

Complications and blood loss after invasive treatments for small renal masses

A systematic review

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ABSTRACT

INTRODUCTION: This systematic review and meta-analysis provides estimates of major complications and estimated blood loss (EBL) for open partial nephrectomy (OPN), conventional laparoscopic partial nephrectomy (LPN), and robot-assisted partial nephrectomy (RAPN). Additionally, it outlines the incidence of major complications associated with percutaneous thermal ablation (TA) in patients with small renal masses (SRMs).

METHODS: We searched MEDLINE, EMBASE, and CINAHL from inception to the end of July 2023. We supplemented the electronic search with a hand search of the references in the included studies and suggestions from two content experts. We used random effect meta-analysis to obtain pooled estimates of major complications and EBL. We used the QUIPS tool for risk of bias assessment and applied a prognosis approach to rate the quality of evidence using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) framework.

RESULTS: We included 65 eligible studies that provided pooled estimates of major complications after OPN of 5.4% (95% confidence interval [CI] 2.9–9.9); after conventional LPN of 4.7% (95% CI 2.6–8.3); after RAPN of 2.9% (95% CI 2.2–3.7); and after TA of 2.5% (95% CI 1.7–3.6). Pooled estimates demonstrating mean EBL of 262 ml (95% CI 200–324) for OPN; 224 ml (95% CI 193–254) for conventional LPN; and 163 ml (95% CI 136–190) for RAPN.

CONCLUSIONS: This review provides the best available estimates of major complications and mean EBL after partial nephrectomy in patients with SRMs.

INTRODUCTION

Small renal masses (SRMs), defined as masses measuring ≤ 4 cm, account for a significant proportion of all renal masses. Between 1988 and 2003, SRMs represented 48–66% of diagnosed renal masses, and this proportion has since increased due to the rise in incidental diagnoses among asymptomatic patients.^{1,2} When malignant, the vast majority of these SRMs are pT1a kidney tumors.³ Compared to historical data, incidentally discovered SRMs tend to be in an earlier disease stage, specifically T1a. This shift in the stage and size of diagnosed renal tumors has led to a change in treatment recommendations for patients with SRMs, prompting the emergence of partial nephrectomy (PN) as the preferred and recommended treatment option, particularly for patients who require preservation of their renal function.⁴⁻⁷

Minimally invasive PN techniques have gained prominence in the surgical management of SRMs. Among these techniques, conventional laparoscopic partial nephrectomy (LPN) and robot-assisted partial nephrectomy (RAPN) have become increasingly preferred over the traditional open partial nephrectomy (OPN).⁶⁻⁸ The main drivers behind this shifting preference are the documented lower morbidity rates and reduced blood loss associated with these approaches. Advances in performing LPN and RAPN have contributed to wider adoption of these surgical alternatives to OPN. Consequently,

KEY MESSAGES

- This review presents the most comprehensive estimates of major complications and EBL associated with OPN, LPN, RAPN, and percutaneous TA in patients with SRMs.
- The pooled proportion of major complications was highest for OPN and lowest for TA. The certainty of evidence ranged from low to moderate.
- EBL was highest during OPN and lowest during RAPN, with LPN showing intermediate values. The certainty of evidence for EBL also varied from low to moderate.
- These findings provide critical insights for patient and physician decision-making, suggesting that minimally invasive approaches like RAPN and TA may offer better safety profiles than OPN and LPN.

patients are thought to benefit from reduced post-operative complications and improved long-term outcomes.⁹⁻¹¹

Similarly, emphasis on less invasive therapies also led to the development of ablative approaches to treating SRMs. Thermal ablation (TA) that uses heating or freezing techniques to effectively target and treat tumors is thought to have an advantage over PN, with fewer complications and a quicker recovery time.¹² Within the realm of TA, percutaneous ablation has demonstrated similar oncologic outcomes and a potential decrease in procedural burdens compared to laparoscopic ablation and is generally favored.⁶⁻⁸

Our focus was on investigating the major complications and estimated blood loss (EBL) associated with the available treatment modalities for SRMs, including OPN, LPN, RAPN, and percutaneous TA. By examining these treatment modalities individually, we aimed to provide insights into patient outcomes in SRM management.

METHODS

We registered the protocol of this review in the International Prospective Register of Systematic Review (PROSPERO); the registration ID is CRD42022308375. We used guidance from Preferred Reporting Items for

Systematic Reviews and Meta-Analyses (PRISMA) in reporting our review.

Data sources and searches

To conduct a comprehensive search, we explored the MEDLINE, EMBASE, and CINAHL databases. Our search encompassed the period from the inception of the databases until the end of July 2023. Additionally, our research team engaged in manual searches of reference lists from the included articles and benefited from the expertise of two urologist members, PR and PV, who provided valuable suggestions.

Eligibility criteria

Inclusion criteria encompassed randomized controlled trials (RCTs), cohort studies, and case series with at least 10 patients undergoing PN or PTA for SRMs. Eligible studies reported major complications (Clavien-Dindo grade \geq III) within 30 days post-procedure¹³ and EBL during PN.

We included studies reporting the number of complications, extracting only those with Clavien-Dindo grade \geq III. For studies not reporting all complications separately, we included those considering a complication as major with a Clavien-Dindo grade \geq III.

Exclusion criteria were studies not providing major complication frequencies or necessary EBL statistics (e.g., mean and standard deviation [SD]). We did not restrict based on publication status, country, or period, but limited to English articles. We excluded studies focused on highly selected patient populations, those not specifying treatments, and those not outlining eligibility criteria for SRM patients.

The types of each procedure are as follows:

- Nephrectomy: Included transperitoneal and retroperitoneal nephrectomy; restricted to OPN, LPN, and RAPN.
- Thermal ablation: Included percutaneous TA; restricted to cryoablation and radiofrequency ablation (RFA). If 80% or more of TA procedures were percutaneous, cryoablation, or RFA, we included the study.

Potentially eligible studies used different SRM definitions (\leq 4 cm, \leq 5 cm, \leq 7 cm). We included studies if \geq 80% of masses were \leq 4 cm.

Study selection and data extraction

Reviewers received detailed instructions for title and abstract screening, full-text reading, risk of bias (ROB) assessment, and data abstraction. Pairs of reviewers independently screened titles and abstracts, reviewed

the full text of potentially eligible studies, abstracted data (JD, RL, HS, DT, JS, WT), and assessed ROB (AS, MK). Reviewers resolved discrepancies through discussion or consultation with a third reviewer (MK). We recorded study country, participants' age, gender, tumor size, sample size, type of intervention, major complications for PN and PTA procedures, and EBL for PN.

Risk of bias

We focused on prognosis related to SRM treatment outcomes, specifically EBL during procedures and major complications within 30 days.¹³ We used the Quality In Prognosis Studies (QUIPS)¹⁴ instrument, considering study design and outcomes. We assessed four QUIPS domains: study participation, outcome measurement, study attrition, and statistical analysis and reporting, excluding prognostic factor measurement and study confounding. Studies with high risk in any assessed domain were classified as high ROB.

Certainty of evidence

To rate the certainty of the evidence, we used the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach specifically tailored for prognostic questions,¹⁵ in which observational studies are initially considered high-certainty evidence. We considered five factors that might lower the certainty of evidence: ROB, inconsistency, imprecision, indirectness, and publication bias.

To address publication bias, we used Begg's test, which is based on assessing whether a significant correlation is seen between the ranks of estimations and their variances. We also used funnel plots to visualize if a publication bias is suspected.

Data analysis

To determine the pooled estimates of EBL, we extracted mean and SD when available. If not reported, we collected the median and interquartile range (IQR) or range, converting them to mean and SD using equations by Wan et al.¹⁶ Pooled means were calculated using the DerSimonian-Laird random effects inverse variance method.

We conducted a Chi-squared test to assess differences in complications among studies with various sample sizes, ROB, and geographic regions. Welch t-tests evaluated potential variations in EBL across studies with different sample sizes and ROB. To assess potential variations in EBL across geographic regions, we used the Kruskal-Wallis test. Sample size was dichotomized into

large and small groups using a 100-patient threshold. Studies were categorized as high or low ROB according to QUIPS criteria, with regions categorized as North America, Europe, Asia, and other areas. All hypothesis tests used a significance level of 0.05. To evaluate the credibility of subgroup analyses based on geographic region, we used the ICEMAN tool.¹⁷

RESULTS¹⁻⁸⁷

Literature search and study characteristics

We screened 3456 titles and abstracts and retrieved 438 possibly eligible full texts, of which 65 studies including 13 452 patients proved eligible (Figure 1).

The details of study characteristics and a summary of findings are presented in Supplementary Table 1 (available at cuaj.ca).

Risk of bias

Of the 65 included studies, 34 proved high ROB. Supplementary Table 2 (available at cuaj.ca) presents the details of bias risk assessments.

Assessment of prognostic factor effect

We assessed the prognostic effect of sample sizes, ROB, and geographic regions. Supplementary Table 3 (available at cuaj.ca) shows the results of prognostic factor analysis. Among studies on OPN, there was a significant difference in major complications across regions ($p=0.003$). Among LPN studies, significant differences in major complications were observed across sample sizes ($p=0.006$), and in EBL across regions ($p=0.005$). The ICEMAN tool (Appendix B; available at cuaj.ca), used to assess credibility, yielded low credibility for all significant effects due to small subgroup sizes. Thus, we report results for pooled estimates of each procedure study group.

Certainty of evidence

To assess the certainty of the evidence, we used the GRADE approach tailored for prognostic questions¹⁵ (Supplementary Table 4; available at cuaj.ca). Our evaluation focused on addressing prognostic questions for our outcomes, with a key emphasis on inconsistency within study groups. This led to a downward adjustment in the certainty rating, based on differences in point estimates among the included studies. For example, in major complications after OPN (Figure 2), estimates ranged from 2–29%, resulting in a very serious rating for inconsistency.

Major complications and estimated blood loss

MAJOR COMPLICATIONS

The pooled proportion of major complications after OPN in the 10 included studies was 5.4% (95% confidence interval [CI] 2.9–9.9). The certainty of evidence was low because of the very serious inconsistency (Figures 2, 3; Supplementary Tables 2, 3 [available at [cuaj.ca](#)]).

The pooled proportion of major complications after LPN from the 11 included studies was 4.7% (95% CI 2.6–8.3). The certainty of evidence was low because of the very serious inconsistency (Figures 2, 3; Supplementary Tables 2, 3 [available at [cuaj.ca](#)]).

The pooled proportion of major complications after RAPN from the 20 included studies was 2.9% (95% CI 2.3–3.8). The certainty of evidence was moderate because of serious inconsistency (Figure 4, Supplementary Tables 2, 3 [available at [cuaj.ca](#)]).

The pooled proportion of major complications after TA from the 15 included studies was 2.5 (95% CI 1.7–3.6). The certainty of evidence was moderate because of serious bias risk (Figure 5; Supplementary Tables 2, 3, Appendix C [available at [cuaj.ca](#)]).

ESTIMATED BLOOD LOSS

The pooled mean of EBL during OPN in the 14 included studies was 262 ml (95% CI 200–324). The certainty of evidence was low because of the very serious inconsistency (Figures 6, 7; Supplementary Tables 2, 3 [available at [cuaj.ca](#)]).

The pooled mean EBL during LPN in the 25 included studies was 224 ml (95% CI 193–254). The certainty of evidence was low because of serious bias risk and serious inconsistency (Figures 6, 7; Supplementary Table 2, 3 [available at [cuaj.ca](#)]).

The pooled mean EBL during RAPN in the 29 included studies was 163 ml (95% CI 136–190). The certainty of evidence was moderate because of serious inconsistency (Figure 8; Supplementary Tables 2, 3, Appendix C [available at [cuaj.ca](#)]).

DISCUSSION

This systematic review and meta-analysis provides estimates of major complications after different PN approaches and TA.

Our assessment of the quality of evidence revealed a low to moderate certainty of evidence for the outcomes of interest. While our analysis provides a comprehensive overview of the available evidence, the qual-

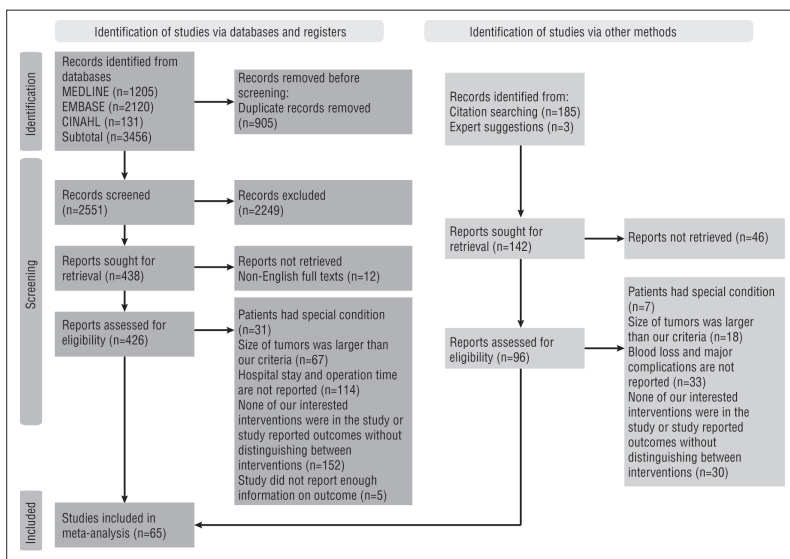


Figure 1. PRISMA flow diagram.

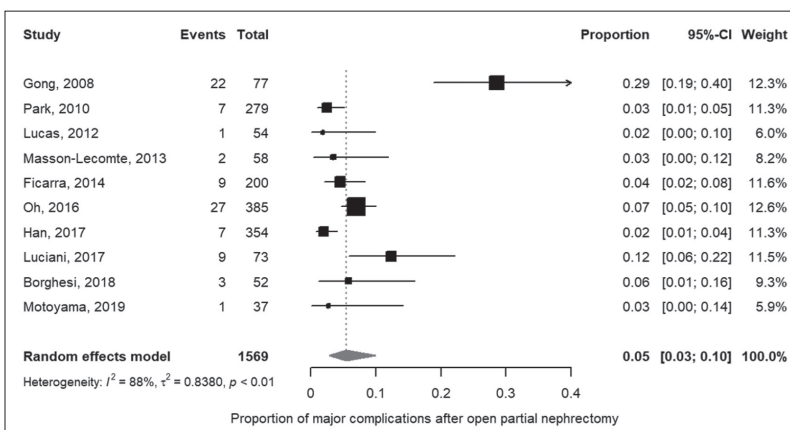


Figure 2. Forest plot of proportion of major complications in patients with SRM, after open partial nephrectomy. CI: confidence interval.

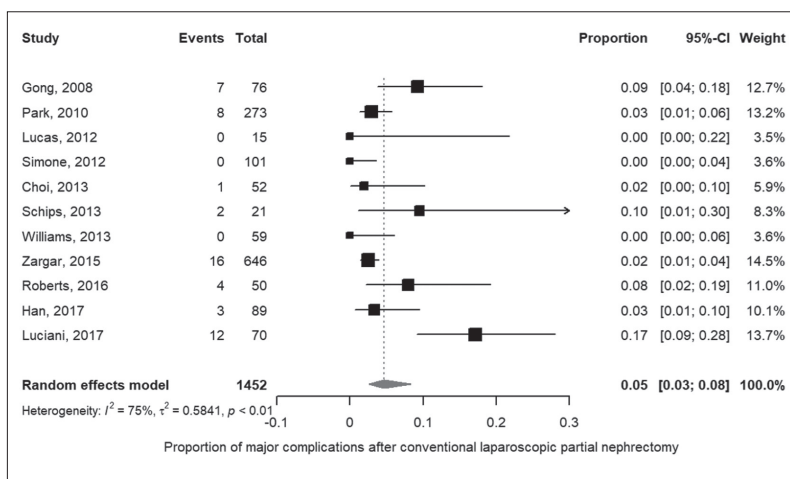


Figure 3. Forest plot of proportion of major complications in patients with small renal mass, after conventional laparoscopic partial nephrectomy. CI: confidence interval.

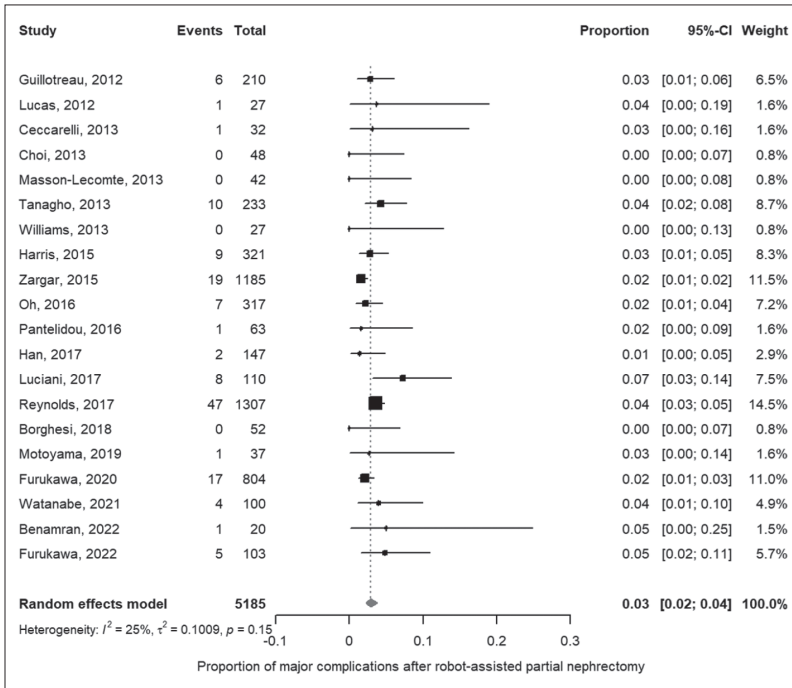


Figure 4. Forest plot of proportion of major complications in patients with small renal mass, after robot-assisted partial nephrectomy. CI: confidence interval.

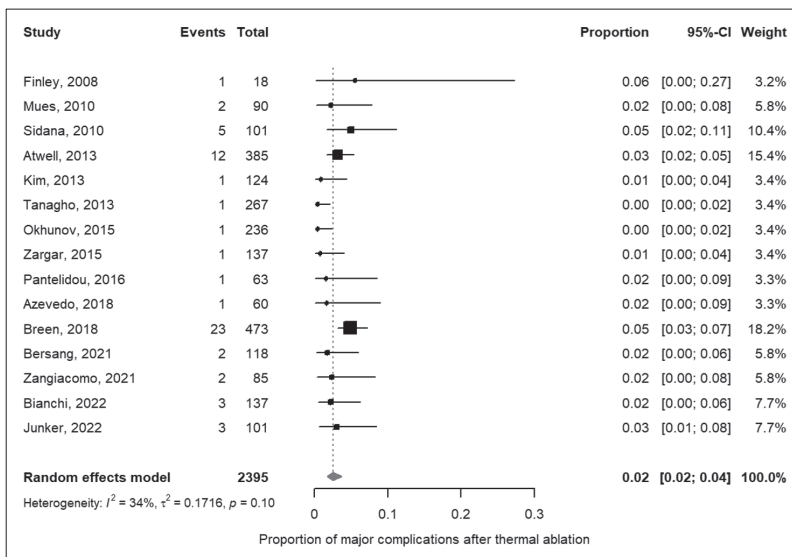


Figure 5. Forest plot of proportion of major complications in patients with small renal mass, after thermal ablation. CI: confidence interval.

ity of the included studies varied, and the certainty of the evidence was limited by factors including ROB, inconsistency, and imprecision.

Strengths and limitations

This systematic review and meta-analysis has several strengths. Our comprehensive literature search

addressed studies from various regions and publication periods. To ensure consistency in eligibility decisions, we established explicit and rigorous criteria and conducted calibration exercises with the reviewers. We employed established frameworks — QUIPs for risk of bias and the GRADE prognosis approach for assessing certainty of evidence. We adapted the ICEMAN instrument for evaluating the credibility of subgroup analyses in prognostic studies.

Our study does, however, have limitations. We restricted eligibility to articles published in English. The included studies varied in their definition of SRMs, with some including tumors larger than our criteria of 4 cm. To address this, we included only studies in which 80% of the patients' tumor sizes met our criteria. Moreover, we faced limitations in accessing detailed patient characteristics such as age, sex, and tumor size, preventing us from fully exploring the sources of heterogeneity in our results.

Studies adopted different definitions of major complications. While some studies identified Clavien-Dindo Grade \geq II as major complications, others set a threshold of Clavien-Dindo Grade \geq III. To mitigate the impact of this heterogeneity in defining major complications, we included only those studies that specifically regarded Clavien-Dindo Grade \geq III as indicative of major complications.

Although microwave ablation is currently used as a heat-based thermal ablative technique worldwide, our systematic review focused on RFA and cryoablation, which were the predominant techniques in the included studies. Future systematic reviews should consider incorporating data on microwave ablation and other emerging ablative modalities, such as irreversible electroporation and stereotactic body radiation therapy, to further explore their impact on clinical outcomes.

Lastly, for major complications after OPN and LPN, and EBL during LPN, we found only low certainty evidence due to the presence of potential bias and inconsistency in results. Also, TA includes cryoablation and RFA, but these methods have different complication rates and indications.

Relation to prior work

Several systematic reviews and meta-analyses have investigated pooled estimations for major complications and EBL; however, none of these reviews specifically focused on OPN, LPN, RAPN, and TA separately, and the research questions differed from our study. They centered around comparative analyses of treatment strategies rather than individual descriptions of each

treatment modality, which distinguishes our current investigation.

A systematic review published in 2014 compared major complications following RFA and PN for patients with SRMs in two groups of studies on tumors at pathological stage of T1a and the other group of studies on tumors at pathological stage of T1.¹⁸ They reported a major complication proportion of 10.2% for OPN, 7.2% for combined RAPN and LPN, and 4.3% for RFA in the T1a group of included studies. In our study, the proportions of major complications for OPN, LPN, RAPN, and TA were lower than those reported in the previous systematic review. One possible explanation is that the prior review included 31 studies that we did not; we included 31 studies published later than 2014 that the prior review did not. Older studies may have encapsulated less contemporary procedures, potentially yielding outcomes that differ in certain aspects and may have been less favorable. It is plausible that older studies encompassed earlier stages of learning curves and were conducted before the refinement of patient selection criteria. Our included studies are more recent, and the estimates are indicative of contemporary practice.

Another systematic review published in 2013 reported the EBL and complications for both LPN and RAPN.¹⁹ Our findings align closely with the slightly lower EBL for RAPN (163 ml vs. 257 ml), potentially indicative of more contemporary outcomes. Notably, our study spans various regions and a more extended timeframe, including European studies, while the previous review focused on North American and Asian studies until June 2012. Furthermore, the earlier review reported higher pooled rates of postoperative complications for both LPN and RAPN compared to our study. The discrepancy could be attributed to their inclusion of all complications, not just major ones, and we maintained rigor by excluding studies lacking clear definitions based on the Clavien grading system. All studies from the previous review were included in our analysis, and we added 35 studies published after 2012, previously unaccounted for in the earlier review.

Another systematic review published in 2017, which specifically addressed major complications following OPN and RAPN, corroborated our findings.²⁰ The major complication rates reported in the earlier review closely mirror our results. Importantly, the 2017 review focused solely on major complications related to OPN and RAPN, unlike our comprehensive analysis, which covers a broader range of procedures and complications.

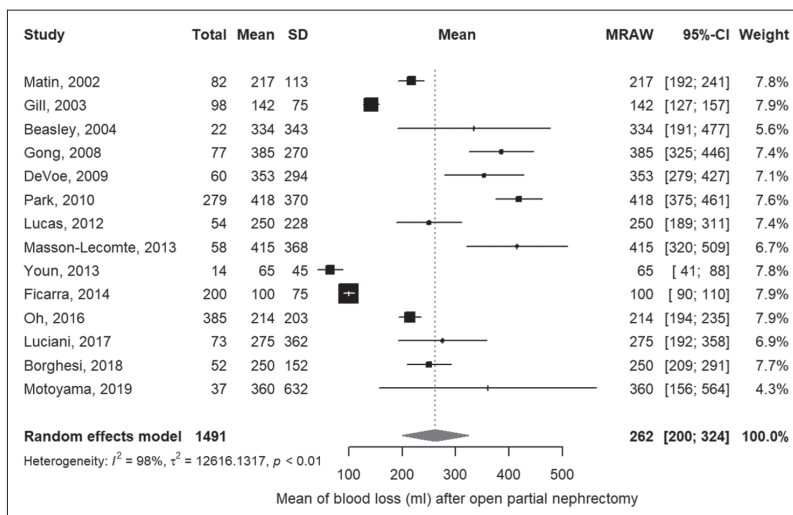


Figure 6. Forest plot of estimated blood loss in patients with small renal mass, after open partial nephrectomy. CI: confidence interval; SD: standard deviation.

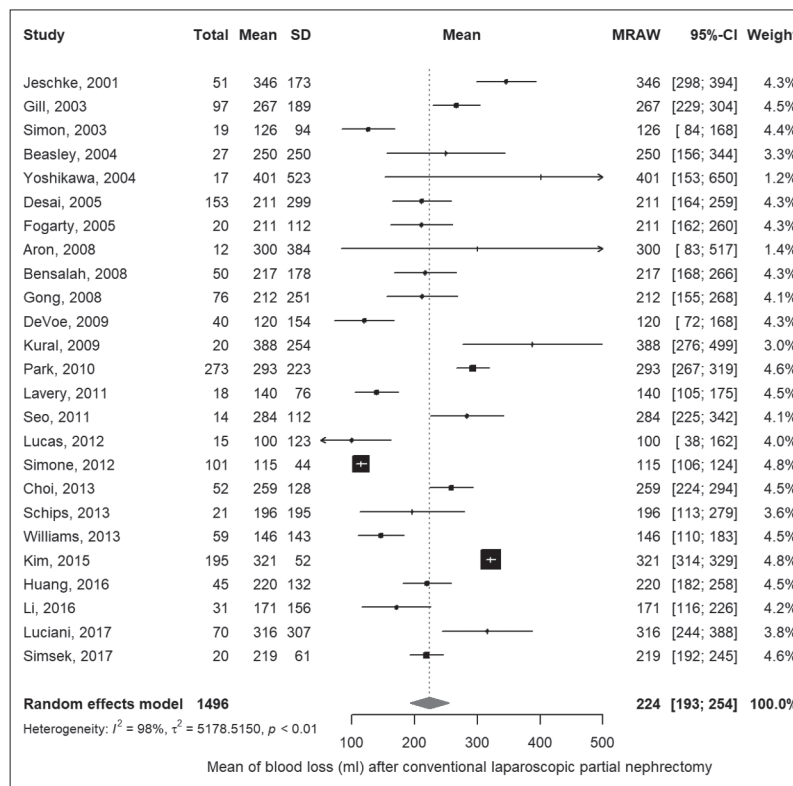


Figure 7. Forest plot of estimated blood loss in patients with small renal masses, after conventional laparoscopic partial nephrectomy. CI: confidence interval; SD: standard deviation.

Implications of findings

Our systematic review and meta-analysis offer crucial insights for clinical practice, providing contemporary data on major complications with various SRMs treatment options and EBL for PN methods. This informa-

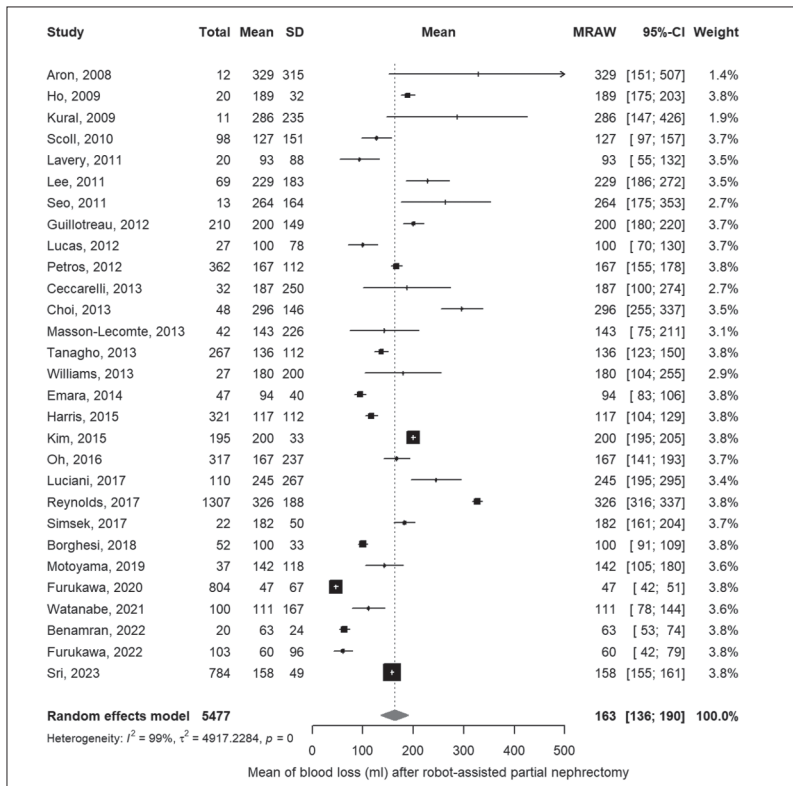


Figure 8. Forest plot of estimated blood loss in patients with small renal mass, after robot-assisted partial nephrectomy. CI: confidence interval; SD: standard deviation.

tion empowers both patients and physicians, fostering informed decision-making and healthcare policy development. In addition, it contributes to the enhancement of existing decision aids,²¹ ensuring that these tools remain reflective of the latest evidence.

Our findings serve as a foundational reference for researchers engaged in values and preference studies. By enriching investigations, our work contributes to a broader understanding of patient preferences in the context of SRM treatment decisions.

Finally, our findings are valuable for informing guideline panels and policy decision makers. We envision our work as a resource for initiatives such as urological guidelines, providing insights into the relative harms of different treatment approaches for SRMs.

CONCLUSIONS

This systematic review and meta-analysis presents the most comprehensive estimates of major complications following PN and PTA, as well as mean EBL for PN in patients with SRM. By synthesizing a large body of evidence, this review enhances our understanding of the harms of each intervention and helps guide clinical practice.

COMPETING INTERESTS: Dr. Richard has participated in advisory boards for Astellas, Bayer, and Novartis; has received speaker honoraria from Abbvie, Astellas, Bayer, Janssen, Knight, Novartis, and Tolmar; and has participated in clinical trials supported by Merck. The remaining authors do not report any competing personal or financial interests related to this work.

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This paper has been peer reviewed.

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