

Original Research Article

Cost-effectiveness analysis of gene expression profiling for breast cancer treatment decisions in India

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Received: 22 March 2025

Revised: 26 March 2025

Accepted: 27 March 2025

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ABSTRACT

Background: Breast cancer is the most common cancer among Indian women, with over 200,000 new cases annually. Gene expression profiling can help identify patients who can safely avoid chemotherapy, reducing unnecessary treatment and complications.

Methods: A decision-analytic model was developed using TreeAge Pro to assess the cost-effectiveness of gene expression profiling versus standard care for ER-positive, node-negative/low-node breast cancer patients in India. A hypothetical cohort of 300,000 patients was analyzed, focusing on cases spared from chemotherapy, relapse rates and costs.

Results: A test with 92% sensitivity and 96% specificity (test 1) could spare 40,000 patients from chemotherapy annually. A tiered pricing model (₹15,000–₹50,000) showed favorable cost-effectiveness over existing tests (Oncotype DX: ₹190,000, CanAssist: ₹65,000). The lowest-cost test (₹15,000) had an ICER of ₹190,200 per case spared, making it a dominant strategy. False negatives resulted in a ₹61 crore annual burden, while false positives added ₹36 crores in unnecessary chemotherapy costs.

Conclusions: Gene expression profiling is cost-effective in India, reducing healthcare costs and improving patient quality of life. Optimizing sensitivity and specificity is essential for maximizing clinical and economic benefits.

Keywords: Breast cancer, Cost effective analysis, Genetics screening

INTRODUCTION

Breast cancer remains the most common cancer among women in India, with an increasing incidence rate that poses significant challenges to the healthcare system.¹⁻³ Current treatment guidelines recommend adjuvant chemotherapy for most patients with early-stage breast cancer; however, recent evidence suggests that a substantial proportion of patients may not benefit from chemotherapy, exposing them unnecessarily to toxicity and incurring avoidable healthcare costs. Gene expression

profiling tests can help identify patients with favorable prognosis who may safely forgo chemotherapy.⁴ While such tests are widely used in high-income countries, their high-cost limits accessibility in resource-constrained settings like India. The development of more affordable alternatives could potentially improve treatment decision-making and resource allocation in the Indian healthcare context.⁵ This study aims to evaluate the cost-effectiveness of gene expression profiling tests for breast cancer treatment decisions in India, with special attention to various pricing strategies that could enhance accessibility while maintaining economic viability.

METHODS

Study type

This was a hypothetical scenario analysis based on comprehensive medical research from domain experts across vizag, Hyderabad and Delhi, utilizing a decision-analytic modeling approach to evaluate the potential impact of gene expression profiling tests in the Indian healthcare context.

Study place

The analysis was conducted across tertiary care cancer centers in Vizag, Hyderabad and Delhi.

Study duration

from 2024 to 2025, leveraging expert interviews and existing epidemiological data.

Eligibility criteria

ER-positive, HER2-negative low to intermediate breast cancer patients. Complete clinical pathology history available

Exclusion criteria

All other types of breast cancers. Stages III and beyond

Procedure

We developed a decision tree model using TreeAge Pro software to compare different testing strategies.

Standard of care (all eligible patients receive chemotherapy). Oncotype DX testing (₹190,000). Can assist testing (₹65,000). Test 1 (₹50,000, sensitivity: 92%, specificity: 96%). Test 2 (₹30,000, sensitivity: 82%, specificity: 88%). Test 3 (₹15,000, sensitivity: 76%, specificity: 81%). The model incorporated test performance characteristics, treatment decisions based on . test results and subsequent clinical outcomes including relapse rates.

Ethical approval

Not applicable, as the study does not involve real patients and is based on a hypothetical scenario and market research.

Statistical analysis

Statistical analysis was performed using SPSS software to evaluate the cost-effectiveness of different testing strategies.

Model parameters

Relapse rates were estimated at 6% for low-risk patients not receiving chemotherapy and 46% for high-risk patients not receiving chemotherapy. For patients receiving appropriate chemotherapy, we assumed a relapse rate of 15%.

Direct medical costs included gene expression test costs (₹15,000 to ₹190,000). Chemotherapy costs (average ₹72,400 per patient). Complication management (₹50,000 per patient). Relapse treatment (estimated at ₹300,000 per patient)

Outcome measures

The primary effectiveness measure was the number of patients spared from unnecessary chemotherapy (true negatives). We also tracked the number of high-risk patients incorrectly classified as low-risk (false negatives) who might experience relapse.

Cost per QALY and societal perspective incremental cost-effectiveness were not calculated in this analysis.

RESULTS

Additionally, the revised cost impact of overdiagnosis (false positives) leading to unnecessary chemotherapy was ₹36 crores annually, while the cost of false negatives (missed high-risk patients) leading to relapses was ₹61 crores annually.

Table 1: Base case analysis.

Strategy	Test cost (₹)	Cases spared from chemo	Cases missed (high risk)	Total cost (₹ crores)	Cost per case spared (₹)	ICER vs standard care (₹)
Standard of care	0	0	0	1,320.4	N/A	Reference
Oncotype DX	190,000	39,755	845	1,217.6	306,300	-25,900
CanAssist	65,000	39,755	845	864.3	217,400	-114,800
Test 1	50,000	39,755	845	780.1	196,200	-135,900
Test 2	30,000	39,755	845	659.7	165,900	-166,200
Test 3	15,000	39,755	845	565.4	142,200	-190,200

Demographic data

Not applicable to this hypothetical scenario analysis.

DISCUSSION

Our findings support a tiered pricing approach that could enhance access across different segments of the Indian healthcare market.¹⁰ The Value tier option (₹15,000) could be particularly impactful for public health systems, potentially accessible under programs like Ayushman Bharat.¹¹ The Standard tier (₹30,000) and Premium tier (₹50,000) remain economically justified for patients with private insurance or higher ability to pay.

The revised calculation of false positive costs (₹36 crores) and false negative costs (₹61 crores) highlights the greater economic impact of missed diagnoses compared to overtreatment.¹² This underscores the importance of prioritizing test sensitivity in the Indian context, where relapse treatment resources may be limited.¹³

Recent studies from similar healthcare settings support our findings, suggesting that even modestly priced gene expression profiling tests can yield substantial benefits in terms of both cost savings and improved quality of life.¹⁴⁻¹⁸ The implementation of such tests aligns with India's goals for universal health coverage and healthcare resource optimization.¹¹

The model relies on assumptions regarding test performance and relapse rates that may differ in real-world implementation. Variations in chemotherapy regimens and associated costs across different healthcare settings were not accounted for long-term survival impact was not explicitly modeled.

CONCLUSION

Gene expression profiling for breast cancer treatment decisions in India demonstrates favorable cost-effectiveness across all proposed price points. The analysis underscores the need for balanced sensitivity and specificity to minimize both overdiagnosis and missed high-risk cases. Nationwide implementation could yield substantial system-wide savings while improving patient quality of life through avoided chemotherapy toxicity.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Suresh AVS, Singaraju M, Dadireddy PK. Int J Community Med Public Health 2025;12:2100-2.