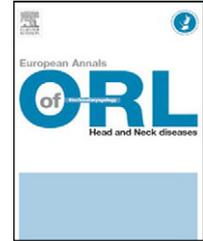




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SFORL GUIDELINES

Initial staging for squamous cell carcinoma of the mouth, larynx and pharynx (except nasopharynx). Part 3: General assessment. 2012 SFORL recommendations

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KEYWORDS

Squamous cell carcinoma;
Oral cavity;
Pharynx;
Larynx;
Initial staging;

Summary

Objectives: The French Society of Otorhinolaryngology (SFORL) set up a work group to draw up guidelines for initial staging of head and neck squamous cell carcinoma. Locoregional and remote extension assessment are dealt with in two separate reports. The present part 3 deals with the assessment of frequent associated symptoms and pathologies, requiring early treatment and the collection of data on a certain number of clinical and paraclinical parameters for therapeutic decision-making in the multidisciplinary team meeting.

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Pain;
Anemia;
Malnutrition;
Comorbidity;
Dental care

Materials and methods: A multidisciplinary critical analysis of the literature was conducted. General assessment here covers screening, assessment and initial management of the following: usual risk factors (smoking, alcohol, HPV), the most frequent medical comorbidities, nutritional status, social and psychological status, dental status, pain and possible anemia. As oncologic management frequently associates surgery, radiation therapy and chemotherapy, the underlying examinations should be early, as part of initial staging. The levels of evidence for the examinations were estimated so as to grade guidelines, failing which expert consensus were established.

Results: The high rates of pain, malnutrition and anemia call for systematic screening and early management, especially as rapidly effective treatments exist. Assessing comorbidity and social and psychological status enables general health status to be assessed, along with possible contraindications to the usual treatments. Tracheal intubation problems may require intubation under flexible endoscopy or jet-ventilation by inter-cricothyroid catheterization from the diagnostic endoscopy stage. Assessment and adapted dental care should be conducted if radiation therapy is likely or certain.

Conclusion: Early management of symptoms and comorbidity and anticipation of subsequent treatment are intended to shorten initial staging time and to collate the data needed for therapeutic decision-making. This assessment should be performed at the same time as the locoregional and remote extension assessment, and is obviously to be adapted according to tumoral extension stage and the possible treatment options.

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Introduction

Pre-therapeutic assessment of squamous cell carcinoma of the oral, cavity larynx and pharynx (excluding the nasopharynx) is controversial. Initial local and cervical lymph-node assessment, remote assessment and exploration for synchronous second locations outside the upper aero-digestive tract are dealt with in parts 1 and 2 of the present guidelines, published separately. The 3rd part of the present guidelines of the French Society of ORL (SFORL) deals with general assessment: i.e., medico-social and psychological parameters, cancer-related symptom management and assessment of contraindications to usual treatment modalities.

Subjects and methods

These guidelines were drawn up by a multidisciplinary group of experts in the field: ENT specialists, and also radiologists, maxillofacial surgeons, radiotherapists, medical oncologists, pathologists, nuclear medicine specialists and anesthesiologists. The aim was to specify management on the basis of a critical analysis of the literature and, where proof was lacking, to establish expert consensus.

The field covered by general assessment was defined as comprising:

- medico-social and psychological assessment;
- screening for and management of the three most frequent symptoms (pain, malnutrition and anemia);
- and pre-planning for possible surgery, radiation therapy and chemotherapy and the associated issues of tracheal intubation, dental care and reconstructive surgery.

The levels of evidence of the selected articles were noted so as to grade the guidelines in line with the French health authority (HAS) guide to literature analysis and guideline grading, itself based on the Sackett scoring system.

Section 1: medico-social and psychological assessment

Guideline 1: Screening for and assessment and management of head and neck cancer risk factors:

- genetic testing is not recommended as part of head and neck cancer assessment (Grade A);
- in case of smoking and/or alcohol intoxication, the following should be noted in the medical records:
 - smoking level (pack-years) and duration,
 - units of alcohol consumed/day;
- for both toxins, it should be noted whether intoxication is on-going or for how long abstinence has been genuine (Grade A);
- regular cannabis consumption should be investigated (Grade A);
- exposure to asbestos, diesel fumes, nickel or pesticides should be investigated. Construction and agriculture are occupational sectors especially concerned: head and neck cancer patients, with or without nicotine/alcohol intoxication, working in these sectors should be referred to an occupational physician to specify exposure and for the patient's case to be registered (professional consensus);

- clinical signs of gastro-esophageal reflux (GER) should be systematically investigated, as it may be a co-factor for certain head and neck cancer locations, notably larynx and hypopharynx (professional consensus);
- systematic exploration for HPV is not recommended, in absence of therapeutic impact (professional consensus).

In the particular case of oropharyngeal carcinoma and/or in absence of alcohol/nicotine-related risk factors, immunohistochemical analysis by anti-P16 antibody is optional for epidemiological purposes (professional consensus).

The main risk factors are alcohol and smoking; double intoxication exerts a synergic effect on onset of head and neck squamous cell carcinoma [1]. It is essential to take full account of these risk factors; cessation immediately following diagnosis improves treatment tolerance and thus limits the risk of evolution. Silverman et al. reported 18% onset of second cancer in smokers who ceased smoking, compared to 30% in those who did not [2].

HPV infection is mainly implicated in the oncogenesis of oropharyngeal and oral cavity tumors, independently of nicotine/alcohol intoxication [3,4]. St Guily et al., in a prevalence study of 523 patients, found HPV in 46.5% of oropharyngeal and 10.5% of oral cavity squamous cell carcinomas [5].

A literature review implicated HPV in 25.9% of 5046 head and neck squamous cell carcinomas, taking all locations together; for oropharynx, oral cavity and larynx, rates were respectively 35.6%, 23.5% and 24% [6]. These findings were confirmed by Hobbs et al.'s meta-analysis of HPV-16, which found a weaker association with laryngeal (odds ratio (OR): 2.0) than tonsillar cancer (OR: 15.1) [7]. Prognosis is fairer in HPV-positive than HPV-negative oropharyngeal tumor [8].

Also to be borne in mind are:

- the impact of immunosuppression, notably in graft recipients;
- the impact of cannabis consumption [9];
- the possible co-factor impact of GER, for which literature reports are contradictory [10].

Guideline 2: exploration for comorbidities:

- comorbidity should be explored for and assessed so as to be taken into account in therapeutic decision-making (Grade B);
- treating comorbidity improves survival and quality of life (Grade B);
- awareness of comorbidities is essential for the multi-disciplinary team meeting (professional consensus).

Comorbidity mainly comprises cardiovascular and respiratory pathology, diabetes, obesity, gastro-intestinal pathology, neurological pathology and synchronous cancer outside the upper aero-digestive tract.

Comorbidity is a major prognostic factor in head and neck squamous cell carcinoma, increasing immediate post-treatment mortality [11]. Complications are significantly more numerous and severe in case of comorbidity [12]. Diagnosis is frequently delayed, with negative impact on quality of life and recurrence-free survival [11–13].

Optimizing the general health status of head and neck cancer patients could reduce morbidity, complications and thus management costs.

Age is not a comorbidity as such, but comorbidities are more frequent in the elderly. This is, of course, taken into account in therapeutic decision-making for elderly patients, in whom assessment and pre-treatment management of comorbidity plays a major role [14].

Guideline 3: social and psychological assessment Guideline (Grade B)

Certain items should be systematically detailed in the patient's file:

- living conditions and quality of immediate social environment: couple (status of partner), alone but not isolated (family, friends, children), seriously isolated, dependent, etc.;
- occupational situation and leisure;
- psychological status at diagnosis: screen for and note known severe depression, anxiety level (French health authority [HAS] scale), psychiatric history;
- need for consultation with psychologist or social worker.

Babin et al. found that the numerous studies of post-treatment quality of life failed to explore all domains (notably, daily life conditions, social relations and leisure), or the influence of anticipated quality of life on initial treatment choice [15]. Head and neck cancers have the particularity of altering physical appearance and phonation and swallowing functions, with serious impact on social life, thus greatly influencing therapeutic decision-making and patient acceptance; the patient's psychological context and living conditions also have great influence.

Two recent studies on ENT cancer patients reported a 6% to 15% rate of depression and 12% to 30% of anxiety [16]; suicide rates are among the highest, just after those for bronchopulmonary or gastric cancer [17].

The patient's living conditions need to be known so as to organize the treatment period and discharge home. As treatment can sometimes be hard to tolerate or may induce sequelae, many patients have to take time off work and/or social life, leading to serious social isolation [18].

The quality of the patient's immediate social environment is an important factor in rehabilitation quality and acceptance of disability [19].

Section 2: screening for and management of three frequent symptoms

Guideline 4: screening for and management of malnutrition:

- weight, height and body-mass index (BMI: weight/height²) and percentage recent weight-loss should be measured in the initial head and neck cancer consultation (Grade C);
- malnourished patients should be referred for dietary consultation as soon as possible after cancer diagnosis (professional consensus);
- satisfactory oral feeding may require medical prescription of analgesics and/or local anesthetics (professional consensus).

Head and neck cancer patients run a serious risk of undernourishment due to an often disadvantaged socio-occupational situation, frequent alcohol/nicotine intoxication and, above all, pain and dysphagia.

Malnutrition prevention and screening should be systematic as from initiation of management. BMI inferior to 18.5 kg/m² correlates significantly with reduced overall survival [20].

As a complement to history taking with estimation of weight-loss and BMI, albuminemia assay allows the Buzby nutrition risk index ($NRI = 1.519 \times [\text{albumin in g/L}] + 0.417 \times [\text{present weight / usual weight}] \times 100$) to be calculated; NRI inferior to 83.5 indicates severe malnutrition.

The recommended daily calorie intake is around 1600 to 2400 kcal, and nitrate intake around 0.2 to 0.35 g/kg/day, or 1.25 to 1.85 g of protein/kg/day (professional consensus). If the oral route does not allow sufficient intake, enteral feeding should be initiated on medical decision, either by nasogastric tube or by gastrostomy.

Certain authors, such as Silander et al., have reported that early gastrostomy improved nutritional status during treatment [21]. Mahdoun et al., however, reported that 11 out of 23 patients fitted with a prophylactic gastrostomy tube used it either never or for less than 2 weeks [22]. In patients at high-risk of dysphagia and choking before, during and after treatment, prophylactic gastrostomy should be considered (professional consensus).

Peri-operative immunonutrition can significantly reduce the rate of complications [23], but is not presently covered by the French health insurance system in head and neck oncology.

Pain is frequent in head and neck cancer; it should be managed as of the first consultation, as it may induce malnutrition by impaired feeding. History taking and clinical examination should detail the characteristics of pain so as to adapt treatment.

Pain due to excessive nociception requires:

- step 1 (paracetamol, non-steroid anti-inflammatories);

Guideline 5: screening for and management of pain:

- symptoms of pain should be investigated and managed;
- the patients should be referred to algology if classic treatments fail to control the pain (professional consensus)

- step 2 (minor morphine derivatives such as codeine, a dihydrocodeine or tramadol);
- or step 3 analgesia (morphine derivative or similar) [24].

For neuropathic pain, anti-epileptics (gabapentin or pregabalin) or antidepressants (imipramine, amitriptyline) or local topical analgesics may be introduced [25]. For mixed pain, double-action molecules (tramadol, oxycodone) are recommended in first line. Treatment frequently associates delayed and rapid action forms to achieve balance and deal with paroxysmal breakthrough pain. Side-effects such as nausea or constipation require special prevention in these often undernourished patients: rigorous respect of dietary health rules (hydration, fiber-rich diet, regular physical exercise) and laxatives.

The form of treatment should be adapted to the patient's symptoms: e.g., dysphagia or choking, where percutaneous, transmucosal or enteral (nasogastric or gastrostomy tube) routes may be useful. Co-analgesic treatment may be associated: corticosteroids, local topical analgesics (anesthetics, healing agents, NSAIs) or antispasmodics.

Guideline 6: screening for and management of anemia:

- anemia is an independent risk factor for poor prognosis;
- it should be screened for, and managed by adapted diet, possibly with i.v. or oral iron supplementation (Grade B);
- indications for allogenic transfusion should be limited (Grade A);
- transfusion strategy should therefore take account of hemoglobinemia, comorbidity and surgical context (Grade C).

Head and neck cancer patients are often found to be anemic at initial staging [26]. There may be several reasons for this: malnutrition due to underfeeding induced by underlying symptoms (odynophagia, dysphagia, choking), chronic blood loss due to hemorrhagic tumor, chronic inflammatory syndrome of tumoral or infectious origin (e.g., bronchopulmonary infection due to iterative false passage), or unbalanced diet entailing deficiencies (frequent excessive alcohol consumption).

Anemia should be detected and corrected during initial staging, being an independent factor of poor prognosis. It can exacerbate postoperative complications [27–29], and

reduce efficacy and tolerance in concomitant radiation or chemotherapy [30].

Adapted diet with iron supplementation is usually effective. Several recent publications showed parenteral iron supplementation to be better and more effective than oral route [31,32]. Peri-operative parenteral iron supplementation limits anemia secondary to surgical hemorrhage [33]; oral administration is slower acting and may be poorly tolerated. Hematopoietic growth factors, such as erythropoietin, are controversial: while effective against anemia, they have failed to show impact on local control and survival [34,35].

The policy of reducing recourse to homologous transfusion applies in head and neck oncology as in other fields, given that the associated morbidity is non-zero. When performed, it should take account of total forecast surgical blood-loss, any cardiopathy, pre-operative hemoglobinaemia or hematocrit, and individual total blood volume. Homologous red blood-cell transfusion guidelines, recommended here, were drawn up by the French national health products safety agency (Agence Française de Sécurité Sanitaire des Produits de Santé: AFSSAPS) in 2003 [36]. Recommended thresholds depend on whether anemia is acute (7 to 10 g/L) or chronic (6 to 10 g/L), and take account of cardiovascular history and tolerance.

Section 3: treatment pre-planning

Guideline 7: dental assessment and care:

- clinical and panoramic X-ray dental assessment should be systematic in head and neck carcinoma ahead of treatment (Grade C);
- any extractions should be performed as soon as possible before radiation therapy or brachytherapy, with treatment initiated only after gum mucosa has healed and at a minimum 2 weeks (professional consensus);
- fluoride protection should be implemented after radiation therapy involving the head and neck (Grade C). The fluoride application splints are produced in advance;
- a prosthetic rehabilitation consultation should be set up before any maxillary surgery (professional consensus);
- clinical and radiological dental assessment should be performed ahead of chemotherapy, especially when there is risk of medullary aplasia (professional consensus).

The objectives of dental assessment as part of initial head and neck cancer staging are:

- to treat acute or latent infection sites liable to induce locoregional (e.g., delayed bone healing) or general (e.g., septicemia during aplasia-inducing chemotherapy) infection during treatment;
- to anticipate possible prosthetic rehabilitation ahead of any surgery sacrificing maxillary bone;

- and to reduce the risk of subsequent maxillary or mandibular osteoradionecrosis (ORN) in the irradiated area by completing appropriate dental care (conservative or other) ahead of radiation therapy [37].

Dental assessment should systematically comprise meticulous clinical examination and panoramic dental X-ray (professional consensus). Exploration for latent dental infection sites may require retro-alveolar views, cone-beam or DentaScan.

Dental care may be conservative or not. In case of extraction, a minimum 2-weeks' interval should be observed before initiating radiation therapy, to allow the bone and mucosa to heal; this should limit, without entirely eliminating, the risk of ORN [38,39].

Cervicofacial radiation therapy entails a risk of definitive xerostomia. Fluoride protection of the remaining teeth is indicated at end of treatment [40,41]. This consists of daily 5–10 minutes application of a fluoridated gel (Fluoracryl Bi Fluoré 2000 gel[®], Sensigel[®], Emoform gel[®]) using a dedicated splint. Treatment should be on a lifetime basis, so long as any teeth remain. The fluoride application splints are usually fitted ahead of radiation therapy, so that fluoridation can be initiated as quickly as possible at end of treatment.

Guideline 8: tracheal intubation and ventilation:

- the SFAR guidelines for difficult intubation apply to head and neck cancer patients (Grade A);
- inter-cricothyroid membrane palpation and investigation of previous cervical radiation therapy should look for signs predicting difficulties of intubation or mask ventilation (Grade B);
- intubation under flexible endoscopy is the technique of choice in case of ENT neoplasia (Grade B);
- supraglottic devices should be avoided (Grade B);
- transtracheal ventilation needs to be well-controlled (Grade B); a jet-ventilation device with tracheal pressure control is to be preferred (Grade C).

Head and neck cancer patients are considered at risk for tracheal intubation failure [42]. Various problems may arise: obstructive or hemorrhagic tumor, oral cavity opening restricted by tumoral invasion of the mastication space, and sequelae from previous treatment of a metachronous second tumor (history of cervical surgery and/or radiation therapy).

There are two ways of getting round such problems in initial diagnostic endoscopy [43]:

- nasotracheal intubation under nasofibroscope is the method of choice when intubation difficulties are expected. It may be performed under local (nasal and pharyngolaryngeal) anesthesia or light sedation [44];
- high-frequency jet ventilation via a transtracheal inter-cricothyroid catheter fitted under local anesthesia is an interesting and reliable option [45,46]. Although considered invasive, associated morbidity is minimal when the team is experienced. A device equipped with safety features avoids pressure trauma. The technique has the

advantage of avoiding the airway obstacle during insufflations, but requires the absence of any major obstacle to expiration.

Coordination with the surgery team is essential for screening patients for intubation issues. Emergency tracheotomy during diagnostic endoscopy without controlled ventilation should be a rare event, but cannot always be avoided.

Guideline 9: chemotherapy work-up:

- indications for chemotherapy should be raised in the multidisciplinary team meeting (professional consensus);
- general health status and comorbidity (cardiac, renal, hepatic, neurologic) should be taken into account ahead of chemotherapy (Grade D);
- onco-geriatric consultation ahead of chemotherapy is recommended in elderly patients (Grade D);
- a complete blood count and liver assessment should be performed ahead of chemotherapy (Grade A);
- renal assessment with creatinine clearance is recommended for chemotherapy including cisplatin or carboplatin (Grade A);
- ECG should be performed ahead of 5-fluorouracil (5FU) chemotherapy (Grade A).

The main anticancer molecules used in initial curative treatment for head and neck squamous cell carcinoma are: platins (cisplatin or carboplatin), 5FU, docetaxel (Taxotère®), and cetuximab (Erbix®). They may be used alone in adjuvant chemotherapy or associated to radiation therapy (radiochemotherapy or potentialized radiotherapy).

Generally speaking, the use of an anticancer molecule is decided in the multidisciplinary team meeting, taking account of the patient's health status and comorbidities. Any intensification should weight benefit against risk. In patients over 70 years of age, benefit is less obvious and an onco-geriatric consultation may help in decision-making [47].

Preliminary examinations depend on the known toxicity of the various molecules:

- platinum (cisplatin and carboplatin) toxicity is mainly hematologic, renal and neurologic. Work-up should comprise:
 - renal function, with creatinemia and renal clearance (Cockcroft-Gault or MDRD (modification of diet in renal disease) formula);
 - and screening for peripheral neuropathy (alcohol-related, diabetic) and hearing loss, with clinical neuro-monitoring throughout treatment. The hyperhydration required with cisplatin 100 mg/m² may be a problem in case of cardiac impairment; in case of known or suspected cardiac insufficiency, specialist advice is recommended;
- fluorouracil toxicity is hematologic, mucosal, cutaneous (hand-foot syndrome) and cardiac. Cardiac toxicity shows as arrhythmia and angina syndrome or myocardial

infarction. ECG is essential. Specialist cardiologic advice is recommended in case of risk factors for coronaropathy or of abnormal ECG. DPD (dihydropyrimidine dehydrogenase) deficiency is a risk factor for overdosage; individualized pharmacokinetic dosing can enhance tolerance without reducing efficacy [48]; systematic screening for DPD deficiency is currently recommended only in clinical trials;

- docetaxel (Taxotère®) toxicity is hematologic, and may induce hypersensitivity reaction, reversible alopecia, unguinal disorder or peripheral edema; it is greatly exacerbated by associated disorder seen on liver assessment: hepatic biology analysis is essential;
- cetuximab (Erbix®) may induce allergic reaction of varying severity, up to anaphylactic shock, but does not show renal, hematologic, neurologic or cardiac toxicity. It frequently leads to acne-like skin rash, and sometimes to diarrhea. No specific work-up is recommended.

Guideline 10: work-up for microanastomosed free-flap cervicofacial reconstruction:

- possible flap harvesting sites should be checked before beginning reconstruction (professional consensus);
- before creating the free flap, cervical vascularization should only be investigated in case of doubt: i.e., when clinical and/or radiological evidence casts doubt on receiver network quality (e.g., known atheromatous disease) (professional consensus);
- Allen's test should be performed before harvesting an antebrachial flap (Grade D); echo-Doppler should be performed in case of the slightest doubt (Grade D);
- lower-limb angio-CT or angio-MRI should be performed before creating a fibular flap (Grade C);
- angio-CT or angio-MRI should be performed before creating an anterolateral thigh or deep inferior epigastric perforator (DIEP) flap (Grade C);

Head and neck cancer treatment has benefited from recent progress in reconstructive surgery, improving esthetic and functional results. Microanastomosed free flaps have proved preferable to pediculated flaps in terms of plasticity, with improved adaptation to the defect, and of the range of available tissues. They are not, however, always feasible. At initial staging, if surgery is considered, the possibilities of reconstructive surgery should be assessed. After history-taking and appropriate clinical examination, certain radiological examinations may be required.

There are two rules for microanastomosed free flaps: to check:

- receiver vessel quality (cervical arteries and veins);
- and the feasibility of donor site harvesting without compromising residual tissue vascularization.

Carotid and jugular permeability can be assessed on echo-Doppler or contrast-enhanced cervicofacial CT

(angio-scan) [49,50]. However, this is recommended only in case of doubt: i.e., when clinical and/or radiological evidence casts doubt on receiver network quality (e.g., known atheromatous disease); these examinations are not mandatory. When doubt persists, the free flap should be performed only once the surgeon has checked receiver vessel quality.

Donor site assessment depends on the type of flap vascularization. If a main terminal vascular axis is to be sacrificed, the intended collateral network should be checked. For antebachial fasciocutaneous flap sacrificing the radial artery, Allen's test theoretically confirms the quality of the ulnar artery and permeability of the superficial and deep palmar arches [51]. As its sensitivity is not optimal, Allen's test should be performed peroperatively, or an echo-Doppler performed pre-operatively [52]. For fibular flap sacrificing the posterior tibial artery, pre-operative radiological vascular exploration is essential [53]; lower-limb angio-CT or angio-MRI are preferable to echo-Doppler in terms of effectiveness and reproducibility in diagnosing anatomic variants in the mode of division of the popliteal artery [54].

Fasciocutaneous flaps with perforating artery pedicle (scapular and parascapular, anterolateral thigh, DIEP, external brachial flaps) show less donor-site morbidity, but are more difficult to harvest. Pre-operative location of the perforating arteries on echo-Doppler or cross-sectional imaging (angio-CT or angio-MRI) is recommended, and has been shown to improve the reliability of and time needed for flap harvesting [55].

Conclusions

Early management of symptoms and comorbidity and treatment pre-planning seek to reduce initial staging time, to collate data for therapeutic decision-making, and to prepare the patient for treatment. Assessment should be performed at the same time as the locoregional and remote extension assessment. It should be adapted to tumor stage and to the possible treatment options.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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