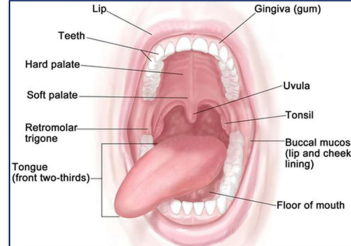


BACKGROUND

- Oral cavity cancer (OCC) includes malignancies affecting various regions within the mouth (Fig. 1).
- OCC ranks as the 13th most common cancer globally^{1,2} and represents approximately 2% of newly diagnosed cancer cases in the United States (US).
- Initial treatment options for non-metastatic OCC include surgical resection - either alone or with adjuvant therapy - as well as definitive radiotherapy.³
- Overall, 5-year relative survival following initial treatment is 70%, but there is substantial sub-group heterogeneity.

Figure 1: Anatomy of the oral cavity



Source: Winslow, T. (2012). Anatomy of the Oral Cavity [Illustration]. Terese Winslow LLC. U.S. Government holds certain rights.

OBJECTIVE

- To characterize the unmet clinical need, cost drivers, and barriers to access in the treatment pathway for non-metastatic OCC in the US in an early health technology assessment (eHTA), to identify potential high-value opportunities for innovative therapeutic modalities.⁴

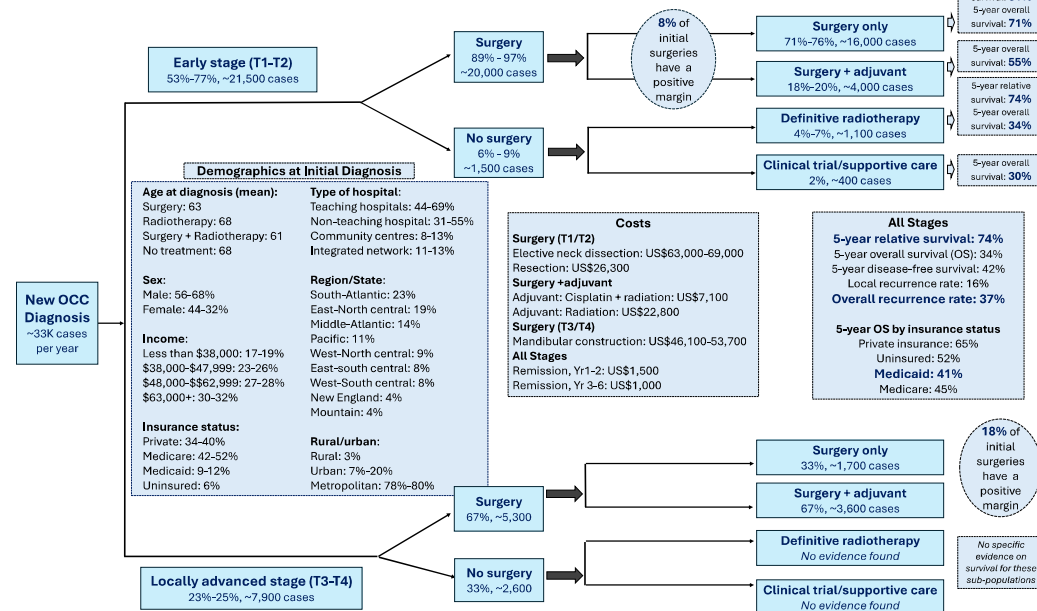
METHODS

- A structured search was conducted in the OVID Medline database on September 6, 2024, using a set of key words related to the epidemiology, health outcomes, costs, and reimbursement trends for OCC.
- Studies using non-US data and published before 2015 were excluded during title, abstract, and full text review.
- Citation mining was used to identify additional studies/ key data elements were missing following preliminary data extraction.
- A data extraction template based on eHTA value frameworks⁴ was developed following a pilot data extraction, with a focus on therapeutic options for localized (stages I-II, T1-T2) and locally advanced (stages III-IVa, T3-T4) OCC.
- The full data extraction was conducted by one primary reviewer (TA) and checked by a secondary reviewer (ND).
- Results were mapped to a clinical diagram adapted from the NCCN's treatment guidelines for Head and Neck Cancer³ (Fig. 2).

RESULTS

- 344 articles were identified in the search, and 21 were selected for full data extraction (n=21).
- Of the extracted studies, 10 were published between 2015 and 2019, and 11 from 2020 to 2024. Four were economic evaluations (19%), and 15 were retrospective cohort studies (71%).
- Most OCC cases are diagnosed at early stages (T1-T2, 53%-77%),⁵⁻⁷ and most patients undergo surgery as the initial treatment (89%-97%), either as a stand-alone procedure (71%-76%) or in combination with adjuvant therapy (18%-20%), with only a small proportion receiving definitive radiotherapy, clinical trials or supportive care (6%-9%).⁸⁻⁹
- The five-year overall survival (OS) rate was 71% for surgery alone and 55% for surgery with adjuvant therapy.⁸⁻⁹
- Non-surgical patients had lower survival rates: definitive radiotherapy (34%) and clinical trial/supportive care (30%).⁸⁻⁹

Figure 2: Care pathway landscape for incident OCC cases in the United States*



* Adapted from the National Comprehensive Cancer Network's treatment guidelines for Head and Neck Cancer. 3

- Although 5-year OS for T1/T2 patients who did not undergo surgery is significantly lower compared to those who had surgery, the relative survival remains similar (81% vs. 74%),⁸ likely due to the higher average age at diagnosis in the 'no surgery' group (68 years) vs. the surgery groups (63 and 61).¹⁰
- The biggest unmet need in the surgery + adjuvant therapy group; (i.e., substantial case count (4,000), and only 55% OS).⁸⁻¹⁰ These patients are likely those with positive margins and other adverse pathologic features.
- Patients with private insurance were more likely to receive necessary surgical treatment compared to those individuals with Medicaid or no insurance¹¹ and had better five-year OS. Younger patients were more likely to undergo surgery..^{8,10}

CONCLUSION

- Current evidence indicates a significant unmet need in the treatment of OCC in the US, especially in the surgery and adjuvant therapy group, highlighting opportunities for more effective therapeutic options.
- The disparity in outcomes based on insurance highlights the need for cost-effective therapies, which would facilitate access.

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