

CANCERS OF THE OESOPHAGUS

PREFERRED MODEL OF CARE AND CRITERIA FOR REFERENCE CENTRES

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A. Type of cancer

Cancer of the Oesophagus (this definition includes gastro-oesophageal junction cancer according to the TNM staging manual 7th edition)

B. Short description of the cancer

In Belgium, cancer of the oesophagus and gastro-oesophageal junction is diagnosed in approximately 1 200 patients per year. In 2010, the age-adjusted incidence rate of oesophageal cancer was 10.4 per 100 000 person years in males, and 2.9 per 100 000 person years in females (Belgian Cancer Registry, 2012).

Its incidence has increased substantially over the last 3 decades and is expected to continue to rise in particular for adenocarcinoma, given the well-known association with Barrett metaplasia. Presenting symptoms are rather aspecific and late in the development of the disease. As a result, the disease is often diagnosed in an advanced stage. Five-year overall survival of all diagnosed patients is low, around 10-15%.

However, more recently improved diagnostic and staging techniques, including advanced endoluminal procedures, have shown a positive impact on the therapeutic strategies and related outcome. Surgery is the mainstay of the treatment with curative option. Acknowledged as one of the most complex surgeries, oesophageal surgery is increasingly performed in a setting of multimodality therapy, i.e. in combination with chemotherapy +/- radiotherapy. Also in the palliative setting, progress has been made with an increasing beneficial impact of endoluminal interventional techniques +/- systemic therapy and/or radiotherapy.

As a result, cancer of the oesophagus and gastro-oesophageal junction requires expertise and a dedicated care pathway to provide the highest quality of care to the patients.

C. Model of care pathway suggested for adult patients with an oesophageal cancer

Model of care pathway	Preferred model
1. <u>Model 1: Reference Centres exclusively (from diagnosis to follow-up)</u> . Once there is a suspicion of the oesophageal cancer A or oesophageal cancer has been diagnosed, the patient should be referred to a Reference Centre. A network with other Reference centres or with specific experts working in other centres is encouraged.	
2. <u>Model 2: Shared care between Reference Centres and peripheral hospitals</u> . Part of the care pathway is performed in the Reference Centre and for another part of the care pathway, the patient is referred (back) to the peripheral hospital.	X



D. Phase(s) of the clinical pathway for which Reference Centres are required

Phase of the Clinical Pathway	Reference Centre	Peripheral centre
MOC	X	X
Diagnostic confirmation and clinical TNM staging	X	X
Therapeutic modalities	X	**
Follow-up	X	X

Multidisciplinary Oncological Consult

All newly diagnosed patients with oesophageal Cancer (OC) are to be discussed at MOC. This MOC can take place at a Peripheral Centre but in such case has to be linked to a second opinion MOC at RC. At this second opinion MOC, all involved care disciplines have to take part i.e. pathologists, imaging specialists, endoscopists/gastroenterologists, oncologists, radiation oncologists, surgeons, all with sufficient expertise in diagnosis and therapy of OC. Paramedical professionals involved in the diagnostic and therapeutic work-up are encouraged to attend the MOC.

Diagnostic confirmation and staging

- Complexity and new approaches
 - Can be performed in a Peripheral Centre: i.e. endoscopy and biopsy, CT, PET/CT, echography, barium swallow. Digitalised imaging that can be edited has to be available at RC second opinion MOC. When deemed necessary, a diagnostic test can be repeated at RC.
 - To be performed in RC only: new technologies and techniques such as endoluminal manipulation/instrumentation (e.g. Endoscopic mucosal resection –EMR– and endoscopic submucosal dissection –ESD–) and interventional imaging (e.g. specific CT guided diagnostic procedures, EUS guided FNA, specific surgical diagnostic procedures).
- Facilities and equipment required
 - Endoluminal equipment
 - Specialised imaging techniques
- Professional expertise required both to perform the diagnostic procedure and to interpret the results:
 - Familiarity with endoluminal /instrumentation – radiological interventional techniques, diagnostic surgeries with specific reference to OC

Comprehensive diagnosis and staging

- Specimens when deemed necessary (e.g. high grade dysplasia, pT1a – EMR/ESD) have to be reviewed by an expert pathologist in RC
- Use of emerging new technologies and techniques (e.g. EMR/ESD, EUS guided FNA)



Therapeutic modalities

- Complexity:
 - o Sufficient experience can only be obtained if therapy is centralised in RC: organ saving techniques (e.g. EMR/ESD), new surgical techniques (e.g. vagal sparing oesophagectomy), new protocols using e.g. existing therapeutic modalities, second line chemotherapy, experimental chemotherapeutic agents and/or biologicals, clinical trials.
 - o **Procedures classified as local care may be delivered locally but only after discussion at the multidisciplinary team in RC and subject to agreement in network clinical guidelines.
- Facilities and equipment required:
 - o RC has to be a one single, one campus located
 - o Radiation oncology: 2 linear accelerators ranging from 6 – 15 Mv with on board imaging; appropriate immobilisation devices, IMRT, brachytherapy, PET/CT
 - o Dedicated Intensive Therapy Unit
 - o Patients are to be clustered in an identifiable OC surgical dedicated sector, including surgical ward, and looked after by a OC specialised dedicated multidisciplinary medical and paramedical team
 - o Simultaneous combination therapies e.g. chemotherapy + concurrent radiotherapy are to be performed in the same centre.
- Expertise required to perform the treatment
 - o Sufficient experience can only be obtained if therapy is centralised in RC.
- Para-medical expertise required:
 - o Dedicated paramedical team including nursing in different areas of diagnostic & therapeutic aspects, physiotherapists, speech therapists, dieticians, oncurses, data managers, psychologists...

Follow-up

- Specific situations require referral to RC (e.g. follow-up of clinical trials, surgical complications, recurrent disease (new MOC mandatory), EMR/ESD follow-up, nutritional issues, toxicity and side effects of multimodal therapy).



E. General and specific criteria for Reference Centres

Human Resources and dedicated team

- *Specialized staff*

Involved specialties are: radiology, nuclear medicine, pathology, endoscopy and interventional endoscopy, radiation oncology, medical/GI oncology, surgery, anaesthesiology and intensive care, pain clinic.

Within each involved specialty, at least one colleague with a special focus on oesophageal cancer has to be identified as an expert in oesophageal cancer. This colleague is taking on the responsibility for all oesophageal cancer issues related to his/her specialty including scientific and educational activities, quality issues and quality assurance, patient centred aspects, and is representing the involved specialty at the second opinion MOC.

- *Multidisciplinary management*

Besides the involved medical specialties, multidisciplinary includes a wide spectrum of paramedical professions, e.g. dieticians, physiotherapists, speech therapists, dosimetrists, physicists, psychologists, oncurses, lab technicians, data nurses and data managers, nursing staff and technologists in different diagnostic and therapeutic segments. All of these professions should designate within their group individuals with a special focus on oesophageal cancer related issues.

Required facilities and equipment

- Options for multidisciplinary consultation (both inpatient and outpatient) should be available
- Audiovisual equipment (e.g. webcam, tele-pathology) is essential
- IT infrastructure for adequate data registration
- Fully integrated electronic medical file
- Surgery: infrastructure for major thoraco/abdominal surgery and related anaesthesiology infrastructure on one campus located facility
- Dedicated Intensive Therapy Unit: patients are to be clustered in a identifiable oesophageal cancer surgery dedicated sector and looked after by EC specialised dedicated nursing staff and intensivists
- On the ward, in particular the surgical ward, the patients are to be clustered in a identifiable oesophageal cancer surgery dedicated sector and looked after by a in oesophageal cancer specialised dedicated nursing staff
- Radiotherapy: 2 linear accelerators ranging from 6 – 15 Mv with on board imaging; appropriate immobilisation devices, IMRT, brachytherapy. Restrict radiotherapy to recognised centres (no referral to satellite centres). Combination therapy (e.g. concurrent radiochemotherapy) has to be administered in one single centre
- Chemotherapy: Restrict chemotherapy to recognised centres for oncologic care
- Interventional imaging PET/CT scan, MRI, High resolution CT
- Collaboration with a reference laboratory for pathology: access to tumour bank, access to molecular biology techniques/technologies



- Other: access to rehabilitation programs
- Facilities to organise and conduct high quality clinical trials

Patient centred care

- Time line:
- Maximum 2 weeks from index endoscopy to 1st MOC
- Maximum 2 weeks between 1st and second RC MOC
- Maximum 2 months between diagnosis and initiation of therapy as decided at the RC MOC
- Maximum 4 weeks between RC MOC and initiation of therapy
 - General practitioner to be involved in every major step of the diagnostic and therapeutic process
 - Continuity of care (care covered 7 days a week by specialised staff, agreements concerning the continuity of care...)
 - Support services for the patient (identification of a care coordinator, support for patient information (e.g. informative flyers on cancer of the oesophagus))
 - Shared care: formal links with collaborative centres (Consideration of E-Health solutions, e.g. shared case management systems, expert systems for tele-expertise and shared repository of cases)
 - For the patient: freedom of choice of his/her treating specialist team and this without any negative financial impact for the patient

Minimal volume of patients

- The work-up towards minimum volumes is time-consuming and is to be seen as a proactive process as it will require the set-up of effective collaboration between the clinical network centres. It is assumed that this process will require a time frame of at least 3 years
- At that time point the minimum hospital volume (taking into account the actual numbers of newly diagnosed patients in Belgium) is 50 new patients/year as registered in the RC MOC
- Within the same context, minimum volume of oesophagectomies for oesophageal cancer is 12/year
- Volume will be linked to quality and quality assurance aspects in order to obtain the accreditation of RC (see point 5)
- These volume criteria are to be re-evaluated and adjusted after another time slot of 3 years

Quality Assurance

- All new patients presenting with oesophageal cancer have to be registered in a registry that will be peer-reviewed and centrally controlled
- Annual activity report ensuring transparency: i.e. containing information on number of new diagnoses, type and location of tumour, comprehensive diagnosis and MOC report, therapeutic protocol and strategy
- Capacity to propose quality indicators (structure, process, outcomes)
 - Measurement of quality indicators proposed by the KCE report 200



- o Curative resection rates for oesophageal cancer
- o Outcome: 90 days mortality after surgery <5%
- o Measurement of 1 and 5-year survival outcomes after surgery or other types of radical treatment, adjusted for the case-mix
- o Number of second opinions
- o Specific protocols for reporting and recording complications
- Exhaustive and reliable information sent to Belgian Cancer Registry
- Compliance with existing guidelines and documentation of deviations from guidelines
- Involvement in quality initiatives (e.g. benchmarking)

Research and other scientific activities

- Involvement in clinical studies (RCTs, cohort studies, translational studies), participation rate in clinical trials
- Publications in peer-reviewed journals
- Link with a tumour bank
- Development of clinical practice guidelines for diagnosis and care

Educational activities: Teaching and dissemination

- Interdisciplinary training
- Training of future experts in oesophageal cancer should involve a dedicated period in a high volume oesophageal cancer centre. In particular for surgeons, one year in a centre with a high volume i.e. >30 oesophagectomies/year
- Tutorship
- Training personnel, specialists
- Organisation / communication in scientific congresses

Additional comments

All above requires an engagement from the responsible health care authorities to provide sufficient funding. Especially, funding for second opinion in expert pathology and radiology is mandatory as well as the funding of the organisational aspects (e.g. the mandatory second opinion MOC, the logistics related to the influx of an increased volume in the RC).