NATIONAL EXPERT-BASED PRACTICE GUIDELINES

COLLEGE OF ONCOLOGY

OESOPHAGEAL CANCER

Version 1. 2020

Oesophageal Cancer Guidelines Expert Panel

These guidelines have been developed by a national multi-institutional and multidisciplinary expert working party, based on international guidelines.

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- Oesophageal cancer guidelines expert panel
- National guidelines oesophageal cancer (full text)
  - Introduction
  - Search for evidence
  - Epidemiology
  - Diagnosis
  - Staging
  - General treatment
  - Localized resectable oesophageal cancer
  - Locally advanced oesophageal cancer
  - Metastatic oesophageal cancer
  - Supportive treatment
  - Follow-up
  - Role of the general practitioner
- TNM classification
- Staging groups
- Abbreviations
- References

NATIONAL GUIDELINES OESOPHAGEAL CANCER

OESOPHAGEAL CANCER

INTRODUCTION

This document provides an overview of the clinical practice guidelines for **oesophageal cancer** and covers a broad range of topics such as screening, diagnosis, treatment, supportive therapy, follow-up and the role of the general practitioner (GP).

These guidelines are developed by a panel of experts (see 'expert panel') comprising clinicians of different specialities and designed by their respective scientific societies.

Current guidelines are based on a systematic review of clinical evidence available at the time they are derived, being in 2019.

The aim of these guidelines is to assist all national care providers involved in the care of patients with oesophageal cancer and to serve as a tool to support the local institutional guidelines and multidisciplinary tumor board (MDT) discussions in Belgium.

SEARCH FOR EVIDENCE

These guidelines are derived from three existing national and international guidelines:

KCE guidelines 2012 [1] & KCE report on surgery indications 2019 [2], ESMO guidelines 2016 [3] & 2019 [4] and NCCN guidelines 2019 [5].

Existing guidelines have been discussed and updated and are finally adapted by the expert panel to correspond to the Belgian context.

The expert panel consisted of experts in various settings and representatives of the relevant professional Belgian societies, involved in the management of oesophageal cancer.

These national guidelines will be regularly updated whenever new evidence emerges concerning clinical practice.

OESOPHAGEAL CANCER

EPIDEMIOLOGY

There are two main histological types of oesophageal cancer, oesophageal squamous cell carcinoma (SCC) and oesophageal adenocarcinoma (AC). The main risk factors for SCC in Western countries are smoking and alcohol consumption, whereas AC mostly occurs in patients with chronical gastro-oesophageal reflux disease and obese persons. [6]

The Belgian Cancer Registry has registered 1.035 new cases of Oesophageal cancer in Belgium in 2017, of which 480 patients (46 %) have been classified as SCC and 513 patients (50 %) as AC. [7] Oesophageal cancer, including squamous cell carcinoma and adenocarcinoma, is considered as a serious malignancy with respect to prognosis and a fatal outcome in the great majority of all cases. [6]

Defining the treatment strategy for patients suffering from oesophageal cancer requires a discussion by a specialized multidisciplinary team including: surgeons, medical oncologists, gastroenterological oncologists, radiation oncologists, radiologists, pathologists, supportive and palliative care specialists, nuclear medicine,.. [4]

DIAGNOSIS

- Mass screening for oesophageal cancer is not recommended. (*Consensus)*
- An upper intestinal endoscopy with biopsies should be performed for all patients with:
  - New dysphagia
  - Gastrointestinal bleeding
  - Recurrent aspiration or emesis
  - Weight loss and/or loss of appetite. *(ESMO)*
- Patients with family history of oesophageal cancer, should only undergo surveillance endoscopic evaluation with biopsies, in case of suspicious lesions. (*Consensus)*
- Patients with Barrett's oesophagus need a follow-up as defined in the guidelines for Barrett's oesophagus. (*Consensus)*
- The differentiation between SCC and AC is of prognostic and clinical relevance.
- Esophagogastroduodenoscopy with biopsies should be performed in all patients. *(ESMO, NCCN, KCE)*
- Sequence of molecular tests to be carried out: https://www.compermed.be/activites/workflows#/cancer/35
  - Testing of biomarkers PDL-1 and MSI has currently no consequences for treatment and is not routinely recommended. *(Consensus)*
  - Testing of HER-2 biomarker is recommended for adenocarcinoma, in metastatic or recurrent setting. *(NCCN)*

STAGING

PET-CT and CT san

For complete staging and evaluation of the therapeutic strategy, high-quality CT scan of thorax/abdomen should be performed. CT scan of the neck should be done for upper oesophagus cancer only. *(ESMO, NCCN, KCE).*

In candidates for curative surgical resection *(other than endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD))* PET-CT scan is obligatory to define N-staging and M-staging. *(ESMO, NCCN, KCE)* Provided this PET-CT scan is performed with oral and IV contrast in an appropriate dose and with appropriate reconstruction method, the classic CT scan thorax/abdomen/neck could be omitted.

To define the T-stage in superficial lesions, patients should be referred for endoscopic resection in an endoscopic expert centre. *(Consensus)*

Restaging by PET-CT scan is necessary after neoadjuvant therapy and after resection in case the initial PET scan showed a PET positive lesion. PET-CT scan is not necessary in case of pT1a after EMR or ESD, as the additional value of PET-CT scan in T1 tumors is very minimal. *(Consensus)*

In case treatment with radiotherapy is decided, it is recommended to perform restaging with PET-CT scan after 4 to 6 weeks to allow inflammation to settle. *(Consensus)*

Ultrasound imaging

The role of endoscopic ultrasound (EUS) for T-staging is controversial and not recommended, but it can be useful for defining early oesophageal cancer (smaller lesions ≤ 2cm). Staging of early oesophageal cancer needs an endoscopic resection. For SSC, ESD is used and for AC, both EMR or ESD could be used. When resection margins are in doubt or if en bloc resection of the tumor by EMR is not possible, ESD is preferred. *(Consensus)* EUS should not be performed in bulky lesions.

EUS for N-staging should be performed to define involved lymph nodes in case the lineation of radiation fields or decisions on surgery could be influenced by the results. In those cases fine needle aspiration (FNA) is mandatory. *(Consensus)*

For restaging, EUS is only necessary if treatment could be affected by the results. In those cases FNA is mandatory. *(Consensus)*

Cervical ultrasound should be performed for staging purposes in case of suspicious lymph nodes on CT scan or PET-CT scan and if these results imply change of treatment. FNA in those cases is mandatory to prove

lymph node involvement. *(Consensus)*

Endoscopy

Tracheo-bronchoscopy should be done in all patients diagnosed with SCC, to exclude trachea invasion.

In case after neoadjuvant treatment the presence of viable tumor is important, a control endoscopy is recommended. This endoscopy needs to be performed after the PET-CT scan to avoid false positive PET lesions. *(Consensus)*

In case after neoadjuvant treatment a "wait and see" policy is prescribed, an endoscopy with biopsy is required. "Wait and see" policy should only be used in case of complete response on PET-CT scan and a negative endoscopy *(within the boundaries of a clinical trial)*. *(Consensus)*

Laparoscopy can be considered for AC in case of suspicion of peritoneal metastases in locally advanced stage (T3/T4) of the distal oesophagus or gastroesophageal junction. However this should upfront discussed and decided on a case by case discussion during a MDT meeting.

Laparoscopy for SCC should not be performed on regular base. *(Consensus)*

GENERAL TREATMENT ASSESSMENT

- A MDT meeting is mandatory for planning of treatment in all oesophageal cancer patients, including metastatic ones.
- During a MDT meeting following items should be discussed and evaluated:
  - The extent of disease and resectability
  - Operability of the patient: cardiac and pulmonary function of the patient should be tested at least once (*during re-assessment after neoadjuvant treatment, clinical judgment could be used to define the need for re-testing cardiac and/or pulmonary function*). *(Consensus)*
  - The nutritional status and history of weight loss according to the ESPEN guidelines (https://www.espen.org/guidelines-home/espen-guidelines). Physical, nutritional and mental support should be offered, when deemed necessary.
  - Oncogeriatric evaluation when necessary. *(Consensus)*
  - All available medical relevant information should be reviewed and discussed. *(Consensus)*
- Oesophageal surgeries have to be performed in nominated reference centres. *(KCE)*
- All fit patients are encouraged to be included in prospective clinical trials. *(Consensus)*

OESOPHAGEAL CANCER

LOCALIZED RESECTABLE OESOPHAGEAL CANCER

Endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) are both recommended for all **T1a** cancers. ESD is preferred to EMR, especially in lesions >15 mm *(importance of section margins)* and in patients diagnosed with SCC. *(ESMO)*

In patients with curative endoscopic resection of AC in context of Barrett's oesophagus, treatment must be followed by radiofrequent ablation (RFA) of residual Barrett's mucosa.

All patients with **T1b, T2N0** or **T1a** endoscopic treatment failure, in good condition, should proceed to surgery. Endoscopic treatment for **T1b** lesions should only take place within the boundaries of a clinical trial.

Patients diagnosed with SCC, who are unfit or unwilling to undergo surgery, should be advised to be treated with chemoradiotherapy. *(ESMO, NCCN)*

Upfront surgery is not recommended for patients with cancer above **T2N0,** in case neoadjuvant treatment is deemed possible. *(NCCN)*

LOCALLY ADVANCED OESOPHAGEAL CANCER

Surgery alone is not a standard treatment in locally advanced disease. In all patients with **T3, T4a, T4b or N+** tumors, neoadjuvant treatment is clearly indicated (chemotherapy or chemoradiotherapy). Treatment should be evaluated and decided on a case by case discussion during a MDT meeting. In case a patient becomes resectable after re-evaluation, surgery should be considered. *(ESMO, NCCN)*

Neoadjuvant in squamous cell carcinoma

For all patients diagnosed with SCC chemoradiotherapy is recommended. Based on the results of the *Chemoradiotherapy for Oesophageal Cancer Followed by Surgery Study* (CROSS), the weekly administration of carboplatin and paclitaxel for 5 weeks and concurrent radiotherapy followed by surgery, is recommended.

Patients with non-resectable SCC or patients unfit or unwilling to undergo surgery should be offered definitive chemoradiotherapy.

Definitive chemoradiotherapy is recommended to all patients with cervically localized tumors *(to avoid pharyngo-laryngectomy)*.

Neoadjuvant in adenocarcinoma

For all patients diagnosed with AC, especially with the largest tumor bulk in the stomach, preferably FLOT should be given in fit patients and FOLFOX in less fit patients. In AC with a very proximal/cervical location chemoradiotherapy should be considered. (*ESMO, NCCN)*
Treatment with chemoradiotherapy should always be evaluated and decided on a case by case discussion during a MDT meeting.
Patients with non-resectable AC or patients unfit or unwilling to undergo surgery should be offered chemotherapy as monotherapy. *(ESMO, KCE)*

Surgery

Surgery after neoadjuvant treatment is recommended as standard of care for all patients with locally advanced oesophageal cancer, when deemed resectable and whenever functional status makes it possible, even when clinically complete response is suspected. Target is complete resection (R0), transthoracic and total two field lymphadenectomy, and three field lymphadenectomy when deemed necessary. *(ESMO, NCCN)*
For esophageal carcinoma at or above the level of the carina, transthoracic esophagectomy with three-field lymph node dissection is preferably recommended. *(NCCN)* After resection, different lymph node stations should be put in different recipients, for easy and precise pathological examination. *(Consensus)*

Minimally invasive esophagectomy *(at least laparoscopy for gastrolysis)* is recommended where feasible. *(Consensus)*
Salvage esophagectomy should be considered in case of local recurrence.
Adjuvant therapy as standard of care is not recommended but should be be evaluated and decided on a case by case discussion during a MDT meeting, or within the boundaries of a clinical trial in case of residual positive nodes. (*Consensus)*

METASTATIC OESOPHAGEAL CANCER

Chemotherapy with or without radiotherapy, stenting (with metal stents), brachytherapy, laser or Argon plasma coagulation (APC) as treatment should be discussed during a MDT meeting. *(KCE)*

Palliative care should be focused on comfort, nutrition and quality of life. *(Consensus)*

Patient's condition, comorbidity, organ function, performance status and expectations should be taken into account. The option for surgery in oligometastatic patients should be discussed during a MDT meeting and surgical patients should be treated within the boundaries of clinical trials. *(Consensus)*

Targeted therapy and immunotherapy are evolving, however, currently the treatment of metastatic fit patients only takes place within the setting of clinical trials. Patients with HER2-positive metastatic adenocarcinoma should be treated with a trastuzumab-containing treatment. *(ESMO)* Different systemic options as 5-FU, paclitaxel, irinotecan, oxaliplatin, ramucirumab are available and can be used in combination regimes.

SUPPORTIVE TREATMENT

A three-step approach of pain drug administration (WHO analgesic ladder) should be followed in patients with pain associated with oesophageal cancer. *(Consensus)*

Patients with oesophageal cancer should be offered specific psychological support from professionals, belonging to the multidisciplinary team. *(Consensus)*

FOLLOW-UP

Follow-up should concentrate on symptom assessment, history, physical examination, nutrition and psychosocial support. *(ESMO)*
For the first 2 years, CT abdomen/thorax should be checked every 3-6 months. Afterwards every 6-12 months for the next 3 years and from then onwards annually. *(NCCN, KCE)*

ROLE OF GENERAL PRACTITIONER

Screening and referrals

- No mass screening is indicated for the general population.
- All patients with a potential or known diagnosis of oesophageal cancer should have access to a multidisciplinary oesophageal reference cancer team for information and support at every stage of diagnosis, treatment and follow-up.
- The general practitioner (GP) should be aware that investigations in primary care are associated with later referrals to a specialist, as communicating the results and organizing the referral may require additional consultations. *(Consensus)*

Communicating the diagnosis

- The GP shall be promptly informed about the diagnosis of oesophageal cancer, if this has been communicated to the patient. Subsequent alterations in prognosis, management or drug treatment should be also communicated promptly and clearly preferably in written form. *(Consensus)*

Follow-up

- The GP shall ensure that the patient is offered follow-up by the multi-disciplinary oesophageal cancer team. This is necessary for the detection of early recurrence and complications and for the appropriate treatment. The GP shall motivate the patient to have a regular follow-up with the specialist. *(Consensus)*

OESOPHAGEAL CANCER

Cancer staging categories for cancer of the esophagus and esophagogastric junction

Category	Criteria
T category	
TX	Tumor cannot be assessed
T0	No evidence of primary tumor
Tis	High-grade dysplasia, defined as malignant cells confined by the basement membrane
T1	Tumor invades the lamina propria, muscularis mucosae, or submucosa
T1a*	Tumor invades the lamina propria or muscularis mucosae
T1b*	Tumor invades the submucosa
T2	Tumor invades the muscularis propria
T3	Tumor invades adventitia
T4	Tumor invades adjacent structures
T4a*	Tumor invades the pleura, pericardium, azygos vein, diaphragm, or peritoneum
T4b*	Tumor invades other adjacent structures, such as aorta, vertebral body, or trachea

TNM classification [8]

N category	
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in 1–2 regional lymph nodes
N2	Metastasis in 3–6 regional lymph nodes
N3	Metastasis in 7 or more regional lymph nodes
M category	
M0	No distant metastasis
M1	Distant metastasis

OESOPHAGEAL CANCER

Adenocarcinoma G Category

GX	Differentiation cannot be assessed
G1	Well differentiated. >95% of tumor is composed of well-formed glands
G2	Moderately differentiated. 50% to 95% of tumor shows gland formation
G3†	Poorly differentiated. Tumors composed of nest and sheets of cells with <50% of tumor demonstrating glandular formation

Squamous cell carcinoma G category

GX	Differentiation cannot be assessed
G1	Well-differentiated. Prominent keratinization with pearl formation and a minor component of nonkeratinizing basal-like cells. Tumor cells are arranged in sheets, and mitotic counts are low
G2	Moderately differentiated. Variable histologic features, ranging from parakeratotic to poorly keratinizing lesions. Generally, pearl formation is absent
G3‡	Poorly differentiated. Consists predominantly of basal-like cells forming large and small nests with frequent central necrosis. The nests consist of sheets or pavement-like arrangements of tumor cells, and occasionally are punctuated by small numbers of parakeratotic or keratinizing cells

Squamous cell carcinoma L category***

LX	Location unknown
Upper	Cervical esophagus to lower border of azygos vein
Middle	Lower border of azygos vein to lower border of inferior pulmonary vein
Lower	Lower border of inferior pulmonary vein to stomach, including esophagogastric junction

*, subcategories; †, if further testing of "undifferentiated" cancers reveals a glandular component, categorize as adenocarcinoma G3; ‡, if further testing of "undifferentiated" cancers reveals a squamous cell component, or if after further testing they remain undifferentiated, categorize as squamous cell carcinoma G3; ***, location is defined by epicenter of esophageal tumor.

STAGING GROUPS – For Squamous cell carcinoma [8]

Clinical Staging (cTNM)

	cT	cN	M
Stage 0	Tis	N0	M0
Stage I	T1	N0-1	M0
Stage II	T2	N0-1	M0
	T3	N0	M0
Stage III	T3	N1	M0
	T1-3	N2	M0
Stage IVA	T4	N0-2	M0
	Any T	N3	M0
Stage IVB	Any T	Any N	M1

Pathological (pTNM)

	pT	pN	M	G	Location
Stage 0	Tis	N0	M0	N/A	Any
Stage IA	T1a	N0	M0	G1	Any
	T1a	N0	M0	GX	Any
Stage IB	T1a	N0	M0	G2-3	Any
	T1b	N0	M0	G1-3	Any
	T1b	N0	M0	GX	Any
	T2	N0	M0	G1	Any
Stage IIA	T2	N0	M0	G2-3	Any
	T2	N0	M0	GX	Any
	T3	N0	M0	G1-3	Lower
	T3	N0	M0	G1	Upper/middle
Stage IIB	T3	N0	M0	G2-3	Upper/middle
	T3	N0	M0	GX	Lower/upper/ middle
	T3	N0	M0	Any	Location X
	T1	N1	M0	Any	Any
Stage IIIA	T1	N2	M0	Any	Any
	T2	N1	M0	Any	Any
Stage IIIB	T2	N2	M0	Any	Any
	T3	N1-2	M0	Any	Any
	T4a	N0-1	M0	Any	Any
Stage IVA	T4a	N2	M0	Any	Any
	T4b	N0-2	M0	Any	Any
	Any T	N3	M0	Any	Any
Stage IVB	Any T	Any N	M1	Any	Any

Postneoadjuvant Therapy (ypTNM)

	ypT	ypN	M
Stage I	T0-2	N0	M0
Stage II	T3	N0	M0
Stage IIIA	T0-2	N1	M0
Stage IIIB	T3	N1	M0
	T0-3	N2	M0
	T4a	N0	M0
Stage IVA	T4a	N1-2	M0
	T4a	NX	M0
	T4b	N0-2	M0
	Any T	N3	M0
Stage IVB	Any T	Any N	M1

OESOPHAGEAL CANCER

STAGING GROUPS – For Adenocarcinoma [8]

Clinical Staging (cTNM)

	cT	cN	M
Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage IIA	T1	N1	M0
Stage IIB	T2	N0	M0
Stage III	T2	N1	M0
	T3	N0-1	M0
	T4a	N0-1	M0
Stage IVA	T1-4a	N2	M0
	T4b	N0-2	M0
	Any T	N3	M0
Stage IVB	Any T	Any N	M1

Pathological (pTNM)

	pT	pN	M	G
Stage 0	Tis	N0	M0	N/A
Stage IA	T1a	N0	M0	G1
	T1a	N0	M0	GX
Stage IB	T1a	N0	M0	G2
	T1b	N0	M0	G1-2
	T1b	N0	M0	GX
Stage IC	T1	N0	M0	G3
	T2	N0	M0	G1-2
Stage IIA	T2	N0	M0	G3
	T2	N0	M0	GX
Stage IIB	T1	N1	M0	Any
	T3	N0	M0	Any
Stage IIIA	T1	N2	M0	Any
	T2	N1	M0	Any
Stage IIIB	T2	N2	M0	Any
	T3	N1-2	M0	Any
	T4a	N0-1	M0	Any
Stage IVA	T4a	N2	M0	Any
	T4b	N0-2	M0	Any
	Any T	N3	M0	Any
Stage IVB	Any T	Any N	M1	Any

Postneoadjuvant Therapy (ypTNM)

	ypT	ypN	M
Stage I	T0-2	N0	M0
Stage II	T3	N0	M0
Stage IIIA	T0-2	N1	M0
Stage IIIB	T3	N1	M0
	T0-3	N2	M0
	T4a	N0	M0
Stage IVA	T4a	N1-2	M0
	T4a	NX	M0
	T4b	N0-2	M0
	Any T	N3	M0
Stage IVB	Any T	Any N	M1

ABBREVIATIONS

AC	Adenocarcinoma
EMR	Endoscopic mucosal resection
ESD	Endoscopic submucosal dissection
GP	General Practitioner
IV	Intravenous
MDT	Multidisciplinary Tumor Board
RFA	Radiofrequent ablation
SCC	Squamous cell carcinoma

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