



KINGDOM OF MOROCCO
MOHAMMED V UNIVERSITY OF RABAT
FACULTY OF MEDICINE AND PHARMACY – RABAT



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**COMPARISON OF SHORT-TERM AND LONG-TERM
OUTCOMES OF LAPAROSCOPY VERSUS
LAPAROTOMY IN RECTAL CANCER :
SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED
CONTROLLED TRIALS**

THESIS

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For the degree
Doctor of Médecine

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العليم الحكيم﴾

سورة البقرة: الآية: 32

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عَلًا وَهَزًّا وَفِصَالَهُ فِي عَمِيرٍ أَنْ أَشْكُرَ لِي

وَلِوَالِدَيْكَ إِلَيَّ الْمَصِيرُ﴾

سورة لقمان: الآية: 14

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KHALED Abdellah

Chef du Service des Ressources Humaines

FMPR

DEDICATIONS

A la mémoire de ma grand-mère Hajja Houda

Partie trop tôt et qui a laissé un grand vide

A mon grand-père Hajj Ali

A ma mère, Fatima KHALFAOUI

A la femme qui m'a donné la vie

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Professeur de chirurgie oncologique digestive

Institut national d'oncologie, Rabat

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Chef de service du service de chirurgie oncologique digestive

Institut national d'oncologie, Rabat

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ABBREVIATIONS LIST

RCT : randomized controlled trial

DFS : Disease-free survival

CRM : Circumferential radial margin

OS : overall survival

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INTRODUCTION

Surgery constitutes the mainstay of rectal cancer treatment . The use of laparoscopy in colorectal pathology has been widely adopted. It has been demonstrated that laparoscopy had better postoperative outcomes and similar oncological outcomes than laparotomy in colon cancer⁵.

In the late 90's , laparoscopy had 3 basic roles in colorectal cancer: diagnosis especially staging, palliative management of patients with incurable colorectal cancer and an unproved role in the treatment of curable cancer. ⁶

In 2005, the Standard Practice Task Force of ASCRS announced that “Laparoscopic techniques for rectal cancer are established and feasible, meanwhile for colon cancer is safe and effective”^{7 8} . (Class II Level of Evidence and Degree of Recommendation B).

Among the first trials that compared short-term and long-term outcomes of laparoscopy and laparotomy in colorectal cancer, the MRC (Medical Research Council) CLASICC controlled trial ⁹ reported a similar longitudinal resection margins and lymph-node yield in both groups, a non-significant higher rate of tumor-positive circumferential resection margins after laparoscopic surgery. No significant differences were found in local recurrences rate or 3-years overall survival [OS], disease-free survival [DFS], and quality of life¹⁰. The authors concluded that tumor-positive circumferential resection margins rate was higher after laparoscopic surgery, as a main conclusion of the study , despite the non-significance of the result¹¹. The last randomized controlled trials , the ACOSOG Z6051 ^{1,2} in 2015-2019 and the ALaCaRT trial ^{3,4} in 2015-2019 could not show the non-inferiority of the laparoscopy in comparison to laparotomy in rectal cancer. In fact, the ten first years of practicing laparoscopy were years when surgeons developed their learning curve and could acquire the needed expertise only after 2010. Therefore, by excluding this learning bias, it is possible to end up with a more fair and correct comparison between the two techniques. It is henceforth relevant to pursue a new meta-analysis that compares the two techniques and excludes studies done during the earlier periods of laparoscopic rectal surgery.

METHODOLOGY

This systematic review and meta-analysis was performed in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement and following the Meta-Analysis and systematic review Cochrane guidelines¹².

I. Eligibility criteria

We aimed at identifying all randomized controlled trials that compared short term outcomes and long term outcomes post laparoscopy and laparotomy in patients with rectal cancer. The inclusion criterias were :

- Randomized controlled trials
- Papers published after 2010.
- Primary Rectal adenocarcinoma.
- Comparison of laparoscopy and laparotomy
- Patients over 18 years old

The exclusion criterias were the following:

- Duplicate or repeat studies
- Meta-analysis, non-comparative studies, conference abstracts, expert opinions, editorials, letters and commentaries.
- Non-human research.
- Interventions on cadavers.
- Articles with languages other than French or English.
- Studies with benign lesions.
- Robotic surgery and transanal mesorectal excisions.
- Single-port laparoscopic surgery.

II. Literature search strategy

A search was performed in the PubMed database and Cochrane library on November 12th 2019. We identified the Medical Subject Headings (MeSH) terms for rectal cancer which is “rectal neoplasm”, and for laparoscopy which is “laparoscopy”, then launched the research by combining the two items.

The following key words and Medical Subject Headings (MeSH) terms were used for both databases:

MESH: rectal neoplasms/Rectal cancer (Title or abstract)/Cancer AND rectum (Title or abstract)/Cancer AND rectal (Title or abstract)/Tumor AND rectum (Title or abstract)/Tumor AND rectal (Title or abstract)/Tumour AND rectum (Title or abstract)/Tumour AND rectal (Title or abstract)/Adenocarcinoma AND rectum (Title or abstract)/Adenocarcinoma AND rectal (Title or abstract)/Rectal resection (Title or abstract),Proctectomy (Title or abstract)/Anterior resection (Title or abstract),Low anterior resection (Title or abstract)/Mesorectal excision (Title or abstract)/Abdominoperineal resection (Title or abstract)/Abdomino-perineal resection (Title or abstract)

MeSH: Laparoscopy/Mini-invasive surgery (Title or abstract)/Mini-invasive surgery (Title or abstract)/Laparoscopic (Title or abstract)

III. Study selection

Study selection was performed in three phases according to the PRISMA statement (Figure 1). After identifying the articles, using the first filter which comprises the inclusion and exclusion criteria, two independent researchers selected articles based on the titles and abstracts. All discrepancies were resolved by discussion and consensus. The same researchers screened full texts and selected studies for inclusion in the systematic review and the meta analysis. Discrepancies at this stage were resolved by discussion and consensus. Six trials met the eligibility criteria and papers from the same trial were analyzed as one study. Four trials

presented two papers for short-term and long-term outcomes, and two presented all outcomes in one paper.

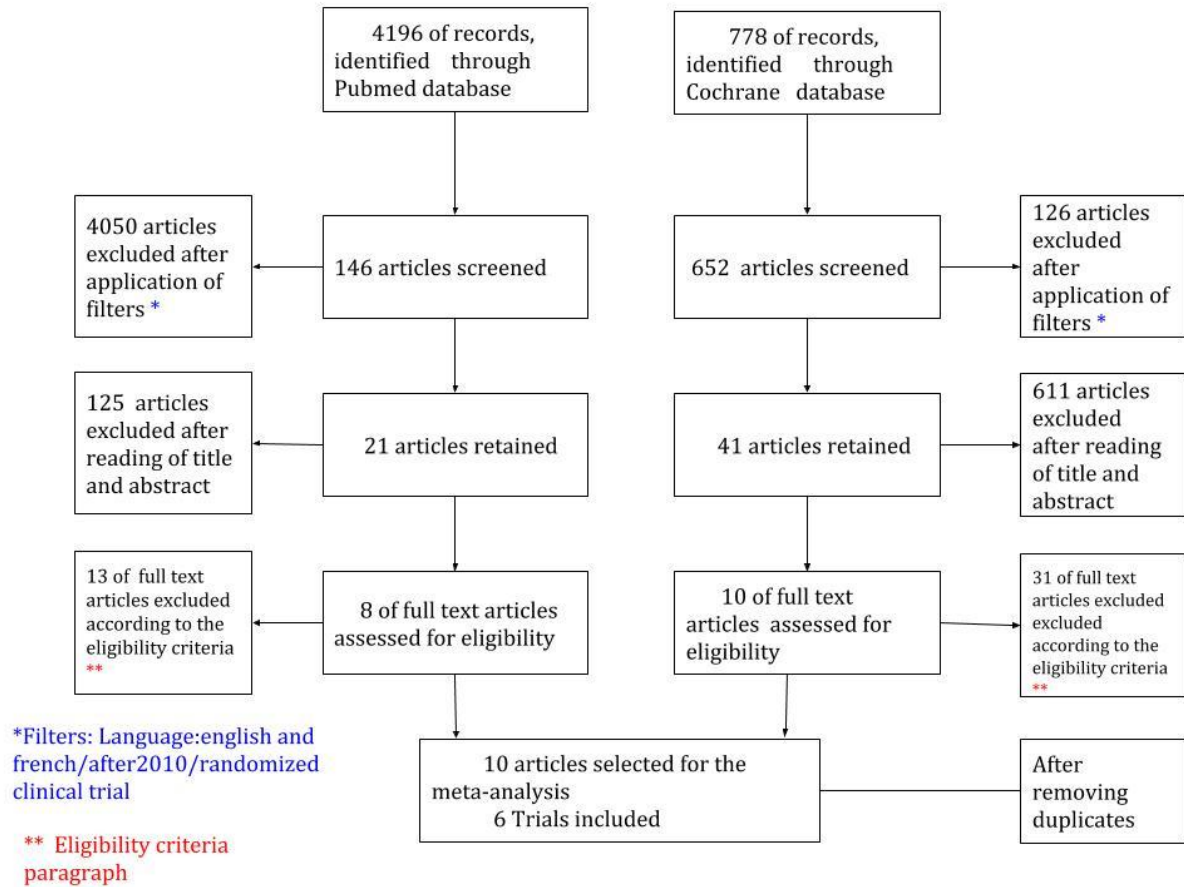


Figure 1: PRISMA diagram

Table 1 represents the selected studies in column, year of publication, Digital Object Identifier of papers studying short-term and long-term outcomes and country in line.

Table 2 represents baseline characteristics of the studied population in each trial.

Tableau 1 : Selected randomized controlled trials in this meta-analysis

Trial	Year of publication	Short-term outcomes	Long term outcomes	Country
COLOR II	2013 2015	Pas et al ¹³	Bonjer et al ¹⁴	Multi-center
ALaCaRT	2015 2019	Stevenson et al ³	Stevenson et al ⁴	Australia
COREAN trial	2010 2014	Kang et al ¹⁵	Jeong et al ¹⁶	Korea
ACOSOG Z6051	2015 2019	Fleshman et al ²	Fleshman et al ¹	USA
Ng's trial	2014	Ng et al ¹⁷	Ng et al ¹⁷	Hong Kong
Liang's trial	2011	Liang et al ¹⁸	Liang et al ¹⁸	China

Tableau 2 : Baseline characteristics of the studied population

First author (Trial name)	Year of publication	Single or multicenter design (SC/MC)	Tumour stage exclusion criteria	Number of participants LAP/OPEN (n)	Female/ Male (n)	Mean age LAP/OPEN (years)	Mean distance of the tumour from anal verge LAP/OPEN (cm)	Types of surgery	Neoadjuvant treatment LAP/OPEN n (%)	Ileostomy LAP/OPEN n (%)	Conversion rate n (%)
Pas et al ¹³	2013										
Bonjer et al ¹⁴ (COLOR II)	2015	MC	T4	699/345	385/669	66.8/65.8	ND	PME, TME, APR	636(91.0)/ 317(92.0)	243 (34.8)/ 131(38.0)	119(17)
Stevenson et al ^{3,4} (ALaCaRT)	2015 2019	MC	T4	238/237	164/311	65.0/65.0	ND	TME, APR	119(50.0)/ 117(49.4)	68.1/59.5	21 (8.8)
Kang et al ¹⁵	2010										
Jeong et al ¹⁶ (COREAN trial)	2014	MC	T4, M1	170/170	120/220	57.8/59.1	5.6/5.3	TME, APR	170(100)/ 170(100)	138(81.2)/ 129 (75.9)	2 (1.2)
Fleshman et al ^{1,2} (ACOSOG Z6051)	2015 2019	MC	T4, M1	240/222	148/314	57.7/57.2	6.1/6.3	TME, APR	236(98.3)/ 215(96.7)	171 (71.3)/ 165(74.3)	27 (11.3)
Ng et al ¹⁷ (Ng's trial)	2014	SC	T4	40/40	34/46	60.2/62.1	6.9/7.1	TME	ND	20(50.0)/ 26(65.0)	3 (7.5)
Liang et al ¹⁸ (Liang's trial)	2011	SC	M1	169/174	147/196	57.3/57.3	ND	LAR, APR	0/0	ND	ND

APR : Abdominoperineal resection/ LAR: Lower anterior resection/ MC: Multicentre/ SC: Single centre / TME: Total mesorectal excision (anterior resection) / PME: Partial (upper) mesorectal excision/ ND: No data/ LAP: Laparoscopic approach/ OPEN : Open approach.

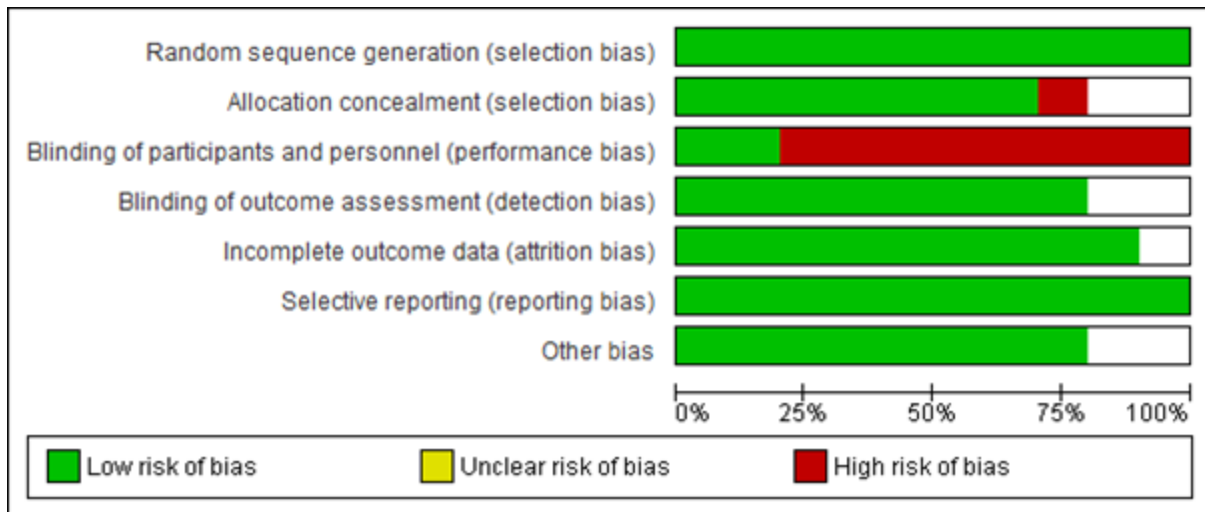
IV. Risk of bias

Risk of bias was assessed by two independent researchers using the Cochrane Collaboration's tool for assessing risk of bias.¹⁹

Figure 2 represents the risk of bias summary.

Figure 2 : The risk of bias summary

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bonjer 2015	+	+	+			+	+
Fleshman 2015	+		-		+	+	+
Fleshman 2018	+	-	-	+	+	+	+
Jeang 2014	+	+	-	+	+	+	+
Kang 2010	+		-	+	+	+	+
Liang 2011	+	+	+	+	+	+	
ng 2014	+	+	-	+	+	+	
Stevenson 2015	+	+	-	+	+	+	+
Stevenson 2019	+	+	-	+	+	+	+
vanderpas 2013	+	+	-	+	+	+	+



V. Outcome measures

1) Short term outcomes

For per operative outcomes, this meta-analysis compared blood loss(mL) and operative duration (min) .

For the post-operative outcomes, the measures included:

- Length of hospital stay (days)
- Reoperation rate (within 30 days from surgery)
- First bowel movement (days)
- Anastomotic leakage rate
- Mortality (from the day of surgery until 30 days after surgery).

Regarding the histology of the specimen, the primary outcomes were:

- Number of removed lymph nodes
- CRM status (circumferential radial margin)

- Completeness of mesorectal excision. On the basis of Nagtegaal et al. classification ²⁰, and in order to make a meta-analysis, we grouped “complete” and “nearly complete” mesorectal excisions as “complete” and were compared with “incomplete” mesorectal excisions.

2) Long term outcomes

The primary outcomes were locoregional recurrence, overall survival and disease free-survival.

VI. Statistical analysis

Analysis was performed using RevMan 5.3 (freeware from the Cochrane Collaboration) Review Manager Web (RevMan Web). The Cochrane Collaboration, 2019. Available at revman.cochrane.org. We used mean and standard deviation when it was provided by the study. According to the Cochrane handbook, the median is very similar to the mean when the distribution of the data is symmetrical, and so occasionally can be used directly in meta-analyses. In addition to that, the width of the interquartile range will be approximately 1.35 standard deviations ²¹. We started from this principle to obtain mean and standard deviation when non-provided, in order to do a meta-analysis.

For the dichotomous data, the statistical method used is the Odds ratios, by means of the Mantel–Haenszel fixed-effects with pertinent 95% confidence intervals (CI). Concerning the continuous data, the statistical method used was the mean difference by the mean of the inverse variance fixed-effect method with pertinent 95% confidence intervals (CI). Results were presented in forest plots, providing an estimate of the mean proportion with a 95% confidence interval (CI).²²

RESULTS

I. Search results

A total of 4196 records were identified through PubMed database search and 778 records through Cochrane database search (Figure 1). After applying the research filters which are: randomized clinical trials, articles written in English or French and published after 2010; 146 records were retained from the PubMed database and 652 records from the Cochrane database. When screening titles, abstracts and full articles, we retained 8 articles and 10 articles from PubMed and Cochrane databases respectively. After removing duplicates, 10 articles were screened for eligibility according to the eligibility criteria previously cited. Papers from the same trial were analyzed as one study, so that a total of 6 trials were analyzed: COLOR II^{13,14}, AlaCart^{3,4}, COREAN trial^{15,16}, ACOSOG Z6051^{1,2}, Ng's trial¹⁷ and Liang's trial¹⁸. There were 4 trials (COLOR II^{13,14}, AlaCart^{3,4}, COREAN trial^{15,16}, ACOSOG Z6051^{1,2}), in which results were reported in two papers, one paper reporting short term outcomes and the other long term outcomes. Ng's trial¹⁷ and Liang's trial¹⁸ presented both short and long term outcomes in the same paper. A total of 1556 patients in the laparoscopic group and 1188 patients in the open group were analyzed in the present meta-analysis (Figure 1).

II. Short term outcomes

1) Per operative outcomes

1.1. Operative duration

Operative duration was reported in all trials. In COLOR II^{13,14} trial and AlaCart trial^{3,4}, results were reported in median and range, therefore, the means and standard deviation were calculated as stated in the statistical analysis section. The analysis showed that operative duration was significantly shorter in the laparotomy group with a mean difference of 28.51 minutes [24.74, 32.28] CI 95% (P < 0.00001) (figure 3).

1.2. Blood loss

Blood loss (mL) was analyzed in five trials, out of 1387 patients in the laparoscopy group and 1012 in the laparotomy group. Results were given in median and range in the COLOR II trial^{13,14}, AlaCart trial^{3,4}, COREAN trial^{15,16} and Ng's trial¹⁷. Therefore, the means and standard deviations were calculated as stated in the statistical analysis section. The findings showed that blood loss was statistically lower in the laparoscopy group: Mean difference -70.62 ml [-88.84, -52.40] CI 95% (P < 0.00001) (figure 4).

Forest plot of perioperative outcomes

Figure 3 : Forest Plot of pooled of estimates of operative duration comparing laparoscopy to laparotomy

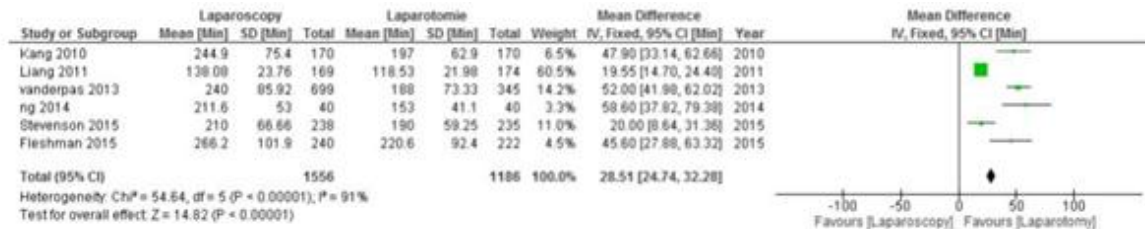
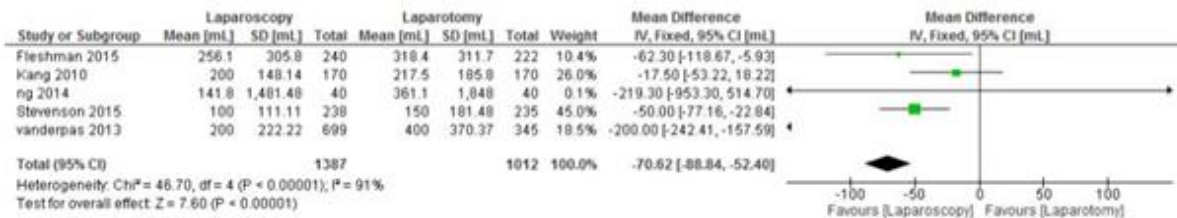


Figure 4 : Forest Plot of pooled of estimates of blood loss (mL) comparing laparoscopy to laparotomy



2) Postoperative morbidity

2.1. Anastomotic leakage

The data concerning anastomotic leakage were reported in all trials with no significant difference between the two groups. Odds ratio 1.14 [0.77, 1.68] CI 95% P = 0.52. (figure 5).

2.2. First bowel movement

First bowel movement was reported in all trials. Results were reported in median and range in AlaCart trial^{3,4}, COREAN trial^{15,16}, Ng's trial¹⁷ and ACOSOG Z6051 trial^{1,2}. The analysis showed that the first bowel movement was faster in the laparoscopy group (mean difference -0.53 days [-0.65, -0.41] CI 95% P < 0.00001) (figure 6).

2.3. Hospital stay

Length of hospital stay (days) was reported in five trials. For missing data, in the COLOR II trial^{13,14}, it affected 15/699 in the laparoscopy group and 8/345 in the laparotomy group. Results were presented in median and range in AlaCart trial^{3,4}, COREAN trial^{15,16} and Ng's trial¹⁷. Findings showed that hospital stay was shorter in the laparoscopy group, but not statistically significant: Mean difference -0.29 days [-0.72, 0.13] CI 95% (P = 0.18) (figure 7).

2.4. Mortality

All trials studied 30-days mortality after surgery. Out of a total of 2742 patients, 1556 were in the laparoscopy group and 1186 patients in the laparotomy group. The analysis showed less mortality in the laparoscopy group but statistically not significant (Odds ratio 0.67[0.28, 1.61] CI 95%. P = 0.37) (figure 8).

2.5. Reoperation

Three trials reported data on reoperation, and findings showed no statistically significant difference between the two groups (Odds ratio 1.18 [0.84, 1.64] CI 95%. P = 0.34) (figure 9).

Forest plot of postoperative outcomes

Figure 5 : Forest Plot of pooled of estimates of anastomtic leakage comparing laparoscopy to laparotomy



Figure 6 : Forest Plot of pooled of estimates of first bowel movement comparing laparoscopy to laparotomy



Figure 7 : Forest Plot of pooled of estimates of lenght of hospital stay in days comparing laparoscopy to laparotomy

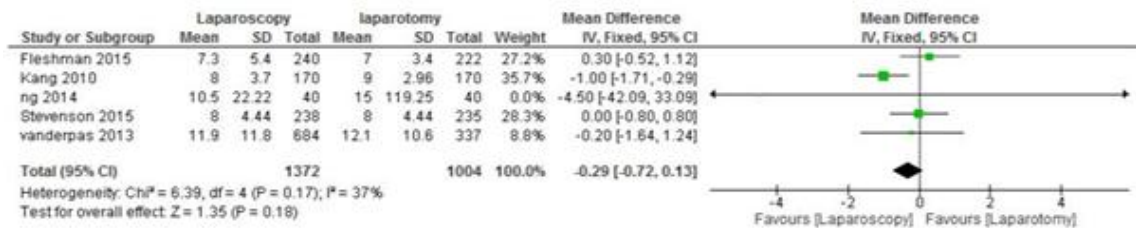


Figure 8 : Forest Plot of pooled of estimates of 30-days mortality after surgery comparing laparoscopy to laparotomy

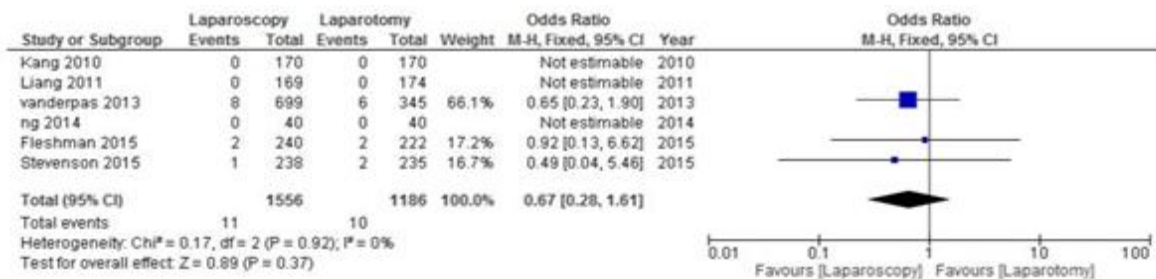


Figure 9 : Forest Plot of pooled of estimates of reoperation comparing laparoscopy to laparotomy



3) Quality of resected specimen

3.1. Harvested lymph nodes

The number of harvested lymph nodes was reported in 5 trials, a total of 1339 patients. There was missing data was 16/699 (2%) in the laparoscopy group and 4/345 (1%) in the laparotomy group in the COLOR II trial^{13,14}. COREAN trial^{15,16} and COLOR II trial^{13,14} reported results using median and range. All the studies were in favour of the laparoscopy, except Ng's trial¹⁷.

The number of harvested lymph nodes was statistically higher in the laparoscopy group: Mean difference -0.46 [-0.83, -0.09] CI 95% (P = 0.01) (figure 10).

3.2. CRM

Positive circumferential resection margins (CRM) ≤ 1mm was reported in five trials. Missing data concerned COLOR II trial with 78/666 (12%) in the laparoscopy group and 26/326 (8%) in the laparotomy group. In the AlaCart trial^{3,4}, data was provided for 211/238 patients in the laparoscopy group and 201/235 patients in the laparotomy group. On the basis of 1249 patients in the laparoscopy group and 933 patients in the laparotomy group, no statistically significant differences were found in the number of positive CRMs between the two groups : Odds ratio 1.07 [0.77, 1.47] CI 95% (P = 0.70) (figure 11).

3.3. Quality of mesorectum

Data on the completeness of mesorectal excision were reported in five trials, including 2337 patients, 1348 in the laparoscopy group and 989 in the laparotomy group. Concerning

missing data, in the COLOR II trial^{13,14}, it was 33/699 in the laparoscopy group and 14/345 in the laparotomy group, and in the AlaCart trial^{3,4}, it was 27/238 in the laparoscopy group and 34/235 in the laparotomy group. In three trials, the classification proposed by Nagtegaal et al.²⁰ was used, describing the excision of the mesorectum as complete, nearly complete or incomplete. In the COLOR II trial^{13,14}, the excision of the mesorectum was qualified as complete, partially complete or incomplete. In Ng’s trial¹⁷, only complete mesorectal excision was reported. In order to do a meta-analysis we considered partially complete mesorectal excision as complete, in the COLOR II trial^{13,14}. We also considered nearly complete as complete in opposition to incomplete, according to Nagtegaal’s paper²⁰.

Thus, we compared incomplete mesorectal excision in the five trials, out of 1348 patients in the laparoscopy group and 989 patients in the laparotomy group. Findings showed that there were no significant differences among the studies: Odds ratio 1.30 [0.85, 1.99] CI 95% (P = 0.23) (Figure 12).

Forest plot of oncological outcomes

Figure 10 : Forest Plot of pooled of estimates of harvested lymph nodes comparing laparoscopy to laparotomy

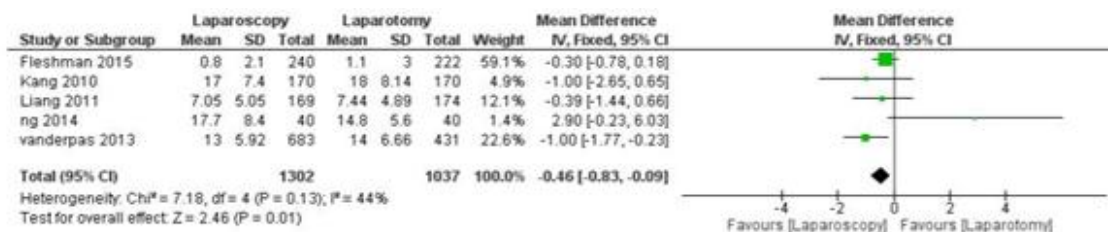


Figure 11 : Forest Plot of pooled of estimates of positive CRM comparing laparoscopy to laparotomy

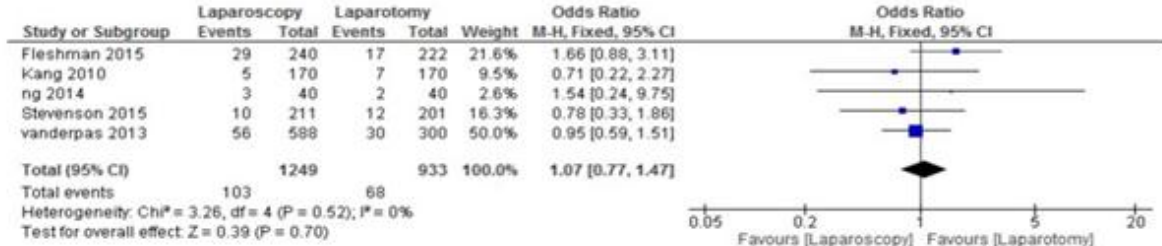
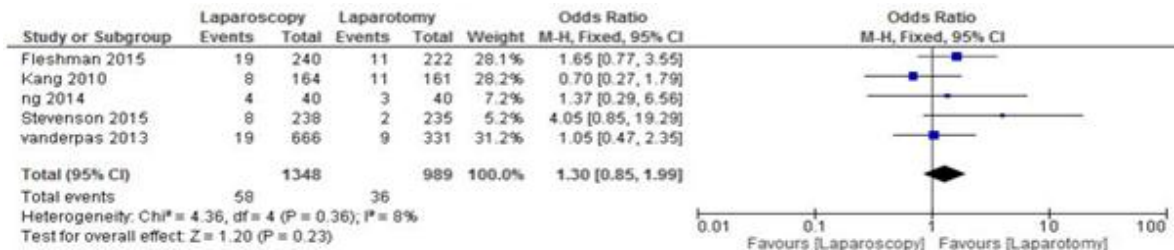


Figure 12 : Forest Plot of pooled of estimates of incomplete mesorectal excision comparing laparoscopy to laparotomy



III. Long term outcomes

Data about long term outcomes were not reported homogeneously between studies. Therefore, we were not able to perform a meta-analysis.

1) Recurrences

In the AlaCart trial⁴, locoregional recurrence rates at 2 years were 5.4% in the laparoscopy group and 3.1% in the laparotomy group [difference, 2.3%; 95% confidence interval (CI), 1.5% to 6.1%; hazard ratio (HR) 1.7; 95% CI, 0.74–3.9]. Four trials reported the locoregional recurrence rate at 3 years. In the COLOR II trial¹⁴, the locoregional recurrence rate at 3 years was 5.0% in the two groups (difference, 0 percentage points; 90% confidence interval [CI], -2.6 to 2.6). In the Corean trial¹⁶, the locoregional recurrence rate at 3 years was 2.6% (1.0 to 6.7) in the laparoscopy group and 4.9% (2.5 to 9.6) in the laparotomy group, difference 2.3% (-1.8 to 6.4). The ACOSOG 6051 trial¹ had studied local, regional and

distant recurrence at 3, 6, 9, 12, 18 and 24 months. Locoregional recurrence rates at 2 years were 2.1% in the laparoscopy group and 1.8% in the laparotomy (P= 0.86). Distant metastasis was similar between the groups (14.6% in the laparoscopy group; 16.7% in the laparotomy group).

In Ng's trial¹⁷ locoregional recurrence rates at 5 years were not different between the two groups : 2.8% in the laparoscopy group and 8.9% in the laparotomy group (P = 0.187).

To conclude, no difference was found between the two groups for locoregional recurrences.

2) Disease-free survival

Two trials presented the disease free survival DFS at 3 years. The COLOR II trial¹⁴ survival rates were 74.8% in the laparoscopy group and 70.8% in the laparotomy group (difference, 4.0 percentage points; 95% CI, -1.9 to 9.9).The Corean trial¹⁶ found a 3 years disease-free survival rate at 72.5% (95% CI 65.0–78.6) for the laparotomy group and 79.2% (72.3–84.6) for the laparoscopy group. Two trials presented the disease free survival at 2 years. For the AlaCart trial⁴, the disease free survival at 2 years was 80% in the laparoscopy group and 82% in the laparotomy group, a difference of 2.0%(95% CI, 9.3% to 5.4%). For the ACOSOG Z6051 trial¹, the 2-years DFS was 79.5% (95% confidence interval [CI] 74.4–84.9) for the laparoscopy group and 83.2% (95% CI 78.3–88.3) for the laparotomy group. Ng's trial¹⁷ concluded that probabilities of being disease-free at 5 years were 83.3% for the laparoscopy group and 74.5 % for the laparotomy group (P = 0.114).

In summary, disease-free survival was the same in the laparoscopy group and in the laparotomy group.

3) Overall survival

Three trials reported overall survival at 3 years. In the COLOR II trial¹⁴, Overall survival rates at 3 years were 86.7% in the laparoscopy group and 83.6% in the laparotomy group (difference, 3.1 percentage points; 95% CI,-1.6 to 7.8).

In the Korean trial¹⁶, the overall survival rates at 3 years were 90.4% (84.9 to 94.0) in the laparotomy group and 91.7% (86.3 to 95.0) in the laparoscopy group. In Liang's trial¹⁸, overall survival rates at 3 years were 76.0% in the laparoscopy group and 82.8% in the laparotomy group (P=0.462).

Two trials studied overall survival at 2 years. In Liang's trial¹⁸, 2-year survival was 82.6% in the laparoscopy group and 91.2% in the laparotomy group (P=0.462).

In AlaCart trial⁴, overall survival rates at 2 years were 94% in the laparoscopy group and 93% in the laparotomy group (difference 0.9%; 95% CI, 3.6% to 5.4%).

Ng's trial¹⁷ reported overall survival at 5 and 8 years, and were 85.9 and 82%, respectively for the laparoscopy group, and 91.3 and 72.7%, respectively for the laparotomy group (P = 0.912).

In summary, no difference was found concerning the overall survival between laparoscopy and laparotomy.

DISCUSSION

Our meta-analysis was in favour of laparoscopy in a significant way for blood loss, first bowel movement and the number of harvested lymph nodes. However, it was non-significantly in favour of laparoscopy for 30-days mortality after surgery and length of hospital stay. It was significantly in favour of laparotomy concerning operation duration.

No significant differences were found concerning anastomotic leakage, reoperation within 30 days, number of positive CRMs and completeness of mesorectum excision.

Also no difference was found in recurrence, disease-free survival and overall survival between laparoscopy group and laparotomy group. We Conducted the search in PubMed for all meta-analysis published and found 38 papers. Post- screening, we retained 24 meta-analyses to discuss short-term outcomes. The results of the meta-analyses were classified in tables from the most recent to the oldest (Table 3, 4, 5). To discuss long term outcomes, we have retained only recent meta-analysis, published in 2018 and 2017.

I. Short term outcomes

1) Per operative outcomes

As expected, the operative duration was shorter in the laparotomy group in our meta-analysis. The same result was reported in the CLASICC trial⁹ and in a systematic review and meta-analysis published in 2012 by A.Arezzo²³.

M. Pedziwiatr's paper²⁴, which is the most recent meta-analysis regarding this topic, didn't cover this outcome, probably judging that literature had already proved it.

Concerning blood loss, the findings showed that it was statistically lower in the laparoscopy group. Thereby, it corroborates literature as in a Arezzo et al. meta-analysis²³.

The CLASICC trial⁹ had studied the blood transfusion requirement, which indirectly reflects blood loss. No difference was found between the laparoscopy group and the

laparotomy group in transfusion requirement, which allows us to conclude that blood loss was almost similar for the two techniques.

2) Postoperative morbidity

As expected, hospital stay was shorter in the laparoscopy group in our meta-analysis, just like in Arezzo et al. meta-analysis²³. As in the CLASICC trial⁹ in which it was 2 days shorter for the laparoscopy group.

For anastomotic leakage, no difference was found in our meta-analysis between the two groups, just like in the CLASICC trial⁹ and in A.Arezzo's meta-analysis²³.

First bowel movement was faster in the laparoscopy group according to our meta-analysis and to A. Arezzo's meta-analysis²³, whereas the CLASICC trial⁹ found no difference between the two groups.

Concerning reoperation, findings showed no difference statistically significant. In A.Arezzo's meta-analysis²³, surgical complications within 30 days were reported, and were significantly in favour of the laparoscopy group. The CLASICC trial⁹ didn't present data concerning this item.

Our meta-analysis, just like A. Arezzo's meta-analysis²³ showed a lower 30-days mortality after surgery in the laparoscopy group but statistically not significant. The CLASICC trial⁹ didn't present data concerning this item.

3) Quality of resected specimen

This systematic review and meta-analysis concluded that the number of harvested lymph nodes was statistically higher in the laparoscopy group. According to the literature, there was no difference in the number of harvested lymph nodes between the laparoscopic and the laparotomy group, as shown in the CLASICC trial⁹ and in M. Pedziwiatr's meta-analysis²⁴.

Published in 2017, which found that lymph node yield depended on several factors like the tumour itself, the patient, neoadjuvant radiochemotherapy, pathologic assessment²⁵ and, of course, the surgeon²⁶. That final point can explain the difference of the findings between literature and this meta-analysis. By selecting only trials done after 2010, we minimized the bias related to the learning curve of the laparoscopy, so the oncological results were more representative.

Concerning positive circumferential resection margins (CRM) \leq 1mm, no difference statistically significant was found between the two groups. Positive circumferential resection margins represented 8.24% in the laparoscopy group comparatively to 7.28% in the laparotomy group, despite missing data representing 8.4% in the laparoscopy group and 6.4% in the laparotomy group. On the same side, a recent meta-analysis made by M. Pedziwiatr²⁴ concluded to the same finding and suggested that the differences in CRM involvement between studies were related to the quality of surgery or (less probably) to the differences in pathologic assessment (there were no use of neoadjuvant therapy or pre-operative differences in T stage between groups). On the other side, the early results from CLASICC trial⁹ showed higher but non-significant rates of circumferential resection margin (CRM) involvement following laparoscopic anterior resection. Nevertheless, at 3-year follow-up the difference in CRM positivity had not translated into a difference in local recurrence rates between laparoscopy and laparotomy.

In our meta-analysis, the completeness of mesorectal excision was similar regardless to the technique used. This result joins the M. Pedziwiatr's meta-analysis²⁴ and which raised the question of the difference of overall survival between complete and nearly complete mesorectal excisions. Through this question, we criticize the real impact of a resection considered almost the same (Nagtegaal et al²⁰) on survival, and indirectly we evaluate the weight of this parameter.

Ten years ago, the CLASICC trial⁹ showed that total mesorectal excision was in favour of the laparoscopy and justifying this finding by the fact that the procedure is technically easier in laparoscopic surgery than in laparotomy. This made us wonder what has changed

over the years, so that the completeness of mesorectal excision became independent of the surgery technique.

Tableau 3 : Table summarizing meta-analysis's short term outcomes (from 2017 to 2019)

	Operative duration	Blood loss	Hospital stay	Anastomotic leakage	First bowel movement	Reoperation within 30 days	30-days mortality after surgery	Number of harvested lymph nodes	Positive circumferential resection margins	Completeness of mesorectal excision
Our meta-analysis	B	A	A	C	A	C	C	A	C	C
(Acuna et al 2019) ²⁷	—	A	A	C	C	C	C	C	C	C
(Lu et al 2019) ²⁸	C	A	A	C	A	—	—	C	—	—
(Nienhüser et al 2018) ²⁹	—	—	—	—	—	—	—	B	C	B
(Memon et al 2018) ³⁰	—	—	—	—	—	—	—	C	C	C
(Lin et al 2018) ³¹	—	A	A	C	A	—	—	C	C	—
(Milone et al 2018) ³²	—	—	—	—	—	—	—	—	C	C
(Martinez-Perez et al 2017) ³³	—	—	—	—	—	—	—	C	C	B
(Pedziwiatr et al 2017) ²⁴	—	—	—	—	—	—	—	C	C	C

Tableau 4 : Table summarizing meta-analysis's short term outcomes (from 2012 to 2017)

	Operative duration	Blood loss	Hospital stay	Anastomotic leakage	First bowel movement	Reoperation within 30 days	30-days mortality after surgery	Number of harvested lymph nodes	Positive circumferential resection margins	Completeness of mesorectal excision
(Martinez-Perez et al 2017) ³⁴	B	A	A	C	A	C	C	C	C	B
(Creavin et al 2017) ³⁵	—	—	—	—	—	—	—	C	C	C
(Zheng et al 2017) ³⁶	B	A	A	—	A	—	A	C	A	C
(Jiang et al 2015) ³⁷	B	A	A	C	A	—	C	C	C	—
(Arezzo et al 2015) ³⁸	B	—	A	C	A	—	—	C	C	—
(Hua et al 2014) ³⁹	—	—	—	C	—	—	—	—	—	—
(Zhang et al 2014) ⁴⁰	B	A	A	C	A	C	C	C	C	C
(Arezzo et al 2013) ²³	A	A	A	C	A	A	A	—	—	—
(Qu et al 2013) ⁴¹	—	A	A	C	A	—	—	C	—	—

Tableau 5 : Table summarizing meta-analysis's short term outcomes (from 2006 to 2012).

	Operative duration	Blood loss	Hospital stay	Anastomotic leakage	First bowel movement	Reoperation within 30 days	30-days mortality after surgery	Number of harvested lymph nodes	Positive circumferential resection margins	Completeness of mesorectal excision
(Wu et al 2012) ⁴²	—	—	—	—	—	—	—	C	—	—
(Trastulli et al 2012) ⁴³	B	A	A	—	A	C	C	C	C	C
(Xiong et al 2012) ⁴⁴	B	A	C	—	A	—	C	C	C	—
(Ohtani et al 2011) ⁴⁵	B	A	C	—	A	—	C	C	C	—
(Huang et al 2011) ⁴⁶	—	—	—	—	—	—	—	C	C	—
(Anderson et al 2008) ⁴⁷	—	A	A	—	A	—	—	B	C	—
(Aziz et al 2006) ⁴⁸	B	—	A	C	A	—	C	C	C	—

A = Significantly in favour of laparoscopy

B = Significantly in favour of laparotomy

C = No significant difference found between laparoscopy and laparotomy

II. Long-term outcomes

We compared long term outcomes of our meta-analysis with the most recent meta-analysis, published in 2018 and 2017. On ten papers, only three analysed loco-regional recurrences, DFS (Disease-free survival) and overall survival.

1) Recurrences

The results have been reported during different periods in the selected trials.

One trial reported locoregional recurrence at 3, 6, 9, 12, 18 and 24 months, another one at 2 years, another trial at 5 years and four others at 3 years.

In our systematic review, no difference was found between the two groups concerning locoregional recurrences. Even in literature, no difference was found between the two groups concerning locoregional recurrence at 5 years according to Nienhüser's meta-analysis²⁹ and Pedziwiatr's meta-analysis²⁴.

2) Disease-free survival

Two trials reported DFS at 2 years, two others at 3 years and one in 5 years.

In our meta-analysis, no difference was found in disease-free survival between laparoscopy and laparotomy. This result is in line with literature.

In Lin's meta-analysis³¹ and In Nienhüser's meta-analysis²⁹ no difference was found in 5 years disease-free survival In M. Pedziwiatr's meta-analysis²⁴ disease-free survival rates were reported at 3 and 5 years and no difference was found between the two groups (p=0.26 and p=0.71 respectively).

3) Overall survival

Three trials reported overall survival at 3 years, two at 2 years and one at 5 and 8 years.

In our meta-analysis, no difference was found concerning the overall survival between laparoscopy and laparotomy. This finding corroborates with literature. As in Lin's meta-analysis³¹ and in Nienhüser's meta-analysis²⁹ where no difference was found in overall survival at 5 years between laparoscopy and laparotomy. In M. Pedziwiatr's meta-analysis²⁴ no difference was found in overall survival at 3 and 5 years between the two groups ($p=0.19$ and $p=0.64$ respectively).

In the 90's the mastery of laparoscopy was defined by the number of hours of practice. Simons Anthony J. M.D.⁴⁹ proposed that operating 11 to 15 completed laparoscopic colectomies are needed to learn the procedure. On this basis, the CLASICC trial⁹ had selected 32 surgeons. In the meta-analysis previously cited, most trials provided no information on the surgical expertise of the credentialed surgeons.

All the trials of our meta-analysis had strict eligibility criteria for including surgeons, and differed from a trial to another. For example, for the COLOR II trial¹⁴, surgical competency was assessed on the basis of review of recorded images or live observations of laparoscopic TME surgeries. Accreditation was done by center instead of individual surgeons⁹. Concerning AlaCart trial⁴, the eligibility criteria required more than 100 laparoscopic colon resections and more than 30 laparoscopic rectal dissections that were verified by operation and pathology reports.

Surgeons were required to submit an unedited video of a laparoscopic total mesorectal excision in a male patient. These reports and videos were independently audited by 2 of the study's senior surgeons³.

The difficulty of this study lies in the diversity of the follow up period, and makes impossible homogenization of the long term outcomes for comparison purposes. For example AlaCart trial⁴, reported 2 years disease-free survival, while COLOR II¹⁴ reported 3 years disease free-survival and this imposed the creation of subgroups to be able to compare the results.

CONCLUSION

This systematic review with a meta-analysis showed that laparoscopic surgery for rectal cancer had lower postoperative morbidity; in addition to higher number of harvested lymph nodes, an equal survival rate and recurrences compared to laparotomy.

Our meta-analysis showed the same short-term outcomes than meta-analysis published after 2010, except the number of harvested lymph nodes which was higher in the laparoscopy in our study while other studies, published before 2010 reported no difference between the two techniques. Our meta-analysis had shown also the same long term outcomes than the most recent meta-analysis, confirming that no difference was found concerning recurrence, disease-free survival and overall survival between laparoscopy and laparotomy.

To date, despite moving forward toward new mini-invasive techniques such as robotic surgery and transanal total mesorectal excision, and despite several randomized trials and meta-analysis, the role of laparoscopy in rectal cancer resection is still debatable. The results from real life large databases could perhaps better clarify the role of laparoscopy in the treatment of rectal adenocarcinoma.

ABSTRACT

Abstract

Methods:

A search was performed in the PubMed database and Cochrane library on November 12th 2019 for randomized controlled trials comparing short-term and long-term outcomes between laparoscopy and laparotomy.

Results:

Six randomized controlled trials met the eligibility criteria, involving a total of 1556 patients in the laparoscopy group and 1188 patients in the laparotomy group.

Our meta-analysis was in favour of laparoscopy in a significant way for blood loss mean difference -70.62 ml [-88.84, -52.40] CI 95% ($P < 0.00001$), first bowel movement mean difference -0.53 days [-0.65, -0.41] CI 95% ($P < 0.00001$) and the number of harvested lymph nodes mean difference -0.46 [-0.83, -0.09] CI 95% ($P = 0.01$). It was non-significantly in favour of laparoscopy for 30-days mortality after surgery odds ratio 0.67 [0.28, 1.61] CI 95% ($P = 0.37$) and length of hospital stay mean difference -0.29 days [-0.72, 0.13] CI 95% ($P = 0.18$). It was significantly in favour of laparotomy for operative duration mean difference of 28.51 minutes [24.74, 32.28] CI 95% ($P < 0.00001$). No significant differences were found in anastomotic leakage odds ratio 1.14 [0.77, 1.68] CI 95% ($P = 0.52$), reoperation within 30 days Odds ratio 1.18 [0.84, 1.64] CI 95% ($P = 0.34$), number of positive CRMs Odds ratio 1.07 [0.77, 1.47] CI 95% ($P = 0.70$) and completeness of mesorectum excision Odds ratio 1.30 [0.85, 1.99] CI 95% ($P = 0.23$) between the two groups. No difference was found in recurrence, disease-free survival and overall survival between laparoscopy group and laparotomy group.

Conclusion:

Laparoscopic surgery for rectal cancer had low postoperative morbidity; in addition to a high oncologic quality of resected specimens and an equal survival rate and recurrences compared to laparotomy. The comparison of the randomized controlled trials published before and after 2010, showed no significant difference in outcomes between the learning period and after.

Résumé

Méthodes: Une recherche des essais contrôlés randomisés comparant les résultats à court et à long terme de la laparoscopie à la laparotomie a été effectuée dans la base de données PubMed et la bibliothèque Cochrane, le 12 novembre 2019.

Résultats: Six essais contrôlés randomisés répondaient aux critères d'inclusion, portant sur un total de 1556 patients dans le groupe laparoscopie et 1188 patients dans le groupe laparotomie.

Notre méta-analyse a montré de manière significative une perte sanguine plus faible; différence moyenne -70,62 ml [-88,84, -52,40] IC 95% (P <0,00001), une reprise de transit plus rapide; différence moyenne de -0,53 jours [-0,65, -0,41] IC 95% (P <0,00001) et un nombre de ganglions lymphatiques prélevés supérieur; différence moyenne -0,46 [-0,83, -0,09] IC 95% (P=0,01) dans le groupe de la laparoscopie. La durée opératoire a été significativement plus courte dans le groupe la laparotomie avec une différence moyenne de 28.51 minutes [24.74, 32.28] CI 95% (P < 0.00001).

Notre méta-analyse a été de manière non significative en faveur de la laparoscopie en terme de mortalité (jusqu'à 30 jours après l'intervention);odds ratio 0,67 [0,28, 1,61] IC 95% (P = 0,37) et en terme de durée d'hospitalisation;différence moyenne de -0,29 jours [-0,72, 0,13] IC 95 % (P = 0,18).

Aucune différence significative n'a été retrouvée entre les deux groupes en matière de fuites anastomotiques; Odds ratio 1,14 [0,77, 1,68] IC à 95% (P=0,52), de reprise chirurgicale dans les 30 jours; Odds ratio 1,18 [0,84, 1,64] IC à 95% (P = 0,34), du statut CRM (marge radiale circonférentielle);Odds ratio 1,07 [0,77, 1,47] IC 95% (P=0,70) et du caractère complet de l'excision du mésorectum; Odds ratio 1,30 [0,85, 1,99] IC à 95% (P = 0,23).

Aucune différence n'a été retrouvée entre le groupe laparoscopie et le groupe laparotomie en termes de résultats à long terme, incluant la récurrence loco-régionale, la survie sans maladie et la survie globale.

Conclusion: La chirurgie laparoscopique pour le cancer du rectum a montré de meilleures suites postopératoires; en plus d'une haute qualité oncologique des spécimens réséqués ainsi qu'un taux de récurrence et de survie égale à celui de la laparotomie. La comparaison des essais cliniques contrôlés randomisés publiés avant et après 2010, n'a pas montré de différence de résultats entre ces deux périodes, correspondant à la période d'apprentissage de la laparoscopie dans la chirurgie rectale et à la période de sa maîtrise.

ملخص

المنهجية المتبعة: تم إجراء بحث عن التجارب المعشاة ذات الشواهد التي تقارن النتائج قصيرة الأمد وطويلة المدى لتنظير البطن مع شق البطن في قاعدة بيانات **PubMed** ومكتبة **Cochrane** في 12 نونبر 2019.

النتائج: حققت ست تجارب منضبطة معشاة معايير التضمين، وتضم ما مجموعه 1556 مريضاً في مجموعة تنظير البطن و 1188 مريضاً في مجموعة فتح البطن.

أظهر تحليلنا التلوي فقدان دم أقل بشكل ملحوظ. متوسط الفرق -70.62 مل [-88.84، -52.40] **IC 95% (P < 0.00001)** واستئناف أسرع للعبور؛ متوسط الفرق -0.53 يوماً [-0.65، -0.41] **IC 95% (P < 0.00001)** كما تمت إزالة عدد أكبر من الغدد الليمفاوية؛ متوسط الفرق -0.46 [-0.83، -0.09] **IC 95% (P = 0.01)** في مجموعة تنظير البطن، أما فيما يخص وقت العملية أقصر، فهو أقصر بشكل ملحوظ في مجموعة فتح البطن مع فارق متوسط قدره 28.51 دقيقة [24.74، 32.28] **IC 95% (P < 0.00001)**. لم يكن التحليل التلوي الذي أجريناه لصالح تنظير البطن من حيث الوفيات (حتى 30 يوماً بعد التدخل)؛ نسبة الأرجحية 0.67 [0.28، 1.61] **IC 95% (P = 0.37)** وأيضاً من حيث طول فترة الاستشفاء؛ متوسط الفرق -0.29 يوماً [-0.72، 0.13] **IC 95% (P = 0.18)** لم يتم ملاحظة فرق كبير بين المجموعتين من حيث التسرب التفاعري؛ نسبة الأرجحية 1.14 [0.77، 1.68] **IC 95% (P = 0.52)**، وكذا جراحة المراجعة في غضون 30 يوماً؛ نسبة الأرجحية 1.18 [0.84، 1.64] **IC 95% (P = 0.34)**، من حالة **CRM** (الهامش الشعاعي المحيطي)؛ نسبة الأرجحية 1.07 [0.77، 1.47] **IC 95% (P = 0.70)** واكتمال استئصال المستقيم الأوسط؛ نسبة الأرجحية 1.30 [0.85، 1.99] **IC 95% (P = 0.23)**.

لم يتم ملاحظة أي فرق بين مجموعة تنظير البطن ومجموعة فتح البطن من حيث النتائج طويلة المدى، بما في ذلك التكرار الموضعي والبقاء على قيد الحياة بدون أمراض البقاء على قيد الحياة بشكل عام.

خلاصة: أظهرت الجراحة التنظيرية لسرطان المستقيم نتائج أفضل في فترة ما بعد الجراحة؛ بالإضافة إلى جودة الأورام العالية للعينات التي تم استئصالها. أما بالنسبة لمعدل تكرار ومعدل البقاء على قيد الحياة فالتقنيتين متساويتين. مع العلم أن مقارنة التجارب السريرية المنضبطة المعشاة المنشورة قبل وبعد عام 2010 لم تظهر أي اختلاف في النتائج بين هاتين الفترتين، المقابلة لفترة تعلم تنظير البطن في جراحة المستقيم لفترة إتقانها.

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PHYSICIAN'S OATH

At the time of being admitted as a member of the medical profession: I solemnly promise that I will devote my life to serve humanity.

- *I will give to my teachers the respect and gratitude that is their due.*
- *I will practice my profession with conscience and dignity.*
- *The health of my patient will be my first consideration.*
- *I will not betray the secrets that are confided in me.*
- *I will maintain by all the means in my power, the honour and the noble traditions of the medical profession.*
- *My colleagues will be my brothers.*
- *I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient.*
- *I will maintain the utmost respect for human life from the time of conception. Even under threat,*
- *I will not use my medical knowledge contrary to the laws of humanity.*
- *I make these promises solemnly, freely and upon my honour*

قسم أبقراط

بسم الله الرحمن الرحيم

أقسم بالله العظيم

في هذه اللحظة التي يتم فيها قبولي عضوة في المهنة الطبية أتعهد علانية:

- أنا أكرس حياتي لخدمة الإنسانية.
- وأنا أحترم أساتذتي وأعترف لهم بالجميل الذي يستحقونه.
- وأنا أمارس مهنتي بوازع من ضميري وشرفي جاعلة صحة مريض هدي الأول.
- وأنا لا أفشي الأسرار المعهودة إلي.
- وأنا أحافظ بكل ما لدي من وسائل على الشرف والتقاليد النبيلة لمهنة الطب.
- وأنا أعتبر سائر الأطباء إخوة لي.
- وأنا أقوم بواجبي نحو مرضاي بدون أي اعتبار ديني أو وطني أو عرقي أو سياسي أو اجتماعي.
- وأنا أحافظ بكل حزم على احترام الحياة الإنسانية منذ نشأتها.
- وأنا لا أستعمل معلوماتي الطبية بطريق يضر بحقوق الإنسان مهما لاقيت من تهديد.
- بكل هذا أتعهد عن كامل اختيار ومقسمة بالله.

والله على ما أقول شهيد.



المملكة المغربية
جامعة محمد الخامس بالرباط
كلية الطب والصيدلة بالرباط



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مقارنة النتائج قصيرة المدى وطويلة المدى لتنظير البطن مقابل شق البطن في سرطان المستقيم: مراجعة منهجية وتحليل تلوي للتجارب المعشاة ذات الشواهد

أطروحة

قدمت و نوقشت علانية يوم:/...../2020

من طرف

السيدة لينة بوعليلا

المزودة في 01 يناير 1996 بمكناس

لنيل شهادة الدكتوراه في الطب

الكلمات الأساسية: التحليل التلوي؛ منظار البطن؛ شق البطن. سرطان المستقيم

تحت إشراف اللجنة المكونة من الأساتذة

رئيس

السيد رؤوف محسن

مدير

أستاذ جراحة أورام الجهاز الهضمي

عضو

السيد مجبر محمد انس

أستاذ جراحة أورام الجهاز الهضمي

عضو

السيد بن قابو أمين

أستاذ جراحة أورام الجهاز الهضمي

عضو

السيد صوادقة أمين

أستاذ جراحة أورام الجهاز الهضمي

السيد الأحدي إبراهيم

أستاذ التخدير والإنعاش