PHAROS, a real-world multi-country European study on patients with high-risk localised and locally advanced prostate cancer receiving radical treatment

Matthias Eiber[1], Daniel M. Aebersold[2], Alfonso Valcarcel Diaz[3], Christian Wetterauer[4], Michael Bach[4], Flavio Camarrone[5], Kathleen Herkommer[1], Honghao Li[6], Fernando Lopez Campos[2], Thomas Mathieu[6], Jonathan Olivier[7], Geneviève Pissart[5], Paul Robinson[8], Mohamed Shelan[2], Hind Stitou[9], Céline Thiriez[6], Maxime Touzot[6], Arnauld Villers[7]

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Presented by Fernando Lopez Campos and Thomas Mathieu at ASCO; June 2nd, 2024; Chicago, Illinois, US

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KEY TAKEAWAY

Treatment in the localised prostate cancer setting has curative intent. This analysis highlights the importance of intermediate endpoints, not only for communicating the unmet need with respect to failure of the primary curative treatment, but also for assessing the efficacy of potential new treatment options.

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NAVIGATION

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CONCLUSIONS

- In this contemporary real-world cohort of high-risk localised and locally advanced prostate cancer patients, we confirm generally slow progression to metastatic disease and low number of deaths in the medium-term.
- However, up to 50% of the patients had an oncologic event (BCR, loco-regional relapse, metastasis) within 5 years after radical treatment while up to 30% had died at 10 years.
- These findings highlight the importance of intermediate endpoints for assessing the unmet need and efficacy of treatment strategies in this setting.

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BACKGROUND

- Primary radical therapy with curative intent is standard of care for patients diagnosed with high-risk (HR) localised (LPC) and locally advanced prostate cancer (LAPC), which translates to 10-year survival rates of 70-80% for radical prostatectomy (RP) and 60-80% for radiotherapy (RT).1-4
- However, despite the aim of cure, up to 70% of patients experience disease progression or distant metastasis at 10 years.1,5
- In the absence of detailed epidemiological data on natural history, routine management, and clinical outcomes in this HR setting, we aimed to explore real world data (RWD) to gain novel insights into patient risk factors and the disease and treatment pathway.

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METHODS

- PHAROS is a retrospective, observational study conducted in five academic centres across four European countries from 1989 to 2022 (France, Germany, Switzerland, Spain).
- All patients with HR LPC and LAPC, according to EAU guidelines, and treated by primary radical prostatectomy (RP) or radiotherapy (RT) ± ADT were eligible. Low- and intermediate-risk prostate cancer patients were excluded from this study (Figure 1).
- Data were accessed in a federated manner (Figure 2), to ensure that patient-level data stays local and secure in each care centre.
- Data were curated, structured and analysed to describe the patient characteristics at the time of radical therapy, subsequent treatment patterns and clinical events including time without biochemical recurrence (BCR), time without loco-regional relapse (LRR), event-free survival (EFS) [defined by composite of BCR, LRR, metastasis or death], time without metastasis, metastasis free survival (MFS) and overall survival (OS), that were estimated by Kaplan-Meier.

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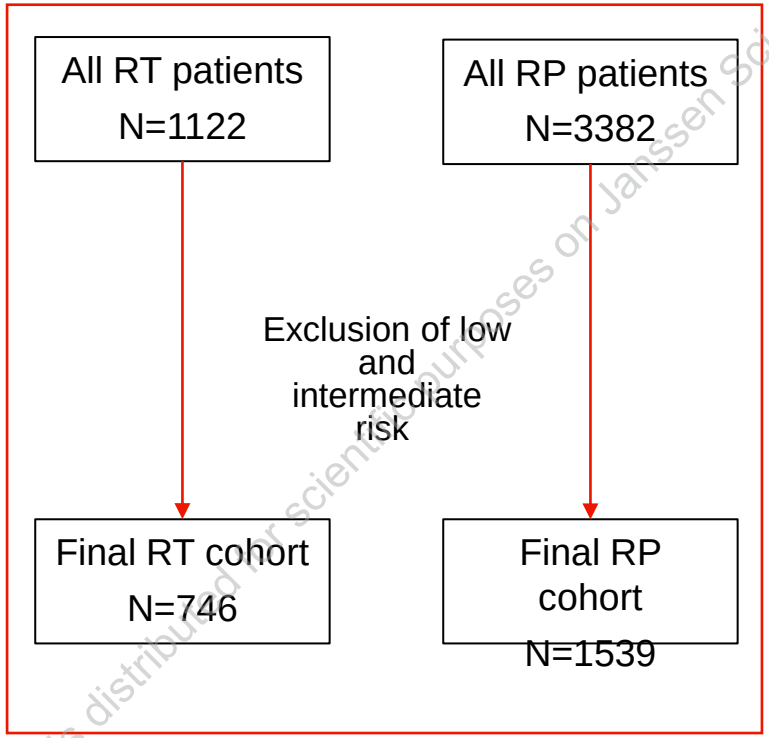
METHODS

Figure 1: Patient data inclusion



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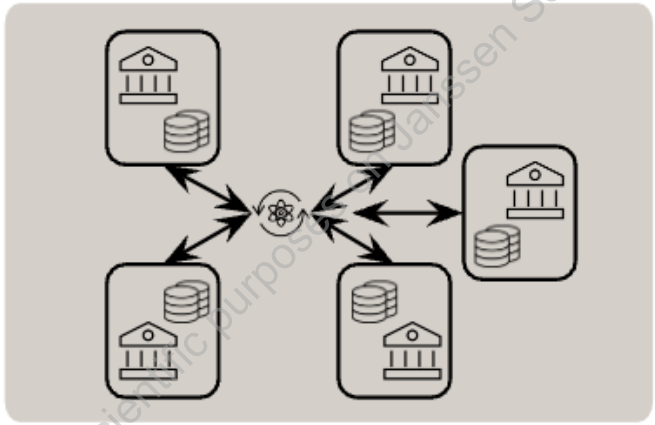
METHODS

Figure 2: Federated data access

Federated data access ensures that:

- Patient-level data stays local and secure in each care center
- Only aggregated data is shared
- Analysis (statistics, machine learning) can be performed across centers



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RESULTS

Baseline characteristics

Table 1: Demographic characteristics of the RP and RT cohort

- Table 1 summarises the baseline characteristics of the cohort. A total of 2303 patients (RP =1539, RT = 764), mostly diagnosed between 2005 and 2020, were included in the study with a mean follow-up of 6.8 years.
- Overall, RP patients were younger and more likely to be HR (LAPC) because of cN+ as compared to RT patients.
- The main reported subsequent / adjuvant treatments were RT for the RP cohort (adjuvant practiced mostly in one centre) and ADT for the RT cohort.

	N=2303	
	RP cohort (N=1539)	RT cohort (N=764)
Follow-up time		
Years	6.0± 4.4	8.5 ± 5.1
Baseline characteristics		
Age, years	65.7 ± 7.1	70.7± 7.7
BMI, Kg/m2	26.7 ± 3.9	27.7 ± 5.1
PSA, ng/mL	14.6 ± 14.4	24.0 ± 19.2
Gleason ≥ 8	45%	52%
(Missing Gleason)	(2%)	(4%)
TNM staging		
cT1-T2	67%	65%
cT3-T4	33%	33%
(Missing T)	(0%)	(2%)
N+	19%	8%
(Missing N)	(10%)	(4%)
EAU risk group		
Localized	55%	65%
Locally advanced	45%	35%
Adjuvant treatment		
Adjuvant treatment reported	14%	81%

Legend : values are expressed in mean (std) or percentage

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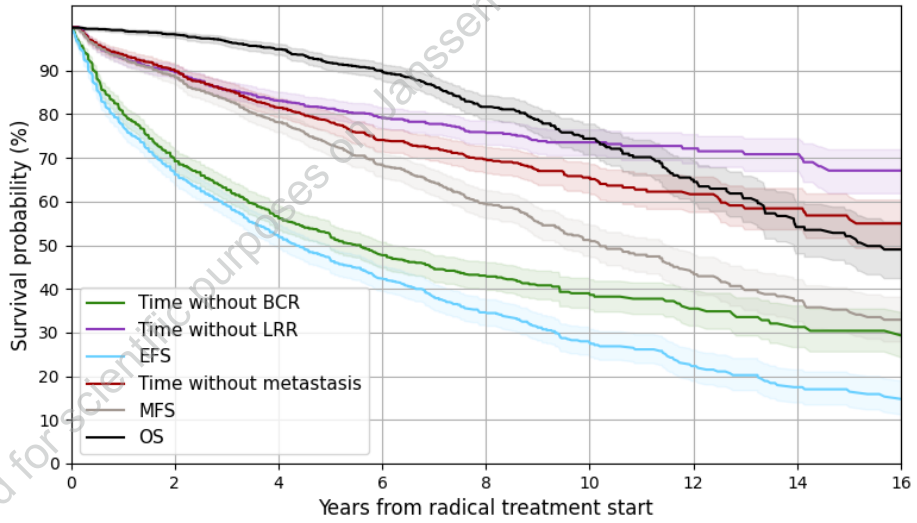
RESULTS

Disease outcomes characteristics

Figure 3: Intermediate and long-term outcomes in RP

- At 5 years, EFS was 48% [0.43-0.54] and MFS was 74% [0.69-0.78]. Time without BCR was 54% [0.48-0.59] and time without metastasis was 79% [0.75-0.83].
- It should be noted that rates of metastasis were higher (30%) in centres with routine access to PSMA PET.
- 249 deaths were observed in the RP cohort with an estimated 10-year OS of 73 % [0.66-0.80].



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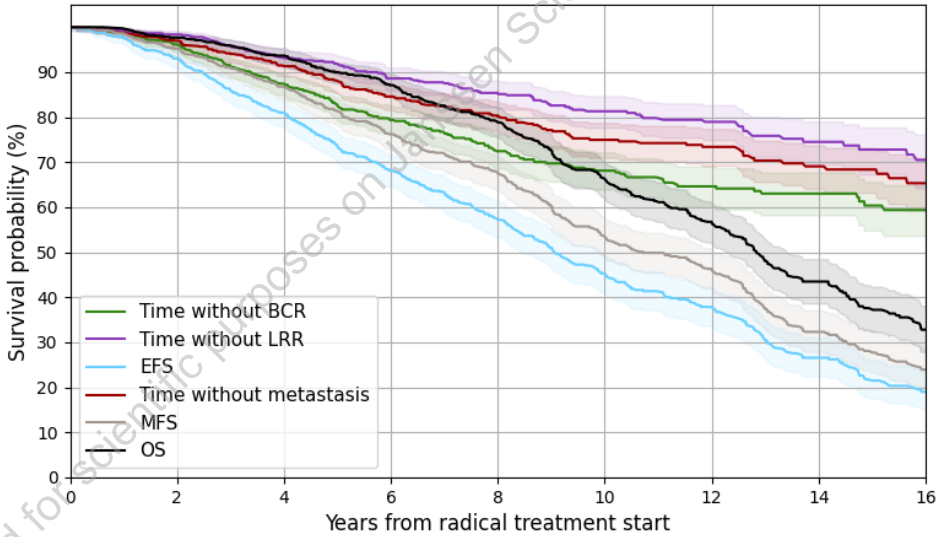
RESULTS

Disease outcomes characteristics

Figure 4: Intermediate and long-term outcomes in RT

- At 5 years, EFS was 74% [0.66-0.81] and MFS was 82% [0.75-0.88]. Time without BCR was 82% [0.75-0.89] and time without metastasis 88% [0.82-0.94].
- 311 deaths were observed in the RT cohort with an estimated 10-year OS of 69% [0.57-0.80].



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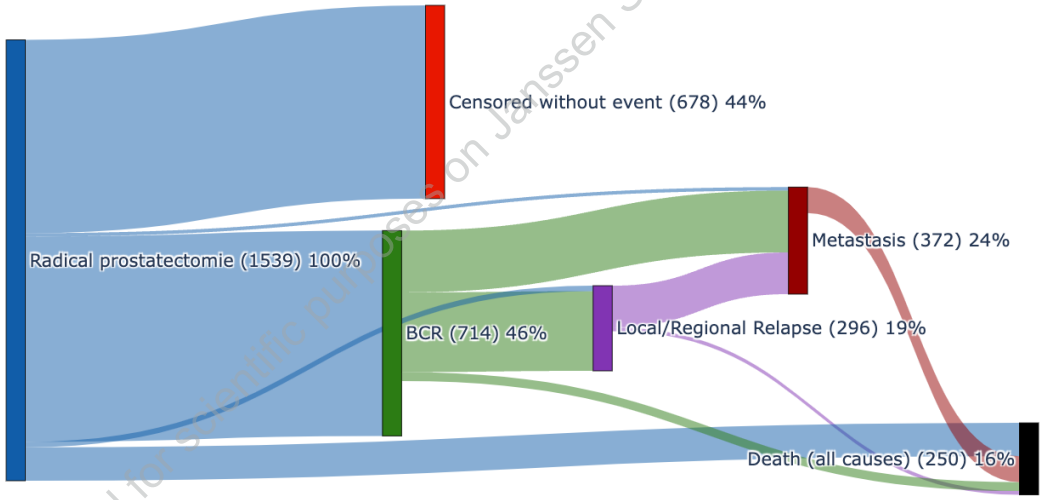
RESULTS

Pathway description and follow-up after relapse

Figure 5: Patient trajectories of the RP cohort

- In the RP cohort, out of 1539 patients, 678 were censored without event and 745 experienced an intermediate event (BCR, LRR or MET)
- The main treatment after the first BCR was RT ± ADT (55% of patients when the treatment was reported)



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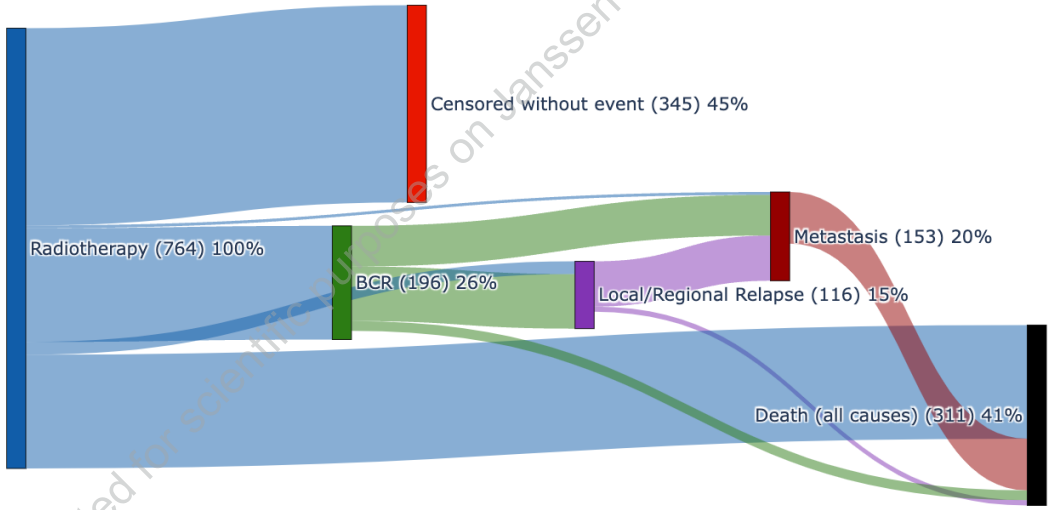
RESULTS

Pathway description and follow-up after relapse

Figure 6: Patient trajectories of the RT cohort

- In the RT cohort, out of 764 patients, 345 were censored without event and 224 experienced an intermediate event (BCR, LRR or MET)
- The main treatment after the first BCR was ADT (62% of patients when the treatment was reported)



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Eiber: shareholder (Lantheus Medical Imaging, Fusion Pharmaceuticals, Telix Pharmaceuticals), honoraria (Janssen, Novartis, Bayer), consulting and advisory role (Eckert and Ziegler, Janssen), research funding (Blue Earth Diagnostics), patent (Posluma), expenses (Blue Earth Diagnostics), other (PAREXEL, BioClinica)
Camarrone: Janssen and GlaxoSmithKline employee and shareholder
Li: Owkin employee and shareholder
Lopez Campos: consulting and advisory role, expert testimony and expenses (Janssen, Astellas Oncology, Bayer, Recordati), research funding (Janssen, Astellas Oncology)
Mathieu: Owkin employee and shareholder
Olivier: consulting and advisory role (Janssen, Ipsen, Astellas Oncology, Bayer, AstraZeneca), expenses (AstraZeneca, Ipsen)
Pissart: Janssen employee and shareholder
Robinson: Janssen employee and shareholder
Shelan: honoraria (Janssen), speaker (Janssen, Debiopharm Group), research (Debiopharm Group), expenses (Debiopharm Group)
Stitou: Janssen employee and shareholder
Thiriez: Owkin employee and shareholder
Touzot: Owkin employee, shareholder (Owkin, OSE Immunotherapeutics, Innate Pharma, Valneva, Dynavax Technologies), consulting and advisory role (Vifor Pharma), expenses (Vifor Pharma)
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