

## **AIM OF THE WORK**

The aim of this work is to study the difference of the level of serum total PSA, prostatic volume and the level of serum total testosterone hormone in diabetic and non-diabetic men.

## **PATIENTS**

The study involved 501 male patients who presented to the Main University Hospital of Alexandria University with different benign urologic problems, 207 patients were diabetics, and the other 294 patients were not diabetics, aged  $\geq 55$  years old.

### **Exclusion criteria included:**

1. Patients with active urinary tract infection.
2. Urologic cancer.
3. Medical or neurological conditions that affect normal urinary function.
4. Diabetics who suffer from end organ damage.
5. Patients who had undergone recent urologic manipulations.

Following counseling and explanation of the procedures to the patients and subjects and assurance of confidentiality and anonymity, an informed consent was obtained from all patients in the study group. This study was approved by the ethical committee of the University of Alexandria.

## METHODS

### All patients were subjected to the following regimen:

#### I- Explanation of the procedure:

Explanation of the clinical and laboratory procedures to all participating individuals with their possible results, outcomes, complications (if any) and their interpretations.

#### II- Detailed History:

- 1- **Personal history:** Name, age, occupation, residence and smoking habits.
- 2- **Present history:** of any symptoms either obstructive or irritative, such as hesitancy, difficulty in starting micturation, straining or weak stream, interruptions in stream, dribbling, urgency, frequency, sense of incomplete evacuation of urine, nocturia, pain, burning sensations or hematuria.
- 3- **Past history:** of previous operations, previous traumas, or episodes of urinary symptoms.
- 4- **Medical history:** of any medical treatments of chronic systemic illnesses such as hypertension. History of drug abuse or alcohol intake was taken also.

#### III- General physical examination:

1. General condition such as signs of anemia and dehydration to detect any chronic illness like chronic renal impairment.
2. Vital signs.
3. Height and weight measurement.
4. Neurological survey for neurological condition that may mimic prostatic obstruction such as Parkinson's disease, neurological complications of diabetes, disseminated sclerosis, and cervical spondylosis.
5. Abdominal examination for signs such as abdominal masses or distended bladder on palpation and percussion and loss of suprapubic skin crease, in addition to signs of previous surgical operations or traumas.
6. Obesity, gynecomastia, anosmia and hair distribution.

#### IV- Local physical examination:

- 1- Skin of scrotum.
- 2- The epididymis was palpated for signs of inflammation.
- 3- The external urinary meatus was examined to exclude stenosis.

- 4- Digital rectal examination (DRE) for prostate examination:<sup>(139)</sup>
  - a. The posterior surface of the prostate was examined for smoothness, convexity and consistency.
  - b. The rectal mucosa was tested for mobility over the prostate.

#### **V- Determination of body mass index (BMI):**

Determination of the body mass index was performed using Mosteller's formula :<sup>(140)</sup>

$$\text{BMI} = \text{weight (in kilograms)} \div \text{height (in meters)}^2$$

#### **VI- Laboratory Investigations:**

- a. **Sample collection:** Six ml of venous blood were withdrawn under standard aseptic technique from each patient at 8 am. Serum was separated for determination of both PSA and serum testosterone levels.
  - b. **Sample storage:** Serum samples were stored at -20°C until assayed.
1. **Quantitative determination of serum total prostate specific antigen (PSA) using electro-chemiluminescence immunoassay:**<sup>(141)</sup>

##### **Principle:**

1. The electro-chemiluminescence immunoassay (ECLIA) for total PSA is intended for use on Cobas<sup>®</sup> immunoassay analyzer<sup>(142)</sup> and is a quantitative in vitro diagnostic test for total PSA measurement in human serum and plasma.
2. PSA in serum samples react with a biotinylated monoclonal PSA-specific antibody labeled with a ruthenium complex to form a sandwich complex.
3. Following addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is then aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then surrounded with procell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

**Results:** were determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

2. **Quantitative determination of serum total testosterone using electro-chemiluminescence immunoassay:**<sup>(143)</sup>

##### **Principle:**

1. The electro-chemiluminescence immunoassay (ECLIA) of serum total testosterone is intended for use on Cobas<sup>®</sup> immunoassay analyzer<sup>(144)</sup> and is a quantitative in-vitro diagnostic test for total testosterone levels measurement in human serum and plasma.

2. Total testosterone in serum sample reacts with a biotinylated monoclonal testosterone-specific antibody. The binding sites of the labeled antibody became occupied by the sample analyte.
3. Following addition of streptavidin-coated microparticles and a testosterone derivative labeled with a ruthenium complex. The complex becomes bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode unbound substances are then removed with procell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

**Results:** were determined via a calibration curve which is instrument-specific generated by a 2-point calibration and a master curve provided via the reagent barcode.

### 3. Quantitative determination of fasting blood glucose (FBG):

The glucose (GLUC) method for the Dimension<sup>®</sup> clinical chemistry system is an *invitro* diagnostic test intended for quantitative determination of glucose in human serum, plasma, urine, and cerebrospinal fluid.

The GLUC method is an adaptation of the hexokinase glucose-6-phosphate dehydrogenase method, presented as a general clinical laboratory method by Kunst, et al<sup>(145)</sup>. The hexokinase (HK) method is the generally accepted reference method for measuring glucose<sup>(146,147)</sup>.

#### Principle:

HK catalyzes the phosphorylation of glucose in the presence of adenosine-5'-triphosphate (ATP), and magnesium to form glucose-6-phosphate (G-6-P), and adenosinediphosphate (ADP). G-6-P is then oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) in the presence of nicotinamide adenine dinucleotide (NAD) to produce 6-phosphogluconate and NADH.

One mole of NAD is reduced to one mole of NADH for each mole of glucose present. The absorbance due to NADH (and thus the glucose concentration) is determined using a bichromatic (340 and 383 nm) end point technique.

### 4. Determination of glycosylated hemoglobin (HbA1c):

The assay for HbA1c is performed using the Roche Unimate immunoassay and the Cobas Integra Analyzer, which is calibrated using a synthetic HbA1c standard.

#### Principle:

The Roche Unimate method is an immunoassay that combines a latex-enhanced competitive turbidimetric immunoassay for determining HbA1c with a colorimetric assessment of total hemoglobin (Hb). The Cobas Integra Analyzer, which is used the Roche Unimate method, was certified by the National Glycohemoglobin Standardization Program (NGSP) in 1997<sup>(148)</sup>.

## **VII. Transabdominal Ultrasonographic imaging of the prostate:<sup>(149)</sup>**

### **a. Technique and normal findings: (Figures 1, 2 and 3)**

- a. The transducer is placed longitudinally in the midline just above the symphysis pubis. The angle of the scan is slightly adjusted downward and the echo-free lumen of the bladder was identified and posterior to it, the prostate is identified. A small amount of urine in the bladder facilitated the examination.
- b. Scanning in transverse fashion above the symphysis pubis with the probe angle sharply downward. The prostate appears symmetrical in cross section, displaying an elliptical or triangular shape and normally measures 3-4 cm transversely and 2-3 cm anteroposteriorly.
- c. The base of the prostate was visualized. The central zone comprised the posterior part of the gland and is often hyperechoic. The midgland was the widest portion of the gland. The peripheral zone formed most of the prostate volume.
- d. The transitional zone was the central part of the gland and is usually hypoechoic. The junction of the peripheral zone and the transition zone is usually distinct posteriorly and is characterized by a hyperechoic region, which results from prostatic calculi or corpora amylacea. The transition zone is often filled with cystic spaces in patients with BPH.
- e. Scanning at the level of the verumontanum and observing the Eiffel tower sign (anterior shadowing) help to identify the urethra and the verumontanum.
- f. The prostate distal to the verumontanum is normally composed mainly of the peripheral zone. The capsule is normally is a hyperechoic structure that can be identified all around the prostate gland.
- g. Several hypoechoic rounded structures can usually be identified around the prostate gland. These are the prostatic venous plexi.
- h. The position of the neurovascular bundles can often be identified by the vascular structures. Imaging in the sagittal plane allows visualization of the urethra. The medial lobes of the prostate are often visualized.

### **b. Prostate volume assessment:**

Of the several formulas that have been developed for this purpose, the most commonly used is the ellipsoid formula, which requires measurement of 3 different prostate dimensions<sup>(150)</sup>.

First, the transverse dimension and the anteroposterior dimension at the estimated point of the widest transverse dimension are measured in the axial plane. Next, the longitudinal dimension is measured in the sagittal plane just off the midline (because the bladder neck often obscures the cephalad extent of the gland). The ellipsoid volume formula is then applied, as follows:<sup>(150)</sup>

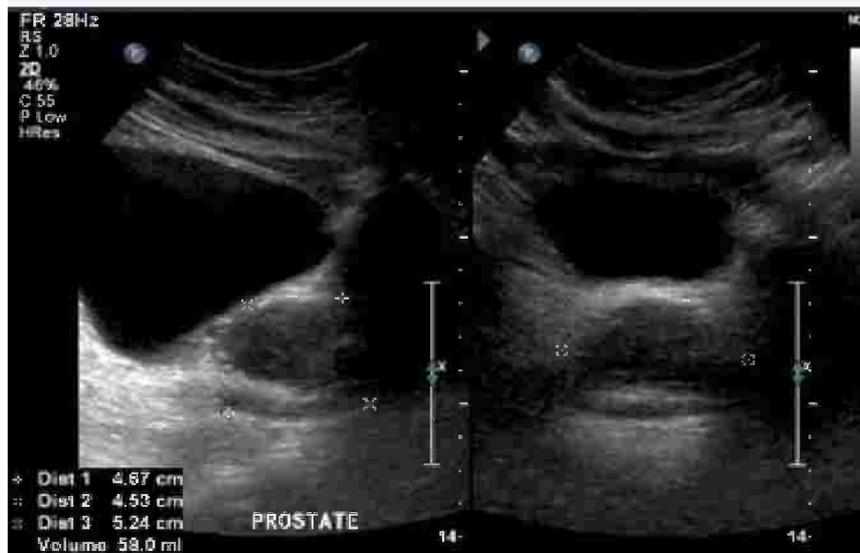
$$\text{Prostate volume} = \text{height} \times \text{width} \times \text{length} \times 0.52$$



**Figure (1):** Transabdominal US image of a transverse view of normal prostate.



**Figure (2):** Transabdominal US image of a sagittal view of enlarged prostate.



**Figure (3):** Determination of the prostate size by determining the height, width and length of the gland.

**Data Processing and Statistical Analysis:**

Data were analyzed using SPSS software package version 18.0 (SPSS, IBM corporation, Chicago, USA). Quantitative data was expressed using Range, mean, standard deviation and median while Qualitative data was expressed in frequency and percent. Qualitative data was analyzed using exact tests such Fisher exact test and Chi-Square test was applied to compare different groups. Quantitative data was analyzed using student t-test to compare between two groups. p value was assumed to be significant at  $\leq 0.05^{(151)}$ .

## RESULTS

The study involved 501 male patients who presented to the Main University Hospital of Alexandria University with different benign urologic problems, 207 patients were diabetics, and the other 294 patients were not diabetics. Different data was collected, analyzed and tabulated according to the study protocol.

### Clinical results:

#### 1. Age range of all patients in the present study:

The mean age (in years) of subjects recruited in the present study was  $60.21 \pm 5.95$  years, ranging between 55.0 and 93.0 years, with a median of 58.0 years (Table 4), (figure 4).

Table (4): Distribution of the studied cases according to age (n=501):

Age (in years)	Value
Minimum	55.0
Maximum	93.0
Mean	60.21
S.D	5.95
Median	58.0

S.D: Standard Deviation.

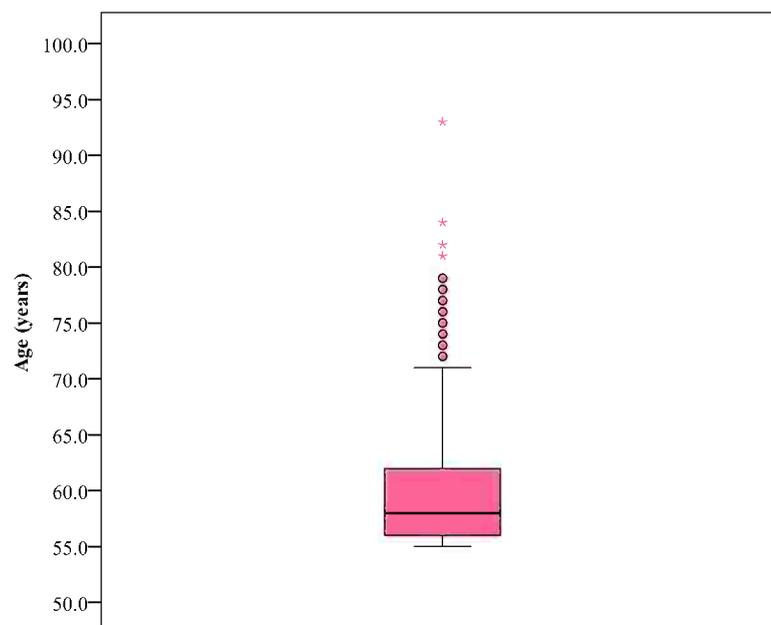


Figure (4): Distribution of the studied cases according to age

**Comparison between the two studied groups according to age:**

**Table (5)** shows comparison between the two groups according to age, where no statistically significant patterns were observed upon analysis ( $p= 0.958$ ;  $p> 0.05$ ):

**Table (5): Comparison between the two studied groups according to age:**

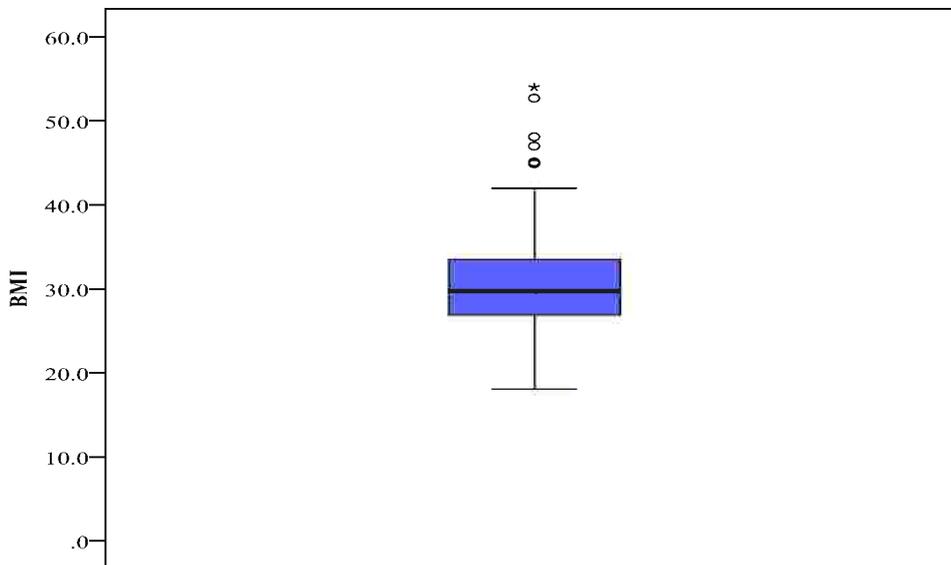
	<b>Diabetic (n=207)</b>	<b>Non-diabetic (n=294)</b>	<b>t</b>	<b>p</b>
<b>Age (years)</b>				
Min. – Max.	55.0 - 78.0	55.0 - 93.0		
Mean $\pm$ SD	60.22 $\pm$ 5.37	60.19 $\pm$ 6.33	0.052	0.958
Median	58.0	58.0		

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$

**2. Body Mass Index (BMI) of all patients in the study:**

The mean body mass index (BMI) of subjects recruited in the present study was  $30.52 \pm 4.78 \text{ Kg/m}^2$ , ranging between 18.10 and  $54.0 \text{ Kg/m}^2$  with a median value of  $29.70 \text{ Kg/m}^2$  (**figure 5**)



**Figure (5):** Body mass index (BMI) of all patients in the study ( $\text{kg/m}^2$ )

**Comparison between the two studied groups according to Body Mass Index (BMI):**

**Table (6)** shows comparison between the two groups according to BMI, where diabetic patients were found to have a higher mean BMI value ( $32.23 \pm 5.04 \text{ kg/m}^2$ ) than mean BMI value ( $29.32 \pm 4.20 \text{ kg/m}^2$ ) of non-diabetic patients, and this was found statistically significant upon analysis ( $p < 0.001$ ).

**Table (6): Comparison between the two studied groups according to Body Mass Index (BMI):**

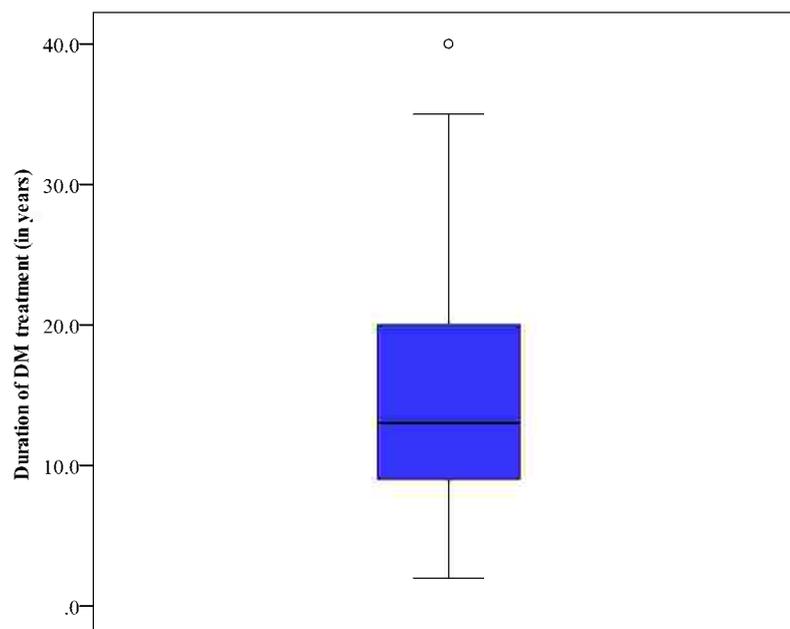
	<b>Diabetic (n=207)</b>	<b>Non-diabetic (n=294)</b>	<b>t</b>	<b>p</b>
<b>BMI (kg/m<sup>2</sup>)</b>				
Min. – Max.	22.40 - 52.70	18.10 - 54.00		
Mean $\pm$ SD	$32.23 \pm 5.04$	$29.32 \pm 4.20$	6.812*	<0.001*
Median	32.20	28.60		

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$

**3. Duration of diabetes mellitus (DM) treatment:**

The mean duration of DM treatment (in years) of the diabetic patients in the study was  $14.24 \pm 7.02$  years, ranging between 2.0 and 40.0 years, with a median of 13.0 years (**figure 6**).



**Figure (6): Duration of diabetes mellitus (DM) treatment**

## Laboratory investigations

### 1. Fasting blood glucose (FBG) and glycosylated haemoglobin (HbA1c) in diabetic patients:

The mean FBG in diabetic patients in the study was  $155.81 \pm 66.10$  mg/dl, ranging between 83.0 and 334.0 mg/dl, with a median of 122.0 mg/dl (Table 7).

The mean HbA1c in diabetic patients in the study was  $7.90 \pm 1.36$  %, ranging between 6.0 and 10.80 %, with a median of 7.60 % (Table 7).

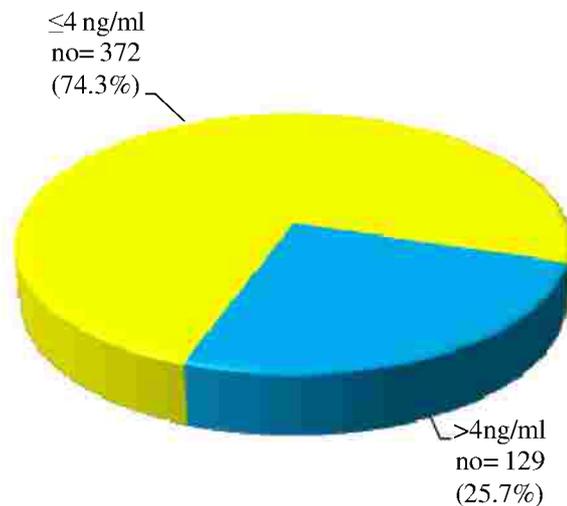
**Table (7): Distribution of the diabetic cases according to FBG and HbA1c:**

	Min. – Max.	Mean $\pm$ SD.	Median
<b>FBG (mg/dl)</b>	83.0 - 334.0	$155.81 \pm 66.10$	122.0
<b>HbA1c (%)</b>	6.0 - 10.80	$7.90 \pm 1.36$	7.60

S.D: Standard Deviation.

### 2. Serum prostate-specific antigen (PSA) in all patients:

The mean serum PSA among cases in the study was  $3.02 \pm 1.89$  ng/ml, ranging between 0.02 and 9.07 ng/ml with a median value of 2.89 ng/ml. When serum PSA values were statistically analyzed with a cut-off value of 4 ng/ml, serum PSA values were  $\leq 4$  ng/ml in 372 patients (74.3%), while were  $> 4$  ng/ml in 129 patients (25.7%). (figure 7)



**Figure (7):** Distribution of the studied cases according to PSA

**Comparison between the two studied groups according to serum PSA:**

Table (8), figure (8), show comparison between the two groups according to serum PSA, where diabetic patients were found to have a lower mean serum PSA ( $2.30 \pm 1.56$  ng/ml) than non-diabetic patients ( $3.53 \pm 1.94$  ng/ml), and this was statistically significant ( $p < 0.001$ ).

**Table (8): Comparison between the two studied groups according to PSA:**

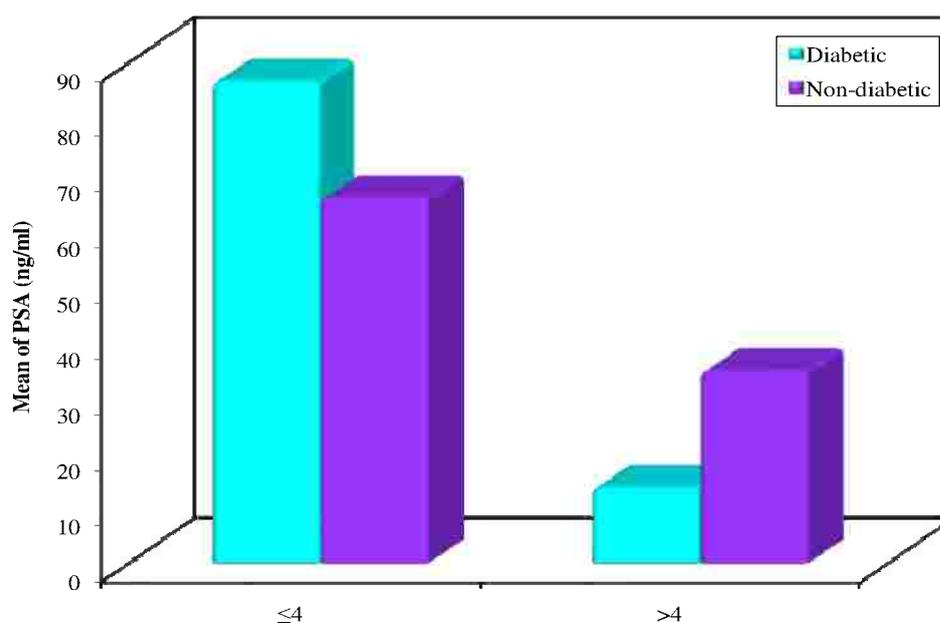
	Diabetic (n=207)	Non-diabetic (n=294)	Test of sig.	p
	No. (%)	No. (%)		
<b>PSA (ng/ml)</b>				
≤ 4	179 (86.5)	193 (65.6)	$\chi^2 = 27.560^*$	<0.001*
> 4	28(13.5)	101 (34.4)		
Min. – Max.	0.02 - 8.03	0.03 - 9.07		
Mean ± SD	$2.30 \pm 1.56$	$3.53 \pm 1.94$	$t = 7.813^*$	<0.001*
Median	2.05	3.21		

p: p value for comparing between the two studied groups

$\chi^2$ : value for Chi square

t: Student t-test

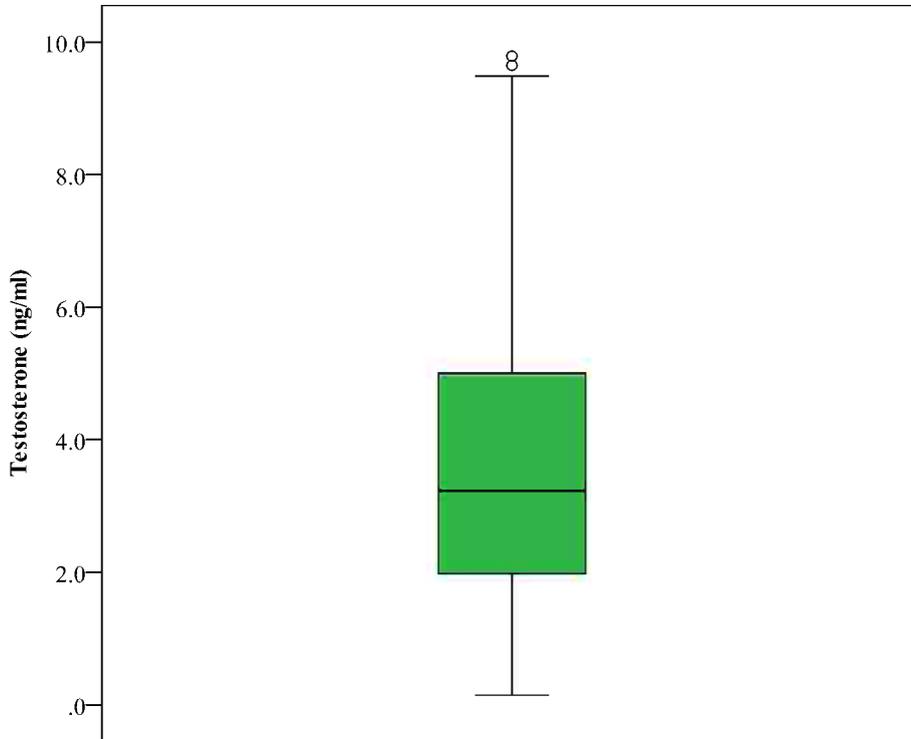
\*: Statistically significant at  $p \leq 0.05$



**Figure (8):** Comparison between the two studied groups according to PSA with a cut-off value: 4 ng/ml

**3. Serum testosterone to all patients:**

The mean serum testosterone among cases in the study was  $3.67 \pm 2.04$  ng/ml, ranging between 0.15 and 9.79 ng/ml with a median value of 3.23 ng/ml. **(figure 9)**



**Figure (9):** Distribution of the studied cases according to testosterone

**Comparison between the two studied groups according serum testosterone:**

**Table (9)** shows comparison between the two groups according to serum testosterone, where diabetic patients were found to have a lower mean serum testosterone ( $3.08 \pm 1.80$  ng/ml) than non-diabetic patients ( $4.09 \pm 2.10$  ng/ml), and this was statistically significant ( $p < 0.001$ ).

**Table (9): Comparison between the two studied groups according to testosterone:**

	<b>Diabetic (n=207)</b>	<b>Non-diabetic (n=294)</b>	<b>t</b>	<b>p</b>
<b>Testosterone (ng/ml)</b>				
Min. – Max.	0.15 - 8.02	0.26 - 9.79	5.764*	<0.001*
Mean $\pm$ SD	3.08 $\pm$ 1.80	4.09 $\pm$ 2.10		
Median	2.83	3.92		

p: p value for comparing between the two studied groups

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$

**Prostate volume:**

**Table (10)** shows comparison between the two groups according to prostate volume, where diabetic patients were found to have a higher mean prostate volume value ( $55.98 \pm 18.87 \text{ cm}^3$ ) than mean prostate volume value ( $51.84 \pm 23.92 \text{ cm}^3$ ) of non-diabetic patients, and this was found statistically significant upon analysis ( $p= 0.031$ ;  $p \leq 0.05$ ).

**Table (10): Comparison between the two studied groups according to prostate volume:**

	<b>Diabetic (n=207)</b>	<b>Non-diabetic (n=294)</b>	<b>t</b>	<b>p</b>
<b>Prostate volume (cm<sup>3</sup>)</b>				
Min. – Max.	25.0 – 139.80	27.0 – 200.0		
Mean $\pm$ SD	55.98 $\pm$ 18.87	51.84 $\pm$ 23.92	2.159*	0.031*
Median	50.80	46.60		

p: p value for comparing between the two studied groups

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$

**PSA density (PSA/ prostate volume) (ng/ml/cm<sup>3</sup>):**

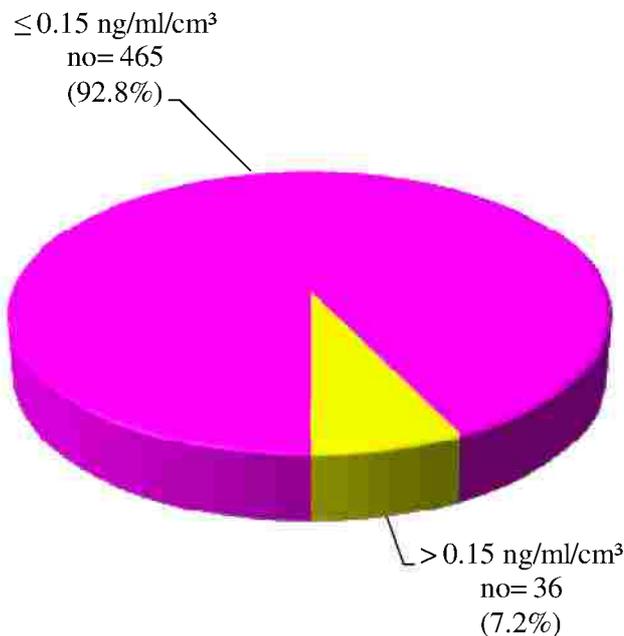
The mean PSA density among subjects in the present study was  $0.067 \pm 0.053$  ng/ml/cm<sup>3</sup>, ranging from 0.0 and 0.301 ng/ml/cm<sup>3</sup>, with a median value of 0.055 ng/ml/cm<sup>3</sup>. When PSA density values were statistically analyzed with a cut-off value of 0.15 ng/ml/cm<sup>3</sup>, PSA density values were  $\leq 0.15$  ng/ml/cm<sup>3</sup> in 465 patients (92.8%), while were  $> 0.15$  ng/ml/cm<sup>3</sup> in 36 patients (7.2%).(Table 11), (figure 10)

**Table (11): Distribution of the studied cases according to PSA density:**

	No.	%
<b>PSA density ng/ml/cm<sup>3</sup></b>		
$\leq 0.15$	465	92.8
$> 0.15$	36	7.2
Min. – Max.	0.0 – 0.301	
Mean $\pm$ SD	$0.067 \pm 0.053$	
Median	0.055	

S.D: standard deviation.

PSA: prostatic specific antigen.



**Figure (10):** Distribution of the studied cases according to PSA density

**Comparison between the two studied groups according to PSA density:**

**Table (12), figure (11),** show comparison between the two groups according to PSA density where diabetic patients were found to have a lower mean PSA density ( $0.049 \pm 0.043$  ng/ml/cm<sup>3</sup>) than mean PSA density ( $0.080 \pm 0.056$  ng/ml/cm<sup>3</sup>) of non-diabetic patients, and this was found statistically significant upon analysis ( $p < 0.001$ ).

**A. PSA density in diabetic patients:**

The mean PSA density among diabetic patients in the study was  $0.049 \pm 0.043$  ng/ml/cm<sup>3</sup>, ranging between 0.0 and 0.182 ng/ml/cm<sup>3</sup> with a median value of 0.038 ng/ml/cm<sup>3</sup>. When PSA density values were statistically analyzed with a cut-off value of 0.15 ng/ml/cm<sup>3</sup>, PSA density values were  $\leq 0.15$  ng/ml/cm<sup>3</sup> in 190 patients (91.8%), while were  $> 0.15$  ng/ml/cm<sup>3</sup> in 17 patients (8.2%), and these results were statistically insignificant ( $p = 0.455$ ;  $p > 0.05$ ).

**B. PSA density in non-diabetic patients:**

The mean PSA density among non-diabetic patients in the study was  $0.080 \pm 0.056$  ng/ml/cm<sup>3</sup>, ranging between 0.001 and 0.301 ng/ml/cm<sup>3</sup> with a median value of 0.071 ng/ml/cm<sup>3</sup>. When PSA density values were statistically analyzed with a cut-off value of 0.15 ng/ml/cm<sup>3</sup>, PSA density values were  $\leq 0.15$  ng/ml/cm<sup>3</sup> in 275 patients (93.5%), while were  $> 0.15$  ng/ml/cm<sup>3</sup> in 19 patients (6.5%), and these results were statistically insignificant ( $p = 0.445$ ;  $p > 0.05$ ).

**Results**

**Table (12): Comparison between the two studied groups according to PSA density:**

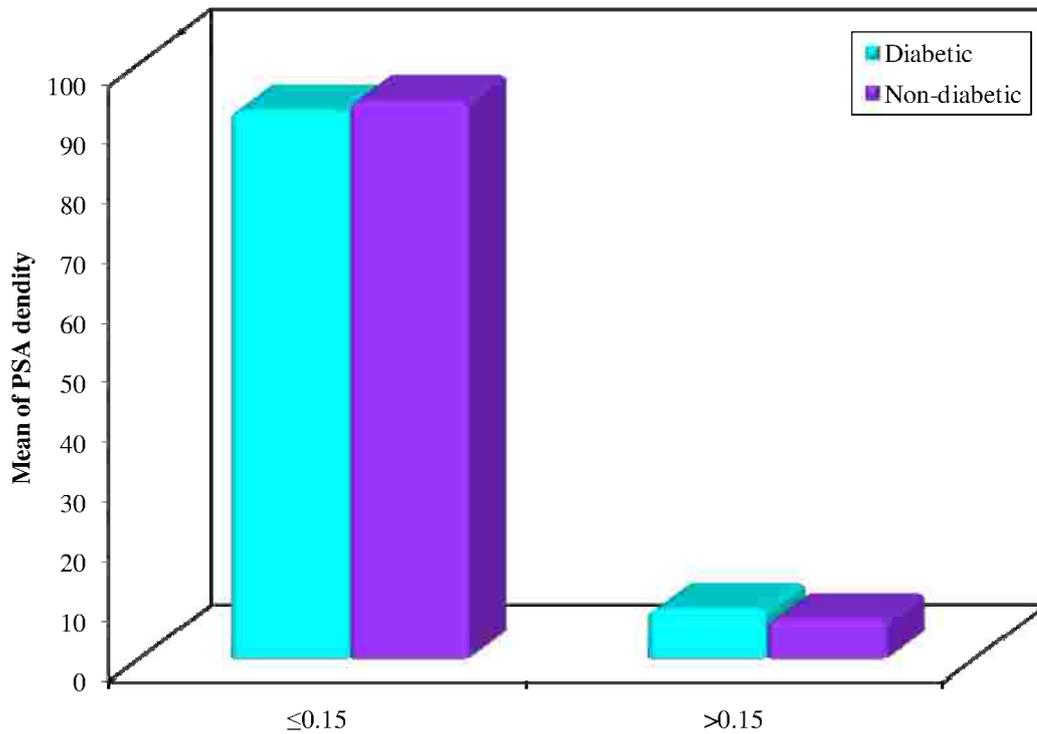
	<b>Diabetic (n=207)</b>	<b>Non-diabetic (n=294)</b>	<b>Test of sig.</b>	<b>p</b>
<b>PSA density ng/ml/cm<sup>3</sup></b>	<b>No. (%)</b>	<b>No. (%)</b>		
≤ 0.15	190 (91.8%)	275 (93.5%)	$\chi^2 = 0.558$	0.455
> 0.15	17 (8.2%)	19 (6.5%)		
Min. – Max.	0.0 – 0.182	0.001 – 0.301	t = 7.037*	<0.001*
Mean ± SD	0.049 ± 0.043	0.080 ± 0.056		
Median	0.038	0.071		

p: p value for comparing between the two studied groups

$\chi^2$ : Chi square test

t: Student t-test

\*: Statistically significant at p ≤ 0.05



**Figure (11): Comparison between the two studied groups according to PSA density with a cut-off value: 0.15 ng/ml/cm<sup>3</sup>**

**Correlation between duration of treatment of DM with different studied parameters in diabetic group:**

**Table (13), figures (12-17)** show that, in diabetic patients statistically significant positive correlation was found between duration of treatment of DM and:

- a. mean FBG values ( $r= 0.310, p< 0.001$ ),
- b. mean HbA1c values ( $r= 0.347, p< 0.001$ ),
- c. mean Prostate volume values ( $r= 0.147, p= 0.034; p\leq 0.05$ )

While statistically significant negative correlations were found between duration of DM treatment and:

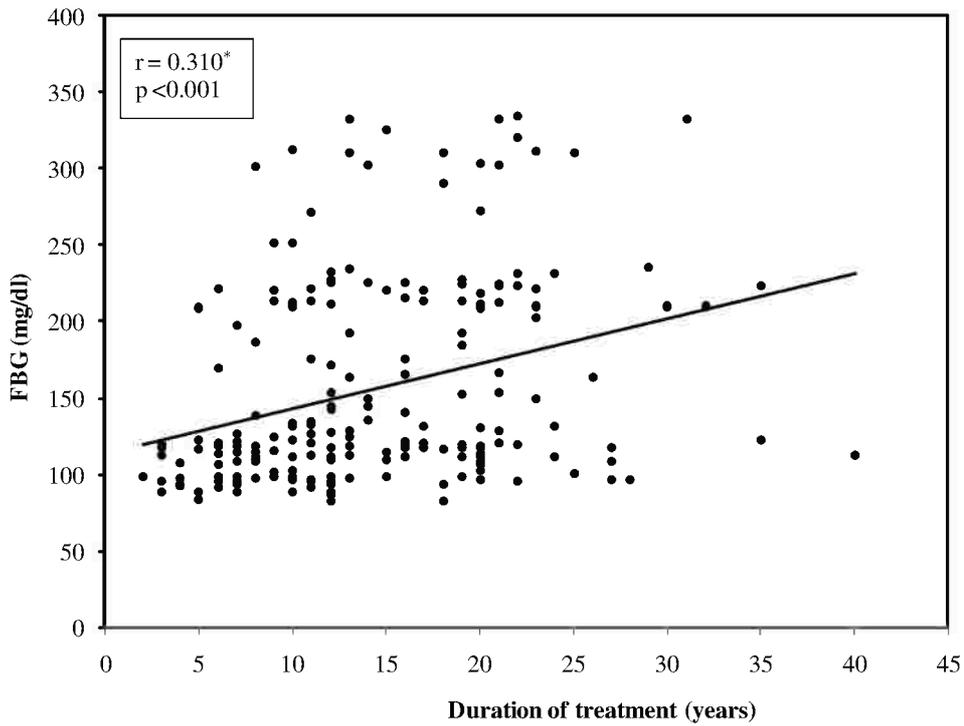
- a. mean serum PSA values ( $r= -0.219, p= 0.002; p\leq 0.05$ ),
- b. mean serum testosterone values ( $r= -0.221, p= 0.001; p\leq 0.05$ ),
- c. mean PSA density values ( $r= -0.203, p= 0.003; p\leq 0.05$ ).

**Table (13): Correlation between duration of treatment of DM with different studied parameters in diabetic group (No= 207):**

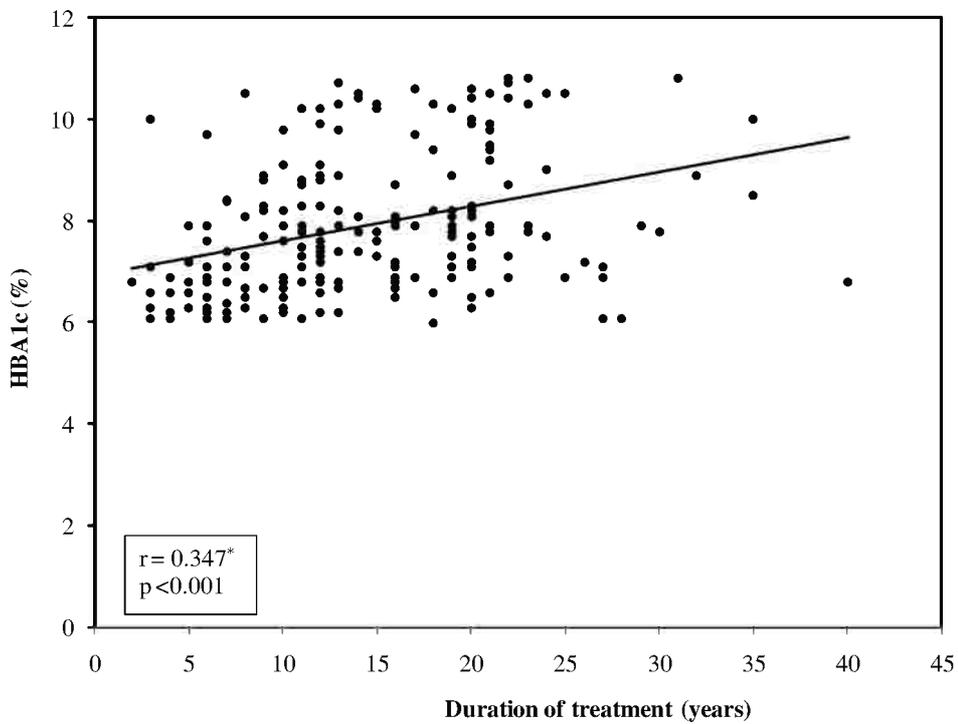
	Duration of treatment	
	r	p
<b>FBG</b>	0.310*	<0.001
<b>HBA1c</b>	0.347*	<0.001
<b>PSA</b>	-0.219*	0.002
<b>Testosterone</b>	-0.221*	0.001
<b>Prostate volume</b>	0.147*	0.034
<b>PSA density</b>	-0.203*	0.003

r: Pearson coefficient

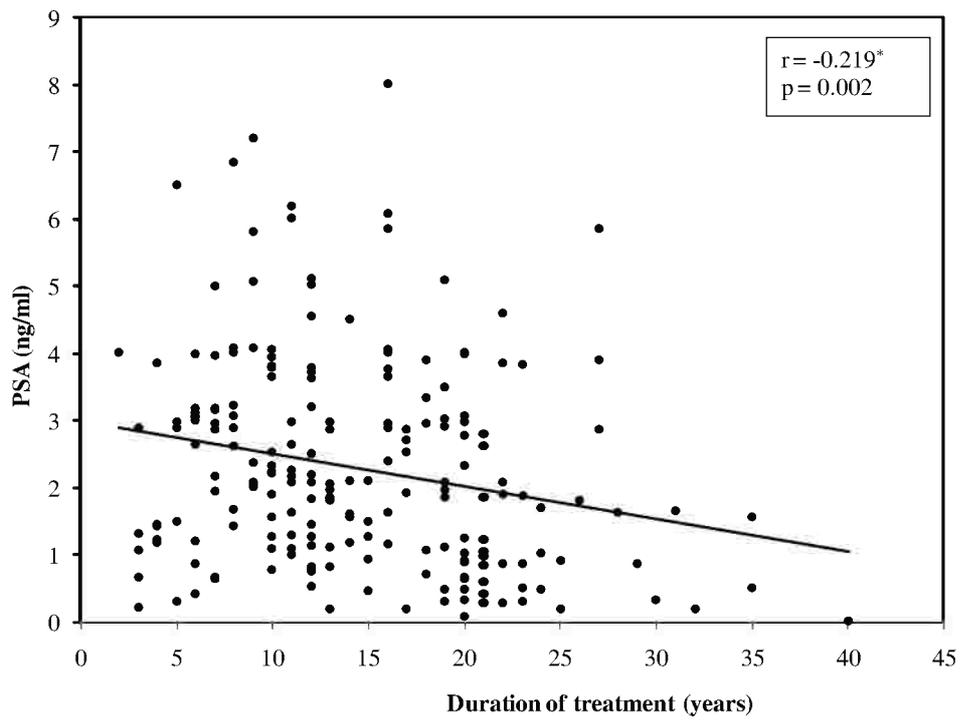
\*: Statistically significant at  $p \leq 0.05$



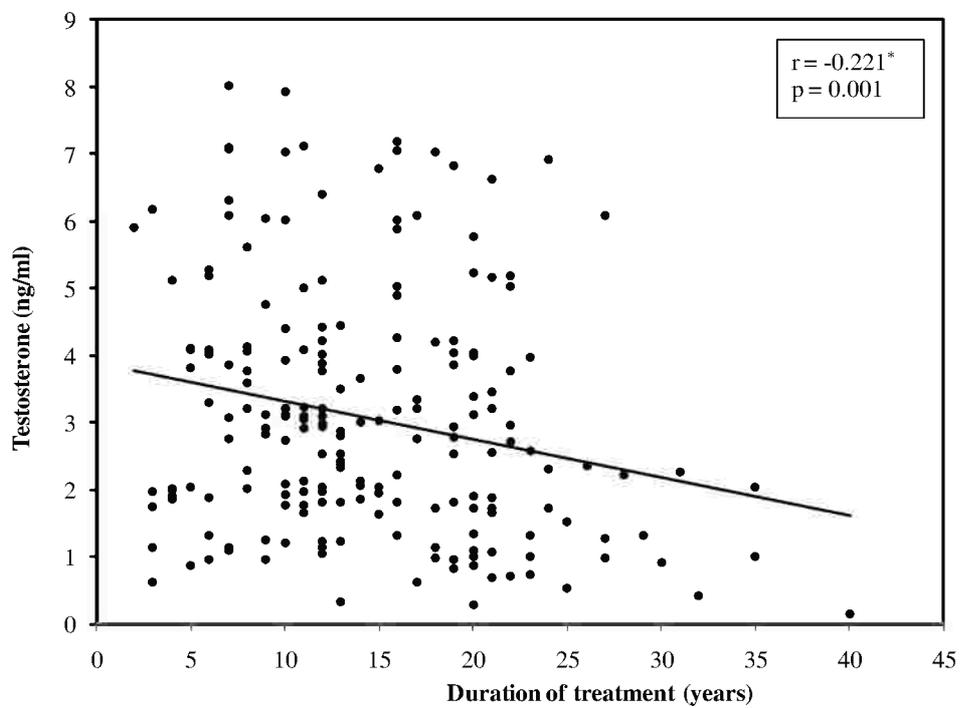
**Figure (12):** Correlation between duration of treatment of DM with FBG in diabetic group



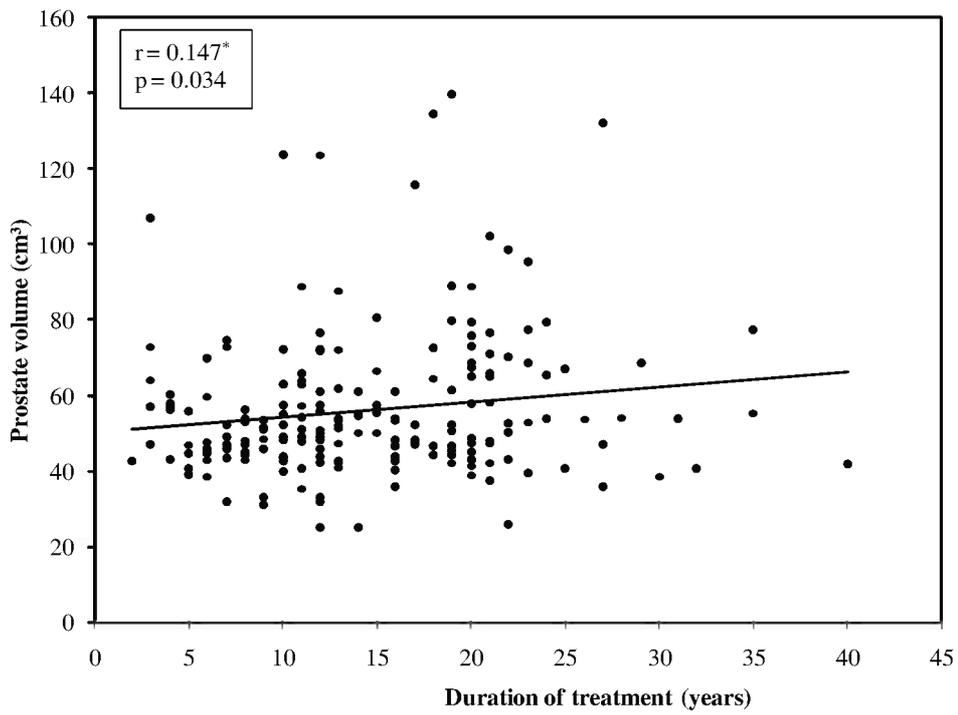
**Figure (13):** Correlation between duration of treatment of DM with HbA1c in diabetic group



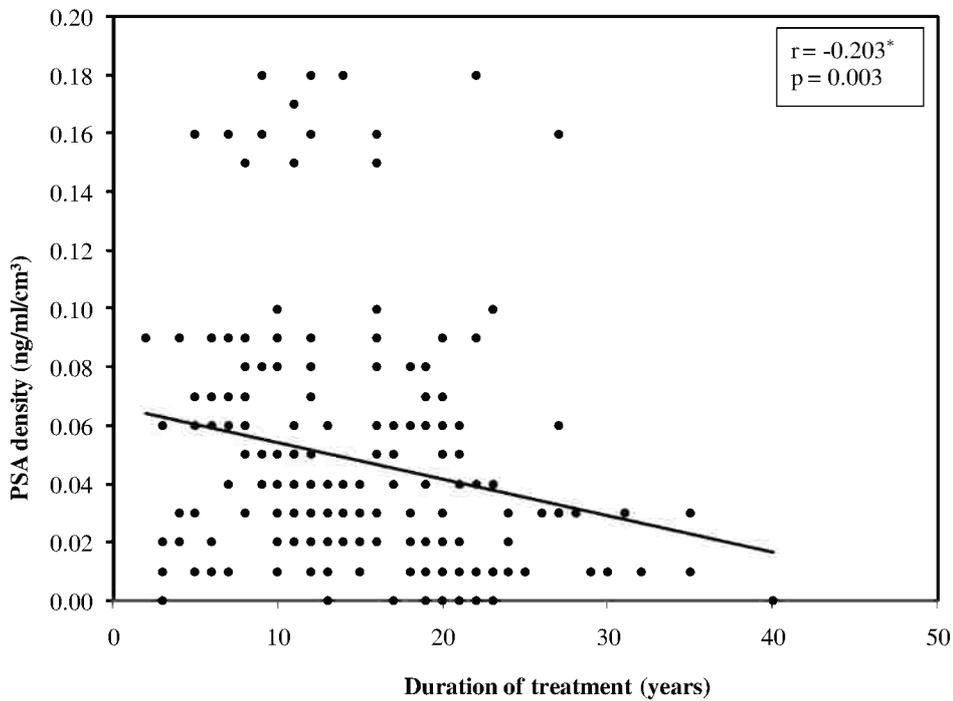
**Figure (14):** Correlation between duration of treatment of DM with PSA in diabetic group



**Figure (15):** Correlation between duration of treatment of DM with testosterone in diabetic group



**Figure (16):** Correlation between duration of treatment of DM with prostate volume in diabetic group



**Figure (17):** Correlation between duration of treatment of DM with PSA density in diabetic group

## **Correlation between Body Mass Index (BMI) with different studied parameters:**

Table (14), figures (18-30) show correlation between BMI with different studied parameters, where:

### **1. In all patients in the study:**

There was statistically significant negative correlation between BMI and:

- a. mean serum PSA values ( $r = -0.476$ ,  $p < 0.001$ ),
- b. mean serum testosterone values ( $r = -0.520$ ,  $p < 0.001$ ),
- c. mean PSA density values ( $r = -0.749$ ,  $p < 0.001$ ), while statistically significant positive correlation was found between BMI and mean prostate volume values ( $r = 0.236$ ,  $p = 0.001$ ;  $p \leq 0.05$ ).

### **2. In diabetic patients:**

There was statistically significant positive correlation between BMI and:

- a. mean FBG values ( $r = 0.155$ ,  $p = 0.026$ ;  $p \leq 0.05$ ),
- b. mean prostate volume values ( $r = 0.236$ ,  $p = 0.001$ ;  $p \leq 0.05$ ).

While statistically significant negative correlation was found between BMI and:

- a. mean serum PSA values ( $r = -0.870$ ,  $p < 0.001$ ),
- b. mean serum testosterone values ( $r = -0.603$ ,  $p < 0.001$ ),
- c. mean PSA density values ( $r = -0.749$ ,  $p < 0.001$ ), while no statistically significant correlation was found between BMI and mean HbA1c values ( $r = 0.127$ ,  $p = 0.068$ ;  $p > 0.05$ ).

### **3. In non-diabetic patients:**

There was statistically significant negative correlation between BMI and:

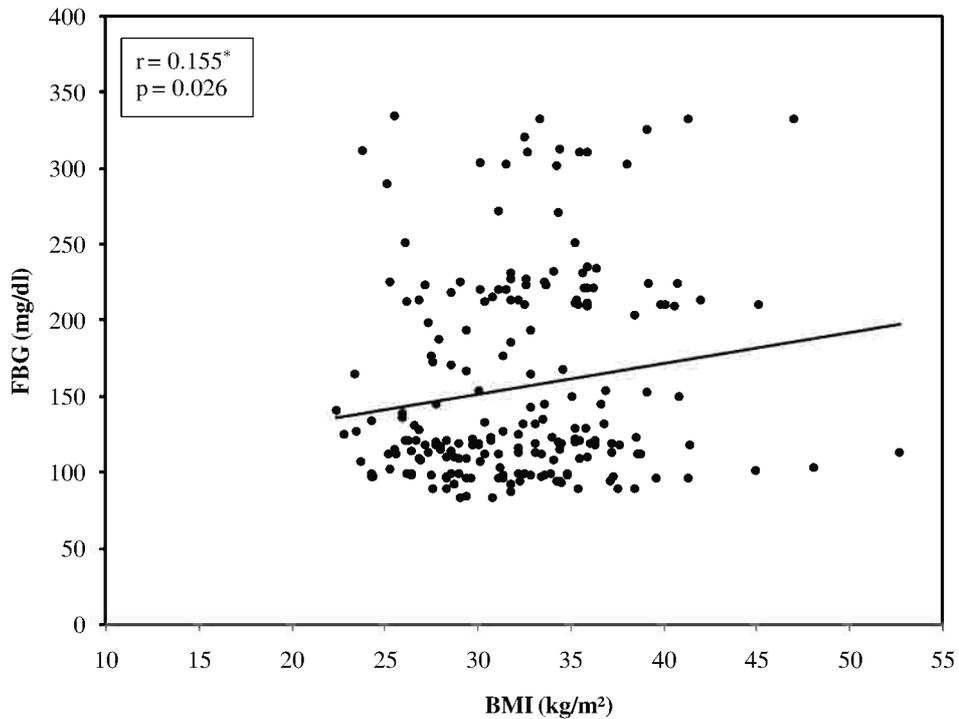
- a. mean serum PSA values ( $r = -0.132$ ,  $p = 0.024$ ;  $p \leq 0.05$ ),
- b. mean serum testosterone values ( $r = -0.407$ ,  $p < 0.001$ ),
- c. mean PSA density values ( $r = -0.477$ ,  $p < 0.001$ ), while statistically significant positive correlation was found between BMI and mean prostate volume values ( $r = 0.906$ ,  $p < 0.001$ ).

**Table (14): Correlation between BMI with different studied parameters:**

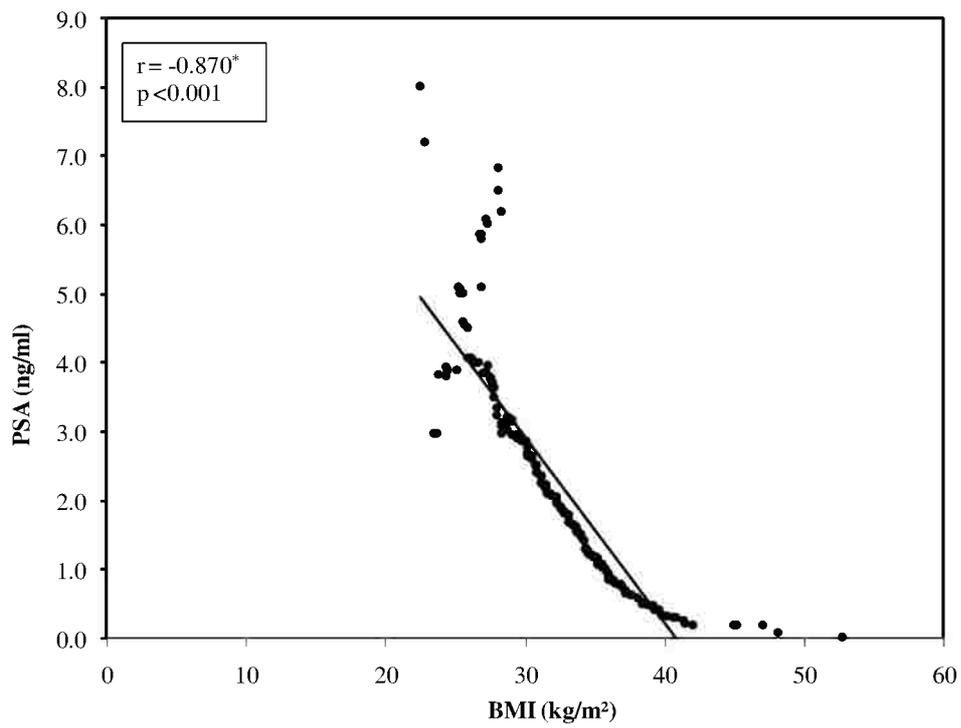
BMI	Diabetics		Non-diabetics		Total cases	
	r	p	r	p	r	p
<b>FBG</b>	0.155*	0.026	-	-	-	-
<b>HBA1c</b>	0.127	0.068	-	-	-	-
<b>PSA</b>	-0.870*	<0.001	-0.132*	0.024	-0.476*	<0.001
<b>Testosterone</b>	-0.603*	<0.001	-0.407*	<0.001	-0.520*	<0.001
<b>Prostate volume</b>	0.236*	0.001	0.906*	<0.001	0.236*	0.001
<b>PSA density</b>	-0.749*	<0.001	-0.477*	<0.001	-0.749*	<0.001

r: Pearson coefficient

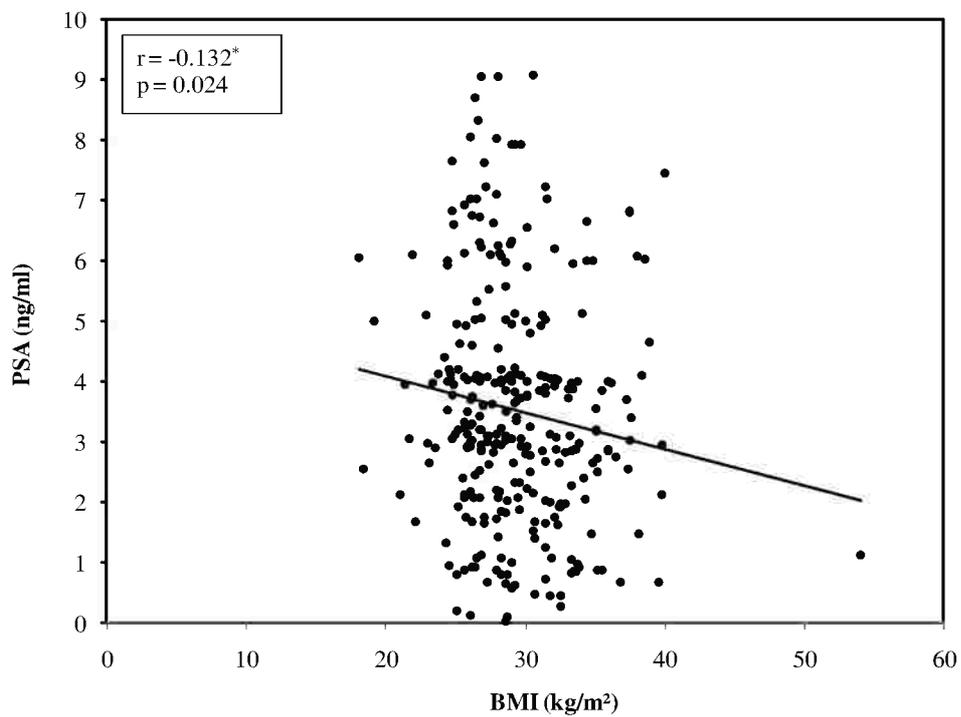
\*: Statistically significant at  $p \leq 0.05$



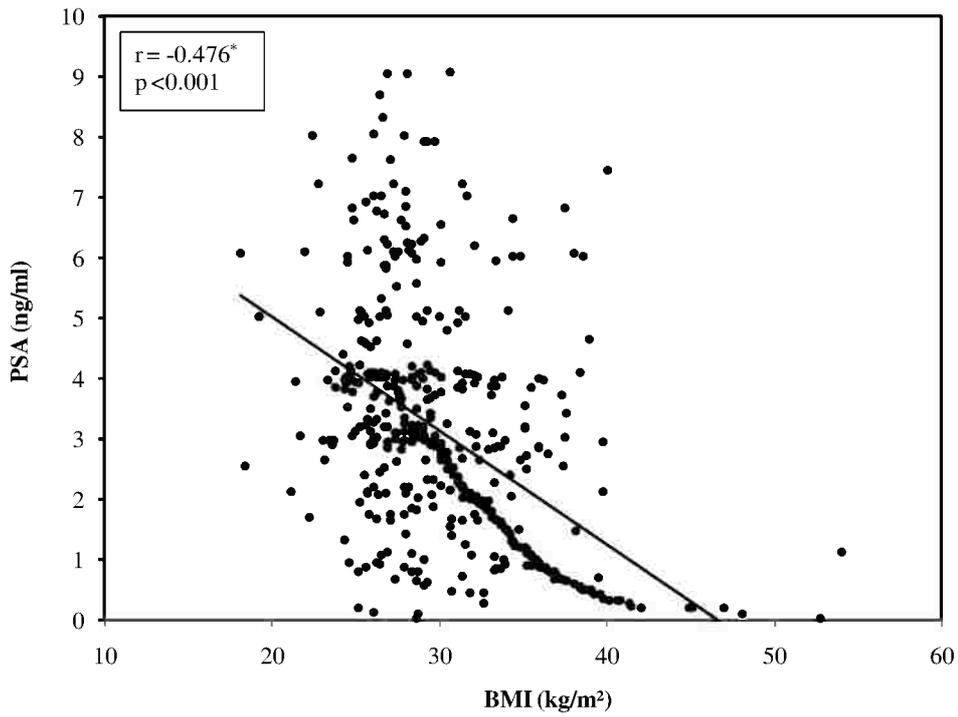
**Figure (18): Correlation between BMI with FBG in diabetics group**



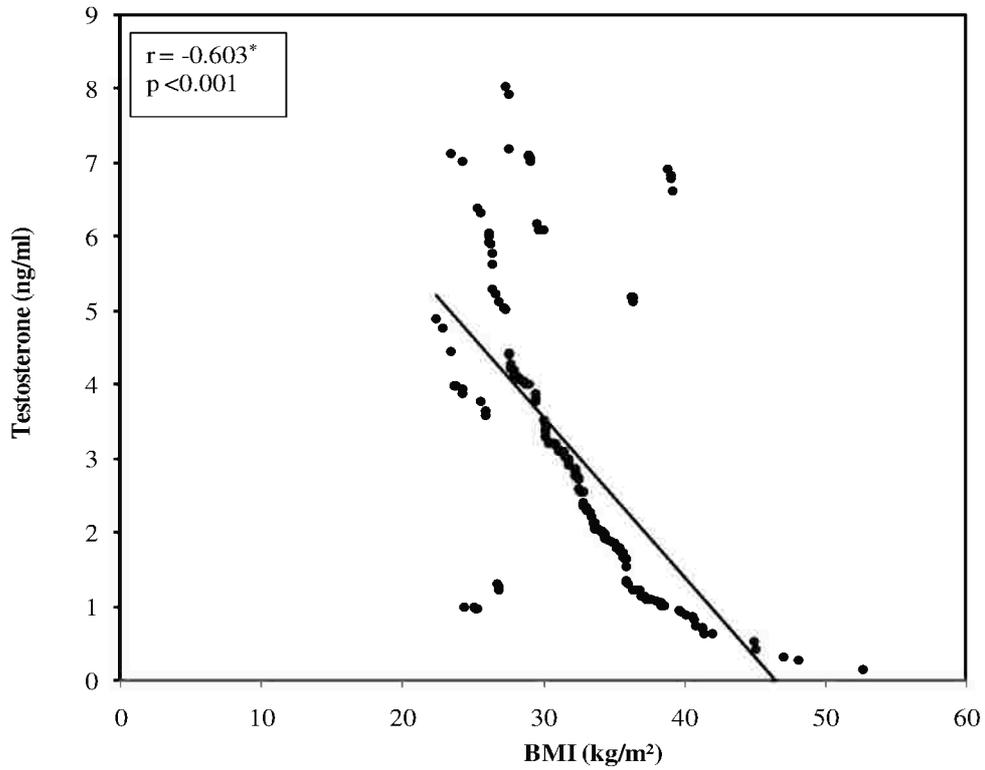
**Figure (19):** Correlation between BMI with PSA in diabetics group



**Figure (20):** Correlation between BMI with PSA in non-diabetics group



**Figure (21):** Correlation between BMI with PSA in each group



**Figure (22):** Correlation between BMI with Testosterone in diabetics group

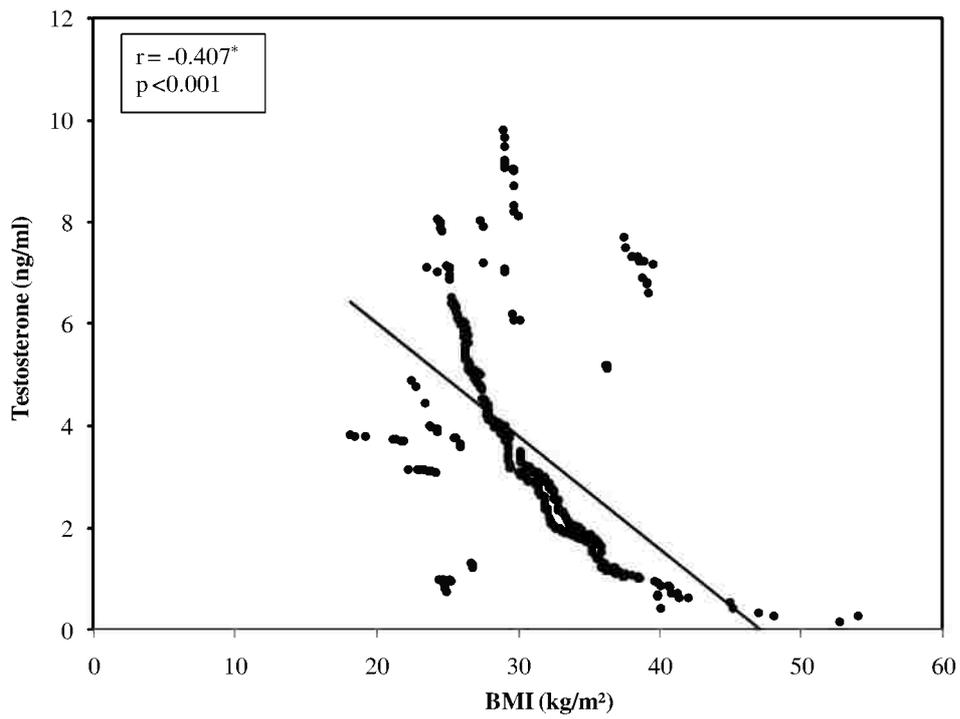


Figure (23): Correlation between BMI with Testosterone in Non-diabetics group

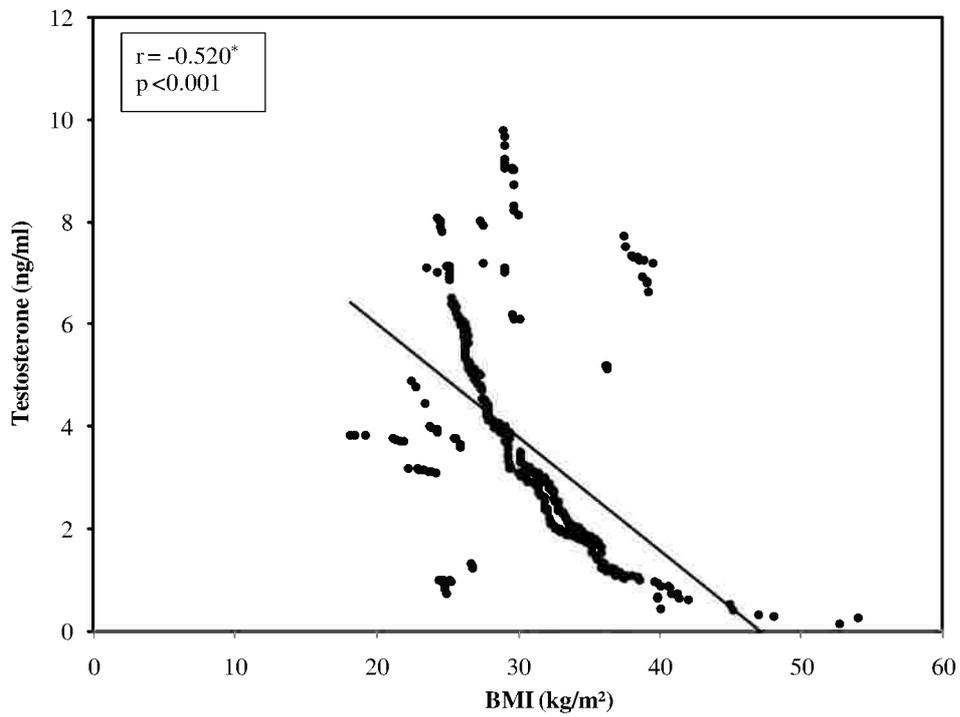


Figure (24): Correlation between BMI with Testosterone in each group

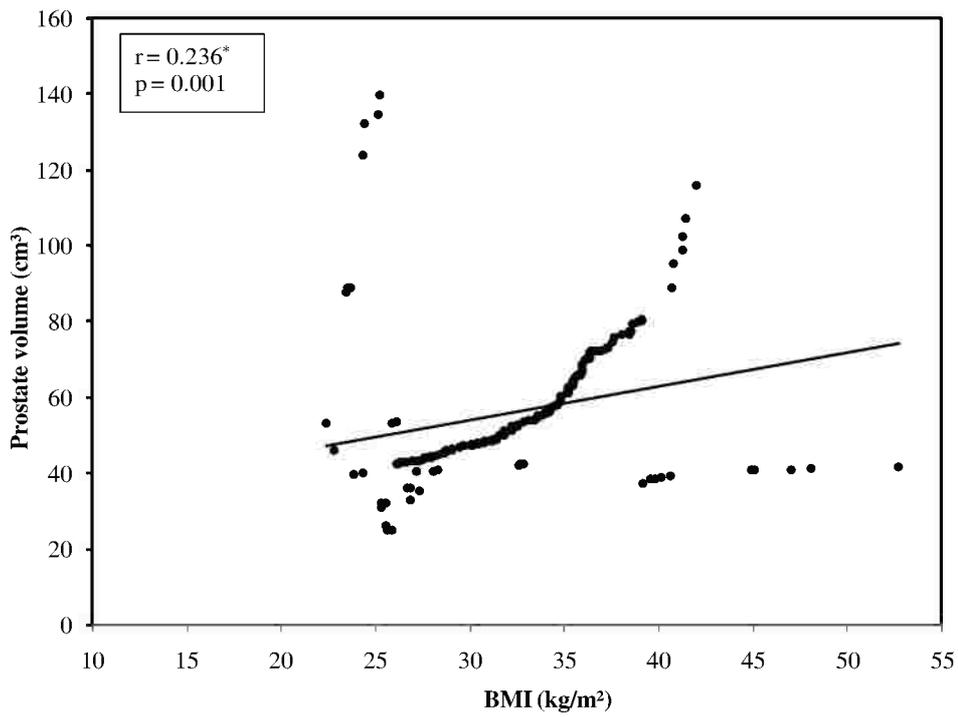


Figure (25): Correlation between BMI with prostate volume in diabetics group

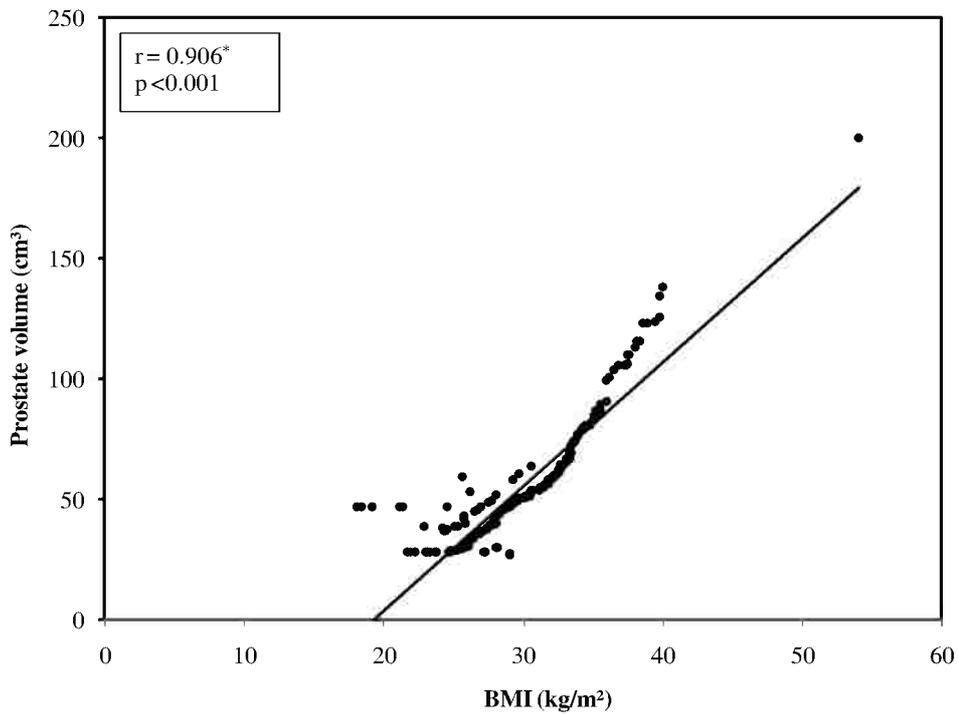
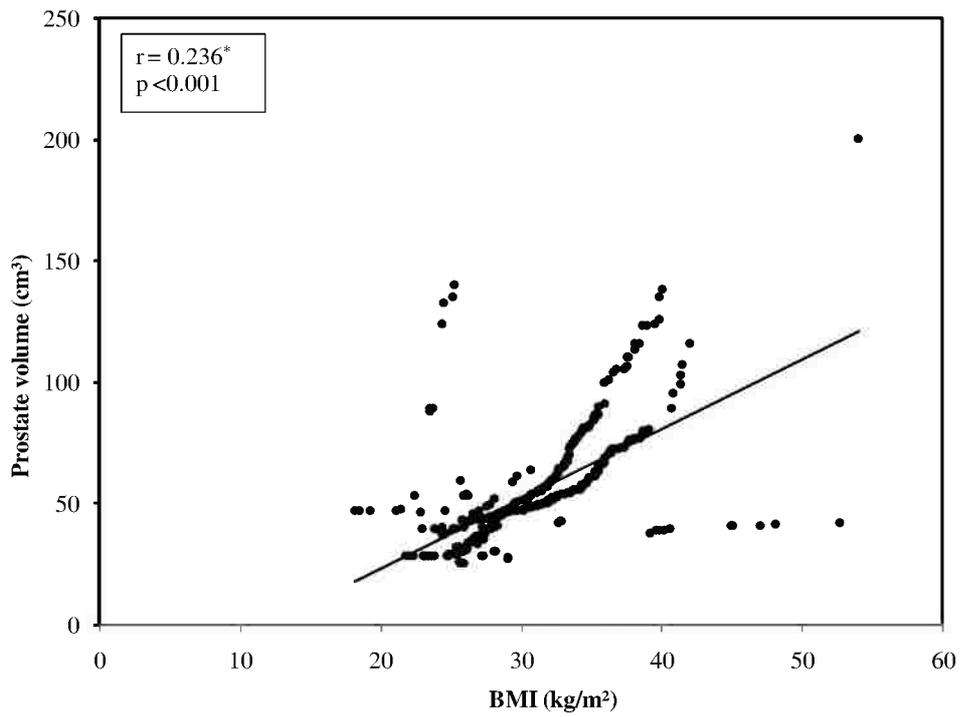
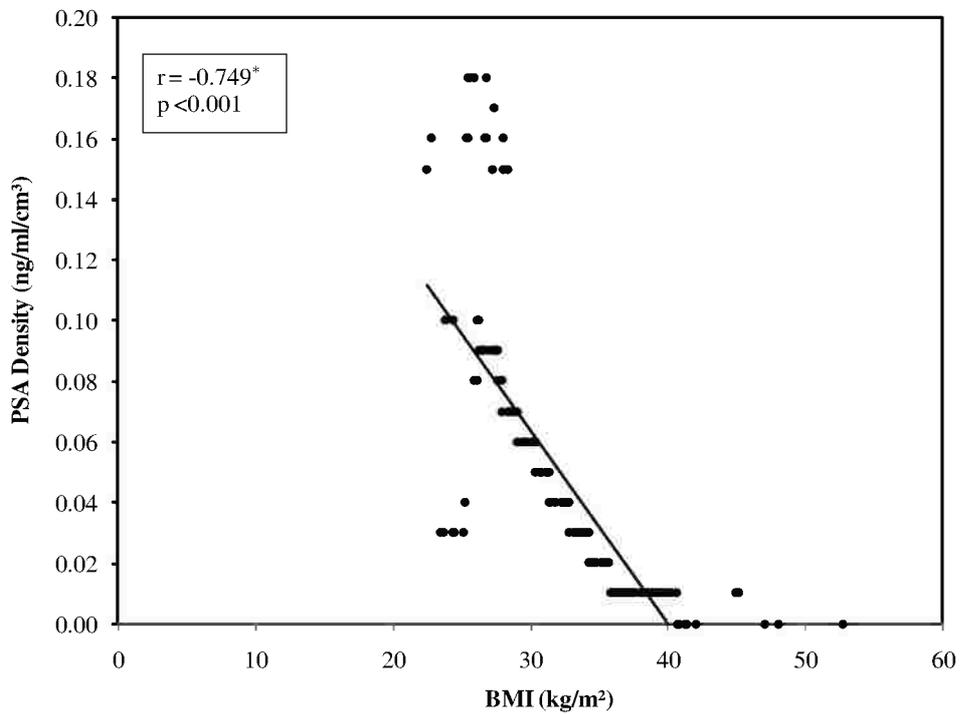


Figure (26): Correlation between BMI with prostate volume in non-diabetics group



**Figure (27):** Correlation between BMI with prostate volume in each group



**Figure (28):** Correlation between BMI with PSA density in diabetics group

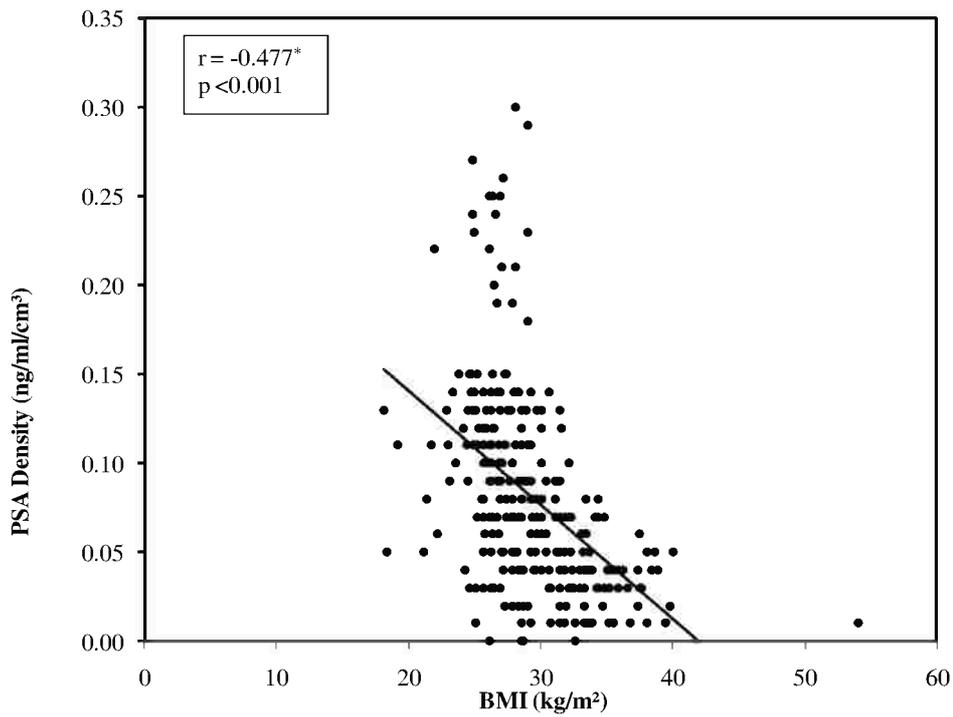


Figure (29): Correlation between BMI with PSA density in non-diabetics group

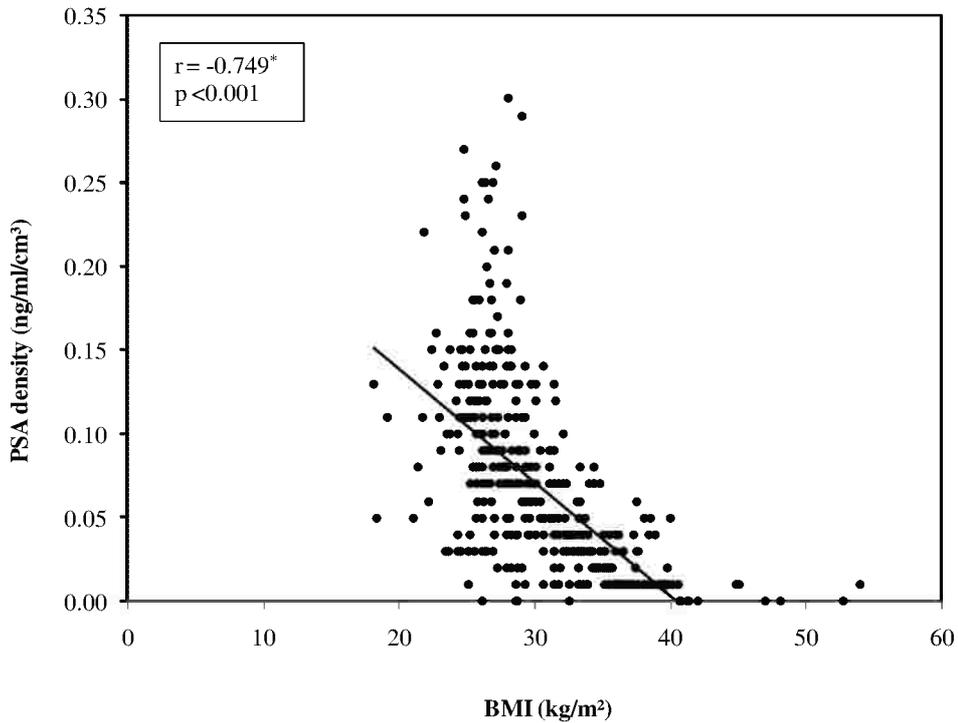


Figure (30): Correlation between BMI with PSA density in each group

**Correlation between PSA density with serum testosterone:**

Table (15), figures (31-33) show the correlation between PSA density with serum testosterone, where:

**1. In all cases of the study:**

There was statistically significant positive correlation between PSA density and serum testosterone ( $r= 0.378$ ,  $p< 0.001$ ).

**2. In diabetic patients:**

There was statistically significant positive correlation between PSA density and serum testosterone ( $r= 0.468$ ,  $p< 0.001$ ).

**3. In non-diabetic patients:**

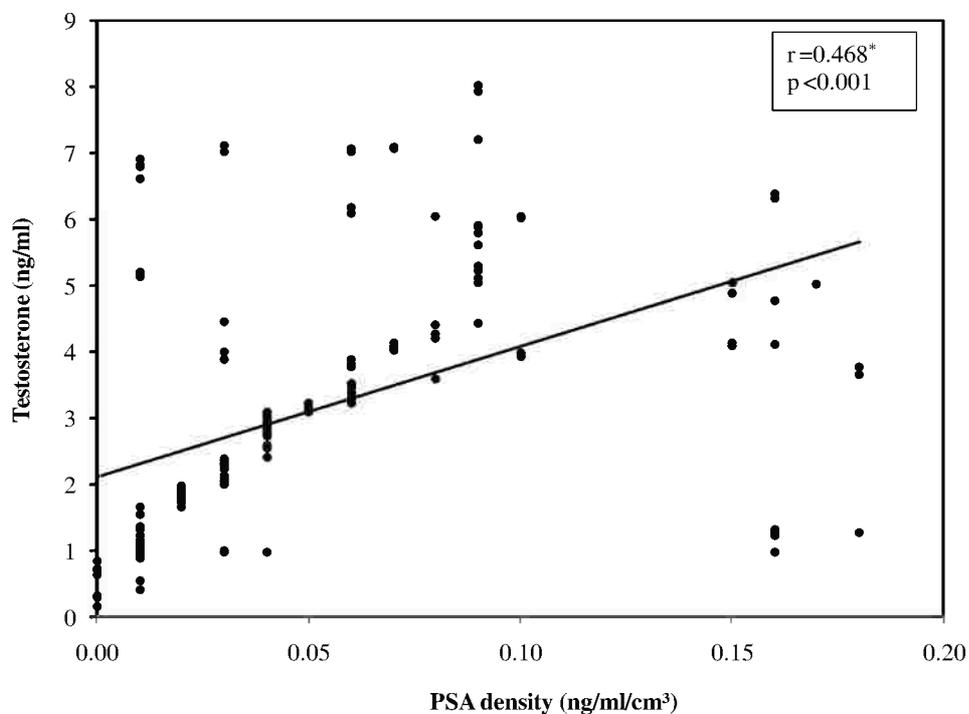
There was statistically significant positive correlation between PSA density and serum testosterone ( $r= 0.270$ ,  $p< 0.001$ ).

**Table (15): Correlation between PSA density with serum testosterone:**

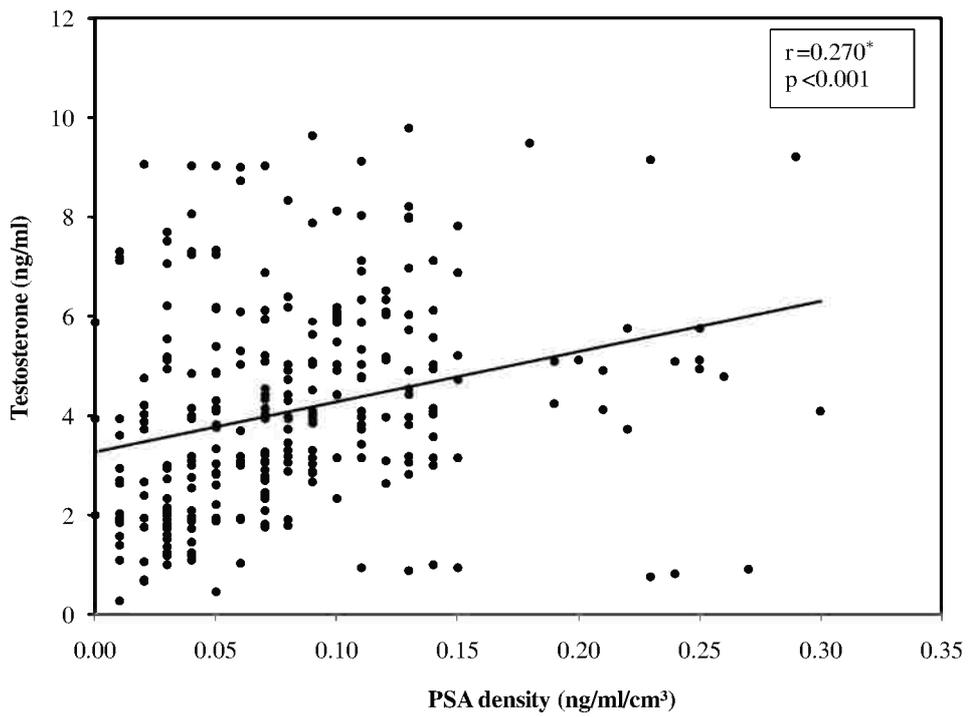
	Diabetics		Non-diabetics		Total sample	
	r	p	r	p	r	p
<b>PSA density vs Testosterone</b>	0.468*	<0.001	0.270*	<0.001	0.378*	<0.001

r: Pearson coefficient

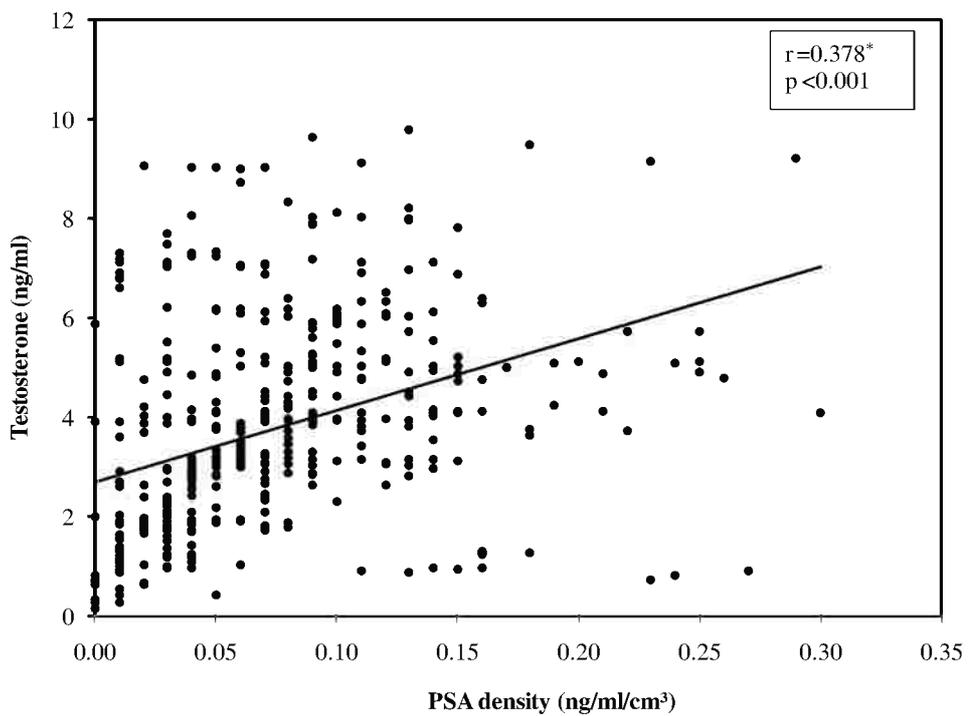
\*: Statistically significant at  $p \leq 0.05$



**Figure (31): Correlation between PSA density with serum testosterone in diabetic group**



**Figure (32):** Correlation between PSA density with serum testosterone in non-diabetic group



**Figure (33):** Correlation between PSA density with serum testosterone in each group

## Results

**Table (16)** shows multiple regression analysis for serum PSA, serum testosterone, prostate volume, and PSA density as regarding the effect of DM and BMI on them, where:

- 1- Both DM and BMI affect serum PSA significantly ( $F= 87.977$ ,  $p< 0.001$ ), also DM effect on PSA appear to be stronger than BMI effect, where each one unit change in DM changes serum PSA by 0.743 unit.
- 2- Both DM and BMI affect serum testosterone significantly ( $F= 96.237$ ,  $p< 0.001$ ), also DM effect on serum testosterone appear to be stronger than BMI effect, where each one unit change in DM changes serum testosterone by 0.400 unit.
- 3- Both DM and BMI affect prostate volume significantly ( $F= 136.430$ ,  $p< 0.001$ ), also DM effect on prostate volume appear to be stronger than BMI effect, where each one unit change in DM changes prostate volume by 4.629 units.
- 4- Both DM and BMI affect PSA density significantly ( $F= 156.697$ ,  $p< 0.001$ ), also DM effect on PSA density appear to be stronger than BMI effect, where each one unit change in DM changes PSA density by 0.020 unit.

**Table (16): Multiple regression analysis for PSA, Testosterone, Prostate volume and PSA density:**

		B	S.E.	t	p	95% CI	
						Lower	Upper
PSA	DM	0.743	0.155	4.795*	<0.001	0.439	1.048
	BMI	-0.166	0.016	10.359*	<0.001	-0.197	-0.134
$F = 87.977^*$ , $p < 0.001^*$ , $R = 0.511$ , $R^2 = 0.261$							
Testosterone	DM	0.400	0.165	2.420*	0.016	0.075	0.724
	BMI	-0.210	0.017	12.305*	<0.001	-0.243	-0.176
$F = 96.237^*$ , $p < 0.001^*$ , $R = 0.528$ , $R^2 = 0.279$							
Prostate volume	DM	4.629	1.633	2.835*	0.005	1.420	7.837
	BMI	3.011	0.168	17.883*	<0.001	2.680	3.341
$F = 136.430^*$ , $p < 0.001^*$ , $R = 0.629$ , $R^2 = 0.396$							
PSA density	DM	0.020	0.004	4.853*	<0.001	0.012	0.028
	BMI	-0.006	0.000	14.784*	<0.001	-0.007	-0.005
$F = 156.697^*$ , $p < 0.001^*$ , $R = 0.621$ , $R^2 = 0.386$							