

# EAU26

## LONDON, GB

### 13-16 March 2026

Cutting-edge Science at  
Europe's largest Urology Congress



**BCG plus mitomycin (BCG+MM) versus BCG-alone as adjuvant intravesical therapy for high-risk, non-muscle-invasive bladder cancer (NMIBC): effects on urinary symptoms and other aspects of health-related quality of life (HRQL) in a randomised trial (BCGMM, ANZUP 1301)**

[www.eau26.org](http://www.eau26.org)

**eau** European  
Association  
of Urology

# Conflict of Interest Disclosure

- I have the following potential conflicts of interest to report

## Advisory Boards

Urogen  
BMS  
Pacific Edge  
AstraZeneca

## Travel / Meeting Support

AstraZeneca  
Telix Pharmaceuticals  
BJUI  
ANZUP

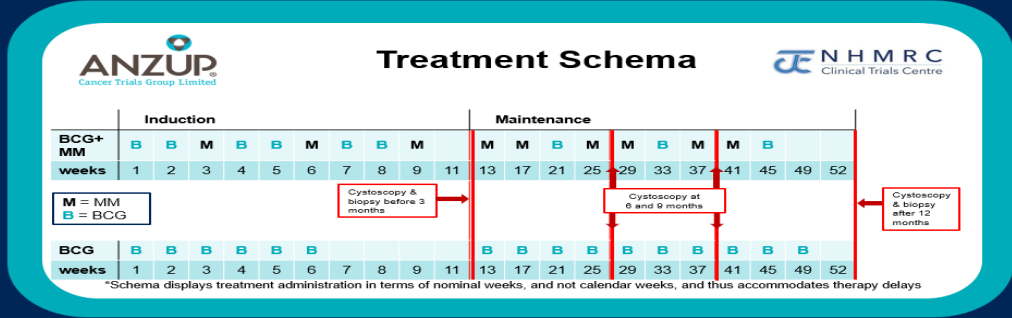
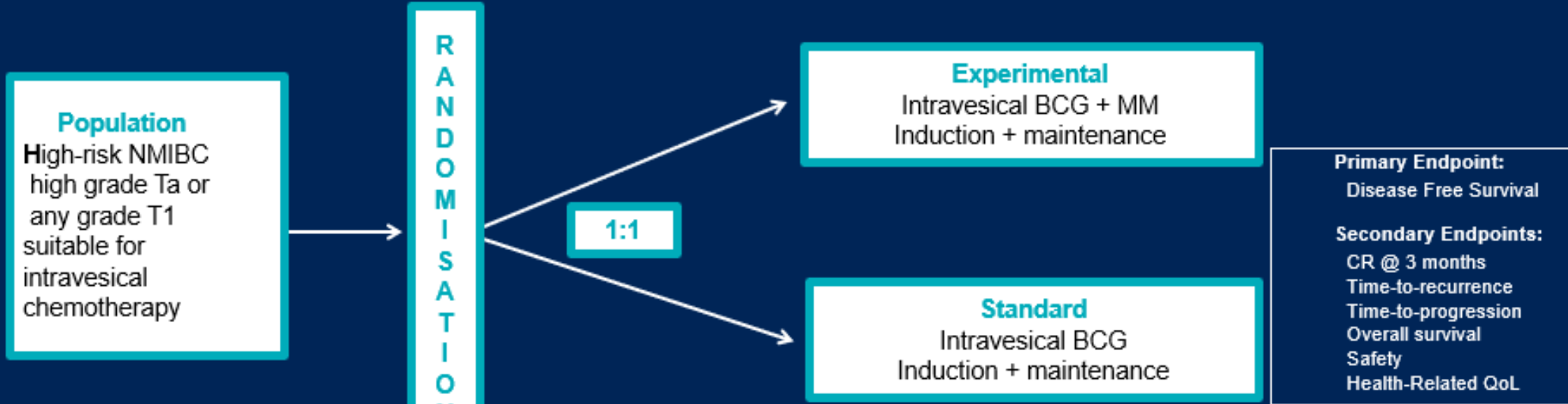
## Research Funding / Support

Telix (C)  
AstraZeneca (C)  
Valar Labs (C)

## Speaker Meetings

BMS  
GSK

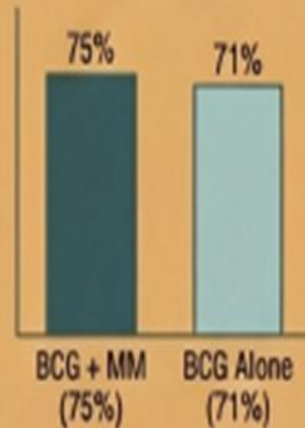
**Adding Mitomycin to BCG as adjuvant intravesical therapy for high-risk, non-muscle-invasive-bladder cancer: a randomised phase 3 trial:  
The BCG+MM Trial (ANZUP 1301)**





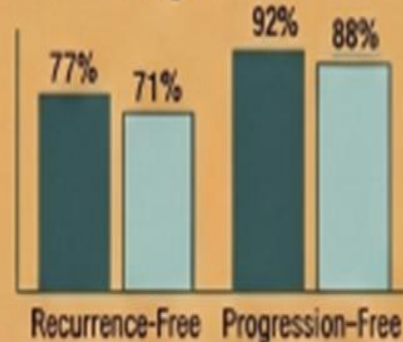
## HIGHLIGHTS

### 2-Year Disease-Free Survival



No significant difference in disease-free survival (DFS) between the combination therapy and BCG alone at 2 years (BCG + MM: 75% vs. BCG Alone: 71% (HR: 0.87, 95% CI 0.65–1.16;  $p=0.3$ ))

### 2-Year Freedom from Recurrence and Progression



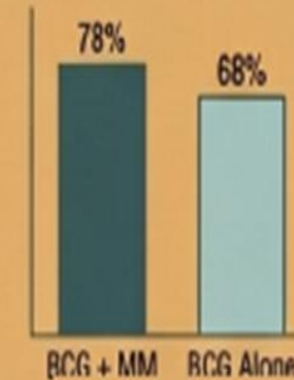
No significant difference in RFS and PFS between the combination therapy and BCG alone at 2 years. (Recurrence-Free: 77% (BCG+MM) vs 71% (BCG). Progression-Free: 92% (BCG+MM) vs 88% (BCG).)

### BCG Utilization



The combination arm significantly reduced the amount of BCG required per patient.

### Treatment Completion

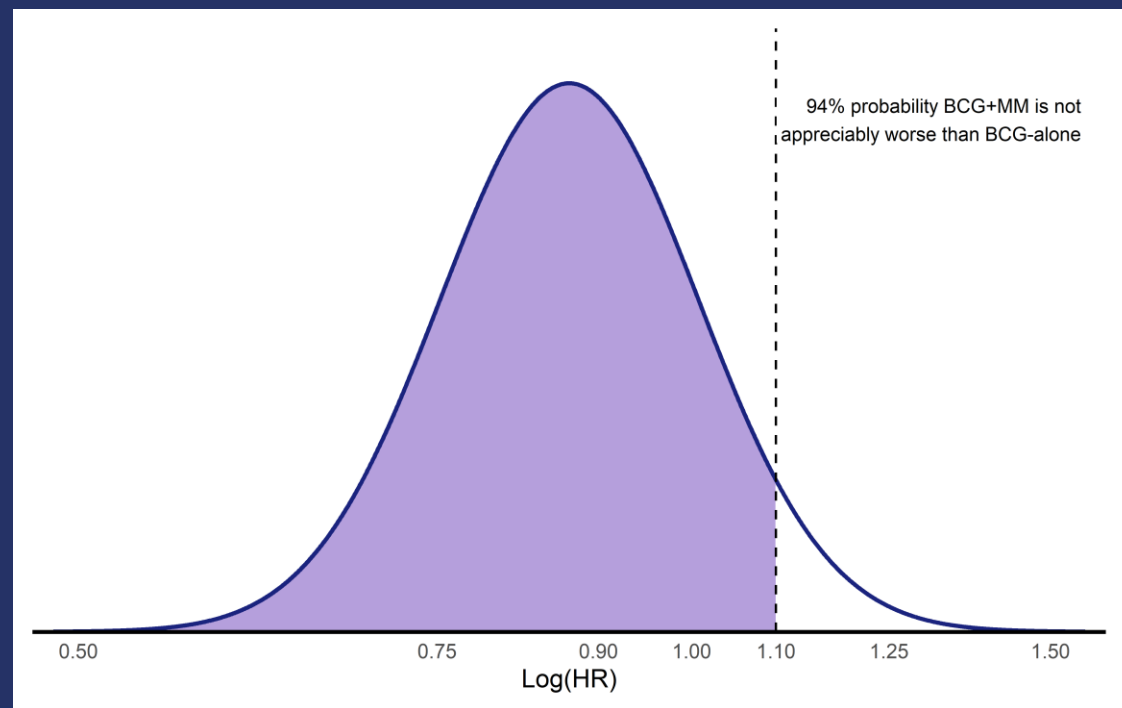
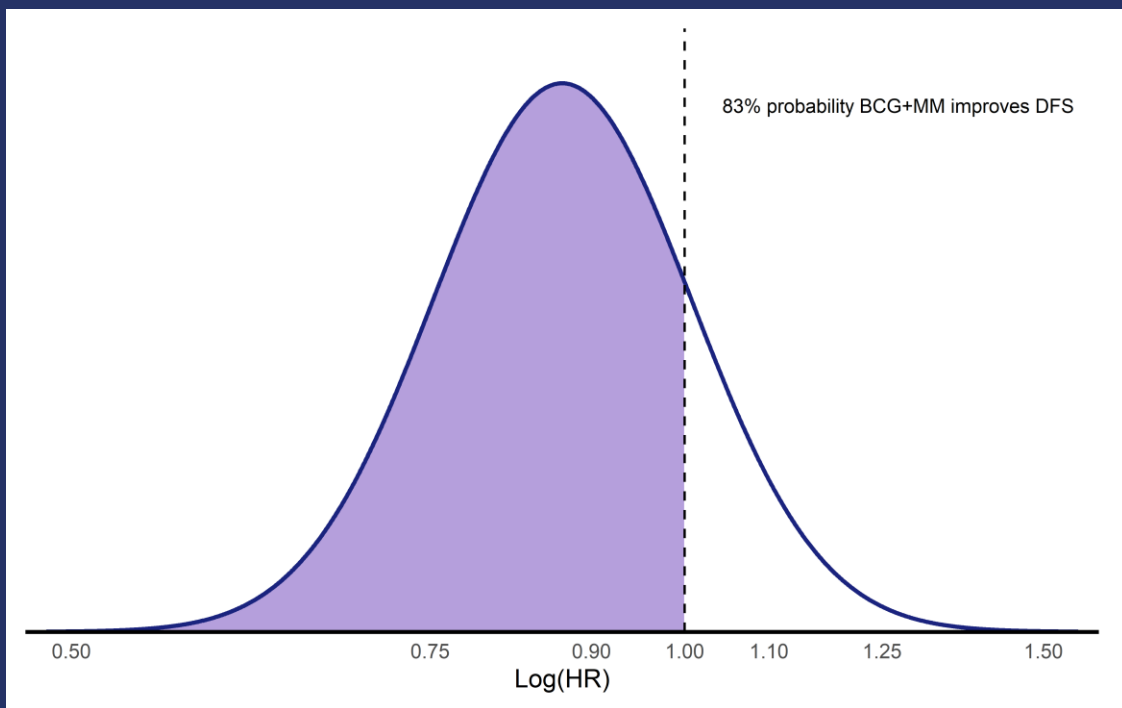


More participants in the combination group completed at least 75% of their planned doses compared to the BCG-alone group. (Completion Rate: 78% (BCG + MM) vs 68% (BCG Alone))

## BCG + Mitomycin Trial – Post-hoc Bayesian Interpretation (non-informative prior)

Probability that BCG+MM improves DFS (HR<1) is **83%**

Probability that BCG+MM is not appreciably worse than BCG-alone (HR<1.10) is **94%**



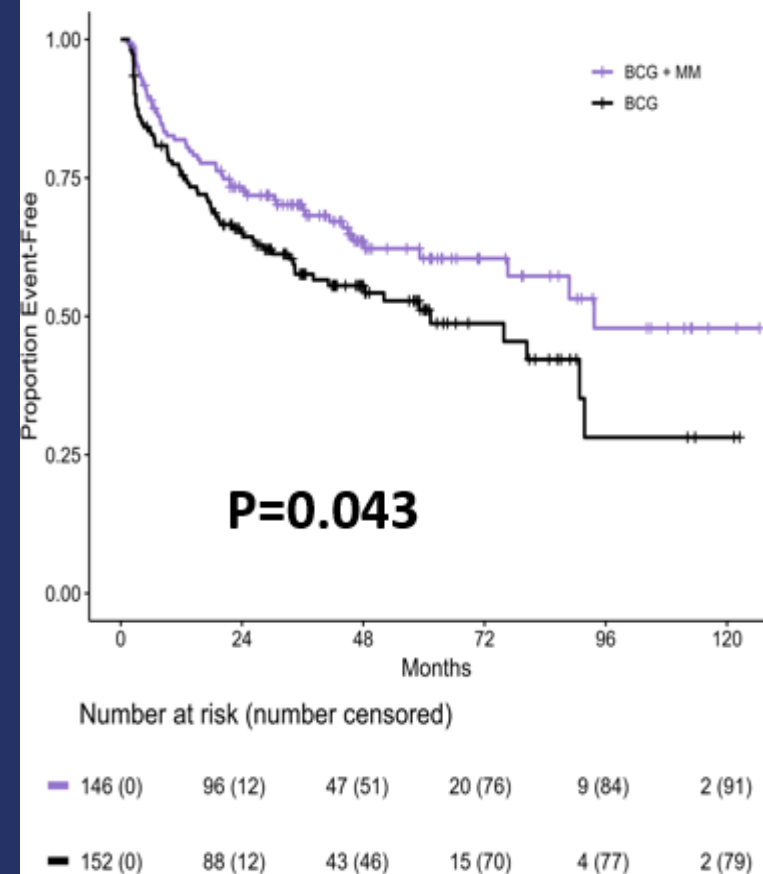
## Subgroup: Higher risk vs Lower risk (DFS)

[All T1, any CIS]      [HGTA only, no CIS]

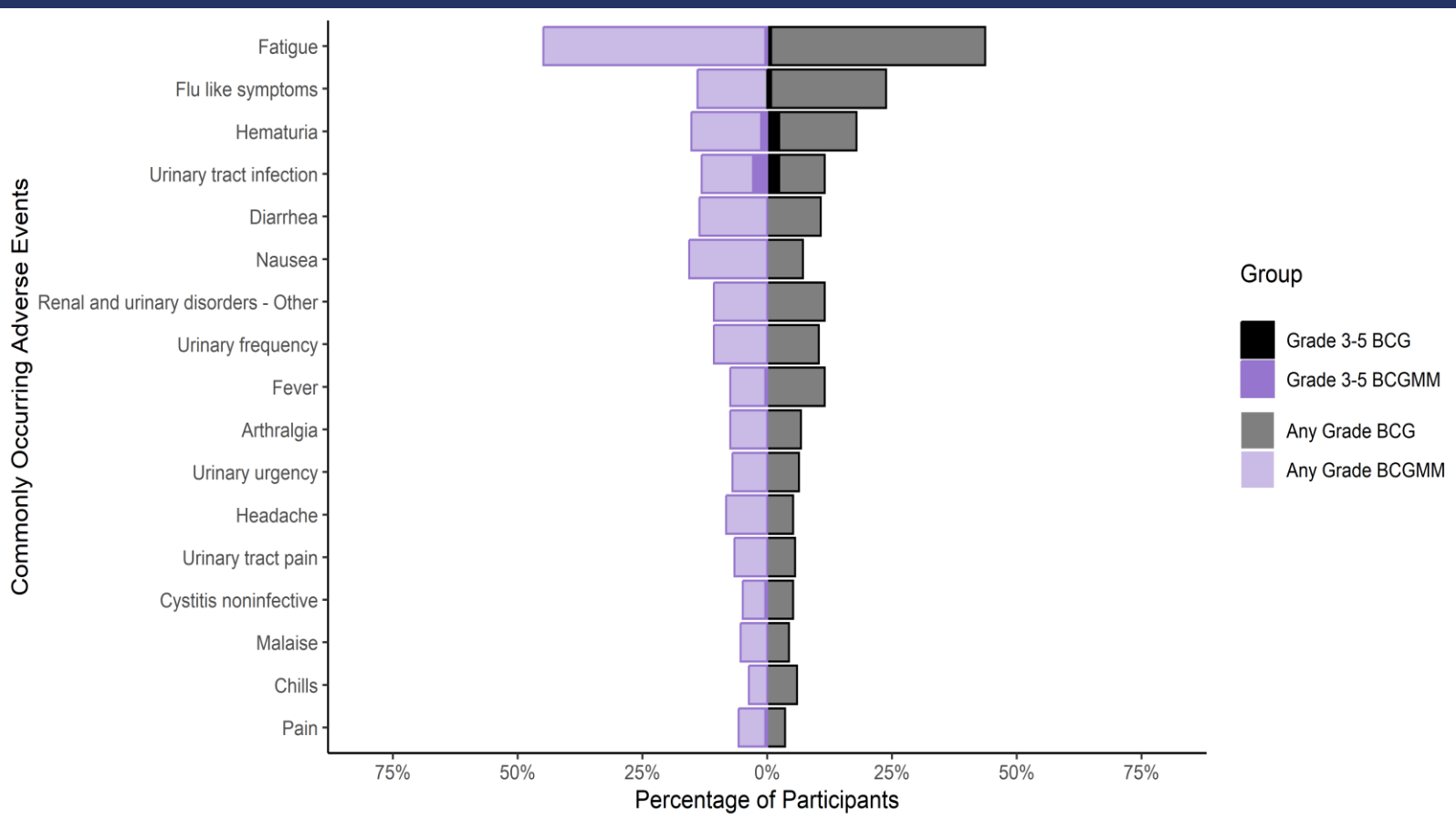
Subgroup	Level	n/N		HR (95% CI)	P-Value
		BCG + MM	BCG		
Tumour stage	T1	42/115	54/119	0.74 (0.49 to 1.11)	0.29
	Ta	49/134	45/133	1 (0.67 to 1.5)	
Carcinoma in situ	Yes	30/69	36/71	0.82 (0.5 to 1.32)	0.78
	No	61/180	63/181	0.89 (0.62 to 1.26)	
Risk group	higher risk [All T1, any CIS]	53/146	71/152	0.69 (0.48 to 0.99)	0.043
	lower risk [HGTA only, no CIS]	38/103	28/100	1.28 (0.79 to 2.09)	

0.25   0.50   1.0   2.0
*favors BCG + MM*
*favors BCG*

### Higher risk [All T1 any CIS] vs lower risk [HGTA only, no CIS]



# Adverse Events (at least 5% of pts in either arm)



**SAEs attributed to therapy**

11/55 (**20%**) in BCG+MM

14/44 (**32%**) BCG alone

## Selected symptoms, functions, and overall quality of life (N=451/501)

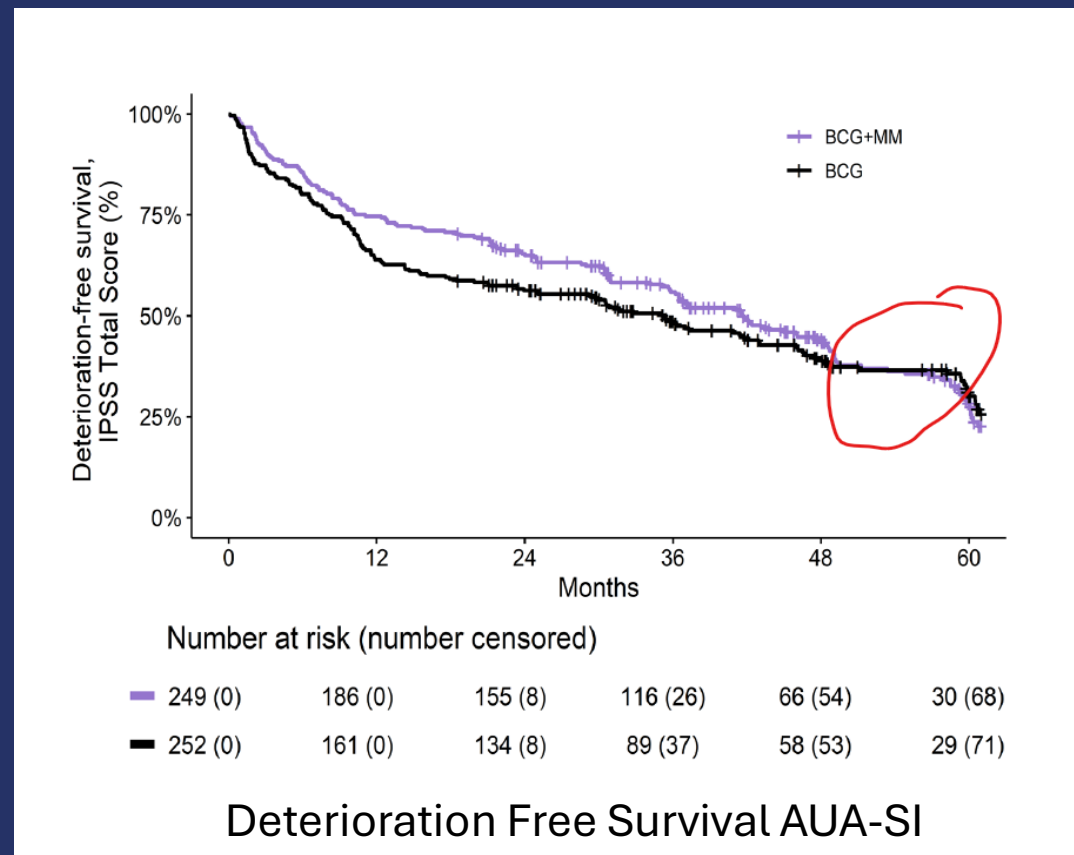
(Least squares mean scores over 5 years, adjusted for score at baseline)

	American Urology Association Symptom Index (0-35 worst, MCID 4)	EORTC NMIBC-24 Urinary Symptoms (0-100 worst, MCID 10)	EORTC QLQ-C30 Physical Function (0-100 best, MCID 10)	EORTC QLQ-C30 Overall Health and Quality of Life (0-100 best, MCID 10)
BCG+MM	7.7	20	88	76
BCG-alone	8.7	21	87	75
Difference favouring BCG+MM	0.9	1.2	0.7	1.5
P-value	0.03	0.3	0.4	0.2

Apparent discrepancies due to rounding

5-year deterioration free survival was not significantly different for any of the QoL measures

	American Urology Association Symptom Index	EORTC NMIBC-24 Urinary Symptoms	Physical Function EORTC QLQ-C30	Overall Health Related QoL EORTC QLQ-C30
BCG+MM	27%	33%	45%	38%
BCG alone	30%	30%	38%	33%
difference	-3%	3%	7%	5%
p value	0.4	0.8	0.06	0.1



- BCG+MM showed **similar efficacy** to BCG alone
- BCG+MM was **better tolerated**
  - Better completion rates
  - Lower symptom burden for BCG+MM (AUA-SI)
- BCG+MM **may be safer**
  - BCG toxicity drives SAEs
  - SAEs attributed to therapy were lower in BCG+MM
- BCG+MM **may be superior**
  - in higher risk pts (post-hoc sub-group)
  - 83% probability BCG+MM improves DFS (Post-hoc Bayesian interpretation)
- BCG+MM required **39% less BCG**

**BCG+MM is a good alternative to BCG alone**

**Wide adoption of BCG+MM could resolve the global BCG shortage**

**Why use standard BCG alone...?**

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European Association of Urology

Original Article

**Bacillus Calmette-Guérin Plus Mitomycin Versus Bacillus Calmette-Guérin Alone for Bacillus Calmette-Guérin-naïve Non-muscle-invasive Bladder Cancer: A Randomised Phase 3 Trial (ANZUP 1301)**

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