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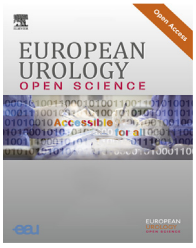

European Association of Urology

Prostate Cancer

Risk Calculator Strategy Before Magnetic Resonance Imaging Stratification for Biopsy-naïve Men with Suspicion for Prostate Cancer: A Cost-effectiveness Analysis

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Abstract

Background and objective: Current guidelines on prostate cancer (PCa) diagnosis recommend risk stratification before prostate biopsy, using either a risk calculator (RC) or magnetic resonance imaging (MRI). The aim of our study was to assess the effectiveness and cost effectiveness of an RC strategy and a direct MRI (dMRI) strategy.

Methods: Data for biopsy-naïve men suspected of having PCa on the basis of elevated prostate specific antigen (PSA) and/or abnormal digital rectal examination (DRE) were retrospectively collected from two large teaching hospitals. The RC and dMRI strategies were evaluated for PCa detection, effectiveness, and costs. The RC strategy used the Rotterdam prostate cancer risk calculator 3/4 and MRI for stratification, while the dMRI strategy directly used MRI findings. Clinically significant (cs)PCa was defined as a Gleason score $\geq$3 + 4.

Key findings and limitations: In total, 1458 men were included for analysis, of whom 944 were in the RC group and 514 were in the dMRI group. The RC strategy significantly reduced MRI use by 47.8% (52.2% vs 99.8%; $p < 0.001$) and reduced costs by 14.3% (€422.45 vs €492.77; $p < 0.001$) in comparison to the dMRI strategy. The number of patients who underwent prostate biopsy (36.5% vs. 40.9%; $p = 0.11$) and the csPCa detection rate (43.5% vs 45.2%; $p = 0.69$) were similar between the groups. The study is limited by its retrospective nature, so the findings should be interpreted with caution.

Conclusions and clinical implications: Both the RC strategy and the dMRI strategy are viable options for PCa diagnosis, with the former significantly reducing MRI use and overall diagnostic costs per person. Therefore, the RC strategy might be preferred

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over dMRI, particularly in contexts aiming for sustainable health care practices that optimize resource allocation and cost effectiveness.

Patient summary: We compared two different approaches for men with a suspicion of prostate cancer. One uses a risk calculator to decide on whether to perform an MRI (magnetic resonance imaging) scan, and the other proceeds directly to MRI. In both cases, prostate biopsy is performed in cases with positive MRI findings. The number of patients who needed a biopsy and the cancer detection rate were similar for the two approaches.

1. Introduction

The diagnostic process for prostate cancer (PCa) is complicated because of unnecessary diagnostics and overdiagnosis [1]. The majority of PCa diagnoses are classified as clinically insignificant (ci)PCa, defined as International Society of Urological Pathology (ISUP) grade group (GG) 1 cancer, and do not require immediate treatment [2]. As PCa remains a frequent malignancy in the male population, optimizing the diagnostic process requires prioritization to mitigate unnecessary health care costs [3,4].

The current European guideline on PCa diagnosis recommends use of a risk calculator (RC) or magnetic resonance imaging (MRI) as a tool to stratify asymptomatic men with elevated prostate-specific antigen (PSA) levels before prostate biopsy is performed [5]. The premise of the guideline is to reduce unnecessary biopsies, but a reduction in unnecessary MRI examinations before biopsy is not considered. Risk stratification directly via MRI can accelerate the diagnostic process, but requires sufficient MRI capacity and is a relatively costly diagnostic procedure. RCs can be used to stratify whether MRI may add value via calculation of PSA density, and can potentially reduce the number of unnecessary MRI scans.

The added diagnostic value of an RC strategy before MRI stratification over a direct MRI (dMRI) strategy remains unclear and little is known about the cost effectiveness of these diagnostic strategies. The aim of our study was to evaluate the effectiveness and costs of a RC strategy versus a dMRI strategy for biopsy-naïve men with suspicion of PCa.

2. Patients and methods

2.1. Study design and population

We conducted a retrospective cohort study in two large teaching hospitals (Spaarne Gasthuis Hoofddorp and Sint Antonius Hospital Nieuwegein) following approval from the local medical ethics committee. To ensure patient confidentiality, data anonymization procedures were implemented, including assignment of unique identifiers and conversion of birth dates to ages, thereby eliminating the need for additional informed consent. Diagnostic strategies for biopsy-naïve PCa patients varied between the hospitals, with one using an RC strategy and the other a dMRI strategy (Fig. 1). With the RC strategy, patients referred for suspected PCa because of elevated PSA and/or an abnormal digital rectal examination (DRE) between April 2021 and April 2022 first underwent transrectal ultrasound (TRUS) followed by risk stratification using the Rotterdam prostate cancer risk calculator (RPCRC)-3/4 [6]. Patients with a PCa risk ≥20% and/or clinically significant (cs)PCa risk ≥4% underwent MRI. With the dMRI strategy, patients referred for suspected PCa between August 2018 and April 2019 directly underwent MRI. Exclusion criteria included PSA <3 ng/ml or >50 ng/ml and a history of previous prostate MRI or prostate biopsies; for the RC group, the absence of TRUS data was also an exclusion criterion.

2.2. Image acquisition and prostate biopsies

Before prostate biopsy, all men underwent biparametric MRI using either a 3.0-T or, if contraindicated, a 1.5-T scanner. The European Society of Urogenital Radiology MRI protocol was used for axial fast spin-echo T1-weighted images of the pelvis [7]. T2-weighted fast-recovery turbo spin-echo images of the prostate were acquired in the axial, sagittal, and coronal planes (slice thickness 3 mm). Axial diffusion-weighted imaging was performed using a spin-echo echo-planar imaging pulse sequence with a slice thickness of 5 mm (b values of 0, 1000 or 1400, and 2000 s/mm^2); apparent diffusion coefficient maps were automatically calculated. Images were prospectively interpreted by experienced radiologists. The standardized 5-point Prostate Imaging-Reporting and Data System (PI-RADS) classification was used according to the PI-RADS v2.1 guidelines [8].

For the RC strategy, eligibility for prostate biopsy was determined via risk stratification using the RPCRC and MRI information, using the same cutoff points as with RPCRC-3/4 [9]. For the dMRI strategy, all patients with a PI-RADS score ≥3 were eligible for prostate biopsy [10]. All prostate biopsies were performed transperineally using either a free-hand cognitive or software fusion approach according to a targeted and systematic template. Specimens were prospectively analyzed by experienced uropathologists and reported according to the ISUP consensus for grading of PCa [2]. csPCa was defined as a Gleason score ≥3 + 4, equivalent to ISUP GG ≥2.

2.3. Cost assessment of diagnostic strategies

In the Dutch health care system, the cost of each diagnosis is labeled with a specific diagnosis treatment combination (DTC). The total activity-based costs for each DTC are represented by a single price, which is revised annually according

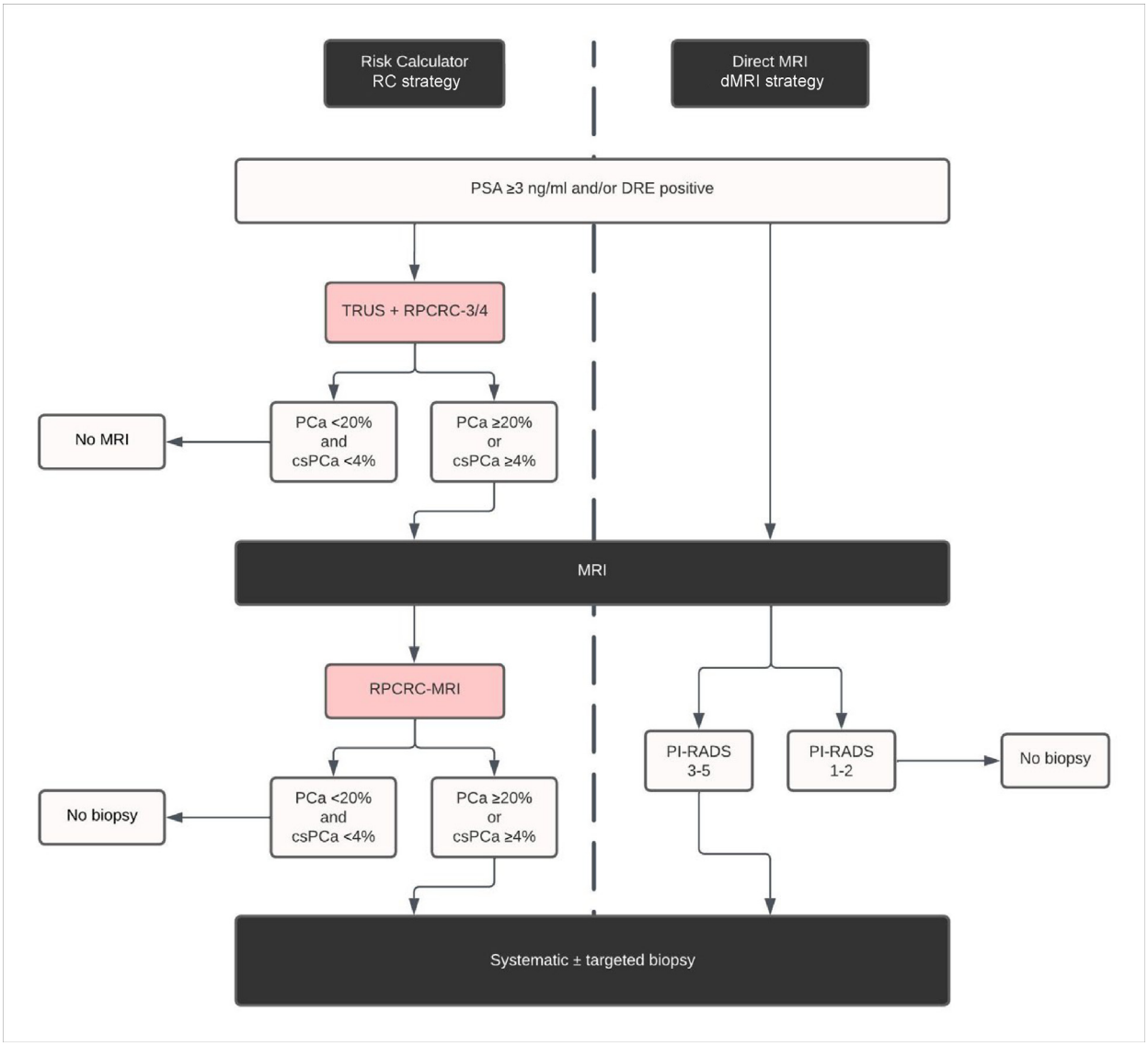

Fig. 1 – Schematic representation of the RC and dMRI strategies. RC = risk calculator; dMRI = direct magnetic resonance imaging; PSA = prostate-specific antigen; DRE = digital rectal examination; TRUS = transrectal ultrasound; RPCRC = Rotterdam prostate cancer risk calculator; PCa = prostate cancer; csPCa = clinically significant PCa; PI-RADS = Prostate Imaging-Reporting and Data System.

to the mean activity costs in that year. Owing to different contracts between insurance companies and hospitals, the DTC price varies between patients, making it difficult to present detailed costs for a diagnostic strategy. However, passerby tariffs, which are hospital-specific but equal for all patients regardless of their insurance, are widely available.

For this study, the average costs per patient for each diagnostic strategy were calculated on the basis of these passerby tariffs. Importantly, although prostate biopsy is a significant diagnostic modality and accounts for a considerable proportion of the diagnostic costs, the two diagnostic strategies are prebiopsy pathways. Therefore, to assess the cost effectiveness of the two prebiopsy strategies, the costs associated with prostate biopsy were excluded from the primary analysis. The average per-patient costs for the RC and the dMRI strategy were calculated and used to determine their cost effectiveness. This approach ensured that the comparison focused on the prebiopsy diagnostic pathways, reflecting the primary objective of the study.

2.4. *Statistical analysis*

Categorical variables are reported as the frequency and percentage. Normally distributed continuous variables are presented as the mean with standard deviation, and non-normally distributed continuous variables as the median with interquartile range (IQR).

The cost effectiveness of the two strategies was assessed by analyzing their average per-patient costs alongside the corresponding csPCa detection rates. Differences in PI-RADS 1–2 findings and ciPCa detection rates were also assessed. For comparison of the two strategy groups, either a χ^2 test or an independent-sample t test was used. A value

of $p < 0.05$ was considered to indicate statistical significance. All statistical analyses were performed with SPSS v28 for MacOS (IBM, Arkmonk, NY, USA).

3. Results

A total of 1458 patients were included in the analysis, of whom 944 were in the RC group and 514 were in the dMRI group. Patient characteristics for the two groups are listed in Table 1. In the RC group, RPCRC-3/4 application significantly reduced MRI use by 47.8% (451/944; $p < 0.001$). Omission of MRI for some patients in the RC group subsequently resulted in a significantly lower detection rate for PI-RADS ≥3 lesions in comparison to the dMRI strategy (33.5% vs 40.1%; $p = 0.04$). Nevertheless, the number of patients who underwent prostate biopsy was comparable, with 36.5% (345/944) in the RC group and 40.9% (210/514) in the dMRI group ($p = 0.11$). csPCa detection rates were also comparable, with 43.5% (150/345) of biopsied men in the RC group and 45.2% (95/210) in the dMRI group harboring csPCa ($p = 0.69$); this corresponds to 15.9% (150/944) of the overall RC cohort and 18.5% (95/514) of the overall dMRI cohort ($p = 0.21$). Similarly, there were no significant differences in the ciPCa detection rate (30.7% vs 30.0%; $p = 0.86$) or benign findings (25.8% vs 24.8%; $p = 0.79$) between the RC and dMRI strategies.

Table 1 – Patient characteristics, radiological and pathological outcomes, and associated costs for the RC and dMRI strategies

	RC strategy (n = 944)	dMRI strategy (n = 514)	p value
Median age, yr (IQR)	68.8 (63–74)	67.4 (62–73)	**<0.001**
Mean PSA, ng/ml (SD)	7.8 (6.2)	8.4 (6.1)	0.06
Digital rectal examination, n (%)			0.23
Normal	700 (74.2)	348 (67.7)	
Abnormal	206 (21.8)	86 (16.7)	
Data missing	38 (4.0)	80 (15.6)	
Underwent MRI, n (%)	493 (52.2)	513 (99.8) [a]	**<0.001**
Median prostate volume, ml (IQR)	53.3 (34–64)	57.2 (35–70)	**0.04**
PI-RADS score, n (%)[b]			**<0.001**
1–2	144 (29.2)	305 (59.5)	
3	56 (11.4)	36 (7.0)	
4	133 (27.0)	81 (15.8)	
5	127 (25.8)	89 (17.3)	
Data missing	33 (6.7)	2 (0.4)	
Underwent prostate biopsy, n (%)	345 (36.5)	210 (40.9)	0.11
Pathological findings, n (%)[b]			
Benign	89 (25.8)	52 (24.8)	0.79
ISUP grade group 1	106 (30.7)	63 (30.0)	0.86
ISUP grade group 2	78 (22.6)	39 (18.6)	0.69
ISUP grade group 3	24 (7.0)	23 (11.0)	
ISUP grade group 4	22 (6.4)	26 (12.4)	
ISUP grade group 5	26 (7.5)	7 (3.3)	
Costs (€)			**<0.001**
MRI	344.06	347.63	
Urology outpatient clinical visit	321.72	145.82	
Average	422.45	492.77	

RC = risk calculator; dMRI = direct magnetic resonance imaging; IQR = interquartile range; PI-RADS = Prostate Imaging-Reporting and Data System; PSA = prostate-specific antigen; ISUP International Society of Urological Pathology, SD = standard deviation.
[a] MRI was omitted for a patient with claustrophobia.
[b] Percentages were calculated using the number of patients who underwent MRI and prostate biopsy as the denominator.

3.1. Assessment of strategy costs

In April 2021, the passerby tariffs for MRI were €344.06 for the RC strategy and €347.63 for the dMRI strategy. The total cost for two urological consultations (including costs associated with ultrasound-based prostate volume measurements) for the RC strategy was €321.72, compared to €145.82 for a single urological consultation for the dMRI strategy. The average per-patient cost for the RC group was €422.45 (95% confidence interval [CI] €402.16–€442.74) up to the point of undergoing prostate biopsy, compared to €492.77 (95% CI €460.21–€525.34) for the dMRI group. This amounts to a cost reduction of 14.3% in favor of the RC strategy ($p < 0.001$; Table 1).

4. Discussion

We analyzed the cost effectiveness of two different diagnostic strategies currently recommended by the European Association of Urology guidelines for PCa diagnosis. At present, RC and dMRI strategies are being used interchangeably and no preferred strategy has been recommended yet. Our findings indicate that both strategies are equally effective in detecting csPCa, suggesting that either approach could be considered as a viable option in clinical practice. However, the RC strategy significantly reduces the need for MRI by 47.6% in compared to the dMRI strategy and thus reduces the average per-patient cost by 14.3%.

Although there is an abundance of studies on diagnostic strategies, comparative studies are scarce. However, our findings are consistent with the literature on this topic and align with findings from two other Dutch studies [11,12]. Wagensveld et al [11] compared a risk-adapted ultrasound-directed (RA-US) and an MRI-directed strategy and found that both were equally effective in detecting csPCa; both strategies detected csPCa in a quarter of the population. However, the RC strategy differed from the one used in our study. The RA-US strategy used the RPCRC-3/4 to decide whether or not to perform prostate biopsy, whereas our RC strategy involves deciding whether or not to perform MRI. As existing risk calculators such as the RPCRC-3/4 primarily assess the probability of detecting (cs)PCa rather than the probability of positive MRI findings, this may contribute to the differences in the detection of PI-RADS ≥3 lesions. The fact that our population underwent further risk stratification using (RPCRC-)MRI explains the difference in the number of prostate biopsies. Similar to our study, the second Dutch study by Reesink et al [12] found that an RC strategy could reduce MRI use by up to 50%. The authors noted that in their low-risk cohort, only one-tenth had a positive MRI finding, highlighting the low false-negative rate while allowing significant avoidance of MRI. However, unlike Wagensveld et al, Reesink et al found that the RC strategy missed csPCa cases more frequently than the dMRI strategy did (19% vs 3% of csPCa cases missed). Again, our RC strategy differs significantly as it uses sequential RCs before and after MRI with different risk

thresholds, which may explain the variation in csPCa detection rates.

With a growing population at risk of having (cs)PCa, diagnostic testing for every individual with elevated PSA is not feasible. Therefore, avoidance of unnecessary diagnostic tests might be instrumental in achieving sustainable health care. While it has been demonstrated that implementation of an RC strategy can halve the number of MRI examinations needed, it increases the number of contact minutes for urologists. Over the years, RCs have notably improved, further easing the burden of PCa diagnostics on both urologists and radiologists [9,13–22]. Additional enhancements for RC strategies, including training for general practitioners on how to effectively and safely use RCs, can yield substantial value and cost savings by reducing unnecessary referrals and diagnostics while ensuring appropriate PCa care [23]. Such advances in RCs should further reduce the number of csPCa cases missed. While the RC strategies in the Dutch studies cited did not use RCs that included MRI findings, the added diagnostic value of these RCs is widely supported in the literature [13–18,24,25]. Missed csPCa cases, however, remain an inherent problem, even for the most accurate RCs. In reality, csPCa cases are not missed but are rather delayed in diagnosis when using RC strategies. Men with elevated PSA typically remain under surveillance, leading to eventual detection of csPCa as PSA values rise. Even though we did not explicitly quantify the proportion of missed/delayed PCa diagnoses and the subsequent impact on health care costs, it is reasonable to hypothesize that these could lead to delayed treatment, potentially resulting in greater health care costs because of more advanced disease at diagnosis.

Our study is not devoid of limitations. First, given the retrospective nature of the study, there is a potential risk of bias. The use of two existing databases, supplemented to complete the data, may have introduced selection bias, so the results should be interpreted with caution. Second, data for the dMRI strategy were collected immediately after the hospital transitioned from risk-adapted stratification to dMRI stratification. During this transitional phase, on the basis of expert opinion, certain patients may not have been treated according to the protocol, leading to deviations from the intended study design. These protocol deviations may have influenced our findings. Third, while we found no statistically significant difference in csPCa detection rates between the groups, the absence of statistical significance does not necessarily imply equivalence. Any difference, whether statistically significant or not, could potentially impact downstream costs associated with diagnostic procedures and treatments. Fourth, we did not calculate the incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) gained, as recommended in previous literature. Even though our results provide valuable insights into the cost differences, future research should incorporate ICER and QALY outcomes for a more comprehensive comparison of the cost effectiveness of these two diagnostic strategies and validate our findings. Furthermore, as not all men underwent prostate biopsy, it remains unclear whether any csPCa cases were missed by either the RC or the dMRI strategy. This underscores the limitations of the current body of research and emphasizes the need for further research.

5. Conclusions

The RC and dMRI strategies demonstrated comparable effectiveness in detecting csPCa, suggesting that either approach could be considered as a viable option in clinical practice. However, to achieve sustainable health care, it is imperative to prioritize risk stratification strategies that not only effectively diagnose csPCa but also optimize resource use and cost effectiveness. Our findings suggest that implementation of an RC strategy could safely reduce the need for MRI and significantly lower the overall diagnostic costs per person. Continuous refinement and evaluation of RCs are essential to maximize their effectiveness and achieve cost efficiency in clinical practice.

Author contributions: Sybren P. Rynja had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Straat, Hagens, Noordzij, Rynja.
Acquisition of data: Straat, Cools Paulino Pereira.
Analysis and interpretation of data: Straat, Hagens.
Drafting of the manuscript: Straat, Hagens.
Critical revision of the manuscript for important intellectual content: Straat, Hagens, Cools Paulino Pereira, van den Bergh, Mazel, Noordzij, Rynja.
Statistical analysis: Straat, Hagens.
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Supervision: Hagens, Noordzij, Rynja.
Other: None.

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