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Survival Rate and Factors Influencing It in Triptorelin-Castrated Metastatic Prostate Cancer Patients

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Abstract

Background: Most newly diagnosed prostate cancers in Benin are metastatic diseases and patients are reluctant to undergo orchiectomy. Still, chemical androgen deprivation therapy is not always available and not every patient can afford it. Thus, it will be interesting to evaluate the results of that therapy in the country. **Objective:** To analyze the survival rate and factors influencing it in metastatic prostate cancer patients who underwent triptorelin-based androgen deprivation therapy at the former Military Teaching Hospital of Cotonou from January 1, 2012, to December 31, 2022. **Patients and Method:** Metastatic prostate cancer patients received intragluteal injections of triptorelin 11.25 mg every 3 months. We retrospectively collected follow-up data from the patients' medical records. By means of the software Stata™ version 15, we performed a descriptive analysis of qualitative data. We used Kaplan-Meier method to estimate the overall survival rate in the whole cohort and in specific subgroups of patients. We compared survival rates by using the log-rank test. **Results:** 68 metastatic prostate cancer patients aged 47 - 86 years (mean = 69.9) with initial PSA ranging from 24.25 to 6334 ng/mL (mean = 666.1) started triptorelin-based castration. The tumor grade in 21 (33.3%), 14 (22.2%), 15 (23.8), 8 (12.7%), and 5 (7.9%) patients was respectively ISUP grade groups 5, 4, 3, 2, and 1. 15 (22.1%), 4 (5.9%), 2 (2.9%), 1 (1.5%), 11 (16.2%), and 7 (10.3%) patients respectively had hypertension, diabetes mellitus, peptic ulcer, asthma, unilateral or bilateral hydronephrosis, and paralysis. The mean nadir PSA level was 22.5 ng/mL (range: 0.01 - 220.25). The mean time to nadir PSA level was 8.9 months (range: 3 - 57). The overall survival rate was 42.6%. There was no significant survival difference between age groups (p = 0.475), relating to the presence of diabetes or hypertension (p = 0.757) or to

the presence of paralysis or hydronephrosis (p = 0.090). The initial PSA level exerted no significant impact on patients' survival (p = 0.461). Neither did the time to PSA nadir (p = 0.263). The PSA nadir less than 4 ng/mL (p = 0.005) and the PSA nadir less than 4 ng/mL achieved in 12 months or less (p = 0.002) were predictive of longer survival rate. The difference in survival rate through the ISUP grade groups was not significant (p = 0.061). **Conclusion:** The overall survival rate was 42.6% at 5 years. Achieving PSA nadir of less than 4 ng/mL in less than 12 months of castration was predictive of longer survival rate in triptorelin-castrated metastatic prostate cancer patients.

Keywords

Metastatic Prostate Cancer, Androgen Deprivation Therapy, Overall Survival, PSA Nadir

1. Introduction

Prostate cancer is the most frequent urological cancer, the second cause of cancer death in males, and its incidence is increasing [1]. It is the first urological cancer in Benin [2] [3] and Cameroon [4]. In West Africa and Benin, most prostate cancers are diagnosed at advanced stages [5] [6] [7] [8] [9]. Androgen deprivation therapy, *i.e.* either a bilateral orchiectomy or continuous use of chemical castration, is the key therapy against metastatic prostate cancer [10]. Chemical armamentarium for castration comprises agonists and antagonists of luteinizing hormone-releasing hormone (LHRH), and androgen-receptors and androgen production pathway targeting agents [10]. In addition to being expensive, chemical castration drugs are hardly available in Benin. Orchiectomy is cheap and easy to perform but most patients in our country reject it as a mutilating procedure. Therefore, we resort to triptorelin, the only LHRH agonist available on our pharmaceutic market in the years 2012s, to treat metastatic prostate cancer patients.

2. Objective

We aim to analyze the survival rate in metastatic prostate cancer patients who underwent triptorelin-based androgen deprivation therapy at the former Military Teaching Hospital of Cotonou from January 1, 2012, to December 31, 2022.

3. Patients and Method

The study site was the former Military Teaching Hospital of Cotonou. From January 1, 2012, to December 31, 2022, we conducted an observational study of a cohort of patients treated with intragluteal injection of triptorelin 11.25 mg every three months. The patient swallowed 50 mg of bicalutamide daily through 30 consecutive days, beginning 8 days before the first injection of triptorelin. Blood was

sampled to measure PSA level 2 days before each next injection of triptorelin. We followed up each patient every 3 months. PSA levels, complaints, urinary tract obstruction complications, skeletal events, or any clinical events were systematically recorded. PSA level was used as the main monitoring tool for patient's response to treatment. Data were retrospectively retrieved from the patients' medical records for analysis. Every patient newly diagnosed with metastatic prostate cancer who had undergone triptorelin-based androgen deprivation therapy was included in the study. We performed a descriptive analysis of qualitative data. Univariate analysis enabled us to evaluate the influence of clinical parameters and pathological characteristics of disease on patients' survival. We also studied the influence of some clinical parameters by comparing patients having a parameter to the patients not having it. Among the parameters which influence on the patients' survival was evaluated, were comorbidities such as hypertension and diabetes, disease complications such as hydronephrosis or neurological deficit, and tumor characteristics such as pre-treatment PSA level and ISUP grade group. As the pattern of per-treatment PSA level decrease is variable from one patient to another, we compared survival rate between patients whose nadir PSA was less than 4 ng/mL and patients whose PSA level was 4 ng/mL or more, and we also compared survival rate between patients whose PSA level dropped below 4 ng/mL in 12 months or less and patients whose nadir PSA dropped below 4 ng/mL in more than 12 months, survival rate between patients whose nadir PSA was below 4 ng/mL in 12 months or less and patients whose nadir PSA level was either below 4 ng/mL in more than 12 months or 4 ng/mL or more in 12 months or more. The statistical significance threshold was p-value < 0.05 within 95% confidence interval. We did all these statistical analyses by means of the software Stata™ version 15. We used Kaplan-Meir method to estimate the overall survival rate in the whole cohort and in specific subgroups of patients. We compared survival rates by using the log-rank test.

4. Results

Patients' demography and clinical parameters are summarized in Table 1 and Table 2. Statistical analysis results are presented in Table 3.

Among 72 patients with metastatic prostate cancer, 68 started the triptorelin-based androgen deprivation therapy. They were 47 through 86 years old. Their mean age was 69.9 ± 9.0 years. Their initial or pre-treatment PSA level ranged from 24.25 to 6334 ng/mL. The mean initial PSA level was 666.1 ± 1214.2 ng/mL.

The nadir PSA level, or the lowest PSA level a patient ever reached during the treatment, ranged from 0.01 to 220.25 ng/mL. The mean nadir PSA level was 22.5 ± 46.1 ng/mL.

The patients achieved the nadir PSA level in 3 through 57 months. The mean time to nadir PSA level was 8.9 ± 9.7 months. 23.5% patients reached a nadir PSA < 4 ng/mL in 12 months or less.

Table 1. Patients' characteristics and evolution (N = 68).

Age and PSA level at diagnosis	Mean (range)
Age (years)	69.9 (47 - 86)
PSA (initial, ng/mL)	666.1 (24.25 - 6334)
Clinical characteristics	**Number of patients (%)**
ISUP grade group	63 (92.6)
1	5 (7.9)
2	8 (12.7)
3	15 (23.8)
4	14 (22.2)
5	21 (33.3)
Paralysis (6 paraplegia* + 1 tetraplegia)	7 (10.3)
Hydronephrosis	11 (16.2)
Hypertension	15 (22.1)
Diabetes	4 (5.9)
Patients' evolution	
Follow-up data	Mean (range)
Follow-up duration (months)	22.1 (3 - 99)
PSA (nadir, ng/mL)	22.5 (0.01 - 220.25)
Time to nadir PSA level	8.9 (3 - 57)
PSA kinetics and deaths	**Number of patients (%)**
PSA < 4 ng/mL in ≤ 12 months	16 (23.6)
Deaths	19 (27.9)

*1 paraplegic patient had also an external oculomotor paralysis.

Table 2. Other clinical data in the patients.

Complications and other treatments	Number of patients (%)
Inguinal hernia	2 (2.9)
Pelvic limb edema (left)	1 (1.5)
Iron + Folic acid for anemia	3 (4.4)
Buprenorphine hydrochloride for pain	4 (5.9)
Zoledronic acid	3 (4.4)
Vitamin D + calcium	5 (7.4)
TURP	15 (22.1)
Ureteral stent	1 (1.5)
Asthma	1 (1.5)
Peptic ulcer	1 (1.5)

Table 3. Analysis of survival rate in the 68 patients' cohort.

	Survival rate (95% confidence interval)			
	1 year	**3 years**	**5 years**	**p-value**
Overall survival[a]	95.2 (82.2 - 98.8)	56.3 (36.0 - 72.4)	42.6 (23.2 - 60.8)	
Age (years)				
<60	75.0 (12.8 - 96.1)	75.0 (12.8 - 96.1)		
60 - 70	82.2 (45.5 - 95.2)	41.1 (10.0 - 70.9)		0.475
70 - 80	94.1 (65.0 - 99.2)	51.3 (20.3 - 75.7)		
>80		80.0 (20.4 - 96.9)		
ISUP grade group[b]				
1	50.0 (0.6 - 91.0)			
2			66.7 (5.4 - 9.5)	
3	85.7 (33.4 - 97.9)	64.3 (15.2 - 90.2)		0.061
4	76.2 (33.2 - 93.5)	19.1 (0.9 - 55.9)		
5	90.9 (50.8 - 98.7)	35.5 (8.6 - 64.5)	11.8 (1.0 - 40.4)	
PSA (initial, ng/mL)				
≤100[c]	80.8 (42.4 - 94.9)			0.461
>100[d]	88.9 (69.4 - 96.3)			
PSA (nadir, ng/mL)				
<4	100	83.1 (47.2 - 95.5)	83.1 (47.2 - 95.5)	0.005
≥4	91.6 (70.2 - 97.8)	29.2 (7.6 - 55.6)	9.7 (0.6 - 34.8)	
<4 in ≤12 mo	100	83.1 (47.2 - 95.5)	83.1 (47.2 - 95.5)	
<4 in >12 mo	100	66.7 (5.4 - 94.5)	0	0.002
≥4 in >12 mo	91.6 (70.2 - 97.8)	29.2 (7.6 - 55.6)	9.7 (0.6 - 34.8)	
Time to PSA nadir				
≤6 months	100	43.7 (17.0 - 67.9)	34.9 (11.3 - 60.2)	
7 - 12 months	100	62.5 (14.2 - 89.3)	62.5 (14.2 - 89.3)	0.263
>12 months	100	83.3 (27.3 - 97.5)	62.5 (14.2 - 89.3)	
HN or paralysis				
Present	86.5 (55.8 - 96.5)		16.5 (1.1 - 48.7)	0.090
Absent	96.2 (75.7 - 99.5)		47.5 (21.3 - 69.9)	
HT or diabetes				
Present	90.9 (50.8 - 98.7)		35.4 (6.1 - 68.0)	0.757
Absent	93.3 (75.7 - 98.3)		38.0 (16.2 - 59.9)	

[a]Overall survival = 17.8 (3.5 - 40.9) at 8 years; [b]Survival rate in ISUP grade group 3 = 32.1 (1.3 - 74.4) at 7 years; [c]Survival rate in PSA ≤ 100 ng/mL patients = 50.5 (13.6 - 79.2) at 4 years 8 years; [d]Survival rate in PSA > 100 ng/mL patients = 39.9 (18.4 - 60.7) at 4 years and 15.0 (1.2 - 44.1) at 8 years; mo = months, HN = hydronephrosis, HT = hypertension.

Of the 68 patients who underwent triptorelin-based androgen deprivation therapy, 15 (22.1%) had hypertension, 4 (5.9%) had diabetes mellitus, 2 (2.9%) had peptic ulcer, 1 (1.5%) had asthma, 11 (16.2%) had unilateral or bilateral hydronephrosis, and 7 (10.3%) had either paraplegia (5 cases), tetraplegia (1 case), or paraplegia and external oculomotor paralysis (1 case).

The tumor grade in 21 (33.3%), 14 (22.2%), 15 (23.8), 8 (12.7%), and 5 (7.9%) patients was respectively ISUP grade groups 5, 4, 3, 2, and 1.

Some patients presented other complications such as inguinal hernia (2 cases), unilateral pelvic limb edema (1 case), and orbital bone metastasis induced exophthalmos (1 case). Additive therapy was necessary in some patients such as oral iron and folic acid for anemia and fatigue (3 cases), sublingual buprenorphine hydrochloride 0.2 mg for painful bones (4 cases), 4 infusions of zoledronic acid 4 mg injected every 4 weeks (3 cases), combined oral vitamin D and calcium (5 cases), transurethral resection of prostate or TURP (15 cases), pigtail ureteral stent insertion (1 case).

As shown in Figure 1, the overall survival rate at 1, 3, and 5 years was respectively 95.2% (95% CI: 82.2 - 98.8), 56.3% (95% CI: 36.0 - 72.4), and 42.6% (95% CI: 23.2 - 60.8). From 8 years on, the overall survival rate was constantly 17.8% (95% CI: 3.5 - 40.9).

Figure 2 shows the influence of age on triptorelin-castrated patients.

The overall survival rate in patients less than 60 years old, 60 through 69 years old, and 70 through 79 years old was respectively 75.0% (95% CI: 12.8 - 96.1), 82.2% (95% CI: 45.5 - 95.2), 94.1% (95% CI: 65.0 - 99.2) at 1 year.

The overall survival rate in patients less than 60 years old, 60 through 69 years old, 70 through 79 years old, and 80 years or more old was respectively 75.0% (95% CI: 12.8 - 96.1), 41.1% (95 CI: 10.0 - 70.9), 51.3% (95% CI: 20.3 - 75.7), and 80.0% (95% CI: 20.4 - 96.9) at 3 years.

There was no significant survival difference between age groups (p = 0.475).

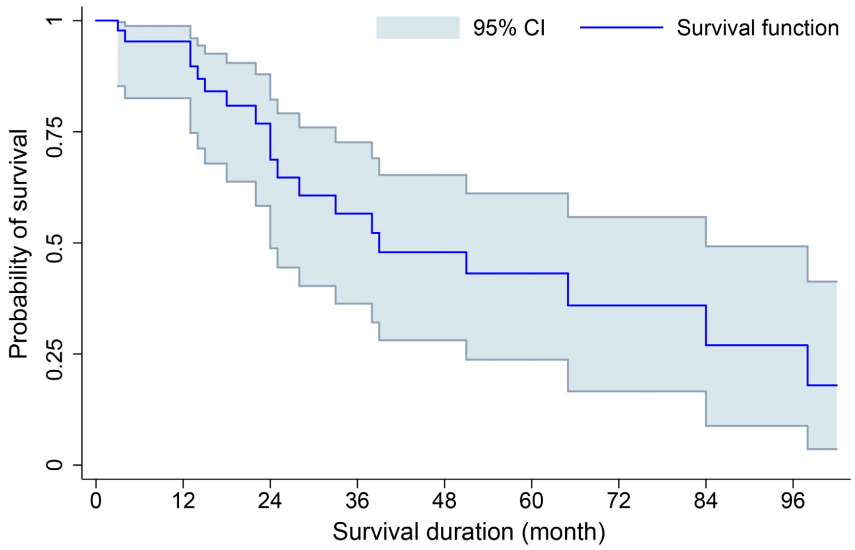

Figure 1. Overall survival in prostate cancer patients treated with triptorelin.

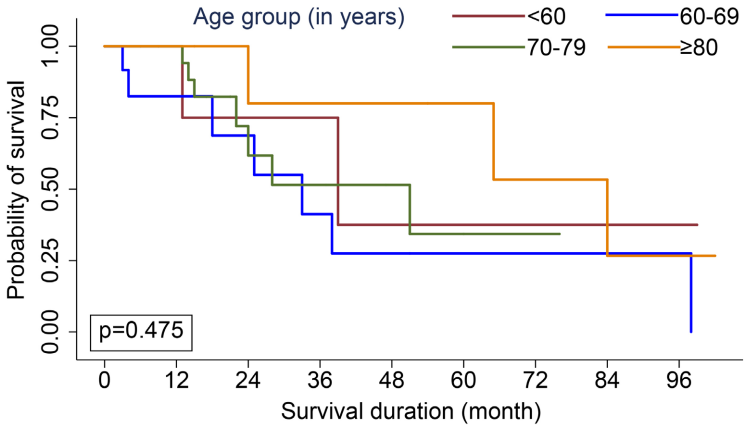

Figure 2. Influence of patients' age on their survival.

The survival rate in patients with hypertension or diabetes and in patients without hypertension or diabetes (**Figure 3**) was respectively, 90.9% (95% CI: 50.8 - 98.7) and 93.3% (95% CI: 75.7 - 98.3) at 1 year, 35.4% (95% CI: 6.1 - 68.0) and 38.0% (95% CI: 16.2 - 59.9) at 5 years. The difference was not significant (p = 0.757).

The survival rate in patients who had hydronephrosis or paralysis and in patients who had neither hydronephrosis nor paralysis was respectively, 86.5% (95% CI: 55.8 - 96.5) and 96.2% (95% CI: 75.7 - 99.5) at 1 year, 16.5% (95% CI: 1.1 - 48.7) and 47.5% (95% CI: 21.3 - 69.9) at 5 years (**Figure 4**). The difference was not significant (p = 0.090).

The survival rate in patients with initial PSA level equal 100 ng/mL or less and the survival rate in patients with initial PSA level above 100 ng/mL were respectively, 80.8% (95% CI: 42.4 - 94.9) and 88.9% (95% CI: 69.4 - 96.3) at 1 year, 50.5% (95% CI: 13.6 - 79.2) and 39.9% (95% CI: 18.4 - 60.7) at 4 years, 50.5% (95% CI: 13.6 - 79.2) and 15.0% (95% CI: 1.2 - 44.1) at 8 years (**Figure 5**). The difference was not significant (p = 0.461).

The survival rates in patients with time to PSA nadir 6 months or less, 7 through 12 months, and more than 12 months, were respectively (**Figure 6**):

- 100% at 1 year, 43.7% (95% CI: 17.0 - 67.9) at 3 years, and 34.9% (95% CI: 11.3 - 60.2) at 5 years.
- 100% at 1 year, 62.5% (95% CI: 14.2 - 89.3) at 3 years, and 62.5% (95% CI: 14.2 - 89.3) at 5 years.
- 100% at 1 year, 83.3% (95% CI: 27.3 - 97.5) at 3 years, and 62.5% (95% CI: 14.2 - 89.3) at 5 years.

There was no significant survival difference according to the time to PSA nadir (p = 0.263).

The survival rate in patients who reached a nadir PSA level of less than 4 ng/mL was 100% at 1 year, 83.1% (95% CI: 47.2 - 95.5) at 3 and 5 years. In patients whose PSA nadir was 4 ng/mL or more, the survival rate was 91.6 (95% CI: 70.2 - 97.8) at 1 year, 29.2 (95%CI: 7.6 - 55.6) at 3 years, and 9.7 (0.6 - 34.8) at 5 years (**Figure 7**). The difference in survival rate was significant (p = 0.005).

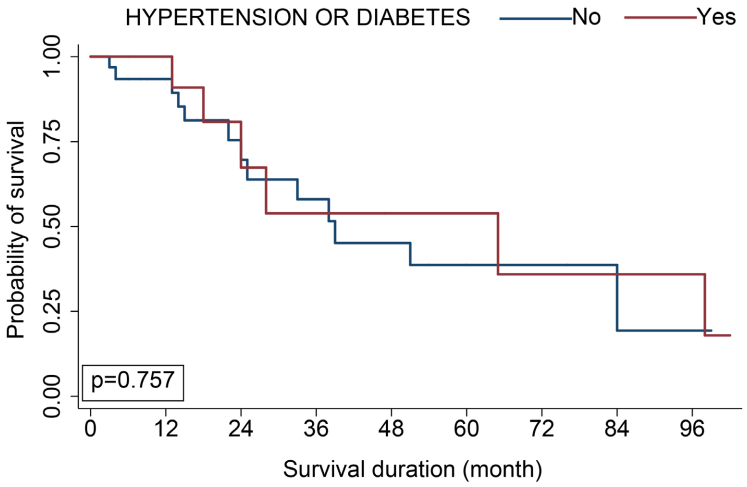

Figure 3. Overall survival rate in patients with or without hypertension and diabetes.

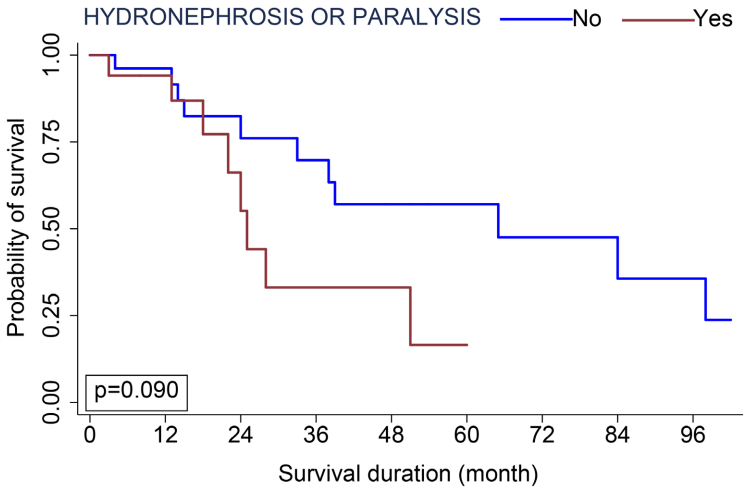

Figure 4. Survival in patients with hydronephrosis or paralysis compared to others.

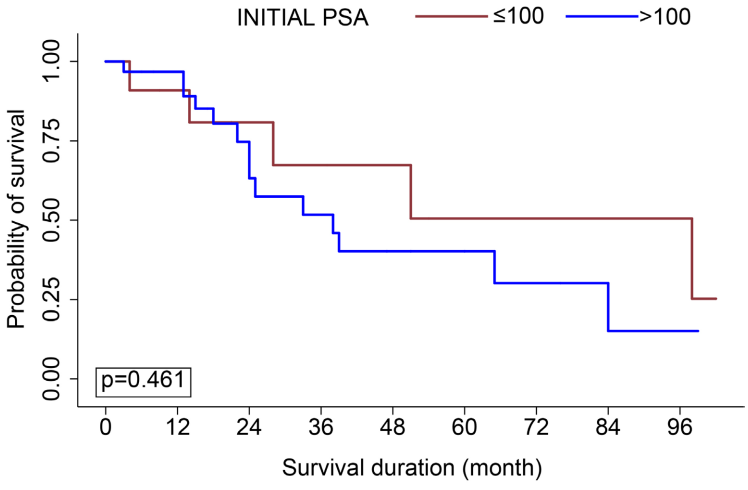

Figure 5. Effect of initial PSA level on patients' survival.

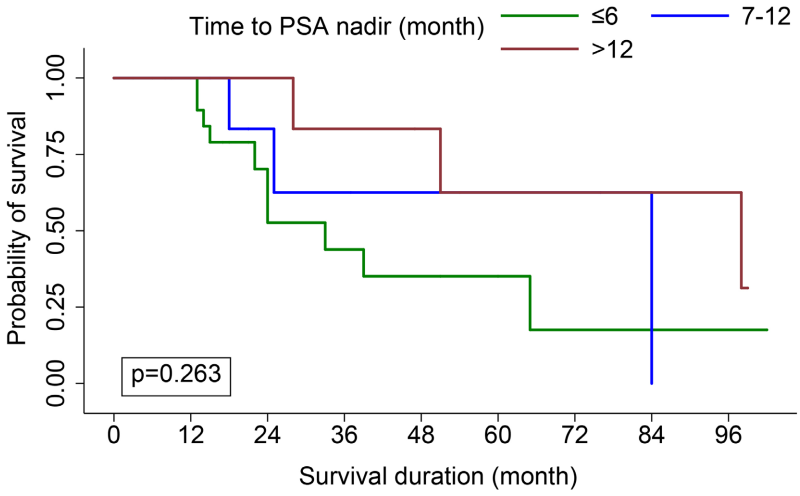

Figure 6. Influence of time to PSA nadir on patients' survival.

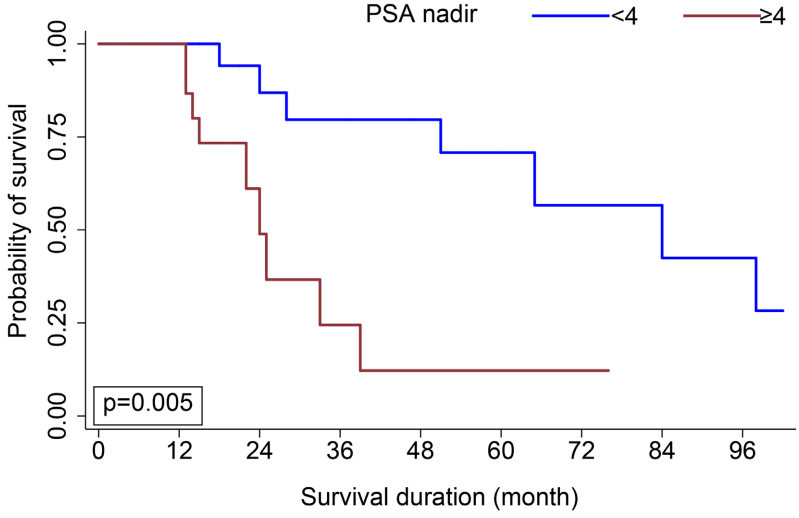

Figure 7. Influence of nadir PSA below or above 4ng/mL on survival rate.

The influence of PSA nadir's kinetic on the patients' survival rate is presented in **Figure 8**.

The survival rate in patients with PSA nadir less than 4 ng/mL in 12 months or less was 100% 1 year, 83.1% (95% CI: 47.2 - 95.5) at 3 years, 83.1% (95% CI: 47.2 - 95.5) at 5 years. In the patients with PSA nadir less than 4 ng/mL in more than 12 months, the survival rate was 100% 1 year, 66.7% (95% CI: 5.4 - 94.5) at 3 years, 0% at 5 years. The survival rate in patients whose PSA nadir never dropped below 4 ng/mL was 91.6% (95% CI: 70.2 - 97.8) at 1 year, 29.2% [95% CI: 7.6 - 55.6) at 3 years, and 9.7% [95% CI: 0.6 - 34.8) at 5 years. The survival rate was significantly different between those groups of patients (p = 0.002).

The survival rate in ISUP grade group 1 was 50.0% (95% CI: 0.6 - 91.0) at 4 months and 0% at 8 years (**Figure 9**).

The survival rate in ISUP grade group 2 patients was 66.7% (95% CI: 5.4 - 9.5) at 5 years and nearly constant thereafter.

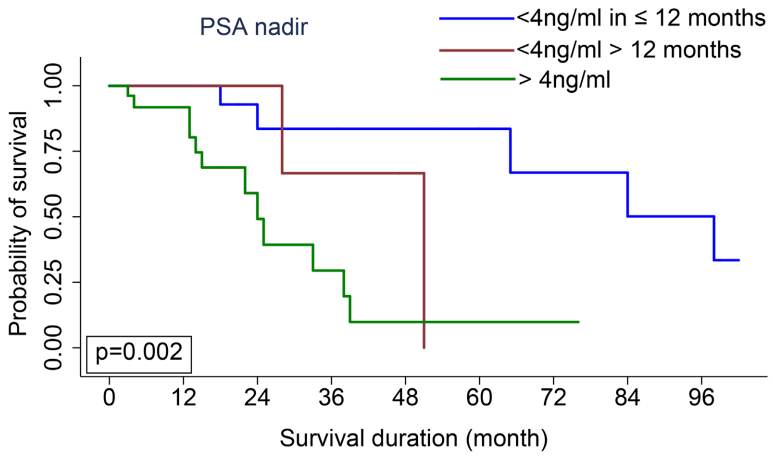

Figure 8. Influence of PSA nadir kinetic on patients' survival rate.

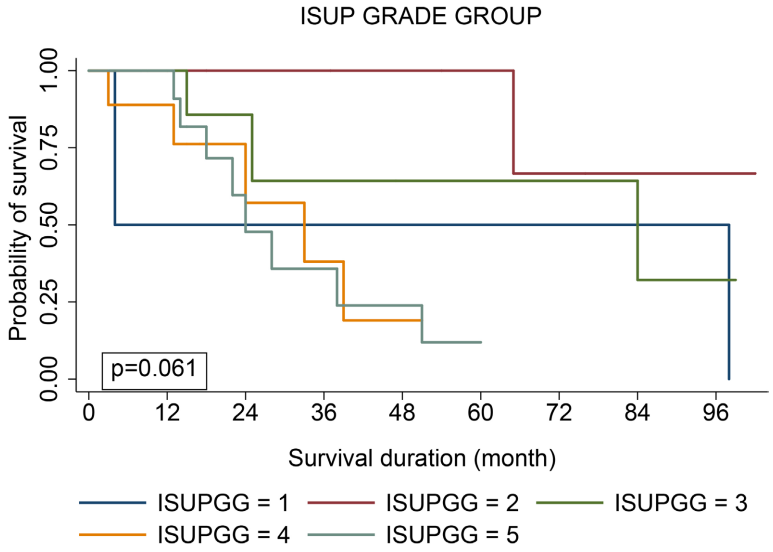

Figure 9. Influence of ISUP grade group on patients' survival rate.

The survival rate in ISUP grade group 3 patients was 85.7% (95% CI: 33.4 - 97.9) at 1 year, 64.3% (95% CI: 15.2 - 90.2) at 3 years, and 32.1% (95% CI: 1.3 - 74.4) at 7 years.

The survival rate in ISUP grade group 4 patients was 88.9% (95% CI: 43.3 - 98.4) at 3 months, 76.2% (95% CI: 33.2 - 93.5) at 1 year, and 19.1% (95% CI: 0.9 - 55.9) at 3 years.

The survival rate in ISUP grade group 5 patients was 90.9% (95% CI: 50.8 - 98.7) at 1 year, 35.5% (95% CI: 8.6 - 64.5) at 3 years, 11.8% (95% CI: 1.0 - 40.4) at 5 years.

The difference of survival rate through the ISUP grade groups was not significant ($p = 0.061$).

5. Discussion

The 68 patients among 72 candidates were able to start the triptorelin-based an-

drogen deprivation therapy. The high cost of triptorelin limited its access to patients who needed it. Still, quite all of them rejected surgical castration for its mutilating effect, which explained that we merely lost to follow-up, those who could not afford chemical castration. Most of them could not afford skeletal events prevention therapy or switching to second line therapy as they became castration resistant.

The overall survival rate in the cohort was 56.3% at 3 years and 42.6% at 5 years which is not far from the median survival of 42 months (or 3.5 years) that James *et al.* [11] estimated in newly diagnosed metastatic prostate cancer patients.

Together with the cancer, demography, comorbidities, tumor characteristics such ISUP grade group, or PSA level might have contributed to patients' survival rate.

On analysis, neither the age nor the presence of comorbidities such as hypertension and diabetes did significantly affect the patients' survival rate. The influence of such complications of advanced prostate cancer as hydronephrosis or skeletal events induced neurological deficit on the patients' survival was not significant. The survival rate in patients with hydronephrosis or paralysis at 5 years was 16.5%, *i.e.* roughly the third of the survival rate of 47.5% in patients with no hydronephrosis and no paralysis. Nevertheless, the difference was not statistically significant. Still, those complications might have contributed to more deaths as they altered the quality of life or the performance status in the affected patients. Ureteral or bladder outlet obstruction and pelvic limbs' neurological deficit frequently complicate metastatic prostate cancer. Our study showed that, despite their evident negative functional impact, metastatic prostate cancer induced hydronephrosis or limbs' paralysis insignificantly reduced the survival rate in the affected patients. De Reijke *et al.* in their patients treated with combined orchiectomy and nilutamide also found that hydronephrosis did not influence the overall survival [12]. In all our paraplegic or tetraplegic patients, the neurological deficit was the complaint which led to the diagnosis of the metastatic prostate cancer. Nevertheless, pelvic limbs' paralysis may also supervene in metastatic prostate cancer patients while castration is ongoing [13]. Furthermore, the survival is insignificantly longer in patients with pretreatment paraplegia compared to patients in whom the paraplegia occurred during castration [13].

The tumor ISUP grade group did not significantly influence the survival rate in the triptorelin-castrated patients. The initial or pre-treatment PSA level or PSA level at diagnosis did not influence the survival in the patients. As for the per-treatment PSA level, its effect was more intricate. A diminishing PSA level might indicate a good response to castration, but it did not necessarily portend a survival gain. Castrated patients who normalized their PSA level, *i.e.* patients in per-treatment PSA level decreased from its initial level down to a level below 4 ng/mL, lived longer than the others. As for the kinetics of per-treatment PSA level, the time to PSA nadir did not influence the survival rate but the survival

rate in patients who reached a PSA nadir < 4 ng/mL in the first 12 months of castration was higher than the survival rate in the patients whose PSA nadir became less than 4 ng/mL beyond the first 12 months of castration. Thus, achieving a PSA nadir < 4 ng/mL in ≤ 12 months much more than merely reaching a PSA nadir < 4 ng/mL was predictive of longer survival. In 2006, Hussain *et al.* demonstrated that at 7 months of castration, patients whose PSA level dropped below 4 ng/mL lived longer, and that below 4 ng/mL, the patients whose PSA level dropped below 0.2 ng/mL lived even longer [14]. Ndiaye *et al.* in 2020, demonstrated that time to PSA nadir significantly influenced the development of cancer resistance to castration [15]. Harshman *et al.* observed that the prostate-specific antigen demonstrated its prognostic role in metastatic prostate cancer even when castration is associated with chemotherapy [16].

6. Conclusion

The overall survival rate was 42.6% at 5 years. Achieving PSA nadir less than 4 ng/mL in less than 12 months of castration was predictive of longer survival rate in triptorelin-castrated metastatic prostate cancer patients. Patients' age, comorbidities such as hypertension and diabetes, pre-treatment PSA level, ISUP grade group, and prostate cancer complications such as hydronephrosis and neurological deficit did not influence the patients' survival rate.

Limitations

The main limitation of this study is that the population's size is relatively reduced.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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