

INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Accuracy of novel urinary biomarker tests in the diagnosis of prostate cancer: a systematic review and network meta-analysis

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Review question / Objective: The purpose of this study was to conduct a network meta-analysis comparing the diagnostic value of different urinary markers for prostate cancer.

Condition being studied: A network meta-analysis(NMA) is an evidence-based technique that uses direct or indirect comparisons to compare the impact of multiple interventions on a disease and to estimate the rank of each measure. Therefore, this study pooled existing evidence and used a network meta-analysis to compare different urine markers (Progenza Prostate Cancer Antigen 3 (PCA3), SelectMDX, ExoDx Prostate Intelliscore (EPI), Mi-ProstateScore (MIPS)) to Evaluating and comparing the diagnostic performance of these urine markers in patients with PCa will provide patients and clinicians with more evidence-based data for the disease to guide selection of appropriate diagnostic methods for screening and diagnostic evaluation of patients with prostate cancer.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 September 2022 and was last updated on 19 September 2022 (registration number INPLASY202290094).

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INTRODUCTION

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comparisons to compare the impact of multiple interventions on a disease and to estimate the rank of each measure. Therefore, this study pooled existing evidence and used a network meta-analysis to compare different urine markers (ProgenSA Prostate Cancer Antigen 3 (PCA3), SelectMDX, ExoDx Prostate Intelliscore (EPI), Mi-ProstateScore (MIPS)) to Evaluating and comparing the diagnostic performance of these urine markers in patients with PCa will provide patients and clinicians with more evidence-based data for the disease to guide selection of appropriate diagnostic methods for screening and diagnostic evaluation of patients with prostate cancer.

METHODS

Participant or population: Participants: Men with elevated PSA levels or abnormal digital rectal examination (DRE) scheduled for prostate biopsy and who provided post-urine samples after digital rectal examination (DRE) but before biopsy, or provided urine samples directly; elevated PSA and/or suspected DRE. 2. Urine markers were used to assist in the diagnosis of prostate cancer; 3. The screening tools included urine markers and no less than two diagnostic methods; 4. The following outcome indicators were reported: true positive (TP), true negative (TN), false positive (FP), false negative (FN), sensitivity (Se), specificity (Sp), accuracy, positive predictive value (PPV) or negative predictive value (NPV). Calculated from known variables (Se and Sp) in cases where NPV, PPV, TP, TN, FP or FN are not reported.

Intervention: Different urine markers (ProgenSA Prostate Cancer Antigen 3 (PCA3), SelectMDX, ExoDx Prostate Intelliscore (EPI), Mi-ProstateScore (MIPS)).

Comparator: PSA.

Study designs to be included: Retrospective, prospective.

Eligibility criteria: Inclusion criteria: Participants: Men with elevated PSA levels

or abnormal digital rectal examination (DRE) scheduled for prostate biopsy and who provided post-urine samples after digital rectal examination (DRE) but before biopsy, or provided urine samples directly; elevated PSA and/or suspected DRE. 2. Urine markers were used to assist in the diagnosis of prostate cancer; 3. The screening tools included urine markers and no less than two diagnostic methods; 4. The following outcome indicators were reported: true positive (TP), true negative (TN), false positive (FP), false negative (FN), sensitivity (Se), specificity (Sp), accuracy, positive predictive value (PPV) or negative predictive value (NPV). Calculated from known variables (Se and Sp) in cases where NPV, PPV, TP, TN, FP or FN are not reported. Exclusion criteria: (1) History of prostate cancer, known taking medications that affect PSA levels, previous prostatectomy, or inability to provide post-DRE urine samples; (2) Exclude studies that are not urine markers or studies with less than two diagnostic methods; (3) Lack of clear inclusion and exclusion criteria in the study; (4) Letters to the editor, editorials, research protocols, case reports, brief communications, non-clinical studies, missing research data, and duplicate published articles, etc.

Information sources: A comprehensive and systematic search of articles published in Pubmed, EMBASE and Web of Science databases was conducted until June 2022.

Main outcome(s): Sensitivity (Se), specificity (Sp), accuracy, positive predictive value (PPV) or negative predictive value (NPV), Accuracy.

Quality assessment / Risk of bias analysis: The Diagnostic Accuracy Research Quality Assessment Tool (QUADAS-2) was used for independent quality assessment using QUADAS-2, and using a funnel plot test to determine publication bias. The Diagnostic Accuracy Research Quality Assessment Tool (QUADAS-2) was used for independent quality assessment using QUADAS-2, and using a funnel plot test to determine publication bias.

Strategy of data synthesis: We use stata software (version 15.1) to aggregate and analyse NMAs using a Markov Monte Carlo simulation chain in a Bayes-based framework. The Stata software will present and describe a network diagram of the different urine markers. In the resulting network graph, each node represents a different urine marker, and the lines connecting the nodes represent direct head-to-head comparisons between urine markers. The size of each node and the width of connecting lines are proportional to the number of studies. To help explain the diagnostic performance, the Surface Under the Cumulative Ranking Curve (SUCRA) was used to calculate the probability of each urine marker and was the most efficient diagnostic method based on a Bayesian approach using probability values, the greater the SUCRA value, the higher the diagnostic performance rating of the urine marker. This study used a funnel plot test to determine publication bias[22]. If the inverted funnel plot is asymmetric, publication bias may exist; otherwise, there is no apparent publication bias.

Subgroup analysis: No.

Sensitivity analysis: No.

Country(ies) involved: China, Surgery, Guizhou Orthopaedic Hospita and Department of Urology, Fenggang County People's Hospital.

Keywords: Accuracy; Prostate cancer; Urinary biomarkers; Diagnosis; Selectmdx; MIPS.

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