

BLADDER CANCER TOXIC EFFECTS—A BCG BALANCING ACT

Patients with non-muscle-invasive bladder cancer typically receive adjuvant BCG instillations for 3 years after they have undergone transurethral resection. However, this maintenance treatment is associated with considerable toxicity (such as fever, dysuria and urge incontinence), often leading to the interruption or cessation of therapy. A new study has determined that, for patients at intermediate risk of recurrence or progression to muscle-invasive disease, 1 year of BCG therapy offers the same protection as 3 years.

“The reason for starting the trial was to search for ways of reducing adverse effects without compromising the treatment outcome,” explains lead investigator Jorg Oddens. The study included 1,316 patients who were followed up for a median of 7.1 years, with a primary end point of disease-free interval before recurrence, progression, metastases or cancer-specific death. Patients were divided into four groups to examine not only the length of treatment but also the dosing: patients were given either the typical, full-dose BCG or 1/3 of that dose for 1 year or 3 years.

Although no difference in toxicity was evident between the four groups, 49% of patients across all groups did not complete their treatment for reasons that included inefficacy. However, stratification of patients on the basis of their risk for recurrence or progression revealed that the different treatment doses and durations were not uniform in their effects. For example, patients classified as intermediate-risk (not T1 or G3) performed better if they received 3 years of the low-dose regimen than 1 year. The same was not true in the full-dose groups. In high-risk patients (T1 or G3), 3 years of maintenance at the full dose was better than 1 year. However, 3 years was not better than 1 year of therapy for high-risk patients receiving the reduced dose.

These results suggest that the survival benefits of BCG maintenance must be balanced against the costs and inconvenience of frequent instillations, as well as the adverse effects. “Next, we will examine the impact of these adverse BCG effects on the decision to discontinue treatment,” concludes Oddens.

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Original article Oddens, J. *et al.* Final results of an EORTC-GU Cancers Group randomized study of maintenance Bacillus Calmette-Guérin in intermediate and high-risk T_a, T₁ papillary carcinoma of the urinary bladder: one-third dose versus full dose and 1 year versus 3 years of maintenance. *Eur. Urol.* doi:10.1016/j.eurouro.2012.10.039