



Will long-term disease specific outcomes of bladder conservation with sequential Bacillus Calmette-Guérin (BCG) and electromotive drug administration Mitomycin-C (EMDA-MMC) for high-risk non-muscle invasive bladder cancer (HR-NMIBC) influence adoption?

Jennifer Lane¹, Zakariya Abdille¹, Christine Gan¹, Kathryn Chatterton¹, Suzanne Amery¹, Ramesh Thurairaja¹, Shamim Khan¹, Sachin Malde¹, Timothy O'Brien¹ and Rajesh Nair¹

¹ Guy's and St Thomas' NHS Foundation Trust, United Kingdom

Background:

Superior short-term outcomes of sequential BCG with EMDA-MMC when treating HR-NMIBC have been reported. Despite this, the regimen has not been widely adopted for bladder conservation and the optimal regimen is yet to be determined. An understanding of long-term oncological outcomes would be important in understanding its true role and may encourage wider adoption.

Methods:

This is a prospective single-centre study of 464 patients, presenting with new HR-NMIBC between June 2009 and July 2017. The bladder conservation schedule followed TURBT with adjuvant 9-week induction consisting of 3 consecutive and identical cycles of; BCG in weeks 1 and 2, followed by EMDA-MMC in week 3. Maintenance was 3-weekly BCG. Cystoscopy was used to assess response at 8 weeks post induction. Primary outcome measures evaluated were recurrence free survival, progression rates and outcomes following salvage treatment.

Results:

249 patients received sequential BCG/EMDA-MMC with a median follow-up of 54 months (4-108). 206/249 (83%) received treatment for high-grade (Ta/T1) disease, and 13/249 (5%) for primary carcinoma in situ. A further 30/249 (12%) received treatment for recurrent or large volume low-grade disease. Of the 196/249 (79%) patients who completed the induction course of treatment 123/196 (63%) have remained disease free during follow-up. 53/196 (27%) patients developed bladder recurrence, of which 22/53 (42%) demonstrated stage migration ($\geq T2$ disease). Of note, 28/53 (53%) developed recurrence within the first three years of treatment. Of the 15/53 (28%) who subsequently underwent radical cystectomy, upstaging on final histopathology was demonstrated in 8/15 (53%) patients, 1/15 (6%) died of metastatic bladder cancer.

Conclusion:

If induction BCG/EMDA-MMC treatment is completed, over two-thirds of patients remain disease free during long term follow-up. This is twice the efficacy quoted for intravesical BCG alone and adds further weight to the adoption of this sequential regimen in bladder preservation for HR-NMIBC.

Keywords: Bladder cancer, BCG - Bacille Calmette-Guérin vaccine, Electromotive drug administration (EMDA), Mitomycin C (Mit-C), Non-muscle invasive bladder cancer

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* **Correspondence:** Dr. Jennifer Lane, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom, jennifer.lane@gstt.nhs.uk