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Intensity Modulated Radiation Therapy Alone Vs Intensity Modulated Radiation Therapy and Brachytherapy for T1-T2N0M0 Oropharyngeal Cancers: Results from A Randomized Controlled Trial

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Published: 1 September 2023

DOI: https://doi.org/10.1016/j.ijrobp.2023.08.056

Abstract

Purpose

To compare clinical outcomes of intensity modulated radiation therapy (IMRT) alone vs IMRT+ brachytherapy (BT) in patients with T1-T2N0M0 oropharyngeal squamous cell cancers (OPSCC).

Methods and Materials

This open-label randomized controlled trial was conducted at Tata Memorial Hospital, Mumbai, India. Patients with stage I and II OPSCC were considered for IMRT to a dose of 50Gy/25#/5 weeks in phase I followed by randomization (1:1) to further treatment with IMRT (20Gy/10#/2 weeks) or BT (¹⁹²Ir high dose rate - 21Gy/7fractions/2 fractions per day). The primary endpoint of the trial was the reduction in xerostomia at 6 months evaluated using ^{99m}Tc salivary scintigraphy. Severe salivary toxicity (xerostomia) was defined as post-treatment salivary excretion fraction ratio <45%. Secondary endpoints were local control (LC), disease free survival (DFS) and overall survival (OS).

Results

Between November 2010 to February 2020, 90 patients were randomized to IMRT(N=46) alone or IMRT+BT(N=44). Eleven patients (8 residual/recurrent disease, 2 lost to follow up, 1 second primary) in the IMRT arm and 9 patients (8 residual/recurrence, 1 lost to follow up) in the BT arm were not evaluable at 6 months for the primary endpoint. At 6 months, xerostomia rates using salivary scintigraphy were 14% (5/35: 95% CI 5%-30%) in the BT arm while it was seen in 44% (14/32: 95%CI 26%-62%) in the IMRT arm (p=0.008). Physician rated RTOG grade ≥ 2 xerostomia at any time point was observed in 30% (9/30) patients in the IMRT arm and 6.7% (2/30) in the BT arm (p=0.02). At a median follow-up of 42.5 months, the 3-year LC in the IMRT arm was 56.4% (95% CI-43%-73%) while it was 66.2% (95% CI: 53%-82%) in the BT arm (P=0.24)

Conclusion

The addition of BT to IMRT for T1-T2N0M0 OPSCC results in a significant reduction in xerostomia. This strongly supports the addition of BT to IMRT in suitable cases.