

INTRODUCTION

- Approximately 45% of lesions with a PI-RADS ≥ 3 are found to have an ISUP grade group ≥ 2 , but mostly in case of PI-RADS 4-5 tumors
- In case of **PI-RADS 3**, only **20% of patients have csPCa** highlighting the **need for a better risk stratification** to avoid unnecessary biopsy
- The **real occurrence of csPCa** following an **MRI-targeted biopsy in PI-RADS 3** lesions has been shown to differ among different patient subgroups depending on the lesion volume, **ranging from 4% to 29%**

OBJECTIVE

To **sub-stratify patients** identified from a large European cohort of patients who underwent **MRI-targeted and systematic biopsies** for **PI-RADS 3 lesions** and to identify **predictive factors of csPCa**

METHODS

Population



- Data retrospectively collected from a prospectively maintained **European multicentric database** of fifteen European tertiary referral-centers.
- Initial database of 4841 patients with positive MRI lesion who underwent **MRI-targeted and systematic biopsies** before RARP for localized PCa between January 2016 and April 2023.

Selection criteria



PI-RADS 3 lesions

Exclusion criteria:

Missing information on clinical, radiological and biopsy data

Primary outcome



The identification of covariates significantly associated with a **risk of csPCa** defined as an **ISUP grade group ≥ 2 on MRI-targeted and systematic biopsies**

Statistical analysis

- Descriptive statistics
- Logistic regression analysis
- AUC of different models
- CHAID analysis

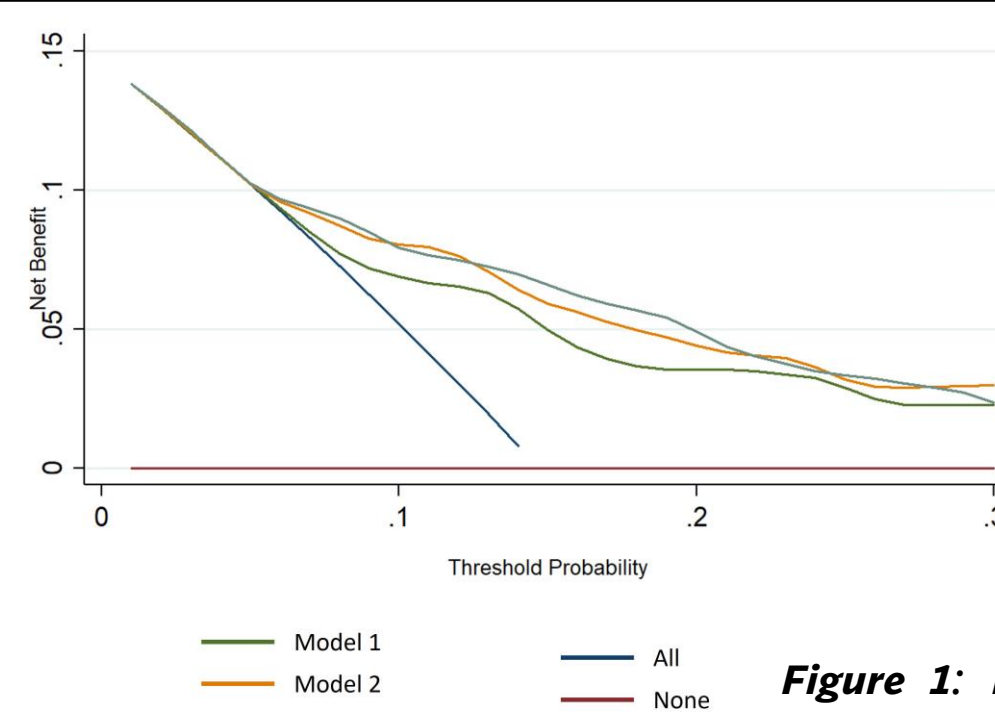


RESULTS

- A total of **790 patients** were included in our final analysis. Among them, 151 patients (**19%**) were **diagnosed with csPCa**.
- On **multivariable analysis**, **age and PSA density** showed significant associations (Table 1). **Three models were tested**.

Table 1: Results of the multivariable logistic regression

		Model 1		Model 2		Model 3	
		OR [95%CI]	p-value	OR [95%CI]	p-value	OR [95%CI]	p-value
Clinical	PSA density	83 [10-699]	<0.001*	1,434 [60-34,049]	<0.001*	1,643 [2,717-41,997]	<0.001*
	Age	1.0 [0.9-1.1]	0.05	1.1 [1.0-1.1]	0.02*	1.1 [1.0-1.1]	0.01*
	Digital rectal exam status	2.2 [0.8-6.2]	0.07	2.2 [0.8-6.3]	0.13	2.1 [0.7-5.9]	0.17
	Index lesion diameter	-	-	0.9 [0.8-1.0]	0.212	0.9 [0.9-1.0]	0.19
	Index lesion localization						
MRI	Ant.	-	-	ref	ref	ref	ref
	Mid	-	-	2.0 [0.7-5.7]	0.18	2.3 [0.8-6.6]	0.12
	Post.	-	-	1.8 [0.7-4.4]	0.2	1.8 [0.7-4.5]	0.19
	Previous biopsy status	-	-	-	-	0.6 [0.3-1.4]	0.21
Area Under the Curve [95%CI]		0.77 [0.74-0.79]		0.78 [0.75-0.79]		0.79 [0.76-0.81]	



The **Decision Curve Analysis** (Fig.1) demonstrated that **the three models improved clinical risk prediction** against threshold probabilities of unfavorable disease **between 0 and 30%**, with Models 2 and 3 being graphically merely superior to Model 1.

Figure 1: Decision curve analysis of the three tested models

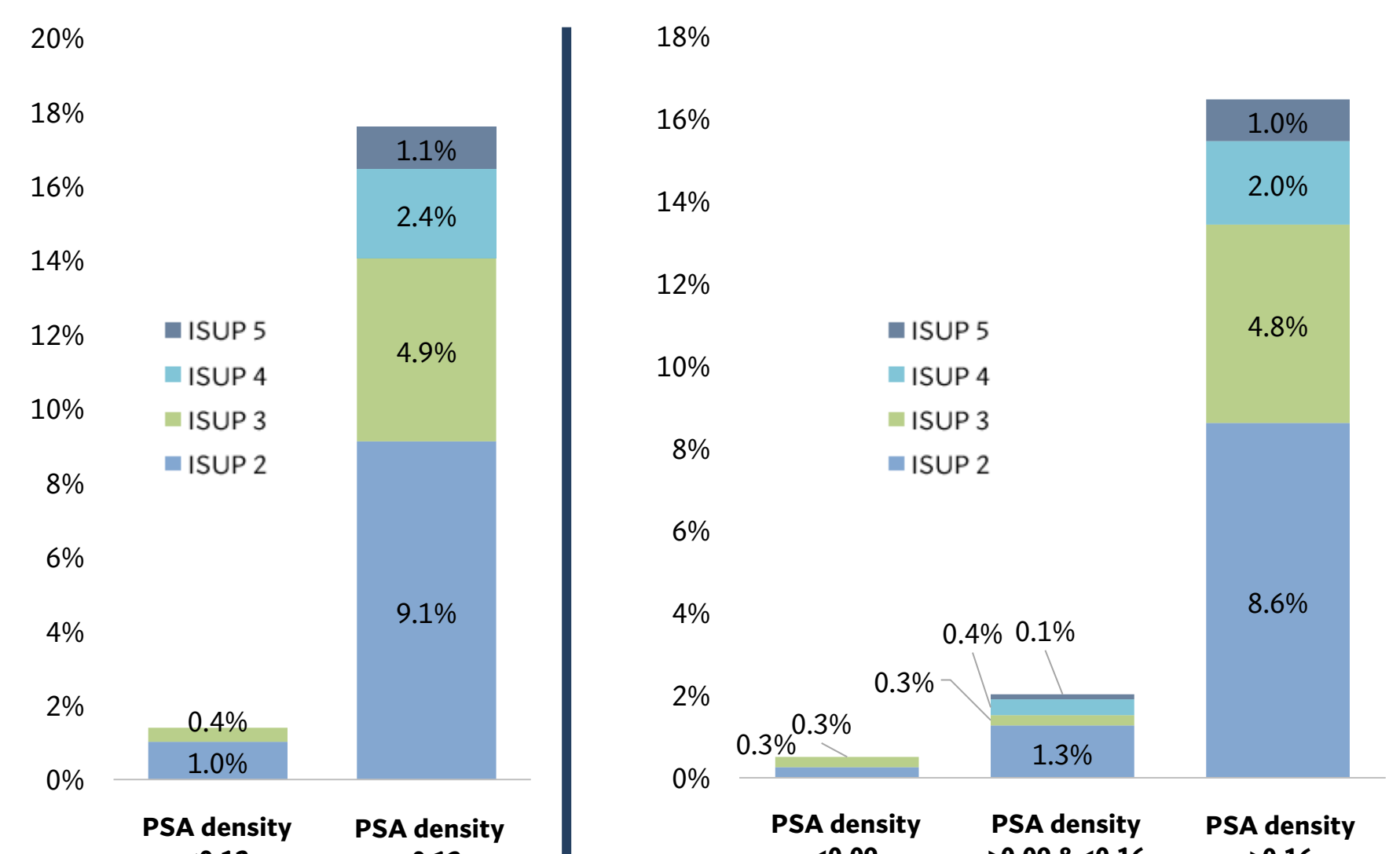


Figure 2: Percentage of csPCa in the different subgroups depicted according to the different cut-off points of the CHAID analysis. PSA = PSA density

- The CHAID analysis**, considering only age and PSA density, identified **PSAd as the sole significant factor influencing the decision tree**. **Cut-offs for PSAd were 0.13 ng/ml/cc for the two-nodes model and 0.09 ng/ml/cc and 0.16 ng/ml/cc for the three-nodes model** (Fig. 2).

CONCLUSION

For individuals with PI-RADS 3 lesions and a PSAd below 0.13, especially below 0.09, prostate biopsy could be omitted, in order to avoid overdiagnosis of non-csPCa. This nuanced strategy may lead to more precise and informed decision-making, potentially sparing certain patients from an unnecessary invasive procedure.