# EP007 Negative pre-biopsy magnetic resonance imaging and risk of significant prostate cancer: Baseline and long-term follow-up results

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**Introduction & Objectives:** Prostate biopsy should be discussed with the patient in case of negative MRI (nMRI) and low clinical suspicious of prostate cancer (PCa). Primary objective was to describe the risk of clinically significant PCa (csPCa) in a nMRI biopsy-naïve population at baseline and during long-term follow-up. Secondary objective was to evaluate clinical factors and PSA as predictors of csPCa at baseline.

**Materials & Methods:** All 503 consecutive biopsy-naïve patients referred in 2007-2017 for biopsy with nMRI (PIRADS1-2) who had systematic 12-core-biopsies (SB) at baseline were included. Clinical factors were digital rectal examination (DRE), PCa family history and PSA. In case of suspicious DRE or PSA kinetics during follow-up, MRI and biopsy were performed. CsPCa was defined as either GG1 with cancer core length >5 mm or ≥3 positive SB in addition to GG≥2(csPCa-1) or any GG≥2(csPCa-2). Univariate and multivariate models were fitted to identify predictors of csPCa risk.

**Results:** At baseline, biopsy showed csPCa-1 in 9%(n=45) and csPCa-2 in 6%(n=29) and non-csPCa in 22%(n=111) (table 1). At median follow-up of 4yrs(IQR:1.6-7.1), 31%(95%CI:27-36) of 415 untreated patients had a second MRI and 24%(95%CI:20-28) a second biopsy which showed csPCa-1 in 5%(21/415,95%CI:3-7), csPCa-2 in 2%(7/415,95%CI:1-3) and non-csPCa in 8%. Overall incidence was 13%(n=66/503,95%CI:7-21) for csPCa-1, 7%(n=36/503,95%CI:5-9%) for csPCa-2 and 2%(n=12/503,95%CI:1.1-3.7) for high risk PCa. Predictors of csPCa risk were PSAd≥0.15ng/mL/mL(OR=2.43[1.19-4.21]), clinical stage≥T2a(OR=3.32[1.69-6.53]) and PCa family history(OR=2.38[1.10-6.16]). Use of PSAd≥0.15ng/ml/ml, abnormal DRE and PCa family history would have decreased from 9% to 2.4% the risk of missing csPCa-1 at baseline while avoiding biopsy in 56%.Risk of csPCa in a negative MRI biopsy-naïve population was 6%-9% at baseline and 7%-13% at long-term follow-up depending on csPCa definition.

**Table 1** Baseline clinical, biological and biopsy results

| Variable | n* | |
|---|---|---|
| Median age, yr (IQR) | 503 | 62.94 (58 - 68) |
| Median BMI, kg/cm$^2$ (IQR) | 406 | 26.27 (23 - 28) |
| PCa family history, n (%) | 447 | 60 (13.4) |
| Median PSA, ng/mL(IQR) | 503 | 6.85 (4.7 - 8) |
| Median prostate volume, mL(IQR) | 489 | 59.89 (40 - 70) |
| **cT stage, n (%) :** | 503 | |
| T1c | | 428 (85) |
| T2a | | 65 (13) |
| T2b | | 6 (1.2) |
| T2c | | 6 (1.2) |
| T3/T4 | | 0 (0) |
| Median PSA density, ng/mL/mL (IQR) | 489 | 0.13 (0.08 - 0.16) |
| PSA density≥ 0.15 ng/mL/mL, n (%) | 489 | 164 (33.5) |
| PSA doubling time, month (IQR) | 320 | 38.81 (12.4 - 51) |
| Median PSA velocity, ng/mL/yr (IQR) | 320 | 1.77 (0.4 - 1.9) |
| **ISUP Grade Group at 1st biopsy series, n (%):** | 156 | |
| GG 1 | | 127 (81) |
| GG 2 | | 21 (14) |
| GG3-5 | | 8 (5) |
| **Diagnosis of PCa at baseline biopsies, n (%)** | | 156 (31) |
| csPCa-1 | | 45 (9) |
| csPCa-2 | | 29 (6) |
| non-csPCa (all definitions) | | 111 (22) |
| benign (no PCa) | | 347 (69) |
| Metastatic stage at diagnosis, n (%) | 503 | 1 (0.2%) |

* Data were not available for all patients (missing data or only one pre-biopsy PSA results)
BMI = body mass index, PSA = prostate specific antigen, ISUP = International Society of Urological Pathology, csPCa = clinically significant prostate cancer. non-csPCa = non-clinically significant prostate cancer

**Conclusions:** Risk of csPCa in a negative MRI biopsy-naïve population was 6%-9% at baseline and 7%-13% at long-term follow-up depending on csPCa definitions.