NATIONAL EXPERT-BASED PRACTICE GUIDELINES

COLLEGE OF ONCOLOGY

PANCREATIC ADENOCARCINOMA

Version 1. 2021

Pancreatic 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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NATIONAL GUIDELINES PANCREATIC CANCER

INTRODUCTION

This document provides an overview of the clinical practice guidelines for **pancreatic adenocarcinoma** and covers a broad range of topics such as screening, diagnosis, treatment, supportive therapy, follow-up and the role of the general practitioner (GP). Other pancreatic cancer types (e.g. Pancreatic Neuroendocrine Tumors) will be covered in a separate, upcoming guideline.

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. A first version was published in 2020.. The guidelines were updated in 2021.

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

SEARCH FOR EVIDENCE

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

KCE guidelines 2017 [1], ESMO guidelines 2015 [2] and NCCN guidelines 2019 [3].

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 pancreatic cancer.

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

PANCREATIC CANCER

EPIDEMIOLOGY

Pancreatic cancer was the fourth most fatal cancer in men, after lung, colorectal, and prostate cancers, and in women, after breast, colorectal and lung cancers, in the year 2014.

The Belgian Cancer Registry has registered 1.855 new cases of pancreatic cancer in Belgium for the year 2017, of which 971 men have been diagnosed and 884 women. [4]
Pancreatic cancer usually manifests in elderly patients with a mean age of onset of 70 years old, according to the Belgian Cancer Registry.
The majority of patients with pancreatic cancer progress to either metastatic or locally advanced disease in the asymptomatic phase. [4, 5]
With a life expectancy of 5% after 5 years, the prognosis of this cancer has not improved during the last 20 years. Surgical excision is the definitive treatment with a 5-year survival rate after resection of 20%. However resection is only possible in 15%–20% of the patients.

Defining the treatment strategy for patients suffering from pancreatic 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,… [2]

DIAGNOSIS

- Mass screening for pancreatic adenocarcinoma is not recommended.
- Diagnosis of pancreatic adenocarcinoma should be considered with the presence of the following risk factors:
  adult-onset diabetes without predisposing features or family history of diabetes, jaundice, unexplained pancreatitis, rapid weight loss and unexplained back pain. *(ESMO, NCCN)*
- The use of serum tumor markers as a diagnostic tool is not recommended, however they can be useful in follow-up as a monitoring tool for the effect of treatment.
- High-quality imaging should be performed at presentation and within 4 weeks before surgery. *(NCCN)*
- Sequence of molecular tests to be carried out:
  https://www.compermed.be/activites/workflows#/cancer/35

STAGING

It is recommended that imaging work-up should be performed before biliary stent placement. However a stent can be considered for symptomatic treatment. *(Consensus)*

For radiology rapportage, the use of the Pancreatic Cancer Radiology Reporting Template (PANC-A, 5-8) is recommended according to the NCC guidelines on Pancreatic Adenocarcinoma version 3.2019. *(NCCN)*

High-quality CT scan thorax/abdomen (with arterial and late portal phases) should be performed for complete staging and evaluation of therapeutic strategy. *(ESMO, NCCN, KCE)*
If a CT scan is unable to accurately stage or characterize the extent of disease, a MRI or PET-CT scan may be valuable. *(KCE*
Additionally, in borderline resectable or locally advanced pancreatic adenocarcinoma a MRI and PET-CT scan can be useful as baseline imaging before neoadjuvant therapy. *(Consensus)*

Endoscopic ultrasound (EUS) with fine needle aspiration (FNA) needs to be performed when there is no certainty about diagnosis of primary pancreatic adenocarcinoma. *(Consensus)*
EUS with FNA should be performed for pathology in case of neoadjuvant treatment for borderline resectable, locally advanced potentially resectable pancreatic adenocarcinoma. *(NCCN)*
In case of metastatic pancreatic cancer, EUS with FNA for pathology should be done before the start of systemic treatment.
EUS is not necessary in patients who need to be treated with upfront surgery. *(Consensus)*

In case laparoscopy is considered in resectable pancreatic cancer (e.g. high risk patients, clinical indication), this should preferably be performed during the same anaesthesia as the main surgery. *(Consensus)*
After neoadjuvant therapy for borderline resectable or locally advanced potentially resectable pancreatic cancer, CT scan may not be reliable to evaluate resectability. Consequently, MRI or PET-CT scan should be used to evaluate therapeutic response and resectability.

GENERAL TREATMENT

- A MDT meeting is mandatory for planning of treatment in all pancreatic cancer patients, including metastatic ones.
- During a MDT meeting following items should be discussed and evaluated:
  - The extent of disease and resectability status as defined in table 1 below *(NCCN)*
  - Operability of the patient: cardiac and pulmonary function 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)*
  - Physical, nutritional and mental support should be offered to the patient, when deemed necessary. *(Consensus)*
  - Oncogeriatric evaluation when necessary. *(Consensus)*
  - All available medical relevant information should be reviewed and discussed. *(Consensus)*

Table 1: Resectability status pancreatic adenocarcinoma [6]

Resectability status	Arterial	Venous
Resectable	No arterial contact with CA, SMA, or CHA	No tumor contact with SMV, PV, or ≤180° contact without vein contour irregularity
Borderline resectable	Head/uncinate process: (I) STC with CHA without extension to CA or hepatic artery bifurcation; (II) STC with SMA of ≤ 180°; (III) STC with variant arterial anatomy. Body/tail: (I) STC with the CA ≤180°; (II) STC with the CA >180° without involvement of the aorta and with intact and uninvolved gastroduodenal artery	(I) STC with the SMV or PV >180°; (II) STC ≤180° with contour irregularity or thrombosis of the vein but with suitable vessel proximal and distal to the site of involvement (allowing for safe and complete resection and vein reconstruction); (III) STC with the IVC
Unresectable	Distant metastasis (including non-regional lymph node metastasis). Head/uncinate process: (I) STC with SMA >180°; (II) STC with CA >180°; (III) STC with the first jejunal SMA branch. Body and tail: (I) STC with the SMA or CA >180°; (II) STC with CA and aortic involvement	Head/uncinate process: (I) unreconstructible SMV/PV due to tumor involvement or occlusion (tumor or bland thrombus); (II) contact with most proximal draining jejunal branch into SMV. Body and tail: unreconstructible SMV/PV due to tumor involvement or occlusion (tumor or bland thrombus)

Adapted from Al-Hawary MM, Francis IR, Chari ST, *et al.* Pancreatic ductal adenocarcinoma radiology reporting template: consensus statement of the Society of Abdominal Radiology and the American Pancreatic Association. Radiology 2014;270:248-60 (3) and NCCN (NCCN Guidelines Version 2. 2017. Pancreatic Adenocarcinoma). CA, celiac axis; SMA, superior mesenteric artery; CHA, common hepatic artery; SMV, superior mesenteric vein; PV, portal vein; STC, solid tumor contact; IVC, inferior vena cava.

- In case of therapeutic response or stable disease after neoadjuvant treatment, surgical exploration is recommended. *(Consensus)*
- Pancreatic surgeries have to be performed in nominated reference centres. (*KCE)*
- All fit patients are encouraged to be included in prospective clinical trials. *(Consensus)*

LOCALIZED RESECTABLE PANCREATIC CANCER

Patients with localized resectable pancreatic adenocarcinoma *(as defined in Table 1)* should be offered upfront surgical resection as standard and the only potentially curative treatment.

The main goal of surgery is to achieve tumor-free (R0) resection margins. Ongoing and future prospective clinical trials show increasing interest in neoadjuvant treatment for resectable pancreatic adenocarcinoma. But currently, neoadjuvant treatment is not a standard recommendation. *(NCCN)* Fit patients should be offered the option to take part in these clinical trials.

The location and the size of the tumor determines the type of surgery:

- Head and uncinate process: pancreaticoduodenectomy.
- Body and tail: distal pancreatectomy with en bloc splenectomy. *(ESMO, NCCN)*
- In germline BRCA mutant cancers a total pancreatectomy should be considered. *(Consensus)*

Lymphadenectomy should be performed as the resection of locoregional and coeliac trunk lymph nodes, and should involve the removal of at least 12 lymph nodes to allow adequate pathological staging. *(UICC-TNM)*

In jaundiced patients with localized resectable pancreatic cancer, upfront surgery without biliary drainage is preferred above pre-operative biliary drainage. The placement of a plastic or metallic biliary stent can be considered, in case of jaundice but this should be evaluated and decided during the MDT meeting or at the multidisciplinary consult (MC). The covered stent should be placed with the proximal edge below the biliary bifurcation at the liver hilum, in order to allow a safe biliodigestive anastomosis at the time of surgery. *(NCCN)*

Adjuvant systemic chemotherapy should be given to all patients after surgical resection, if fit and well recovered from surgery. The recommended duration of adjuvant chemotherapy is 6 months. Treatment with FOLFIRINOX is preferred above Gemcitabine. (*NCCN*)
In less fit and elderly patients Gemcitabine can be considered as an option. Adjuvant treatment should start as soon as the patient is recovered, ideally within 2 months after surgery, but not later than 3 months.

Adjuvant radiotherapy is generally not recommended, but can be considered in case of R1-resection in addition to chemotherapy. This should be discussed during a postoperative MDT meeting.

BORDERLINE RESECTABLE NON-METASTATIC PANCREATIC CANCER

Neoadjuvant systemic chemotherapy should be given in patients with borderline resectable pancreatic adenocarcinoma.
The recommended duration of neoadjuvant chemotherapy is 2 months.
Treatment with FOLFIRINOX is preferred above Gemcitabine with Nab-Paclitaxel *(currently only reimbursed for metastatic treatment).* (*NCCN)*
Neoadjuvant (chemo) radiotherapy, including stereotactic body radiotherapy, following neoadjuvant chemotherapy might improve R0 resectability rates.

Evaluation of resectability after neoadjuvant chemotherapy should be done with CT scan thorax/abdomen together with MRI or PET-CT scan, as used before the start of neoadjuvant therapy *(as defined in Table 1)*,. (*NCCN)*

Adjuvant systemic chemotherapy should be given to all patients after surgical resection of borderline resectable pancreatic adenocarcinoma.
The recommended duration of adjuvant chemotherapy is 4 months.
The overall duration of systemic chemotherapy is recommended to cover a period of 6 months in total. *(Consensus)*
Treatment with FOLFIRINOX is preferred above Gemcitabine with Nab-

Paclitaxel as adjuvant systemic chemotherapy, and is based on response after neoadjuvant chemotherapy. (*Consensus)*
Adjuvant radiotherapy can be considered in case of R1-resection. This should be evaluated and decided during the postoperative MDT meeting. *(ESMO)*

LOCALLY ADVANCED UNRESECTABLE NON-METASTATIC PANCREATIC CANCER

The management of patients with locally advanced unresectable non-metastatic pancreatic cancer *(as defined in Table 1)*, should be discussed during a MDT meeting. (*Consensus)*

Locally advanced unresectable non-metastatic pancreatic adenocarcinoma should be treated with systemic chemotherapy. Treatment with FOLFIRINOX is preferred above Gemcitabine with Nab-Paclitaxel as systemic chemotherapy in fit patients (however only reimbursed only in metastatic setting). Consolidating (chemo) radiotherapy, including stereotactic body radiotherapy, can contribute to a delay or prevention of local progression. Hence, preventing pain and/or obstructive symptoms. Any other treatment modality, such as local ablation, or immunotherapy should be preferably done in clinical trial setting. (*Consensus)*

High-quality imaging every 2 months is recommended to evaluate the response to systemic therapy and potential resectability.
In case a patient becomes resectable, surgery should be considered followed by adjuvant systemic chemotherapy. (*Consensus)*

RESECTABLE PANCREATIC CANCER WITH OLIGOMETASTASES

Oligometastatic disease is defined as less than five metastases in only one organ. Although surgery is not recommended for metastatic disease in pancreatic cancer, it might have a role in highly selected patients, as does stereotactic body radiotherapy.
The management of the resectability of patients with pancreatic cancer with oligometastases should be discussed during a MDT meeting. *(Consensus)*

METASTATIC PANCREATIC CANCER

Metastatic pancreatic cancer should be treated with systemic chemotherapy. The decision about the type of first line systemic chemotherapy, i.e. FOLFIRINOX or Gemcitabine with Nab-Paclitaxel, is recommended to be discussed and decided during a MDT meeting and with the patient in view of the patient's general condition, organ function and expectations.

After progression, the patient can be considered for the next line of treatment such as 5-FU with Leucovorin and liposomal irinotecan. *(NCCN)*

Endoscopic management of symptoms is preferred above surgical palliation. Radiotherapy can be applied for palliative purposes such as relieving pain, bleeding or obstructive symptoms.
Palliative care should be focused on comfort, nutrition and quality of life. *(ESMO, NCCN)*

LOCAL RECURRENCE OF RESECTED PANCREATIC CANCER

Surgical resection of locoregional recurrence of resected pancreatic cancer is not recommended. In case of limited local recurrence without metastases, surgery with or without neoadjuvant therapy can be considered and should be discussed during a MDT meeting, or take place within a clinical trial setting. *(ESMO, NCCN)*

Recurrent pancreatic cancer should be treated with systemic chemotherapy. The decision about the type of systemic chemotherapy is recommended to be taken during a MDT meeting. *(Consensus)*

Patient preferences should always be taken into account with regard to nutrition and pain assessment. *(Consensus)*

SUPPORTIVE TREATMENT

Consensus guidelines:

- A three-step approach of pain drug administration (WHO analgesic ladder) should be followed in patients with pain associated with pancreatic cancer.
- Patients with pancreatic cancer should be offered specific psychological support from professionals belonging to the multidisciplinary team.

FOLLOW-UP

Follow-up should concentrate on symptom assessment, combination of CA19-9 and CEA serum tumor marker *(NCCN, KCE)*, history, physical examination, nutrition and psychosocial support.

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)*

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 pancreatic adenocarcinoma should have access to a multidisciplinary cancer reference team for information and support at every stage of diagnosis, treatment and follow-up. *(Consensus)*
- 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. Timely referral is necessary. *(Consensus)*

Communicating the diagnosis

- The GP shall be promptly informed about the diagnosis of pancreatic adenocarcinoma, 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 pancreatic 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)*

TNM CLASSIFICATION [7]

Primary tumor (*T*)		Regional lymph nodes (*N*)		Distant metastases (M)	
*T*1	Maximum tumor diameter ≤2 cm	*N*0	No regional lymph node metastasis	M0	No distant metástasis
*T*2	Maximum tumor diameter >2 cm but ≤4 cm	*N*1	Metastasis in 1–3 regional lymph nodes	M1	Distant metastasis
*T*3	Maximum tumor diameter >4 cm	*N*2	Metastasis in ≥4 regional lymph nodes		
*T*4	Tumor involves the celiac axis or the superior mesenteric artery (unresectable primary tumor)				

Stage			
Stage 1A	*T*1	*N*0	M0
Stage 1B	*T*2	*N*0	M0
Stage 2A	*T*3	*N*0	M0
Stage 2B	*T*1–*T*3	*N*1	M0
Stage 3	Any *T*	*N*2	M0
	*T*4	Any *N*	
Stage 4	Any *T*	Any *N*	M1

PANC-A 5-8: RADIOLOGY REPORTING TEMPLATE [3]

PRINCIPLES OF DIAGNOSIS, IMAGING, AND STAGING
PANCREATIC CANCER RADIOLOGY REPORTING TEMPLATE[c]

Morphologic Evaluation			
Appearance (in the pancreatic parenchymal phase)	☐ Hypoattenuating	☐ Isoattenuating	☐ Hyperattenuating
Size (maximal axial dimension in centimeters)	☐ Measurable	☐ Nonmeasurable (isoattenuating tumors)	
Location	☐ Head/uncinate (right of SMV)	☐ Body/tail (left of SMV)	
Pancreatic duct narrowing/abrupt cutoff with or without upstream dilatation	☐ Present	☐ Absent	
Biliary tree abrupt cutoff with or without upstream dilatation	☐ Present	☐ Absent	

PANCREATIC CANCER

Arterial Evaluation				
SMA Contact	☐ Present	☐ Absent		
Degree of solid soft-tissue contact	☐ ≤180	☐ >180		
Degree of increased hazy attenuation/stranding contact	☐ ≤180	☐ >180		
Focal vessel narrowing or contour irregularity	☐ Present	☐ Absent		
Extension to first SMA branch	☐ Present	☐ Absent		
Celiac Axis Contact	☐ Present	☐ Absent		
Degree of solid soft-tissue contact	☐ ≤180	☐ >180		
Degree of increased hazy attenuation/stranding contact	☐ ≤180	☐ >180		
Focal vessel narrowing or contour irregularity	☐ Present	☐ Absent		
CHA Contact	☐ Present	☐ Absent		
Degree of solid soft-tissue contact	☐ ≤180	☐ >180		
Degree of increased hazy attenuation/stranding contact	☐ ≤180	☐ >180		
Focal vessel narrowing or contour irregularity	☐ Present	☐ Absent		
Extension to celiac axis	☐ Present	☐ Absent		
Extension to bifurcation of right/left hepatic artery	☐ Present	☐ Absent		
Arterial Variant	☐ Present	☐ Absent		
Variant anatomy	☐ Accessory right hepatic artery	☐ Replaced right hepatic artery	☐ Replaced common hepatic artery	☐ Others (origin of replaced or accessory artery) _____
Variant vessel contact	☐ Present	☐ Absent		
Degree of solid soft-tissue contact	☐ ≤180	☐ >180		
Degree of increased hazy attenuation/stranding contact	☐ ≤180	☐ >180		
Focal vessel narrowing or contour irregularity	☐ Present	☐ Absent		

PANCREATIC CANCER

Venous Evaluation			
MPV Contact	☐ Present	☐ Absent	☐ Complete occlusion
Degree of solid soft-tissue contact	☐ ≤180	☐ >180	
Degree of increased hazy attenuation/stranding contact	☐ ≤180	☐ >180	
Focal vessel narrowing or contour irregularity (tethering or tear drop)	☐ Present	☐ Absent	
SMV Contact	☐ Present	☐ Absent	☐ Complete occlusion
Degree of solid soft-tissue contact	☐ ≤180	☐ >180	
Degree of increased hazy attenuation/stranding contact	☐ ≤180	☐ >180	
Focal vessel narrowing or contour irregularity (tethering or tear drop)	☐ Present	☐ Absent	
Extension	☐ Present	☐ Absent	
Other			
Thrombus within vein (tumor, bland)	☐ Present ☐ MPV ☐ SMV ☐ Splenic vein	☐ Absent	
Venous collaterals	☐ Present ☐ Around pancreatic head ☐ Porta hepatis ☐ Root of the mesentery ☐ Left upper quadrant	☐ Absent	

PANCREATIC CANCER

Extrapancreatic Evaluation		
Liver lesions	☐ Present ☐ Suspicious ☐ Indeterminate ☐ Likely benign	☐ Absent
Peritoneal or omental nodules	☐ Present	☐ Absent
Ascites	☐ Present	☐ Absent
Suspicious lymph nodes	☐ Present ☐ Porta hepatis ☐ Celiac ☐ Splenic hilum ☐ Paraaortic ☐ Aortocaval ☐ Other_____	☐ Absent
Other extrapancreatic disease (invasion of adjacent structures)	☐ Present • Organs involved: _____	☐ Absent
Impression		
	Tumor size: _____	Tumor location: _____
Vascular contact	☐ Present • Vessel involved: _____ • Extent: _____	☐ Absent
Metastasis	☐ Present (Location _____)	☐ Absent

ABBREVIATIONS

BRCA	Breast cancer
CA 19-9	Carbohydraatantigen 19-9
CEA	Carcino-embryonaal antigen
GP	General Practitioner
MDT	Multidisciplinary Tumor Board

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