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Original Article

Age-specific reference ranges of prostate-specific antigen in the elderly of Amirkola: A population-based study

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KEYWORDS
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Abstract *Objective:* To determine the age-specific reference ranges of prostate-specific antigen (PSA) in the older men in the city of Amirkola.
Methods: This cross-sectional study is a part of Amirkola Health and Ageing Project (AHAP) which has been conducted as a cohort study since 2011 in Amirkola, a city in northern Iran. The demographic information of all men aged 60 and older were collected through questionnaires and interviews and the PSA measurements were performed using ELISA and Diametra kit. The acquired data were analyzed afterwards.
Results: A number of 837 elderly men with a mean age of 69.99±7.72 years participated in this study. The serum PSA level (95th percentile) was determined to be 0.9 (0–4.89) ng/mL in the age group of 60–64 years, 1.1 (0–4.88) ng/mL in the age group of 65–69 years, 0.93 (0–9.01) ng/mL in the age group of 70–74 years, 1.3 (0–7.95) ng/mL in the age group of 75–79 years, 1.9 (0–11.98 ng/mL) in the age group of 80–84 years, and 1.45 (0–33.17) ng/mL in the 85 and older group. The serum PSA level was significantly correlated with age ($p=0.000$).
Conclusion: This study indicated that there is a direct correlation between the age and serum PSA levels. The use of age-specific reference range could guide clinicians on the incidence of prostate cancer in this population and perhaps reduce the number of unnecessary tests in this population group.

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1. Introduction

Prostate cancer (PCa) is one of the most common types of cancers and the second-leading cause of death in men after lung cancer [1]. Late diagnosis is the main problem in this type of cancer (usually in stages 3 and 4), and its early stages are without any symptoms [2].

One of the tests that has always been used for early detection and screening of prostate cancer is measuring the serum level of prostate-specific antigens (PSAs), which despite all the limitations of its sensitivity and specificity, is the most commonly used method along with the physical examination [3]. PSA is produced from epithelial cells of the prostate gland in reaction to the activation of its androgenic receptors. Although PSA has relatively high tissue specificity, there are many factors including age, race and ethnicity, lifestyle, geographical area and smoking that can change the serum PSA levels without being related to prostate diseases. The clinical significance of this issue is the disruption in case finding [4,5].

The upper limit of normal PSA (4 ng/mL) is not precise for all ages [6], and the age-specific values of PSA are more useful for screening [7]. Since PSA increases with prostate hyperplasia, its level should be lower in younger individuals. Moreover, a 4 ng/mL cut-off is less successful in estimating the risk of cancer in young individuals and may cause unnecessary biopsy in elderly men with benign prostatic hyperplasia [8—11]. In other words, the aim of using the age-specific reference range of PSA is to improve the diagnostic accuracy of the PSA screening test, which means increasing its sensitivity in younger men and reducing the rate of biopsy in elderly patients [12].

The age-specific reference ranges for PSA were first indicated by Osterling et al. [13]. There is an increasing concern about the general application of these reference ranges. Due to the impact of racial and geographical differences, each community has its own reference range [7,14—17]. Age is one of the key risk factors for prostate disease, in a way that the probability of PCa increases by age [18]. For a healthy man without PCa, the concentration of serum PSA increases by about 3.2% (0.04 ng/mL) per year. Osterling et al. [13] reported that the concentration of serum PSA is directly correlated with age and it is not like we can have one reference range of PSA for men in all age groups.

Many studies are being conducted in this field all around the world [7,14—16], but few of them have been conducted in Iran with fewer samples of elderly men aged 60 and over [5,19,20]. The standard reference range for serum PSA levels in Iranian men without prostate disease is not available and establishing a reference range of serum PSA levels for healthy Iranian men will be desirable. This study is a step for determining an age-specific reference range of PSA for elderly men without prostate cancer. Therefore, the aim of this study is to determine the age-specific reference range of PSA in the age groups of elderly men in Amirkola.

2. Materials and methods

This cross-sectional study is a part of the comprehensive cohort project titled "Amirkola Health and Ageing Project" (AHAP) (registration No. 892917), which has been conducted since 2011 on all individuals aged 60 and over in Amirkola, in northern Iran [21]. AHAP is mainly concerned with geriatric medical problems such as falls, bone fragility and fractures, cognitive impairment and dementia, depression, poor mobility and functional dependence as well as chronic diseases like PCa. People aged 60 years and over were invited to participate in this study through posters distributed all around the city and were assessed by a broad range of biochemical and hormonal tests run at the baseline and the follow-up.

Their files have been saved at the research center. Therefore, we contacted all of them or their families on the phone in order for a follow-up. In this study, PCa was diagnosed through self-report and medical records. All participants signed a written informed consent. In addition, the AHAP cohort study was approved by the Medical Ethics Committee of Babol University of Medical Sciences (code 1801).

The healthcare practitioners were trained in a workshop to use the questionnaire and assessed the elderly population in public health clinics of Amirkola. All of the elderly people who completed the questionnaire were included in the study. On the other hand, those elderly people who were not able to answer the questions due to cognitive impairment were excluded from the study.

The demographic data of all elderly men (837 individuals) were collected by questionnaires and interviews. The prostate cancer was diagnosed through self-report, in which case the participant was excluded from the study. To evaluate the status of those with prostate cancer, we followed up and contacted all of them or their families at the research center or at home in the second wave of AHAP after 5 years.

All of the participants gave a venous blood sample. The measurement of PSA levels in the serum was performed at the Cellular and Molecular Biology Research Center of the Health Research Institute in Babol University of Medical Sciences using the ELISA method and the Diametra kit made in Foligno (PG) Italy. Like most studies in Iran, the normal cut-off point was considered to be 4 ng/mL [5,20—22] although some researchers applied different values which have more of a research aspect [17].

The quantitative variables were described using the mean and the standard deviation. Moreover, the variable "age" was categorized in several groups and description of the main research variables was based on this categorization. Then, the collected data were analyzed by SPSS18 (SPSS Inc, Chicago, IL, USA) using one-way analysis of variance (ANOVA), *t*-test and Pearson correlation coefficient and displayed in tables and diagrams. A *p*-value of less than or equal to 0.05 was considered to be statistically significant.

3. Results

In the present study, 837 elderly men aged 60—92 years were studied. The mean age of the individuals was 69.99±7.72 years. Overall, 443 elderly men (53%) were in the age group of 60—69 years and 394 individuals (47%) were in the age group of 70 years and over. The majority of

the participants (60.7%) were illiterate and 34.5% were smokers (Table 1).

The descriptive statistics of PSA levels in men of each age group in Table 2 indicated that there was a significant difference between PSA levels in different age groups ($p=0.000$). The lowest mean PSA level (1.47±1.78 ng/mL) belonged to the young stage group (60–64 years) and the highest mean PSA level (3.91±8.45 ng/mL) belonged to the oldest one (85+ years).

Overall, seven elderly people had PSA levels higher than or equal to 19.9 ng/mL or over. Since the files for the information of these elderly people were kept at the research center, all of them or their families were contacted after 5 years in order for a follow-up. The results showed that only two of them had died—one of them from PCa and another one from myocardial infarction. Two of the remaining men had benign prostatic hyperplasia (BPH) and were still alive and three others had urinary problems but not cancer or BPH.

According to Table 3, the normal range of PSA (95th percentile) increased by age (from 4.89 ng/mL in the age group of 60–64 years to 33.17 ng/mL in the 85+ age group).

Based on these values, the reference range of PSA level was determined to be 0.9 ng/mL (range: 0–4.89 ng/mL) for the age group of 60–64 years, 1.1 ng/mL (range: 0–4.88 ng/mL) for the age group of 65–69 years, 0.93 ng/mL (range: 0–9.01 ng/mL) for the age group of 70–74 years, 1.3 ng/mL (range: 0–7.95 ng/mL) for the age group of 75–79 years, 1.9 ng/mL (range: 0–11.98 ng/mL) for the age group of 80–84 years, and 1.45 ng/mL (range: 0–33.17 ng/mL) for the 85+ age group.

Generally, the mean serum PSA level of the elderly had increased in different age groups with the increase of age (Fig. 1).

Moreover, the Pearson correlation test indicated that there was a significant relation between PSA levels and age ($r=0.18$, $p<0.001$). In other words, with the increase of age, the serum PSA levels increased too. The relation between the serum PSA levels and smoking was not significant (Figs. 2 and 3).

Table 1 Socio-demographic characteristics of the older adults in the city of Amirkola.

Investigated variables	Number	Percent
Age, year		
60–64	280	33.5
65–69	163	19.5
70–74	150	17.9
75–79	138	16.5
80–84	64	7.6
80+	42	5.0
Educational level		
Illiterate	508	60.7
Primary &secondary	238	28.4
High school & university	91	10.9
Smoking		
No	548	65.5
Yes	289	34.5
IPSS		
Mild	385	46.0
Moderate	165	19.7
Severe	287	34.3
Total	837	100.0

IPSS,International Prostate Symptom Score.

Table 2 Distribution of serum PSA levels according to age group.

Age, year	PSA (ng/mL)			PSA 95% CI (ng/mL)		PSA (ng/mL)		
	n	Mean	SD	Lower	Upper	Min	Max	*p*-Value
60–64	280	1.47	1.78	1.26	1.68	0	11.5	0.000
65–69	163	1.63	2.29	1.28	1.99	0	24.7	
70–74	150	2.01	3.32	1.47	2.54	0	23.6	
75–79	138	2.12	2.87	1.64	2.61	0	19.9	
80–84	64	3.05	4.43	1.94	4.16	0	28.0	
85+	42	3.91	8.45	1.28	6.54	0	40.7	
Total	837	1.95	3.28	1.73	2.17	0	40.7	

CI, confidence interval; SD, standard deviation; PSA, prostate-specific antigen.

4. Discussion

PCa is a major public health problem and one of the leading causes of death among the men around the world [28]. The main problem with the PCa is that it is usually diagnosed very late and its early stages are without any symptoms [1]. PSA-based screening is useful for early diagnosis of PCa [29]. Based on the results of the present study, the serum PSA level increases with age in all age groups of the elderly people

Table 3 Percentile value for serum PSA levels according to age groups.

Age (year)	Men, *n*	Serum PSA level (ng/mL) percentile value								
		2.5th	5th	10th	25th	50th[a]	75th	90th	95th	97.5th
60–64	280	0.00	0.00	0.00	0.43	0.90	1.87	3.79	4.89	6.19
65–69	163	0.00	0.00	0.03	0.55	1.10	2.00	3.47	4.88	6.16
70–74	150	0.00	0.00	0.00	0.31	0.93	2.35	3.87	9.01	14.25
75–79	138	0.00	0.00	0.00	0.38	1.30	2.69	5.15	7.95	12.08
80–84	64	0.00	0.00	0.05	0.81	1.90	3.06	7.06	11.98	19.74
85+	42	0.00	0.00	0.01	0.5	1.45	2.92	5.23	33.17	40.29
Total	837	0.00	0.00	0.00	0.49	1.01	2.20	4.16	5.98	11.06

PSA, prostate-specific antigen.
[a] Median of data.

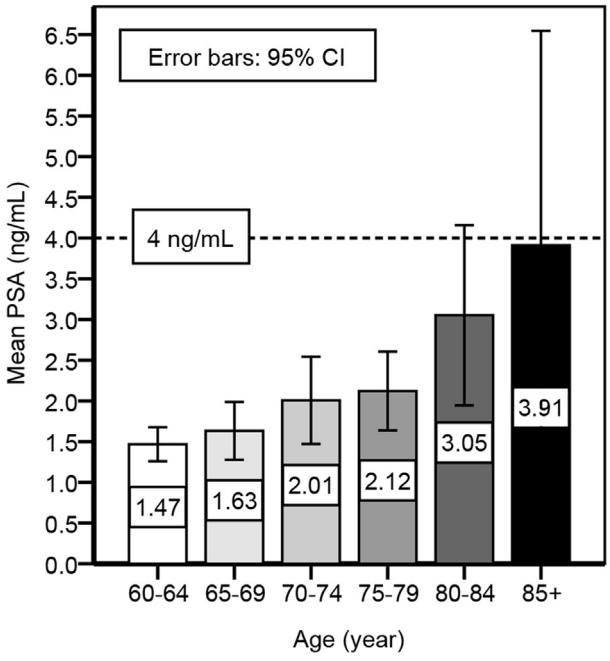

Figure 1 Mean serum PSA levels (ng/mL) according to age groups. CI, confidence interval. IPSS, International Prostate Symptoms Scale; PSA, prostate-specific antigen.

($p=0.000$). In other similar studies too, the PSA levels increased with age [7,16,30,31]. Since the PSA levels are influenced by various factors such as age and race, the determination of the age-specific reference range for PSA in each community can increase the value of the PSA test [7,20].

According to the findings of this study, the normal range of PSA (95th percentile) has increased by age and the values for each age group of the study were determined to be as follows: The normal range of PSA is 4.89 ng/mL for the age group of 60–64 years, 4.88 ng/mL for the age group of 65–69 years, 9.01 ng/mL for the age group of 70–74 years, 7.95 ng/mL for the age group of 75–79 years, 11.98 ng/mL for the age group of 80–84 years, and 33.17 ng/mL for the 85+ age group, respectively. In a similar study conducted in Beijing, China, the normal range of PSA was 4.11 ng/mL in the age group of 60–69 years, 5.56 ng/mL in the age group of 70–79 years, and 7.28 ng/mL in the age group of 80 and over [12], which had a significantly lower PSA level in each age group compared to our study. In another similar study in Syria, conducted on men with no prior history of PCa, the normal range of PSA was 4.8 ng/mL in the age group of 60–69 years and 5.8 ng/mL in the age group of 70–80 years [29]. In addition, in another study in Qazvin, Iran, the amount of PSA (95th percentile) was 5.7 ng/mL in the age group of 60–69 years, and 6.8 ng/mL in the age group of 70–79 years [27], which were close to the values of the present study. Accordingly, it can be said that in addition to age, race has a great impact on the amount of PSA in individuals.

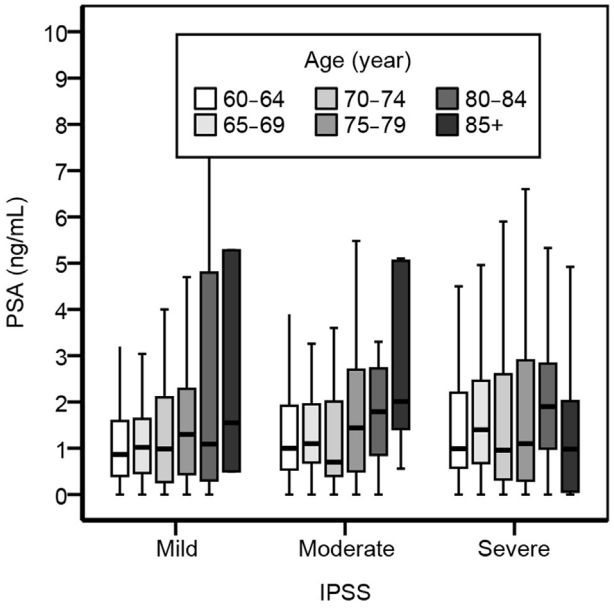

Figure 2 Median serum PSA levels (ng/mL) according to age groups. IPSS, International Prostate Symptoms Scale; PSA, prostate-specific antigen.

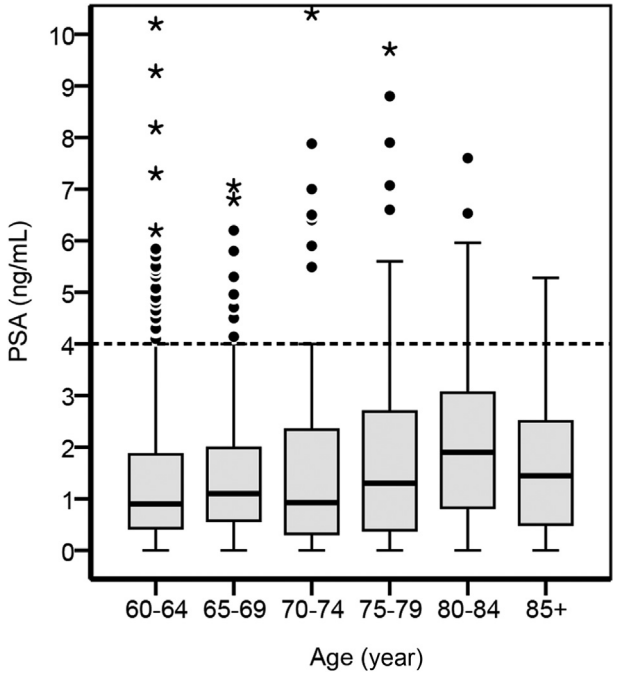

Figure 3 Serum PSA levels (ng/mL) according to the age and International Prostate Symptoms Scale (IPSS) score; PSA, prostate-specific antigen.

The findings of this study indicated that the lowest mean and standard deviation of PSA level (1.47 ± 1.78 ng/mL) were associated with the young stage group (60–64 years) and the highest mean and standard deviation of PSA level (3.91 ± 8.45 ng/mL) belonged to the old stage group (85+ years). In another study, the lowest mean serum PSA level in men belonged to the young stage group (40–49 years) with 0.55 ng/mL and the highest mean belonged to the old stage group (over 80 years) with 2.24 ng/mL [12]. Moreover, in another similar study in Iran, the mean PSA level increased by age, but the mean PSA level in each age group was lower compared to the present study [5]. In another study in Beijing, China, the mean PSA levels (95th percentile) were reported to be 1.16 (4.11) ng/mL, 1.34 (5.56) ng/mL and 2.97

Table 4 Comparison of serum PSA reference ranges among different countries.

Age groups (year)	PSA level 95 percentile (ng/mL) in age groups							
	Iran (current study)	China (Taiwan) [7]	Saudi Arabia (Al-Khobar) [23]	Singapore [24]	China (Beijing) [12]	US (African-American) [25]	Korea [26]	Iran (Qazvin) [27]
60–69	4.88	5.11	5.41	4.00	4.11	11.30	4.00	5.7
70–79	7.89	6.24	6.29	6.31	5.56	12.50	4.55	6.8
80+	11.99	6.61	6.84	6.61	7.29	—[a]	6.18	—

PSA, prostate-specific antigen.
[a] No data.

(7.28) ng/mL respectively in the age groups of 60–69, 70–79 and over 80 years [30].

In this study, the mean PSA level and the confidence interval of 95% were 1.47 (1.26–1.68) ng/mL in the age group of 60–64 years, 1.63 (1.28–1.99) ng/mL in the age group of 65–69 years, 2.01 (1.47–2.54) ng/mL in the age group of 70–74 years, 2.12 (1.64–2.61) ng/mL in the age group of 75–79 years, 3.05 (1.94–4.16) ng/mL in the age group of 80–84 years and 3.91 (1.28–6.54) ng/mL in the age group of 85 years and over. Although the mean PSA level increased with age but it was not noticeable for the trend of median of PSA level through the age groups specially aged 85 years and over. It seems that elderly people with severe or advanced disease may have died before this age. These people are probably healthier people. In another study conducted on men without prostate cancer in Nigeria, this amount was 1.68 (1.58–1.78) ng/mL in the age group of 40–49 years, 1.93 (1.84–2.00) ng/mL in the age group of 50–59 years and 2.73 (2.27–3.18) ng/mL in the age group of 60–69 years, which were all higher than the values acquired in our study [32].

Regarding the results of the present study, the normal PSA level increased by age from 2.5th percentile to 95th percentile. As a result, the normal PSA level increased from 0.00 ng/mL to 4.89 ng/mL in the age group of 60–64 years and 0.0 ng/mL to 33.17 ng/mL in the age group of 85 years and over. According to these values, the reference range of PSA level was more than 4 ng/mL (normal PSA cutoff point) in all age groups. In a similar study in Australia, the PSA values increased from 5th percentile to 95th percentile in a way that the normal PSA level increased from 0.4 ng/mL to 7.5 ng/mL in the age group of 70–74 years and 0.1 ng/mL to 18.0 ng/mL in the age group of 90 years and over [16]. In another study in China, the PSA values increased from 5th percentile to 95th percentile and the increase was from 0.4 ng/mL to 4.42 ng/mL in the age group of 60–69 years and 0.34 ng/mL to 6.52 ng/mL in the age group of 70–79 years [33]. Moreover, in a study in Taiwan, China, the PSA values increased from 5th percentile to 95th percentile and the increase was from 0.33 ng/mL to 5.11 ng/mL in the age group of 60–69 years and 0.30 ng/mL to 6.24 ng/mL in the age group of 70–79 years [7]. This difference might have been due to the genetic, environmental, nutritional, geographical or other unknown factors.

According to the findings of the present study, the concentration of the serum PSA in participants was positively correlated with their age ($r=0.18$, $p<0.001$). There was also a positive correlation in other similar studies in China ($r=0.31$, $p<0.001$) [7], and Shiraz (Iran) ($r=0.28$, $p<0.001$) [20].

Among all elderly people who participated in the present study ($n=837$), only seven people had a PSA level higher than or equal to 20 ng/mL, of whom only one died from prostate cancer after a 5-year follow-up. Although we did not do a biopsy to detect PCa, it seems reasonable that if the high PSA level was due to PCa, it should have appeared in their clinical manifestations during this 5 years period.

Table 4 summarizes the present study's results in comparison with the previous reports. It shows that PSA levels are higher than some other studies. However, these findings are similar to the results of another study in Iran [27] and a study in the United States [25]. This difference might have been due to genetic, racial differences, dietary habits or environmental factors [7,12,23–27].

One of the strengths of the present study was the conduction of a population-based cohort study and the high participation rate of the elderly men in Amirkola. On the other hand, as self-reported diagnosis was a major limitation, the true incidence of PCa maybe higher than reported. However, in a population based study with a large sample size that most of them did not have any PCa, it was not possible and logical to get prostate tissue samples or digital rectal examination from elderly people without any indication. Also culturally, it was not acceptable to do a digital rectal examination for elderly people without any problem. Another limitation was that some older people might have had PCa in the early stages but had died from other diseases before the diagnosis of PCa.

5. Conclusion

This study indicated that the PSA level was affected by age and the age-specific reference range of PSA in Iranian men was different with other races. Using the reference range could guide clinicians on the incidence of PCa in this population and perhaps reduce the number of unnecessary tests in this population group where there is a low mortality rate from PCa.

Author contributions

Study design: Hosseini Seyed Reza.
Data acquisition: Habibian Tara.
Data analysis: Bijani Ali.
Drafting of manuscript: Zabihi Ali.
Critical revision of the manuscript: Hosseini Seyed Reza, Zabihi Ali.

Conflicts of interest

The authors declare no conflict of interest.

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