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Original Article

Correlation of serum prostate-specific antigen with Gleason score and Gleason grade group in patients with prostate adenocarcinoma at a tertiary care hospital

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ABSTRACT

Background: Prostate cancer is the most frequently diagnosed cancer among men, with the highest incidence seen in western countries. Prostate-specific antigen is widely used as a screening tool for the detection of prostate cancer. Gleason grading system is the most commonly used pathological grading system for prostate cancer. This system is also a powerful prognostic factor and helps in determining clinical outcome.

Materials and Methods: A retrospective cross-sectional study was done in the Department of Pathology, Tribhuvan University Teaching Hospital from January 2023 to June 2024. A total of 56 histopathologically and/or immunohistochemically confirmed cases of prostate adenocarcinoma with documented serum prostate specific antigen level, Gleason score and Grade were included in the study. Serum prostate specific antigen level was compared with Gleason score and Gleason grade. Correlation was done using Spearman's rank correlation coefficient. P-value of ≤0.05 was considered to be statistically significant.

Results: The mean age of the patients was 70.9 years with a mean serum prostate specific antigen of 55.6 ng/ml. 63% of the patients had serum prostate specific antigen level above 20 ng/ml. The most common Gleason score was 9. Gleason grade 5 was the most common Gleason grade. Statistically significant correlation of serum prostate specific antigen with Gleason score and Grade was established with p-value <0.05.

Conclusions: This study highlights that prostatic acinar adenocarcinoma predominantly affects older males. A strong positive correlation was observed between higher serum prostate specific antigen levels and advanced Gleason scores and Gleason grades. The findings underscores the importance of prostate specific antigen monitoring in high-risk groups.

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INTRODUCTION

Prostate cancer is the most frequently diagnosed cancer among men, with the highest incidence seen in western countries.[1] Prostate cancer is the second most common malignancy in the males and the fifth leading cause of cancer death among men in the world. Prostate cancer accounts for 3.8% cancer deaths among males.[2] According to GLOBOCAN 2022, the prevalence of prostate cancer is 1.5 per 100000 population in Nepal.[3] Advances in health services and screening programs have led to increasing incidence of prostate cancer in developing countries as

well.[4] There is a wide range of differences in the incidence of prostate cancer globally. This difference might be due to variation in the usage of prostate-specific antigen testing.[5]

Prostate-specific antigen is a glycoprotein secreted by both normal and neoplastic prostatic tissue with a half-life of 2.2 days.[6] Serum prostate-specific antigen (PSA), secreted by prostatic epithelial cells, is elevated in prostate cancer.[7] PSA is widely used as a screening tool for the detection of prostate cancer. Introduction of PSA as a screening tool has led to an increasing diagnosis of prostate cancer even in young individuals and at an early stage.[8] Besides its role as a screening tool, PSA is also used to monitor response to therapy, surveillance following diagnosis, and risk stratification in patients with prostate cancer.[9] The cut-off value of PSA may vary among different institutions. However, the general approach is to biopsy patients with an observed minimum value of 4ng/ml.[10] The PSA group can be subclassified into three groups: low risk (PSA 4-10 ng/ml), intermediate risk (PSA 10-20 ng/ml), and high risk (PSA > 20 ng/ml).[10] PSA is valuable as a prognostic marker for monitoring disease recurrence and treatment response.[11]

Similarly, the most common pathological grading system for the prostate is the Gleason Grading System (GGS). This system is also a powerful prognostic factor and helps in determining clinical outcome.[12] The Gleason grading system, introduced in 1966 by Donald F. Gleason, remains the most widely accepted grading system in the evaluation of prostate carcinoma. The GGS evaluates the histological pattern and the sum of the two most common patterns, i.e., primary and secondary patterns, the total of which is reported as the obtained Gleason score. Gleason score has been found to correlate with the biological behavior of prostate adenocarcinoma.[13] Gleason score equal to 6 is classified into prognostic grade group 1, Gleason score 3+4=7 to group 2, Gleason score 4+3=7 to group 3, Gleason score 8 to group 4, and Gleason score 9-10 to group 5.[14] Gleason grading of prostate is one of the grading systems used for predicting overall and cancer specific survival. PSA, along with the Gleason score, improves the forecast of pathological staging of prostate carcinoma.[15]

There are various risk stratification systems for prostate cancer. These risk stratification systems incorporate serum PSA and the Gleason grading system along with clinical T stage.[16,17] The treatment modalities of prostate cancer vary according to risk group. The Gleason grade group directly influences clinical management.[18] Active surveillance is recommended for patients with Gleason grade group 1, whereas radical and multimodal therapy are recommended for patients with higher Gleason grades.[16–18]

Establishing a correlation between serum PSA level, Gleason score, and grade can non-invasively aid in risk stratification and avoid the need for repeated biopsies and radical prostatectomies. In the context of Nepal, there is a relative lack of knowledge and awareness about prostate cancer screening.[5] There are only few studies that correlate serum PSA with Gleason score and grade in patients with prostatic adenocarcinoma with an adequate sample size.[19] Most of the studies show a relationship between serum PSA and prostatic lesions.[19–22] Therefore, there is need to validate correlation between serum PSA and Gleason score and grade in our population. Hence, this study aims to evaluate the correlation between serum PSA and the Gleason grading system in patients with histologically and/or immunohistochemically confirmed prostate adenocarcinoma.

Present study was carried out with the objectives to determine serum PSA level in prostate cancer and their subcategories into different risk groups, to calculate the frequency of age, serum PSA level, and Gleason score distribution, to determine the correlation between Serum PSA level and Gleason score, and to determine the correlation between Serum PSA and Gleason grade.

MATERIALS AND METHODS

The present study was a retrospective, analytical, cross-sectional study conducted in the Department of Pathology, Tribhuvan University Teaching Hospital from January 2023 to June 2024. Ethical clearance was taken from the institutional review committee before initiation of the study. This study included all cases with prostate core biopsy diagnosed with prostatic adenocarcinoma received in the department of pathology over 18 months (January 2023 to June 2024). A consecutive non-probability sampling technique was used for the collection of data. Data were extracted from the histopathological forms archived in the department of pathology. For the missing serum PSA value, data were extracted from the archives of the department of urology. Serum PSA levels were measured by Chemiluminescence microparticle Immunoassay technique CMIA using Abbott ARCHITECT ci4100 immunoassay system. Serum PSA level of <4.0 ng/ml was considered normal. Radical prostatectomy, transurethral or transrectal resection of prostate specimen were also excluded. The pathologists working in the Department of Pathology at Tribhuvan University Teaching Hospital did histopathological reporting and diagnosis. The pathologists were non-blinded to serum PSA. The Gleason score and grade were assigned as per the Gleason grading system of the International Society of Urological Pathology 2019 consensus.[23] 56 cases were included in the present study that fulfilled the inclusion criteria. Age of the patient, prebiopsy serum PSA level, Gleason score, and Gleason grade group were all recorded in Microsoft Excel 2016. The mean, frequency, and percentage were calculated, and cross tabulation was done using Statistical package for social sciences (SPSS), version 26. Spearman's rank correlation coefficient was used to test the relationship between serum PSA, Gleason score, and Gleason grade group. The level of statistical significance was set at ≤ 0.05.

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RESULTS

There were 56 confirmed cases of prostatic acinar adenocarcinoma (classified as per World Health Organization classification of tumors, Urinary and Male Genital Tumors, 2022, 5th edition) in our study.[24] The mean age was 70.9 years. The most common age group was 66-75 years, which accounts for 29/56 (52%) of the patients. There were two patients in the age group 35-45 years, and four patients were above 85 years [Table 1].

Table 1: Age distribution of the patients (n=56)

Variable	Mean	Subgroup	Frequency	Percentage
Age (years)	70.9	35-45	2	3%
		46-55	1	2%
		56-65	9	16%
		66-75	29	52%
		76-85	11	20%
		>85	4	7%
		Total	**56**	**100%**

The mean serum PSA level was 55.6 ng/ml. Most of the patients [35/56 (63%)] had serum PSA levels above 20ng/ml, and none of the patients had serum PSA levels below 4ng/ml. Twelve patients [12/56 (21%)] had serum PSA levels between 4-10 ng/ml, and nine patients [9/56 (16%)] had serum PSA levels between 10.01-20 ng/ml. Most of the patients were in the high-risk group. [Table 2].

Table 2: Distribution of serum prostate specific antigen (PSA) level of the patients (n=56)

Variable	Mean	Subgroup	Frequency	Percentage
Serum PSA level (ng/ml)	55.6	4.00-10	12	21%
		10.01-20	9	16%
		>20	35	63%
		Total	**56**	**100%**

Twenty-two patients [22/56 (39%)] had a Gleason score of 9, which was the most common Gleason score. Thirteen patients [13/56 (23%)] had a Gleason score of 6, while Gleason scores 7, 8, and 10 were found in 8/56 (14%), 7/56 (13%), and 6/56 (11%) patients, respectively [Table 3].

Table 3: Distribution of Gleason Score of the patients (n=56)

Variable	Subgroup	Frequency	Percentage
Gleason score	6	13	23%
	7	8	14%
	8	7	13%
	9	22	39%
	10	6	11%
	Total	**56**	**100%**

Gleason grade 5 was the most common, with more than 28/56 (>50%) patients within this grade group. There were thirteen patients [13/56 (23%)] in Gleason grade 1, while Gleason grades 2, 3 and 4 were observed in 5/56 (9%), 3/56 (5%), and 7/56 (13%) patients, respectively [Table 4].

Table 4: Distribution of Gleason Grade of the patients (n=56)

Variable	Grade group	Frequency	Percentage
Gleason grade	1	13	23%
	2	5	9%
	3	3	5%
	4	7	13%
	5	28	50%
	Total	**56**	**100%**

18 out of 23 patients with Gleason score 9 had serum PSA levels>20ng/ml. Similarly, 5 out of 6 patients with a Gleason score 10, had serum PSA levels of>20ng/ml. The results showed that higher Gleason scores and grades are associated with higher serum PSA levels. There was statistically significant positive correlation of serum PSA with Gleason score (ρ=0.664, p<0.01) and Gleason grade (ρ=0.682, p<0.01). Similarly, there was a statistically significant positive correlation of serum PSA levels with age (ρ=0.282, p<0.05). Table 5 shows cross tabulation of serum PSA categories with respect to Age, Gleason score and Gleason grade.

Table 5: Cross tabulation of serum PSA levels with respect to age group, Gleason score and Gleason grade

Variable	Subgroup	Serum PSA level (ng/ml)			Spearman's rank correlation coefficient (ρ)	p-value
		4.00-10	10.01-20	>20		
Age (years)	35-45	0	1	1	0.282	0.035
	46-55	0	0	1		
	56-65	3	1	5		
	66-75	8	5	16		
	76-85	1	2	8		
	>85	0	0	4		
Gleason score	6	9	3	1	0.664	<0.01
	7	1	2	5		
	8	1	0	6		
	9	1	3	18		
	10	0	1	5		
Gleason grade	1	9	3	1	0.682	<0.01
	2	1	2	2		
	3	0	0	3		
	4	1	0	6		
	5	1	4	23		

DISCUSSION

The mean age of the patients was 70.9 years, with most of the patients between the 66-75 years age group in our study. In a study conducted in Pakistan by Hussain SA et al., most

of the patients were between 66-75 years of age, with a mean age of 65.71 years.[25] Similar studies conducted in Nigeria by Mohammed U et al. had found a common age group of 61-70 years, with a mean age of 68 years, and Udoh et al. observed a mean age of 68.22 years.[7,26] These findings are concordant with our study. The mean serum PSA level was 55.6 ng/ml, which is comparable to previous studies conducted by Sharma et al. (mean serum PSA level 55.2 ng/ml) and Deepika Gurumurthy et al. (mean serum PSA level 55.11 ng/ml).[27,28] However, the study conducted by Shah et al. in Nepal found a mean serum PSA level of 170ng/ml in patients with prostatic adenocarcinoma.[19] Similar study conducted in Nepal by Shah and Pandey et al. found a mean age of 67 years and a mean PSA level of 55.72 ng/ml.[20] In the study conducted by Hirachan et al., mean age was 72 years.[22] Similarly, in the study conducted by Pudasaini et al., malignancy of prostate was common in 70-79 years age group patients with mean age of 66.57 years, and serum PSA level was more than 20 ng/ml (Table 6).[21]

Table 6: Distribution of mean age, common age group and mean serum PSA level in different studies

Authors/year	Mean age (years)	Common age group(years)	Mean serum PSA (ng/ml)
Hussain et al, 2022[25]	65.71 yrs.	66-75 yrs.	40.31 ng/ml
Mohammed U et al, 2024[7]	68 yrs.	61-70 yrs.	43.18 ng/ml
Sharma et al, 2023[27]	68.8 yrs.	N/A	55.2 ng/ml
Udoh et al, 2020[26]	68.2 yrs.	N/A	55.31 ng/ml
Deepika et al, 2015[28]	68 yrs.	60-70 yrs.	55.11 ng/ml
Shah et al, 2019[19]	N/A	N/A	170.7 ng/ml
Shah and Pandey et al, 2020[20]	67.67 yrs.	61-70 yrs.	55.72 ng/ml
Hirachan et al, 2018[22]	72.9 yrs.	71-80 yrs.	N/A
Pudasaini et al, 2019[21]	66.57 yrs.	70-79 yrs.	N/A
Present study	70.9 yrs.	66-75 yrs.	55.6 ng/ml

N/A= Not Available

In our study, 35/56 patients (63%) had serum PSA levels of more than 20ng/ml, which is similar to previous studies. There was significant positive correlation between patients' age and serum PSA level in patients with prostate adenocarcinoma in the current study, which is in contradiction to the study conducted by Hussain SA et al.[25] However, the study conducted by Lynn et al. showed a mild positive correlation between age and serum PSA level.[29] Similarly, the study conducted by Oesterling et al. showed higher correlation between age and serum PSA level with r-value of 0.43 and p-value 0.001.[30] In a study conducted by Mohammed U et al., there was association between age and serum PSA level (Table 7).[7] This difference might be due to various interfering factors such as medications, body mass index, prostatic volume and technical errors.[31]

Table 7: Relationship between serum PSA levels with Age in different studies

Authors/year	P-value
Hussain et al, 2022[25]	0.222
Lynn et al, 2000[29]	0.01
Oesterling et al, 1993[30]	0.001
Mohammed U et al, 2024[7]	0.047
Present study	0.035

Our study showed that the majority of patients (n=35) with prostatic adenocarcinoma had a serum PSA level more than 20ng/ml. In the present study majority of patients with Gleason score of 6 had serum PSA between 4-10ng/ml, whereas the majority of patients with Gleason score of 10, had serum PSA level more than 20ng/ml. None of the patients with Gleason score 10 had a serum PSA level between 4-10 ng/ml. Our study demonstrated that a higher serum PSA level correlated with a higher Gleason score, with $\rho=0.664$ and p-value<0.01. The findings are comparable to studies conducted by Hussain SA et al., Udoh et al., Ngwu PE et al. and Sharma et al.[25–27,32] There was a weak positive correlation found between serum PSA level and Gleason score in the study conducted by Mohammed U et al.[7] In the present study, most of the patients with prostate adenocarcinoma were of Gleason score 9. The most frequent Gleason score was 5-7 in the study conducted by Mwakyoma et al. in Tanzania.[11] Similarly, the most common Gleason score in the studies conducted by Sharma et al. and Hussain et al. was 7.[25,27] In our study, among 22 patients with Gleason score 9, 18 had serum PSA level more than 20ng/ml. Most patients had serum PSA levels more than 20ng/ml across all Gleason scores, except for Gleason score 6. Among 56 patients, 13 patients had Gleason grade 1, with 9 patients having serum PSA level between 4-10ng/ml, and only 1 with serum PSA level more than 20ng/ml. Among 28 patients with Gleason grade 5, 23 patients had serum PSA level more than 20ng/ml. Our study showed that higher Gleason grade is associated with higher serum PSA level. There is a good correlation between serum PSA level and Gleason grade with $\rho=0.682$ and $p<0.01$. Our results are similar to studies conducted by Ekta rani et al., Hussain et al. and Sharma et al.[25,27,33] Meanwhile, certain studies showed that serum PSA did not have any strong correlation with Gleason score and Gleason grade. In a study conducted by Gurumurthy et al. in 2015, though there was an increase in serum PSA level, with an increase in Gleason grade, it was not statistically significant (Table 8).[28] This discrepancy might be due to interobserver variability in Gleason scoring. Furthermore, our study used 5 5-tier Gleason grade system whereas Gurumurthy et al. used 4 4-tier Gleason grading system.[28] In the study conducted by Abubaker et al., the serum PSA concentration had a statistically significant association with the Gleason grade groups, and patients with high PSA concentrations being more likely to have a high tumor grade group. This study also demonstrated most cases with high Gleason score and Gleason grade implying high level of tumor aggressiveness.[34]

Table 8: Relationship between serum PSA level with Gleason score and Grade in different studies

Authors/year	P-value
Hussain et al, 2022[25]	0.001
Rani et al, 2023[33]	0.001
Mohammed U et al, 2024[7]	0.175
Sharma et al, 2023[27]	0.000
Udoh et al, 2020[26]	0.01
Deepika et al, 2015[28]	0.75
Abubakar et al, 2018[34]	0.000
Ngwu PE et al, 2019[32]	0.01
Present study	<0.01

Results from our study help clinicians to triage patients for risk stratification and improve risk communication with the patients. The results may also reduce likelihood of unnecessary biopsies in patients with low serum PSA levels. However, this was a single-center retrospective study, so the results may not be generalizable.

Authors acknowledge limitations of the present study, which are: small sample size, which weakens the correlation strength. Also, the Gleason scores and grades were assigned by pathologists who were non-blinded to serum PSA levels. This may lead to expectation bias and overestimation of the correlation between serum PSA and Gleason score and grade. Similarly, missing cases in the records may cause selection biases.

CONCLUSIONS

Present study showed a strong positive correlation between serum PSA level and the Gleason Grading System. Higher Gleason score and grade are associated with higher serum PSA level. Gleason grading system, when combined with pretreatment serum PSA level, can guide management and predict the outcome of the patients. In the setting of our population, future multicenter studies with larger cohorts and a prospective design are recommended to validate these findings and explore their broader clinical utility in the management of prostate cancer.

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