EDITORIAL COMMENT

RE: A urine-based genomic assay to triage patients with hematuria for cystoscopy

De Jong et al. report results of a prospective multi-center validation study of a urine-based assay in 838 patients investigated for hematuria. The authors concluded that this assay has an AUC of 0.93 (92% sensitivity, 73% specificity).

Urine biomarkers for the detection of cancer is an area of considerable research. The authors utilize a biomarker panel comprising of three mutations and three DNA methylation targets to maximizes the sensitivity of the assay (reference 22). Many research groups have reported highly sensitive assays in development cohorts however, few hold true in subsequent validation studies. Results of the current study are commended, and the authors should be congratulated.

The authors proposed that the current assay should be used as a triage tool in patients with microscopic hematuria. This patient cohort comprised of 350 patients of which only 14 patients (4%) had a diagnosis of cancer. This low number of cancers remains a limitation. A sensitivity analysis of an enriched cohort of bladder cancer patients of different grades and stages would be needed. Further, the assay does not provide a read out for all patients and 167 (16.6%) patients had inconclusive results. Data regarding cost analysis of a biomarker directed triage approach would be eagerly awaited.

Finally, how sensitive is sensitive enough? A recent study on patients' perspectives on urine biomarkers suggest that >60% of patients require a urine biomarker to achieve a sensitivity of >95%.[1] This remains a challenging task however, it should be acknowledged that cystoscopy itself is not 100% sensitive.

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References

1. Tan, W. S., Teo, C. H., Chan, D. et al.: Mixed-methods approach to exploring patients' perspectives on the acceptability of a urinary biomarker test in replacing cystoscopy for bladder cancer surveillance. BJU International, **124:** 408, 2019