

# INPLASY PROTOCOL

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None declared.

## A meta-analysis of the detection rate of mouth opening difficulty in patients with oral cancer

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**Review question / Objective:** P:Patients with oral cancer with limited mouth opening were clearly diagnosed, MIO $\leq$ 35 mm O:Detection rate of mouth opening restriction in patients with oral cancer S:Observational studies (including prospective, retrospective, and cross-sectional studies).

**Condition being studied:** Oral Cavity Cancer (OCC) is the sixth most common malignancy in the world, with a high incidence rate, and is increasingly becoming a global public health concern. Difficulty in opening the mouth is one of the common complications in the treatment of advanced oral cancer, but it can also occur before treatment. Mouth opening difficulties may be self-limiting and improve over time, but in many patients some level of mouth opening limitation is progressive development and may even cause permanent injury. Moderate to severe mouth opening restriction reduces speech clarity and impairs eating or chewing function (or even dysphagia), seriously affecting the patient's health and quality of life.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 June 2022 and was last updated on 15 June 2022 (registration number INPLASY202260064).

### INTRODUCTION

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one of the common complications in the treatment of advanced oral cancer, but it can also occur before treatment. Mouth opening difficulties may be self-limiting and improve over time, but in many patients some level of mouth opening limitation is progressive development and may even cause permanent injury. Moderate to severe mouth opening restriction reduces speech clarity and impairs eating or chewing function (or even dysphagia), seriously affecting the patient's health and quality of life.

## METHODS

**Participant or population:** Patients with oral cancer with limited mouth opening ( $MIO \leq 35$  mm).

**Intervention:** None.

**Comparator:** None.

**Study designs to be included:** Observational studies (including prospective, retrospective, and cross-sectional studies).

**Eligibility criteria:** Inclusion criteria: ① Observational study of mouth opening limitation in patients with the study type of oral cancer (including prospective, retrospective, and cross-sectional studies) ② The subjects were patients with oral cancer with limited mouth opening (defined as adult  $MIO \leq 35$  mm) ③ The outcome measure was the detection rate of mouth opening restriction in oral cancer patients. Exclusion criteria: Exclusion criteria: ① non-Chinese and English literature; ② repeated published literature; ③ literature unable to extract data; ④ review; ⑤ excluded limited mouth opening caused by joints, inflammation, trauma and other factors.

**Information sources:** China Knowledge Network (CNKI), Web Network (VIP), Wanfang Data Knowledge Service Platform (WanFang Data), China Biomedical Literature Database (CBM), PubMed, Ovid /

Medline, EMBase, The Cochrane Library, Web of Science / Scisearch and Registers of clinical trials.

**Main outcome(s):** Meta-analysis showed that the overall rate of mouth opening limitation detection in patients with oral cancer was 42.7% [95% CI (27.0%~59.1%)]. The results of subgroup analysis showed that the detection rate of mouth opening difficulty in patients with oral cancer at presentation, 3 months after surgery, 6 months after surgery and 1 year or more was 9.6% [95% CI (9.0%~55.8%)] , 75.2% [95% CI (68.3%~81.5%)] , 59.1% [95% CI (38.8%~77.9%)] , 22.3% [95% CI (2.0%~54.3%)] , respectively. The detection rate of mouth opening difficulty in patients with T1-T2 and T3-T4 oral cancer was 38.6% [95% CI (26.0%~52.0%)] , 99.6% [95% CI (93.9%~1.0%)] , respectively. The detection rate of mouth limitation in patients with molar, gingival, tongue, salivary gland, oral base and oral lip was 93.1% [95% CI (68.5%~1.0%)] , 68.1% [95% CI (52.9%~81.7%)] , 46.1% [95% CI (11.6%~82.7%)] , 26.1% [95% CI (15.9%~37.5%)] , 21.9% [95% CI (0.7%~54.0%)] , 3.1% [95% CI (0.0%~9.3%)] , respectively.

**Quality assessment / Risk of bias analysis:** The MINORS entries were used for the literature quality evaluation.

**Strategy of data synthesis:** Meta analysis was performed on the included literatures using stata15.0 software, and the effect analysis statistics were expressed by the combination rate and 95% confidence interval (CI). The heterogeneity of the research literature was tested by using  $\chi^2$  Inspection ( $\alpha = 0.05$ , in combination with  $I^2$  value), if  $I^2 < 50\%$ ,  $P > 0.1$ , it indicates that there is homogeneity among the studies, and the fixed effect model is selected for meta-analysis; If  $I^2 < 50\%$  and

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$P < 0.1$ , it indicates that there is heterogeneity between studies but within an acceptable range, and the fixed effect model is used for consolidation; If  $I^2 \geq 50\%$ ,  $P \leq 0.1$ , it is considered that there is great heterogeneity between studies, which needs to be analyzed by random effect model. Subgroup analysis can be used to explore the source of heterogeneity. Subgroup analysis can be carried out by taking different time, location and tumor stage as grouping factors. The stability of meta-analysis results was evaluated by sensitivity analysis. According to the funnel chart, combined with egger's and begg's tests, determine whether there is publication bias. The difference was statistically significant ( $P < 0.05$ ).The Meta-analysis of the included literature was performed using the stata15.0 software, and the effect analysis statistics were represented by the pooled rate and 95% confidence intervals (confidence interval, CI).

**Subgroup analysis:** Subgroup analysis was performed using time, site, and tumor stage as group factors.

**Sensitivity analysis:** Sensitivity analysis was performed by eliminating individual studies one by one.

**Country(ies) involved:** China (Chengdu University of Traditional Chinese Medicine).

**Keywords:** Oral neoplasms; Difficulty opening mouth; Prevalence; Meta-analysis.

**Contributions of each author:**

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Author 3 - Zhao Yan.

Author 4 - Chen Weihong.

Author 5 - Zhang Jinfeng.

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