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Original Article

Health Management and Policy Section

Do Operational Protocol Changes in Health Insurance have a Social Impact? A Retrospective Cohort analysis of Tamil Nadu State-sponsored Health Insurance Scheme Delivery in the Breast Cancer Treatment Package

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ABSTRACT

Introduction: Endocrine management is an important component of breast cancer treatment to prevent recurrence and metastasis for a period of at least five years. Health insurance providers offer cashless treatment for this management on a monthly basis, which leads to frequent hospital visits and is a major reason for treatment default. We obtained special permission to deliver this treatment quarterly from the Government of Tamil Nadu-sponsored state health insurance scheme. This study analysed the outcome of this policy change and its social impact.

Aim: To analyse the outcome of the operational change in implementing the insurance scheme.

Materials and Methods: A retrospective cohort study was conducted at Government Villupuram Medical College Hospital, Tamil Nadu, India, from October 2020 to July 2024. All consecutive patients except male breast cancer and patients who received treatment only once were included in the study. A total of 71 patients' data involving 533 hospital visits were analysed. To assess differences between paired samples in the bivariate groups, the Wilcoxon signed-rank test was applied. A p-value of <0.05 was considered significant.

Results: Data analysis showed a statistically significant reduction in hospital visits: mean 8.04 visits (SD 4.60) versus an expected mean of 19.87 visits (SD 12.00). Out-Of-Pocket Expenditure (OOPE) toward travel expenses was Rs 412 per patient (SD 402) compared with Rs 1,042 per patient (SD 1,126) under routine treatment without rule relaxation. There were also savings in lost daily income due to the change in the insurance protocol for this endocrine management package for breast cancer.

Conclusion: Quarterly follow-up treatment of endocrine management is effective, and the flexibility of state-sponsored health insurance schemes has a substantial social impact by reducing OOPE in cancer care.

Keywords: Chief minister's comprehensive health insurance scheme, Hormone receptor, Pradhan mantri jan arogya yojana

INTRODUCTION

Breast cancer is the second most common cancer globally, accounting for 11.6% of all cancers according to Global Cancer Observatory (GLOBOCAN 2022) [1]. Breast cancer development is influenced by hormones, as cancer cells express estrogen and progesterone receptors. Of all breast cancers, 48% are hormone receptor-positive and require endocrine management during treatment [2]. Endocrine therapy used to be given for a minimum of two years, but evidence suggests that extending therapy to five years reduces recurrence by about 50% [3], and extending beyond five years improves disease-free survival in node-positive disease [4]. These endocrine therapies are given to hormone receptor-positive patients after primary treatment for breast cancer is completed. In a developing country like India, the primary treatment for breast cancer-including surgery, chemotherapy, and radiotherapy-is available only in tertiary care health centers, and patients are often forced to receive endocrine therapy at the same center [5].

Breast cancer patients visit their oncologist at tertiary centers far from their place of residence to receive monthly endocrine therapies, since these drugs are prescribed only by oncologists for breast cancer. Patients from rural areas have to travel every month to the treating center to refill their medication, as these are stocked only in specialty medical centers. Frequent travel, loss of daily wages, lack of a caregiver, and family commitments all contribute to patients defaulting on follow-up treatment. This situation is worse for patients who receive free treatment in government institutions, since they cannot miss scheduled appointments owing to the large patient load. The only relief for patients of lower socio-economic status is that their treatment is covered under state-sponsored health insurance schemes, which helps save on medicine costs.

Considering the importance of endocrine therapies in improving overall survival and disease-free survival, most social security health schemes for the underprivileged in India provide endocrine treatments free of cost. But these are offered monthly, and patients need to visit health facilities every month, leading to frequent loss of daily wages and increased OOPE [6]. Women from rural backgrounds find it difficult to maintain continuous, uninterrupted follow-up treatment. Follow-up recommendations for breast cancer by international agencies like National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) [6,7] suggest follow-up every 3-4 months is sufficient. However, the insurance companies' protocols-especially schemes under state-sponsored health schemes that operate under tight budgets- do not allow longer interval approvals. In the study center, the Government of Tamil Nadu's CMCHIS scheme [8-10] has been implemented since 2013, in which the endocrine treatment package

for breast cancer was originally approved every 30 days. This protocol was not practically feasible to implement. Therefore, as per NCCN follow-up recommendations [7], representations were made to the appropriate scheme-implementing authority, and the protocol was changed to approvals every three months. The treatment under this new quarterly protocol began in October 2020. This study aims to determine the operational impact of this change on patient convenience, operational challenges, cost-benefit analysis, and the possibility of expanding these changes to other treatment protocols in the insurance approval process.

MATERIALS AND METHODS

A retrospective cohort study was conducted at Government Villupuram Medical College Hospital, Tamil Nadu, India, on patients receiving endocrine therapy under CMCHIS from October 2020 to July 2024. Before conducting the study, approval was obtained from the institutional scientific research committee and the Institutional Ethics Committee (IEC Approval No: GVMC/IEC/2024/2).

Inclusion and Exclusion criteria: Data were collected for patients who received endocrine therapy under CMCHIS benefits. Data for all consecutive patients who received endocrine management since October 2020 were collected from the hospital's medical records and the insurance portal. After excluding non-insured patients, 84 patients' data were compiled. Of these, 13 patients who received treatment for only one month due to the COVID-19 pandemic, patients who belonged to other hospitals, and male breast cancer patients were excluded from the analysis.

Study Procedure

A total of 71 patients were included in the study, all of whom received treatment during the study period. Among them, 21 patients were already on endocrine therapy before October 2020 under the standard monthly protocol, which is the usual insurance approval process. These patients were transitioned to the new protocol in October 2020. The remaining 50 patients began endocrine therapy after October 2020. All 71 patients received endocrine therapy based on the special quarterly approval process.

During the study, one patient who started endocrine therapy in 2012 completed the full 10-year management period. For every quarterly treatment availed, two hospital visits were considered saved, and the cost saved was calculated for travel and lost daily wages. Travel cost was calculated based on the distance between the hospital and the patient's taluk or district headquarters. For travel up to 10 km, Rs 10 was used as the base fare; up to 50 km, Rs 25; up to 100 km, Rs 50, reflecting the State Transport Corporation base fares for different bus categories. The daily wage base was taken from the Government of India's daily wage under the Mahatma Gandhi National Rural Employment Scheme (MGNREGS), as adopted by the Government of Tamil Nadu, which is Rs 281 per day [10].

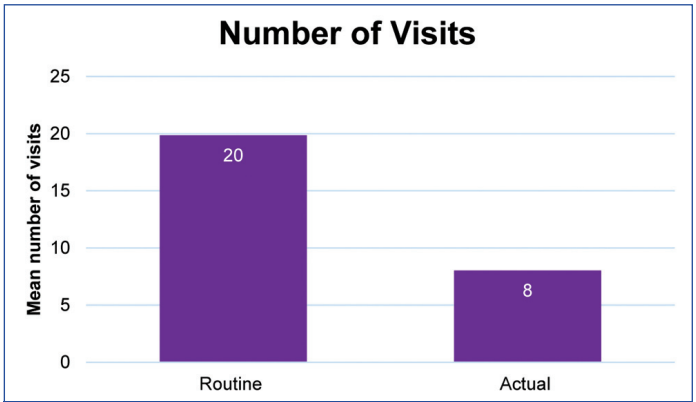
STATISTICAL ANALYSIS

The collected data were entered in Microsoft Excel 2016 and analysed with IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows, Version 29.0 (Armonk, NY:IBM Corp). Descriptive statistics (frequency and percentage) were used for categorical variables, and the mean, median, Interquartile Range (IQR), and Standard Deviation (SD) were used for continuous variables. Normality was assessed with the Shapiro-Wilk test. The data were skewed; hence, the Wilcoxon signed-rank test was used. A p-value of <0.05 was considered significant.

RESULTS

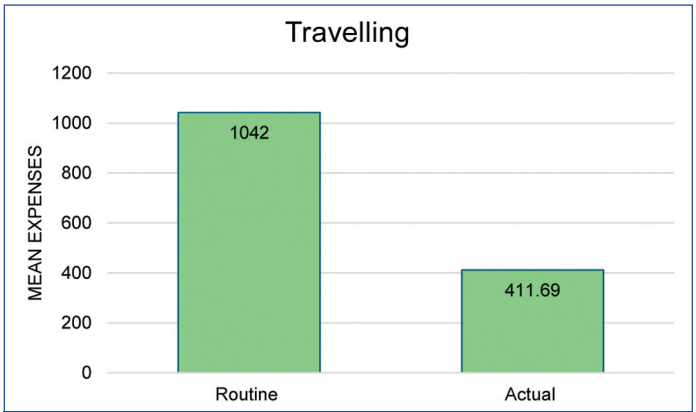
Of the 71 patients included in the study, 59 were on aromatase inhibitor-based treatment, 12 on tamoxifen-based treatment (83.1% vs 16.9%), and the majority belonged to the 41-60 years age group (45 patients, 63.4%).

Patients included in the study came from a geographical distribution around the study centre, ranging from 10 to 160 km (SD 29.17), involving 16 taluks/districts. All 71 patients, during the study period, to avail outpatient treatment under the relaxed rule, had a total of 533 hospital visits (mean 8.04 visits, SD 4.6) versus an expected 1,411 visits (mean 19.87 visits, SD 12) [Table/Fig-1].



[Table/Fig-1]: Number of visits (mean: routine visits vs actual visits done).

When these hospital visits were considered for OOPE toward travel expenses, the cost was Rs 412 per patient (SD 402) compared with Rs 1,042 per patient (SD 1,126) under routine treatment without rule relaxation [Table/Fig-2] (IQR: Rs 1,967 vs Rs 5,901) [Table/Fig-3]. Each hospital visit incurs direct or indirect income loss for the patient, since most are day labourers or depend on agriculture or related activities. When the loss of income is prevented due to the relaxed insurance rule, it translates into a financial benefit for each patient (Mean Rs 5,584 vs Rs 2,259 with SD 3,371 vs 1,293) [Table/Fig-4].



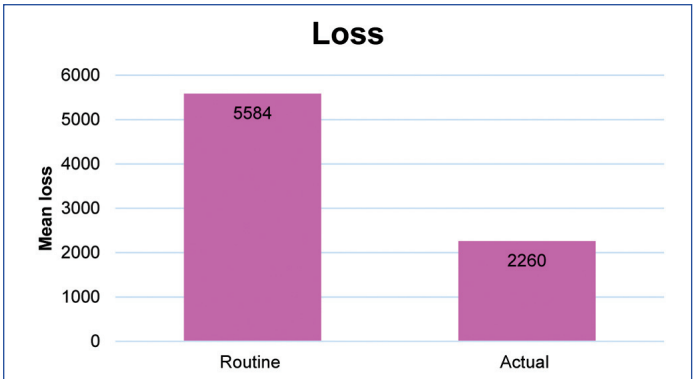
[Table/Fig-2]: Travel expenses (mean: routine visits vs actual visits).

	Routine number of visit	Actual visit	Routine travel expenses (Rs)	Actual travel expenses done (Rs)	Loss due to routine visit (Rs)	Loss due to actual visit (Rs)
Mean	20	8	1042.11	411.69	5584.38	2259.87
Median	19	8	620.00	250.00	5339.00	2248.00
SD	12	5	1126.53	402.11	3371.64	1293.33
Range	43	16	5940.00	1980.00	12083.00	4496.00
Minimum	2	1	60.00	20.00	562.00	281.00
Maximum	45	17	6000.00	2000.00	12645.00	4777.00
IQR	21	7	1120.00	400.00	5901.00	1967.00

[Table/Fig-3]: Descriptive statistics (N=71).

When the data are analysed by incorporating the number of visits, travel, and prevention of income loss, there is a statistically significant advantage for treatment under the relaxed insurance rule (Z=-7.28, -7.27, -7.28, respectively; p=0.0005) [Table/Fig-5].

Over the 45 months of data, 47 of 71 patients (66.2%) had 100% compliance without any interruption in treatment. Fifteen patients (21.1%) had one default for scheduled treatment [Table/Fig-6].



[Table/Fig-4]: Loss of income (mean: routine visits vs actual visit).

Variables		N	Mean Rank	Sum of Ranks	Z	p-value
Actual visit-routine number of visit	Negative ranks	70a	35.50	2485.00	-7.279b	0.0005
	Positive ranks	0b	0.00	0.00		
	Ties	1c				
	Total	71				
Actual travel done - routine travel	Negative ranks	70d	35.50	2485.00	-7.274b	0.0005
	Positive ranks	0e	0.00	0.00		
	Ties	1f				
	Total	71				
Loss due to actual visit - loss due to routine visit	Negative ranks	70g	35.50	2485.00	-7.279b	0.0005
	Positive ranks	0h	0.00	0.00		
	Ties	1i				
	Total	71				

[Table/Fig-5]: Wilcoxon Signed Ranks Test; a) Actual Visit < Routine Number of Visit; b) Actual Visit>Routine Number of Visit; c) Actual Visit=Routine Number of Visits; d) Actual Travel Done < Routine Travel; e) Actual Travel Done > Routine Travel; f) Actual Travel Done=Routine Travel; g) Loss due to Actual Visit < Loss due to Routine Visit; h) Loss due to Actual Visit > Loss due to Routine Visit; i) Loss due to Actual Visit=Loss due to Routine Visit.

No. of default incidents	Frequency	Percent
Nil	47	66.2
1	15	21.1
2	6	8.5
3	1	1.4
4	2	2.8
Total	71	100.0

[Table/Fig-6]: Compliance (No. of default incidents).

DISCUSSION

The management of breast cancer has changed over the last century from merely achieving disease control to improving overall survival and attaining a cure. The introduction of endocrine management using hormone blockers like tamoxifen in the 1970s [11] and aromatase inhibitors in the 1980s [12] played a crucial role in improving overall survival. Tamoxifen is the preferred drug for endocrine therapy in premenopausal women after completing chemotherapy [13]. For postmenopausal women after completing chemotherapy, the drug of choice for endocrine management is an aromatase inhibitor [14]. Endocrine therapy should be taken for at least five years, and there is an established benefit if therapy is continued for more than five years, up to 10 years [4]. In the Indian context as well, 5-10 years of endocrine therapy is advised after completing the primary treatment [15].

Since these therapies need to be taken for years, there is a real possibility that patients will default on treatment. The main barriers to continuous follow-up care in breast cancer without default are financial constraints (20.3%) and difficulty in commuting (13.4%), according to a study conducted at AIIMS, India [16]. The primary way to overcome financial constraints is through health insurance schemes. The oldest state-sponsored insurance scheme in India is the Employees' State Insurance Scheme, which primarily targets employees in the organised sector. But long-term cancer treatment, which impoverishes households, requires public-sector backup in the form of a social security scheme [17], especially for low-income populations. One such scheme began in Andhra Pradesh in 2007 [18], followed by Tamil Nadu in 2009 and expanded in the present form in 2012 [8]. These health insurance schemes helped reduce medical expenses and mitigate some out-of-pocket costs.

The Government of India has undertaken a decade-long mission to control non-communicable diseases, and as part of this, the National Health Mission has been taking steps to decrease cancer morbidity and mortality and to reduce the likelihood of families falling into poverty due to health expenditure. One such initiative is the government-sponsored health insurance scheme Prime Minister's Jan Arogya Yojana (PM-JAY) for eligible family members. As the world's largest health insurance scheme, PM-JAY could not cover all 1,200 treatment packages in full. PM-JAY is implemented in Tamil Nadu in association with CMCHIS-PM-JAY. This scheme has improved patient compliance and outcomes [18], but some ground-level implementation issues require minor changes to be made. Real-world data show that 71.1% of patients on endocrine treatment achieve full compliance [19]. Compliance in this study was verified based on hospital visits to refill the drug every three months; any delay of more than one month was considered a default. Analysing the 45 months of data, 47 of 71 patients (66.2%) had 100% compliance without interruption. Defaults occurred during the second wave of the Coronavirus Disease-19 (COVID-19) pandemic, and none were due to changes in the treatment protocol. This finding is in line with international guidelines from NCCN, American Society of Clinical Oncology (ASCO), ESMO [5,9], etc., and suggests that the data on treatment compliance among Indian patients are on par with the National Cancer Grid follow-up guidelines [19].

From the hospital administration's perspective, the workload has decreased by two-thirds due to this relaxation of the insurance protocol, which helps healthcare workers focus on the primary management of other new cancer patients. The average monthly outpatient count at the study centre has been around 200-220 patients over the last four years. This relaxation in the insurance protocol has saved 878 patient-visit slots, which translates to four months of saved consultation time. With a reduced follow-up patient load, doctors can spend more time on a patient-centric approach for newly diagnosed cancer patients, which will improve the quality of care [20].

Developing countries like India [21], where there is a shortage of qualified oncologists, especially in third-tier towns and rural areas, and for resource-limited government-run facilities, can benefit indirectly in many ways from these practical, logistics-based relaxations in government-sponsored health schemes. From the insurance companies' perspective, there were no additional expenses incurred, and they have saved manpower in processing the additional claims under the routine treatment protocol.

Limitation(s)

This change has also had limitations, such as the challenge of maintaining drug stock to dispense for three months duration. In developed countries like the United Kingdom, the supply chain for cancer drugs can provoke public outcry that reaches Parliament, raising debates on the issue [22]. This aspect is particularly important toward the end of procurement periods established in government purchase rules. Therefore, this kind of change cannot be implemented for treatment packages involving slow-moving or high-cost drugs, such as oral lapatinib for breast cancer or gefitinib for lung cancer. This study is an impact assessment conducted at a single institute; if the same analysis were applied to the entire state, the results might lead to similar changes across other treatment packages with a larger social impact.

CONCLUSION(S)

The idea of relaxing this insurance protocol was considered during the COVID-19 lockdown to ensure seamless and uninterrupted treatment for breast cancer patients and to reduce morbidity. This small change in the protocol has helped save time and costs and has improved compliance both directly and indirectly. Even after the pandemic situation has settled, the revised protocol continues to be followed, and data show a positive impact. This government-sponsored scheme offers more than 1,200 treatment packages, and many such small adjustments can be made based on feedback from the ground, which will benefit all stakeholders and ultimately reduce out-of-pocket expenditure for economically weaker sections of the country.

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