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Cost-effectiveness of prostate cancer screening with multiparametric magnetic resonance imaging in the Brazilian Unified Health System

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Abstract

Objective: To evaluate the cost-effectiveness of two diagnostic strategies for prostate cancer screening in men with prostate-specific antigen (PSA) ≥ 3 ng/mL from the perspective of the Brazilian Unified Health System (SUS). **Methods:** A decision-tree analytical model was developed using efficacy data from the Göteborg-2 randomized controlled trial. The compared strategies were: Strategy 1 (PSA + multiparametric MRI [mpMRI] with selective biopsy for PI-RADS 3–5 findings) and Strategy 2 (PSA + universal systematic biopsy). Direct costs were estimated from the SIGTAP/DATASUS table (2024). Effectiveness was defined as detection of clinically significant prostate cancer (ISUP grade ≥ 2). Two scenarios were analyzed: (A) mpMRI costs included in both strategies; (B) mpMRI costs excluded from Strategy 2. Mean cost, effectiveness, incremental differences, and incremental cost-effectiveness ratio (ICER) were calculated. **Results:** In Scenario A, Strategy 2 showed higher effectiveness (0.1732 vs. 0.1554), with an incremental cost of R$153.99 and an ICER of R$8,631.43 per additional case detected. In Scenario B, Strategy 2 was economically dominant (ICER = −R$6,530.95). The mpMRI-guided strategy reduced biopsies by 58% and overdiagnosis of ISUP 1 tumors by 50%. Sensitivity analysis confirmed the robustness of results. **Conclusion:** mpMRI improves the diagnostic efficiency of prostate cancer screening; however, its cost-effectiveness within the SUS critically depends on the technology financing model, requiring structured planning for equitable incorporation.

Keywords: Unified Health System; Prostatic Neoplasms; Multiparametric Magnetic Resonance Imaging; Cost-Effectiveness Analysis; Prostate-Specific Antigen.

Resumo

Objetivo: Avaliar a relação custo-efetividade de duas estratégias diagnósticas para o rastreamento do câncer de próstata em homens com antígeno prostático específico (PSA) 3 ng/mL, sob a perspectiva do Sistema Único de Saúde (SUS). **Métodos:** Foi desenvolvido um modelo analítico de árvore de decisão utilizando dados de eficácia do ensaio clínico randomizado Göteborg-2. As estratégias comparadas foram: Estratégia 1 (PSA + RM multiparamétrica [RMmp] com biópsia seletiva para achados PI-RADS 3–5) e Estratégia 2 (PSA + biópsia sistemática universal). Os custos diretos foram estimados a partir da tabela SIGTAP/DATASUS (2024). A efetividade foi definida como a detecção de câncer de próstata clinicamente significativo (grau ISUP 2). Dois cenários foram analisados: (A) custos da RMmp incluídos em ambas as estratégias; (B) custos da RMmp excluídos da Estratégia 2. Foram calculados o custo médio, efetividade, diferenças incrementais e a razão de custo-efetividade incremental (ICER). **Resultados:** No Cenário A, a Estratégia 2 apresentou maior efetividade (0,1732 vs. 0,1554), com um custo incremental de R$ 153,99 e um ICER de R$ 8.631,43 por caso adicional detectado. No Cenário B, a Estratégia 2 foi economicamente dominante (ICER = -R$ 6.530,95). A estratégia guiada por RMmp reduziu o número de biópsias em 58% e o sobrediagnóstico de tumores ISUP 1 em 50%. A análise de sensibilidade confirmou a robustez dos resultados. **Conclusão:** A RMmp melhora a eficiência diagnóstica do rastreamento do câncer de próstata; entretanto, sua relação custo-efetividade dentro do SUS depende criticamente do modelo de financiamento da tecnologia, exigindo um planejamento estruturado para uma incorporação equitativa.

Palavras-chave: Sistema Único de Saúde; Neoplasias da Próstata; Imagem por Ressonância Magnética Multiparamétrica; Análise de Custo-Efetividade; Antígeno Prostático Específico.

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1. INTRODUCTION

Prostate adenocarcinoma is the most incident malignancy in the Brazilian male population, excluding non-melanoma skin tumors. Estimates from the National Cancer Institute (INCA) for the 2023–2025 triennium indicate 71,730 new cases annually, corresponding to an estimated risk of 66.84 per 100,000 men.[1,2] Globally, prostate cancer represents the second most frequent malignancy in men, with approximately 1.4 million new cases annually.[3] Population-based studies conducted in Brazil have documented relevant regional disparities in mortality and survival from this neoplasm, with worse outcomes in the North and Northeast regions, suggesting inequalities in access to timely diagnosis and treatment.[4,5]

PSA-based screening, widely implemented since the 1990s, demonstrated a relative 13% reduction in disease-specific mortality after 23 years of follow-up in the European Randomized Study of Screening for Prostate Cancer (ERSPC); however, the absolute benefit was modest (0.22%) and accompanied by significant overdiagnosis.[6] The low specificity of PSA results in high false-positive rates, unnecessary biopsies, and detection of indolent neoplasms, estimated in 20% to 50% of diagnosed cases.[7-9] Santos et al.,[10] in a study published in the Revista de Saúde Pública, highlighted the need for shared decision-making instruments for prostate cancer screening in Brazil, given the imbalance between risks and benefits of this practice.

In this context, multiparametric magnetic resonance imaging (mpMRI) of the prostate has emerged as a technology capable of improving diagnostic accuracy, allowing direct visualization of suspicious lesions and objective risk stratification using the PI-RADS classification system.[11] Randomized clinical trials such as PROMIS, PRECISION, and Göteborg-2 demonstrated that MRI-based strategies increase the detection of clinically significant cancer, reduce the diagnosis of low-grade tumors, and allow safe omission of biopsies in 25% to 30% of cases with a negative examination.[12-16]

Economic evaluations conducted in European public health systems indicate that strategies incorporating mpMRI and selective biopsy present ICERs ranging from €5,872 to €56,487 per quality-adjusted life year (QALY), values frequently within accepted willingness-to-pay thresholds.[17-19] However, implementation within the SUS faces relevant structural challenges: equipment acquisition and maintenance costs, limited installed capacity, scarcity of specialized radiologists, and marked regional variability in access to advanced imaging examinations.[20,21] Recent epidemiological studies have documented heterogeneous temporal trends in prostate cancer mortality across Brazilian regions, highlighting significant disparities in diagnostic and therapeutic access. Additionally, analyses of oncological treatment costs and technological infrastructure within the Unified Health System (SUS) reinforce the need for contextualized economic evaluations to support decisions regarding the incorporation of new technologies into the public health system[4,22]. Secondary data from the Brazilian Unified Health System (SUS) information systems have been applied to multiple oncological conditions to characterize regional inequalities in hospitalizations and mortality in Brazil.[34]

Despite a growing body of international evidence, a significant gap persists regarding cost-effectiveness studies contextualized for public health systems in middle-income countries. Direct extrapolation of results from other settings is inadequate given differences in relative costs, utilization patterns, and resource availability.[23] The present study aims to evaluate the cost-effectiveness of two diagnostic strategies for prostate cancer screening in men with PSA ≥ 3 ng/mL from the SUS perspective, generating quantitative evidence to support technology incorporation decisions.

2. METHODS

2.1 Study design and perspective

This is a health economic evaluation study, specifically a cost-effectiveness analysis, conducted from the SUS perspective, considering only direct medical costs. The analytical model, based on a decision tree, was developed in R software (version 4.3.2, R Foundation for Statistical Computing), which is appropriate for representing short-term diagnostic processes with sequential, non-recurrent events.[24,25]

2.2 Population and clinical data source

The target population comprised asymptomatic men with PSA ≥ 3 ng/mL, with no previous diagnosis of prostate cancer, eligible for initial diagnostic investigation. Clinical efficacy parameters were entirely derived from

the Göteborg-2 randomized controlled trial, published in 2024 in The New England Journal of Medicine, which randomized 900 patients (444 to Strategy 1 and 456 to Strategy 2).[16]

2.3 Compared strategies

1. **Strategy 1 — MRI-guided screening with selective biopsy:** all individuals with PSA ≥ 3 ng/mL underwent multiparametric MRI. Only patients with a positive examination (PI-RADS 3–5) were submitted to prostatic biopsy. Patients with a negative MRI (PI-RADS 1–2) were not biopsied.
2. **Strategy 2 — Screening with universal systematic biopsy:** all individuals with PSA ≥ 3 ng/mL underwent systematic transrectal prostatic biopsy. Strategy 2 was modeled under two scenarios: Scenario A (inclusion of mpMRI costs in both strategies, replicating the clinical trial protocol) and Scenario B (exclusion of mpMRI costs from Strategy 2, simulating an alternative clinical practice within the SUS without prior MRI).

2.4 Costs

Direct medical costs were estimated from the SIGTAP/DATASUS Table, December 2024 edition. The following procedures were included: total PSA (code 02.02.03.009-0; R$3.41), serum creatinine (02.02.01.021-8; R$1.57), complete blood count (02.02.02.038-0; R$4.11), coagulation panel (02.02.08.006-6; R$2.63), transrectal prostate ultrasound (02.05.02.014-0; R$20.91), multiparametric prostate MRI (02.06.01.013-9; R$268.75), needle prostate biopsy (02.01.01.042-0; R$32.85), and histopathological examination (02.03.01.006-6; R$15.44). All values were expressed in Brazilian reais (R$), without application of a discount rate given the time horizon restricted to the diagnostic phase. The SIGTAP/DATASUS table is one of the most comprehensive epidemiological databases in Brazil, integrating multiple health information systems widely used in cost and outcome research.[35]

2.5 Effectiveness measure

Effectiveness was defined as the probability of detecting clinically significant prostate adenocarcinoma (ISUP grade ≥ 2) per screened patient. This measure reflects a clinically relevant outcome, aligned with the minimization of overdiagnosis of indolent neoplasms.[26]

2.6 Economic analysis

For each strategy and scenario, the following parameters were estimated: mean cost per screened patient (C), mean effectiveness (E), incremental cost difference ($\Delta C = C_2 - C_1$), incremental effectiveness difference ($\Delta E = E_2 - E_1$), and incremental cost-effectiveness ratio (ICER = $\Delta C/\Delta E$), expressed in R$ per additional case of clinically significant cancer detected. No explicit willingness-to-pay threshold was adopted, given the absence of consensus in Brazil for diagnostic technologies within the SUS.[27]

2.7 Sensitivity analysis

A deterministic univariate sensitivity analysis was conducted, varying the mpMRI cost by ±20% of the base value (R$268.75), resulting in a range of R$215.00 to R$322.50. All other parameters were held constant.

2.8 Ethical aspects

The study used exclusively publicly available aggregated secondary data, without access to individualized information. It is therefore exempt from review by a Research Ethics Committee, in accordance with Brazilian National Health Council Resolution No. 510/2016.

3. RESULTS

3.1 Clinical parameters of the model

The clinical probabilities incorporated into the decision model were derived from the Göteborg-2 trial (Table 1). Under Strategy 1 (PSA + mpMRI + selective biopsy), multiparametric MRI findings allowed 58.1% of patients (PI-RADS 1–2) to be spared from initial biopsy. Among the 41.9% referred for the procedure due to positive imaging (PI-RADS 3–5), the detection rate for clinically significant prostate cancer (ISUP grade ≥ 2) was 63.9%, while ISUP grade

1 tumors accounted for 36.1% of diagnoses. Conversely, in Strategy 2 (PSA + systematic biopsy), no malignancy was detected in 65.1% of the screened population. Within the biopsied cohort of this group, the prevalence of ISUP ≥ 2 tumors was 49.6%, with advanced disease (ISUP 4–5, N+, or M+) identified in 8.8% of cases.

Table 1. Clinical parameters of the decision model (Göteborg-2 trial).

Parameter	Probability	Source data
MRI positive (PI-RADS 3–5) — Strategy 1	41.9%	186/444
MRI negative (PI-RADS 1–2) — Strategy 1	58.1%	258/444
Significant cancer (ISUP ≥ 2) given biopsy — Strategy 1	63.9%	69/108
ISUP 1 cancer given biopsy — Strategy 1	36.1%	39/108
No cancer given biopsy — Strategy 1	41.9%	78/186
No cancer — Strategy 2	65.1%	297/456
Significant cancer (ISUP ≥ 2) — Strategy 2	49.6%	79/159
ISUP 1 cancer — Strategy 2	50.3%	80/159
Advanced disease (ISUP 4–5/N+/M+) — Strategy 2	8.8%	14/159

Source: Hugosson et al.[16]

3.2 Unit costs

The unit costs for all procedures included in the model were sourced from the SIGTAP/DATASUS database (December 2024 edition) and are summarized in Table 2. Among the diagnostic resources, multiparametric prostate MRI (R$ 268.75) constituted the most significant cost component by a substantial margin. This was followed by needle prostate biopsy (R$ 32.85) and subsequent histopathological examination (R$ 15.44). Laboratory assessments, comprising complete blood count (R$ 4.11), total PSA (R$ 3.41), coagulation panel (R$ 2.63), and serum creatinine (R$ 1.57), accounted for a comparatively minor proportion of the total diagnostic expenditure. These standardized reimbursement values, as defined by the Brazilian Unified Health System (SUS), were applied uniformly across all simulated patients within the decision model.

Table 2. Unit costs of procedures in the SUS (SIGTAP/DATASUS, 2024).

Resource	SIGTAP Code	Value (R$)
Total PSA	02.02.03.009-0	3.41
Serum creatinine	02.02.01.021-8	1.57
Complete blood count	02.02.02.038-0	4.11
Coagulation panel	02.02.08.006-6	2.63
Transrectal prostate ultrasound	02.05.02.014-0	20.91
Multiparametric prostate MRI	02.06.01.013-9	268.75
Needle prostate biopsy	02.01.01.042-0	32.85
Histopathological examination	02.03.01.006-6	15.44

Source: SIGTAP/DATASUS Table, December 2024 edition.

Figures 1 and 2 present the decision trees of the analytical model for Scenarios A and B, respectively, with transition probabilities, costs, and outcomes at each decision node.

3.3 Cost-effectiveness analysis

In Scenario A, with mpMRI costs included in both strategies, Strategy 1 had a mean cost per patient of R$432.23 and effectiveness of 0.1554. Strategy 2 had a mean cost of R$586.22 and effectiveness of 0.1732. The incremental analysis yielded ΔC of R$153.99 and ΔE of 0.01784, corresponding to an ICER of R$8,631.43 per additional clinically significant cancer case detected. The simple cost-effectiveness ratio (C/E) was R$2,781.40 for Strategy 1 and R$3,384.64 for Strategy 2.

In Scenario B, without including mpMRI costs in Strategy 2, the mean cost of Strategy 1 remained at R$432.23, whereas that of Strategy 2 decreased to R$315.72. The incremental analysis showed ΔC of −R$116.51, maintaining ΔE of

0.01784, resulting in a negative ICER of −R$6,530.95, characterizing the economic dominance of Strategy 2. The simple C/E of Strategy 2 in this scenario was R$1,822.86 per detected case.

The number needed to screen (NNS) to detect one additional clinically significant cancer case with Strategy 2 compared to Strategy 1 was approximately 56 patients (1/0.01784). Strategy 1 reduced the number of biopsies performed by 58.1% and the diagnosis of ISUP 1 tumors by approximately 50% (8.8% vs. 17.5%). The complete results by strategy and scenario are summarized in Table 3.

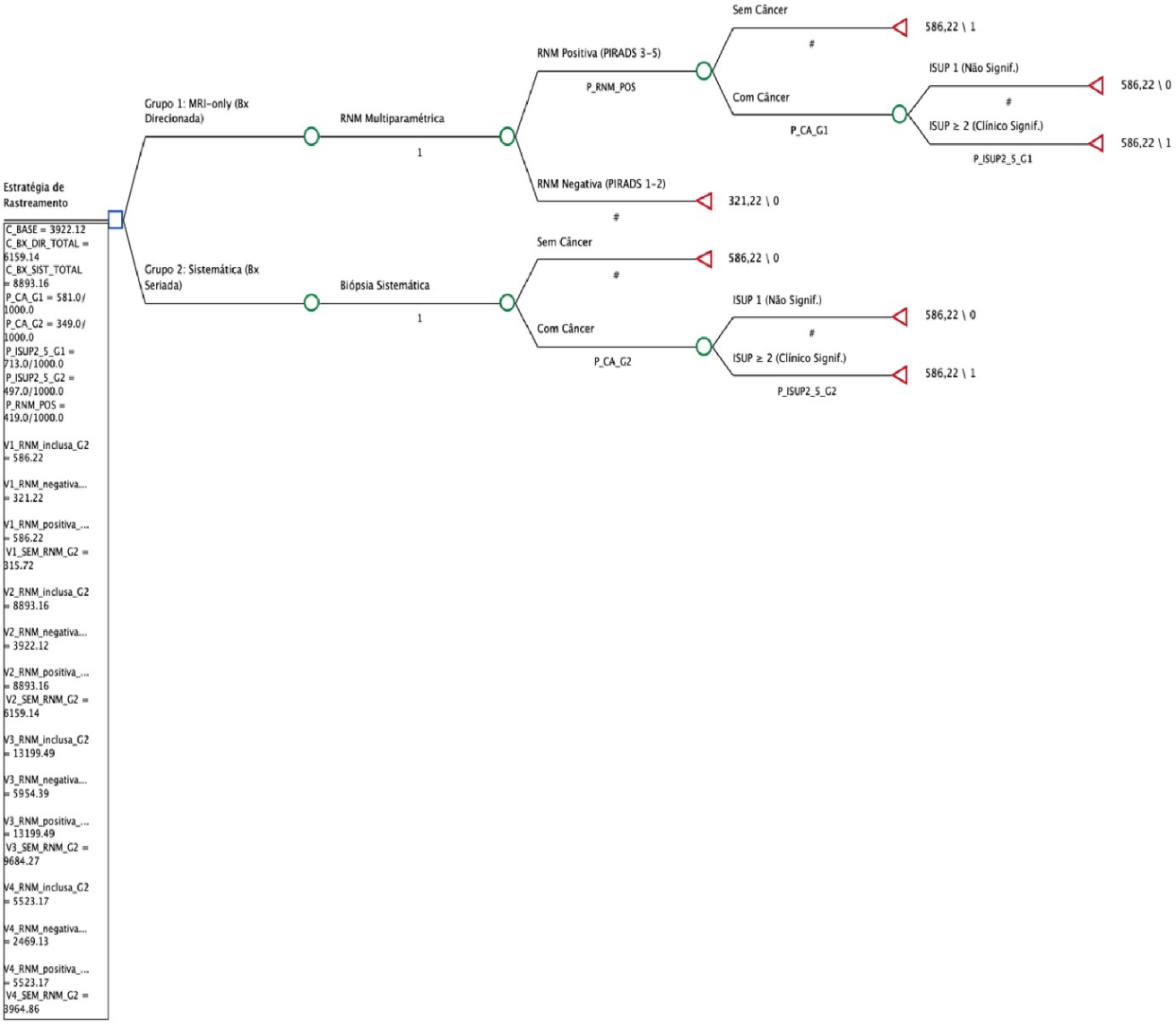

Figure 1. Decision tree of the analytical model — Scenario A (mpMRI cost included in both strategies). Values at terminal nodes represent cost (R$) and effectiveness.

Table 3. Costs, effectiveness, and incremental cost-effectiveness ratio by strategy and scenario.

Scenario	Strategy	Mean cost (R$)	Effectiveness	C/E (R$/case)	ICER (R$/additional case)
A	Strategy 1 (PSA+MRI+selective Bx)	432.23	0.1554	2,781.40	—

Note: Effectiveness = probability of detecting clinically significant cancer (ISUP ≥ 2). ICER = incremental cost-effectiveness ratio. Bx = biopsy.

Scenario	Strategy	Mean cost (R$)	Effectiveness	C/E (R$/case)	ICER (R$/additional case)
A	Strategy 2 (PSA+MRI+systematic Bx)	586.22	0.1732	3,384.64	—
A	**Incremental difference**	**+153.99**	**+0.01784**	—	**8,631.43**
B	Strategy 1 (PSA+MRI+selective Bx)	432.23	0.1554	2,781.40	—
B	Strategy 2 (PSA+systematic Bx)	315.72	0.1732	1,822.86	—
B	**Incremental difference**	**−116.51**	**+0.01784**	—	**−6,530.95 (dominant)**

Note: Effectiveness = probability of detecting clinically significant cancer (ISUP ≥ 2). ICER = incremental cost-effectiveness ratio. Bx = biopsy.

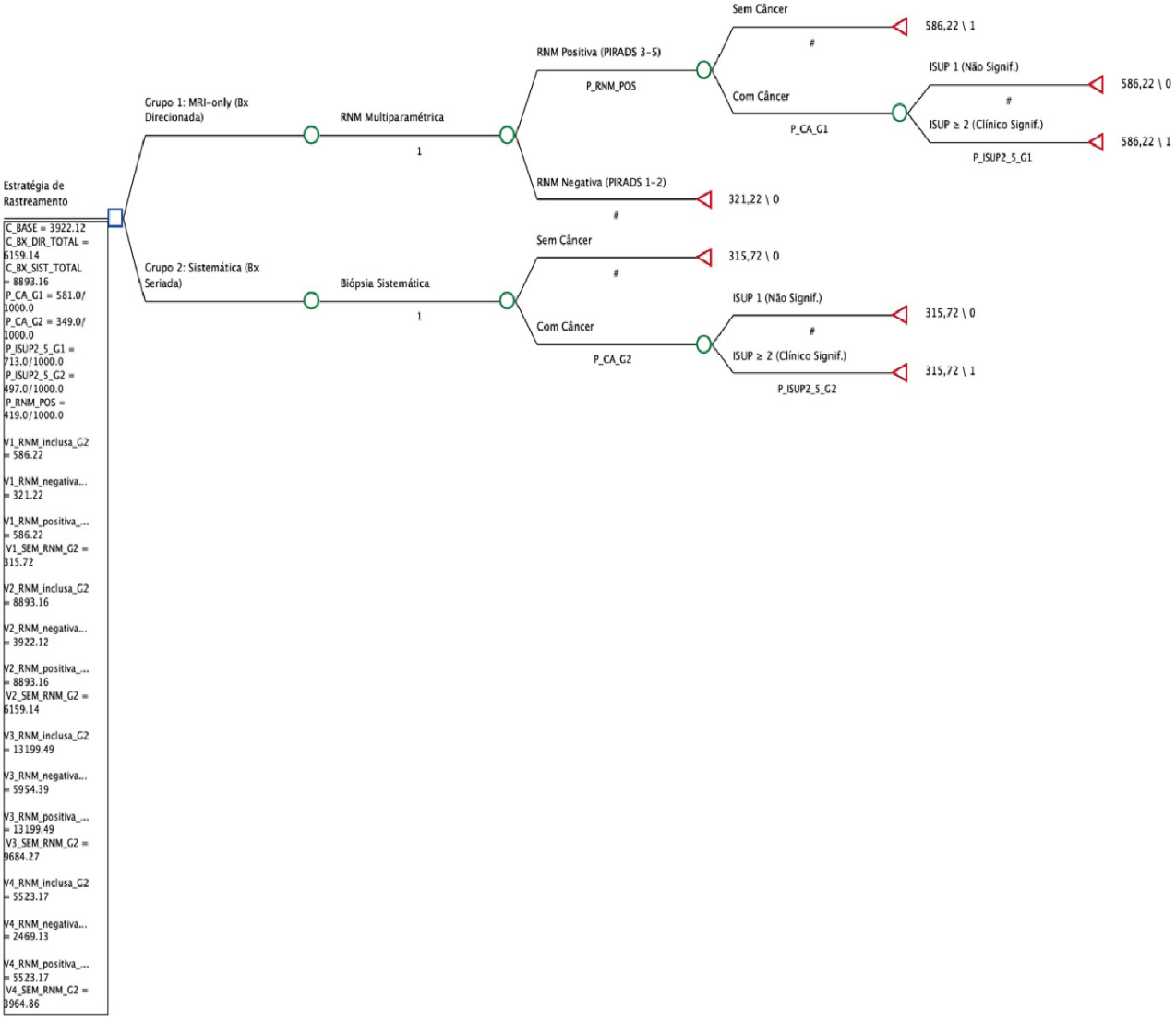

Figure 2. Decision tree of the analytical model — Scenario B

(mpMRI cost excluded from Strategy 2, simulating clinical practice within the SUS).

3.4 Sensitivity analysis

The results of the univariate sensitivity analysis are presented in Table 4. In Scenario A, variations in mpMRI cost of ±20% (ranging from R$ 215.00 to R$ 322.50) produced no change in the incremental cost difference (ΔC = R$ 153.99) or the ICER (R$ 8,631.43 per additional case detected), given that mpMRI costs were assigned equally to both strategies. In Scenario B, the same cost variation resulted in ICERs ranging from −R$ 3,518.09 (at −20%) to −R$ 9,543.81 (at +20%), with Strategy 2 maintaining economic dominance throughout the entire range analyzed. These findings indicate that the model's conclusions are robust to uncertainty in mpMRI pricing, particularly under conditions representative of actual SUS clinical practice.

4. DISCUSSION

The present study demonstrated that the economic impact of incorporating multiparametric MRI as a triage tool in prostate cancer screening within the SUS is critically dependent on the financing model adopted. In Scenario A, with universal availability of the technology, a trade-off was observed between cost efficiency and diagnostic effectiveness, with no dominance between strategies. In Scenario B, reflecting scenarios in which MRI is not systematically available, systematic biopsy demonstrated strong economic dominance.

Table 4. Univariate sensitivity analysis of mpMRI cost (±20% of base value).

Variation	MRI cost (R$)	Cost E1 (R$)	ΔC-A (R$)	ICER-A (R$/case)	ICER-B (R$/case)
−20%	215.00	378.48	153.99	8,631.43	−3,518.09
−15%	228.44	391.92	153.99	8,631.43	−4,271.31
−10%	241.88	405.36	153.99	8,631.43	−5,024.52
−5%	255.31	418.80	153.99	8,631.43	−5,777.74
Base	**268.75**	**432.23**	**153.99**	**8,631.43**	**−6,530.95**
+5%	282.19	445.67	153.99	8,631.43	−7,284.16
+10%	295.62	459.11	153.99	8,631.43	−8,037.38
+15%	309.06	472.55	153.99	8,631.43	−8,790.59
+20%	322.50	485.98	153.99	8,631.43	−9,543.81

Note: In Scenario A, both strategies include mpMRI cost; in Scenario B, only Strategy 1 includes it. E1 = Strategy 1.

These findings are broadly consistent with economic evaluations conducted in European public health systems. Vynckier et al.,[17] in a systematic review of cost-effectiveness studies in Europe, identified ICERs ranging from €5,872 to €56,487 per QALY for strategies incorporating MRI. Hao et al.,[18] based on the Swedish STHLM3-MRI trial, demonstrated reductions of up to 50% in biopsies and overdiagnosis, with ICERs of approximately €20,000 per QALY. Keeney et al.[19] corroborated that the cost-effectiveness of MRI is particularly sensitive to examination cost and prior risk stratification. Although our ICERs, expressed per additional case detected, are not directly comparable to ICERs in QALYs, the observed patterns are consistent.

Within the Brazilian context, results must be interpreted in light of the specificities of the SUS. Recent evidence indicates that prostate cancer mortality exhibits heterogeneous temporal trends across Brazilian regions, with persistent increases in certain areas suggesting significant disparities in diagnostic access.[4] The incorporation of MRI as a mandatory component of screening pathways could paradoxically deepen these inequities, creating a two-tier diagnostic pathway: an optimized, advanced imaging-based pathway for populations with access to tertiary centers, and a conventional pathway for populations in regions with lower technological availability.[21]

Santos et al.,[10] in a study on shared decision-making tools for prostate cancer screening published in the Revista de Saúde Pública, emphasized that the best available evidence points to an imbalance between the risks and benefits of conventional screening, reinforcing the need for strategies that minimize harms. In this regard, the 58% reduction in biopsies and 50% reduction in overdiagnosis observed with the MRI-guided strategy represents a substantial advance in minimizing iatrogenic harm.

Steffen et al.,[28] in an analysis published in Physis: Revista de Saúde Coletiva, argued that population-based prostate cancer screening in Brazil carries more risks than benefits, a position aligned with INCA's recommendation against population-based screening. The incorporation of MRI could alter this balance by significantly reducing the

harms associated with screening, although our findings demonstrate that the economic benefit is fundamentally dependent on the financing model.

Santos Silva et al.[22] analyzed outpatient oncological treatment costs within the SUS, demonstrating that late diagnosis and palliative treatments are associated with worse outcomes and higher costs. Although our model is restricted to the diagnostic phase, it is plausible that more efficient detection of clinically significant cancers through MRI could generate downstream savings by preventing late-stage diagnoses and advanced disease treatments. Long-term modeling studies are needed to quantify this potential benefit.

The heterogeneous distribution of MRI equipment in Brazil, concentrated in capital cities and more economically developed regions,[29] constitutes a relevant structural barrier. Pragmatic implementation within the SUS could adopt a stratified approach, reserving MRI for patients with intermediate-risk characteristics where the informational value of imaging would be maximized, while maintaining a direct diagnostic pathway for patients at very low or very high risk.

From a clinical perspective, recent evidence indicates that systematic biopsy retains independent diagnostic value even in the presence of MRI, detecting 5–10% of ISUP ≥ 2 cancers not visualized on imaging.[30,31] The decision to add systematic to targeted biopsy should be individualized, considering risk factors such as PSA density, family history, and ethnicity.[32,33]

4.1 Limitations

The present study has limitations that should be acknowledged. The time horizon restricted to the diagnostic phase does not incorporate long-term outcomes such as treatment, disease progression, quality of life, or mortality. The absence of QALYs as an effectiveness measure limits comparisons with conventional willingness-to-pay thresholds and with other health interventions.

Efficacy parameters were derived from a clinical trial conducted in Sweden, with a predominantly Caucasian population and access to high-quality diagnostic resources. Transferability to the Brazilian context involves assumptions that may not be entirely valid, given heterogeneity in the quality of MRI equipment and radiological expertise within the SUS.

The model did not incorporate biopsy complication costs (infections, hemorrhages, hospitalizations) or indirect costs, which systematically underestimates the costs of Strategy 2. The sensitivity analysis was limited to the deterministic univariate approach, without probabilistic analysis with cost-effectiveness acceptability curves.

5. CONCLUSION

The incorporation of multiparametric MRI as a triage tool in prostate cancer screening provides substantial clinical benefits, reducing the number of biopsies by 58% and overdiagnosis of indolent neoplasms by 50%. However, its economic impact within the SUS is critically dependent on the financing model: with universal MRI availability, systematic biopsy achieves higher effectiveness at an incremental cost of R$8,631.43 per additional case detected; without attributing this cost, systematic biopsy demonstrates economic dominance.

The results suggest that MRI incorporation into the SUS should be planned as a structured initiative, with coordinated investments in equipment, professional training, standardized protocols, and sustainable financing. Partial or heterogeneous implementation may fail to produce the expected economic benefits and could potentially deepen healthcare inequities. SUS managers are recommended to consider the MRI-guided approach primarily in settings where the technology is available with quality assurance, while progressively expanding access and installed capacity to ensure regional equity.

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