



BMJ Open Cost of breast cancer diagnosis and treatment in India: a scoping review protocol

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ABSTRACT

Introduction Breast cancer is the foremost cause for mortality among women. The non-communicable disease imposes significant economic expenses to communities. Its economic impact includes both direct and indirect healthcare costs. This scoping review will map key concepts underpinning the current direct and indirect expenses of breast cancer in India.

Methods and analysis This scoping review will follow ‘Arksey and O’Malley’s’ approach and updated methodological guidance from the Joanna Briggs Institute. The Cochrane library, Econ Papers, Embase, ProQuest central, PubMed and SCOPUS will be searched for peer-reviewed scientific journal publications from the year 2000 to 2021. Reference lists of included articles and preprint repositories will be searched for additional and unpublished literature. Independent screening (title, abstract and full text) and data extraction will be carried out against the defined inclusion criteria. The results will be narratively summarised and charted under the conceptual areas of this scoping review. The research gaps and scope for future research on the topic will be identified. Findings will be reported using the Preferred Reporting Items for Systematic Reviews extension for Scoping Reviews.

Ethics and dissemination Ethics clearance will not be obligatory because this scoping review will only involve publicly available data. The review’s findings will be disseminated through social media and a presentation in a national or international conference related to economics and healthcare. The findings will be published in a scientific journal that is peer-reviewed.

INTRODUCTION

India’s epidemiological transition has increased the burden of both communicable and non-communicable disease (NCD). Among the NCD, cancers are the most prevalent. Within the Indian context, breast cancer, lung cancer, oral cancer, stomach and cervical cancer are commonly predominant.¹ Breast cancer is a severe illness, mainly affecting the women of reproductive age in India, with high medical costs and economic impact.² In 2020, the worldwide cancer incidence and

Strengths and limitations of this study

- Breast cancer diagnosis and treatment costs in India will be investigated using an established, rigorous and systematic approach.
- The extensive search in databases and grey literature is aimed at including published and unpublished research from the past two decades.
- The literature search is limited to English language.
- The quality of articles in the scoping review will not be assessed.

fatalities reached 19.3 million and 10 million, respectively. For the year 2020, the estimated incidence of cancer among females in India was 712 758 (104 per 100 000).^{3 4} The origin of breast cancer is unclear. However, several risk factors are known to be associated with the disease, such as age, genetics, genes, radiation exposure, obesity, delayed pregnancy and alcohol.⁵ According to the ‘International Agency for Research on Cancer’ (IARC), delayed diagnosis leads to poorer probable outcome or prognosis of the breast cancer disease.⁶ It is the most predominant cancer in women, accounting for about a quarter of all cancer cases in Indian cities, and ranking second in rural India.^{3 7}

According to the ‘National Cancer Registry Programme’, breast cancer accounts for 25%–32% of all female cancers in cities like Ahmedabad, Bengaluru, Bhopal, Chennai, Delhi, Hyderabad and Kolkata.⁵ Breast cancer incidence rates are growing with an annual percentage rise ranging from 1.4% to 2.8%, which is more evident in urban regions such as Bengaluru, Chennai, Delhi and Hyderabad than in rural areas.^{1 4 8} The Indian Council for Medical Research (ICMR) reported 1.5 lakh new breast cancer cases in 2019, with 70 000 deaths per year. In India, only 66% of women with breast cancer survive for 5 years, compared with 90% of women in the USA.⁹

According to a study conducted by the IARC in 2020, in the previous year, 150 000 people had been diagnosed with breast cancer.⁸ Breast cancer is primarily associated with increased life expectancy, changes in population reproductive patterns (eg, later age at first birth), overweight and obesity, lower levels of physical activity, social development and growth, and embracing western lifestyles (WHO, 2020).⁸⁻¹⁰

Cancerous breast tissue originates from breast milk providing milk ducts and lobules.⁵ Breast cancer is categorised as ductal carcinomas and lobular carcinomas. Invasive ductal carcinoma is the most common type accounting for around 70% of tumours, whereas invasive lobular carcinomas account for 15%–20% of tumours.^{5,6,11} Breast cancer is classified into the five stages depending on the size and spread of the lump or tumour in breast: stage 0 (also known as ‘Ductal Carcinoma in Situ’), ‘stage I’, ‘stage II’, ‘stage III’ and ‘stage IV’.⁷ The stage of cancer is determined by a series of specialist physical exams, mammography, ultrasonography, aspiration, biopsies, bone scans and blood tests. Oncologists use a comprehensive strategy to treat breast cancer such as, surgery, hormone therapy, chemotherapy, radiation therapy and biological therapies.¹² Despite advancements in therapy and awareness initiatives, the dangers linked with breast cancer continue to grow in India. Poor diagnosis and costly treatment lead to a high death rate.⁹ The typical cost of treatment including radiation, surgery, and investigations costs between INR5 and 6 lakhs (about US\$6700 to US\$8000). Six rounds of chemotherapy with tailored treatment cost more than INR20 lakhs (US\$27 000).⁵

Expenditures have risen as a result of expensive infrastructure, new technology-based research costs, and newer medicines. Statistics suggest only one in every two women with breast cancer survive, implying a 50% mortality rate. The high mortality rate of breast cancer can be attributed to the lack of awareness about the disease, as majority of the breast cancers are identified at an advanced stage, resulting in poor response to treatment and high treatment costs.⁹⁻¹³ Because of patients lack of knowledge on their disease condition they fail to approach suitable medical facilities, therefore, most breast cancers are detected at an advanced stage. Patients in urban areas are predominantly identified at stage 2, when the lesions become palpable lumps; but in rural regions these lesions are diagnosed only after they have progressed to metastatic tumours.^{14,15} The cost of targeted therapy on the WHO Essential Medicine List for ‘stage I HER2 +breast cancer’ human epidermal growth factor receptor 2) breast cancer, for example, is projected to be comparable to roughly ten years of average yearly income in India.^{10,16} As breast cancer treatment is getting expensive, primary prevention is the key to breast cancer management. Breast cancer has a one hundred percent success rate if detected early and a high survival percentage till the middle stages. Approximately half of all breast cancer patients in India are in stages 3 and 4, when the chances of survival are exceedingly low and treatment costs are

considerable. According to the ICMR, less than 5% of women in India have their breasts screened. Breast cancer has a low survival rate since it is detected late. If a variety of early detection measures were improved, breast cancer mortality may be lowered. Raising knowledge of the benefits and potential risks of breast screening, as well as making it more widely available, could also help in promoting early identification of this disease and consequently reducing the associated costs.^{8,9,17} The 2030 Agenda endorsed by the General Assembly for Sustainable Development in September 2015, comprises 17 Sustainable Development Goals (SDGs). Among 17 SDGs, SDG 1 and 3 have set a target which aim for the abolition of all kinds of poverty and a one-third decrease in NCD-related early death respectively, by 2030.¹⁸ Breast cancer is a prominent cause of death in recent decades, posing a significant societal and economic threat. As a result, governments must understand the economic burden (direct and indirect expenses) of breast cancer in order to effectively allocate resources. Direct expenses include medical and non-medical expenditures incurred as a result of resource usage owing to inpatient and outpatient healthcare occurrences connected with diagnosis and treatment. These also include transportation and caregivers’ costs. Indirect expenses, on the other contrary, include productivity loss owing to work absenteeism (morbidity) and death from cancer (mortality) at early age.¹⁹ Direct and indirect expenses together form the economic burden of breast cancer.

In India, the amount of information accessible on the economic impact of breast cancer is limited.²⁰⁻²³ Although studies on expenses associated with breast cancer²⁴⁻²⁶ and state wise cost of breast cancer^{27,28} are available, a comprehensive review of literature on costs of breast cancer in India is missing.²⁹ To fill this void, a scoping review assessment of the literature on the evidence on the cost of diagnosis and treatment of breast cancer in India will be performed. The major objective is to collect data on the direct and indirect costs of breast cancer diagnosis and treatment in India. Additionally, this scoping study can serve to evaluate the impact of illnesses on society, aiding policymakers and decision-makers in forecasting future healthcare expenditures and making resource allocation choices.

METHODS AND ANALYSIS

Protocol design

The Arksey and O’Malley’s scoping review methodological framework,³⁰ guidance by Levac *et al*,³¹ and JBI updated methodological guidance (Peters *et al*) were used in preparation of this protocol.^{2,32} The current procedure and future scoping review would be documented using the ‘Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocols extension for Scoping Reviews guidelines’ (PRISMA-ScR; online supplemental file 1).^{33,34} The scoping review will be carried out in five different stages:

Table 1 PCC framework (eligibility criteria) for study selection

Criteria	Determinants
Population	Female participants with breast cancer
Concept	Cost associated with breast cancer disease management
Context	India

PCC, Population-Concept-Context.

1. Identification of the research question.
2. Identifying relevant studies.
3. Selection of eligible studies.
4. Data extraction and charting results.
5. Collating, summarising and reporting the results.

Stage 1: identification of the research question

The main research question is: ‘What is the cost (direct and indirect) associated with breast cancer in India among the female population aged 18 years and above? These include costs associated with diagnosis and treatment.’ Research subquestions include: What are the direct and indirect expenses of breast cancer treatments (all stages) in India?

Stage 2: identifying relevant studies

Eligibility criteria

To discover relevant literature, a comprehensive search strategy was established, which was supported by key inclusion criteria. The eligibility criteria is defined based on ‘Population-Concept-Context’ framework recommended by the ‘JBI methodology for scoping reviews’ (table 1).³⁵

Population

The scoping review will examine studies including Indian women aged 18 and above who have been diagnosed with breast cancer. Studies on breast cancer that includes male population and does not report cost data separately for the female population, will not be considered.

Concept

This scoping review’s main goal is to investigate and quantify the costs of breast cancer detection and treatment in India. It will include cost or expenditure categorised as direct and indirect costs. Studies that include cost of diagnosis and treatment with specific modalities will be included. The direct cost will cover the total medical cost, which include the cost of diagnostic and screening such as, physical examination, mammograms, ultrasonography, fine-needle aspiration test (FNAC), bone scans, blood tests, biopsies and cost of treatment such as, hospitalisation cost (including cost of surgery), drug cost, radiotherapy cost, chemotherapy, hormone therapy, biological treatment, consultation cost and non-medical cost (transportation, food, and lodging). Indirect cost will include total patient wage loss, total caregiver wage loss, spending on hired help, productivity loss.^{36 37} Direct and

indirect cost will also be provided for all stages of breast cancer treatment (stages 0–4).³⁸ Studies that assess the cost of many cancers simultaneously; but do not provide the specific break down of costs for breast cancer will be excluded.

Context

The purpose of this scoping review is to assess the economic impact of breast cancer in India. As a result, it would evaluate research in India at all stages (0–4) of breast cancer.³⁸ This review will consider research done in any clinical setting (eg, inpatient, outpatient) or health-care institution (eg, hospitals, health centres, nursing homes) throughout all Indian states.

Search strategy

Only literature published from 2000 onwards in English language will be considered. A search of several electronic databases was used as the major source of literature: The Cochrane library, EconPapers, Embase, ProQuest central, PubMed and Scopus. The secondary source of potentially relevant material was for grey literature from Google Scholar and Shodhganga: a reservoir of Indian theses @ INFLIBNET. We will manually examine the reference lists of included research, reports, related reviews and publications, as well as preprint repositories, for the inclusion of further relevant studies. Authors will be contacted. In cooperation with a medical librarian, the team devised a search technique to find a complete list of relevant terms pertaining to the cost of breast cancer diagnosis and treatment in India. A primary search on PubMed was initiated to identify articles for this review. The key words used to describe the relevant articles will be listed and used to develop a full search strategy for PubMed. Initially “breast cancer” OR “breast oncology” OR “breast neoplasm” OR “mammary gland” OR “carcinoma” AND “diagnostic cost” OR “cost”, “treatment cost” OR “economic burden” OR “cost of disease” OR “cost of treatment” OR “cost of diagnosis” AND “India” OR “LMIC” OR “developing countries” was used for mapping relevant studies. The search strategy was customised and modified consisting of all keywords and index terms for Scopus, The Cochrane library, Embase, Econ Papers and ProQuest Central databases. A search will also be done through scientific repositories such as, the cancer institute and research centre and the population-based cancer registries repository.

The search terms from each concept of the search strategy were merged with appropriate boolean operators to produce the final relevant reports and articles. An example of the search strategy is provided below in table 2 and search results for PubMed are provided in an online supplemental file 2.

Stage 3: selection of eligible studies

Identified studies from search on different databases will be collated and imported to Zotero V.5.0. Duplicates will be removed at compilation stage, and the citations and their abstracts will consecutively be transferred

Table 2 Search strategy

#	Keywords
1	("Breast Cancer" OR "Cancer of Breast" OR "Mucin like Carcinoma" OR "BRCA 1 Protein" OR "BRCA 2 Protein") OR ("Cancer" OR "Neoplasm" OR "Carcinoma")
2	("Healthcare Cost" OR "Diagnosis Cost" OR "Treatment Cost" OR "Direct Cost" OR "Indirect Cost" OR "Caregiver Cost" OR "Societal Cost" OR "Disease Burden" OR "Cost Utility Analysis" OR "Cost Effectiveness Analysis" OR "Cost Benefit Analysis" OR "Disease Cost" OR "Estimation of Cost" OR "Medical Cost")
3	("India" OR "Republic of India" OR "Bharat" OR "Hindustan" OR "LMIC" OR "Developing Country")
4	#1 AND #2 AND #3

to Microsoft Excel for screening process. A two-stage screening process comprising:

1. Title and abstract screening.
2. Full-text review will be carried out.

Based on the eligibility criteria, two independent reviewers will do the screening of title and abstract (table 3) and studies that do not address the research question will be removed. Any disagreements between the reviewers will be resolved involving a third reviewer, an expert in health economics. Further, the screening of full text will be done for articles that meets the inclusion criteria. Disagreements will be resolved by involving a subject expert. Both the stages will follow an identical process and the result will be documented on Microsoft Excel spreadsheets. Reasons for exclusion of studies will be informed and documented at the full-text screening stage.

Stage 4: data extracting and charting results

Data from the included full text articles will be extracted by two reviewers independently using a custom data extraction form (online supplemental file 3) developed by the research team in Microsoft Excel. The data extracted will capture the study components as follows:

1. Details of the study (Study title, aim or research question, the authors, year of publication, state/district/union territories, geographic location, objectives, methodology, and sample size).

2. Population (eg, age, gender, target population, population excluded and sample size).
3. Type of cancer—breast cancer stages (stage 0–4).
4. Diagnostic and treatment modalities (eg, physical examination, mammograms, ultrasonography, FNAC, bone scans, blood tests and biopsies, surgery, radiation therapy, chemotherapy and/or targeted therapy).
5. Study setting (eg, clinical settings—public (government) and private).
6. Type of costs reported—diagnostic costs, treatment costs, direct costs, indirect costs.
7. Study design, study duration, data collection period/year, cost-related data collection methods, result summary, other measures reported, key findings.
8. Relevant Conclusion.

During the piloting phase, any adjustments will be made as needed. As the scoping review progresses, the data extraction technique will be updated or adjusted. Any changes or amendments that are required during the actual review will be documented in the scoping review report. The findings will be evaluated with the team to see if the data extracted meets the scoping reviews goals and objectives.³⁹ The resolution of differences between the reviewers will be discussed with a subject expert or a senior reviewer.³²

Table 3 Inclusion and exclusion criteria

Criteria	Inclusion criteria	Exclusion criteria
Population	Female participants aged 18 years and above diagnosed with breast cancer	Female participants not diagnosed with breast cancer but undergone screening will be excluded
Concept	All studies concerning the expenses related with breast cancer disease management, including direct and indirect costs	Prediagnosis screening cost
Context	India	Non-Indian studies or studies with a focus on LMICs or South Asia in which the expenses for India are not reported separately.
Types of evidence sources	Quantitative, qualitative and mixed-methods studies	Letter to the editor, viewpoint, reviews, editorials and perspectives
Timeframe	Studies published from January 2000 onwards	Articles published before 2000
Language	Studies published in English	Non-English articles

Table 4 Study timeline

Scoping review steps	Status
1. Identifying the research questions	Completed
2. Identifying relevant studies	Completed
▶ Search terms and inclusion/exclusion criteria	Ongoing 2 Weeks
▶ Conducting the search	4 weeks
3. Selection of eligible studies	
▶ Title and abstract screening	
▶ Full-text screening	
4. Data extraction and charting	4 weeks
5. Data analysis and reporting the results	6 weeks

Stage 5: collating, summarising and reporting the results

To exhibit the search process, a 'PRISMA' flow diagram will be used.⁴⁰ The flow diagram will help display the decision-making process, as well as the outputs of the searches, the exclusion of duplicated citations, study selection, complete retrieval, additional bibliography mining and presentation of the final summary.

Studies will be grouped by costs type (direct or indirect), settings, and study design along with key findings. A descriptive statistics, such as measures of frequencies and central measures of tendency will be used to reflect the kind of research design, costs of treatment examined, and costs identification criteria.⁴¹ The results will be summarised and analysed and will be presented in a graphical, tabular, or in a detailed descriptive structure that aligns to the purpose and scope of the review.³² Thematic and narrative approach will also be incorporated for the analysis of quantitative and qualitative studies.⁴² Inadequacies and limitations in the current literature will be identified and summarised.

Study timeline is depicted in [table 4](#).

PATIENT AND PUBLIC INVOLVEMENT

This scoping review procedure was not informed by a patient and public participation strategy or organisation. The design and development of the procedure were neither patient-centred nor public-centred.

ETHICS AND DISSEMINATION

This scoping review procedure describes a strategy for searching and mapping the literature on breast cancer management costs for individuals with breast cancer in a rigorous and methodical manner. Because this scoping review will solely contain publicly available data, therefore ethical approval is not obligatory. The findings of this study will be presented at a national or international conference related to economics and healthcare and published in peer-reviewed journal. The authors expect that our analysis of the present status of breast cancer diagnostic and treatment research will help to steer future research and to guide clinical practice and public

policy-makers and bring awareness among patients, clinicians, decision-makers, third party payers about the out-of-pocket expenditure for breast cancer. It will also help to understand the economic burden of breast cancer in India.

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Contributors PCB, HTH, PS, KKK, JBK, VSD, PP and AR contributed to the title and conception or design of the review. PCB, HTH, PS and KKK drafted the protocol manuscript with suggestions from PP, VSD, JBK and AJNS. PCB, HTH, PS and KKK developed and conducted the preliminary searches. JBK, VSD and PP assisted in developing the search strategy, and protocol development. AR and AJNS coordinated between departments and furnished administrative support. All the authors have proofread the protocol and given the final approval of the version to be published.

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