

## Original Investigation

### Systematic review, meta-analysis and statistical analysis of laparoscopic supracervical hysterectomy vs endometrial ablation

#### Azadi et al. Systematic review of LSH vs. Endometrial Ablation

Greg J. Marchand<sup>1</sup>, Ali Azadi MD<sup>2</sup>, Katelyn Sainz<sup>1</sup>, Ahmed Masoud<sup>1</sup>, Sienna Anderson<sup>1</sup>, Stacy Ruther<sup>1</sup>, Kelly Ware<sup>1,3,4</sup>, Sophia Hopewell<sup>1</sup>, Giovanna Brazil<sup>1</sup>, Alexa King<sup>1</sup>, Jannelle Vallejo<sup>1,3</sup>, Kaitlynn Cieminski<sup>1</sup>, Anthony Galitsky<sup>1</sup>, Allison Steele<sup>4,5</sup>, Jennifer Love<sup>4,5</sup>

<sup>1</sup>The Marchand Institute for Minimally Invasive Surgery, Mesa, AZ USA

<sup>2</sup>Star Urogynecology, Peoria, Arizona

<sup>3</sup>Washington University of Health and Science, San Pedro, Belize

<sup>4</sup>International University of Health Sciences, Basseterre, St. Kitts

<sup>5</sup>Midwestern University School of Medicine, Glendale, Arizona

**Address for Correspondence:** Juan Luis Alcazar

Phone: +4809990905 e.mail: gm@marchandinstitute.org ORCID: orcid.org/0000-0003-4724-9148

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#### Abstract

**Objective:** This meta-analysis aims to compare the effect of laparoscopic supracervical hysterectomy with endometrial ablation (EA) regarding the general and menstrual-related quality of life in women opting for surgical treatment for abnormal uterine bleeding.

**Material and Methods:** We searched PubMed, Cochrane Library, SCOPUS, and Web of Science for relevant clinical trials. Our main outcomes of interest included quality of life assessed using medical outcomes survey short form 36 (SF-36), survey short form 12 (SF-12), operation time, time from operation to discharge, pain, fever, and hemoglobin level. Screening and data extraction were performed independently and the analysis was conducted using Review Manager Software v5.4.1.

**Results:** We included four clinical trials, results of SF-12 score showed that for both MCS and PCS, the overall mean difference revealed no significant difference between both groups (MD= -4.15 [-16.01, 7.71], (P=0.49), and (MD= 2.67 [-0.37, 5.71], (P = 0.08) respectively. Subgroup analysis of the SF-36 score showed that only two components (general health and social

function) were significantly improved in the hysteroscopy group ( $P < 0.01$ ), the other six components were not significant ( $P > 0.05$ ). The overall mean difference favored EA group significantly in terms of operation time (MD=72.65 [35.48, 109.82], ( $P = 0.0001$ ), time from operation to discharge (MD=13.61 [3.21, 24.01], ( $P = 0.01$ ), hemoglobin level outcome (MD=0.57 [0.40, 0.74], ( $P < 0.01$ ), and pain score (SMD= 0.46 [0.32, 0.60], ( $P < 0.01$ ).

**Conclusion:** Laparoscopic supracervical hysterectomy has better outcomes in regards to quality of life. This includes patient indicated responses to social health, general health, and superior hemoglobin levels at all measured points postoperatively. EA, however, consistently is associated with less operative time, a shorter hospital stay and is also considered as a more minimally invasive technique which also can also result in satisfying outcomes.

**Keywords:**

## Introduction

Abnormal uterine bleeding (AUB) is one of the most common gynecological problems that affects a quarter of women in the United States (1). It significantly impairs the quality of life of many women and accounts for a fifth of all hospital gynecology referrals (2). Menorrhagia is subjectively defined by some authors as excessive cyclic menstrual bleeding occurring over several consecutive cycles (3) and is objectively defined as a menstrual blood loss of 80 mL or more per menstrual cycle by other authors (4). Only 34% of females complaining of menorrhagia reported bleeding of more than 80 mL (5). Therefore, there is a large discrepancy between women's perception of their menstrual bleeding and accurate measurement of the amount of blood loss (6). Endometrial polyps, adenomyosis, and fibroid are common structural abnormalities of the uterus, which are associated with menorrhagia (7,8). AUB can also result from an abnormality of the endometrium (hyperplasia or malignancy), a disorder of ovulation, and coagulation defects (9).

Generally, a medical approach is used as the first line for the treatment of abnormal uterine bleeding, but it has a comparably high failure rate. About 42% of women using the intrauterine hormonal system and 77% of those on oral drugs will need to undergo surgical treatment within five years (10). The two most common surgical approaches for the treatment of AUB are hysterectomy, where the uterus is removed, and endometrial ablation, where the endometrium is thermally destroyed with uterine preservation (11). Abdominal hysterectomy had been the only definite treatment of AUB, until the development of endoscopy introduced laparoscopic hysterectomy and hysteroscopic endometrial ablation (12). Most women prefer the laparoscopic approach because it has a less invasive nature and a shorter hospital stay (13). Laparoscopic supracervical hysterectomy only removes the uterine body, which is the main source of abnormal uterine bleeding (14). This is also sometimes referred to subtotal or partial hysterectomy. In many cases, this procedure offers a less complex surgery that avoids difficult surgical dissection around the cervix and bladder (15). Although controversial, many authors have suggested leaving the cervix and its ligaments can reduce the risk of vaginal vault prolapse, and most authors agree it can reduce the risk of ureteric injury in some cases (16). The availability of newer surgical equipment and the improvements in laparoscopic training have simplified laparoscopic supracervical hysterectomy.

Endometrial ablation is an effective and minimally invasive surgical technique that has been developed to remove the entire thickness of the endometrium while sparing the uterine body (17,18). After endometrial ablation, any residual endometrium is theoretically beneath the created scar, and as a result this prevents further bleeding. Although it improves the general and

menstrual-related quality of life, about 20% of women who have this treatment will require a hysterectomy for relief of their symptoms at some point (19). In our meta-analysis, we aim to compare the effect of laparoscopic supracervical hysterectomy with endometrial ablation regarding the general and menstrual-related quality of life in women opting for surgical treatment for abnormal uterine bleeding.

## **Material and Methods**

This systematic review and meta-analysis was performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (20) and the guidelines reported in the Cochrane Handbook for Systematic Reviews of Interventions (21). Informed consent was not applicable to this study as it is a systematic review performed according to the PRISMA statement protocol.

### **Search strategy**

The online databases which we used to search were: Web of Science, SCOPUS, Cochrane CENTRAL, and PubMed without any restrictions on time or languages. We used the keywords: “ablation”, “hysterectomy”, “laparoscop\*”, and “bleeding” and combined these words by “AND” or “OR” according to the suitable manner for the search.

### **Eligibility criteria**

We included all the studies that have the following criteria: 1) patients: women with abnormal uterine bleeding, 2) intervention: laparoscopic supracervical hysterectomy, 3) comparator: endometrial ablation or resection, 4) outcomes: quality of life assessed using medical outcomes survey short form 36 (SF-36), survey short form 12 (SF-12), operation time, time from operation to discharge, pain, fever, and hemoglobin level, 5) study design: only randomized clinical trials (RCTs) were included. Studies that have other criteria were excluded; 1) non-randomized clinical trials, 2) patients treated with hysterectomy using other techniques, 3) single-armed trials, or with different comparators other than endometrial ablation or resection, 4) Animal trials, 5) studies that have no available full-text.

### **Screening of search results**

We exported the results of the search into Endnote X8.0.1 (Build 1044), with the removal of duplicates automatically by computer. After that, the studies were screened manually in two steps; first, title and abstract screening, then full-text screening for the preliminary included studies in the first step. We included the articles on the bases of our criteria for eligibility and removed studies that didn't have these criteria.

### **Data extraction and analysis**

After the screening step, we extracted the data from the selected studies and categorized the outcomes into two main groups: 1) baseline and demographic data of patients in each study, including; age, BMI (kg/m<sup>2</sup>), parity, preoperative hemoglobin level, and incidence of dysmenorrhea. 2) outcomes: quality of life assessed using the medical outcomes survey short form 36 (SF-36), which consists of eight components (general health, physical function, the limitation on life functions(physical), the limitation on life functions (emotional), mental health, social function, vitality, and pain), survey short form 12 (SF-12) which consists of two

components (physical component summary and mental component summary ), operation time, time from operation to discharge, pain, fever, and hemoglobin level.

### **Statistical analysis**

We used Review Manager Software (RevMan 5.4.1) to perform our analysis. We expressed dichotomous outcomes using percent and total, while continuous outcomes were expressed using mean difference (MD) and standard deviations (SD), relative to 95% confidence interval (CI). In the case of outcomes reported by different tools or parameters, we used the standardized mean difference in the analysis. Heterogeneity was assessed using statistical  $I^2$  test and P-value of the Chi-square test, where outcomes with  $I^2 > 50\%$ ,  $P < 0.1$  were considered heterogeneous, while outcomes with  $I^2 < 50\%$ ,  $P > 0.1$  were considered homogeneous. We analyzed the homogenous data using a fixed-effects model, while heterogeneous outcomes were analyzed using the random-effects model.

### **Quality assessment**

We evaluated the quality of this systematic review and meta-analysis using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines According to the Cochrane risk of bias (ROB) tool for clinical trials(22). We performed the risk of bias (ROB) for the included studies. The Cochrane risk of bias assessment tool includes the following domains: random sequence generation (selection bias), allocation sequence concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias) and other potential sources of bias. The authors' judgment was categorized as 'Low risk', 'High risk', or 'Unclear risk' of bias.

## **Results**

### **Summary of included studies**

Our literature search and references retrieved 127 studies; twenty studies have met our criteria and included in the full-text screening. Four studies full-filled our eligibility criteria after full-text screening and included in our meta-analysis. Figure 1 illustrates the PRISMA statement of our literature search. We conducted an analysis of 1018 patients from four studies (23–26) treated by either Laparoscopic supracervical hysterectomy (LSH) or endometrial ablation or resection (EA). A total of 517 underwent LSH, while 501 patients underwent EA. The mean age of patients in the LSH group is  $47.2+4.77$  years, while that of the EA group is  $47.55+4.6$  years. Table 1 shows a detailed summary of the included participants, their demographic characteristics, BMI, Parity, Preoperative hemoglobin, and the number of patients who suffered from dysmenorrhea.

### **Results of risk of bias assessment**

The risk of bias assessment result yields an overall moderate risk, according to Cochrane's tool (21). Regarding randomization, All studies were at low risk of randomization (23–26). As for allocation concealment, two studies reported insufficient details; therefore, they were categorized as "unclear risk"(25,26), Sestis et al. 2011(24) reported adequate allocation concealment, so it was put to low risk, Study cooper et al. 2019(23) showed inadequate concealment of allocation, so it was put to high risk. Concerning blinding of participants and personnel, all studies did not report sufficient details about blinding of participants and personnel, so they were put to unclear risk, except Sestis et al. 2011 that reported adequate blinding of participants and personnel, so it

was categorized as low risk. As for blinding of outcome assessment, blinding was likely effective in all studies, so they were at low risk (23–26). All studies were at low risk of attrition bias. Moreover, all studies were at low risk of selective reporting. There was no other bias in all studies except cooper et al. 2019 with unclear risk(23). A detailed illustration of the risk of bias of included trials is summarized in figure 2.

### Analysis of outcomes

**1. Short Form Survey 12 (SF-12):** Two studies reported the SF-12 outcome (23,26). SF-12 consists of a physical component score (PCS) and mental component score (MCS). Regarding MCS, the overall mean difference showed that there was no significant favoring of either group over the other (MD= -4.15 [-16.01, 7.71], (P=0.49), Pooled data were heterogeneous (P < 0.01); I<sup>2</sup> = 99%. Regarding PCS, there was no significant difference between both groups (MD= 2.67 [-0.37, 5.71], (P = 0.08)). Pooled analysis were heterogeneous (P = 0.001); I<sup>2</sup> = 91% as shown in figure 3. We could not solve heterogeneity in both components either by the leave-one-out method or subgroup analysis because only two studies had reported the outcome.

**2. Survey Short Form 36 (SF-36):** SF-36 outcome was reported by two studies (24,25). SF-36 consists of eight components (General health, Physical function, Limitation on life functions (physical), Limitation on life functions (emotional), Mental health, Social function, Vitality, and pain). Regarding the general health component, the overall mean difference favored the LSH group significantly (MD=10.25 [7.12, 13.38], (P < 0.01)), Pooled analysis was homogenous (P = 0.74); I<sup>2</sup> = 0%.

As for physical function component, the total mean difference showed no significant difference between both groups (MD= 10.64 [-8.08, 29.36], (P = 0.27)), data was heterogeneous (P < 0.01); I<sup>2</sup> = 96%. Concerning the Limitation on life functions (physical) component, the combined mean difference showed no significant change between both groups (MD= 1.83 [-1.56, 5.22], (P = 0.29)), Pooled studies was homogenous (P = 0.41); I<sup>2</sup> = 0%.

The analysis of the limitation on life functions (emotional) component yielded no significant variation between both groups (MD=-7.07 [-28.72, 14.59], (P = 0.52)). Data was heterogeneous (P < 0.01); I<sup>2</sup> = 97%. As for Mental health the comprehensive mean difference showed no significant change between both groups (MD=-5.33 [-21.20, 10.55], (P = 0.51)).The analysis showed heterogeneity (P < 0.01); I<sup>2</sup> = 96%. With regard to the social function component, the total mean difference favored the LSH group significantly (MD=16.94 [8.32, 25.56], (P = 0.0001)), Data was heterogeneous (P = 0.003); I<sup>2</sup> = 88%.

Vitality component analysis clarified no significant change between both groups (MD=0.22 [-21.73, 22.17], (P = 0.98)). The analysis showed heterogeneity (P < 0.01); I<sup>2</sup> = 98%. The analysis of the pain component showed that there was no significant favoring of either group over the other (MD= 7.67 [-4.48, 19.83], (P = 0.22)). Pooled studies were heterogeneous (P = 0.0002); I<sup>2</sup> = 93%. Detailed analysis for each item in SF-36 outcome is shown in figure 4.

Heterogeneity could not be solved in this outcome either by the leave-one-out method or subgroup analysis because only two studies had reported the outcome.

**3. Operation time (in minutes):** Three studies(23–25) reported operation time. The total mean difference favored EA group significantly (MD=72.65 [35.48, 109.82], (P = 0.0001)). Pooled studies were heterogeneous (P < 0.01); I<sup>2</sup> = 98% as shown in figure 5. We could not solve heterogeneity either by the leave-one-out method or subgroup analysis.

**4. Time from operation to discharge (in hours):** Cooper et al. 2019 and Zupi et al. 2003(23,25) reported the time from operation to discharge. The analysis favored the EA group over the LSH group significantly (MD=13.61 [3.21, 24.01], (P = 0.01)). Data was heterogeneous (P = 0.02); I<sup>2</sup> = 81% as shown in figure 6. Heterogeneity could not be solved either by leaving one out method or by subgroup analysis.

**5. Hemoglobin (g/dl):** Sestis et al. 2011 and zupi et al. 2003(24,25) reported hemoglobin levels postoperatively. Hemoglobin level was significantly lower in EA group than LSH group (MD=0.57 [0.40, 0.74], (P < 0.01)). Pooled analysis was homogenous (P = 0.22); I<sup>2</sup> = 34% as shown in figure 7.

**6. Pain:** Pain outcome was reported by two studies (23,25). The pain score was assessed by two different scales; therefore, we performed analysis using a standardized mean difference. The overall standardized mean difference favored the EA group significantly (SMD= 0.46 [0.32, 0.60], (P < 0.01)). The analysis was homogenous (P = 0.45); I<sup>2</sup> = 0% as shown in figure 8.

**7-Fever:** Two studies (23,25) reported fever outcomes postoperatively. The total mean difference showed no significant variation between both groups (MD= 0.00 [-0.01, 0.02], (P = 0.54)). Data was homogenous (P = 0.76); I<sup>2</sup> = 0% as shown in figure 9.

## Discussion

Some authors have suggested that when limiting comparison to success rates, that surgery has superior results than different oral medications in the treatment of menstrual bleeding in improving the quality of life of women affected by AUB (27). This is not to say, however, that there is complete agreement across all medical and surgical therapies. For example, Madhu et al., found that there was no significant difference between thermal balloon ablation (TBA) as a conservative surgery and levonorgestrel intrauterine system (28). While hysterectomy is the only curative treatment that prevents menstrual bleeding by 100% in all cases, it also carries a high risk for serious complications. Endometrial ablation has been suggested to be the second line of treatment after failure of medical treatment rather than a hysterectomy by several authors (29). The best surgical treatment for abnormal uterine bleeding, therefore, remains controversial. In this systematic review and meta-analysis, we aimed to find the optimal surgical intervention for the treatment of AUB by comparing the outcomes of only laparoscopic supracervical hysterectomy (LSH) and endometrial ablation or resection (EA). We chose to compare LSH to EA instead of comparing total laparoscopic hysterectomy (TLH) or laparoscopic assisted vaginal hysterectomy (LAVH) because many authors feel LSH is more minimally invasive than TLH and LAVH because the surgery does not include the creation of a colpotomy or division of the utero-sacral ligaments. Therefore we aimed to compare two very minimally invasive procedures. In terms of quality of life, we found that laparoscopic supracervical hysterectomy (LSH) was significantly superior to Endometrial ablation (EA) in general health (MD=10.25 [7.12, 13.38], (P < 0.01)) and in social function (MD=16.94 [8.32, 25.56], (P = 0.0001)). However, in other components of SF-36 (Physical function, the limitation on life functions (physical), the limitation on life functions (emotional), Mental health, Vitality, and pain), there was no significant difference between LSH and EA. Although the analysis didn't show a significant difference between both groups in terms of quality of life (except in general health and social function), one study, Cooper et al.,(30) reported higher satisfaction and quality of life in the LSH group than the EA group at 15 months of randomization. In fact, this study showed there was only 3% dissatisfaction with the LSH compared to a 13% dissatisfaction rate reported in the EA group. Moreover, 69% of women in the LSH group reported a maximum state of quality of life with a

quality of life percentage score of 100, compared to only 55% of women who reported a 100% score in the EA group. Zupi et al. 2003 (31) showed similar results on their 2-year follow-up questionnaire. In contrast, O'Connor et al. (32), reported no significant statistical difference regarding satisfaction in the laparoscopic supracervical hysterectomy group and the endometrial ablation group. The follow-up study by Zupi et al. 2015(33) also showed a better quality of life regarding physical and mental components after 14 years. Sesti et al. (34) also reported a worsening of quality of life in the EA group between 12 months and two years. This is consistent with other non- randomized trials who reported improvement of psychological outcomes and quality of life after hysterectomy (35)(36).

LSH was significantly better than EA regarding postoperative hemoglobin level, which usually reflects the overall amount of blood loss in each group in the three months following the operation (MD=0.57 [0.40, 0.74], (P < 0.01)). This was in spite of statistically significant longer operation time (MD=72.65 [35.48, 109.82], (P = 0.0001)) and a longer duration of hospital stay (MD=13.61 [3.21, 24.01], (P = 0.01)) in the LSH group compared to the EA group. Cooper et al. (30) showed similar results. The only reasonable explanation for this relative drop of hemoglobin level in the EA group, is that the intact uterus must in some cases still be producing cyclic menstrual bleeding despite the surgery, and that the LSH group was likely no longer menstruating in any reasonable capacity.

Other authors, however, have reported that thermal balloon ablation causes a significant decrease in menstrual bleeding and in some cases better hemoglobin levels postoperatively(37). Middleton et al. reported that LSH had adverse impacts on the emotional state of patients. These authors explained their results as coming from the psychological effects of the patients losing their uterus in hysterectomy (38).

On the other hand, EA showed significantly lower pain reported compared to LSH (SMD= 0.46 [0.32, 0.60], (P < 0.01) in our analysis. This may explain why many women prefer EA to LSH as it is truly a less invasive procedure, and many women may be afraid of the rare, but possible, major complications that could occur during hysterectomy (39). However, no major complications were reported in our included studies of LSH. This result was also found by a recent Cochrane study (40) that failed to find any major complications in their reported groups. Therefore, we feel it is appropriate to assert out that supracervical hysterectomy is associated with better improvement in dyspareunia and cyclic pain with no higher risk of postoperative complications (30) than EA by several authors.

The main limitations of our study are the paucity of clinical trials that compare the two surgical treatment procedures and the low sample size. Another limitation would be that our analysis was limited to those studies using specific forms in the assessment of the quality of life of the patients receiving the surgical procedures. This could explain, in addition to the different follow-up durations, the great heterogeneity in the analysis of most of our outcomes.

Despite these limitations, this is the first meta-analysis the authors are aware of that compares supracervical hysterectomy as a minimally invasive technique with endometrial ablation or resection as a more conservative minimally invasive surgical procedure. As for the strong points of our analysis, all the studies included were clinical trials, which helped to ensure the most substantial evidence, as stated according to the GRADE tool. Another strong point of our analysis is that all the included studies were found to be generally at a low risk of bias using our assessment tools.

## Conclusion

Laparoscopic supracervical hysterectomy may have better outcomes in regards to quality of life than endometrial ablation, specifically regarding patient reported social health, patient reported general health, and clinical postoperative hemoglobin levels. EA, however, seems to have less operative time and a shorter hospital stay. Therefore, EA is also considered to be a reasonable technique with satisfying outcomes for many women suffering from AUB.

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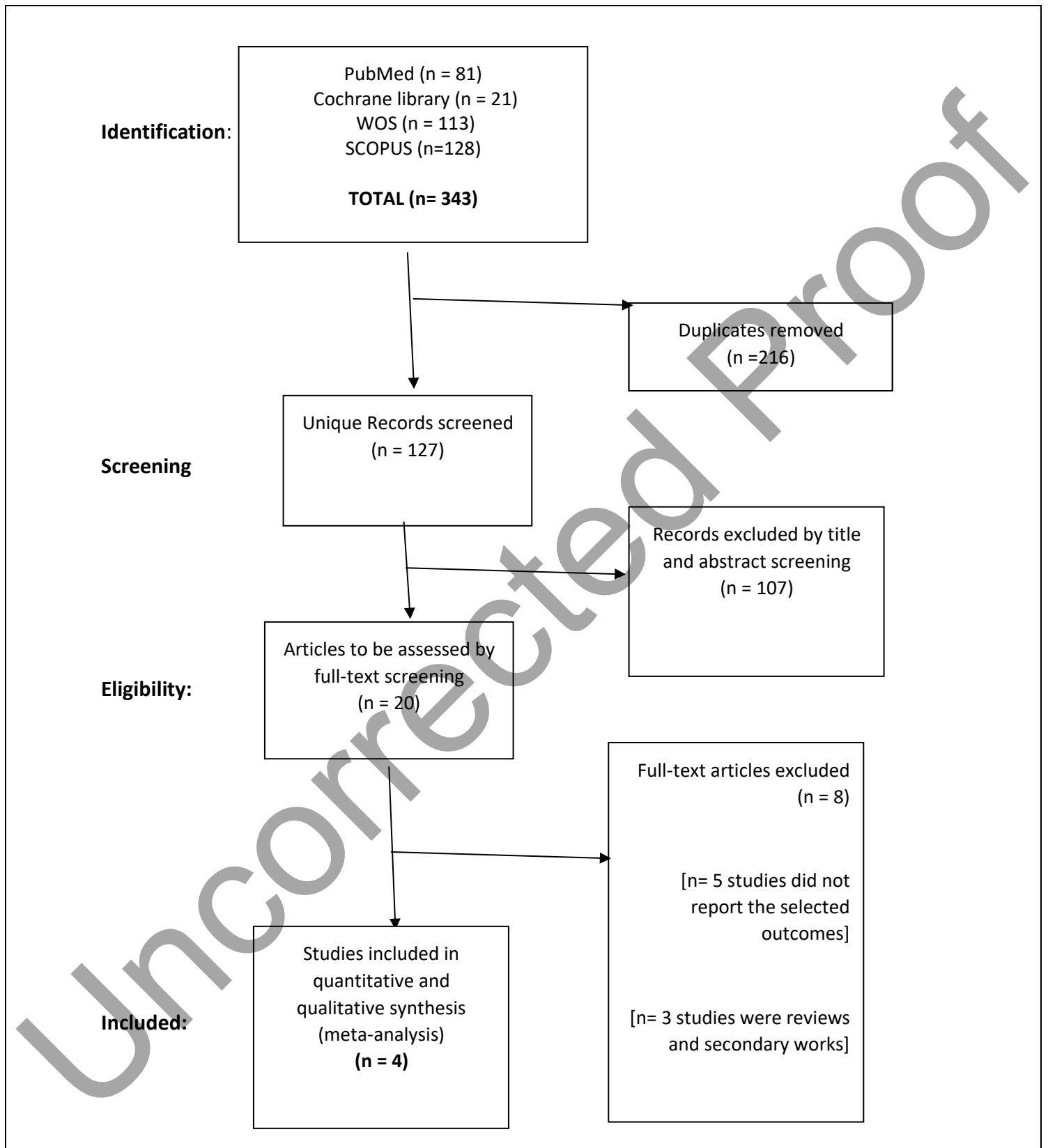
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**Figure 1.** Shows the PRISMA statement of our literature search

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
cooper2019	+	-	?	+	+	+	?
sesti2011	+	+	+	+	+	+	+
zupi2003	+	?	?	+	+	+	+
zupi2015	+	?	?	+	+	+	+

Figure 2. Shows a detailed illustration of the risk of bias of included trials

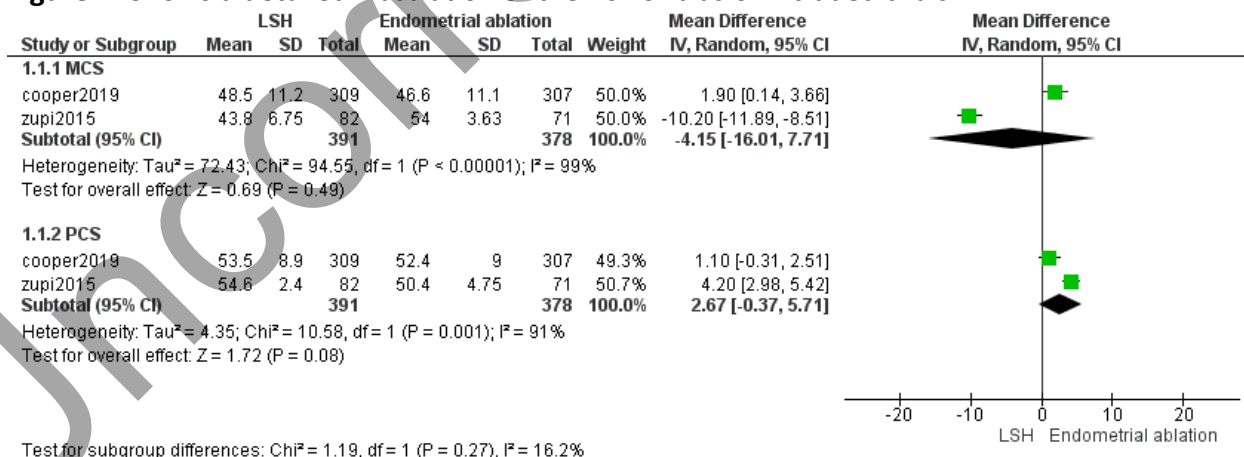


Figure 3. Shows a forest plot for the analysis of SF-12 outcome

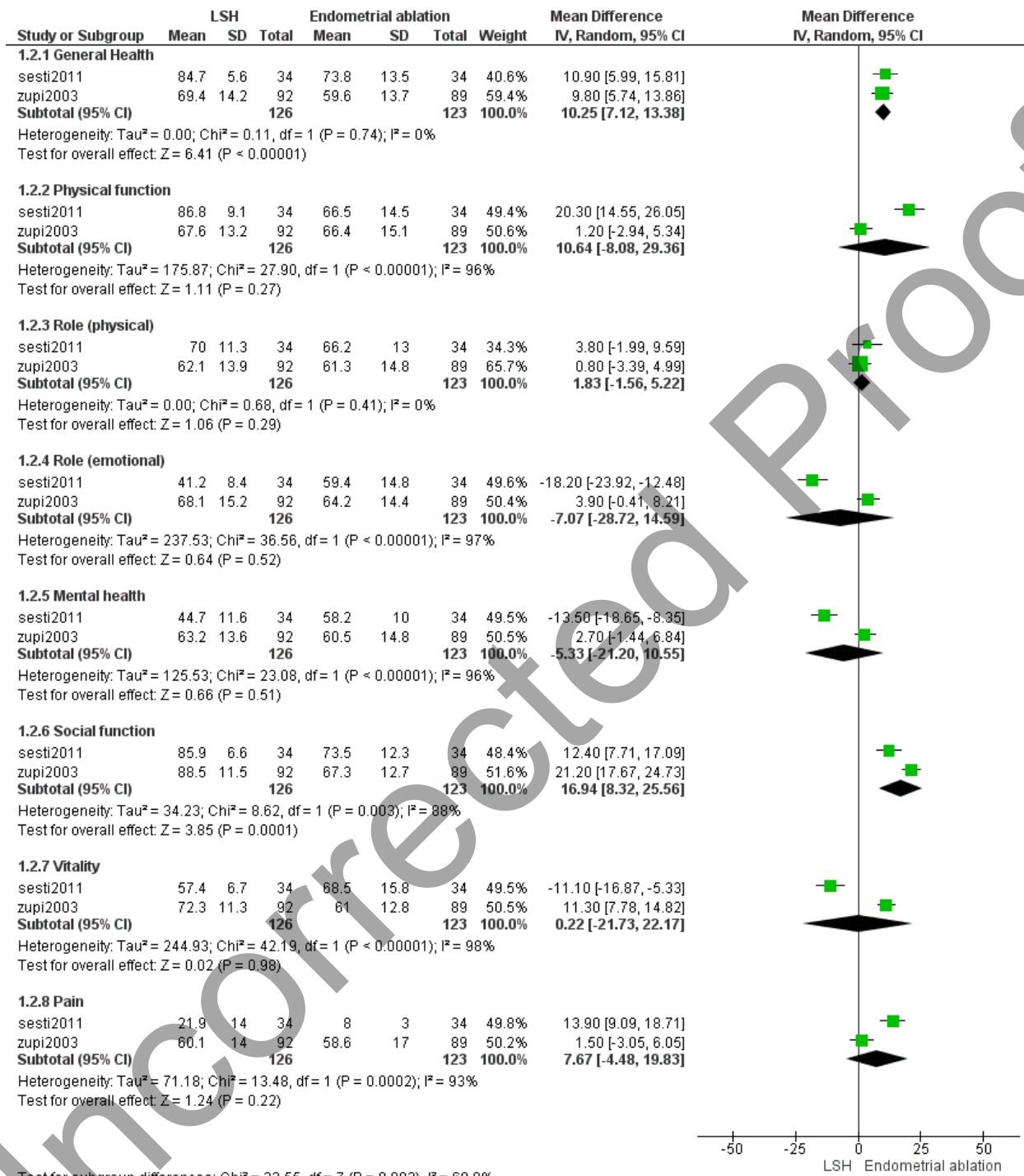


Figure 4. Shows a forest plot for the analysis of SF-36 outcome

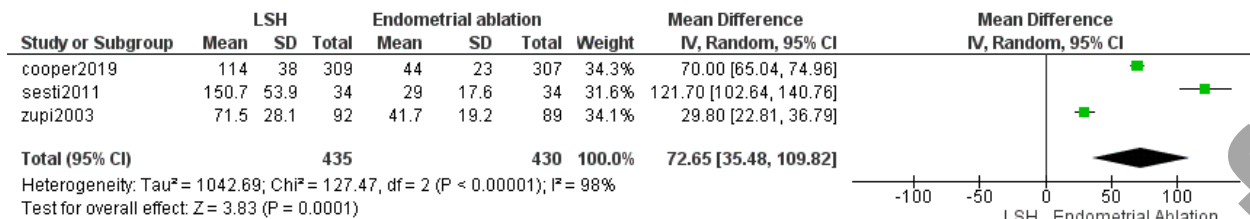


Figure 5. Shows a forest plot for the analysis of operation time outcome

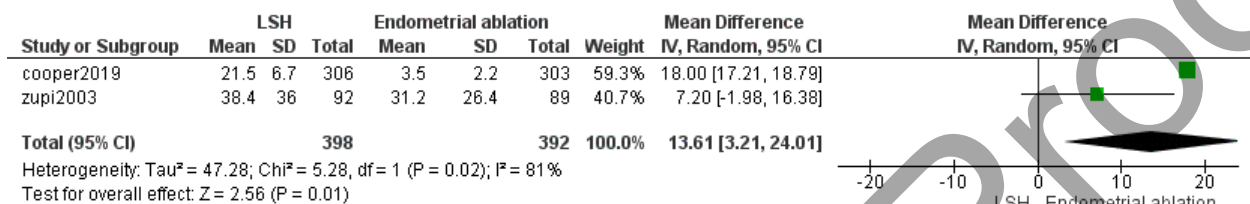


Figure 6. Shows a forest plot for the analysis of time from operation to Discharge outcome

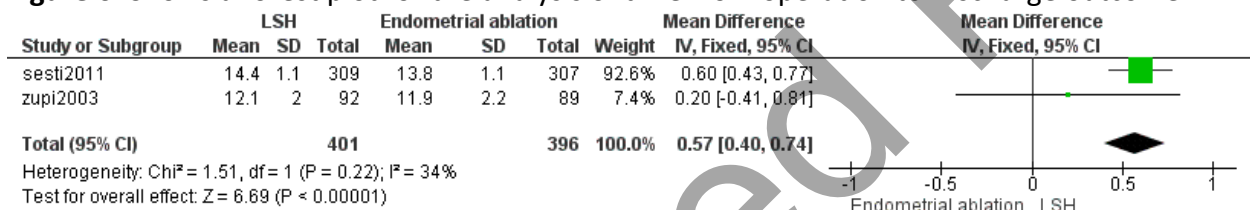


Figure 7. Shows a forest plot for the analysis of hemoglobin outcome

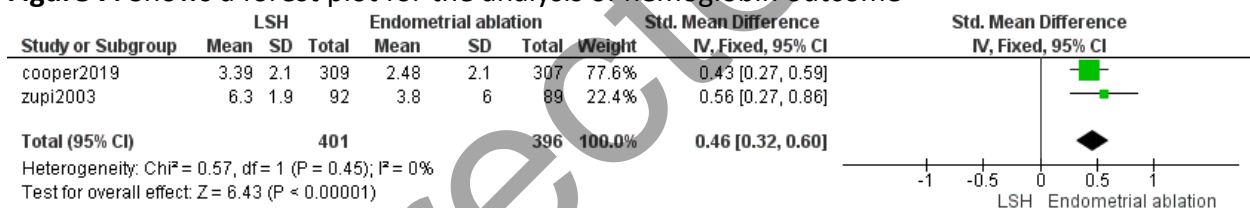


Figure 8. Shows a forest plot for the analysis of pain outcome

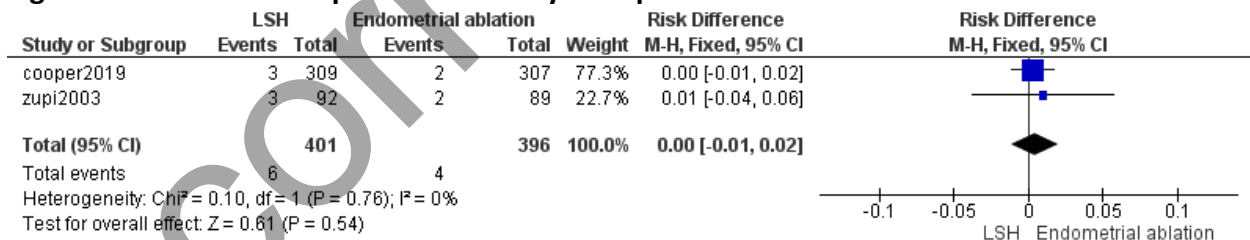


Figure 9. Shows a forest plot for the analysis of fever outcome





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