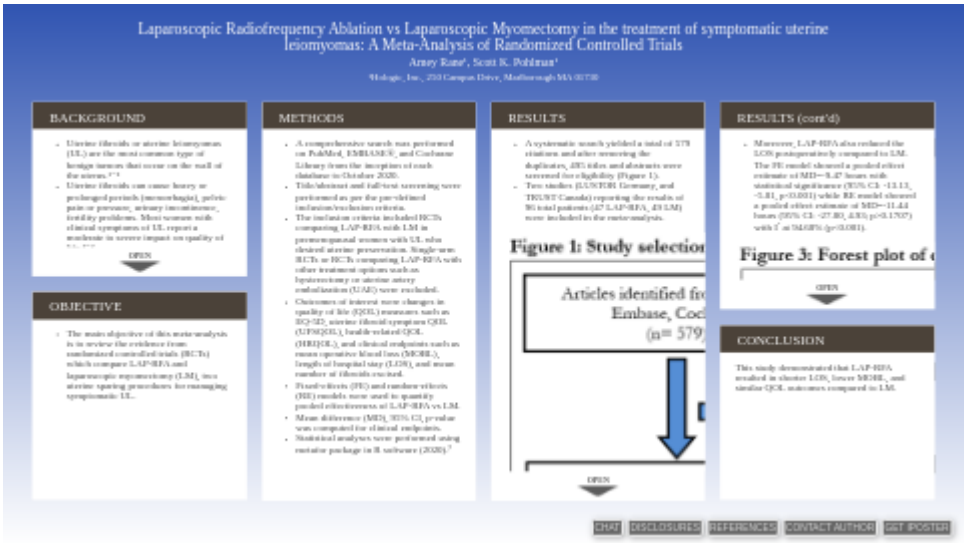
Laparoscopic Radiofrequency Ablation vs Laparoscopic Myomectomy in the treatment of symptomatic uterine leiomyomas: A Meta-Analysis of Randomized Controlled Trials



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PRESENTED AT:

BACKGROUND

- Uterine fibroids or uterine leiomyomas (UL) are the most common type of benign tumors that occur on the wall of the uterus.[1–2]
- Uterine fibroids can cause heavy or prolonged periods (menorrhagia), pelvic pain or pressure, urinary incontinence, fertility problems. Most women with clinical symptoms of UL report a moderate to severe impact on quality of life.[1–2]
- Myomectomy is the second most common procedure performed to address uterine fibroids and the current care standard for minimally invasive surgery, however, it is associated with substantial intraoperative blood loss and post-procedural complications and requires significant surgical skill to perform safely.[3–6]
- Laparoscopic radiofrequency ablation (LAP-RFA) is an alternative minimally invasive, outpatient, uterine sparing procedure for UL treatment.[3–6]

OBJECTIVE

- The main objective of this meta-analysis is to review the evidence from randomized controlled trials (RCTs) which compare LAP-RFA and laparoscopic myomectomy (LM), two uterine sparing procedures for managing symptomatic UL.

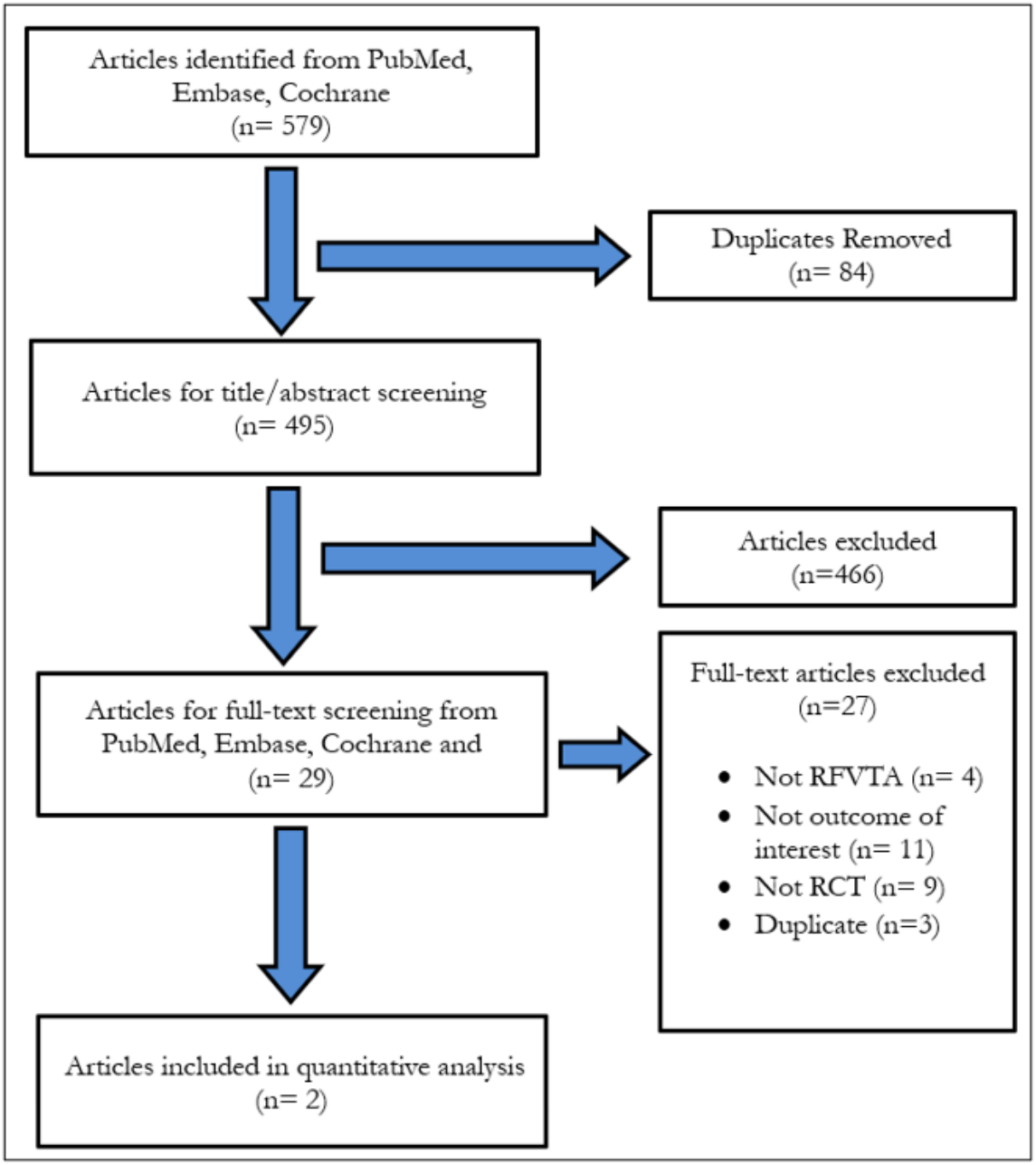
METHODS

- A comprehensive search was performed on PubMed, EMBASE®, and Cochrane Library from the inception of each database to October 2020.
- Title/abstract and full-text screening were performed as per the pre-defined inclusion/exclusion criteria.
- The inclusion criteria included RCTs comparing LAP-RFA with LM in premenopausal women with UL who desired uterine preservation. Single-arm RCTs or RCTs comparing LAP-RFA with other treatment options such as hysterectomy or uterine artery embolization (UAE) were excluded.
- Outcomes of interest were changes in quality of life (QOL) measures such as EQ-5D, uterine fibroid symptom QOL (UFSQOL), health-related QOL (HRQOL), and clinical endpoints such as mean operative blood loss (MOBL), length of hospital stay (LOS), and mean number of fibroids excised.
- Fixed-effects (FE) and random-effects (RE) models were used to quantify pooled effectiveness of LAP-RFA vs LM.
- Mean difference (MD), 95% CI, p-value was computed for clinical endpoints.
- Statistical analyses were performed using metafor package in R software (2020).[7]

RESULTS

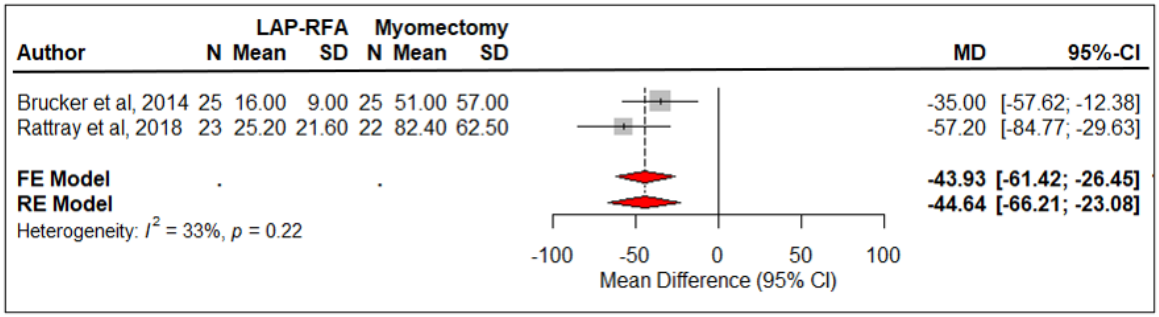
- A systematic search yielded a total of 579 citations and after removing the duplicates, 495 titles and abstracts were screened for eligibility (Figure 1).
- Two studies (LUSTOR Germany, and TRUST Canada) reporting the results of 96 total patients (47 LAP-RFA, 49 LM) were included in the meta-analysis.

Figure 1: Study selection diagram



- LAP-RFA reduced MOBL compared to LM with statistical significance. The FE model showed a pooled effect estimate of MD=-43.93 ml (95% CI: -61.42, -26.45, $p<0.001$) while RE model showed a pooled effect estimate of MD=-44.64 ml (95% CI: -66.21, -23.08; $p<0.001$) with I^2 at 32.83% ($p<0.001$).

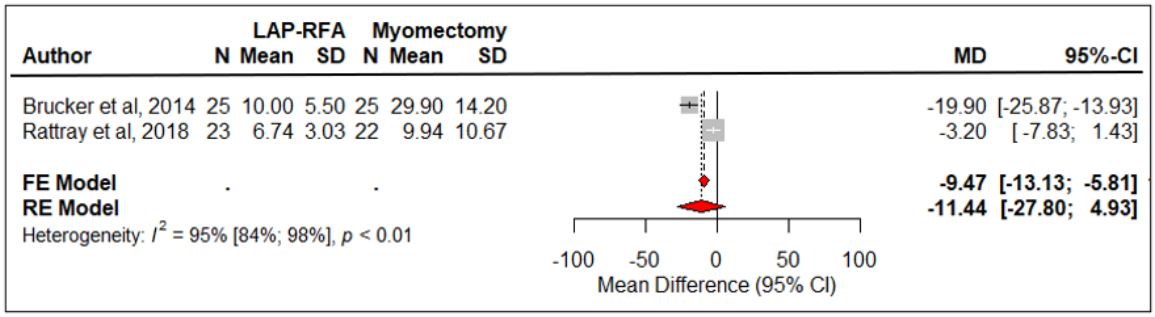
Figure 2: Forest plot of difference in Means (95% CI) for mean operative blood loss



RESULTS (CONT'D)

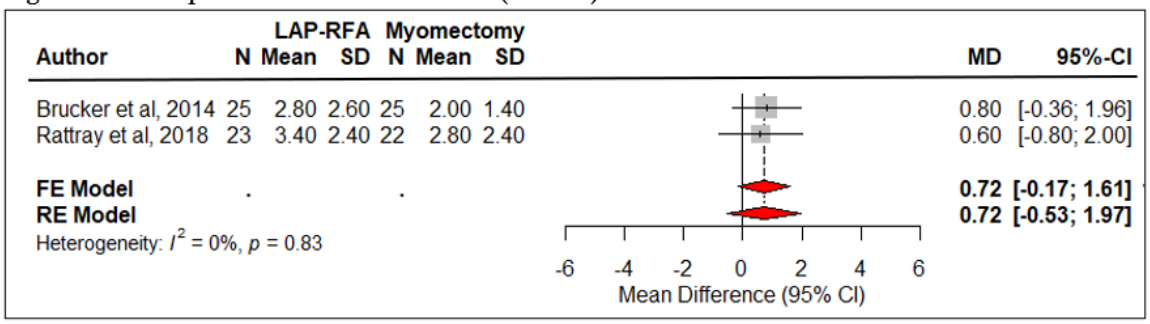
- Moreover, LAP-RFA also reduced the LOS postoperatively compared to LM. The FE model showed a pooled effect estimate of MD=-9.47 hours with statistical significance (95% CI: -13.13, -5.81, p<0.001) while RE model showed a pooled effect estimate of MD=-11.44 hours (95% CI: -27.80, 4.93; p>0.1707) with I^2 at 94.68% (p<0.001).

Figure 3: Forest plot of difference in Means (95% CI) for length of hospital stay



- Overall, LAP-RFA treated more fibroids than LM but the results were not statistically significant (RE: MD=0.72 (95% CI: -0.17, 1.61; p>0.114).

Figure 4: Forest plot of difference in Means (95% CI) for mean number of fibroids excised



- Improvement in QOL endpoints was similar for LAP-RFA and LM (EQ-5D: p=0.8750, UFSQOL: p=0.7019, HRQOL: p=0.6220). Patients in LAP-RFA and LM had comparable symptom severity and health-related quality of life scores at baseline.

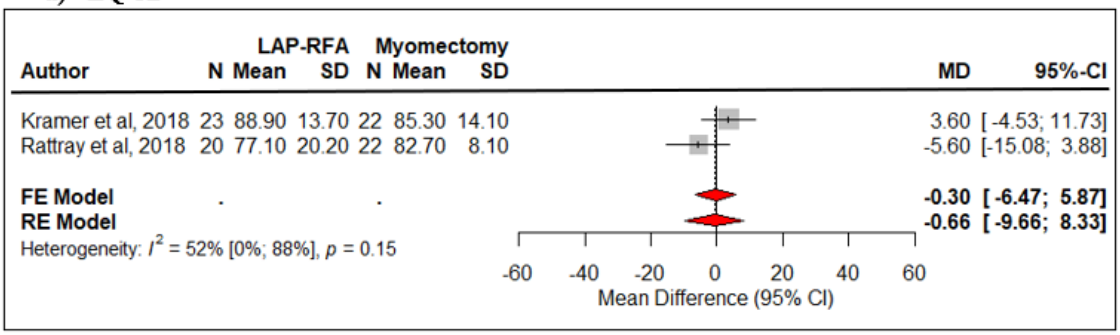
Table 1: Baseline HRQOL and Symptom Severity scores

	Study	LAP-RFA	LM
HRQOL	LUSTOR	77.17±20.361	70.21 ± 22.245
	TRUST-Canada	39.8±25.5	47.9±23.9
Symptom Severity	LUSTOR	39.9±26.88	41.84 ± 23.156
	TRUST-Canada	SS: 61.55±19.8	SS: 58.4±18.8

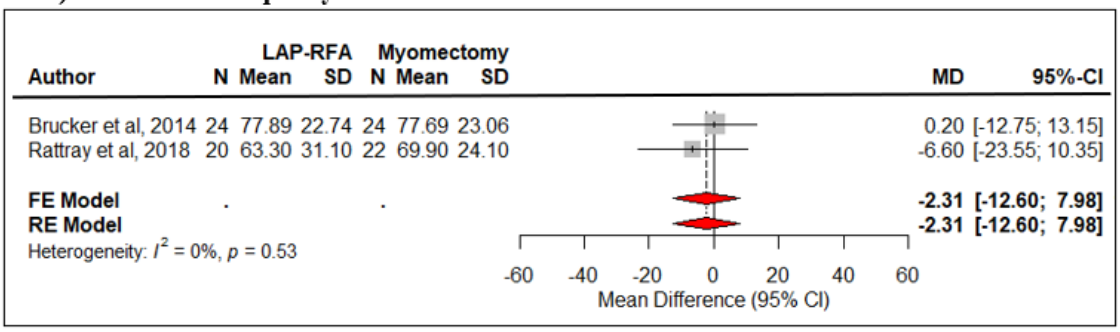
HRQOL=Health related quality of life. Both HRQOL and Symptom Severity are components of Uterine Fibroid Symptom and Health Related Quality of Life (UFS-QOL) assessment tool

Figure 5: Forest plot of difference in Means (95% CI) for 3-month post-procedure quality-of-life outcomes

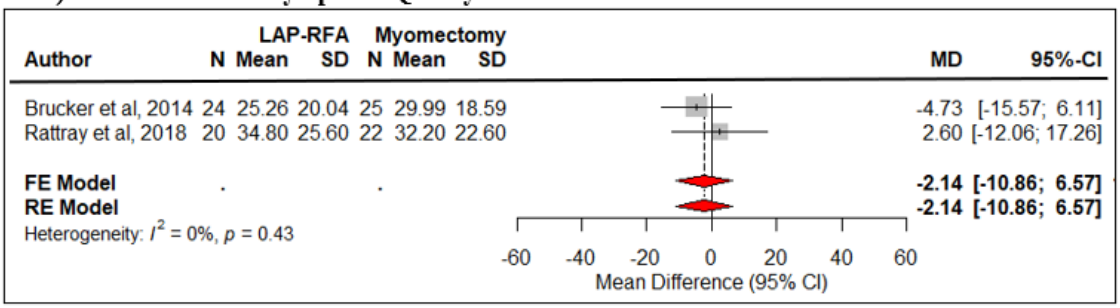
a) EQ-5D



b) Health-related quality of life



c) Uterine Fibroid Symptoms Quality of life



LIMITATIONS

- The review included RCTs with 3 months follow-up period. RCTs that examine the efficacy of LAP-RFA vs LM with long-term follow-up are needed.
- The RCTs included in this meta-analysis had how sample size (45-50 patients in each RCT) that could greatly impact the confidence intervals of the pooled estimates.

CONCLUSION

This study demonstrated that LAP-RFA resulted in shorter LOS, lower MOBL, and similar QOL outcomes compared to LM.

DISCLOSURES

This study was conducted by Hologic, Inc., Marlborough, MA. AR and SP are employees of Hologic, Inc. This information is intended for an audience with knowledge and expertise in health care economic analysis for use in device acquisition, coverage, and/or reimbursement decisions on a population basis.

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