

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

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Received: 5 May 2016 / Accepted: 17 May 2016 / Published online: 9 June 2016
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Abstract Improving the quality and effectiveness of care is a key priority of any health policy. The outcomes of health care can be considered as indicators of effectiveness or quality. The scientific literature that evaluates the association between the volume of activity and the outcome of health interventions has greatly developed over the past decade, but, for practical reasons, ethical and social issues, a few randomized controlled studies were made to evaluate this association, although there are numerous observational studies of outcome and systematic reviews of the studies themselves. The colorectal surgery is the most studied area and it represents the ideal testing ground to determine the effectiveness of the quality indicators because of the high incidence of the disease and the wide spread in the territory of the structures that aim to tackle these issues. Numerous studies have documented an association between the large number of colo-rectal surgical procedures and the quality of results. In particular, the volume of activity is one of the characteristics of measurable process that can have a significant impact on the outcome of health care. In conclusion, the ability to use volume thresholds as a proxy for quality is very tempting but it is only part of reality. Infact, the volume–outcome relationship strictly depends on the type of cancer (colon vs rectum) and it appears somehow stronger for the individual surgeon than for the hospital; especially for the 5-year

overall survival, operative mortality and number of permanent stoma.

Keywords Accreditation · Volumes of surgery · Laparoscopy · Surgical wards · Colorectal surgery

Introduction

The colorectal surgery deals with all those benign or malignant diseases affecting the terminal part of the small intestine, the colon-rectum and anus. The colon-rectum is the union of two organs which, albeit in anatomical–functional continuity, are quite different both from the surgical and the prognostic point of view. Colorectal surgery is not just cancer surgery. The extreme heterogeneity of the diseases treated, however, makes it necessary to narrow the discussion to only cancers because of the relevant socio-economic implications of it and because the studies available makes it an ideal ground for discussion.

Colorectal cancer has the highest occurrence in the Italian population, with nearly 52,000 diagnoses in 2014 (14 % of all new cancers) [1]. In Italy, 113 new cases of colorectal cancer per 100,000 are diagnosed in men and 80 new cases per 100,000 in women. The total number of people who have been diagnosed with colorectal cancer is growing rapidly in both sexes with an average annual increase of 3 % for men and 2 % for women over the last 15 years [2]. The most frequent anatomic location, amounting to about 70–75 %, is at the recto-sigmoid junction.

The colorectal carcinomas, are usually neoplasms with a low malignant potential, especially at older ages. Surgery if performed at an early stage, has excellent healing capabilities. Although the incidence is increasing, mortality

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appears stationary. The survival rate varies depending on the stage in which the disease is diagnosed. The 1 year survival rate in rectal cancer is higher than that of patients with colon cancer (75 and 70 % respectively), while the percentages of survival at 5 years becomes almost the same (51 and 48 %). The percentage of patients alive at 5 years after diagnosis of rectal cancer are, respectively, 85 % for early stages and 40 % for locally advanced stages. About 50 % of all patients diagnosed with colorectal cancer are alive after a period of at least 5 years after the diagnosis of cancer [3].

The number of people who have been diagnosed with cancer of the colon and rectum is likely to increase both for demographic reasons (aging population) as for diagnostic and therapeutic advances. Low Rectal cancer (between 2 and 10 cm from the anal verge) has some peculiarities that makes it very different in terms of natural history and treatment from the higher level cancers, which has more similarities with the colon cancer [4]. A classification that expresses the real complexity of the disease should therefore consider a division between intraperitoneal colorectal cancer (colon + higher rectum) and the extraperitoneal rectum cancer (lower rectum) [5]. While prognostically the results of therapy in extraperitoneal and intraperitoneal colorectal cancer are aligning, it must be emphasized that the technical complexity and functional outcomes between the two are very different. Extraperitoneal rectal cancer represents a complex multidisciplinary challenge. It is often embraced after neoadjuvant therapy and it requires a conservative surgery of the anal sphincter up to 80 % of cases. In addition, approximately 90 % of these patients experience after surgery, a change in bowel, urinary and sexual habits: hence the need to manage facilities that can integrate surgery with postoperative rehabilitation [6–8].

Literature review

The complex nature of the relationship that links the processes and outcomes of health interventions, makes it impossible to globalize scientific evidence of individual studies with local and temporal limited characteristics. The review of the scientific literature represents only a preliminary step to identify goals that will then be contextualized to the social reality, science and technology [9]. Surgical techniques are constantly improving, the diagnostic workup, the therapeutic approach and the final results are today characterized by considerable differences on the territory [3, 10]. It has been demonstrated that in major surgery, the volume of interventions impacts favorably in terms of prognosis, reduce mortality, morbidity, length of stay and functional outcome [11].

Colon cancer

The most studied clinical outcome in the literature is the inpatient death or death within 30 days from surgery (perioperative mortality). Available evidence is sufficient to show a positive association between higher hospital volumes and lower mortality in colorectal surgery for cancer. Concerning this endpoint the median threshold seems to be around 80 cases/year in colon cancer [12]. The Cochrane Colorectal Cancer Group [10] analysis emphasize that the 5-year survival was not associated with higher hospital volume. Perioperative mortality is also investigated for its association to the volume of activity of a single surgeon. In this case, the available evidence does not show a significant correlation. A weak association between high volume of activity of surgeons and lower colostomy rates was demonstrated for colon cancers (median threshold of 20 cases/year). A number of other clinical outcomes (e.g., anastomotic leak, complications, recurrence, hospital stay), was investigated to study the association with the volume of activity in surgery for colon cancer; none results in a strong association [13].

Results are similar in Italy as reported by Lenzi [14]. In accordance to the AGENAS report [15] the higher is the number of surgical procedures in an hospital, the lower are mortality, complications, length of hospital stay and costs. As regards to the colon cancer mortality within 30 days of surgery, it decreases significantly to the achievement of at least 50/70 procedures/year and it continues to decrease with the increasing volume of activity.

Rectal cancer

Most of the literature tries to classify centers based on the volume of activity identifying low volume as those with less than 10 resections of rectum/year and high-volume centers those with more than 20/year [16, 17]. For rectal cancer, where challenging is the anatomic definition rather than the complexity of pathology, thresholds as a proxy for quality are more difficult to detect. Concerning inpatient death or death within 30 days from surgery, available evidence are not so clear to show a positive association between higher hospital volumes and lower mortality. In fact, contrasting with the review of colon cancer surgery, The Cochrane Colorectal Cancer Group [10] underlined that there was a significant association between high-volume hospitals and improved 5-year survival rates whereas no such association was demonstrated for perioperative mortality. Concerning other clinical outcomes, higher hospital volume was associated with significantly lower rates of permanent stomas and a lower number of reoperation. Worse results were observed in Surgical Units performing no more than 12 resection/year [18]. A larger

number of studies demonstrated significantly better 5-year survival and operative mortality for high-volume surgeons. [10, 19].

Results confirm the presence of a volume–outcome relationship in colorectal cancer surgery, based on hospital and surgeon caseload. The volume hospital ratio is highlighted in the study by Harmon [20] where, by comparing the volume of surgeons with that of the centers, it is shown that surgeons with a high number of procedures perform excellent results whatever the number of the same type of surgical procedures are carried out in hospitals in which they operate. The overall quality of evidence was low as they all included observational studies by design. In addition there were discrepancies in the definitions of anatomy, caseload and colorectal specialist. There were significant differences between countries data, making it imperative that every country established audit systems to guide changes in the service provision based on local data, and facilitate centralization of services as required.

Criteria to identify the hospital units entitled to perform colo-rectal surgery for cancer

To create a shared model of evaluation for both surgical departments and professional skills, it has been drawn up a list of quality indicators referring to a paper published in the Journal of the National Cancer Institute [21]. Fifty-nine parameters were included to which 30 Italian experts surveyed, rated from 1 to 9 in relation to the relevance of the topic. Through this method (RAND/UCLA) an analysis which proposed a set of requirements to ensure good practice in colorectal surgery was performed. The subsequent discussion on cataloging and quantification of the minimal hospital, volume and organization requirements is, therefore, based on both the experience gained from the work on an updated analysis and review of the literature.

Hospital requirements

The Hospital must have the amenities of a First level Hospital as it is identified by Regulations for definition of quality, structural, technological and quantitative standards of hospital care (following the law 135/2012). The Hospital must ensure directly, or through arrangements or agreements with other accredited structure, specialized skills that can ensure the following services necessary to perform colorectal surgery:

- Oncology;
- Gastroenterology;

- Radiology: The following imaging modalities are needed: ultrasonography, computed tomography (CT) and magnetic resonance imaging (MRI);
- Interventional radiology;
- Interventional endoscopy;
- Radiotherapy;
- Nuclear medicine;
- ICU;
- Pain therapy service;
- Pathology service;
- Ostomy service control;
- Psycho-oncology;
- Pelvic floor rehabilitation service;
- Dietitian.

Tumor board

An interdisciplinary and multi-professional organization, establishing a specific course of treatment, is required. The colorectal tumor board is composed of at least five professionals: Surgeon,

- Oncologist;
- Radiologist;
- Radiotherapist;
- Pathologist.

The tumor board should discuss at least 90 % of cancer cases. The discussion and specific conclusions should be verbalized and available to the patient. The meetings of the multidisciplinary team should be periodic and can be organized into headquarters when all the specializations are present or carried out in “Network” if multidisciplinary figures are not all available in the same place. The task of the tumor board is to take charge of the patient in a diagnostic therapeutic flowchart (DTF) that must meet the following requirements.

Clinical responsibility

At the time of case presentation, it must be identified a responsible clinician who becomes the reference for the patient and that takes care of organizing the staging of the disease. The method of taking in charge the various phases of the clinical course should be clearly expressed and the waiting list guaranteed and considered as minimum requirement. The guidelines adopted are clearly shared not only between all components of the tumor board, but also with the patient.

Diagnostic phase

Pre-operative assessment must be scheduled within 7 days from the taking in charge of the patient. The DTF must not

exceed 4 weeks. In the presence of a severely symptomatic patient (intestinal obstruction or bleeding) channels for a quick access to diagnostic tests should be activated; and the treatment to ensure resolution of the urgency and adequate nutritional support where necessary need to be guaranteed.

Cyto-histopathological diagnosis

The pathology service must ensure the receipt and reading of “fresh” specimens to diagnose colon and rectum diseases. The pathologist plays a vital role, since he is responsible not only for the histological diagnosis of cancer, but also for its biological and functional characterization so that a set of prognostic and predictive parameters of crucial importance for the subsequent therapeutic choices can be identified. The use of neoadjuvant therapy also involves the need to be able to assess additional parameters (e.g., regression rate) for a correct definition of the tumor residual. In the area of oncology proteomic and phenotypic characterization of the tumor (KRAS, BRAF and EGFR mutation status; presence of alterations of MSI/MMR). It favors a correct diagnosis of hereditary forms allowing the follow-up in the descendants and collateral. The sampling that allows a correct pathological staging must occur in accordance with the guidelines of the College of American Pathologists (CAP) and the Royal College of Pathologists 2014 [22, 23]. Important requirement is the intraoperative possibility of cyto-histopathological examination particularly for very low rectal cancer where it is often important in choosing whether to perform a sphincter-saving surgery. It is finally required that pathology reports would be complete within 2 weeks, in order to allow patient beginning possible adjuvant treatment.

Surgical path

The surgical procedure, in case of primary surgery should be performed within 30 days from the date of diagnosis. In patients who have undergone neoadjuvant therapy, the reevaluation should be scheduled after 8 weeks, and surgery has to be carried out not more than 12 weeks after the end of treatment [24]. Once surgical indication has been certified, the patient go to a preoperative evaluation of surgical risk and verification of therapeutic measures to treat correctable elements. Patients who are candidate to undergo a temporary or permanent stoma should be assessed preoperatively by an enterostomist. It is suggested the application of the ERAS (Enhanced Recovery After Surgery) programs for the optimization of the perioperative period. During the surgical preoperative evaluation, it must be explained to the patient the surgical path, including the delivery of information material [25, 26].

Surgery

The surgical team must have competence and expertise in colorectal surgery. The operating room must be equipped with the technology necessary to the execution of minimally invasive surgery. The equipment must be certified and monitored regularly.

Anesthesiology

The involved anesthesiologists should be educated to the pathology and share the following therapeutic lines:

- Intraoperative and immediate post-operative management with a fluid restriction approach;
- Maintaining hemodynamic stability;
- Maintenance of normothermia;
- Patient extubation during the awakening;
- Monitoring of the patient in the recovery room for a short period;
- Re-transfer the patient to the surgical ward reserving the post-operative intensive care unit spot to selected cases;
- Post-operative analgesia management through the use of epidural catheter.

Post-operative outcome

The post-operative must follow a written and shared “perioperative care” protocol. The presence and involvement of a dedicated nursing team is indispensable. It is suggested to have a structured presence of physiotherapists who can start a motor and respiratory postoperative rehabilitation program. In patients with stomas, education and stoma management must begin during hospitalization. The surgeon must take charge of emergencies related to possible complications of the postoperative, to provide rapid access to the diagnosis and treatment; he should oversee and verify firsthand the diagnostic tests laid down in emergency. The patient may be discharged when able to satisfy the daily needs for mobility and nutrition. The surgeon must also take care of the postoperative multidisciplinary meeting, which has to be organized in the shorter period possible when an adjuvant treatment is expected.

Follow-up

The patient’s continuity of care must be guaranteed by the multidisciplinary team during the entire duration of follow-up. The surgeon or the clinical responsible has to take charge of the diagnostic communication. It is suggested to have a psychological support for the patient. Follow-up examinations need to be appropriately required. Guidelines

Table 1 ICD-9-CM coding for colorectal neoplasms

Diagnosis	Procedure
153 malignant tumor of the colon	4573 right colectomy
154 malignant tumor of the sigmoid colon	4575 left colectomy
1975 secondary colorectal cancers	458 total colectomy
2304 rectal in situ carcinoma	485 abdominal perineal rectal resection
	4849 rectal resection with “pull through”
	4835 local excision of a rectal lesion or tissue
	4863 anterior rectal resection
	4869 other rectal resection

have to be well kept in mind along with patients and disease characteristics.

Volume requirements

The adequacy of a center, intended as a single Complex Operative Unit and not as the Hospital, is reasonably assured, in terms of patient safety, by the execution of a minimum of surgical procedures for colorectal cancer. According to national and international literature, [10, 11, 14, 15, 17, 18, 27, 28] to obtain the Colorectal Surgery accreditation, it is considered necessary:

Intraperitoneal colo-rectal hospital volume

To be accredited in Colorectal Surgery, a center should perform at least 50 elective cancer resections/year, with mortality <5 % (according to ICD9-CM codes: Table 1).

Extraperitoneal rectal hospital volume

To be accredited in Colorectal Surgery a center should perform at least 15 elective rectal cancer resections/year, with mortality <3 % (according to ICD9-CM codes: Table 1).

Caseloads surgeon volume

To be accredited in Colorectal Surgery in the center must to work at least two surgeons with at least 20 cases/year of colorectal surgery for cancer.

The latest national data, arising from the national program outcomes for 2014, showed a penetration of the laparoscopic approach for colon and rectum of respectively 27.7 and 33.3 % [15]. According to a recent Italian survey [29] the laparoscopic approach to colorectal cancer appears to be the method with the best cost-effectiveness ratio; for this reason, the authors suggest the extension of the use of laparoscopic surgery in the field of colorectal cancer. It is, therefore, desirable that at least 50 % of colorectal surgery

is performed laparoscopically. This objective can be set as the end of an accreditation program that goes through a period of 3 years. In addition to the volume of surgical procedures for the accreditation of single operative units, the following requirements for surgeons should be considered:

- To perform a laparoscopic surgery for colon cancer the surgeon must have a series of at least 20 laparoscopic resections for cancer with tutors.
- To perform a laparoscopic surgery for colon cancer the surgeon must have a series of at least 20 laparoscopic resections for benign disease.
- To perform a laparoscopic surgery for rectal cancer the surgeon must have a series of at least 5 cases of open surgery for extraperitoneal rectal cancer and satisfy the two previous requirements of laparoscopic colon surgery.

Course for accreditation

For centers that do not have adequate experience, but are willing to be accredited, specific accreditation courses have to be organized. Two possible situations can be identified:

- A center does not have enough experience in accordance with accreditation criteria, but acquires a surgeon with sufficient experience in colorectal surgery.
- A center does not have enough experience according to the accreditation criteria but intends to acquire it. In this case a specific training programs will be provide both, in accredited facilities or within the operative unit, thanks to the mentorship of experienced colleagues.

To apply for accreditation, the Health Department of the Complex Operational Unit shall certify the presence of the organizational features and the above requirements. Hospital administrators of the Unit have to certificate the presence of suitable structural and organizational features, and also quantitative and qualitative standards. Periodic clinical audits have to be organized and results have to be

published Accrediting applications and confirmations will be evaluated every 12 months. Volume and mortality data declared will be compared with Ministry of Health data from hospital discharge form archive.

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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