

Laparoscopic vs. open total mesorectal excision for treatment of rectal cancer

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ABSTRACT

Introduction. Because definitive long-term results are not yet available, the oncologic safety of laparoscopic surgery in rectal cancer remains controversial. Laparoscopic total mesorectal excision (LTME) for rectal cancer has been proposed to have several short-term advantages in comparison with open total mesorectal excision (OTME). However, few prospective randomized studies have been performed. **Objectives.** The main purpose was to evaluate whether there are relevant differences in safety and efficacy after elective LTME for the treatment of rectal cancer compared with OTME in a tertiary academic medical center. **Material and methods.** This comparative non-randomized prospective study analyzes data of 20 patients with middle and low rectal cancer treated with low anterior resection (LAR) or abdomino perineal resection (APR) from November 2005 to April 2006. Follow-up was determined through office charts or direct patient contact. Statistical analysis was performed using χ^2 test and Student's t-test. **Results.** Ten patients underwent LTME and 10 patients underwent OTME. No conversion was required in the LTME group. Mean operating time was shorter in the laparoscopic group (LTME) (186.7 vs. 204.4 min, $p < 0.007$). Less intraoperative blood loss and fewer postoperative complications were seen in the LTME group. An earlier return of bowel motility was achieved after laparoscopic surgery. There was no 30-day mortality and the overall morbidity was 20% in the LTME group vs. 40% in the OTME group. The mean number of harvested lymph nodes was greater in the laparoscopic group than in OTME group (10.2 ± 2.5 vs. 8.3 ± 3). Mean follow-up time was 12 months (range 9-15 months). No local recurrence was found. **Conclusion.** LTME is a feasible procedure with acceptable postoperative morbidity and low mortality, however it is technically demanding. This series confirms its safety, while oncologic results are at present comparable to the OTME published series, with limitation of a short follow-up period though. Further

Escisión Total de Mesorrecto Laparoscópica vs. Abierta en el tratamiento del cáncer de recto

RESUMEN

Introducción. Se ha propuesto que la escisión total de mesorrecto laparoscópica (ETML) para el tratamiento del cáncer rectal, conlleva una mejoría en los resultados quirúrgicos a corto plazo, en comparación con la escisión total de mesorrecto abierta (ETMA). Sin embargo, pocos estudios prospectivos aleatorios se han realizado. **Objetivos.** El motivo principal por el que se realizó el estudio, fue para evaluar las diferencias relevantes en cuanto a seguridad y eficacia después del tratamiento electivo del cáncer rectal con ETML, comparada con ETMA en un centro médico académico de tercer nivel. **Material y métodos.** En este estudio prospectivo, comparativo y no aleatorio, se analizaron variables de 20 pacientes con cáncer de recto medio y bajo, tratados quirúrgicamente con resección anterior baja (RAB) o resección abdominoperineal (RAP) en un período de noviembre de 2005 a abril de 2006. El seguimiento se llevó a cabo mediante encuestas y contacto directo con los pacientes en la consulta externa de cirugía de colon y recto. El análisis estadístico fue realizado usando la prueba de χ^2 y T de Student. **Resultados.** Diez pacientes fueron sometidos a ETML y diez a ETMA. No se requirió conversión en el grupo de ETML. La mediana de tiempo quirúrgico fue más corta en el grupo laparoscópico (ETML) (186.7 vs. 204.4 min, $p < 0.007$). Se obtuvo menor tasa de sangrado transoperatorio en el grupo de ETML, así como menor número de complicaciones postoperatorias. Más aún, se obtuvo un retorno menos prolongado de los movimientos intestinales en el grupo laparoscópico. No se registró mortalidad de 30 días, mientras que la morbilidad total fue de un 20% en el grupo de ETML contra un 40% en el grupo de ETMA. La media de ganglios linfáticos resecaos fue mayor en el grupo laparoscópico que en el abierto (10.2 ± 2.5 vs. 8.3 ± 3). La media del tiempo de seguimiento fue de 12 meses (rango 9-15 meses). No se registró recurrencia local. **Conclusiones.** La ETML es

randomized studies are necessary to evaluate long-term clinical outcome.

Key words. Laparoscopy. Rectal cancer. Total Mesorectal Excision.

INTRODUCTION

Colorectal cancer is a common malignant disease with more than 800,000 new cases diagnosed each year and is a leading cause of morbidity and mortality. It ranks second only to cancers of lung and breast as cause of cancer-related death in men and women, respectively.¹

Surgical therapy for rectal cancer has evolved since Ernest Miles first described the abdominoperineal resection (APR) in 1908.² By the 1920s, he had reduced the recurrence rate from almost 100% to approximately 30%, thus making his technique the gold standard at that time. Several modifications were proposed to improve locoregional control and survival.³

Low anterior resection (LAR) has been the mainstay of surgical therapy for rectal cancer since the 1970s. Worldwide local recurrence rates have averaged 30% and 5-year survival rates have ranged from 27% to 42%.⁴⁻⁶

The introduction of total mesorectal excision (TME) in 1982 by Heald gained general acceptance and good oncological outcomes: better functional results, lower local recurrence, and longer survival rates.^{3,7,8}

TME became the gold standard procedure for cancer of the middle and lower third of the rectum and includes the routine excision of the intact mesorectum by precise sharp dissection of the areolar tissue between the visceral and parietal layers of the pelvic fascia.³

Over the past 10 years laparoscopy has become the gold standard for the surgical management of many diseases of the digestive tract.^{9,10}

Since the first series of successful laparoscopic colon resections reported in 1991, the laparoscopic techniques for colorectal diseases have been widely accepted.⁹⁻¹¹

Although many studies have shown the benefits of laparoscopy for colon cancer, including decreased

un procedimiento fiable de realizar, con una morbilidad postoperatoria aceptable y mortalidad baja; no obstante es técnicamente demandante. Esta serie confirma su seguridad, mientras que los resultados oncológicos son actualmente comparables con las series publicadas de ETMA; sin embargo con la limitante de un seguimiento a corto plazo. Se requieren de más estudios aleatorios controlados para evaluar los resultados obtenidos en el seguimiento a largo plazo.

Palabras clave. Laparoscopia. Cáncer de Recto. Escisión Total Mesorectal.

surgical trauma, reduction in perioperative complications, prompt recovery, and survival comparable to conventional surgery, only a few studies have reported the benefits of laparoscopy for rectal cancer.^{12,13}

Procedural complexity has limited the widespread penetration of laparoscopic TME. While there are accumulating reports confirming the technical feasibility of the procedure, its oncologic safety remains controversial.^{9,14,15}

The objectives of this study were to compare open versus laparoscopic mesorectal total excision, assess the feasibility and efficacy of the laparoscopic approach, prospectively examine our experience with laparoscopic TME, analyze the short-term results, and discuss the role of this procedure in treatment of rectal cancer.

MATERIAL AND METHODS

Twenty patients (nine women and 11 men) with low rectal cancer underwent TME with LAR or APR for low rectal carcinoma from November 2005 to April 2006 by surgeons from the department of colorectal surgery in a tertiary academic medical center in Mexico City.

Patients with histologically proven adenocarcinoma of the middle and lower third of the rectum, defined preoperatively as the lower margin of the tumor within 10 cm of the anal verge measured by rigid sigmoidoscopy, were recruited.

In case of tumors less than 3 cm from the anal verge, abdominoperineal resection was performed. For tumors 3 cm from anal verge or above, sphincter-preserving TME was routinely attempted unless there was clinical or radiological involvement of the external anal sphincter.

Ten procedures were performed laparoscopically and 10 by open technique.

Both groups have similar preoperative staging of rectal cancer and epidemiologic data. Tumor stage

Table 1. Clinical and demographic data.

	Open group	Laparoscopic group
Age mean (years)	60.21 (45-85)	57.24 (47-68)
Sex (n)		
Male	6	5
Female	4	5
TNM Stage		
I	5	4
II	5	6
III	0	0
IV	0	0

was defined according to the TNM classification^{16,39} (Table 1).

Inclusion criteria

Patients diagnosed with rectal adenocarcinoma below the peritoneal reflection were included in the study.

Exclusion criteria

Patients diagnosed with tumor pathology other than adenocarcinoma (e.g. lymphoma), those in emergency situations (e.g. acute obstruction, hemorrhage, perforation), and those unwilling to take part in the study were excluded.

Data entry

Patient data were recorded prospectively and supplemented on short-term follow-up visits including standard demographics, operative procedure, location of the tumor, and final pathologic diagnosis. Morbidity and mortality were also included.

The clinical data examined and recorded include tumor localization, duration of surgery, blood loss, histopathologic study, time to onset of borborygmus and to flatus passage, time to resumption of oral intake (liquids), postoperative hospital stay, and morbidity.

Perioperative management

Informed consent was obtained from each patient.

Chest x-ray, abdominal CT scan, colonoscopy, and endorectal ultrasound were routinely performed for staging.

Patients with radiologic T3, T4 or node-positive disease were given neoadjuvant chemoradiation.

Operation was scheduled six weeks after completion of radiotherapy.

All patients received mechanical bowel preparation (polyethylene glycol) plus three doses of erythromycin and neomycin the day before surgery. Prophylactic antibiotic was administered (cefuroxime 1.5 g) on induction of anesthesia and two more doses postoperatively.

Preoperative care was standardized for both laparoscopic and open resection groups. Preoperative assessment included physical examination, liver function test, and carcinoembryonic antigen assay.

Operative technique

A single colorectal surgeon performed all operations with a standard technique. Heald, *et al.* described open resection with TME and details of the technique were reported previously.^{17,18}

We describe the laparoscopic procedure. Conversion was defined as when any part of the procedure, other than specimen delivery, had to be completed with an open technique.

General anesthesia was administered to all patients. Patients are placed in lithotomy position with Trendelenburg and a urinary catheter is inserted after induction of anesthesia. Pneumoperitoneum is established and routine abdominal exploration under the guide of the laparoscope with "no touch" technique is performed. The visceral pelvic fascia along with the mesorectum is kept intact during the course of rectal dissection.

Subsequent to TME approach, high ligation of the inferior mesenteric artery close to its origin and of the inferior mesenteric vein is performed. The rectum and its mesentery are sharply dissected to the anal hiatus ensuring *en bloc* resection of the mesorectum with harmonic scalpel.

The lateral ligaments are gradually divided from the inner limit of the inferior hypogastric nerve fibers. Ideally, the pelvic splanchnic nerves should be left intact. Denonvillier's fascia is dissected anteriorly; while posteriorly the rectosacral fascia, anococcygeal fascia, and pubococcygeus muscle are divided. S2-S4 sacral splanchnic nerves should be identified and protected.

Rectal cross clamping is performed 1.5 to 3 cm below the tumor with an endo-cutter.

An impermeable wound protector is used at the specimen extraction site.

The double stapling technique was performed in LAR. The anastomosis was created intracorporeal and a 10 mm drainage tube was routinely placed in

the pelvic cavity. A loop ileostomy for fecal diversion was created in all patients in the laparoscopic LAR group and in three patients in the open LAR group. Loop ileostomy is usually indicated to avoid anastomotic leakage or dehiscence in colorectal surgery. They are especially indicated in the presence of risk factors such as an anastomosis site closer than 5 cm from the anal margin, radiotherapy, bowel obstruction, wound infection or poor surgical expertise.

Patients were discharged once they were ambulatory, capable of independent stoma care, and had no major complications.

Follow-up

Closure of the ileostomy, following radiologic verification of the colorectal anastomosis integrity, was performed two to three months after resection in patients with no adjuvant therapy and four weeks after they finished their adjuvant chemotherapy and radiotherapy. Patients with T3, T4 and/or node-positive disease received postoperative adjuvant chemotherapy.

Patient's first follow-up was six weeks postoperatively to assess stoma care and to arrange ileostomy closure in the LAR group, then every three months after ileostomy closure for one year. Carcinoembryonic antigen was evaluated at each visit and colonoscopy was performed one year after surgery.

Abdominal CT scan and chest x-ray were performed every six months.

Statistical analysis

Statistical analysis was performed using chi-square test and Student's t-test to determine statistical difference between the laparoscopic and open resection groups.

A p value less than 0.05 was considered statistically significant. Statistical analysis was performed with SPSS for Windows®.

RESULTS

From November 2005 to April 2006, 20 patients presented with non-metastatic adenocarcinoma of the middle and lower third of the rectum. Ten procedures were performed laparoscopically and ten were performed open. TME was accomplished in all patients.

In the laparoscopic LAR group the anastomosis was below the peritoneal reflection. The anastomotic height was within 2 cm of the dentate line in two patients and at or below the dentate line in two patients; in the open group the numbers were two and two, respectively. Two colonic J pouches and two end-to-end anastomosis were performed in the laparoscopic LAR group, as were also in the open group.

Table 2. Surgical outcome.

	Open group	Laparoscopic group
LAR	4	4
APR	6	6
Conversion		0
Cancer cells in surgical margins	0	0
Pathologic type (n)		
Highly differentiated adenomatous carcinoma	4	3
Intermediately differentiated adenomatous carcinoma	6	6
Slightly differentiated adenomatous carcinoma	0	1
Lymphatic nodes (mean) n	8.3 (± 3)	10.2 (± 2.5)
Recurrence	0	0
Mortality	0	0

Table 3. Results of postoperative recovery.

	Open group	Laparoscopic group	p
Operative time (min)	204.4 (120-240)	186.7 (125-210)	< 0.007
Operative bleeding (mL)	229.1 (159-400)	136.7 (100-350)	< 0.007
Reinstitution of oral intake (d)	3 (2-6)	2 (2)	< 0.05
Hospitalization (d)	8.5 (4-13)	6.5 (4-12)	< 0.05

Table 4. Postoperative complications.

Complication	Open group	Laparoscopic group
Wound infection	1	2
Anastomotic leakage	1	0
Fistula	1	0
Sexual dysfunction	1	0

A loop ileostomy for fecal diversion was created in all patients from the laparoscopic LAR group and in three patients from the open LAR group.

The mean operative times for laparoscopic and open procedures were 186.7 min (range, 125-210) and 204.4 min (120-240) $p < 0.007$, respectively; whereas the mean operative blood loss was 136.7 mL (range, 100-350) and 229.1 (150-400) $p < 0.007$, respectively (Tables 2 and 3).

There was a significant difference in time to reinstitute oral intake in the laparoscopic group (2) versus OTME (3, range 2-6) $p < 0.05$.

Postoperative hospital stay was shorter in the laparoscopic group (6.5, range 4-12) versus the open group (8.5, range 4-13) $p < 0.05$.

A significant difference in terms of recovered lymph nodes was found in the LTME (10.2 ± 2) versus OTME (8.3 ± 3) $p < 0.05$.

There was no 30-day mortality. Six patients developed early complications (Table 4).

Morbidity was lower in the laparoscopic group compared to the control group (20% vs 40%).

In the laparoscopic group two patients developed wound infection. In the open TME group one patient had persistent erectile dysfunction at the conclusion of follow-up, one patient had a colonic fistula, one patient presented anastomotic leakage, and one patient presented wound infection.

All surgical margins were negative for cancer cells and no recurrence was found during follow up, which ranged from nine to 15 months.

DISCUSSION

Rectal cancer persists as a significant worldwide problem.^{9,19,20} Despite the improvements during the last two decades in preoperative staging, surgical technique, and adjuvant therapy, local recurrence remains a significant problem.²⁰⁻²²

The technique of TME for the treatment of cancer of the middle and distal third of the rectum is increasingly recognized as a new benchmark of quality.

Developed and popularized by Heald, it represents at present the gold standard, with a 5- and 10-year local recurrence rate of 4% in curative cases; and a 5-year tumor-free survival rate of 78%.^{9,22-24}

Conventional rectal mobilization by blunt dissection has been associated with a high local recurrence rate.²²

Heald, *et al.* and Enker, *et al.* have reported low local recurrence rates in patients with rectal cancer by sharp meticulous perimesorectal dissection and total mesorectal excision. With the introduction of TME, local recurrence rates have been reliably decreased below 10% after curative resection, approximately 6.6% in published series.²⁴⁻²⁶

In the original series by Heald, *et al.* TME was performed in patients with upper rectal cancer.

Lopez-Kostner, *et al.* demonstrated that outcomes of upper rectal cancer treatment in terms of local recurrence and survival were similar to those of sigmoid cancer and that TME was not necessary in upper rectal lesions.¹⁹ Routine TME in upper rectal cancer is now considered unnecessary.

The importance of the complete removal of lymphatic vascular tissue surrounding the rectum and a free circumferential margin has been recognized in the management of rectal cancer.^{27,28}

Recently, the concept of TME has gradually changed. It is defined as complete removal of circumferential fatty tissue around rectum with autonomic nerve preservation.^{1,3,29}

However, the anastomotic leakage rates are high in series of patients with TME and is associated with increased morbidity.^{20,23,28}

The laparoscopic approach to resection for rectal cancer remains controversial due to fears that oncologic principles will be compromised.^{9,21,23,24}

However, the early results of LTME have provided optimism for the oncologic safety and have showed advantages of minimally invasive surgery including earlier return of bowel function, resumption of preoperative activity, shorter hospitalization, and improved cosmesis.

As a technically demanding procedure, laparoscopic TME is currently limited to a number of specialized centers.²²⁻²⁵

Several patient- and tumor-related risk factors for the development of local recurrence have been identified and are being addressed by regimens of pre- or postoperative adjuvant therapy.^{15-18,39}

Surgical dissection along the connective tissue space between rectal and parietal pelvic fascia with complete mesorectal excision results in reliable excision of all relevant lymphatic pathways with preservation of continence and sexual function.

The local recurrence rate after rectal cancer surgery is believed to be related to conventional and total mesorectal excision (TME) techniques. Studies now show that the wide variation in results between centers and among surgeons depends, at least in part, on differences in surgical technique.²¹⁻²⁶

The available evidence for TME is largely composed of retrospective series, although the benefits of TME compare favorably to established conventional controls. Recent studies have clarified the benefit of adjunctive radiotherapy with TME.³⁹

Total mesorectal excision (TME) is the surgical gold standard treatment for middle and lower third rectal carcinoma. Laparoscopy has gradually become accepted for the treatment of colorectal malignancy after a long period of questions regarding its safety.

LTME is a feasible but technically demanding procedure (12% conversion rate) and appears to have clinically measurable short-term advantages in patients with primary resectable rectal cancer.

Minimally invasive TME can be performed safely and efficiently by colorectal surgeons with adequate experience in open and laparoscopic techniques.

Several large prospective studies have reported encouraging results with laparoscopic colorectal surgery for cancer.^{13,18-26,29}

Laparoscopy amplifies images and helps to identify the interspace of loose connective tissue between the visceral and parietal pelvic fascia. Besides, it is easier to identify and protect the pelvic autonomic nerve fiber and plexus of its magnifying effect.

Due to high specialty, the TME requires long and arduous training, more experience when performed laparoscopically.^{22-26,30-32}

In the present study, there was no 30-day mortality and 20% in the LTME experienced early complications. These results compare favorably with open TME series.³³⁻³⁶

The present study demonstrated the short-term benefits that are recognized in general laparoscopic colorectal surgery (less blood loss, quicker return to normal diet, less pain, less narcotic use and less immune response).

It seems likely that LTME is associated with longer operative time. However, in this study we found less operative time in the laparoscopic group and no conversion rate.

No significant differences in terms of local recurrence rate, mortality, morbidity or resection margins were found.

Recovered lymph nodes were significantly greater in the LTME group. Postoperative hospital stay in

the present study was comparable to other series of laparoscopic TME.³²⁻³⁷

Quah, *et al.* suggested that laparoscopic TME might be associated with increased male sexual dysfunction. In their study, however, the open technique was used to complete the distal rectal dissection during which nerve damage is most likely. In contrast, we found in this series a case of erectile dysfunction in the OTME group.^{16,38}

There was no port-site metastasis in the present series, a finding that concurs with recent literature.³¹⁻³⁶

This study shows a small number of patients and short mean follow-up time to conclude on the long-term oncologic outcomes of laparoscopic TME. However, the local recurrence rate in the present study is comparable to other laparoscopic TME series as well as open TME series.

The long-term impact on oncological endpoints awaits the findings of large randomized trials.

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