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Determining the Impact of Genomic Classifier Testing on Patient-Reported Quality of Life in Men at High-Risk of Post-Prostatectomy Recurrence: Results from the G-MINOR Trial

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INTRODUCTION AND OBJECTIVE: Current evidence supports consideration of adjuvant radiotherapy (RT) following prostatectomy (RP) in high-risk patients. However, only a limited number of men at high-risk of recurrence receive adjuvant RT. Decipher is a tissue-based genomic classifier (GC) developed and validated in the post-RP setting as a predictor of metastasis. We conducted the first prospective randomized trial assessing the impact of GC testing on adjuvant therapy use. We determine the impact of GC testing on patient reported outcomes (PRO) in men at high-risk of post-RP recurrence.

METHODS: The **G**enomics in **M**ichigan **I**mpacti**N**g **O**bservation or **R**adiation (G-MINOR) trial is a prospective, cluster-crossover, unblinded, randomized study of 356 patients from 12 centers in the Michigan Urological Surgery Improvement Collaborative (MUSIC). Patients were enrolled between January 2017 - August 2018. Eligible patients had undergone RP within 9 months of enrollment, had pT3-4 disease and/or positive surgical margins, and a post-RP PSA <0.1ng/mL. Patients were assigned to either the GC or usual-care based (UC) group using cluster-crossover block randomization assignments. Patients in both arms received a CAPRA-S derived recurrence risk score. PROs were obtained using the Expanded Prostate Cancer Index Composite (EPIC-26) survey at baseline, 3, 6, 12, and 24 months after RP.

RESULTS: A total of 232/240 eligible patients (97%) had complete PRO data for this analysis. Median age was 65 years and baseline PSA was 6 ng/mL and 6.7 ng/mL in the UC and GC groups, respectively. At 12 months follow up, those in the GC arm had no significant change in adjusted mean difference in domain score from baseline compared to those in the UC arm for urinary irritative function (1.53, 95% CI [-1.48 – 4.55], p=0.32), urinary incontinence (1.08, 95% CI [-5.27 – 7.44], p=0.74), or sexual function (-2.26, 95% CI [-8.85 – 4.33], p=0.50). This remained true at 24 months for all three domains [urinary irritative function; (0.13, 95% CI [-3.06 – 3.33], p=0.93)], [urinary incontinence; (-1.26, 95% CI [-7.84 – 5.33], p=0.71)], [sexual function; (0.15, 95% CI [-6.77 – 7.07], p=0.97)].

CONCLUSIONS: In the first ever randomized trial testing the clinical utility of a GC in localized PCa, longitudinal PROs were not significantly different between study arms. While post-operative RT use was greater in men who underwent GC testing, no impact was observed on recovery of PROs in urinary or sexual function.

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