

# Treatment of rectal adenocarcinoma by laparoscopy and conventional route: a brazilian comparative study on operative time, postoperative complications, oncological radicality and survival

## *Tratamento cirúrgico do adenocarcinoma de reto por laparoscopia e por acesso convencional: estudo comparativo de tempo cirúrgico, complicações pós-operatórias, radicalidade oncológica e sobrevida*

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### A B S T R A C T

**Objective:** To compare two surgical routes (laparoscopic and conventional) for the treatment of rectal cancer with regard to postoperative complications, oncological radicality and survival. **Methods:** This is a retrospective study of 84 patients with rectal cancer who were admitted to the Barretos Cancer Hospital between 2000 and 2003. Only individuals who underwent elective operations with curative intent were included. The surgical approach was subjectively chosen rather than by location of the tumor. **Results:** The laparoscopic access was used by 50% of patients. There was no difference ( $P > 0.05$ ) between the two groups regarding age, sex, topography, staging, neoadjuvant and adjuvant treatment, number of dissected lymph nodes, size of surgical specimen, surgical margins, blood transfusions, postoperative complication rates, hospital stay and overall survival. Surgical time was longer in the laparoscopic group (median: 210x127, 5 min,  $P < 0.001$ ). A reduction in surgical time was noted with the increasing number of laparoscopies performed by the team ( $\rho = -0.387$ ,  $P = 0.020$ ). **Conclusion:** The laparoscopic and conventional routes, for the treatment of rectal cancer, were equivalent with respect to postoperative complications, oncological radicality and survival. However, the operative time was longer in the laparoscopic group.

**Key words:** Colorectal surgery. Laparoscopy. Postoperative complications. Survival analysis. Colorectal neoplasms.

### INTRODUCTION

Colorectal cancer affects approximately one million people each year worldwide. It is the fourth most frequent tumor in men (after lung, prostate and stomach) and third in women (after breast and cervix)<sup>1</sup>. In Brazil, the National Cancer Institute estimated about 27,000 new cases of the disease in 2008<sup>2</sup>.

The guidelines describe various forms of surgical treatment for rectal cancer, depending on the location and staging of the disease. These methods include local resection (transanal endoscopic polypectomy and operation) and radical resection (low anterior resection, total mesorectal excision and abdominoperineal amputation)<sup>3</sup>. Laparoscopy has been increasing in recent years as an access route for rectal surgery. The few prospective studies published on

laparoscopic rectal cancer showed less intraoperative bleeding, faster recovery, less consumption of analgesic medications, reduced formation of intestinal adhesions, decreased postoperative morbidity, decreased length of stay and better quality of life in the first year after surgery. When compared to the conventional route, laparoscopy showed no difference in postoperative mortality, recurrence and survival in cancer patients<sup>4-10</sup>. In spite of the advantages described, the short-term costs of laparoscopic rectal surgery are slightly larger when compared to conventional open procedures<sup>7,11</sup>.

In Brazil, there are few services where the operations of the rectum are performed by laparoscopy, and therefore the number of publications is limited. Aiming to fill this gap, this study aimed at comparing two surgical approaches (laparoscopic and conventional) for the

Study conducted at the Barretos Cancer Hospital – Pius XII Foundation. Developed in the Postgraduate Program, Universidade Federal de São Paulo (UNIFESP), São Paulo, Brazil.

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treatment of adenocarcinoma of the rectum in relation to surgical time, postoperative complications, oncological radicality and overall survival.

## METHODS

This is a retrospective cohort study, conducted with 84 patients with malignant neoplasm of the rectum who were consecutively admitted in the Pio XII Foundation - Hospital de Câncer de Barretos, in the period between January 2000 and January 2003. The study included only individuals submitted to elective procedures with curative intent and without bowel obstruction. We excluded patients with familial colonic polyposis, synchronous cancers or metastatic disease.

Following the protocol recommended by the Barretos Cancer Hospital, patients with cancer of the rectum located four inches from the anal verge underwent neoadjuvant chemotherapy and radiotherapy. The radiotherapy regimen consisted of daily applications of 180cGy, distributed in three fields in the pelvis (one posterior and two lateral), with 10Mev energy up to a dose of 5.040cGy. Chemotherapy was performed in the first five days of radiation therapy and in its last five days, with daily intravenous administration of fluorouracil (420mg/m<sup>2</sup>) and folinic acid (20mg/m<sup>2</sup>). The operation was performed between four and six weeks after completion of neoadjuvant treatment. Patients underwent abdominal rectosigmoidectomy with primary mechanical anastomosis, except in cases where the lower distal margin less than two inches from the dentate line. In these cases, there was abdominoperineal amputation. In patients undergoing neoadjuvant therapy a loop ileostomy was made to protect the anastomosis.

The choice of surgical approach (laparoscopic or conventional) was subjective, according to clinical criteria, availability of material and equipment to perform the procedure. The indications of the approach were not based on tumor location.

All patients underwent mechanical bowel preparation with oral oral sodium phosphate on the eve of the operation. The scheme was adopted with antibiotics metronidazole (1.5 g) and gentamicin (5mg/kg) during anesthesia induction. This scheme was extended to 24 hours after the operation.

The operation was performed according to conventional classical descriptions already established<sup>12-14</sup>, following the oncologic principles described by Heald for resection of mesorectum<sup>15,16</sup>. In laparoscopic operations, the pneumoperitoneum was instilled by modified Hasson technique in the supra-umbilical region<sup>17,18</sup>. Carbon dioxide was used to inflate the abdominal cavity, using the flow of two liters per minute to achieve the maximum working pressure of 12 mmHg. The ports were arranged as follows: 1) 10 mm trocar in the umbilical region (optical element);

2) 12mm trocar on a line represented by the intersection 2cm superior to the anterior superior iliac crest and right lateral border of the rectus abdominis muscle; 3) 5mm trocar on the right flank, and 4) 10 or 5 mm trocar on the left flank. In cases of abdominoperineal amputation, the left trocar was put in a place previously marked by the stoma therapist.

In laparoscopic access we initiated by the dissection of the peritoneum medial to the sigmoid mesocolon for the exposure, isolation and ligation of the inferior mesenteric artery. He went on to dissection from medial to lateral to the left paracolic gutter, resulting in the identification of the left ureter and gonadal vessels. We continued the dissection cranially until the lower edge of the pancreas and identification of the inferior mesenteric vein, which was ligated. We proceeded with the release of tissue between the upper edge of the pancreas and transverse mesocolon toward the splenic angle. Next, we performed the detachment of the left paracolic gutter, from the left iliac vessels to the splenic angle of the colon. With the exposure of the descending and transverse colons, release of the intercoloepiploic ligament was carried out. Dissection continued caudally toward the promontory, where the hypogastric nerves were identified and preserved. The retrorectal pelvic space, the lateral wings and the anterior rectal wall were dissected down to the levator ani muscle.

For rectosigmoidectomies we sought to ensure the bowel wall distal margin of at least 2cm and perirectal fat margin of 4cm. In the case of tumors above the peritoneal reflection, the release of the perirectal fat was performed laparoscopically and the section of the rectum through endostapler (3.8 / 30mm) of 12mm through the right flank trocar. In tumors located below the reflection, after the completion of the laparoscopic dissection of the extraperitoneal rectum, patients underwent suprapubic transverse incision and manually sectioning the rectum by means of conventional linear stapler (fixed or articulated - 3.8mm).

The indication for adjuvant chemotherapy depended on the stage, histological type of tumor, degree of differentiation, preoperative CEA, age and the clinical condition of the patient. The protocol for first-line adjuvant treatment included daily administration of fluorouracil and folinic acid (20mg/m<sup>2</sup> and 425mg/m<sup>2</sup>, respectively) for a period of five days and 28 day intervals, under the guidance of the chemotherapy service.

The study population was characterized using descriptive statistics. Numerical variables were compared using the Student t test or the nonparametric Mann-Whitney test, depending on the assessed adherence to normality using the Kolmogorov-Smirnov test. Categorical variables were compared through the Chi-square association test or Fisher's exact test, depending on the expected values in

contingency tables. The Spearman correlation coefficient was used to assess the correlation between surgical time and number of transactions. For the analysis of survival we used the Kaplan-Meier method, the being curves compared by log-rank test. The level of significance in all tests was 5%.

Before surgery, patients were informed about the procedure, risks and possible intraoperative and postoperative complications. All participants signed a consent form. This study was approved by the Pio XII Foundation Ethics Research Committee and the Universidade Federal de São Paulo (UNIFESP), under number 0886/04.

## RESULTS

The laparoscopic approach was used in 50% of patients. None of the individuals in the laparoscopic group required conversion to conventional surgery. Table 1 shows the distribution of cases according to the access and their sociodemographic and clinical characteristics. There was no statistically significant difference regarding age, sex, topography of rectal cancer and clinical stage. We noticed a difference in body mass index between the two groups, being slightly higher among patients operated by the conventional route (median: 26.4 versus 23.5 kg/m<sup>2</sup>,  $P = 0.05$ ).

There was no difference between groups with regard to the proportion of patients who underwent neoadjuvant treatment, adjuvant treatment and type of surgical resection. Median regional lymph nodes dissected during surgery, the size of the surgical and hospital days were similar between the two groups. The proportion of surgical margins smaller than 2 cm did not differ between the two approaches (Table 2). There was no significant correlation between the number of dissected nodes and

the number of procedures performed, both by laparoscopy ( $\rho = 0.022$ ,  $P = 0.892$ ) and conventionally ( $\rho = -0.264$ ,  $P = 0.091$ ).

Surgical time was significantly higher with laparoscopic access when compared to conventional surgery (median time: laparoscopy = 210min; conventional = 127.5 min,  $P < 0.001$ ) (Table 2). In the group of patients undergoing laparoscopic operations we noticed a significant reduction in surgical time with increasing number of laparoscopic procedures performed by the surgeon ( $\rho = -0.387$ ,  $P = 0.020$ ). The median operative time in the first phase (up to 20 operations) was 240 minutes, while in the second half (21 to 40 procedures), 180 minutes ( $P = 0.027$ ). In the conventional surgery group there was no correlation between surgical time and number of surgeries accumulated during the study ( $\rho = -0.162$ ,  $P = 0.317$ ). Figures 1 and 2 show the correlation between surgical time and number of operations accumulated during the study, according to each surgical approach.

The overall rates of postoperative complications were 26.2% and 42.9% respectively for the laparoscopic and conventional groups ( $P = 0.108$ ). Considering only complications directly related to the surgical procedure (wall dehiscence, abscesses, bladder dysfunction, sexual dysfunction, incisional hernia, anastomotic dehiscence and peritonitis), their complication rates were 14.3% and 31.0% ( $P = 0.068$ ). There were no differences in rates of isolated postoperative complications between the two groups (Table 3).

The median follow up of patients were similar, 66.5 months for patients undergoing laparoscopy and 70.4 months for the conventional access ( $P = 0.163$ ). There was no difference in the probabilities of overall survival between the groups in five years, equal to 75.9% and 78%, respectively, for patients who had laparoscopic and conventional surgery ( $P = 0.908$ ).

**Table 1** – Sociodemographic and clinical Variables.

		Laparoscopy	Conventional	p
Gender	Female	21 (50.0%)	23 (54.8%)	0.66
	Male	21 (50.0%)	19 (45.2%)	
Age (years)	Median (years)	56.5	59.5	0.62
BMI (kg/m <sup>2</sup> )	Median (kg/m <sup>2</sup> )	23.5	26.4	0.05
CEA (preoperative)	Median (µg/l)	3.5	3.2	0.37
Hemoglobin (preoperative)	Median (g%)	12.9	13.0	0.41
Topography in the rectum	Lower 1/3	10 (23.8%)	12 (28.6%)	0.80
	Mid 1/3	10 (23.8%)	11 (26.2%)	
	Upper 1/3	22 (52.4%)	19 (45.2%)	
Staging	EC I	9 (21.4%)	6 (14.3%)	0.67
	EC II	22 (52.4%)	23 (54.8%)	
	EC III	11 (26.2%)	13 (31.0%)	

**Table 2 –** Variables related to treatment.

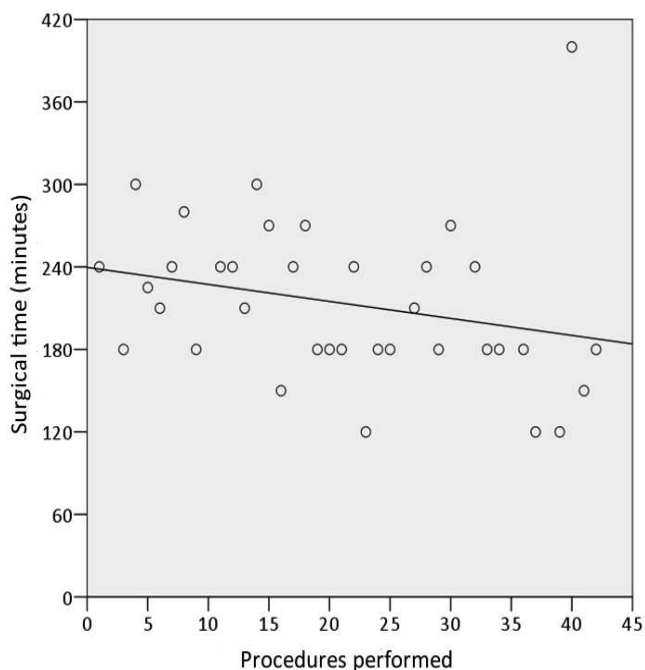
		Laparoscopy	Conventional	p
Neoadjuvant Treatment	Not	22 (52.4%)	19 (45.2%)	0.51
	Yes	20 (45.6%)	23 (54.8%)	
Adjuvant Treatment	Not	15 (35.7%)	13 (30.1%)	0.64
	Yes	27 (64.3%)	29 (69.9%)	
Surgical Procedure	Amputation of the rectum	10 (23.8%)	9 (21.4%)	0.70
	Rectosigmoidectomy	32 (76.2%)	33 (78.6%)	
Surgical margin	< 2 cm	10 (23.8%)	10 (23.8%)	0.14
	2 the 5 cm	20 (47.6%)	27 (64.3%)	
	> 5 cm	12 (28.6%)	5 (11.9%)	
Red Blood Cell Pack	Median (units)	1.0	1.0	0.75
Number of lymph nodes Dissected	Median (number)	6.0	8.0	0.51
Size of Specimen	Median (cm)	21.0	20.0	0.92
Surgical time	Median (minutes)	210.0	127.5	< 0.001
Time of hospitalization	Median (days)	6.0	7.0	0.38

## DISCUSSION

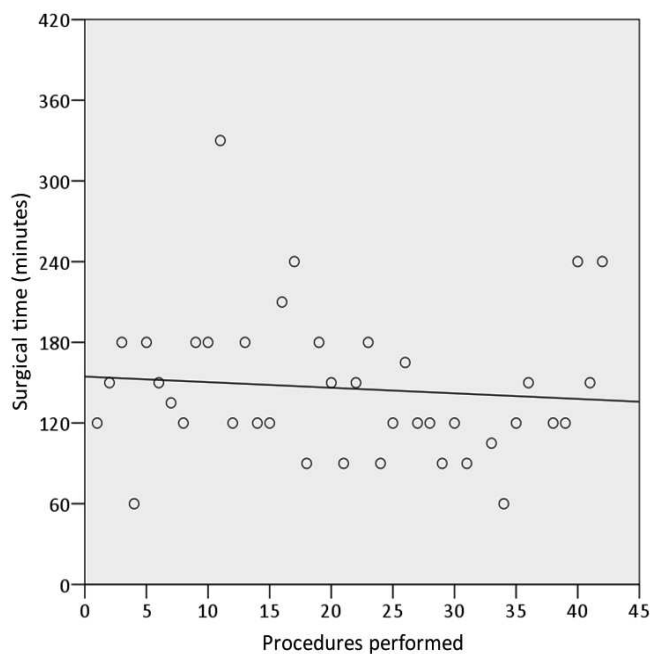
Although the study groups were not randomly obtained, they are perfectly comparable. Among all variables, only BMI was different, being lower in patients who underwent laparoscopy. However, the observed difference between groups is small and probably is without

clinical significance and surgical treatment, regardless of statistical significance.

Other variables that could interfere with postoperative complications such as age, hemoglobin level, preoperative topography of the lesion, staging and treatment performed (type of surgery, adjuvant and neoadjuvant therapy) showed no differences between the two analyzed



**Figure 1 -** Correlation between surgical time and number of laparoscopy operations previously performed by the surgeon ( $\rho = 0.387, P = 0.020$ ).



**Figure 2 -** Correlation between surgical time and number of conventional operations previously carried out by the surgeon ( $\rho = 0.162, P = 0.317$ ).

**Table 3** – Variables related to post-operative complications.

		Laparoscopy	Conventional	p
Postoperative complication	Yes	11 (26.2%)	19 (45.2%)	0.07
	No	31 (73.8%)	23 (54.8%)	
Wall Dehiscence	Yes	6 (14.3%)	7 (16.7%)	0.76
	No	36 (85.7%)	35 (83.3%)	
Intra-abdominal Abscess	Yes	4 (9.5%)	8 (19.0%)	0.21
	No	38 (90.5%)	34 (81.0%)	
Dehiscence of anastomosis	Yes	0 (0.0%)	2 (6.1%)	0.48
	No	32(100.0%)	31 (93.9%)	
Peritonitis	Yes	0 (0.0%)	1 (2.4%)	1.00
	No	42(100.0%)	41 (97.6%)	
Pulmonary infection	Yes	0 (0.0%)	1 (2.4%)	1.00
	No	42(100.0%)	41 (97.6%)	
Bladder dysfunction	Yes	3 (7.1%)	0 (0.0%)	0.24
	No	39 (9.29%)	42(100.0%)	
Sexual dysfunction	Yes	1 (2.4%)	0 (0.0%)	1.00
	No	41 (97.6%)	42(100.0%)	
Incisional hernia	Yes	0 (0.0%)	3 (7.1%)	0.24
	No	42(100.0%)	39 (92.9%)	
Reoperation	Yes	0 (0.0%)	3 (7.1%)	0.24
	No	42(100.0%)	39 (92.9%)	

groups. It must be noted, however, that the variables related to operative morbidity (ASA classification of risk, Goldman, performance status) were not included in the analysis, since in many cases this information was not reported in the medical record. Thus, it became impossible to adequately compare the groups with regard to surgical morbidity.

It is necessary to emphasize that selection bias was the main limitation of this study, since the data were retrospectively collected, without randomization. It is natural that for new surgical procedures the intentional selection of more favorable patients occurs at the beginning of the learning curve, as probably happened in this study. One clue is that this difference was observed in relation to BMI between groups, being lower in the group that underwent laparoscopy.

There was no detectable difference in the length between the two access routes. This finding is not in accordance with the literature. Clinical trials and meta-analysis comparing the two approaches for colorectal cancer are unanimous in declaring that the length of stay is shorter when laparoscopy is used<sup>4,7,9,10,19,20</sup>. The probable explanation for this unexpected result is the characteristic service of the Barretos Cancer Hospital. Patients come from various states in the country, traveling long distances from their origins. Hospital discharge is then delayed to reduce the effects of possible complications such as postoperative anastomotic leakage, infection of the abdominal wall, among others.

The overall rate of postoperative complications was lower in the group that underwent the laparoscopic

procedure. This difference was not significant from a statistical viewpoint, possibly due to the small number of cases in each group. For this observed difference to be significant from the statistical point of view, it would take at least 124 cases in each group analysis (assuming an alpha error of 5% and beta error of 20%). The matter is controversial, even for clinical trials. While some trials found a reduction of postoperative morbidity when laparoscopy was used<sup>5,9,10</sup>, others found no difference when compared to laparotomy<sup>4,6-8,20,21</sup>.

Interestingly, in this study, all cases of sexual or bladder dysfunction after the operation occurred only in patients who had undergone laparoscopy. Quah *et al.*<sup>22</sup> evaluated 170 patients with rectal cancer undergoing mesorectal resection who were randomly allocated to receive treatment by laparoscopy or conventional laparotomy. The bladder and sexual functions of patients were evaluated by questionnaire before and after surgery. The results showed an increase in sexual dysfunction in men undergoing laparoscopy (impotence and worsening of ejaculation), but not in relation to bladder function. This effect was also observed in the CLASICC clinical trial conducted in the UK<sup>23</sup>. In this study, the bladder function was similar among those who underwent rectal surgery by laparoscopy or conventional surgery. The male sexual function tended to worsen in patients undergoing laparoscopy. The study authors identified the total mesorectal excision and conversion to open surgery as predictors of male sexual dysfunction. According Schiedeck *et al.*<sup>24</sup>, the broad view provided by laparoscopy could be

related to a more extended pelvic dissection, favoring nerve damage.

The median time of laparoscopic surgery was significantly higher than the conventional. This finding has also been described in some clinical trials and meta-analysis<sup>4,6,7,9,21</sup>. This fact is explained by the learning curve involved in surgical procedures. Figure 1 clearly shows the reduction of surgical time with increasing experience of the surgeon and his team with the laparoscopic procedure. However, when looking at the surgical time spent with the conventional route, we found that there was no significant decrease over time.

These differences demonstrate the technical profile of the surgical team at the beginning of the study, which fully dominated conventional surgery, but not completely laparoscopy. By the learning curve in this study and considering a mathematical model of linear regression, it is estimated that it would take about 90 laparoscopic procedures in the rectum for the team in question to achieve the same surgical time average achieved in conventional surgery. However, this number should not be taken as a rule or standard to achieve, since the educational institutions and surgeons have different fundamentals and skills in laparoscopy. What we see is that the learning curve of laparoscopic colorectal surgery is much slower when compared to other laparoscopic procedures such as cholecystectomy, appendectomy and correction of hiatal hernia.

Rectal operations performed laparoscopically and conventionally seem to be equivalent with regard to oncological safety. The present study showed similar survival probabilities in both groups studied, which was also described by other authors<sup>5-7,25-27</sup>. This study also observed the equivalency as for oncological radicality according to surgical approach, with no difference in the size of the specimen, the number of dissected lymph nodes and the surgical margins. Lujan *et al.*<sup>4</sup> found a slight, but significant,

increase in the number of lymph nodes removed by laparoscopy. However, the works of Arteaga *et al.*<sup>20</sup> and Pechlivanides *et al.*<sup>28</sup> observed no difference between the two groups regarding the number of dissected nodes. Nevertheless, it is necessary to emphasize that the number of lymph nodes dissected in this study was lower than previously reported by other authors<sup>4,28</sup>. For all patients, regardless of the access, we respected the principle of ligation of inferior the mesenteric vessels as cranial as possible (close to the abdominal aorta) to allow the removal of more lymph nodes. It might be objected that the reduced number of lymph nodes was due to lack of experience of the laparoscopic surgical team at the beginning of the study. However, the number of dissected lymph nodes did not correlate with the number of operations performed in any of the groups. A possible explanation for the low number of dissected lymph nodes may be found in the technical processing of the specimen.

As for the surgical margins, the results are contradictory. Trials from Lujan *et al.*<sup>4</sup>, Guillou *et al.*<sup>8</sup>, and the meta-analysis by Anderson *et al.*<sup>27</sup> showed that rates of compromised surgical margins were similar between groups. However, there is at least one clinical trial that observed a higher rate of positive margins in patients who had laparoscopic anterior resection<sup>25</sup>, while another noted wider surgical margins when laparoscopy was used<sup>20</sup>.

In summary, this retrospective study found that laparoscopic and conventional routes for the treatment of adenocarcinoma of the rectum proved to be equivalent with regard to oncological radicality and safety, though operative time was significantly higher in the laparoscopic approach. Although laparoscopy has presented a lower rate of postoperative complication, the observed difference was not statistically significant, probably due to the small number of cases.

## R E S U M O

**Objetivo:** Comparar duas vias cirúrgicas (laparoscópica e convencional) para o tratamento de câncer de reto no que se refere às complicações pós-operatórias, radicalidade oncológica e sobrevida. **Métodos:** Trata-se de estudo retrospectivo com 84 pacientes com câncer retal que foram admitidos no Hospital do Câncer de Barretos entre 2000 e 2003. Somente os indivíduos que se submeteram à operações eletivas (intenção curativa) foram incluídos. A via cirúrgica foi escolhida subjetivamente e não com base na localização do tumor. **Resultados:** O acesso laparoscópico foi utilizado por 50% dos pacientes. Não houve diferença ( $P > 0,05$ ) entre os dois grupos em relação à: idade, sexo, topografia, estágio, tratamento neoadjuvante e adjuvante, número de linfonodos regionais dissecados, tamanho da peça cirúrgica, margens cirúrgicas, transfusões de sangue, taxas de complicações pós-operatórias, dias de hospitalização e a taxa de sobrevida global. O tempo cirúrgico foi maior no grupo laparoscópico (mediana: 210x127,5min,  $P < 0,001$ ). Houve diminuição do tempo cirúrgico com o aumento do número de laparoscopias realizadas pela equipe ( $\rho = -0,387$ ,  $P = 0,020$ ). **Conclusão:** As vias laparoscópica e convencional, para o tratamento de câncer de reto, foram equivalentes em relação às complicações pós-operatórias, radicalidade oncológica e sobrevida. Contudo, o tempo cirúrgico foi maior no grupo da laparoscopia.

**Descritores:** Cirurgia colorretal. Laparoscopia. Complicações pós-operatórias. Análise de sobrevivência. Neoplasias colorretais.



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