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ORIGINAL PAPER

Cost-effectiveness analysis of short biparametric magnetic resonance imaging protocol in men at risk of prostate cancer

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Summary

Objectives: To compare the cost-effectiveness of a short biparametric MRI (BP-MRI) with that of contrast-enhanced multiparametric MRI (MP-MRI) for the detection of prostate cancer in men with elevated prostate-specific antigen (PSA) levels.

Materials and methods: We compared two diagnostic procedures for detection of prostate cancer (Pca), BP-MRI and MP-MRI, in terms of quality-adjusted life years (QALY), incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) for a hypothetical cohort of 10,000 patients. We compared two scenarios in which different protocols would be used for the early diagnosis of prostate cancer in relation to PSA values. Scenario 1. BP-MRI/MP-MRI yearly if > 3.0 ng/ml, every 2 years otherwise; Scenario 2. BP-MRI/MP-MRI yearly with age-dependent threshold 3.5 ng/ml (50-59 years), 4.5 ng/ml (60-69 years), 6.5 ng/ml (70-79 years).

Results: BP-MRI was more effective than the comparator in terms of cost (160.10 € vs 249.99€) QALYs (a mean of 9.12 vs 8.46), ICER (a mean of 232.45) and NMB (a mean of 273.439 vs 251.863). BP-MRI was dominant, being more effective and less expensive, with a lower social cost. Scenario 2 was more cost-effective compared to scenario 1.

Conclusions: Our results confirmed the hypothesis that a short bi-parametric MRI protocol represents a cost-efficient procedure, optimizing resources in a policy perspective.

KEY WORDS: *Cost-effectiveness analysis; Magnetic Resonance Imaging; Multiparametric MRI; Bi-parametric MRI; Prostatic cancer.*

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INTRODUCTION

Prostate cancer (Pca) is very common in men and is frequently associated with long-term survival in affected subjects (1). In most cases, it remains asymptomatic for a long time; about 29% of localized Pca is classified as very low or low risk with slow growth (1-2). Conventionally, suspicion of Pca is based on *digital rectal examination* (DRE) and/or elevated *prostate specific antigen* (PSA), and is then typically confirmed by prostate biopsy (1, 3). According to PI-RADS v2.1 guideline, *multiparametric MRI* (MP-MRI) proved to be valuable in the Pca diagnostic process in men with high levels of PSA (2, 3).

According to recent studies, *dynamic contrast enhancement* (DCE) use has been resized in PI-RADS version 2.1, restricted to the interpretation of ambiguous findings in the peripheral zone (2, 4-6). Particularly, its role is limited to upgrading category PI-RADS score 3 to PI-RADS score 4 (2, 5). However, this upgrading could be unnecessary in decision-making (performing biopsy or not) (7). In addition, MP-MRI protocol has some disadvantages, including longer time and higher cost, and the use of gadolinium-based contrast agents that may be problematic for patients with a glomerular filtration rate < 30 ml/min; moreover, the risk of potential brain accumulation is well described (8). For these reasons some authors have proposed a short protocol, using the *biparametric MRI* (BP-MRI) (9-11). The diagnostic value of BP-MRI in detecting suspected lesions in the *peripheral zone* (PZ) and the *transitional zone* (TZ) has been validated (10-11) and is justified because: a) ensures lesion identification and localization in any prostatic area; b) avoids the use of gadolinium-DTPA; c) examination lasts about 15 minutes; d) allows money saving.

With this paper, we tried to put together our experience with prostate MRI and that regarding the cost-analysis of imaging studies.

This study investigates cost-effectiveness of patients with suspect Pca, tailoring an approach based on risk stratifications for a both safe and cost-effective management.

The objective of this simulated cost-effectiveness study is therefore to determine the potential cost-effectiveness of BP-MRI protocol compared to MP-MRI for Pca diagnosis.

MATERIALS AND METHODS

Target population

Target population includes a hypothetical cohort of 10,000 men aged between 50-79 years of age, with PSA level > 3 ng/ml and no previous prostate biopsy. The base case was a 65-year-old man, performing prostatic MRI because of elevated PSA levels and/or clinically significant DRE.

These demographic features are based on the median age of the Pca onset (1, 12). The model was tested by age groups in order to examine the cost-effectiveness, given varying levels of cancer prevalence and life expectancy.

No conflict of interest declared.

Since it was a simulated study, no patients or animals were involved, and ethical approval or informed consent were not necessary.

Procedures compared

The procedures assessed in the model are:
Strategy 1. Detecting prostate cancer with non-contrast BP-MRI;
Strategy 2. Detecting prostate cancer with MP-MRI.
Using our base case, we first observed the optimal strategy. Then, we compared costs and QALYs among the two strategies. We evaluated the cost-effectiveness of each strategy for three age groups with a different Pca prevalence. Several economic-based models assessed some hypothetical screening strategies based on PSA thresholds, in relation to age categories (11-16). Our analysis, based on age and PSA stratification, try to better understand the potential impact of BP-MRI on QALY and costs. We weighted pros and cons of two hypothetical different scenarios, joining PSA values and BP-MRI/MP-MRI:
Scenario 1. BP-MRI/MP-MRI yearly if > 3 ng/ml, every 2 years otherwise;
Scenario 2. BP-MRI/MP-MRI yearly with age dependent threshold 3 ng/ml (50-59), 4.5 ng/ml (60-69), 6.5 ng/ml (70-79).

Study design and decision analysis model

We conducted a simulation study based on a model of decision analysis, according to the guidelines established by the Panel on Cost-Effectiveness in *Health and Medicine* (17). In this case study, two variables are considered: cost and clinical effectiveness. This study is performed from a health care perspective, and we consider only direct costs of diagnostic tests, assessing whether BP-MRI adds enough value to justify costs. In the first case, the tree will produce the expected survival rate, in the second the life expectancy in years, and finally, in the third case, the life expectancy in QALYs. Other variables are *incremental cost-effectiveness ratio* (ICER) and *net monetary benefit* (NMB) (Table 1).
Using an analysis software (*OpenMarkov; CISIAD, UNED, Madrid, Spain*), we tried to assess prospectively whether BP-MRI is convenient compared to the current strategy (MP-MRI). In a cost-effectiveness analysis, we refer to an incremental cost threshold considered economically sustainable and therefore acceptable. We identify the optimal strategy with a WTP of € 30.000 per QALY earned, threshold calculated on average daily earnings based on Eurostat statistics for 2017 (18). We set the time horizon to 10 years.
The entire cohort is distributed in final health states, each associated with a volume of costs.

Quality of life

Our model (state-transition model) demands to define the "*health states*" and therefore to specify the "*transition rules*" linked to the corresponding health status. Like quality of life indicators, health utilities specify the patient's experience of disease and are included in the model. To calculate the total QALYs for each diagnostic strategy, we based on previously published data (19-20) and quality of life scores obtained from health-related quality of life questionnaires. We used the *Short Form health survey* (SF-12) *Memorial Anxiety Scale for Prostate Cancer* (MAX-PC), the *Decisional Conflict Scale* (DCS), the *Centre of Epidemiologic Studies Depression scale* (CES-D) and the E*ysenck Personality Questionnaire* (EPQ) 11-16 as tools to measure general health-related quality of life and anxiety. Details of these questionnaires have been described in Literature (20-22). QALYs are calculated by multiplying the duration of time spent in a health state by this utility score associated with that health state.

Sources of probabilities and cost estimates

Table 2 lists all parameters of the model. At our institution, prostate MRI is performed on a 1.5T scanner (*Philips Medical Systems, Healthcare, Eindhoven, the Netherlands*). We suggest a BP-MRI protocol with axial T1W gradient-echo sequence with fat-suppression technique (THRIVE) imaging, multiplanar T2W FSE imaging, axial DWI sequence and *apparent diffusion coefficient* (ADC) map calculation. Direct medical costs, analyzed from a health care perspective, included costs of diagnostic procedures, calculated considering the initial investment of equipment, additional costs during use, maintenance costs, years of use, personnel costs, materials used (provided by the *Hospital Technical Department*). Direct cost of MP-MRI was 249.44 €, direct cost of BP-MRI was 160.10 €. Performance characteristics and utility values of cross-sectional imaging were derived from published information: prevalence of prostate cancer, probability of detecting clinically significant cancer (Table 2) (23).
Sensitivity rates of BP-MRI and MP-MRI in the detection of Pca are 86.7% (80.8, 91.3%) and 93.9% (87.9-99.9%) respectively (4, 6, 11, 23-25). Specificity values of BP-MRI and MP-MRI in the detection of Pca are 90.9% (87.4-93.6) and 88.1% (84.3-91.3), respectively (Table 3) (4, 6.24-26). BP-MRI had a high accuracy (89.1%) and negative predictive value (92.7%) for clinically significant prostate cancer (Gleason score ≥ 3+4, and/or volume > 0.5cc, and/or

Table 1.
Description of terms "QALY", "ICER", "NMB" and "WTP", and how they are calculated.

QALY	Quality-adjusted life years are a measure of longevity, in units of years of life, adjusted for the 'quality' of life during those years. It is the arithmetic product of life expectancy and a measure of the quality of the remaining life years (quality of life coefficient). A way of determining the quality of a particular health state is to use a standard descriptive systems questionnaire.
ICER	The incremental cost-effectiveness ratio is a statistic used in cost-effectiveness analysis to summarize the cost-effectiveness of a health care intervention. It is defined by the difference between two possible interventions: ICER = (C1 - C0) ÷ (E1 - E0), where C1 and E1 are the cost and effect in the intervention group and where C0 and E0 are the cost and effect in the control care group.
NMB	Net monetary benefit represents the value of an intervention in monetary terms when a willingness to pay threshold is known. NMB is calculated as: (incremental benefit x threshold) – incremental cost.
WTP	A willingness-to-pay threshold, according to the World Health Organization (WHO), represents "*an estimate of what a consumer of health care might be prepared to pay for the health benefit*".

Table 2.
Model Inputs.

Parameter	Value	Sensitivity values	Source
Prevalence of cancer in men aged 51-60 years	0.44	0.00-0.90	1, 31
Prevalence of cancer in men aged 61-70 years	0.65	0.00-0.90	1, 31
Prevalence of cancer in men aged 71-80 years	0.71	0.00-0.90	1, 31
Probability cancer is clinically significant	0.50	0.00-0.90	1, 31
Prevalence of Pca in men with abnormal PSA	61%	53%, 69%	1, 31
Incidence of significant Pca in PSA ranges, mg/l, 1 to < 3.0	9%		1, 31
Incidence of significant Pca in PSA ranges, mg/l, 3.0-10.0	12%		1, 31
Incidence of significant Pca in PSA ranges, mg/l, > 10.0	40%		1, 31
DRE findings, Normal	6%		1, 31
DRE findings, Abnormal	57%		1, 31
Prostate volume, ml, 25-40 cm^3	8%		1, 31
Prostate volume, ml, 40 - 60 cm^3	19%		1, 31
Prostate volume, ml, > 60 cm^3	27%		1, 31
Model duration	10 years	5, 10 years	Long-term and short-term assessed
Starting age	50	55, 70	23
Cost of mpMRI scan	249.44 €		Hospital Technical Department
Cost of bpMRI scan	160.10 €		Hospital Technical Department
PSA threshold	3.0 ng/ml		14, 15

Pca = Prostate Cancer; PSA = Prostate Specific Antigen; DRE = Digital Rectal Examination; MP-MRI = Multi-Parametric Magnetic Resonance Imaging; BP-MRI = Bi-Parametric Magnetic Resonance Imaging.

Table 3.
Comparison of diagnostic accuracy of the abbreviated biparametric versus the full multiparametric protocol.

Parameter	Abbreviated biparametric protocol	Full multiparametric protocol	Source
Sensitivity (%) *	86.7 (80.8, 91.3)	93.9 (87.9, 99.9)	24-28
Specificity (%) *	90.9 (87.4, 93.6)	88.1 (84.3, 91.3)	24-28
Positive predictive value *	82.4 (76.1, 87.5)	78.4 (72.0, 83.90	24-28
Negative predictive value *	92.7 (89.5, 95.2)	92.6 (89.8, 95.5)	24-28
Overall diagnostic accuracy *	89.1 (86.2, 91.6)	87.6 (84.6, 90.3)	24-28

* *Data in parentheses are 95% CIs.*

extraprostatic extension) (10-11). Life expectancy was estimated from *Eurostat Statistics Life Tables* (18).

Sensitivity analysis

We performed univariate sensitivity analysis to calculate any variations of each single parameter. Its execution involves recalculating each value of the parameter of interest. It allows us to identify the threshold beyond which, for the variation of that parameter, the diagnostic strategy is no longer optimal. Then, we performed a probability sensitivity analysis by recompiling 10.000 times at random for each parameter. This approach simultaneously considers the uncertainty of each parameter using the Monte Carlo simulation. We assigned a beta distribution to utilities and a range distribution to costs.
Table 1 shows the results of the univariate sensitivity analysis and the costs of our model. NMB is defined as the difference between the value of the benefits obtained and the cost of obtaining them and may be calculated as follows: NMB = ΔQALY • WTP - Δcost, where WTP (*Willingness To Pay*) is the cost-effectiveness acceptability threshold considered in the analysis.

RESULTS

Baseline analysis

Using BP-MRI for diagnosis costed 160.10 €, yielded an average QALY of 9.12 and an average NMB of 273,439. Diagnosis of a Pca performed with MP-MRI costed 249.99€ per patient, yielded an average of 8.46 QALY and an average NMB of 251,863. ICER was 496.33 for 50-59 years' group, 111.68 for 60-69 years' group, and 89.34 for 70-79 years' group (Table 4). For the base case, BP-MRI is identified as an optimal procedure at a willingness to pay 30.000 € per QALY gained. For scenario 1 (Table 5), mean costs per patient were respectively 3602.25€ for BP-MRI and 5612.4€ for MP-MRI. For BP-MRI, corresponding mean QALY was 9, mean ICER was 395.79 and mean NMB 266.397. For MP-MRI mean QALY was 8.9, mean ICER was 630.16 and mean NMB was 261.387. In case of scenario 2 (Table 4), mean costs per patient were respectively 3191.32 € for BP-MRI and 4972.17€ for MP-MRI. For BP-MRI, corresponding mean

Table 4.
QALY, ICER and NMB among the 2 strategies (BP-MRI, MP-MRI).

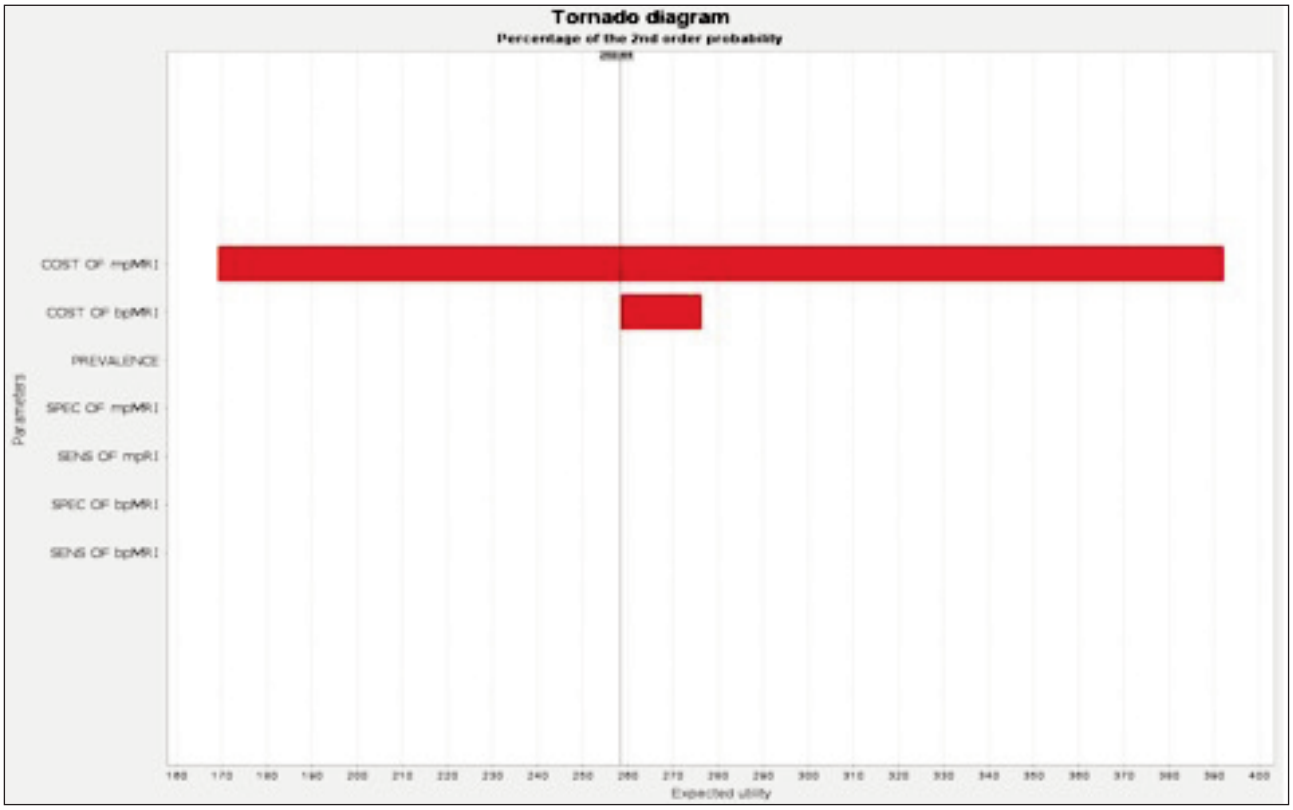
	50-59 y	60-69 y	70-79 y
QALY BP-MRI	9.08	9.09	9.19
QALY MP-MRI	8.9	8.29	8.19
ICER	496.33	111.68	89.34
NMB BP-MRI	272.239	272.539	275.539
NMB MP-MRI	266.750 (dominated)	245.839 (dominated)	243.000 (dominated)

QALY = Quality Adjusted Life Years; ICER = Incremental Cost Effectiveness Ratio; NMB = Net Monetary Benefit; MP-MRI = Multi-Parametric Magnetic Resonance Imaging; BP-MRI = Bi-Parametric Magnetic Resonance Imaging.

Table 5.
Costs, QALY, ICER and NMB among 2 scenarios.

SCENARIO	Cost BP-MRI	QALY, ICER, NMB BP-MRI	Cost MP-MRI	QALY, ICER, NMB MP-MRI
SCENARIO 1 Screen yearly if PSA > 3.0 ng/ml, every 2 years otherwise	3602.25 €	Mean QALY 9 Mean ICER 395.79 Mean NMB 266,397	5612.4€	Mean QALY 8.9 Mean ICER 630.16 Mean NMB 261,387 Dominated
SCENARIO 2 Screen yearly with age dependent threshold 3.5 (50-59), 4.5 (60-69), 6.5 (70-79)	3191.32 € (mean)	Mean QALY 9.09 Mean ICER 342.58 Mean NMB 269,508	4972.17€ (mean)	Mean QALY 9 Mean ICER 554.65 Mean NMB 265,027 Dominated

Figure 1.
A tornado diagram for 50-59 years' group. The horizontal axis represents the variation in the expected utility for each parameter.



QALY was 9.09, mean ICER was 342.58 and mean NMB 269.508. For MP-MRI mean QALY was 9, mean ICER was 554.65, mean NMB 265,027. MP-MRI procedure was dominated. Using the ICER decision rule, we can see that the most cost-effective option is BP-MRI, and all other options are dominated.

Probabilistic cost-effectiveness sensitivity analysis

We built a cost-effectiveness acceptability curve representing the probability of a scenario to be cost-effective related to one or more comparators, related to threshold values of WTP. In case of Scenario 1, for a willingness to pay of € 30.000/QALY, there is 96% probability of BP-MRI being the optimal procedure; the probability of MP-MRI being optimal is 4%. The probabilistic sensitivity analysis indicates that BP-MRI is dominant and cost-effective in 96% when WTP is 30.000 €/QALY earned. In case of Scenario 2, for example in the 50-59 years group, when willingness to pay is above € 10.000/QALY, performing BP-MRI is always the most beneficial decision. Tornado analysis (Figure 1) identified only two parameters that significantly affected the NMB: cost of MP-MRI and cost of BP-MRI.

Discussion

We performed a cost-effective evaluation of a short protocol BP-MRI for Pca detection. Then, we correlated its use in two hypothetical scenarios with introduction of PSA threshold and age stratification. BP-MRI was dominant (more effective and less expensive) over MP-MRI with an ICER that was below the acceptability threshold values considered (30.000 €/QALY earned).

Overall, both BP-MRI and MP-MRI proved to be highly effective diagnosing clinically significant cancer across age groups. BP-MRI has a slightly higher QALY value, probably due to the lack of contrast media and a shorter examination, which provide better patient comfort. We also considered two possible scenarios with PSA value introduction, the first with a PSA threshold > 3 ng/ml for all ages, the second based on the increasing value of PSA according to age (27). The best scenario in terms of cost-effectiveness is the second, with an average cost of €3191.32 for BP-MRI and €4972.17 for MP-MRI. Our analysis also revealed that even a minimal improvement in BP-MRI sensitivity leads to a high cost-effectiveness ratio thanks to savings due to avoiding contrast media. Consequently, BP-MRI has a better ICER and NMB than MP-MRI. Sensitivity analyses indicated a cost-saving of €89.34 for each BP-MRI performed instead of MP-MRI, representing significant earnings for *National Health System* (NHS). Differences in QALY are small and fluctuate steadily from 0.1 to 1. Although MRI is an expensive procedure, this approach has brought the best NMB, with spending values within the WTP threshold, with appropriate use of public money. Our analysis, based on age and PSA stratification, suggests that it can be cost-effective in all age and PSA categories we studied (11-14, 27-28). Use of *contrast enhanced transrectal ultrasound* (CE-TRUS) was also proposed but, unlike liver or pancreatic lesions, contrast enhanced ultrasound is less suitable in

Pca detection (29-31). The most common comparative diagnostic methods respect to MRI are TRUS, CE-TRUS and, more recently, micro-ultrasound; these methods can be better evaluated by a dedicated future study (32). Our study shows that BP-MRI effectively has a significant role detecting Pca; also, it could reasonably reduce the number of biopsies, thanks to its high sensitivity in identification and in localization of index lesions < 5 mm and < 7 mm (33). This approach leads to a reduction in biopsies amount, which represents a considerable spending, as well as a significant impact on the patient's life.

PSA screening may be useful to reduce mortality related to Pca (14, 16, 33). With a PSA cut off value of 3 ng/ml, the positive predictive value is 24%, compared to 10% in case of a threshold of 1.0 ng/ml (24, 27, 29, 33). A higher threshold leads to greater specificity and reduced sensitivity, minimizing the number of unnecessary negative biopsies. Diagnosis and management of Pca can be implemented by multivariate stratification based on patient risk (PSA, DRE, age), associated with BP-MRI (scenario 2). Some trials show that stratifying patients can be a winning strategy to maximize benefits and reduce costs for both diagnosis and therapy (14, 29-37). An important implication of BP-MRI, however, regards the PIRADS assessment categories, as already well explained in PIRADS guidelines v2.1 (2). The PIRADS 3 category for a finding in PZ will be not upgraded, as the DCE sequence is not performed; thus, the proportion of PIRADS 3 will increase, with a decrease in the amount of PIRADS 4 (6-11, 37, 38). This reallocation could lead to further investigations for the patient, with subsequently diagnostic pathway modifications and additional costs.

Nevertheless, our hypothesis is validated by the recent changes of PI-RADS system, where DCE's role is to distinguish PI-RADS 3 versus PI-RADS 4 lesions, in case of T2 - DWI/ADC mismatch (25-31, 34-37).

It is important to note that our study is retrospective and based on hypothetical constructs with inherent limitations, as many economic models, and the results are based on findings of excellence centers. Real-life could be different. Some clinical hypotheses have been formulated about age ranges and age limits. In addition, patients were assumed not to have contraindications to the contrast agent. PSA presents some risks inherent in its low specificity: high rate of false-positives, biopsy complications, risk of overdiagnosis and overtreatment, with consequent sexual and urinary problems (17, 30). A short protocol may not be suitable for all patients and specific individual needs: for example, imaging of tumor extension and local recurrence may require additional sequences or the use of DCE. We agree with PIRADS V2.1 guideline, which recommends DCE use in following cases: previous negative biopsies and increase of PSA; suspicion of disease and no findings on prior BP-MRI; previous prostate surgery; hip orthopedic implants that could degrade DWI weighted imaging.

Our results confirmed the hypothesis that a short MRI protocol represents a possible cost-effective strategy, optimizing resources in a policy perspective.

This study investigates cost-effectiveness of patients with suspect Pca, tailoring an approach based on risk stratifications for a both safe and cost-effective management, keeping in mind medicolegal implications, as for other pathologies.

Furthermore, we suggest the inclusion of BP-MRI as surveillance diagnostic test in patients with suspect Pca, putting this improvement into a prospective long-term evolution in health economics and without any presumption to replace the existing protocols.

We believe that this paper could represent a starting point to rediscuss the importance of the MRI protocol according to the risk stratification of patients.

Conclusions

In an efficient multidisciplinary model that takes care of the patient with suspect Pca, from the beginning to the diagnosis, BP-MRI is valuable for its high sensitivity in lesions identification, with similar results with respect to MP-MRI. BP-MRI is cost-effective and economically sustainable in the perspective of NHS and therefore can represent a valid diagnostic option, being a potential viable alternative to MP-MRI.

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