

# Defining intermediate-risk prostate cancer suitable for active surveillance with PSA 10-20 ng/ml: pathological outcome analysis of a population-level dataset

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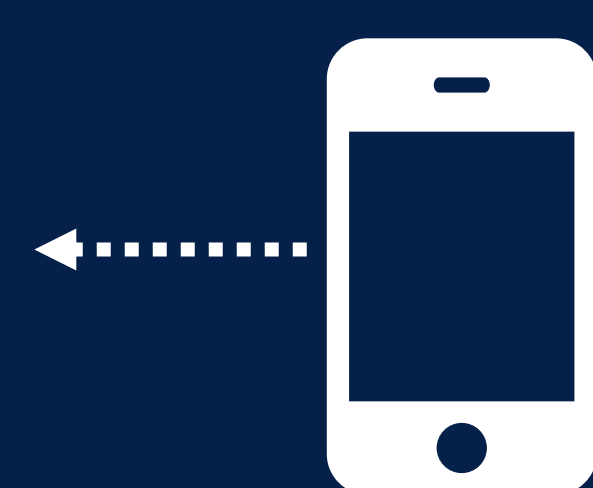
## INTRODUCTION

- National Comprehensive Cancer Network prostate cancer guidelines use grade group (GG) 2 or PSA 10-20 ng/mL as features that define favorable intermediate-risk disease
- Active surveillance (AS) may be an option for some men within this risk category
- We utilized the Surveillance, Epidemiology, and End Results (SEER) Prostate with Watchful Waiting (SEER-WW) database to determine the risk of pathologic upgrading or upstaging according to PSA level (<10 vs. 10-20 ng/mL) and GG (1 vs. 2) in men with favorable intermediate-risk localized prostate cancer who underwent radical prostatectomy (RP).

## METHODS

- Study population was obtained from the new SEER-WW database
- After multiple imputation, the cohort was restricted to men aged ≤80 years, cT1-2cN0M0, PSA ≤20ng/ml, biopsy GG ≤2, percent positive cores (PPC) ≤33% and underwent RP (n=29,120)
- Patients with no surgical pathology were excluded (n=2,572), giving a final cohort of 26,548
- The primary outcome was adverse pathology, defined as any pathologic upgrading (≥GG 3) or any upstaging to non-organ confined disease (≥pT3a).
- Multivariable logistic regression was performed to determine predictors of adverse pathology at RP

# Men diagnosed with grade group 1 prostate cancer and a PSA 10-20 ng/ml may be suitable for active surveillance



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## RESULTS

### Clinical characteristics (Grade group 1)

	PSA <10 ng/mL (N=15301)	PSA 10-20 ng/mL (N=1731)	p
Age at diagnosis, years	59.7 ± 7.0	61.8 ± 6.8	<0.001
Race			<0.001
White	12649 (82.7%)	1330 (76.8%)	
Black	4030 (26.3%)	259 (15.0%)	
Others/Unknown	883 (5.8%)	142 (8.2%)	
Clinical T stage			0.247
T1	11271 (73.1%)	1298 (75.0%)	
T2	4030 (26.3%)	433 (25.0%)	
PSA, ng/mL	5.1 ± 1.9	13.1 ± 2.7	< 0.001
% positive cores	17.1 ± 8.0	16.6 ± 8.1	0.026
Insurance			< 0.001
Insured	14723 (96.2%)	1619 (93.5%)	
Medicaid	422 (2.8%)	85 (4.9%)	
Uninsured	156 (1.0%)	27 (1.6%)	
Marital status			< 0.001
Married	12729 (83.2%)	1341 (77.5%)	
Single	2572 (16.8%)	390 (22.5%)	
Pathologic upgrading at RP			< 0.001
No	14410 (94.2%)	1530 (88.4%)	
Yes	891 (5.8%)	201 (11.6%)	
Pathologic upstaging at RP			< 0.001
No	14149 (92.5%)	1478 (85.4%)	
Yes	1152 (7.5%)	253 (14.6%)	
Adverse pathology			< 0.001
No	13470 (88.0%)	1349 (77.9%)	
Yes	1831 (12.0%)	382 (22.1%)	

### Clinical characteristics (Grade group 2)

	PSA <10 ng/mL (N=8367)	PSA 10-20 ng/mL (N=1149)	p
Age at diagnosis, years	61.5 ± 6.9	62.9 ± 6.8	<0.001
Race			0.004
White	6813 (81.4%)	889 (77.4%)	
Black	1038 (12.4%)	176 (15.3%)	
Others/Unknown	516 (6.2%)	84 (7.3%)	
Clinical T stage			0.001
T1	5872 (70.2%)	860 (74.8%)	
T2	2495 (29.8%)	289 (25.2%)	
PSA, ng/mL	5.4 ± 1.9	12.9 ± 2.6	< 0.001
% positive cores	19.2 ± 7.7	18.9 ± 7.9	0.226
Insurance			< 0.001
Insured	8072 (96.5%)	1060 (92.3%)	
Medicaid	204 (2.4%)	69 (6.0%)	
Uninsured	91 (1.1%)	20 (1.7%)	
Marital status			< 0.001
Married	6783 (81.1%)	874 (76.1%)	
Single	1584 (18.9%)	275 (23.9%)	
Pathologic upgrading at RP			< 0.001
No	7002 (83.7%)	875 (76.2%)	
Yes	1365 (16.3%)	274 (23.9%)	
Pathologic upstaging at RP			< 0.001
No	6969 (83.3%)	828 (72.1%)	
Yes	1398 (16.7%)	321 (27.9%)	
Adverse pathology			< 0.001
No	6027 (72.0%)	672 (58.5%)	
Yes	2340 (28.0%)	477 (41.5%)	

### Odds ratios of PSA level and biopsy grade group predicting adverse pathology

		Univariate (OR, 95% CI)	Multivariable OR* (OR, 95% CI)
PSA, ng/mL	10-20 vs. <10	1.99 (1.82-2.17)	1.87 (1.71-2.05)
Biopsy grade group	2 vs. 1	2.82 (2.64-3.00)	2.56 (2.40-2.73)

\* Adjusted for age, year of diagnosis, race, clinical stage and percent positive cores

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