Clinical Outcomes of Definitive Radiotherapy Delivered by Helical Tomotherapy

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ABSTRACT

Objective: To assess the disease response and patient survival outcomes for cancer patients treated with helical tomotherapy.

Study Design: Descriptive study.

Place and Duration of the Study: The Tomotherapy Unit of Jinnah Postgraduate Medical Centre, Karachi, Pakistan, from October 2020 to August 2023.

Methodology: A retrospective analysis was conducted on the data of patients who underwent definitive radiation at Tomotherapy Centre. The evaluation of disease response utilised CT scans performed three months after completing radiotherapy, following RECIST criteria. Survival and disease-free status were determined through telephonic interviews with the patients.

Results: A total of 654 patients received treatment on Tomotherapy, of which, 143 underwent definitive Radiotherapy. The average age was 51 ± 16.8 years, with 85 (59.4%) males. The predominant area subjected to definitive radiation was the head and neck, accounting for 65 cases (45.5%), trailed by the gastrointestinal tract and pelvis with 52 (36.4%) and 26 (18.2%) cases, respectively. Response assessment revealed a complete response in 73 (52.14%) patients, partial response in 47 (33.5%), stable disease in 11 (7.85%), and progressive disease in 9 (6.4%). Currently, 108 (77%) patients are alive. Twenty-eight (20%) patients experienced local or distant disease development. Among them, 6 (4.3%) patients had local recurrence, and 22 (15.7%) developed metastatic disease.

Conclusion: Helical tomotherapy offers promising disease control and survival outcomes, making it a viable treatment modality for cancer patients in a lower middle-income country. These findings highlight the importance of careful patient selection and optimising resource utilisation for curative treatments to enhance cancer care in Pakistan.

Key Words: *Radiotherapy, Tomotherapy, Radiotherapy technique, Multidisciplinary treatment, Peer-review practice*.

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INTRODUCTION

Definitive radiotherapy, i.e. treatment of the disease solely with radiation, is the curative modality of choice for cancer cases in which upfront surgery carries a high risk of surgical morbidity.[1] In these cases, definitive radiotherapy with or without adjuvant chemotherapy is preferred in order to preserve organ functionality and retain quality of life. Cancers that are treated primarily with definitive radiation involve the head and neck region (nasopharynx, hypopharynx, oropharynx, and larynx), rectum, cervix, oesophagus, and prostate.

In the treatment of head and neck cancers, definitive radiotherapy is particularly useful for larynx preservation and is comparable in efficacy to surgery.

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IMRT (intensity-modulated radiation therapy) has rapidly evolved to become the standard of care for head and neck squamous cell carcinomas (HNSCCs) since it optimises dose coverage while minimising the radiation exposure to normal tissues and reducing the risk of toxicity.[2] Kataria *et al*. conducted a study examining the clinical results of adaptive radiotherapy in patients with head and neck cancers including oropharynx (58.3%), larynx (13.9%), and hypopharynx (27.8%) subtypes. They discovered that 80.5% of patients attained complete response according to the RECIST criteria (the response evaluation criteria in solid tumours) after the initial follow-up.[3]

For cervical cancer, RT in general, typically demonstrates favourable survival outcomes, with rates of 78% for overall survival, 90% for pelvic control, and 69% for disease-free survival being reported by one study.[4] Definitive radiotherapy outcomes for prostate cancer are also positive, with a retrospective analysis performed in the US showing 10-year metastasis-free survival rates of 96%, 92%, and 80% for cases of low, intermediate, and high-risk diseases, respectively.[5] A study investigating the clinical outcomes for oesophageal squamous cell carcinoma treated with definitive radiotherapy reported

cause-specific survival rates of 82.6% and local control rates of 86.3% at the five-year checkpoint.[6]

In recent years, helical tomotherapy has evolved as an innovative advancement in IMRT, helical integrating the properties of a linear accelerator and CT machine.[7] It makes use of a rotating gantry system and binary multileaf collimator to administer highly precise radiation doses that conform to tumour shape and volume.[8]

Tomotherapy setup is unique as it allows for both imaging and treatment simultaneously. The megavoltage CT (MVCT) imaging component enables clinicians to view the targeted regions both prior to and during the course of treatment and map out any morphological changes that occur.[9] This results in greater precision and delivery of targeted, conformal doses of radiation while decreasing the likelihood of toxic irradiation to normal tissues and related adverse effects. These advantages make helical tomotherapy useful particularly for tumours located near sensitive structures, such as in head and neck cancers.

As the study centre is the only place where helical tomotherapy service is provided, the study aimed to evaluate approximately three years' worth of data from cancer patients who underwent definitive radiation treatment using helical tomotherapy, in terms of three months post-treatment response according to the RECIST criteria, recurrence and survival outcomes.

METHODOLOGY

After obtaining approval from the Institutional Review Board of the Jinnah Postgraduate Medical Centre, Karachi, Pakistan, a retrospective analytical study was conducted by reviewing medical records. All the patients who received definitive radiation at tomotherapy from October 2020 to August 2023 were included. Exlusion criteria were patients who discontinued treatment prematurely, those referred out due to machine breakdown, and those who received radiation as an adjuvant modality following surgery.

For each patient, a contrast-enhanced CT scan with a 3-mm slice thickness was conducted in the treatment position using personalised immobilisation devices. Treatment planning employed Multiplan software (Accuray precision 3.3) for inverse planning, and treatment was administered *via* tomotherapy utilising the radixact x9 model. This system utilises 6-MV photons and incorporates mounted MV CT for image guidance. All patients in the study were required to undergo concurrent chemotherapy as indicated. The implementation of neoadjuvant chemotherapy was specifically given to patients with locally advanced nasopharynx and rectal cancer. In cases of prostate cancer, all enrolled patients were classified as locally advanced. As part of their comprehensive treatment approach, these patients received standard concurrent hormone therapy.

During radiotherapy, patients were seen weekly in the clinic. Acute radiation toxicity was graded according to the RTOG and the EORTC (European Organisation for Research and Treatment of Cancer) toxicity criteria.[10] After the completion of treatment, the first follow-up was conducted after four weeks. Other follow-up appointments were scheduled every three months for the first two years, followed by every six months in the 3rd year. Clinical examinations were conducted during follow-up appointments, and imaging of the respective region was performed as per the clinical indication.

Initial imaging was performed three months post-radiation to assess the response, utilising RECIST criteria for the assessment of definitive radiation. The main components of RECIST include: Complete response (CR) defined as the disappearance of all disease; partial response (PR) defined as at least a 30% decrease in the sum of the longest diameters of target lesions; stable disease (SD) defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease; and progressive disease (PD) defined as at least a 20% increase in the sum of the longest diameters of target lesions or the appearance of new lesions. For prostate cancer patients, the nadir value of PSA from medical records was used for response evaluation, with a nadir value of <0.2 ng/ml considered as the response after three months of definitive radiation. Survival and disease-free status were determined through medical records and telephonic interviews with the patients.

The data were entered and analysed in SPSS version 23.0. Demographics and clinical characteristics of categorical variables were reported as frequencies and percentages. The categorical variables included in the analysis were gender, cancer stage, site of radiation, concurrent chemotherapy administration, prostate cancer risk group, hormone therapy administration, response to treatment, follow-up status, recurrence type, and site of metastasis. Numerical variables, such as age, were reported as means with standard deviations where appropriate.

RESULTS

Over a span of three years, a total of 654 patients underwent treatment using tomotherapy. Among them, 143 received definitive radiotherapy (Table I). The average age was 51 ± 16.8 years and majority 85 (59.4%) were males. The most common stage of presentation was Stage III 82 (57%) followed by Stage IVA 40 (28%). The predominant area subjected to definitive radiation was the head and neck, accounting for 65 cases (46%), trailed by the gastrointestinal tract and pelvis 52 (36%) and 26 (18%) cases, respectively. A significant majority, 119 patients (83%), received concurrent chemotherapy as an integral component of their treatment. Among the 10 (7%) patients with prostate cancer, all were diagnosed with locally advanced disease and received hormone therapy as part of their treatment. Fourteen (10%) patients did not undergo chemotherapy; among them, 10 (7%) patients had T1 glottis cancer and were treated solely with radiation. The remaining four patients, with oesophageal and cervical cancers, were denied chemotherapy.

Out of the initial 143 patients, three were lost to follow-up. Upon response assessment, complete response was observed in 73 patients (52%), partial response in 47 (34%), stable disease in 11 (8%), and progressive disease in 9 (6%) (Figure 1). Among T1 glottis patients, 8 (80%) out of 10 exhibited complete response, with none experiencing disease progression of the 10 patients with prostate cancer, 7 (70%) were classified as high risk and 3 (30%) as intermediate risk unfavourable group. All 10 patients achieved a nadir PSA of <0.2 ng/ml three months after definitive radiation.

At the time of analysis, 108 (77%) patients were alive. Among them, majority (n = 66, 61%) had complete responses on the initial CT scan of assessment and 34 (31%) had PR. A total of 28 (20%) patients experienced local or distant disease development. Among them, 6 (4%) had local recurrence, and 22 (16%) developed metastatic disease, with the lung being the most prevalent site of metastasis in 16 cases (11%). Out of 17 who expired, 4 had local recurrence and 13 had distant metastases.

Table I: Baseline characteristics.

Baseline characteristics	n (%)
Total patients treated on tomotherapy	654
Patients receiving definitive radiation	143 (100)
Mean age (years)	51.3 ± 16.8
Male gender	85 (59.4%)
Site	
Head and Neck	65 (46%)
Larynx	25 (17%)
Nasopharynx	19 (13%)
Hypopharynx	14 (10%)
Oropharynx	7 (5%)
GIT	52 (36%)
Rectum	31 (22%)
Oesophagus	21 (15%)
Pelvis	26 (18%)
Cervix	14 (10%)
Prostate	10 (7%)
Vagina	2 (1%)
Stage of cancer	
Stage 1	10 (7%)
Stage 2	11 (8%)
Stage 3	82 (57%)
Stage 4	40 (28%)
Concurrent chemotherapy	119 (83%)
Hormone	10 (7%)

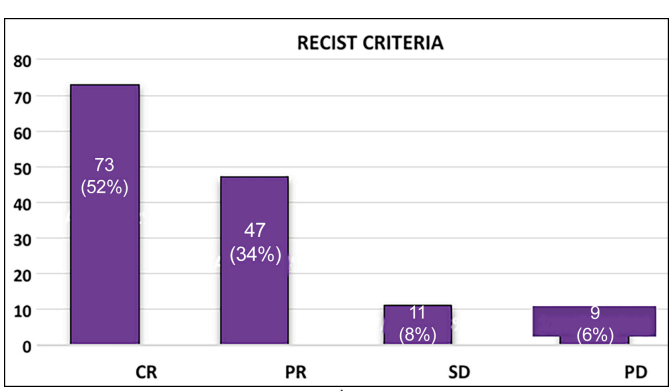

Figure 1: Response assessment on 1st CT scan post radiation.

DISCUSSION

Helical tomotherapy, which delivers advanced, image-guided intensity-modulated radiation therapy (IMRT), has become increasingly popular in cancer treatment due to its promising patient outcomes compared to conventional radiotherapy. At the Cyberknife and tomotherapy-radiation oncology centre, extensive experience has been gained using one of the first and only helical tomotherapy systems in Pakistan. As the sole user of this technology in the country, a suitable workflow was established within the department, highlighting several benefits compared to older conventional systems. The central goal of the setup is to exclusively target curative cases, resulting in 93 (65%) patients receiving definitive treatment for cancer.

While definitive radiotherapy (RT) is typically a standard treatment option for most of the early-stage cancers, the present study revealed that the majority of patients were in stage 3 (57%) and stage 4A (28%).[11] These patients primarily had head and neck tumours (specifically hypopharynx and nasopharynx) and gastrointestinal (GIT) tumours (including rectum and oesophagus). Recent data from the Cancer Registry of Pakistan indicated that head and neck cancers rank among the top five most common cancers across all age groups and both genders. Pakistan faces a significant public health challenge due to the high mortality rates associated with head and neck cancers.[12,13] In the present study, 65 patients (46%) were treated for head and neck cancer, making it the most frequently treated site with RT at the authors' institute, followed by gastrointestinal tract (GIT) and pelvic malignancies. These findings underscore the urgent need for targeted public health interventions, particularly in enhancing treatment facilities and services to better address the specific needs of cancer patients.

IMRT, which works on the principle of pixel-by-pixel intensity modulation of the emitted radiation, allows for precise dose distribution and enhances the therapeutic ratio.[14,15] The transition from conventional two-dimensional (2D) treatment planning to IMRT has significantly benefited the treatment of head and neck cancers.[16] Head and neck tumours are located close to important organs, so it is essential to carefully map these organs along with the tumour to define the exact tumour boundaries and calculate radiation doses accurately, considering the complex shapes and structures in the area.[17] Helical tomotherapy, in particular, offers more precise and conformal radiation doses, minimising exposure to surrounding healthy tissues compared to standard IMRT. A retrospective analysis of 147 patients with early and locoregionally advanced squamous cell head and neck cancer (SCCHN) treated with helical tomotherapy (HT) reported a 3-year locoregional failure (LRF) and distant metastasis (DM) rate of 25% and 13%, respectively.[18] In contrast, this study observed a local recurrence rate of 4.3% and a distant metastasis rate of 16% across all cancer patients treated, suggesting that helical tomotherapy may offer improved control over these critical outcomes.

Concurrent chemoradiotherapy is a standard treatment for many types of tumours.[19] This study highlights the high percentage of patients receiving concurrent chemoradiotherapy (83%), with a notable exception in cases of early glottis tumours. This differentiation is likely due to the generally better prognosis and less aggressive nature of early glottis tumours, which might not require the additional chemotherapy component. This approach has led to a complete response in 80% of these cases.[20]

Computed tomography (CT) plays a major role in the assessment of tumour response. Tumour is principally assessed by the RECIST criteria.[21] In this cohort, nearly half of the patients (50%) achieved a complete response, indicating a significant reduction or disappearance of the tumour. The varying responses to treatment help in predicting the outcomes and adjusting personalised therapeutic approaches for better efficacy.

Another region in which IMRT has been used as a therapeutic option is the pelvis. This study included patients with cervical and prostate cancers, out of which, all 10 prostate cancer patients achieved a nadir PSA of <0.2 ng/ml three months after the definitive radiation. This improvement correlates with the available scientific literature. A study in China conducted on advanced prostate cancer patients, depicted a complete response in 21 out of 67 patients, partial response in 37 out of 67 patients and stable disease in 9 out of 67 patients, post-IMRT.[22] Similarly, close to 50% of the cervical cancer patients in a Chinese study achieved a complete response to IMRT.

The majority of patients (77%) treated with definitive radiotherapy on helical tomotherapy were alive at the time of evaluation, indicating a generally favourable survival rate for this treatment modality. Among the 31 patients who died, head and neck cancer accounted for the largest proportion of deaths. The prevalence of stage three and four cancers in these patients suggests that advanced disease at presentation is a significant factor contributing to mortality.

Locoregional recurrence is a critical factor that negatively impacts both the long-term survival and quality of life of the cancer patients. A retrospective analysis over ten years highlights the safety and efficacy of helical tomotherapy in treating prostate cancer, demonstrating favourable acute and late toxicity profiles along with encouraging disease control outcomes.[23] Complementing these findings, another study on locally advanced rectal cancer treated with neo-adjuvant chemotherapy and helical tomotherapy under daily image guidance reported impressive 4-year local control rates post-surgery.[24] In the present study, a local recurrence was observed at a rate of less than 5%, with distant recurrences primarily occurring in patients who did not respond to the treatment. These findings draw attention to the role of definitive radiotherapy with helical tomotherapy in achieving robust local control, thereby reinforcing its significance in the management of cancer to minimise recurrence rates and enhance patient outcomes.

This study meticulously analysed various outcomes, including survival rates, recurrence patterns, and treatment efficacy, providing a thorough understanding of the effectiveness of this advanced radiotherapy technique. All cases were discussed in site-specific tumour board meetings to ensure a multidisciplinary approach to treatment planning, and peer-review meetings were conducted to validate and optimise the proposed treatment plans.[25] However, the follow-up period for this study was relatively limited, which may have influenced the ability to capture long-term outcomes, such as late recurrences or delayed treatment-related toxicities, which are crucial for a complete assessment of treatment efficacy. Moreover, as a single-centre study, the findings may not be fully applicable to other settings. Multi-centre studies are typically more representative of broader patient populations and diverse clinical practices, which would enhance the generalisability of the results.

CONCLUSION

The study demonstrates that helical tomotherapy is an effective treatment modality for achieving disease control and favourable survival outcomes, with patients undergoing the definitive radiotherapy showing a promising survival rate of 77%. Thoughtful patient selection can significantly reduce the machine burden and waiting time in resource-limited settings. The findings highlight the feasibility of utilising advanced radiotherapy technologies in LMIC, where the use of cost-effective services for definitive and curative treatments can improve patient care. Future studies incorporating comprehensive dosimetric evaluations and statistical stratification based on cancer site, stage, and histopathology are essential to better understand variations in treatment response.

ETHICAL APPROVAL:

Ethical approval was obtained prior to data collection from the Institutional Review Board of Jinnah Postgraduate Medical Centre (JPMC) with approval number F2-81/2024-GENL/274/JPMC.

PATIENTS' CONSENT:

Informed consent was obtained from all patients or the patients' families.

COMPETING INTEREST:

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:

FS: Contributed to the design of the work and was involved in the acquisition and analysis of data.
YA: Design of the work and the interpretation of data.
RT: Acquiring data and drafting of the manuscript.
TM: Design of the work and critical revision of the manuscript for the important intellectual content.
All authors approved the final version of the manuscript to be published.

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