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Diagnostic Yield and Early Outcomes of Radical Prostatectomy Without Prior Histopathologic Diagnosis: A Single-Arm Systematic Review and Meta-analysis

Alec Anceno

Alec.Anceno@med.usc.edu

University of Southern California

Fernando Loyola-Nieto

Cleveland Clinic

Raymundo A. Munoz

University of Colorado Anschutz

Betsabe Petra Carreño-Hinojosa

Yale School of Medicine

Alejandro Calvillo-Ramirez

University of Chicago

Isait Alvarado

Mercer University

Nathan Joseph Silva Godinho

Universidade Federal de Minas Gerais

Marco Antonio Andrade

Universidade Federal de Minas Gerais

Alejandro Bautista-Perez-Gavilan

Cleveland Clinic

Daniel Magdaleno

Hospital General Dr. Manuel Gea Gonzalez

Juan Carlos Angulo-Lozano

Rockefeller University

Mitchell G. Goldenberg

University of Southern California

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Abstract

Purpose

To evaluate the pathological, oncological, and functional outcomes of radical prostatectomy (RP) performed without prior histopathologic confirmation of prostate cancer in patients with a high clinical suspicion of clinically significant prostate cancer (csPCa).

Methods

We systematically searched PubMed, Embase, Google Scholar, and Cochrane databases for studies evaluating biopsy-free RP. Adult men with a high clinical suspicion of csPCa based on multiparametric MRI and/or PSMA-PET with elevated PSA or PSA density were included. A single-arm random-effects meta-analysis was performed to estimate the pooled proportions of csPCa, benign pathology, overtreatment, and positive surgical margins (PSM).

Results

Eleven studies comprising 648 patients were included, csPCa was identified in 94.2% of patients (95% CI, 88.4–97.2), whereas benign pathology occurred in only 0.3%. The pooled overtreatment rate was 5.7%, and PSM was observed in 25.4% of cases. Study-level subgroup analysis suggested a higher diagnostic yield in biopsy-naïve cohorts than in cohorts including patients with a previous negative biopsy (95% vs. 80%; p = 0.005), with no significant differences according to imaging modality or surgical approach. Functional outcomes suggested favorable early urinary continence and erectile function recovery; however, heterogeneous and incomplete reporting precluded quantitative synthesis, and these findings were based on descriptive data only. Overall risk of bias was serious, primarily because of verification bias arising from participant selection.

Conclusions

Biopsy-free RP is a promising imaging-driven strategy for highly selected patients with a high probability of csPCa, achieving a high pathological yield of clinically significant disease with a very low observed rate of benign surgery. However, the observed PSM rate of 25.4%, whose interpretation is limited by the absence of a comparator arm, together with the limited, predominantly retrospective evidence, precludes routine clinical adoption.

Introduction

In 2025, prostate cancer accounted for 30% of new cancer diagnoses among men in the United States and was the second leading cause of cancer-related death in this population [1]. There were 1.4 million

new PCa cases reported worldwide in 2022 with the estimated 5-year prevalence exceeding 5 million cases globally, with marked geographic differences in incidence and mortality [2, 3]. Several screening modalities have emerged since PSA testing, including PSMA-PET, mpMRI, and predictive models integrating clinical and imaging data [4–6]. mpMRI has shown strong diagnostic performance, with a pooled sensitivity and specificity of 69% and 84% in one meta-analysis [7]. In the multicenter randomized PRECISION trial, MRI-based assessment allowed 28% of patients (71/252) to avoid biopsy altogether, while reducing the detection of clinically insignificant cancer and improving the detection of clinically significant disease [8]. Within the last decade, the development of prospective trials that eliminate the need for biopsy [9] has led to an increasing number of men being evaluated for clinically significant prostate cancer (csPCa) before biopsy-based histologic confirmation [10, 11]. Nevertheless, tissue diagnosis by transrectal or transperineal prostate biopsy is considered a prerequisite before definitive treatment, as recommended by the NCCN [12] and EAU Guidelines [13].

Recently, an increasing number of studies have explored biopsy-free radical prostatectomy (RP) in patients with a high clinical suspicion of prostate cancer based on imaging findings, elevated biomarker levels, or a combination of these factors [14]. This approach has been driven by advances in imaging, the increasing predictive value of MRI and targeted diagnostics, and biopsy-related adverse effects such as infection, bleeding, urinary retention, and patient anxiety [14, 15]. Furthermore, up to 20% of clinically significant cancers may be missed on biopsy as false negatives, delaying diagnosis [16]. Proponents suggest that, in carefully selected men with highly suspicious imaging findings and elevated PSA levels, the probability of clinically significant PCa may be sufficiently high to justify surgical management without a biopsy, thereby avoiding biopsy-related morbidity [17].

Undoubtedly, this biopsy-free approach remains controversial. Critiques emphasize that a biopsy provides histologic confirmation, tumor grading, and information that can influence treatment selection, and that omitting a biopsy raises concerns about overtreatment, diagnostic uncertainty, and patient counseling [18]. Currently, the available evidence is limited, and heterogeneous, as most published studies involve small cohorts and differ in patient selection criteria, imaging protocols, follow-up duration, and surgical indications. Although several prospective cohort studies have been reported, prospective comparative evidence evaluating this strategy remains limited [9]. As a result, it remains unclear whether outcomes after RP without prior biopsy are comparable to those achieved with the current standard pathway requiring histopathologic confirmation before definitive treatment [18]. We conducted this systematic review and meta-analysis to synthesize outcomes of RP performed without prior biopsy and evaluate the potential benefits and limitations of this imaging-driven pathway.

Methods

2.1 Protocol and Registration

This systematic review and meta-analysis followed the Cochrane Handbook [19] and PRISMA guidelines [20]. The protocol was prospectively registered in the International Prospective Register of Systematic

Reviews (PROSPERO) (protocol: CRD420261375912).

2.2 Eligibility Criteria

Studies were included if they aligned with the PIO framework: (P) Population – adult men (≥ 18 years) with high clinical suspicion of csPCa based on multiparametric MRI (mpMRI; PI-RADS ≥ 4) and/or positive PSMA-PET, with elevated prostate-specific antigen (PSA) or PSA density and no confirmed distant metastases; both biopsy-naïve patients and those with a prior negative biopsy and rising suspicion were eligible. (I) Intervention – RP (open, laparoscopic, or robot-assisted). (O) Outcomes – oncologic efficacy, functional outcomes, safety with reporting of at least one prespecified primary outcome required for inclusion.

Studies were excluded if they were case reports, series with fewer than 5 patients, reviews, editorials, conference abstracts without full-text publication, or animal or in vitro studies.

2.3 Study Design and Search Strategy

Searches were conducted in PubMed, Embase, Google Scholar, and the Cochrane Library, with the final search performed on May 11, 2026. No language restrictions or sample-size filters were applied. The complete search strategy for each database is provided in the **Supplementary Document**.

2.4 Study Selection and Data Extraction

Two reviewers (R.M. and I.A.) independently screened studies using Rayyan software [21]. Disagreements were resolved by consensus, with consultation of a third reviewer (A.A.) when necessary. Data were extracted by one reviewer using a standardized data extraction form and independently verified by a second reviewer against the original publications. For the three comparative studies, only data from the biopsy-free arm were included in the meta-analysis, whereas comparator-arm data were retained for descriptive perioperative and functional comparisons. Extracted variables are listed in Supplementary Table 1.

2.5 Endpoints and Definitions

The primary outcomes were the proportion of patients with csPCa (ISUP grade ≥ 2) on final pathology, the false-positive surgery rate (defined as benign disease on final pathology), and the positive surgical margin (PSM) rate. Secondary outcomes included the overtreatment rate (surgery in the absence of csPCa, i.e., benign disease or ISUP grade 1), pathologic stage, biochemical recurrence, urinary continence, and perioperative outcomes.

2.6 Quality Assessment

Two reviewers (F.L.N. and A.C.R.) independently assessed the risk of bias of the included (non-randomized) studies using the Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I) tool. Small-study effects were explored using funnel plots and Egger’s regression test for outcomes reported

by at least 10 studies. Disagreements were resolved through discussion and consensus, with a third reviewer (A.A.) consulted if needed.

2.7 Statistical Analysis

A single-arm meta-analysis of proportions was performed using a random-effects logistic-normal (generalized linear mixed) model with logit transformation and maximum-likelihood estimation of the between-study variance, yielding pooled proportions with 95% confidence intervals (CIs) for each dichotomous outcome (rationale for model selection in Supplementary Methods); the DerSimonian-Laird model with Hartung-Knapp adjustment served as a sensitivity analysis. 95% prediction intervals were also calculated. Heterogeneity was assessed using Cochran's Q test and the I^2 statistic, with $I^2 \geq 50\%$ considered substantial. Robustness was assessed via leave-one-out analysis and Baujat plots. Prespecified subgroup analyses were performed by imaging modality (mpMRI alone, combined mpMRI plus PSMA-PET, or mixed imaging cohorts), biopsy history (biopsy-naïve vs. prior negative biopsy), and surgical approach; a random-effects meta-regression based on publication year was performed to assess temporal trends. Analyses were conducted in R (version 4.6.0; R Foundation for Statistical Computing, Vienna, Austria) using the meta and metafor packages within RStudio. Statistical significance was set at $p < 0.05$.

Results

The literature search identified 622 records; after removal of duplicates and title/abstract and full-text screening, 11 studies comprising 648 patients who underwent biopsy-free RP met the inclusion criteria (Fig. 1). Three studies were comparative (biopsy-free vs. biopsy-confirmed) prostatectomy studies, of which only the biopsy-free arm was analyzed. One additional eligible cohort (Niu et al., 2024 [22]) was excluded a priori because of patient overlap with a larger registered cohort (Li et al., 2026 [23]). Study characteristics are summarized in **Table 1**.

Oncologic and Pathologic Outcomes

On final pathology, the pooled proportion of csPCa was 94.2% (95% CI 88.4–97.2) (Fig. 2). Because pathology was ascertained only in operated patients, with the surgical specimen serving as the reference standard, this proportion reflects the diagnostic yield of the selection pathway rather than the positive predictive value (PPV) of imaging in the broader suspicious population. Only two of the 648 operated patients had benign final pathology (2/648, crude proportion 0.3%), yielding a pooled proportion of 0.3% (95% CI 0–6.6%; $k = 11$, $I^2 = 0\%$) (Fig. 3A). When indolent disease (ISUP grade 1) was additionally considered, the pooled proportion of surgery without clinically significant cancer (overtreatment) was 5.7% (95% CI 2.7–11.4; $I^2 = 51\%$). PSM were reported in 10 studies and pooled to 25.4% (95% CI 16.0–37.8; $k = 10$, $I^2 = 43\%$; prediction interval 6–66%) (Fig. 3B). Perioperative outcomes were summarized descriptively in **Table 1** because heterogeneous reporting precluded meta-analysis.

Subgroup and Meta-regression Analyses

The proportion of csPCa did not differ by imaging modality (test for subgroup differences p = .71) or surgical approach (p = .11) (Fig. 4A and 4C). In contrast, diagnostic yield differed by biopsy history (p = .005): biopsy-naïve cohorts reached 95% (95% CI 90–98), whereas cohorts that included men with a prior negative biopsy reached 80% (95% CI 64–90) (Fig. 4B). Because the lower-yield stratum comprised only two small studies (Magdaleno 2025 [11], n = 18; Yang F 2020 [24], n = 17), this finding is considered hypothesis-generating. Random-effects meta-regression showed no association between the csPCa proportion and publication year (p = .39).

Sensitivity Analyses and Small-study Effects

Sensitivity analyses were consistent with the primary estimate (range 92.0-95.3%) and showed no evidence of small-study effects for csPCa; funnel-plot asymmetry was detected for PSM but is of uncertain interpretation given the small number of studies (Supplementary Results, Figs. 1–2).

Risk of Bias

The overall risk of bias was serious across all 11 studies (Supplementary Fig. 3), driven by the participant selection domain, as outcomes were ascertained only from patients selected for surgery, with the surgical specimen as the reference standard (verification bias).

Functional Outcomes

Among the included studies, five reported urinary continence outcomes: Li et al. [23], Liu et al. [17], Razdan et al. [16], Cao et al. [25], and Yang C et al. [26]. At 3 and 6 months, continence rates ranged from 76% to 100% and from 94% to 100% respectively, across the studies by Li et al. [23], Liu et al. [17], Cao et al. [25], and Yang C et al. [26]. Biopsy-naive patients had higher continence rates than biopsy-exposed patients through 9 months (all $p \leq 0.05$), converging by 12 months (100% vs 99%, p = 0.07) [16].

Sexual function outcomes were reported by Yang C et al. [26] and Razdan et al. [16]. Although the outcomes were measured differently, Yang C et al. [26] assessed the ability to achieve erections, whereas Razdan et al. [16] evaluated the ability to engage in penetrative intercourse. Both studies reported more favorable sexual function recovery during follow-up among patients who underwent surgery without prior biopsy with Razdan et al. [16] reporting statistically significant differences at every follow-up timepoint.

Discussion

This systematic review and single-arm meta-analysis pooled 648 patients from 11 studies who underwent RP without prior histopathologic confirmation. On final pathology, 94.2% had csPCa, while benign surgery was rare (0.3%) and overtreatment, defined as surgery without csPCa, occurred in 5.7%. PSM were observed in approximately one in four patients (25.4%). Because final pathology was available only for patients selected for surgery, these estimates reflect the diagnostic yield of the overall selection pathway rather than the diagnostic accuracy of imaging in the broader population with suspicious findings. Despite the high pooled estimate, the wide prediction interval (57%–100%) indicates substantial uncertainty in the yield that may be expected across future clinical settings with different patient-selection criteria. Our high pooled csPCa yield is consistent with prior work showing that combined mpMRI/PSMA-PET can approach near-certain csPCa prediction at high SUVmax thresholds [6, 27]. However, imaging alone has limited specificity: mpMRI's positive predictive value ranges from 34–68% across studies [28, 29], underscoring the rationale for molecular adjuncts like PSMA-PET. PSMA PET-CT is more accurate than conventional imaging for detecting nodal and distant metastases (92% vs 65% in proPSMA) and improves staging before surgery [30].

Diagnostic yield was lower in cohorts including men with a prior negative biopsy (about 80%) than in biopsy-naïve cohorts (about 95%). This finding came from only two small studies and should be treated as hypothesis-generating. Still, it is biologically plausible, since a previous negative biopsy points to a lower pretest probability of significant cancer. A similar pattern is seen in repeat-biopsy populations, where csPCa detection is only moderate even with targeted biopsy [31]. The 25% PSM rate is the least reassuring finding of this review.

Several limitations must be acknowledged. We did not analyze a biopsy-confirmed comparator arm, so we cannot say whether this rate is higher than in the standard pathway, or whether it simply reflects the higher-volume, higher-grade tumors selected by imaging. Margin status was also not consistently adjusted for pathologic stage or grade across studies, which limits further interpretation. All 11 studies were rated at serious overall risk of bias, driven by participant selection (verification bias), because outcomes were only available in operated patients. Other limitations include a small and geographically concentrated evidence base (mostly from China), heterogeneous selection and imaging criteria, limited prospective comparative evidence, and inconsistent reporting of long-term oncologic and functional outcomes.

Future work should move beyond single imaging thresholds toward validated multivariable models. A nomogram combining PI-RADS, PSMA SUVmax, and PSA density improved specificity over SUVmax alone (AUC 0.936) [5]. Standardized reporting of intraprostatic PSMA activity is also needed [27].

Conclusions

RP without prior biopsy is a promising approach for managing select patients with a high pretest probability of csPCa through an imaging-driven strategy. PSM were common and the evidence base remains small, mostly retrospective, and at serious risk of bias. Further prospective clinical trials and

comparative studies are needed to validate its feasibility before it can be recommended in routine practice.

Declarations

Conflict of interest

The authors declare no competing interests.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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Author Contribution

A.A., D.M., and M.G.G. contributed to the conceptualization of the study. A.A., F.L.N., A.C.R., and N.J.S.G. contributed to software development, while A.C.R., D.M., J.C.A.L., and M.G.G. performed validation. A.A., F.L.N., R.A.M., and A.C.R. conducted the formal analysis. A.A. coordinated data curation and project administration, with contributions from F.L.N., R.A.M., B.P.C.H., A.C.R., I.E.A., N.J.S.G., M.A.A., and A.B.P.G. D.M., J.C.A.L., and M.G.G. supervised the study. All authors contributed to the methodology, investigation, drafting, and critical revision of the manuscript and approved the final version.

Data availability

All data generated or analysed during this study are included in this published article.

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Table

Table 1 is available in the Supplementary Files section.

Figures

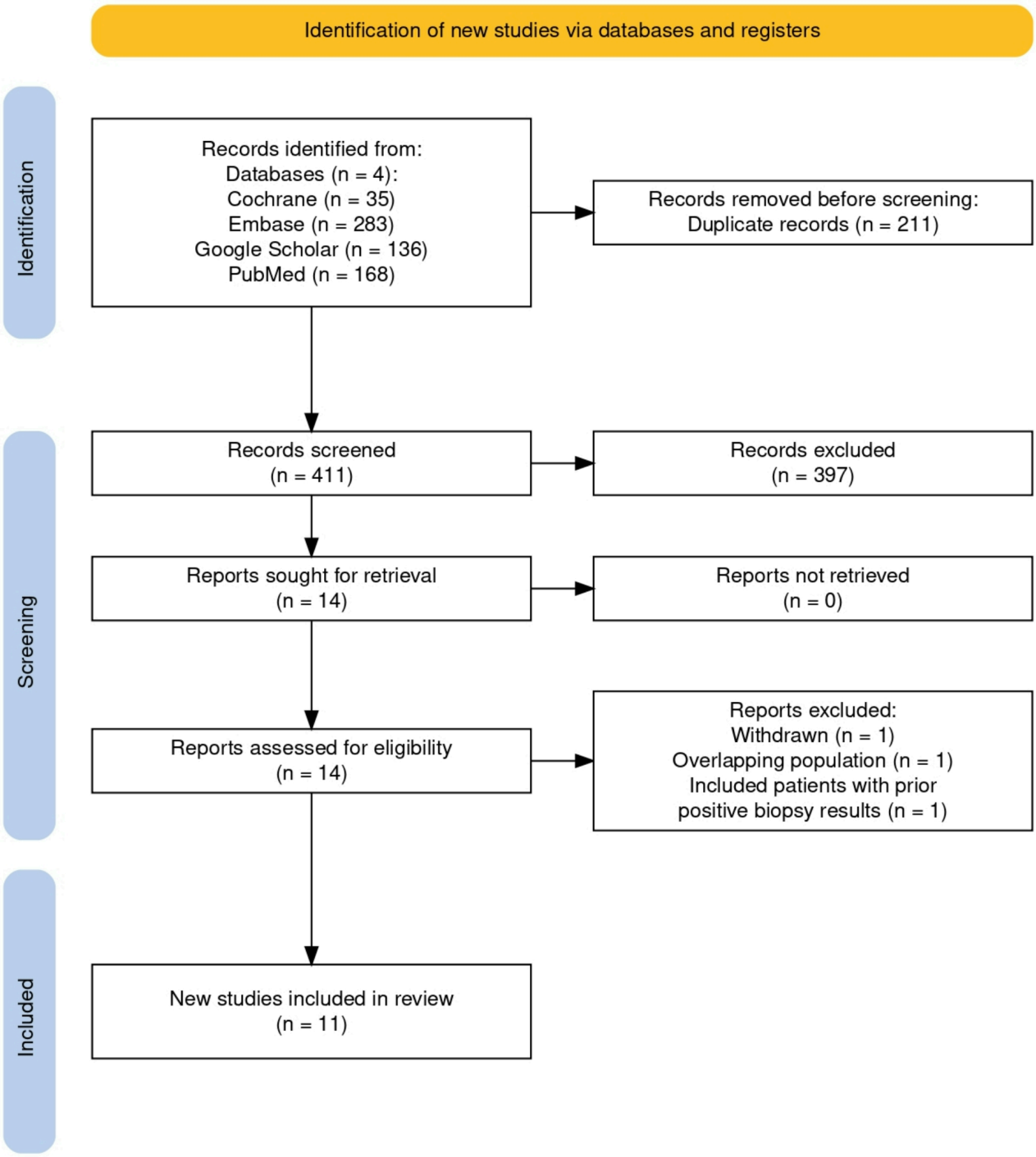


Figure 1

PRISMA 2020 flow diagram of study identification, screening, and inclusion.

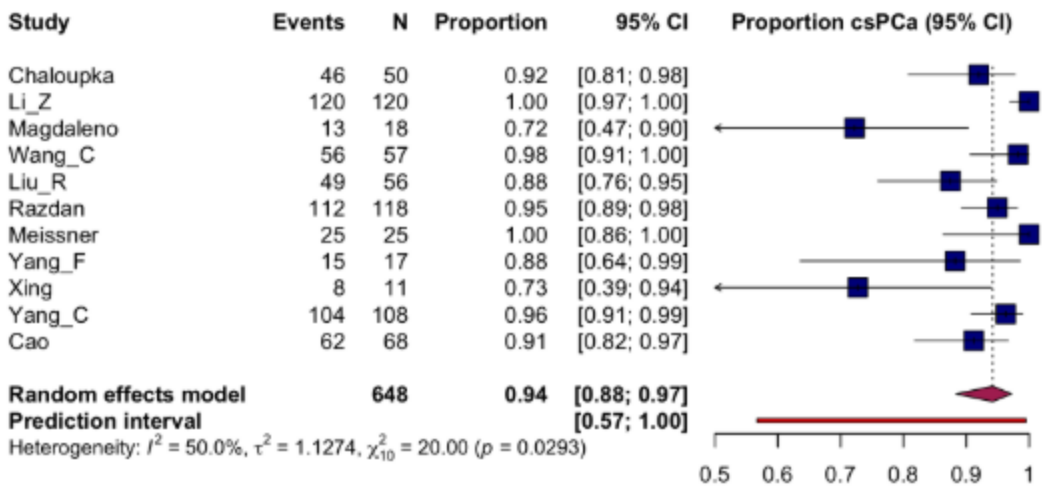
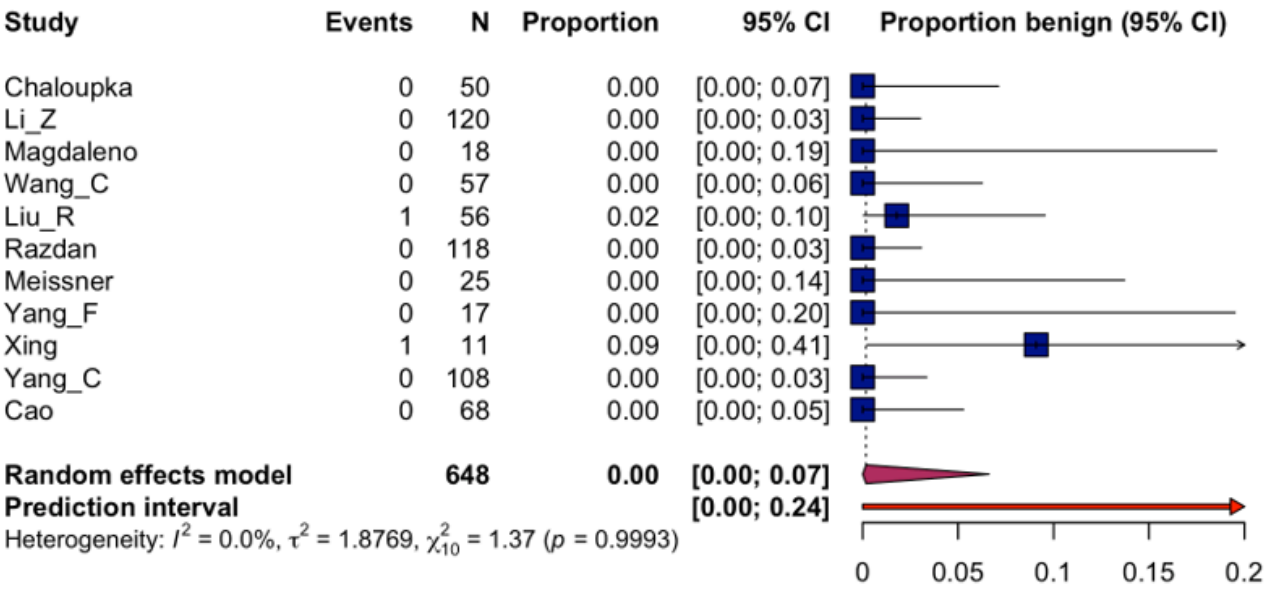


Figure 2

Forest plot of the pooled proportion of csPCa (ISUP grade ≥2) on final pathology among patients undergoing biopsy-free RP.



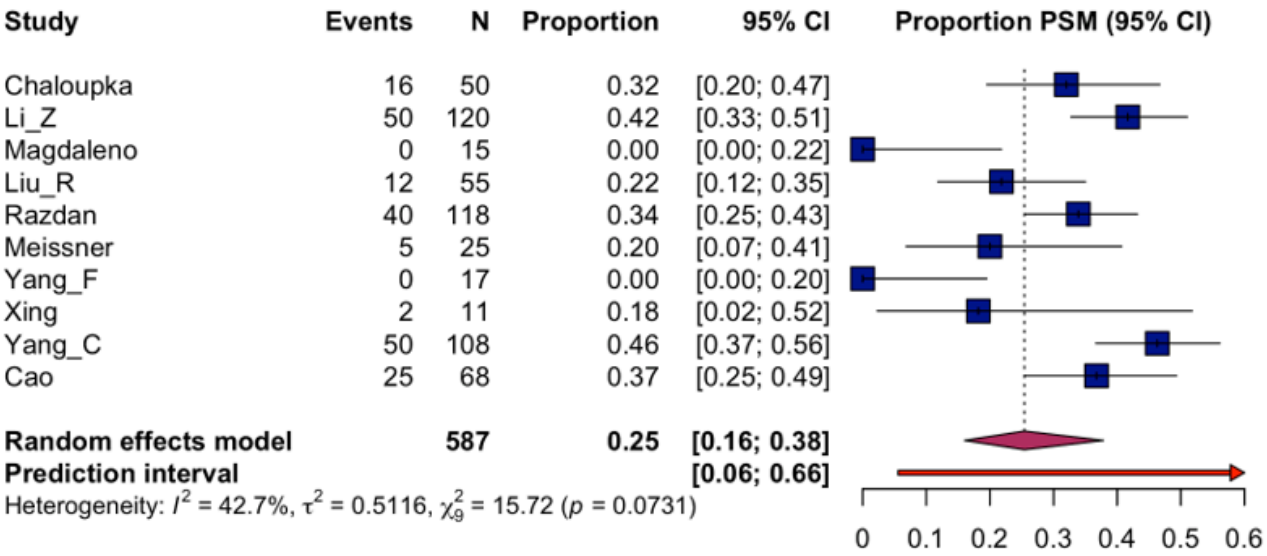
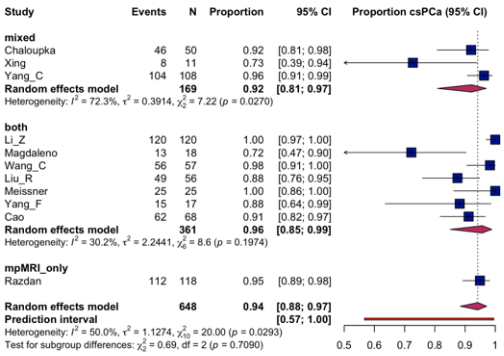
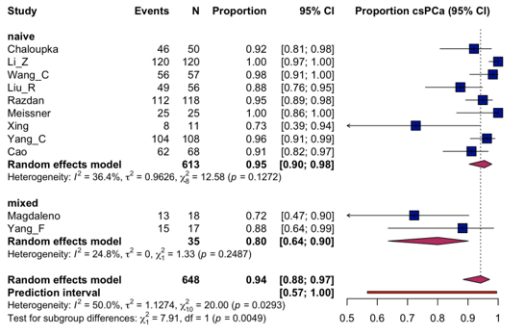


Figure 3

Forest plots of (A) false-positive surgery (benign final pathology) and (B) PSM.





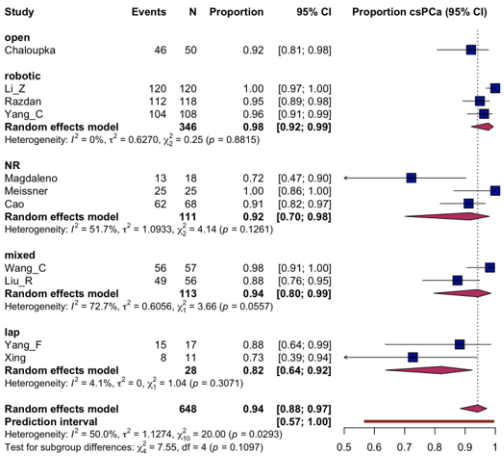


Figure 4

Subgroup forest plots of the csPCa proportion by (A) imaging modality (mpMRI only, mpMRI plus PSMA-PET, or mixed imaging protocols), (B) biopsy-history composition, and (C) surgical approach, with tests for subgroup differences.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementarydocumentWJU.docx
- Table1.docx