Trajectory timelines and treatment efficacy of ^{177}Lu-PSMA-617 radioligand therapy for metastatic castration-resistant prostate cancer: Real-world data from 50 consecutive cases treated in a single Canadian center

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ABSTRACT

Introduction: We aimed to evaluate the efficacy and safety of lutetium-177-PSMA-617 in patients with metastatic castration-resistant prostate cancer (mCRPC) following approval in the real-world Canadian clinical context.

Methods: Data on the first 50 patients with mCRPC who were treated with lutetium-177-PSMA-617 at a single center in Quebec, Canada, were retrospectively analyzed. Patients were treated with 7.4 GBq of lutetium-177-PSMA-617 administered every six weeks for up to six cycles.

Results: Median (95% confidence interval [CI]) patient age and pre-radioligand therapy prostate-specific antigen levels were 72.55 (65.92–76.77) years and 49.19 (15.61–180.65)

KEY MESSAGES

- 177Lu-PSMA-617 was effectively implemented in a universal healthcare system in Québec, demonstrating real-world feasibility outside of clinical trials.
- Only 26% of patients completed all six cycles of 177Lu-PSMA-617, with PSA declines of ≥50% in 51% of patients and a median overall survival of 13.0 months after a mean followup of 8.5 months, aligning with outcomes seen in the phase 3 VISION trial.
- The study's retrospective nature and limited followup duration constrain the robustness of long-term safety and efficacy conclusions.

ng/mL, respectively. Median (95% CI) time between oncologist referral for radioligand therapy and nuclear medicine consultation or first dose of lutetium-177-PSMA-617 were 12 (7.0–32.0) and 42 (28.0–54.0) days, respectively. Overall, 26.0% of patients completed six radioligand therapy cycles. Declines in prostate-specific antigen levels of 25%, 50%, and 90% were reached in 57%, 51%, and 17% of patients, after a median of two, two, and three cycles, respectively. At last followup, after a mean followup time of 8.5 months, 61% (25/41) of patients not on ongoing therapy were alive, with an estimated median overall survival of 13.0 months (95% CI 8.0–not reached).

Conclusions: Real-world data show that use of lutetium-177-PSMA-617 in patients with mCRPC is feasible in a universal healthcare system, with comparable oncologic activity to that observed in the phase 3 VISION trial. The study is limited by the short followup and its retrospective nature.

INTRODUCTION

In 2022, lutetium-177 (^{177}Lu)-PSMA-617 (^{177}Lu vipivotide tetraxetan) was approved by Health Canada, the United States (US) Food and Drug Administration (FDA), and the European Medicines Agency (EMA) for patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC).[1-3] These approvals were based on the results of the phase III VISION trial, which showed prolonged progression-free survival (PFS) and overall survival (OS) with the addition of ^{177}Lu-PSMA-617 to standard of care in patients with PSMA-positive mCRPC previously treated with ≥1 androgen receptor pathway inhibitor (ARPI) as well as taxane-based chemotherapy.[4]

However, clinical trials routinely exclude certain clinically relevant patient populations, such as patients with poor functional status, making it important to collect real-world data to understand how to integrate treatments into clinical practice.[5] This is particularly true of ^{177}Lu-PSMA-617, which as the first radioligand therapy (RLT) to be approved for use in metastatic prostate cancer requires nuclear medicine imaging techniques and the involvement of the multidisciplinary team to identify and treat patients who could benefit from this treatment.[6] Several studies have reported on the use of ^{177}Lu-PSMA-617 in real-world clinical practice in the pre-approval setting.[7-11] Recently, several retrospective analyses of data on patients in mCRPC treated with ^{177}Lu-PSMA-617 post-approval in the US have demonstrated antitumor activity and a favorable toxicity profile.[12,13]

However, real-world post-approval data from institutions within a single-payer universal health care system are scarce and no study has yet characterized real-world experience with ^{177}Lu-PSMA-617 in Canada. The objective of this study was to evaluate the efficacy and safety of ^{177}Lu-PSMA-617 in this specific context.

METHODS

This study was a single-center, retrospective analysis of the first 50 patients with mCRPC who were treated with ^{177}Lu-PSMA-617 at the Centre hospitalier universitaire de Québec-Université Laval (CHUQ-UL). We screened the institutional database for patients who had received ≥1 cycle of ^{177}Lu-PSMA-617 between November 2022 and September 2024. To have received ^{177}Lu-PSMA-617, patients had to have mCRPC, have progressed on taxane-based chemotherapy

and ARPI agents, and have had confirmed PSMA-positive lesions, which was defined as having ≥1 PSMA-positive metastatic lesion and no PSMA-negative lesions. The presence of PSMA-positive lesions was defined as gallium-68 (^{68}Ga)-PSMA-11 uptake greater than that of liver parenchyma in ≥1 metastatic lesions of any size in any organ system. Patients with ≥1 fluorine-18 (^{18}F)-fluorodeoxyglucose (FDG)-avid lesions on positron emission tomography (PET) scan that were negative on PSMA-PET/computed tomography (CT) scan were not considered for treatment with 177Lu-PSMA-617.

Because of the retrospective nature and quality improvement aims of this study, informed consent forms were not required; however, a data protection impact assessment was approved by the Québec Commission on Access to Information.

Procedures

Based on the imaging results, the referring oncologist may recommend treatment with ^{177}Lu-PSMA-617 and refer the patient to the nuclear medicine for further evaluation. The nuclear medicine consultation occurs after imaging, to confirm treatment eligibility and discuss the therapy with the patient.

Treatment consisted of 7.4 GBq of ^{177}Lu-PSMA-617 administered every 6 weeks for up to 6 cycles, in the absence of progression or severe toxicity, as determined by the treating physician.

A PSMA-PET/CT scan was conducted at baseline for all patients and 44 patients (88%) also had an FDG-PET/CT scan at baseline. Patient's candidacy for ^{177}Lu-PSMA-617 was determined by nuclear medicine physicians based on single or dual PET results and the absence of a significant volume of non-PSMA avid disease.

A single-photon emission computed tomography (SPECT)/CT scan was typically acquired in the first, third, and fifth treatment cycles to evaluate disease progression on ^{177}Lu-PSMA-617.

Blood was drawn and laboratory assessments performed during each treatment cycle to evaluate the response and tolerance to treatment. Patients were also questioned by the treating physician about possible adverse events (AEs) before each treatment cycle.

Outcomes

Efficacy was determined based on prostate-specific antigen (PSA) response rates and OS. PSA25, PSA50, and PSA90 response rates were defined as percentages of patients who achieved at least 25%, 50%, or 90% decline in PSA relative to baseline at any time during the treatment, respectively. The estimated OS was defined as the time from treatment initiation to death from any cause or last follow-up alive. Patients for whom treatment with ^{177}Lu-PSMA-617 was ongoing were excluded from the OS analysis.

Times from referral for treatment by an oncologist (urology visit) to first consultation with a nuclear medicine specialist, as well as from urology visit to first treatment with ^{177}Lu-PSMA-617 were calculated.

AEs were identified based on information available in clinical records and grading was subsequently assigned following the available description based on the Common Terminology Criteria for Adverse Events (CTCAE) version 5.

Statistical analysis

Categorical variables are presented as number and percentage, while median and range are presented for continuous variables. Kaplan-Meier analysis was used to calculate OS. A *P* value of less than 0.05 was considered statistically significant. Statistical analyses were performed using SAS®.

RESULTS

Patients

The first 50 consecutive patients with mCRPC who were treated with ^{177}Lu-PSMA-617 at the CHUQ-UL were included in the analysis (Figure 1). The median age of these patients was 72 years (interquartile range [IQR] 65.92–76.77) at the time of the first treatment cycle (Table 1). Of these 50 patients, 45 (90%) had an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0–1 and 37 (74%) had previously received ≥3 lines of treatment for mCRPC at baseline. Overall, 31/50 patients (62%) had bone metastases at baseline, with 15/50 patients (30%) having visceral metastases.

The median time from consultation with an oncologist who referred patients for ^{177}Lu-PSMA-617 therapy to consultation with a nuclear medicine specialist was 12 days (range: 7.0–32.0), while the median time from consultation with an oncologist to initiation of treatment with ^{177}Lu-PSMA-617 was 42 days (range: 28.0–54.0) (Figure 2).

At the time of data analysis, 13 patients (26%) had completed 6 cycles of treatment, while treatment was interrupted in 28 patients (56%). Treatment interruption is defined as discontinuation of therapy before completion of the 6 cycles. The reasons for discontinuation varied and included a combination of biochemical, clinical and/or radiographic progressions. Decision to interrupt treatment was taken by treating the nuclear medicine physician and/or oncologist. Treatment was still ongoing for 9 patients (18%). Overall, 23 patients (46%) received >3 cycles of ^{177}Lu-PSMA-617. Of the 41 patients for whom treatment was not ongoing and who were included in OS analyses, 21 patients (51%) had received >3 cycles of ^{177}Lu-PSMA-617 and 13 (32%) had completed the full course of 6 cycles.

Efficacy

Of the 47 patients included in the PSA response analysis (Figure 1), 27 (57%) achieved a 25% decrease in PSA from baseline, while 24 (51%) and 8 (17%) achieved 50% and 90% decreases, respectively (Figure 3). Of the 8 patients who achieved a PSA90 response, 7 had completed all planned treatment cycles, indicating that higher response rates may be associated with treatment completion. Most patients who exhibited a PSA25 response and PSA50 response did so by the second cycle (20/27 patients [74%] and 13/24 patients [54%], respectively), with all responders reaching these responses by the third cycle. Time to PSA90 response was variable; of the 8 PSA90 responders, 2 patients (25%) responded by each of the second, third, and sixth cycles, and 1 patient (12.5%) responded by each of the fourth or fifth cycles (Figure 4). When considering only the 41 patients for whom treatment was not ongoing at the time of data analysis, 22 (56.4%) achieved a 25% decrease in PSA from baseline, while 20 (51.3%) and 8 (20.5%) achieved 50% and 90% decreases, respectively.

For the 41 patients included in the OS analysis (Figure 1), median OS was 13.0 months (95% confidence interval [CI] 8.0–not reached [NR]), with a median follow-up time of 8.5 months (95% CI 6.9–9.9 months) (Figure 5).

Tolerability
The most commonly reported total AEs, based on available chart documentation, were fatigue (n=30), dry mouth (n=26), nausea (n=12), pain (n=11), and anemia (n=8). Of the hematologic AEs reported, anemia (n=8) and thrombocytopenia (n=3) were the most common. Overall, 4 grade 3 AEs were reported in two patients. One patient experienced anemia and two genitourinary AEs but he completed without interruption all cycles of RLT. The other patient had developed a grade 3 hematologic AEs (thrombocytopenia) and was withdrawn from treatment after only one cycle due to rapid deterioration of his condition. Upon grade 4 thrombocytopenia, he was observed prior to cycle 5, but treatment was discontinued due to rapid deterioration of his condition. (Table 2).

DISCUSSION

In this study, we report the real-world efficacy and the trajectories of patients who fulfilled the VISION trial inclusion criteria and received ^{177}Lu-PSMA-617 for mCRPC. While others have also recently reported real-world outcomes with ^{177}Lu-PSMA-617 therapy,[12,13] this study is, to our knowledge, the first real-world series using dual molecular imaging (FDG and PSMA-PET/CT) to select patients for ^{177}Lu-PSMA-617, as well as the first to report outcomes and timelines between clinician referral and the administration of the first dose in a universal health care system.

In the CHUQ-UL cohort, the PSA50 response rate was 53.3% and the median estimated OS was 13.0 months, which is in-line with outcomes reported in the phase III VISION trial setting in which PSA50 response was 46.0% and median OS was 15.3 months.[4] Of note, 88% of the patients included in our study were selected based on dual FDG and PSMA PET imaging results. Although the eligibility was assessed only visually, without strict criteria such as those used in the TheraP trial,[14] this dual-tracer selection might nevertheless have prevented some patients who would have been eligible for ^{177}Lu-PSMA-617 based on the VISION criteria from receiving RLT. This may potentially have improved ^{177}Lu-PSMA-617 efficacy in terms of PSA response, by depleting our cohort of predicted poor-responders (i.e., patients with metabolically active, poorly targeted lesions).

On the other hand, other factors that could have unfavorably impacted ^{177}Lu-PSMA-617 therapy efficacy in terms of OS include the baseline characteristics of the patients, as well as the number of cycles of therapy received. Some baseline characteristics of patients in the CHUQ-UL cohort were similar to those included in the analysis set for imaging-based PFS from the VISION trial (^{177}Lu-PSMA-617 arm). For instance, in the CHUQ-UL cohort (vs. VISION), the median age at therapy start was 72.6 years (vs. 71.0 years) and the median baseline PSA was 60 ng/mL (vs. 90 ng/mL).[4] However, baseline characteristics such as a median number of lines of systemic therapy (excluding androgen deprivation therapy) before ^{177}Lu-PSMA-617 of 3 (vs. 2 in VISION) and a percentage of patients with visceral metastasis of 30% (vs. 21%) may indicate a more advanced disease state in our cohort vs. in the VISION trial,[4] which may have contributed to the shorter OS and may have counterbalanced the intended better selection of patients with dual-tracer PET/CT. Despite thorough analyses, baseline disease characteristics such as metastasis location, grade group, prior lines of treatment, and number of treatment cycles did not significantly correlate with overall survival in our cohort (data not shown). This suggests that the relatively small sample size of our cohort prevented statistical significance or that other factors may contribute more substantially to survival outcomes in this population.

In the CHUQ-UL cohort, patients received a median of 4 cycles of ^{177}Lu-PSMA-617 (vs. 5 in the VISION trial).[4] At first sight, this slight difference in the number of cycles received might have contributed to the OS difference between VISION and this series, particularly given the fact that the number of cycles received was the main factor associated with OS in a multivariate analysis.[15] While the cause of ^{177}Lu-PSMA-617 cessation in the CHUQ-UL cohort remains to be established, the systematic use of SPECT/CT after the third dose is unlikely to have prompted nuclear medicine physicians to stop ^{177}Lu-PSMA-617 earlier without significant clinical or biochemical progression, as the decision to stop the treatment typically relied on a combination of clinical, biochemical and/or imaging progression, and was made by treating the nuclear medicine physician and/or an oncologist and in selected bases after multidisciplinary tumor board selection. The more advanced mCRPC disease in our cohort, leading to earlier progression despite better initial PSA response, is likely to have prevented treatment completion in most cases and shortened the OS. Only 26% of patients in the CHUQ-UL cohort (vs. 45% in VISION) received the full 6 cycles of ^{177}Lu-PSMA-617.[4]

The tolerability profile was favorable, with only 4 grade 3 AEs and 1 grade 4 AE occurring among the 50 patients treated with ^{177}Lu-PSMA-617, which is in-line with previous studies of ^{177}Lu-PSMA-617.[4,14,16] The most commonly occurring AEs were fatigue, dry mouth, nausea, pain, and anemia; however, due to the retrospective nature of the study and the relatively short follow-up (mean of 8.5 months), some adverse events may not have been fully captured. Despite this limitation, our results are in line with the most commonly reported AEs in the VISION trial.[4]

It is important to mention that other studies have also reported on the efficacy and tolerability of ^{177}Lu-PSMA-617 in the real-world setting.[7-13] In these studies, reported PSA50 response rates were between 32% and 61%.[7-13] While these studies demonstrated ^{177}Lu-PSMA-617 efficacy in the real-world setting, they were mostly conducted in high-volume centers with extensive resources. Here we show evidence of both the efficacy and feasibility of using ^{177}Lu-PSMA-617 in the context of a single center within a universal health care system. The median time to treatment initiation in this setting was numerically shorter with that seen in the context of the American health care system, even though imaging and treatment availability remain major limiting factors in real-world setting.[12]

This study has several limitations, mainly due to its retrospective nature. First, criteria for initiation of PSMA-targeted RLT in our practice were less strict and, to some extent, more subjective than in prospective clinical trials with pre-defined eligibility criteria. However, this better reflects the real-world decision-making context. Second, the retrospective nature of the study limited the quality of the AE data, which was largely dependent on the details included in the physician's notes. This might have led to a decrease in the number of AEs reported in this study. Third, our study did not collect conventional imaging radiographic progression data, as is typically done in prospective trials. Instead, the imaging follow-up mostly relied on SPECT/CT after the third and fifth cycles of ^{177}Lu-PSMA-617. Therefore, we decided to not include analysis of conventional imaging radiographic progression as part of this study. Nonetheless, the OS and biochemical response results may be considered rigorous despite the retrospective nature of the analysis.

CONCLUSIONS

The results are consistent with the efficacy and safety of ^{177}Lu-PSMA-617 observed in the VISION trial, in a Canadian real-world clinical setting and support the feasibility of its implementation in the context of a universal health care system.

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FIGURES AND TABLES

Figure 1. Flow diagram for analysis. ^{177}Lu : lutetium-177; CHUQ-UL: Centre hospitalier universitaire de Québec-Université Laval; OS : overall survival; PSA : prostate-specific antigen; RLT: radioligand therapy.

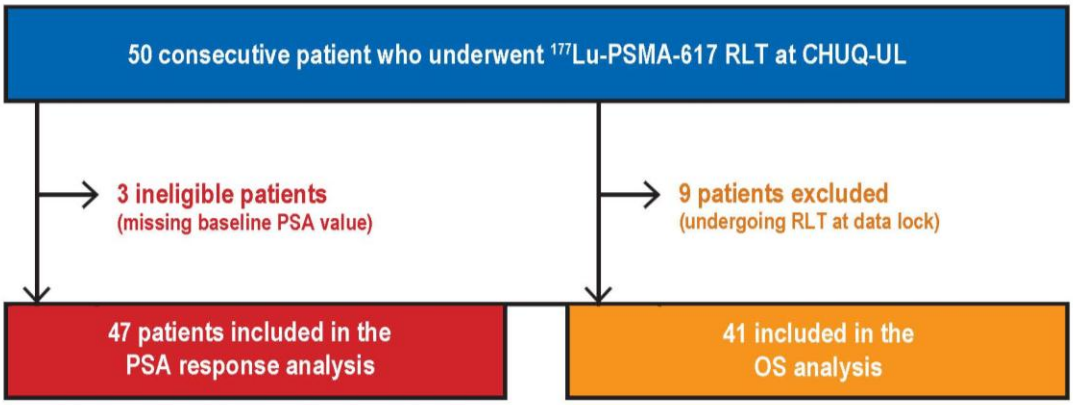

Figure 2. Time from oncology consultation to nuclear medicine consultation and treatment ^{177}Lu: lutetium-177; CT: computed tomography; FDG: fluorodeoxyglucose; PSMA: prostate-specific membrane antigen.

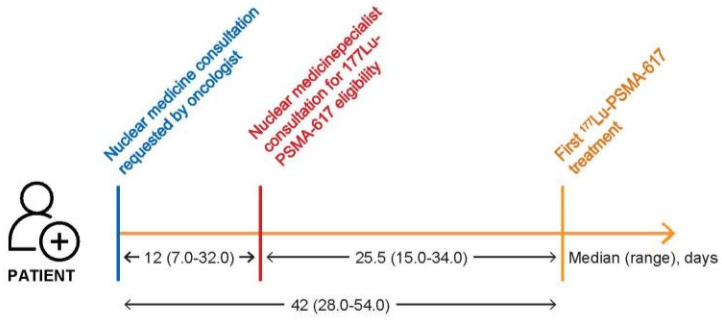

Figure 3. Waterfall plot of best PSA response. (A) Waterfall plot of best PSA response with lutetium-177. (B) Time to reach PSA response. (C) Kaplan-Meier estimated OS. CI: confidence interval; OS: overall survival; PSA: prostate-specific antigen; PSA25: ≥25% reduction in PSA from baseline; PSA50: ≥50% reduction in PSA from baseline; PSA90: ≥90% reduction in PSA from baseline.

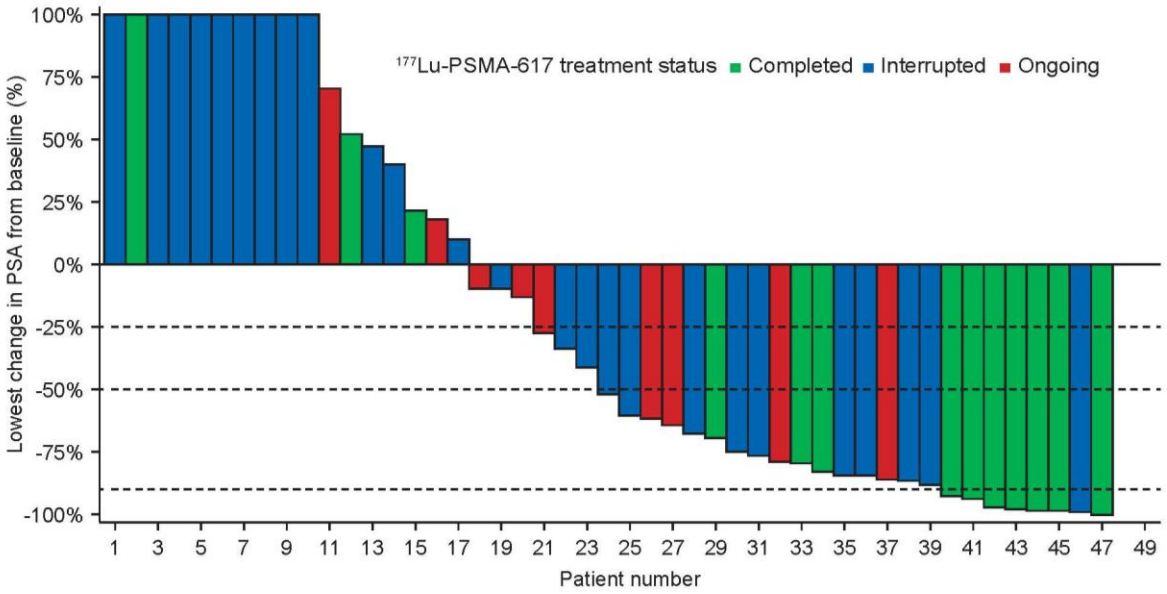

Figure 4. Time to reach prostate-specific antigen (PSA) response.

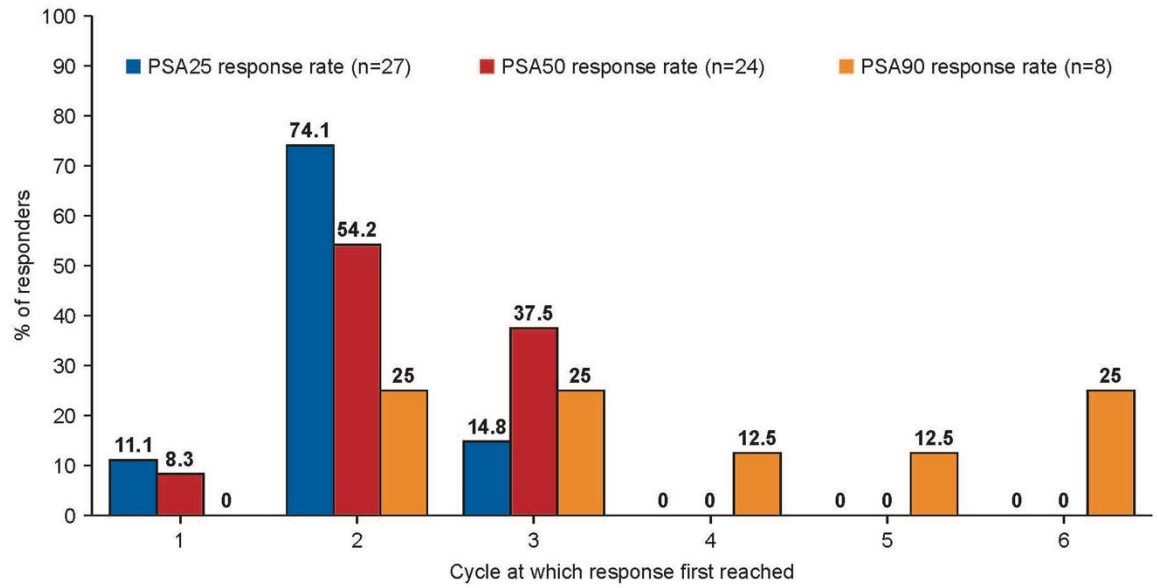

Figure 5. Kaplan-Meier estimated overall survival. CI: confidence interval.

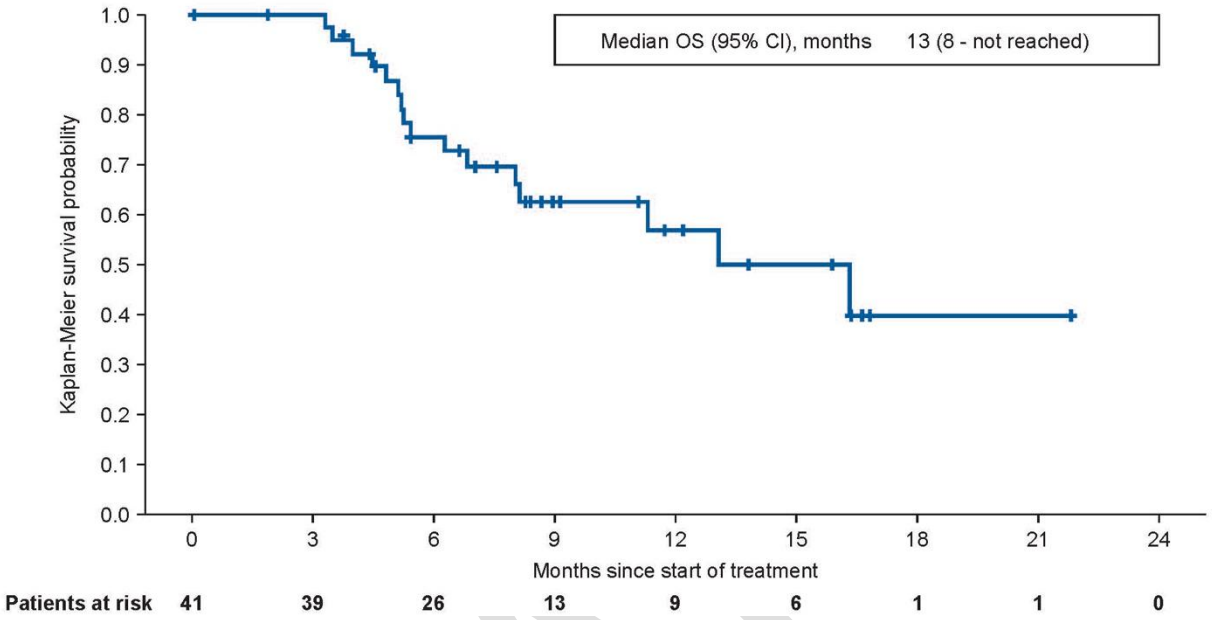

Table 1. Baseline patient characteristics	**All patients (n=50)**	
Age at first ^{177}Lu-PSMA-617 therapy treatment (years)	72.5	65.92–76.77
ECOG PS		
0	15	30.00%
1	30	60.00%
2	5	10.00%
ISUP group at prostate cancer diagnosis		
1	8	16.00%
2	2	4.00%
3	7	14.00%
4	12	24.00%
5	12	24.00%
Unknown	9	18.00%
Time since initial prostate cancer diagnosis[a] (years)	6.46	3.79–10.87
Baseline PSA (ng/mL)[b]	49.19	15.61–180.65
Number of treatment lines before ^{177}Lu-PSMA-617		
2	13	26.0%
3	29	58.0%
4	7	14.0%
5	1	2.0%
Number of metastases assessed by FDG PET[c]		
0	1	2.3%

1–5	6	13.6%
5–10	4	9.1%
>10	24	54.5%
Unknown	9	20.5%
Number of metastases assessed by PSMA PET		
1–5	2	4.0%
5–10	4	8.0%
>10	36	72.0%
Unknown	8	16.0%
Location of metastases by FDG PET[d]		
Bone, any	25	58.1%
Lymph node only	5	11.6%
Visceral	13	30.2%
Location of metastases by PSMA PET		
Bone (only or with lymph node metastases)	31	62.0%
Lymph node only	4	8.0%
Visceral	15	30.0%
Number of ^{177}Lu-PSMA-617 cycles received (including ongoing patients)		
≤3	27	54.0%
>3	23	46.0%
Number of ^{177}Lu-PSMA-617 cycles received (excluding ongoing patients)		
≤3	20	54.0%
>3	21	51.2%
^{177}Lu-PSMA-617 cycles status (excluding ongoing patients)		
Completed (6 cycles received)	13	31.7%
Interrupted	28	68.3%
Ongoing (≥1 cycle received)	9	(NA)

Data are presented as median [range] or n (%). [a]Data missing for 3 patients; [b]Defined as last PSA value before starting ^{177}Lu-PSMA-617 therapy; data missing for 2 patients; [c]Data missing for 6 patients; [d]Data missing for 7 patients. ^{177}Lu: lutetium 177; ECOG: Eastern Cooperative Oncology Group; FDG: fluorodeoxyglucose; ISUP: International Society of Urological Pathology; NA: not applicable; PET: positron emission tomography; PS: performance status; PSA: prostate-specific antigen; PSMA: prostate-specific membrane antigen.

Table 2. Numbers of reported AEs by CTCAE term and grade				
CTCAE V.5	**Grade**			
	1	**2**	**3**	**4**
General				
Fatigue	29	1	0	0
Pain	9	2	0	0
Epigastric discomfort	1	0	0	0
Weight loss	1	0	0	0
Hot flush	1	0	0	0
Sweating	1	0	0	0
Weakness	1	0	0	0
Gastrointestinal				
Dry mouth	25	1	0	0
Nausea	11	1	0	0
Gastrointestinal (constipation or diarrhea)	6	0	0	0
Vomiting	3	0	0	0
Dysgeusia	3	0	0	0
Altered taste	2	0	0	0
Loss of appetite	2	0	0	0
ALP elevation	0	2	0	0
Elevated bilirubin	0	1	0	0
Anorexia	1	0	0	0
Genitourinary				
Genitourinary other	1	0	1	0
Hydronephrosis	0	0	1	0
Renal impairment	0	1	0	0
Hematologic*				
Anemia	2	4	1	0
Thrombocytopenia	0	2	1	1
Lymphocytopenia	0	1	0	0
High ALP	0	1	0	0
Neutropenia	0	1	0	0

*As reported in clinical notes, irrespective of laboratory reports. Data represent number of times specific AEs were reported; note: AEs could be reported multiple times per patient and CTCAE classification was determined taking into account the context described by physicians in the medical notes. AE: adverse event; ALP: alkaline phosphatase; CTCAE: Common Terminology Criteria for Adverse Events.