Evaluation of the UroVysion™ Test in Predicting Recurrence and/or Progression of Disease in Patients Receiving initial BCG for Primary High Grade Ta-T1 and CIS Urothelial Carcinoma of the Bladder


Introduction
•We performed a multi-center prospective study that enrolled patients with high grade non-muscle invasive bladder cancer (NMIBC) and treated with BCG regimen at risk for recurrence and progression of disease.
•The UroVysion FISH assay (UroVysion) has been reported to predict response to BCG therapy.
•Herein, we validated the association of UroVysion results with BCG-naive patients at risk of subsequent disease recurrence/progression.

Materials and Methods
•We performed a multi-center prospective study that enrolled patients with primary high grade Ta-T1 tumors, CIS or recurrent NMIBC who initiated BCG therapy.
•UroVysion testing was performed on urine specimens collected prior to the first instillation of BCG therapy, at time of the 6th instillation, and at 3-month surveillance.
•Clinicians were blinded to the UroVysion results for specimens at 3-month surveillance.
•Patients were monitored for disease recurrence by cystoscopy following standard of care intervals.
•Follow up data were collected at time of recurrence or progression.

Results
•The study included 151 patients (80% men) with stages of Ta (42%), T1 (25.8%), CIS alone (17.9%), Ta+CIS (2%), and T1+CIS (7.3%). At baseline, 43.9% (65/148) were UroVysion positive.
•There were 46 events, including 36 recurrences and 10 progressions.
•KM survival curves demonstrate significant reduced event free survival for UroVysion positive tests at baseline, 6-week and 3-month surveillance (Figure).
•Patients with a positive UroVysion test at baseline prior to BCG or at 6 week instillation were more likely to experience recurrence or progression at 6 months and 9 months but differences at 3 months were not statistically significant.

Conclusions
•Approximately one-third of patients who initiate BCG have recurrence or progression events within 9 months of diagnosis.
•A positive UroVysion assay at baseline and at the conclusion of BCG therapy was associated with a significantly increased likelihood of experiencing such an event at 6 and 9 months.
•These data may be utilized for guiding management as well as clinical trial enrollment.