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ORIGINAL PAPER

A national perspective on the management of high-risk BCG-unresponsive non-muscle-invasive bladder cancer in Romania

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Summary *Purpose: BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) remains a persistent challenge. This study examines Romanian urologists' clinical practices, focusing on treatment preferences and awareness of emerging therapies for BCG-unresponsive disease*
Methods: A cross-sectional, web-based survey comprising 24 items was distributed to selected urologists who manage NMIBC via professional mailing lists. Data were collected between May 15 and June 30, 2025.
Results: Out of 400 invited urologists, 216 completed the survey. Radical cystectomy (RC) was the most preferred treatment for BCG-unresponsive NMIBC, recommended by 67% of respondents, followed by tumor resection with surveillance (15%), repeat BCG instillation (14%), and intravesical chemotherapy (4%). Neither clinical trials nor intravenous checkpoint inhibitors were used. Among those using intravesical chemotherapy, gemcitabine was the most commonly used agent (85%), followed by mitomycin C (5%), gemcitabine/docetaxel (4%), gemcitabine/mitomycin C (3%), docetaxel (2%), and valrubicin (1%). Oncological safety concerns were the main barrier to adopting bladder-sparing therapies. Awareness of FDA-approved therapies for BCG-unresponsive disease, Nadofaragene firadenovec, Nogapendekin alfa inbakicept-pmln, and Pembrolizumab, was limited; 61% of urologists were unaware of all three, and only 1% had used any. BCG shortages were reported by 93% of respondents at some point, who adapted by reducing doses and prioritizing high-grade T1 and CIS cases. Most recognized intravesical chemotherapy as an alternative and were willing to use it if needed.
Conclusions: Though RC remains the predominant approach for BCG-unresponsive cases, over half of urologists' report using intravesical chemotherapy, reflecting interest in bladder-sparing strategies rather than newly approved FDA agents.

KEY WORDS: *Non-muscle invasive bladder cancer; BCG unresponsive; Practice pattern; Survey; Romania; Urologists.*

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INTRODUCTION

High-risk (HR) *non-muscle-invasive bladder cancer* (HR-NMIBC) continues to pose a significant clinical challenge, characterized by its propensity for recurrence and progression despite adherence to established therapeutic protocols. The current standard of care, comprising complete transurethral resection followed by intravesical *Bacillus Calmette-Guérin* (BCG) therapy administered through induction and maintenance over 1 to 3 years, offers suboptimal long-term disease control in a substantial subset of patients (1, 2). Importantly, approximately 20% of cases progress to muscle-invasive disease, a transition that significantly worsens prognosis (3). For patients classified as BCG-unresponsive, *radical cystectomy* (RC) is the guideline-endorsed intervention; however, its adoption is frequently hindered by surgical ineligibility or patient refusal due to its invasive nature and associated morbidity (1, 2). The therapeutic landscape for such patients remains constrained. The global BCG shortage, first emerging in 2012, has served as a catalyst for the investigation of alternative intravesical agents (4). In this evolving context, intravesical chemotherapeutic regimens, including *gemcitabine* (Gem), *mitomycin C* (MMC), valrubicin, and sequential combinations such as *Gemcitabine/Docetaxel* (Gem/Doce) and Gem/MMC, have garnered increasing clinical interest, despite the absence of formal regulatory approval. Emerging evidence suggests that these agents may offer favorable efficacy along with a more tolerable safety profile in appropriately selected patients (5).
Despite the availability of clinical guidelines, evidence indicates that urologists, including subspecialists in urologic oncology, often deviate from recommended protocols in the management of NMIBC, even in well-resourced settings (6, 7). This underscores the critical need for practice-based surveys, particularly in the context of BCG-unresponsive disease, where current guidelines offer limited therapeutic direction beyond recommending RC for patient's ineligible for surgery. In Romania, the publicly funded healthcare system, administered by the National Health Insurance House, provides coverage for standard oncologic therapies; however, access to novel agents is frequently delayed due to fiscal limitations and reimbursement hurdles (8). To date, no national survey has been conducted to assess real-world NMIBC management in Romania, particularly in BCG-unresponsive cases or in

BCG-naïve patients during periods of supply shortage. The present study was designed to address these critical gaps by evaluating current clinical practices, identifying barriers to optimal care, and informing strategies to align NMIBC management with evidence-based standards despite prevailing systemic constraints.

Materials and methods

Survey method

A cross-sectional web-based survey was conducted to assess current clinical practices among Romanian urologists managing NMIBC. The survey was distributed through the official mailing lists of the *Romanian Association of Urology* and the *Romanian College of Physicians*, targeting all registered practicing urologists in the country. Participation was voluntary, anonymous, and confidential. No personal, institutional, or patient-level data were collected. The questionnaire was hosted on a secure platform (*Microsoft Forms*) and required approximately 10 minutes to complete. The survey was open from May 15 to June 30, 2025, with 3 reminder emails sent at regular intervals to maximize participation. All responses were automatically captured into a secure, access-restricted database, available only to the study investigators. The study complied with institutional research ethics standards, and no formal ethical approval was required due to the anonymized, non-interventional design. The authors confirm the availability of and access to all original data reported in this study.

Questionnaire design

The survey comprised 24 items structured around key domains in NMIBC management, including BCG-unresponsive definitions, salvage therapies, novel agents used to treat BCG-unresponsive disease, and resource limitations (***Supplementary Table 1***). Questions were thematically grouped and varied in format to optimize clarity and

Supplementary Table 1.
Summary of survey questionnaire.

Domain		Question
Baseline characteristics	1	What is your primary urological practice?
	2	Which of the following best describes your primary practice?
	3	How many years of experience do you have in managing NMIBC?
	4	Which guidelines do you follow for the management of NMIBC?
Clinical data and treatment strategies for BCG-unresponsive disease	5	Do you consider high-grade (HG) stage Ta disease (without CIS or T1) to be high-risk?
	6	How often do you treat high-risk, BCG-unresponsive NMIBC patients?
	7	How confident are you in identifying true BCG-unresponsive disease versus suboptimal BCG administration (e.g., dosing, timing, maintenance)?
	8	What proportion of your high-risk, BCG-unresponsive, NMIBC patients have CIS, either alone or in combination with papillary NMIBC?
	9	How many individual NMIBC patients considered BCG unresponsive did you personally see or treat in the past 6 months?
	10	What is your management strategy for high-risk NMIBC patients who are BCG-unresponsive?
	11	What is the typical time gap between confirmation of BCG-unresponsive disease and initiation of alternative treatment in your center?
	12	Are multidisciplinary tumor boards involved in therapeutic decisions for BCG-unresponsive NMIBC cases in your institution?
Salvage treatments	13	If you have chosen to give intravesical chemotherapy for high-risk BCG-unresponsive patients, what is your most commonly used intravesical drug or drug combination?
	14	How familiar are you with sequential intravesical gemcitabine/docetaxel as a salvage or rescue treatment for high-risk BCG-unresponsive NMIBC?
	15	If you have chosen to give intravesical chemotherapy for BCG-unresponsive patients, have you used this as an induction or maintenance regimen?
	16	Do you consider intravesical chemotherapy for intermediate-risk, BCG-unresponsive NMIBC?
	17	Why do you think intravesical chemotherapy is not used more frequently as an initial bladder preservation option in high-risk BCG-unresponsive NMIBC?
Emerging therapies	18	Are you aware of the newly FDA-approved drugs for BCG-unresponsive disease, such as nadofaragene firadenovec (Adstiladrin), Anktiva, and pembrolizumab?
	19	If you are aware of these newly FDA-approved drugs for BCG-unresponsive disease, are you using any of them in Romania?
Treatment barriers & access issues	20	Based on the patients you see and the healthcare system in Romania, what are the main factors influencing your choice of therapy for BCG-unresponsive disease?
	21	If cost of therapy is a major factor for choosing a treatment option, what range is considered acceptable for you and your patients?
	22	Previously or currently, have you faced a BCG shortage problem when treating high-risk NMIBC patients?
	23	In case of a BCG shortage, how do you treat BCG-naïve NMIBC patients?
	24	Are you aware of published data on the use of intravesical chemotherapy as an alternative to BCG for high-risk BCG-naïve NMIBC?

NMIBC: non-muscle invasive bladder cancer.

response accuracy. Question formats included multiple choice, single-best-option, ranking, and Likert-scale items. Skip logic was not implemented, and all questions were mandatory to ensure completeness.

Statistical analysis

Descriptive statistics were used to summarize responses from all participants. Categorical variables were expressed as frequencies and percentages. All calculations were performed using Microsoft Excel. Since the online survey was designed using mandatory-response logic, participants were required to answer each question to proceed; therefore, no missing data were recorded. Additionally, no "*don't know*" or "*prefer not to answer*" options were provided, in order to encourage definitive responses and minimize ambiguity. No inferential statistics were applied, as the aim of the study was to characterize national practice patterns in BCG-unresponsive disease rather than to test specific hypotheses.

Results

Participant demographics and clinical practice profiles

The survey was distributed to 400 urologists, with 216 completing it, resulting in a response rate of 54%. Among respondents, 48% identified as general urologists, 47% as urologic oncologists, 3% as endourologists, and 2% represented other subspecialties. In terms of practice setting, 37% reported working in community-based practice, 43% in academic institutions, and 20% in a hybrid of both environments. A majority of respondents (53%) reported 5-10 years of experience managing NMIBC, while 30% had over 10 years, 9% more than 20 years, and 8% less than 5 years. Regarding guideline adherence, 80% of urologists reported following the *European Association of Urology* (EAU) guidelines, 10% adhered to *National Comprehensive Cancer Network* (NCCN) guidelines, 8% to *American Urological Association/Society of Urologic Oncology* (AUA/SUO) guidelines, and 2% reported using a combination of all three.

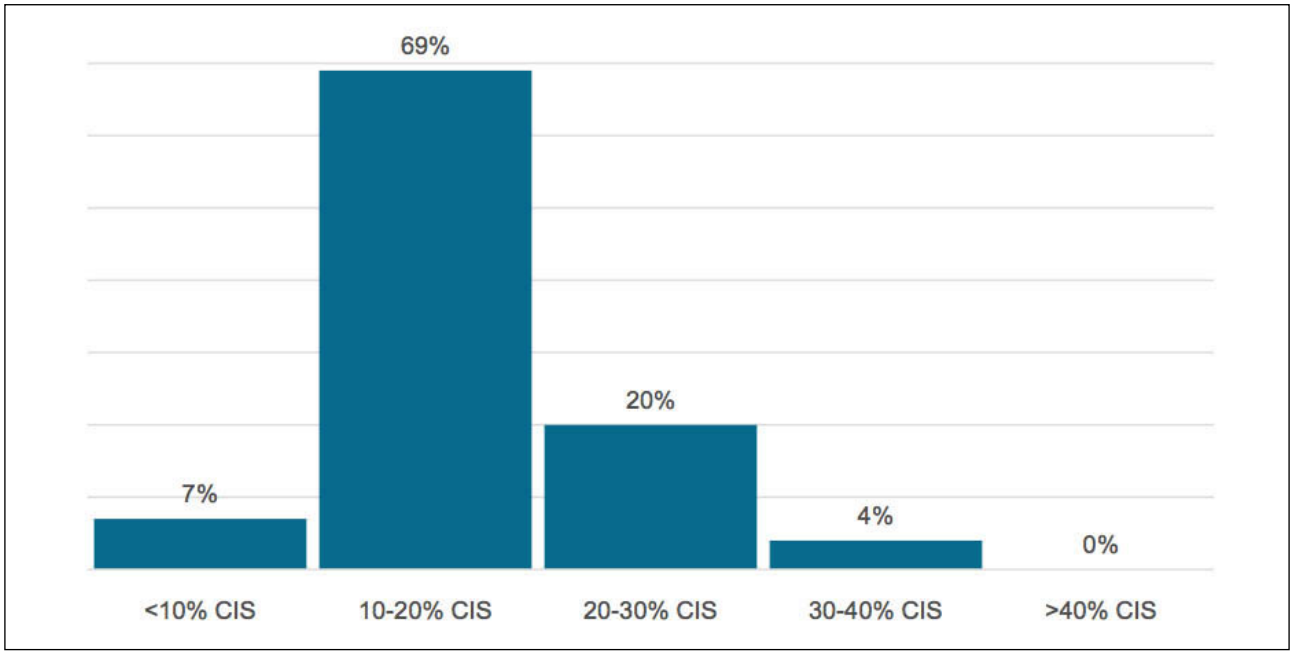
Strategies for managing high-risk BCG unresponsive disease

In the 6 months preceding the survey, urologists reported a wide range of experience in managing patients with BCG-unresponsive NMIBC. The majority (65%) treated between 5 and 10 patients per month, while 20% managed more than 10 patients monthly, and 15% treated fewer than five. When asked about their confidence in identifying BCG-unresponsive disease based on guideline-defined criteria, 69% of respondents indicated they were confident or very confident in their assessments. In contrast, 31% expressed only limited or no confidence.

Regarding the proportion of *carcinoma in situ* (CIS) tumors in HR, BCG-unresponsive disease, the majority of respondents (69%) reported that CIS accounted for 10-20% of cases (Figure 1). Interestingly, only 50% of urologists considered all cases of *high-grade* (HG) Ta disease to be HR. Another 47% classified it as HR only when the tumor is multifocal and recurrent. Crucially, a small minority (3%) did not view HG Ta disease as HR, distinguishing it from CIS and T1 tumors.

In managing HR, BCG-unresponsive NMIBC, RC was the most preferred treatment. It was the top choice for 67% of urologists, with another 31% reporting they use it occasionally. Only 2% said they never use it. In contrast, just 4% of respondents selected intravesical chemotherapy as their primary treatment, although 53% reported using it occasionally, and 43% said they don't use it at all.

Figure 1.
Distribution of CIS among high-risk BCG-unresponsive NMIBC cases.



BCG: Bacillus Calmette-Guérin; NMIBC: Non-Muscle Invasive Bladder Cancer; CIS: Carcinoma in situ.

Interestingly, 14% opted to repeat BCG therapy, and 15% chose resection followed by active surveillance as their preferred option. Notably, none of the surveyed urologists reported using intravenous checkpoint inhibitors or enrolling patients in clinical trials as part of their treatment strategy (Figure 2).
Of note, when alternative treatments to RC were pursued for BCG-unresponsive disease, 22% of urologists-initiated therapy within 2 weeks of diagnosis, 52% within 2 to 4 weeks, and 26% after more than 4 weeks. In terms of decision-making, only 11% consistently utilized a *multidisciplinary tumor board* (MDTs), while 59% engaged such boards occasionally, and 30% did not involve them at all.

Use of intravesical chemotherapy in BCG-unresponsive disease

Among urologists who considered intravesical therapy for BCG-unresponsive disease, Gem emerged as the predominant agent, reported by 85% of respondents. Other agents were used far less frequently, including MMC (5%), sequential Gem/Doce (4%), Gem/MMC (3%), valrubicin (1%), and Doce monotherapy (2%) (Figure 3).
When asked specifically about their familiarity with intravesical Gem/Doce for the treatment of BCG-unresponsive disease, 19% of urologists indicated they were entirely unfamiliar with this therapeutic approach.
When urologists were asked whether they would consider intravesical chemotherapy for intermediate-risk patients with BCG-unresponsive disease, 49% stated unequivocally that they would not consider this option under any circumstances. Fifty-six percent of urologists report that concerns about oncological safety, particularly the fear of disease progression, are the primary reasons for the limited adoption of intravesical chemotherapy as a bladder-sparing approach in BCG-unresponsive NMIBC. Additional contributing factors are outlined in Figure 4.

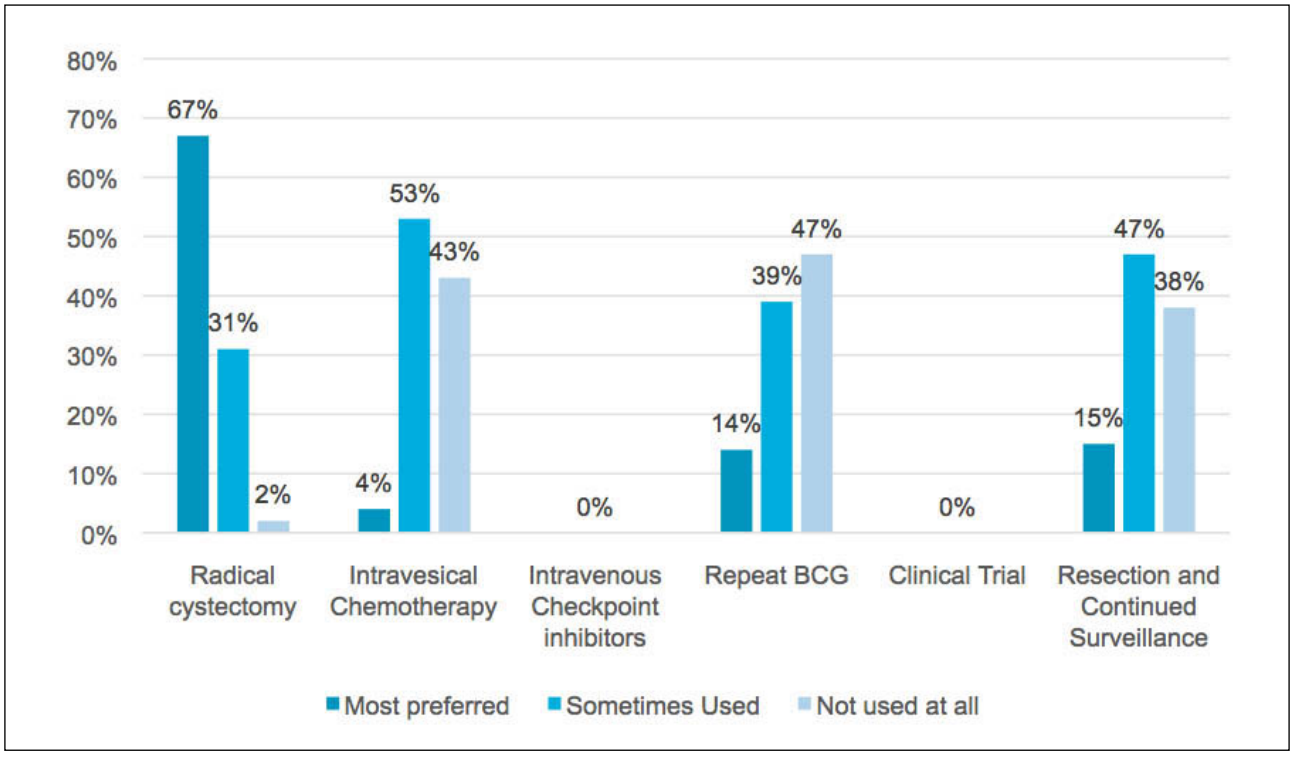
Awareness of novel FDA-approved agent in BCG-unresponsive disease

Among the recently FDA-approved therapies for BCG-unresponsive NMIBC—nadofaragene firadenovec (Adstiladrin), Anktiva (nogapendekin alfa inbakicept), and pembrolizumab, 61% of urologists were unaware of all 3 agents, 30% reported familiarity with all, and 9% had heard of at least one. Interestingly, only 1% reported using these new agents in their clinical practice.

Treatment selection in BCG-unresponsive disease

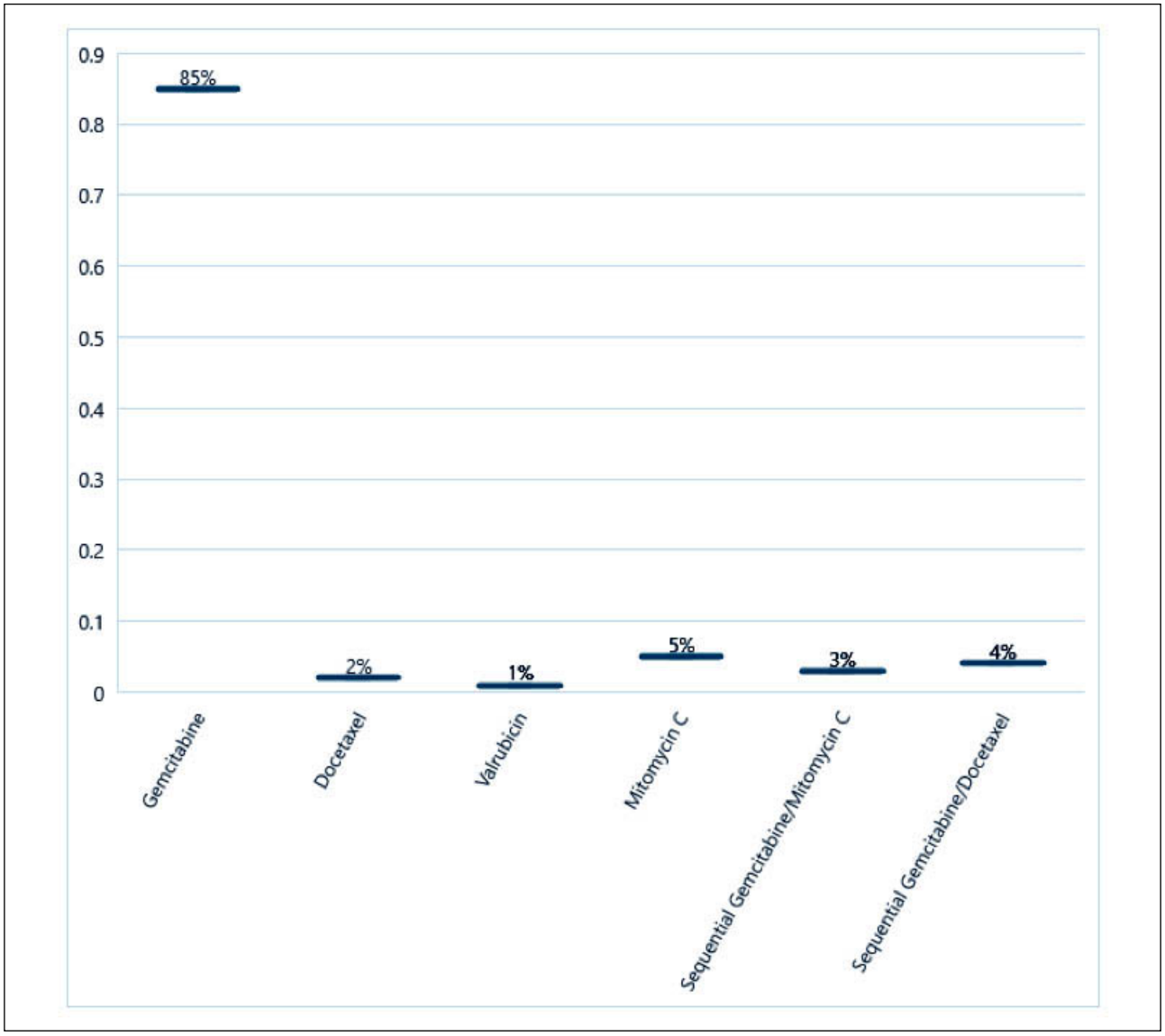
In the context of the Romanian healthcare system, the factors influencing the choice of therapy for BCG-unresponsive disease were reported as follows: cost of therapy (41%), drug availability (32%), patient preference (12%), and national healthcare system guidelines (15%).
When asked what price range is considered acceptable for both clinicians and their patients, 67% of urologists indicated a preference for treatments priced between $100 and $1,000. Meanwhile, 24% showed a preference for treatments under $100, with just 9% considering options in the $1,000-$10,000 range.

Figure 2.
Therapeutic approaches for managing high-risk, BCG-unresponsive NMIBC.



BCG: Bacillus Calmette-Guérin; NMIBC: Non-Muscle invasive bladder cancer.

Figure 3.
Most commonly utilized intravesical chemotherapy agents for BCG-unresponsive disease.



BCG: Bacillus Calmette-Guérin.

Strategies for managing NMIBC amid the BCG shortage

A majority of urologists (60%) reported having experienced BCG shortages in the past, though not within the last 6 months. For 33%, the shortage remains an ongoing challenge, while 7% have never encountered such an issue in their clinical practice. In response to BCG shortages, urologists have adopted various mitigation strategies. These include prioritizing BCG for patients with high-grade T1 tumors and CIS over those with high-grade Ta disease, or reserving it for the highest-risk groups. Dose reduction, typically to one-half or one-third of the standard dose, is also commonly employed. A detailed summary of these approaches is shown in Figure 5.

A substantial proportion of urologists (97%) reported awareness of existing literature evaluating intravesical chemotherapy as a potential alternative to BCG in the treatment of HR, BCG-naïve NMIBC.

Discussion

Managing HR BCG-unresponsive disease remains a significant challenge for urologists. Current guidelines continue to recommend RC as the standard treatment in this setting, but they offer limited guidance for patients who are either unfit for surgery or decline it altogether (1,2). In this survey, RC was still the most preferred option, with 67% of respondents selecting it as their top choice. These findings are consistent with a 2023 survey conducted by the *Arab Association of Urology* (AAU), where RC was also the most favored strategy for managing HR BCG-unresponsive disease, chosen in 50% of cases (9). Nonetheless, clinical practice patterns in the management of BCG-unresponsive disease demonstrate marked regional disparities. In a U.S.-based survey involving 259 urologists, only 24% reported routinely performing RC in this setting (10). Real-world data collected across 3 continents further highlight this

Figure 4.
Reasons for the limited adoption of intravesical chemotherapy as a bladder-sparing approach in BCG-unresponsive disease.

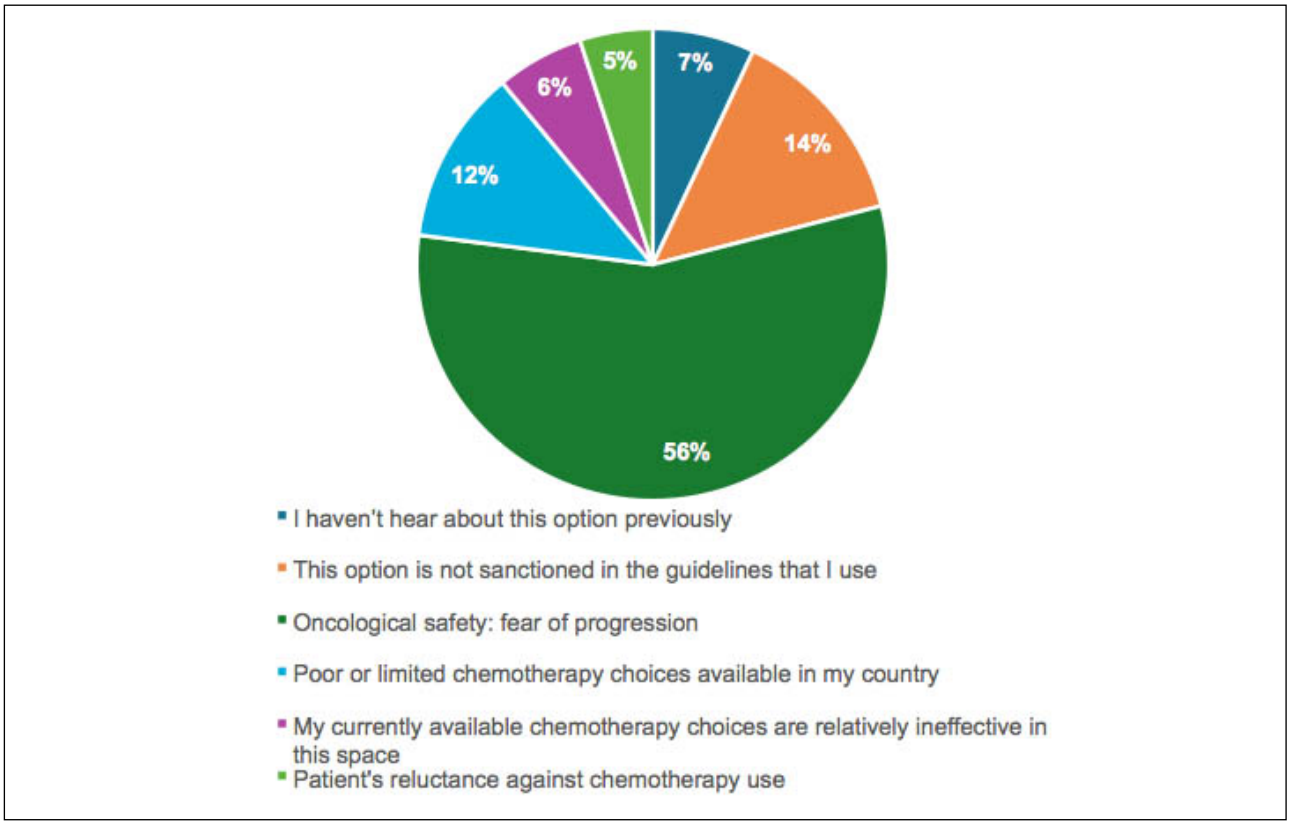
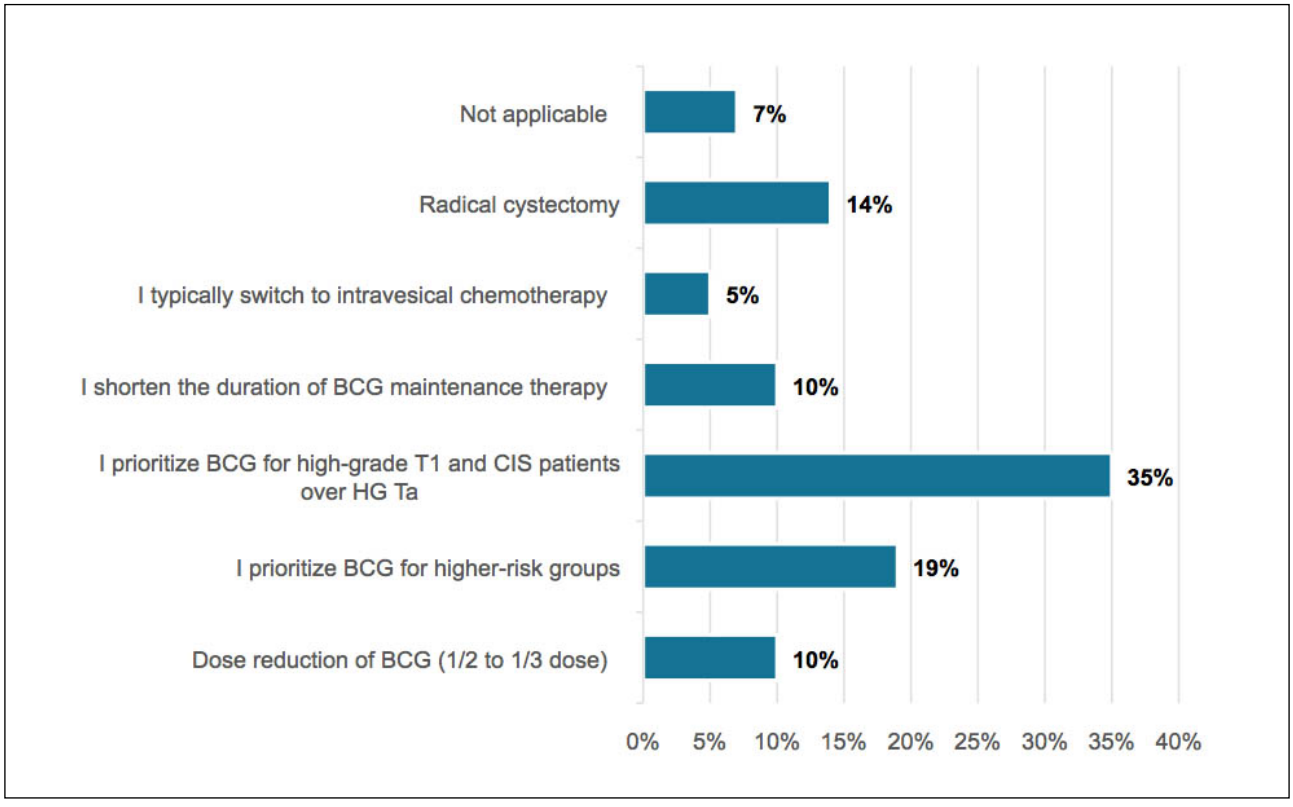


Figure 5.
Treatment strategies for BCG-naïve cases during BCG shortages.



variability: in European countries such as France, Germany, Italy, and the United Kingdom, RC was implemented in approximately 15-30% of cases. By contrast, its utilization in Asia was significantly lower, with only 7% of urologists in China and 13% in Japan adopting RC as a treatment strategy in this context (11).

Among urologists who utilize intravesical chemotherapy for BCG-unresponsive disease, the selection of agents demonstrates substantial regional variability. In our survey, 85% of respondents favored single-agent Gem. In the Arab world, Gem (60%) and MMC (19%) were the most commonly used agents (9). Similarly, U.S. data indicated Gem (49%), MMC (23%), and sequential Gem/Doce (15%) as the predominant regimens (10). In China, anthracycline-based therapies were more prevalent, with epirubicin (37%) and doxorubicin (34%) most frequently employed (11). In Europe, MMC emerged as the most widely used agent (12). A recent meta-analysis underscores the limited efficacy of Gem monotherapy in BCG-unresponsive NMIBC. While 24-month RFS rates reach ~40% in high-grade papillary-only cases, they fall to ~20% in those with CIS. In contrast, sequential regimens such as Gem/Doce and Gem/MMC have shown superior outcomes. These combinations achieve 24- month RFS rates exceeding 40%, even in CIS-containing cohorts (13, 14).

Importantly, despite not being endorsed by current clinical guidelines, repeat BCG instillation, repeat resection, and continued surveillance remain favored strategies among a notable proportion of urologists. In our survey, 14% of respondents preferred repeat BCG therapy, while 15% opted for continued surveillance. Similar trends were observed globally: in the Arab world, 12% and 8% of urologists, respectively, reported favoring these approaches (9). Repeat resection was utilized by 21% of urologists in China, 35% in Japan, and between 24% and 46% across various European countries for BCG unresponsive disease. In the U.S., up to 37% of respondents indicated they might still employ these strategies (11).

Of note, neither clinical trials nor intravenous immune checkpoint inhibitors were utilized by urologists in Romania, a trend that mirrors findings from surveys conducted in the Arab world (9). This stands in contrast to the U.S., where 14% of urologists reported employing checkpoint inhibitors, and a subset actively enrolled patient in clinical trials (10). Furthermore, data from China, Japan, and Europe indicate broader adoption of immunotherapy in this setting, with 37.6% of clinicians reporting the use of pembrolizumab and 26.4% utilizing nivolumab (12).

In our survey, awareness of recently FDA-approved therapies for BCG-unresponsive NMIBC, nadofaragene firadenovec, Nogapendekin alfa inbakicept-pmln, and pembrolizumab, was limited, with 61% of urologists unfamiliar with all 3 agents. Notably, only 1% reported incorporating any of these treatments into clinical practice, highlighting a significant gap between regulatory approval and real-world adoption. Although 4 agents, intravesical valrubicin (1998), intravesical nadofaragene firadenovec (2022), systemic pembrolizumab (2020), and intravesical nogapendekin alfa inbakicept (2024), have received FDA approval for HR BCG-unresponsive NMIBC, their indications are largely confined to CIS, with one-year complete response rates below 50% and treatment costs exceeding $200.000 per year for each agent with Nogapendekin alfa inbakicept-pmln surpassing $500.000. In contrast, Gem/Doce offers a substantially more cost-effective alternative, with an estimated annual cost of approximately $3.300, while demonstrating better efficacy (15). Furthermore, the limited global availability of these approved agents reinforces the clinical utility of intravesical chemotherapy, particularly in resource-constrained settings where access to novel therapies remains restricted. Notably, economic considerations appear to play a critical role in the treatment selection for NMIBC, particularly in the Arab world, where less costly but less effective options, such as resection alone, are more commonly employed in low- and middle-income countries (9).

In our survey, 60% of urologists reported previous BCG shortages, though not within the past 6 months, while 33% indicated ongoing supply constraints at the time of the survey. Similarly, in the Arab survey, 68% of respondents reported an ongoing shortage, and 21% noted prior disruptions that had resolved within the preceding 6 months (9). Urologists in Romania have responded similarly to those in other regions of the world by reducing BCG doses or prioritizing its use for higher-risk groups.

A notable finding from this study is the limited use of MDTs, with only 11% of Romanian urologists reporting regular involvement of these boards in decision-making for BCG-unresponsive disease therapy. The involvement of MDTs, particularly in complex cases where bladder-preserving strategies are considered, helps ensure optimal, individualized care by reducing variability and aligning treatment with evidence-based protocols (16). In Romania, the underutilization of MDTs may contribute to suboptimal clinical decision-making, underscoring the need for structural reforms and greater integration of collaborative care models.

This survey marks the first effort to assess how Romanian urologists manage BCG-unresponsive NMIBC, offering key insights into treatment strategies during the BCG shortage and awareness of alternative therapies. However, limitations exist. The reliance on six-month retrospective self-reporting may introduce recall bias. Additionally, as

Declarations

Ethical approval and consent for participate: *Not applicable.*

Availability of data and material: *Not applicable.*

Competing interests: *Not applicable.*

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Authors' contributions: *MB: Conceptualization, data interpretation, methodology, writing-original draft preparation. BAB: Methodology, data interpretation, writing-review & editing. MAC: Conceptualization, data interpretation, methodology, writing-original draft preparation. EI: data interpretation, writing-review & editing. MBB: data interpretation, writing-review & editing. NC: data interpretation, writing-review & editing. MAO: Conceptualization, methodology, writing-review & editing, Supervision.*

the survey targeted only urologists, the role of medical oncologists in second-line treatment decisions remains unclear.

Conclusions

RC remains the most commonly chosen treatment for BCG-unresponsive NMIBC in Romania, though there is still considerable variation in the use of alternative approaches. Notably, over half of surveyed urologists reported occasional use of intravesical chemotherapy in this context. Although awareness and clinical adoption of FDA-approved therapies remain limited, primarily due to financial and logistical barriers, most respondents were familiar with emerging evidence on new intravesical therapies, particularly sequential Gem/Doce therapy in both BCG-naïve and unresponsive settings. These findings underscore the urgent need to expand access and enhance clinician education on the efficacy of novel intravesical therapies in BCG-unresponsive setting. Empowering Romanian urologists with such resources could facilitate broader adoption of bladder-preserving approaches without compromising oncologic outcomes for NMIBC patients.

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