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Which Test is the Best? In the Diagnosis and monitoring of Bladder Carcinoma

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Bladder cancer is one the top ten most common cancer types in the world, with approximately 550,000 new cases annually [1]. It is expensive to diagnose, treat, and monitor Bladder cancer [2]. Evidences indicates that non-invasive urine-based tests can improve the diagnosis, treatment and monitoring of patients, improving results and reducing costs [2] Biomarkers such as ImmunoCyt/uCyt+, UroVysion, NMP-22, bladder tumor antigen, CxBladder, and Xpert Bladder Cancer are available. Not many biomarkers have high sensitivity and specificity. However, Cytology has high specificity but not good enough sensitivity [3]. Fourteen studies showed a diagnostic accuracy of 72% sensitivity and 83% specificity of the UroVysion kit. Many studies showed that the UroVysion has higher sensitivity than urine cytology. However, most other studies have demonstrated that UroVysion has lower specificity than urine cytology [3-7]. UroVysion (Abbott Molecular, Inc., Illinois, USA) is based on multicolor fluorescence in situ hybridization (FISH). It has been used in the USA following its FDA approval in 2001. In Japan it was approved in 2017 [8]. Cystoscopy and urine cytology are used to detect bladder cancer in Japan, A Japanese study concluded that UroVysion FISH alone is insufficient to detect bladder cancer and that cystoscopy is essential for the detection or follow up of bladder cancer cases. They found that combined urine cytology and UroVysion FISH detected 40% of urothelial carcinoma cases, but 60% of the cases were not detected. The use of combined UroVysion FISH and urine cytology is considered a reasonable procedure for the detection of non muscle invasive bladder carcinoma [8].

Present studies indicate the significance of uncertain urine cytology findings and suggest the use of urine biomarkers [9]. Voided urine resulted in a sensitivity of 25.8% and a specificity of 100% , while the NMP22 showed a sensitivity and specificity of 12.9% and 100%, respectively [10]. Urinary Bladder Cancer (UBC) antigen Rapid qualitatively and quantitatively revealed a sensitivity of 61.3% and 64.5%, with a specificity of 77.3% and 81.8% [10]. Compared to urinary cytology, UBC tests alone as well as UBC tests in combination with bladder washing cytology revealed higher sensitivities in detecting low- and high-grade tumors, but at the expense of a lower specificity. Thus, currently cystoscopy cannot be replaced by any of the evaluated methods [10]. Further reports [7] showed that the sensitivity and specificity of the NMP22 BladderChek test were 37.9% and 95.8%, respectively, while the sensitivity and specificity of urine cytology were 54.2% and 97.6%, respectively. The reports showed that urine cytology is superior to the NMP22 BladderChek test, and combined use of the two tests improves the sensitivity in the detection of the primary [11].

UroVysion FISH was found to be positive in a high proportion of pathologically confirmed urachal carcinoma (urachal carcinomas are rare tumors that occur predominantly in the dome of the urinary bladder.) Its chromosomal aberrations may be different from those of urothelial carcinoma. More studies are needed to clarify their genetic background. Not all tumors showing abnormalities by FISH are urothelial carcinomas [8]. A study in Japan confrmed the effectiveness of two consecutive UroVysion tests in predicting recurrence after TURBT. Further studies may help to determine a suitable interval for cystoscopy follow-up [9]. Application of FISH Urovysion to cultured CTCs (Circulating tumor cells) from bladder cancer could help to confirm their origin and sharing of chromosomal abnormalities [10] A Korean study suggested that the NMP22 test should be added to the diminishing criteria for MME (manual microscopic examination) to improve accuracy. The combination of urine sediment imaging analysis and NMP22 test can assist in the review of specimens [11]. The combination of Fluorescence in Situ Hybridization (FISH) and nuclear matrix protein 22 (NMP22) could increase the sensitivity and specificity of bladder carcinoma management. A systematic literature search was carried out in PubMed, Embase, Cochrane Library, Web of Science, Chinese National Knowledge

Infrastructure, and Wanfang database dated up to October 2018. The systematic review showed that the combination model of FISH plus NMP22 may do better than FISH or NMP22 alone in bladder cancer detection. [12].

Once more, marker combination is supported. This covers the genetic susceptibility to chemicals with the level of detoxification and nuclear matrix protein in bladder cancer patients. A relationship between NMP22 level in urine, GST (glutathione S-transferase) level in blood and NAT2(N-acetyltransferase 2) genotype was observed. Also the isoenzyme GST-π in urine seems useful as a marker of bladder cancer . Taken together, UroVysion FISH was found to be positive in a high proportion of urachal carcinoma as well [13-15]. ApoA-1 showed high sensitivity and specificity, so it could be a useful biomarker in the diagnosis of bladder cancer as well [16]. In summary, At some point, these biomarkers might reduce the total of follow-up cystoscopies, may be by intermittent follow-up scheme alternating between cystoscopy and biomarker testing. The main biomarker purpose should be to exclude high grade tumor recurrence without the need for any invasive procedures. Finally, systematic reviews implied that the diagnostic performance of combination models might outperform single tests alone in bladder cancer detection [17].

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