Abstract Code: IUC24412-78

The Safety and Efficacy of a Modified Di Stasi Regime for Patients with Non-Muscle Invasive Bladder Cancer During Times of Bacillus Calmette-Guérin Shortage

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Background: Intravesical Bacillus Calmette-Guérin (BCG) is an important treatment for non-muscle invasive bladder cancer (NMIBC). BCG combined with electromotive drug administration (EMDA) mitomycin C (MMC) can decrease the risk of bladder cancer recurrence and disease progression when compared with BCG monotherapy. The standard Di Stasi induction protocol involves nine weeks of alternating intravesical BCG and EMDA MMC instillations. Due to global BCG shortages, exacerbated by the COVID-19 pandemic, modified regimes have been implemented. We sought to evaluate the safety and efficacy of a modified Di Stasi regimen during a period of BCG shortage.
Methods: We conducted a retrospective cohort analysis of 40 consecutive patients being treated for high-risk NMIBC between 2021 and 2022. 19 patients completed a modified Di Stasi regime (three BCG and six EMDA MMC) compared to 21 patients who completed the standard regime (six BCG and three EMDA MMC). Patient demographics, histology and recurrence rate over three years were collected from the electronic patient records and analysed.
Results: A Chi-square test showed no significant difference in characteristic data between the two cohorts. Recurrence-free survival at 36 months was analysed using Kaplan-Meier survival analysis and was 71.4% in the standard Di Stasi cohort compared to 62.2% in the modified Di Stasi cohort. The Log-rank method yielded a non-significant difference in the rate of recurrence-free survival at 36 months ($p=0.638$). The mean time to recurrence was significantly longer in the modified Di Stasi cohort, 29.7 ± 2.6 months vs 20.9 ± 1.6 months ($p < 0.0001$). Total recurrence in the modified Di Stasi group was 36.8% (n=7) and 30.0% (n=6) in the standard Di Stasi cohort ($p=0.59$). Mortality from bladder cancer at 36 months between the two groups was not significant, 10.5% (n=2) in the modified Di Stasi vs 0.0% (n=0) in the standard Di Stasi ($p=0.13$).
Conclusions: This modified Di Stasi protocol demonstrated comparable recurrence-free survival at 36 months and a prolonged mean time to recurrence. In future periods of BCG shortage, a modified regime may be considered as an alternative to the conventional Di Stasi protocol and offer similar clinical outcomes.