

Longitudinal Assessment of Urine Tumor DNA in High-Risk Non–Muscle-Invasive Bladder Cancer Patients

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Disclosures

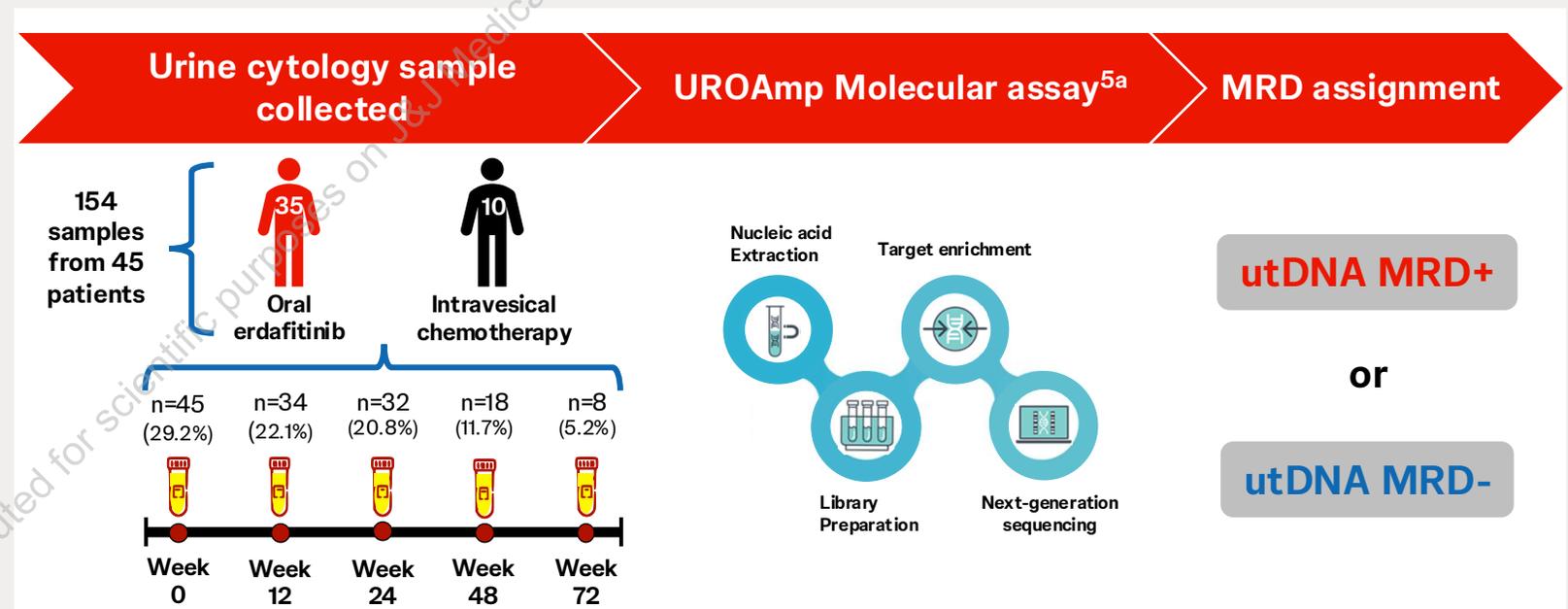
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utDNA Profiling in High-Risk Non-Muscle-Invasive Bladder Cancer to Identify Minimal Residual Disease

- Evidence indicates that despite TURBT for HR NMIBC, some patients still harbor residual molecular disease as reflected by the presence of utDNA^{1,2}
 - These patients may have poorer outcomes than those without utDNA MRD¹⁻⁴
- utDNA profiling detects urothelial carcinoma-associated mutations and can be used to identify utDNA MRD
- Here we report results of urine-derived MRD status in patients enrolled in the THOR-2 study (NCT04172675)

- Cohort 1 of THOR-2 included 73 patients with *FGFR+*, BCG-treated papillary-only HR NMIBC following TURBT
- 154 voided urine cytology samples were collected from 45 patients, pooled across both oral erdafitinib (n=35) and intravesical chemotherapy (n=10) arms



The data cutoff was July 11, 2024.

BCG, bacillus Calmette-Guérin; FGFR, fibroblast growth factor receptor; HR, high risk; MRD, minimal residual disease; NMIBC, non-muscle-invasive bladder cancer; TURBT, transurethral resection of bladder tumor; utDNA, urine tumor DNA. ^autDNA was assessed by the UROamp assay (Convergent Genomics, South San Francisco, CA). utDNA MRD status was determined per manufacturer's recommendations. Figure reproduced with permission from Convergent Genomics, South San Francisco, CA.

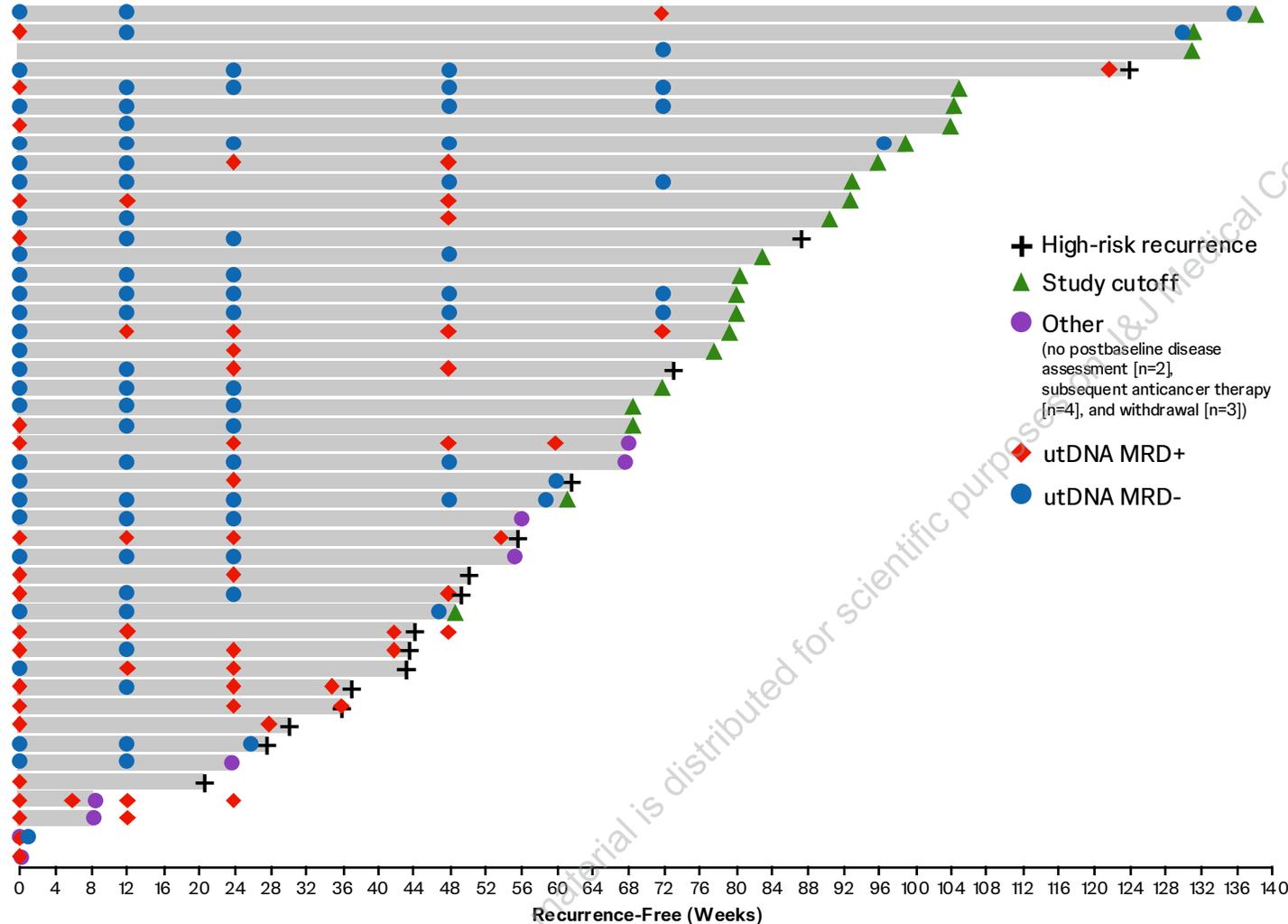
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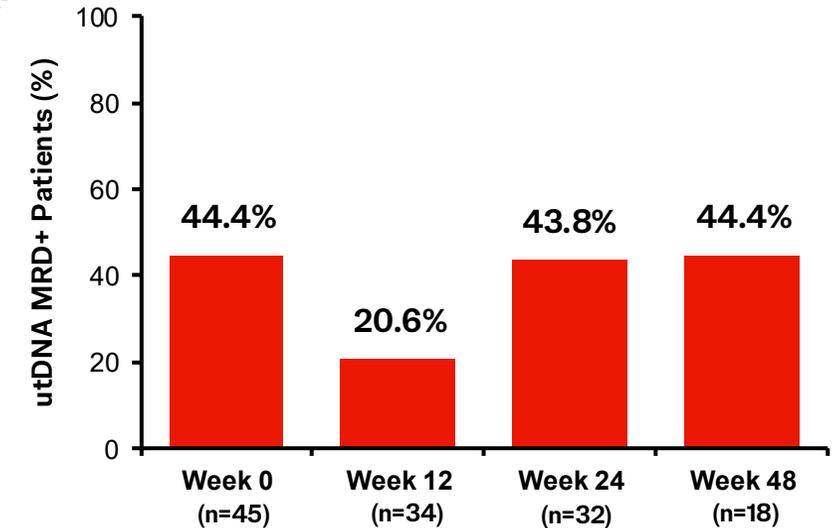
Treatment-Induced Changes in utDNA MRD



utDNA MRD assignment



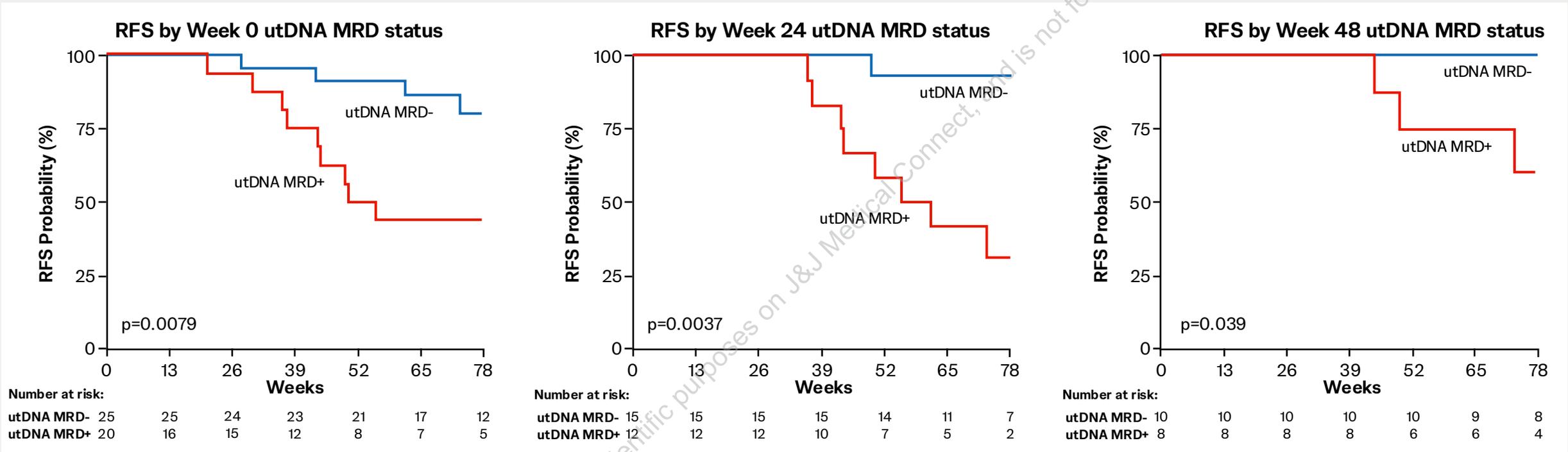
utDNA MRD positivity over time



- 44.4% of evaluable patients had positive Week 0 utDNA MRD results
- There was ≈ 2.2 -fold reduction in utDNA MRD positivity from Week 0 to Week 12
- utDNA MRD positivity varied over 48 weeks in individual patients



utDNA MRD Status Was Associated With RFS Outcomes



- Week 0 and on-treatment utDNA MRD positivity was associated with significantly worse RFS outcomes at all evaluated time points
- Among evaluable patients who were utDNA MRD- at Week 0:
 - 87.5% (21/24) remained recurrence free for >1 year
 - In paired Week 0 and Week 12 samples: 94.4% (17/18) were recurrence free for >1 year
- Among evaluable patients who were utDNA MRD+ at Week 0:
 - 50.0% (8/16) experienced recurrence in <1 year
 - In paired Week 0 and Week 12 samples: 66.7% (2/3) experienced recurrence in <1 year

RFS, recurrence-free survival.



Conclusions

- In patients with HR NMIBC from THOR-2, utDNA MRD status appeared to be associated with clinical outcomes
 - utDNA MRD positivity at any evaluated time point was prognostic for HR NMIBC recurrence in patients treated with oral erdafitinib or intravesical chemotherapy
 - utDNA MRD negativity at Week 0 and treatment-related reduction in utDNA MRD was associated with better long-term outcomes
- These findings support further investigation into the predictive value potential of longitudinal utDNA profiling to understand whether sustained utDNA positivity (MRD) may be associated with poorer prognosis in HR NMIBC



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