

IDENTIFYING KEY CRITERIA FOR HEALTH TECHNOLOGY ASSESSMENT OF ADJUVANT TREATMENT OF EARLY BREAST CANCER IN BRAZIL

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INTRODUCTION

- Early breast cancer (EBC) refers to cancer that is confined to the breast or detected in the breast and locoregional lymph nodes in the women with node positive neoplasm. (1)
- Brazilian Public Healthcare System offers chemotherapy as an option of adjuvant therapy, in addition to trastuzumab for HER2-positive subgroup patients. Despite those treatments, part of the patients will still relapse and, at some point, die due to the disease. Therefore, new drugs were developed and began to be evaluated in the adjuvant setting. (2)
- Multicriteria Decision Analysis (MCDA) comprises a broad set of methodological approaches and offers a framework, addressing all relevant criteria for establishing the value of a technology. (3)
- The partial MCDA approach has been used in some cases of healthcare decision-making process in order to establish a set of criteria and elicit weights. (4)
- The DEMATEL (Decision Making Trial Evaluation Laboratory) method holds an approach that has been applied in many MCDA problems in order to set up weights for the studied criteria, as the partial MCDA. (5)
- In MCDA field, the DEMATEL method has been vastly applied to identify and to rank key criteria when there is a cause-effect relation among them. (6-8)
- The aim of this study is to identify key criteria and their relevance to the health technology assessment (HTA) process for EBC adjuvant therapies in Brazil.

METHODS

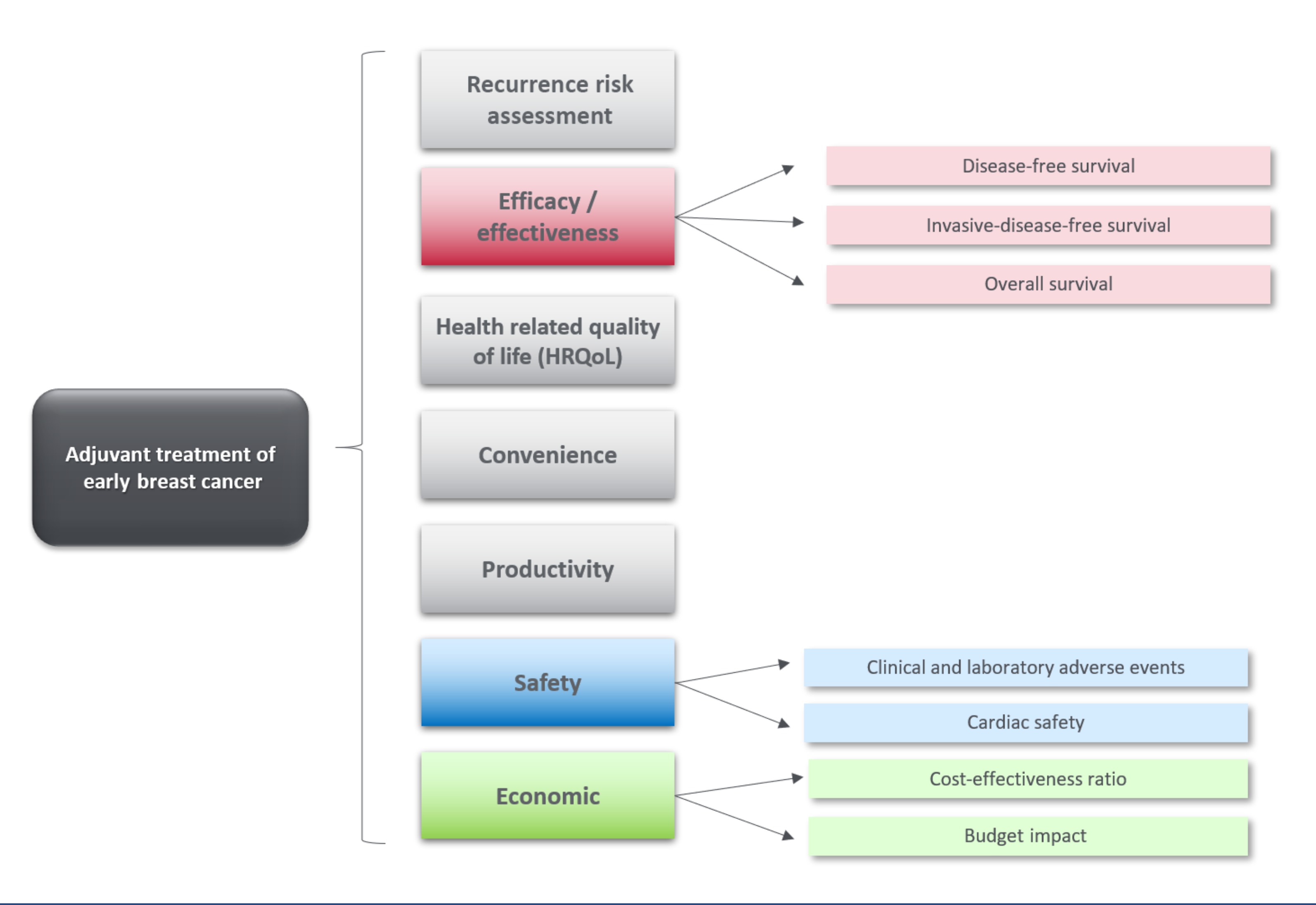
- To identify and rank key criteria, it was realized a face-to-face one-day meeting with 4 specialists’ groups: oncologists with experience in the treatment of EBC, patients’ representants, public payers with experience in health technology reimbursement process, and HTA experts (n=3 each).
- In order to search criteria considered important within adjuvant therapies for EBC context, a systematic literature review was conducted until September 2018 through The Cochrane Collaboration, Medline via PubMed, Latin American and Caribbean Literature in Health Sciences (LILACS) and Center for Reviews and Dissemination (CRD).
- DEMATEL method was applied for the weighting process and to classify each criterion as cause or effect.
 - Each participant group entered in a consensus to establish the influence degree that each criterion exerts over the other.
 - It was used a verbal scale in which 0 means no influence; 1 weak influence; 2 moderate influence; 3 high influence and 4 very high influence.

RESULTS

- The final set was compounded by 11 criteria: invasive-disease–free survival (iDFS), disease-free survival (DFS), overall survival (OS), adverse events (AEs), cardiac safety, cost-effectiveness ratio (ICER), budget impact (BI), recurrence risk assessment (RRA), health-related quality of life (HRQoL), productivity and convenience (Figure 1).

- Some of those criteria could be aggregated in categories. Thus, iDFS, DFS and OS compose the efficacy category, AEs and cardiac safety compose the safety category, and ICER and BI compose the economic category (Figure 1).

Figure 1. Set of criteria



- For the oncologists, RRA was the most important criterion (weight 11.06%) and it was classified as cause. DFS, OS and iDFS were classified as effect and they reached the 2nd, 3rd and 5th positions, respectively. HRQoL was in 4th position, as cause. The economics criteria (BI and ICER) were in the last positions. ICER was the least important criterion (4.67%) and it was classified as effect (Table 1).

- For patients’ representants the most important criterion was HRQoL (16.39%), classified as a cause, followed by RRA (12.56%). OS, iDFS and DFS were classified as cause, in 3rd, 4th and 7th positions, respectively. The AEs and cardiac safety criterion had the same weights (5.63% each) in 9th position, and they were classified as cause. It is important to note that this criterion was positioned below ICER, productivity, DFS and convenience. BI was the least important criterion for this group (5.43%; effect), but ICER reached the 5th position, being classified as cause (Table 1).

- Public payers identified BI and ICER as relevant criteria; however, they were classified as effect, due to them direct dependence on clinical outcomes (1st [12.18%] and 2nd [11.74%] positions, respectively). RRA was in the third one (11.59%; cause). DFS was in 4th position (11.29%; cause), followed by HRQoL (10.25%; effect). Cardiac safety was in 9th and AEs in 10th positions, but here AEs was classified as effect. Convenience was the least important criterion (5.08%; cause) (Table 1).

- For HTA experts, HRQoL was the most important criterion (11.01%) and t was classified as effect, followed by OS (10.98%; cause). As patients’ representants group, cardiac safety and AEs had the same weight, and both were classified as cause. However, in this scenario they attained the 3rd position (10.03% each). ICER and BI were classified as effect, in 6th (9.45%) and 8th (7.73%) positions. Again, convenience was the least important criterion (6.29%; cause) (Table 1).

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Table 1. Results from DEMATEL application (consensus)

Ranking	Oncologists	Patients’ representants	Public payers	HTA experts
1 st	RRA (11.06%) Cause	HRQoL (16.39%) Cause	BI (12.18%) Effect	HRQoL (11.01%) Effect
2 nd	DFS (11.01%) Effect	RRA (12.56%) Cause	ICER (11.74%) Effect	OS (10.98%) Cause
3 rd	OS (10.99%) Effect	OS (11.64%) Cause	RRA (11.59%) Cause	Cardiac safety and AEs (10.03%) Cause
4 th	HRQoL (10.89%) Cause	iDFS (9.55%) Cause	DFS (11.29%) Cause	DFS (9.81%) Cause
5 th	iDFS (10.52%) Effect	ICER (9.36%) Cause	HRQoL (10.25%) Effect	iDFS (9.51%) Cause
6 th	Productivity (9.31%) Effect	Productivity (9.09%) Effect	iDFS (8.73%) Cause	ICER (9.45%) Effect
7 th	AEs (8.68%) Effect	DFS (8.59%) Cause	Productivity (8.43%) Effect	Productivity (8.62%) Effect
8 th	Cardiac safety (8.42%) Effect	Convenience (6.14%) Cause	OS (8.18%) Effect	BI (7.73%) Effect
9 th	Convenience (7.24%) Effect	AEs and Cardiac safety (5.63%) Cause	Cardiac safety (6.92%) Cause	RRA (6.54%) Cause
10 th	BI (7.19%) Cause	BI (5.43%) Effect	AEs (5.60%) Effect	Convenience (6.29%) Cause
11 th	ICER (4.67%) Effect	-	Convenience (5.08%) Cause	-

HTA: health technology assessment; RRA: recurrence risk assessment; iDFS: invasive-disease–free survival; DFS: disease-free survival; OS: overall survival; AEs: adverse events; ICER: cost-effectiveness ratio; BI: budget impact analysis; HRQoL: health-related quality of life.

- The criteria ranking per category showed that efficacy was the main criteria for all groups (Figure 2).

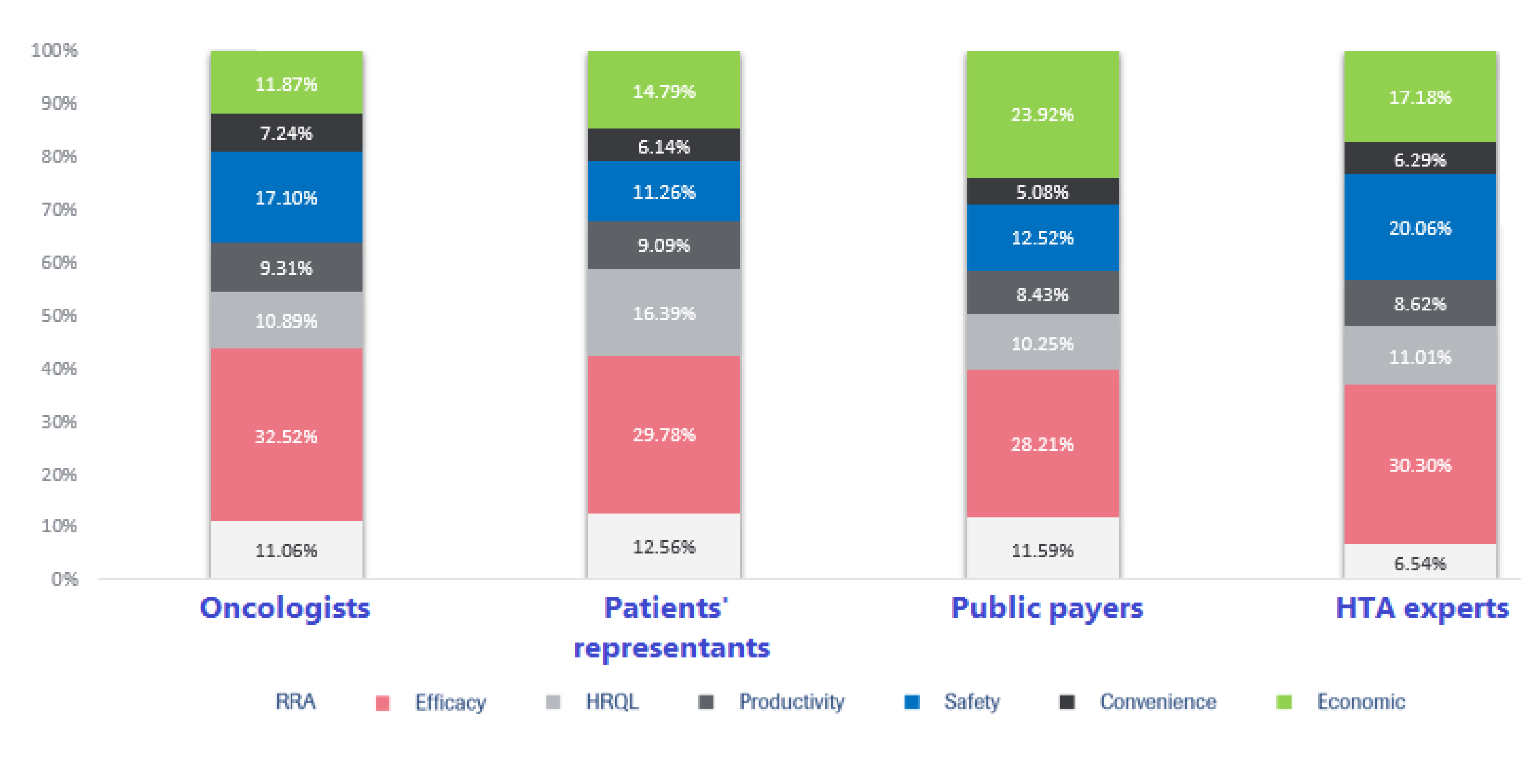
- Oncologists and HTA experts prioritized safety after efficacy (Figure 2).

- Patients' representants prioritized HRQoL, while public payers prioritized economic category after efficacy (Figure 2).

- Economic category was in the 3rd position for all groups, except for public payers, which considered safety in this position (Figure 2).

- Convenience was the least important criterion for all groups (Figure 2).

Figure 2. Criteria ranking per category



LIMITATIONS

- The consensus formed by each group represented a point of view formed by three specialists’ representants.

- A bigger sample could perform the process with more clarity in relation to the point of view of each specialist's group.

CONCLUSIONS

- 11 criteria were considered relevant in the context of adjuvant therapies in EBC in Brazil, according to four experts’ groups.

- Through DEMATEL application was possible to know the main criteria on each specialist’s group.

- Efficacy was the main category and convenience got the last place in the ranking.