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INVITED COMMENTARY

Fasting times in serum PSA assay

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Prostate-specific antigen (PSA) test for prostate cancer is the only serum-based cancer screening test that is widely accepted. A large number of PSA tests are done in developed countries such as the United States due to the recommendation that men be screened annually starting at age 50. With the rapid economic development and increased access to healthcare, countries like China have also experienced a dramatic increase in the utilization of PSA test. This trend is unlikely to change significantly despite the recent recommendation against routine PSA screening by the US Preventive Health Task force.

As a screening test, PSA's normal upper limit is set at 4 ng ml⁻¹ by most physicians, although some prefer to use 2.5 ng ml⁻¹ as the cutoff value. Men with increased PSA levels are usually referred for prostate biopsy by an urologist to rule out prostate cancer. For this reason, accurate PSA testing is important. Although many preanalytic and analytic variables can influence the test results, an important variable that can be controlled is the fasting time before the blood draw. Because older men often have concerns of other health issues, it may be assumed that most routine PSA tests may be performed along with other lab tests such as lipid panel or metabolic panel. As a result, many men will fast before the PSA test, although how fasting affects PSA measurement was unclear. A previous study by Tuncel *et al.*¹ examined the effects of fasting times in a group of 80 men, but the fasting times did not exceed 8 h and the sample size was relatively small.

Another important utility of PSA test is to monitor disease recurrence after surgery, radiation therapy or hormonal therapy for the treatment of prostate cancer. In this setting, it is the trend over time that gives indications of disease remission *vs* recurrence. As a result, it is very important to eliminate preanalytic variables that may affect the measurement, since an increase in PSA level causes concern for disease recurrence and may prompt clinical intervention. Fasting time is an important variable here if it affects the results.

In the article "Fasting time and serum PSA levels," published in *Asian Journal of Andrology*, Lau *et al.*² investigated the effects of fasting times on the measured PSA levels in a very large community-based cohort of 157 276 men. The average fasting time was 12.7 h with a minimum, and maximum fasting time of 1 and 16 h, respectively. Age-specific reference ranges for Caucasian males were used, although race was not taken into consideration in the study. The authors developed a dynamic mathematical model to calculate the percentage of individuals expected to experience a change in PSA diagnostic interpretation (e.g. normal *vs* abnormal result) based on variations in fasting time. The results indicate that fasting time has a statistically significant effect on serum PSA levels, and an increased fasting time is generally associated with a modest increase in the number of patients with abnormal PSA values, particularly at the extremes. The peak PSA levels were observed at 4 h of fasting, which may be due to diurnal variation. Simulating the changes that would occur in PSA values if fasting times were altered revealed that the percentage change in the number of abnormal PSA values can range from -1.07% to 1.63%, which would translate into minimal

clinical effect. The authors recommend that the optimal time to obtain an accurate PSA level is fasting for 7–9 h, which avoids the increased PSA levels observed with fasting extremes as well as possible diurnal rhythm variations that may exist in shorter fasting times.

This is an interesting study with meaningful results. The authors have addressed obvious limitations such as potential recall errors by the patients and the nonrandomness of the cohorts. Based on these findings, it seems that fasting time may not be a concern for prostate cancer screening as the small variations (~1%) is unlikely to change the PSA value over or under the threshold for most patients. However, for patients monitored for disease recurrence such as those after surgery or radiation for high risk prostate cancer, or for patients with advanced prostate cancer treated with conventional hormonal therapy or the newer agents, testing PSA under similar fasting conditions (7–9 h) may be advisable for consistent testing, since the trend in serial PSA tests are critical for clinical decision-making.

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Re: Fasting times in serum PSA assay

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Many clinicians do not realize that a significant proportion of the variation in any laboratory test may be due to preanalytic factors. Understanding which preanalytic factors are most important and controlling for these is an important consideration in interpretation any test. Our recent paper¹ argued that in most circumstances the small amount of preanalytic variation in prostate-specific antigen levels introduced through fasting time variation is unlikely to be significant. However, as the commentator on our paper correctly points out,² there may be circumstances where even small variations in prostate-specific antigen could alter interpretation and therefore a standardized fasting time could be advised.

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