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ORIGINAL ARTICLE

Prognostic Effect of KELIM Score of Prostate-Specific Antigen in Hormone-Sensitive Prostate Cancer Patients Treated With Novel Androgen Receptor Inhibitors: Pioneering New Ways

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ABSTRACT

Background: The prognostic value of the PSA ELIMination rate constant K (PRO-KELIM) score was investigated in patients with metastatic castration-sensitive prostate cancer (mCSPC) treated with novel androgen receptor inhibitors.

Methods: This multicenter retrospective study included 160 patients diagnosed with prostate adenocarcinoma between 2011 and 2024 who received enzalutamide or abiraterone during the mCSPC and had at least three PSA measurements within the first 100 days of treatment. The patients were categorized into favorable (PRO-KELIM ≥ 1.0) and unfavorable (PRO-KELIM < 1.0) groups. Progression-free survival (PFS) and overall survival (OS) were analyzed using the Kaplan–Meier survival analysis and Cox regression.

Results: Median PFS was significantly higher in the favorable group than in the unfavorable group (not reached vs. 40.0 months, $p < 0.001$). The estimated 2-year PFS rates in the favorable and unfavorable groups were 78% and 52%, respectively. In multivariate analyses, a high PRO-KELIM score (HR 2.99; 95% CI 1.35–6.66, $p = 0.007$) and good initial response to treatment ($p = 0.001$) were independent favorable prognostic factors for PFS. The median OS did not differ significantly between the groups ($p = 0.27$). PRO-KELIM score was not an independent prognostic factor for OS ($p = 0.76$).

Conclusion: These findings suggest that the PRO-KELIM score can be a valuable prognostic tool in the mCSPC to assess early treatment response and predict disease progression.

1 | Introduction

Prostate cancer is the most common cancer in men in the United States, accounting for 29% of all cancer cases and approximately 300,000 new cases annually. It is also the second most common cause of cancer-related deaths in men [1]. For many years, androgen deprivation therapy (ADT) has been the standard treatment for metastatic castration-sensitive prostate cancer (mCSPC). However, in recent years, there has been a significant evolution in the treatment of mCSPC. In high-quality clinical trials, the addition of androgen receptor pathway inhibitors, such as docetaxel, abiraterone acetate, enzalutamide, and apalutamide, to ADT has been shown to significantly improve overall survival (OS) compared with ADT alone [2–5]. Nevertheless, the importance of individualized treatment and patient follow-up has increased following these important advances in mCSPC owing to the high incidence and mortality rates of prostate cancer. For many years, PSA biochemical measurements have been widely used in routine clinical practice for both the early and metastatic stages of prostate cancer, providing valuable prognostic information regarding the course of the disease. Given the limitations of PSA, such as the kinetic strategy based on these two time points being affected by inter-center variability of PSA concentrations measured by different assays, as well as the limitations of PSA, the search for more sensitive and reliable prognostic tools is ongoing [6].

The ELIMination rate constant K (KELIM) is a biomarker initially developed to determine the rate of decline of tumor markers over the course of treatment, and is considered an important parameter for assessing sensitivity to chemotherapy. The KELIM score, which is obtained by ELIMination rate constant (K) modeling of cancer antigene-125 (CA-125), has been used to evaluate treatment efficacy, especially in diseases such as ovarian cancer, and has been shown to provide a clinically significant prognostic value in various studies. In general, a high KELIM score is associated with chemosensitivity and effective treatment [7, 8]. Subsequently, this modeling approach was applied to prostate-specific antigen (PSA) levels, and the prognostic significance of the KELIM score obtained by modeling PSA kinetics during the first 100 days of treatment in patients with prostate cancer was examined. The KELIM score is an independent prognostic factor for both progression-free survival (PFS) and overall survival, especially in patients with metastatic castration-resistant prostate cancer treated with taxanes [9].

This study aimed to investigate the prognostic significance of the PSA KELIM (PRO-KELIM) score in patients with metastatic castration-sensitive prostate cancer treated with new-generation anti-androgen agents. The primary objective was to provide valuable insights that could contribute to clinical practice, particularly in the evaluation of treatment response and the prediction of patient prognosis. In this context, the potential role of the PRO-KELIM score will be assessed, especially in terms of the early identification of treatment-sensitive patients and individualization of treatment strategies. To the best of our knowledge, this is the first study to explore this topic within the context of the mCSPC.

2 | Material and Methods

2.1 | Patients and Data Collection

This study was designed as a multicenter retrospective analysis. It included patients diagnosed with prostate adenocarcinoma between 2011 and 2024 who received either enzalutamide or abiraterone treatment for metastatic hormone-sensitive prostate cancer and had a minimum of three PSA measurements within the first 100 days. All patients received ADT in combination with either abiraterone or enzalutamide. ADT consisted of GnRH agonists for all patients, and short-term bicalutamide was used in some cases based on clinician preference. Baseline demographic characteristics, including age, Eastern Cooperative Oncology Group (ECOG) performance score, comorbidities, and clinicopathological data, such as the Gleason score, history of definitive treatment, metastasis sites, and pretreatment lactate dehydrogenase levels (LDH) during the metastatic period. Additionally, data on PSA levels, early treatment response, disease progression, and survival status were documented. The study data were sourced from the hospital databases and patient files.

2.2 | KELIM Score

The KELIM score was calculated according to an approach similar to that used in previous studies that evaluated the prognostic impact in patients with prostate and ovarian cancer. In these studies, a threshold value of one was used for the KELIM score. In patients with mCSPC, 3 consecutive PSA values within the first 100 days following the initiation of enzalutamide or abiraterone were included in the calculation and logarithmically transformed to eliminate the right skewness of the data. The PSA longitudinal kinetics were modeled using the nonlinear mixed-effect model, which was previously described based on studies on CA-125 kinetics [7, 9–11]. Similar to the aforementioned studies, patients with PRO-KELIM < 1.0 were categorized into the unfavorable group and those with PRO-KELIM ≥ 1.0 were categorized into the favorable group and analyzed.

2.3 | Statistical Analysis

Analyses were performed using the SPSS software version 26.0. Descriptive analyses were presented as means, standard deviations, medians, interquartile ranges, and minimum and maximum values for the numerical variables. The normality of the distribution of continuous variables was assessed using both visual methods (histograms) and analytical methods (Kolmogorov–Smirnov test). Descriptive analyses for categorical variables were presented as frequencies and percentages. Comparisons of continuous variables between groups defined according to the PRO-KELIM score were performed using the Student's *t*-test (or the Mann–Whitney *U* test under non-parametric conditions), while the chi-square test was used for comparisons of categorical variables. ECOG, favorable-unfavorable, definitive treatment groups, LDH categorization, organ metastases, treatment type, Gleason score, progression-free survival, and overall survival according to the initial response status were

TABLE 1 | Baseline demographic and clinical characteristics of patients according to PRO-KELIM groups.

	Total ($n = 160$)	PRO-KELIM ≥ 1.0 (Favorable) (n:82)	PRO-KELIM < 1.0 (Unfavorable) ($n = 78$)	p
Age (Mean ± SD)	71.44 ± 7.84	70.75 ± 7.15	72.16 ± 8.51	0.097*
ECOG-PS, n (%)				0.25
0	40 (25.2)	22 (26.8)	18 (23.4)	
1	92 (57.9)	50 (61.0)	42 (54.5)	
2	27 (17.0)	10 (12.2)	17 (22.1)	
Gleason score, n (%)				0.07
3 + 3	7 (4.4)	1 (1.2)	6 (7.7)	
3 + 4	13 (8.1)	3 (3.7)	10 (12.8)	
3 + 5	2 (1.3)	0 (0)	2 (2.6)	
4 + 3	12 (7.5)	8 (9.8)	4 (2.5)	
4 + 4	30 (18.8)	16 (19.5)	14 (17.9)	
4 + 5	35 (21.9)	22 (26.8)	13 (16.7)	
5 + 3	1 (0.6)	0 (0)	1 (1.3)	
5 + 4	29 (18.1)	13 (15.9)	16 (20.5)	
5 + 5	29 (18.1)	18 (22.0)	11 (14.1)	
ADT, n (%)	100 (100)	100 (100)	100 (100)	1.00
Definitive treatment, n (%)				0.15
No	135 (84.4)	72 (87.8)	63 (80.8)	
Yes	25 (15.6)	10 (12.2)	15 (19.2)	
LDH, n (%)				0.56
Normal	144 (90)	74 (90.2)	70 (89.7)	
1.5x > ULN	16 (10)	8 (9.8)	8 (10.3)	
Lymph node metastasis, n (%)				0.60
No	49 (30.6)	27 (32.9)	22 (28.2)	
Yes	111 (69.4)	55 (67.1)	56 (71.8)	
Liver metastasis, n (%)				0.15
No	147 (91.9)	78 (95.1)	69 (88.5)	
Yes	13 (8.1)	4 (4.9)	9 (11.5)	
Lung metastasis, n (%)				0.04
No	133 (83.1)	73 (89.0)	60 (76.9)	
Yes	27 (16.9)	9 (11.0)	18 (23.1)	
Bone metastasis, n (%)				0.84
No	13 (8.1)	7 (8.5)	6 (7.7)	
Yes	147 (91.9)	75 (91.5)	72 (92.3)	
Treatment type, n (%)				0.44
Abiraterone	87 (54.4)	47 (57.3)	40 (51.3)	
Enzalutamide	73 (45.6)	35 (42.7)	38 (48.7)	
First treatment response, n (%)				0.04
Complete response	6 (3.8)	5 (6.1)	1 (1.3)	
Progressive disease	6 (3.8)	0 (0)	6 (7.7)	
Partial response	111 (69.4)	59 (72.0)	52 (66.7)	
Stable disease	24 (15.0)	13 (15.9)	11 (14.1)	
PSA nadir, Median (IQR)	0.10 (0.744)	0.048 (0.324)	0.44 (2.465)	*< 0.001**

Note: Italic values indicate statistically significant results $p < 0.05$ *Student t-test, Data are presented as median (IQR: interquartile range = 25th–75th percentiles).
Abbreviations: ADT, Androgen deprivation therapy; ECOG PS, Eastern Cooperative Oncology Group Performance Score; LDH, Lactate dehydrogenase; ULN, Upper limit of normal.

analyzed using the log-rank test. Survival rates were calculated using the Kaplan-Meier survival analysis. Receiver operating characteristic (ROC) curve analysis was used to evaluate the prognostic value of the Kelim1 score in relation to survival. PRO-KELIM score was categorized according to median value and established groups 'favorable and unfavorable' In the multivariate analysis, the independent factors for predicting survival using the possible factors determined in the binary analyses were examined using Cox regression analysis with the backward selection method. Statistical significance was set at $p < 0.05$. Correlation analysis used to determine the relationship between PRO-KELIM score and PSA nadir.

2.4 | Ethics

This study was designed and conducted in accordance with Good Clinical Practice and the Declaration of Helsinki. This study was approved by the Clinical Research Ethics Committee of Alanya Alaaddin Keykubat University (approval date: 12.02.2025/03-01).

3 | Results

3.1 | Patient Population

A total of 160 patients were included in this study. The mean age of all patients, with standard deviation, was 71.44 ± 7.84 years (minimum–maximum: 51.0–91.0). There were 78 patients (48.8%) in the PRO-KELIM < 1.0 (unfavorable) group and 82 patients (51.2%) in the PRO-KELIM ≥ 1.0 (favorable) group. In the entire patient group, 15.6% of the patients received definitive treatment at diagnosis. In addition to ADT, 87 (54.4%) and 73 (45.6%) patients were treated with abiraterone and enzalutamide, respectively, during castration sensitivity. The median PSA nadir level in the entire study population was 0.10 (IQR: 0.744); in the favorable and unfavorable groups, the median values were 0.048 (IQR: 0.324) and 0.44 (IQR: 2.465), respectively ($p = 0.001$). Baseline

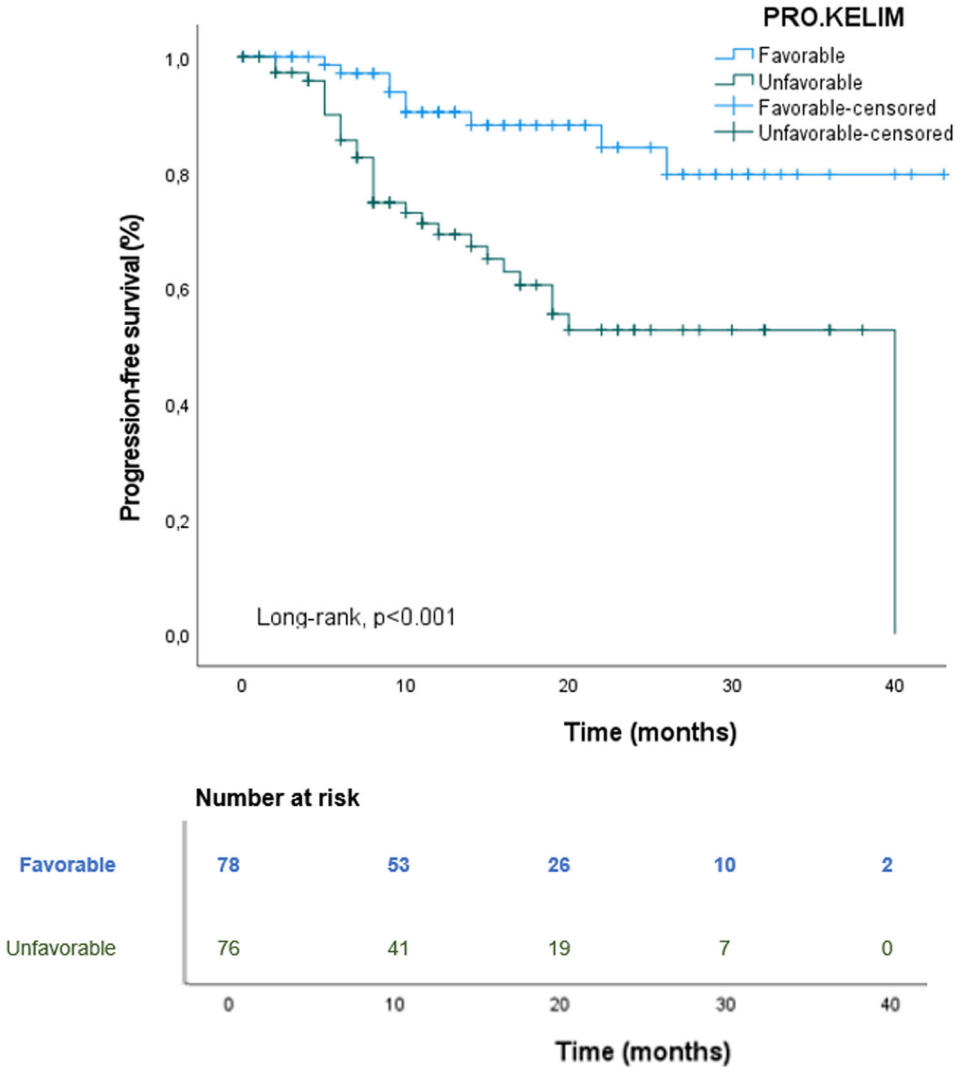

FIGURE 1 | Kaplan–Meier curves for progression-free survival according to PRO-KELIM groups. [Color figure can be viewed at wileyonlinelibrary.com]

demographic and disease-related parameters were generally similar in the unfavorable and favorable groups and the details are presented comparatively in Table 1.

3.2 | Primary Analysis

The median PFS was not reached in the favorable group, but the median PFS was calculated as 40.0 months in the unfavorable group, and progression-free survival was significantly higher in the favorable risk group ($p < 0.001$) (Figure 1). In addition, the estimated progression-free survival rates at 2 years were 78% and 52% in the favorable and unfavorable groups, respectively. In the analysis in terms of overall survival, the median OS was again not reached in the favorable group, while the median OS in the unfavorable group was calculated as 49.0 months (95% CI: 27.1–70.8 months), and no statistically significant difference was found between the groups in terms of overall survival ($p = 0.27$) (Figure 2). In addition, the estimated overall survival rates at 2 years were 72% and 55% in the favorable and unfavorable groups, respectively.

3.3 | Secondary Analysis

As shown in Table 2, patients with a favorable PRO-KELIM score had significantly longer PFS than those with an unfavorable score (mean PFS: 37.4 vs. 26.0 months, $p < 0.001$). In multivariate analysis, an unfavorable score remained an independent predictor of shorter PFS (HR: 2.99; 95% CI: 1.35–6.66; $p = 0.007$). Liver metastasis was associated with worse PFS in univariate analysis ($p = 0.005$), with a borderline significance in multivariate analysis ($p = 0.060$). Poor initial treatment response (SD or PD) was significantly associated with shorter PFS, and remained significant in the multivariate model (SD: HR 2.94, $p = 0.001$; PD: HR 24.06, $p < 0.001$). Other variables including ECOG-PS, metastasis sites, Gleason score, and treatment type were not independently associated with PFS ($p > 0.05$). Median PFS could not be estimated in some subgroups due to high censoring; therefore, mean PFS values were reported for descriptive purposes.

In multivariate analyses of overall survival, only a good initial response to treatment was found to be an independent favorable risk factor ($p = 0.004$). PRO-KELIM score was not an independent prognostic factor for overall survival ($p = 0.76$). In addition, a significant inverse correlation was found between the PRO-KELIM score and PSA nadir level ($p < 0.001$, $\rho = -0.388$).

4 | Discussion

Our results showed that a higher PRO-KELIM score was significantly associated with longer progression-free survival in patients

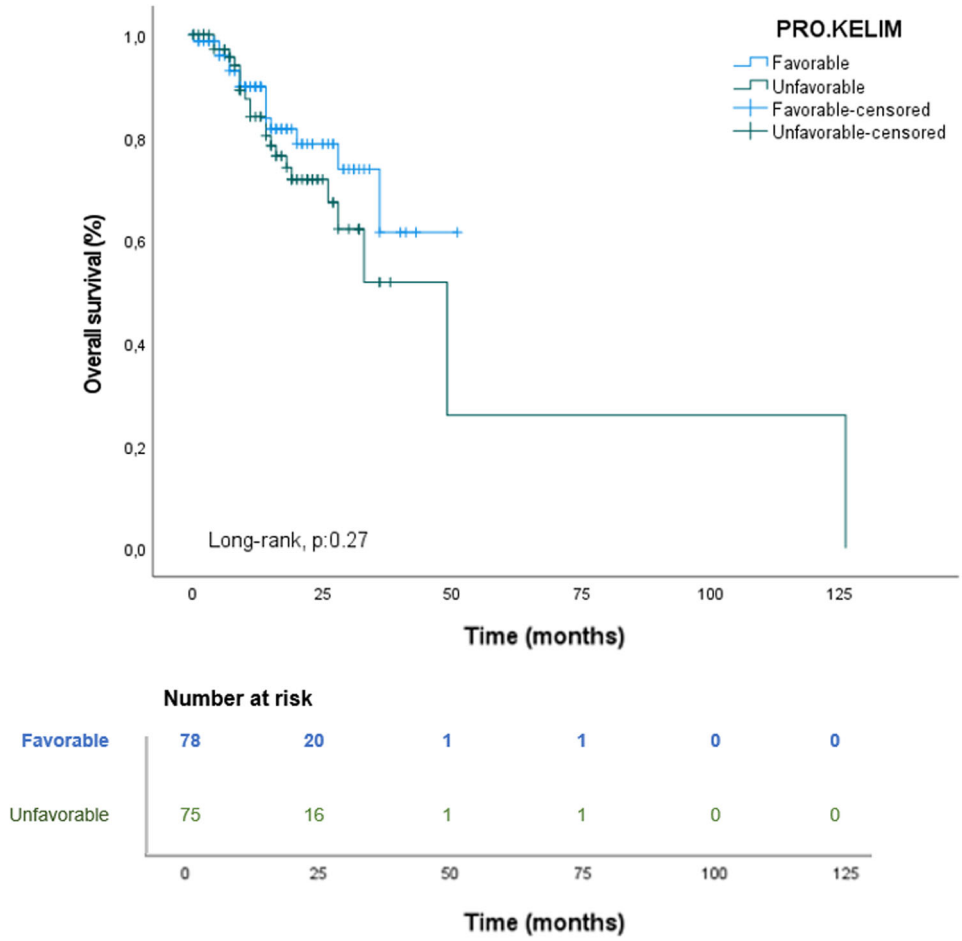

FIGURE 2 | Kaplan–Meier curves for overall survival according to PRO-KELIM groups. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 | Univariate and multivariate analyses for progression-free survival.

Variable	Univariate analyses			Multivariate Analyses HR (95% CI)	
	Median PFS (95% CI) months	Mean PFS (95% CI) months	*p**		*p***
PRO-KELIM					
Favorable	Not estimable	37.4 (34.0–40.8)	*< 0.001*	ref.	*0.007*
Unfavorable	40.0 (Not estimable)	26.0 (22.0–30.1)		2.99 (1.35–6.66)	
ECOG-PS				0.199	
0	Not estimable	31.0 (25.4–36.7)	*0.025*	ref	—
1	Not estimable	34.8 (31.4–38.3)		1.36 (0.56–3.34)	0.491
2	22.0 (9.4–34.5)	23.7 (16.8–30.5)		2.26 (0.89–5.74)	0.084
Lymph node metastasis				—	
No	Not estimable	33.1 (28.8–37.4)	0.253	—	—
Yes	40.0 (20.2–59.7)	29.7 (25.8–33.6)		—	—
Liver metastasis					
No	Not estimable	32.6 (29.6–35.6)	*0.005*	2.68 (0.958–7.52)	0.060
Yes	Not estimable	11.8 (7.7–15.9)		ref	
Lung metastasis				—	
No	Not estimable	32.7 (29.6–35.9)	0.294	—	—
Yes	26.0 (Not estimable)	24.9 (19.1–30.8)		—	—
Bone metastasis				—	
No	Not estimable	25.2 (17.9–32.4)	0.654	—	—
Yes	Not estimable	32.0 (28.8–35.1)		—	—
Gleason score				—	
Gleason score < 8	Not estimable	27.9 (20.0–35.7)	0.327	—	—
Gleason score ≥ 8	40.0 (11.7–62.9)	32.1 (28.9–35.3)		—	—
Treatment type					
Abiraterone	40.0 (16.7–63.2)	29.9 (26.0–33.8)	0.115	1.25 (0.57–2.72)	0.563
Enzalutamide	Not estimable	33.8 (30.1–37.6)		ref	—
First treatment response, *n* (%)				*< 0.001*	
Complete Response	Not estimable	Not estimable	*< 0.001*	—	—
Partial Response	22.0	Not estimable		ref	—
Stable Disease	14.0	Not estimable		2.94 (1.13-7.62)	*0.001*
Progressive Disease	4.0	Not estimable		24.06 (7.55-76.67)	*< 0.001*

Note: *Log-rank test. **Cox regression analysis. Median PFS could not be estimated in some subgroups due to a high proportion of censored observations. 95% confidence intervals for median PFS were not estimable in certain subgroups because of limited events or excessive censoring. Mean PFS values are presented for descriptive purposes where median estimates were not calculable. Mean PFS was not reported for subgroups with no events or insufficient data for reliable estimation.
Abbreviations: CI, Confidence interval; ECOG PS, Eastern Cooperative Oncology Group Performance Score; HR, Hazard ratio; LDH, Lactate dehydrogenase; PFS, Progression-free survival; ULN, Upper limit of normal.

with metastatic castration-sensitive prostate cancer, suggesting its utility as an early prognostic indicator of treatment response. The baseline characteristics of the study cohort and comparison groups were well-balanced and consistent with the existing literature, supporting the reliability of the survival analyses.

To our knowledge, this is the first study evaluating the prognostic significance of PRO-KELIM in mCSPC patients treated with next-generation hormonal therapies. While the score was significantly associated with PFS, no difference was observed for OS, possibly due to the relatively long follow-up required. Based on this study, we believe that the PRO-KELIM score can be used as a simple, inexpensive, and effective marker for predicting the prognosis of patients with mCSPC treated with new-generation anti-androgens.

Several studies have been conducted on the PSA kinetics at various stages of prostate cancer. The prognostic significance of various models, such as one-time PSA measurements, PSA nadir, PSA doubling time, PSA measured 6-8 months after the

start of treatment have been investigated. For example, in the LATITUDE study, PSA levels ≤ 0.1 ng/mL in the first 6 months of androgen deprivation therapy (ADT) with or without abiraterone indicated a good long-term response to treatment [12]. In a more recent study, in the PEACE-1 trial (ADT alone or ADT with docetaxel, with or without abiraterone), PSA levels ≤ 0.2 ng/mL and ≤ 4 ng/mL at 8 months of treatment were strongly associated with long-term survival outcomes [13]. In addition, in apalutamide-treated mHSPC patients, achieving an ultralow PSA nadir has been shown to be associated with better cancer control outcomes, such as prostate cancer developing castration resistance and overall survival [14]. The use of PSA kinetics instead of a single fixed PSA value measurement has also been brought to the agenda, and it has been previously shown in the literature that PSA values measured at different times with the use of abiraterone in the COU-AA-301 and COU-AA-302 studies in patients who did not receive chemotherapy and who had previously received chemotherapy may be associated with overall survival in patients with metastatic castration-resistant prostate cancer [15]. It was also recently concluded that a high KELIM score was positively correlated with overall survival in patients with metastatic castration-resistant prostate cancer treated with docetaxel chemotherapy [16]. While PSA levels at 6 or 8 months are established prognostic markers in mHSPC, the PRO-KELIM score offers a dynamic, early-phase assessment of PSA kinetics within the first 100 days of treatment. This enables potentially earlier identification of treatment response and prognosis. Although KELIM has been more extensively validated in chemotherapy settings, its application in ARPI-treated patients remains under investigation. Our study contributes to this evolving field by evaluating its prognostic potential in a real-world ARPI-treated mHSPC population. We believe PRO-KELIM may serve as a practical and timely tool for patient monitoring during early treatment.

5 | Limitations

Although our study had some important findings, these results should be interpreted with caution. The main limitations of our study are that it was planned retrospectively and the PSA values measured at different centers were recorded. The number of patients included in the study was relatively small; therefore, subgroup analysis was unreliable in terms of statistical power. This was mainly due to the retrospective design and limited access to novel androgen receptor inhibitors in our country during much of the study period, where docetaxel was more frequently preferred in the hormone-sensitive setting. Additionally, important clinical variables such as disease volume and timing of metastatic presentation could not be included in the multivariate analysis due to incomplete data availability in retrospective records, which is a recognized limitation of this study. Prospective studies with larger numbers of patients may better elucidate the clinical importance of PRO-KELIM scores.

6 | Conclusion

To our current knowledge this is the first study evaluating KELIM score in castration sensitive metastatic prostate cancer receiving abiraterone or enzalutamide with ADT. The PRO-KELIM score was significantly associated with progression-free survival in metastatic castration-sensitive prostate cancer treated with new-generation anti-androgen agents. PRO-KELIM may be a simple, effective, inexpensive, and important prognostic tool that can be used in routine practice to assess early responses to treatment and predict disease progression.

Institutional Review Board Statement

This study was designed and conducted in accordance with Good Clinical Practice and the Declaration of Helsinki. This study was approved by the Clinical Research Ethics Committee of Alanya Alaaddin Keykubat University (approval date: 12.02.2025/03-01).

Author Contributions

Yusuf Ilhan and Ismail Beypinar Contributed to the study conception and design. Yusuf Ilhan, Murat Araz, Ali Fuat Gurbuz, Muslih Urun, Berrak Mermit Ercek, Ozden Ozilice, Canan Yildiz and Onur Yazdan Balcik participated in material preparation and data collection. Semiha Urvay, Hacer Demir and Yusuf Ilhan contributed to literature review. Yusuf Ilhan, Ozden Ozilice and Ismail Beypinar was used for statistical analysis. Ismail Beypinar conducted a critical evaluation of this study's findings. The first draft of the manuscript was written by Yusuf Ilhan. All authors commented on and revised the previous versions of the manuscript. All the authors have read and approved the final manuscript.

Acknowledgments

The authors have nothing to report.

Consent

The need for patient consent was waived because of the retrospective nature of the study.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data is available upon reasonable request from the corresponding author.

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