INPLASY PROTOCOL

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None declared.

Clinical characteristics and prognosis of Chinese patients with AL Amyloidosis: a scoping review

Wu, Y[1]; Wang, X[2]; Wang, B[3]; Cao, X[4]; Xu, L[5]; Liu, W[6]; Pi, J[7].

Review question / Objective: **To present the current status of research on prognostic factors in Chinese patients with AL amyloidosis and to identify research gaps.**
Eligibility criteria: **We included retrospective or prospective observational studies that reported the association between any factor for a population of patients with AL amyloidosis in Chinese population. Chinese population was defined as literature participants enrolled from healthcare institutions in mainland China. The prognostic factors of overall survival (OS), progression-free survival (PFS) or end-stage renal disease (EDSR) in the Chinese patients with AL amyloidosis was summarized the rang value of hazard ratio (HR). We excluded case reports, reviews, consensus, thesis and questionnaires.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 December 2021 and was last updated on 28 December 2021 (registration number INPLASY2021120124).

INTRODUCTION

Review question / Objective: **To present the current status of research on prognostic factors in Chinese patients with AL amyloidosis and to identify research gaps.**

Rationale: **To describe the prognostic factors 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 include**

studies that investigated prognostic factors in adult patients with AL and extract the baseline characteristics, prognostic factors and result of multivariate analysis from each included article. For data analysis, we will summarize the number of studies reported for each prognostic factor and use the hazard ratio (HR) with 95% confidence interval to summarize the effect estimate of overall survival (OS), progression-free survival (PFS) or end-stage renal disease (EDSR). The scoping review will be performed according to the preferred reporting items for scoping review (PRISMA) extension statement.

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 monoclonal light chain of κ or λ type as either an intact molecule or a fragment. The processes of AL amyloidosis lead to organ dysfunction and death, most notably from cardiac involvement. AL amyloidosis is also a rare disease with an incidence of 8 to 10 cases per million person-years, a median age at diagnosis of 63, and a median survival time if left untreated of 12 months. The incidence rate of AL amyloidosis was from 8.8 to 15.5 per million years, and increased between 40 to 58 per million years after 2010. Currently, according to prognostic factors for AL amyloidosis in existing narrative reviews, the factors related to the extent of cardiac involvement is the major prognostic factors of AL amyloidosis, and 10% or greater plasma cells at diagnosis, the Ig FLC level at diagnosis, the number of organs involved, and the serum uric acid level have all been associated with prognosis. Recently, a several original clinical studies have been conducted to investigate prognostic factors of AL amyloidosis in Chinese population. However, there is no review of the prevalence and the clinical data of AL amyloidosis in Chinese patients. This scoping aims to present the current status of research on prognostic factors in Chinese patients with AL amyloidosis and to identify 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、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 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
#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: There will be no limitation.

Comparator: There will be no limitation.

Study designs to be included: Retrospective or prospective observational studies.

Eligibility criteria: We included retrospective or prospective observational studies that reported the association between any factor for a population of patients with AL amyloidosis in Chinese population. Chinese population was defined as literature participants enrolled from healthcare institutions in mainland China. The prognostic factors of overall survival (OS), progression-free survival (PFS) or end-stage renal disease (EDSR) in the Chinese patients with AL amyloidosis was summarized the rang value of hazard ratio (HR). We excluded case reports, reviews, consensus, thesis and questionnaires.

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): Describe the number of univariate analysis and multivariate analysis in the included studies. Summary the number of studies reported for each prognostic factor of different outcomes, then count how many studies reported significant results and how many reported non-significant results.

Quality assessment / Risk of bias analysis: The quality of included the prognostic studies was assessed using the QUIPS (Quality In Prognosis Studies) tool. The methodological quality of the studies was independently completed by two reviewers. Any discrepancies between authors were resolved by the senior author. The following six domains of QUIPS were considered: 1) study participation, 2) study attrition, 3) prognostic factor measurement, 4) outcome assessment, 5) study confounding, 6) statistical analysis and reporting.

Strategy of data synthesis: We will conduct random effect meta-analyses in RevMan 5.3. Software and used HRs with their 95% confidence intervals (CIs) for all pooled effect estimates.

Subgroup analysis: No subgroup analysis.

Sensitivity analysis: No sensitivity analysis.

Country(ies) involved: China.

Keywords: AL amyloidosis; Prognostic factors; Overall survival; Meta-analysis.

Contributions of each author:

Author 1 - Yu Wu drafted and revised the protocol, then will perform or supervise analyses, provide substantive suggestions for revision or critically reviewed subsequent iterations of the manuscript.
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