

# Access to timely cancer treatment initiation in India: extent, determinants and trends



Pritam Halder,<sup>a,j</sup> Jyoti Dixit,<sup>a,j</sup> Nidhi Gupta,<sup>b</sup> Nikita Mehra,<sup>c</sup> Ashish Singh,<sup>d</sup> Pankaj Malhotra,<sup>e</sup> Anisha Mathew,<sup>f</sup> Lalit Kumar,<sup>f,g</sup> Amal Chandra Kataki,<sup>h</sup> Sudeep Gupta,<sup>i</sup> and Shankar Prinja<sup>a,\*</sup>



<sup>a</sup>Department of Community Medicine and School of Public Health, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India

<sup>b</sup>Department of Radiation Oncology, Government Medical College and Hospital, Chandigarh, India

<sup>c</sup>Department of Medical Oncology, Adyar Cancer Institute, Chennai, Tamil Nadu, India

<sup>d</sup>Department of Medical Oncology, Christian Medical College, Vellore, Tamil Nadu, India

<sup>e</sup>Department of Clinical Haematology and Medical Oncology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India

<sup>f</sup>Department of Medical Oncology, All India Institute of Medical Sciences (AIIMS), New Delhi, India

<sup>g</sup>Department of Medical Oncology, Artemis Hospitals, Gurugram

<sup>h</sup>Department of Gynaecologic Oncology, Dr. B. Borooah Cancer Institute, Guwahati, Assam, India

<sup>i</sup>Department of Medical Oncology, Tata Memorial Centre, Mumbai, Maharashtra, India

## Summary

**Background** Treatment delays are significantly associated with advanced stage, poor response to treatment, increased mortality risk, poor health outcomes, increased healthcare expenditures among cancer patients. However, factors associated with these delays have not yet been robustly evaluated. In order to bridge this gap, we determined the delayed time to treatment initiation (TTI) among cancer patients in India, ascertained its determinants, and assessed the trends of delayed TTI.

**Methods** We analysed data collected from 6695 cancer patients seeking outpatient/daycare treatment, recruited at purposively selected seven healthcare facilities across six states of India. Data on socio-demographic and clinical characteristics including date of cancer diagnosis, date of treatment initiation, cancer site, stage and type of treatment were collected to determine the median TTI and ascertain its determinants among cancer patients in India. Time to treatment initiation was calculated as the duration (days) between diagnosis of cancer (histologically/clinically) and date of initiation of treatment. Multi-variable logistic regression was employed to analyse the relationship between the outcome variable (TTI) and each explanatory variable. A Cox Proportional Hazard (CPH) model was used to conduct time-to-event analysis, and to assess the impact of government-funded health insurance on timely cancer treatment initiation.

**Findings** The median (IQR) overall TTI was 20 (7–39) days, with a mean of 53.7 days (SD, 192.9). The TTI was higher for those having head and neck cancer (median TTI: 29 days, IQR: 10.5–55.5) and those receiving radiotherapy as initial treatment (27.5 days, IQR: 10–49.5). Younger patients, those educated up to graduation level and males had significantly lower odds of delayed TTI. As compared to patients who were diagnosed between 1995 and 2017, those diagnosed after 2018 had a 36% (26–46%) higher odds of timely initiation of treatment within 30 days. Upon stratifying by enrolment under PM-JAY, we found that while the access for timely treatment initiation increased by 33% for those who were not enrolled, vs. 90% among those enrolled under PM-JAY. Overall, this shows significant improvement in timely initiation of cancer treatment as a result of introduction of PM-JAY.

**Interpretation** The study highlights the positive impact of government-funded health insurance schemes on the timely access to cancer treatment in India. Our study recommends expanding AB PM-JAY cancer packages to include cost-effective treatments, increasing population coverage under screening programs and promoting e-RUPI to reduce financial constraints associated with diagnostic services to address delayed treatment initiation due to unknown cancer stages.

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\*Corresponding author.

E-mail addresses: [shankarprinja@gmail.com](mailto:shankarprinja@gmail.com), [prinja.shankar@pgimer.edu.in](mailto:prinja.shankar@pgimer.edu.in) (S. Prinja).

<sup>j</sup>Joint first authorship.

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### Research in context

#### Evidence before this study

The delay in access to timely cancer treatment initiation is an important public health problem leading to upstaging of cancer contributing to further degrading health implications, increasing mortality and morbidity. Despite this majority of the studies have focused on the initiation of treatment (yes/no), neglecting the duration of time between the diagnosis and initiation of treatment. We have searched for English language articles in PubMed on 20th February 2024 without any time restriction, using the search terms “(Carcinoma OR Neoplasm OR Cancer) AND (Time-to-Treatment OR “time to treatment” OR TTI OR “treatment initiation” OR delay OR “waiting time”) AND (extent) AND (association OR determinant) AND (trend)”. A total of 366 results were found, of which 8 were systematic reviews. Most of the studies were sustained to single type of cancer having limited geographical variation with smaller sample size. None of the studies have documented the trends of access to TTI, or any analysis of impact of policy interventions to improve timely access to care. Above all, there was no nationally representative study from India.

#### Added value of this study

We have able to provide the extent, determinants of access to TTI among cancer patients irrespective of site, stage, locality, residence and ethnicity across the nation (India). This is the

first ever study to cover all types of cancer patients in a nationally representative sample. We have also provided the differences across each type of cancer group. We found that income and gender are important factors which are associated with delayed TTI, even if the delay is small. Longer delays in TTI are attributable to poor educational status, lack of knowledge about disease staging, and lack of entitlement to any financial protection benefits such as insurance. Another major finding of our study is that the delays in TTI in India has been declining, and this improvement in timely access to treatment is further accentuated by enrolment in India's national insurance program – *Ayushman Bharat Pradhan Mantri Jan Arogya Yojana* (PM-JAY).

#### Implications of all the available evidence

Understanding the extent and determinants of access to TTI is crucial for crafting effective preventive, promotive and curative strategies at national level. Our study findings imply that the access to cancer treatment coverage under India's PM-JAY scheme should be further enhanced to bolster the timely access to treatment. In addition, focus of timely detection through primary care linked screening programs at Health and Wellness Centres will help in early detection, which will facilitate linkage for treatment and provision of cost-effective treatment.

### Introduction

According to GLOBOCAN 2020 report, high-income countries (HIC) have three times higher cancer incidence rates than low- and middle-income countries (LMICs).<sup>1</sup> Estimates indicate that 50% of cancer diagnoses and 58% of cancer-related fatalities worldwide occur in Asia. According to the GLOBOCAN 2022 estimates, the global age-standardized incidence rate (ASIR) for all cancers is 196.9 per 100,000 individuals. Men have a higher ASIR (212.6 per 100,000) compared to women (186.3 per 100,000). The global age-standardized mortality rate (ASMR) for cancer is 91.7 per 100,000, with males (109.8 per 100,000) again exhibiting a higher mortality rate than females (76.9 per 100,000).<sup>2,3</sup> In India, the cancer burden reflects unique patterns compared to global averages. The ASIR for all cancers is 98.5 per 100,000 individuals, with females exhibiting a higher incidence (100.8 per 100,000) compared to males (97.1 per 100,000). In contrast, the ASMR is higher in males (66.5 per 100,000) than in females (62.6 per 100,000), with an overall mortality rate of 64.4 per 100,000 population.<sup>2,3</sup> In India, breast cancer accounts

for the highest proportion of cancer cases overall (13.6%), followed by lip and oral cavity cancers (10.2%). Lung cancer ranks as the fourth most common cancer (5.8%).

One of the reasons for higher share of the cancer mortality in LMICs like India is the late diagnosis and delays in the initiation of treatment. The delay in time to treatment initiation (TTI) may lead to further upstaging of cancer disease, which is associated with poorer health outcomes and increased complications.<sup>4,5</sup> Besides poorer health outcomes, delayed TTI may lead to increased healthcare expenditures for treatment of advanced disease and its complications.<sup>6,7</sup>

The delayed TTI in the context of cancer, and its adverse health impact is well documented, which was further highlighted during the COVID-19 pandemic.<sup>8–11</sup> Subsequently, several model-based evaluations showed that this resulted in excess cancer mortality.<sup>12</sup> More recently, latest epidemiological data on cancer mortality from several countries has validated that these delays in TTI as well as disruptions in cancer treatment led to an increase in cancer deaths.<sup>13–15</sup>

Another important aspect of this public health challenge to TTI is from an equity perspective. Several of the demand side barriers to TTI are poor education, lower socioeconomic status, socio-cultural belief, gender, distance from healthcare facility, and access to appropriate financial protection such as insurance. Each of these places the poor and vulnerable at a disadvantage. The supply side barriers are due to lack of manpower, infrastructure, services; weak referral pathways and unrecognised stakeholder accountability, which are again an issue in LMICs.<sup>16–18</sup>

Several efforts at the global and national level have been undertaken to reduce these barriers for TTI as well as access to cancer treatment. The World Health Organisation (WHO) commemorated the World Cancer Day with the theme “close the care gap”. Similarly, the Sustainable Development Goals call for achieving universal health coverage (UHC), including financial risk protection, access to quality essential healthcare services.<sup>19</sup> Removing barriers to timely access to cancer treatment, India launched the government-funded health insurance program for poor population, i.e., *Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana* (AB PM-JAY). More than 1/4th of the total therapeutic procedures covered in the health benefits package of PM-JAY comprise of oncology treatments.<sup>20</sup>

Despite the importance of TTI for cancer, much of the available evidence only focusses on the dichotomous outcome of treatment being accessed or not, without much attention on its timeliness.<sup>21,22</sup> There are very few studies related to access to timely treatment initiation on all types of cancers among a large population. The limited published literature pertains to smaller geographic areas, in single type of cancer, and with small sample size.<sup>23–26</sup> There are no Indian studies using a nationally representative data. In order to bridge this gap in evidence which holds significant importance from a UHC lens, we undertook this analysis among a large sample of 12,148 cancer patients to determine the delayed time to treatment initiation, ascertain its determinants, and to assess the trends of delayed time to treatment initiation.

## Methods

We analysed the data on 12,148 cancer patients who were interviewed to collect data on health care costs and quality of life, as part of the Indian National Cancer Database for Cost and Quality of Life (CaDCQoL). The present cross-sectional study was conducted at selected seven leading cancer care hospitals across six states of India. We employed a multistage stratified sampling technique for the selection of healthcare facilities. Firstly, we selected states/regions based on the Epidemiological Transition Level (ETL) of the top 10 cancers in India. ETL state groups were defined by the proportion of cancer-related Disability-Adjusted Life Years

(DALYs) in 2016, classified into high, middle, and low ETL states. Chandigarh (Punjab) and Tamil Nadu were randomly selected from high ETL states, while Delhi & Maharashtra, and Assam were chosen from middle and low ETL states, respectively. At the second stage, seven healthcare facilities which cater to largest volume of oncology patients were purposively selected. Notably, two of these hospitals rank among the top 10 hospitals for cancer treatment claims under AB PM-JAY scheme. At the third stage, patients were selected using the Probability Proportional to Size (PPS) method across different Disease Management Groups (DMGs) at these healthcare facilities. Detailed methodology of sample selection and data collection are published elsewhere.<sup>27</sup>

Systematic random sampling was used to recruit the participants from October 2020 to March 2022. Patients irrespective of age and gender, diagnosed with any type of cancer, seeking care from the outpatient and inpatient departments, were recruited prospectively across the selected healthcare facilities. Both the participants on-treatment and on follow-up were included.

Out of the total 12,148 cancer patients, 9787 participants were recruited from outpatient department (OPD). However, data was not available for either of the two variables, i.e., date of diagnosis, or date of treatment initiation, for 2361 patients which precluded the opportunity to compute TTI.<sup>27</sup> We have also compared socio-demographic characteristics of included 6695 patients with overall sample to rule out any selection bias (Supplementary Table S1).

TTI was calculated from the duration (days) between diagnosis of cancer (histologically/clinically) and date of initiation of treatment. The data on these two variables was obtained from the clinical records available in the hospital during the data collection. By directly accessing the medical records, we ensured the accuracy and consistency of these dates, thus minimizing any potential recall bias. Using this information, we stratified the patients according to the year of diagnosis and compared the time to treatment initiation (TTI) across stratified group of patients diagnosed before and after the implementation of government funded health insurance scheme (AB PM-JAY). While majority of the studies have reported TTI cut-offs of >30 days for solid tumours,<sup>3,25,28,29</sup> there is no universally agreed upon threshold for TTI. Varying thresholds of delayed TTI has been reported in different studies ranging from 7 to 90 days. The cut-offs used in various studies are  $\geq 7$  days,<sup>30</sup>  $\geq 14$  days,<sup>30</sup>  $\geq 30$  days,<sup>4,26,28,29</sup>  $\geq 45$  days,<sup>28</sup>  $\geq 60$  days,<sup>24,31</sup>  $\geq 75$  days<sup>32,33</sup> and  $\geq 90$  days.<sup>34</sup>

However, we have used a TTI threshold of >30 days to determine the association between delayed initiation of therapy and explanatory variables, which is broadly representative across most solid tumours and aligns with findings from several key studies.<sup>35–37</sup> This threshold also resonates with clinical opinion in the Indian context, particularly considering the resource

constraints and logistical challenges often encountered while accessing cancer care.

The explanatory variables were as follows – age, gender, educational status, area of residence, marital status, number of family members, socio-economic status estimated based on monthly per capita consumption expenditure (MPCE), status of enrolment under financial benefit scheme, type of financial protection scheme, primary cancer site, stage, and type of treatment.

Data were entered in Microsoft Excel (Microsoft Office 365) and analysed using STATA v17 (StataCorp LLC, College Station, TX). Baseline characteristics were summarized using counts and percentages for categorical variables (such as age-group, occupation, education) and mean  $\pm$  standard deviation (SD) or median (Interquartile range, IQR) for continuous variables (such as age, time to treatment initiation delay).<sup>38</sup> Multiple thresholds of TTI delay were used to determine association between delayed TTI and various socio-demographic and clinical characteristics (Supplementary Tables S7–S14 of the Supplementary appendix). Factors which were found to be significantly associated with delayed TTI using different thresholds were documented separately (Supplementary Tables S7–S14). Binary logistic regression was employed to analyse the relationship between the outcome variable and each explanatory variable, and crude odds ratios were calculated for each variable. Explanatory variables with crude odds ratios having a p-value  $< 0.2$  were selected for further analysis.<sup>39–41</sup> Subsequently, multivariable logistic regression was conducted using all eligible explanatory variables to obtain adjusted odds ratios (Supplementary Table S15). A p-value  $< 0.05$  was considered statistically significant in this analysis.

Further, in order to calculate the year wise delayed TTI, we generated a scatterplot with the year of diagnosis on the x-axis and TTI on the y-axis. Additionally, we determined the trend, represented by the line of best fit, depicting delayed TTI over the years. Subsequently, we documented this trend for each specific cancer type.

Additionally, a Cox Proportional Hazard (CPH) model was used to conduct time-to-event analysis, considering treatment initiation as the event of interest among all cancer patients and year of diagnosis as the explanatory variable. This model was adjusted for age group, gender, education, residence, marital status, number of family members, health insurance, wealth quintile, primary cancer site, cancer stage, and type of treatment.

To examine the effect of the national flagship insurance program - AB PM-JAY launched in 2018, the trendline was reconstructed based on patients diagnosed during 1995–2017 compared to those diagnosed during 2018–2022. The key assumption of the Cox model is that the hazard ratio (the ratio of the hazard rates between two groups being compared) is constant

over time. In other words, the hazard functions for different groups being compared are proportional. This has been checked using Kaplan–Meier observed survival curves (Fig. 1). The proportional-hazards assumption has not been violated, as the predicted and observed curves are close together. This analysis was further stratified into patients who were PM-JAY beneficiaries and non-beneficiaries. Kaplan Meier curves were also produced to graphically represent the cumulative probability of treatment initiation. A steeper slope indicates a higher rate of event (i.e., treatment initiation).

### Ethical considerations

Ethical approval was obtained individually from the Institute Ethics Committee of all the participating centres. A written informed consent was obtained from all study participants. For participants below the age of 18, parental or guardian consent was sought.

### Role of the funding source

There is no role of any agency in study design, data analysis, data interpretation or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

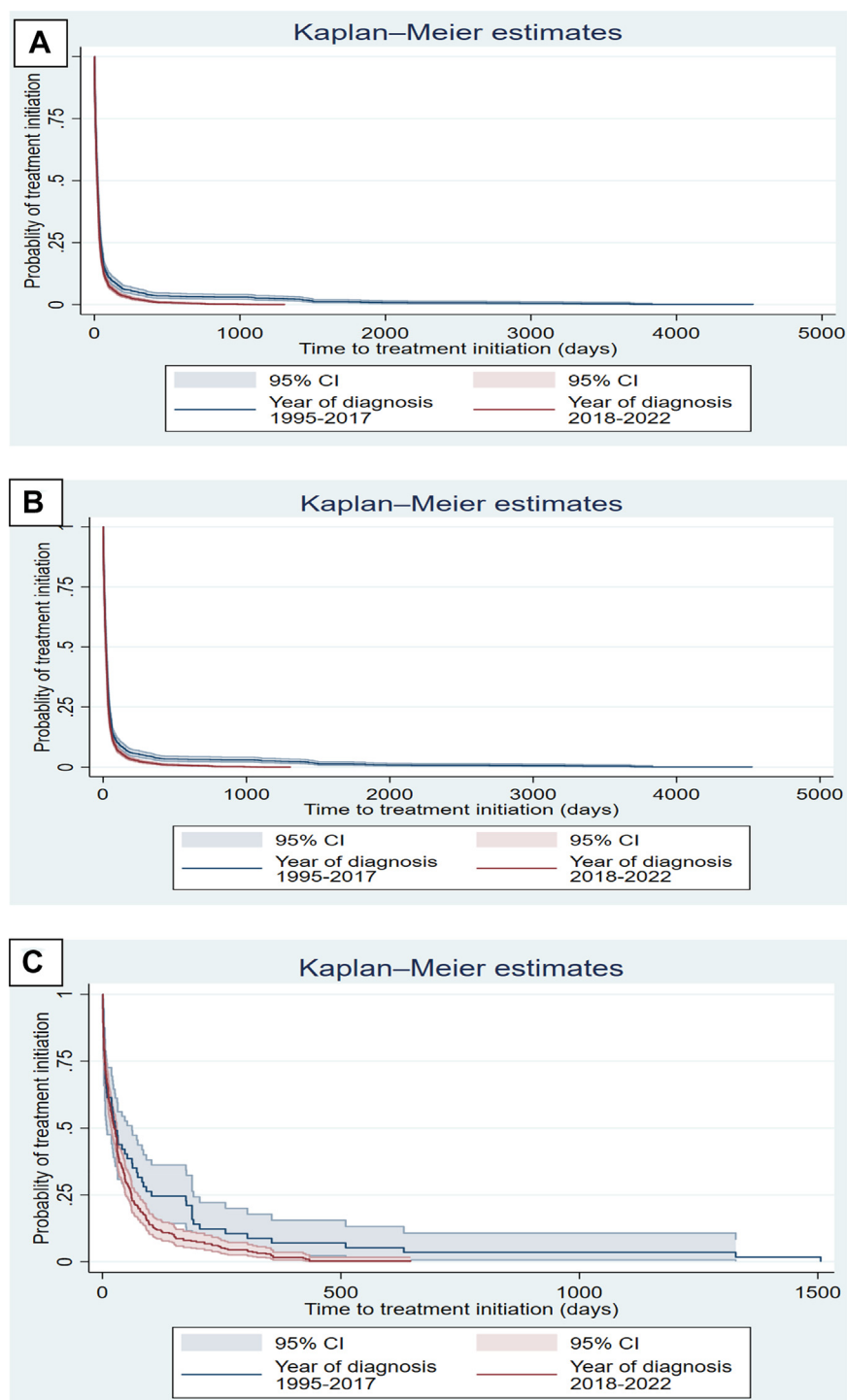
## Results

### Study population

The study population comprised 6695 cancer patients of whom 61% were females. The mean age of the participants was 48.7 years. Majority cancer patients were residing in rural areas (60.2%), and were married (80.1%). Almost two-fifth (39.4%) participants were not covered through any financial protection scheme. Among those who were covered, 48.6% were covered under government-funded health insurance schemes, and the remaining ones were supported through philanthropists (7.7%) and voluntary private health insurance (1.9%). The information on cancer stage could be elicited for only 53% patients, with 36% representing stage 3 and 4 of cancer. Nearly half of the participants were undergoing chemotherapy (49.42%) followed by combination therapy (10.7%). We included patients diagnosed with haematological cancers (25.6%), breast cancer (25.3%), reproductive and genitourinary cancers (18.5%), gastro-intestinal (GIT) (10.6%) and head & neck cancer (9.2%). Baseline characteristics of the included participants were comparable with the overall patients (Supplementary Table S1, Supplementary appendix). Detailed participant characteristics are provided in Supplementary Table S3 of the Supplementary appendix.

### Overall time to treatment initiation (TTI)

The median (IQR) time to initiate treatment from the date of cancer diagnosis was 20 (7–39) days, with a mean of



**Fig. 1:** Cox proportional hazard model showing the probability of treatment initiation along the TTI as per year of diagnosis (1995–2017 vs. 2018–2022): Adjusted values (A) Overall cancer patients, (B) Not availing AB PM-JAY, (C) Availing AB PM-JAY.

53.7 days (SD, 192.9). The distribution of TTI was found to be skewed (Shapiro Wilk test,  $p < 0.001$ ). Based on different treatment delay cut-offs ranging from 7 to 90

days, 64%, 51%, 30%, 17.5%, 12.7%, 9.5% and 8% patients were found to have a treatment delay of  $\geq 7$  days,  $\geq 14$ ,  $\geq 30$ ,  $\geq 45$ ,  $\geq 60$ ,  $\geq 75$  and  $\geq 90$  days respectively.

### Time to treatment initiation (TTI) by strata

**Table 1** summarizes the socio-demographic and clinical characteristics of the patients stratified by delayed TTI at threshold of 30 days. At TTI cut-off of  $\geq 30$  days, patients aged 46–60 years (32.1%), females (32.1%), illiterate (31%) or those educated up-to primary and middle level (32%), separated/divorced/widow/widower (34.7%), and those residing in rural areas (31.8%) reported highest TTI in excess of 30 days. The proportion of patients reporting more than 30 days delay in TTI was highest among GIT cancers (34.1%), followed by breast cancer (33.4%); while least delay was seen in case of reproductive and genitourinary cancers (19.5%). Higher proportion of stage 3 cancer patients (34.5%) reported a delay in initiation of treatment by more than 30 days followed by Stage 1 cancer (33.9%). Further, patients undergoing radiotherapy (35%) reported higher delay as compared to surgery (32%) and chemotherapy (27.9%) (**Table 1**).

Comparative analysis between patient groups having delayed TTI of <30 days and >30 days suggested that patients in whom therapy was initiated between Days 0 and 30 were younger (77% vs. 23% patients in the age group of 0–30 years), more educated (70.2% vs. 29.8%), and were covered through financial benefit schemes (69% vs. 31%) when compared with those treated beyond 30 days (**Table 1**).

### Time to treatment initiation (TTI) by type of cancer and type of treatment

The median TTI for each cancer type was significantly different ranging from 11 to 29 days ( $p < 0.001$ ). The median TTI (IQR) was highest among patients with head and neck cancer, 29 days (10.5–55.5) followed by breast cancer, 25 days (10–43), and least among haematological cancers, 11 days (4–27) as shown in **Fig. 2A**. Based on the type of treatment, radiotherapy had the highest median (IQR) TTI (days), [27.5 (10–49.5)] and supportive therapy had the lowest median TTI (days) [9 (2–54)] (**Fig. 2B**). The mean and median delayed TTI estimates stratified by type of cancer and type of treatment are described in **Supplementary Table S4** of the Supplementary appendix.

### Factors associated with delayed time to treatment initiation

Multivariable analyses of clinical and socioeconomic factors that were associated with TTI across different cut-offs are summarized in **Table 2**. **Table 2** shows that the female gender and poor wealth status have a significant association with any delayed TTI, starting with as short as 7 days delay, implying a stronger effect. In addition, as compared to surgical treatment, other therapeutic modalities also have a stronger association with even shorter threshold delays. Higher education, a known sign of disease and the enrolment in a financial protection scheme offers protection against longer

delays in treatment initiation. All other solid tumours have delayed TTI, as compared to haematological malignancy, irrespective of TTI threshold.

The detailed associations between determinants and different types of cancers with delayed TTI across various thresholds are documented in **Supplementary Tables S7–S14** of the Supplementary appendix.

### Trend analysis of delayed TTI (1995–2022)

Overall, we observed a declining trend in delayed TTI (slope value of  $\beta = -7.64$ ) (**Supplementary Fig. S1**). This trend was consistent across all types of cancers. Reproductive and genitourinary cancers exhibited the steepest decrease ( $\beta = -14.58$ ), nearly twice the overall value. Breast cancer demonstrated the second most rapid decrease, characterized by a  $\beta$  value of  $-9.11$ , while haematological cancers exhibited a less pronounced decline with a  $\beta$  value of  $-6.04$  (**Fig. 3**). The overall declining trend of delayed TTI significantly intensified after 2018, evidenced by a steeper slope with a  $\beta$  value of  $-13.20$  (**Supplementary Fig. S8**, Supplementary appendix). Comparable declining patterns were noted across all types of cancer, as illustrated in **Supplementary Figs. S9–S14** of the Supplementary appendix.

As compared to patients who were diagnosed between 1995 and 2017, those diagnosed after 2018 had a 36% (26–46%) higher odds of timely initiation of treatment within 30 days. Upon stratifying by enrolment under PM-JAY, we found that while the access to timely treatment initiation increased by 33% for those who were not enrolled, the timely access to cancer treatment increased by 90% among those enrolled under PM-JAY. Overall, this shows significant improvement in timely initiation of cancer treatment as a result of PM-JAY [**Table 3**].

### Discussion

In the present study, we have examined the extent, determinants, and trends of timely access to cancer treatment in India. More importantly, we examined the impact of PM-JAY on timely initiation of cancer treatment.

Our study leads to six important findings. First, overall, there is a declining trend in delayed TTI over the years, possibly attributed to increased knowledge, improved care seeking behaviour, reduced stigma and fear, improved transportation, healthcare infrastructure, advances in oncology treatment leading to better outcomes with less toxicity, economic growth, and health promotion initiatives by both government and non-governmental organizations.<sup>42,43</sup> Second, the slope of this decreasing trend was notably higher among patients availing benefits under AB PM-JAY, suggesting higher probability of timely treatment initiation for cancer patients as a result of enrolment.



This may be attributed to expansion of cancer care services under national flagship insurance program, AB PM-JAY launched in 2018 to provide universal health coverage to 500 million Indians. The health benefit packages (HBPs) under AB PM-JAY to cover procedures related to both cancer diagnosis and treatment have increased from 112 to 557 between 2018 and 2022 respectively.<sup>20</sup> Such initiatives appear to have helped in decreasing the financial barriers to access and improve early initiation of treatment.<sup>44</sup>

Third, we found the important role of social determinants in timely cancer treatment as shown in [Table 2](#). Income was observed to be an important determinant of delayed TTI, having lower odds of delayed TTI (>7, >14 days) among higher income groups as compared to lower income groups. This is consistent with previously published studies,<sup>28,45,46</sup> and may be attributed to factors like inequities, limited access to healthcare, financial constraints,<sup>30,31</sup> and increased exposure to infection and mortality among cancer patients during the COVID-19 pandemic, particularly affecting lower socioeconomic groups.<sup>47,48</sup>

Evidence suggests that cost of treatment poses a significant barrier to accessing cancer care in India. More recently, it has been shown that PM-JAY has resulted in significant reduction in out-of-pocket expenditure and financial toxicity.<sup>49</sup> These factors are likely to have contributed to easing barriers to accessing timely treatment. Additionally, it was found that breast cancer patients enrolled under financial benefit schemes (government/private) had higher odds of delayed TTI when the delayed TTI thresholds were lower (>7, >14 days). However, as the delayed TTI thresholds increased (>60, >75, >90 days), the odds decreased, suggesting initial delays in TTI due to administrative formalities associated with the schemes. Once these formalities were completed, the schemes facilitated faster TTI, which is in concurrence with published literature.<sup>26,29</sup>

Fourth, highest median TTI was observed among patients whose cancer stage was not known (i.e., the stage was not mentioned in the medical record of the patient). This might be due to lack of access to proper diagnostic procedures, lack of trained manpower or health facility; leading to uncertainty of staging, which might cause improper/delayed decision making regarding the appropriate treatment initiation. In breast cancer patients, higher odds were contributed by stage 3 (2.60). These findings align with similar observations in other studies,<sup>33,50</sup> suggesting that advanced cancer stages may contribute to delayed treatment initiation, with factors such as social stigma, fear and financial toxicity associated with cost-intensive cancer treatment, potentially exacerbating this delay. This finding has important implications for the existing cancer screening programmes. The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases &

Variable	Total N = 6695 N <sup>a</sup> (%)	Patients by TTI, N (%)		Chi-square p-value
		<30 days <sup>b</sup> N = 4682	≥30 days <sup>b</sup> N = 2013	
Age-group (years)				
0–15	158 (2.36)	131 (82.91)	27 (17.09)	<0.001
16–30	575 (8.59)	433 (75.30)	142 (24.70)	
31–45	1814 (27.09)	1289 (71.06)	525 (28.94)	
46–60	2724 (40.69)	1849 (67.88)	875 (32.12)	
>60	1424 (21.27)	980 (68.82)	444 (31.18)	
Sex				
Male	2633 (39.33)	1925 (73.11)	708 (26.89)	<0.001
Female	4062 (60.67)	2757 (67.87)	1305 (32.13)	
Educational status				
No education	1290 (19.27)	891 (69.07)	399 (30.93)	0.012
Primary and middle	2299 (34.34)	1569 (68.25)	730 (31.75)	
Up to Senior secondary	2099 (31.35)	1479 (70.46)	620 (29.54)	
Graduation and above	1007 (15.04)	743 (73.78)	264 (26.22)	
Residence				
Rural	4036 (60.28)	1814 (68.22)	845 (31.78)	0.013
Urban	2659 (39.72)	2868 (71.06)	1168 (28.94)	
Marital status				
Unmarried	587 (8.77)	460 (78.36)	127 (21.64)	<0.001
Married	5366 (80.15)	3738 (69.66)	1628 (30.34)	
Separated/Divorced/Widow/ widower	742 (11.08)	484 (65.23)	258 (34.77)	
Number of family members				
<5	3589 (53.61)	2481 (69.13)	1108 (30.87)	0.123
>5	3106 (46.39)	2201 (70.86)	905 (29.14)	
MPCE quintile				
Poorest	1500 (22.40)	1020 (68.00)	480 (32.00)	0.119
Poor	1387 (20.72)	973 (70.15)	414 (29.85)	
Middle	1250 (18.67)	857 (68.56)	393 (31.44)	
Rich	1208 (18.04)	862 (71.36)	346 (28.64)	
Richest	1350 (20.16)	970 (71.85)	380 (28.15)	
Financial benefit scheme				
AB-PMJAY	553 (8.26)	380 (68.72)	173 (31.28)	0.166
Other State/Central Government Sponsored Schemes	2701 (40.34)	1851 (68.53)	850 (31.47)	
Employer supported (other than govt./PSU) health protection	91 (1.36)	66 (72.53)	25 (27.47)	
Voluntary private insurance	130 (1.94)	95 (73.08)	35 (26.92)	
Philanthropists	515 (7.69)	366 (71.07)	149 (28.93)	
Others	64 (0.96)	42 (65.63)	22 (34.38)	
Not covered	2641 (39.45)	1882 (71.26)	759 (28.74)	
Primary site				
Head and Neck	712 (10.63)	493 (69.24)	219 (30.76)	<0.001
Breast	619 (9.25)	412 (66.56)	207 (33.44)	
GIT	1694 (25.3)	1117 (65.94)	577 (34.06)	
Haematological	715 (10.68)	483 (67.55)	232 (32.45)	
Reproductive and genitourinary	1714 (25.6)	1379 (80.46)	335 (19.54)	
Others	712 (10.63)	493 (69.24)	219 (30.76)	
Stage				
1	298 (4.45)	197 (66.11)	101 (33.89)	<0.001
2	773 (11.55)	528 (68.31)	245 (31.69)	
3	1469 (21.94)	962 (65.31)	507 (34.51)	

(Table 1 continues on next page)

Variable	Total N = 6695 N <sup>a</sup> (%)	Patients by TTI, N (%)		Chi-square p-value
		<30 days <sup>b</sup> N = 4682	≥30 days <sup>b</sup> N = 2013	
(Continued from previous page)				
4	979 (14.62)	667 (68.13)	312 (31.87)	
Unknown	3176 (47.44)	2328 (73.30)	848 (26.70)	
Current treatment				
Chemotherapy	3309 (49.42)	2384 (72.05)	925 (27.95)	0.002
Radiotherapy	234 (3.50)	152 (64.96)	82 (35.04)	
Palliative Care	126 (1.88)	88 (69.84)	38 (30.16)	
Surgery	393 (5.87)	267 (67.94)	126 (32.06)	
Combination therapy	722 (10.78)	471 (65.24)	251 (34.76)	
Maintenance therapy	170 (2.54)	130 (76.47)	40 (23.53)	
Supportive care	41 (0.61)	30 (73.47)	11 (26.83)	
Hormone therapy	227 (3.39)	149 (65.64)	78 (34.36)	
others	1473 (22.00)	1011 (68.64)	462 (31.36)	

<sup>a</sup>Column percentage. <sup>b</sup>Row percentage.

**Table 1: Patient characteristics based on delayed TTI threshold ≥30 days.**

Stroke (NPCDCS), now renamed as National Programme for Prevention & Control of Non-Communicable Diseases (NP-NCD) has been in operation since November 2016, however population coverage has been extremely low. Only 1.1% population have received cervical cancer screening, and less than 1% have received breast or oral cancer screening till date.<sup>51</sup> The coverage of screening needs to be expanded so that early detection is undertaken.

Last, there was highest delay observed for radiotherapy treatment followed by chemotherapy as compared to surgery, which is an important argument for strengthening public healthcare infrastructure for provision of radiotherapy to cancer patients in India as well as inclusion of cost-effective chemotherapeutic agents in HBPs under AB PM-JAY.<sup>52,53</sup> Radiotherapy is the most resource intensive speciality of oncology treatment requiring expensive and dedicated infrastructure. Presently, India possesses a total of around 779 teletherapy machines, out of which nearly one-third are telecobalt units, and the remaining are linear accelerators.<sup>54</sup> Similarly, among the 175 available simulators, nearly one-third are X-ray simulators, while the remaining are CT simulators.<sup>55,56</sup> In most high-income countries, there is at least 1 radiotherapy unit available for every 250,000 people.<sup>57</sup> This, on an average, would mean four radiotherapy machines per million population. Applying this factor to India would translate into a total requirement of 5000 radiation therapy units in India, as of now. Based on the number of existing installed units in India, this still would mean a shortfall of >4000 machines. According to the WHO, there should be 1 teletherapy unit for every million people. There would still be a major shortage of approximately 571 units since the minimum amount of teletherapy units needed is closer to 1350 than the 779 units

currently in use. This deficient infrastructure leads to long waiting periods for initiation of radiation treatment. Similarly, chemotherapy contributed to 1.44 times higher odds of delayed TTI as compared to surgery. This is probably due to higher cost associated with chemotherapy, as outlined by another study reporting higher odds of CHE and impoverishment due to chemotherapy as compared to other treatment modalities including radiotherapy, surgery, hormone therapy etc.<sup>49</sup>

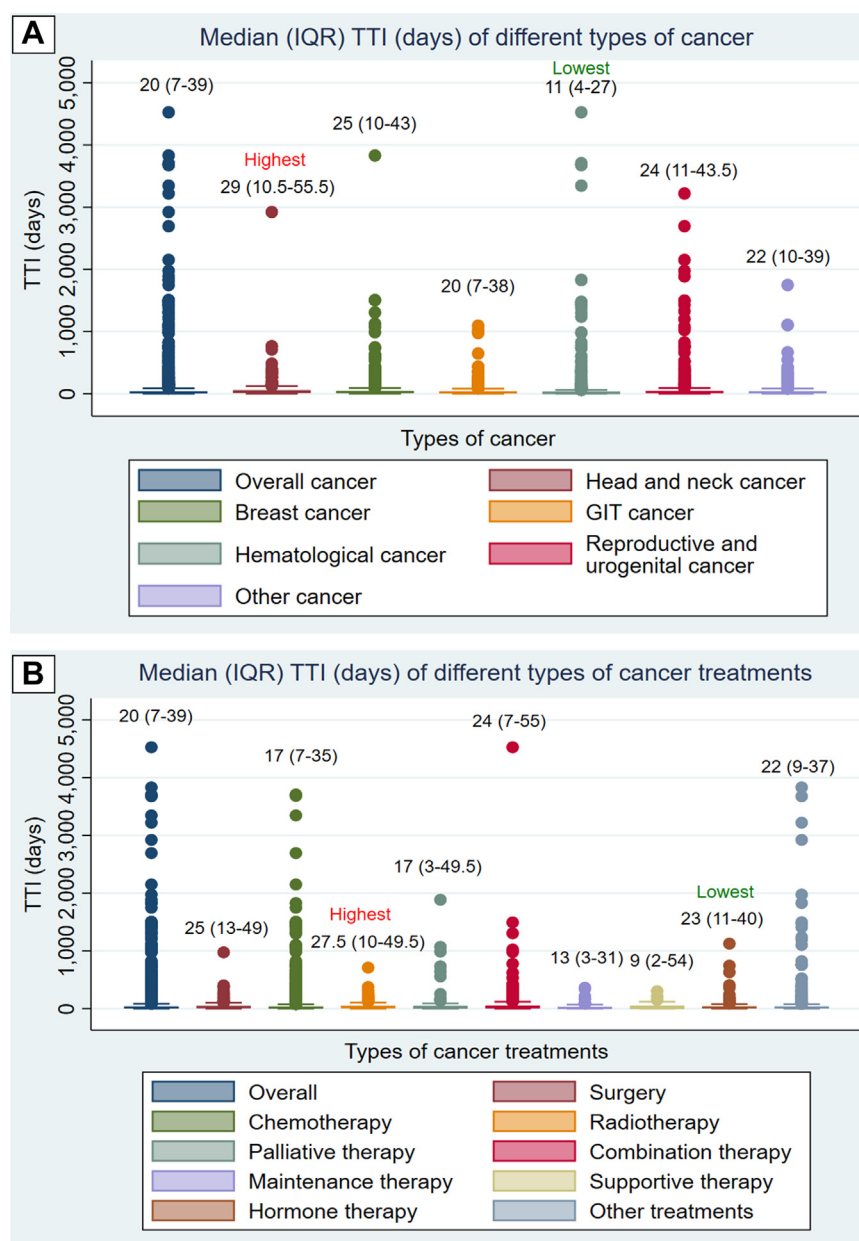
The overall median (IQR) TTI (days) was found to be 20 days (IQR: 7–39). Globally, studies have reported a wide range of TTI values, spanning from 17 to 135 days among participants with diverse cancer types.<sup>24,26,29,33,50,58</sup> The overall median TTI estimated in our study (20 days, IQR: 7–39 days) is indeed shorter than that reported in the US and UK studies.<sup>25,31</sup> One of the reasons could be difference in the type of cancers included in these studies. Cone et al. (2020) focused specifically on non-metastatic breast, prostate, non-small cell lung (NSCLC), and colon cancers,<sup>31</sup> while Khorana et al. (2019) included only early-stage cancers such as breast, prostate, lung, colorectal, renal, and pancreas.<sup>25</sup>

Another, and more important reason for such an observation is a difference in the definition of TTI. Khorana et al. estimated TTI using dates of initial cancer diagnosis either clinically or histologically established as per FORDS definition and earliest cancer-directed treatment.<sup>25</sup> On the other hand, we estimated TTI as difference of duration between histologically confirmed diagnosis (not clinically) and the date of initiation of treatment. Another potential reason for shorter time period for delayed TTI in our hospital-based study is the that patients who had longer delays might have been missed in our study as they did not have the opportunity to be enrolled in our study.

Further, in our study, the median (IQR) TTI (days) was observed to be highest among patients with head and neck cancer [29 (10.5–55.5)], followed by breast cancer [25 (10–43)], and lowest among patients with haematological cancers [11 (4–27)]. These findings align with previous research, reporting higher TTI values [40 (28–54.8)] among head and neck cancer patients.<sup>26</sup> Similarly, various studies have reported TTI values ranging from 17 to 127 days among breast cancer patients.<sup>24,25,50,58</sup>

In our study, we found that radiotherapy had the highest median TTI of 27.5 days (IQR: 10–49.5), followed by surgery at 25 days (IQR: 13–49). Notably, Babatunde et al. reported lower TTI values for surgery (17 days) and higher values for radiotherapy (135 days) in breast cancer patients.<sup>45,46</sup> Surgical treatments generally had shorter TTIs compared to radiotherapy. This trend is consistent with findings from multiple studies, possibly due to limited radiotherapy infrastructure and high radiotherapy utilization rate (RTU) which is the proportion of patients with cancer requiring at least one





**Fig. 2:** Box and whisker plot representing the median (IQR) TTI (days) as per different types of cancers (A) and different types of cancer treatments (B).

treatment of radiotherapy during the course of their disease. RTU is highest for LMICs as majority of patients present with locally advanced disease leading to long waiting periods.<sup>25,59</sup> We also found that chemotherapy had a median TTI of 17 days, shorter than 39 days reported in another study. This discrepancy may be due to the use of post-surgery chemotherapy among breast cancer patients.<sup>50</sup> Additionally, delayed TTI has also been found to be significantly associated with gender and area of

residence. Increased TTI observed in female patients highlights the barriers for women to access timely treatment including their role as caregivers at home, financial barriers, cultural and social barriers associated with stigma. Similarly, increased TTI seen among patients reporting from rural areas highlights the geographical barriers associated with skewed urban distribution of majority of cancer centres leading to long travel times, language barriers, food, stay, support required from attending caregiver, etc.

Characteristics	Adjusted odds ratio (95% Confidence interval) of Delayed time to treatment initiation (≥30 days)
Age-group (years)	
>60	Reference
0–15	0.63 (0.37–1.07)
16–30	0.99 (0.75–1.31)
31–45	0.94 (0.80–1.10)
46–60	1.02 (0.88–1.17)
Sex	
Male	Reference
Female	1.04 (0.90–1.19)
Education (minimum)	
No education	Reference
Primary and middle	1.08 (0.93–1.25)
Up to Senior secondary	0.99 (0.84–1.17)
Graduation and above	0.87 (0.72–1.07)
Residence	
Rural	Reference
Urban	1.17 (1.04–1.31)
Marital status	
Unmarried	Reference
Married	1.11 (0.83–1.50)
Separated/Divorced/Widow/widower	1.19 (0.85–1.68)
Number of family members	
<5	Reference
>5	0.99 (0.89–1.12)
Financial benefit scheme	
None	Reference
Government	1.04 (0.92–1.17)
Private	1.02 (0.84–1.24)
MPCE quintile	
Poorest	Reference
Poorer	1.00 (0.85–1.18)
Middle	1.08 (0.91–1.27)
Richer	0.94 (0.78–1.12)
Richest	0.94 (0.79–1.13)
Primary site	
Haematological	Reference
Head and Neck	2.12 (1.64–2.74) <sup>a</sup>
Breast	2.08 (1.64–2.65) <sup>a</sup>
GI <sup>a</sup>	2.01 (1.58–2.57) <sup>a</sup>
Reproductive and genitourinary	2.17 (1.78–2.64) <sup>a</sup>
Others	1.91 (1.53–2.38) <sup>a</sup>
Stage	
1	Reference
2	0.92 (0.69–1.23)
3	1.03 (0.79–1.35)
4	0.95 (0.72–1.26)
Unknown	1.07 (0.81–1.40)
Treatment	
Surgery	Reference
Chemotherapy	1.03 (0.81–1.29)
Radiotherapy	1.20 (0.85–1.70)

(Table 2 continued on next column)

Characteristics	Adjusted odds ratio (95% Confidence interval) of Delayed time to treatment initiation (≥30 days)
(Continued from previous column)	
Palliative Care	1.03 (0.66–1.61)
Combination therapy	1.19 (0.91–1.55)
Maintenance therapy	1.28 (0.83–1.98)
Supportive care	1.05 (0.50–2.19)
Hormone therapy	1.05 (0.74–1.50)
Others	1.11 (0.87–1.42)
<sup>a</sup> p-value < 0.05 (significant).	
<b>Table 2: Determinants of delayed time to treatment initiation (≥30 days) among all cancer patients.</b>	

Together with these key findings, an important recommendation of the study is that AB PM-JAY should prioritise the expansion of cancer packages under HBPs, by including the cost-effective treatments. Secondly, there is a need to increase the infrastructure for radiotherapy, promoting local production of quality equipment like linear accelerators and provide affordable and equitable radiation treatment by rationalising the existing HBPs pertaining to radiotherapy. Thirdly, as unknown cancer stage has also been observed as a determinant of delayed TTI, so there should be more focus on increasing the population coverage under screening programmes. To address the financial hardships associated with diagnostic services, innovative financing models such as e-RUPI could be used. e-RUPI is a digital payment solution designed and launched by the National Health Authority (NHA) in India, to deliver a cashless and contactless means of payment through an electronic voucher, which can be used for specific health services.<sup>60</sup> Lastly, while TTI delays as short as 7–14 days may impact clinical outcomes in certain solid tumours, the relationship between TTI and clinical outcomes varies by cancer type and stage.<sup>35–37</sup> Assessing these outcomes falls beyond the scope of this study, which focuses mainly on measuring the extent of delayed TTI, identifying its determinants, and evaluating the impact of government-funded health insurance on timely cancer treatment initiation. We recommended undertaking community-based longitudinal studies to ascertain the impact of delayed TTI on clinical outcomes as a future area of research.

We would like to mention several methodological strengths of our study. This is the first study to have comprehensively estimated determinants of delay in treatment initiation in daycare/outpatient setting at various thresholds on such a large sample of 6695 cancer patients. Given the use of the multistage stratified sampling technique for selection of states and healthcare facilities, we believe our sample is representative of the national cancer patient population in India.

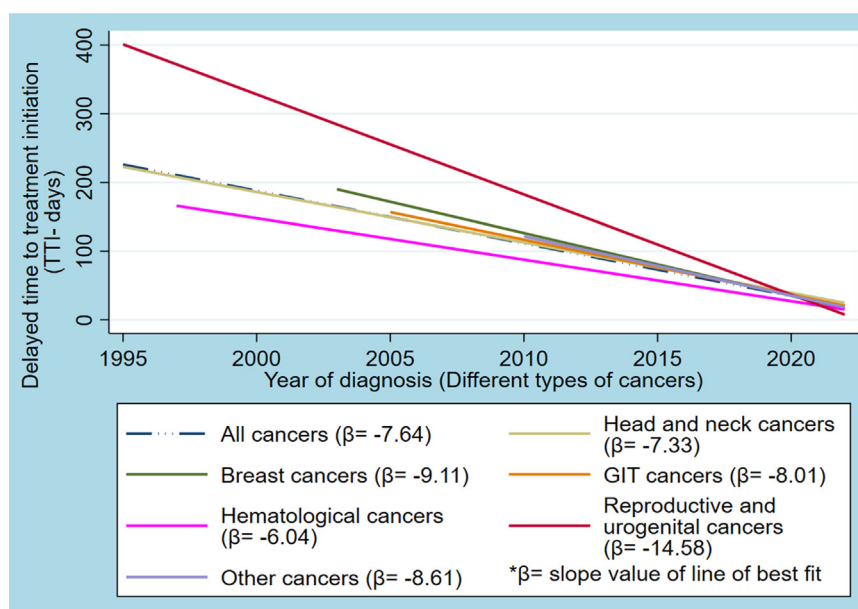


Fig. 3: Distribution and trend of delayed TTI (days) of different types of cancers with time (year).

Two of the selected hospitals in our sample, are among the top 10 hospitals in terms of cancer treatment claims as part of the national insurance scheme in India.<sup>27</sup> Our sample population included cancer patients from all age groups, socio-economic categories, and with any type of cancer (solid and haematological), thus making it more representative and generalizable. The distribution of cancer types in our sample is also in line with the GLOBOCON 2022 and Indian National Cancer registry data.<sup>2,61</sup> Several of these socio-demographic and clinical characteristics influence the care seeking behaviour of

the patients and are predictors of TTI. Hence, our sample is nationally representative to capture all variation across these factors. We would like to highlight that besides the large sample size, the other contribution is that we provide site-specific estimates (head and neck, breast, GIT, haematological, reproductive and genitourinary cancers) stratified by cancer stage and treatment on cancer treatment timeliness along with determinants of delayed TTI. Furthermore, our study is the first study which estimates the determinants of delayed TTI for cancer daycare/outpatient care.

Variable	Cox proportional hazard model			
	Unadjusted		Adjusted	
Overall cancer patients (N = 6695)				
Year of diagnosis	Hazard ratio (95% CI)	p-value	Hazard ratio <sup>a</sup> (95% CI)	p-value
1995–2017	Reference	-	Reference	-
2018–2022	1.20 (1.12–1.28)	<0.001	1.36 (1.26–1.46)	<0.001
Not availing AB-PMJAY (N = 6142)				
Year of diagnosis	Hazard ratio (95% CI)	p-value	Hazard ratio <sup>b</sup> (95% CI)	p-value
1995–2017	Reference	-	Reference	-
2018–2022	1.19 (1.12–1.28)	<0.001	1.33 (1.24–1.43)	<0.001
Availing AB-PMJAY (N = 553)				
Year of diagnosis	Hazard ratio (95% CI)	p-value	Hazard ratio <sup>b</sup> (95% CI)	p-value
1995–2017	Reference	-	Reference	-
2018–2022	1.42 (1.06–1.90)	0.019	1.90 (1.35–2.66)	<0.001

<sup>a</sup>Refers to adjusted with age group, gender, education, residence, marital status, number of family members, health insurance, wealth quintile, primary cancer site, cancer stage, type of treatment. <sup>b</sup>Refers to adjusted with age group, gender, education, residence, marital status, number of family members, wealth quintile, primary cancer site, cancer stage, type of treatment.

**Table 3: Cox proportional hazard model showing the association of TTI with year of diagnosis among overall cancer patients as per availing of AB-PMJAY.**

We would also like to mention some of our limitations. The determinants pertaining to the supply side (health system and healthcare services) were not captured as part of the CaDCQoL study,<sup>27,49</sup> thereby limiting the extent to which these factors could be studied. However, this limitation does not confound the results of our time trend analysis and the impact assessment of the government-funded health insurance scheme. Any variations in the health system likely remained consistent across both the groups i.e., PMJAY users and non-users, and since we are using difference-in-difference analysis, its effect would be multifaceted in the overall effect size. We also acknowledge that the rollout of the national insurance scheme (AB PM-JAY) likely exhibited geographic variation in terms of both intensity and timing. However, through our use of a multistage stratified sampling technique, we ensured the representativeness of states, healthcare facilities, and patients in our study sample. Given the representativeness of the sample, we believe that our study documents a real-world effect of PMJAY on TTI for cancer treatment given the variation in scheme implementation across states and over time.

Patients who had longer delays might have been missed in our study as they may not have had an opportunity to be enrolled yet, particularly in the most recent years. While we do recognise that this may influence the overall estimation of TTI as well as overall trends, however, this does not impact our co-proportional hazard model used to evaluate the impact of PMJAY, as the non-PMJAY serves as a control and mitigate the impact of any such selection bias. We recommended undertaking community-based longitudinal studies to assess the same as a future area of research. Sampling of patients at different stages might have led to over-representation of cancers with longer survival rates in our study sample. However, the findings of trend analysis and impact of government-funded health insurance scheme on delayed TTI along with key determinants of delayed TTI are less likely to be confounded by these factors as distribution of participants experiencing delayed TTI (threshold >30 days) based on primary cancer site, stage, and type of treatment were consistent across the different groups at three different time periods i.e., 1995–2010, 2011–2016 and 2017–2022 (Supplementary Tables S2 and S5 of the Supplementary appendix). We also recognize the limitation in our ability to capture delays starting from the initial suspicion of cancer to histological confirmation. By using the date of confirmed diagnosis as the starting point, we may have underestimated the true delay. However, since the operational definitions used are standardised across all years (1995–2022), TTI trends and its determinants are not likely to be confounded by these factors. We could not examine the barriers in access to cancer care from a resource centric perspective by categorizing treatments based on resource

requirements and the expertise, which could have provided a more nuanced understanding of access barriers contributing to treatment delays. However, we have reported our estimates on delayed TTI for each treatment type. We recommended an exploration on understanding of the structural challenges affecting timely treatment initiation in low-resource settings as an important area of future research. Lastly, we could not account for patient-related factors such as adherence to medical advice and follow-up appointments in our analysis as they are difficult to measure and control for in studies, although they significantly impact TTI.

## Conclusion

Our study attempts to provide evidence on determinants of delayed TTI among cancer patients in India. The timely access to cancer treatment has improved over the last three decades through government programs such as PMJAY and other health system strengthening interventions, however strengthening early detection and prompt treatment will require robust screening programs and the integration of cancer care into primary health care (PHC) and Comprehensive Primary Health Care (CPHC) systems, particularly at the Health and Wellness Centres (HWCs) established under the Ayushman Bharat initiative. These centres are pivotal in providing decentralized healthcare services and can play a crucial role in routine screening and early diagnosis.

## Contributors

Conceptualisation: SP, PH, JD. Data curation: SP, PH, JD. Formal analysis: SP, PH, JD. Funding acquisition: SP. Investigation: SP, JD, PH, NG, NM, AS, PM, AM, LK, ACK, SG. Methodology: SP, PH, JD. Project administration: SP, JD, NG, NM, AS, PM, AM, LK, ACK, SG. Resources: SP, JD, NG, NM, AS, PM, AM, LK, ACK, SG, PH. Software: SP, PH, JD. Supervision: SP, JD, NG, NM, AS, PM, AM, LK, ACK, SG. Validation: SP, JD, PH, NG, NM, AS, PM, AM, LK, ACK, SG. Visualisation: SP, JD, PH, NG, NM, AS, PM, AM, LK, ACK, SG. Writing – original draft: JD, PH, SP. Writing – review & editing: SP, JD, NG, NM, AS, PM, AM, LK, ACK, SG.

## Data sharing statement

The datasets and analysis will be available upon request. The study investigators retain ownership of their data. Any requests for access to data should be made directly to study investigator.

## Declaration of interests

All authors declare no conflict of interest.

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## Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.lansea.2024.100514>.

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