NMP22 ENHANCES THE DETECTION RATE OF BOTH LOW AND HIGH GRADE BLADDER CANCERS

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A multicenter clinical trial (33 sites) enrolled 769 patients with risk factors for bladder cancer (hematuria, lower urinary tract symptoms) but with no previous history of urinary tract malignancy. All patients underwent cystoscopy and subsequent TURBT (if necessary) and had NMP22 and voided urine cytology performed. Upper tract imaging procedures were performed if hematuria was present. Fifty-six patients were found to have bladder cancer: 5-T0 (papilloma), 20-Ta, 5-Tis, 11-T1, 13-T2 to T4, 2-Tx (tumors seen, patient refused biopsy). Using a cut-off value of 5.0 U/mL, NMP22 detected 3/5-T0, 11/20-Ta, 4/5-Tis, 8/11-T1, 11/13-T2 to T4, 2/2-Tx; voided urine cytology detected 0/5-T0, 3/20-Ta, 4/5-Tis, 5/11-T1, 7/13-T2 to T4, 0/2-Tx. Overall, with superficial cancers (T0, Ta, T1), NMP22 had a sensitivity of 61.1% (22/36) and voided urine cytology had a sensitivity of 22.2% (8/36). With invasive cancer (T2 to T4), NMP22 detected 79.2% (19/24) whereas voided cytology detected 50% (12/24).