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**Real-world Clinical Outcomes of Autologous Stem
Cell Transplantation in Chinese Patients with Newly
Diagnosed Multiple Myeloma: A Systematic
Literature Review**

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ADMINISTRATIVE INFORMATION

Support - This work was supported by a grant from the Special Program for Talent Introduction and Training of the Hebei Provincial Department of Science and Technology.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2025110069

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 November 2025 and was last updated on 21 November 2025.

INTRODUCTION

Review question / Objective To better guide the use of ASCT and maximize its clinical benefits in Chinese ndMM patients, this study aimed to leverage existing real-world evidence (RWE) to evaluate ASCT's clinical impact, characterize its real-world utilization, and generate actionable insights to inform future research and clinical decision-making.

Condition being studied Multiple myeloma (MM) is a malignant clonal plasma cell disorder and the second most common hematologic malignancy worldwide, primarily affecting older adults. Despite therapeutic advances, MM remains incurable. In China, the standardized incidence was 1.15 per 100,000, with a rising disease burden (disability-adjusted life years increasing by 134% from 1990 to 2019).

Autologous stem cell transplantation (ASCT), introduced in the 1980s, has significantly improved overall survival (OS) and remains a cornerstone of frontline treatment for transplant-eligible patients with newly diagnosed MM (ndMM). However, its utilization in China remains low, with only 11.3% of patients undergoing ASCT, and the highest uptake (33.8%) observed among those aged 45–49. Despite the rise of newer therapies—including proteasome inhibitors (PI), immunomodulatory drugs (IMiD), monoclonal antibodies, and chimeric antigen receptor T-cell (CAR-T) therapies—ASCT continues to offer distinct clinical advantages, providing deeper and more durable responses, longer progression-free survival (PFS), and standardized protocols supported by decades of clinical experience. It is also more cost-effective, particularly in resource-limited healthcare systems like China 10. However, ASCT is invasive, requires hospitalization and intensive support, and may not be suitable for frail or elderly patients. In contrast,

novel therapies are less invasive and better tolerated but often expensive, less accessible, and lack long-term real-world data.

METHODS

Search strategy Embase, run on Jan 15, 2025

Searches Results

1 'Multiple Myeloma'/exp 122,395

2 ('multiple myeloma' or 'multiple myelomas' or 'Myelomatosis' or 'Kahler Disease' or 'Plasma Cell Myeloma'):ti,ab,kw 92,681

3 #1 OR #2 122,777

4 #3 AND [2015-2024]/py 61,845

5 #4 AND [embase]/lim AND [english]/lim 57,704

6 #5 AND ([article]/lim OR [article in press]/lim OR [conference abstract]/lim OR [conference paper]/lim OR [data papers]/lim OR [short survey]/lim OR [preprint]/lim) 46,264

7 ('China' or 'Chinese'):ti,ab,kw 702,188

8 #6 AND #7 676

9 ('newly diagnosed' or 'untreated' or 'first line' or 'first-line' or 'frontline' or 'primary' or 'initial' or 'preliminary' or 'naïve' or 'de novo' or 'first visit'):ti,ab,kw 676

10 #8 AND #9 676

11 ('prospective*' or 'retrospective*' or 'observation*' or 'cross-section*' or 'cross section*' or 'real world' or 'real-world' or 'cohort*' or 'survey*' or 'questionnaire' or 'case series' or 'case-series' or 'registr*'):ti,ab,kw 7,587,614

12 #10 AND #11 375

MEDLINE, run on Jan 15, 2025

Searches Results

1 exp Multiple Myeloma/ 50,311

2 (multiple myeloma or multiple myelomas or Myelomatosis or Kahler Disease or Plasma Cell Myeloma).ti,ab,kw. 51,743

3 1 or 2 65,952

4 limit 3 to yr="2015 -current" 26,476

5 limit 4 to english language 24,928

6 limit 5 to (address or autobiography or bibliography or biography or case reports or clinical trial protocol or comment or consensus development conference or consensus development conference, nih or dictionary or directory or duplicate publication or editorial or "expression of concern" or government publication or guideline or interactive tutorial or interview or introductory journal article or lecture or legal case or legislation or letter or news or newspaper article or patient education handout or personal narrative or portrait or practice guideline or published erratum or "research support, american recovery and reinvestment act" or research support, nih, extramural or research support, nih, intramural or research support, non us gov't or research support, us gov't, non phs or research support, us

gov't, phs or retracted publication or "retraction of publication" or "review" or "scientific integrity review" or video-audio media or webcast) 14,598

7 5 not 6 10,330

8 (China or Chinese).ti,ab,kw. 640,670

9 7 and 8 230

10 (newly diagnosed or untreated or first line or first-line or frontline or primary or initial or preliminary or naive or de novo or first visit).ti,ab,kw. 3,793,292

11 9 and 10 104

12 (prospective* or retrospective* or observation* or cross-section* or cross section* or real world or real-world or cohort* or survey* or questionnaire or case series or case-series or registr*).ti,ab,kw. 5,301,206

13 11 and 12 60

Web of Science, run on Jan 15, 2025

Searches Results

1 TS=(multiple myeloma or multiple myelomas or Myelomatosis or Kahler Disease or Plasma Cell Myeloma) 71,151

2 PY="2015-2024" 22,990,475

3 #1 AND #2 38,857

4 TS=(animal\$ not human\$) 809,065

5 TI="case report" 191,830

6 #4 or #5 999,793

7 #3 not #6 38,016

8 TS=(China or Chinese) 1,009,548

9 #7 AND #8 506

10 TS=(newly diagnosed or untreated or first line or first-line or frontline or primary or initial or preliminary or naive or de novo or first visit) 4,314,681

11 #9 AND #10 173

12 TS=(prospective* or retrospective* or observation* or cross-section* or cross section* or real world or real-world or cohort* or survey* or questionnaire or case series or case-series or registr*) 5,777,505

13 #11 AND #12 92

CNKI, run on Jan 15, 2025 (core Chinese journal)

Searches Results

1 TKA=('多发性骨髓瘤' + '浆细胞骨髓瘤' + '浆细胞瘤' + '恶性浆细胞病' + '骨髓浆细胞病') 7,744

2 TI=('综述' + '研究进展' + '概述' + '总结' + '共识' + '指南' + '病例报告' + '约稿' + '观点' + '评述' + '书评' + '交流' + '动物模型' + '小鼠' + '大鼠') 811,941

3 1 not 2 7,191

4 TKA=('初诊' + '初治' + '一线治疗' + '初始' + '首次' + '初次') 655,997

5 5 and 6 1,478

6 TKA=('前瞻' + '回顾' + '观察性研究' + '横断面' + '横截面' + '真实世界' + '队列' + '问卷调查' + '病例系列' + '登记' + '注册') 1,325,191

7 7 and 8 251

WANFANG, run on Jan 15, 2025 (core Chinese journal)

Searches Results

1 主题=("多发性骨髓瘤" or "浆细胞骨髓瘤" or "浆细胞瘤" or "恶性浆细胞病" or "骨髓浆细胞病") 7,595

2 题名=("综述" or "研究进展" or "概述" or "总结" or "共识" or "指南" or "病例报告" or "约稿" or "观点" or "评述" or "书评" or "交流" or "动物模型" or "小鼠" or "大鼠") 816,955

3 1 not 2 6,912

4 主题=("初诊" or "初治" or "一线治疗" or "初始" or "首次" or "初次") 379,490

5 5 and 6 943

6 主题=("前瞻" or "回顾" or "观察性研究" or "横断面" or "横截面" or "真实世界" or "队列" or "问卷调查" or "病例系列" or "登记" or "注册") 1,056,127

7 7 and 8 171

VIP, run on Jan 15, 2025 (core Chinese journal)

Searches Results

1 (M=("多发性骨髓瘤" or "浆细胞骨髓瘤" or "浆细胞瘤" or "恶性浆细胞病" or "骨髓浆细胞病") OR R=("多发性骨髓瘤" or "浆细胞骨髓瘤" or "浆细胞瘤" or "恶性浆细胞病" or "骨髓浆细胞病")) 7,546

2 T=("综述" or "研究进展" or "概述" or "总结" or "共识" or "指南" or "病例报告" or "约稿" or "观点" or "评述" or "书评" or "交流" or "动物模型" or "小鼠" or "大鼠") 769,503

3 1 not 2 6,831

4 M=("初诊" or "初治" or "一线治疗" or "初始" or "首次" or "初次") OR R=("初诊" or "初治" or "一线治疗" or "初始" or "首次" or "初次") 424,949

5 5 and 6 969

6 M=("前瞻" or "回顾" or "观察性研究" or "横断面" or "横截面" or "真实世界" or "队列" or "问卷调查" or "病例系列" or "登记" or "注册") OR R=("前瞻" or "回顾" or "观察性研究" or "横断面" or "横截面" or "真实世界" or "队列" or "问卷调查" or "病例系列" or "登记" or "注册") 1,044,233

7 7 and 8 170.

Participant or population Transplant-eligible ndMM in Chinese patients.

Intervention ASCT.

Comparator Non-ASCT treatments.

Study designs to be included Observational studies (prospective, retrospective, or cross-sectional).

Eligibility criteria Eligible studies were observational (prospective, retrospective, or cross-

sectional) and focused on ASCT or non-ASCT treatments for transplant-eligible ndMM in Chinese patients. Exclusion criteria included clinical trials (phases I–III), preclinical studies, case reports/series, non-human studies, clinical guidelines, reviews, and studies involving mixed or relapsed/refractory cohorts.

Information sources Electronic bibliography databases.

Main outcome(s) Clinical outcomes including treatment response across different treatment phases, ASCT-related outcomes (mobilization, engraftment times, hematologic recovery), and survival outcomes (PFS and OS).

Additional outcome(s) (1) study characteristics (design, setting, data sources); (2) patient profiles (demographics, clinical staging including Durie-Salmon and International Staging System [ISS], monoclonal protein, cytogenetic features, and comorbidities); (3) treatment protocols (detailed therapeutic regimens and treatment phases); and (4) safety outcomes (adverse event types, incidence, and Common Terminology Criteria for Adverse Events [CTCAE] grading).

Quality assessment / Risk of bias analysis The quality of non-randomized studies will be assessed using the Newcastle–Ottawa Scale (NOS), which evaluates three domains: (1) selection of study groups, (2) comparability of groups, and (3) ascertainment of exposure or outcome. Each study will receive a total score from 0 to 9, with higher scores indicating better methodological quality. Based on the NOS score, studies will be classified as high quality (7–9), moderate quality (4–6), or low quality (0–3).

Strategy of data synthesis A single-arm meta-analysis will be performed using a random-effects model to pool data from studies with comparable populations, interventions, and outcome measures. Heterogeneity across studies will be assessed using the I^2 statistic. When substantial heterogeneity is present ($I^2 > 50\%$), subgroup analyses will be conducted to explore potential sources of heterogeneity. If meta-analysis cannot be performed due to heterogeneity or insufficient data, results will be summarized descriptively.

For outcomes reported within the same treatment phase, comparisons of pooled estimates will be made using Cochran's Q test for continuous variables and chi-square tests for categorical variables. Hazard ratios (HRs) and 95% confidence intervals (CIs) for identical prognostic factors from

Cox regression analyses related to overall survival following ASCT will also be synthesized using meta-analytic methods. Forest plots will be produced to present the pooled results.

All statistical analyses will be conducted using R software (version 4.2.0), with statistical significance defined as a two-sided p-value < 0.05.

Subgroup analysis Subgroup analyses were performed when I^2 was greater than 50% to explore potential sources of heterogeneity.

Sensitivity analysis Sensitivity analyses will be conducted to evaluate the robustness of the results by examining the influence of studies with potential methodological concerns, atypical findings, or high influence on pooled estimates.

Country(ies) involved China.

Keywords Newly diagnosed multiple myeloma, autologous stem cell transplantation, China, systematic review, meta-analysis.

Contributions of each author

Author 1 - Jiawen You.

Author 2 - Yuanyuan Zhang.

Author 3 - Yuan Meng.

Author 4 - Yiming Zhao.

Author 5 - Huiqing Huang.

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