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Does conversion during laparoscopic rectal oncological surgery increases post-operative complications and anastomotic leakage rates? A meta-analysis

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Does conversion during laparoscopic rectal oncological surgery increases

Post-operative complications and anastomotic leakage rates?

A meta-analysis.

Structured Abstract

Objective

To evaluate, regarding previous published studies, post-operative outcomes between patients undergoing rectal cancer resection performed by totally laparoscopic approach (LAP) compared to those who underwent per-operative conversion (CONV).

Methods

Studies comparing LAP versus CONV for rectal cancer published until December 2017 were selected and submitted to a systematic review and meta-analysis. Articles were searched in Medline and Cochrane Trials Register Database. Meta-analysis was performed with Review Manager 5.0.

Results

Twelve prospective and retrospective studies with a total of 4503 patients who underwent fully laparoscopic approach for rectal cancer and a total of 612 patients who underwent conversion were included. Meta-analysis did not show any significant difference on overall mortality between both approaches (OR = 0.47, 95%CI = 0.18-1.22, p = 0.12). However, Meta-analysis showed that anastomotic leakage rate, wound abscess rate and post-operative morbidity rate were significantly decreased with totally laparoscopic approach (OR = 0.37, 95%CI = 0.24-0.58, p < 0.0001; OR = 0.29, 95%CI = 0.19 – 0.45, p < 0.00001; OR = 0.56, 95%CI = 0.46-0.67, p < 0.00001 respectively).

Conclusion

This meta-analysis suggests that conversion increases anastomotic leakage, overall morbidity and wound abscess rates without increasing mortality rate for patients who underwent rectal resection for cancer.

INTRODUCTION

Colorectal laparoscopic surgery rates have widely increased owing to favorable short-term outcomes and similar long-term outcomes compared to open approach¹. In France, recent guidelines led to emphasize laparoscopic approach for rectal cancer surgery². However, in contrast to colon cancer³, evidences for minimally invasive techniques in rectal cancer are still limited. Only a few clinical trials have demonstrated the safety or the benefit of laparoscopic surgery for rectal cancer compared with open surgery⁴⁻⁷. Recents randomized clinicals trials have focused on the non inferiority of laparoscopic surgery^{8,9}. Additional large randomized trials are required in order to provide data for combined analysis. Laparoscopic rectal oncologic surgery is technically demanding especially during pelvic dissection. The technical difficulties due to narrow pelvis and/or large anterior tumor, might explain the higher conversion rate to open surgery, ranging from 8% to 34%. Male gender, obesity, large rectal tumors, hard dissection and transection of lower rectum are additional reasons for conversion^{10,11}. The real impact of conversion to open surgery on outcomes is still debated in the literature. Several reasons may explain conflicting reports on the short-term outcomes of converted-to-open cases. First, most of the previous studies have included both colon and rectal cancers leading to statistical bias¹². Secondly, the impact of conversion to open surgery has been specifically assessed by non-randomized studies¹³⁻¹⁷. Thirdly, most of these studies have only included a limited number of patients^{13,14, 18-22}. A recent systematic review and meta-analysis²³ have suggested that conversion to open surgery was significantly associated with increased operative time as well as wound infection rate. However, this study focused on articles published before June 2013 and meanwhile five studies focusing on rectal cancer and including 1891 patients^{5,13-15,24} were published since 2013 with conflicting results. Thus, we conducted a meta-analysis of comparative studies published at the date of

December 2017 reporting postoperative results between converted-to-open rectal cancer (CONV) cases with laparoscopically completed (LAP) cases. When it was possible, we established sources of heterogeneity in our results.

METHODS

Data Sources

We performed a systematic duplicate review of the literature published until December 2017. We did our research of abstracts in the Med-Line and Pub Med Database, the Cochrane data Base and Cochrane Clinical Trials Registry, with the following search terms according to PICO criteria²⁵ : Patients « rectal cancer » AND/OR « rectal neoplasm » , Intervention: « laparoscopic surgery », AND « open surgery », AND « minimally invasive surgery», Comparison: AND « conversion », Outcome: AND “morbidity”. We report all studies in English. Two data researchers compared their articles independently researched (BM, MF). No unpublished data, no solely published abstracts were used in the analysis.

Inclusion and exclusion criteria

All human clinical trials and studies comparing outcomes after totally laparoscopic resection of rectal cancer and conversion were identified. We collected quantitative data on post-operative mortality, post-operative anastomotic leakage, post-operative overall morbidity, post-operative wound abscess rates. Studies in which the outcomes of interest were not reported on the two approaches or one cannot deduce from the published results for both procedures were excluded from the meta-analysis.

Outcome definitions

The primary outcome of this systematic review was overall mortality rate and the secondary outcomes were anastomotic leakage (AL), overall morbidity, wound abscess and reoperation rates. Post-operative mortality rate was defined as death occurring in the 30 days after the surgery or during hospitalization. Although AL has been defined by the International Study Group of Rectal Cancer²⁶ or by expert college²⁷: clinical AL was defined as discharge of faeces or gas from a drain site or wound as well as localized abscess or generalized

peritonitis with tenderness, fever, and leukocytosis. Radiological AL was defined as leakage detected in an asymptomatic patient by a postoperative contrast medium enema. Postoperative morbidity was defined as post-operative complications in the 30 days after the surgery.

Data reviewing and extraction

Two investigators (BM, MF) independently reviewed those databases, read titles, abstracts and full-text articles selected to extract study data. They also reviewed bibliography of selected articles and published meta-analysis on the subject. Consensus was performed if necessary with a third author (AA). The following data were extracted from each study: first author, year of publication, study population characteristics, study design, number of patients operated on each approach (LAP and CONV), definition of conversion when available and end point data (operative time, length of postoperative hospital stay, postoperative complications, mortality, anastomotic leakage, reoperation, blood transfusion, previous chemoradiotherapy/ radiotherapy, tumor stage, sphincter preserving, abdominoperineal resection). Post-operative surgical complications included were: anastomotic leak, wound infection, wound abscess. Quality of the studies was checked with Prisma statement and MINORS score^{28,29}. An ideal minor score was > 8 for non-comparative studies and >12 for comparative studies.

Statistical analyses

All statistical analysis were performed using Review Manager 5.0 software (Cochrane collaboration, Oxford, United Kingdom). If no evidence of heterogeneity was found, a fixed model was used otherwise a random effects model was used. Heterogeneity was assessed by I² statistics with values-up to above 50% for presence of heterogeneity. Odds-Ratio (OR) was calculated for each trial from the number of evaluable patients and their two-sided 95%

Confidence Intervals (ICs) were used to confirm effect size estimation and test criterion. The Mantel–Haenszel odds ratio (or Peto Odds Ratio when necessary) was calculated for dichotomous variables, and the relative risk was calculated for rare events if necessary. P-value for overall effect was calculated with the Z test and significance was set with p value <0.05. Publication bias and a sensitivity analysis were also performed.

RESULTS

Trials characteristics

A total of 68 studies were retrieved. Process to find clinical trial is show in the Flow –Chart (figure 1). Of these studies, 56 were excluded because of type of studies, design of trial, absence of main primary outcome. Finally, 12 studies were included with 5 prospective studies^{14-17,19} and 7 retrospective studies^{10,13,18,21,22,24,30}, which were published as full-length articles. Among those studies there were a total of 4503 patients who underwent fully laparoscopic approach for rectal cancer and a total of 612 patients who underwent conversion. Main characteristics of these 12 studies are shown in tables 1-3. Quality of the studies were assessed by Prisma statement where all studies have a high level of quality and MINORS score where all studies had a score more than 8/16 for non-comparative studies and more than 12/24 for comparative studies.

Results of meta-analysis

Mortality

Six among the 12 studies included reported post-operative mortality rate after rectal cancer. Overall mortality in LAP group was 1.2% (30/2608) and 2.0 % (8/399) in CONV group. Meta-analysis did not showed any significant difference between both (OR = 0.47, 95%CI = 0.18-1.22, p = 0.12) (Figure 2).

Anastomotic leakage

Nine among the twelve studies reported anastomotic leakage rate with 3132 patients in LAP group and 250 patients in CONV group. Anastomotic leakage rate were 5.3 % in LAP group (167/3132) and 16.8% in CONV group (45/250). Meta-analysis demonstrated that

anastomotic leakage rate was significantly decreased with fully laparoscopic approach (OR = 0.37, 95%CI =0.24-0.58, $p < 0.0001$). (Figure 3).

Wound abscess

Five among the 12 studies reported post-operative wound abscess rate including 1338 patients in LAP group and 192 patients in CONV group. Wound abscess rate were 6.3 % in the LAP group (101/1598) compared to 17.1 % in CONV group (33/192). Meta-analysis reported wound abscess rate was significantly decreased with fully laparoscopic approach (OR =0.29, 95%CI = 0.19 – 0.45, $p < 0.00001$). (Figure 4).

Post-operative overall morbidity

Eleven among the 12 studies reported post-operative overall morbidity rate with 4358 patients in LAP group and 600 patients in CONV group. Overall morbidity rate was 26.3% (1150/4358) in the LAP group and 39.2 % (235/600) in the CONV group. Meta-analysis showed post-operative morbidity rate was decreased with fully laparoscopic approach (OR = 0.56, 95%CI = 0.46-0.67, $p < 0.00001$) (figure 5).

Reoperation

Eight among the 12 studies reported reoperation rate including 2576 patients in LAP group and 338 patients in CONV group. Reoperation rate were 7.0 % in LAP group (180/2576) and 9.8% in CONV group (33/338). Meta-analysis did not showed any significant difference between both approaches (OR = 0.88, 95%CI = 0.58-1.33, $p = 0.54$). (Figure 6).

Sensitivity analysis and publication bias

Sensitivity analysis and publication bias estimation were performed with the aim to estimate statistically significant results. Sensitivity analysis was performed because of source of heterogeneity in the results ($i^2 > 49\%$) for anastomotic leakage rate, overall morbidity rate, combined Odds Ratio were calculated with a fixed-effects model and a random-effects model, and the results were compared. Furthermore, it is known that statistically significant data are more published than the others, so our results might be influenced **a little by a publication bias, especially for anastomotic leakage and wound infection rates. (figures 7-9).**

DISCUSSION

The present meta-analysis suggests that conversion to open of a laparoscopic resection for rectal cancer does not impact mortality rate. However, it seems to be associated with increased rate of overall postoperative morbidity in comparison with the laparoscopically completed cases. Conversion cases suffered from significantly more anastomotic leakage and wound infection rates.

In this study, conversion rate have been relatively high exceeding 30%. However, impact on the patient's outcomes remain still unclear, and its consequence is still debated in the literature. While some authors have reported that conversion to open surgery is associated with longer hospital stay, more postoperative morbidity and even poor oncological results; others have not demonstrated any impact. Nevertheless, these conflicting results have been assessed by non-randomized studies which have included a limited number of patients. Thus, 87 per cent of studies included in our meta-analysis were non-randomized studies (Table 1) and 71 percent of these included less than 300 patients) (Table 1).

In this metanalysis, yielding 4503 patients of whom 612 needed a conversion (13.6%). This meta-analysis reported similar mortality rates between CONV and LAP groups according to published studies (Table 1). On the contrary to the previous meta-analysis²³, overall morbidity rate, anastomotic leakage and wound infection were significantly higher in CONV groups as compared with LAP group. Postoperative complications were 1.5 time, wound abscess 2.3 times, and anastomotic leakage 3.2 times more common, in CONV group than LAP group respectively.

A recent meta-analysis including colon and rectal studies showed that overall morbidity rate (OR= 1.16, 95%CI [0.86-1.56]), reoperation rate and anastomotic leakage rate (OR= 1.08,

95%CI [0.88-1.33] were similar in converted patients and fully laparoscopic approach. However, the heterogeneity of their study population with colon and rectal resections might explained this result³¹.

Several factors related to the surgeon, the rectal tumor, the patient, and/or the surgical procedure, may explain these results. For example, late conversion specifically in low and difficult rectal cases may lead to inadequate surgery and increase postoperative complications.

The result of this meta-analysis raise several questions and first of all the need to define what we call a conversion. In a previous study, conversion was defined as “any unplanned incision or a planned incision longer than 6 cm that was necessary for exteriorization of the resected specimen and fashioned the anastomosis”³². However, most studies of our meta-analysis used a definition only based on the length of incision. Furthermore, no data regarding both timing (early versus late) and/or reason (preemptive versus reactive) for conversion were available in these studies. However, several authors hypothesized that their strategy of early such as preemptive conversion would allow avoiding complications due to a long and laborious dissection. Future studies on this subject should analyze the impact of factors such as the timing of conversion and its causes on the patient’s outcomes.

The second concern is the systematic “up-to-down” approach during laparoscopic TME. While laparoscopy gets a better view, laparoscopic mobilization of the rectum remains a demanding technique that may be hardly performed especially in patients with well-known risk-factors of conversion (obese patient, male gender, narrow pelvis, and T3 bulky tumors). Several authors have suggested a « down-to-up » instead of « up-to-down » TME approach using an endoscopic trans-anal approach, in order to overcome these limitations. This new approach gives new options in difficult known cases and might allow to reduce conversion

rate. For example, reduced duration of pneumoperitoneum and Trendelenburg position favorably improved respiratory parameters. This novel strategy in mid and low rectal cancers seems associated with promising surgical and oncologic outcomes³³⁻³⁶. The French 'ETAPGRECCAR11' Trial designed as a multicentric phase III non-inferiority trial will compare endoscopic trans-anal TME to laparoscopic TME for rectal cancer³⁷.

One of the major concern is to determine if laparoscopic approach is appropriate for rectal tumor. Recently a meta-analysis raised this question³⁸. In this study, the complete/intact mesorectal excision rate was significantly lower after laparoscopic approach compared to open rectal resection. Their significant higher rate of superficial mesorectal defect might be explained by iterative grasping or traction from laparoscopic instruments that is particularly frequent in complex rectal cancer cases. According to a recent meta-analysis of randomized controlled trial, robotic surgery led to lower rate of conversion to open surgery with similar short-term outcomes. However, the quality of evidence remains moderate³⁹.

There are a number of limitations of our study that must be considered. First, the results of this meta-analysis should be interpreted with caution because of the quality of studies included. Although, no direct comparison by randomized controlled trial is ethically possible, most of the studies included were retrospective and no one was case-matched. Consequently, both groups (converted and totally laparoscopic patients) were not comparable in four studies^{13, 14, 16, 17} (Table 1). Secondly, there are several definition of anastomotic leak in the different studies even. Thirdly, heterogeneity of this meta-analysis is present because of type of studies (retrospective studies) and especially definition of the outcomes of the studies. Random effect models help to face the heterogeneity of the studies but results should be interpreted carefully. Moreover, the rate of conversion was very disparate, ranging from 7.2% to 33.9%. Finally, neither timing of conversion nor the cause

(preemptive versus reactive) were reported, therefore we could not test this hypothesis in the present meta-analysis.

In conclusion, our meta-analysis suggests that conversion to open of a laparoscopic rectal resection for cancer impair significantly post-operative outcomes (ie, wound infection, anastomotic leakage). Further studies are needed to better understand the real impact of timing and/or reason of conversion. New surgical approach such as transanal laparoscopic TME or robotic surgery seem attractive in order to decrease conversion rate and postoperative complications.

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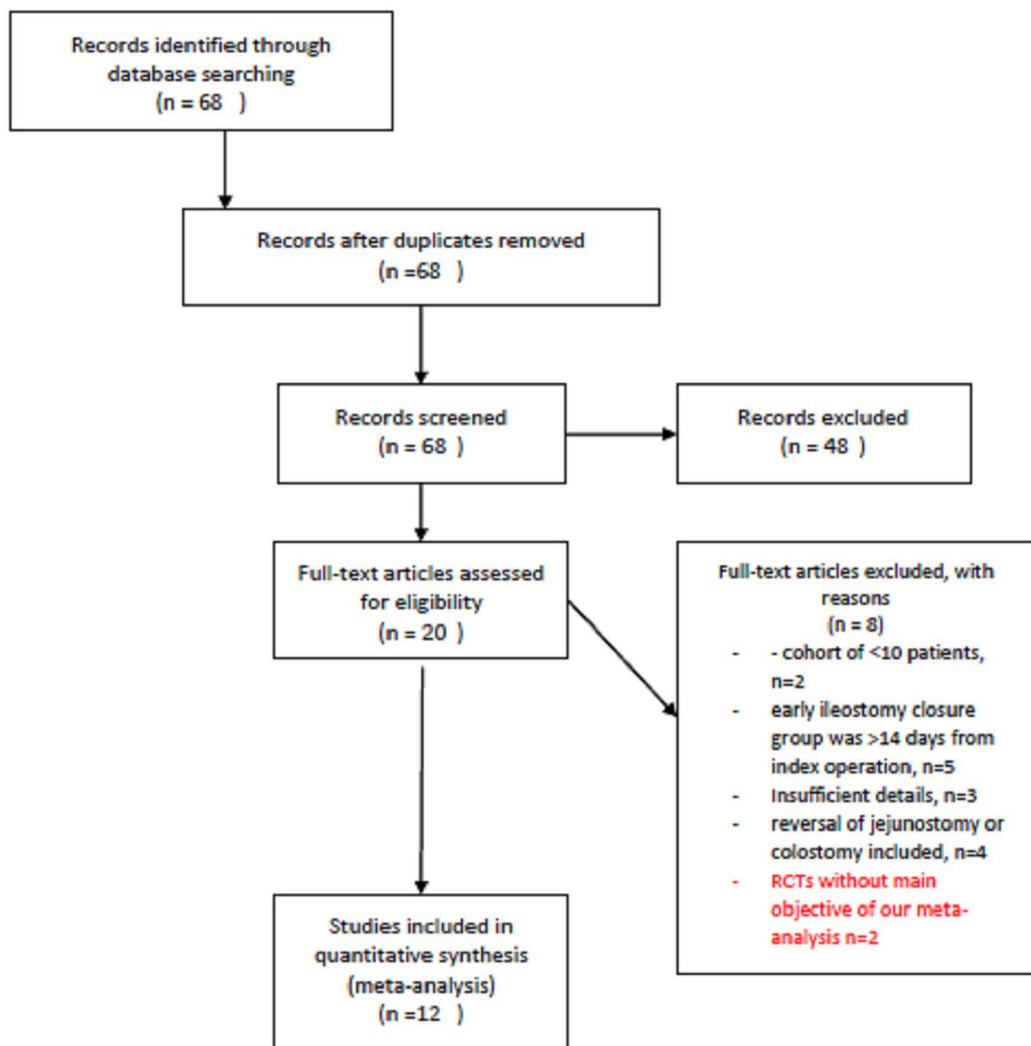
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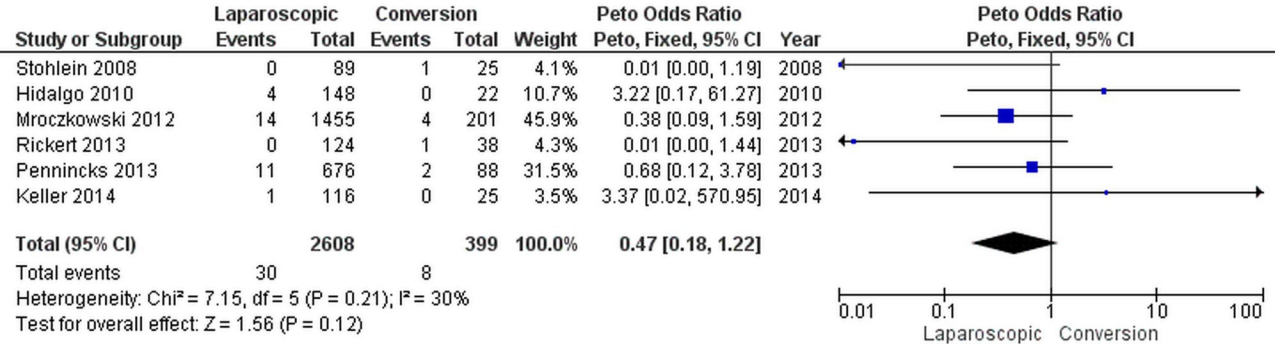
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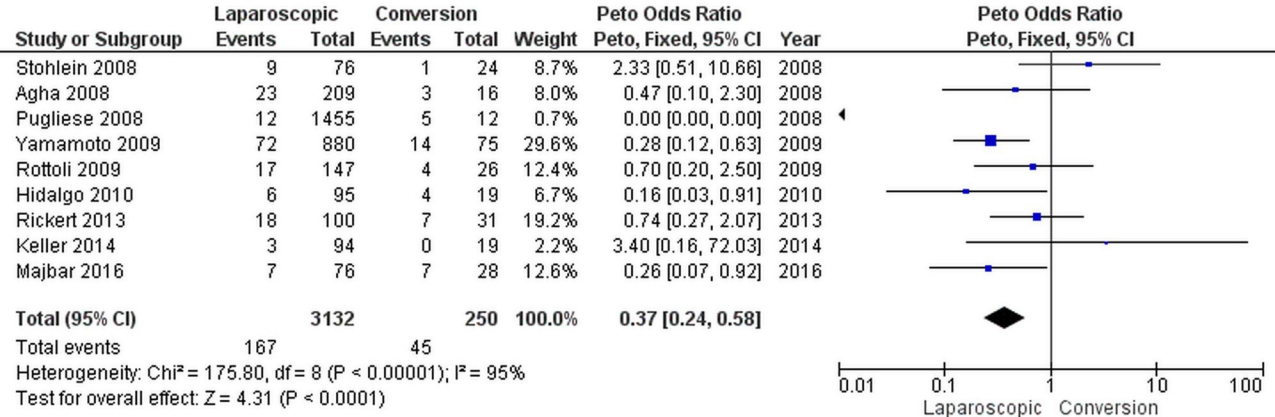
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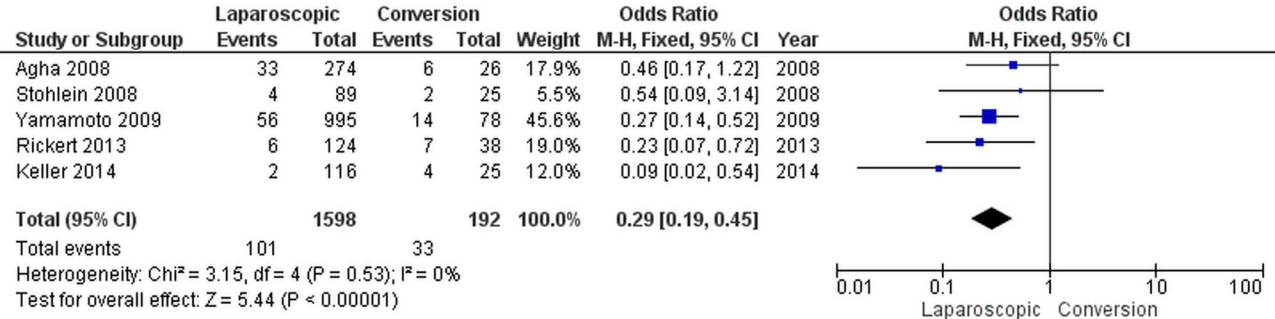
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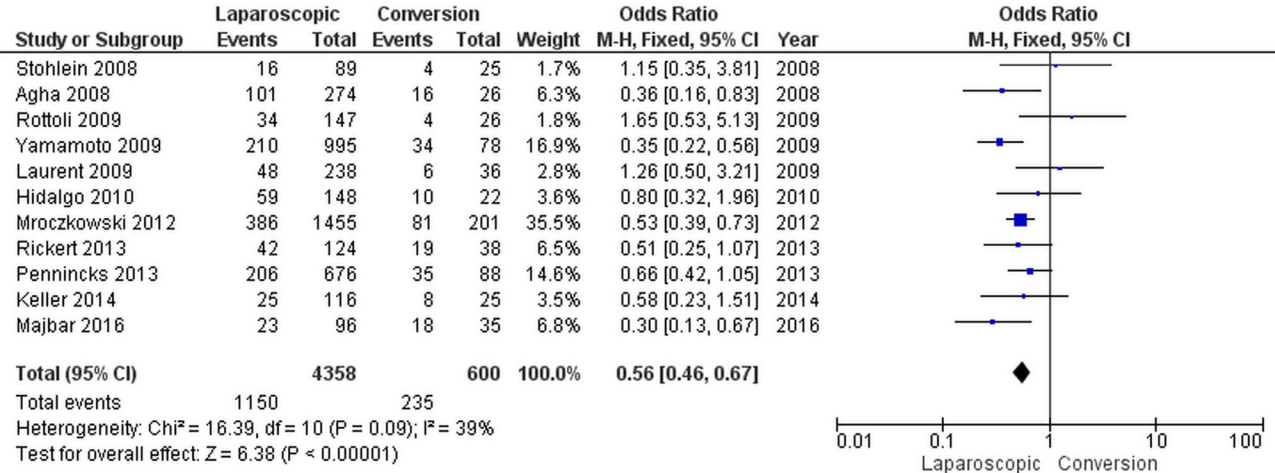
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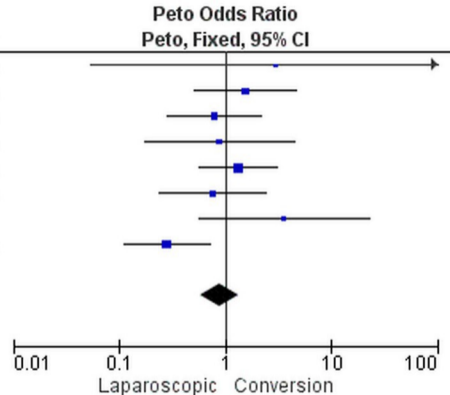


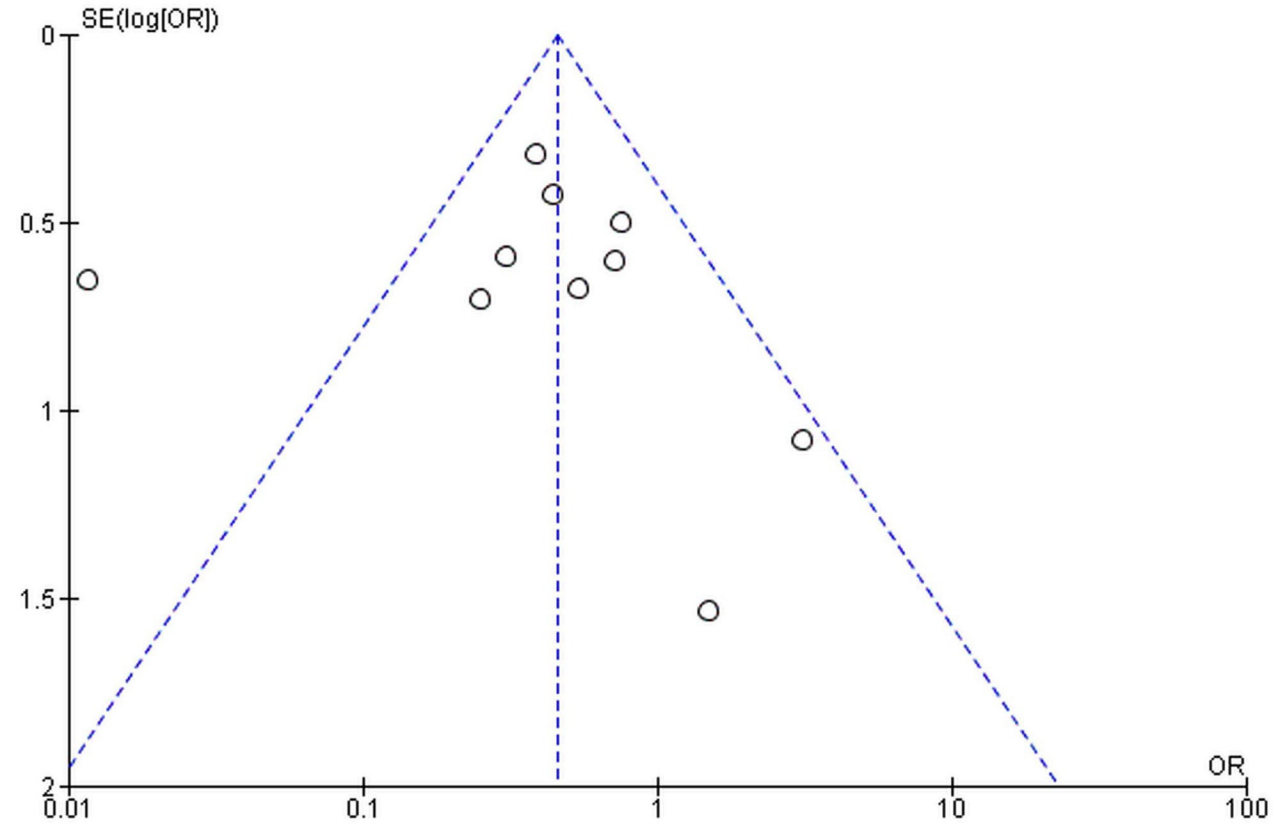


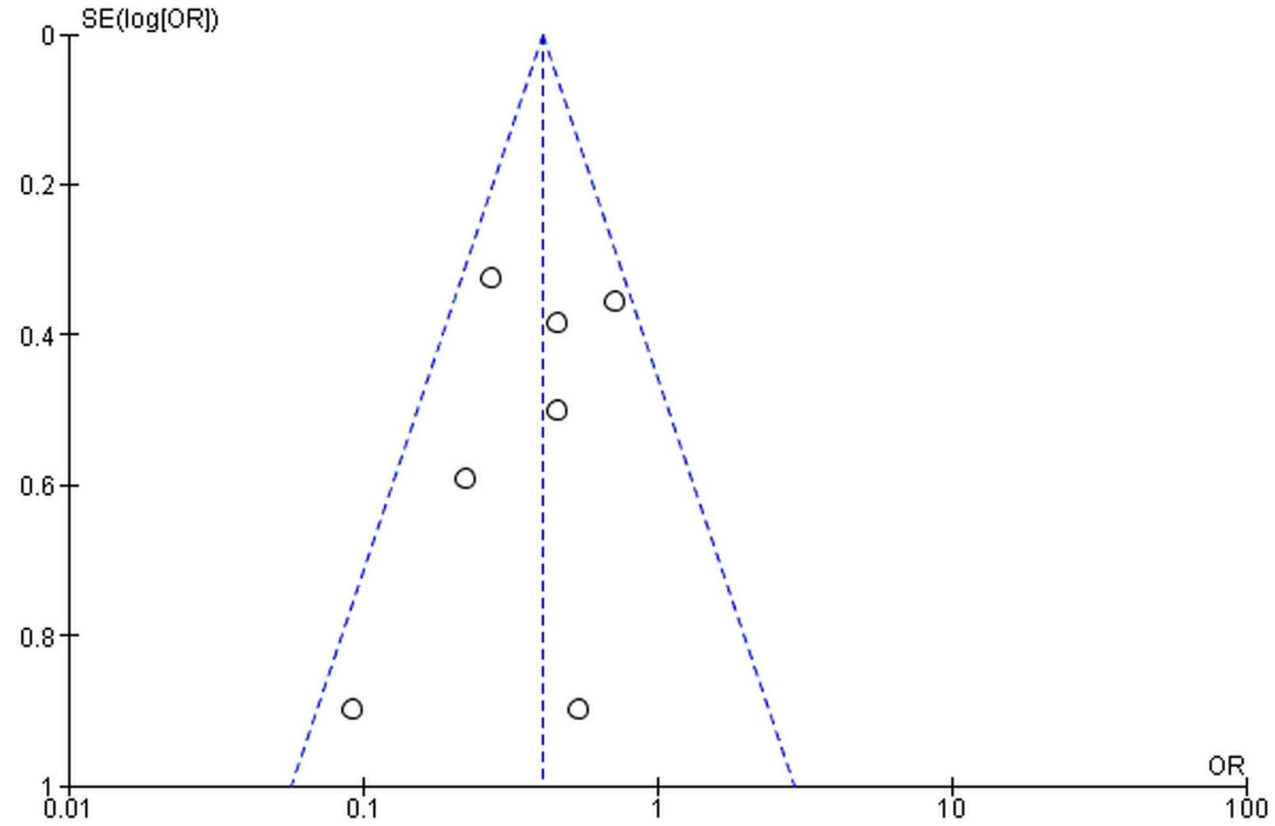


Study or Subgroup	Laparoscopic		Conversion		Weight	Peto Odds Ratio		Year
	Events	Total	Events	Total		Peto, Fixed, 95% CI		
Agha 2008	3	274	0	26	1.1%	3.01 [0.05, 170.35]	2008	
Rottoli 2009	26	147	3	26	14.0%	1.55 [0.51, 4.72]	2009	
Yamamoto 2009	52	995	5	78	16.5%	0.79 [0.28, 2.21]	2009	
Hidalgo 2010	12	148	2	22	6.6%	0.88 [0.17, 4.46]	2010	
Pennincks 2013	51	676	5	88	24.0%	1.32 [0.56, 3.08]	2013	
Rickert 2013	13	124	5	38	13.1%	0.76 [0.24, 2.42]	2013	
Keller 2014	8	116	0	25	5.0%	3.59 [0.56, 23.13]	2014	
Majbar 2016	15	96	13	35	19.7%	0.28 [0.11, 0.72]	2016	
Total (95% CI)		2576		338	100.0%	0.88 [0.58, 1.33]		

Total events 180 33
Heterogeneity: $\text{Chi}^2 = 10.17$, $\text{df} = 7$ ($P = 0.18$); $I^2 = 31\%$
Test for overall effect: $Z = 0.61$ ($P = 0.54$)







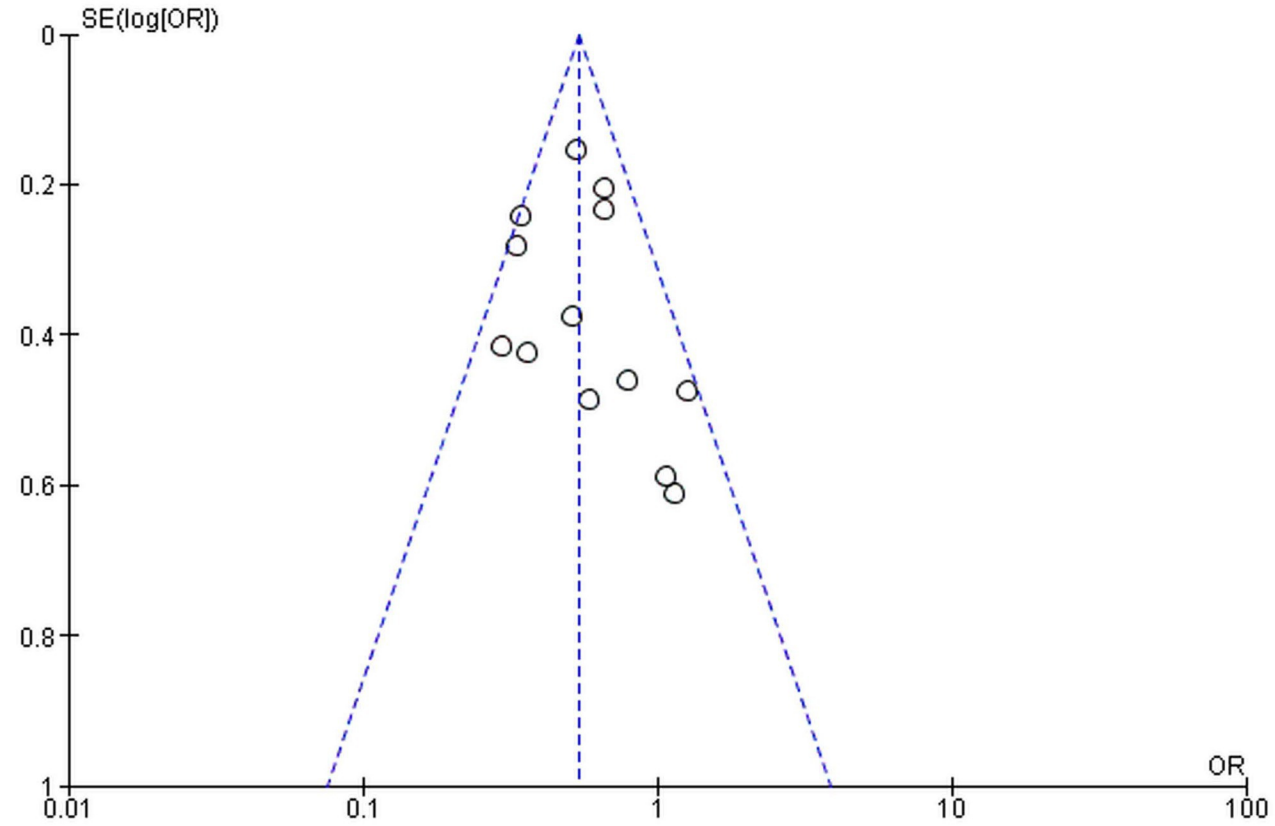


Table 1 : baseline characteristics of individual studies

references	Study design	Minors score	Quality of studies	Rectal resection		Gender (male)		Mean age		Mean BMI		Previous RTT or RCT		Definition of conversion	T3/T4		SPS/APR	
				LAP	CONV	LAP	CONV	LAP	CONV	LAP	CONV	LAP	CONV		No	LAP	CONV	LAP
<i>Agha</i> ¹³	RS	10/16	High	274	26	166	21	64.7	64.5	26.2	29*	117	14	Yes	146	18	209/57	16/10
<i>Keller</i> ¹⁴	PS	18/24	High	116	25	63	17	63.1	63.5	28.7	27.5	63	19*	No	39	13	94/22	19/6
<i>Rickert</i> ¹⁵	PS	18/24	High	124	38	69	27	63	69*	25.1	25.8	63	22	Yes	51%	47%	110/14	31/7
<i>Rottoli</i> ¹⁶	PS	18/24	High	147	26	NA	NA	63.2	64.3	24.9	27.3*	32	1	Yes	73	15	147/0	26/0
<i>Yamamoto</i> ¹⁷	PS	16/24	High	995	78	625	48	62.9	63.8	22.7	24.6	6	0	Yes	258	26	880/115	75/3
<i>Mroczkowski</i> ³⁰	RS	12/16	High	1455	201	NA	NA	NA	NA	NA	NA	NA	NA	Yes	NA	NA	na	na
<i>Laurent</i> ¹⁰	RS	20/24	High	238	36	NA	NA	NA	NA	NA	NA	NA	NA	Yes	NA	NA	na	Na
<i>Pennincks</i> ²⁴	RS	16/24	High	676	88	na	na	Na	na	na	na	449	59	No	na	na	456/220	68/20
<i>Majbar</i> ²¹	RS	10/16	High	96	35	47	17	Na	na	na	na	62	17	Yes	na	Na	76/20	28/7
<i>Hidalgo</i> ²²	RS	10/16	High	148	22	96	12	Na	na	na	na	na	na	Yes	na	Na	95/53	19/3
<i>Ströhlein</i> ¹⁹	PS	14/24	High	89	25	53	19	Na	na	na	na	13	5	No	35	12	76/13	24/1
<i>Pugliese</i> ¹⁸	RS	10/16	High	145	12	NA	NA	NA	NA	NA	NA	NA	NA	No	na	Na	145/0	12/0

Legends: LAP : full laparoscopic approach, CONV : conversion group, BMI : Body Mass Index RTT: radiotherapy, RCT : chemoradiotherapy, SPS : sphincter preserving surgery, APR : abdominoperineal resection

Table 2 : Perioperative data

References	Tumor size		Upper/low-middle rectum location (%)		UICC stages : I-II/III-IV (%)		Operative time (min)		Blood loss (ml)		Blood transfusion (%)	
	LAP	CONV	LAP	CONV	LAP (I-II/III/IV)	CONV (I-II/III/IV)	LAP	CONV	LAP	CONV	LAP	CONV
<i>Agha</i> ¹³	na	Na	18/82	19/81	61/39	34,5/65,6	216+/57	258+/-800*	na	na	2	12*
<i>Keller</i> ¹⁴	na	Na	na	Na	66/34	48/52*	242+/-70	260+/-80*	50	200	0	0
<i>Rickert</i> ¹⁵	na	na	28/72	18/82	49/51	53/47	345	363	na	na	na	Na
<i>Rottoli</i> ¹⁶	na	na	37/63	38/62	na	na	285	342*	80	265*	8	19
<i>Yamamoto</i> ¹⁷	na	na	61/36	73/27	74/26	67/33	270	295*	14	20*	na	Na
<i>Mroczkowski</i> ³⁰	na	na	na	na	na	na	na	na	na	na	na	na
<i>Laurent</i> ¹⁰	na	na	na	na	na	na	na	na	na	na	na	Na
<i>Pennincks</i> ²⁴	na	na	na	na	na	na	na	na	na	na	na	Na
<i>Majbar</i> ²¹	na	na	na	na	na	na	na	na	na	na	na	Na
<i>Hidalgo</i> ²²	na	na	na	na	na	na	na	na	na	na	na	Na
<i>Ströhlein</i> ¹⁹	na	na	na	na	57/43	64/36	na	na	na	na	na	Na
<i>Pugliese</i> ¹⁸	na	na	na	na	na	na	229	310*	na	na	na	Na

Na= Not applicable

LAP : full laparoscopic approach, CONV : conversion

Table 3 : Postoperative data

References	Postoperative complications		Wound infection		Anastomotic leakage		Mortality		Hospital stay		Réoperation		Morbidity dindo>2		Blood transfusion	
	LAP	CON V	LAP	CON V	LAP	CONV	LAP	CONV	LAP	CONV	LAP	CONV	LAP	CONV	LAP	CONV
<i>Agha¹³</i>	101	16*	33	6*	23/209	3/16	0	0	10	10.5	3	0			3	3*
<i>Keller¹⁴</i>	25	8*	2	4	3/94	0/19	1	0	4.4	6.8*	8	0	na	na	0	0
<i>Rickert¹⁵</i>	42	19	6	7	18/110	7/31	0	1	12	15*	13	5	16	7	na	Na
<i>Rottoli¹⁶</i>	34	4	na	na	17/147	4/26	0	0	8	9	26	3	na	na	12	5
<i>Yamamoto¹⁷</i>	210	34*	56	14	72/880	14/75	0	0	14	20*	52	5	na	na	na	Na
<i>Mroczkowski³⁰</i>	386	81	na	na	na	Na	14	4*	na	na	na	na	na	na	na	na
<i>Laurent¹⁰</i>	48	6	na	na	na	na	0	1	na	na	na	na	na	na	na	Na
<i>Pennincks²⁴</i>	206	35	na	na	na	na	11	2	na	na	51	5	na	na	na	Na
<i>Majbar²¹</i>	23	18*	na	na	7/76*	7/28	na	na	na	na	15	13*	na	na	na	Na
<i>Hidalgo²²</i>	59	10	na	na	6/95	4/19	4	0	na	na	12	2	22	3	na	Na
<i>Ströhlein¹⁹</i>	16	4	4	2	9/76	1/24	0	1	na	na	na	na	na	na	na	Na
<i>Pugliese¹⁸</i>	na	na	na	na	12/145	5/12*	na	na	na	na	na	na	na	na	na	Na

LAP : full laparoscopic approach, CONV : conversion

References	Overall survival		R0 resection		Overall recurrence		Local recurrence		Distal recurrence		Follow-up
	LAP	CONV	LAP	CONV	LAP	CONV	LAP	CONV	LAP	CONV	
Agha	na	na	243	18	na	na	13	1	35	5	23
Keller	na	na	na	na	8/115	0	3	0	5	0	38
Rickert	92%	84%	123	37	na	na	4	1	11	3	34
Rottoli	87.8%	76%	146	25	17	7	3	1	na	na	46/36
Yamamoto	na	na	na na	na	na na	na	na na	na	na	na	26
Mroczkowski	na	na	na	na	na	na	na	na	na	na	na
Laurent	na	na	na	na	na	na	8	1	40	7	
Pennincks	na	na	588	75	na	na	na	na	na	na	
Strohlein	na	na	72/96	19/19	na	na	6/89	4/24	na	na	32
Majbar	na	na	na	na	na	na	na	na	na	na	
Pugliese	na	na	na	na	na	na	6	0	16	1	39
Guillou	na	na	na	na	na	na	na	na	na	na	
Van der pas	na	na	454/499	94/104	na	na	na	na	na	na	na

NA= not applicable