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Quality of life after primary TORS vs IMRT for patients with early-stage oropharyngeal squamous cell carcinoma (QoLATI/DAHANCA34): A multicentre, open-label, randomised phase 2 trial

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Background

Evidence comparing transoral robotic surgery (TORS) and (chemo)radiotherapy ((C-)RT) for early-stage oropharyngeal squamous cell carcinoma (OPSCC) remains limited. We aimed to compare swallowing-related quality of life (QoL), objective swallowing outcomes, and late toxicity.

Methods

QoLATI/DAHANCA34 was a national, multicentre, open-label, parallel-group, randomised phase 2 trial conducted at five Danish hospitals. Patients with T1–2, N0–1, M0 OPSCC were randomly assigned (2:1) to TORS-based treatment incorporating staging neck dissection or (C-)RT. The primary endpoint was swallowing-related QoL at 12 months assessed with MD Anderson Dysphagia Inventory (MDADI). Secondary endpoints included modified barium swallow study and fiberoptic endoscopic evaluation of swallowing, late toxicity, feeding tube dependency, and survival and disease control. Analyses followed a modified intention-to-treat principle. This trial was registered: NCT04124198.

Results

Between February 25, 2019, and November 19, 2024, 138 patients were randomly assigned to the TORS group or (C-)RT group. 136 were included in the primary analysis (92 TORS; 44 (C-)RT). Seventy-three (79%) patients were treated with TORS alone, four (4%) received TORS with adjuvant (C-)RT and 15 (16%) were redirected to (C-)RT after staging neck dissection. At 12 months, the adjusted difference in change from baseline MDADI score between groups was 5.1 points (95% CI 0.3–9.9; $p=0.04$), favouring TORS. Objective swallowing, late toxicity, survival, and disease control outcomes did not differ between groups. Motor nerve impairment after neck dissection was present in 9 (10%) patients.

Conclusions

TORS-based treatment was associated with better swallowing-related QoL, although the difference did not reach the prespecified threshold for clinical relevance. Objective swallowing outcomes, survival, and disease control were comparable between groups. These findings support both treatments as options for selected patients, guided by patient preferences.

Legal entity responsible for the study

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Disclosure

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