# INPLASY PROTOCOL

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# Corresponding author: Jianhua Zhou

zhoujh@sysucc.org.cn

## Author Affiliation:

Sun Yat-sen University Cancer Center

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**Review Stage at time of this submission:** Piloting of the study selection process.

Conflicts of interest: The authors disclosed no relevant relationships.

# INTRODUCTION

**Review question / Objective:** To review the diagnostic performance of CEUS LI-RADS 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

# Diagnostic performance of CEUS LI-RADS for differentiating HCC and other non-HCC malignancies: a systematic review and meta-analysis

Li, L<sup>1</sup>; Hu, Y<sup>2</sup>; Zhou, J<sup>3</sup>.

**Review question / Objective:** To review the diagnostic performance of CEUS LI-RADS 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 reviewing the diagnostic performance of CEUS using the LI-RADS criteria.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 June 2020 and was last updated on 21 June 2020 (registration number INPLASY202060077). 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 reviewing the diagnostic performance of CEUS using the LI-RADS criteria.

### **METHODS**

Search strategy: MeSH and free words will be used in the literature search strategy.

Participant or population: Patients at high risk for HCC aged >18 years old; CEUS LI-RADS version 2016 or 2017 was adopted; available reference standard; lesions without previous treatment before imaging.

Intervention: CEUS LI-RADS version 2016 or 2017 was adopted. 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 recordingrecommended in the CEUS LI-RADS technical recommendations should be met.

**Comparator: Not applicable.** 

Study designs to be included: Both retrospective and prospective studies demonstrating the percentage of HCC, other non-HCC malignancies and benign lesions in each LR categories or.

**Eligibility criteria:** Studies meet the above PICO critera.

**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.

Main outcome(s): The specificity, PLR, and sROC curve of CEUS for differentiating HCC and non-HCC malignancies using LI-RADS LR5 criteria will be demonstrated.

Additional outcome(s): The sensitivity and NPV using LI-RADS LRM criteria will receive part of interest.

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: The diagnostic performance of CEUS LI-RADS will be synthesized using the bivariate model. The Q test and I2 statistic will be used to assess the heterogeneity. Statistical analysis will be completed by STATA and RevMan.

Subgroup analysis: None.

Sensibility analysis: Sensibility analysis will be done.

Language: Without restrictions.

Country(ies) involved: All the countries involved.

Keywords: Contrast Media; Ultrasonography; Diagnostic imaging; Ll-RADS; liver Neoplasms; Hepatocellular carcinoma; Other non-HCC malignancies; Systematic review; Meta-analysis

#### **Contributions of each author:**

Author 1 - Lingling Li - The author 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 whole study.