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Prostate Cancer Screening Using a Quick One-Step PSA Test

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Abstract: Background and aim: A one-step prostate-specific antigen (PSA) test was studied in a largepopulation to improve the convenience and lower the cost of prostate cancer (PC) screening.The PSA rapid test kit aids in the diagnosis of PC by detecting human PSA in serum or plasma at or above a threshold level of 4 ng/mL. The aim of this study is to screen PC usinga Quick One-Step PSA Test.
Materials and Methods: Between July 2020 and August 2021, at National institute of urology and nephrology, Cairo, Egypt, Male attendees were offered PC screening utilizing the PSA quick test. A total of 305 men's blood samples were tested. The test was interpreted by two independent observers. Following that, the remaining serum samples were examined using a standard quantitative technique.
Results: Of 305 participants, 118 had a PSA value of less than 4 ng/mL, and 55 presented a PSA value higher than 4 ng/mL. A total of 63 participants had a PSA value between 4 and 10 ng/mL. A total of 12 participants presented a PSA value > 10 ng/mL; 10 was judged as positive. The intensity of the color reaction was implying a strong positive correlation between the two methods (correlation test: P< 0.0001).
Conclusion: The one-step test is a good preliminary screening method from which positive results may be quantified to provide a semi-quantitative estimate of the degree of PSA rise. The test is inexpensive, easy to do, and provides results in a timely manner.

Keywords: Prostate Cancer, PSA Rapid Test, Screening

1. INTRODUCTION

Prostate cancer (PC) is one of the most frequent cancers in males globally and one of the leading causes of cancer mortality [1]. The significant increase in PC diagnoses is assumed to be due to the widespread adoption of the prostate-specific antigen (PSA) test [2]. PSA levels are commonly measured to identify individuals who have a higher risk of prostate cancer [3]. The currently available serum or plasma-based immunoassays are coupled with time-consuming sample processing and the requirement for complex technical equipment. As a result, different strip tests based on immunochromatographic measures of serum or whole blood have been developed for the qualitative and semi-quantitative estimation of PSA [4].
Without definitive information on the concentration of PSA in the blood, visual assessment of the currently available whole blood tests allows for a yes or no judgment [5]. Although this type of qualitative assay is adequate for clinical decision-making, the predictive information associated with circulating PSA levels is lost. Furthermore, inter-individual heterogeneity in

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visual evaluation of the test strip at the assay's detection limit may result in significant analytical mistakes.

Rapid methods for qualitative PSA testing have become popular in recent years. These are based on immunochromatographic methods for serum or plasma. These gadgets are quick, easy to use, and very affordable [6]. Despite their widespread usage in other countries, these devices have only just been accessible in Egypt, and their analytical performance has yet to be assessed. Depending on whether or not the patient's PSA value exceeds 4ng/ml, the results are interpreted as either negative or positive. The analytical performance of the Rapid test PSA is compared to that of a well-established gold technique.

In this study, to address the limitations of prior tests and enable reliable quantitative and quick PSA testing, we assessed an upgraded PSA assay and a newly built reader. This technology might be used in point-of-care testing and for first cancer screening.

2. MATERIALS AND METHODS

Between July 2020 and August 2021, 305 male patients with or without prostate illness 39 years (32–48) were studied. The males were all examined at Egypt's National Institute of Urology and Nephrology.

2.1 Control and Patients

To detect the levels of PSA, a blood sample from each patient was taken shortly before the test for use in the conventional laboratory procedure. Before being centrifuged, the blood samples were allowed to coagulate for 1 hour at room temperature. The sera were then tested right away using an IMMULITE System analyzer PSA assay, as directed by the manufacturer. The samples were then retested for PSA using a Forte Rapid test PSA (BIOMERIHA INC.) USA. Two blinded analysts performed the tests. As per normal operating practice, the serum samples were then frozen at -80°C. Some samples were chosen at random from patients who had tested positive for PSA and were only thawed once for semi quantitative analysis with the Fortel Rapid test PSA. An additional 18 blood samples from female patients were examined as negative controls and to determine the specificity of the fast PSA in an in-house internal qualitycontrol monitoring programme.

2.2 Principle of Fortel PSA (BIOMERIHA INC.)

The Fortel PSA fast test is a sandwich immunosorbent cassette test in which 200 L of serum is put to the sample pad, which then migrates across the conjugate pad, mobilizing anti-PSA conjugate. By capillary action, the combination travels down a membrane and interacts with anti-PSA antibody coated on the test area. A pink-rose band forms in the test area when PSA is present. The PSA concentration in the sample determines the color intensity of this band. Unbound mobile monoclonal anti-human PSA antibodies move through the membrane to an immobilized anti-immunoglobulin (Ig) antibody control zone. The monoclonal anti-human PSA and anti-Ig antibodies create a complex, resulting in the creation of a pink-rose band. After 20 minutes, the test device is placed on a level surface and the findings are read. Only when a pink-rose band develops in the control zone is the test process valid. This control band represents a PSA concentration of 4.0 ng/ml. The test result will be invalid if the control line does not show, and if just the control band appears, the PSA level in the sample is less than 4.0ng/ml. Furthermore, positive and negative procedural controls were applied to validate the Fortel PSA fast test's performance. If no band emerged in the test region, the tests were classified as negative; if a band occurred, the tests were classified as positive (+) or strong

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positive (++), based on the intensity of the color reaction in comparison to the control band **(Figure 1)**.

AB

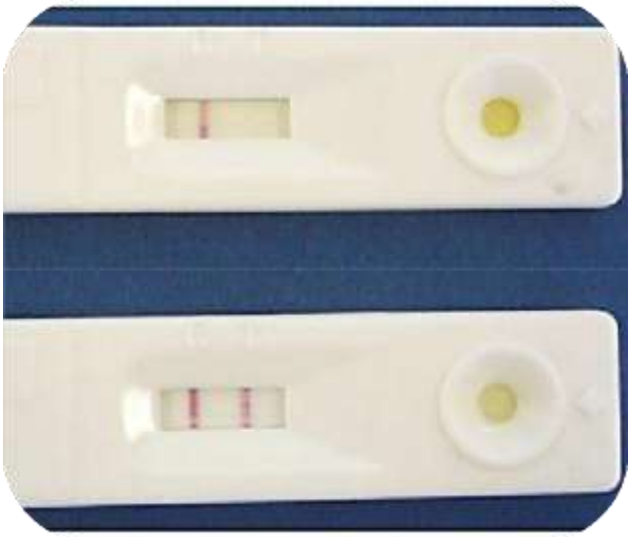

Figure 1: A quick Fortel PSA test. (A) There are no bands in the test zone (negative). (B) In the test zone, a red band appears (positive)

2.3 Statistical analysis

The accuracy, analytical sensitivity, analytical specificity, and predictive values of the Fortel PSA quick tests were determined by comparing them to the quantitative IMMULITE analyzer (gold standard) PSA results (using the threshold value of 4 ng/ml to identify positive or negative findings). The Fortel PSA quick test's sensitivity, specificity, accuracy, positive and negative predictive values were computed. The ratio of genuine positive outcomes to the total of true positive and false negative results was established as sensitivity. The ratio of genuine negative findings to the total of true negative and false positive results was used to calculate specificity. The ratio between real positive findings and the total of all positive results was established as the positive predictive value. The ratio between true negative results and the sum of all negative results was defined as negative predictive value. The ratio between the sum of true observations and the total observations was used to define accuracy.

3. RESULTS

This was a comparative study that included 305 male patients. The demographic characteristics of the 305 enrolled participants: the median age was 39 years (IQR 32–48), 115 (37.7%) had at least secondary school education, while 2 (0.6%) of the participants had received no formal education. Enrolled participants were employed 206 (67.5%) and 112 (36.7%) were rarely checked for routine health check-up per year as shown in **Table (1)**.

Table (1): Baseline demographic characteristics of the 305 participants joined in the study

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Parameters	**N=305**	**(%)**
Median age, years (IQR)	39 (32–48)	
Educational level		
- No education	27	8.8%
- Primary school	37	12.3%
- Secondary school	115	37.7%
- College or higher	124	40.6%
- Not available	2	0.6%
Employment status		
- Unemployed	99	29.5%
- Employed	206	67.5%
Frequency of routine health checks per year		
- More than once/year	92	30.2%
- One/year	56	18.4%
- Rarely	112	36.7%
- Never	45	14.6%

Of 305 participants, 118 had a PSA value of less than 4 ng/mL, and 55 presented a PSA value higher than 4 ng/mL. A total of 63 participants had a PSA value between 4 and 10 ng/mL **(Table 2)**. A total of 12 participants presented a PSA value > 10 ng/mL; 10 was judged as positive. As shown in (**Figure 2)**, the intensity of the color reaction was implying a strong positive correlation between the two methods (Pearson's correlation test: r=0.39, P< 0.0001).

Table (2): Correlation of PSA rapid test interpretations with PSA quantitative values.

Total Quant. PSA ng/ml	**N=305**	**Fortel Rapid test PSA**		**Accuracy**
		Negative	**Positive**	
<3	118	113	5	95.8%
3-4	95	79	16	83.2%
4-5	55	41	14	25.4%
5-10	8	0	8	100%
10-20	12	2	10	83.3%
>20	17	4	13	76.5%

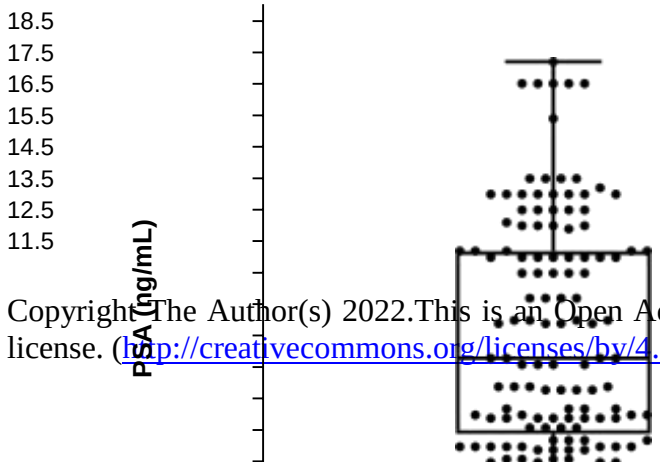

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Figure 2: PSA quantifiable values in all samples with a PSA value between 0 and 20 ng/mL were plotted according to the intensity of the red bands in PSA rapid testing.

4. DISCUSSION

The rate of PC incidence continues to rise dramatically. Because radical therapy techniques are currently restricted, it is critical to diagnose and treat prostate cancer early [7]. Prostate cancer screening may thus be beneficial for early treatment start. Although prostate cancer screening is still a contentious topic in oncology [8]. It is well acknowledged that the PSA test is one of the most important and effective methods for diagnosing prostate cancer [9].The PSA fast test had adequate analytical performance in the current investigation, and the authors endorse it as a first screening tool in resource-constrained situations. Positive screening test findings would be followed by semi-quantitative analysis with the PSA RT (Rapid test) and, if needed, ELISA quantification.

Although our study's overall specificity was 93.0%, it was lower in the PSA range of 4–5 ng/mL, where false-positive findings were prevalent (74.6%) detected in the present study, would not really affect patient management because in the proposed testing algorithm, positive RT results would be confirmed initially by a semi quantitative RT procedure or by a quantitative technique beside, this is a critical category in which it is critical to do follow-up to rule out the existence of illness. The PSA RT, on the other hand, yielded unambiguously favorable findings in all individuals with PSA levels greater than 10 ng/ml. When blood PSA levels over 10 ng/ml, the risk of PC increases, and the PSA RT was able to clearly discriminate between the positive and negative individuals.

Our findings suggest that this PSA RT device be used in locality hospitals and clinicsto help in the differential diagnosis of prostate and other urinary tract illnesses. The test is simple to do and does not require complicated equipment or an experienced analyst. It is also inexpensive and takes less than 40 minutes to complete. Currently, most PC patients arrive late to central hospitals, when medicinal therapies have lost their effectiveness in changing the disease's trajectory. As a result, adoption of this screening technique would allow for early diagnosis and treatment. However, because the PSA RT has a poor negative predictive value of 90.2 %, it should always be used in conjunction with a digital rectal examination and other clinical findings to rule out any potentially serious issues.

The test's main flaw appears to be its lack of accuracy in the PSA range of 4–5 ng/mL.As a result, more accuracy is required in order to reduce the amount of false-positive outcomes. Nonetheless, the one-step PSA RT test may be beneficial in general practice or urology, as well as for mass screening. PSA testing might be reviewed as a technique of mass screening for PC

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if the test could be adapted to allow administration at home.

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