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Promising urine test could improve early detection and clinical management of bladder cancer: IARC Evidence Summary Brief No. 3

Lyon, France, 20 May 2022 – The International Agency for Research on Cancer (IARC) has released a new IARC Evidence Summary Brief, titled "Improving Early Detection and Clinical Management of Bladder Cancer", in which researchers from IARC and partners argue for the validation of a simple and cost-effective urine test that could significantly improve early detection and management of bladder cancer, including among high-risk populations.

The test, which was developed by IARC scientists, detects the presence of specific mutations in the promoter of the telomerase reverse transcriptase (*TERT*) gene in urine samples. It has shown its excellent performance for the detection of bladder cancer in urine samples in two independent studies: the DIAGURO study in France and the Golestan Cohort Study in the Islamic Republic of Iran.

These *TERT* promoter mutations (TERTpm) have been detected at a high frequency (60–85%) in all stages and grades of bladder cancers and are the most frequent genetic alterations.

"IARC has developed a droplet digital PCR (ddPCR) assay that detects TERTpm in urine samples (uTERTpm)," explains Dr Florence Le Calvez-Kelm, a scientist in the Genomic Epidemiology Branch at IARC and co-author of this third IARC Evidence Summary Brief. "The uTERTpm biomarker offers a significant opportunity as a simple and non-invasive biomarker for screening and early detection, because it is detectable years before the clinical diagnosis of bladder cancer. We therefore call on funders to support more research to validate uTERTpm as a urinary biomarker for the detection of bladder cancer in order to aid its clinical implementation as soon as possible."

Bladder cancer

Bladder cancer is the 10th most common cancer type worldwide. Every year, about 600 000 people are diagnosed with bladder cancer worldwide and more than 200 000 people die from this disease.

Bladder cancer is one of the most challenging and expensive cancers to diagnose and treat. Its diagnosis relies mainly on cystoscopy, an invasive and expensive procedure.

Most bladder cancers are diagnosed at an early stage, when they are highly treatable. However, about 25% of bladder cancers are diagnosed at later stages.





Even early-stage bladder cancer can recur after initial treatment (31–78% recurrence at 5 years). Therefore, people with bladder cancer typically need to be followed up closely for years after treatment, which may include performing repeated invasive procedures such as cystoscopy.

A cost-effective tool to screen high-risk populations

The new IARC Evidence Summary Brief also stresses that uTERTpm testing, followed by cystoscopy or urography, could provide a cost-effective tool for screening of high-risk populations (smokers and workers exposed to bladder carcinogens).

Although bladder cancer screening is currently not recommended by the clinical guidelines or urological societies, probably because none of the commercially available urine tests have shown appropriate performance for this purpose, screening high-risk populations would enable improvement in bladder cancer survival, by reducing the stage at which the cancer is discovered.

"The uTERTpm test could provide a cost-effective alternative to invasive examinations for the detection and monitoring of bladder cancer, leading to improved quality of life for patients and reduced health-related costs," says Dr Emmanuel Vian, a urologist at the Protestant Clinic of Lyon, France, and co-principal investigator of the DIAGURO study. "The validation of the uTERTpm biomarker in international studies would provide valuable information to aid its clinical implementation. It could also lead to the development of screening strategies in high-risk groups, who would benefit from close surveillance with a simple, non-invasive test."

Note to the Editor:

This IARC Evidence Summary Brief is the third in a series of scientific <u>Evidence Summary Briefs</u> published by IARC to call attention to the findings of evidence-based studies in key aspects of cancer prevention.

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