PROMISE: Overview of therapeutic management and disease progression in patients with localized prostate cancer based on the French National Health Data System (SNDS)

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Key messages

This study provides real-word data on the therapeutic management and progression per stage for patients with LPC.

The results indicate that progression occurs more frequently and rapidly among HR patients vs non-HR patients despite more intense treatment, confirming a medical need in these patients.

The likelihood of transitioning to BCR or to advanced stage increases over time, with HR LPC to advanced reaching 12.4% by 48 months.

Conclusion

PCa therapeutic management and progression observed on this French cohort of 794,632 patients are coherent to clinical practices and literature.

Phase 3 studies are currently ongoing to evaluate therapeutic intensification strategies for this specific population.

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Regulatory framework
SNDS study authorised by the CESREES on 18/03/2021 (TPS3648332) and by the CNIL on 06/04/2021. (DR-2021-097) - CNAM agreement signed on 09/06/2022.

Abbreviations
BCR: Biochemical recurrence
LPC: Localized Prostate Cancer
HR LPC: patients treated as high risk LPC
HIFU: High Intensity Focalised Ultrasounds
non-HR LPC: patients treated as non high risk LPC
NT LPC: untreated LPC patients
PCa: Prostate cancer
SNDS: French National Health Data System

Background

Enhanced epidemiological knowledge aids clinicians and policymakers in making more informed decisions regarding screening, diagnosis, and treatment options. It is critical to understand how prostate cancer progresses in early stages, as this knowledge influences treatment planning and ultimately prognosis. Improved epidemiological data can elucidate patterns of disease progression, helping to identify high-risk patients who may benefit from more intensive treatment.

Objective

The goal of this French real-world study was to describe the epidemiology of localized prostate cancer (LPC), to characterize therapeutic management strategies and the progression of the disease and the difference in those aims facing high risk (HR) disease.
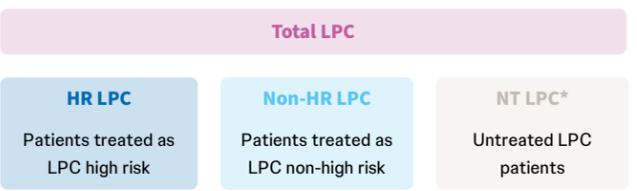
Methodology

Design

This nationwide cohort study included all adult males managed for prostate cancer in France between 2015 and 2019. Patients were identified in the French National health database (SNDS) thanks to specific ICD-10 codes (C61) linked to hospitalization or specific treatments, including prostatectomies and other pre-defined therapies.

Stages classification

The algorithm used to classify patients according to the disease stage was developed with the scientific committee. After exclusion of patients in advanced stages [1], identification of early stages was based on treatment received and their modalities [2,3]. LPC patients were classified into three subgroups:

Total LPC		
HR LPC	**Non-HR LPC**	**NT LPC***
Patients treated as LPC high risk	Patients treated as LPC non-high risk	Untreated LPC patients

*This includes both patients under active surveillance, as well as those who are too old or have comorbidities that preclude treatment (not distinguishable).

Outcome definition

Treatments considered: No treatment; HIFU or cryotherapy; Brachytherapy; Radical prostatectomy without lymph node dissection; Radiotherapy only; Radical prostatectomy with lymph node dissection; hormonoradiotherapy.

Time to death / Overall survival: The time to death was defined as the time between the start date of the considered stage up to the date of death. Death all-causes are considered in the analysis.

The time to progression-free survival by stage were defined as the time between the start date of the considered stage and the date of death or date of next stage, whichever occurs first.
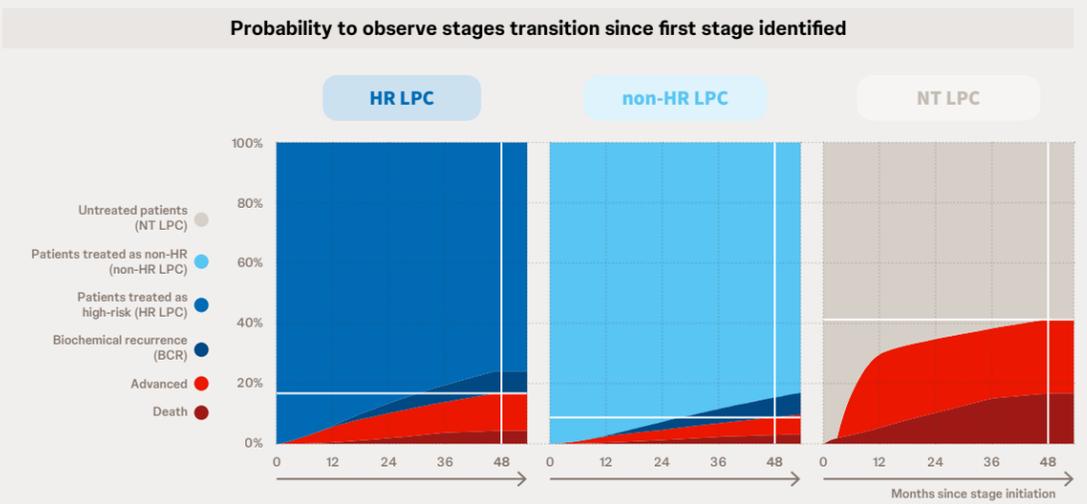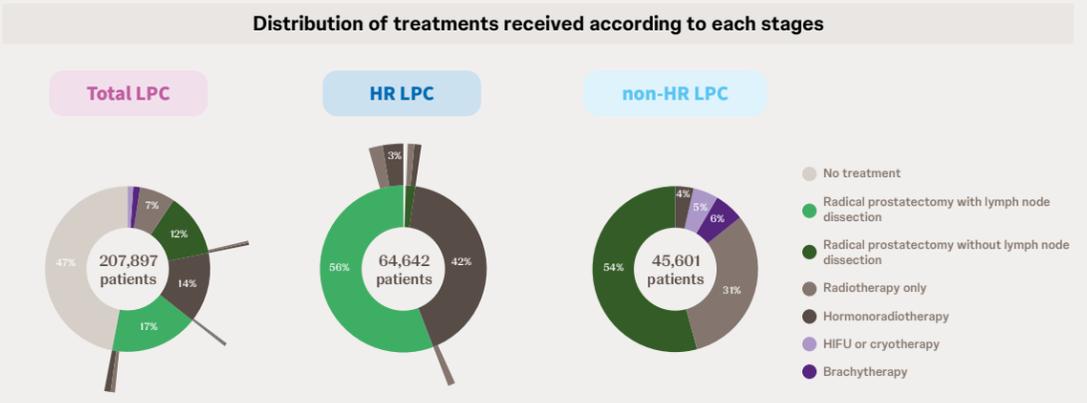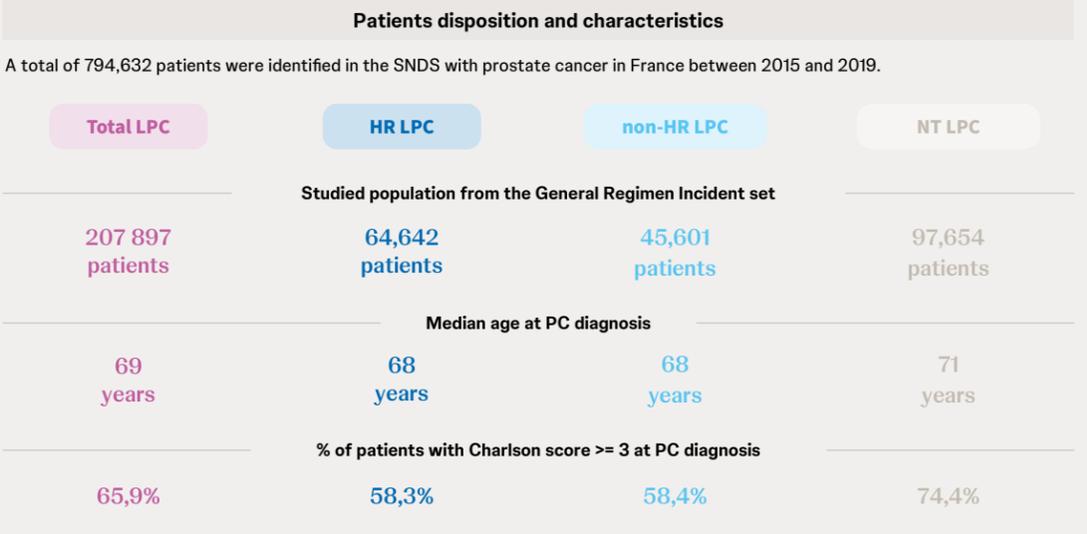
Statistical analysis

Description of treatments received are provided for patients incident of stages during the study period 2015-2019.

Progression free survival (PFS, i.e. progression to another stage or death, whichever occurred first) and Overall survival (OS) were analyzed using Kaplan Meier estimator and probability of transition were assessed using multi-state models. Analysis were performed among patients affiliated to the general regimen insurance scheme, incident of stage.

Ref
1) PROMISE: Identification des cancers avancés de la prostate en France à partir de la base médico-administrative du SNDS. DSVR AFCROs 2023.
https://static.hevaweb.com/web/PDF/7b26b767a2946-a0-janssen-vf-web.pdf
2) PROMISE: Identification des cancers précoces de la prostate en France à partir de la base médico-administrative du SNDS. DSVR AFCROs 2025.
https://static.hevaweb.com/web/PDF/ed2bdca404686-j-j-promise-poster-dsvr2025-web.pdf
3) Vue d'ensemble de la prise en charge des stades précoces du cancer de la prostate en France entre 2015 et 2019 à partir des données du Système National des Données de Santé (SNDS). SFRO 2025
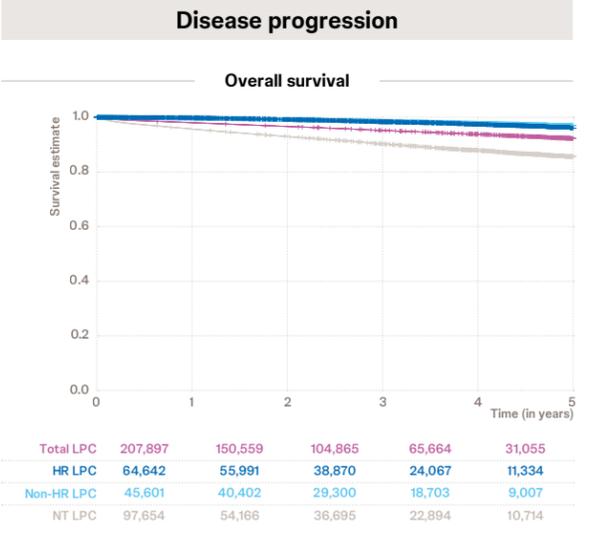https://static.hevaweb.com/web/PDF/19281fe2f3c86-poster-j-j-promise-sfro2025-v4.pdf

Results

Patients disposition and characteristics

A total of 794,632 patients were identified in the SNDS with prostate cancer in France between 2015 and 2019.

Total LPC	HR LPC	non-HR LPC	NT LPC
Studied population from the General Regimen Incident set			
207 897 patients	64,642 patients	45,601 patients	97,654 patients
Median age at PC diagnosis			
69 years	68 years	68 years	71 years
% of patients with Charlson score >= 3 at PC diagnosis			
65,9%	58,3%	58,4%	74,4%

Distribution of treatments received according to each stages

Legend:
- No treatment
- Radical prostatectomy with lymph node dissection
- Radical prostatectomy without lymph node dissection
- Radiotherapy only
- Hormonoradiotherapy
- HIFU or cryotherapy
- Brachytherapy

Probability to observe stages transition since first stage identified

Legend:
- Untreated patients (NT LPC)
- Patients treated as non-HR (non-HR LPC)
- Patients treated as high-risk (HR LPC)
- Biochemical recurrence (BCR)
- Advanced
- Death

Key results

For non-HR LPC, the probability of remaining in this stage is high but gradually decreases over time, from 97.3% at 12 months to 84.6% at 48 months. The likelihood of transitioning from non-HR LPC to Biochemical Recurrence (BCR) is low in the first year (0.3%) but rises to 6.6% by year four.
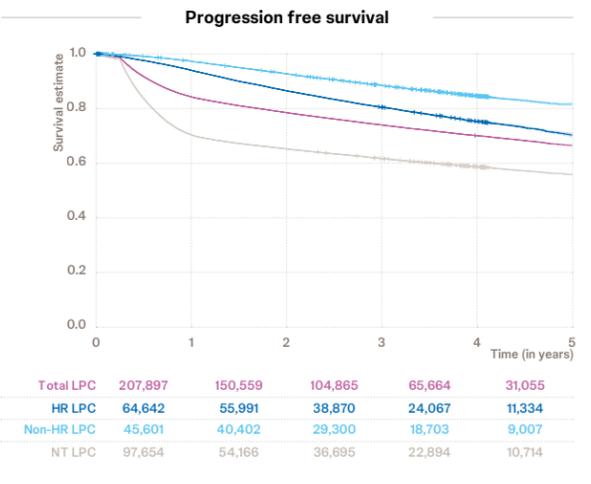
For HR LPC, the probability of staying in this stage decreases from 94.0% at 12 months to 75.9% at 48 months. The likelihood of transitioning to BCR or to advanced stage increases over time, with HR LPC to advanced reaching 12.4% by 48 months. The risk of death in HR LPC patients also increases steadily, though it remains lower than the probability of stage progression (4.3% at 48 months).

Disease progression

Overall survival

Total LPC	207,897	150,559	104,865	65,664	31,055
HR LPC	64,642	55,991	38,870	24,067	11,334
Non-HR LPC	45,601	40,402	29,300	18,703	9,007
NT LPC	97,654	54,166	36,695	22,894	10,714

Key results:

The Kaplan-Meier survival estimates across different PCa stages show distinct survival trajectories over five years:

- Non-HR LPC and HR LPC patients had nearly identical survival curves, with 97% and 96% survival rates at five years, respectively.

- Not Treated patients had the lowest survival rate at five years (86%, 95% CI: 0.85-0.86), showing a steady decline in survival over time.

Progression free survival

Total LPC	207,897	150,559	104,865	65,664	31,055
HR LPC	64,642	55,991	38,870	24,067	11,334
Non-HR LPC	45,601	40,402	29,300	18,703	9,007
NT LPC	97,654	54,166	36,695	22,894	10,714

Key results:

The Kaplan-Meier progression-free survival curves reveal distinct survival patterns over five years:

- Non-HR LPC patients showed a slower decline in progression-free survival, with 82% (95% CI: 0.81-0.82) still progression-free at five years, the highest among all groups.

- HR LPC patients had a slightly lower five-year progression-free survival rate of 70% (95% CI: 0.70-0.71), reflecting a greater risk of progression compared to non-HR LPC.

- Not Treated LPC patients had the lowest five-year progression-free survival rate (56%, 95% CI: 0.55-0.56), showing a steady and significant decline over time.

Prostate Cancer