INPLASY PROTOCOL

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Conflicts of interest: None declared. Diagnostic Performance of Quantitative and Qualitative Elastography for the Differentiation of Benign and Malignant Cervical Lymph Nodes: A protocol for systematic review and meta-analysis

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Review question / Objective: Studies have shown inconsistent results regarding the diagnostic performance of quantitative and qualitative elastography for the differentiation of benign and malignant cervical lymph nodes. This meta-analysis aimed to estimate the diagnostic performance of ultrasound elastography in patients with cervical lymphadenopathy.

Condition being studied: Based on the fact that malignant lesions are usually harder than normal tissue, many studies have explored the diagnostic value of ultrasound elastography for the differentiation of benign and malignant superficial cervical lymph nodes. However, there is a lack of large sample study on the diagnostic value of ultrasound elastography in cervical lymph nodes. So it is necessary to perform a metaanalysis to assess the diagnostic value of ultrasound elastography for the differentiation of benign and malignant cervical lymph nodes.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 May 2021 and was last updated on 31 May 2021 (registration number INPLASY202150109).

INTRODUCTION

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METHODS

Search strategy: PubMed, Web of Science, Cochrane Library, and Chinese biomedical databases will be searched from their inceptions to the May 30, 2021, without language restrictions. The search strategy for PubMed is shown in Table 1. Other online databases will be used in the same strategy.

Participant or population: The patients should be those who with enlarged lymph nodes in the neck.

Intervention: No intervention

Comparator: This study compare SWE with SE for diagnosing benign and malignant cervical lymph nodes.

Study designs to be included: We will search PubMed, Web of Science, Cochrane Library, and Chinese biomedical databases from their inceptions to the May 30, 2021, without language restrictions. Two authors will independently carry out searching literature records, scanning titles and abstracts, full texts, collecting data, and assessing risk of bias. Review Manager 5.2 and Stata14.0 software will be used for data analysis.

Eligibility criteria: This study will only include high quality clinical cohort or case control studies.

Information sources: PubMed, Web of Science, Cochrane Library, and Chinese biomedical databases.

Main outcome(s): The primary outcomes include sensitivity, specifificity, positive and negative likelihood ratio, diagnostic odds ratio, and the area under the curve of the summary receiver operating characteristic.

Quality assessment / Risk of bias analysis: Two authors will independently select the trials according to the inclusion criteria, and import into Endnote X9. Then remove duplicated or ineligible studies. Screen the titles, abstracts, and full texts of all literature to identify eligible studies. All essential data will be extracted using previously created data collection sheet by 2 independent authors. Discrepancies in data collection between 2 authors will be settled down through discussion with the help of another author. The following data will be extracted from each included research: the first authors surname. publication year, language of publication, study design, sample size, number of lesions, source of the subjects, instrument, "gold standard," and diagnostic accuracy. The true positives, true negatives, false positives, and false negatives in the fourfold (2×2) tables were also collected. Methodological quality was independently assessed by 2 researchers based on the quality assessment of studies of diagnostic accuracy studies (QUADAS) tool. The **QUADAS** criteria included 14 assessment items. Each of these items was scored as "yes" (2), "no" (0), or "unclear"(1). The QUADAS score ranged from 0 to 28, and a score ≥22 indicated good quality. Any disagreements between 2 investigators will be solved through discussion or consultation by a 3rd investigator.

Strategy of data synthesis: The search strategy for PubMed is shown in Table 1. Other online databases will be used in the same strategy.

Subgroup analysis: The summary receiver operating characteristic curve and corresponding area under the curve were obtained. The threshold effect was assessed using Spearman correlation coefficients. The Cochrans Q-statistic and I test were used to evaluate potential heterogeneity between studies. If significant heterogeneity was detected (Q test P 50%), a random effects model or fixed effects model was used. We also performed sub group and meta-regression analyses to investigate potential sources of heterogeneity. To evaluate the influence of single studies on the overall estimate, a sensitivity analysis was performed. We conducted Beggs funnel plots and Eggers linear regression tests to investigate publication bias.

Sensitivity analysis: We calculated the pooled summary statistics for sensitivity, specificity, positive and negative likelihood ratio, and diagnostic odds ratio with their 95% confidence intervals.

Language: No restriction.

Country(ies) involved: China.

Keywords: shear wave elastography, strain elastography, meta-analysis, lymph nodes.

Contributions of each author:

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