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ORIGINAL PAPER

Stereotactic radiotherapy in oligometastatic prostate cancer: A single-center experience

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Summary ***Introduction: Oligometastatic prostate cancer represents an intermediate disease state potentially amenable to metastasis-directed therapies such as stereotactic body radiotherapy (SBRT), aiming to delay disease progression and postpone systemic treatment.***

Aim: The aim of this study was to evaluate the real-world outcomes of SBRT in patients with hormone-sensitive oligometastatic prostate cancer.

Methods: This single-center retrospective study included patients with hormone-sensitive oligometastatic prostate cancer staged with PSMA PET and treated with SBRT at a tertiary center between January 2022 and March 2024. The primary endpoint was hormone therapy-free survival (HTFS). Secondary endpoints included event-free survival (EFS), local control, overall survival (OS), and toxicity.

Results: A total of 34 patients were included, predominantly with low-volume disease (79.4% with a single metastasis). SBRT achieved significant biochemical responses (PSA50 in 69.7%; median PSA nadir 0.19 ng/mL). HTFS rates were 85.2% and 74.6% at 12 and 24 months, respectively, with the median not reached. Median EFS was 16.2 months. Local control was 84.2%, and 24-month OS was 87.8%. Toxicity was minimal, with no grade ≥ 3 adverse events. A PSA nadir ≤ 0.20 ng/mL and ISUP ≤ 2 were associated with improved outcomes.

Conclusions: SBRT may delay systemic therapy without compromising disease control in oligometastatic prostate cancer. Its integration into personalized treatment strategies, guided by biological and biochemical factors, represents a promising therapeutic approach.

KEY WORDS: *Stereotactic radiotherapy; Prostate neoplasms; Oligometastatic disease; Event-free survival; Androgen deprivation therapy; PSMA PET.*

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INTRODUCTION

Prostate cancer remains one of the most prevalent malignancies among men worldwide, ranking as the second most frequently diagnosed cancer and the fifth leading cause of cancer-related mortality. According to GLOBOCAN 2022, approximately 1.5 million new cases and 397,000 deaths were reported, reflecting a substantial clinical and economic burden (1). The rising incidence is likely related to population aging, widespread use of *prostate-specific antigen* (PSA) testing, advances in early detection, and improved access to healthcare (1, 2).

The clinical course of prostate cancer is highly heterogeneous, ranging from indolent, organ-confined disease to aggressive forms progressing to locally advanced or metastatic stages. Androgen receptor signaling plays a central role in disease progression, making *androgen deprivation therapy* (ADT) the cornerstone of treatment in advanced disease. However, despite initial responses, many patients eventually develop castration-resistant prostate cancer, often associated with metastatic spread and poorer outcomes (2, 3).

Advances in imaging, particularly PSMA PET, have significantly reshaped the management of prostate cancer by enabling earlier and more accurate detection of limited metastatic disease, outperforming conventional imaging techniques (4). This has contributed to refining the concept of oligometastatic prostate cancer, defined as a limited number of metastatic lesions, typically up to 3-5, representing an intermediate state between localized and widespread disease (5, 6). This concept has been further refined in contemporary consensus statements and guidelines (7, 8).

This state may represent a therapeutic window in which *metastasis-directed therapy* (MDT), including SBRT, can delay disease progression and defer systemic treatment. SBRT enables the delivery of high-dose radiation with high precision over a limited number of fractions, achieving effective local control with low toxicity (9).

Prospective randomized trials such as STOMP and ORIOLE have demonstrated that MDT can delay systemic therapy and reduce early disease progression (10, 11). Subsequent studies have confirmed high local control rates and favorable safety profiles, leading to the inclusion of SBRT as a treatment option in international guidelines (8, 9, 12, 13).

Despite these advances, uncertainties remain regarding optimal patient selection, the role of concomitant ADT, and the long-term impact on survival. Moreover, most available data derive from highly specialized centers, limiting generalizability.

The aim of this study was to evaluate the real-world experience of a tertiary center in the treatment of patients with hormone-sensitive oligometastatic prostate cancer using

SBRT, focusing on its role in delaying systemic therapy while maintaining disease control.

Materials and methods

This was a retrospective, observational, non-interventional study based on the analysis of clinical records of patients with hormone-sensitive oligometastatic prostate cancer treated with SBRT at a tertiary center between January 2022 and March 2024.

The study was approved by the *Ethics Committee of the Faculty of Medicine of the University of Coimbra* (CE 239-2025). Given the retrospective design, the requirement for informed consent was waived in accordance with applicable national legislation.

Eligible patients were adult men (≥ 18 years) with histologically confirmed prostate adenocarcinoma, previously treated with curative intent, who developed oligometastatic recurrence (≤ 5 lesions) documented by PSMA PET and were treated with SBRT in the hormone-sensitive setting. Patients with polymetastatic disease (> 5 lesions), absence of PSMA PET staging, treatment modalities other than SBRT, or insufficient clinical data were excluded. Patient selection was performed within a multidisciplinary team setting.

Data were retrospectively collected from electronic medical records and organized into an anonymized database. Variables included demographic data, primary tumor characteristics (ISUP grade and pathological stage), prior treatments, and features of oligometastatic disease, including lesion location, number, size, SUVmax, and pre-SBRT PSA levels. Time to oligorecurrence was defined as the interval between primary treatment and imaging-confirmed recurrence and categorized as ≤ 36 months or > 36 months.

SBRT was delivered using *volumetric modulated arc therapy* (VMAT) with cone-beam CT image guidance, in accordance with ESTRO-ACROP recommendations. The *gross tumor volume* (GTV) corresponded to lesions identified on PSMA PET, with expansion to *planning target volume* (PTV) according to anatomical location. Dose constraints for organs at risk were applied based on institutional protocols. Ultra-hypofractionated regimens (24-30 Gy in 3-5 fractions) were used.

Patients were followed with PSA measurements every 3-6 months, and imaging reassessment was performed as clinically indicated. Biochemical response parameters included PSA nadir, ≥ 50% PSA reduction (PSA50), and time to PSA nadir.

The primary endpoint was HTFS, defined as the time from SBRT to initiation of ADT. Secondary endpoints included EFS, OS, biochemical progression (≥ 25% PSA increase from nadir), radiological progression, local control, and development of new metastases. Toxicity was assessed using CTCAE version 5.0.

Categorical variables were summarized as frequencies and percentages, and continuous variables as median and *interquartile range* (IQR). Survival outcomes were estimated using the Kaplan-Meier method and compared using the log-rank test. A two-sided p-value < 0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics (*version 27.0; IBM Corp., Armonk, NY, USA*).

Results

Patient characteristics

Between January 2022 and March 2024, 34 patients with hormone-sensitive oligometastatic prostate adenocarcinoma were treated with SBRT at our institution. Baseline characteristics are summarized in Table 1.

The median age at SBRT was 73.5 years (IQR 64.0-78.0). Most patients had intermediate-risk disease, with a predominance of ISUP grade ≤ 2 (73.5%). Primary treatment consisted mainly of radical prostatectomy (97.1%), with locally advanced disease (≥ pT3) in 58.8%. Only one patient had nodal involvement at surgery.

Before developing oligometastatic disease, 22 patients (64.7%) received at least one additional therapy, most commonly salvage radiotherapy. The most frequent metastatic site was nodal (52.9%), followed by bone (29.4%) and locoregional recurrence (23.5%). Most patients presented with a single metastatic lesion (79.4%), while 20.6% had two or more lesions.

The median size of the largest metastasis was 10 mm (IQR

Table 1.
Baseline clinicopathological characteristics of the cohort.

Variable	Category	N (%) or Median (IQR)
Age (years)	-	73.5 (IQR: 64.0-78.0)
ISUP Grade Group	≤ 2	25 (73.5%)
	≥ 3	8 (23.5%)
Primary Treatment	Radical Prostatectomy	33 (97.1%)
	Radical Radiotherapy	1 (2.9%)
Pathological T stage (pT)	≤ pT2	11 (32.4%)
	≥ pT3	20 (58.8%)
Nodal Involvement (pN1)	Yes	1 (2.9%)
Previous Adjuvant Treatments	Salvage radiotherapy	15 (44.1%)
	Adjuvant hormone therapy	5 (14.7%)
	Adjuvant radiotherapy	3 (8.8%)
	Other treatments	3 (8.8%)
Metastatic Site	Bone	10 (29.4%)
	Nodal	18 (52.9%)
	Locoregional recurrence	8 (23.5%)
Number of metastases	1	27 (79.4%)
	≥ 2	7 (20.6%)
Largest Metastasis Size (mm)	-	10 mm (IQR: 8-15)
SUVmax (PET-PSMA)	-	9.8 (IQR: 6.6-27.1)
Pre-SBRT PSA (ng/mL)	-	0.64 ng/mL (IQR: 0.35-1.22)
Time to Oligorecurrence (months)	≤ 36 months	7 (21.2%)
	> 36 meses	26 (78.8)

8-15), median pre-SBRT PSA was 0.64 ng/mL (IQR 0.35-1.22), and median PSMA PET SUVmax was 9.8 (IQR 6.6-27.1). Median time to oligorecurrence was 90.2 months (IQR 43.8-155.1), exceeding 36 months in 78.8% of patients.

Treatment and biochemical response

The median total SBRT dose was 30 Gy (range 28.5-30), delivered in 5 fractions (range 3-5), corresponding to a median dose per fraction of 6 Gy (range 6-10). The most frequently used regimen was 30 Gy in 5 fractions (82.4%), followed by 30 Gy in 3 fractions (14.7%) and 24 Gy in 3 fractions (2.9%).

A PSA50 response was observed in 23 patients (69.7%). At first evaluation ≥ 3 months after SBRT, median PSA was 0.33 ng/mL (IQR 0.12-0.71), corresponding to a median relative decline of 50.0% (IQR 7.2-75.0).

Median PSA nadir was 0.19 ng/mL (IQR 0.06-0.42), reached after a median of 5.8 months (IQR 3.5-8.5). Among 33 evaluable patients, 18 (54.5%) achieved a PSA nadir ≤ 0.20 ng/mL. Median follow-up was 30.4 months (95% CI 27.1-33.6). At last follow-up, median PSA was 0.26 ng/mL (IQR 0.06-0.59).

Oncologic outcomes

Hormone Therapy-Free Survival (Primary Endpoint): During follow-up, 11 patients (32.4%) initiated ADT, at a median PSA of 1.67 ng/mL (IQR 0.71-3.04). Treatment consisted of LHRH agonist alone in 5 patients (14.7%), androgen receptor pathway inhibitors (ARPI) alone in 4 (11.8%), and combination therapy in 2 (5.9%).

Median HTFS was not reached. Estimated HTFS rates at 12 and 24 months were 85.2% (95% CI 73.2-97.2) and 74.6% (95% CI 59.3-89.9), respectively (Figure 1). Among patients initiating ADT, 4 (36.4%) required treatment escalation after a median of 6.0 months (IQR 5.1-9.1).

Event-Free Survival (EFS): During follow-up, 27 patients (79.4%) experienced progression. The first event was biochemical progression in 22 patients (81.5%), radiological progression in 2 (7.4%), initiation of ADT in 2 (7.4%), and death in 1 (3.7%).

Overall, biochemical progression occurred in 23 patients (67.6%) after a median of 16.1 months (IQR 8.5-25.9). Median EFS was 16.2 months (95% CI 9.0-23.4), with estimated rates of 61.8% (95% CI 45.5-78.1) and 40.7% (95% CI 24.0-57.4) at 12 and 24 months, respectively (Figure 2).

Local Control and New Metastases: Post-SBRT imaging was available in 19 patients, of whom 16 maintained local control (84.2%). New metastases developed in 13 patients (68.4%) after a median of 17.9 months (IQR 12.2-24.2), most frequently in bone and lymph nodes (38.5% each), followed by the prostate bed (23.1%).

Among 14 patients with documented progression patterns, progression was predominantly driven by new metastases (78.6%), while isolated local failure was uncommon (7.1%).

Overall Survival (OS): Four deaths (11.8%) occurred during follow-up, none were attributed to prostate cancer. Median OS was not reached, with estimated survival rates of 97.1% and 87.8% at 12 and 24 months, respectively.

Figure 1.
Kaplan-Meier curve for HTFS.

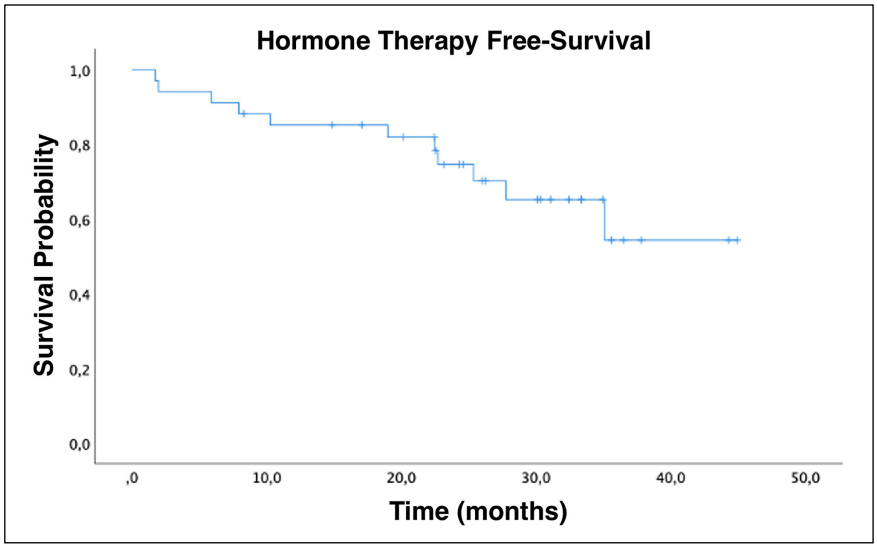

Figure 2.
Kaplan-Meier curve for EFS.

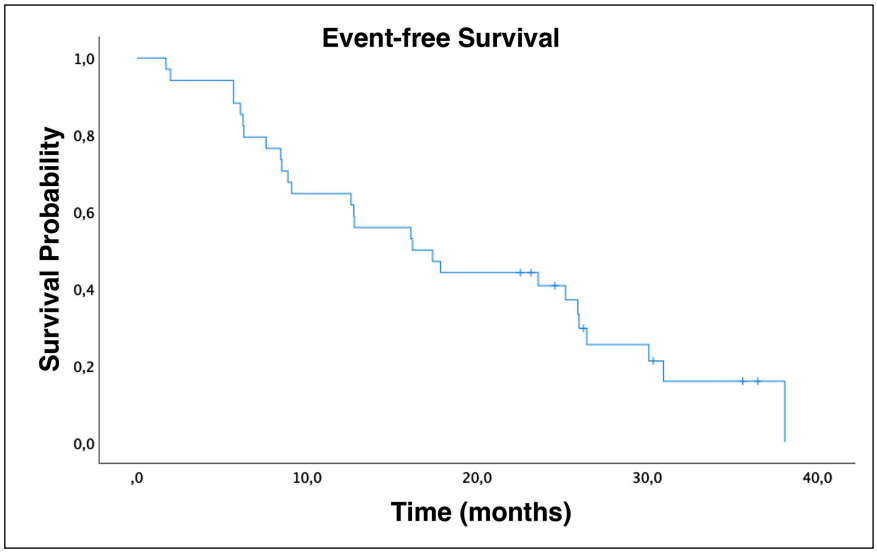

Table 2.
Univariate Cox proportional hazards regression analyses of prognostic factors for hormone therapy–free survival and event-free survival.

Variable	HR	IC 95%	P
Hormone therapy–free survival (HTFS)			
ISUP ≥ 3 vs ≤ 2	5.58	1.5-19.8	0.008
≥ 2 *vs* 1 metastases	0.86	0.19-4.03	0.855
Time to Oligorecurrence > 36 *vs* ≤ 36 months	0.50	0.15-1.73	0.274
Bone vs on-bone metastases	1.00	0.26-3.89	0.995
Pre-SBRT PSA (ng/mL)	0.99	0.69-1.43	0.960
PSA50 response (≥ 50% *vs* < 50%)	0.36	0.09-1.38	0.136
Nadir PSA (≤ 0.20 ng/mL *vs* > 0.20 ng/mL)	0.12	0.03-0.60	0.010
Event-Free Survival (EFS)			
ISUP ≥ 3 *vs* ≤ 2	3.20	1.25-8.23	0.016
≥ 2 *vs* 1 metastases	0.92	0.37-2.30	0.850
Time to Oligorecurrence > 36 *vs* ≤ 36 months	0.66	0.26-1.68	0.383
Bone vs on-bone metastases	1.57	0.69-3.56	0.280
Pre-SBRT PSA (ng/mL)	0.88	0.68-1.14	0.328
PSA50 response (≥ 50% *vs* < 50%)	0.45	0.20-1.02	0.056
Nadir PSA (≤ 0.20 ng/mL *vs* > 0.20 ng/mL)	0.14	0.05-0.45	0.001

Table 3.
Univariable survival analyses according to Ki67 and PSA-IHC expression (simplified). Only significant associations are presented. No relevant differences were observed for rPFS or CRPC-FS.

HTFS			
Variable	**Group**	**HTFS 24 months (%)**	**p (log-rank)**
ISUP	≤ 2 ≥ 3	81.4% 45%	0.003
Nadir PSA	≤ 0.20 ng/mL > 0.20 ng/mL	87.2% 54.2%	0.002
PSA50	≥ 50% reduction < 50% reduction	NA 65.0%	0.120
Bone metastases	No Yes	72.7% 66.7%	0.995
Metastases number	1 ≥ 2	75.7% NA	0.855
Time to Oligorecurrence	≤ 36 months > 36 months	53.6% 73.7%	0.265
EFS			
Variable	**Group**	**Median EFS (IC95%)**	**p (log-rank)**
ISUP	≤ 2 ≥ 3	25.9 months (22.7-29.2) 23.2 months (15.0-31.4)	0.010
Nadir PSA	≤ 0.20 ng/mL > 0.20 ng/mL	26.4 months (25.5-27.4) 12.6 months (7.7-17.5)	< 0.001
PSA50	≥ 50% reduction < 50% reduction	25.2 months (14.7-35.7) 8.9 months (7.9-9.9)	0.051
Bone metastases	No Yes	16.2 months (0-32.4) 12.6 months (0-26.3)	0.276
Nº metástases	1 ≥ 2	16.2 months (8.4-24.0) 25.2 months (0-66.5)	0.853
Time to Oligorecurrence	≤ 36 months > 36 months	16.2 months (0-36.1) 16.1 months (3.2-29.0)	0.378

NA: Not assessed due to the small number of patients at risk.

Toxicity

Treatment-related adverse events were reported in 4 patients (11.8%), all of low grade: grade 1 in 3 patients (8.8%) and grade 2 in 1 (2.9%). The most frequent toxicity was genitourinary, namely urinary incontinence (8.8%). One case of localized bone pain (2.9%) was also observed.
All events were late; no acute toxicity or grade ≥ 3 adverse events were reported.

Prognostic factors and subgroup analysis

In univariate analysis, ISUP grade and PSA nadir ≤ 0.20 ng/mL were significantly associated with both HTFS and EFS. Patients with ISUP ≥ 3 and those not achieving a PSA nadir ≤ 0.20 ng/mL had worse outcomes.
PSA50 showed a trend toward association with EFS but did not reach statistical significance. No significant associations were observed for other variables.
In subgroup analyses, HTFS at 24 months was significantly lower in patients with ISUP ≥ 3 and PSA nadir > 0.20 ng/mL. Similar findings were observed for EFS. No significant differences were identified according to metastatic site, number of lesions, or time to oligorecurrence (Tables 2, 3).

Discussion

This study supports the role of SBRT in hormone-sensitive oligometastatic prostate cancer as an effective strategy to delay the initiation of androgen deprivation therapy, without compromising short- to mid-term disease control. HTFS, as the primary endpoint, is particularly relevant in this setting, as it reflects not only tumor control but also preservation of quality of life by postponing the adverse effects associated with ADT. These findings are consistent with the STOMP and ORIOLE trials, which demonstrated that metastasis-directed therapy can delay systemic treatment and reduce early disease progression in selected patients (10, 11).
The systematic use of PSMA PET for staging represents a key strength of this study. Current evidence suggests that the efficacy of SBRT depends on the ability to identify and treat all macroscopic disease, with untreated lesions associated with a higher risk of progression (4, 11). In this context, PSMA PET likely contributes to improved patient selection and optimization of outcomes (4, 8).
Despite the favorable HTFS outcomes, the EFS results and progression patterns highlight the systemic nature of the disease, even in the oligometastatic setting. The predomi-

nance of new metastases as the main pattern of failure suggests the presence of undetected micrometastatic disease, consistent with previous reports (9, 12, 14, 15). While SBRT provides excellent local control, distant progression remains its main limitation, explaining its greater impact on intermediate endpoints rather than overall survival (9, 16).

Prognostic factors played an important role in outcome stratification. A PSA nadir ≤ 0.20 ng/mL was associated with improved HTFS and EFS, representing a potentially useful marker of treatment response, consistent with prior PSMA-guided studies (12, 14). In contrast, PSA50 showed less prognostic consistency, possibly reflecting variability in early PSA kinetics.

The association between ISUP grade ≥ 3 and worse outcomes further underscores the importance of tumor biology, suggesting that not all patients benefit equally from a purely local approach (2, 3, 10). In patients with more aggressive disease, SBRT may need to be integrated into a broader therapeutic strategy.

Emerging evidence, including the RADIOSA trial, supports this concept, demonstrating a benefit from combining SBRT with short-course ADT in selected patients (17). These findings highlight the need for individualized treatment strategies based on clinical and biological characteristics.

Overall survival outcomes should be interpreted cautiously. The high survival rates and absence of disease-specific mortality reflect the relatively indolent course of oligometastatic disease, while the limited follow-up and sample size preclude definitive conclusions regarding survival benefit (9, 16).

SBRT demonstrated a favorable safety profile, with low toxicity and no grade ≥ 3 adverse events, consistent with existing literature and supporting its feasibility in routine clinical practice (9, 11, 12, 15).

This study has several limitations, including its retrospective design, small sample size, and potential selection bias.

Additionally, HTFS may be influenced by clinical decision-making rather than purely biological factors. The lack of systematic imaging in all patients also limits the assessment of progression patterns.

This study provides real-world evidence supporting SBRT as a safe and effective treatment option in oligometastatic prostate cancer. In particular, its ability to delay the initiation of ADT represents a clinically meaningful benefit.

Outcomes in terms of EFS, local control, and toxicity were consistent with the literature, supporting the role of SBRT in prolonging disease control in selected patients, although without eliminating the risk of systemic progression.

Future efforts should focus on integrating SBRT into personalized treatment strategies based on tumor biology, biochemical response, and metastatic burden.

Declarations

Ethical approval and consent for participate: *This study was conducted in accordance with the principles of the World Medical Association Declaration of Helsinki. Ethical approval was obtained from the Comissão de Ética para a Saúde do Centro Hospitalar e Universitário de Coimbra (Ethics Committee for Health of the Coimbra University Hospital Centre), under protocol number No. CE- 239/2025. Given the retrospective and observational nature of the study, the requirement for informed consent was waived by the Ethics Committee.*

Consent for publication: *Not applicable.*

Availability of data and material: *The datasets generated and/or analyzed during the current study are not publicly available due to ethical and legal restrictions imposed by the hospital's data protection policies, but de-identified data may be available from the corresponding author upon reasonable request and with appropriate institutional approvals.*

Competing interests: *The authors declare that they have no competing interests.*

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Authors' contributions: *AMF: Study conception and design; acquisition of clinical data; data curation; data analysis and interpretation; drafting of the original manuscript; critical revision for important intellectual content; JMC: Data curation; data analysis and interpretation; preparation of tables and figures; drafting of sections of the manuscript; ETS: Data curation; data analysis and interpretation; critical revision of the manuscript; PN: Study conception and design; supervision; contribution to manuscript writing and editing; critical revision for important intellectual content; AF: Study conception and design; supervision; critical revision for important intellectual content; final approval of the manuscript;*

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