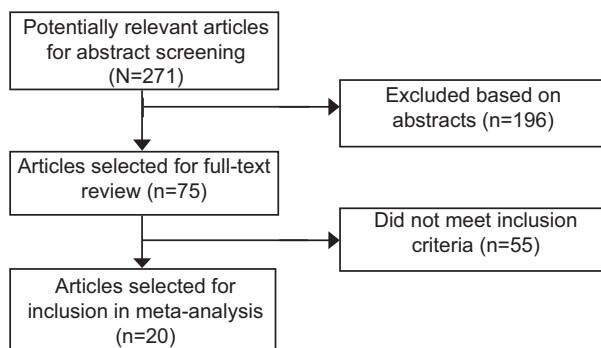
The forest plots shown in Figure 2A–F illustrate the change in pain scores for the 20 studies at each of the six time points. Table 2 and Figure 3 summarize these results, presenting the arithmetic mean overall pain score at each of the six time points. Table 2 and Figure 3 present unweighted data; when we repeated the analysis with scores weighted by study size, the results were indistinguishable from the unweighted results.

No trial collected data at all six of the chosen time points; the number of trials contributing to the pain score at a single time point ranged from eight to 13 (Table 2). Local anesthetic substantially decreased mean pain scores except at postoperative day 1 or at 24 hours (Table 2).

We performed secondary analyses to assess the treatment effect in subgroups and thus to evaluate the justifiability of combining all 20 studies. The decrease in pain scores was similar for studies that reported mean and median scores when evaluated separately and for studies that reported VAS and McGill pain scores (data not shown). Further subanalyses compared the results according to geographic location (the United States,<sup>9–12,22,23,27</sup> Europe,<sup>13–18,20,21,24,26</sup> and Australia or New Zealand)<sup>8,19,25</sup> and yielded similar results for mean decrease in pain scores (data not shown). The 20 studies used several different local anesthetic agents, which we broadly grouped into short-acting<sup>14,15,17–19,24</sup> and long-acting agents.<sup>8–13,16,20–23,25–27</sup> The mean decrease in pain scores was similar (data not shown).

We grouped the site of local anesthetic application into topical tubal,<sup>8,9,11,12,14,16–18,23,27</sup> injection,<sup>10,13,15,19,22</sup> and intraperitoneal administration.<sup>20,21,24–26</sup> The decrease in pain scores at all time points was similar across these groups.

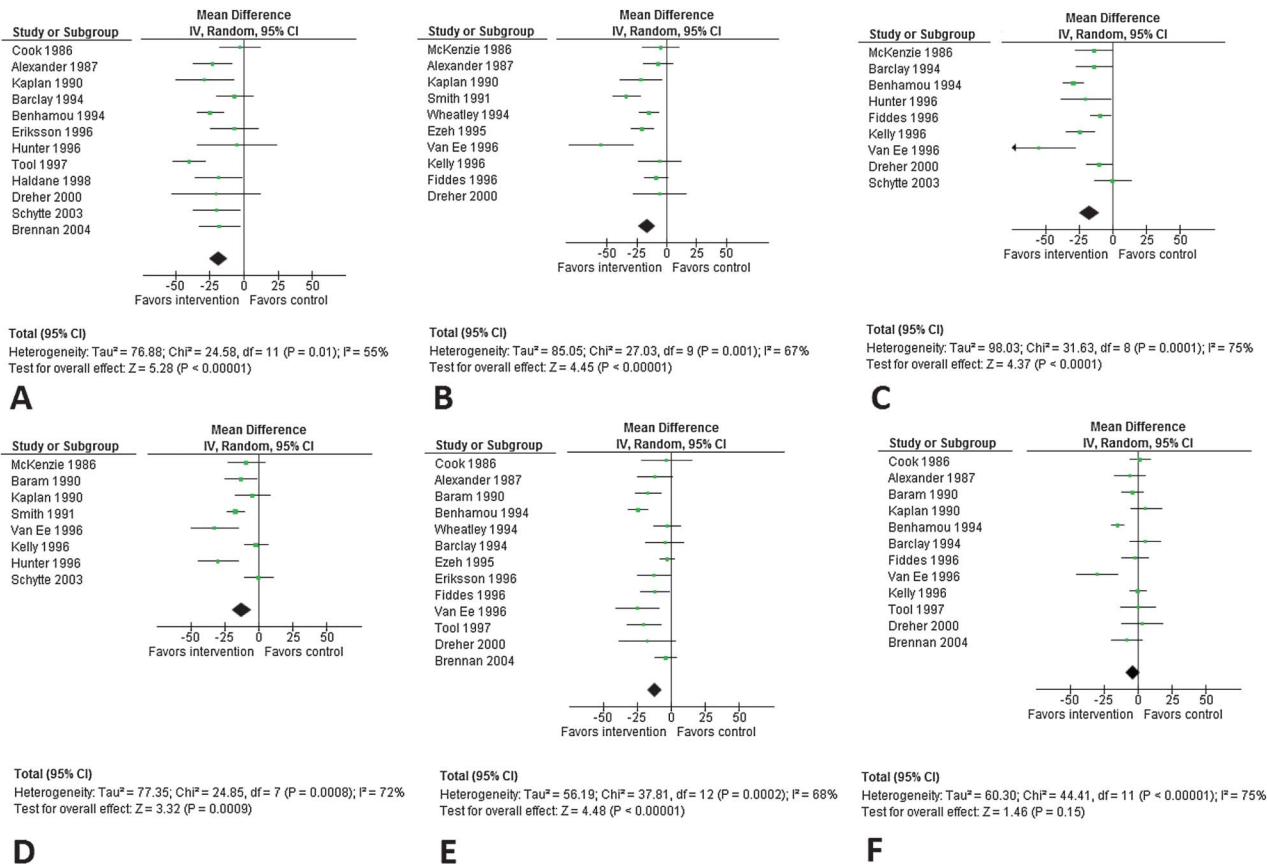
The final subanalyses compared studies performed tubal ligation using clips ( $n=570$ )<sup>8,14,16–19,21,25–27</sup> compared with those studies with rings ( $n=525$ ).<sup>9–13,15,20,22–24</sup> Patients in the control groups had substantially greater pain after rings than after clips ( $P=.008$ ) (Table 3). In the intervention groups, however, pain scores were similar between the clip and ring patients ( $P=.86$ ). A clinically meaningful benefit (ie, greater than 9 points)<sup>34–36</sup> was seen at all time points in the studies that applied rings, whereas the benefit was somewhat smaller when studies using clips were analyzed alone.



**Fig. 1.** Flowchart of article selection for the meta-analysis. Harrison. *Reducing Pain After Laparoscopic Tubal Ligation*. *Obstet Gynecol* 2014.







**Fig. 2.** Forest plots showing decrease in pain scores across the six time points: **A.** 30 minutes, **B.** 1 hour, **C.** 2 hours, **D.** 4 hours, **E.** 8 hours or discharge, and **F.** 24 hours or postoperative day 1. IV, initial value; CI, confidence interval.

Harrison. *Reducing Pain After Laparoscopic Tubal Ligation. Obstet Gynecol* 2014.

Thus, both patients receiving clips and rings had decreased postoperative pain in the intervention groups; however, the benefit was greater in the patients who received rings.

**CONCLUSION**

In this meta-analysis of 20 randomized, double-blind, placebo-controlled trials with 1,095 participants, we

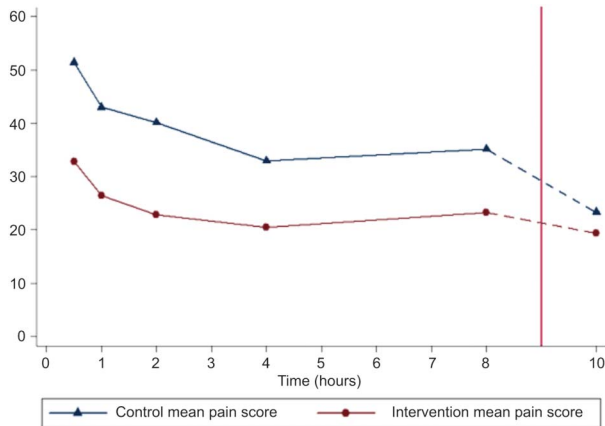
found the use of local anesthetic during laparoscopic tubal ligation decreases postoperative pain up to 8 hours after surgery in women undergoing tubal ligation by clip or rings. Unfortunately, we found no studies regarding this intervention after tubal ligation with cauterly. The benefit of local anesthetic was greatest at 30 minutes after extubation, and the benefit disappeared by postoperative day 1. This is

**Table 2.** Mean Difference in Pain Scores Across Time Points

Time	No. of Studies Included	n <sub>i</sub> /n <sub>c</sub>	Mean Decrease in Pain Score (95% CI)	Mean % Decrease in VAS	P*
30 min	12	287/299	18.6 (11.7–25.5)	36.5	<.001
1 h	10	261/259	16.6 (9.3–24.0)	37.6	<.001
2 h	9	248/246	17.4 (9.6–25.2)	44.0	<.001
4 h	8	227/224	12.5 (5.1–19.9)	39.2	<.001
8 h	13	364/362	11.9 (6.7–17.1)	33.6	<.001
24 h or postoperative day 1	12	303/301	3.9 (–1.4 to 9.2)	17.1	.15

n<sub>i</sub>, number in the intervention group; n<sub>c</sub>, number in the control group; CI, confidence interval; VAS, visual analog scale.

\* Paired t test.



**Fig. 3.** Mean pain scores across the six time points for control and intervention groups.

Harrison. *Reducing Pain After Laparoscopic Tubal Ligation. Obstet Gynecol* 2014.

biologically plausible; the local anesthetics used in these trials have half-lives ranging from 1 to 5 hours<sup>31</sup>; thus, the greatest anesthetic effect would be expected shortly after surgery.

The VAS pain scale is widely used by clinicians to gauge postoperative pain. A clinically relevant decrease in VAS scores has been estimated to be 9 mm<sup>34</sup> to 13 mm,<sup>35</sup> or a 30–33% decrease in VAS from baseline.<sup>36</sup> This meta-analysis shows a reduction in pain score of greater than 9 mm and greater than 33% in each time point up to 8 hours after surgery, consistent with pain relief that would be clinically meaningful to the patient.<sup>34–36</sup>

Decreased postoperative pain has been linked to increased patient satisfaction.<sup>37,38</sup> Decreased postoperative pain leads to decreased recovery time<sup>39</sup> and a decrease in unplanned admission after ambulatory surgery.<sup>40,41</sup> These results indicate that by using local

anesthetic during interval tubal ligation, physicians can decrease pain in the immediate recovery period and thus may be able to decrease unexpected admissions. In our own hospital, introduction of local anesthetic during tubal ligation in 2006 was followed in the next years by a substantial decrease in unplanned admissions from the postanesthesia care unit as a result of severe postoperative pain. Because many other factors have changed in pain management over the years since these studies were done, we cannot attribute our local decrease in admissions for pain to this intervention alone.

Silicone ring application is somewhat less common in the United States, perhaps because of greater postoperative pain.<sup>42,43</sup> Our subanalyses confirmed that the control groups receiving rings had more pain than the control group with clips; however, the addition of local anesthetic brought the pain scores of the ring group to a level equal to the clip group. Therefore, local anesthetic is beneficial to both groups, but more so for patients given rings during tubal ligation. We are unable to comment on electrocautery, because none of the trials using electrocautery met inclusion criteria for this meta-analysis.

As a result of the variety of interventions in these trials, we cannot make a specific recommendation about the drug or dosage of local anesthetic to use in tubal ligations. The results of the subanalyses demonstrated no evidence of a greater benefit with the use of long-acting anesthetic, or administering the anesthetic topically, through injection or in the peritoneal space.

We made several assumptions in this meta-analysis. Grouping the time points was necessary to synthesize the results of all 20 trials but may have led to some errors in classifying the time of pain score measurements. To be able to use all 20 studies in the meta-analysis, we estimated means from the medians.

**Table 3.** Mean Pain Scores at Each Time Point for Trials Using Clips Compared With Trials Using Rings for Tubal Ligation

Time	Clips			Rings			P*
	Control	Intervention	Δ	Control	Intervention	Δ	
30 min	47.4±10.7	36.7±11.7	10.7	54.6±14.3	28.7±14.4	25.9	.09
1 h	41.7±12.7	27.9±14.5	13.8	45.6±13.1	23.0±11.7	22.7	.21
2 h	38.1±14.0	23.3±9.1	14.8	44.8±15.3	17.9±12.5	26.9	.29
4 h	20.6±0.7	19.4±0.7	1.2	36.2±12.5	19.5±15.7	16.7	.09
8 h	26.6±12.0	21.4±8.2	5.2	43.6±10.7	23.1±13.2	20.5	.01
24 h	15.3±6.5	15.3±6.1	0.0	28.8±10.3	21.0±10.1	7.9	.17

Δ, clips compared with Δ rings.

Data are mean pain score±standard deviation unless otherwise specified.

\* Independent samples *t* test.



We also assumed pain scores on the 0–5 Modified McGill Pain Scale could be converted to the VAS by multiplying by a conversion factor of 20. Our subgroup analyses showed the magnitude of the difference in pain scores between the treatment and placebo groups was similar whether studies reported means or medians or whether they used VAS or the Modified McGill Pain Scale. We also restricted our search criteria to only published, English language studies. It is possible there are unpublished trials or trials published in other languages that are omitted from this meta-analysis.

This meta-analysis demonstrates the effectiveness of using a local anesthetic to reduce postoperative pain in patients undergoing laparoscopic tubal ligation under general anesthesia. We recommend using this intervention in patients undergoing tubal ligation to decrease discomfort after surgery. This simple, inexpensive, and quick intervention may increase patient satisfaction as well as be more cost-effective for hospitals.

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