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European Association of Urology

Bladder Cancer

EAU Guidelines on Nonmuscle-invasive Bladder Cancer (TaT1 and CIS) – A Summary of the 2026 Guidelines Update

Paolo Gontero[a], *Paramananthan Mariappan*[b], *Benjamin Pradere*[c], *Bhavan P. Rai*[d], *Fredrik Liedberg*[e], *Eva Compérat*[f], *Jeremy Yuen-Chun Teoh*[g], *Marco Moschini*[h], *Francesco Soria*[a], *Bas W.G. van Rhijn*[i], *Joyce Baard*[j], *Alison Birtle*[k], *Maresa Botha*[l], *Otakar Capoun*[m], *David D'Andrea*[n], *Edoardo Fiorini*[o], *Alexandra Masson-Lecomte*[p], *Thomas Seisen*[q], *Shahrokh F. Shariat*[n], *Emma J. Smith*[l,*], *Viktor Soukup*[m], *Robert Wood*[l], *Evanguelos N. Xylinas*[r], *José L. Dominguez-Escrig*[s]

[a] *Department of Urology, Città della Salute e della Scienza, University of Torino School of Medicine, Torino, Italy;* [b] *Edinburgh Bladder Cancer Surgery (EBCS), The University of Edinburgh, Western General Hospital, Edinburgh, United Kingdom;* [c] *Department of Urology UROSUD, La Croix du Sud Hospital, Quint-Fonsegrives, France;* [d] *Department of Urology, Freeman Hospital, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK;* [e] *Institute of Translational Medicine, Lund University, Malmö, Sweden; Department of Urology, Skåne University Hospital, Malmö, Sweden;* [f] *Department of Pathology, Medical University of Vienna, Vienna, Austria;* [g] *S.H. Ho Urology Centre, Department of Surgery, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong;* [h] *Department of Urology, IRCCS Ospedale San Raffaele, Milan, Italy; Vita-Salute San Raffaele University, Milan, Italy;* [i] *Department of Surgical Oncology (Urology), Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands;* [j] *Department of Urology, Amsterdam UMC, University of Amsterdam, Amsterdam, The Netherlands;* [k] *Rosemere Cancer Centre, Lancashire Teaching Hospitals NHS Foundation Trust, Preston, United Kingdom;* [l] *EAU Guidelines Office, Arnhem, the Netherlands;* [m] *Department of Urology, General Teaching Hospital and 1st Faculty of Medicine, Charles University Praha, Prague, Czech Republic;* [n] *Department of Urology, Comprehensive Cancer Center, Medical University Vienna, Vienna General Hospital, Vienna, Austria;* [o] *Associazione PaLiNUro, Milan, Italy;* [p] *Department of Urology, Université de Paris, APHP, Saint Louis Hospital, Paris, France;* [q] *GRC 5 Predictive Onco-Uro, Sorbonne University, AP-HP, Urology, Pitie-Salpetriere Hospital, Paris, France;* [r] *Department of Urology, Bichat-Claude Bernard Hospital, AP-HP, Université de Paris, Paris, France;* [s] *Department of Urology, Fundación Instituto Valenciano de Oncología, Valencia, Spain*

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Abstract

Background and objective: This publication represents a summary of the updated 2026 European Association of Urology (EAU) Guidelines for nonmuscle-invasive bladder cancer (NMIBC), TaT1 and carcinoma *in situ* (CIS). The information presented herein is limited to urothelial carcinoma, unless specified otherwise. The aim is to provide practical recommendations on the clinical management of NMIBC, with a focus on clinical presentation.

Methods: For the 2026 guidelines on NMIBC, new and relevant evidence was identified, collated, and appraised via a structured assessment of the literature. Databases searched included MEDLINE, EMBASE, and the Cochrane Library. Recommendations within the guidelines were developed by the panel to prioritise clinically important care decisions. The strength of each recommendation was determined according to a balance between desirable and undesirable consequences of alternative management strategies, the

* Corresponding author. EAU Guidelines Office Patient Representative, Arnhem, The Netherlands. Tel.: +31 (0) 26 389 0680.
E-mail address: e.smith@uroweb.org (E.J. Smith).

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Classification
Diagnosis
Follow-up
Guidelines
Intravesical chemotherapy
Prognosis
Radical cystectomy
Transurethral resection (TUR)
Urothelial carcinoma

quality of the evidence (including the certainty of estimates), and the nature and variability of patient values and preferences.

Key findings and limitations: Key recommendations emphasise the importance of thorough diagnosis, treatment, and follow-up for patients with NMIBC. The guidelines stress the importance of defining patients' risk stratification and treating them appropriately. Key updates in the 2026 NMIBC Guidelines summary include: the addition of two new tables addressing risk factors for bladder cancer and prognostic factors for progression in subtypes; the addition of two new tables summarising the treatment options for Bacillus Calmette–Guérin (BCG)-unresponsive tumours; inclusion of a new section addressing the addition of immune checkpoint inhibitors to BCG in selected high- and very high-risk NMIBC BCG-NAÏVE patients; a new table addressing the role of urinary markers in follow-up; and the addition of a new section on pragmatic de-intensification strategy for NMIBC.

Conclusions and clinical implications: This overview of the 2026 EAU guidelines offers valuable insights into risk factors, diagnosis, classification, prognostic factors, treatment, and follow-up of NMIBC. They are designed for effective integration into clinical practice.

Patient summary: The EAU has issued updated clinical practice guidelines on NMIBC. The guidelines provide recommendations for diagnosis, treatment, and follow-up, with a particular focus on quality of life for patients.

1. Introduction

This summary represents the updated European Association of Urology (EAU) guidelines for nonmuscle-invasive bladder cancer (NMIBC), comprising Ta, T1, and carcinoma *in situ* (CIS). The information presented is limited to urothelial carcinoma, unless otherwise specified. The aim is to provide practical recommendations for clinical management of NMIBC, with a focus on clinical presentation and recommendations.

It must be emphasised that clinical guidelines present the best evidence available to the experts, but following guideline recommendations will not necessarily result in the best outcome. Guidelines can never replace clinical expertise when making treatment decisions for individual patients, but rather help to focus decisions that also take the personal values, preferences, and individual circumstances of patients into account. Guidelines are not mandates and do not purport to be a legal standard of care.

2. Methods

For the 2026 NMIBC Guidelines, new and relevant evidence has been identified, collated, and appraised through a structured assessment of the literature. A broad and comprehensive scoping exercise covering all areas of the NMIBC Guidelines was performed. A detailed search strategy is available online: https://uroweb.org/guidelines/non-muscle-invasive-bladder-cancer/publications-appendices.

Recommendations within the Guidelines are developed by the panels to prioritise clinically important care decisions. The strength of each recommendation is determined by the balance between desirable and undesirable consequences of alternative management strategies, the quality of the evidence (including certainty of estimates), and the nature and variability of patient values and preferences. Strong recommendations typically indicate a high degree of evidence quality and/or a favourable balance of benefit to harm and patient preference. Weak recommendations typically indicate the availability of lower quality evidence, and/or an equivocal balance between benefit and harm, and uncertainty or variability of patient preference [1].

3. Guidelines

3.1. *Epidemiology and aetiology*

Bladder cancer (BC) is the sixth most commonly diagnosed cancer worldwide [2]. The worldwide age-standardised incidence rate (per 100 000 person/yr) is 9.3 in males and 2.4 in females, and 23.2 in males and 5.9 in females in the European Union (EU) [2]. The worldwide BC age-standardised mortality rate (per 100 000 person/yr) is 3.1 for males versus 0.80 for females [2]. Approximately 75% of patients with BC present with disease confined to the mucosa (stage Ta, CIS) or submucosa (stage T1) [3].

Table 1 summarises the main BC risk factors stratified into modifiable, nonmodifiable, and partly modifiable risk according to the existence of an established causality or a mere association with the disease. Tobacco smoking is the most important risk factor, followed by occupational exposure [4].

3.2. *Pathological staging, grading and classification systems*

3.2.1. *Definition of nonmuscle-invasive BC*

Urothelial tumours confined to the mucosa and invading the lamina propria are classified as stage Ta and T1, respectively (Table 2) [5], while intra-epithelial, high-grade (HG) tumours confined to the mucosa are classified as CIS (Tis), as shown in the latest tumour, node, metastasis (TNM) classification (Table 2) [6].

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Table 1 – Risk factors for bladder cancer

Nature of Risk Factor	Risk Factors	Causality versus Association
Modifiable	Tobacco smoking, including passive smoking	
	Occupational exposure: Aromatic amines, polycyclic aromatic hydrocarbons and chlorinated hydrocarbons, for example, industrial plants that process paint, dye, metal, and petroleum products	Causality established
	Diet: • Protective: Flavonoids, Mediterranean diet, cruciferous vegetables, fruits[a], vitamin B[a], high-quality diet defined by established dietary indices[a] • Increased recurrence risk: Vitamin E	
	Exercise	Association
	Obesity (waist-to-hip ratio)	
Nonmodifiable	Genetics • 17 susceptibility loci • Detoxification pathways, mainly glutathione S-transferase 1 (GSTM1)	Association
Partly Modifiable	Schistosomiasis	Causality established
	Environmental factors: Chlorination and arsenic exposure to drinking water	
	Pelvic radiation	Association
	Drugs: • Cyclophosphamide • Pioglitazone	

[a] Reported to be protective only in females.

Table 2 – 2025 tumour node metastasis classification of urinary bladder cancer

T – Primary tumour	
TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Ta	Non-invasive papillary carcinoma
Tis	Carcinoma *in situ:* "flat tumour"
T1	Tumour invades subepithelial connective tissue
T2	Tumour invades muscle
T2a	Tumour invades superficial muscle (inner half)
T2b	Tumour invades deep muscle (outer half)
T3	Tumour invades perivesical tissue
T3a	Microscopically
T3b	Macroscopically (extravesical mass)
T4	Tumour invades any of the following: prostate stroma, seminal vesicles, uterus, vagina, pelvic wall, abdominal wall
T4a	Tumour invades prostate stroma, seminal vesicles, uterus or vagina
T4b	Tumour invades pelvic wall or abdominal wall
N – Regional lymph nodes	
NX	The regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single lymph node in the true pelvis (hypogastric, obturator, external iliac, or presacral)
N2	Metastasis in multiple regional lymph nodes in the true pelvis (hypogastric, obturator, external iliac, or presacral)
N3	Metastasis in common iliac lymph node(s)
M – Distant metastasis	
M0	No distant metastasis
M1a	Nonregional lymph nodes
M1b	Other distant metastases

3.2.2. *T1 subclassification*

Retrospective cohort studies have demonstrated that the depth and extent of invasion into the lamina propria (T1 substaging) are of prognostic value [5,7]. The use of T1 substaging is recommended by the 2022 World Health Organization (WHO) classification of tumours [8].

3.2.3. *CIS*

CIS is an intra-epithelial, HG, noninvasive urothelial carcinoma (UC). It is often multifocal and can occur in the bladder, but also in the upper urinary tract (UUT), prostatic ducts, and urethra [9]. CIS may be classified as: primary – isolated CIS with no previous or concurrent papillary tumours and no previous CIS; secondary – CIS detected during follow-up of patients with a previous tumour that was not CIS; or concurrent – CIS in the presence of any other urothelial tumour in the bladder [10].

3.2.4. *Histological grading systems and their prognostic value*

In 2022, the WHO released an updated histological grading classification system that essentially dichotomises urothelial carcinomas into low-grade (LG) and HG, as compared to the older WHO 1973 system that distinguishes between grade 1 (G1), grade 2 (G2), and grade 3 (G3) categories [8]. In spite of the WHO supporting the 2004/2016/2022 classification system for clinical use, both classification systems are prognostic for progression, but not for recurrence [11]. Notably a 3-tier (LG/G1-G2, HG/G2 & HG/G3) or 4-tier hybrid combination (LG/G1, LG/G2, HG/G2 and HG/

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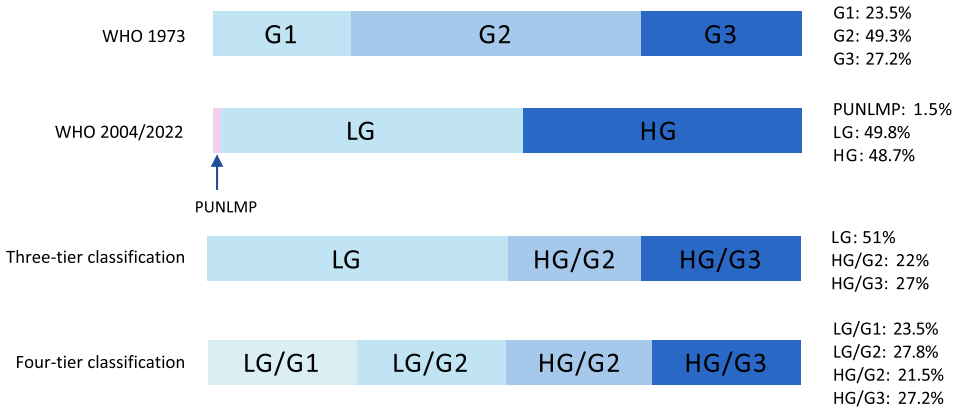

Fig. 1 – Schematic representation of tumours according to the WHO 1973, WHO 2004/2022 grading systems and a 3-tier and 4-tier hybrid combination of the two systems. The percentages refer to the rate of each grade for the WHO 1973, the WHO 2004/2022 and the corresponding calculated 3-tier and 4-tier systems in a multicentre cohort of 5145 patients with primary Ta, T1 NMIBC. G = grade; HG = high-grade; LG = low-grade; PUNLMP = papillary urothelial neoplasm of low malignant potential; WHO = World Health Organization.

G3) of both classification systems is superior to either classification system alone for predicting progression, as it divides the large group of patients with HG tumours into two subgroups (G2/G3) with different prognoses [12,13] (Fig. 1).

3.2.5. *Subtypes of UC and lymphovascular invasion*

Several subtypes of UC have been defined. In the WHO 2022 classification update, all subtypes are considered HG [8]. The presence of lymphovascular invasion (LVI) in transurethral resection of bladder tumour (TURB) specimens is associated with an increased risk of pathological upstaging and worse prognosis [14].

3.2.6. *Tumour markers and molecular classification*

No tumour marker or molecular classification is currently suitable for pathological stratification in routine clinical practice [15]. Table 3 reports the main recommendations for the pathological classification of BC.

3.3. *Diagnosis*

A focused patient history and urological examination are mandatory. Haematuria is the most common finding in NMIBC [16]. CIS might be suspected in patients experiencing lower urinary tract symptoms, especially irritative voiding symptoms. Recommendations for the primary assessment of NMIBC are presented in Table 4.

3.3.1. *Imaging*

Computed tomography (CT) urography is used to detect papillary tumours in the urinary tract, indicated by contrast enhancement, filling defects, and/or hydronephrosis [17]. Intravenous urography (IVU) is an alternative if CT is not available [18]. Ultrasound (US) may be performed as an adjunct to physical examination, as it has moderate sensitivity for a wide range of abnormalities in the upper and lower urinary tract [19]. Multiparametric magnetic resonance imaging (mpMRI) might provide additional information regarding the local staging of BC [20].

3.3.2. *Urinary cytology*

Cytology is useful, particularly as an adjunct to cystoscopy, in any patient with HG tumours (sensitivity up to 84%); it is not designed to detect LG/G1 tumours (sensitivity 16%) [21]. A standardised reporting system redefining urinary cytology diagnostic categories was published in 2022 by the Paris Working Group [22].

3.3.3. *Urinary molecular marker tests*

Driven by the low sensitivity of urine cytology in LG tumours, numerous urinary tests have been developed [23]. Currently, none of these markers can be recommended in routine clinical practice for diagnosis [24] or follow-up (Section 3.6 and Table 18 for the performance of urinary marker tests for follow-up).

3.3.4. *Cystoscopy*

The diagnosis of papillary BC ultimately depends on cystoscopic examination of the bladder and histological evaluation of sampled tissue. CIS can be suspected through cystoscopy and urine cytology and confirmed by histological evaluation of multiple bladder biopsies [31].

Table 3 – Recommendations for pathological bladder cancer classification

Recommendations	Strength rating
Use the 2025 Tumour, Node, Metastasis system for classification of the depth of tumour invasion (staging).	Strong
Use the 2004/2022 World Health Organization grading classification systems. If available, use a hybrid system based on both the 1973 and 2004/2022 WHO grading classification systems.	Strong
Do not use the term "superficial" bladder cancer.	Strong

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Table 4 – Recommendations for the primary assessment of non-muscle invasive bladder cancer

Recommendations	Strength rating
Take a patient history, focusing on urinary tract symptoms and haematuria.	Strong
Use renal and bladder ultrasound and/or computed tomography (CT) urography during the initial work-up in patients with haematuria.	Strong
Once a bladder tumour has been detected, perform a CT urography in selected cases (eg, tumours located in the trigone, or multiple- or high-risk tumours).	Strong
If a magnetic resonance imaging (MRI) is performed for local staging of bladder cancer (BC), it should be done before transurethral resection of bladder tumour (TURBT).	Strong
Perform cystoscopy with or without biopsy confirmation in patients with symptoms suggestive of BC. It cannot be replaced by cytology or by any other non-invasive test.	Strong
Use a flexible cystoscope, if available, in both males and females. In male patients, apply irrigation "bag squeeze" to decrease procedural pain when passing the proximal urethra.	Strong
Describe all macroscopic features of the tumour (site, size, number and appearance) and mucosal abnormalities during cystoscopy. Use a bladder diagram.	Strong
Use voided urine cytology as an adjunct to cystoscopy to detect high-grade tumour.	Strong
Perform cytology on at least 25 ml fresh urine or urine with adequate fixation. First morning urine is not suitable due to the frequent presence of cytolysis.	Strong
Use the Paris System 2nd Edn., for cytology reporting.	Strong

Table 5 – Recommendations for transurethral resection of the bladder, biopsies and pathology report

Recommendations	Strength rating
Perform a transurethral resection of the bladder tumour (TURBT) followed by pathology investigation of the obtained specimen(s) as a diagnostic procedure and initial treatment step in patients suspected of having bladder cancer (BC).	Strong
Perform TURBT systematically in individual steps: • bimanual palpation under anaesthesia before starting the procedure and at the end; • insertion of the resectoscope, under visual control with inspection of the whole urethra; • thorough inspection of the whole urothelial lining of the bladder; • biopsy from the prostatic urethra (if indicated); • cold-cup bladder biopsies (if indicated); • resection of the tumour; • recording of findings in the surgery report/record, including visual impression of grade/stage; and • precise description of the specimen(s) for pathology evaluation.	Strong
Performance of individual steps	
Perform en bloc resection or resection in fractions.	Strong
Avoid cauterisation as much as possible during TURBT to avoid tissue deterioration.	Strong
Take biopsies from abnormal-looking urothelium.	Strong
Take multiple biopsies (mapping biopsies from the trigone, bladder dome, right, left, anterior and posterior bladder wall) or perform fluorescence-guided (photodynamic diagnosis [PDD]) biopsies, in case of normal upper tract on contrast computed tomography, normal-looking urothelium at cystoscopy, and positive urine cytology.	Strong
Take a sample of the prostatic urethra if there is positive urine cytology without evidence of tumour in the bladder, or if abnormalities of the prostatic urethra are visible.	Strong
Take a sample biopsy of the prostatic urethra in cases of bladder neck tumour, suspicion of bladder carcinoma *in situ* (CIS) and/or T1 disease. If a sample was not taken during the initial procedure, it should be performed at the time of the second resection, if the latter is needed.	Weak
Use methods to improve tumour visualisation during TURBT, if available.	Weak
Refer the specimens from different biopsies and resection fractions to the pathologist in separately labelled containers. Submit the tumour base separately, especially in large and multifocal tumours or when en bloc resection is not feasible.	Weak
The TURBT record must describe tumour location, appearance, size and multifocality, all steps of the procedure, extent, macroscopic completeness of resection, as well as any complications.	Strong
In patients with positive cytology but negative cystoscopy, exclude an upper tract urothelial carcinoma, CIS in the bladder (by mapping biopsies or PDD-guided biopsies), and tumour in the prostatic urethra (by prostatic urethra biopsy).	Strong
Perform a second TURBT in the following situations: • after incomplete initial TURBT, or in case of doubt about completeness of a TURBT; • if there is no detrusor muscle in the specimen after initial resection, with the exception of Ta LG/G1 tumours and primary CIS; or • in T1 tumours.	Strong
If indicated, perform a second TURBT within 2 to 6 wk after the initial resection. This second TURBT should include resection of the primary tumour site.	Weak
Inform the pathologist of prior treatments (intravesical therapy, radiotherapy, etc.).	Strong
The pathological report should specify tumour location, tumour grade and stage, lymphovascular invasion, subtypes of urothelial carcinoma, presence of CIS and detrusor muscle.	Strong

3.3.5. Transurethral resection of TaT1 bladder tumours (TURB)

The goal of TURB in Ta/T1 BC is to establish an accurate pathological diagnosis and staging, and completely remove all visible lesions. Transurethral resection of bladder tumours should be performed systematically in individual steps (Table 5), using either a fractioned (piecemeal resection) or en bloc technique. The latter has been shown to improve pathological accuracy (T1 substaging) and potentially reduce recurrences in selected cases [32,33]. Bimanual palpation may provide critical information on bladder mobility and potential infiltration of adjacent structures [34]. Surgical checklists have been shown to increase surgical quality and decrease recurrence rates [35].

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3.3.6. Endoscopic biopsies

3.3.6.1. Bladder biopsies. CIS can present as a velvet-like, reddish area, indistinguishable from inflammation, or it may not be visible at all; therefore, biopsies from suspicious urothelium should be taken. In patients with positive urine cytology and normal-looking mucosa at cystoscopy, mapping biopsies are recommended [36,37].

3.3.6.2. Prostatic urethral biopsies. Involvement of the prostatic urethra and ducts in men with NMIBC has been reported [38]. The risk of prostatic urethra or duct involvement is higher if the tumour is located at the trigone or bladder neck, in the presence of bladder T1G3 or CIS, and in cases of multiple tumours [39]; therefore, a biopsy from the prostatic urethra is necessary in some cases [38,40].

3.3.7. New methods of tumour visualisation

As a standard procedure, cystoscopy and TURB are performed using white light (WL). However, the use of WL alone can lead to missed lesions that are present but not visible, which is why new technologies are being developed.

3.3.7.1. Photodynamic diagnosis (fluorescence cystoscopy or blue light cystoscopy). Photodynamic diagnosis (PPD) has been shown to have higher sensitivity than WL, particularly for the detection of *CIS,* with lower sensitivity [41]. Several studies have shown a lower risk of recurrence and improved time to recurrence for PDD [42–44] although one randomised controlled trial (RCT) found no benefit at 3 yr [45].

3.3.7.2. Narrow-band imaging (NBI). Several studies have demonstrated improved cancer detection for NBI-assisted flexible cystoscopy and NBI-guided biopsies and resection [46–48], while the benefit on the reduction of recurrence remains controversial [48–51].

3.3.8. Second resection (second TURB)

According to a contemporary systematic review, patients with T1 disease have pooled rates of 31.4% for any residual disease and a 2.8% risk of upstaging [52]. A second TURB can increase recurrence-free survival (RFS) [53,54], improve outcomes after bacillus Calmette–Guérin (BCG) treatment [55], and provide prognostic information [56,57]. Retrospective evaluation showed that a second resection performed 14–42 d after the initial resection provides longer RFS and progression-free survival (PFS) compared to a second resection performed after 43–90 d [58].

3.3.9. Pathology report

Pathological investigation of the specimen(s) obtained by TURB and biopsies is an essential step in the decision-making process for BC [59].

3.4. Predicting disease recurrence and progression

3.4.1. Ta and T1 tumours

Treatment should take into account the risk of recurrence and prognosis for the patient. Several clinical and pathologic tumour factors are associated with poor oncologic outcomes (Table 6). To predict the risk of disease recurrence and/or progression, several prognostic models for specified patient populations have been introduced. Recommendations for stratification of NMIBC are presented in Table 7.

3.4.1.1. Scoring models using the WHO 1973 classification system.

i. *The 2006 European Organisation for Research and Treatment of Cancer (EORTC) scoring model*

The 2006 EORTC scoring model is based on the six most significant clinical and pathological factors in patients mainly treated by intravesical chemotherapy [60]. Using this model, individual probabilities of recurrence and progression at 1 and 5 yr may be calculated.

ii. *Club Urológico Español de Tratamiento Oncológico (CUETO) scoring model for patients treated with BCG*

The CUETO model predicts the risk of recurrence and progression for patients treated with 12 doses of intravesical BCG over a 5- to 6-mo period following TURB and is based on the evaluation of seven prognostic factors. Using this model, the calculated risk of recurrence is lower than that obtained by the EORTC tables. For progression, the probability is lower only in patients at high risk [61]. The lower risks in the CUETO model may be attributed to the use of BCG in this sample.

iii. *The 2016 EORTC scoring model for patients treated with maintenance BCG*

In intermediate- and high-risk patients without CIS treated with 1 to 3 yr of maintenance BCG, EORTC risk groups and nomograms for patients treated with BCG were developed [62].

Table 6 – Clinical and pathologic factors in relation to risk of progression

Prognostic factors	Risk of progression
High percentage of subtype(s)	Very high risk of progression
Presence of CIS and/or T1 disease	
Lymphovascular invasion	
Pure micropapillary, sarcomatoid, nested and plasmacytoid subtype, or NE subtype	
Multifocal tumours	
Residual tumour or incomplete TURBT	
Absence of CIS and LVI, Ta disease	High risk of progression
Solitary tumour	
Complete TURBT with no residual tumour	

CIS = carcinoma *in situ*; LVI = lymphovascular invasion; NE = neuroendocrine; TURBT = transurethral resection of the bladder tumour.

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Table 7 – Clinical composition of the EAU NMIBC prognostic factor risk groups based on the WHO 2004/2016 or the WHO 1973 grading classification systems[a]

Risk group	
Low Risk	• A primary, single, TaT1 LG/G1 tumour < 3 cm in diameter without CIS in a patient ≤70 yr • A primary Ta LG/G1 tumour without CIS with at most ONE of the additional clinical risk factors
Intermediate Risk	• Patients without CIS who are not included in either the low-, high-, or very high-risk groups
High Risk	• All T1 HG/G3 without CIS, EXCEPT those included in the very high-risk group • All CIS patients, EXCEPT those included in the very high-risk group
	Stage, grade with additional clinical risk factors: • Ta LG/G2 or T1G1, no CIS with all 3 risk factors • Ta HG/G3 or T1 LG, no CIS with at least 2 risk factors • T1G2 no CIS with at least 1 risk factor
Very High Risk	Stage, grade with additional clinical risk factors: • Ta HG/G3 and CIS with all 3 risk factors • T1G2 and CIS with at least 2 risk factors • T1 HG/G3 and CIS with at least 1 risk factor • T1 HG/G3 no CIS with all 3 risk factors

The category of LG tumours (WHO 2004/2016) also includes patients with tumours classified as PUNLMP. Additional clinical risk factors are: age >70; multiple papillary tumours; and tumour diameter >3 cm. The scoring model is based on individual patient data, but it does not consider patients with primary CIS (high risk) or with recurrent tumours, as well as some pathologic parameters like subtypes of urothelial carcinoma and LVI. Nevertheless, based on data from the literature, all patients with CIS in the prostatic urethra, with subtypes of urothelial carcinoma or with LVI, should be included in the very high-risk group. Patients with primary (pure) CIS should be considered in the high-risk group. Patients with recurrent tumours should be included in the intermediate-, high-, or very high-risk groups according to their other prognostic factors.

[a] Only one of the two classification systems (WHO 1973 or WHO 2004/2016) is required to use this table.

3.4.1.2. Scoring model using the WHO 2004/2016 and WHO 1973 classification systems.

i. EAU NMIBC 2021 scoring model

This model was developed to create prognostic factor risk groups using individual patient data (IPD) from patients with primary tumours treated with TURB ± intravesical chemotherapy, using both the WHO 1973 and WHO 2004/2016 classification systems [63]. This is the only available model in which the WHO 2004/2022 classification system is included as one of the parameters to calculate an individual patient's risk group and probability of progression. The 2021 EAU NMIBC scoring model determines the risk of tumour progression, but not recurrence, in patients not receiving BCG; therefore, the 2006 EORTC scoring model can be used to calculate an individual's risk of disease recurrence in patients mainly treated with intravesical chemotherapy.

3.4.2. Primary CIS

Without any treatment, approximately 54% of patients with CIS experience progression to muscle-invasive disease [64]. There are no reliable prognostic factors; however, some studies have reported a worse prognosis in patients with concurrent CIS and T1 tumours compared to those with primary CIS [65,66], in patients with extended CIS [67] and in patients with CIS in the prostatic urethra [38]. The response to intravesical treatment with BCG or chemotherapy is an important prognostic factor for subsequent progression and death caused by BC [61,68,69].

3.4.3. Histological subtypes

Various histological subtypes exist each carrying unique prognostic implications (Table 6) [70]. Understanding the differences between these subtypes is critical for risk stratification, as their biological behaviour can differ significantly from conventional UC.

3.4.4. Patient stratification into risk groups

To facilitate treatment recommendations, the Guidelines recommend the stratification of patients into risk groups based on their probability of progression to muscle-invasive disease [63]. The clinical compositions of the EAU NMIBC prognostic factor risk groups are provided in Table 7. Web (www.nmibc.net) and mobile applications have been developed to facilitate the determination of a patient's risk group in daily clinical practice. The individual probability of disease progression at 1, 5, and 10 yr for the EAU NMIBC risk groups is presented in Table 8. A new AI-based risk model for progression has been shown to outperform the EAU 2021 model, but further validation is necessary [71]. The heterogeneous group of intermediate-risk NMIBC has been sub-stratified using a three-tier model based on five clinical risk factors [72] that has been validated using a European cohort [73]. Table 9 summarises recommendations for the stratification of NMIBC.

3.5. Disease management

Recommendations for adjuvant therapy in TaT1 tumours and for therapy of CIS are presented in Table 12. Recommendations for the treatment of TaT1 tumours and CIS according to risk stratification are presented in Table 13. Figs. 2 and 3 summarise the treatment strategy for primary or recurrent toumours without previous BCG and recurrence during or after intravesical BCG, respectively.

3.5.1. Smoking cessation, office-based fulguration and active surveillance

It has been confirmed that smoking increases the risk of tumour recurrence and progression in patients with NMIBC [87], as well as mortality in all patients with BC [88]; therefore, patients should be counselled to stop smoking, ideally integrating structured cessation interventions [89]. In

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Table 8 – Probabilities of disease progression in 1, 5 and 10 yr for the EAU NMIBC risk groups[a]

Risk group	Probability of Progression and 95% Confidence Interval (CI)		
	1 Yr	5 Yr	10 Yr
New Risk Groups with WHO 2004/2016			
Low	0.06% (CI: 0.01%–0.43%)	0.93% (CI: 0.49%–1.7%)	3.7% (CI: 2.3%–5.9%)
Intermediate	1.0% (CI: 0.50%–2.0%)	4.9% (CI: 3.4%–7.0%)	8.5% (CI: 5.6%–13%)
High	3.5% (CI: 2.4%–5.2%)	9.6% (CI: 7.4%–12%)	14% (CI: 11%–18%)
Very High	16% (CI: 10%–26%)	40% (CI: 29%–54%)	53% (CI: 36%–73%)
New Risk Groups with WHO 1973			
Low	0.12% (CI: 0.02%–0.82%)	0.57% (CI: 0.21%–1.5%)	3.0% (CI: 1.5%–6.3%)
Intermediate	0.65% (CI: 0.36%–1.2%)	3.6% (CI: 2.7%–4.9%)	7.4% (CI: 5.5%–10%)
High	3.8% (CI: 2.6%–5.7%)	11% (CI: 8.1%–14%)	14% (CI: 10%–19%)
Very High	20% (CI: 12%–32%)	44% (CI: 30%–61%)	59% (CI: 39%–79%)

[a] Table 8 does not include patients with subtypes of UC, LVI, CIS in the prostatic urethra, primary CIS, or recurrent patients. Please note that these percentages refer to patients who were not (immediately) treated with adjuvant BCG instillations after their primary TURBT.

Table 9 – Recommendations for stratification of non-muscle-invasive bladder cancer

Recommendations	Strength rating
Stratify non-muscle-invasive bladder cancer (NMIBC) patients into four risk groups to predict progression without bacillus Calmette-Guérin (BCG) therapy, according to Table 7. A patient's risk group can be determined using the 2021 European Association of Urology (EAU) risk group calculator available at www.nmibc.net.	Strong
Use the 2006 European Organisation for Research and Treatment of Cancer (EORTC) scoring model to predict the risk of tumour recurrence in individual patients not treated with BCG.	Strong
Use the 2016 EORTC scoring model or the Club Urologico Español de Tratamiento Oncologico (CUETO) risk scoring model to predict the risk of tumour recurrence and progression in individual patients treated with BCG intravesical immunotherapy (the 2016 EORTC model is calculated for 1 to 3 yr of maintenance, the CUETO model for 5 to 6 mo).	Strong

patients with a history of small Ta LG/G1 tumours, fulguration or laser vaporisation of small papillary recurrences on an outpatient basis can reduce the therapeutic burden [90]. With recurrence in LG (G1) Ta tumours being more likely to be low grade and noninvasive [91], the risk of progression to a higher grade or stage is rare [92]. Expectant management or active surveillance (AS) may offer an alternative to TURB and office-based fulguration in selected patients, mainly those with recurrent LG(G1) Ta NMIBC; however, the evidence in support of this approach is limited [93,94].

3.5.2. *Adjuvant intravesical treatment*

Although TURB by itself can eradicate a TaT1 tumour completely, these tumours commonly recur and can progress to muscle-invasive bladder cancer (MIBC). It is therefore necessary to consider adjuvant therapy in all patients.

3.5.2.1. Postoperative irrigation. A number of studies suggest the efficacy of continuous irrigation in the prevention of early recurrences [95]. In an RCT, short-term postoperative irrigation with 2000 ml over 3 h was shown to be noninferior to overnight irrigation [96].

3.5.2.2. Intravesical chemotherapy. A single, immediate, postoperative intravesical instillation of chemotherapy

Studies have consistently shown that after TURB, single instillation (SI) significantly reduces the recurrence rate compared to TURB alone [97–99]. A SI reduced the 5-yr recurrence rate by 14%; however, only patients with pri-

Table 10 – Categories of high-grade recurrence during or after BCG

Whenever a MIBC is detected during follow-up.
BCG-refractory tumour
1. If T1 HG/G3 tumour is present at 3 mo [171–173].
2. If Ta HG/G3 tumour is present after 3 mo and/or at 6 mo, after either re-induction or first course of maintenance [174].
3. If CIS (without concomitant papillary tumour) is present at 3 mo and persists at 6 mo after either re-induction or first course of maintenance. If patients with CIS present at 3 mo, an additional BCG course can achieve a complete response in >50% of cases [10,167,174].
4. If HG tumour appears during BCG maintenance therapy[a].
BCG-relapsing tumour
Recurrence of HG/G3 tumour after completion of BCG maintenance, despite an initial response [175].
BCG-unresponsive tumour
BCG-unresponsive tumours include all BCG refractory tumours and those that develop T1/Ta HG recurrence within 6 mo of completion of adequate BCG exposure[b] or develop CIS within 12 mo of completion of adequate BCG exposure [176].
BCG-exposed tumour [177,178]
1. BCG-resistant if Ta HG/G3 or CIS is present at 3 mo evaluation after induction BCG only.
2. Delayed relapse after adequate or inadequate BCG.
BCG intolerance
Severe side effects that prevent further BCG instillation before completing treatment [179].

BCG = bacillus Calmette-Guérin; CIS = carcinoma *in situ*; G = grade; HG = high-grade; LG = low-grade; MIBC = muscle-invasive bladder cancer.

[a] Patients with LG recurrence during or after BCG treatment are not considered to be a BCG failure.

[b] Adequate BCG is defined as the completion of at least 5 of 6 doses of an initial induction course plus at least 2 out of 6 doses of a second induction course or 2 out of 3 doses of maintenance therapy.

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Table 11 – Treatment options for BCG-unresponsive tumours – Papillary Ta/T1

Papillary Ta/T1								
Compound	Study design	n	FU (mo)	DFS (%)			PFS	≥Grade 3 adverse events
				3 mo	6 mo	12 mo		
Intravesical								
NADOFARAGENE FIRADENOVEC[a] [74]	Phase III Ta/T1 Cohort NCT02773849	48	20.2	72.9		42.8		G1-2 66.0% G ≥ 3 4%
CREMOSTIMOGENE GRENADENOREPVEC [75]	Phase II BOND II NCT02365818	9		33 Ta 50, T1 0				G1-2 82.5% G ≥ 3 4.5%
N-803 Nogapendekin Alfa Inbakicept + BCG[a] [76]	Phase II/III QUILT 3032 CB	82	20.7			55.4		G1-2 86% G ≥ 3 23%
TAR 200[a] [77]	Phase II b SunRISe-1 C4 NCT04640623	52	12.8		85.3	70.2	78.8	Any G 80.8% G ≥ 3 13.5%
RITE [78]	Phase III HYMN NCT01094964	33	36			53 vs. 24 c at 18 mo n/s		G1-2 81%
EMDA-MMC [79]	Phase II	18	35	77.7		72.2		23.1 % local/11.5 Allergic
Systemic								
PEMBROLIZUMAB[a] [186]	Phase II Cohort B KEYNOTE-057 NCT02625961	132	45.4	85		43.5% (HR) 41.7%		G1-2 59% G ≥ 3 15%
ATEZOLIZUMAB [84]	Phase II Cohort B SWOG 1605 NCT02844816	55	41	67	53	49	90.9	G1-2 70% G ≥ 3 14%
ERDAFITINIB [187]	Phase II THOR-2 Cohort 1 NCT04172675	73	13.4		96% vs 73%	77 % vs. 41%		G1-2 100% vs 83% G ≥ 3 36.7% vs 0%

BCG = bacillus Calmette-Guérin; DFS = disease-free survival; FDA = United States Food and Drug Administration; FU = follow-up; G = grade; HR = high-risk; n = number; PFS = progression-free survival.
[a] FDA-approved drug.

mary tumours or patients with intermediate-risk recurrent tumours with a prior recurrence rate of <1 recurrence/yr, and those with a 2006 EORTC recurrence score <5 benefited [97]. SI with mitomycin C (MMC), epirubicin, or pirarubicin [97], as well as gemcitabine [99], have all been shown to lower the intravesical recurrence rate. Prevention of tumour cell implantation should be initiated within the first few hours after TURB. To allow for optimal compliance with this level 1 evidence, clinical teams are encouraged to explore barriers and facilitators within their practice [100].

Additional adjuvant intravesical chemotherapy instillations

The need for further adjuvant intravesical therapy depends on prognosis. In patients at low-risk, a SI reduces the risk of recurrence and is considered to be the standard [97]. However, for other risk categories, an SI remains an incomplete treatment due to the considerable likelihood of disease recurrence and/or progression.

(a) *Single installation only versus SI and further repeat instillations* – In one study, further chemotherapy instillations after SI improved RFS in patients with intermediate-risk [101].
(b) *Repeat chemotherapy instillations versus no adjuvant treatment* – A meta-analysis showed an absolute reduction of 13–14% for patients treated with TURB and chemotherapy instillations compared to those with TURB alone [102].
(c) *Single instillation + further repeat instillations versus later repeat instillations only* – An RCT comparing SI of MMC with an instillation of MMC delayed until 2 wk after TURB (followed by further repeat instillations in both treatment arms) showed a significant reduction of 9% in the risk of recurrence at 3 yr in favour of SI [103]. Since the author's definition of the risk groups differed significantly in the initial publication, they adapted their patient stratification in the second analysis and consistently showed improved efficacy of SI followed by repeat MMC instillations [104]. Another RCT found no impact of SI with epirubicin followed by further chemotherapy or BCG instillations in a cohort of patients predominantly at high-risk of BC [105].
(d) *The optimal schedule of intravesical chemotherapy instillations* – The length and frequency of repeat chemotherapy instillations are still debated [106]; however, it should not exceed 1 yr [107].

3.5.2.3. Measures to improve the efficacy of intravesical chemotherapy.

(a) *Adjustment of pH, duration of instillation, and drug concentration*

Two RCTs showed that optimised intravesical administration of MMC reduced recurrence rates by a combination of measures (higher MMC dose, oral sodium

Table 12 – Treatment options for BCG-unresponsive tumours – Carcinoma *in situ* ± papillary

Carcinoma *in situ* ± papillary								
Compound	Study design	*n*	FU (mo)	Complete response (%)			PFS	Adverse events
				3 mo	6 mo	12 mo		
Intravesical								
NADOFARAGENE FIRADENOVEC[a] [74]	Phase III Cis Cohort NCT02773849	103	19.7	53.4	40.8	24.3		G3 4%
CREMOSTIMOGENE GRENADENOREPVEC (CG0070) [75]	Phase II	45			58 CIS 50 CIS+P			G1-2 82.5% G ≥ 3 4.5%
N-803 Nogapendekin Alfa Inbakicept + BCG[a] [76]	Phase II/III QUILT 3032 CA	82	23.9	55.0	56.0	45.0		G1-2 86% G ≥ 3 23%
TAR 200[a] [77]	Phase II b SunRISe-1 C2 NCT04640623	81	20.2	78.8	58.8	45.9	94.3	Any G 83.5% G ≥ 3 12.9%
RITE [78]	Phase III HYMN NCT01094964	61	36	30 vs. 47				G1-2 81%
EMDA-MMC [79]	Phase II	8	36	62.5		35.5		23.1 % local / 11.5 Allergic
VALRUBICIN[a] [80,81]	Phase III	87	30		21			86% Bladder 50% other 20 SAEs 2 TRSAEs
GEMCITABINE DOCETAXEL [82]	Phase II	19	14		75 HR RFS	69 HR RFS	91.4	G1-2 75% G ≥ 3 2.5%
Systemic								
PEMBROLIZUMAB[a] [83]	Phase II Cohort A KEYNOTE-057 NCT02625961	96	36.4	41.0		18.7		G1-2 53.0% G ≥ 3 13%
ATEZOLIZUMAB [84]	Phase II Cohort A SWOG 1605 NCT02844816	74	41	43	27.0		90.5	G1-2 70.0% G ≥ 3 14%
CETRELIMAB [77]	Phase II b SunRISe-1 C3 NCT04640623	28	29.2			38.5		Any G 53.6% G ≥ 3 7.1%
Combination intravesical and systemic								
CREMOSTIMOGENE GRENADENOREPVEC + PEMBROLIZUMAB [85]	Phase II CORE-001 Trial NCT04387461	35	26.5	82.9%	57.1%	51.4 %		G3 14.3%
TAR 200 + CETRELIMAB [77]	Phase II b SunRISe-1 C1 NCT04640623	53	33.4			55.6		Any G 92.5% G ≥ 3 37.7%

BCG = bacillus Calmette-Guérin; CIS = carcinoma *in situ*; DFS = disease-free survival; FDA = United States Food and Drug Administration; FU = follow-up; G = grade; HR = high-risk; n = number; PFS = progression-free survival; RFS = recurrence-free survival.
[a] FDA-approved drug

bicarbonate, and refraining from drinking) [108], or by adding cytosine arabinoside [109]. Another trial reported that a duration of a 1-h instillation of MMC was more effective compared to a 30-min instillation [110]. Another RCT using epirubicin documented that concentration is more important than treatment duration [111].

(b) *Device-assisted intravesical chemotherapy*

- Microwave-induced hyperthermia effect (RITE) – One RCT showed improved 24-mo RFS with MMC plus microwave hyperthermia compared to BCG in patients at intermediate and high risk [112].
- Conductive chemohyperthermia – RCTs in intermediate-risk NMIBC showed no DFS advantage over standard MMC at 24 mo [113,114]. A small high-risk study reported early outcomes comparable to BCG [115].
- Electromotive drug administration – Sequential MMC with EMDA plus BCG demonstrated efficacy in a small RCT in patients with high-risk disease [116].

3.5.2.4. Intravesical bacillus Calmette–Guérin immunotherapy.

3.5.2.4.1. Efficacy of BCG. Recurrence rate – Five meta-analyses have confirmed that BCG after TURB is superior to TURB alone or TURB plus chemotherapy for preventing the recurrence of NMIBC [117–121]. Three RCTs of intermediate- and high-risk tumours have compared BCG with epirubicin and interferon (IFN) [122], MMC [123], or epirubicin alone [124], and have confirmed the superiority of BCG for the prevention of tumour recurrence. An IPD meta-analysis demonstrated a 32% reduction in the risk of recurrence for BCG compared to MMC in trials with BCG maintenance, but a 28% increase for patients treated without BCG maintenance [117]. In addition, a Cochrane system-

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Table 13 – Recommendations for adjuvant therapy in TaT1 tumours and for therapy of carcinoma *in situ*

General recommendations	Strength rating
Counsel smokers to stop smoking.	Strong
The type of further therapy after transurethral resection of the bladder tumour (TURBT) should be based on the risk groups shown in Section 6.3 and Table 6.1. For determination of a patient's risk group, use the 2021 European Association of Urology (EAU) risk group calculator available at www.nmibc.net.	Strong
In patients with tumours presumed to be at low risk and in those with small papillary recurrences (presumably Ta LG/G1) detected more than 1 yr after previous TURBT, offer one immediate single chemotherapy instillation.	Strong
Offer postoperative saline or water continuous irrigation of the bladder to patients who cannot receive a single instillation of chemotherapy.	Strong
Patients with small, recurrent low-grade (LG) Ta tumours can be effectively and safely offered office fulguration.	Strong
Offer active surveillance (AS) and/or chemoablation to selected patients with presumed LG tumours as an alternative to endoscopic ablation.	Weak
In patients with high-risk tumours, full-dose intravesical bacillus Calmette-Guérin (BCG) for one to 3 yr (induction plus 3-weekly instillations at 3, 6, 12, 18, 24, 30, and 36 mo), is indicated. The additional beneficial effect of the second and third years of maintenance should be weighed against its added costs, side effects and access to BCG. Immediate radical cystectomy (RC) should also be discussed with the patient.	Strong
In patients with very high-risk tumours, discuss immediate RC. Intravesical full-dose BCG instillations for 1 to 3 yr remain an option for selected patients, particularly those who decline or are unfit for RC.	Strong
Discuss the benefits and harms of adding sasanlimab and durvalumab to BCG with maintenance in selected BCG-naïve patients with high- and very high-risk NMIBC.	Strong
Offer transurethral resection of the prostate, followed by intravesical instillation of BCG, to patients with CIS in the epithelial lining of the prostatic urethra, if a bladder sparing strategy is considered.	Weak
Cautiously offer quinolones to treat BCG-related side effects[a].	Weak
The definition of "BCG-unresponsive" should be respected because it most precisely defines the patients who are unlikely to respond to further BCG instillations.	Strong
Offer an RC to patients with BCG-unresponsive tumours.	Strong
Offer patients with BCG-unresponsive tumours, who are not candidates for RC due to comorbidities, or who decline RC, preservation strategies (intravesical chemotherapy, chemotherapy and microwave-induced hyperthermia, electromotive administration of chemotherapy, intravesical- or systemic immunotherapy; preferably within clinical trials).	Weak
Discuss high-risk and very patients with high-risk within a multidisciplinary board, when possible.	Strong
Recommendations – technical aspects for treatment	
Intravesical chemotherapy	
If given, administer a single immediate instillation of chemotherapy within 24 h after TURBT.	Weak
Omit a single immediate instillation of chemotherapy in any case of overt or suspected bladder perforation or bleeding requiring bladder irrigation.	Strong
The optimal schedule and duration of further intravesical chemotherapy instillation is not defined; however, it should not exceed 1 yr.	Weak
If intravesical chemotherapy is given, use the drug at its optimal pH and maintain the concentration of the drug by reducing fluid intake before and during instillation.	Strong
The length of individual instillation should be a minimum of 1 h and up to 2 h.	Weak
BCG intravesical immunotherapy	
Absolute contraindications of BCG intravesical instillation are: • during the first 2 wk after TURBT; • in patients with visible haematuria; • after traumatic catheterisation; and • in patients with symptomatic urinary tract infection.	Strong

[a] The side-effect profile of quinolones and fluoroquinolones resulted in the adoption of European regulation restricting their use [86].

atic review confirmed that BCG is more effective in reducing the recurrence rate than MMC [125].

Progression rate – Two meta-analyses have shown that BCG therapy delays and potentially lowers the risk of tumour progression [121,126]. In one meta-analysis, tumours progressed in 9.8% of patients treated with BCG versus 13.8% in the control groups. The magnitude of the reduction was similar in patients with Ta/T1 papillary tumours and in those with CIS [126]. An RCT with long-term follow-up demonstrated significantly fewer distant metastases and better overall- and disease-specific survival in patients treated with BCG compared to epirubicin [124]. In contrast, an IPD meta-analysis and Cochrane review were not able to confirm any statistically significant difference between MMC and BCG for progression, survival, and cause of death [117,125]. The reduction in the risk of progression was observed if a BCG maintenance schedule was applied.

Influence of other factors – Two meta-analyses have suggested a possible bias in favour of BCG arising from the inclusion of patients previously treated with intravesical chemotherapy [127]. However, BCG maintenance was more effective than MMC in the reduction of recurrence rate, both in patients previously treated and in those not previously treated with chemotherapy, in an IPD meta-analysis [117].

3.5.2.4.2. BCG strain. Several studies have not suggested any clear difference in efficacy between the different BCG strains [126,128,129].

3.5.2.4.3. BCG toxicity. BCG intravesical treatment is associated with more side effects compared to intravesical chemotherapy [125,126]. However, serious side effects are encountered in <5% of patients and can be treated effectively in almost all cases [130]. Major complications can occur after systemic absorption of the drug; therefore, contraindications of BCG intravesical instillation should be

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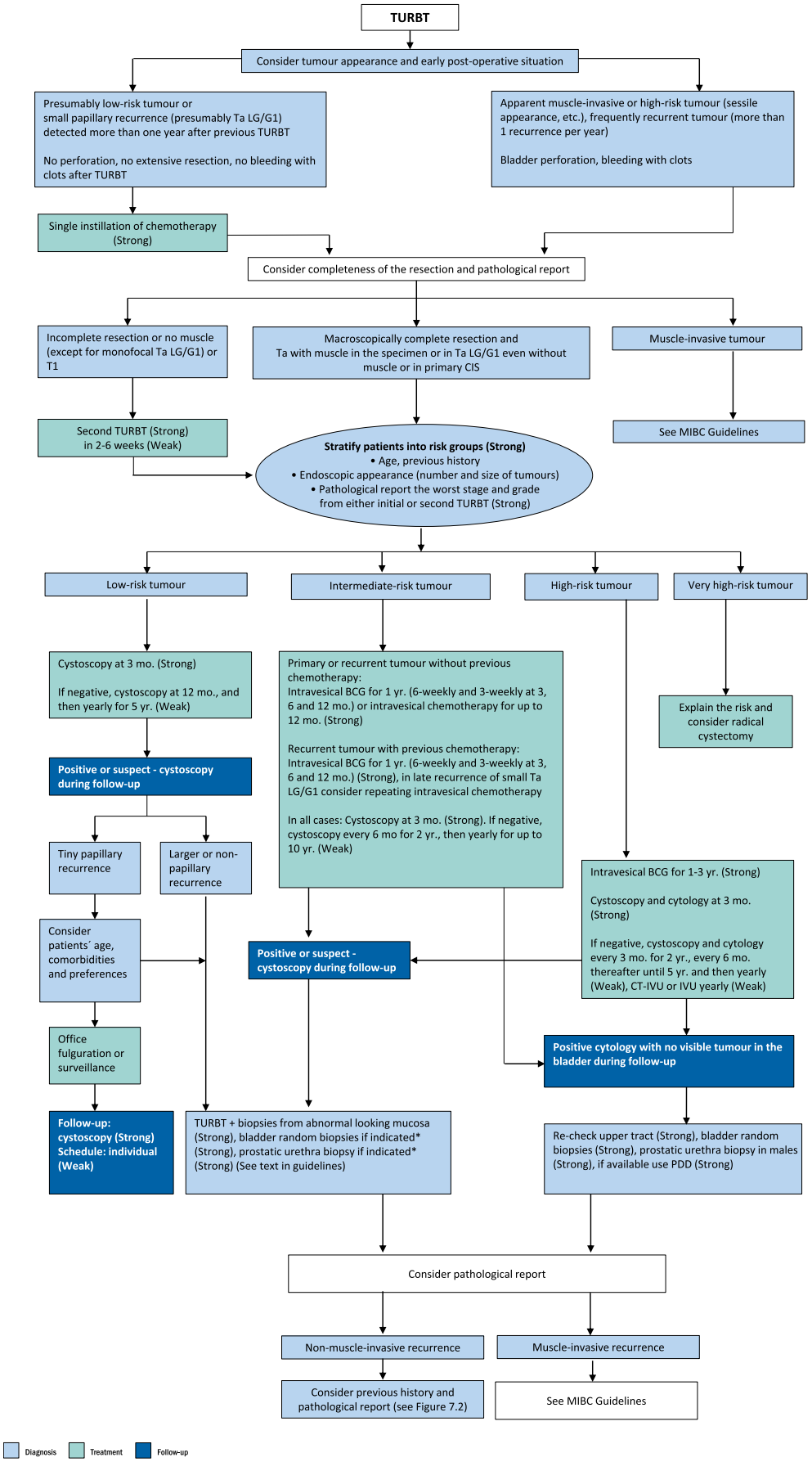

Fig. 2 – Treatment strategy in primary or recurrent tumour(s) without previous BCG. BCG = bacillus Calmette-Guérin; CIS = carcinoma in situ; CT = computed tomography; IVU = intravenous urography; MIBC = muscle-invasive bladder cancer; PDD = photodynamic diagnosis; TURBT = transurethral resection of the bladder tumour.

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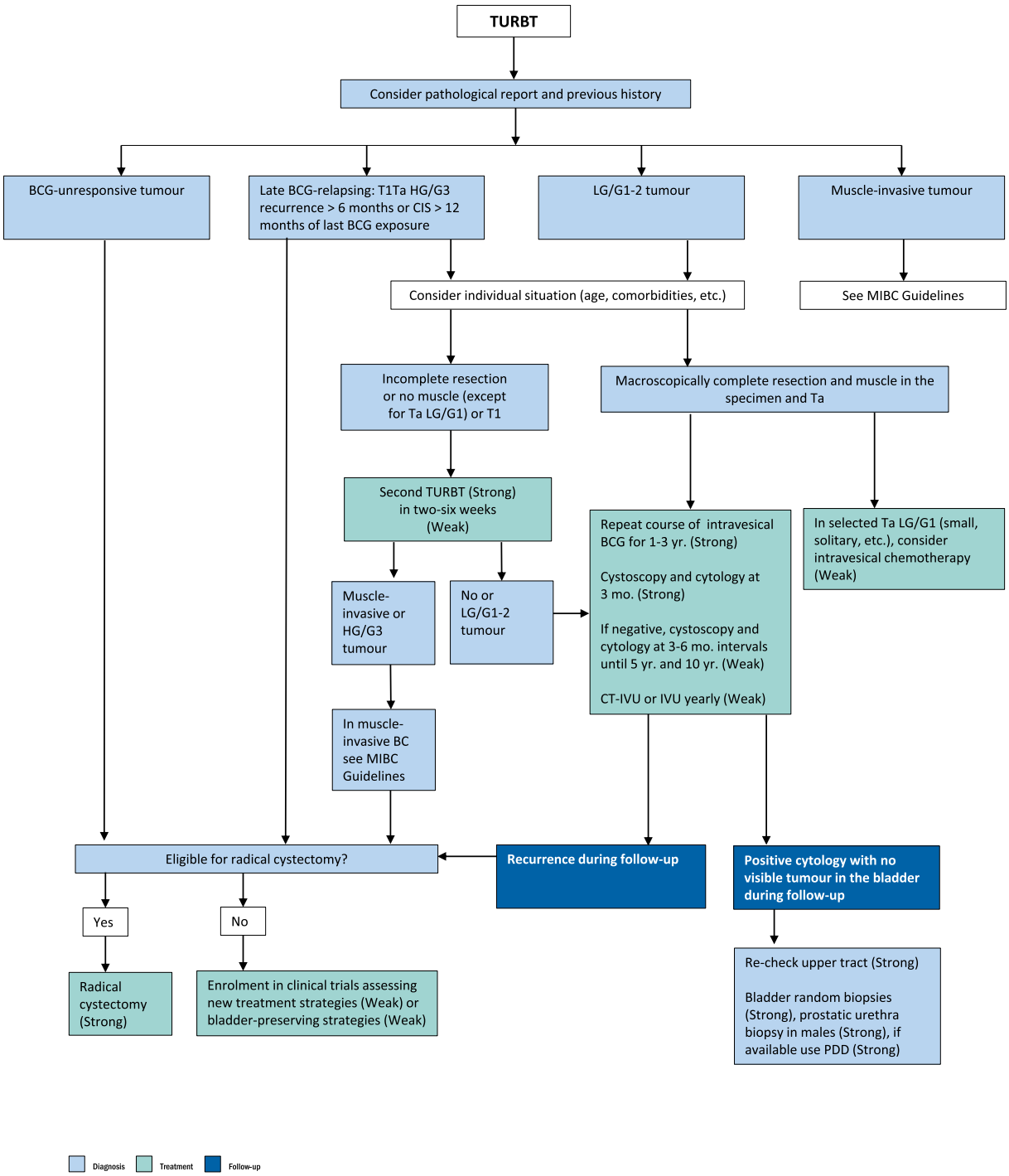

Fig. 3 – Treatment strategy in recurrence during or after intravesical BCG. BCG = bacillus Calmette-Guérin; CIS = carcinoma in situ; CT = computed tomography; HG = high-grade; IVU = intravenous urography; LG = low-grade; PDD = photodynamic diagnosis; TURBT = transurethral resection of the bladder tumour.

respected (Table 12). Side effects can be reduced by administering quinolones in conjunction with BCG instillations [131].

3.5.2.4.4. Optimal BCG schedule. Induction BCG instillations are given according to the empirical 6-weekly schedule [132]. For optimal efficacy, BCG must be given in a maintenance schedule [117,121,126,133]. The NIMBUS trial demonstrated that a reduced number of instillations proved inferior to the standard schedule with regard to time to first recurrence [134]. Another RCT showed that in patients with high-risk tumours, a maintenance schedule with only one instillation every 3 mo for 3 yr was not superior to induction therapy alone, which suggested that one instillation may be suboptimal compared with three instillations in each maintenance cycle. A meta-analysis concluded that at least 1 yr of maintenance BCG is required to obtain superiority of BCG over mitomycin C (MMC) for prevention of recurrence or progression [133]. The EORTC RCT showed that full-dose BCG with 3 yr of maintenance (three weekly instillations at 3, 6, 12, 18, 24, 30, and 36 mo) significantly

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reduces recurrence compared to 1 yr in patients with high-risk disease. In contrast, 1 yr of maintenance appears to be sufficient in patients with intermediate-risk, with no additional benefit from longer treatment maintenance [135].

3.5.2.4.5. Optimal dose of BCG. To reduce BCG toxicity, instillation of a reduced dose was proposed. The CUETO study compared one-third dose to full-dose BCG and found no overall difference in efficacy. A further reduction to one-sixth dose resulted in a decrease in efficacy with no decrease in toxicity [136]. The EORTC did not find any difference in toxicity between one-third and full-dose BCG, but one-third dose BCG was associated with a higher recurrence rate, especially when it was given only for 1 yr [135,137]. In another meta-analysis patients who received less than half of the standard BCG dose experienced less adverse events compared to patients receiving the full dose, but faced more unfavourable outcomes such as higher rates of disease recurrences [138].

3.5.2.5. Combination therapy.

3.5.2.5.1. Intravesical BCG plus chemotherapy versus BCG alone. In one RCT, a combination of MMC and BCG was shown to be more effective in reducing the risk of disease recurrence while increasing toxicity compared to BCG monotherapy [139]. Two meta-analyses demonstrated improved disease-free survival, but no benefit in PFS in patients treated with combination treatment compared to BCG monotherapy [140,141].

3.5.2.5.2. Combination treatment using interferon. In a meta-analysis, a combination of BCG and IFN-2α did not show a clear difference in recurrence and progression over BCG alone [142]. In one study, weekly MMC followed by monthly BCG alternating with IFN-2α showed a higher probability of recurrence compared to MMC followed by BCG alone [143].

3.5.2.5.3. Sequential chemotherapy instillations (gemcitabine plus docetaxel). Retrospective data have accumulated where sequential gemcitabine and docetaxel instillations have been used in patients recurring after induction BCG and BCG-unresponsive disease [144,145]; in patients with recurrence after BCG induction but not fulfilling the criteria for BCG-unresponsive disease [146]; as well as in BCG-naïve patients with high-risk [147,148].

3.5.2.5.4. Combination treatment with immune checkpoint inhibitors versus BCG alone. The *CREST* trial evaluated the addition of the systemic PD-1 inhibitor sasanlimab to standard BCG induction and maintenance for up to 2 yr versus BCG induction alone plus sasanlimab versus BCG induction and maintenance alone in patients with BCG-naïve high-risk NMIBC [149]. At 36 mo, event-free survival was significantly improved in the sasanlimab plus BCG arm versus BCG alone. No benefit was observed for sasanlimab when given with BCG induction alone. Grade ≥3 treatment-related adverse events occurred in 29.8% of patients receiving sasanlimab plus BCG compared with 6.3% of those receiving BCG alone. Immune-related toxicities were reported in over 40% of patients; these were grade ≥3 in 14% and required hospitalisation in 10%.

The POTOMAC trial assessed whether adding 1 r of intravenous durvalumab to standard BCG induction plus up to 2 yr of maintenance could improve outcomes in patients with high-risk NMIBC compared with BCG alone or BCG induction plus durvalumab. The trial showed an early and sustained improvement in DFS with a significantly higher 2-yr DFS in the durvalumab plus full BCG regimen versus the control while no significant benefit was seen when durvalumab was combined with BCG induction only. Grade 3-4 treatment-related adverse events, mostly immune-mediated, occurred in 21% of patients receiving durvalumab plus full BCG compared with 4% in the control group [150].

In contrast the ALBAN trial found that adding 1 yr of intravenous atezolizumab to 1 yr of BCG maintenance did not improve event-free survival compared with BCG maintenance alone in patients with high-risk NMIBC [151].

At present, sasanlimab and durvalumab may be considered potential add-on options to BCG in carefully selected, well-informed patients; however, these strategies should be approached cautiously, as more mature data are needed and any potential benefits must be weighed against toxicity within a shared decision-making framework.

3.5.3. Intravesical chemoablation and neoadjuvant treatment

Neoadjuvant

Two small neoadjuvant RCTs have reported conflicting results on the ability of neoadjuvant administration of MMC to improve outcomes over the standard approach [152,153].

Chemoablation

In recurrent LG [154] and recurrent Ta tumours [155], 4 and 6 intravesical MMC instillations achieved complete response in 37% and 57% of the patients, respectively. In an update of the latter RCT evaluating chemoablation with 40 mg/40 ml of intravesical MMC three times/wk for 2 wk without preceding biopsy versus standard TURB, no difference in the 12-mo RFS was observed (36% in the chemoablation group vs 43% in the TURB group) [155]. Another RCT compared UGN-102, a mitomycin-containing reverse thermal gel, to TURB alone in patients with LG intermediate-risk NMIBC [156]. The 3-mo complete response rate (CRR) was similar between both groups. In an ongoing phase 3 single-arm study, the same treatment schedule achieved a 79% CRR at 3 mo in patients with recurrent LG intermediate-risk NMIBC, which was maintained in 82% at 1 yr [157]. Despite the lack of long-term outcomes, chemoablation could represent an effective alternative treatment to TURB for well-selected patients with NMIBC.

3.5.4. Radical cystectomy for NMIBC

There are several reasons to consider immediate RC for selected patients with NMIBC:

- Some patients with NMIBC experience disease progression to muscle-invasive disease.
- Patients who experience disease progression to the muscle-invasive stage might have a worse prognosis than those who present with ‘primary’ muscle-invasive disease [158,159].

The potential benefit of RC must be weighed against its risks, morbidity, and impact on quality of life (QoL) and dis-

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Table 14 – Recommendations for the treatment of TaT1 tumours and carcinoma *in situ* according to risk stratification

Recommendations	Strength rating
European Association of Urology (EAU) risk group: Low	
Offer one immediate instillation of intravesical chemotherapy after transurethral resection of the bladder tumour (TURBT).	Strong
EAU risk group: Intermediate	
In general, chemotherapy (the optimal schedule is unknown) is a reasonable first-line option in the majority of patients. One-yr full-dose Bacillus Calmette-Guérin (BCG) treatment (induction plus 3-weekly instillations at 3, 6, and 12 mo), is an alternative option. The final choice should reflect the individual patient's risk of recurrence and progression as well as the efficacy and side effects of each treatment modality. Offer one immediate chemotherapy instillation to patients with small papillary recurrences detected more than 1 yr after previous TURBT.	Strong
EAU risk group: High	
Offer intravesical full-dose BCG instillations for 1 to 3 yr but discuss immediate radical cystectomy (RC).	Strong
EAU risk group: Very high	
Offer RC or intravesical full-dose BCG instillations for 1 to 3 yr, particularly to those who decline or are unfit for RC.	Strong

cussed with patients in a shared decision-making process. It is reasonable to propose immediate RC in those patients with NMIBC who are at very high risk of disease progression [38,60,61,160–163]. Early RC is recommended in patients with BCG-unresponsive tumours and should be considered in BCG-relapsing HG tumours. A delay in RC may lead to decreased disease-specific survival [164].

3.5.5. Primary treatment by disease type

3.5.5.1. Primary treatment by risk category. Recommendations for primary treatment of NMIBC according to risk category for progression (low risk, intermediate risk, high risk, and very high risk) are reported in Table 14.

3.5.5.2. Treatment of carcinoma in situ. The detection of concurrent CIS increases the risk of recurrence and progression of TaT1 tumours [60,61]. Carcinoma *in situ* cannot be cured by an endoscopic procedure alone; the diagnosis of CIS must be followed by further treatment, either intravesical BCG instillations or radical cystectomy.

In retrospective evaluations of patients with CIS, a CRR of 48% was achieved with intravesical chemotherapy and 72–93% with BCG. Up to 50% of complete responders might eventually show recurrence with a risk of invasion and/or extravesical recurrence [67,165–167]. A meta-analysis comparing intravesical BCG to intravesical chemotherapy in patients with CIS has shown a significantly increased response rate after BCG and a reduction of 59% in the odds of treatment failure with BCG [168]. In an EORTC-GUCG meta-analysis of tumour progression, in a subgroup of 403 patients with CIS, BCG reduced the risk of progression by 35% compared to intravesical chemotherapy or immunotherapy [126]. The combination of BCG and MMC was not superior to BCG alone [169].

Patients with CIS are at high risk of extravesical involvement in the UUT and in the prostatic urethra. Patients with CIS in the epithelial lining of the prostatic urethra can be treated by intravesical instillation of BCG [168,170]; however, the data are insufficient to provide clear treatment recommendations, and radical surgery should be considered [170].

3.5.6. Treatment of failure of intravesical therapy

3.5.6.1. Recurrence during or after intravesical chemotherapy. Patients with NMIBC recurrence during or after a chemotherapy regimen can benefit from BCG instillations. Prior intravesical chemotherapy has no impact on the effect of BCG instillations [117].

3.5.6.2. Recurrence during or after intravesical BCG therapy.

3.5.6.2.1. Definitions of BCG failure. Several categories of BCG failures, broadly defined as any HG disease occurring during or after BCG therapy, have been proposed (Table 10). Nonmuscle-invasive BC may not respond at all (BCG refractory) or may relapse after initial response (BCG relapsing). *BCG unresponsive*, which combines BCG refractory and early BCG relapses after receiving 'adequate BCG' (Table 10), defines a disease category associated with an increased risk of progression where additional BCG is unlikely to provide benefit [171]. Conversely, patients who experience recurrence with HG NMIBC after BCG without meeting BCG-unresponsive criteria (either received 'inadequate BCG' or had late relapse) are termed *BCG-exposed* and may benefit from additional BCG therapy [177].

3.5.6.2.2. Treatment of BCG-unresponsive tumours. Patients with BCG-unresponsive disease are unlikely to respond to further BCG therapy; RC is therefore the standard and preferred option. Currently, several bladder preservation strategies are being investigated, such as cytotoxic intravesical therapies [180,181], device-assisted instillations [78,79], intravesical immunotherapy [182], combination of intravesical immune-therapies [183], systemic immunotherapy [184], or gene therapy [75,185]. The treatment options for BCG-unresponsive tumours, separately for CIS-containing Ta/T1 disease and papillary-only NMIBC, are summarised in Tables 11 and 12, respectively. A detailed overview of the different intravesical and systemic treatment options for BCG-unresponsive tumours is provided in the full text EAU NMIBC Guidelines: https://uroweb.org/guidelines/non-muscle-invasive-bladder-cancer.

3.5.6.2.3. Treatment of BCG-exposed tumours and BCG relapses. Various studies suggest that repeat-BCG therapy is appropriate for BCG exposure NMIBC [178,188].

3.5.6.2.4. LG recurrences after BCG. Treatment decisions in LG recurrences after BCG should be individualised according to tumour characteristics. Importantly, LG recurrence after BCG in an intermediate-risk NMIBC setting should be distinguished from LG events occurring in patients originally classified as high-risk or very high-risk, as the latter generally warrant a more intensive therapeutic and follow-up approach. A summary of treatment options according to

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Table 15 – Treatment options for the various categories of BCG failure

Category	Treatment options
BCG-unresponsive	Radical cystectomy. Enrolment in clinical trials assessing new treatment strategies. Other bladder-preserving strategies in patients ineligible for or refusing RC, including approved new treatment strategies when available.
BCG-relapsing: TaT1 HG recurrence >6 mo or CIS >12 mo of last BCG exposure	Radical cystectomy or repeat BCG course according to a patient's individual situation. Enrolment in clinical trials assessing new treatment strategies. Other bladder-preserving strategies.
BCG exposed	Repeat BCG course or RC according to the patient's individual situation. Enrolment in clinical trials assessing new treatment strategies.
LG recurrence after BCG for primary intermediate-risk tumour	Repeat BCG or intravesical chemotherapy. Enrolment in clinical trials assessing new treatment strategies.

Table 16 – Proposed follow-up schedule based on the patient's risk category

Risk group	Cytology[a]	Cystoscopy	Imaging	Duration of follow-up
Low	No	At 3 and 12 mo Then annually	Not systematic	5 yr
Intermediate (not including HG/G3 subgroup)[a]	No	At 3 mo Then every 6 mo for 2 yr Then annually	Not systematic	10 yr
High and Very High	Yes[b]	Every 3 mo for 2 yr Then every 6 mo up to 5 yr Then annually	Computed tomography (CT) annually up to 5 yr, then CT every 2 yr up to 10 yr	Life long

[a] Intermediate-risk HG/G3 subgroup should be followed-up as high-risk
[b] At the same intervals as cystoscopy

the different categories of BCG failures is reported in Table 15.

3.5.7. *Multidisciplinary tumour board*

A multidisciplinary tumour board (MTB) approach, including reassessment of radiology and pathology, is associated with a changed treatment plan in up to 44% of patients with BC [189–192]. Therefore, patients with high-risk and very high-risk NMIBC will especially benefit from MTB discussion and such an approach is recommended for these patients.

3.6. *Follow-up of patients with NMIBC*

Due to the risk of recurrence and progression, patients with NMIBC must be followed up after treatment. The first cystoscopy should always be performed 3 mo after TURB in all patients with TaT1 tumours and CIS [193]. The subsequent frequency and duration of cystoscopy and imaging follow-up should reflect the individual patient's degree of risk. Table 16 presents a possible follow-up schedule based on the patient's risk category. Recommendations for follow-up of patients after TURB are shown in Table 17.

Table 17 – Recommendations for follow-up of patients after transurethral resection of the bladder for non-muscle-invasive bladder cancer

Recommendations	Strength rating
Base follow-up of TaT1 tumours and carcinoma in situ (CIS) on regular cystoscopy.	Strong
Patients with low-risk Ta tumours should undergo cystoscopy at 3 mo. If negative, subsequent cystoscopy is advised 9 mo later, and then yearly for 5 yr.	Weak
Patients with intermediate-risk Ta low-grade tumours should undergo cystoscopy at 3 mo. If negative, subsequent cystoscopy can be repeated every 6 mo for 2 yr, and then annually for 10 yr. The subgroup of patients with intermediate-risk Ta that are high-grade should be followed up as high-risk (see below).	Weak
Patients with high-risk and those with very high-risk tumours should undergo cystoscopy and urinary cytology at 3 mo. If negative, subsequent cystoscopy and cytology should be repeated every 3 mo for a period of 2 yr, and every 6 mo thereafter until 5 yr, and then annually lifelong.	Weak
Take yearly and long-term upper tract imaging (computed tomography [CT] urography) for high-risk and very high-risk tumours.	Weak
During follow-up in patients with positive cytology and no visible tumour in the bladder, mapping biopsies or photodynamic diagnosis-guided biopsies (if equipment is available) and investigation of extravesical locations (CT urography, prostatic urethra biopsy) are recommended.	Strong

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Table 18 – Performance of multiplex urine markers in the surveillance setting

Multiplex urinary marker	Target	Sensitivity Overall[a]	HG[a]	Specificity Overall[a]	HG[a]	n studies / patients
XPERT BC MONITOR [25]	5 mRNAs (*ABL1, CRH, IGF2, ANXA10, UPK1B*)	52–91	79–100	41–91	76–91	11 studies 2800 pts
EpiCheck [26]	15 DNA methylations	62–90	78–95	82–88		6 studies 2236 pts
CX BLADDER [27]	5 mRNAs (*IGF, HOXA, MDK, CDC, IL8R*)	93	95	61	–	1 study 763 pts
UROMONITOR [28,29]	DNA mutations *FDFR 3 + TERT + KRAS*	49–93	–	86–99	–	5 studies 1190 pts
Galeas Bladder [30]	Multiple DNA mutations (n = 443 in 23 genes)	86	100	63	–	1 study 293 pts

DNA = deoxyribonucleic acid; FDFR = fibroblast growth factor receptor; HG = high-grade; KRAS = Kirsten rat sarcoma viral oncogene homolog; mRNA = messenger ribonucleic acid; n = number; TERT = telomerase reverse transcriptase.

[a] Ranges refer to the lowest and the highest value, respectively reported from available individual studies or systematic reviews.

Noninvasive follow-up options include urinary cytology and molecular markers, used alongside flexible cystoscopy to improve detection of HG disease or to guide and potentially reduce cystoscopy frequency. To replace cystoscopy, markers must reliably detect recurrences across risk groups. Although sensitivity for LG recurrences remains limited (40–65%), some 'multiplex' urinary markers that detect multiple genetic alterations show high sensitivity for recurrences, particularly in HG disease, and very high negative predictive values, supporting their potential future role in follow-up. Additionally, two randomised trials explored the use of marker-guided surveillance in low/intermediate-risk patients [194] and HG tumours [195], respectively, with both studies showing noninferiority compared to standard surveillance. Table 18 summarises the performance of multiplex urine markers in the surveillance setting.

3.7. Patient-reported outcome measures and quality indicators for NMIBC

Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) have been developed to gauge the impact of treatment and surveillance on patients with a view to improving the quality of care. The use of PROMs is an important endpoint for quality metrics and RCTs should systematically incorporate PROMs for patient-centred research design [196]. Evidence-based QIs and QPIs are designed to be surrogates of good practice and, consequently, outcomes. Several QIs for BC have been suggested. Successful implementation of a QI programme has the potential to inspire and catalyse clinical excellence in contemporary BC practice [197].

3.8. Pragmatic de-intensification strategy for NMIBC

Managing NMIBC is increasingly challenging due to ageing populations and rising healthcare costs, requiring efficient, patient-centred care. Evidence supports de-intensified strategies such as AS, chemoablation, and office fulguration for recurrent LG Ta disease without compromising oncological safety [198].

Guidelines recommend shared decision-making to reduce treatment intensity where appropriate, including omitting detrusor muscle resection in LG Ta tumours, selective use of single post-TURBT chemotherapy, selective re-TURB in high-risk NMIBC, conservative options for recurrent LG Ta disease, BCG as an alternative to cystectomy in selected very patients with high-risk, bladder-preserving approaches for BCG-unresponsive disease, reduced surveillance intensity, and supportive care in frail patients.

Author contributions: Emma J. Smith had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Gontero, Smith.
Acquisition of data: Gontero, Baard, Birtle, Botha, Capoun, Compérat, D'Andrea, Dominguez-Escrig, Fiorini, Liedberg, Mariappan, Masson-Lecomte, Moschini, Pradere, Rai, van Rhijn, Seisen, Shariat, Smith, Soria, Soukup, Teoh, Wood, Xylinas.
Analysis and interpretation of data: Gontero, Baard, Birtle, Botha, Capoun, Compérat, D'Andrea, Dominguez-Escrig, Fiorini, Liedberg, Mariappan, Masson-Lecomte, Moschini, Pradere, Rai, van Rhijn, Seisen, Shariat, Smith, Soria, Soukup, Teoh, Wood, Xylinas.
Drafting of the manuscript: Gontero, Smith.
Critical revision of the manuscript for important intellectual content: Gontero, Baard, Birtle, Botha, Capoun, Compérat, D'Andrea, Dominguez-Escrig, Fiorini, Liedberg, Mariappan, Masson-Lecomte, Moschini, Pradere, Rai, van Rhijn, Seisen, Shariat, Smith, Soria, Soukup, Teoh, Wood, Xylinas.
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company speaker honoraria fees from Johnson & Johnson, Astellas, MSD, Merck, Accord and Bayer; serving as a company consultant to MSD, Bayer, Macrogenics and Ipsen; serving on the advisory board of Macrogenics, Johnson & Johnson, Astellas, Merck and AstraZeneca; being a trustee/medical advisor to Fight Bladder Cancer; and being a member of the ESMO Educational Committee. E.M. Compérat reported serving as a company consultant to Daiitchi, Johnson & Johnson and Astra. J.L. Dominguez-Escrig reported receiving company speaker honoraria fees from Presurgy, BMS and Angiodynamics; attending advisory board meetings as a company consultant to Astellas; and participation in clinical trials by Janssen, Arquer, Physion, Combat BRS, Ipsen, Storz, Uromonitor, Fidia Farmaceutici and Angiodynamics. P. Mariappan reported receiving company speaker honoraria fees from BMS, Janssen Cilag, Medac Pharma and Photocure; serving on the core committee of the International Bladder Cancer Group; receiving grants or research support from Nucleix; and participation in clinical trials by Nucleix. A. Masson-Lecomte reported receiving company speaker honoraria fees from Astellas Pharma, BMS, Ferring, Medac and MSD; attending advisory board meetings as a company consultant to Janssen Global Bladder Cancer and Pfizer; being an academy faculty adviser to Photocure; receiving grants or research support from Ferring and Ipsen Pharma; and participation in clinical trials by Janssen Cilag and MSD. B. Pradere reported receiving company honoraria or consultation fees from Astellas Pharma, Ferring, Johnson & Johnson, Laboratoires MSD, Ipsen Pharma and Photocure; serving as a company consultant to Johnson & Johnson; and participation in clinical trials by AstraZeneca and Johnson & Johnson. B.P. Rai reported receiving company speaker honoraria fees from Ipsen, Janssen Cilag and Bayer. B.W.G. van Rhijn reported receiving advisory board meeting company consultation fees from Cepheid. T. Seisen reported receiving company honoraria or consultation fees from ADACAP, Astellas, Bayer, BMS, Ipsen, Janssen, MSD, Pfizer and VitaDX; receiving grants or research support from Institut de Recherche Servier and Ipsen; receiving fellowship or travel grant support from Institut de Recherche Servier; and participation in clinical trials by AstraZeneca, Ferring, Janssen and Roche. S.F. Shariat reported receiving company honoraria or consultation fees from Astellas Pharma, AstraZeneca, Bayer Austria, BMS, Ferring, Johnson & Johnson, MSD and Pfizer; and is the owner of four patents. J. Teoh reported receiving company speaker honoraria fees from Ferring Pharmaceuticals, Olympus Corporation and Astellas; serving as a company consultant to Johnson & Johnson, Ferring and MSD; receiving grants or research support from Olympus Corporation; and participation in clinical trials by AstraZeneca, BMS and Johnson & Johnson. E.N. Xylinas reported receiving company honoraria or consultation fees from Pfizer, Astellas, AstraZeneca, Boston Scientific, BMS, Ferring, Johnson & Johnson, Merck, MSD and Pfizer; receiving grants or research support from AstraZeneca, Boston Scientific and Ferring; participation in clinical trials by AstraZeneca, Janssen Cilag, MSD and Pfizer; and serving in a leadership role for the Association Française d'Urologie. D. D'Andrea reported receiving company speaker honoraria fees from Merck, Photocure, Olympus and Pfizer; and serving as a company consultant to Cepheid. O. Capoun reported receiving company honoraria or consultation fees from Accord Healthcare, Astellas Pharma, AstraZeneca, Bayer, Janssen and Novartis; and participation in clinical trials by Bayer and Janssen. M. Moschini reported receiving company honoraria or consultation fees from Janssen Cilag, Medac Pharma, Photocure and Johnson & Johnson; and serving as a company consultant to Pfizer Italiana. F. Soria reported receiving company honoraria or consultation fees from Medac Pharma, Johnson & Johnson, Photocure, Pfizer, AstraZeneca and Cepheid; and participation in clinical trials by Fidia Farmaceutici, Janssen, Steba biotech and Catalym. F. Liedberg, V. Soukup, E. Fiorini, M Botha, E.J. Smith and R. Wood have nothing to declare.

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