

## RESEARCH ARTICLE

# Clinical Audit in Radiation Oncology: Results from One Academic Centre in Delhi, India

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### Abstract

The objective was to analyze the radiotherapy (RT) practice at the cancer centre of a tertiary academic medical institution in Delhi. This audit from an Indian public institution covered patient care processes related to cancer diagnosis, integration of RT with other anti-cancer modalities, waiting time, overall treatment time, and compliance with RT. Over a period of one year, all consecutively registered patients in radiotherapy were analyzed for the audit cycle. Analysis of 1,030 patients showed median age of 49.6 years, with presentation as stage I and II in 14.2%, stage III and IV in 71.2% and unknown stage in 14.6%. A total of 974 (95%) were advised for RT appointment; 669 (68.6%) for curative intent and 31.4% for palliation. Mean times for diagnostic workup and from registration at cancer centre to radiotherapy referral were 33 and 31 days respectively. Median waiting time to start of RT course was 41 days. Overall RT compliance was 75% and overall duration for a curative RT course ranged from 50 days to 61 days. Non-completion and interruption of RT course were observed in 12% and 13% respectively. Radiotherapy machine burden in a public cancer hospital in India increases the waiting time and 25% of advised patients do not comply with the prescribed treatment. Infrastructure, machine and manpower constraints lead to more patients being treated on cobalt (74%) and by two-dimensional (78%) techniques.

**Keywords:** Radiotherapy audit - waiting time - overall time - compliance - treatment machine

*Asian Pacific J Cancer Prev*, 14 (5), 2829-2834

### Introduction

In our present state of cancer care globally, around half of the approximately 28 million cancer survivors worldwide underwent radiotherapy (RT) at some point in their treatment (Global Cancer Facts and Figures, 2011). The WHO expert group, in 1990s, estimated the need for radiotherapy in more than 50% of all cancer patients as part of their treatment and approximately 40% of the cures in cancer can be attributed directly to the benefits of radiotherapy (Porter et al., 1999). More recently, by collecting data from various international sources, Delaney et al. (2005) showed that the optimal radiotherapy utilization rate for all cancers should be 52.3%.

At least 50% to 60% of cancer patients in the developing world can benefit from radiotherapy (Pal and Mittal, 2004). As well as being effective, radiation therapy is less expensive than both surgery and chemotherapy. A high standard of radiotherapeutic practice must be sought in all phases of patient management with the most suitable technique, dose, fractionation and time regime by a particular department (Dische, 1984). Audit provides the opportunity for practitioners to monitor and modify their own service delivery through the collection of local and timely information. National Institute for Clinical

Excellence (NICE), UK has defined audit as “a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change” (National Institute for Clinical Excellence, 2002).

Clinical audit in radiotherapy is being introduced in many countries as a quality improvement tool. International Atomic Energy Agency (IAEA) has a long history of providing assistance for education and support of radiotherapy professionals, and review of the radiotherapy practice with a focus on developing countries. For this, IAEA (2007) has published a document to encourage comprehensive audits of radiotherapy practices, which includes a checklist describing various patient related procedures. The patterns of care studies (PCS) are example of audits which were designed to establish the national practice for cancer patients during a specific period. Published PCS reports had an impact on the clinical management of cancers of cervix, breast, and head and neck etc. (Shikama et al., 2003; Eifel et al., 2004; Ang et al., 2012).

A recent vision document prepared by European Society for Therapeutic Radiology and Oncology (ESTRO) in 2012 has placed emphasis on the development of radiation oncology as a major contributor to cancer

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cure, and to sensitize national and international policy makers, healthcare management, industrial and corporate partners, and other professional oncology societies to recognize this. One component of this document states that “all patients are entitled to access healthcare systems that enable the highest quality radiotherapy delivered within a safe healthcare environment” (Valentini et al., 2012).

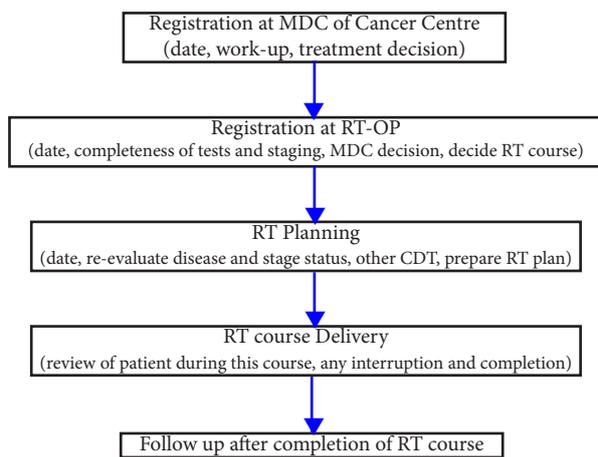
Audit gives information about patient care related to radiotherapy process, the waiting time for radiotherapy, its effect on overall treatment time, intention of treatment, compliance to radiotherapy, and its integration with other anticancer modalities. Thus, it has the potential to improve radiotherapy practice in developing countries and better the treatment outcomes. These audit outcomes will be relevant for many low and middle income countries where radiation therapy facilities are sparse. From our literature search, the present report from an academic and a major cancer centre in India is the first comprehensive audit of the mentioned parameters from this part of the world.

## Materials and Methods

The objective of this study was to analyze the radiotherapy practice at the cancer centre of a tertiary academic medical institution with emphasis on treatment intent, combination of radiotherapy with other modalities, compliance to RT treatment decision, waiting time and overall treatment time. It was not intended to analyze survival, loco-regional status and other treatment related outcomes.

This retrospective audit included patients registered from 1st September 2006 to 31st August 2007 in one unit of radiotherapy department at the Dr. B.R. Ambedkar Institute Rotary Cancer Hospital (IRCH), at All India Institute of Medical Sciences (AIIMS), New Delhi. IRCH is also a regional cancer centre under the National Cancer Control Programme, Government of India. In the subsequent text, IRCH is mentioned as centre/cancer hospital and AIIMS is mentioned as the institute. The inclusion criteria for this audit consisted of: biopsy proven malignancy, patient willing and appointed for radiotherapy course at this centre. Patients excluded for the audit were those who received radiotherapy for recurrence, salvage or re-irradiation, and in whom the record was incomplete as regards site and treatment plan. Documentation of patient’s consent for radiotherapy was reviewed for entry into this retrospective study. Cancer therapy which includes the first course of radiotherapy is delivered to 3500-4000 patients annually at this cancer hospital. This study aimed to assess 1000 patients, approximately 25% of all in need of radiotherapy during the covered duration of one year for this report, in order to obtain a sound real world picture.

The cancer hospital of the institute has evolved site/neoplasm wise multi-disciplinary clinics (MDC). The audit cycle started from the date of registration at MDC, the first site of contact at this centre, and extended till the completion of radiotherapy course. This unit of radiotherapy is devoted to treating patients mainly of head and neck (HNC), gastrointestinal, gynecologic, lung and pediatric malignancies and registers a small subset of patients with other/rare malignancies. Patients entered into



**Figure 1. Data Collection Process for this Radiotherapy Audit**

this audit were those who received treatment decision for RT mainly from the MDC, and occasionally referred from other specialties of AIIMS and/or from other hospitals and were subsequently registered at radiotherapy outpatient (RT-OP) clinic. In our institutional practice, patients undergo clinical assessment, investigations, diagnosis of the particular type of cancer before they are sent to the MDC of our centre for registration and treatment plan/decision. Patients who are referred from other specialties and outside and those who have incomplete staging may require further investigations including imaging, endoscopy, biopsy etc. Date of biopsy was considered as date of cancer diagnosis for this audit. The staging classification/grouping for this analysis were done according to the AJCC cancer staging manual (2002). The treatment decision taken earlier at the MDC may be reviewed and altered at the RT-OP depending upon patient’s host and disease factors. After this evaluation, the appointment for radiotherapy course was given at the RT-OP clinic visit. It is also simultaneously recorded whether patient has received or would be prescribed other cancer-directed modalities (CDT) like surgery and chemotherapy. During this audit period, the radiotherapy department of this cancer centre had three telecobalt machines, two high energy linear accelerators, two brachytherapy (one LDR and another HDR) machines and one simulator.

A pro forma containing 53 parameters was designed specifically to collect information relevant to the objective of this audit. The radiotherapy practice in this cancer hospital is documented in two different files maintained by this centre. The first patient file, prepared at the time of registration at centre, documented the investigations, site and stage, treatment decision at MDC and all treatment modalities delivered. The second file, generated at the time of radiotherapy planning incorporated the details of radiotherapy delivery and its course. For this audit both the files were retrieved and all relevant data collected and analyzed. The data collection for this audit process is depicted in the Figure 1.

## Results

### Patient demographics

During this audit cycle of one year, 1,500 patients were

registered under one unit in the RT-OP and 1030 patients fulfilled the audit criteria. Mean age of patients was 49.6 years, with majority in the age group of 41-60 years (48%) and male to female ratio was 2.6:1. Forty-six percent of the patients came from outside Delhi (Table 1).

Site and stage wise distribution is depicted in Table 2. Overall 71% (734/1030) presented with stage 3 and 4 disease, and 60% of HNC were stage 4.

### Radiotherapy practice

Out of 1030 patients, 974 received an appointment for radiotherapy, and the rest 56 patients were considered

**Table 1. Patient Characteristics**

Characteristic	No.	%
Age	1-82 years	1030 100
	<21 years	94 9
	21-40 years	165 16
	41-60 years	493 48
	>60 years	278 27
Sex	Male	745 72
	Female	285 28
Home address	Delhi	372 36
	NCR	178 17
	Outside NCR	480 46

\*NCR=National Capital Region, designated areas around Delhi

**Table 2. Site and Stage Distribution (n=1030)**

	n	I	II	III	IV	Unknown
HNC	611	16	71	135	374	15
LUNG	40	-	-	12	27	1
GYNE	63	10	11	22	10	10
GIT	136	1	2	119	10	4
LYM/LU	99	15	17	10	8	49
MISC	81	-	2	2	5	72
Total	1030	42 (4%)	103 (10%)	300 (29%)	434 (42%)	151 (15%)

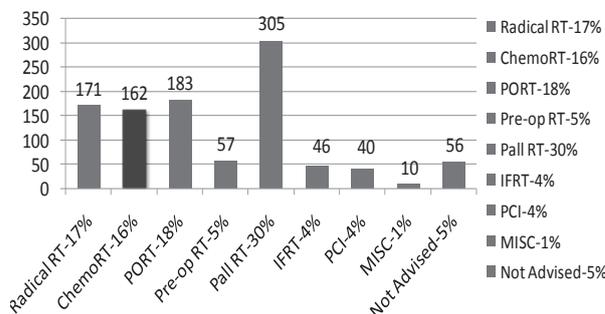
\*Stage 3 and 4=734/1030 (71.2%); HNC=Head and Neck Cancer, GYNE=gynecologic cancer, GIT=gastrointestinal cancers, LYM/LU=Lymphoma and leukemia, MISC=others/Rare neoplasm

**Table 3. Radiotherapy Practice**

Characteristic	No.	%
Radiotherapy at IRCH registered for this audit	1030	100
Advised	974	94.5
Not advised	56	5.4
RT course started at IRCH	732	75.0
Did not start RT at IRCH	242	25.0
Treatment received outside before IRCH registration	182	17.6
Surgery	88	48.3
Radiotherapy	1	0.5
Chemotherapy	72	39.6
Combined therapy	21	11.5
Treatment modalities advised at MDC		
Radical RT	171	17.0
Chemo -RT	162	16.0
Post-op RT	183	18.0
Pre-op RT	57	5.0
Palliative RT	305	30.0
IFRT	46	4.0
PCI	40	4.0
Misc	10	1.0
Not advised	56	5.0

\*Stage 3 and 4=734/1030 (71.2%); HNC=Head and Neck Cancer, GYNE=gynecologic cancer, GIT=gastrointestinal cancers, LYM/LU=Lymphoma and leukemia, MISC=others/Rare neoplasm

unsuitable at RT-OP evaluation (Table 3). Treatment intent in 974 appointed patients was curative in 669 (68.6%) and palliative in 305 (31.4%) (Figure 2). Seventy five percent (732/974 patients) complied to receive the radiotherapy course at this centre. It was observed that



**Figure 2. Radiotherapy Appointment and Treatment Type.** PORT=Post operative radiotherapy; IFRT=Involved field radiotherapy; PCI=prophylactic cranial irradiation; MISC=others

**Table 4. Audit Cycle of Registration and Waiting Times (site wise and treatment type wise)**

Audit cycle	Number (patients)	Range (days)	Mean (days)	Median (days)
Registration & diagnosis				
Diagnosis to IRCH registration	800	1-1157	33	-
IRCH registration to diagnosis	230	1-358	33	-
IRCH registration to RT registration	1030	1-807	31	-
RT registration to start of RT (site-wise)				
All	732	1-397	53	41
HN cancers	439	2-344	48	38
GI cancers	89	1-177	50	46
Gynaec cancers	46	1-397	48	34
Lung	23	1-349	58	32
Lymphoma & leukemia	80	1-307	88	76
Others	55	-	-	-
RT registration to start of RT (treatment type-wise)				
Radical RT	136	6-195	39	34
Chemo-RT	122	1-92	53	52
Post-op RT	144	2-246	53	45
Palliative RT	204	1-349	49	30

\*Stage 3 and 4=734/1030 (71.2%); HNC=Head and Neck Cancer, GYNE=gynecologic cancer, GIT=gastrointestinal cancers, LYM/LU=Lymphoma and leukemia, MISC=others/Rare neoplasm

**Table 5. Radiotherapy Compliance and Overall Treatment Time (n=974)**

	Patients	%
Radiotherapy compliance at IRCH (curative=669 patients)		
Treated	528	79
Did not comply	141	21
Audited for compliance	464**	-
a) Completed optimally	348	75
b) Completed with interruption	60	13
b.1 Toxicity	23	
b.2 Replan of phases	19	
b.3 Unknown	14	
b.4 Social reasons	4	
c) Incomplete RT course	56	12
c.1 defaulted	26	
c.2 toxicity	12	
c.3 disease progression	7	
c.4 Unknown	10	
c.5 Death	1	
Radiotherapy compliance at IRCH (palliative=305 patients)		
Treated	204**	67
Did not attend	101	33

\*\*RT records were audited in 668\*\*out of 732 treated patients

**Table 6. Median Duration of Radiotherapy Course (days) vs. Treatment Modalities in Various Sites**

Site	Radical RT (range)	Chemo RT (range)	Postop RT (range)	Preop RT (range)	Overall median duration
Head and neck	51(29-180)	53(37-122)	50.0(33-100)	50(25-57)	50
Gastrointestinal	-	55 (43-89)	41.5(35-49)	6 (5-36)	55
Gynecological	40 (39-56)	41 (36-51)	39.0(28-80)	-	61**

\*OTT=overall treatment time in radiotherapy; For gynecologic. \*\*malignancies the overall duration is calculated combining the external radiotherapy and brachytherapy. Gap between External RT and Brachytherapy=12 days (median)

17.6% (182/1030) of the patients had received some form of CDT before being registered at the centre.

#### *Audit of registration, waiting times, and treatment process*

The various time periods in this audit is depicted in Table 4. Eight hundred (77.6%) patients were diagnosed with malignancy prior to their referral (from other disciplines of this institute or from outside) for registration at the cancer hospital, mean duration from the cancer diagnosis to registration being 33 days (Range: 1-1157 days). In comparison, 22.4% (230/1030) were diagnosed with cancer after registration at this centre; their mean diagnosis time was 33 days (Range: 1-358 days). Mean duration from registration at the centre to registration in RT-OP was 31 days (Range: 1-807 days). Median waiting time from RT-OP registration to start of RT was 41 days (Range: 1-397 days).

#### *Radiotherapy compliance and duration of radiotherapy course*

Compliance to RT showed 732 (75%) of the appointed patients were started on radiotherapy course (Table 5). Radiotherapy record files of 64 patients did not show all details; 668 RT files were complete for retrieval. Our audit cycle showed that curative radiotherapy course was started for 464 (out of 669 appointed) patients; 75% completed the treatment optimally, 13% completed RT with interruption, and 12% did not complete the curative course. Out of 305 patients advised the palliative radiotherapy, 204 (67%) received the intended course and rest were noncompliant. Overall treatment time (OTT) duration was maximum for gynecological (61 days) and least for HNC (50 days). For gynecologic malignancies the overall duration was calculated combining the external radiotherapy and brachytherapy (Table 6).

#### *Radiotherapy technique and fractionation*

In this audit, curative patients received five daily fractions per week where as palliative RT consisted of five fractions per week or 1-3 fractions. Out of 668 RT records audited, details of technique were available in 455/464 curative and 189/204 palliative treated patients (overall 644 out of 732 patients planned, 88%). For curative treatment, telecobalt and linear accelerator (LINAC) machines were utilized for 76% (356/464) and 22% (99 patients) respectively. Brachytherapy was delivered to 31 (7%) patients in the curative group. For palliative intent 90% of patients were treated on a telecobalt machine and 92% were treated by 2D planning. In the group treated curatively, some form of three dimensional image based

conformal radiotherapy like 3D conformal radiotherapy (3D CRT), intensity modulated radiotherapy (IMRT) was used to treat 15% of the patients and the rest 85% were treated with 2D or virtual simulation. The audit for dose and fraction schedule for the two different treatment intents showed the median values of 60 Gy and 30 fractions for curative and 20 Gy in 5 fractions for the palliative groups respectively.

## Discussion

Clinical audit in radiotherapy, as stated by the European Commission, "is a systematic review of the procedures and practices followed. Modifications of practices are implemented where indicated and new standards applied as necessary" (European Society of Radiology, 2011). The increasing use of radiation therapy and rapid technological developments have stressed the importance of proper justification, optimization and quality assurance (Dische, 1984; IAEA, 2007; Soimakallio et al., 2011; Valentini et al., 2012).

India has a very low density of radiotherapy services, approximately 0.3 megavoltage high-energy machine per 100,000 population compared to the western standards of one or more machine per million (Barton et al., 2006). A survey by Murthy et al. (2008) has shown a wide gap in the availability and access of radiotherapy facilities in most parts of India, mainly in the public-funded hospitals. Recent trends show an increase in the radiotherapy cost over the last decade, due to new facilities being established in private sector, with interlinked quality assurance and technological evolution (Van de Werf et al., 2012). Government funded public institutions need to evaluate the standards of radiotherapy service. Audit of radiotherapy practice from a developing country like India with existing constraints like poor manpower, infrastructure, and paucity of facilities, together with poor compliance and loss to follow-up, will provide an insight into the current service, and generate evidence for future practice (Dinshaw, 1996). The present paper from a tertiary academic medical institution will be, to some extent, reflective of the radiotherapy care process in India. The results of this audit are compared with similar published literature pertaining to common cancers of this part of the world.

Cancer diagnostic evaluation is complex and often conducted in a sequential process in a healthcare system. A Danish cancer registry study by Hansen et al. (2011) showed that system level delay from first contact with General Practitioner (GP) to the start of cancer treatment was 55 days and overall delay from the first experience of symptoms to the institution of CDT was 98 days. Present audit analyzed the diagnostic workup at two levels: from cancer diagnosis outside to referral to this centre, and patient's presentation at IRCH to establishment of cancer diagnosis at this centre, and both had a mean duration of 33 days. Nearly 78% reached this cancer hospital one month after diagnosis was established, revealing a health system hurdle. The Danish study showed similar delay for patients undergoing investigation at GP level (Hansen et al., 2011). Olesen et al. (2009) have described concern

regarding the time lag at health system levels to establish a cancer diagnosis and start the cancer therapy.

Overall stage distribution in this analysis showed stages I and II in 14.2%; III and IV in 71.2% and unknown in 14.6% of the patients. Another report on Indian HNC patients showed stage III –IV presentation in 80-90% (Rao et al., 1998). Between 50-80% of breast and cervical cancers in the low and middle income countries present in stage III and higher, compared to less than 20% in the western countries (Barton et al., 2006).

The treatment advice in this study was curative and palliative in 65% and 30% respectively, and 5% of the radiotherapy referrals were unsuitable. A retrospective study from an Asian country showed similar rate of 63% for curative RT (Bhatt et al., 2009). Clinical audits from Australia and Sweden show the curative radiotherapy practice in 45-54% and palliation for approximately 50% (Stevens and Firth, 1996; Moller et al., 2003); whereas 75% of all cancer patients receive curative radiation therapy in USA (ASTRO Factsheet, 2004). The reasons for above disparities can be issues related to ignorance, socio-economic condition, access to health care and uniform lack of screening.

Waiting times for cancer care continue to be an important issue in many countries and vary depending upon the tumor type and integration of different CDT (Benk et al., 2006; Rutqvist, 2006; Williams et al., 2007; Hansen et al., 2011). Radiotherapy capacity has not increased proportionally with demand for its logistic utilization, resulting in increasingly long delays in most countries. In our study, median waiting time from registration to start of RT was 41 days, much beyond the international standards of approximately 4 weeks in Denmark and UK (Williams et al., 2007; Hansen et al., 2011). Longer waiting duration in breast and hematologic malignancies often occurs due to sequential integration of radiotherapy with chemotherapy. Similar observations have been made by Hansen et al. (2011) and Benk et al. (2006). The overall median time from disease detection to the start of first adjuvant therapy for postoperative breast cancer patients in Canada was 96 days; the waiting time being longer in 2003 compared to 1999 (102 v. 90 days,  $p < 0.001$ ) (Rayson et al., 2007).

Any delay beyond the standards set by the Joint Council for Clinical Oncology (JCCO) not only results in cancer progression and thereby lower cure rates but also becomes a source of concern and anxiety for the patient (Joint Council for Clinical Oncology, 1993; Jensen et al., 2007). Recent audit of waiting times from UK showed that the percentage of patients exceeding the maximum recommended wait of 28 days for radical or adjuvant postoperative radiotherapy was 55% in England, 44% in Scotland and 74% in Wales (Williams et al., 2007) It is a well known fact that if the capacity is less than the demand, a queue will appear and a waiting list will develop. A model has been developed in Denmark to overcome the problem of inadvertent delay in appointment such that the patients are divided into categories according to their waiting time guarantee and for each category a maximum waiting time is defined (Thomsen and Norrevang, 2009).

The compliance to recommended cancer treatments

outside the context of clinical trials differs in the regular practice. There is a paucity of good data in published literature regarding treatment course compliance and interruption. In the present audit, 75% of the patients advised radiotherapy received the treatment course at this centre. In the curatively planned, 75% completed the treatment optimally; and rest 25% had interruption or incomplete treatment. In head and neck and cervical cancer, treatment interruptions for radiation or chemo-radiotherapy are noted in 35-55% of the patients (Serkies and Jassem, 2004; Patel et al., 2008; Fesinmeyer et al., 2009; Sethi et al., 2010). At one Chicago county hospital, 40% of the patients planned for chemo-radiotherapy did not receive the treatment course (Patel et al., 2008). Patients who do not receive CDT after diagnosis need to be identified since it adversely impacts the national resources.

The influence of OTT on disease control and survival has received a lot of attention in the management of solid tumors. This audit showed median duration of RT course for HNC to be 50 days, 55 days for gastrointestinal cancers, and 61 days for gynecological malignancy. The overall treatment time for most cancers remained within the acceptable range. This is important because prolongation of radiotherapy course is considered to be one of the factors for treatment failure particularly in head and neck and gynecologic cancers (Trott, 1990).

In 2011, tele-cobalt to LINAC ratio in India was 277/157(1.8:1) (Kron et al., 2012). In this analysis, 74% and 14% patients were delivered the radiotherapy course by tele-cobalt and LINAC respectively. Another audit from Asia showed that 42% and 58% of patients were treated on cobalt-60 and LINAC respectively (Bhatt et al., 2009). In general, conformal radiotherapy and IMRT were delivered to approximately 70% and 25% of the patients respectively in Japan (Numasaki et al., 2009). A quality survey in Europe showed that 72% of the institutions deliver 3D image-based radiation therapy (Budiharto et al., 2008). In Europe, IMRT is used for 50%, somewhat less compared to USA; and this figure drops to 25% in India and South Africa (Salminen et al., 2011) In the present audit, 78% were treated by 2D planning and the rest 22% were delivered image-based 3D conformal or IMRT. These practices reflect on the machine and manpower limitations in a public cancer hospital.

In conclusion, this report from a public hospital in India showed that more than 70% of patients present in stage III-IV, at a median age of 49 years and the cancer diagnosis took up 33 days' time. There is a median waiting time of 41 days for start of radiotherapy, and compliance to the prescribed radiotherapy is met by 75% of the advised patients. Overall duration for the RT course ranges from 50 to 61 days and less than 25% are delivered image-based 3-D radiation therapy. Machine burden and manpower constraints are the reasons for above outcomes seen in our audit.

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