Abstract number 18-50

ElectroMotive Drug Administration (EMDA) of Mitomycin C as first line salvage therapy in high risk "BCG-failure" non muscle invasive bladder cancer: 3 years followup outcomes

Di Gianfrancesco L, Racioppi M, Ragonese M, Palermo G, Lenci N, Sacco E, Bassi PF

Catholic University of the Sacred Heart, Dept. of Urology, Rome, Italy

Objectives

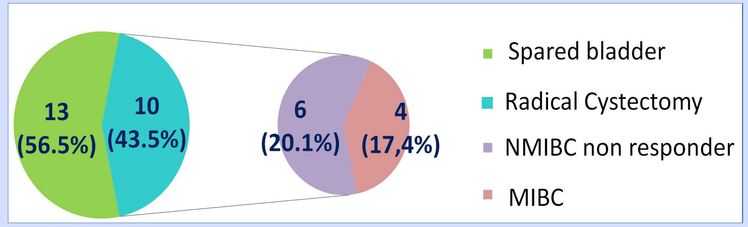
Intravesical BCG is the first-line treatment in high grade non muscle invasive bladder cancer (HG-NMIBC). Forty-50% of these patients experience recurrent disease. Alternative therapeutic strategies to early cystectomy have been developed with the aim to preserve the bladder. The aim of this study was to explore a role of EMDA®-MMC as first line salvage treatment in patients suffering from HGNMIBC unresponsive to BCG.

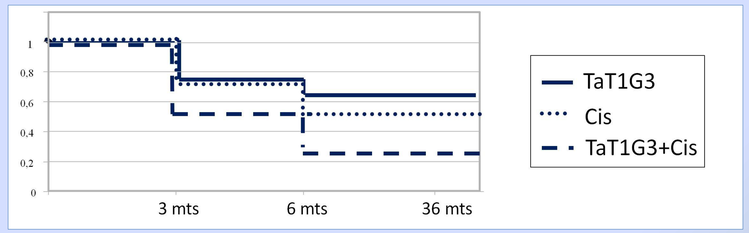
Materials & Methods

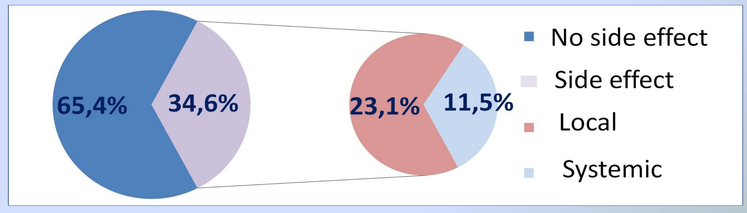
A prospective, single-center, non-randomized Phase II study was carried out in order to evaluate the efficacy in terms of response and progression rate and safety of the EMDA®-MMC treatment in 26 (21 male, 5 female) consecutive patients with HGNMIBC unresponsive after at least one cycle of intravesical immunotherapy with BCG. Patients underwent an EMDA®-MMC induction cycle (40 mg of MMC diluted in 100 ml of PPI retained in the bladder for 30 minutes with 20 mA pulsed electric current) of 6 weekly instillations and then a monthly maintenance cycle for a total of 6 treatments. Followup was based on bladder bioptic mapping (with sampling in the prostatic urethra for men), voiding and washing urinary cytology and radiological study of the upper urinary tract. In order to analyze disease-free survival Kaplan-Meier curves were constructed and Log-rank test was applied.

Results

After 3 years of follow-up, 16 patients (56.5%) preserved their native bladder, 10 patients (43.5%) underwent radical cystectomy, in 26.1% of cases (6 patients) for recurrent HGNMIBC and in 17.4% of cases (4 patients) for progression to muscle-invasive disease. Stratifying patients based on TNM classification (TaT1G3, Cis or TaT1G3+Cis), disease-free rates at 3 years followup were 62,5%, 50% and 33% with statistically significant differences (p value < 0.05). Regarding toxicity, 3 patients (11.5%) had a severe adverse systemic event of hypersensitivity to the MMC while 6 patients (26.1%) had local side effects.







Conclusions

The EMDA®-MMC is a safe and effective tool in the long term conservative treatment of the high-risk NMIBC unresponsive to BCG, as second line "sparing bladder" therapy in selected patients. Multicenter studies with larger number of patients and longer followup may justify a wider use of EMDA®-MMC.