

## Retrospective observational study to assess the treatment pathway and patient journey among men who undergo radiotherapy for high-risk localised and locally advanced prostate cancer in Sweden: ODYSSEY

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**Introduction & Objectives:** Although radiotherapy (RT) is the most used primary treatment for men with high-risk localized or locally advanced prostate cancer (HR-LAPC), men remain at significant risk of local-regional or distant progression. The ongoing ATLAS trial investigates apalutamide in men with HR-LAPC receiving primary RT. ODYSSEY aims to create a real-world (RW) cohort of men with HR-LAPC by mimicking ATLAS selection criteria. Here we report baseline characteristics and RW mortality outcomes in the ODYSSEY cohort.

**Materials & Methods:** The Prostate Cancer Database of Sweden (PCBaSe) was used to identify a RW cohort of HR-LAPC men diagnosed 2006-2019 who received primary RT (external beam radiation therapy [EBRT] 74-82 Gy, EBRT + Brachytherapy, and hypofractionated  $\geq 2.4$  Gy)  $\leq 12$  months of diagnosis and mimicked the ATLAS HR selection criteria: Gleason score (GS) 7 or 8 (4+4, 3+5) AND  $>33\%$  cores contain cancer, GS 8 (5+3) or 9-10, GS $\geq 7$  AND T3, GS 7 AND PSA $\geq 20$ , or T4. Baseline characteristics at date of PC diagnosis were summarized using descriptive statistics. Subsequent therapy (i.e., ADT, androgen deprivation therapy) initiated following adjuvant therapy, was used as a proxy for disease progression. Outcomes were analysed using cumulative incidence plots and Kaplan-Meier estimates.

**Results:** Baseline characteristics demonstrated a RW cohort with 7,952 HR-LAPC cases: median age 70 years; median PSA 13 ng/mL; clinical stage 3 38%; clinical stage 4 1.1%; Charlson Comorbidity Index 1-2 28%; Charlson Comorbidity Index 3 4.3%. GS in the RW cohort: 7(3+4) in 9.2%, 7(4+3) in 37%, 8(3+5) in 4.9%, 8(4+4) in 17%, 8(5+3) in 0.6%, 9 in 29% and 10 in 1.8%. Baseline characteristics of the ATLAS clinical trial cohort have been previously shared<sup>1</sup>. The RW cohort received EBRT (55%), EBRT + brachytherapy (23%), and hypofractionated RT (22%). For the RT cohort, median time to ADT or death post RT was 12 (95% CI; 11-12) years. At 10-years post RT, risk (95% CI) of disease progression was 35% (33-36%) and risk of death due to PC or other causes was 2.5% (1.9-3.2%) and 16% (14-18%), respectively. Men that progressed within 3 years of RT were at higher risk of death due to PC compared to men without disease progression during this timeframe. For the overall RW cohort, 10-year survival rate post RT was 71% (70-73%).

**Conclusions:** PCBaSe is an enriched database capturing 98% of all PC cases in The Swedish Cancer Registry. This large RW cohort of men with HR-LAPC leveraged the breadth of variables in PCBaSe to mimic eligibility criteria for ATLAS. The alignment in characteristics between the ATLAS

and RW cohort and the availability of survival information highlights the potential value of using RW data to supplement PC trials. <sup>1</sup>Sandler HM. Abstract #5084 and Poster #267 presented at ASCO 2022. Washington, DC.