INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Role of endoscopic ultrasound-guided liver biopsy: a meta-analysis

Zeng, KY[1]; Jiang, ZP[2]; Yang, J[3].

Review question / Objective: **To make an overall evaluation on efficacy and safety of endoscopic ultrasound-guided liver biopsy for liver parenchymal diseases as well as focal liver lesions and to evaluate factors relevant to efficacy and safety.**
Condition being studied: **Endoscopic ultrasound-guided liver biopsy; liver parenchymal diseases; focal liver lesions.**
Information sources: **A systematic search of the following databases: PubMed, Embase and Cochrane Library was performed based on the searching strategies: [(endoscopic ultrasound) or (EUS)] and [(liver) or (hepatic) or (hepatocellular)] AND [(biopsy) OR (aspiration) OR (fine needle) OR (core needle)].This search was restricted to studies on human and studies published in English language. Bibliographies of the retrieved articles were checked to identify additional relevant articles.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 April 2021 and was last updated on 05 April 2021 (registration number INPLASY202140021).

INTRODUCTION

Review question / Objective: **To make an overall evaluation on efficacy and safety of endoscopic ultrasound-guided liver biopsy for liver parenchymal diseases as well as focal liver lesions and to evaluate factors relevant to efficacy and safety.**

Condition being studied: **endoscopic ultrasound-guided liver biopsy; liver parenchymal diseases; focal liver lesions.**

METHODS

Participant or population: **Inclusion: Patients who were suspicious of liver**

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parenchymal diseases or focal liver lesions and underwent endoscopic ultrasound-guided liver biopsy. Exclusion: Patients who were under 18 years old.

Intervention: Endoscopic ultrasound-guided liver biopsy.

Comparator: None.

Study designs to be included: Randomized controlled trials or observational studies with more than 10 patients.

Eligibility criteria: Inclusion criteria: (1) Patients were suspicious of liver parenchymal diseases or focal liver lesions and underwent endoscopic ultrasound-guided liver biopsy. (2) Randomized controlled trials or observational studies with more than 10 patients. (3) Outcomes were reported as at least one of the following items: rate of successful histological diagnosis established, rate of adequate specimen acquired, presence of adverse events. (4) If two retrieved studies were based on the same population or the population of one study was included in another study, we included the latest study. Exclusion criteria (1) Studies the population of which had been included in another study cohort or studies that reported the same cohort. (2) Studies focusing on pediatric patients or patients younger than 18 years old.

Information sources: A systematic search of the following databases: PubMed, Embase and Cochrane Library was performed based on the searching strategies: [(endoscopic ultrasound) or (EUS)] and [(liver) or (hepatic) or (hepatocellular)] AND [(biopsy) OR (aspiration) OR (fine needle) OR (core needle)]. This search was restricted to studies on human and studies published in English language. Bibliographies of the retrieved articles were checked to identify additional relevant articles.

Main outcome(s): The primary aim of this analysis is to evaluate efficacy of endoscopic ultrasound-guided biopsy of liver parenchymal diseases and focal liver lesions. For liver parenchymal diseases, efficacy will be assessed in terms of the following outcomes: diagnostic yield and specimen adequacy. A liver specimen is deemed to have diagnostic yield if it allows pathologists to make a successful histological diagnosis. Liver specimen satisfying the following criterion will be deemed as adequate: total specimen length≥15 millimeters and presence of complete portal tracts≥6. For focal liver lesions, efficacy of endoscopic ultrasound-guided liver biopsy will be assessed by diagnostic yield and specimen adequacy assessed by rapid on-site evaluation (ROSE). Diagnostic yield and specimen adequacy will be presented as rate of successful histological diagnosis established per biopsy and rate of adequate specimen acquired per biopsy.

Additional outcome(s): The secondary aim of this analysis is to evaluate safety of EUS-LB which will be assessed through rate of adverse events after endoscopic ultrasound-guided biopsy of liver parenchymal diseases and focal liver lesions. An adverse event was defined as any incident deviating from the expectant post-biopsy clinical course.

Quality assessment / Risk of bias analysis: For observational study, we will use the Newcastle-Ottawa scale to assess quality of studies and a study with 6 or more stars is deemed to have high quality. For randomized controlled trials, we will use the Cochrane Collaboration risk of bias tool and a study with low risk of bias in at least 5 items is deemed as having high quality.

Strategy of data synthesis: Stata version 15.0 software (StataCorp, College Station, TX) will be used in this meta-analysis to calculate the pooled value of the outcomes (diagnostic yield and specimen adequacy) and corresponding 95% confidence interval (CI). Inter-study heterogeneity is evaluated by chi-square-based Q statistic combined with I2 statistic. Q statistic at a $P<0.1$ demonstrates the presence of significant heterogeneity. I2 statistic is a quantitative indicator for inter-study heterogeneity. I2

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values more than 50% are also regarded as significant heterogeneity and I2 values of 75%-100% are regarded as considerable heterogeneity. If significant heterogeneity is not observed, we will utilize fixed-effect model. Random-effect model will be used when observing significant heterogeneity.

Subgroup analysis: Subgroup analyses will be performed to test interactions based on needle type(core needle vs. FNA needle), needle gauge (19G vs. 22G) and core needle brands (Acquire Franseen-tip needle vs. Sharkcore Fork-tip needle). To assess whether statistically significant differences exists between subgroups, the "metareg" command will be used and a P value between subgroups of <0.05 is thought to be statistically significant.

Sensitivity analysis: A sensitivity analysis will be performed by omitting 1 study to check whether heterogeneity was caused by any one included study.

Country(ies) involved: China.

Keywords: Endoscopic ultrasound; Liver biopsy; Liver parenchymal diseases; Focal liver lesions.

Contributions of each author:
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Author 3 - Jie Yang.

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