Evaluation of Fortel prostate-specific antigen test versus conventional quantitative prostate-specific antigen assay

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Background
Prostate-specific antigen (PSA) is a protein produced by normal prostate cells. This enzyme participates in the dissolution of the seminal fluid coagulum and plays an important role in fertility. The highest amounts of PSA are found in the seminal fluid; some PSA escapes the prostate and can be found in the serum.
Aim
To determine accuracy, sensitivity, specificity of the one-step PSA test (Fortel Test) 'FDA approved' for screening for prostate cancer in comparison to a conventional quantitative assay.
Patients and methods
This prospective cohort clinical study was conducted at the tertiary care hospital at the Urology Department, Outpatient Clinic, Faculty of Medicine, Ain Shams University from January 2022 till June 2022 and performed on a total of 150 patients who were over 50 years old or over 40 years old with a family history of prostate cancer.
Results
Our study results revealed that Fortel PSA test had high sensitivity (97.2%), specificity (96.2%), positive predictive value (95.9%), and negative predictive value (97.4%) in the accuracy of screening of prostatic cancer.
Conclusion
The Fortel PSA test is a simple, feasible, and reproducible tool for prostate cancer screening. The lower cost, ease of handling, and rapid procedure could make this test useful in the general practitioner or urologist office setting as well as for mass primary prostate cancer screening.

Keywords:
Fortel test, prostate cancer, prostate-specific antigen

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Introduction

For the detection of prostate cancer, an elevated serum prostate-specific antigen (PSA) is the most common laboratory abnormality, as the majority of men with early prostate cancer have no symptoms. However, PSA is clinically imprecise as benign and malignant processes both can elevate the serum marker. Despite the risks and benefits of serum PSA screening, it is the most useful tool available for the detection of early prostate cancer, giving affected individuals the best chance for cure [1].

The serum-based or plasma-based immunoassays currently available are associated with time-consuming sample processing and the need for sophisticated technical equipment, which is one of the major obstacles of detecting prostate cancer in Egypt. Rapid test is simpler and less time consuming, around 10–20 min [2].

PSA rapid screen test is a chromatographic immunoassay, which generates a positive or negative result for PSA values more than or less than 4 ng/ml, respectively [3].

Patients and methods

This prospective cohort clinical study was conducted at the Tertiary Care Hospital at the Urology Department, Outpatient Clinic, Faculty of Medicine, Ain Shams University from January 2022 till June 2022 and was performed on a total of 150 patients. During this study, 170 patients were assessed for eligibility and 150 patients were included in the study. Of all eligible patients, 12 patients were excluded from the study based on the inclusion criteria and eight patients refused to participate in of the study. No patients over 40 years old and under 50 years old with a family history of prostate cancer were included in the study.

Sample size was calculated using PASS 11.0 and based on a study carried out by Ibrahim *et al.* [4] and Miano *et al.* [5].

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Study population

Inclusion criteria

(1) Age: over 50 years old or over 40 years old with a family history of prostate cancer.
(2) Sex: male.

History taking with particular emphasis on urological history.

Patient evaluation and examination with digital rectal examination to evaluate prostate size and detect any suspicious nodules (must be done after drawing the blood sample).

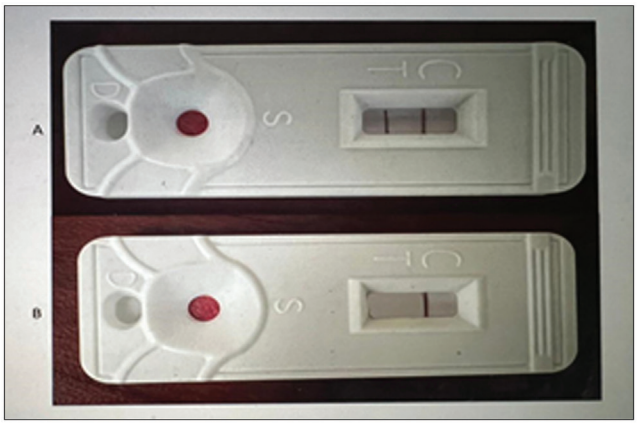
Investigations

(1) Laboratory investigations: PSA total.
(2) Follow up: clinical and laboratory evaluation.

Study procedures

The Fortel PSA test is a chromatographic lateral flow immunoassay, containing a filter membrane coated with PSA-specific antibodies and colored gold colloidal reagents labeled with PSA-specific antibodies [5]. It is produced by Biomerica and was costing 150 EGP at the time of the study. The PSA test cassette is provided with a pipette and a buffer/wash solution. The fingertip should be swabbed with an alcohol swab and 30 s should be allowed for the alcohol to dry. Then the fingertip is pricked with a sterile lancet to obtain one or two drops of blood; a pipette is provided to draw up the blood sample and then to transfer it to the sample well (round hole) marked with an 'S' on the PSA cassette. After 90 s, five drops of a buffer/wash solution is added to the diluent well marked with a 'D' to allow the blood to migrate (Fig. 1). Interpretation of the test must be done after 10 min. For comparative purposes, a blood sample of around 5 ml from each patient was collected immediately before the test for use in the standard laboratory method.

Figure 1



PSA Fortel test: (a) positive test. A colored band develops on the test region. (b) Negative test. No band develops on the test region. PSA, prostate-specific antigen.

Ethical considerations

Approval was obtained from the ethics committee at Ain Shams University before starting the research and all patients consented to be included in this study after explanation of the study procedures and the follow-up course.

Statistical analysis

Statistical Package for the Social Sciences (SPSS, IBM SPSS statistics for windows, Armonk, NY: IBM Corp), version 26 was used for the analysis. Descriptive statistics were done and numerical variables were presented as median (interquartile range) or mean (SD) according to normality. Categorical variables were presented as frequencies (percentages). Shapiro–Wilk normality test was done. Comparison between different variables was performed using the χ^2 test and the Mann–Whitney test best cutoffs. P values less than 0.05 were considered significant.

Results

Table 1 shows that baseline characteristics of the studied cases. Mean±SD of baseline age was 57.73 ± 4.90 years.

Table 2 shows that median (interquartile range) of the PSA value was 3.8 (2.3–8). The clinical PSA value was negative in 78 (52%) cases and positive in 72 (48%) cases.

Table 3 shows that the Fortel PSA test value was negative in 77 (51.3%) cases and positive in 73 (48.7%) cases.

Table 1 Descriptive for demographic data of the studied patients

	N=150
Age	
Mean±SD	57.73 ± 4.90
Range	50–65
Sex [*n* (%)]	
Male	150 (100.0)

Table 2 Descriptive for prostate-specific antigen of the studied patients

		N=150
PSA value	Median (IQR)	3.8 (2.3–8)
	Range	0.3–390
PSA [*n* (%)]	Negative <4	78 (52.0)
	Positive >4	72 (48.0)

IQR, interquartile range; PSA, prostate-specific antigen.

Table 3 Descriptive for Fortel prostate-specific antigen test of the studied patients

Fortel PSA test	*n* (%)
Negative	77 (51.3)
Positive	73 (48.7)
Total	150 (100.0)

PSA, prostate-specific antigen.

Table 4 shows that there was no statistically significant difference between negative and positive Fortel PSA tests regarding mean age of the studied patients.

Table 5 shows that there was highly statistically significant difference between negative and positive clinical PSA test regarding Fortel PSA value.

Among the 78 participants with a PSA value less than 4 ng/ml, 75 (96.2%) were correctly interpreted as negative using the Fortel PSA test, whereas three were interpreted as positive.

Among the 72 participants with a PSA value more than 4 ng/ml, 70 (97.2%) were correctly interpreted as positive using the Fortel PSA test, whereas two were interpreted as negative.

Table 6 shows that:

Among the 10 participants with a PSA value less than 1 ng/ml, 100 (100%) were correctly interpreted as negative using the Fortel PSA test.

Among the 18 participants with a PSA value 1 to less than 2 ng/ml, 18 (100%) were correctly interpreted as negative using the Fortel PSA test.

Among the 17 participants with a PSA value 2 to less than 3 ng/ml, 17 (100%) were correctly interpreted as negative using the Fortel PSA test.

Among the 33 participants with a PSA value 3 to less than 4 ng/ml, 30 (90.9%) were correctly interpreted as negative using the Fortel PSA test, whereas three were interpreted as positive.

Table 7 shows that THE Fortel PSA test had high Sensitivity, specificity, positive predictive value, and negative predictive value in the accuracy of screening of prostatic cancer.

Regarding digital rectal examination of participants:

Among the 150 participants, DRE of 140 were insignificant, seven had hardness (suspicious nodule) affecting one lobe and three had hardness affecting both lobes of the prostate.

Regarding the size of prostate, we could reach the upper border of the prostate in 108 participants and could not reach it in 42 participants.

Discussion

Prostate cancer is the second most common cancer and the fifth leading cause of cancer-associated mortality among men worldwide [6]. Screening for prostate cancer with serum PSA aims to detect prostate cancer at an early, intervenable stage amenable to curative treatment and reduction in overall and disease-specific mortality [7].

Since Catalona *et al.* [8] first demonstrated in 1991 that determination of PSA could be used as a first-line screening test for prostate cancer in men without suspicious digital rectal examination findings, PSA testing has been widely applied. This has resulted in a spike in prostate cancer incidence rates, as previously undetectable cases of prostate cancer were unmasked [7].

However, prostate cancer screening is still controversial, as the potential benefits and harms continue to be debated among health professionals. The controversy over PSA screening includes the possibilities of detecting insignificant prostate cancers that would never lead to death (overdiagnosis) and then treating these prostate cancers (overtreatment). Other issues include cost and convenience, which are possible reasons why the rate of PSA screening is low [9].

Since screening for prostate cancer with serum PSA represents a major conflict and often may be associated with increased harms such as overdiagnosis and complications of treatment for indolent disease [10], investigating the efficacy and safety of PSA testing to screen for prostate cancer was highlighted as a main point of interest [11].

Nevertheless, screening for prostate cancer remains highly controversial because of limitations in randomized trials including contamination and underrepresentation of black men. Difficulty of shared, informed decision-making between patients and primary care providers about PSA screening may also contribute to practice variations [11].

Consequently, this study was conducted and aimed to determine the accuracy, sensitivity, and specificity

Table 4 Comparison for Fortel prostate-specific antigen test regarding demographic data of the studied patients

	Fortel PSA test		Test value	*P* value	Significance
	Negative	Positive			
	N=77	*N*=73			
Age					
Mean±SD	57.71±4.95	57.74±4.88	−0.032	0.975	NS
Range	50–65	50–65			
Sex [*n* (%)]					
Male	77 (100.0)	73 (100.0)	NA	NA	NA

PSA, prostate-specific antigen. •Independent *t* test. *P* value more than 0.05: nonsignificant (NS); *P* value less than 0.05: significant (S); *P* value less than 0.01: highly significant (HS).

Table 5 Relation between clinical prostate-specific antigen value and Fortel prostate-specific antigen value of the studied patients

	Total number	PSA [*n* (%)]		Test value*	*P* value	Significance
		Negative <4	Positive >4			
		N=78	*N*=72			
Fortel PSA test						
Negative	77	75 (96.2)	2 (2.8)	130.670	0.000	HS
Positive	73	3 (3.8)	70 (97.2)			

PSA, prostate-specific antigen. *χ^2 test. *P* value more than 0.05: nonsignificant (NS); *P* value less than 0.05: significant (S); *P* value less than 0.01: highly significant (HS).

Table 6 Relation between clinical prostate-specific antigen value in different ranges and Fortel prostate-specific antigen value of the studied patients

	PSA [*n* (%)]			
	<1	1 to <2	2 to <3	3 to <4
	No.=10	No.=18	No.=17	No.=33
Fortel PSA test				
Negative	10 (100)	18 (100)	17 (100)	30 (90.9)
Positive	0	0	0	3 (9.1)

PSA, prostate-specific antigen.

of one-step PSA test (Fortel Test) 'FDA approved' in comparison to a conventional quantitative assay.

This prospective cohort clinical study was conducted at a Tertiary Care Hospital at the Urology Department, Outpatient Clinic, Faculty of Medicine, Ain Shams University from January 2022 till June 2022 and performed on a total of 150 patients who were over 50 years old or over 40 years old with a family history of prostate cancer.

Our study results revealed that the Fortel PSA test had high sensitivity (97.2%), specificity (96.2%), positive predictive value (95.9%), and negative predictive value (97.4%) in its accuracy of screening of prostatic cancer.

Different studies were done assessing accuracy, sensitivity, and specificity of one-step PSA test in screening the prostate cancer, some of them agree and others differ from our results.

The results of the Fortel PSA test were comparable to those of other one-step PSA tests described in the previous literatures.

Ashida *et al.* [7] conducted a study that enrolled 1429 men for PC screening using the PSA SPOT test to evaluate a rapid, one-step, qualitative PSA test, called the PSA SPOT test, as a possible way to enhance the convenience and reduce the cost of prostate cancer screening in a large population and revealed that the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of the test were 79.9, 93.0, 65.4, 96.6, and 91.2%, respectively.

In concordance with our results, Miano *et al.* [5] conducted a study that enrolled 188 men using the one-step PSA RapidScreen test for screening of PC to increase the acceptance rate and reduce the cost of the screening program for prostate cancer and reported that accuracy, and negative and positive predictive values of PSA RapidScreen test were 94, 98, and 89%, respectively. Among the 104 patients with a PSA value of 4 ng/ml, 94 were correctly interpreted as negative and 10 were positive with PSA RapidScreen test, determining the specificity of the test (94/104=90.4%).

This is consistent with the results of the study conducted by Shigeno *et al.* [12], who reported a sensitivity of 89.5% and specificity of 94.2%. Also, Dok *et al.* [13] reported a sensitivity of 100% and specificity of 90% using the one-step PSA screening test.

Table 7 Diagnostic characteristics of Fortel prostate-specific antigen test in the screening of prostatic cancer

Parameter	TP	TN	FP	FN	Accuracy	Sensitivity	Specificity	PPV	NPV
Fortel PSA test	70	75	3	2	96.7%	97.2%	96.2%	95.9%	97.4%

NPV, negative predictive value; PPV, positive predictive value; PSA, prostate-specific antigen.

In a study by Berg *et al.* [14], a PSA one-step test (Uralen) showed a high acceptance rate due to a well-conducted publicity campaign and because it proved to be a fast, easy to perform, and inexpensive test with a sensitivity of 91% and a specificity of 81%.

These findings are in line with the reported findings of Madersbacher *et al.* [15], who performed a study of 238 men using Oncoscreen one-step PSA screening test reporting a sensitivity and specificity of 93% in screening prostrate cancer.

The one-step PSA test we describe is very easy to administer and can be performed without costly additional equipment. The low cost and speed of the test make it useful and convenient as a tool for primary prostrate cancer screening, even in general practitioner or urologist office settings. The economic drawbacks to PSA mass screening could be overcome using this one-step PSA test [7].

The strength points of this study are that it is a prospective study design and having no patients lost to follow-up during the study period. The low cost and speed of the test make it useful and convenient as a tool for primary prostrate cancer screening.

The limitations of the study are worthy of mention including the relatively smaller sample size relative to the previous studies, not being a multicentric study, and this represents a significant risk of publication bias. Another limitation is that this test seems to be of poor accuracy in the PSA range 3–4 ng/ml. As such, greater precision is needed to minimize the number of false-positive results.

Conclusion

As evident from the current study, the Fortel PSA test is a simple, feasible, and reproducible tool for PC screening. The lower cost, ease of handling, and rapid procedure could make this test useful in the general practitioner or urologist office setting as well as for mass primary PC screening.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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