INPLASY PROTOCOL

To cite: Li et al. Compare the diagnostic performance of CEUS and MR/CT LIRADS categories for differentiating HCC and other non-HCC malignancies：a systematic review and meta-analysis. Inplasy protocol 202060056. doi: 10.37766/inplasy2020.6.0056

Received: 15 June 2020

Published: 15 June 2020

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Support: **None.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None.

Compare the diagnostic performance of CEUS and MR/CT LIRADS categories for differentiating HCC and other non-HCC malignancies：a systematic review and meta-analysis

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Review question / Objective: **To compare the diagnostic performance of CEUS and MR/CT LI-RADS categories for differentiating HCC and other non-HCC malignancies.**
Condition being studied: **Imaging plays an important role in diagnosing HCC because the diagnosis of HCC in patients at high risk for HCC can be established by imaging instead of pathological assessment. CEUS shows advantages in diagnosing HCC so that several guidelines recommend it as the first or second-line tool for HCC. But the guideline from America holds different attitudes toward the diagnostic performance of CEUS since CEUS features of non-HCC malignancies may be similar to that of HCC. To further clear the diagnostic performance of CEUS in differentiated non-HCC malignancies from HCC, we focus on comparing the diagnostic performance of CEUS and MR/CT.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 June 2020 and was last updated on 15 June 2020 (registration number INPLASY202060056).

INTRODUCTION

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METHODS

Participant or population: (1) Adults aged >18 years old (2) Patients at high risk for HCC according to CEUS-LIRADS and CT/MR diagnostic LIRADS (3) CEUS or CT/MR LIRADS was adopted to diagnose HCC (4) Available reference standard (5) Lesions without previous treatment before imaging.

Intervention: CEUS: Blood-pool agents such as Lumason/SonoVue and Definity/Luminity were adopted instead of combined blood-pool and Kupffer cell agents. A minimum requirement of imaging-recommended and recording-recommended in the CEUS LI-RADS technical recommendations should be met. CT/MR, extracellular contrast agents or hepatobiliary contrast agents were required. Multidetector CT (≥8 detector rows) for CT and 1.5T or 3T for MR were necessary. As for images, arterial phase, portal venous phase and delayed phase for CT, pre-contrast unenhanced T1-weighted, multiphase T1-weighted imaging and T2-weighted imaging for MRI were acquired.

Comparator: Not applicable.

Study designs to be included: Both retrospective and prospective studies.

Eligibility criteria: Studies meet the above PICO criteria.

Information sources: We will search the MEDLINE (through OVIDSP), CENTRAL (through OVIDSP), Embase, and Scopus databases for studies published for primary studies assessing per-lesion diagnostic performance of CEUS or MR or both from 2014 to current, without restrictions on language. MeSH and free words will be used in the literature search strategy. In addition, we will manually search for relevant studies by screening the references of retrieved studies.

Main outcome(s): The sensitivity, specificity, PLR, NLR, DOR of CEUS, or MR/CT LIRADS for differentiating HCC and non-HCC malignancies will be demonstrated. SROC curves of CEUS or MR/CT LI-RADS will be given.

Additional outcome(s): The percentage of HCC, non-HCC malignancies, and benign lesions in each LR category in patients at high risk for HCC using CEUS or CT/MR.

Data management: Two reviewers independently extracted data that we need and differences will be reconsidered together with a third reviewer until an agreement was reached.

Quality assessment / Risk of bias analysis: The quality of the included diagnostic accuracy studies will be appraised by the Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) tool. Included primary studies will also be assessed by two reviewers independently and differences will be reconsidered together with a third reviewer until an agreement was reached. Publication bias will be also given.

Strategy of data synthesis: Diagnostic performance of CEUS and MR/CT LI-RADS will be synthesized using the bivariate model. The random effect model will be used to synthesize the percentage of HCC and non-HCC malignancies of LR categories. The Q test and I2 statistic will be used to assess the heterogeneity.

Subgroup analysis: Subgroup analysis will be done according to country, study type, patients, lesions, reference standard and index texts.

Sensibility analysis: Sensibility analysis will be made.

Language: English.

Country(ies) involved: China.

Keywords: LI-RADS, HCC, other malignanlies, diagnostic, systematic review, meta-analysis.

Contributions of each author:

Author 1 - Lingling Li - Author 1 drafted the manuscript and provided statistical analysis.

Author 2 - Yixin Hu - The author contributed to the development of the selection criteria and the risk of bias assessment strategy.

Author 3 - Jianhua Zhou - The author designed the study.