Results of the application of a multiparametric non-invasive test enabling cancer risk stratification in patients with recurrent lower urinary tract symptoms

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Over a period of 97 months, within the framework of the research project, 663 cytological examinations of urine sediment cells (USC) were performed in patients of both sexes. Apparently healthy individuals as well as patients reporting recurrent lower urinary tract symptoms were recruited from three hospital-based Urology Clinics and a Gynecology Clinic. Based on medical interviews and cytological findings, a study group (77 patients) and a reference group (66 patients) were established. In both groups, an extended evaluation was performed. The extended test, referred to as Cytourofish(+), included thin-layer cytology of USC, analysis of selected histochemical markers (PCNA, p53, Ki67, CK20), interphase cytogenetic assessment of interstitial deletion of chromosome 9p21, detection of the TERT gene promoter variants, and application of the BladderEpiChek test. Following the standardization of pre-laboratory and laboratory procedures, the analyses yielded 213 Negative for High-Grade Urothelial Carcinoma (NHGUC), 135 Atypical Urothelial Cells (AUC), and 76 Suspicious for High-Grade Urothelial Carcinoma (SHGUC) results. Based on the obtained experience, a part of the immunohistochemical (p53, Ki67, CK20) and cytogenetic (interstitial deletion 9p21) analyses was discontinued due to the lack of results suggestive of potential abnormalities. In its current form, the comprehensive multiparametric Cytourofish(+) test, applied under established specific laboratory conditions, generates multiple parameters with possible implications for cancer risk evaluation. The next objective of the ongoing project is to develop a machine learning-based system modeling the decision-making process.