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Introduction & Objectives: Prostate cancer (PCa) is the most common type of cancer among men in Europe. Current recommendations for screening and diagnosis are based on prostate-specific antigen (PSA) levels and digital rectal examination (DRE). Whereby, patients with PSA-detected prostate cancer are largely overdiagnosed and overtreated. To reduce this phenomenon, new products related with prostate cancer detection have recently hit the market.

We present an initial series of patients who were diagnosed with SelectMDx tool as the only commercially available test for prostate cancer in Poland.

Materials & Methods: A group of twelve patients from a single urological office, who underwent a commercial test to identify patient's risk for aggressive prostate cancer – SelectMDx (MDxHealth) between July 2018 and January 2019, was evaluated. The test was performed to facilitate the decision to perform prostate biopsy in men with elevated PSA levels (>4 ng/ml), abnormal DRE or family history of PCa. Ten ml of first voided urine samples after standardized DRE consisting of three strokes per lobe, were collected, supplemented with patients characteristics (age, family history of PCa) and clinical parameters (PSA, prostate volume, DRE, history of PCa biopsy) and immediately send to relevant laboratory. Patients with results indicating an increased probability of high-grade prostate cancer obtained by SelectMDx test, underwent transrectal ultrasound (TRUS)-guided prostate biopsy.

Results: Select MDx test was performed for 12 patients, one of them was excluded from further study due to the questionable results. The mean age was 67,2 (± 7,2) years, with a median PSA level of 8,1 ng/ml. Five patients (41%) obtained very low risk for PCa and not decided to undergo prostate biopsy. The other six patients with high risk of aggressive PCa (34-81%) and increased risk of harboring high-grade disease (10-54%), decided to perform prostate biopsy.

We compared SelectMDx outcome with PSA levels and PSA density by ROC analysis. The AUC for the PSA score was 0.72 (95% Confidence Interval [CI]: 0.62-0.82) compared to AUC 0.75 (95%CI: 0.66-0.84) for PSA density. Within group of patients with high risk of aggressive PCa statistically significant interdependence ($p < 0.05$) was observed between PSA level and likelihood of detecting PCa upon biopsy ($r_s = 0.753$), probability for high-grade versus low-grade disease ($r_s = 0.714$). Very high Spearman correlation coefficient was observed between likelihood of detecting PCa upon biopsy and probability for high-grade disease ($r_s = 0.98$).

Conclusions: Prostate biopsy confirmed SelectMDx results for patients with increased risk of PCa by obtaining high Gleason score (≥ 7). Patients with a Very Low Risk SelectMDx test avoid immediate biopsy, they remain under the care and supervision. Still SelectMDX test should be interpreted in combination with other clinical data and relevant guidelines in the decision for biopsy.