RADIATION ONCOLOGY

Compliance With Radiotherapy Treatment in an Apex Cancer Center of India

Nehal R Khanna, MD[1]; Sarbani Ghosh Laskar, MD[1]; Tejpal Gupta, MD[1]; and Jai Prakash Agarwal, MD[1]

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Radiotherapy (RT) plays an integral role in treatment protocols for most cancers either as a single modality or as a part of multimodal comprehensive cancer care for patients planned with curative or palliative intent. Noncompliance to planned RT treatment is associated with inferior outcomes across multiple sites.[1-4] Noncompliance could be the omission of RT altogether from the multimodal treatment protocol, delay in the initiation of RT, prolonged RT course because of the gap, or premature RT conclusion of RT. Compliance is also perceived as an indicator of the quality of care offered by an institute and may affect the overall oncologic outcomes.[5]

The cause of noncompliance varies across institutes and regions and combines social, financial, and logistic reasons. Identifying the rate of noncompliance, its causes, and factors affecting them can help us develop an insight toward implementing mitigation measures that may contribute significantly to the quality improvement process. Our institute, Tata Memorial Center, is an apex cancer center in the country, with around 45,000 new registrations annually, and the department of radiation oncology offers RT to approximately 9,000 patients. We undertook a retrospective audit to determine the incidence of noncompliance and its causality in the patients being offered radiation therapy appointments in 2019.

Patients are registered with specific Disease Management Groups managing specific tumor types and sites, undergo multidisciplinary joint clinic discussion, and are then referred for RT. Once issued an appointment (after careful evaluation of the role, efficacy, and feasibility of RT) for RT, these patients are simulated and planned for the RT treatment protocol. Counseling is done before the initiation of RT, emphasizing the efficacy of treatment and expected side effects. On-treatment patients are reviewed at least at a weekly interval to keep a check on the tolerance and response to RT. As a part of routine practice in the radiation oncology department, noncompliant patients are identified at the end of every working week, their RT charts are reviewed, and the patients are subsequently contacted and recounseled. The information gained is documented in RT charts, electronic medical records, and Radiation Oncology Information System (ROIS). Noncompliance in our study is defined as the fulfillment of any one of the criteria mentioned below:

1. Not attending the simulation for RT planning despite being scheduled for the same.
2. Planned for RT but has defaulted the starting/initiation of RT treatment.
3. Received at least one or more fractions of planned RT in TMH and then defaulted the remaining planned radiation.

Patients who had planned or unplanned changes in the treatment protocol (omission of RT or modification in RT plan/premature conclusion/undue gap with delayed conclusion) prescribed by the treating radiation oncologist because of toxicity or any other reason were not included in the study.

In the year 2019, 45,369 patients were registered in our institute. Of the 8,607 ROIS appointments given in that year, 197 (2.28%) patients were found to be noncompliant. Of these, 112 (56.9%) were males and 85 (43.1%) were females, with a median age of 55 years (mean 52.2 years, range 8-82 years). The majority of them were married 174 (88.3%). Around one third of noncompliant patients were illiterate (33%), almost half were unemployed (53.3%), and only 9.6% had health insurance. Almost half of the noncompliant patients were from outside the state of Maharashtra (47.2%), 29.9% belonged to Mumbai (Mumbai Metropolitan Region), 18.8% were from within the state of Maharashtra, and five patients were from other countries. The mean distance between the local residence and the treating center is 20.5 km, with some patients coming from places as far as 77 km away (n = 101). Ninety-seven patients defaulted RT simulation (49.2%), 53 defaulted RT starting (26.9 %), and 47 defaulted while on RT (23.9%). Half of these had either head and neck (29.9%) or gynecologic (20.8%) malignancies. Patients with breast cancers had the least noncompliance rates (0.02%). Most of the patients had locally advanced/locoregional (136; 69%) and were planned for multimodality treatment (117; 59.4%) with either definitive chemoRT (62; 31.5%) or adjuvant RT/ChemoRT (55; 27.9%). Most of these patients were planned for external beam RT (185; 93.9%) and with curative intent (174; 88.3%). The

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cause for noncompliance could be ascertained in 135 patients (68.5%). The common causes of noncompliance were the desire to continue treatment closer to home (21.5%) followed by logistics (17%), lack of confidence in the efficacy of the planned therapy (17%), and financial reasons (11.8%).

The literature available from our country regarding noncompliance of patients on RT is sparse, with available data focusing majorly on specific tumor types.[6-11] The studies published globally mention a wide range of noncompliance across institutions and regions.[1-5] The comparison of these results from these studies is challenging as the definition of noncompliance varies. The studies from our country show variable but high noncompliance rates across a spectrum of urban tertiary care centers, academic ones, and centers operating in rural parts of the country.[6-11] Our institute is an apex tertiary care center with a dedicated oncology infrastructure. Despite the large number of patients being offered RT, the noncompliance rate in our department is 2.28%, significantly less than the reported incidence in other institutes. However, the definitions of noncompliance vary across studies.[1,4,6-11]

Illiteracy and poor socioeconomic status are associated with poor compliance.[4] Around one third of noncompliant patients were illiterate (33%), and almost half were unemployed (53.3%). Patient registration is done in service categories depending upon the economic status of general (or converted to no-charge category later on) and private. The distribution of category in noncompliant patients was in accordance with the routine registrations that year, reflecting that no particular category of patients is more noncomplaint and vice versa. This could reflect on the policy to help nonaffording patients through multiple schemes running in the institute and the department. The economic status of the patient could not be accurately calculated and hence not mentioned in this study. Low socioeconomic status is a statistically significant predictor of noncompliance.[11]

Our institute gets a referral from all over the country and from overseas. This is reflected in our data as only 29.9% belonged to Mumbai. The distance between the local residence and the treating center is a known cause of noncompliance. Our institute supports many patients with short- and long-term accommodation around the institute and to-and-fro transportation. Compared with western countries, only one third of Indians are covered under public or private health care insurance schemes.[12] However, barely one tenth (9.6%) of noncompliant patients had health insurance. Thomas et al[13] reported almost twice treatment delays in indigent patients compared with the insured ones, essentially because of nonmedical or logistical reasons. Most of the patients had locally advanced/locoregional (136; 69%) and were planned for multimodality treatment (117/197%) with either definitive ChemoRT (62; 31.5%) or adjuvant RT/ChemoRT (55; 27.9%). Only 46 (23.4%) of them were planned for single-modality (RT) treatment. Multimodal treatment is often associated with increased toxicity and a prolonged course of treatment, which may hamper compliance to the planned treatment.[10] Choosing optimal therapy, especially multimodal in locally advanced cases, is of immense importance. The incidence of noncompliance of brachytherapy patients in our study is 1.27%. Most of the patients who defaulted palliative RT were planned for fractionated treatments (73.9%) compared with a single fraction (26%). This emphasizes the need for a shorter course of treatment for patients being treated with palliative intent.

The causes of noncompliance vary across different regions, institutes, types of malignancies, and patient populations and could be a combination of social, financial, and logistic reasons.[14] The cause of noncompliance is known in around two thirds of our patients (135; 68.5%). The most common cause of noncompliance in our patient population was the intent to take RT/complete further Rx at their native place (29; 21.5%). As mentioned earlier, most of our patients came from outside the city of Mumbai. The National Cancer Grid, a network of major cancer centers across India with a planned decentralization of oncologic care, immensely helps our patients receive quality care outside TMH all over the country. Access to good quality care at or around their native place has made patients comfortable taking treatment while being in the comfort of their homes. Comprehensive support (socioeconomic, accommodation, logistic, nutrition, transfusion, education, etc) along with prospective tracking of noncompliant patients has reduced the rates of noncompliance from $>$ 20% to $<$ 5% in the pediatric oncology department of our institute.[14] Similarly, patients in our department are actively involved in support group sessions and receive assistance from dedicated medical social workers with financial, logistic, and accommodation assistance. These measures could have contributed to the low incidence of noncompliance in our patients. Financial issues were seen in only one tenth of our patients (16; 11.9%). Better compliance is reported with hypofractionation vs. conventional fractionation in adjuvant breast cancer RT.[15] Similarly, the lowest noncompliance rate was seen in patients with breast cancer in our study (4 patients of 1,659/0.2%). This could be attributed to the short course of radiation (hypofractionation) in these patients, thereby shortening the overall treatment duration.

Rigorous patient counseling while planning for RT is imperative in ensuring confidence in the efficacy of a treatment modality and acceptance of the expected tolerance to the same and improves adherence to the planned treatment protocol, which might have a subsequent impact on the overall oncologic outcome. The other causes of noncompliance in our study were lack of confidence in the curative potential of the treatment (23; 17.0%), fear of treatment/toxicity (seven; 5.2%), and frustration because of the prolonged treatment course (5; 3.7%). The majority

of patients who had a lack of confidence in the planned oncologic treatment switched to alternative therapy (especially Ayurveda). It is vital to integrate indigenous alternate therapies like Ayurveda, Yoga, Naturopathy, etc with the oncologic plan to enhance the patient's confidence in the planned treatment.

We propose a prospective study of active tracking of noncompliant patients, further evaluating the causes of noncompliance and factors affecting the same, which are followed by incorporating mitigation measures to improve compliance. Some points from our study that can be incorporated in other centers, especially those with high patient throughput, are mentioned below:

1. Holistic approach toward treatment, which includes all aspects of care: oncologic, social, financial, personal, and mental.
2. Optimum counseling (individual and group) done by the clinicians and support staff, which includes social workers, dieticians, etc, during individual sessions and during patient support group meetings.
3. Red flagging of patients at high risk for noncompliance (poor social support, financial issues, advanced-stage patient planned for multimodality treatment, etc).
4. Adherence to the RT time points.
5. Systematic review of patients on treatment for assessment of toxicities and review of socioeconomic factors that may lead to noncompliance.
6. Development of financial models to assure financial assistance (Ayushmaan Bharat)
7. One fifth of patients desired RT at native place/combination of personal, logistic, and financial reasons. Development of networks (National Cancer Grid) or collaborative groups to encourage the decentralization of services and ensure an optimum cancer care continuum.
8. Gainful employment/vocational rehabilitation for post-treatment to improve self-sustenance.

AFFILIATION

[1]Department of Radiation Oncology, Tata Memorial Centre, Homi Bhabha National Institute, Mumbai, India

CORRESPONDING AUTHOR

Jai Prakash Agarwal, MD, Department of Radiation Oncology, Tata Memorial Centre, Homi Bhabha National Institute, Dr E Borges Road, Parel, Mumbai, India PIN 400012; e-mail: jpthm@hotmail.com.

AUTHOR CONTRIBUTIONS

Conception and design: Nehal R. Khanna, Sarbani Ghosh Laskar, Jai Prakash Agarwal
Administrative support: Jai Prakash Agarwal
Provision of study materials or patients: All authors
Collection and assembly of data: All authors
Data analysis and interpretation: All authors
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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