SUMMARY

Background: About 10,000 persons are diagnosed as having carcinoma of the oral cavity or the throat in Germany every year. Squamous-cell carcinoma accounts for 95% of cases.

Methods: We systematically reviewed the pertinent literature on predefined key questions about these tumors (which were agreed upon by a consensus of the investigators), concerning imaging, the removal of cervical lymph nodes, and resection of the primary tumor.

Results: 246 clinical trials were selected for review on the basis of 3014 abstracts. There was only one randomized, controlled trial (evidence level 1–); the remaining trials reached evidence levels 2++ to 3. Patients with mucosal changes of an unclear nature persisting for more than two weeks should be examined by a specialist without delay. The diagnosis is made by computed tomography or magnetic resonance imaging along with biopsy and a standardized histopathological examination. Occult metastases are present in 20% to 40% of cases. Advanced disease (stages T3 and T4) should be treated by surgery followed by radiotherapy, with or without chemotherapy. 20% of the patients overall go on to have a recurrence, usually within 2 to 3 years of the initial treatment. The 5-year survival rate is somewhat above 50%. Depending on the radicality of surgery and radiotherapy, there may be functional deficits, osteoradionecrosis, and xerostomia. The rate of loss of implants in irradiated bone is about 10% in 3 years.

Conclusion: The interdisciplinary planning and implementation of treatment, based on the patient’s individual constellation of findings and personal wishes, are prerequisites for therapeutic success. Reconstructive measures, particularly microsurgical ones, have proven their usefulness and are an established component of surgical treatment.

Cite this as:
Composition of the guideline group (professional societies, institutions)

<table>
<thead>
<tr>
<th>Professional Societies, Institutions</th>
<th>Members</th>
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<tr>
<td>German Society for Oral, Maxillary, and Facial Surgery</td>
<td>Wolff K.-D., Grötz K., Reinert S., Pistner H.</td>
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<tr>
<td>German–Austrian–Swiss Working Group for Maxillary and Facial Tumors (DOSAK)</td>
<td>Freich, B.</td>
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<td>German Working Group on Maxillofacial Surgery</td>
<td>Reichert, T.</td>
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<td>German Society for Dental, Oral, and Maxillofacial Medicine</td>
<td>Schliephake, H.</td>
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<td>German Society for Oto-Rhino-Laryngology, Head and Neck Surgery</td>
<td>Bootz F., Westhofen M.</td>
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<td>German Medical Association</td>
<td>Boehme, P.</td>
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<td>National Association of Statutory Health Insurance Physicians</td>
<td>Beck, J.</td>
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<tr>
<td>German Society of Pathology</td>
<td>Burkhardt A., Ihrler S.</td>
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<tr>
<td>German Society of Radiooncology</td>
<td>Fietkau R., Budach W., Wittlinger M.</td>
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<tr>
<td>German Society of Hematology and Oncology</td>
<td>Keilholz U., Gauler T., Eberhardt W.</td>
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<tr>
<td>German Society of Plastic and Reconstructive Surgery</td>
<td>Horch R., Germann G.</td>
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<td>Head and Neck Working Group of the German Roentgen Society</td>
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<td>Conference of Nurses in Oncology (KOK) of the German Cancer Society</td>
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<tr>
<td>Oral and Facial Pain Working Group of the German Society for the Study of Pain (DGSS)</td>
<td>Schmitter M.</td>
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<tr>
<td>Supportive Oncology, Rehabilitation and Social Medicine (ASORS) Working Group of the German Cancer Society</td>
<td>Lübbe A.</td>
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<tr>
<td>Tumor Pain Working Group of the German Society for the Study of Pain (DGSS)</td>
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<td>Patients’ representative</td>
<td>Manley W.</td>
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<tr>
<td>German Association for Social Work in the Healthcare System, German National Center for Tumor Diseases</td>
<td>Bikowski K.</td>
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<tr>
<td>German Federal Speech Therapy Association</td>
<td>Nusser-Müller-Busch R.</td>
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<tr>
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<td>Singer S., Danker H.</td>
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Despite repeated campaigns to raise the profile of oral cavity cancer, public awareness is low and there are diverging opinions regarding the nature and extent of diagnosis, treatment, and follow-up care. It was therefore perceived necessary to formulate an evidence-based treatment recommendation in the form of an S3 guideline. This required close cooperation among medical and dental professional bodies. The target group primarily comprises doctors and dentists working in the prevention, diagnosis, treatment and follow-up of oral cavity cancer, together with allied professionals involved in outpatient and inpatient care. The guideline thus represents an important basis for interdisciplinary cooperation in patient management at head and neck tumor centers.

Methods

This first evidence-based guideline for oral cavity cancer was organized under the aegis of the German Guideline Program in Oncology of the German Cancer Society (DKG), German Cancer Aid (DKH), and the Association of Scientific Medical Societies in Germany (AWMF) (http://leitlinienprogramm-onkologie.de). The guideline group was composed of 33 representatives from 21 professional societies and organizations (Table 1). Under the overall leadership of the German Society for Oral, Maxillary, and Facial Surgery, the group members started by defining 37 aspects of the diagnosis, treatment, and follow-up of oral cavity cancer that required clarification. With the support of the Division of Evidence-based Medicine at the Charité in Berlin, the group conducted a systematic de novo literature review on five key questions related to imaging, neck dissection, and resection of the primary tumor. The evidence level of the publications was established. Following a systematic search for international guidelines and evaluation of the methods of potentially relevant guidelines by means of the Appraisal of Guidelines for Research and Evaluation (AGREE) tool, the SIGN-90 guideline (Scottish Intercollegiate Guidelines Network, www.sign.ac.uk) was chosen as source of established evidence for use in guideline adaptation.

The primary systematic de novo research into the five defined key questions was carried out in Medline and Embase, via the platform OvidSP, on 26 January 2011 (Figure 1). The 3014 relevant abstracts yielded 246 studies which were eventually narrowed down to 117 publications relevant for further analysis (Figure 2). Each was assigned a level of evidence (LoE) ranging from 1++ (high-quality meta-analysis) to 4 (expert opinion) according to the SIGN classification (Table 2). Investigation of previously published meta-analyses yielded two that were relevant to the key questions. The methodology of the literature review and search strategy is described in detail in the guideline report at http://leitlinienprogramm-onkologie.de/Leitlinien.7.0.html (in German). At a concluding consensus conference, the nominal group technique was employed to produce answers to the key questions on the basis of the research, and recommendations, divided into three
categories (Table 3), were formulated. Finally, to support the implementation and documentation of the guideline’s effects on patient care, 10 quality indicators were derived from the strong guideline recommendations, defined, and agreed according to the standardized methods of the German Guideline Program in Oncology (http://leitlinienprogramm-onkologie.de/uploads/media/G-I-N2012_Updating_QI_GGPO.pdf). These quality indicators can be generated from clinical cancer registry data and will form a central component of the survey forms of the head and neck tumor module at oncology centers.

The evidence level of the 246 relevant studies was predominantly graded 2++ to 3. One prospective randomized controlled trial received a grade of 1–. A systematic search for existing meta-analyses and systematic reviews in Medline and Embase identified two meta-analyses, which were then also included.

In agreement with all of the professional societies, 76 statements and recommendations were formulated. Some of the most important of these will now be discussed. Statements (evidence-based, but without explicit treatment recommendations) are identified by the abbreviation “St”.

**Results**

**Diagnosis**

All patients with mucosal lesions of unknown origin and more than 2 weeks’ duration (Figures 3 and 4) should immediately be referred to a specialist (LoE good clinical practice [GCP]). This includes:

- White or red spots anywhere on the oral mucosa
- A mucosal defect or ulceration
- Swelling anywhere in the oral cavity
- Loosening of one or more teeth for no known reason, not connected with periodontal disease
- Persistent foreign body sensation, particularly when unilateral
- Pain
- Difficulty or pain in swallowing
- Speech difficulties
- Reduced mobility of the tongue
- Numbness of the tongue, teeth, or lips
- Bleeding of unknown origin
- Neck swelling
- Fétor
- Altered dental occlusion.

To exclude synchronous secondary tumors, patients undergoing primary diagnosis of oral cavity cancer should also be examined by an ear, nose, and throat (ENT) specialist and endoscopy should be considered (LoE GCP). The incidence of synchronous metastases is 4% to 33%, depending on the size of the primary tumor; they are particularly frequent in stages T3 and T4 and in patients with level IV lymph node involvement (6).

Computed tomography (CT) or magnetic resonance imaging (MRI) should be performed (LoE 3, recommendation level [RL] B) (7, e1, e2). A panoramic section is one of the basic tools in dental diagnosis and...
TABLE 2

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*www.sign.ac.uk/Guidelines/fulltext/50/annexb.html; RCT, randomized controlled trial

should be obtained before the commencement of specific tumor therapy (LoE GCP). Positron emission tomography (PET)-CT plays no part in the primary diagnosis of the local extension of a known oral cavity cancer (LoE 2+, St) (8, e3–e8). Patients with advanced oral cavity cancer (stage III, IV) should undergo CT of the thorax (LoE 3, RL A) to exclude pulmonary involvement (filia, metastasis) (9, 10, e9, e10). Patients with suspected tumor recurrence in the head and neck region in whom CT and/or MRI are inconclusive can proceed to PET-CT (LoE 3, RL 0) (11, 12, e11, e12).

According to the results of a meta-analysis, in diagnosing recurrence PET-CT possesses higher sensitivity (80%) than the combination of CT and/or MRI (75% and 79%) (11); the specificity (86%) is lowered by false-positive findings in inflammatory lesions. Fluorodeoxyglucose (FDG)-PET, however, was found to be more reliable than CT and/or MRI, with sensitivity of 100% and specificity of 61% to 71% (12). Previously undetected primary tumors and distant metastases can also be diagnosed more reliably with PET-CT than with CT or MRI (13).

Surgical treatment

The treatment of oral cavity cancer must be decided on a case-by-case basis by an interdisciplinary tumor board with representatives from oromaxillofacial surgery, ENT, radiotherapy, oncology, pathology, and radiology (LoE GCP). The patient’s individual circumstances should be taken into account. Before deciding to operate, the interdisciplinary team must consider whether tumor-free resection margins can be achieved and what postoperative quality of life can be expected for the patient (LoE 3, RL A) (14, 15, e13–e19).

In oral cavity cancers adjudged to be curatively resectable, surgery—in combination with immediate reconstruction if required—should be performed whenever the patient’s general condition permits. Patients with advanced tumors should receive postoperative treatment (LoE 3, RL B) (14, e20–e22). Reconstructive measures should be a standard part of surgery planning which should always take into account the overall oncological situation. The expected functional or esthetic improvement must justify the measures planned (LoE 3, RL A) (15, e23, e24). In considering reconstruction, it must be recalled that a distance of less than 1 mm between the histologically demonstrated tumor margin and the resection line counts as a positive margin of resection (16, 17); a distance of 1 to 3 mm between tumor and resection line is viewed as a narrow, 5 mm or more as a safe margin. The intraoperative frozen-section histology technique may help to avoid a positive resection margin, which is associated with a poorer prognosis (LoE GCP). The continuity of the lower jaw should be preserved, provided tumor invasion of bone is found neither on diagnostic imaging nor intraoperatively (LoE 3, RL B) (18, 19, e25–e28).

In 20% to 40% of cases of oral cavity cancer there is occult metastasis to the cervical lymph nodes. Levels I to III are almost always affected, level V very rarely (LoE 3, St) (20, e29–e43). All patients with clinically normal lymph-node status (cN0), regardless of their T category, should undergo elective neck dissection (LoE 3, RL A) (21, 22, e44–e52). In the case of clinical suspicion of lymph node involvement (cN+), the appropriate lymphadenectomy—usually modified radical neck dissection—should be carried out (LoE 3, RL A) (23, 24, e53–e59). The likelihood that an oral cavity cancer involving cervical lymph nodes of levels I to III will also affect level IV is generally stated as 7% to 17%, and the corresponding figure for level V is 0 to 6% (25, 26).

The histopathology report on the resected material should encompass tumor location, size, histological type, and stage; depth of invasion; invasion of lymph vessels, blood vessels, and perineural tissues; infiltration of local structures; R status; and pT classification (27). Postoperative treatment should be discussed in the interdisciplinary tumor conference.

Conservative treatment

Postoperative radiotherapy or radiochemotherapy is advisable in the case of advanced T category (T3/T4), narrow or positive resection margin, perineural...
invasion, vessel invasion, or lymph node involvement (LoE 1++, RL A) (28, 29, e60–e67). The total radiotherapy dose is generally divided into a number of individual doses, either conventionally fractionated (1.8–2.0 Gy daily, 5 days/week), accelerated (>10 Gy/week), or hyperfractionated (1.1–1.2 Gy twice daily).

In conventional fractionation the total dose of around 70 Gy is administered in daily doses of 1.8–2.0 Gy, 5 days per week. Possible modifications are hypofractionation, hyperfractionation, and accelerated fractionation. Hyperfractionation, preferentially employed in palliative treatment, involves individual doses much higher than the usual 1.8–2.0 Gy. Hyperfractionation entails administration of smaller doses but more of them; the total dose can be increased. One meta-analysis showed that hyperfractionation achieved not only better locoregional tumor control but also a 3.4% improvement in overall 5-year survival compared with conventional fractionation (30).

Postoperative radiotherapy should be started as soon as possible and completed by no more than 11 weeks after surgery (LoE 2++, RL B) (31, 32). Primary radiochemotherapy should be preferred to radiotherapy alone in patients with advanced, nonoperable, and non-metastized oral cavity cancer (LoE 1++, RL A) (33, 34). The relative survival advantage conferred by chemotherapy in addition to radiotherapy is particularly great in patients under 60 years of age (22% to 24%) and still appreciable in those between 60 and 70 (12%) (30, 33). Cisplatin is important in this regard: cisplatin alone and combinations including cisplatin show equal effect, but polychemotherapy without cisplatin leads to significantly poorer results (30, 33–35).

There are indications that intensity-modulated radiotherapy (IMRT) can reduce the frequency and severity of radiation-induced xerostomia (LoE 3, St) (36).

**Palliative treatment**

Although chemotherapy with palliative intent can achieve response rates of 10% to 35%, there is no evidence of prolongation of survival (37). For palliative radiotherapy, too, there are no evidence-based studies demonstrating efficacy in incurable head and neck cancers. Palliatively treated patients should be referred for professional supportive therapy at an early stage.

**Dental rehabilitation**

Patients who have received surgical treatment and/or radiotherapy for oral cavity carcinoma should be offered either an implant or a conventional prosthesis to restore their ability to chew, with regular dental follow-up thereafter. Any dental surgery should be performed by specialists well acquainted with this clinical picture (LoE 3, RL B) (38, e68–e72). Infected osteoradionecrosis may arise in the irradiated jaw, for example after dental extraction; the frequency of this complication has been given as 5% (38). Although advances in dental implantology have considerably expanded the prosthetic options, an implant loss rate of ca. 10% after 3 years has to be expected in irradiated bone (39).

**Follow-up**

Around a fifth of patients treated for oral cavity cancer experience a local recurrence of their tumor. The recurrence is diagnosed within 2 years in 76% of cases and in a further 11% during the 3rd year after completion of primary treatment (40). Even in symptom-free patients, the maximum interval between follow-up visits should be 3 months in the first 2 years and 6 months in years 3 to 5. A structured follow-up plan should be drawn up for each individual patient. Patients should be regularly interrogated about their quality of life. After 5 years’ follow-up they should attend routine tumor screening (LoE GCP). The primary goal of follow-up is therefore careful clinical and radiological (CT, MRI) examination of the oral cavity and neck to exclude newly
developing cancers. According to the results of a retrospective study, only 61% of such tumors are symptomatic; in other words, they go unnoticed by 39% of patients (40).

**Conclusion**

Treatment of oral cavity cancer is an interdisciplinary task for which an S3 guideline has now been issued. The complex diagnostic and therapeutic decision processes involved, together with the implementation of multimodal treatment plans, demand the skills and experience found only at tumor centers. Consistent adherence to the treatment recommendations laid out in the guideline will be crucial to its success. The implementation of the guideline and its effect on patient care can be assessed on the basis of 10 interdisciplinarily agreed indicators for the quality of diagnosis, treatment, and follow-up which will be measured and evaluated at the clinical cancer registries and certified centers.

The newly published clinical practice guideline for oral cavity cancer can be downloaded from the following websites (in German):

- www.awmf.org/leitlinien/aktuelleleitlinien.html
- www.leitlinienprogramm-onkologie.de/OL/leitli
  nien.html
- www.krebsgesellschaft.de/wub_lievidenzba
  siert,120884.html
- www.krebshilfe.de
- www.mkg-chirurgie.de

**Conflict of interest statement**

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Dr. Follmann is employed by the German Cancer Society.

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The Diagnosis and Treatment of Oral Cavity Cancer

Klaus-Dietrich Wolff, Markus Follmann, Alexander Nast

eREFERENCES


