Validity of prostate health index and percentage of [-2]pro-prostate-specific antigen as novel biomarkers in the diagnosis of prostate cancer first reported Omani tertiary hospitals experience

Safana Salim Al Saidi
Ministry of Health, Oman

Statement of the Problem: Prostate cancer is the leading cancer in older men. When prostate cancer is detected early (organ defined), it is potentially curable by radical prostatectomy. As per the Ministry of Health (MOH) Oman Cancer Incidence Registry, cancer of prostate is the second most common cancer (in males) and seventh most common cancer (in both males and females), with 57 cases were diagnosed in 2011. Therefore, early detection is important and prostate-specific antigen (PSA) is widely used as a laboratory test for this purpose. However, despite its wide use, its value in screening men particularly asymptomatic is controversial particularly in term of risks and benefits of early detection.

Methods: This is an observational prospective study that included 136 male patients aged (mean±SD: 67±8.89; range 45-90) who were scheduled for prostate biopsy in two different tertiary care teaching hospitals in Muscat, Oman. Blood specimens from these patients were collected at the same setting before obtaining the prostatic biopsy; the sera were stored at -200 °C until analysis. Laboratory measurements of the three prostate specific antigen (PSA) markers (tPSA, fPSA and [-2]proPSA) were processed using UniCell DxI 600 Access Immunoassay System (Beckman Coulter, USA). Calculation of Prostate Health Index (phi) using Access Hybritech phi® software was performed too. The histopathological report of the prostatic biopsy for each patient was obtained from the histopathology laboratory of the concerned hospital along with the clinical and laboratory data through the Hospital Information System (HIS).

Results: The study showed that Phi has the best validity markers as compared with other prostate markers. It gave sensitivity and specificity of 82.1% and 80.6%, respectively with AUC of 0.81 at cutoff value of 41.88. The remaining prostate markers showed sensitivities and specificities of 78.6% and 25.9% for tPSA; 35.7% and 92.6% for %fPSA; 64.3% and 82.4% for %p2PSA; and 75% and 35.2% for age-adjusted tPSA, respectively. Their AUCs at the best cutoff values were 0.67 at 10.1 µg/L for tPSA; 0.70 at 11.6% for %fPSA; 0.55 at 1.4% for %p2PSA and 0.50 for age-adjusted tPSA.

Conclusion: The study has proved the usefulness of Phi and its component assays in predicting the diagnosis and prognosis in men who are suspected of having prostate cancer. The use of Phi outperforms other conventional prostate markers; tPSA and fPSA, when used alone or in combination. Phi appears to be more accurate than tPSA and fPSA in terms of excluding prostate cancer before biopsy; hence it helps the physicians to avoid unnecessary biopsies, particularly in patients with gray zone tPSA level. Phi is the strongest marker that also correlates proportionally with Gleason Score and therefore it is also useful in predicting the aggressiveness of the disease.

Biography
Safana Salim Al Saidi is a Chemical Pathologist and Specialist, working at the Directorate General of Quality Assurance Centre, Ministry of Health, Oman. She has graduated from Medical College, Sultan Qaboos University, Oman in 2003 as a Medical Doctor and completed her Residency training program in Clinical Biochemistry by Oman Medical Specialty Board (OMSB) in 2014. Presently she is a Fellow of the Royal College of Pathologist, UK. She has three publications to her credit and has great interest in conducting researches which are of help to the patients.