INPLASY

Clinical treatment landscape and patient characteristics of Chinese high/very high-risk non-muscle invasive bladder cancer (NMIBC): A scoping review

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ADMINISTRATIVE INFORMATION

Support - MSD China.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - Authors Wenting Huang and Liang Ding are employed by MSD China. Other authors report no conflict of interest.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 May 2026 and was last updated on 28 May 2026.

INTRODUCTION

Review question / Objective 1. To summarize the treatment landscape of Chinese population with high/very high-risk NMIBC. 2. To summarize patient characteristics on high/very high-risk NMIBC in China. 3. To summarize diagnosis-related data on high/very high-risk NMIBC in China.

Background Bladder cancer(BC) is among the most prevalent malignancies worldwide, ranking as the 10th most common cancer globally and the 7th in males, with marked male predominance. According to recent global burden estimates, BC accounts for over 600,000 new cases and approximately 220,000 deaths annually, and represents one of the costliest malignancies to manage long-term due to high recurrence rates and prolonged follow-up requirements. Clinically, BC is pathologically and prognostically stratified into two core subgroups based on tumor invasion depth: non-muscle-invasive bladder cancer(NMIBC) and muscle-invasive bladder cancer(MIBC). NMIBC accounts for approximately 75% of all bladder cancer cases, among which non-invasive papillary carcinoma(Ta) stage accounts for 70%, invasion of the lamina propria(T1) stage for 20%, and tumor in situ(Tis) stage for 10%. Tis stage tumors are poorly differentiated, carry a high risk of muscularis propria invasion, and are classified as high-risk malignancies.

Risk factors influencing recurrence and progression of NMIBC include tumor number, size, stage, grade, recurrence frequency, and the presence of carcinoma in situ(Tis). According to recurrence risk and prognosis, NMIBC is stratified into different risk groups. Risk stratification for NMIBC in Chinese Society of Clinical Oncology(CSCO) guideline categorizes into four levels: low, intermediate, high, and very high, while the National Comprehensive Cancer Network(NCCN) guideline categorizes into three levels: low, intermediate and high. Although a gap exists between Chinese and international

guidelines in defining High-risk and very high-risk NMIBC, both highlight patients with the highest risk of progression and to encourage urologists to promptly assess and adapt their treatment approach when required.

Globally, the standard treatment for high-risk NMIBC is intravesical BCG therapy; however, suboptimal tolerability of BCG and limited duration of response contribute to a high risk of recurrence and progression, with 5-year rates of 50-70% for recurrence and 10-30% for progression. Most patients will eventually undergo radical cystectomy(RC), leading to significant physiological and psychological burdens. In China, the utilization rate of BCG is limited. Unpublished data from NIS009914 study shows that the real-world utilization rate of BCG for high/very highrisk NMIBC is low, approximately 30%-50%, primarily due to a shortage of BCG. In CSCO guideline, for BCG-naive patients with high/very high-risk NMIBC, various treatments beyond BCG, such as intravesical chemotherapy and chemoradiation, are also recommended. Compared with BCG, intravesical chemotherapy and chemoradiotherapy have poorer therapeutic effects in controlling tumors and preventing recurrence, and their toxic side effects are more prominent, which may affect the quality of life of patients. This reflects an unmet medical need in high-risk NMIBC, underscoring the importance of exploring novel therapeutic strategies. Recent years have witnessed transformative progress in managing high-risk/very high-risk NMIBC, particularly for BCG-naive and BCG-unresponsive disease, with breakthroughs in immunotherapy, targeted agents, chemotherapy optimization, and novel intravesical delivery systems.

Rationale Chinese and international guidelines differ in risk stratification, leading to varied clinical decisions. Intravesical BCG, the first-line standard, is constrained by global supply shortages, low response rates, and high recurrence. Meanwhile, new therapies including immunotherapy, targeted agents, and novel intravesical agents have expanded treatment options but increased decision complexity due to the absence of unified application guidelines. Furthermore, varying drug accessibility driven by approval status, insurance coverage, and regional medical resources has widened treatment heterogeneity across China, resulting in a complex treatment landscape for high- and very high-risk NMIBC in China.

This study aims to systematically characterize the current real-world clinical treatment landscape and patient characteristics of high-risk and very-high-risk NMIBC in China, offering comprehensive and evidence-based insights into contemporary clinical practice patterns. By clarifying the actual status of diagnosis, risk stratification, treatment selection, and disease management across different regions and medical centers, it will help deepen the understanding of prominent unmet medical needs, existing therapeutic dilemmas, and gaps in current clinical care. Furthermore, the findings are expected to provide reliable real-world evidence to support evidence-based clinical decision-making for urologists and oncologists, optimize individualized treatment strategies, and ultimately facilitate the improvement of clinical outcomes and long-term prognosis for patients with high-risk and very-high-risk NMIBC.

Given the complex and rapidly evolving treatment landscape of high- and very high-risk NMIBC in China, a scoping review was conducted. This design enables broad mapping of existing real-world evidence to clarify current research status, identify knowledge gaps and unmet needs, and provide an overview to support clinical decision-making and future research for this patient population.

METHODS

Strategy of data synthesis The scoping review will be conducted and reported in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines. This study will search 3 English electronic databases (Cochrane Library, Medline (PubMed) and Embase) and 2 Chinese databases(China National Knowledge Infrastructure(CNKI) and China Science and Technology Journal (VIP)) for English and Chinese publications from Jan.1st 2022 to search date. A comprehensive search strategy will be developed in collaboration with an information specialist, consisting of 3 main categories: (1) non-muscle invasive bladder cancer; (2) high-risk or very high risk; (3) Chinese population.

Preliminary search strategy (for both full-text articles and conference abstracts)

PubMed

#1. "Non-Muscle Invasive Bladder Neoplasms"[Mesh] OR NMIBC[tw] OR Non-Muscle Invasive bladder cancer*[tw] OR NonMuscle Invasive bladder cancer*[tw] OR Non-Muscle Invasive bladder carcinoma*[tw] OR NonMuscle Invasive bladder carcinoma*[tw] OR Non-Muscle Invasive bladder neoplasm*[tw] OR NonMuscle Invasive bladder neoplasm*[tw] OR Non-Muscle Invasive bladder tumor*[tw] OR NonMuscle Invasive bladder tumor*[tw] OR Non-Muscle Invasive bladder tumour*[tw] OR NonMuscle Invasive bladder tumour*[tw] OR nonmuscle

invasive urothelial carcinoma*[tw] OR non-muscle invasive urothelial carcinoma*[tw] OR nonmuscle invasive urothelial cancer*[tw] OR non-muscle invasive urothelial cancer*[tw] OR superficial bladder cancer*[tw] OR non-muscle-invasive transitional cell carcinoma*[tw] OR nonmuscle-invasive transitional cell carcinoma*[tw] OR non-muscle-invasive transitional cell cancer*[tw] OR non-muscle-invasive transitional cell cancer*[tw]
#2. high-risk*[tw] OR highest risk*[tw] OR HR[tw]
#3. "China"[Mesh] OR China OR Chinese OR Taiwan OR Taiwanese OR Formosan 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
#4. #1 AND #2 AND #3 Filters: from 2022 - 2026
CNKI（期刊、学位、会议，中英文扩展：是，中文）
(SU%=非肌层浸润性膀胱癌+非肌层浸润膀胱癌+NMIBC+非肌层浸润性尿路上皮癌+表浅性膀胱癌+浅表性膀胱癌+非肌层浸润性移行细胞癌 OR TKA % 非肌层浸润性膀胱癌+非肌层浸润膀胱癌+NMIBC+非肌层浸润性尿路上皮癌+表浅性膀胱癌+浅表性膀胱癌+非肌层浸润性移行细胞癌) AND (SU%=高危+极高危 OR TKA % 高危+极高危) AND 2022-2026.

Eligibility criteria Inclusion Criteria
1.Population
1)Chinese patients aged 18 years or older with high or very high-risk NMIBC patients.
2)According to CSCO guideline, the criterion for high risk is high-grade (G_3) tumors simultaneously meeting any one of the following criteria: carcinoma in situ (CIS); T_1 stage; tumor diameter >3 cm; multiple tumors or recurrent tumors, consistent with the definition of high-risk NMIBC.
3)The criterion for very high risk is meeting any one of the following criteria: BCG-unresponsive disease; variant histology; lymphovascular invasion; invasion of the prostatic urethra.
2.Interventions
1)No limitation.
3.Comparisons
1)No limitation.
4.Outcomes
1)Treatment landscape: Treatment regimen, Schedule (including but not limited to Time to initiate, Dosage, Time on treatment, etc.) and Sample size of each treatment.
2)Patient characteristics: Gender, Age, Eastern Cooperative Oncology Group Performance Status (ECOG PS), Tumor (T) stage, Pathological subtypes, High risk/very high risk features, Treatment history, Response status to BCG treatment, Rate of recurrence, and Rate of patients getting RC.
3)Diagnostic information: Diagnosis method, Criteria for risk stratification, and Time to diagnosis.
5.Time
1)Publication date: 2022–Search date.
6.Study Design
1)Real-world study.
7.Other
1)Chinese or English literature, with conference abstracts included.
Exclusion Criteria
1.Literature that included mixed populations without clearly distinguishing NMIBC, high-risk, very-high-risk patients or Chinese.
2.Studies that did not report any of these outcomes.
3.Literature published prior to 2022.
4.Clinical trial, systematic reviews, narrative reviews or preclinical studies.
5.Unpublished studies or protocol.

Source of evidence screening and selection
Two reviewers will independently review each title and abstract from the searches following the inclusion and exclusion criteria. Full text of all potentially relevant literature will be acquired for more detailed scrutiny after the review of titles and abstracts. Two reviewers will then independently perform a full-text screening process. During the study selection process, any disagreements between the reviewers will be resolved by discussion. If necessary, a third independent reviewer will help to make the final decision. A PRISMA flow diagram will be constructed to show the full study-selection process.
Data of included studies will be independently extracted by two reviewers utilizing a standardized form. Disagreements will be addressed through discussion, and a third reviewer will be consulted if needed. For multiple publications of the same study, they will be consolidated and assessed based on the patient characteristic. If the patient characteristic are consistent, only the publication with the largest sample size will be used for data extraction.
The following data will be extracted from the included studies:
Treatment landscape: Treatment regimen, Schedule(including but not limited to Time to

initiate, Dosage, Time on treatment, etc.) and Sample size of each treatment.
Patient characteristics: Gender, Age, Eastern Cooperative Oncology Group Performance Status(ECOG PS), Tumor(T) stage, Pathological subtypes, High risk/ very high risk features, Treatment history, Response status to BCG treatment, Rate of recurrence, and Rate of patients getting RC.
Diagnostic information: Diagnosis method, Criteria for risk stratification, and Time to diagnosis. Study characteristics: Title, First author and year(Study ID), Study design, Study location(Province/City), Study centre, Study period and Funding sources.

Data management Data management Software and Hardware:
The data involved in this study will be stored in Microsoft Word or Excel file. The referenced literature will be stored in Endnotes 9 software. All data will be backed-up in two separate hardware to avoid data loss.
Description of Data Preparation and Methods for Data Retrieval and Collection:
Only data from published full-text articles and conference abstracts will be included in this evidence mapping. We will manage citations using EndNote 21. For study selection, all potential publications identified from the searches will be screened using Rayyan. The data from included studies will be accurately collected and recorded electronically, utilizing Microsoft Word and/or Excel file.
All data collected for the study should be recorded accurately, promptly, and legibly. 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.

Language restriction This scoping review was limited to Chinese or English literatures.

Country(ies) involved China.

Keywords Clinical treatment landscape; patient characteristics; Chinese; high/very high-risk; non-muscle invasive bladder cancer; scoping review.

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