

INPLASY PROTOCOL

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None declared.

Treatment and outcomes of Chinese patients with AL Amyloidosis: a scoping review and meta analysis

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Review question / Objective: To understand the treatment patterns and outcomes of AL amyloidosis in Chinese population, and identify future research gaps.

Condition being studied: 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 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 treatment of domestic patients. This situation brings great difficulties to doctors in clinical practice. Due to the absence of systematic review describing treatment of AL amyloidosis in Chinese population, we conduct this scoping review. This scoping review aims to systematically search and analyze published data to understand the current treatment patterns of AL amyloidosis in China that having been assessed by evidence and identify future research gaps.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 October 2021 and was last updated on 26 October 2021 (registration number INPLASY2021100096).

INTRODUCTION

Review question / Objective: To understand the treatment patterns and outcomes of AL amyloidosis in Chinese population, and identify future research gaps.

Rationale: To describe the treatment patterns and outcomes of AL Amyloidosis in China, we will conduct a systematic search in the databases of PubMed, EMBASE and CNKI using search terms

“amyloidosis”, “ amyloidos * ” “ amyloido* ” , “ AL amyloidosis” and “China”. and limit the search results to only literatures published in the past 10 years. Case reports, reviews , consensus , thesis and questionnaires will be excluded in this study. We will describe the treatment patterns of AL amyloidosis in China. The scoping review will be performed according to the preferred reporting items for scoping review (PRISMA) extension statement. We will include literatures that reported Chinese patients with AL amyloidosis and extract the baseline characteristics, treatment patterns and outcomes of patients from each included article. For data analysis, we will summarize the baseline characteristics of patients, and conduct a meta-analysis to synthesize the outcome measurements of treatment regimens when the homogeneity of clinical characteristics (such as populations and treatment regimens, outcome measurements) are acceptable.

Condition being studied: 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 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 treatment of domestic patients . This situation brings great difficulties to doctors in clinical practice. Due to the absence of systematic review describing treatment of AL amyloidosis in Chinese population, we conduct this scoping review. This scoping review aims to systematically search and analyze published data to understand the current treatment patterns of AL amyloidosis in China that having been assessed by evidence and identify future research gaps.

METHODS

Search strategy: 1、 EMBASE #1. 'AL amyloidosis'/exp OR ("light-chain" NEAR/3 amyloidos* OR AL NEAR/3 amyloidos*):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 Liao-ning 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 Gui-zhou OR Yunnan OR Shaanxi OR Gansu OR Qinghai):ab,ti,ff | #3. #1 AND #2 | 2、 Pub Med #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 Shaanxi 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.

Participant or population: AL Amyloidosis in Chinese population. Chinese population is defined as literature participants enrolled from healthcare institutions in mainland China.

Intervention: No limitation.

Comparator: No limitation.

Study designs to be included: Interventional and non-interventional study.

Eligibility criteria: We will include studies enrolling patients with AL Amyloidosis in Chinese population. But we will exclude studies that included patients with current multiple myeloma. Case reports, reviews, consensus, thesis and questionnaires will also be excluded.

Information sources: We will conduct a systematic search in the databases of PubMed, EMBASE and CNKI. The following items will be used to develop our search strategy: "amyloidosis", "amyloidos*" "amyloido*", "AL amyloidosis", "China".

Main outcome(s): Primary Outcome: Hematologic response: overall response rate (ORR), complete response/remission (CR), very good partial response rate (VGPR), partial response (PR). Organ response: cardiac response, renal response, liver response. Secondary Outcomes: time to hematologic response, time to organ response, regression-free survival (PFS), overall survival (OS). Adverse events: adverse events (any grade), adverse events (3-4 grade), specific adverse events (3-4 grade).

Quality assessment / Risk of bias analysis: For the assessment of RCTs, we will refer to Cochrane bias risk assessment tool7. We will assess the following criteria: random sequence generation, allocation concealment, blinding (masking), incomplete outcome data, selective reported and other bias. For the assessment of single arm studies, we will refer to "Quality Assessment Tool for Before-After (Pre-Post) Studies With No Control Group" developed by the National Heart, Lung, and Blood Institute (NHLBI). For the assessment of cohort studies, we will refer to "Newcastle-Ottawa Scale8 (NOS)".

Strategy of data synthesis: We will conduct a meta-analysis to synthesize the outcome measurements of treatment regimens when the homogeneity of clinical characteristics (such as populations and treatment regimens, outcome measurements) were acceptable. For single-arm data analysis, R software (meta-package, the R Core Team 2020) will be used to combine data by a fixed-effects model, where the incidence and its 95% confidence interval (CI) will be combined for dichotomous outcome, change data before and after the treatment and its 95% CI will be combined for continuous outcomes. For studies with no events, we will add a fixed value (0.5) to the cells of the table. When heterogeneity is significant ($P \leq 0.1$ and $I^2 \geq 50\%$) and the source of heterogeneity could not be identified by subgroup analysis, we will use a random-effects model to pool the result. If the sources of heterogeneity are identified, we will conduct subgroup analysis to pool the data. Subgroup analysis factors for heterogeneous exploration are Mayo cardiac staging, and organ involvement (kidney/cardiac /liver involvement).

Subgroup analysis: Subgroup analysis will be performed on primary outcomes and PFS/OS for studies involved only newly diagnosed patients. Subgroup factors are as following: 1) Genetic characteristics: t (11,14), 1q21, 17p-/13q-; 2) Mayo cardiac staging; 3) Organ involvement: kidney/cardiac/liver involvement.

Sensitivity analysis: Studies with less than 10 cases will be considered for sensitivity analysis on primary outcome.

Language: No limited.

Country(ies) involved: China.

Keywords: AL amyloidosis; treatment patterns; meta analysis.

Contributions of each author:

Author 1 - Jin Lu drafted and revised the protocol, collected the data, then will perform or supervise analyses, provide

substantive suggestions for revision or critically reviewed subsequent iterations of the manuscript.

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