



Compliance of Radiotherapy Treatment at a Tertiary Cancer Center in India—A Clinical Audit

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Abstract

Introduction Noncompliance to planned radiotherapy (RT) treatment is associated with inferior outcomes and also serves as an indicator of quality of care offered to the patients. Identification of the rate of noncompliance and its causative factors can help us develop an insight toward implementing mitigation measures thereby improving the quality of treatment.

Objective To ascertain the incidence of noncompliance and the factors affecting the same in patients offered RT appointments.

Materials and Methods We retrospectively reviewed the records of patients from January 1, 2019, to December 31, 2019, who were noncompliant (defaulted RT simulation or defaulted initiation of RT or defaulted planned RT during the course of RT but excluding planned/unplanned treatment breaks or early conclusions prescribed by the treating radiation oncologist) for the planned RT treatment.

Results Of the 8,607 appointments (7,699 external beam RT and 908 brachytherapy) given to the patients attending the radiation oncology outpatient department in the year 2019, a total of 197 (2.28%) patients were found to be noncomplaint. 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–neck (29.9%) or gynecological (20.8%) malignancies. Patients with breast cancers had the least noncompliance rates (0.02%). The cause for noncompliance was ascertained in 135 patients (68.5%). The common causes of noncompliance were the desire to continue treatment closer to home (21.5%) followed by logistic (17%), lack of confidence in the curative potential of the planned therapy (17%), and financial reasons (11.8%). Patients with head–neck and gynecological malignancies were more often with advanced staged disease and were planned multimodal treatment protocols. The majority of the

Keywords

- compliance
- external beam
- radiotherapy

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23 patients who defaulted palliative RT were planned for fractionated treatments (73.9%).

Conclusion The incidence of noncompliance in patients planned for RT in our institute can be considered optimum. Appropriate counseling of patients at the time of scheduling appointment, upfront identification of patients at high risk of noncompliance, and assisting patients with financial and logistic challenges are imperative to ensure adherence to planned treatment schedule.

Introduction

Radiotherapy (RT) plays an integral role in treatment protocols for most of the cancers either as a single modality or as a part of multimodal comprehensive cancer care for patients planned with curative or palliative intent. In patients treated with curative intent, noncompliance to planned RT treatment is associated with inferior outcomes across multiple sites.^{1–4} Noncompliance could be omission of RT altogether from multimodal treatment protocol, delay in the initiation of RT, prolonged RT course due to gap, or premature conclusion of RT. Compliance is also perceived as an indicator of quality of care offered by an institute and may have an impact on the overall oncological outcomes.⁵ RT noncompliance can serve as a behavioral biomarker to identify high-risk patients who may require additional interventions.⁴

The cause of noncompliance varies across institutes and regions and is a combination of social, financial, and logistic reasons. Identification of the rate of noncompliance, its causes, and factors affecting them can help us develop an insight toward implementing mitigation measures which may contribute significantly to the quality improvement process. Our institute is a tertiary cancer center in the country. Every year we have more than 45,000 new registrations, and the department of radiation oncology offers RT to around 9,000 patients annually with curative or palliative intent. We undertook this study to determine the incidence of noncompliance and its causality in the patients being offered radiation therapy in our department in the year 2019.

Materials and Methods

This study is a retrospective audit of practice in the department of radiation oncology at our center. Patients registered with specific Disease Management Groups (DMGs) managing specific tumor types and sites (e.g., Gynecologic Oncology DMG, Breast Cancer DMG) undergo multidisciplinary joint clinic discussion and 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 initiation of RT with emphasis on the efficacy of treatment as well as expected side effects, and 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 department of radiation oncology,

noncompliant patients are identified at the end of every working week, their RT charts are reviewed, and the patients are subsequently contacted. The information regarding the same (reason for noncompliance/counseling/advice given by the treating radiation oncologist, etc.) is documented in RT charts, electronic medical records, treating unit audit charts, and radiation oncology information system (ROIS). Same procedure is followed for patients who do not attend the simulation on the scheduled date as well as patients who do not turn up for starting the planned RT treatment. The incidence of noncompliance, the distribution of such patients within various DMGs, demographic profile, and treatment-related variables were noted for all patients.

Noncompliance in our study is defined as fulfillment of any one of the criteria mentioned herewith.

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 at Tata Memorial Hospital (TMH).
3. Received at least one or more fractions of planned RT in TMH and then defaulted the remaining planned radiation in TMH.

Medical records of the patients who were given appointment through the ROIS from January 1, 2019, to December 31, 2019, were screened for noncompliance. Patients who had planned or unplanned change in treatment protocol (omission of RT/modification in RT plan/premature conclusion/undue gap with delayed conclusion) prescribed by the treating radiation oncologist due to toxicity or any other reason were not included in the study. The primary outcome was to ascertain the incidence of noncompliance. Secondary outcome was to determine the causative factors for the same. We retrospectively reviewed the charts of the noncompliant patients who fulfilled the inclusion criteria.

Statistical Analysis

Descriptive analysis was done on Statistical Package for Social Sciences (SPSS) version 22.0 software (IBM Corp., Armonk, New York, United States).

Ethics

Ethics committee approval was obtained from the institutional ethics committee dated May 15, 2020, project number 900631. The procedures followed were in accordance with the ethical standards of the responsible committee on

human experimentation and with the Declaration of Helsinki 1964, as revised in 2013. Waiver of informed patient consent was obtained from the ethics committee.

Results

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 median age of 55 years (mean 52.2 years, range 8–82 years). Majority of them were married (174; 88.3%). Around one-third of noncompliant patients were illiterate (33%) and almost half were unemployed (53.3%) and only 9.6% had a 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) and 18.8% from within the state of Maharashtra, and 5 patients were from other countries. The mean distance between the local residence 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–neck (29.9%) or gynecological (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 (117/197) either with definitive chemo-RT (62; 31.5%) or adjuvant RT/chemo-RT (55; 27.9%). Majority of these patients were planned for external beam RT (185; 93.9%) and with curative intent (174; 88.3%).

The 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 logistic (17%), lack of confidence in the efficacy of the planned therapy (17%), and financial reasons (11.8%).

The characteristics of these patients are enlisted in ►Tables 1 to 3. The distribution of noncompliant patients

as per the definition are listed in ►Table 1 and with respect to the DMGs in ►Table 2. The cause of noncompliance is listed in ►Table 4.

Discussion

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 too mention a wide range of noncompliance across institutions and regions (►Table 5).^{1,6–21} 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 rate across a spectrum of urban tertiary care centers, academic ones, and centers operating in rural part of the country.^{6–11} Our institute is a 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, though the definitions of noncompliance vary across studies.^{1,4,6–21} The distribution of gender (males 112; 56.9%) was reflective of the routine registrations in the year 2019 emphasizing that there is no

Table 1 Incidence of noncompliance

Total appointments given in the year 2019	8,607 (7,699 EBRT, 908 brachytherapy)
Total number of noncompliant patients	197 (2.28%)
Defaulted RT simulation	97 (49.2%)
Defaulted RT starting	53 (26.9%)
Defaulted while on RT	47 (23.9%)
Noncompliance as per the type of RT	185 EBRT, 12 brachytherapy
Noncompliance as per the intent of RT	174 curative, 23 palliative

Abbreviations: EBRT, external beam radiation therapy; RT, radiotherapy.

Table 2 Incidence of noncompliance with respect to the DMGs

DMG	<i>n</i>	Percentage of noncompliance	Appointment in 2019	DMG-wise noncompliance
Total	197	%	8,607	2.2%
Head–neck oncology	59	29.9%	2,271	2.59%
Gynecological oncology	41	20.8%	919	4.46%
Gastrointestinal oncology	30	15.2%	679	4.4%
Thoracic oncology	24	12.2%	1,064	2.2%
Neuro-oncology	15	7.6%	562	2.6%
Pediatric, hematolymphoid, and bone and soft tissue oncology	16	8.1%	1,095	1.4%
Uro-oncology	8	4.1%	358	2.2%
Breast oncology	4	2%	1,659	0.2%

Abbreviation: DMG, disease management group.

Table 3 Distribution of patients with noncompliance

N	197; 2.28%			
Gender	Male, 112; 56.9%	Female, 85; 43.1%		
Age	Mean, 52.2 y	Median, 55 y	Range, 2–82 y	
Marital status	Married, 174 (88.3%)	Unmarried, 19 (9.6%)	Widow/widower, 4 (2%)	
Religion	Hindu, 146 (74.1%)	Muslim, 34 (17.3%)	Others, 17 (8.6%)	
Permanent address	Mumbai	59 (29.9%)		Only 42 patients could arrange accommodation in Mumbai
	Outside Mumbai, within Maharashtra	37 (18.8%)		
	Outside Maharashtra	93 (47.2%)		
	Foreign	5 (2.5%)		
	Unknown	3 (1.5%)		
Distance between TMC and local residence (n = 101)	Mean, 20.5 km	Median, 19 km	Range, 0–77 km	
Health insurance	Yes, 19 (9.6%)	No, 178 (90.4%)		
Status employment	Employed, 54 (27.4%)	Unemployed, 105 (53.3%)	Retired/lost job, 15 (7.6%)	Not known, 23 (11.7%)
Education status	Illiterate, 65 (33%)	School level, 95 (48.2%)	Postschool (undergraduate/graduate/postgraduate), 37 (18.8%)	
Registration category	Private = 39 (19.8%)	General C = 133 (67.5%)	General NC = 20 (10.2%)	Foreign = 5 (2.5%)
Performance status at the time of giving RT appointment	Mean/median KPS 80	Range KPS 50–100	KPS 80 and above 169 (85.7%)	KPS 60 and less 6 (3%)
Comorbidities	Yes, 65 (33%)	No, 132 (67%)		
Substance abuse	Yes, 72 (36.6%)	No, 125 (63.4%)		
Intent of treatment	Radical, 174 (88.3%)	Palliative, 23 (11.7%)		
Type of RT planned	EBRT, 185 (93.9%)	Brachytherapy, 12 (9.1%)		
Stage	Localized, 37 (18.8%)	Locally advanced/locoregional, 136 (69%)	Oligometastatic, 2 (1%)	Metastatic, 22 (11.2%)
Treatment protocol	Definitive chemo-RT, 62 (31.5%)	Definitive RT, 46 (23.4%)	Adjuvant RT/chemo-RT, 55 (27.9%)	Others, 34 (17.3%)

Abbreviations: C, Charge; EBRT, external beam radiation therapy; KPS, Karnofsky performance status; NC, No charge; RT, radiotherapy; TMC, Tata Memorial Centre.

gender-specific predilection for noncompliance in our study. The same was true for the marital status and age of the patients. The distribution of the patients with respect to their religion was in accordance with the Indian Census 2011, underscoring the impact of diverse religions and beliefs on noncompliance in our institute.

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%). We could not capture the data on the family income. Patient registration is done in service categories depending on the economic status into 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 patients are more noncompliant and vice versa. This could reflect on the policy to help nonaffording patients through multiple schemes running in the institute as well as in the department. The economic status of the patient could not be accurately calculated, hence not mentioned in this study. Low socioeconomic status is a statistically significant predictor of noncompliance.¹¹

Our institute being a tertiary cancer care institute offering comprehensive care gets referral from all over the country as well as from overseas. This is reflected in our data as only 29.9% belonged to Mumbai (Mumbai metropolitan region) and 18.8% from within the state of Maharashtra. Half of the noncompliant patients were from outside the state, and five patients were from other countries. Distance between the local residence and the treating center is a known cause of

Table 4 Cause of noncompliance

Cause unknown	62 (31.5%)
Cause known	135 (68.5%)
Wishes RT at native place. RT referral letter issued	29 (21.5%)
Lack of confidence in the efficacy of the planned treatment	23 (17.0%)
Financial issues	16 (11.9%)
Long distance from local residence + other logistic issues	23 (17.0%)
Delay in start of RT	12 (8.9%)
Scared of treatment/toxicity	7 (5.2%)
Frustration due to prolonged treatment course	5 (3.7%)
Someone sick/died at native place	3 (2.2%)
Others	17 (12.6%)

Abbreviation: RT, radiotherapy.

noncompliance. The mean distance from the patient's place of stay in Mumbai (local residence) and our institute in our study is 20.5 km with some patients coming from places as far as 77 km away. Our institute through the medical social workers (MSWs) supports a large number of patients with short- and long-term accommodation around the institute along with to and fro transportation. We found that only nine such patients, who resided in the institute-assisted accommodation had defaulted. In the year 2019, we also referred 6,427 patients for RT outside our institute. As compared with Western countries, only one-third of Indians are covered under public or private health care insurance schemes.²² However, barely one-tenth (9.6%) of noncompliant patients had a health insurance. Thomas et al reported almost twice treatment delays in indigent patients as compared with the insured ones essentially due to nonmedical or logistical reasons.²³

Poor performance status, substance abuse, and presence of comorbidities are associated with nonadherence to treatment guidelines.²⁴ However, in our study, most of the patients (85.7%) had a performance status (Karnofsky performance status) of 80 and above at the time of issue of RT appointment, and only one-third of them had known comorbidities (65; 33%) or history of substance abuse (72; 36.5%). None of these patients were admitted in our institute while on RT. Most of the patients had locally advanced/locoregional (136; 69%) and were planned for multimodality treatment (117/197) either with definitive chemo-RT (62; 31.5%) or adjuvant RT/chemo-RT (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 prolonged course of treatment which may hamper the 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%. Literature regarding the

same is nonexistent. The 12 patients who defaulted brachytherapy were planned for either intracavitary or perineal interstitial brachytherapy for gynecological cancers. All of them defaulted immediate post-external beam radiation therapy (EBRT) except for one who defaulted post one session of brachytherapy. Most of our patients who undergo brachytherapy for breast malignancies and sarcomas are treated as inpatients, and there was no incidence of noncompliance in them.

RT is an effective modality for palliation of symptoms. Among the palliative patients who defaulted, majority of them were planned for fractionated treatments (73.9%) compared with single fraction (26%). The most common fractionated schedules were 20Gy/5Fr (34.7%) or 30Gy/10Fr (26%) in noncompliant patients. Among single fraction schedules, 10Gy/SF (17.3%) and 8Gy/SF (8.6%) were the most common. Most of these patients did not turn up for treatment at all (47.8%) or defaulted RT simulation (30.4%). The patients who defaulted after starting RT (21.7%) could not complete more than four fractions. All of these patients were planned for fractionated treatment. Among these palliative patients, majority were planned for treatment with conventional technique (73.9%) compared with conformal technique (26.1%). This emphasizes the need of shorter course of treatment for patients being treated with palliative intent.

The causes of noncompliance vary across differed regions, institutes, type of malignancy, patient population, and could be a combination of social, financial, and logistic reasons. Treatment-related toxicity is also a common cause of noncompliance; however, in our study, the patients with unplanned RT completion or gap prescribed by the treating radiation oncologist due to toxicity or other reasons were not included. Cause of noncompliance was 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. In the year 2019, we referred 6,427 patients for RT outside TMH essentially due to the same reason. National Cancer Grid which is a network of major cancer centers across India with a planned decentralization of oncological care immensely helps our patients in receiving quality care outside TMH all over the country. Access to good quality care at or around their native place has made patients comfortable in taking treatment while being in the comfort of their homes. At times, social, logistic, and financial reasons too may compel them to abandon the treatment.²⁵ Comprehensive support (socioeconomic, accommodation, logistic, nutrition, transfusion, education, etc.) along with prospective tracking of noncomplaint patients has reduced the rates of noncompliance from >20 to <5% in the pediatric oncology department of our institute.²⁵ Similarly, patients in our department are actively involved in support group sessions and receive assistance from dedicated MSWs 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%).

Table 5 List of publications addressing non-compliance

Author	Country/region	Cancer type/region	Definition of non-compliance	Percentage of noncompliance	Inference
Mohanti et al ⁶	India	Head-neck cancers	Incomplete treatment. Further details NA	38%	Compliance better for curative intent treatment
Sharma et al ⁷	India	Elderly head-neck cancer	Incomplete treatment. Further details NA	38%	Compliance better for early stage disease and fair general condition
Pandey et al ⁸	India	Head-neck cancers	Incomplete treatment. Further details NA	23%	Preference for traditional healers, logistic, and financial reasons
Gupta et al ⁹	India	All	Incomplete treatment. Further details NA	12.8%	Age, advanced stage, concomitant chemotherapy, logistics
Palwe et al ¹⁰	India	All	Incomplete treatment. Further details NA	6.7%	Advanced stage, logistics, and toxicities
Dutta et al ¹¹	Rural India	Cervical cancer	Defaulted EBRT, defaulted brachytherapy	25%, 36%	Socioeconomic and logistic reasons
Ohri et al ¹²	United States	All	Treatment interruptions	21.7%	Low socioeconomic status
Badakhshi et al ¹	Germany	Breast cancers	Complete omission of RT	5.5%	Logistics, chronic health issues
Borras et al ¹³	Spain	All	<90% of planned dose received	1%	70.7% has interruptions due to machine issues and personal reasons
Bhatt et al ¹⁴	Nepal	All	Incomplete treatment. Further details NA	18.9%	Long duration of treatment, toxicities
Arrossi et al ¹⁵	Argentina	Cervical cancer	Details NA	30%	Socioeconomic issues
Ferreira et al ¹⁶	Portugal	Head-neck cancers	Treatment interruptions	25%	Machine breakdown, toxicity
Ma et al ¹⁷	United States	Breast cancer	Omission of RT	4%	Older patients
Patel et al ¹⁸	United States	Head-neck cancers	Incomplete/prolonged treatment	35%	Poor locoregional control
Sayan et al ¹⁹	Syrian refugees in Turkey	All	Details NA	20.3%	Multiple demographic and clinical factors
Potters et al ²⁰	United States	Breast and prostate cancer	Incomplete treatment	3%, 1%	Toxicity
Jihan et al ²¹	Morocco	All	Incomplete/interrupted treatment	6.5% in young and 18.7% in old patients	Older patients had poor compliance

Abbreviations: EBRT, external beam radiation therapy; NA, not available; RT, radiotherapy.

Rigorous patient counseling while planning for RT is imperative in ensuring confidence in the efficacy of a treatment modality, acceptance of the expected tolerance to the same and improves adherence to planned treatment protocol which may have a subsequent impact on the overall oncological 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 (7; 5.2%), and frustration due to prolonged treatment course

(5; 3.7%). Optimum counseling can ameliorate these issues and improve compliance. Majority of patients who had lack of confidence in the planned oncological treatment switched to alternative treatment (especially Ayurveda). It is vital to integrate indigenous alternate therapies such as Ayurveda, Yoga, Naturopathy, etc. with the oncological plan to enhance patient's confidence in the planned therapy.

For more than a decade, the RT appointments and planning process is streamlined by the ROIS ensuring adherence

to RT planning time points. Hence, the delay in starting of RT as a cause was seen in very few patients (12; 8.9%). This delay in starting RT was more of patients own perception than an actual delay in starting the planned RT. Half of our patients defaulted the scheduled simulation appointment (97; 49.2%), one-fourth did not turn up for starting RT (53; 26.9%), and remaining defaulted while on RT (47; 23.9%). The loss of man-hours in the planning process (simulation, contouring, and planning) for 100 patients (defaulted RT starting/while on RT) becomes significant for a busy department like ours. Better compliance is reported with hypofractionation versus conventional fractionation in adjuvant breast cancer RT.²⁶ Similarly, the lowest noncompliance rate was seen in patients with breast cancer in our study (4 patients out of 1,659; 0.2%). This could be attributed to the delivery of short course of radiation (hypofractionation) in these patients and thereby shortening of the overall treatment duration.

Our study has the limitation of its data being captured in a retrospective manner. We could not capture the financial status. Our study did not analyze the impact of noncompliance on oncological outcomes. The cause of noncompliance is not known for one-third of the patients ($n = 62$; 31.5%). We propose a prospective study of active tracking of noncompliant patients, further evaluating their causes of noncompliance and factors affecting the same to be followed by incorporation of mitigation measures to further reduce the incidence of noncompliance to almost nil in our patient population. Some points that come forward from our study that can be incorporated in other centers especially those with high patient throughput are mentioned herewith.

- Holistic approach toward treatment which includes all aspects of care oncological, social, financial, personal, and mental.
- Optimum counseling (individual and group) done by the clinicians and support staff which includes social workers, dieticians, etc. during individual sessions as well as during patient support group meetings.
- Red flagging of patients at high risk for noncompliance (poor social support, financial issues, advanced stage patient planned for multimodality treatment, etc.).
- Adherence to the RT time points.
- Frequent review of patients on treatment for assessment of toxicities as well as review of socioeconomic factors that may lead to noncompliance.
- Development of financial models to assure financial assistance.
- 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 decentralization of services and ensure optimum continuum of cancer care.
- Gainful employment/vocational rehabilitation for post-treatment to improve self-sustenance.

Conclusion

The incidence of noncompliance in patients planned for RT in our institute can be considered optimum. Appropriate

counseling of patients at the time of scheduling appointment, upfront identification of patients at high risk of noncompliance, and assisting patients with financial and logistic challenges are imperative to ensure adherence to planned treatment schedule.

Note

The manuscript has been read and approved by all the authors, the requirements for authorship have been met, and that each author believes that the manuscript represents honest work.

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Conflict of Interest

None declared.

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