INPLASY

The value of the PRIMARY score in the diagnosis of clinically significant prostate cancer

INPLASY202520038

doi: 10.37766/inplasy2025.2.0038

Received: 6 February 2025

Published: 7 February 2025

Li, LY; Zhai, LY; Lin, YX; Xu, GY; Lin, AL.

Corresponding author:
liangyu li

lly990725@163.com

Author Affiliation:
Department of Urology, The Second Affiliated Hospital of Chongqing Medical University, Chongqing 400072, ChinaDepartment of Urology, The Second Affiliated Hospital of Chongqing Medical University, Chongqing 400072, China.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202520038

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 February 2025 and was last updated on 7 February 2025.

INTRODUCTION

Review question / Objective The value of the PRIMARY score in the diagnosis of clinically significant prostate cancer.

Rationale We retrieved relevant studies from the databases of PUBMED, EMBASE, Web of Science, SCOPUS and Cochrane Library up to April 16, 2024. We adopted the standard method for diagnostic evaluation meta-analysis recommendations. The receiver operating characteristic curve (SROC) was drawn, which represents the generalized receiver operating characteristic. To determine how confounding factors affect the results, meta-regression analysis was employed.

Condition being studied Prostate cancer refers to epithelial malignant tumors that occur in the prostate, and the incidence increases with age.Prostate cancer (PCa) is the fourth most common cancer in the world and the second leading cause of cancer-related deaths among American men.MRI is widely used in the diagnosis of csPCa and improves the detection rate of csPCa, but it is not a perfect diagnostic method. The recently proposed PRIMARY score based on 68 Ga-PSMA PET/CT showed good diagnostic performance for csPCa. This study aimed to evaluate the value of the PRIMARY score in the diagnosis of csPCa by a systematic review and meta-analysis.

METHODS

Search strategy We retrieved relevant studies from the databases of PUBMED, EMBASE, Web of Science, SCOPUS and Cochrane Library up to April 16, 2024.

Participant or population The study population consisted of patients who underwent prostate

needle biopsy only, all of whom underwent 68Ga PSMA PET prior to biopsy.

Intervention Grouped according to the PRIMARY score of the study population.

Comparator The study population was grouped according to the PRIMARY score, with less than 3 as negative and greater than or equal to 3 as positive.

Study designs to be included The study was considered for inclusion if all of the following requirements were met: (1) The study population was patients who had undergone prostate biopsy only; (2) 68Ga PSMA PET examination was performed before biopsy; (3) Taking pathological findings as the gold standard; (4) Can accurately extract the relevant data of PRIMARY score.

Eligibility criteria Studies were excluded if one of the following: (1) the article was a review or meta-analysis; (2) Overlapping reporting populations (in this case, select the publication with the most detailed information and/or the most recent publication); (3) Abstracts of papers, conferences or books only.

Information sources Information was sourced from PUBMED, EMBASE, Web of Science, SCOPUS, and Cochrane Library databases.

Main outcome(s) 1032 patients from the five studies included in this study were examined. The sensitivity, specificity, positive predictive value, and negative predictive value of the combined PRIMARY Score for the diagnosis of csPCa were 0.90 (95% CI, 0.85-0.93), 0.62 (95% CI, 0.54-0.70), and 0.69 (95% CI, 0.85-0.93), respectively. 0.56-0.833) and 0.80 (95% CI, 0.73-0.87). The diagnostic odds ratio was 14 (95%CI, 10 to 21), the positive likelihood ratio 2.4 (95%CI, 2.0 to 2.9), and the negative likelihood ratio 0.16 (95%CI, 0.12 to 0.22). The area under the SROC curve was 0.87 (95%CI, 0.84-0.90). There was no significant heterogeneity in sensitivity among the studies (I2=0.24, P=0.40), but there was high heterogeneity in specificity (I2=60.85, P=0.04). Meta-regression analysis did not find a source of heterogeneity.

Quality assessment / Risk of bias analysis Quality assessment of Diagnostic Accuracy Studies (QUADAS-2) was used to assess the quality of the included studies. [12] Two authors evaluated each study separately. Disagreements were resolved through discussion, and in case of remaining disagreements, consensus was reached through third-party arbitration.

Strategy of data synthesis We used standard methods recommended in diagnostic evaluation meta-analyses. A receiver operating characteristic curve (SROC) was plotted, which represents the generalized receiver operating characteristic. To determine how confounding factors affected the results, a meta-regression analysis was performed.

Subgroup analysis Subgroup analyses were performed using the following criteria: (1) the countries of the study subjects were divided into two groups; (2) PSA level was divided into two groups; (3) Puncture strategies were divided into two groups; (4) Study types were divided into two groups.

Sensitivity analysis None.

Language restriction We searched only literature whose language was English.

Country(ies) involved China.

Other relevant information None.

Keywords PSMA; prostate-specific membrane antigen; PET; multi-parametricMRI; prostate cancer; diagnosis.

Contributions of each author

Author 1 - liangyu li.
Email: lly990725@163.com
Author 2 - lingyun Zhai.
Email: zhailingyun@cqmu.edu.cn
Author 3 - Yuxiang lin.
Email: 2021150105@stu.cqmu.edu.cn
Author 4 - Guangyong Xu.
Email: xgy1128@163.com
Author 5 - Anlong lin.
Email: 990190219@qq.com