Real-World Clinical Outcomes Among Localized Prostate Cancer Patients With External Beam Radiation Therapy Across Different Risk Stratifications

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Key Takeaway

There remains a critical unmet need for more effective therapeutic strategies to improve long-term prognosis in high-risk localized prostate cancer patients who undergo external beam radiation therapy.

Conclusions

Although patients with high-risk and low/intermediate-risk LPC had similar baseline characteristics, following EBRT, high-risk patients experienced significantly shorter metastasis-free survival compared to patients with low/intermediate-risk disease status.

Further, high-risk patients also had an almost twofold increased risk of metastasis, BCR, or death relative to low/intermediate-risk patients.

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Poster

https://www.congresshub.com/Oncology/SUO2025/Apalutamide/Patel-Real-World

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Disclosures

G. Brown is an employee of New Jersey Urology and has received consulting fees from Johnson & Johnson. L. Karsh is an employee of AdventHealth Medical Group Urology. C. Patel and S. Burbage are employees and stockholders of Johnson & Johnson. C. Rossi, F. Kinkead, F. Lee, Y. Wang, G. Wong, and D. Pilon are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Johnson & Johnson. K. Joshi was an employee of Johnson & Johnson at the time the study was conducted. B. Lowentritt is an employee of Chesapeake Urology Associates and has received consulting fees from Johnson & Johnson. N. Shore is an employee of START Carolinas/Carolina Urologic Research Center and has received consulting fees from Johnson & Johnson.

Background

- External beam radiation therapy (EBRT), a common type of cancer treatment that uses radiation to damage cancer cells, has long been used to treat localized prostate cancer (LPC)[1]
- Although prognosis for patients after undergoing EBRT is favorable, patients with high-risk (HR) features (e.g., T3-T4 staging, Gleason score ≥8, and prostate-specific antigen [PSA] level ≥20 ng/mL) face a higher likelihood of disease recurrence and poorer prognosis compared with those who have low/intermediate-risk (L/IR) LPC[2]
- Despite these differences in prognosis, there is limited evidence on the clinical outcomes of patients with LPC across different risk stratifications treated with EBRT in the United States (US)

Objective

- To compare clinical outcomes for patients with LPC who undergo EBRT, stratified by HR and L/IR LPC

Methods

Data sources

- Clinical data from Precision Point Specialty (PPS) Analytics, collected as part of routine clinical care from private, community-based urology practices in the US, linked with insurance claims data from the Komodo Research Dataset (KRD+) was used (study period: 1 January 2016 - 31 August 2024)
- Data were de-identified and Health Insurance Portability and Accountability Act (HIPAA) compliant

Study design

- A retrospective, longitudinal cohort analysis utilizing score-weighted cohorts of HR and L/IR patients with LPC who underwent EBRT was conducted
- The index date was defined as the date of the first claim for an EBRT procedure
- The baseline period was defined as the 12-month period prior to the index date
- The observation period was defined as the time from the index date until the earliest of the end of clinical/claims activity or end of data availability (i.e., 31 August 2024)
- Patients were categorized into mutually exclusive cohorts (i.e., HR or L/IR LPC) based on pre-index tumor staging, Gleason score, and PSA level assessed within 180 days pre-index

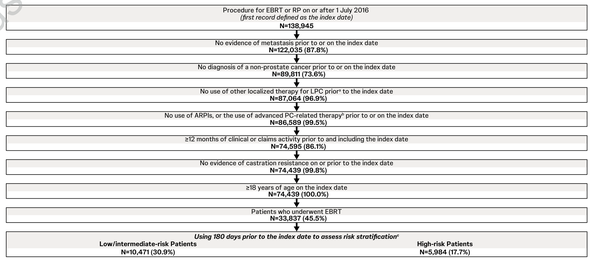
Study outcomes

- Metastasis-free survival (i.e., time from index to metastasis or death from any cause) was compared between HR and L/IR patients with LPC who underwent EBRT during the observation period
- Event-free survival (i.e., time from index to biochemical recurrence, metastasis, or death from any cause) was compared between HR and L/IR patients with LPC who underwent EBRT during the observation period

Statistical analysis

- Inverse probability of treatment weighting (IPTW) was used to balance baseline characteristics between the HR and L/IR patient cohorts[3]
- Baseline characteristics between treatment cohorts were considered balanced after weighting, as indicated by standardized differences <10%[4]
- Weighted Kaplan-Meier analyses were used to evaluate the proportion of patients with event-free survival and metastasis-free survival during the observation period
- Weighted Cox proportional hazards models were used to calculate hazard ratios and 95% confidence intervals (CIs) for comparison of metastasis-free survival rate and event-free survival rate between HR and L/IR patient cohorts

Figure 1. Patient flowchart



Notes:

a. Other therapies for LPC included cryotherapy, interstitial prostate brachytherapy, and high-intensity focused ultrasound.

b. Advanced PC-related therapies included ARPIs, chemotherapy, immunotherapy, estrogens, radiopharmaceuticals, and PARP inhibitors.

c. Patients with insufficient information to classify in either the low/intermediate-risk or the high-risk cohort were excluded from the study.

Abbreviations: ARPI: androgen receptor pathway inhibitor; EBRT: external beam radiation therapy; LPC: localized prostate cancer; PARP: poly ADP-ribose polymerase; PC: prostate cancer.

Results

Patient characteristics

- Overall, 5,984 patients with HR LPC and 10,471 patients with L/IR LPC who underwent EBRT were included in this study (**Figure 1**)
- Baseline patient characteristics were well-balanced between the weighted cohorts, with standardized differences <10% (**Table 1**)
- The mean (median) number of days receiving EBRT was 37.2 (43.0) days for HR patients and 36.1 (41.0) days for L/IR patients
- The mean (median) observation period was 46.4 (44.1) months for HR patients and 47.6 (45.7) months for L/IR patients

Table 1: Baseline characteristics

	Weighted Population[a,b]		
	High-risk N=5,984	Low/Intermediate-risk N=10,471	Standardized Difference (%)
Age, mean ± SD [median]	70.8 ± 7.3 [71.0]	70.5 ± 7.2 [71.0]	4.4
Race/ethnicity, n (%)			
White	2,962 (49.5)	5,205 (49.7)	0.4
Black or African American	1,021 (17.1)	1,761 (16.8)	0.7
Asian or Pacific Islander	98 (1.6)	154 (1.5)	1.4
Hispanic or Latino	47 (0.8)	85 (0.8)	0.3
Unknown	1,856 (31.0)	3,267 (31.2)	0.4
Geographic region, n (%)			
South	3,255 (54.4)	5,688 (54.3)	0.1
Midwest	1,292 (21.6)	2,297 (21.9)	0.9
Northeast	1,000 (16.7)	1,746 (16.7)	0.1
West	436 (7.3)	737 (7.0)	1.0
Unknown	1 (0.0)	3 (0.0)	1.0
Payer type, n (%)			
Medicare	4,592 (76.7)	7,957 (76.0)	1.7
Commercial	1,083 (18.1)	1,979 (18.9)	2.1
Medicaid	110 (1.8)	186 (1.8)	0.4
Unknown	200 (3.3)	349 (3.3)	0.1
Year of EBRT procedure (index year), n (%)			
2016	2 (0.0)	4 (0.0)	0.5
2017	763 (12.7)	1,341 (12.8)	0.2
2018	840 (14.0)	1,501 (14.3)	0.9
2019	907 (15.2)	1,568 (15.0)	0.5
2020	818 (13.7)	1,417 (13.5)	0.4
2021	1,007 (16.8)	1,739 (16.6)	0.6
2022	913 (15.2)	1,584 (15.1)	0.4
2023	720 (12.0)	1,284 (12.3)	0.7
2024	16 (0.3)	33 (0.3)	0.9
Time between initial PC diagnosis and index date, months, mean ± SD [median]	11.6 ± 23.2 [3.9]	12.4 ± 23.5 [3.6]	3.5
Use of first-generation anti-androgen therapy, n (%)	549 (9.2)	823 (7.9)	4.7
Use of bone anti-resorptive therapy, n (%)	194 (3.2)	264 (2.5)	4.3
Quan-CCI, mean ± SD [median]	3.3 ± 1.7 [3.0]	3.2 ± 1.7 [3.0]	1.8

Notes:

a. The propensity score was obtained from a logistic regression model where index treatment was the dependent variable and with the following baseline characteristics as independent variables: age, ethnicity, geographic region, payer, year of index date, time between initial PC diagnosis and index date, use of first-generation anti-androgen therapy, use of bone anti-resorptive therapy, and baseline Quan-Charlson comorbidity index. Patients with unknown geographic region were grouped into the west category.

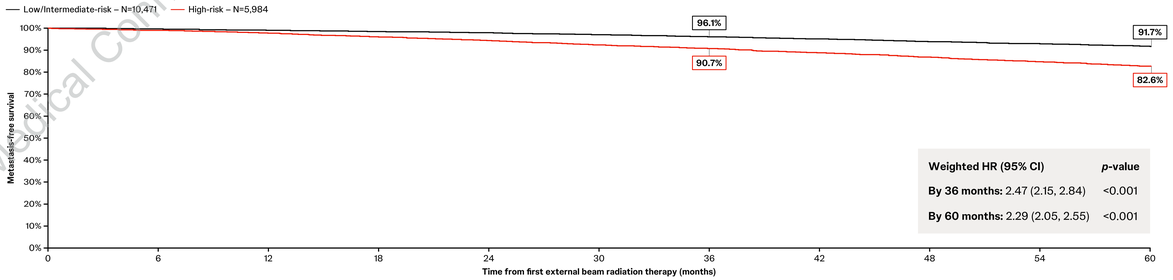
b. Of note, the number of patients reported in this weighted population represents the sum of weights for the corresponding non-weighted patients, rounded to the nearest integer. The proportions displayed were calculated before the rounding and may be slightly different than if they were calculated based on rounded numbers.

Abbreviations: CCI: Charlson Comorbidity Index; EBRT: external beam radiation therapy; PC: prostate cancer; SD: standard deviation.

Clinical outcomes

- **Metastasis-free survival**
  - By 36 months, HR patients had a statistically significant 2.47 times greater rate of metastasis or death relative to L/IR patients (hazard ratio: 2.47, 95% CI: 2.15, 2.84; p<0.001; **Figure 2**)
  - By 60 months, HR patients had a statistically significant 2.29 times greater rate of metastasis or death relative to L/IR patients (hazard ratio: 2.29, 95% CI: 2.05, 2.55; p<0.001; **Figure 2**)

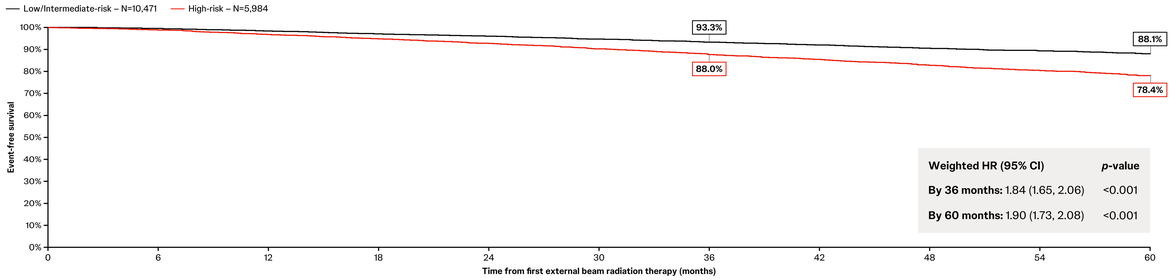
Figure 2: Weighted Kaplan-Meier rates of metastasis-free survival



Abbreviations: CI: confidence interval; HR: hazard ratio.

- **Event-free survival**
  - By 36 months, HR patients had a statistically significant 1.84 times greater rate of BCR, metastasis or death relative to L/IR patients (hazard ratio: 1.84, 95% CI: 1.65, 2.06; p<0.001; **Figure 3**)
  - By 60 months, HR patients had a statistically significant 1.90 times greater rate of BCR, metastasis or death relative to L/IR patients (hazard ratio: 1.90, 95% CI: 1.73, 2.08; p<0.001; **Figure 3**)

Figure 3: Weighted Kaplan-Meier rates of event-free survival



Abbreviations: CI: confidence interval; HR: hazard ratio.

Limitations

- This observational study relied on administrative claims and clinical data, which may contain coding inaccuracies or omissions
- While the linkages between the PPS and KRD+ data sources are comprehensive, any mis-linkages may lead to misclassification and potential information bias
- Although we attempted to account for all observable confounding covariates in our balancing with IPTW, it is possible that some relevant confounders were not measured or were unavailable in the data

References

1. Boladeras A, et al. *Rep Pract Oncol Radiother.* 2016;21(3):181–187. 2. Karsh L, et al. *Prostate.* 2024;84(11):1047–1055. 3. Austin PC. *Multivariate Behavioral Research.* 2011;46(3):399–424. 4. Austin PC. *Statistics in Medicine.* 2009;28(25):3083–3107.

Prostate Cancer

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