

WJG 20th Anniversary Special Issues (15): Laparoscopic resection of gastrointestinal**Laparoscopic approach to gastrointestinal malignancies:
Toward the future with caution**

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Abstract

After the rapid acceptance of laparoscopy to manage multiple benign diseases arising from gastrointestinal districts, some surgeons started to treat malignancies by the same way. However, if the limits of laparoscopy for benign diseases are mainly represented by technical issues, oncologic outcomes remain the foundation of any procedures to cure malignancies. Cancerous patients represent an important group with peculiar aspects including reduced survival expectancy, worsened quality of life due to surgery itself and adjuvant therapies, and challenging psychological impact. All these issues could, potentially, receive a better management with a laparoscopic surgical approach. In order to confirm such aspects, similarly to testing the newest weapons (surgical or pharmacologic) against cancer, long-term follow-up is always recommendable to assess the real benefits in terms of overall survival, cancer-free survival and quality of life. Furthermore, it seems of crucial importance that surgeons will be correctly trained in specific oncologic principles of surgical oncology as well as in modern miniinvasive technologies. Therefore, laparoscopic treatment of gastrointestinal malignancies requires more caution and deep

analysis of published evidences, as compared to those achieved for inflammatory bowel diseases, gastroesophageal reflux disease or diverticular disease. This review tries to examine the evidence available to date for the use of laparoscopy and robotics in malignancies arising from the gastrointestinal district.

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Key words: Gastrointestinal cancer; Laparoscopic; Oncology; Laparoscopic surgery; Robotic surgery; Surgical outcomes; Oncologic outcomes

Core tip: Laparoscopic treatment of gastrointestinal malignancies requires more caution and deep analysis of published evidences, as compared to those achieved for benign diseases. Oncologic outcomes remain the foundation of any procedures to cure malignancies, hence a long-term follow-up is always recommendable in order to assess overall survival, cancer-free survival and quality of life.

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INTRODUCTION

From an epidemiologic point of view, gastrointestinal malignancies represent a vast share of both incidence and mortality for cancer worldwide (Figure 1)^[1]. Therefore, the widespread adoption of the minimally invasive (endoscopic, laparoscopic and robotic) approach to cure these malignancies was an attractive and valuable consequence, and many surgeons reported tangible benefits of

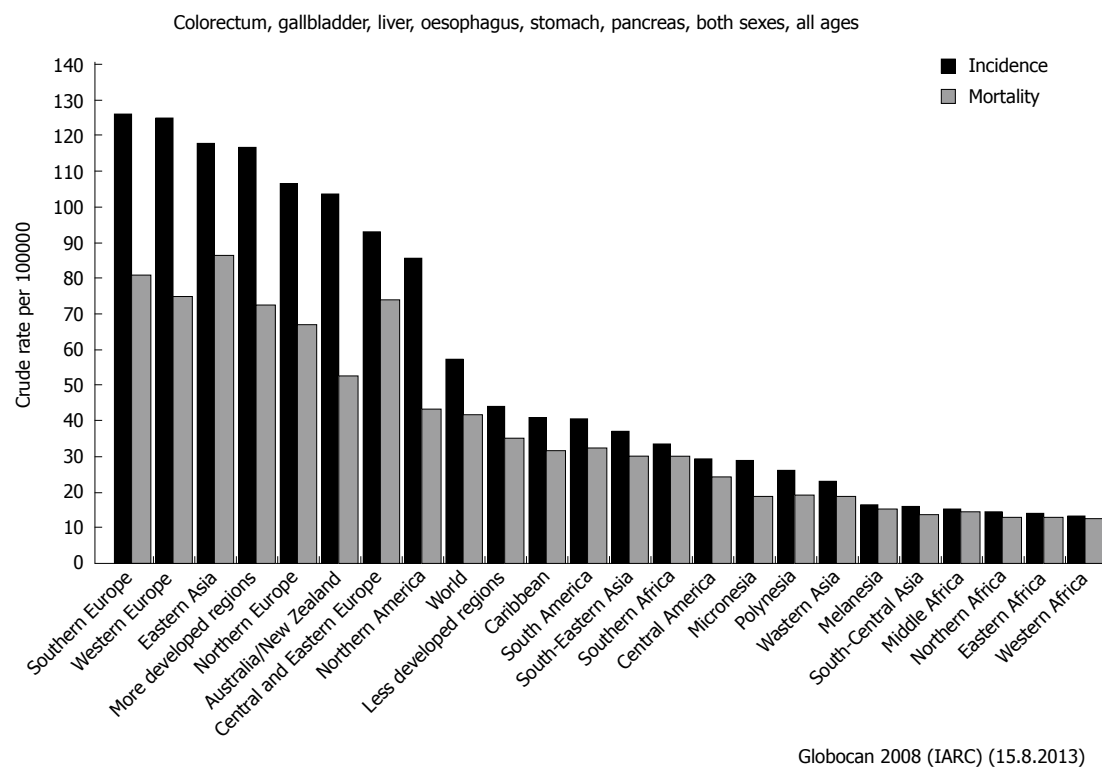


Figure 1 Incidence and mortality from the most important gastrointestinal malignancies worldwide^[1].

this technique in terms of morbidity, return to normal activities and mortality.

Nevertheless, the popularity of miniinvasive surgery (MIS) among both surgeons and patients, mixed with some industrial pressure, could have also played a role in the worldwide diffusion and explosion of new technologies.

The proven advantages of laparoscopy are mainly represented by better short-term outcomes including fewer wound complications, less pulmonary impairment, reduction of postoperative pain, shorter length of postoperative stay and, eventually, better cosmetic result. Moreover, there is a well-recognized role of laparoscopy in decreasing the pro-inflammatory and immunologic response to surgery that are, hypothetically, related to an improved immediate or even long-term oncologic result^[2]. For all these issues, the laparoscopic technique in oncology seem to be very promising^[3].

However, if the limits of MIS are mainly represented by technical issues and patients conformation for benign diseases, oncologic outcomes remain the foundation of any procedure to cure malignancies. Mostly, any laparoscopic procedure should follow the same standard of care of open surgery, including oncologic principles, such as wide margins of resection and extended lymphadenectomy. Such prerequisites often require very good skills that are generally limited to high volume centers with subspecialized teams.

Historically, the first concerns about MIS for cancer were represented by the possibility of port-site metastasis and lower number of lymphnodes retrieved, but none of these issue has been confirmed successively^[4,5].

Moreover, advanced laparoscopy for gastrointestinal malignancy requires the whole specimen extraction (often with regional nodes) through a minilaparotomy, thus flawing one of the strongest advantages of MIS represented by short incisions.

Most of the reviewers concluded that, although slowly, colorectal oncologic resections had been recognized to have a non-inferior cancer-free survival and superior short-term results, while the laparoscopic approach to gastric and solid organs malignancies will require further studies with longer follow-up^[3,6].

The role of laparoscopy is known to be important in staging gastrointestinal malignancies, limiting the number of unnecessary laparotomies for carcinosis or occult metastasis. Many palliative procedures such as gastrointestinal by-pass, gastrostomy, jejunostomy and colostomy or radiofrequency ablations are easily carried out with MIS^[6].

The pure endoscopic treatments of both esophago-gastric and colorectal small malignancies (precancerous or T1 lesions) are well accepted among cancer professionals for being as safe and as curative as traditional resections, and they will not be considered further in this review. Therefore, we focused on the full laparoscopic (and robotic) treatment of gastrointestinal malignancies, including those arising from the esophagus, stomach, liver and biliary system, pancreas, small bowel and colorectum. If not otherwise specified, malignancies are intended to be carcinomas: other histopathological subtypes, such as neuroendocrine or sarcomas, will not be considered.

A Pubmed, Embase and Cochrane databases bibliography search was conducted until September 2013, including important cross-matched manual references. References to historical reports and older articles were limited to the minimum. A particular attention was reserved to data arising from randomized controlled clinical trials (RCTs) (or meta-analyses) with long-term follow-up. Oncologic results will be considered of utmost interest, in order to assess overall survival, cancer-free survivals and quality of life, rather than feasibility of the procedure itself and short-term outcomes.

ESOPHAGUS

The three-field (Mc Keown procedure) has been the treatment of choice for esophageal cancer for many years. This procedure, as well as the so-called Ivor-Lewis (two-field esophagectomy with esophagogastric intrathoracic anastomosis) and the Orringer procedure (transhiatal esophagectomy) are all feasible by laparoscopy (thoracoscopy) or hybrid (with open surgery combined) technique^[7]. MIS for esophageal cancer has spread worldwide, reducing the significant perioperative complications (mainly respiratory). However, many debates still exist on the real efficacy and cost-effectiveness of minimally invasive esophagectomy (MIE). If these complex operations should be performed by the open traditional approaches or carried out by the laparoscopic and thoracoscopic route is still far to be demonstrated by the surgical community^[2].

Several technical variables, such as the role of laparoscopic, thoracoscopic or combined steps, the usefulness of the prone or supine position, the choice of stapled or hand-sawn anastomosis and the route of stapled suture are under study. Last, the general poor quality of studies published leads to a great caution, when dealing with outcomes and oncologic results^[8]. All of these issues contribute to jeopardize the surgical results and perioperative complications data reporting. Moreover, it should be considered how technical demanding this kind of surgery is, even in the traditional open way, with very few centers having sufficient case-load to gain adequate specific proficiency.

A single-center review^[7] of more than 1000 patients (thoraco-laparoscopic McKeown and Ivor-Lewis operations compared) reported global excellent results, with a morbidity and mortality rate of less than 2% and 1%, respectively; with the best approach being the thoraco-laparoscopic Ivor-Lewis. A well-conducted review on MIE concluded that both laparoscopy and thoracoscopy are at least comparable to open surgery in terms of outcomes for non-locally advanced cancers, but the open transthoracic route is superior when considering field exposure^[9].

The only prospective, multicentric RCT including few patients^[10], and one large retrospective cohort study also confirmed the superiority of MIE in terms of postoperative pulmonary complications (13% in the thoraco-

laparoscopic MIE, 38% in the thoracoscopic MIE, and 39% in the open group)^[11]. Another ongoing trial was designed to evaluate the benefits of laparoscopic gastric mobilization during Ivor-Lewis intervention in terms of postoperative complications^[12]. Moreover, a recent review failed to find any important differences between the two classic stapled anastomosis techniques (transoral anvil introduction and transthoracic) during Ivor-Lewis esophagectomy for cancer^[13].

If many review articles report how MIE statistically decreases blood loss, length of stay, and perioperative morbidity at the price of increased operative time and costs, large-scale multicentric trials are still lacking, and few studies had long-term follow-up^[14]. Hanna *et al.*^[15] selected thirty of the largest and best designed trials concerning MIE for cancer (including only 1 RCT). The author concluded that in most studies a suboptimal lymphadenectomy was carried out, with an average number of nodes retrieved below the standard (over 23), while no homogeneous complications reporting was available. However, the final oncologic outcomes for each stage (disease-free survival and overall survival) were comparable to those achieved by the open traditional surgery.

Lastly, robotic-assisted MIE was also employed in the treatment of esophago-gastric malignancies, but very few studies, even of poor quality, failed to demonstrate real advantages of this method as compared to open surgery^[16,17]. A monocentric trial targeted to robotic MIE started recently^[18].

In conclusions, due to the relative low frequency of esophageal cancer (especially in Western countries), the technical difficulties, the debated approach (two-field, three-field, transhiatal) and lack of literature evidence, the MIE, although promising, should be reserved to specialized centers within controlled trials.

STOMACH

The standard of care is open gastric resection with complete D2 lymphadenectomy for curable gastric cancer in both Western and Eastern countries, although a debate lasting decades on the extent of lymphadenectomy has been carried on. However, some endoscopic techniques (such as submucosal dissection) are recognized to be appropriate for selected patients with T1 cancers^[2]. More controversies still persist regarding laparoscopic gastric resection (LGR) and sentinel node mapping, in those patients who are unfit for endoscopic resection or who have more advanced tumors.

Almost every gastric procedure is feasible by the laparoscopic route, including distal and the more challenging total gastrectomy with intracorporeal anastomosis^[19,20] and formal lymphadenectomy^[21], but also gastric resections and sentinel node sampling are recommended in selected cases.

The limit of the widespread adoption of the LGR is represented by the technical difficulties (mainly anastomosis) and the oncologic safety. Indeed, the standard D2

lymphadectomy, although feasible with few complications^[22,23] is technically demanding, but mandatory for all advanced tumors.

Several review articles and meta-analysis reported that laparoscopy was a safe alternative, if not superior (perioperative outcomes), to open surgery for the treatment of early and advanced gastric cancer^[24-30], but data on long-term survival, quality of life and cost effectiveness are still lacking^[31,32].

One of the most updated review, including only comparative trials with a pooled cohort of more than 1000 patients^[33], and another^[34], that included 8 RCTs (more than 700 patients) reached the same conclusions. LGR is better or comparable in the early perioperative results with similar long-term outcomes respect to open surgery, although at the price of longer duration of surgery and technical difficulties. Other two meta-analysis by Wang *et al*^[35] and Chen *et al*^[36] reached the same conclusions in terms of oncologic effectiveness (node dissection) and outcomes. Many benefits of LGR are also confirmed in elderly people suffering for comorbidities according an enormous Chinese database^[37].

Large Asian trials with longer follow-up are still ongoing, and only one European study reported data on 10-years follow-up^[38]. To the present, one recent RCT (KLASS trial) reported early results: the authors confirmed equivalent outcomes of laparoscopic and open approach to gastrectomy for cancer^[39].

A crucial point of concern is represented by the steep learning curve, although a paper reported encouraging results of LGR initiated by experienced surgeons in open gastrectomy and laparoscopy who received adequate training^[40].

Most of the papers on LGR come from Eastern countries due to the high volumes of disease, high rates of early cancers and perhaps less diffusion of obesity that can obstacle laparoscopy. Therefore, the reported proportions of LGR rises to more than 20% in Japan in a recent review article^[41]. However, some good results are also reported from many Western countries including Europe^[42,43] and an international panel published some guidelines for the introduction and diffusion of the technique^[44].

More recently, the introduction of the robotic approach to perform very complex operation, including gastric surgery, seems to be promising in order to reduce some of the technical difficulties of laparoscopy^[41]. However, very few rigorous studies were published on robotic approach for gastric cancer and a recent meta-analysis^[45] ended up selecting only 3 RCTs comparing robotic and laparoscopy. The pooled results showed no significant differences between the two approaches in terms of complications, mortality, conversion, length of stay and number of nodes retrieved. On the other hand, blood loss resulted inferior by robotics, at the price of an increased operative time and costs. If laparoscopic treatment of gastric cancer is still debated, this is even more for robotics, especially in terms of real benefits for patients.

Recent systematic review and meta-analysis of few

retrospective comparative trials seem to confirm superiority of LGR as compared to open surgery also when dealing with gastrointestinal stromal tumours (GISTs)^[46,47].

LIVER, GALLBLADDER AND BILIARY TRACT

Since the advent of advanced laparoscopic techniques and availability of efficacious transection devices, many authors reported the feasibility of liver resections by the key-hole approach, both for malignancies and benign disease. Some retrospective and review studies (including very few comparative trials) provided relative evidence to support further development of case-load and research, to assess safety of laparoscopic hepatectomy for cancer patients or, if any, superiority as compared to standard surgery^[48-50].

In 2007, the most acknowledged hepatobiliary surgeons worldwide met in Luisville (United States) to find an international common position on laparoscopic liver surgery (LLS): although few relevant data was available, the experts concluded that this kind of surgery (or hybrid technique, including hand-assisting) is safe and effective, in the hand of trained surgeons and under the control of societies and government. The preferred indications (despite for malignancy) were represented by solitary lesions of less than 5 cm in maximum diameter located in segments 2 to 6^[51]. On the other hand, many surgeons began LLS dealing with benign diseases involving left lateral segments^[52], while others brought the indications toward upper limits^[53]. An international multi-institutional review article proposed the laparoscopic approach to left-sided hepatectomies as the future gold-standard of care^[54].

LLS for cancer [including both hepatocellular carcinoma (HCC) and colorectal metastasis (CRM)] seems to offer oncologic results similar to those of laparotomy^[55]. Excellent results were also achieved form 3 specialized European centers with large experience in HCC^[56].

Laparoscopy seems to add also some benefits in terms of reducing early complications in the subset of patients affected by HCC and cirrhosis^[57]. In a case-matched analysis published by Lee *et al*^[58] LLS for HCC showed similar long-term outcomes but some early clinical advantages (complications and hospital stay) as compared to open surgery. Feasibility, less morbidity and shorter hospital stay were also found in patients after hepatectomies carried out for CRM^[59,60].

Another very large (300 patients, 103 cancerous) single-center case-matched experience form Chicago (United States)^[61] concluded that miniinvasive hepatectomy (including major resections) compared favourably with contemporaneous controls operated by the open approach without any oncological detriment. Positive parameters included blood loss, transfusion requirement, overall complications, postoperative stay and, surprisingly, operative time.

In the most recent and rigorous review of available studies, carried out by Rao *et al*^[62] for the Cochrane

Library, the author reported that no conclusion can be drawn on the benefits or harm of laparoscopy versus open technique for liver resection. These unsatisfactory data are consequence of lacking of any published RCT that met strong scientific criteria, although some are still ongoing.

R0 resection represents the main goal of treatment when dealing with hilar cholangiocarcinoma (Klatskin tumor), gallbladder cancer or extrahepatic bile duct cancer. Regional lymphadenectomy should be also performed in order to reduce recurrences^[63,64]. Therefore, the laparoscopic approach to hilar structures is very challenging, even for a skilled laparoscopist, although MIS is highly accepted to confirm resectability and avoid unnecessary laparotomies. Some recent retrospective multicentric studies reported encouraging and oncologically acceptable laparoscopic procedures for hilar and gallbladder malignancies, but in the hands of very experienced surgeons working in highly subspecialized surgical units^[65].

With the widespread adoption of laparoscopic cholecystectomy, it seems that an increased number of incidental gallbladder cancer could be diagnosed nowadays. However, no difference in survival was demonstrated, if the surgeon decides to perform a more aggressive resection immediately or during a second look intervention^[66,67]. Theoretically, this fact leads to correctly plan the adequate operation and to reach maximum oncologic results by both open delayed resection or immediate laparoscopy. Nevertheless, the experiences of laparoscopic second look resections and lymphadenectomy for gallbladder cancer are almost anecdotal^[68]. Some authors reported initial experiences with the use of single-port laparoscopic technique for specific group of selected patients with malignancy and liver dysfunction^[69].

Robotics could play a role in development of minimally invasive techniques for hepato-biliary malignancies due to easier dissection in deep and narrow spaces and for the possibility of knot-tying of vascular structures. Good short-term results were reported for robotic-assisted liver resections for HCC and CRM^[70,71], while robot-assisted radical resection for gallbladder cancer is both feasible and safe^[72] in specialized environments.

A recent paper targeted to a matched comparison of robotic and laparoscopic liver resections failed to show significant differences between the two techniques^[73]. Long-term outcomes, larger patient records and comparative studies (with open surgery and pure laparoscopy) are not available yet.

PANCREAS

Pancreatic cancer still represents one of the major challenge for the oncologic surgeons due to complex reconstruction, high perioperative morbidity and mortality and poor overall survival. Thus, the advent of laparoscopy was advisable and exciting, in order to minimize operative complications and maximize the early recovery of the patients. On the other hand, the specific technical

difficulties and the relative low incidence of pancreatic cancer, have limited the laparoscopic approach to few specialized centers with great experience in both pancreatic surgery and advanced laparoscopy^[74]. Moreover, the problem of pancreatic remnant fistula is the same that in open surgery, while some initial and more recent sporadic port-site recurrences were reported in literature^[75].

Historically, the first procedure carried out by laparoscopy was distal pancreatectomy for benign disease, because it does not require any anastomosis. However, the preservation of the spleen, when dealing with benign or neuroendocrine tumor, remains challenging^[76,77].

A very comprehensive review of the literature by Iacobone *et al.*^[78] found more than 300 articles regarding laparoscopic left or distal pancreatectomies (LDP), but most were case-series, with short-term follow-up, different techniques and confused data reporting. Similar findings were reported by Borja-Cacho *et al.*^[79]. In addition, the experiences with pancreatic adenocarcinoma or Intraductal Papillary Mucinous Neoplasm (IPMN) were much more limited^[80].

One of the largest single-center case series on LDP was published from the Memorial Sloan Kettering Center^[81] on more than 300 cases over a 7-year period, resulting in excellent outcomes (27% *vs* 40% of postoperative complication, $P = 0.03$, as compared to standard surgery). LDP seems to be almost the standard of care for many centers, in order to achieve a systematic reduction of blood loss and postoperative stay, although a careful patients selection is often advocated^[82].

A comparative study demonstrated the cost-effectiveness of LDP as compared to open surgery, when considering the reduction of hospital stay (5 d *vs* 7 d, $P < 0.001$)^[83], while another^[84] reported increasing experience and more complex patients selection although maintaining the same morbidity over a 11-years period.

When limiting literature search to case-matched study, Pericleous^[85] identified only 4 articles that fit for quality assessment (but none was a RCT): results were that LDP had a longer operative time, but reduced length of postoperative stay without any differences in perioperative morbidity and mortality, as compared to open surgery. Another similar and more recent meta-analysis^[86] found 18 comparative studies including more than 1800 patients. LDP reduced blood loss, length of hospital stay, and overall complications, without increasing the duration of surgery significantly. However, no definitive conclusions were drawn regarding the oncologic safety, although the rate of margins positivity was comparable between open and laparoscopic resection.

As the numbers of laparoscopic advanced procedures increase, some centers began to perform also laparoscopic pancreatodudenectomies (LPD) for malignancies. Some advantages over traditional surgery and comparable oncologic outcomes are reported, although long learning curves limit these initial experiences to subspecialized surgical teams^[87-92].

A single center case series (from United Kingdom)^[93]

with a final review, identified an increasing number of LDP and LPD performed, but almost all were reported in poor quality studies and limited number of patients. The authors concluded that laparoscopic pancreatic procedures should be reserved to selected cases with benign to low grade malignancies. Nonetheless, major vessels resection for malignant involvement have also been reported to be completed by laparoscopy^[94].

Few articles reported the oncologic main outcomes, including numbers of nodes harvested, margins of resection, disease-free survival and overall survival. A review by Fischer *et al*^[95] was specifically targeted to laparoscopic pancreatectomies for malignancies to assess those issues. Early results seemed to be oncologically adequate for LDP, while literature, in general, was highly insufficient for LPD. Another recent review of Kudsi *et al*^[96] concluded that, although becoming highly popular, LDP for aggressive tumors may not be appropriate due to the lack of oncologic safety studies.

A very recent single-center series of 200 consecutive laparoscopic pancreatic resections (including LDP, LPD and other more limited procedures) reported excellent result with the use of a robotic controlled laparoscope holder^[97].

Some surgeons argue that full robotic surgery could ease many difficult technical maneuvers of the laparoscopic approach, including biliary and pancreatic anastomosis or preservation of the spleen^[98-101]. Others^[102-104] reported more encouraging early experiences with robotic-assisted pancreatectomies as compared to open approach. A meta-analysis of Zhang *et al*^[105] including 7 trials suggested that robotic pancreatectomy is as safe and efficient as, if not superior to, open surgery but the evidence is highly insufficient.

To the present, those excellent results with robotics are far to be reproducible in most centers worldwide.

SMALL BOWEL

Due to the relative low incidence of small bowel carcinomas, most of the laparoscopic resections carried out for malignancy include gastrointestinal stromal tumours (GISTs). According to the well-known peculiar biologic tumoral behaviour, very wide margin and formal lymphadenectomy are unnecessary for GISTs^[106]. Therefore, it seems that laparoscopy could be particularly indicated to manage these neoplasms and a variety of endoscopic, laparoscopic, and hybrid techniques are described to surgically excise GISTs of different anatomic locations^[107].

However, few papers are specifically targeted to small bowel resections and quality of studies is generally poor (no randomization). Nevertheless, initial experiences reported the laparoscopic treatment of small bowel GISTs to be safe and effective, without oncologic outcome impairment^[108,109].

A retrospective comparative study^[110] including 9 and 11 patients each arm only, analyzed laparoscopic approach

to small bowel tumors compared to open surgery. Despite the insignificant number of patients and the statistical insufficiency of the sample, the authors found how laparoscopic resection favoured short-term outcomes in selected cases. Other similar results were also published^[111].

In conclusions, although many of the results advocated for small bowel GISTs are extrapolated from gastric series, it seems that laparoscopic resections of GISTs lead to excellent outcomes in term of perioperative and oncologic outcomes.

COLON AND RECTUM

To the present, laparoscopic treatment of colorectal cancer has becoming the gold standard of care, and has gained large diffusion worldwide^[112-114]. The main reasons are represented by the highest number of good quality studies published, including many RCTs with long follow-up and meta-analysis, the high incidence of colorectal cancer, that permits adequate case-load and the acceptable technical challenge^[115,116].

Although laparoscopic colorectal resection (LCR) is feasible in around 90% of elective cancer patients^[117] and excellent results are achieved also outside clinical trials^[118], many smaller centers still continue to perform routine colorectal operation using the traditional open approach due to the lack of laparoscopic expertise or devices and, probably, some socio-economic disparities^[119]. The widespread acceptance of laparoscopic rectal resections, in which some surgeon have demonstrated advantages of robotics, has been slower compared to colon resections.

The most important multicenter RCTs were published in the early 2000's from the Clinical Outcomes of Surgical Therapy Study Group (COST trial)^[120], led by Nelson of the Mayo Clinic (Rochester, MN, United States), the Colon Cancer Laparoscopic or Open Resection Study Group (COLOR trial)^[121] arisen in Europe, the United Kingdom Medical Research Council (MRC CLASSIC trial)^[122], and the Barcellona^[123] and the Australasian (ALCCAS Trial)^[124] groups.

All these trials confirmed, in the short-term period, that the use of laparoscopic colon resection maximizes the outcomes without compromising oncological results. Surprisingly, the Barcellona^[123] trial showed an increased survival in the stage III patients treated laparoscopically, while the CLASSIC trial^[122] reported inferior results for laparoscopic anterior rectal resection that lead the authors to advise against the adoption of this specific procedure.

A meta-analysis^[125] of the first four randomized trials (COST, COLOR, CLASSIC and Barcellona, involving 1765 patients overall), with at least 3 years of complete follow-up, confirmed that laparoscopy for colon cancer was oncologically safe (3-year disease-free survival rates in the laparoscopically assisted and open arms were 75.8% and 75.3%, respectively; the 3-year overall survival rates 82.2% and 83.5%; without any difference between stages).

In addition, a very comprehensive review and meta-analysis from the Cochrane Group^[126] including the best 25 RCTs (3526 patients) stated that, although operative time was longer in the laparoscopic surgery, many parameters such as the intraoperative blood loss, postoperative pain and ileus, hospital stay and quality of life at the 30th day were superior in comparison to open surgery. Therefore, total morbidity and local (surgical) morbidity were decreased in the laparoscopic groups. General (non-surgical) morbidity and mortality were not different between both groups. Some benefits of LCR for cancer rather than the oncologic outcome, could be stronger in the elderly people^[127] or in the long-term period, including reduction of adhesions and incisional hernias^[128].

On the other hand, when considering the absolute values (rather than statistic difference) of some of the short-term advantages of the trials, only very few benefits were detectable (for example 5-9 *vs* 6-12 postoperative days)^[126], with comparable overall morbidity and mortality, while some trials reported increased duration of surgery for LCR^[129].

The oncologic long-term results were also tested in the COST trial, demonstrating the non-inferiority of LCR in terms of disease-free 5-year survival, overall 5-year survival and sites of recurrence^[130]. Similarly, the long-term outcomes of the COLOR^[131] trial found a statistically insignificant difference in favour of open colectomy, while the Barcellona^[132] trial confirmed how LCR was associated with a reduced risk of tumor relapse. Also the CLASSIC trial^[133] confirmed, after a 5-year analysis, the oncological safety of laparoscopic surgery for both colonic and rectal cancer. A more recent Australasian RCT reported similar long-term oncologic outcomes (recurrence and survival) between open and LCR, although it found some short-term surrogate oncological markers (smaller distal resection margin) to be worst in the laparoscopic group^[134].

Another specific meta-analysis from the Cochrane Group^[4], including 33 RCTs and 3346 patients, concluded that laparoscopic resection of carcinoma of the colon is associated with a long-term outcome not different from that of open colectomy, although more RCTs are needed to confirm long-term outcomes for rectal cancer and the real incidence of incisional hernias and adhesions.

Recent pioneeristic experiences begin to report the application of NOTES (Natural Orifice Transluminal Endoscopic Surgery)^[135,136] or SILC (Single Incision Laparoscopic Colectomy)^[137] for colon cancer, but they should be considered absolutely insufficient to be proposed in routine clinical practice.

Data supporting the routine laparoscopic approach to rectal cancer are still incomplete, and the first experiences failed to confirm oncologic safety (CLASSIC trial, not statistically significant increase of positive margins)^[122], while a specific Cochrane review^[138] including 80 poor quality studies and only 1 RCT did not assess safety of the procedure. However, many data come from patients

operated at the end of the nineties or beginning of the twenties, thus justifying some technical mistake in the hands of surgeons without great experience. Moreover, there is also a generalized scientific confusion in the definition of rectal cancer, the distinction between low and medium rectal cancer, the standardization of total mesorectal excision (TME) and the need of perioperative radiochemotherapy. All these issues contribute to jeopardize results and increase difficulties in data reporting.

A very recent RCT from the same group (European centers) of COLOR trial^[139] was targeted to laparoscopic treatment of rectal cancer (LRR) with more encouraging results in terms of similar safety, excision margins, and completeness of resection to that of open surgery. Indeed, completeness of the resection was not different between laparoscopy and open surgery (88% *vs* 92%; $P = 0.250$), while a positive circumferential resection margin (< 2 mm) and a median distal resection margin were of 10% and 3 cm in both groups respectively. Recovery was confirmed to be improved after laparoscopic surgery, although the results for the primary endpoint - locoregional recurrence - are expected by the end of 2013.

Similar early good results were reached by another recent Korean trial^[140] (170 patients each arm of study), when considering blood loss, pain and recovery, that were superior in the laparoscopic group without differences in the margin of resection. Moreover, a very large (more than 4000 patients) non-randomised Spanish trial^[141] concluded that laparoscopic surgery is the best option for the surgical treatment of rectal cancer, with similar rates of local recurrence and survival.

Despite the lack of any evidence to support its use, some surgeons began to perform colorectal surgery by the robotic-assisted technique^[142-144]. A large retrospective review of colorectal operation in the United States found the percentage of robotic operations to be less than 3%, without any tangible advantages over conventional laparoscopy (except for decreased conversion rates) and higher rate of postoperative bleeding^[145].

To resolve the intrinsic difficulty of performing a formal laparoscopic TME, many centers with the available technology and expertise, introduced the use of robot to perform LRR^[146]. However, robotic rectal surgery is at least more expensive than laparoscopy^[147] and probably equivalent in terms of short term results^[148]. Nevertheless, oncologic early results (number of harvested nodes, distal and circumferential margins, port-site recurrence) lead to consider robotic rectal resections safe^[149,150]. A prospective, international, multicenter, RCT was recently designed to test robotic versus standard LRR^[151].

CONCLUSION

The dramatic widespread popularity of laparoscopy has significantly changed the surgical approach to gastrointestinal malignancy toward less invasive, miniinvasive, laparoscopic, hybrid and robotic interventions. Excellent

Table 1 Recommended approach to gastrointestinal malignancies

District	Open surgery	Laparoscopic surgery	Robotic	Level of Evidence ¹
Esophagus	Standard	Accepted	Pioneeristic	LE 2
Stomach (proximal)	Standard	Being accepted	Pioneeristic	LE 3
Stomach (distal)	Standard	Accepted	Pioneeristic	LE 2
Liver (major resection)	Standard	Pioneeristic	Pioneeristic	LE 4
Liver (minor resection)	Standard	Being standard	Pioneeristic	LE 3
Gallbladder	Standard	Pioneeristic	Pioneeristic	LE 5
Biliary tree	Standard	Pioneeristic	Pioneeristic	LE 5
Pancreas (head)	Standard	Pioneeristic	Pioneeristic	LE 4
Pancreas (body-tail)	Standard	Being standard	Pioneeristic	LE 3
Small bowel	Standard	Being standard	Pioneeristic	LE 5
Colon	Accepted	Standard	Pioneeristic	LE 1
Rectum	Standard	Being standard	Pioneeristic	LE 2

¹Oxford Centre for Evidence-Based Medicine. Levels of Evidence Working Group. "The Oxford 2011 Levels of Evidence". Available from: URL: <http://www.cebm.net/index.aspx?o=5653>.

results in terms of reduction of postoperative "stress" (including immunologic response, pain, overall morbidity, length of stay, self-corporeal appearance and mortality) have been reported from North America, Europe and Eastern countries.

Laparoscopy is now accepted and, probably, recognized as the gold standard in the management of colorectal malignancy in most of hospitals worldwide. GISTs should also be treated by laparoscopy whenever feasible, and very good results have recently been reported for gastric (mainly distal stomach), esophageal and pancreatic (mostly tail) cancers as well. Total gastrectomy, pancreaticoduodenectomy and major hepatic resections (except for left lateral segments) should be considered pioneeristic operations, reserved to few surgeons within rigorous clinical protocol studies (Table 1).

However, the lack (and the intrinsic difficulty of techniques) of RCTs still leaves many important unresolved issues. The cornerstone of oncologic safety, the real benefits for the cancerous patients and the cost-effectiveness, in the setting of limiting health care resources, are the principal ones. It is also well established that advanced laparoscopic techniques, especially for malignant disease, should be initiated and carried out only in selected tertiary centers with the greatest surgical experience in both laparoscopy and surgical oncology. Moreover, every new laparoscopic program should be tutored, monitored and validated by a final and a long-term oncologic follow-up.

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