# INPLASY PROTOCOL

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**None declared.**

# Diagnosis for Chinese patients with Light Chain Amyloidosis: A scoping review

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**Review question / Objective:** **The objective of this scoping review was to map the available literature in diagnosis of AL amyloidosis and to consolidate recommendations for practice and future research in China.**

**Background:** **Immunoglobulin light chain (AL) amyloidosis is the most common type of systemic amyloidosis which is characterized by a clonal population of bone marrow plasma cells that produces a mono-clonal light chain of κ or λ type as either an intact molecule or a fragment. This insoluble protein deposits in tissues and interferes with organ function. The incidence of amyloidosis is not well documented, but probably falls between 5 and 13 per million per year. One Literature conducted in France reported that the yearly incidence of AL amyloidosis is 12.5 (95%CI, 5.6 – 19.4) cases per million inhabitants. The nationwide epidemiological data for AL amyloidosis in China is lacking. Moreover, the specific situation of Chinese patients with AL amyloidosis is still unclear. The relevant guidelines and consensus are mainly based on European and American research, and there is a lack of data on clinical epidemiology, diagnosis and treatment of domestic patients.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 October 2022 and was last updated on 24 October 2022 (registration number INPLASY2022100096).

## INTRODUCTION

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**Rationale:** To describe the diagnosis of AL Amyloidosis in China, we conducted a systematic search in the databases of PubMed, EMBASE and CNKI using search terms “amyloidosis”, “ amyloidos * ” “ amyloido* ” , “ AL amyloidosis” and “China”. and limited the search results to only literatures published in the past 10 years. The scoping review were performed according to the preferred reporting items for scoping review (PRISMA) extension statement. We included literatures that reported Chinese patients with AL amyloidosis and extracted the diagnostic data of patients from each included article. For data analysis, we summarized the characteristics and results of the recently published studies on diagnosing AL Amyloidosis in China. Biopsy was still the most important method for AL Amyloidosis diagnosis in China. In addition, combined tests and some adjuvant methods played essential roles in the diagnosis. Further research was required to determine an acceptable and feasible diagnostic algorithm after symptom onset.

## METHODS

**Strategy of data synthesis:** 1、 EMBASE #1. 'AL amyloidosis'/exp OR ("light-chain" NEAR/3 amyloidos * OR AL NEAR / 3 a m y -loidos*): ab,ti,kw | #2. 'China'/exp OR China OR (Chinese OR Taiwan OR Hong Kong OR Hongkong OR Macau OR Macao OR Beijing OR Shanghai OR Tianjin OR Chongqing OR Inner Mongolia OR Tibet OR Guangxi OR Sinkiang OR Ningxia OR Xinjiang OR Hebei OR Shanxi OR Liaoning OR Jilin OR Heilongjiang OR Jiangsu OR Zhejiang OR Anhui OR Fujian OR Jiangxi OR Shandong OR Henan OR Hubei OR Hunan OR Guangdong OR Hainan OR Sichuan OR Guizhou OR Yunnan OR Shanxi OR Gansu OR Qinghai):ab,ti,ff | #3. # 1 A N D # 2 |

2、 PubMed # 1. "Immunoglobulin Light-chain Amyloidosis"[Mesh] OR ("Light chain"[tiab] AND Amyloidos * [tiab]) OR "AL amyloidos*"[tiab] OR "Amyloidosis AL” [tiab] | #2. "China"[Mesh] OR China OR Chinese OR Taiwan OR Hong Kong OR Hongkong OR Macau OR Macao OR Beijing OR Shanghai OR Tianjin OR Chongqing OR Inner Mongolia OR Tibet OR Guangxi OR Sinkiang OR Ningxia OR Xinjiang OR Hebei OR Shanxi OR Liaoning OR Jilin OR Heilongjiang OR Jiangsu OR Zhejiang OR Anhui OR Fujian OR Jiangxi OR Shandong OR Henan OR Hubei OR Hunan OR Guangdong OR Hainan OR Sichuan OR Guizhou OR Yunnan OR Shanxi OR Gansu OR Qinghai | #3. #1 AND #2 |

3、 CNKI（期刊、学位、会议，中英文扩展：否） | #1. SU%=轻链淀粉样变性+轻链淀粉样变性病+轻链淀粉样变+轻链型淀粉样变性+轻链型淀粉样变性病+轻链型淀粉样变 OR TKA=轻链型 /NEAR 3 淀粉样变 OR 轻链型 /NEAR 3 淀粉样变性 OR 轻链型 /NEAR 3 淀粉样变性病 OR 轻链 /NEAR 3 淀粉样变 OR 轻链/NEAR 3 淀粉样变性 OR 轻链 /NEAR 3 淀粉样变性病.

**Eligibility criteria:** The published academic papers related on diagnosis of AL amyloidosis were screened from 1 January 2000 to 15 September 2021. The inclusion criteria were 1) Chinese patients who have suspected AL amyloidosis without age restriction , 2) published in English or Chinese, 3) having a sample size of at least 25 patients, 4) original studies included both experimental studies and observational studies, and 5) having information on the diagnosis of AL amyloidosis. Exclusion criteria were as

follows: case reports, review, consensus, thesis, questionnaire, duplication, and correspondence.

**Source of evidence screening and selection:** Two reviewers screened literatures after reading titles and abstracts of the search results. All potentially relevant citations were requested and inspected in detail using the full-text version. Disagreements were resolved by discussion, with assistance from a third party if necessary. A PRISMA flow diagram was constructed to show the full Literature-selection process.

**Data management:** Data items were reviewed as follows: 1) clinical characteristics, such as age, sex, stage, type, organ involvement, and diagnostic delay; 2) diagnostic yield of Congo red staining, using different kinds of tissues; 3) LC light chains classification method; 4) radiological tools, flow cytometry, genetic tests and other routine biomarkers, such as 24 hours urinary protein, NT-pro-BNP or BNP and alkaline phosphatase. The data extraction form can be found in the protocol. A pretested data extraction form based on the PICOT (population, intervention, control, outcome, and time) structure was used to perform the data extraction. Data from each literature review were extracted by one reviewer and double-checked by another using a standard data extraction form. Data were extracted as follows: first author, title, year of publication, publication journal, country of study, study design, diagnostic delay, Congo red staining (biopsies, performance, and others), amyloid typing method (proportion and performance), AL Amyloidosis typing method (proportion and performance), organ involvement (diagnostic methods and corresponding performance).

**Language restriction:** No limited.

**Country(ies) involved:** China.

**Keywords:** Diagnosis; Light chain amyloidosis; biomarker; China; Scoping review.

**Contributions of each author:**

Author 1 - Juan Li drafted and revised the protocol, collected the data, then performed or supervised analyses, provided substantive suggestions for revision or critically reviewed subsequent iterations of the manuscript.
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