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Clinicopathological Study of Prostate Diseases and Its Correlation with PSA Level, Size of Prostate and Gleason's Scoring System in Case of Prostatic Carcinoma

Dr. Sonia Mahmuda Haque[1], Dr Farhana Rahman[2], Dr Nayeema Rahman[3], Dr Rumana Yasmin[4], Dr. Kajol Akter[5], Dr Sampurna Sen[6]

1. *Assistant Professor, Department of Pathology, Shaheed Monsur Ali medical college, Dhaka, Bangladesh.*
2. *Assistant Professor, Department of Pathology, Shaheed Monsur Ali Medical College, Dhaka, Bangladesh.*
3. *Assistant Professor, Department of Pathology, Shaheed Monsur Ali Medical College, Dhaka, Bangladesh.*
4. *Assistant Professor, Department of Pathology, Dhaka central international medical college, Dhaka, Bangladesh.*
5. *Associate Professor, Department of Pathology, International Medical College, Dhaka, Bangladesh.*
6. *Assistant Professor, Department of Pathology, Addin Sakina Medical College, Jashore, Bangladesh.*

Corresponding author: *Dr. Sonia Mahmuda Haque, Assistant Professor, Department of Pathology, Shaheed Monsur Ali medical college, Dhaka, Bangladesh.*

ABSTRACT

Background: *Prostate gland diseases significantly impact adult males globally, with an increasing prevalence due to aging populations. The primary conditions affecting the prostate are inflammation, benign prostatic hyperplasia (BPH), and tumors, with BPH being the most common. Prostatic carcinoma is also prevalent, with a high lifetime risk. Prostate cancer incidence increases with age, and early detection relies on digital rectal examination, transrectal ultrasonography, and PSA testing.*

Aim of the study: *The study aims to find out correlation between PSA, Gleasons scoring system and HER-2/NEU gene in prostatic cancer.*

Methods: *This study, conducted from July 2017 to June 2019 at BIRDEM General Hospital, enrolled 110 male patients aged 50-100 with clinical signs of prostatic diseases. Patients provided written informed consent and met specific inclusion criteria. Specimens were obtained via TURP, simple or radical prostatectomy, preserved in 10% neutral buffered formalin and examined for pathological lesions. PSA levels were measured using an immunoassay, and Gleason scoring was used for carcinoma categorization. Data were collected via questionnaires and analyzed using SPSS software.*

Result: *The study analyzed 110 prostatic disease cases, with patients averaging 67.7 years. The most common diagnosis was BPH with inflammation (50.9%), followed by BPH without inflammation (35.5%) and adenocarcinoma (13.6%). Urgency (80%), increased micturition frequency (78.2%), poor stream (78.2%), and urinary retention (77.3%) were the most common symptoms. There was a significant correlation between serum PSA levels and prostate size ($p < 0.001$), with higher PSA levels indicating larger prostates and a higher likelihood of adenocarcinoma. The most frequent Gleason score was 4+4=8 (40%). HER2/neu overexpression showed a marginal correlation with PSA levels ($p=0.053$).*

Conclusion: *The study found that the most common age group for prostatic diseases was 61-70 years. Benign prostatic hyperplasia (BPH) was the most frequent lesion. Grade II (31-50g) prostate size was common on ultrasound. Most patients had a PSA level of 0-5 ng/ml, aiding early diagnosis and reducing morbidity.*

Keywords: *Prostate Diseases, PSA Level, Size of Prostate, Gleason's Scoring System and Prostatic Carcinoma.*

I. Introduction

Worldwide, diseases of the prostate gland are responsible for significant morbidity and mortality among adult males [1]. With increasing longevity and an aging population, the pathology of the prostate may claim a separate domain of its own [2]. Mainly, three pathologic processes affect the prostate gland, namely inflammation, benign prostatic hyperplasia and tumors. Of these three, benign prostatic hyperplasia is the most common. Prostatic carcinoma is also a common lesion in men [3]. Globally, 210 million males are affected by benign prostatic hyperplasia [4]. Benign prostatic hyperplasia is predominantly attributed to aging, genetic factors and hormonal disturbance [5]. Benign prostatic hyperplasia (BPH) is increasingly frequent with advancing age, with

peak age group 70 to 79 years [6]. Only 50% of those who have microscopic evidence of BPH have clinically detectable enlargement of the prostate and of those individuals [3]. There is a one in six-lifetime probability of being diagnosed with prostate cancer [3]. The incidence and mortality of the disease show a big geographical difference [7]. Based on autopsy studies, cancer of the prostate increases from 20% in men in their 50s to approximately 70% in men between the ages of 70 and 80 years [3]. American Cancer Society's estimate for prostate cancer in the United States for 2013 was 238,590 [8]. In Pakistan, prostatic cancer is the fifth most common tumor, occurring in 7.3% of all men [9]. Localized prostate cancer is asymptomatic and is detected by suspicious nodules on rectal examination. Most prostatic cancer arises away from the urethra, and therefore, urinary symptoms occur late. Patients with advanced cancer may present with urinary symptoms [3]. Skillful rectal examination remains the most practical and efficient method for the detection of prostatic carcinoma. The combination of digital rectal examination, transrectal ultrasonography and PSA represents a powerful diagnostic triad for the detection of early prostatic carcinoma [10]. The histological term prostatitis implies the presence of pathological infiltration of the prostate by inflammatory cells. It is estimated that 50% of male in the United States experience prostatitis during their lifetime [8]. The histological evidence of inflammation in the prostate is found in prostatitis syndromes, BPH, prostate cancer and other conditions [11]. The pathologist usually gives little attention to prostatic inflammation unless it is particularly florid because the clinical importance of the observation remains largely undefined [12]. The establishment of a standardized histopathological classification system of prostatitis was permitted for further studies. Serum PSA estimation, supplemented with biopsy procedures, represents a powerful diagnostic tool for diagnosing both benign and malignant prostatic diseases. Song et al. (2011) revealed that aggressiveness of glandular inflammation and stromal inflammation were correlated with PSA level [13]. Sharma et al. found a positive correlation of PSA values with Gleason's score [14]. The human epidermal growth factor receptor 2 (HER-2/neu) is an oncoprotein. It plays a major role in proliferation, cell growth and differentiation [15]. The binding of specific ligands to the extracellular domain of HER2/neu forms hetero-dimers and, that way, initiates cell signaling, resulting in the inhibition of apoptosis and activation of tumor cell growth and invasion. Overexpression of HER2/neu protein has been related to the progression of many types of tumors. Despite the receptor's clinical importance for breast cancer, the role of HER-2/neu in prostatic carcinoma is still controversial [16]. Therefore, HER-2/neu inhibition becomes a possible treatment strategy for hormone-refractory prostatic carcinoma patients. Moreover, very few studies have been done on prostatic lesions in our country. This prompts us to investigate the clinic-pathological correlation of prostatic biopsy with special reference to the size of the prostate, the pattern of chronic prostatitis, serum prostate-specific antigen, Gleason's scoring system and HER2/neu in prostatic carcinoma.

II. Methodology & Materials

This study was conducted from July 2017 to June 2019. Patients attending BIRDEM General Hospital, Dhaka, Bangladesh, fulfilling the inclusion criteria, were enrolled in this study after giving written informed consent. A total of 110 samples were collected.

Inclusion Criteria:

- Male patients with clinical symptoms and signs of prostatic diseases
- Male patients with age between 50 to 100 years.
- The patient was admitted to BIRDEM General Hospital, and transurethral resection was done (TURP)
- Presence of pathological lesions in prostate on histopathological study

Exclusion Criteria:

- Patients with neurogenic bladder have urinary problems but normal prostate
- Patients who refuse to cooperate

Specimens were taken from the cases by transurethral resection of the prostate (TURP), simple prostatectomy or radical prostatectomy. Specimens were kept in 10% neutral buffered formalin. Specimens were grossly examined. The size of the resected prostate gland and quantity of TURP of the prostate were recorded. Abnormalities, like an increase in size and gross characteristics such as nodular or cystic changes, were noted. Measurement of prostate-specific antigen (PSA) was done in all symptomatic patients. A serum or plasma-based immunoassay was used to measure PSA. The Gleason scoring system was used to categorize prostatic carcinoma.

Diagnosis of each prostatic disease was made clinically by signs and symptoms, ultrasonography, immunological estimation of prostate-specific antigen and histopathological examination of prostatic specimens. Correlation of demographic variables, clinical signs and symptoms, size of prostate and PSA with different types of prostatic diseases were done. In the case of adenocarcinoma of the prostate, the relationship between PSA and

Gleason's scoring system was evaluated. Immunohistochemistry was done to see her-2/neu gene expression in prostatic carcinoma.

In purposive sampling, the sampling unit that was considered to be most representative of the population was selected. Data were collected by preformed questionnaire. Each patient's data was collected through interviews, direct observation, clinical profile, and investigation reports, which were available using a structured questionnaire and data collection sheet. Demographic variables were collected. Symptoms (dribbling of urine, increased frequency, urinary retention, inguinal swelling, hematuria, and incontinence) were recorded. The size of the prostate was determined by ultrasonography and recorded in a data collection sheet. Ethical clearance for the study was taken from the Institutional Review Board (IRB) of BIRDEM General Hospital.

Data analysis:

Continuous variables (age, PSA level, size of prostate) were summarized as mean ± SD and categorical variables (clinical signs and symptoms, Gleason's score) were summarized as frequency or proportion. The data were presented in table or diagrammatic form. A correlation test was done to see the correlation between pathological diseases with different variables. The entered data were checked, verified and analyzed by appropriate computer software using SPSS software for Windows (version 17.0, SPSS, Inc., Chicago, IL). For all analyses, the level of significance was set at 0.05, and a p-value <0.05 was considered significant.

III. Result

The study analyzed 110 cases of prostatic diseases, with a mean age of 67.7±10.5 years among the patients. The most common (50.9%) histological diagnosis was BPH with inflammation, followed by BPH without inflammation, which accounted for 35.5% of cases. Adenocarcinoma was identified in 13.6% of the cases (Table 1). In patients with BPH and inflammation (n=56), inflammation was most commonly found in the peri glandular and mixed locations (33.9% each), with the focal extension being predominant (66.1%). Mild inflammation (Grade 1) was seen in 60.7% of cases, while moderate (23.2%) and severe (16.1%) inflammation were less frequent (Table 2). The most common clinical presentations were urgency (80%), increased frequency of micturition (78.2%), poor stream (78.2%), and urinary retention (77.3%). Hesitancy was noted in 71.8% of patients, and a burning sensation during micturition was present in 50.9%. Fever was the least frequent symptom, reported by 16.4% of the patients (Figure 1). The study found a significant correlation between serum PSA levels and prostate size ($p < 0.001$). Patients with PSA levels of 0-5 ng/ml mostly had Grade II enlargement (42.7%), while those with PSA levels above ten ng/ml had larger prostates, with 50% in Grade III and 16.7% in Grade IV (Table 3). There was a significant relation between PSA levels and prostatic lesion types ($p < 0.001$). The majority of the patients with PSA levels of 0-5 ng/ml had benign prostatic hyperplasia with inflammation (58.5%), whereas adenocarcinoma was rare (2.4%). As PSA levels increased, adenocarcinoma was seen in 30% of cases with PSA levels of 5.1-10 ng/ml and 55.6% with levels above ten ng/ml (Table 4). Table 5 shows that 4+4=8 (40%), which was the most frequent Gleason score, was followed by 4+3=7 (33.3%). Group 1 (<3+3=6) and Group 5 (>4+5=9) both accounted for 13.3% of cases each, whereas no instances were found in Group 2 (3+4=7). The average Gleason score was 3.40±1.18. The association between HER2/neu overexpression and the Gleason grade group was nonsignificant (p=0.086). Most cases with higher Gleason grades (Groups 4 and 5) showed HER2/neu scores of 3+, while lower grade groups had fewer cases of HER2/neu overexpression. Specifically, 5 out of 6 cases in Group 4 and 2 out of 2 cases in Group 5 had a HER2/neu score of 3+ (Table 6). PSA levels and HER2/neu overexpression had a marginally significant correlation (p=0.053). Eight out of nine patients with PSA levels >10 ng/ml had a HER2/neu score of 3+, although fewer cases with high HER2/neu expression were seen in individuals with lower PSA levels. Particularly, HER2/neu scores at PSA levels of 0–5 ng/ml were primarily 1+ and 2+, with no instances reporting a 3+ (Table 7).

Table 1: Distribution of 110 cases of prostatic diseases according to age and histological diagnosis

Variables	Frequency (n)	Percentage (%)
Age (Mean±SD)	67.7±10.5	
Type of lesions		
Benign prostatic hyperplasia	39	35.5
Benign prostatic hyperplasia with inflammation	56	50.9
Adenocarcinoma	15	13.6

Table 2: Pattern of inflammation in patients with BPH (n=56)

Types	Frequency (n)	Percentage (%)
Anatomical location		
Glandular	8	14.3
Periglandular	19	33.9
Stromal	10	17.4

Mixed	19	33.9
Extension		
Focal	37	66.1
Multifocal	14	25
Diffuse	5	8.9
Inflammation grade		
Grade 1 (Mild)	34	60.7
Grade 2 (Moderate)	13	23.2
Grade 3 (Severe)	9	16.1

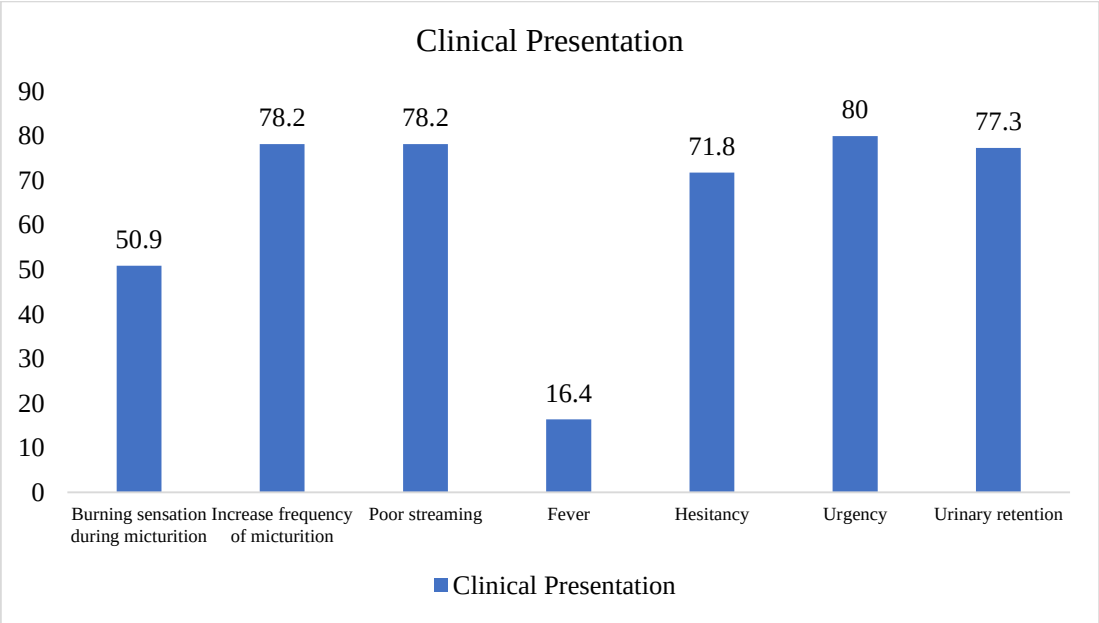

Figure 1: Bar diagram showing the clinical presentation of study patients (N=110)

Table 3: Correlation of Serum PSA level with ultrasound size of prostate

PSA level (ng/ml)	N	USG grade of prostate				
		Grade I	Grade II	Grade III	Grade IV	p-value
0-5	82	35(29.6%)	35(42.7%)	12(14.6%)	0(0.0%)	<0.001s
5.1-10	10	0(0.0%)	6(60.0%)	3(30.0%)	1(10.0%)	
> 10	18	0(0.0%)	6(33.3%)	9(50.0%)	3(16.7%)	
Total	110	35(31.8%)	47(42.7%)	24(21.8%)	4(3.6%)	

Table 4: Serum PSA level in different histological type of prostatic lesions

PSA level (ng/ml)	N	Histological type lesion			p-value
		Adenocarcinoma	Benign prostatic hyperplasia	Benign prostatic hyperplasia with inflammation	
0-5	82	2(2.4%)	32(39.0%)	48(58.5%)	<0.001s
5.1-10	10	3(30.0%)	3(30.0%)	4(40.0%)	
>10	18	10(55.6%)	4(22.2%)	4(22.2%)	
Total	110	15(13.6%)	39(35.5%)	56(50.9%)	

Table 5: Grade group and Gleason's score in adenocarcinoma (n=15)

Group	Gleason's score	Frequency (n)	Percentage (%)
1	<3+3=6	2	13.3
2	3+4=7	0	0
3	4+3=7	5	33.3
4	4+4=8	6	40
	3+5=8		
5	>4+5=9	2	13.3
Total		15	100
Mean ±SD	3.40±1.18		

Table 6: Association of HER2/ neu over expression with Gleason grade group (n=15).

HER2/neu score	Gleason grade group					p-value
	1	2	3	4	5	
0	0	0	0	0	0	0.086ns
1+	1	0	0	0	0	
2+	0	0	3	1	0	
3+	1	0	2	5	2	
Total	2	0	5	6	2	

Table 7: Association of HER2/neu over expression with PSA level (n=15)

HER2/neu score	PSA level			p-value
	0-5ng/ml	5.1-10ng/ml	>10ng/ml	
0	0	0	0	0.053s
1+	1	0	0	
2+	2	1	1	
3+	0	2	8	
Total	3	3	9	

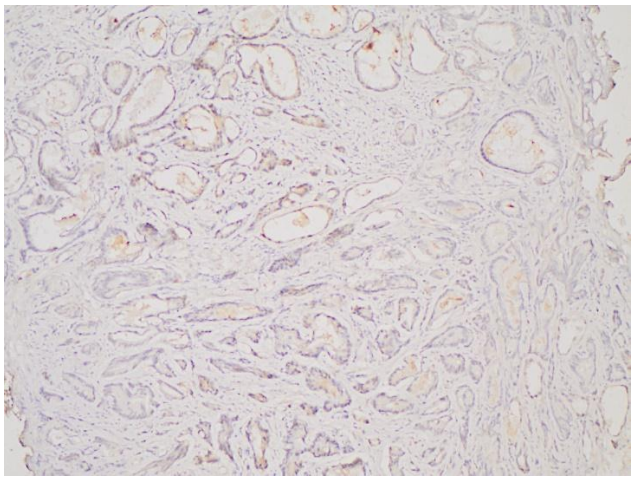

Figure 1: 2+ Her-2/new positivity.

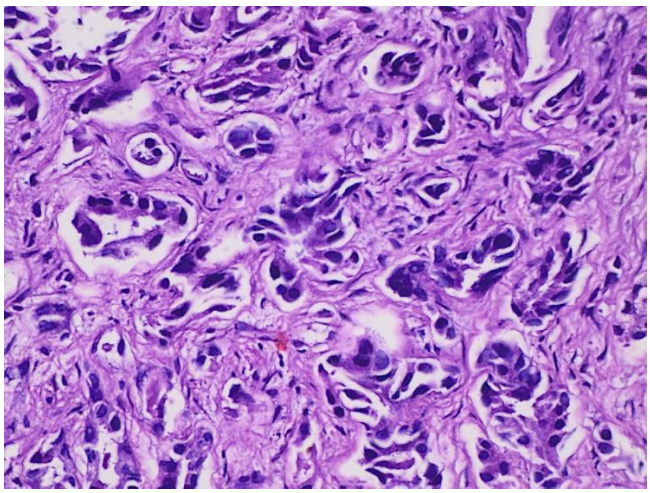

Figure 2: Histopathological feature of prostatic adenocarcinoma, Glesson score (3+3)=6/10 (Grade Group-1).

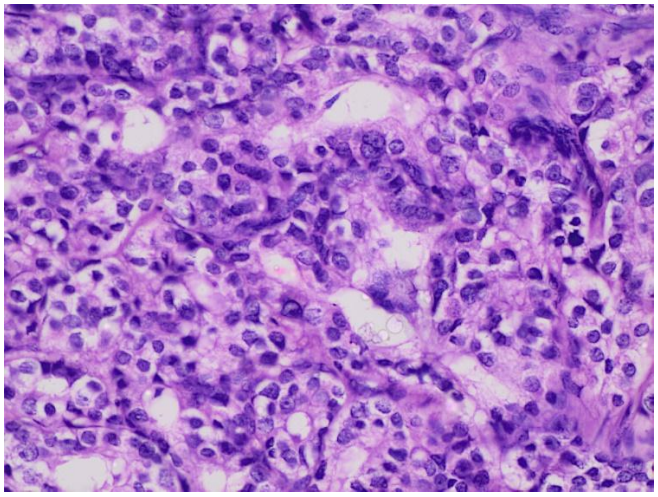

Figure 3: Histopathological feature of prostatic adenocarcinoma, Glesson score (5+3) = 8/10 (Grade Group-4).

IV. DISCUSSION

Prostatism is common in the geriatric age group. Prostatitis, benign prostatic hyperplasia and carcinoma cover almost the entire spectrum of prostatic diseases [17]. Benign prostatic hyperplasia and carcinoma of the prostate are increasingly frequent with advancing age [18]. BPH is an extremely common disorder in men over the age of 50 years. The prevalence of this disease is highly significant in most communities [18]. Prostate cancer is responsible for 3% of all deaths in men over the age of 55 years. It is the second most common cause of cancer-related death in men [20]. So, to overcome this problem, the study was designed to find out the prostatic diseases and their correlation with PSA level, size of the prostate, expression of HER2/neu oncoprotein, and Gleason's scoring system in the case of prostatic carcinoma in Bangladesh. In the present study, the Mean±SD of age was 67.7±10.5. Our results correlate with the study of Popli et al., who conducted a prospective study of 100 BPH patients; the majority of the study group was in the age group of 61- 70 years (48.5% cases) [7]. The mean age of presentation of study patients was 68.66 years, which correlates with our study's 67.7 years. Lakhey et al. also found that 67.61 years was the mean age for presentation of patients with prostatic diseases [21]. In the present study, on histological examination, 39 (35.5%) cases were diagnosed as BPH, 56 (50.9%) cases were BPH with inflammation, and 15 (13.6%) cases were adenocarcinoma. The major histological lesions were BPH with inflammation, which is comparable with the findings of [18]. It was a prospective study done in Kathmandu Medical College and Teaching Hospital and benign prostatic hyperplasia was the common histological lesion encountered at 74.2%, and prostatic adenocarcinoma was 10.6%. One study done by Kumar et al. found common pathological lesion BPH for 80.33% and prostatic adenocarcinoma for 10.66%, which is consistent with our study [17]. Shakya et al. also found that among 106 cases, BPH (75.4%) cases, BPH with inflammation (17%) cases and adenocarcinoma (7.54%) cases [2]. Different clinical complaints of the patients were studied. The most frequent clinical presentation was urgency (80.0%), followed by less common symptoms, hesitancy (71.8%), increased frequency of micturition (78.2%), poor streaming of urine (78.2%), pain during micturition (50.9%) and fever were (16.4%). Kumar et al. found that the most frequent findings of patients with prostatic diseases were frequency and hesitancy (85.3%), urgency (60%), poor stream of urine (90%), pain during micturition (67%), which is similar to this study [17]. In BPH, symptoms were in decreasing order: urgency > urinary retention > hesitancy > increased frequency of micturition > poor streaming of urine > burning sensation during micturition > fever. In adenocarcinoma of prostate cases, symptoms were in decreasing order as increased frequency of micturition > urgency > urinary retention > poor streaming of urine > hesitancy > fever > pain during micturition. These findings correlated with the study of Anushree et al., in which frequency is the most common symptom in benign lesions, followed by difficulty in voiding, acute retention and dysuria [22]. Malignant lesions had common symptoms of acute and chronic urinary retention, hesitancy, weak stream, urgency and increased frequency of micturition [19]. Urgency followed by difficulty in voiding was the most common symptom encountered in BPH. Dysuria was the most commonly encountered symptom in malignant cases; other symptoms, such as incomplete voiding and poor stream, were also noted [23]. PSA is an important tumor marker for prostate cancer. Its level in the blood can also increase in various settings, such as infection and inflammation [24]. According to USG, the size of the prostate was divided into four grades. Among the 82 cases with PSA levels between 0-5 ng/ml, the majority had smaller prostates, with 29.6% in Grade I (20-30g) and 42.7% in Grade II (31-50g), while only 14.6% had Grade III (51-80g) and none had Grade IV (>80g). For the 10 cases with PSA levels between 5.1-10 ng/ml, no patients had Grade I prostates, but 60% had Grade II, 30% had Grade III, and 10% had Grade IV. In the 18 cases with PSA levels above ten ng/ml, none were found in Grade I, while 33.3% were in Grade II, 50% in Grade III, and 16.7% in Grade IV. As PSA levels increase, there is a clear trend toward larger prostate sizes, with higher

PSA levels showing more cases in the larger prostate grades (III and IV). The p-value of less than 0.001 confirms a statistically significant relationship between PSA levels and prostate size. A study done by Poply et al. found that the maximum number of cases was in grade II (40.6%). The majority of cases with PSA level < 4ng/ml were in grade II (23.7%). PSA levels> 10ng/ml were in maximum cases of grade III (12.9%) and Grade II (6.9%) [7]. Among patients with PSA levels of 0-5 ng/ml, 39.0% were diagnosed with benign prostatic hyperplasia (BPH), 58.5% had BPH with inflammation, and only 2.4% had adenocarcinoma. In the 5.1-10 ng/ml range, 30.0% had adenocarcinoma, with the remainder evenly split between BPH (30.0%) and BPH with inflammation (40.0%). For those with PSA levels above ten ng/ml, 55.6% had adenocarcinoma, while 22.2% had BPH and 22.2% had BPH with inflammation. Overall, adenocarcinoma was diagnosed in 13.6% of cases, while benign conditions accounted for 35.5% of BPH and 50.9% of BPH with inflammation. These findings indicate that higher PSA levels are strongly associated with adenocarcinoma, whereas lower levels are linked to benign conditions, with a significant p-value of <0.001 highlighting this correlation. In a retrospective study done by Kathib et al., the majority of benign lesions had prostate-specific antigen levels < 5ng/ml and almost all cases of adenocarcinoma showed PSA levels >20ng/ml [23]. BPH, as well as prostatitis patients, had PSA levels graded as <4ng/ml, 4-10ng/ml, and > 10ng/ml were 47.8%, 34.8% and 17%, respectively [7]. So, the results of our study were comparable with numerous other studies done by other studies [25,26]. A study done by Popli et al. observed that the mean PSA level of BPH patients was 6.46ng/ml, PSA in patients having prostatitis was 3.1ng/ml and in patients harboring malignancy was 34.22ng/ml [7]. The mean PSA in the case of malignancy is higher than 118.9ng/ml in our study. This is attributable to the higher level of serum PSA in the Bangladeshi population. Prostatic adenocarcinoma was graded according to the Gleason grading system, and Gleason scoring was done. In our study, the most common Gleason score was 8, found in 40% of cases. In a study done by Kumar et al., the most common Gleason scores were 7 and 9, found in 37.5% of patients [17]. Similar results to those of Kumar et al. were found in a study done by others [6]. Tell the results of PSA and Gleasons score with HER2/NEU gene.

Limitation of the study: The study had several limitations. It relied on histopathological examinations of resected prostate tissue, introducing potential selection bias by excluding patients managed non-surgically. The cross-sectional design limits the ability to establish causal relationships. Additionally, the study did not account for potential confounders such as comorbid conditions, medications, or lifestyle factors that could influence PSA levels and prostate pathology.

V. CONCLUSION

In conclusion, the most common age group for prostatic diseases was 61-70 years. Benign prostatic hyperplasia (BPH) was the most frequent lesion, with a mean age of 68.94 years. BPH with inflammation had a mean age of 65.85 years, and prostate carcinoma had a mean age of 71.77 years. The most common ultrasound findings for prostate size were grade II (31-50g) in 34.4% of cases and grade I (20-30g) in 29.6% of cases, with most having a PSA level of 0-5 ng/ml. PSA level higher in carcinoma and significant correlation with PSA and HER2/NEU. This study, conducted at BIRDEM General Hospital, highlights patterns of prostatic diseases, aiding in early diagnosis and potentially reducing morbidity and mortality.

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