



Re: Sequential Combination of Mitomycin C Plus Bacillus Calmette-Guerin (BCG) Is More Effective but More Toxic Than BCG Alone in Patients with Non-Muscle-Invasive Bladder Cancer in Intermediate-and High-Risk Patients: Final Outcome of CUETO 93009, A Randomized Prospective Trial

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Eur Urol 2014 Oct; 6. pii: S0302-2838(14)00963-4. doi: 10.1016/j.eururo.2014.09.026. [Epub ahead of print]

EDITORIAL COMMENT

EAU Guideline recommendation in non-muscle invasive bladder cancer (NMIBC) is that patients who have intermediate or high risk for recurrence and intermediate risk for progression should receive early single dose intravesical chemotherapy followed by maintenance or a minimum of 1 year of BCG. Intravesical Mitomycin C (MMC) plus Bacillus Calmette-Guerin (BCG) treatment schemes were studied. However, MMC+BCG were not found to be superior to BCG alone (1,2). In the present study, authors conducted a randomized prospective trial on combination of MMC+BCG (n=192) or BCG alone (n=190). EORTC definition of NMIBC intermediate and high-risk patients were included in the study. Unlike previous reported studies, disease-free interval at 5 years for MMC+BCG was found to be significantly better (HR: 0.57; 95% CI, 0.39 -0.83; p=0.003) than BCG alone. In an interim analysis, excessive toxicity was observed in MMC+BCG than BCG alone group. Consequently MMC dose was reduced from 30 mg to 10 mg. However, toxicity remained higher in the MMC+BCG group. Especially in EORTC high-risk NMIBCs, MMC+BCG is better than BCG alone, but with worse toxicity. In conclusion, despite some limitations, the results of Solsona et al. provided a new potential bladder-sparing management alternative, but it has higher toxicity. Additional studies are required to confirm these findings and availability of a less toxic intravesical chemotherapeutic agent.

SUGGESTED READING

1. Kaasinen E, Wijkstrom H, Malmstrom PU, et al. Alternating mitomycin C and BCG instillations versus BCG alone in treatment of carcinoma in situ of the urinary bladder: a nordic study. *Eur Urol*. 2003;43(6):637-45.
2. Oosterlinck W, Kirkali Z, Sylvester R, et al. Sequential Intravesical Chemoimmunotherapy with Mitomycin C and Bacillus Calmette-Gue crin and with Bacillus Calmette-Guecrin Alone in Patients with Carcinoma in Situ of the Urinary Bladder: Results of an EORTC Genito-Urinary Group Randomized Phase 2 Trial (30993). *European Urology*. 2011;59(3):438-46.

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