Randomisation was stratified by centre, CIS and prior BCG response. Primary outcomes were DFS and complete response (CR) at three months in patients with CIS at randomisation. A log-rank test was performed to compare arms on an intention-to-treat basis.

RESULTS: Between May 2010 and July 2013, 104 patients were randomised. 48 (46%) assigned to RITE and 56 (54%) control. Median DFS was 35.1 months (IQR: 23.1-445.3 months) with no difference between treatment arms (HR 1.32, [0.83-2.1], p=0.23). Three-month CR in CIS patients for both treatment arms were similar (RITE: 75% vs control: 80%, p=0.62). DFS in patients with papillary-only disease was higher in RITE patients (HR 0.42, [0.19-1.03], p=0.0531) but not significantly different in CIS-only patients (HR 1.61, [0.8-3.2], p=0.17). Papillary disease and concurrent CIS patients had significantly better DFS in the control arm (HR 6.9, [2.06-23.25], p<0.001). No difference in adverse events between treatment arms were observed.

CONCLUSIONS: The HYMN trial did not show an overall difference between RITE and the control arm. However, there was a benefit for RITE in participants with papillary-only disease. RITE was well tolerated with comparable adverse events compared with BCG. Further trials are needed to investigate the efficacy of RITE in CIS patients.

Source of Funding: Cancer Research UK funded the trial administration (trial number CRUK/09/012). Kyowa Hakko UK Ltd kindly gave the trial a total of GBP75,000 which helped to fund the procurement and maintenance costs of the Synergo system. Medical Enterprises Europe B.V. supplied the Synergo system at a discounted rate and its associated disposables to the participating sites. All funders had no role in the study design, data collection, data analysis, data interpretation, writing of the report and in the decision to submit the paper for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

PD19-09

PERFORMANCE OF A NOVEL URINE-BASED BIOMARKER FOR THE MONITORING OF BLADDER CANCER RECURRENCE

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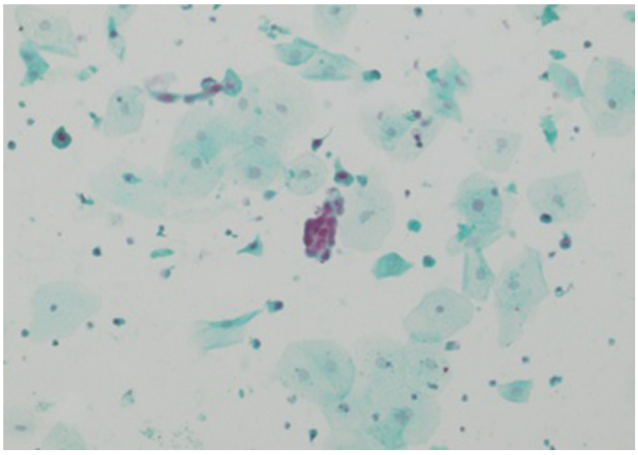
INTRODUCTION AND OBJECTIVES: The accurate detection of low-grade (LG) urothelial cell carcinoma (UCC) may be challenging, particularly in cases where cytomorphologic features overlap with those of non-neoplastic changes. CellDetect is a unique histochemical stain which enables color discrimination, in addition to morphological examination, for the differentiation between benign and malignant cells in urine specimens. A multi-institutional blinded study has recently shown that this color feature significantly improves the sensitivity for LG tumors when compared to standard urine cytology. The objective of the present study was to confirm this performance in an independent cytology laboratory.

METHODS: Voided urine samples were collected from a first cohort of patients undergoing routine cystoscopic surveillance. To enrich the study with positive cases, a second cohort of patients scheduled for transurethral resection (TURBT) was also enrolled. The patients from both cohorts had a documented history of bladder cancer. Urine samples were processed into two cytocentrifuge smears and each slide was stained with either CellDetect or standard cytology stain. Both specimens were observed by a cytopathologist blinded to the final diagnosis. The results were then compared to the gold standard (biopsy for positive cases and biopsy or cystoscopy for negative cases).

RESULTS: 73 patients were enrolled in this study, among which 51 were UCC-negative and 22 UCC-positive. The sensitivity of CellDetect was 82% compared to 59% for standard cytology (p<0.05) while the specificity was not significantly different (86% versus 94%). Moreover, the urine-based biomarker was able to detect 73% of the LG tumors compared to 45% by standard cytology. In addition, it correctly diagnosed 91% of the HG tumors compared to 73% for standard stain.

CONCLUSIONS: This study validates the usability of CellDetect in clinical settings. Particularly, it confirms its ability to accurately identify UCC recurrence throughout all cancer grades. This could be particularly useful in LG cases where cytomorphologic criteria overlap with benign reactive conditions.



Source of Funding: Zetiq Technologies Ltd.

PD19-10

THE CHEMOABLATIVE EFFECT OF VESIGEL INSTILLATION IN PATIENTS WITH NMIBC – RESPONSE RATE AND 1-YEAR DURABILITY

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INTRODUCTION AND OBJECTIVES: Endoscopic resection of low-grade (LG) tumors in patients with non-muscle invasive bladder cancer (NMIBC) is limited by incomplete imaging of all lesions, deep resections that preclude use of immediate intravesical therapy, and significant pain that hastens drainage of any intravesical agent. VesiGel, a novel sustained release thermosensitive hydrogel formulation of Mitomycin C (MMC), was developed to overcome these limitations. This study evaluated the primary chemoablative properties of VesiGel in the treatment of patients with LG NMIBC as an alternative to transurethral resection of bladder tumor (TURBT).

METHODS: 64 patients with LG NMIBC who were all eligible for TURBT were enrolled in the study after informed consent was obtained. The study consisted of 3 groups: Group A- VesiGel 0.06% (40mg at 64mL gel; n=20); Group B- VesiGel 0.12% (80mg at 64mL gel; n=22), and Group C- MMC 0.1% (40mg in 40mL water; n=23). All patients underwent 6 weekly instillations. Response was evaluated 2-4 weeks after the last instillation via cystoscopy and biopsy. Patients who demonstrated a CR were followed without any additional treatment. Recurrence and follow up were calculated based on the first cystoscopy