Comparative Analysis of DysphagiaOptimized IMRT vs Standard IMRT in Oral Cavity Cancer Treatment: A Single - Center Study

Ramyavardhani Mamidala[1], Prathipati Navyasri[2], Kotlapati Sudhakar[3], Jyothi Jonnadula[4], Prattipati Srinivas[5], Thota Ajay[6]

[1]Kamineni Academy of Medical Sciences and Research Centre, Hyderabad, Telangana, India – 500068
Email: *ramyavardhani08[at]gmail.com*

[2]Kamineni Academy of Medical Sciences and Research Centre, Hyderabad, Telangana, India – 500068
Email: *dr.navya1818[at]gmail.com*

[3]Kamineni Academy of Medical Sciences and Research Centre, Hyderabad, Telangana, India – 500068
Email: *suda97321[at]gmail.com*

[4]Kamineni Academy of Medical Sciences and Research Centre, Hyderabad, Telangana, India – 500068
Email: *drjyothi. oncologist[at]gmail.com*

[5]Kamineni Academy of Medical Sciences and Research Centre, Hyderabad, Telangana, India – 500068
Email: *samsrinivas93[at]gmail.com*

[6]Kamineni Academy of Medical Sciences and Research Centre, Hyderabad, Telangana, India – 500068
Email: *thota. ajay1[at]gmail.com*

Abstract: <u>*Objective*</u>*: This study investigates the efficacy of Dysphagia Optimized Intensity Modulated Radiotherapy (Do - IMRT) compared to Standard Intensity Modulated Radiotherapy (S - IMRT) in managing dysphagia and overall treatment efficacy among patients with oral cavity cancers treated at the Department of Radiation Oncology, Kamineni Academy of Medical Sciences and Research Centre, Hyderabad.* <u>*Methods:*</u> *We enrolled 300 patients diagnosed with oral cavity cancers from July 2022 to July 2024, randomly assigning them to either the Do - IMRT group (n=150) or the S - IMRT group (n=150). Dysphagia severity was assessed using the Dysphagia Severity Rating Scale (DSRS) at baseline, during treatment, and at a 6 - month follow - up. Treatment outcomes, including overall survival rates and treatment - related toxicities, were analyzed.* <u>*Results:*</u> *Patients treated with Do - IMRT demonstrated significantly reduced dysphagia, as evidenced by lower DSRS scores during treatment and at 6 months post - treatment (p < 0.01) compared to the S - IMRT group. Overall survival rates were similar (DoIMRT: 78%, S - IMRT: 75%). Treatment - related toxicities were reduced in the Do - IMRT group (15% vs.30%, p < 0.05), indicating better tolerability.* <u>*Conclusion:*</u> *Do - IMRT significantly improves dysphagia outcomes without compromising overall survival in patients with oral cavity cancers. This approach offers potential as a superior treatment strategy for dysphagia management in this population.*

Keywords: Dysphagia, Optimized Intensity Modulated Radiotherapy (Do - IMRT), Standard Intensity Modulated Radiotherapy (S - IMRT), Oral Cavity Cancer, Single - Center Study

1. Introduction

Oral cavity cancers, which involve regions such as the lips, tongue, gums, floor of the mouth, and inner cheeks, are among the most common malignancies affecting the head and neck. These cancers can severely impact fundamental functions like speaking, eating, and swallowing, with dysphagia—difficulty swallowing—being a particularly debilitating complication. Dysphagia not only reduces the ability to consume food and liquids but also significantly impairs overall quality of life, leading to malnutrition, weight loss, and an increased risk of aspiration pneumonia (Lang et al., 2018). Managing this condition, while still effectively treating the cancer, presents a complex challenge for clinicians.

Radiotherapy has been a cornerstone in the management of oral cavity cancers, especially for locally advanced cases where surgery might not be sufficient. The advent of Intensity Modulated Radiotherapy (IMRT) revolutionized cancer treatment by allowing for high - precision targeting of cancerous tissues. IMRT adjusts radiation doses to focus on the tumor while sparing the surrounding healthy tissues, which is crucial in a region as functionally critical as the oral cavity (Bhide et al., 2013). Standard IMRT (S - IMRT) has proven to be effective in improving local tumor control and survival rates. However, despite these advancements, S - IMRT does not always offer adequate protection to the delicate swallowing structures such as the pharynx, larynx, and esophagus. As a result, many patients still experience significant post - treatment dysphagia, which can lead to long - term difficulties and complications.

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Recognizing this issue, Dysphagia Optimized IMRT (Do - IMRT) was introduced as a more refined approach to radiation therapy. The key innovation in Do - IMRT lies in its focus on reducing radiation exposure to specific structures involved in swallowing, including the base of the tongue, the pharyngeal constrictor muscles, and the larynx, without compromising the tumor's radiation dose (Wang et al., 2015). By prioritizing the protection of these critical areas, Do - IMRT seeks to preserve the patient's ability to swallow post - treatment, thereby enhancing their overall recovery and quality of life.

This study aims to assess the effectiveness of DoIMRT compared to S - IMRT in a clinical setting, specifically focusing on patients with oral cavity cancers. Conducted at the Kamineni Academy of Medical Sciences and Research Centre in Hyderabad, the study involves a comprehensive analysis of 300 patients treated with either Do - IMRT or S - IMRT. The primary goal is to determine whether the adoption of Do - IMRT leads to a significant reduction in dysphagia rates, and whether it provides better long - term functional outcomes for patients. Additionally, the study examines secondary outcomes such as tumor control, treatment - related toxicities, and overall survival rates, providing a holistic evaluation of the benefits and limitations of each radiotherapy approach.

By comparing these two advanced radiotherapy techniques, this study hopes to contribute valuable insights into optimizing cancer treatment strategies for oral cavity cancers, balancing the need for effective tumor control with the preservation of critical functions like swallowing. The findings could potentially influence future clinical practices, leading to improved treatment protocols and better patient quality of life.

2. Literature Survey

The management of dysphagia in oral cavity cancer patients has long been a challenge in radiation oncology due to the delicate balance between effective tumor control and preservation of swallowing function. Traditional radiotherapy methods, including conventional Intensity Modulated Radiotherapy (IMRT), have been instrumental in improving tumor targeting while reducing damage to surrounding tissues (Bhide et al., 2013). However, these approaches often fall short in mitigating dysphagia, which remains a significant complication affecting patient quality of life (Lang et al., 2018).

Recent advancements in radiotherapy have introduced Dysphagia Optimized IMRT (Do - IMRT), which aims to further minimize radiation exposure to critical swallowing structures such as the larynx and pharyngeal constrictors (Wang et al., 2015). Studies have shown that Do - IMRT can significantly reduce dysphagia severity and improve functional outcomes compared to Standard IMRT (S - IMRT) without compromising overall survival or disease control (Lee et al., 2013). These findings highlight the potential of Do - IMRT to enhance patient care by addressing the limitations of conventional techniques and providing a more refined approach to managing dysphagia in oral cavity cancers.

3. Methodology

3.1 Study Design

This single - center, prospective, randomized study was conducted at the Department of Radiation Oncology, Kamineni Academy of Medical Sciences and Research Centre, Hyderabad. The objective was to compare Dysphagia Optimized Intensity Modulated Radiotherapy (Do - IMRT) and Standard Intensity Modulated Radiotherapy (S - IMRT) in patients with oral cavity cancers. The study included patients randomized into two groups and followed through their treatment and follow - up periods.

3.2 Study Population:

3.2.1 Inclusion Criteria:
- Histologically confirmed oral cavity cancer
- Clinical stages I - IV
- Performance status of 0 - 2 (ECOG scale)
- Informed consent provided

3.2.2 Exclusion Criteria:
- Prior radiation therapy to the head and neck region
- Concurrent malignancies
- Significant comorbidities that could interfere with treatment or follow - up

3.2.3 Sample Size:
- Total of 300 patients
- Randomized into Do - IMRT (n=150) and SIMRT (n=150) groups
- Sample size calculated to detect meaningful differences in dysphagia outcomes with 80% power and a significance level of 0.05

3.3 Randomization and Group Assignment:

- Patients were randomly assigned to DoIMRT or S - IMRT groups using a computer- generated randomization list
- Randomization performed by an independent statistician to ensure unbiased allocation

3.4 Radiotherapy Protocols:

Dysphagia Optimized IMRT (Do - IMRT):
a) Planning: Utilized advanced planning algorithms to minimize dose to critical swallowing structures such as the larynx, pharyngeal constrictors, and esophagus
b) Treatment Planning System: Eclipse™ (Varian Medical Systems)
c) Delivery: Linear accelerator with IMRT capabilities; treatment plans designed to minimize exposure to dysphagia - related structures

Standard IMRT (S - IMRT):
a) Planning: Applied conventional IMRT techniques with standard optimization parameters
b) Treatment Planning System: Eclipse™ (Varian Medical Systems)

Delivery: Standard IMRT delivery methods, focusing on tumor control with less emphasis on sparing

swallowing structures

3.5 Assessment of Dysphagia Evaluation Tools:

- Dysphagia Severity Rating Scale (DSRS) Time Points for Assessment:
- Baseline - Prior to radiotherapy
- During Treatment - Weeks 3 and 5
- Post - Treatment - 6 - month follow - up
- Scoring - DSRS ranges from 1 (normal swallowing) to
- 7 (unable to swallow)

3.6 Evaluation of Survival and Toxicities:

- Overall Survival and Progression - Free Survival:
- Data Collection - Medical records and follow - up visits Overall Survival (OS) - Time from diagnosis to death from any cause
- Progression - Free Survival (PFS) - Time from diagnosis to disease progression or recurrence Treatment - Related Toxicities -
- Grading System: Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 Assessment Time Points - Baseline, during treatment, and follow - up
- Key Toxicities - Mucositis, dermatitis, and swallowing - related pain

3.7 Statistical Analysis:

Descriptive Statistics:

- Summary of continuous variables using means, standard deviations, medians, and ranges Categorical variables summarized using frequencies and percentages

Comparative Statistics:

- Continuous Variables: Independent t - tests
- Categorical Variables: Chi - square tests
- Significance Level: p - value < 0.05

Survival Analysis:

- Overall Survival and Progression - Free Survival:
- Kaplan - Meier method
- Group Comparisons: Log - rank test

Toxicity Analysis:

- Incidence Comparison: Chi - square tests

3.8 Ethical Considerations:

- Ethical Approval - Institutional review board approval obtained
- Informed Consent - Written informed consent was acquired from all participants before enrolment in the study

4. Results & Discussion

This study demonstrated that Dysphagia Optimized IMRT (Do - IMRT) significantly reduces dysphagia severity compared to Standard IMRT (S - IMRT) in patients with oral cavity cancers, with lower DSRS scores during treatment and at the 6 - month follow - up. These findings are consistent with previous studies on the optimization of radiation

techniques to spare swallowing - related structures, which have shown improved functional outcomes. The comparable overall survival and progression - free survival rates suggest that optimizing IMRT for dysphagia does not compromise the efficacy of tumor control.

Importantly, treatment - related toxicities, including Grade 3 or higher mucositis and dermatitis, were significantly lower in the Do - IMRT group, leading to improved patient quality of life during and after treatment. Recent studies have also emphasized the role of precise radiation targeting in reducing radiation - induced side effects. Lee et al. (2013) reported that optimized dose - volume parameters can significantly impact dysphagia outcomes postradiotherapy. Similarly, a systematic review by Nutting et al. (2011) indicated that advancements in IMRT planning can lead to improved patient quality of life, particularly in head and neck cancers. Moreover, McMahon et al. (2014) highlighted the multidisciplinary approach necessary for the effective management of dysphagia in cancer patients, reinforcing the importance of minimizing treatmentrelated toxicity while preserving critical functions.

The single - center design limits the generalizability of the findings. Additionally, longer follow - up is required to assess long - term dysphagia outcomes and tumor control.

Table 1: Patient Demographics and Clinical Characteristics

Demographic Variable	Do - IMRT (n=150)	S - IMRT (n=150)	p - value
Mean Age (years)	62 (45 - 80)	61 (46 - 79)	0.45
Gender (Male)	2: 1	2: 1	-
Stage II (%)	40	42	0.32
Stage III (%)	35	34	0.85
Stage IV (%)	25	24	0.78

Table 2: Dysphagia Outcomes

Time Point	Do - IMRT DSRS (mean)	S - IMRT DSRS (mean)	p – value
Baseline	2.1	2.3	0.34
During Treatment (W3)	3.2	5.6	<0.01
During Treatment (W5)	3.6	5.9	<0.01
6 - month follow - up	2.5	4.0	<0.01

Table 3: Overall Survival and Progression – Free Survival

Survival Metric	Do - IMRT (%)	S - IMRT (%)	p - value
2 – year Overall Survival	78	75	0.65
2- year Progression - Free	65	60	0.58

Table 4: Treatment - Related Toxicities

Toxicity Grade	Do - IMRT (%)	S - IMRT (%)	p - value
Grade 1	20	25	0.23
Grade 2	25	25	1.00
Grade 3 or higher	15	30	0.02

5. Conclusion

Dysphagia Optimized Intensity Modulated Radiotherapy (Do - IMRT) provides a notable benefit for patients with oral cavity cancers. Specifically, it helps in significantly reducing the severity of swallowing difficulties, known as dysphagia, which is a common and troubling side effect of cancer

treatment. Additionally, Do - IMRT results in fewer treatment - related side effects, making the overall experience of undergoing radiotherapy less harsh for patients.

Despite these improvements in managing side effects, Do - IMRT does not negatively impact the chances of surviving cancer. The survival rates for patients receiving Do - IMRT are similar to those receiving Standard IMRT (S - IMRT), meaning that this advanced technique does not reduce the effectiveness of the treatment in controlling the cancer.

Given these benefits, Do - IMRT is an advantageous choice for treating oral cavity cancers. It not only helps patients swallow more comfortably but also reduces the discomfort and complications often associated with radiation therapy. This makes Do - IMRT a preferred option for improving the quality of life for patients undergoing treatment for oral cavity cancers.

6. Future Scope

The findings of this single - center study on Dysphagia Optimized Intensity Modulated Radiotherapy (DoIMRT) versus Standard Intensity Modulated Radiotherapy (S - IMRT) in oral cavity cancers pave the way for several important avenues of future research. Expanding this study to a multi - center trial could enhance the generalizability of the results across diverse patient populations and treatment settings. Long - term follow - up studies are also needed to assess the durability of dysphagia improvements and overall quality of life post - treatment. Additionally, investigating the cost - effectiveness of Do - IMRT compared to S - IMRT will be crucial for integrating this approach into standard clinical practice. Further research could explore the optimization of Do - IMRT protocols to balance efficacy and toxicity while personalizing treatment plans based on individual patient characteristics. Ultimately, these efforts could lead to more refined radiotherapy strategies, improved patient outcomes, and advancements in the management of oral cavity cancers.

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