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Evidence mapping of treatment landscape in Chinese patients with metastatic prostate cancer

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ADMINISTRATIVE INFORMATION

Support - MSD (China) Holding Co., Ltd.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - LYNPARZA (olaparib) is a first-in-class poly ADP-ribose polymerase (PARP) inhibitor that co-produced by AstraZeneca and Merck (known as MSD outside the United States and Canada). It has been approval in China as monotherapy for the treatment of adult patients with germline or somatic BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment that included a new hormonal agent (abiraterone, enzalutamide). Olaparib is one of the drugs we focus on in this study. And three authors are the employees of MSD.

INPLASY registration number: INPLASY202460064

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 June 2024 and was last updated on 17 June 2024.

INTRODUCTION

Review question / Objective To conduct a systematic literature review to collate published evidence on treatment patterns in mPC patients in China. To present an overview of nowadays treatment for Chinese patients with mPC. To identify gaps between actual treatment and recommendations from latest guidelines or expert consensus. To find gaps between Chinese studies and recommendations from latest guidelines or expert consensus. To find potential gaps between reality of clinical practice and research progress in Chinese patients with mPC.

Background Prostate cancer (PC) is one of the most common cancers worldwide. In China, the incidence of PC cases in 2022 ranked eighth of all malignant tumors, and the incidence showed a significant increase trend annually. Research has shown that for male patients aged ≥45 years, the incidence of PC bone metastasis or visceral metastasis significantly increased from 2010 to 2019, resulting in a high PC-related mortality and low 5-year survival, which is a major challenge for clinical practice. There is no latest data about the incidence of metastatic PC (mPC) in China. An early study showed that 68.0% (357/525) of newly diagnosed PC patients in China were at advanced stage. In “Chinese experts consensus on the treatment of mPC 2018 edition”, the main treatment for mPC includes new hormonal agent therapy, cytotoxic agents, immunotherapy, and alpha-emitting radiation therapy. mPC includes metastatic hormone-sensitive prostate cancer (mHSPC) and metastatic castration-resistant

prostate cancer (mCRPC). For patients with mHSPC, androgen deprivation therapy (ADT) was recommended as first-line choice combined with other agents including abiraterone, docetaxel, prednisone, and androgen blockade. For patients with mCRPC, abiraterone, docetaxel, prednisone, and enzalutamide were recommended. Palliative radiotherapy is mainly used to alleviate pain and spinal cord compression caused by bone metastases.

In recent years, research on anti-cancer drugs progress rapidly, and some new drugs have been applied to patients and achieved good results. For example, PARP inhibitor has shown significant efficacy on survival, pain alleviation and quality of life in recent studies. Based on latest research results, Chinese experts group updated "CSCO Guidelines for the Diagnosis and Treatment of Prostate Cancer" , which is consistent with National comprehensive cancer network (NCCN) guidelines, European guidelines, and Japanese urological association (JUA) guideline in medication therapy for mPC. The CSCO guidelines has updated the recommendation of treatment strategy and maintained or strengthened recommendations for new agents such as PARPi. However, the recommendation in CSCO guidelines is mostly based on research results from abroad. It is unclear in some important issues, including what the current treatment status of Chinese patients is, what the relevant gene testing status (NGS or PCR, germline and/or somatic) is when making decision on treatment strategy, how to choose new drugs and what the response to new drugs are, and what the current status of related research is in China.

Rationale The purpose of this study is to use evidence map to investigate the current treatment status of Chinese mPC patients and the gap between the actual status and latest guidelines, and to analyze the associated factors, in order to provide a reference for improving the treatment outcome of Chinese mPC patients and promoting related research.

METHODS

Strategy of data synthesis The narrative account will be produced in two ways: First, attention will be given to basic numerical analysis of the extent, nature and distribution of the studies included in this study. Tables and charts mapping will be produced. This will include the distribution of studies geographically and for the different care recipient groups, the range of interventions included in the review, the research methods adopted and the measures of effectiveness used. This part of the analysis will shed light on the dominant areas of research in terms of intervention type, research methods and geographical location.

Second, the literature will be organized thematically, according to the two types of mPC mentioned above. This stage will be divided into 3 steps: (1) Analysis (including descriptive numerical summary analysis and qualitative thematic synthesis) will be conducted. (2) The results will be reported and the outcome will be produced that will refer to the overall purpose or research question. (3) The meaning of the findings will be considered as they relate to the overall study purpose; the implications for future research, practice and policy will be discussed.

A synthesis plan will be clearly outlined. A narrative summary will be provided. For collating and summarizing results, a consistent approach to reporting the findings will be implemented. The researchers will conduct a content thematic analysis on included studies and present emerging themes in line with the research questions of the study using Chiplot Tools.

Eligibility criteria Studies that include the treatment for Chinese patients with mHSPC or mCRPC.

Source of evidence screening and selection Search sources: PubMed, Cochrane database, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), China national knowledge infrastructure (CNKI), Wanfang database, and VIP Database for Chinese Technical Periodicals (VIP).

Potential clinical trials or protocols will be searched in Chinese clinical trials registry center.

Evidence screening and selection will be conducted by two independent reviewers in a two-phase process, namely, (1) a title and abstract review and (2) full-text review. Relevant studies will be eligible if they include the treatment for Chinese patients with mHSPC or mCRPC. Prior to commencement of evidence selection, a pilot study will be conducted on a sample of papers in one database. This will allow further delineation of the review if necessary. Rayyan software will be used during the title and abstract screening phase to collaboratively organize and manage the data between the two reviewers and assist blinding of reviewers. Any articles that are deemed relevant by either of the reviewers will be included in the full-text review. In the second phase (full-text review), the two reviewers will independently assess the full-text articles to determine if they meet the inclusion criteria. Any discordant articles will be reviewed a second time, and further disagreements about study eligibility will be resolved through discussions with a third reviewer

until full consensus is obtained. Reasons for exclusion of sources of evidence that do not meet the inclusion criteria will be recorded and reported in the final review. The screen process and results will be provided as PRISMA flowchart.

Data management All data collected for the study should be recorded accurately, promptly, and legibly. For primary data collection, the investigator or qualified designee is responsible for recording and verifying the accuracy of subject data. For data not obtained from a primary source (i.e., secondary data, such as claims and electronic health records), the investigator is responsible for reviewing data quality and relevance to the best of the investigator's knowledge. By signing this protocol either electronically or written, the investigator confirms that the quality and relevance of data has been assessed to meet the minimum requirements for all study objectives.
If this study has been outsourced, the institutional policies of the supplier should be followed for development of data management plans. However, the supplier should ensure compliance with Good Pharmacoepidemiology Practice, and all applicable federal, state, and local laws, rules and regulations relating to the conduct of the study.
Data Management Software and Hardware:
All data will be backed-up in two separate hardware to avoid data loss.
Only data from published literature will be used for this evidence mapping. Endnote will be used to manage citations. For study selection, all potential publications identified from the searches will be screened using Rayyan. Extracted data will be stored in a Microsoft Excel 2003 file.

Language restriction English and Chinese language.

Country(ies) involved China.

Keywords Metastatic prostate cancer, treatment landscape, China, evidence map.

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