BJU Int 2026; **137:** 639–649 doi:10.1111/bju.70126

BJUI
BJU International

Original Article

Quality of life and cost-effectiveness of intravesical gemcitabine/docetaxel vs BCG in BCG-naïve non-muscle-invasive bladder cancer

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Objective

To compare intravesical gemcitabine/docetaxel (Gem/Doce) vs standard-of-care bacillus Calmette–Guérin (BCG) in intermediate-/high-risk non-muscle-invasive bladder cancer (NMIBC), as patient-reported physical-psychological quality of life (QoL) and cost-effectiveness estimation are pivotal to evaluate adjuvant intravesical treatments yet are rarely evaluated head-on.

Patients and Methods

In a prospective per-protocol analysis (Gem/Doce 39 patients; BCG 44 patients), survival endpoints (recurrence-free survival [RFS], progression-free survival [PFS]) and National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE)-graded adverse events (AEs) were recorded. QoL was assessed at baseline, post-induction, and at 6 and 12 months using the European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire-30-item core (EORTC QLQ-C30) and 24-item QLQ-NMIBC (QLQ-NMIBC24) and mapped to the EuroQoL five Dimensions five Levels (EQ-5D-5L) using an Indian tariff to estimate quality-adjusted life years (QALYs). Direct medical costs were recorded, and incremental cost-effectiveness ratios (ICERs) were calculated per QALY and recurrence/progression outcomes.

Results

Patients receiving Gem/Doce achieved higher 1-year RFS (94.74% vs 75%, hazard ratio 0.44; $P = 0.02$) and PFS (100.00% vs 93.19%, $P = 0.09$). The AEs were fewer with Gem/Doce (12.82% vs 34.10%, $P = 0.028$); Grade 3 events occurred only with BCG (4.65%). Gem/Doce showed significantly higher global health, physical/role/emotional functioning and sexual health scores at 6–12 months, with reduced fatigue, urinary symptoms and intravesical-treatment problems. Mean QALYs improved with Gem/Doce (0.8807 vs 0.7198), and with an ICER of ₹504 000 Indian Rupees ($6072 United States Dollars) per QALY – well within India's willingness-to-pay threshold and far below international benchmarks. Additional gains included +1.38 recurrence-free months overall and +2.82 in high-risk patients, achieved at acceptable incremental cost, indicating pragmatic cost profile against avoided recurrences and QoL gains.

Conclusions

Sequential Gem/Doce delivered optimal short-term survival outcomes, favourable patient-reported QoL and safety profile, and attractive cost per avoided recurrence/progression compared with BCG, supporting its adoption as a clinically and economically viable alternative in resource-constrained NMIBC care.

Keywords

NMIBC, gemcitabine/docetaxel, quality-of-life, BCG, ICER

Introduction

Urinary bladder cancer ranks as 17th most common malignancy in India, with 5-year prevalence of 35.7 per million population [1]. Its management expenditure is amongst the costliest of all cancer entities, averaging from ₹5 to 7 lakh (10^5 Indian Rupees) ($7000–10 000 United States Dollars [USD]) in Indian scenario [2,3]. Urothelial carcinoma

accounts for 90% of bladder cancer cases in India, further stratified as muscle-invasive bladder cancer (MIBC) and non-MIBC (NMIBC) based on depth of invasion [4]. Approximately 70% patients have NMIBC at presentation, which is managed initially with transurethral resection of bladder tumour (TURBT) followed by risk-stratification and adjuvant intravesical therapy in intermediate- and high-risk categories to reduce recurrence and progression [4,5]. NMIBC is associated with 50–70% recurrence rate and 10–20% progression risk (to MIBC); nevertheless, 5-year survival rate remains at 80–90%, leading to recurring long-term costs for additional radiological/endoscopic surveillance, tumour resections and adjuvant therapies added to other hidden lifestyle cost modifications [4–6]. The superiority of adjuvant intravesical BCG in preventing recurrence and progression of NMIBC is well established; however, its significant adverse effects often impact patient tolerance and contribute to treatment cessation [5,7]. Furthermore, ongoing worldwide standardisation and production constraints have necessitated evaluation of effective alternatives for both first-line and salvage settings. Amongst them, intravesical gemcitabine/docetaxel (Gem/Doce) combination has demonstrated comparable oncological outcomes with a favourable tolerability profile [8,9].

Treatment-related adverse events (AEs), along with restrictions in work-productivity and social participation during treatment course significantly affect quality of life (QoL) [2,7]. However, only a limited number of studies have systematically compared QoL outcomes between intravesical Gem/Doce and BCG in NMIBC. Existing literature predominantly focuses on oncological efficacy and safety, whereas QoL outcomes are infrequently reported or are derived from non-standardised single-centre experiences. Consequently, strong comparative evidence assessing validated patient-reported QoL measures and economic impact of intravesical Gem/Doce vs BCG remains scarce, particularly within Indian healthcare settings [10,11]. This study sought to address this gap through patient-reported outcomes and cost-effectiveness evaluation between these two therapeutic modalities.

Patients and Methods

This prospective randomised interventional study was conducted in the Department of Urology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, from June 2023 to April 2025, after obtaining approval from the Institute Ethical Committee (Reference number: 2024/EC/7066).

Study Population

Patients aged 18–80 years with localised urinary bladder lesion(s) and Eastern Cooperative Oncology Group (ECOG) performance status 0–2, with histopathological diagnosis of Ta/T1 NMIBC (urothelial carcinoma) after complete TURBT and categorised as intermediate- or high-risk (as per the European Association of Urology [EAU]-NMIBC risk classification) were included [4]. Exclusion criteria comprised the presence of metastatic disease, concomitant upper tract urothelial carcinoma, variant histopathology, prior exposure to either intravesical therapies within 6 months, pregnancy, and active UTI or genitourinary tuberculosis. Sample size estimation was based on Indian bladder-cancer prevalence data from GLOBOCAN 2020, supplemented with departmental patient footfall statistics. *Post hoc* power analysis based on prior observed recurrence-free survival (RFS) difference between Gem/Doce and BCG groups (Δ = 12%, α = 0.05, β = 0.20) indicated requirement of a minimum of 72 participants (36 per group) to achieve 80% statistical power. Eligible participants were counselled in detail regarding both adjuvant modalities under evaluation, and those providing informed consent underwent software-based block randomisation (using SealedEnvelope software [12], maintaining a 1:1 allocation ratio (block size = four) to minimise selection bias) into two adjuvant treatment arms:

Group I: intravesical Gem/Doce.

Group II: intravesical BCG.

The allocation sequence was created by an independent statistician not involved in patient recruitment or data analysis, and sequentially numbered, opaque, sealed envelopes were used to maintain allocation concealment until enrolment. Induction phase of either intravesical therapy was initiated 3–4 weeks after TURBT. Surveillance cystoscopy and urine cytology was performed 2 weeks after the induction phase and every 3 months during the maintenance phase until completion. On suspicious cystoscopy or cytology findings, additional diagnostic procedures—random bladder biopsies, urethral biopsies, upper tract barbotage cytology, CT urography—were employed. Subsequent management, involving either continuation of intravesical therapy or further surgical intervention, was guided by histopathological analysis. The analysis followed a per-protocol design, including only those patients who completed the induction and maintenance intravesical therapy schedules and follow-up assessments.

Protocol for Gem/Doce Group (Group I)

The induction phase comprised six weekly cycles of sequential intravesical instillation of 1000 mg gemcitabine followed by 40 mg docetaxel, each diluted in 50 mL normal saline, as per established protocol [9]. After post-induction surveillance, maintenance instillations were administered

monthly, for up to 12 months in intermediate-risk and 36 months in high-risk cases.

Protocol for BCG Group (Group II)

The induction phase involved six weekly instillations of 80 mg Onco-BCG followed by maintenance phase as per the Southwest Oncology Group (SWOG) schedule (three weekly instillations at the third, sixth, and then every 6 months thereafter, for a total duration of 1 year in intermediate-risk and 3 years in high-risk patients).

Parametric Elucidation

Data were recorded until 1 year of maintenance therapy in both treatment groups. Oncological outcomes, AEs, patient-reported QoL measures, and treatment-related costs were evaluated at baseline (pre-induction), post-induction, and at 6- and 12-months during the maintenance phase. RFS was stated as the time from induction initiation to relapse/recurrence detection during surveillance. Progression-free survival (PFS) referred to the time from induction to disease progression (T2–T4 lesion development, radical cystectomy requirement, radiological lymph node involvement, or metastasis detection). Cancer-specific survival denoted the time from induction to death attributed to bladder cancer, while overall survival represented the time from induction to death from any cause. AEs were classified and graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 5 [13].

The QoL Evaluation

Individual QoL outcomes were assessed at predefined time points using two validated Hindi-language questionnaires: the European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire-30-item core (EORTC QLQ-C30, version 3.0) and its NMIBC–specific module the 24-item EORTC QLQ-NMIBC24, with legal authorisation from EORTC [14,15]. The QLQ-C30 evaluates five functional domains (physical, role, emotional, cognitive, and social functioning), three symptom domains (fatigue, pain, nausea/vomiting), global health status/QoL scale, and six single-item measures (dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial difficulties) [14]. The QLQ-NMIBC24 evaluates urinary symptoms, malaise, future worries, bloating/flatulence, and sexual functioning [15]. Raw scores in each instrument were averaged and linearly transformed to a 0–100 scale: higher functional/global health scores indicate better QoL, whereas higher symptom scores denote greater burden [14,15].

The Quality-Adjusted Life Year (QALY) Estimation

The patient-reported EuroQoL five Dimensions five Levels (EQ-5D-5L) questionnaire evaluates five dimensions—mobility, self-care, activities, pain/discomfort, anxiety/depression—to provide a QALYs utility score, where a score of '1' indicates perfect health and '0' indicates death [16]. The QLQ-C30 and QLQ-NMIBC24 scores were converted to EQ-5D-5L scores using the Versteegh et al. (2012) [16] mapping algorithm with a validated Indian value set (Jyani et al. (2022) [16–18]). The 1-year QALY was calculated with the trapezoidal area under the curve of RFS/PFS with linear interpolation using the following formula:

$QALY_{0-12months} = \sum(U_k + U_{k+1})/2 \times \Delta t_{k\rightarrow k+1}$ – where U is utility value, k is time interval index, and $\Delta t_{k\rightarrow k+1}$ is duration between consecutive utility measurement points [17].

Cost-Effectiveness Analysis

Cost analysis was performed in Indian Rupees (INR, ₹) from the healthcare payer's perspective based on actual per-patient expenditure at the present centre (central government-funded tertiary level public hospital), and converted to USD using the average exchange rate during study period 2023–2024 fiscal year ($1 = ₹83) to facilitate international comparison. The costs of intravesical therapy, TURBT, surveillance procedures, radical cystectomy, and AE management were recorded for each patient and averaged for comparative analysis. Incremental cost-effectiveness ratios (ICERs) were calculated as [19]:

$ICER = [Cost_{Gem/Doce} - Cost_{BCG}] \div [Effect_{Gem/Doce} - QALY_{BCG}]$, where effects were assessed in terms of QALYs gained and RFS/PFS events. Interpretation was performed against Indian's willingness-to-pay (WTP) thresholds of ₹200 000–600 000 per QALY (~$2400–7200 USD) (1–3 × GDP per capita per QALY) [20,21].

Statistical Analysis

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS®), version 25 (IBM Corp., Armonk, NY, USA). Evaluation involved unpaired *t*-test/Mann–Whitney *U* test for continuous variables, and chi-square/Fisher's exact test for categorical variables. The Kaplan–Meier method was used for survival analyses. Hazard ratios (HRs) with corresponding 95% CIs were computed using Cox proportional-hazards regression. A $P \leq 0.05$ was taken as statistically significant.

Results

After appraising eligibility criteria and excluding patients lost to follow-up, data of 39 patients in Group I and 44 patients in Group II who completed adjuvant intravesical treatments were analysed. The Consolidated Standards of Reporting Trials (CONSORT)-style flow diagram (Fig. 1) summarises patient screening, randomisation, allocation, and follow-up.

Fig. 1 The CONSORT diagram of study design.

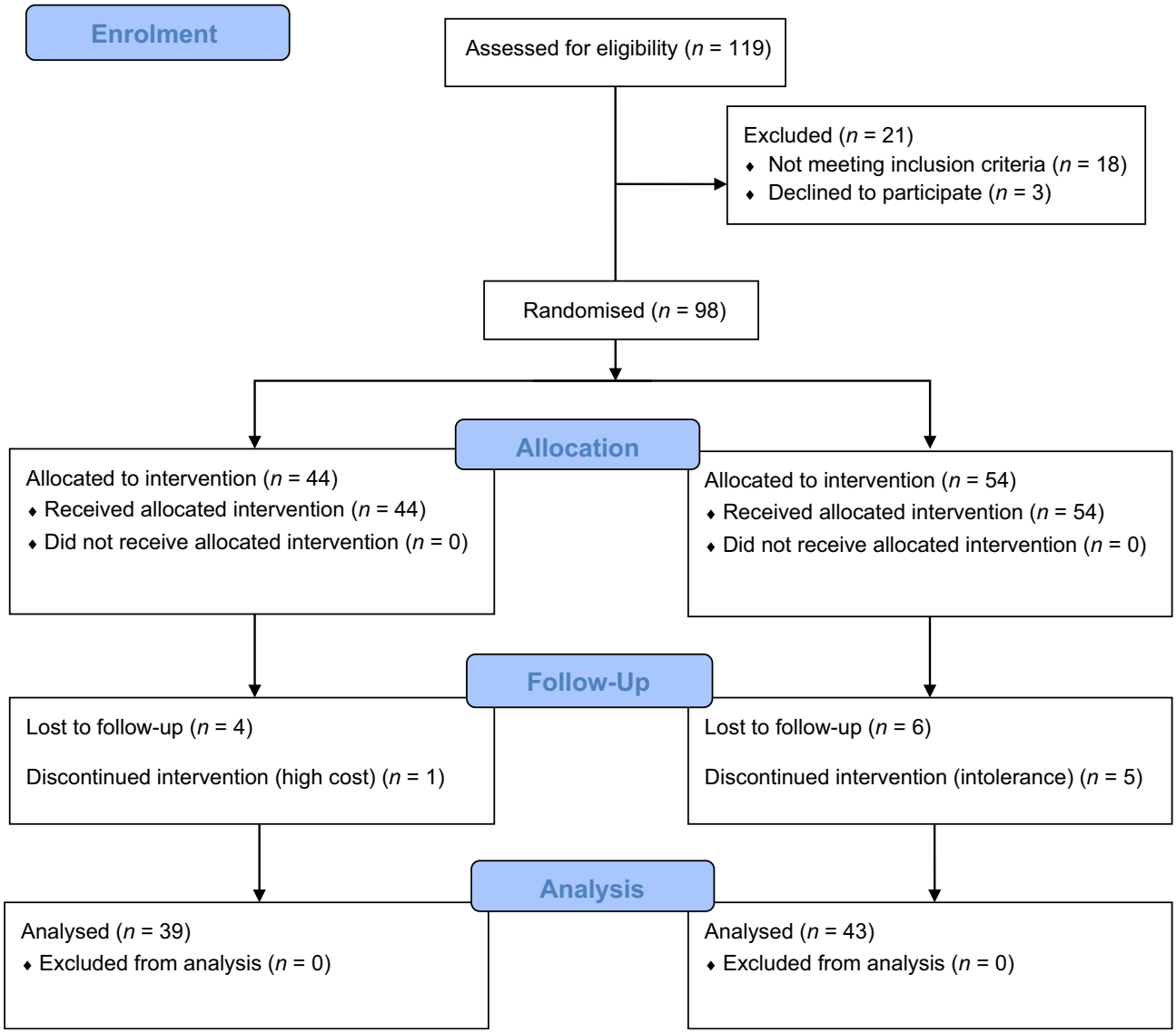

Table 1 delineates the baseline characteristics and survival analysis between the two groups.

Recurrence rates were significantly lower with Gem/Doce than BCG (overall and in the intermediate-risk category), with a HR indicating a lower risk of recurrence with Gem/Doce therapy. No progression occurred in Gem/Doce, whereas three BCG patients (one of intermediate-, two of high-risk categories) progressed at 9–11 months and underwent radical cystectomy. One high-risk BCG patient died from procedure-related complications after cystectomy, while a high-risk patient in the Gem/Doce group died of an unrelated acute cardiac event during the 10th month. Survival outcomes favoured Gem/Doce, supporting its non-inferiority to BCG in limiting recurrence and disease progression. AEs were significantly lesser and milder with Gem/Doce, suggesting better tolerability. A total of 10 AEs occurred in the Gem/Doce group and 47 in the BCG group. Grade 1 events were more frequent with Gem/Doce (60.0%) than BCG (25.5%, $P = 0.047$), while Grade 2 were fewer (40.0% vs 70.2%, $P = 0.09$). No Grade 3 events occurred with Gem/Doce, compared to 4.3% in the BCG group ($P = 0.99$). Rates of bladder spasms, frequency, urgency, and dysuria were comparable between groups ($P > 0.05$).

Table 2 and Figures S1 and S2 highlight the EORTC QLQ-C30 and QLQ-NMIBC24 raw score and sub-scores analyses at defined time points. The Gem/Doce group had significantly lower QLQ-C30 raw scores than the BCG group after

Table 1 Baseline characteristics and survival outcome analyses.

Baseline characteristics			
Variable	**Group I, intravesical Gem/Doce group (*n* = 39)**	**Group II, intravesical BCG group (*n* = 44)**	***P***
Age years, mean (SD)	62.09 (11.74)	59.23 (13.28)	0.28*
Sex, male, *n* (%)	25 (64.10)	30 (68.19)	0.69†
Multifocal (>1) growth(s), *n* (%)	19 (48.72)	23 (52.27)	0.75†
Size, cm, mean (SD)	3.06 (1.48)	3.65 (1.38)	0.76*
Histopathological diagnosis, *n* (%)			
Ta LG	5 (12.82)	7 (15.91)	0.85†
Ta HG	11 (28.21)	12 (27.27)	
T1 LG	21 (53.85)	23 (52.27)	
T1 HG	2 (5.13)	2 (4.55)	
EAU NMIBC Risk Group classification, *n* (%)			
Intermediate	29 (74.36)	31 (70.45)	0.71†
High	10 (25.64)	13 (29.55)	

Survival outcomes, *n* survivors/*N* (%)				
Variable	**Group I, intravesical Gem/Doce group (*n* = 39)**	**Group II, intravesical BCG group (*n* = 44)**	**HR (95% CI)**	***P***
RFS at 6 months	37/39 (94.87)	38/44 (86.36)	0.36 (0.11–0.89)	0.19‡
RFS at 12 months	36/38§ (94.74)	33/44 (75)	0.44 (0.18–0.93)	**0.02**‡
RFS – Intermediate-risk group at 6 months	29/29 (100)	27/31 (87.10)	0.22 (0.04–0.76)	**0.04**‡
RFS – Intermediate-risk group at 12 months	28/29 (96.55)	25/31 (80.64)	0.38 (0.09–1.20)	0.06‡
RFS – High-risk group at 6 months	09/10 (90)	10/13 (76.92)	0.62 (0.18–1.86)	0.41‡
RFS – High-risk group at 12 months	08/09§ (88.89)	08/13 (61.53)	0.69 (0.21–1.92)	0.16‡
PFS at 6 months	39/39 (100)	44/44 (100)	-	1.00‡
PFS at 12 months	38/38§ (100)	41/44 (93.19)	0.41 (0.07–1.05)	0.09‡
Cancer-specific survival at 6 months	39/39 (100)	44/44 (100)	-	1.00‡
Cancer-specific survival at 12 months	39/39 (100)	43/44 (97.73)	0.39 (0.05–1.02)	0.35‡
Overall survival at 6 months	39/39 (100)	44/44 (100)	-	1.00‡
Overall survival at 12 months	38/39 (97.44)	43/44 (97.73)	0.96 (0.15–3.85)	0.94‡

AEs, *n*/*N* (%)			
Variable	**Group I, Intravesical Gem/Doce group (*n* = 39)**	**Group II, Intravesical BCG group (*n* = 44)**	***P***
Patients with any AE	5/39 (12.82)	15/44 (34.10)	**0.028**†
Total AEs, *n*	10	47	–
Grade 1 AEs	6/10 (60.0)	12/47 (25.5)	**0.047**†
Grade 2 AEs	4/10 (40.0)	33/47 (70.2)	0.09†
Grade 3 AEs	0/10 (0.00)	2/47 (4.3)	0.99†
Bladder spasms	4/10 (40)	9/47 (19.1)	0.21†
Frequency	2/10 (20)	6/47 (12.8)	0.62†
Urgency	2/10 (20)	7/47 (14.9)	0.66†
Dysuria	1/10 (10)	10/47 (21.3)	0.67†
Macroscopic haematuria	0 (0.0)	1/47 (2.1)	0.99†
UTI	0 (0.0)	3/47 (6.4)	0.99†
Non-infective cystitis	1/10 (10.0)	5/47 (10.6)	0.99†
Fatigue	0 (0.0)	5/47 (10.6)	0.57†
Fever	0 (0.0)	1/47 (2.1)	0.99†

**Independent t-test. †Chi-square test (or Fisher's exact test if sample size <5). ‡Log-rank test (for survival outcomes). §After excluding mortality due to other causes. Bold values statistically significant at P < 0.05.*

induction and at 6 months. Global health status was consistently higher in the Gem/Doce group, reaching statistical significance at 6 and 12 months. Physical functioning improved significantly with Gem/Doce at induction, and at 6 and 12 months, while role and emotional functioning were significantly better at 6 months. Evaluating the QLQ-NMIBC24 score, urinary complaints, malaise, sexual health, and intravesical treatment-related problems improved significantly after induction and during maintenance phase with Gem/Doce therapy compared to BCG. Other symptom scores were also lower in the Gem/Doce arm, although not statistically significant.

Table 2 The EORTC QLQ-C30 and QLQ-NMIBC24 raw and sub-score analyses.

EORTC QLQ-C30 score analysis												
EORTC QLQ-C30 scales	**D1 (before induction), mean (SD)**			**D2 (after induction), mean (SD)**			**D3 (after 6 months), mean (SD)**			**D4 (after 12 months), mean (SD)**		
	Group I (Gem/Doce)	**Group II (BCG)**	***P***	**Group I**	**Group II**	***P***	**Group I**	**Group II**	***P***	**Group I**	**Group II**	***P***
Raw Score	48.37 (1.87)	48.78 (2.41)	0.35	46.42 (1.65)	50.90 (2.44)	**<0.001**	46.40 (1.23)	48.65 (5.36)	**0.041**	46.10 (1.18)	46.29 (7.64)	0.87
Global health status/QoL	71 (2.46)	72.1 (2.23)	0.89	76 (1.23)	74.1 (2.7)	0.35	79.5 (2.88)	74.7 (2.5)	**0.041**	77.2 (2.72)	73.4 (2.66)	**0.028**
Functional scales												
Physical Functioning	72 (2.5)	73.9 (2.46)	0.78	74.6 (2.5)	77.2 (2.9)	**0.006**	79.3 (2.31)	82.3 (2.62)	**0.011**	77.6 (2.31)	79.1 (2.92)	**0.045**
Role Functioning	70 (1.5)	69.6 (2.57)	0.91	72 (2.28)	69.9 (2.1)	0.089	74.6 (2.4)	70.1 (2.91)	**0.033**	72.1 (2.56)	69.1 (2.61)	0.095
Emotional Functioning	68.4 (1.7)	68.8 (2.23)	0.66	73 (2.67)	71.7 (2)	0.071	75.4 (2.96)	70.7 (2.31)	**0.044**	72.4 (2.12)	69.5 (2.18)	0.27
Cognitive Functioning	79.2 (2.52)	78.5 (2.23)	0.72	80.5 (3.2)	81.6 (2.5)	0.057	83.8 (2.72)	82.2 (2.66)	0.115	85.2 (2.90)	83.6 (2.98)	0.081
Social Functioning	68.7 (2.48)	69.2 (2.7)	0.83	72.4 (2.65)	71.7 (2.33)	0.159	76.2 (2.32)	72.6 (2.81)	0.152	74.3 (2.65)	70.1 (2.88)	0.069
Symptoms scales/items												
Fatigue	30.5 (2.46)	31.4 (2.57)	0.86	26 (1.8)	28.9 (1.6)	0.092	25.7 (1.83)	27.5 (1.9)	0.086	23.6 (1.9)	26.7 (1.44)	0.055
Nausea/vomiting	22 (2.3)	23.1 (2.4)	0.69	20 (1.66)	22.8 (2.7)	**0.044**	18 (1.62)	21 (1.33)	**0.029**	17 (1.32)	21.8 (1.67)	**0.005**
Pain	28.6 (2.13)	29.4 (2.9)	0.88	27 (1.92)	30.6 (1.32)	0.131	24 (1.33)	29 (1.29)	0.137	24.6 (1.87)	29.7 (1.54)	0.115
Dyspnea	26.5 (1.7)	25.2 (1.46)	0.66	24 (1.22)	23.1 (1.5)	0.81	23.6 (1.91)	24.1 (1.11)	0.62	23.9 (1.77)	25 (1.89)	0.55
Insomnia	34 (1.48)	35.4 (1.9)	0.71	33.2 (2.8)	33.5 (2.8)	0.48	27.4 (1.88)	31 (2.78)	**0.039**	24.6 (1.27)	27.4 (1.45)	**0.024**
Appetite loss	32 (1.6)	33.1 (2.24)	0.8	37 (2.32)	36.9 (2.94)	0.078	32 (2.86)	30.2 (2.32)	0.093	29 (1.56)	32.5 (1.31)	0.76
Constipation	18 (1.52)	19.6 (1.7)	0.85	18 (1.9)	19.1 (2.32)	0.44	16 (1.77)	18.9 (1.65)	0.35	15 (1.73)	17.5 (1.67)	0.83
Diarrhoea	20.9 (1.4)	19.2 (2.03)	0.83	16 (1.8)	17.9 (1.2)	0.067	14 (1.83)	15.1 (1.2)	0.188	15 (1.63)	17.4 (1.75)	0.167
Financial difficulties	5.6 (2.7)	7.2 (3.5)	0.07	5.3 (2.2)	6.5 (2.5)	0.13	5.5 (2.4)	6.8 (3.0)	0.14	5.6 (2.5)	6.7 (2.6)	0.38

EORTC QLQ-NMIBC24 score analysis												
EORTC QLQ-NMIBC24 scales	**D1 (before induction), mean (SD)**			**D2 (after induction), mean (SD)**			**D3 (after 6 months), mean (SD)**			**D4 (after 12 months), mean (SD)**		
	Group I (Gem/Doce)	**Group II (BCG)**	***P***	**Group I**	**Group II**	***P***	**Group I**	**Group II**	***P***	**Group I**	**Group II**	***P***
Raw score	38.37 (2.27)	39.48 (3.14)	0.86	36.84 (1.79)	39.0 (1.91)	**<0.001**	36.07 (1.31)	38.27 (1.37)	**<0.001**	35.18 (1.50)	37.08 (1.54)	**0.036**
Individual parameters, signs (−) and (+) indicate whether higher scores are worse or better, respectively												
Urinary symptoms (−)	28.1 (2.82)	30 (2.91)	0.66	26.1 (2.88)	30.6 (2.86)	**0.044**	23.6 (2.81)	27.3 (2.12)	**0.033**	18.5 (1.78)	22.3 (1.98)	**0.006**
Malaise (−)	20.3 (2.33)	21 (2.12)	0.53	16.1 (2.91)	22.2 (2.32)	**0.017**	14.8 (2.91)	21.7 (2.67)	**0.015**	10.6 (1.12)	17.3 (1.34)	**0.04**
Future worries (−)	30.1 (2.45)	31.9 (3.2)	0.66	29.9 (1.88)	31.8 (2.90)	0.55	27.6 (2.44)	28.4 (2.24)	0.92	26.5 (1.89)	27.6 (2.23)	0.78
Bloating and flatulence (−)	30.6 (2.56)	32.6 (2.69)	0.57	29.1 (1.52)	32.2 (2.86)	0.67	28.5 (2.67)	30.9 (2.12)	0.095	29.3 (1.28)	30.2 (2.86)	0.32
Sexual functioning (+)	31.4 (3.67)	29.2 (2.12)	0.7	33.1 (1.44)	29.3 (2.32)	**0.035**	32.4 (2.86)	29.5 (2.86)	0.063	32.9 (1.12)	29.6 (2.91)	0.096
Male sexual problems (−)	22.4 (2.32)	23.7 (2.99)	0.53	19.5 (1.93)	21.4 (2.45)	0.072	19.7 (1.45)	22.7 (2.67)	**0.042**	19.1 (1.55)	21.3 (2.56)	0.82
Intravesical treatment issues (−)	29.5 (2.12)	34.4 (2.12)	0.6	27.4 (2.6)	34.3 (2.89)	**0.025**	26.6 (2.91)	34.1 (2.89)	**0.01**	26.6 (1.78)	32.2 (2.89)	**0.04**
Sexual intimacy (−)	34.7 (2.58)	34.8 (3.2)	0.53	32.2 (1.4)	32.3 (2.91)	0.79	31.4 (2.65)	33.4 (2.99)	0.82	31.2 (1.95)	32.1 (2.98)	0.78
Risk of contaminating partner (−)	26.6 (2.91)	29 (2.12)	0.81	24.6 (2.86)	25.3 (2.81)	0.59	24.1 (2.23)	24.6 (2.23)	0.92	23.4 (2.23)	24.8 (2.78)	0.074
Sexual enjoyment (+)	31.2 (2.66)	30.7 (2.21)	0.75	32.7 (2.32)	31.5 (2.71)	0.65	34.5 (2.94)	31.7 (2.86)	**0.035**	33.2 (2.82)	31.7 (2.23)	0.27

Bold values statistically significant at P < 0.05.

Table 3 summarises the comparative cost distribution and cost-effectiveness outcomes of the two intravesical regimens evaluated. Although additional procedures such as BCG re-induction, radical cystectomy, and systemic chemotherapy were significantly higher in the BCG group, the mean per-dose and total treatment costs per-patient remained higher in the Gem/Doce group due to greater upfront drug acquisition costs. Despite this, Gem/Doce achieved a higher mean per-patient QALY gain (0.8807 vs 0.7198), corresponding to an incremental improvement of 0.1609. The ICER for Gem/Doce was ~₹58 800 ($709) per recurrence-free month and ₹90 100 ($1086) per progression-free month, both within an acceptable range considering the clinical burden of NMIBC recurrence. The overall ICER per QALY gained was ₹504 000 ($6072), suggesting cost-effectiveness in comparison with international WTP thresholds. Although upfront cost of drug acquisition was higher in Gem/Doce group, the gain in

Table 3 Cost-effectiveness analysis between both groups.

Associated procedural costs, mean (SD)			
Cost component distribution between both groups, INR (₹); USD ($)	**Group I, intravesical Gem/Doce group (*n* = 39)**	**Group II, intravesical BCG group (*n* = 44)**	***P***
Mean per-dose cost	₹7603 (1750); $91.6 (21.1)	₹1710 (395); $20.6 (4.8)	<**0.001**
Mean per-patient cost for induction phase (six doses in each group)	₹45 618 (4286); $549.6 (51.6)	₹10 260 (967); $123.6 (11.7)	<**0.001**
Mean per-patient cost for uninterrupted 1-year maintenance phase (12 doses of Gem/Doce, nine doses of BCG)	₹91 236 (6062); $1099.2 (73.0)	₹15 390 (1185); $185.4 (14.3)	<**0.001**
Mean per-patient cost for maintenance phase in present cohort	₹90 274 (5733); $1087.6 (69.1)	₹13 982 (977); $168.5 (11.8)	<**0.001**
Mean per-patient cost for maintenance phase in intermediate-risk category in present cohort	₹90 182 (5988); $1086.5 (72.1)	₹14 621 (1038); $176.3 (12.5)	<**0.001**
Mean per-patient cost for maintenance phase in high-risk category in present cohort	₹88 783 (6132); $1069.7 (73.9)	₹12 564 (935); $151.4 (11.3)	<**0.001**
Additional procedures in cohorts, *n*			
TURBT	3	10	–
Additional BCG doses (for re-induction and maintenance cycles)	21	81	
Radical cystectomy	0	3	
Systemic chemotherapy	0	3	
Cost of procedures at present centre (central government-funded tertiary level public hospital)			
TURBT	₹12 000 (3500); $144.6 (42.2)		
Radical cystectomy	₹67 500 (7200); $813.3 (86.7)		
Systemic chemotherapy	₹20 500 (3200); $247.0 (38.6)		
Mean per-patient cost of additional procedures	₹1293.5 (167.2); $15.6 (2.0)	₹11 875.4 (1204.3); ($143.1 (14.5)	<**0.001**
Mean per-patient cost of additional procedures in intermediate-risk category	₹885.52 (162.60); $10.7 (2.0)	₹7364.89 (786.1); $88.7 (9.5)	<**0.001**
Mean per-patient cost of additional procedures in high-risk category	₹4623.1 (868.5); $55.7 (10.5)	₹19 147.7 (1473.8); $230.7 (17.8)	<**0.001**
Mean total cost per patient in present cohort	₹117 186.2 (7160.5); $1411.9 (86.3)	₹36 117.4 (1827.6); ($435.7 (22.0)	<**0.001**
Mean total cost per patient in intermediate-risk category	₹116 686.5 (7363.2); $1405.9 (88.7)	₹32 245.9 (1621.9); $388.5 (19.5)	<**0.001**
Mean total cost per patient in high-risk category	₹119 024.1 (7528.3); $1433.0 (90.7)	₹41 971.7 (1995.4); $505.7 (24.0)	<**0.001**

Cost-effectiveness analysis					
Overall cohort					
Variable	**Group I, intravesical Gem/Doce group (*n* = 39)**	**Group II, intravesical BCG group (*n* = 44)**	**Δ, Group I – Group II**	**ICER (rupees per unit gain)**	**ICER (USD per unit gain)**
Mean per-patient cost (rupees)	₹117 186.20	₹36 117.40	₹81 068.80	–	
QALYs (12 months)	0.8807	0.7198	0.1609	₹504 000/ QALY	$6072/ QALY
RFS at 12 months, %	94.74	75	+19.74	₹410 700 per additional recurrence avoided	$4948 per recurrence avoided
Recurrence-free month (AUC*)	11.30	9.02	+1.38 months	₹58 800 per recurrence-free month	$709 per recurrence-free month
PFS at 12 months, %	100	93.19	+6.81	₹1 190 140 per additional progression avoided	$14 337 per progression avoided
Progression-free months (AUC*)	12.00	11.10	+0.90 months	₹90 076 per progression-free month	$1086 per progression-free month
Intermediate-risk category					
Mean per-patient cost (rupees)	₹116 686.50	₹32 245.90	₹84 440.60	—	

Table 3 (continued)

Cost-effectiveness analysis					
Overall cohort					
Variable	**Group I, intravesical Gem/Doce group (*n* = 39)**	**Group II, intravesical BCG group (*n* = 44)**	**Δ, Group I − Group II**	**ICER (rupees per unit gain)**	**ICER (USD per unit gain)**
QALYs (12 months)	0.8637	0.7262	0.1375	₹614 000/ QALY	$7398/ QALY
RFS at 12 months, %	96.55	80.64	+15.91	₹530 800 per additional recurrence avoided	$6393 per recurrence avoided
Recurrence-free month (AUC*)	11.93	10.49	+1.44 months	₹58 677 per recurrence-free month	$706 per recurrence-free month
High-risk category					
Mean per-patient cost (rupees)	₹119 024.10	₹41 971.70	₹77 052.40	—	
QALYs (12 months)	0.9874	0.7019	0.2855	₹2,69 900/ QALY	$3251/ QALY
RFS at 12 months, %	88.89	61.53	+27.36	₹281 700 per additional recurrence avoided	$3393 per recurrence avoided
Recurrence-free month (AUC*)	10.70	7.88	+2.82 months	₹27 297 per recurrence-free month	$329 per recurrence-free month

**AUC = trapezoidal area under the 0–6–12-month survival curve using observed 6- and 12-month points (baseline RFS/PFS assumed 100%).*

QALYs and prevention of recurrence/progression helped to counterbalance the overall economic burden.

Discussion

Non-MIBC is stated as a chronic condition with frequent recurrences and high prevalence, necessitating stringent surveillance and adjuvant managements to reduce recurrence and progression. Treatment costs along with drug-related toxicities can impose significant physical and psychological burden for patients and healthcare systems [2–5,11]. Intravesical BCG remains the standard of care for adjuvant management of intermediate- and high-risk NMIBC, effectively reducing recurrence and progression, but is limited by failure rates of 20–40%, progression in 10–12% cases, significant treatment-related toxicity, and a global shortage in recent years [1,5,6,12]. Sequential intravesical Gem/Doce has emerged as a promising option for both BCG-unresponsive and treatment-naïve NMIBC, offering comparable oncological outcomes with limited systemic toxicity. Multicentric analyses show RFS rates at 12 months ranging between 85% and 90% for Gem/Doce and 71–80% for BCG, with 1-year PFS exceeding 90% in both arms [5,8,9]. Nevertheless, its clinical application in Indian settings remains limited and understudied, which was the aim in the present study. Stage distribution was comparable across cohorts, with Ta low-grade (LG) cases in 12.82% vs 15.91% (BCG), Ta high-grade (HG) in 28.21% vs 27.27%, T1 LG in 53.85% vs 52.27%, and T1 HG in 5.13% vs 4.55% cases of Gem/Doce and BCG groups, respectively. The observed sub-staging variation compared with global datasets, including the absence of carcinoma *in situ* (CIS), likely reflects real-world loco-regional heterogeneity and risk factors dissimilitude, which is further strengthened by similar epidemiological pattern of NMIBC and negligible prevalence of CIS in Indian scenarios [11,22]. At the 12-month follow-up, a lower recurrence hazard and absence of progression or mortality at 1 year highlight the feasibility of Gem/Doce as an alternative first-line intravesical regimen, particularly in Indian settings facing BCG supply constraints.

Recent consensus emphasises the inclusion of QoL assessments using validated tools for physical-psychological impact apart from survival outcomes estimation [2,10,11,14,15]. In this study, patient-reported outcomes were measured using the validated EORTC QLQ-C30 and QLQ-NMIBC24 module. Gem/Doce offered optimal patient-reported outcomes compared with BCG, with higher global health status, better functional scores, and reduced symptom burden after induction and throughout maintenance. Specifically, fatigue and nausea were significantly alleviated, urinary symptoms and malaise improved, and sexual health were better preserved with Gem/Doce. The use of these scales in NMIBC was recently validated in prospective study by Beeren et al. [23], as well as in the EAU Research Foundation (RF) NIMBUS trial [10]. In India, Kumar et al. [24] and

Pareek et al. [11] confirmed their utility in real-world NMIBC care. Pareek et al. [11] found QLQ-C30 scores significantly lower for Gem/Doce at induction (16.6 vs 20.6) and maintenance (15.5 vs 18.1), while QLQ-NMIBC24 scores favoured Gem/Doce (7.87 vs 10.9 at induction; 6.7 vs 9.97 at maintenance), confirming its exemplary QoL trajectory [11]. Interim results from the ECOG-American College of Radiology Imaging Network (ACRIN) EA8212 (BRIDGE) phase III trial (ClinicalTrials.gov identifier: NCT05538663) indicate improved tolerability, efficacy, and treatment adherence with Gem/Doce in BCG-naïve high-risk NMIBC owing to the lower toxicity profile and better lifestyle preservation [9–11,14,15,25]. The QoL advantage of Gem/Doce persists through induction and maintenance phases, reflecting durable benefit and greater patient acceptability. Overviewing biological rationale, gemcitabine's S-phase-directed cytotoxicity and docetaxel's microtubule stabilisation act synergistically, producing local tumoricidal activity with minimal systemic exposure. BCG's efficacy depends on intact cellular immunity, and prior mycobacterial exposure—from tuberculin sensitisation or neonatal BCG vaccination—may lead to immunosenescence, variable response, and higher reactogenicity, often necessitating dose reduction or discontinuation. Prolonged instillations further contribute to cumulative local and systemic toxicity [9,11,24].

Non-MIBC is amongst the costliest malignancies to manage due to high recurrence rates and lifelong surveillance, with annual expenses reaching €5.5 billion in Europe and ₹5–7 lakh ($7000–10 000 USD) in India [3,26]. Michaeli et al. [26] stated that 10-year costs rise with risk category – €2214 for low-risk, €4758 for intermediate-risk, and €11 325 for high-risk NMIBC – comprising direct treatment costs and indirect expenses from work loss, travel, and QoL reduction (contributing 5–65% of total costs). Therefore, cost-reduction while maintaining effective oncological and QoL outcome remains priority in cancer care. The present analysis shows that intravesical Gem/Doce delivers a consistent clinical and patient-centred advantage over BCG. At 12 months, Gem/Doce achieved higher RFS (94.74% vs 75%) and PFS (100% vs 93.19%) rates alongside an optimal QALY improvement (0.8807 vs 0.7198) mirrored within risk strata. The ICER was ₹504 000 per QALY gained ($6072/QALY), remaining well within India's WTP threshold and far below international reference standards ($50 000–$150 000/QALY). These findings indicate that, despite higher upfront drug costs, Gem/Doce therapy represents a clinically effective and economically acceptable alternative in the long term by offsetting expenditures from recurrence-related procedures [9,19–21,27]. Bakula et al. [5] and Bukavina et al. [28] reported Gem/Doce induction costing 125% higher than BCG induction, though reduced hospitalisation due to better tolerability and avoidance of radical cystectomy strengthen its cost-effectiveness.

Recurrence-free month gains increased by +1.38 months overall, +1.44 months in the intermediate-risk group, and +2.82 months in the high-risk group with Gem/Doce therapy, reflecting superior cost efficiency. This enhanced disease control translates directly into fewer repeat TURBTs, hospitalisations, and cystectomies—procedures that collectively account for the majority of treatment-related expenditure [26–28]. Fewer mild (Grade 1–2) AEs and absence of severe (Grade ≥3) toxicity align with its favourable patient-reported QoL compared to BCG, particularly during maintenance phases when cumulative AEs typically reduce treatment adherence [8,23,24,26–28]. Although BCG remains cheaper upfront, it is limited by high toxicity, treatment discontinuation, and recurrent global shortages, leading to incomplete treatment and greater downstream costs. These factors collectively shift the value proposition toward a more tolerable regimen with sustained adherence and reduced complication-related expenditures [8,21]. Hence, despite being costlier, the enhanced efficacy and improved QoL offered by Gem/Doce may overshadow apparent cost advantages of BCG in the Indian context, particularly when weighed against BCG shortages and long-term healthcare expenditures in management of NMIBC recurrence and progression. From a policy perspective, strategies such as price regulation, generic production, inclusion of Gem/Doce in government-sponsored health insurance schemes, and rational patient selection could improve affordability and accessibility, helping to align clinical effectiveness with economic sustainability in resource-limited Indian settings.

This study has certain limitations that merit consideration. The relatively short follow-up duration (12 months) restricts evaluation of long-term survival trends, particularly in high-risk NMIBC where late events are not uncommon. Though validated patient-reported tools were used, inherent subjectivity of self-reported QoL and cultural influences may affect comparability with international datasets. Small sample size across subgroups limits detection of subtle survival estimates. Moreover, single tertiary-care centre analysis may introduce institutional practice bias and limit extrapolation to broader healthcare settings. The cost analyses were based on direct treatment and hospitalisation costs in a government-funded institution and did not fully incorporate indirect societal costs or expenditure in private health setups (with probable higher drug costs but extensive increment in additional procedures cost), which could have altered cost-effectiveness estimates.

Conclusion

The findings of present study provide short-term preliminary evidence supporting Gem/Doce as a pragmatic, clinically comparable, and potentially cost-effective alternative to BCG for managing intermediate- and high-risk NMIBC in India.

Further large multicentre studies with extended follow-up are warranted to validate these findings. An extensive health-economic modelling would further strengthen the evidence.

Acknowledgement

None.

Disclosure of Interests

The authors have no conflicts of interest to declare.

Funding Information

No funding was received.

Author Contributions

Study concept and design: Aviral Srivastava, Sameer Trivedi. Surgical procedures performed by: Sameer Trivedi, Yashasvi Singh, Ujwal Kumar, Lalit Kumar. Data acquisition: Aviral Srivastava, Sameer Trivedi, Ujwal Kumar, Sahil Data, Anil Kumar. Data analysis: Aviral Srivastava, Sameer Trivedi, Yashasvi Singh, Ujwal Kumar, Lalit Kumar. Manuscript writing: Aviral Srivastava. Manuscript revision: Sameer Trivedi. Statistical analysis: Sameer Trivedi, Yashasvi Singh, Ujwal Kumar, Lalit Kumar, Satya Narayan Sankhwar.

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Abbreviations: AE, adverse event; CIS, carcinoma *in situ*; CONSORT, Consolidated Standards of Reporting Trials; CTCAE, Common Terminology Criteria for Adverse Events; EAU, European Association of Urology; ECOG, Eastern Cooperative Oncology Group; EORTC QLQ-(C30) (NMIBC24), European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire-(30-item core)(24-item NMIBC); EQ-5D-5L, EuroQoL five Dimensions five Levels; Gem/Doce, gemcitabine/docetaxel; HG, high grade; HR, hazard ratio; ICER, incremental cost-effectiveness ratio; INR, Indian Rupees; lakh, 10^5 Indian Rupees (₹); LG, low grade; (N)MIBC, (non-)muscle-invasive bladder cancer; PFS, progression-free survival; QALY, quality-adjusted life year; QoL, quality of life; RFS, recurrence-free survival; TURBT, transurethral resection of bladder tumour; USD, United States Dollars; WTP, willingness-to-pay.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Fig. S1. Graphical derivation of EORTC QLQ-C30 score component analysis between both groups.

Fig. S2. Graphical derivation of EORTC QLQ-NMIBC24 score component analysis between both groups.