

ST019

INTRODUCTION

Bladder cancer is among the ten most common cancers globally and the most common cancer of the urinary system\*. It typically arises from the urothelium but may originate in other locations. Bladder cancer commonly presents as painless hematuria (blood in urine) which may be gross or microscopic.

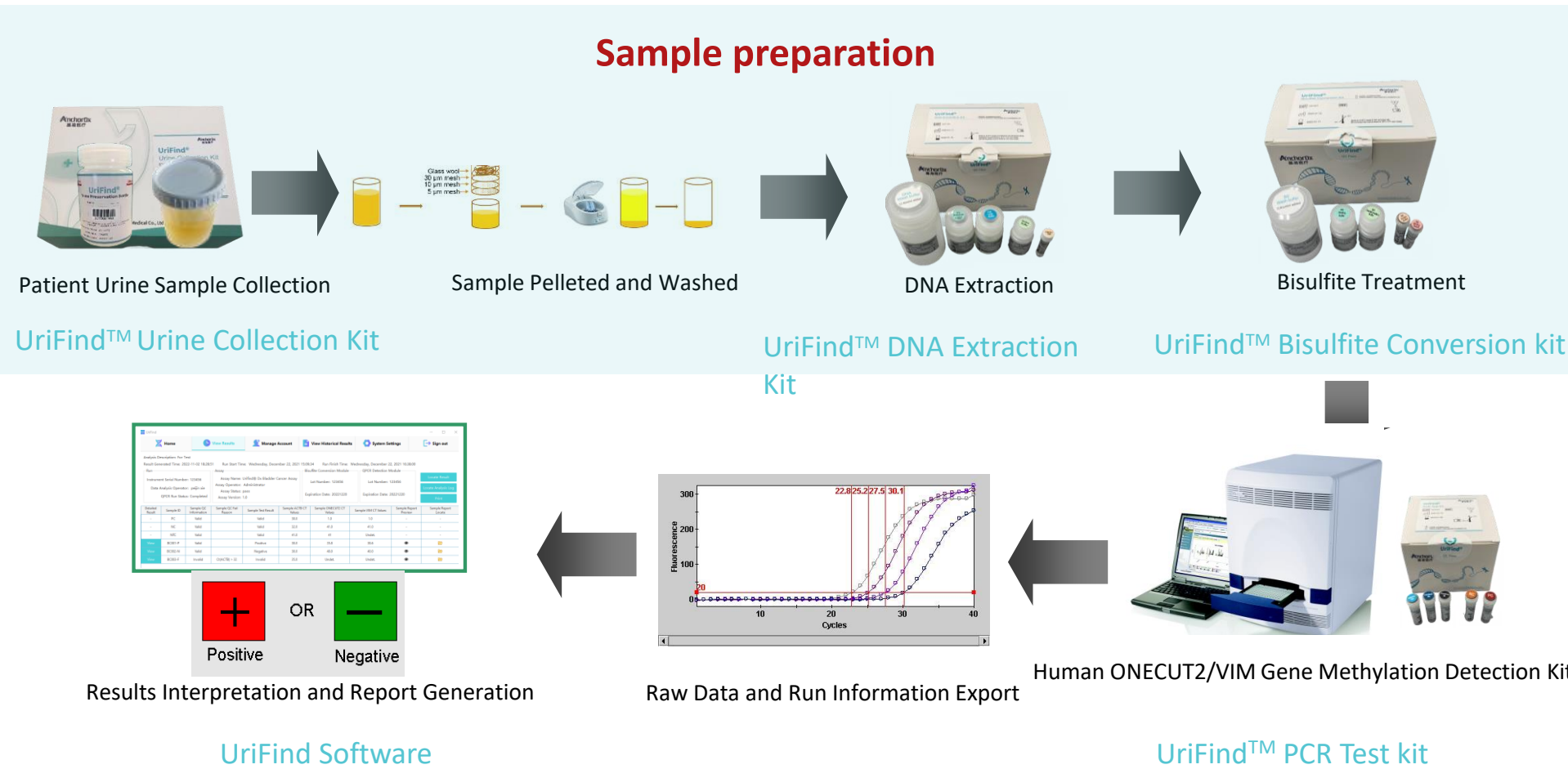
The gold standard for the diagnosis and monitoring of urothelial carcinoma (UC) typically involves invasive and painful procedures like cystoscopy. Current non-invasive methods are often costly and have low sensitivities.

The UriFind® Dx Human Bladder Cancer Assay is an *in vitro* methylation detection test to detect the methylation status of two biomarkers and a conserved reference gene in human gDNA isolated from urine samples.

UriFind assay showed a compelling sensitivity and specificity in a retrospective cohort. The reported study (NCT04314245) aimed to further validate its performance in a large-scale multicenter prospective cohort in China.

\*Halaseh et al, Cureus. 2022 Jul; 14(7): e27330

MATERIALS AND METHODS



A total of 1,082 UC patients, 1,049 controls with benign urogenital diseases, 78 healthy participants, and 236 patients with non-UC cancers were recruited from 19 hospitals. Urine samples were collected before therapy and analyzed using UriFind® (a quantitative PCR of *ONECUT2* and *VIM* methylation), Fluorescence In Situ Hybridization (FISH), and urinary cytology. Sensitivity, specificity, and accuracy were evaluated compared to the standard diagnostic procedure.

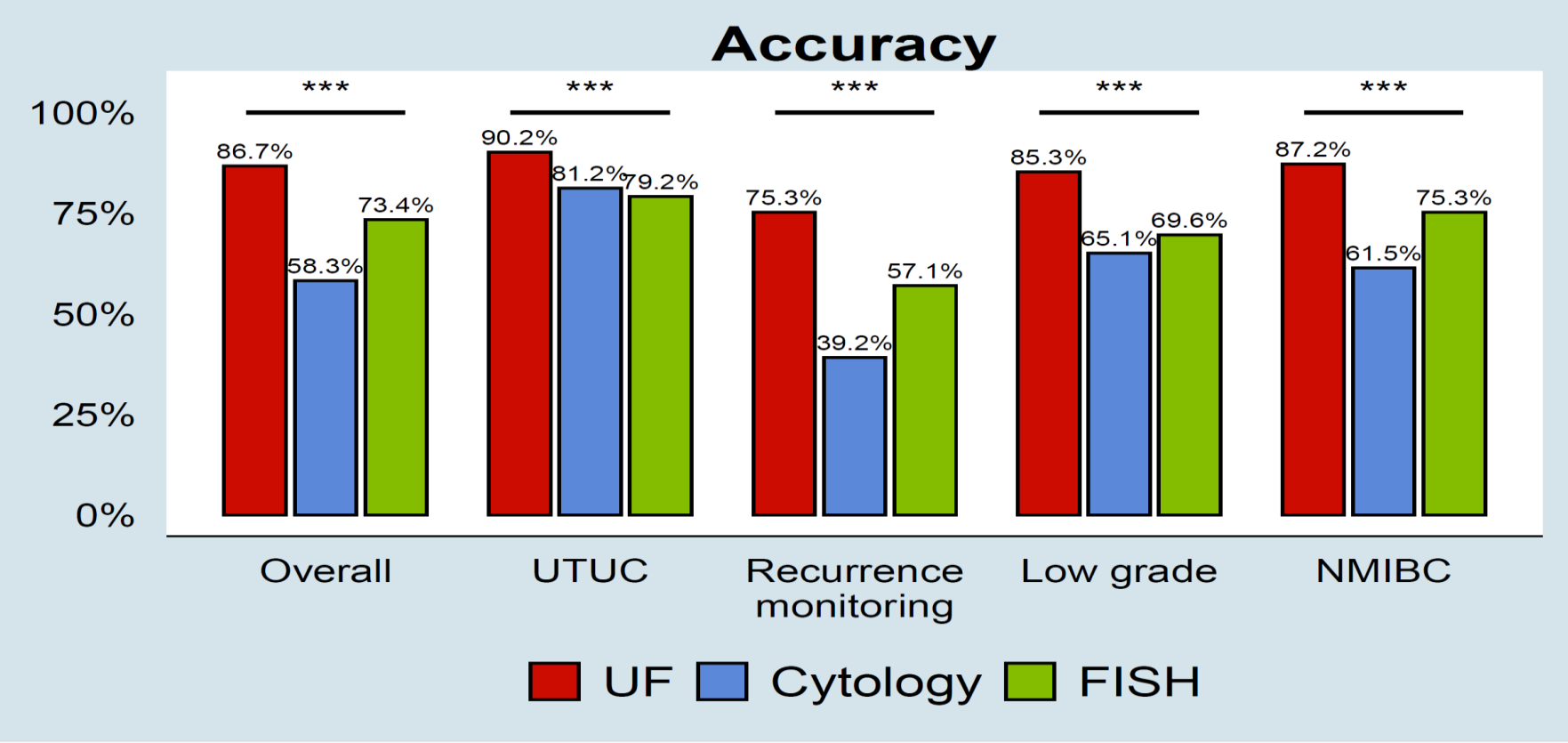
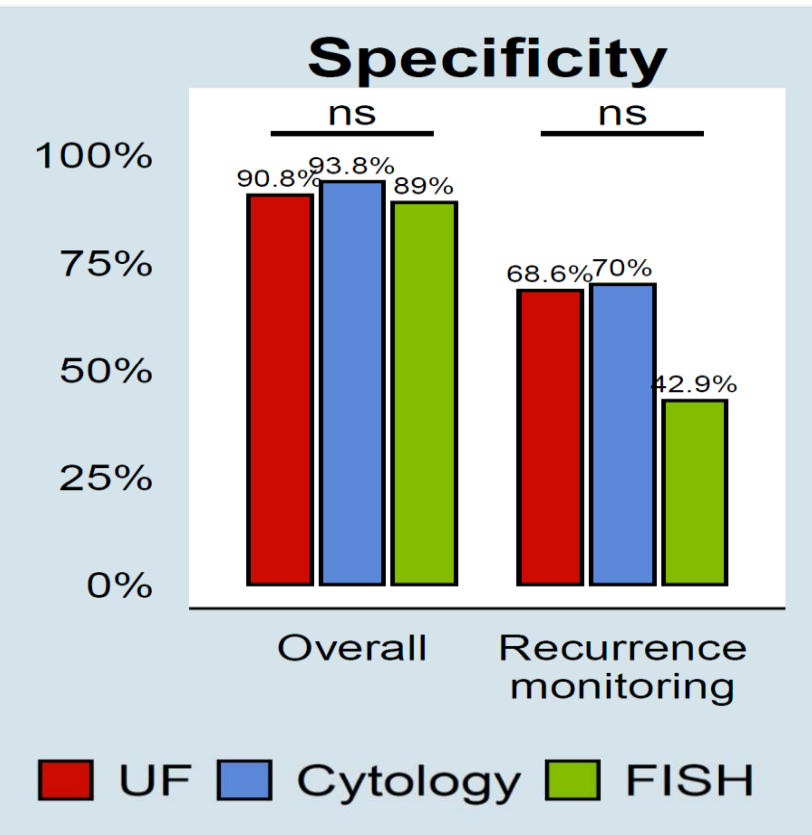
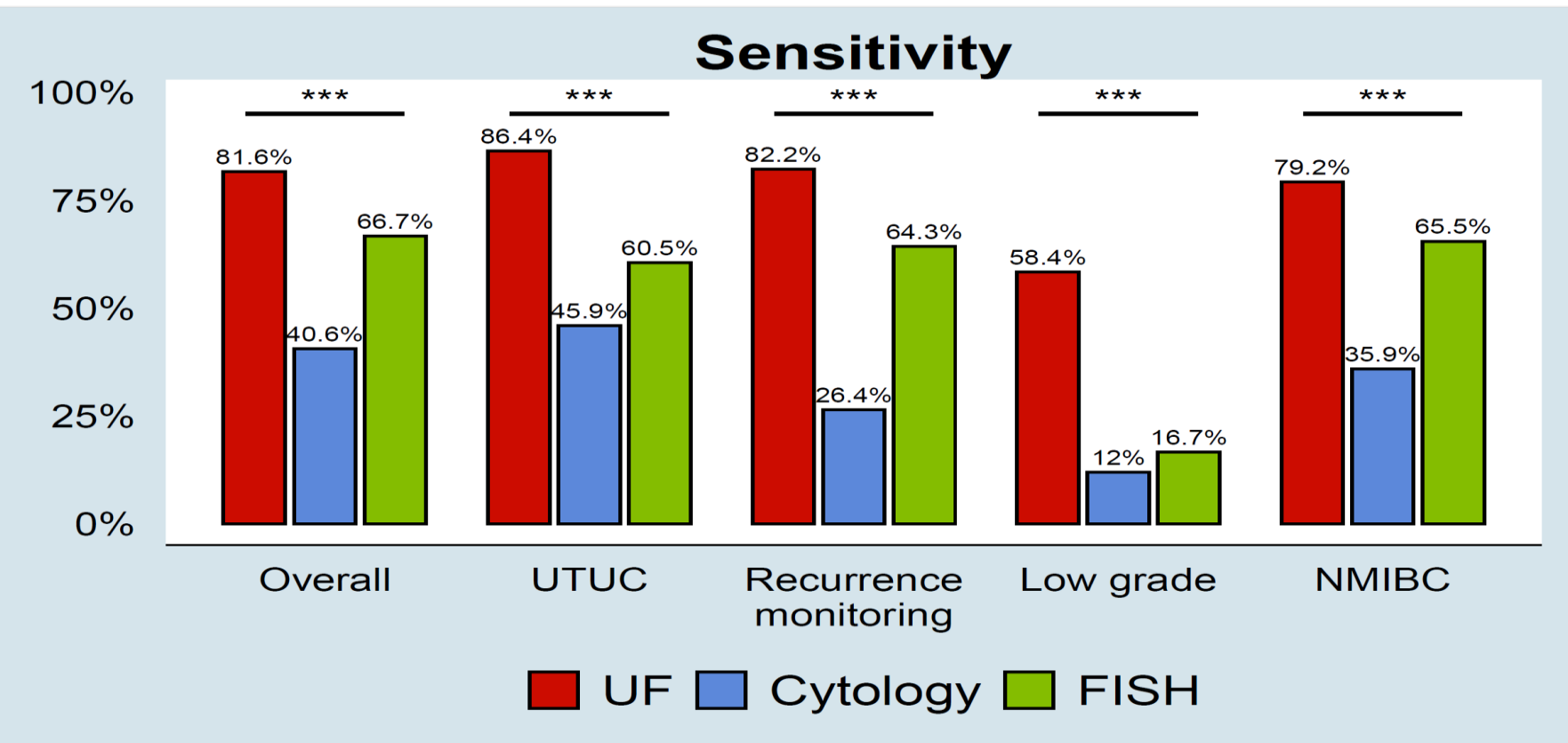
RESULTS SUMMARY

The UC group consisted of 702 cases of non-muscle-invasive UC (64.9%), 238 cases of muscle-invasive UC (22.0%), and 142 cases with unavailable stage (13.1%). The patients with low-, high-grade, and unavailable-grade UC were 274 (25.3%), 715 (66.1%), and 93 (8.6%), respectively.

UriFind® demonstrated an overall sensitivity of 81.6%, specificity of 90.8%, and accuracy of 86.7%. The specificity for healthy controls and other cancer patients (excluding UC) was 100% and 88.6%, respectively. UriFind® showed significantly higher overall sensitivity and accuracy compared to urinary cytology (40.6% and 58.3%) and FISH (66.7% and 73.4%), while maintaining similar specificity to cytology (93.8%) and FISH (89%).

Importantly, compared to cytology and FISH, UriFind® exhibited significantly improved sensitivity in the whole course management, including low-grade tumors (58.4% vs. 12% and 16.7%), small and single tumors (63.6% vs. 32.7% and 47.1%), residual tumors after therapy (72% vs. 16.7% and 0%), and recurrent tumors (82.2% vs. 26.4% and 64.3%).

RESULTS



UriFind:

Overall PPV - 0.88  
Overall NPV - 0.86

CONCLUSIONS

The performance of UriFind® has been extensively validated in this cohort of 2,445 cases. With similar specificity and significantly higher sensitivity than urine cytology and FISH, UriFind® is a rapid, high-throughput, noninvasive, and promising approach for early diagnosis, minimal residual tumor detection, and surveillance in the whole course management of UC. Its implementation could reduce the burden of cystoscopy and unnecessary second TURBT.

UF – UriFind; UTUC - Upper tract urothelial cancer; NMIBC - non-muscle invasive bladder cancer