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Study on Early Prostate Cancer Antigen (EPCA) and existent risk factors of prostate cancer, Sudan: A case-control study

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Abstract

Background: Early prostate cancer antigen (EPCA), a nuclear matrix protein, has recently been recommended as a hopeful biomarker for early prostate carcinogenesis.

Objectives: To evaluate the validity of serum early prostate cancer antigen (EPCA) in the early detection of prostate cancer (PCa) and the characteristics of Sudanese patients diagnosed with prostate cancer.

Method: In this study, seventy men were considered as a case subject, who were diagnosed as cancer prostate at Gezira Hospital for Renal Disease and Surgery (GHRDS), Sudan during the period February 2018 to July 2019. Randomly selected sixty patients of BPH patients and forty-five apparently healthy men as controls group. EPCA, and PSA estimations were performed from serum samples using the principle of Enzyme Linked Immunosorbent Assay (ELISA).

Results: There was significant association between age, family history, residence, unhealthy habits, education, BMI, occupations and prostate cancer, results also revealed a significant elevation between the means of the serum levels of both early prostate cancer antigen and prostate specific antigen of the patients with prostate cancer when compared with the control groups. EPCA biomarker offered the best performance statically (P= 0.00) and highest specificity (81%) and sensitivity (94%) in prostate cancer detection in Sudanese males over PSA biomarker.

Conclusions: Cases of studied prostate cancer linked to many risk factors. Serum levels of early prostate cancer antigen and prostate specific antigen were significantly increased in patients with prostate cancer, however, our data proposed that EPCA has higher power statistical value, so could be utilized as a prostate cancer specific and sensitive biomarker for early detection of prostate cancer.

Keywords: EPCA; PSA; Prostate Cancer; Sudan

1. Introduction

Prostate cancer (PCa) is one of the major threats to the healthcare system in many countries of the world, and it significantly causes more deaths for men [1]. One of the most important risk factors of prostate cancer is advancing age, in addition to the African American race, the patient's family history, a lot of research and scientific studies showed

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significant relationship between male hormones (androgens) and prostate cancer, but the full picture of hormones roles' needs more studies.

In addition to the effects of lifestyle such as diet and exercise, which confirmed their role in the risk or prevention of prostate cancer, as many studies showed the prevalence of obesity among patients with prostate cancer [2], several statistics reports also showed the prevalence of smoking among patients with prostate cancer and the possibility of considering it as one of the risk factor for prostate cancer [3]. Besides economic and social factors have a noteworthy impact on the spread of prostate cancer, such as population density, educational level, and finally income level [4].

The spread of prostate cancer generally in Africa and Sudan particularly, which finds low priority of healthcare due to the poor proficiencies in developing countries and the conflicting policies about developing the healthcare system, in addition, spread of other diseases such as malaria, tuberculosis and human immunodeficiency virus [5]. It should be noted that most of the health service centers are located in big cities only, which reduces the ability of the Ministry of Health to offer diagnostic and treatment services for prostate cancer patients to citizens who live in rural and peripheral areas. [6].

The remarkable expansion in detecting new cases of prostate cancer took place after the development of an effective diagnostic method; serum prostate specific antigen (PSA) is a useful biomarker for screening and monitoring disease progression in patients with prostate cancer [7]. PSA was first discovered in 1980 and is responsible for the liquefaction of seminal fluid and its secretion into the seminal plasma. PSA is associated with plasma proteins in serum and form different isoforms [8]. PSA is considered one of the most prevalent biomarker, and it showed effectiveness in the early detection of prostate cancer, despite that, there are some shortcomings, as PSA is not intended for the detection of prostate cancer patients due to the lack of sensitivity (80%) and specificity (50%); This leads to many men to undergo repeated biopsies because of abnormally high PSA concentration. later, some of these cases have clinical disease, but for many others, elevated PSA levels do not indicate for prostatic carcinogenesis [9].

More truthfully, there is an urgent necessity for adopt new prostate specific biomarker that can detect individuals with prostatic carcinogenesis even when individuals' biopsy samples are morphologically negative. Early Prostate Cancer Antigen (EPCA), designated as a novel nuclear matrix protein that has been verified to be expressed in prostate cancer tissues only. EPCA was first invented by Paul et al, which observed in very high concentration in patients with prostate cancer only than other populations. Furthermore, the study also revealed that the sensitivity and specificity of serum EPCA for healthy controls at a cutoff of 1.7 were (92%) (100%) respectively [10].

Immunohistochemically analyses reveal that EPCA is expressed in the prostate gland and associated with malignant prostate, and identified as being expressed in patients who diagnoses with prostate carcinoma even in biopsied tissue samples that are morphologically normal. In addition, the positive immunostaining for EPCA protein was also noted in the benign glands of the negative biopsies from men who were eventually diagnosed with prostatic carcinogenesis, suggesting that up-regulation of EPCA may be apparently involved in the earlier stage of prostatic carcinogenesis and EPCA can be used as a potential predictive marker in PCa [11]. EPCA detected only in the patients with prostate cancer, not in other diseases.

In this study, we investigated the role EPCA and PSA to differentiate prostate cancer from benign diseases in Sudanese patients. In addition, we further examined the characteristics of patients diagnosed with prostate cancer in central Sudan (Gezira state).

2. Material and methods

A case control study was conducted which included prostate cancer patients, benign prostate hyperplasia patients and apparently healthy individuals. Early Prostate Cancer Antigen (EPCA) and Prostate Specific Antigen (PSA) biomarkers were determined in serum samples from case and control subjects. In this study seventy-five men were considered as a case subject, who were diagnosed as cancer prostate at Gezira Hospital for renal Disease and Surgery (GHRDS), Sudan during the period February 2018 to July 2019.

Randomly select sixty patients of BPH patients and forty-five apparently healthy men. The diagnosis of PCa and BPH was based on the clinical evaluation, biochemical (PSA, EPCA) and prostate tissue biopsy.

The inclusion criteria were men 40 years old and more, the cases subjects were newly diagnosed and they did not receive any kind of treatment during samples collection; while patients with prostatitis, sexually transmitted infections,

patients with chronic renal failure, patients on finasteride or dutasteride therapy for the prostatic disease were excluded. The control included BPH and healthy patients were included only in this study.

Weight, height and Body Mass Index (BMI) for all subjects were measured, all subject's height and weight were taken. (BMI) was calculated using the below mentioned equation. According to the World Health Organization (WHO) BMI was divided into (4) categories, readings were taken to the nearest 0.1 kg and 0.1 cm [12].

$$\text{BMI} = \frac{(\text{Weight in Kg})}{(\text{Height in m})2}$$

We used an interviewer administered questionnaire to ask the cases and the controls about their demographic, socioeconomic, and geographical afflation, as well as clinical data including family history of prostate cancer. Laboratory investigations data were also recorded.

2.1. Sample processing and analysis

Five ml of blood samples were collected into plain container from the subjects in a relaxed mood without any prior prostate manipulation. The blood was centrifuged within 20 minutes after collection at 3000 revelations per minute for 10 min, the samples were stored at -70 °C until analysis. EPCA and PSA was measured using the sandwich Enzyme Linked Immunosorbent Assay (ELISA) by full-automated machine (ELITE) according to the manufacturer's recommendations.

For statistical analyses the Statistical Software Package (version 24) for Windows (SPSS, Chicago, IL, USA) was used. The non-parametric Kruskal Wallis test of variance was carried out. A two-sided P value lower than 0.05 was considered statistically significant. Correlation analyses between variables were determined using Pearson's bivariate correlation test, also formula for sensitivity, specificity, odd ratio, positive and negative predictive values were achieved.

The reference ranges for PSA are considered normal up to 4.0 ng/ml. Since there were no reference values for EPCA because they were used for research purposes, a high reading was taken compared to the control group.

3. Results

In total, 180 participants were enrolled; 75 were prostate cancer patients, 60 were BPH patients and 45 were apparently healthy subjects, control groups included BPH and apparently healthy subjects in this study. As showed in table (1), the almost cases occur in men over 46 years 98.7 % (74/75), and 10.6% (8/75) of the patients were positive family history. The majority of the patients were married 90.3% (68/75). Among the study population 75% (40/75) of cases had one or more of the unhealthy habits like smoking and intake tobacco, 24% (18/75) of cases were smokers, and more than 22.6% (17/75) of the prostate cancer patients were intake tobacco, and more than 8% (6/75) of patients were smoking and tobacco intake.

Most of the study patients 74.7% (56/75) were inhabitants of rural areas. Besides the most of the patients were non educated (62.7%) 47/75. Moreover, 24% (18/75) of the patients were underweight with BMI (<18.5), and 45.3% (34/75) were in normal weight with BMI (18.5-24.9), but 21.3 (16/75) of the patients were high BMI (≥25). Finally, occupations with low physical activity such as office workers, free jobs and retired represented more than 36% (27/75) of patients. However, 64% (48/75) of the patients were farmers and workers. Statistical analysis indicates that there is a significantly high association between the prostate cancer risk and age, unhealthy habits, BMI and occupations factors (P=0.000).

Table (2) demonstrated that range of PSA values from 4.62 to 1030 ng/ml in PCa patients, with a mean ±SE of 67.52±123.66 ng/ml and from 2.45 to 92.78 ng/ml in BPH patients, with the mean ±SE value being 15.41±20.68 ng/ml, and in apparently healthy group has mean ±SE of 1.93±1.04 ng/ml with the concentration values fell between 0.33 to 3.80 ng/ml. Values reach statistical significance and higher in PCa than BPH and apparently healthy groups (P=0.04).

furthermore, EPCA values ranged from 6.8 to 78.3 ng/ml in PCa patients, with a mean ±SE of 23.87±13.72 and from 0.74 to 12.66 ng/ml in BPH patients, with the mean ±SE value being 4.38±3.22, The EPCA values in apparently healthy group range fell between 0.74 to 10.13 ng/ml with the mean ±SE value being 4.04±2.74. also, the EPCA values reach statistical significance and superior in the PCa group (P=0.00).

Table 1 Risk factors and its association between prostate cancer and control groups. No 180

Groups / **Risk factors**		**Prostate cancer group (N= 75)**	**Control group (N=105)**	**P. value***
Age	≥45	1 (1.3%)	2 (2%)	0.000
	≤46	74 (98.7%)	103(98%)	
Family history	Positive	8 (10.6%)	6 (10%)	0.004
	Negative	67 (89.3%)	99 (90%)	
Marital status	Married	68 (90.6%)	97 (92.4%)	0.492
	Single	2 (2.6%)	2 (1.9 %)	
	Widow	5 (6.6%)	6 (5.7%)	
Residence	Rural	56 (74.7%)	68 (64.8%)	0.004
	Urban	19 (25.3%)	37 (35.3%)	
Unhealthy Habits	Smoking	18 (24%)	12 (11.4%)	0.000
	Tobacco	17(22.6%)	14 (13.3%)	
	Smoking and tobacco	6 (8 %)	5 (4.7%)	
	No habit	25 (32%)	31 (29.5%)	
Education Levels	Illiterate	47 (62.7%)	33 (31.4%)	0.045
	Primary	16 (21.3%)	27 (25.7%)	
	Secondary	10 (13.3%)	30 (28.5%)	
	University	2 (2.6%)	15 (14.2%)	
BMI	Underweight	18 (24%)	14 (13.3%)	0.000
	Normal weight	34 (45.3%)	40 (38%)	
	Overweight	16 (21.3%)	29 (27.6%)	
	Obese	7 (9.3%)	17 (16.1%)	
Occupations	Farmer	23 (30.6%)	16 (15.2%)	0.000
	Worker	25 (33.3%)	23 (21.9%)	
	Office worker	7 (9.3%)	24 (22.8%)	
	Free job	8 (10.6%)	15 (14.2%)	
	Retired	12 (16%)	27 (25.7%)	

P. value: P. value ≤ 0.05 is considered significant.

Table 2 Comparison of the means serum of EPCA and PSA in prostate cancer, prostatic hyperplasia and apparently healthy groups. No 180

Groups / **Bio-marker**	**Prostate cancer (N= 75) Mean ± SD (range)**	**Prostatic hyperplasia (N= 60) Mean ± SD (range)**	**Apparently healthy (N= 45) Mean ± SD (range)**
PSA ng/ml	67.52±123.66 (4.62-1030)	15.41±20.68 (2.45-92.78)	1.93±1.04 (0.33-3.80)
EPCA ng/ml	23.87±13.72 (6.80-78.30)	4.38±3.22 (0.74-12.66)	4.04±2.74 (0.74-10.13)

PSA: Prostate Specific Antigen**, EPCA**: Early Prostate Cancer Antigen, **N**: number of cases, **SD**: Standard deviation.

Regarding of PCa group versus control group, including BPH and healthy men groups as control subjects. As showed below in table (3), the cut-off value of serum PSA was (>7.84) ng/ml optimally identified the patients with prostate cancer from those who are non-cancerous; at this cut-off value the sensitivity of PSA was (69%), specificity was (83.1%), positive predictive value was 78.3%, negative predictive value was (75.2%), and odds ratio was (11.01). The PSA values reach statistical significance and higher in PCa than in control groups (P=0.04).

According to serum of EPCA level, the cut-off value (> 7.71) ng/ml optimally identified the patients with prostate cancer from those who are non-cancerous; at this cut-off value the sensitivity of EPCA was (94%), specificity was (81%), positive predictive value was (78%), negative predictive value was (95%), and odds ratio was (74.3). The EPCA values reach statistical significance and highest in the PCa group (P=0.00).

Table 3 The cut off, sensitivity, specificity, PPV & NPV and odds ratio for EPCA and PSA in prostate cancer and control groups

Parameter	PSA	EPCA
Cut off (ng/ml)	>7.84	>7.71
Sensitivity%	69%	94%
Specificity%	76.3%	81%
PPV %	71.3%	78%
NPV %	75.2%	95%
O.R	11.01	74.3
P. value*	0.04	0.00

PSA: Prostate Specific Antigen; EPCA: Early Prostate Cancer Antigen; PPV%: Positive Predictive Value%; NPV%: Negative Predictive Value%; O.R: Odds Ratio: P. value: P. value ≤ 0.05 is considered significant. *By Kruskal Wallis Test (Non parametric test).

4. Discussion

Despite the fact in Sudan that prostate cancer ranked first among all cancers in men, few publications showed the characteristics of patients diagnosed with prostate cancer [13]. In current study, possible common prostate cancer risk factors for among patients (n = 75) referred to at Gezira Hospital for Renal Disease and Surgery (GHRDS), Gezira state, Sudan, which included age, BMI, history of family, intake of tobacco, residence and occupation.

Age is significant associated with prostate cancer risk, which is infrequent among men younger than 40 years of age. The incidence rate of prostate cancer increases intensely after age exceed 55 years, following a similar trend for other epithelial carcinomas, this trend is obvious in prostate cancer rates in worldwide, as well as in both low and high healthcare countries [14].

This study revealed that prostate cancer is principally a disease of older men and is infrequent below the age of 45 years and the mean age for prostate cancer patients was (66.96) years. In addition, the result of our study is consistent with previous studies conducted the average age of prostate cancer patients in South Africa through white men 69.7 years and black men 68.9 years [15], however, the average age of prostate cancer patients for our study is slightly less than the results of another study conducted in South Africa men's [16], and the same observation was recorded in another study conducted in Uganda [16]. We conclude that prostate cancer is more diagnosed among Sudanese men with advanced age because there is ignorance of the prostate cancer symptoms and the lack of availability of early examination centers for prostate cancer.

Many previous studies documented body size and its measurement by calculated body mass index, which relates both weight and height. Its value appears high in obesity status, and it often results when consumes large amounts of calories and inactivity [17]. Obesity is considered one of the most important factors among the modified risk groups for prostate cancer.

The results of research showed that the body mass index of the prostate cancer group is (21.11), and this predicts that BMI showed negative relationship with prostate cancer incidence, and with obesity as well. This is consistent with many of the results of studies conducted by Batikhi. which organized surveys in many different residential areas to define the

role of obesity in the incidence of cancer [18]. Also, our results are similar in conclusion to study that included a population of older veterans [19]. However, it is not consistent with previous studies indicating that BMI increases the risk of prostate cancer [20,21], while other studies did not outline any relationship between obesity and prostate cancer risk [22].

In a previous study, Giovannucci and his colleagues found an increased risk of prostate cancer of more than 58% in obese subjects between the ages of 50 and 59, and no other age groups included in the study showed a strong risk of prostate cancer. Thus, the association between age and obesity reveals why many scientific studies expressed contradictory results on the risk of obesity among prostate cancer patients [23].

The presence of a family history could be considered one of the risk factors for prostate cancer incidence, this risk factor could reflect a mutual set of inherited characteristics and lifestyles practiced by family members [17]. Compared with men without a positive family history, men with a father or brother diagnosed with prostate cancer are at a two to threefold higher risk of being diagnosed, and the risk is nearly nine fold higher for men with both [24]. The results of family history the patients in this study are consistent with previous studies, which reported that approximately 15% of cases diagnosed with prostate cancer had a first-degree relative, such as a brother or father with the same type of cancer [25].

It should be noted that 9 % of cases of prostate cancer are the result of genetic mutations, in addition to that half of the cases of men at the age of less than 45 years are caused by genetic conditions from one of the family members, however, several studies showed that the genetic mutations tendency increases the risk of developing prostate cancer not in a significant way as found in the cases with family history of prostate cancer [17].

The effect of smoking in prostate cancer is one of the most important factors affecting public health, in the US Surgeon General's report issued in 2014, it was verified that there is a positive association between smoking and the risk of prostate cancer [26]. To evaluate the effect of smoking and its relationship to prostate cancer risk, follow up study was conducted including 5366 men with prostate cancer who were followed for 22 years and it was observed that there were 524 deaths from prostate cancer compared to those who had never smoked [27]. In further study, Hsing and et al. showed relative risks of 1.8 and 2.1 for smoking and tobacco intake, respectively [28], probably this study agrees with data published on the relation between smoking, tobacco intake and prostate cancer incidence. The potential biological factor that causes elevation in the incidence of prostate cancer is the promotion and activation roles in tumor areas as a result of the carcinogens present in tobacco or nicotine.

Several documented studies were investigated to expose any association involving the men's sexual history, such as marital status and cases diagnosed with various types of cancer. This study revealed the impact of marital status on cases of men with prostate cancer. We concluded there is no significant association between marital status and prostate cancer, this agreed with Kenneth et al, who expressed that marriage is often assumed to be synonymous with elevated sexual activity [29].

However our results were disagrees with a meta-analysis of case control studies conducted by Dennis et, al. which reported a positive association between increasing number of sexual partners and prostate cancer risk (RR = 1.2; 95% CI:1.1–1.3) [30] , although a recent study by Spence et al showed a reduced risk of PCa with multi-sexual partners (OR 0.78, 95% CI 0.61–1.00) [31], we did not find conclusive evidence if marital status own any relationship to prostate cancer risk, so further research is essential to unravel the potential of marital status role in prostate cancer incidence.

In general, there is a difference between the residential location and its association with the spread of cancer. Many studies reported on cases of cancer living in rural and urban areas, and showed a significant spread of cancer in the rural population [32] [33]. In dissimilarity, other studies showed that rural population has an inverse or no association with diagnosis of carcinoma [34] [35]. Sudan and many other countries, the rural population suffers from being deprived of the social and economic benefits that most urban populations possess. In addition, a lot of research found that rural residents suffer from obesity, lack of physical activity, smoking and chronic diseases [36].

The results of our study showed that there is significant relation between the patient's place of residence and the risk of prostate cancer, as we found that most of our research cases lived in rural areas such as villages or small towns, so the nature of this regions are agricultural campuses (Gezira scheme), and this reinforces the hypothesis that most of the residents of these areas are exposed to pesticides and herbicides, and this is consistent with the report of the National Cancer Institute issued in USA [37]. Another possible hypothesis that could be considered is the incidence of prostate cancer among patients in rural areas is partially due to the spread of poverty and low quality level of education and

healthcare systems compared to urban residents, which in turn affects healthy behaviors and full utilization of healthcare services in rural areas.

Few recent studies showed the role of the nature of occupation and exposure to the risk of prostate cancer. Several chemical agents have evidence of their presence in humans and the prevalence of prostate cancer, including cadmium, malathion, arsenic, and other inorganic arsenic compounds [38]. In the current study (33.3%) (30.6%) of prostate cancer patients were workers and farmers respectively, this explains the fact of those types of occupations are more likely to be exposed to one or to a variety of chemical agents, without excluding the opportunity of interfaces between those agents. However, additional investigations are needed to identify specific exposures or circumstances potentially associated with PCa among subjects employed in these occupations.

In Sudan, the insufficiency of health awareness is obvious in most of the cases diagnosed with prostate cancer which present at advanced local or metastases stages. Most of the patients attend for examination only after suffering from excessive problems in the urinary tract. Also this is common in sub-Saharan African countries because of absence systematic screening practices, unlike in developed world countries which have an advanced healthcare system, where the patients utilize PSA screening and other early detection techniques to diagnosis prostate cancer.

Otherwise, we found that deficiencies were significantly associated with the PSA test, impairing its role as an ideal tumor marker. PSA is a protein that is produced in the prostate gland and is not produced in the prostate gland at a very high rate in the case of cancer, but is released inappropriately into the blood serum with the disease. One of the disadvantages of the PSA test is the large number of false positive biopsies and the high rate of over-diagnosis and over-treatment [39]. In a multi-country European study randomizing (162,387) men for prostate cancer screening, PSA testing (75.9%) reported false positive results [40]. PSA level showed high level in cases of benign prostatic hyperplasia (BPH) without prostate cancer being detected, and we also find PSA at a high rate incases with advanced age. In addition, there are an inverse relationship between BMI and PSA level in the blood. Recently, the European Randomized Prostate Cancer Study (ERSPC) proposed that there is no clear PSA threshold with high sensitivity and specificity [41].

Therefore, find new and alternative tumor markers instead of PSA has been the focus of interest and goals of many recent studies so far in order to find specialized biomarkers for early detection of prostate cancer and provide opportunities to explore more effective treatment options in easily treatable disease stages. Through this research, we were able to identify early prostate cancer antigen (EPCA) as a promising and useful biomarker. EPCA was proved to be highly specialized for detecting men with prostate cancer.

In Sudan, there is no related obtainable data concerning the serum levels of early prostate cancer antigen in Sudanese prostate cancer cases, up to date, our study in EPCA is considered the first study in Sudan so our finding data were compared to other none Sudanese patients results. In this study, the mean prostate specific antigen level was a significantly increased in the prostate cancer group (67.52±123.66 ng/ml) compared with BPH and apparently healthy subjects (15.41±20.68 ng/ml) (1.93±1.04 ng/ml) respectively, with ($P = 0.04$), and this reflects the ability of PSA in distinguishing suspected patients with prostate cancer from other noncancerous, this finding is similar to that stated by Sajjad Ahmad [42], who found a significant difference in the mean of serum level of prostate specific antigen between the cases group (25.7±21.6) and control groups (12.7±6.9) ng/ml ($P = 0.01$), which occur due to the irregular leakage of PSA into the circulation which is controlled by PSA expression in malignant epithelium and distortion glandular architecture of prostate gland [43].

EPCA was detectable in all subjects included cases and controls, our study results showed that obviously the mean serum EPCA levels were significantly increased in the cancer patients group (23.87±13.72 ng/ml) with ($P=0.00$), from the previous results we realized that EPCA marker can be used to distinguish between controls and PCa patients. This agrees with the results obtained by Dhir and this college who showed elevated EPCA level among many prostate cancer patients compared to other groups, specifically the healthy subjects ($P < 0.0001$), and so showed EPCA as novel prostate cancer biomarker as it is sensitive and specific for prostate cancer diagnosis [11]. Despite a small sample size of the study population, there was a statistically significant increase in serum EPCA levels in samples obtained from prostate cancer patients subjects.

The present study exposed that the specificity and sensitivity of PSA for detecting prostate cancer was only approximately (76.3%) and (69%) respectively, while that the specificity and sensitivity of EPCA was (81%) and (94%) respectively, therefore, the use of EPCA biomarker could enhance the positive and negative predictive values of prostate cancer screening, so it may be applied more accurately to detect prostate cancer. Furthermore, EPCA antigen was determined to structurally and functionally belong to proteins of nuclear matrix, which acting a vital role of regulators in DNA replication, transcription and gene expression. Many studies, comprising both experiments and clinical studies,

have demonstrated that the nuclear matrix proteins are exactly related to carcinogenesis of various organizations especially of prostate [44] [45].

Level of EPCA biomarker is significantly elevated in malignant prostate tumor only, this may be due to the abnormal leakage of EPCA into the circulation influenced by the level of EPCA expression in malignant epithelium, this agrees with other findings in a study done earlier by Zhao el. al. who found the significantly increased level of EPCA in patients with prostate cancer in comparison to non-prostate cancer subjects, ($P<0.001$) [46].

5. Conclusion and Recommendation

This study concluded that there is a significantly association between age, unhealthy habits, BMI, education, family history, residence occupations factors and the prostate cancer risk. In addition, this study determined that the serum levels of early prostate cancer antigen and prostate specific antigen are significantly increased in patients with prostate cancer, our results concluded that EPCA has higher sensitive and specific values than PSA. EPCA could be used as routine test in screening centers of prostate cancer for early diagnosis, and also help in decreasing the number of unnecessary prostatic biopsies.

Study limitation

Obstacles and shortcomings that encountered during the conducting of this research, which must be mentioned; were the relatively small sample size due to scarcity of cases in hospitals, the difficulty of finding financial sources from other parties to fund the research and the short-term storage of tested serum samples for EPCA measurement.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that there is no conflict of interest.

Statement of ethical approval

The ethical committee of University of Gezira approved this study. Informed consent were obtained from each participant before collecting the samples.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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