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[-2]proPSA for predicting biochemical recurrence of prostate cancer earlier than total PSA after radical prostatectomy: an observational prospective cohort study.

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BACKGROUND: There is an unmet clinical need for more biochemical specific tests that may detect clinically significant recurrent PCa at an early stage after radical prostatectomy (RP). Our purpose is to test the hypothesis that p2PSA (index test) detects prostate cancer relapse (BCR) earlier than the current reference standard test (total PSA, tPSA) in patients who underwent RP for localized PCa.

METHODS: This is an observational, prospective, cohort, follow-up study in patients subjected to RALP (Robotic assisted laparoscopic radical prostatectomy) for clinically localized PCa from January 2013 to July 2013 at a high-volume Institution (450 average RP/year). A blood sample, for tPSA and p2PSA, was prospectively drawn after 3, 6, and 12 months and then every 6 months during the following two years. Outcome Measurements and Statistical Analysis: The primary outcome is to determine whether or not kinetics in rising of p2PSA significantly anticipates the tPSA kinetics. Exploratory data analysis was used to identify relationship between different variables.

RESULTS: Over 134 patients 20 BCRs were detected according to tPSA cut-off. Five patients showed a contemporary increase of tPSA and p2PSA, 11 presented a p2PSA increase earlier than tPSA increase (13.9 months ±9.7). In four patients, the increase of PSA was not associated with a p2PSA > 0.8 pg/ml. The correlation between tPSA and p2PSA according to Sperman's rho

coefficient was statistically significant at 3, 6, 18 and 30 months: 0.416 ($p<0.01$), 0.255 ($p<0.01$), 0.359 ($p<0.01$) and 0.413 ($p<0.01$) respectively. When subjects were stratified according to stage/grade and margins (positive vs. negative), patients with higher stage and positive surgical margins could be considered the target categories. The low rate of observed BCR and high rate of p2PSA false positive are the main limitations.

CONCLUSIONS: The current findings showed that p2PSA might be more sensitive than tPSA in detecting earlier BCR within 3-year follow-up. Further studies with a longer follow- up and larger population remain mandatory before considering p2PSA for clinical decision- making.

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