

Esophageal surgery in Italy. Criteria to identify the hospital units and the tertiary referral centers entitled to perform it

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Abstract Esophageal cancer incidence is rapidly increasing in the western countries. Adenocarcinoma has recently become the most frequent subtype because of the changes in lifestyle. As observed for other types of surgery, even for esophageal surgery better results have been observed in centers with high volume of activity. Countries with formal policies of centralization, as Great Britain and The Netherlands, have got lower mortality and longer survival than those obtained before the centralization program introduction and of those countries without centralization programs. However, concerns about accessibility to high volume hospitals for lower level social strata have emerged in different countries. In Italy most of the esophagectomies for cancer are performed in very low volume centers with limited experience. High volume centers with >20 cases/year are few but, even if managing patients with more severe comorbidities have got a lower mortality and a shorter length of stay. The Aim of this paper is to identify the organizational, structural and volume requirements for accreditation of a center as an esophageal surgery center. Special attention must be given to a multidisciplinary approach involving different highly skilled specialists with the creation of a multidisciplinary team and individualized diagnostic and therapeutic pathways.

Keywords Esophageal cancer · Esophagectomy · Volume outcome · High volume hospitals · Centralization

Introduction

Esophageal tumor ranks eighth in frequency and sixth in mortality among all cancers worldwide [1–3]. Adenocarcinoma and squamous cell carcinoma are the most frequent subtypes, accounting for 98 % of all esophageal tumors [4]. In recent years, there has been a change in the main histologic subtype of esophageal cancer, with a rise in the incidence of adenocarcinoma, probably due to different lifestyles [5]. Adenocarcinoma is more frequent in western countries as a result of an increase in the prevalence of gastroesophageal reflux disease and obesity, while squamous cell cancer is more frequent in eastern countries, reflecting alcohol and tobacco abuse [3]. Despite the improvement in techniques and perioperative care strategies to manage esophageal tumors, esophagectomy is the mainstay of therapy but it remains a demanding procedure associated with a high rate of complications and perioperative mortality. Moreover, prognosis is still poor with an overall 5 year-survival ranging from 20 to 30 % [6, 7] notwithstanding improvements due to multimodal treatment modalities. Promising results are emerging with the introduction of minimally invasive surgery. Even if minimally invasive esophagectomy represents a challenging procedure for well skilled surgeons too, it seems to provide better results in terms of blood loss, respiratory complications and length of stay, without oncological outcome jeopardy [8, 9]. Concentration of cases in referral centers seems to be the most valuable option to offer high level of care to these patients.

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Hospital volume

Since 1979, a relationship between high volume hospital and outcome has been demonstrated in complex surgical procedures [10]. Some studies in the literature examined the correlation between high volume centers and esophageal cancer surgery by analyzing different health care systems in Europe, USA, and in the Eastern countries, demonstrating a lower surgical mortality in high volume (2.8–5 %) compared to low volume centers (8.4–13 %) [11–14]. Furthermore, lower complication rate and length of hospital stay, as well as an improvement in the overall survival have been demonstrated in high volume hospitals [12]. A political decision to centralize care for the most complex surgical interventions has been adopted in some countries, such as the United Kingdom, and the results of this formal policy have highlighted the importance of concentrating cases in high volume centers to achieve the best quality of care. These results about volume were also confirmed in other countries, such as the United States, where no formal centralization process has been undertaken. An interesting study by Munasinghe et al. compared the difference in in-hospital mortality and length of hospital stay after esophagectomy in UK and USA, two countries with extremely different health systems, over the period 2005–2010. Globally, in-hospital mortality was greater in US hospitals; but, when analysis was done on high volume centers only, results were comparable between the two countries. The authors demonstrated also that surgery in low volume hospital was a predictor of mortality [15]. In Canada as well, a formal policy of centralization of esophageal cancer surgery determined a reduction in perioperative mortality rate from 9.1 to 3.6 % and a 38 % reduction in hospital stay [13]. In the Netherlands, the length of hospital stay decreased from 21 to 17 days, the in-hospital mortality fell from 14.3 to 4.7 %, and 2-year overall survival improved significantly, after the introduction of a formal policy of centralization [16].

Despite positive results due to centralization of complex surgical procedures, improvements are not comparable in all population strata. Prevailing disparities exist according to several patient and sociodemographic characteristics for utilization of high volume hospitals. In the United States, Caucasians with private insurances are more likely to receive surgery at high volume hospitals, than African Americans, Hispanics, or public-insured patients [17]; this might be caused by different possibility of access to top level institution among different insurances.

The same scenario is present in South Korea, where elderly or patients with low salary or living in rural areas are more likely to receive treatment in low volume hospitals [14]. Even in UK, although a public health system is

present, patients with high Multiple Deprivation Index are more likely to be treated at low volume hospitals, than patients with higher income [18].

One of the most debated topics is the correct definition of high volume hospital. To determine the “cut off” value, some studies have addressed this issue [11, 19, 20]. Heneman et al. [19] showed that in The Netherlands, increasing annual hospital volume was associated with a directly proportional decrease in mortality up to 40–60 esophagectomies/year, after which a plateau was reached. A wide retrospective study in the United States [20] on 4080 esophageal resections for cancer over the period 1998–2005 supported the cut off value of 15 esophagectomies/year to define a high volume center. Other authors supposed that results improve, increasing the volume of activity without a plateau effect [11]. Currently, the shared cut off value to define a high volume center is 20 esophagectomies/years.

High volume hospitals guarantee the gold standard of care by means of continuously updated diagnostic and therapeutic tools, high quality multidisciplinary staff entering in the patients care process, and a good structural organization. In the 2000s, the UK developed the centralization of care by means of the National Health Service (NHS) Cancer Plan. Hospitals were organized in 30 cancer networks; each network has a referral center. Although the process of reorganization is not yet completed and regional differences exist, integration of diagnostic and therapeutic approaches and multidisciplinary teams provided a 7 % increase in overall survival from 1998 to 2005 [21].

In Italy no formal policy of centralization exists and generally esophagectomy is widespread among the country. According to PNE-AGENAS data, in 2014, 161 hospitals, with a median of two esophagectomies/year, performed 764 esophagectomies; 133 hospitals treated 1–5 esophagectomies/year; only eight centers performed more than 15 esophagectomies/year. In Lombardy, over the period 2005–2011, 2,801 esophagectomies were performed, 67 % in centers with <20 esophagectomies/year. The results showed a statistically significant relation between reduction of mortality rate and number of resections performed in low (≤ 7), intermediate (7–20), and high (> 20) volume centers: mortality was 5.7, 2.6, and 1.7 %, respectively. Median length of stay was 20 days in high volume hospitals and more than 25 days in low volume centers, despite major comorbidities in patients treated at high volume hospitals [22]. In Italy, centralization of care is needed, to improve management and survival of esophageal cancer patients. This is a process that cannot be left to the single patient initiative to find the best center, but should be structured by scientific society and the national healthcare system.

The Aim of this work is to identify the basic standards needed for a surgical unit to obtain the accreditation to perform esophageal surgery.

Esophageal surgery center accreditation

Each surgery unit wishing to obtain accreditation as esophageal surgery center should satisfy the following requirements.

Structural requirements

The hospital must have structural requirements defined for first level hospitals, as identified by the law 135/2012. Particularly the hospital must be able to guarantee:

- Endoscopy with high definition endoscopes and instruments; possibility to perform operative endoscopy and EUS
- Radiology with US, TC, MRI, PET and interventional Radiology
- Pathology
- Intensive care unit
- Oncology
- Radiotherapy
- Minimally invasive equipped operating rooms
- Otolaryngology
- Physiotherapy.

Operative endoscopy and interventional radiology must be available on a 24 h basis while some of the facilities such as PET, Radiotherapy, Oncology, should be available even in a sort of hospital network with easy access.

The hospital medical staff must include: surgeons, gastroenterologists performing operative endoscopy, radiologists and interventional radiologists, pathologists, anesthesiologists and intensivists, oncologists, radiotherapists, nutritionists, otolaryngologists; eventually available on an hospital network there should also be psychologists,

infectologists, pulmonologists, palliative care specialists. Among the paramedical staff, physiotherapists and dedicated nurse are of the utmost importance.

Volume requirements

On the basis of the previously presented data, each surgical division (not the whole hospital), should carry out a minimum of 20 esophagectomies/year with a mortality rate of <5 % to ensure adequate levels of safety. Centers performing 20–50 esophagectomies/year will be defined “High Volume Center” and those performing >50 esophagectomies/year “Very High Volume Center”.

Diagnosis and procedures necessary for the accreditation will be identified according to the ICD-9-CM classification (Table 1).

Organizational requirements

The hospital must organize specific diagnostic-therapeutic pathways (DTP) for esophageal cancer patients. This pathway must be designed by a multidisciplinary team (MDT) and then tailored for each single patient according to his needs. The MDT that has to validate the DTP might eventually include specialized experts on a network basis.

The multidisciplinary team (MDT) meetings the MDT must be composed by a surgeon, an oncologist, a radiotherapist, a radiologist, a gastroenterologist, and a pathologist; a specialist in nuclear medicine is also recommended. The MDT must have competence to evaluate patients and diseases. Each medical consultation shall provide a written medical report. The MDT meeting has to be planned periodically (possibly weekly), in-hospital or in a hospital network.

Job description physicians must have expertise and qualification in esophagology. Each physician will have a specific assignment.

Clinical responsibility a clinical supervisor (CS) for each patient must be identified and will be the referral

Table 1 Diagnosis and procedures according to ICD-9-CM classification

Diagnosis	Procedure
150.0 Malignant neoplasm, cervical esophagus	42.40 Esophagectomy
150.1 Malignant neoplasm, thoracic esophagus	42.41 Partial esophagectomy
150.2 Malignant neoplasm, abdominal esophagus	42.42 Total esophagectomy
150.3 Malignant neoplasm, upper third of the esophagus	43.9 Total gastrectomy
150.4 Malignant neoplasm, middle third of the esophagus	43.91 Total gastrectomy with intestinal interposition
150.5 Malignant neoplasm, lower third of the esophagus	
150.8 Malignant neoplasm, other specified part of esophagus	
150.9 Malignant neoplasm of esophagus, unspecified site	
151.0 Malignant neoplasm, cardia	

doctor for the patient. He is responsible to organize and accurately disclose DTP steps to the patient.

Diagnostic phase the CS guarantees the correct pathway and timing of exams for staging and treatment plans. The diagnosis and staging should be completed within 2–4 weeks from the diagnosis. Dedicated sessions for pre-operative work-up should be provided. In case of urgent situations (i.e. severe dysphagia) the diagnostic pathway should be hastened and therapeutic procedures, such as feeding jejunostomy/gastrostomy or endoscopic stenting, should be rapidly available.

Multidisciplinary approach after diagnosis and staging, each case must be discussed by the MDT to establish a personalized therapeutic pathway. If necessary, other experts can get involved (i.e. otolaryngologist in case of pharyngeal cancer). Multidisciplinary discussions will be held at the end of staging, after neoadjuvant treatment, after surgery, after adjuvant therapy, and during follow-up, if needed.

Diagnostic and operative endoscopy must be available in the hospital and meet standard levels of appropriateness; the service must be available 24 h a day, in case of emergency. In case of suspected or confirmed neoplasia, the endoscopist must address the patient to subsequent examinations.

Diagnostic radiology must be available in the hospital and meet standard levels of appropriateness; the service must be available 24 h a day in case of emergency, together with a service of interventional radiology.

Diagnostic pathology must be available at least during all working hours, and must carry out molecular analysis, if indicated. In ambiguous cases, a second opinion must be provided.

Surgery is intended as a “Patient-Centered Care”. The development and application of a perioperative program, such as ERAS (enhanced recovery after surgery) protocols, are recommended. Primary surgery will be done within 30 days from diagnosis. In case of neoplasia submitted to neoadjuvant treatment, restaging must be done 4–6 weeks after treatment and surgery must be performed 2–4 weeks after restaging. In cases of early lesions or patients not suitable for neoadjuvant treatments, primary surgery too must be discussed by MDT.

For each surgical patients a risk assessment will be performed. In addition to standard examinations, all patients must be evaluated in terms of respiratory function and submitted to respiratory physiotherapy, such as Pre-operative Inspiratory Muscle Training. Furthermore, nutritional risk assessment and eventual preoperative nutritional support (such as preoperative immunonutrition, feeding naso-enteral tube or jejunostomy) must be provided. At the pre-operative surgical evaluation the patient will be extensively informed about surgery.

Surgeon must be skilled in esophageal, gastric, colorectal, and cervico-thoracic surgery and must be able to perform: esophagectomy with cervical or intrathoracic esophago-gastroplasty, transhiatal esophagectomy, esophagectomy with esophago-coloplasty, esophago-gastrectomy with abdominal or intrathoracic esophago-jejuno-plasty or esophago-coloplasty, pharyngo-laryngo-esophagectomy with pharyngo-gastroplasty or pharyngo-coloplasty (if needed in collaboration with otolaryngologist or plastic/reconstructive surgeon). Surgeon must be able to use orthotopic, retrosternal and subcutaneous route of reconstruction. If indicated, minimally invasive procedures could be performed.

Anesthesia and analgesia: dedicated anesthesiologists will work together with surgeons with intraoperative guidelines are as follows: Goal Directed Fluid Therapy, use of blended anesthesiologic techniques with epidural administration of drugs, hemodynamic monitoring, maintenance of normothermia, early extubation of the patient at the end of anesthesia, management of the patient at the end of anesthesia. Access to intensive care unit should be reserved only in selected cases. Management of postoperative analgesia by means of thoracic epidural catheter or patient controlled epidural analgesia (PCEA).

A written protocol must be provided. A dedicated team with nurses and physiotherapists will mobilize patients according to motor and respiratory rehabilitation protocols. Planned bronchial toilette with fiberscope is recommended for the first postoperative days.

Surgeon must manage postoperative medical or surgical complications, favoring the execution of the diagnostic exams and of the therapeutic procedures, even dealing with other specialists.

Patient will be discharged once discharge criteria will be accomplished. If appropriate, enteral nutrition must be organized at home. Social workers will be contacted to identify rehabilitation structures.

Audit should be periodically scheduled to analyze results, examine coherence with the written protocols, discuss complications in a morbidity-mortality report fashion, and solve eventual problems.

Follow-up the MDT will plan the follow-up according to guidelines, patient’s characteristics and pathologic stage.

How to be entitled to perform esophageal surgery in Italy

To obtain the accreditation, Medical Direction of the Hospital will have to certify structural, organizational, volume, and quality requirements. DTP must be prepared. The Medical Direction will allow regular audits with publication of the results. Requests and confirmations of

accreditation will be evaluated every 6 months. Volume of activity and mortality of each center will be compared with data of the Ministry of Health.

Specific accreditation pathways are established to credit hospitals that do not have expertise. Two different situations have been identified:

1. The hospital lacks the required experience, but acquires an expert esophageal surgeon. The surgeon will have to certify his experience.
2. The hospital lacks the required experience, but expresses the interest in acquiring it. An appropriate training course will be provided by means of a partnership, preferably with a very high volume center, and a mentoring activity shall be planned to certify and wave capability to care esophageal patients locally.

Compliance with ethical standards

Conflict of interest The Authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Statement of human and animal rights This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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