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Real-World Clinical Outcomes Among Patients With Localized Prostate Cancer Undergoing Radical Prostatectomy

Neal Shore[1], Benjamin Lowentritt[2], Charmi Patel[3], Frederic Kinkead[4], Sabree Burbage[3], Carmine Rossi[4], Yuxi Wang[4], Gordon Wong[4], Francesca Lee[4], Dominic Pilon[4], Lawrence Karsh[5], Gordon Brown[6]

[1]START Carolinas/Carolina Urologic Research Center, Myrtle Beach, SC, USA; [2]Chesapeake Urology, Towson, MD, USA; [3]Johnson & Johnson, Horsham, PA, USA; [4]Analysis Group, Inc., Montréal, Canada; [5]AdventHealth Urology, Denver, CO, USA; [6]New Jersey Urology, Cherry Hill, NJ, USA

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 received radical prostatectomy

Conclusions

Although patients with high-risk and low/intermediate-risk localized prostate cancer had similar baseline characteristics, following radical prostatectomy, high-risk patients experienced significantly lower metastasis-free survival compared to patients with low/intermediate-risk disease status

Further, high-risk patients also had an almost two-fold increased risk of metastasis, biochemical recurrence, or death relative to low/intermediate-risk patients

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Poster

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

Background

- Radical prostatectomy (RP) is an important, potentially curative treatment option for localized prostate cancer (LPC)[1,2]
- Although prognosis for patients after receiving RP is favorable, patients with high-risk (HR) features (eg, 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[3,4]
- Despite these differences in prognosis, there is limited evidence on the clinical outcomes of patients with LPC across different risk stratifications receiving RP in the United States (US)

Objective

- To compare clinical outcomes for patients with LPC who underwent RP, 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: January 1, 2016–August 31, 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 RP was conducted
- The index date was defined as the date of the first claim for an RP 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 (ie, August 31, 2024)
- Patients were categorized into mutually exclusive cohorts (ie, HR or L/IR LPC) based on pre-index tumor staging, Gleason score, and PSA level assessed within 180 days pre-index

Study outcomes

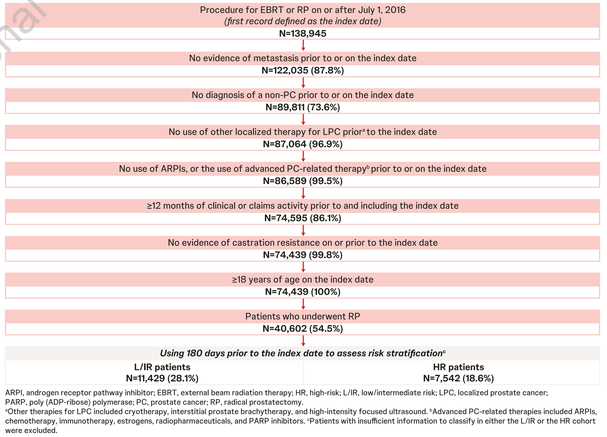
- Metastasis-free survival (ie, time from index to metastasis or death from any cause) was compared between HR and L/IR patients with LPC who underwent RP during the observation period
- Event-free survival (ie, time from index to biochemical recurrence [BCR], metastasis, or death from any cause) was compared between HR and L/IR patients with LPC who underwent RP 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[5]
- Baseline characteristics between treatment cohorts were considered balanced after weighting, as indicated by standardized differences <10%[6]
- 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

Patient selection criteria

Figure 1: Patient flowchart



ARPI, androgen receptor pathway inhibitor; EBRT, external beam radiation therapy; HR, high-risk; L/IR, low/intermediate risk; LPC, localized prostate cancer; PARP, poly (ADP-ribose) polymerase; PC, prostate cancer; RP, radical prostatectomy.
[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 L/IR or the HR cohort were excluded.

Results

Table 1: Baseline characteristics

	Weighted population[a,b]		
	HR N=7,542	L/IR N=11,429	Standardized difference (%)
Age, mean ± SD [median]	63.9 ± 6.9 [64.0]	63.6 ± 7.0 [64.0]	4.0
Race/ethnicity, n (%)			
White	3,966 (52.6)	6,001 (52.5)	0.2
Black or African American	1,054 (14.0)	1,601 (14.0)	0.1
Asian or Pacific Islander	97 (1.3)	139 (1.2)	0.6
Hispanic or Latino	59 (0.8)	91 (0.8)	0.2
Unknown	2,366 (31.4)	3,597 (31.5)	0.2
Geographic region, n (%)			
South	4,272 (56.6)	6,440 (56.4)	0.6
Midwest	1,645 (21.8)	2,548 (22.3)	1.2
West	843 (11.2)	1,293 (11.3)	0.4
Northeast	781 (10.4)	1,145 (10.0)	1.1
Unknown	1 (0.0)	3 (0.0)	0.8
Payer type, n (%)			
Medicare	3,526 (46.8)	5,224 (45.7)	2.1
Commercial	3,434 (45.5)	5,336 (46.7)	2.3
Medicaid	185 (2.5)	277 (2.4)	0.2
Unknown	396 (5.2)	591 (5.2)	0.3
Year of RP (index year), n (%)			
2016	0 (0.0)	2 (0.0)	1.9
2017	949 (12.6)	1,463 (12.8)	0.6
2018	1,015 (13.5)	1,589 (13.9)	1.3
2019	1,139 (15.1)	1,733 (15.2)	0.2
2020	1,014 (13.5)	1,539 (13.5)	0.0
2021	1,232 (16.3)	1,867 (16.3)	0.0
2022	1,177 (15.6)	1,744 (15.3)	1.0
2023	1,002 (13.3)	1,483 (13.0)	0.9
2024	13 (0.2)	5 (0.0)	4.0
Time between initial PC diagnosis and index date, months, mean ± SD [median]	6.9 ± 16.2 [2.5]	7.2 ± 13.7 [2.8]	2.3
Use of first-generation anti-androgen therapy, n (%)	114 (1.5)	88 (0.8)	7.0
Prior ADT use, n (%)	163 (2.2)	123 (1.1)	8.6
Quan-CCI, mean ± SD [median]	2.7 ± 1.2 [2.0]	2.7 ± 1.2 [2.0]	2.0

ADT, androgen deprivation therapy; CCI, Charlson Comorbidity Index; HR, high-risk; L/IR, low/intermediate risk; PC, prostate cancer; RP, radical prostatectomy; SD, standard deviation.
[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 ADT, and baseline Quan-CCI. 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.

Patient characteristics

- Overall, 7,542 patients with HR LPC and 11,429 patients with L/IR LPC who underwent RP were included in this study (**Figure 1**)
- Baseline patient characteristics were generally well-balanced between the weighted cohorts, with standardized differences <10% (**Table 1**)
- The mean (median) observation period was 45.0 (42.2) months for HR patients and 49.2 (48.7) months for L/IR patients

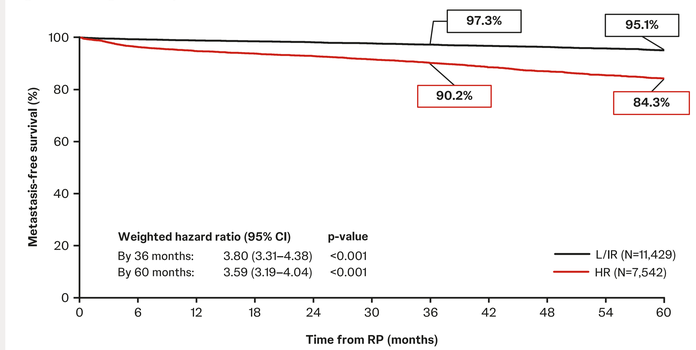
Clinical outcomes

- **Metastasis-free survival**
  - By 36 months, HR patients had a statistically significant 3.80 times greater rate of metastasis or death relative to L/IR patients (hazard ratio 3.80, 95% CI: 3.31–4.38; p<0.001; **Figure 2**)
  - By 60 months, HR patients had a statistically significant 3.59 times greater rate of metastasis or death relative to L/IR patients (hazard ratio 3.59, 95% CI: 3.19–4.04; p<0.001; **Figure 2**)
- **Event-free survival**
  - By 36 months, HR patients had a statistically significant 3.49 times greater rate of BCR, metastasis or death relative to L/IR patients (hazard ratio 3.49, 95% CI: 3.28–3.71; p<0.001; **Figure 3**)
  - By 60 months, HR patients had a statistically significant 3.37 times greater rate of BCR, metastasis or death relative to L/IR patients (hazard ratio 3.37, 95% CI: 3.18–3.57; p<0.001; **Figure 3**)

Limitations

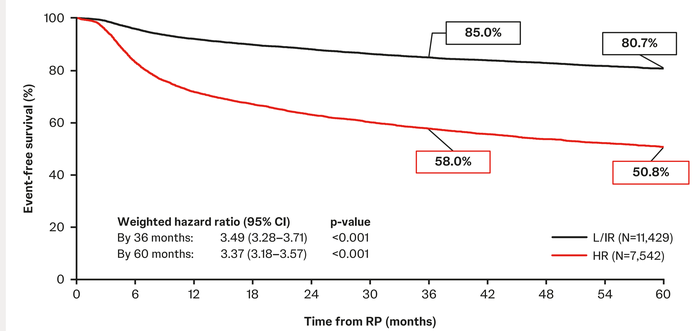
- This observational study relied on administrative claims and clinical data, which may contain coding inaccuracies or omissions
- While the linkages between the PPS and KRD+ data sources are comprehensive, any mis-linkages may lead to mis-classification and potential information bias
- Although we attempted 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

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



CI, confidence interval; HR, high-risk; L/IR, low/intermediate risk; LPC, localized prostate cancer; RP, radical prostatectomy.

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



CI, confidence interval; HR, high-risk; L/IR, low/intermediate risk; LPC, localized prostate cancer; RP, radical prostatectomy.

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Prostate Cancer

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