

Analyzing the effect of open versus laparoscopic intersphincteric resection(ISR) for low rectal cancer: a meta-analysis.

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Abstract

Background: Intersphincteric resection (ISR) has swiftly increased worldwide together with open and laparoscopic technique. Though, there are some concerns for which effect is minor among the two procedures in relations to postoperative result such as operative time, blood loss, lymph node resected etc. Similarly there are other concerns for the explanation of ISR, surgical practice, oncological result, anal function, and quality of life.

Objective: The aim of this article is to study the effects between laparoscopic and open intersphincteric resection for low rectal cancer.

Method: A computer-based online research of studies addressing laparoscopic and conventional open intersphincteric resection for low rectal carcinoma published in between 2010 and 2017 years was performed in electronic database (PubMed, Medline and Google scholar). The effect of open and laparoscopic intersphincteric resection for low rectal cancer was assessed. Selective studies were analyzed by the Review Manager 5.3 software.

Results: A total of 8 studies, involving a total of 718 patients, were identified. A meta-analysis showed that open ISR had less operative time over laparoscopic ISR method (WMD = -37.62, 95% CI [-26.31, 48.93], $P < 0.00001$), blood loss in laparoscopic ISR was less than open ISR (WMD = -148.15, 95% CI [-175.70, -120.61], $P < 0.00001$), wound infections showed no significant difference between the two groups (OR = 0.57, 95% CI [0.14, 2.33], $p = 0.44$) and the was less overall morbidity in the laparoscopic ISR than the open ISR (OR = 0.61, 95% CI [0.41, 0.89], $p = 0.01$).

Conclusion: Laparoscopic intersphincteric resection proves to be safer and more feasible as compared to the open surgery and expected to be a standard operation method for low rectal cancer.

Keywords: Intersphincteric resection, Open, Laparoscopic, Rectal cancer, Neoplasm.

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I. Introduction

Surgical remedies associated with colorectal cancer is generally determined by the tumor location and degree of tumor extension. Advancements in surgical devices and techniques have aided surgeons in the anal preservation of many of their patients. Nonetheless, careful resection is still necessary for rectal cancers located in very close proximity near the anus regardless, in order to secure safer distal and radial margins in the anal canal. Therefore, surgical treatment for lower rectal cancer must seek a balance between curability and maintenance of function. On the other hand, abdominoperineal resection (APR) is frequently performed in circumstances when the anus is technically and/or functionally impossible to be preserved. Some paramount anus-preserving surgical methods consist of sphincter muscle resection and intersphincteric resection (ISR) as defined by Schiessel[1], which is currently highly favored as a corrective treatment for these specific site cancers and has become universally implemented around the world[2-4]. This procedure is initiated to prevent permanent colostomy for very low rectal cancers which might previously have required APR. The ISR procedure includes both transabdominal and transanal approaches. The internal sphincter is transabdominally and transanally divided from the external sphincter by dissecting the intersphincteric space (plane) accompanied by coloanal anastomosis which is then performed using a hand-sewn technique. Many studies on the surgical, oncologic, and functional outcomes of patients after ISR have been reported and observed as well[5-24].

With technical advancements, laparoscopic surgery has proven itself with the advantages it possesses in treating rectal cancer[25]. Although, the learning curve and technical difficulties have limited the widespread application of laparoscopic sphincter-preserving TME, laparoscopic ISR is helpful in the management of ultralow rectal cancer. With the application of this technique the need for performing abdominoperineal resection seems to have decreased in patients with very low rectal tumors[26, 27]. For this reason, laparoscopic surgery has progressively gained a clear role in colon cancer treatment[28]. The road to the development of laparoscopic surgery for rectal cancer has been more challenging, due to the technical and anatomical adversities related to this approach. It has been clearly shown that oncological and short term outcomes are equivalent to open surgery, given the well-recognized advantages of laparoscopy in terms of faster recovery and cosmesis[29] . The laparoscopic approach to rectal cancer, specifically lower rectal cancer, requires special expertise and should be performed in high volume colorectal cancer centers, since the surgeon is one of the most critical factors for the best outcome[30, 31]and a long learning curve is needed[32, 33], Furthermore, with respect to open surgery, laparoscopy enables a better vision in the pelvis. This is important in order to achieve a good nerve sparing technique and an appropriate total mesorectal excision, with a clear exposure of the plane between the rectum and the vagina or the seminal vesicles and the prostate, and, finally, of the pelvic floor. This is also true for an ISR, since an accurate and bloodless up to down dissection can be carried out between the pelvic diaphragm hiatus and the rectum, thus entering in the intersphincteric space. From the beginning of this century several experiences with laparoscopic ISR are recorded in literature [7, 27, 34-36].

The aim of this is review is to perform a meta-analysis to provide evidence for evaluating the effects of laparoscopic versus open surgery in low rectal cancer.

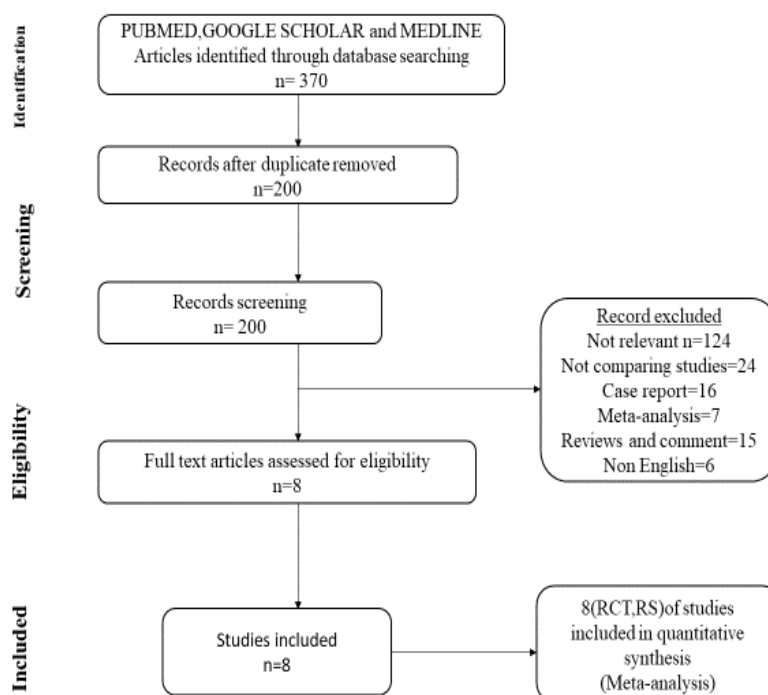
II. Materials and Methods

We completed a literature search in PubMed, Medline, and Google scholar using the search terms Intersphincteric resection, Open, Laparoscopic, Rectal cancer, Neoplasm. All titles and abstracts of publications were screened to select articles describing laparoscopic and open intersphincteric resection of the low rectal cancer. Full-text articles of preliminary included studies were screened.

2.1 Data extraction

Data extraction was independently performed by using specially designed data extraction sheets. After we collected 8 full papers, the author, study interval, the number of cases of surgery, operation time, bloodloss, lymph node dissected, hospital length of stay, anastomotic leakage, anastomotic stricture, woundinfection, ileus, intraabdominal abscess and overall morbidity were all considered.

Fig 1. Summary of included studies



2.2. Inclusion criteria

The studies of interest were confirmed as CRC by pathology or histology and undergoing intersphincteric resection (ISR) by means of laparoscopic surgery or conventional open surgery. The studies must include those indices: compared with the laparoscopic group and the open group; operation time, blood loss, lymph node dissected, hospital length of stay, anastomotic leakage, anastomotic stricture, wound infection, ileus, intraabdominal abscess and overall morbidity. Selected literature must indicate the surgical approach for the laparoscopic group and open group, and there are 2 sets of data comparison of the situation. Recent literature as a recent one, and the original literature with complete data was selected.

2.3. Exclusion criteria

A single study of the uncontrolled group, non-comparative study of benign diseases, non-English papers and animal studies were excluded. Repeated publication of the literature, failure to provide valid data, or no full text of the literature were excluded from our study. Case report, letters, meta-analysis review were also excluded.

2.4. Table 1: Basic information of included studies

Authors	Nationality	Study interval	Type of study	No. patient OP/LAP	Total no. patients
C.laurentet al[37]	France	1990-2007	RCNT	65/110	175
Li-jen kuo et al[38]	Taiwan	2006-2011	RCNT	30/28	58
Jun soek et al[39]	Korea	1999-2009	RCNT	80/130	210
Yoshiya.F et al[36]	Japan	2005-2008	RCNT	19/35	54
Seichiro .Y et al[40]	Japan	2002-2011	RCNT	22/22	44
Pan chi et al[41]	China	2006-2013	RCNT	48/89	137
Nobuhira.M et al[42]	Japan	2008-2013	RCNT	6/19	25
Vish.Det al[43]India		2013-2015	RCNT	39/34	73

2.5. Statistical analysis

The meta-analysis was performed using the Review Manager software 5.3 that was provided by the Cochrane Collaboration. Continuous variables were pooled using the mean difference (MD) with a 95% confidence interval (95% CI), and dichotomous variables were pooled using the odds ratio (OR) with a 95% CI. Studies that reported only the median, range, and size of the trial, the means and standard deviations were calculated according to Hozo et al.[44]. Statistical heterogeneity was evaluated by I^2 , and it was considered to be high if the I^2 statistic was greater than 50%. The fixed effects model was used for studies with low or moderate statistical heterogeneity, and the random effects model was used for studies with high statistical heterogeneity.

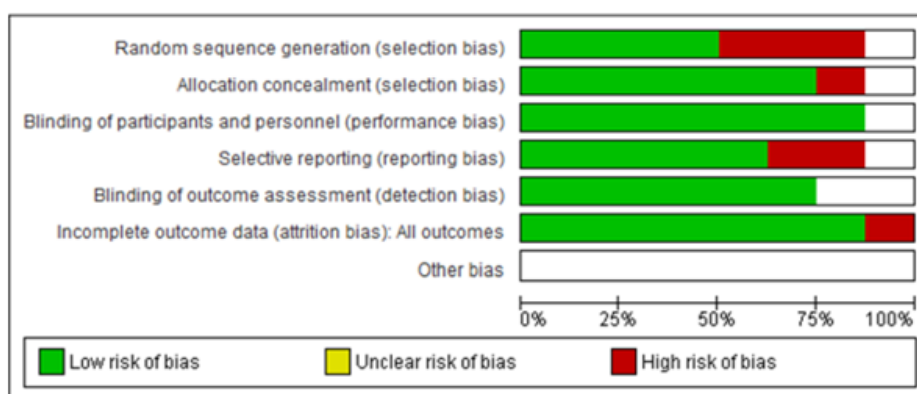


Fig 2. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Selective reporting (reporting bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias): All outcomes	Other bias
C.laurent 2007	+	+	+	+	+	+	
Jun seok 2009	+	+	+	+	+	+	
li-jen kuo 2011	-		+	-		-	
nobuhira mastuhashi 2013	+	+	+	+	+	+	
pan chi 2013	-	+	+	+	+	+	
seichiro yamamoto 2011		+	+	+	+	+	
vishwas D. 2015	-	-		-		+	
yoshiya fujimoto 2008	+	+	+		+	+	

Fig 3. Risk of bias summary: review authors' judgments about each risk of bias item for each included study.

III. Results

3.1. General characteristic of the analyzed patients.

A total of 370 studies were searched. Of these searched studies, 200 remaining after duplicates removed, 200 articles were screened, and records excluded were 124 not irrelevant, 16 reports, 7 meta-analysis, 15 reviews and comment, and 6 non-English studies. 8 Full-text articles were carefully studied and 8 were included in the quantitative study as shown in Figure 1. The studies included were comparing laparoscopic versus open intersphincteric resection. The studies were 1 paper from china, Pan chi et al [41], 3 papers from Japan, Yoshiya fujimoto et al [36], Seichiro Yamamoto et al [40] and Nobuhira matsuhashi et al [42], 1 paper from Korea, Jun soek et al [39], 1 paper from France C.learent et al [37], 1 paper from India , Vishwas D.pai et al [45] and 1 paper from Taiwan Li-jen kuo et al [38]. All the 8 papers were randomized control trials with n=776 participant as shown in Table 1. There was the open groups with n=309 participants and laparoscopic group with n=467 participants. Studies reported outcomes such as operative time, intraoperative blood loss, lymph node harvest, length hospital of stay, anastomotic leakage, anastomotic stricture, wound infection, ileus, intraabdominal abscess, and overall morbidity. Meta-analysis result are shown in Table 2. The Risk of bias for included studies is shown in Figure 2 and Figure 3.

3.2. Operative time

Seven studies [36-42] reported a significant difference of operative time between the laparoscopic group compared to the open group (WMD= -37.62, 95% CI [-26.31, 48.93], P < 0.00001). Longer operative time was observed in the lap ISR group. A fixed effect model was used due to significant heterogeneity (p<0.00001, I² = 94%) Heterogeneity: Chi² = 103.42, df = 6 (P < 0.00001); I² = 94%. Test for overall effect: Z = 6.52 (P < 0.00001). Notably, the outcome from the study of Fujimoto et al. significantly differed from the others. Upon matching the procedures, we found that this group performed more lateral lymph node dissections in the open group, which is time-consuming. We also found out that, longer time observed in Laparoscopic ISR was due procedural difficulties .Figure 4

3.3. Blood loss

Seven studies [36, 38-43] reported that significantly less blood was reduced in the laparoscopic group compared to the open group (WMD= -148.15, 95% CI [-175.70,-120.61],P < 0.00001). A fixed effect model was used due to significant heterogeneity (p<0.00001, I² = 96%). Heterogeneity: Chi² = 138.49, df = 6 (P < 0.00001); I² = 96%. Test for overall effect: Z = 10.54 (P < 0.00001). Figure 5

3.4. Hospital length of stay

Seven studies [36-38, 40-43] reported the length of hospital stay. There was a significant difference found between the two groups (WMD= -4.32, 95% CI [-5.35, -3.28], p=8.18). Laparoscopic method showed a shorter hospital stay. Significant heterogeneity was noted; thus, the fixed effect model was used (p=0.95, I² =91%) Heterogeneity: Chi² = 185.54, df = 6 (P < 0.00001); I² = 97%.Test for overall effect: Z = 8.18 (P < 0.00001). Figure 6

3.5. Lymph node harvest

Seven studies [36, 38-43] reported the number of harvested lymph nodes. After pooling the results, we found no significant difference between the two groups (WMD=-0.69, 95% CI-1.99, 0.60], p=0.29). No statistical significance was noted. Heterogeneity: Chi² = 21.74, df = 6 (P = 0.001); I² = 72%.Test for overall effect: Z = 1.05 (P = 0.29). Figure 7

3.6. Anastomotic leakage

Five studies [36, 39-42] reported anastomotic leakage, but one study Nobuhira Masuhashi[42] recorded no incidence. Four studies were involved in the meta-analysis and there was no significant difference was found between the two groups for anastomotic leakage (OR= 0.69, 95% CI [0.27, 1.77], p=0.44). No significant heterogeneity was noted; thus, the fixed-effect model was used. Heterogeneity: Chi² = 1.35, df = 3 (P = 0.72); I² = 0%. Test for overall effect: Z = 0.78 (P = 0.44). Figure8

3.7. Anastomotic stricture

Three studies [36, 39, 41] reported anastomotic strictures and there was no significant difference was found between the two groups for anastomotic stricture (OR= 1.06, 95% CI [0.28, 3.99], p=0.93). No significant heterogeneity was noted; thus, the fixed-effect model was used. Heterogeneity: Chi² = 0.79, df = 2 (P = 0.67); I² = 0%. Test for overall effect: Z = 0.09 (P = 0.93). Figure 9

3.8. Ileus

Five studies [36, 39-42] reported ileus and there was no significant difference was found between the two groups for ileus (OR= 0.74, 95% CI [0.26, 2.07], p=0.58). No significant heterogeneity was noted; thus, the fixed-effect model was used. Heterogeneity: Chi² = 1.94, df = 4 (P = 0.75); I² = 0%. Test for overall effect: Z = 0.58 (P = 0.56). Figure 10

3.9. Wound infection

Three studies [36, 40, 41]reported wound infection and there was no significant difference was found between the two groups for wound infection (OR= 0.57, 95% CI [0.14, 2.33], p=0.44). No significant heterogeneity was noted; thus, the fixed-effect model was used. Heterogeneity: Chi² = 1.55, df = 2 (P = 0.46); I² = 0%. Test for overall effect: Z = 0.78 (P = 0.44). Figure 11

3.10. Intraabdominal abscess

Three studies [39, 41, 42] reported infra-abdominal abscess and there was no significant difference was found between the two groups (OR= 0.68, 95% CI [0.13, 3.60], p=0.65). No significant heterogeneity was noted; thus, the fixed-effect model was used. Heterogeneity: Chi² = 0.10, df = 2 (P = 0.95); I² = 0%. Test for overall effect: Z = 0.46 (P = 0.65). Figure 12

3.11. Overall morbidity

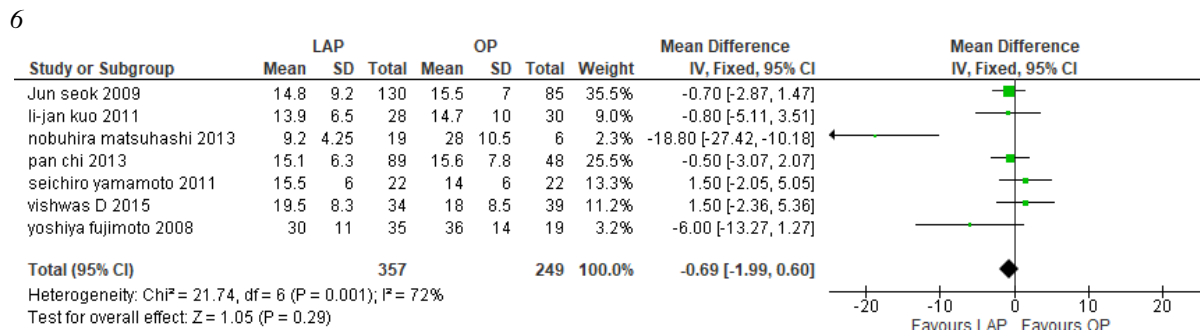
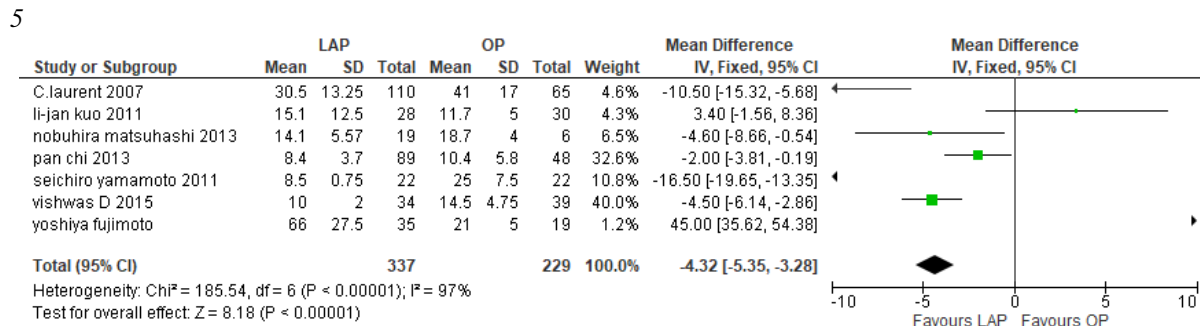
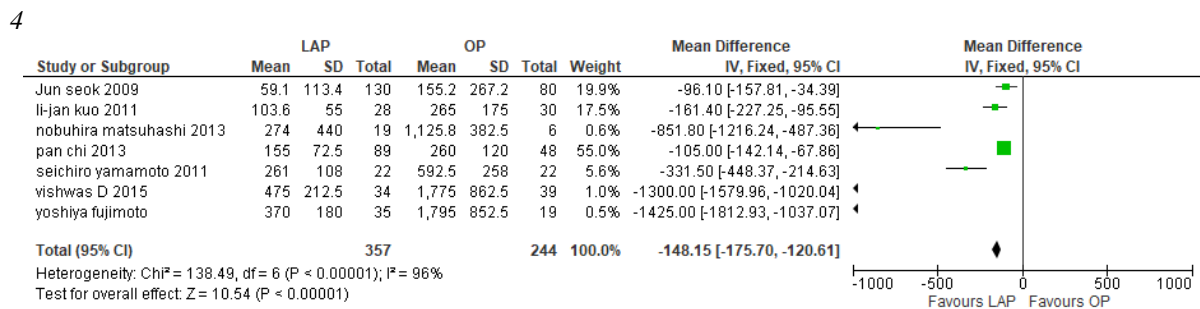
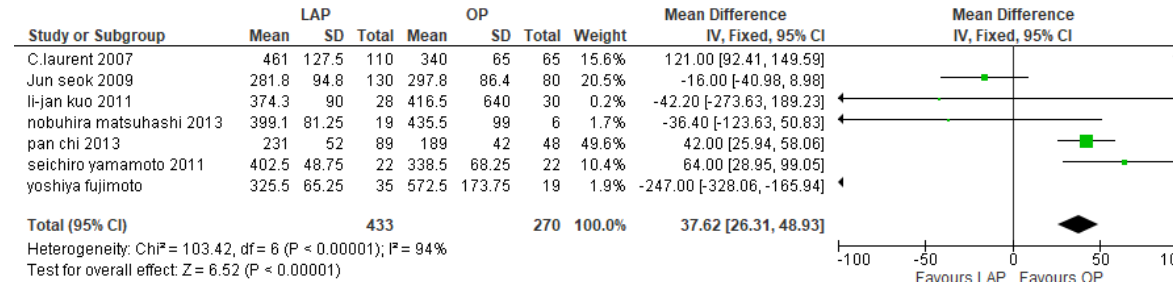
Five studies [36, 37, 39-41] reported that significantly less overall morbidity in the laparoscopic group compared to the open group (OR= 0.61, 95% CI [0.41, 0.89], p=0.01). Significant heterogeneity was noted; thus, the fixed-effect model was used. Heterogeneity: Chi² = 1.26, df = 4 (P = 0.87); I² = 0%. Test for overall effect: Z = 2.57 (P = 0.01). Figure 13

Table 2: Meta-analysis results

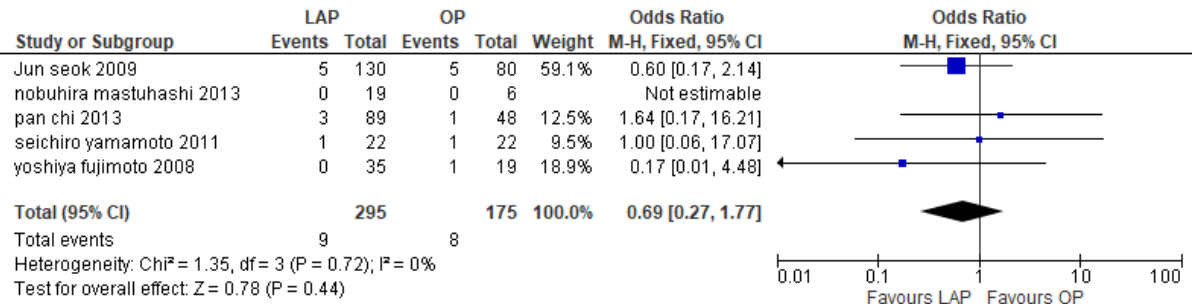
Indicators	Statistical result	Statistical testing		Heterogeneity analysis	
		Z	P	X ²	P
Operative time	-37.62(26.31,48.93)	6.52	0.01	103.42	<0.00001
Blood loss	-148.15 (-175.70, -120.61)	10.54	0.01	138.49	<0.00001
Length of stay	-4.32(-5.35, -3.28)	8.18	0.01	185.54	<0.00001
Lymph node	-0.69(-1.99,0.60)	1.05	0.001	21.74	0.29
Anastomotic leakage	0.69(0.27,1.77)	0.78	0.44	1.35	0.72

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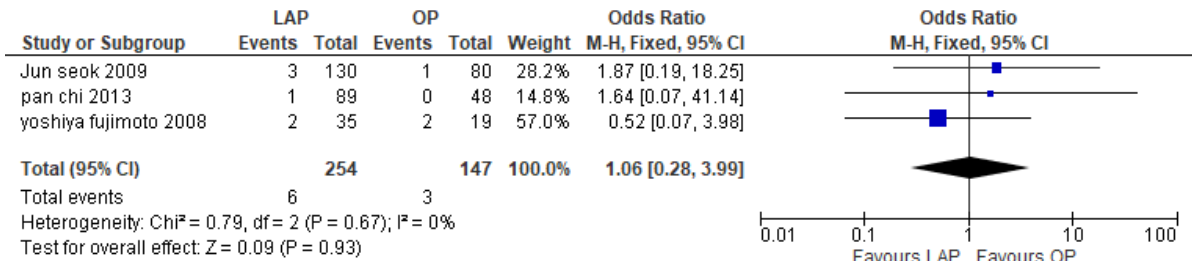
Anastomotic stricture	1.06(0.28,3.99)	0.09	0.93	0.75	0.67
Ileus	0.74(0.26, 2.07)	0.58	0.56	1.92	0.75
Wound infection	0.57(0.14,2.33)	0.78	0.44	1.55	0.46
Intra-abscess	0.68(0.13,3.60)	0.46	0.65	0.10	0.95
Overall morbidity	0.61(0.41,0.89)	2.52	0.01	1.26	0.87



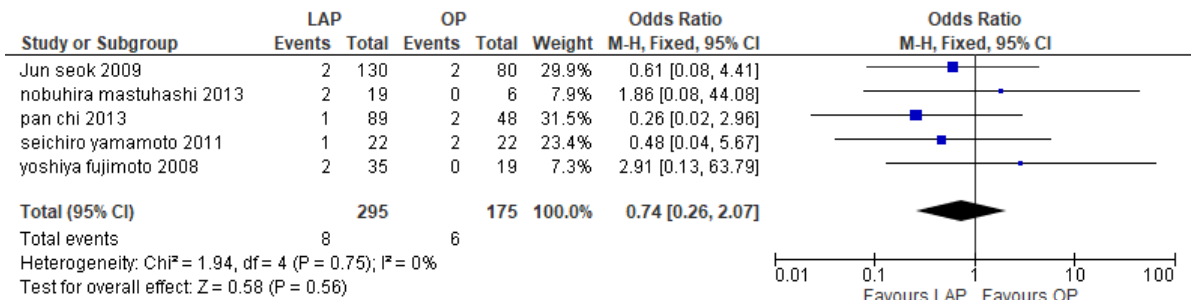
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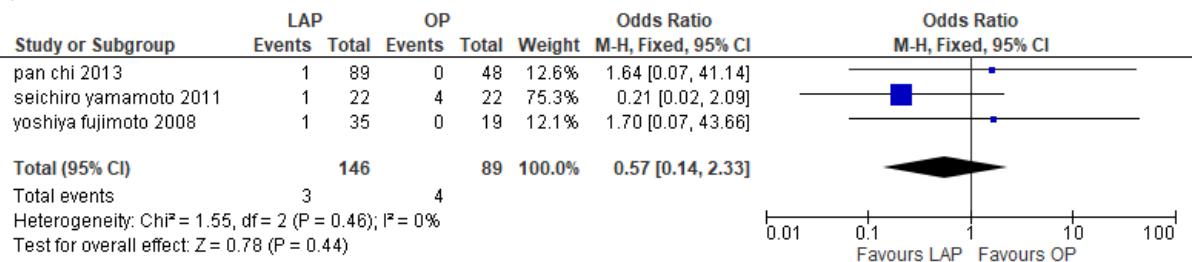
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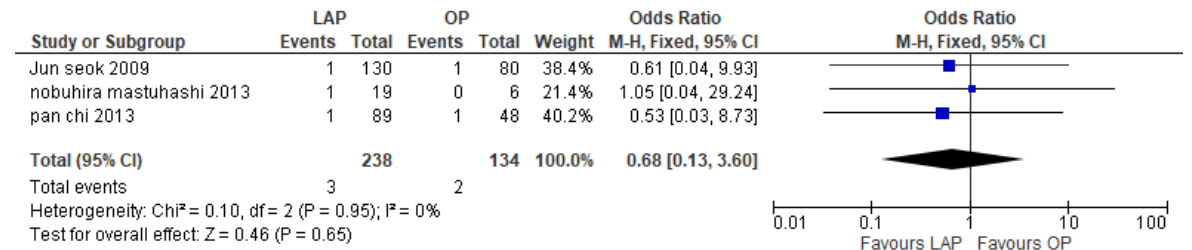
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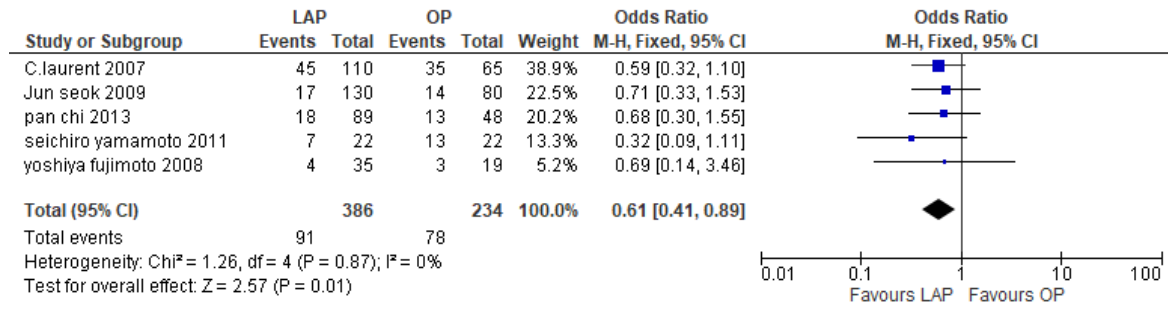
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IV. Publication bias

The funnel plot on the overall morbidity is shown in Figure 14. Because all studies laid inside the 95% CI limits, no evidence of publication bias was noted. Egger test was performed to provide statistical evidence regarding funnel plot symmetry. Result still did not reveal any evidence of publication bias in overall morbidity (Heterogeneity: Chi² = 1.26, df = 4 (P = 0.87); I² = 0%). Lymph node harvest (Heterogeneity: Chi² = 21.74, df = 6 (P = 0.001); I² = 72%). Figure 15

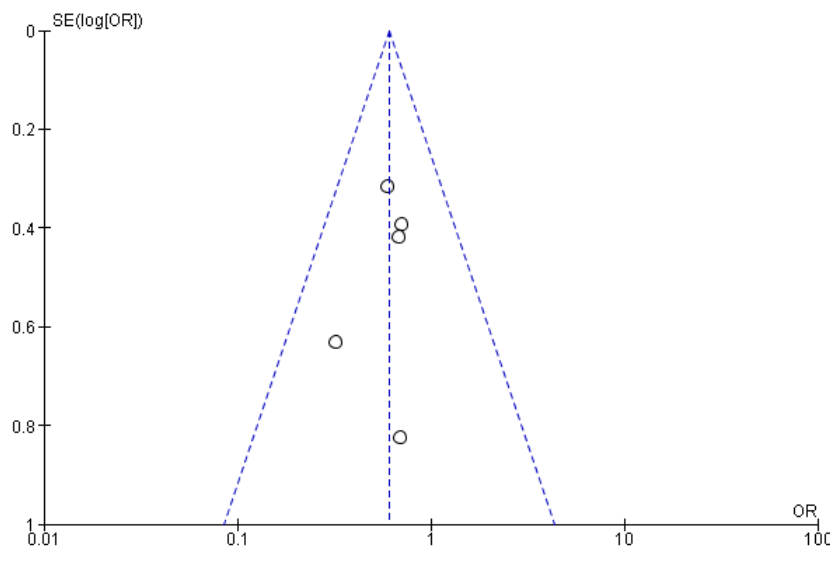


Fig 14. Funnel plot of comparison: Laparoscopic ISR versus open ISR, outcome: overall morbidity.

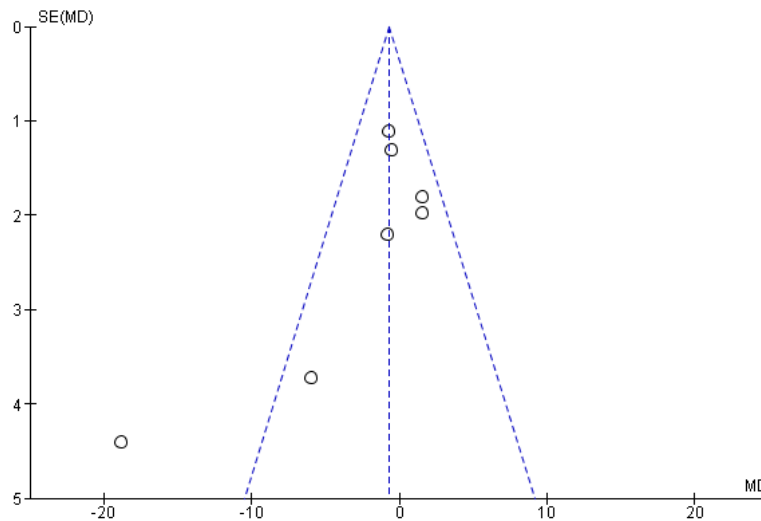


Fig 15. Funnel plot of comparison: Laparoscopic ISR versus open ISR, outcome: lymph node harvested.

V. Discussion

The drive to impose laparoscopic surgery as a remedy for lower rectal cancers because of its decreased amount of blood loss, reduced incision-related complications, and earlier recovery for patients has progressively improved towards being accepted as a minimally invasive technique. The feasibility and safety of this technique in treating rectal cancer fortunately has been demonstrated in prior procedures.

Particularly in the lower rectum, surgeons have found that laparoscopic surgery offers better visibility when operating in the lower pelvic cavity such as, when dissecting the mesorectum plane, dividing lateral ligaments, mobilizing the pelvic floor, or dissecting the intersphincteric groove [46, 47]. This procedure also permits the pelvic autonomic nerves associated to defecation, urination, and sexual function to be effortlessly seen under the camera so it can be well-preserved which in return may provide a better recovery for patients and more successful surgeries. Whether patients receive increased benefits from laparoscopic surgery compared with open surgery in ISR still remains debatable. Laparoscopy has been easily adopted for colon surgery, but is slowly gaining acceptance by the surgical community for rectal cancer. This is because of the initial concerns about adequacy of free resection margins and lymph node retrieval, while performing a TME for middle and low rectal cancer. Two published meta-analyses show that laparoscopic rectal cancer surgery may achieve an oncological clearance similar to the quality outcomes of the open surgical approach[48, 49].

Accordingly, we conducted a meta-analysis to evaluate whether laparoscopic surgery provides less significant effects on patients in terms of complications during surgery. Surprisingly, the aftermath of the meta-analysis exhibited a reduction in operative time for open ISR compared to laparoscopic ISR (WMD=-37.62, 95% CI [-26.31, 48.93], $P < 0.00001$). The short-term outcomes revealed that operation times were longer for laparoscopic surgery. Procedural complexity is unavoidable, leading many to resort to open surgery or endure longer operation times before the surgeon gains adequate practice [2, 40]. Kuo et al. [38] compared the short-term outcomes of patients who received the laparoscopic ISR procedure during the initial 18 months in which they began performing the procedure to the patients who underwent this surgery after the initial 18 months. They had discovered that operation times were significantly shorter, and an increased number of lymph nodes were able to be retrieved, as the surgeon gained more competence of the procedure. In spite of this, studies are still vital to reveal the learning curve pattern and provide surgeons with a probable time frame for becoming more skilled in conducting laparoscopic ISR for low rectal cancers. In our study there was also significantly less blood loss confirmed in favor of laparoscopic surgery in comparison to open surgery (WMD= -148.15, 95% CI [-175.70, -120.61], $P < 0.00001$). In a sequence of analysis done, less blood lost was stated which confirms that when done correctly and without complications the laparoscopic approach truly proves the impressive advantages it has since the size of the incision made in a laparoscopic procedure is so much smaller than the large incision done in the open method. This reduces the probability of a blood transfusion being needed to recompense for blood loss, which is an advantage for surgeons and patients. Moreover, the overall morbidity rate was lower with laparoscopic surgery for all of the included studies (OR= 0.61, 95% CI [0.41, 0.89], $p=0.01$). Simultaneously, individual analysis was done on anastomotic leakage, anastomotic stricture, wound infection, ileus and intra-abdominal abscess and all results were relatively the same between the two groups. Furthermore, there was a shorter duration in hospital length of stay for laparoscopic ISR than the open ISR (WMD= -4.32, 95% CI [-5.35, -3.28], $p=8.18$). Despite that there were five studies that did seem to confirm a decrease in length of stay at the hospital after the laparoscopic approach compared to the open surgery[37, 39-42] since the healing in the laparoscopic surgery is far less drastic which can lead to a more speedy recovery and decrease infection rate for patients.

Continuing with the earlier meta-analysis, [50, 51] the laparoscopic ISR group had significantly less blood loss than the open ISR group. With the development of surgical tools as well as techniques, electrocoagulation instruments such as, electrotome and harmonic scalpel have been extensively used, both of which importantly contributes in the decrease of blood loss in surgery. Though, we believe that laparoscopic surgery offers an extravagant and clearer image, pendlimari et al [52], and with the assistance of a long handle, surgeons can reduce the needless injury to blood vessels. To an even greater extent, the laparoscopic ISR group can permit less blood loss because of this advantage. Laparoscopic surgery is a minimally invasive technique that has a smaller incision length and less postoperative pain when compared to conventional open surgery [53, 54]. Therefore, when it comes to postoperative recovery, past studies found that patients in the laparoscopic ISR group had less postoperative days and earlier time to first flatus. We found that there weren't any other major differences between the laparoscopic group and open group but, the laparoscopic group had few lymph nodes harvested. We believe that the number of lymph nodes harvested was related with preoperative chemoradiotherapy and tumor stage. Besides, the learning curve of different pathologists can also affect the recognition of the lymph nodes. And in survival situations, laparoscopic ISR was not inferior to open ISR in 3-year and 5-year survival [55-57].

It is recognized that this review has four major limitations and uncontrolled variables that can falsify results. First, all studies available in this field were non-randomized, which may reduce each of the studies' consistency between the two groups. Second, in the included studies, various types of complications and various diagnostic criteria were adopted. Third, the limited number of studies may influence the statistical power, so more trials will have to be performed to show the results more strongly. Lastly, the experience and skill of each surgeon likely differed within the studies, specifically in performing laparoscopic ISR for lower rectal cancers, which can create an inevitable bias based on whether or not they attained satisfactory results.

In conclusion, this meta-analysis indicated that Laparoscopic ISR proves to have milder effects and is safe and feasible for the treatment of low rectal cancer. Open ISR in this current study resulted in shorter operation times, although Laparoscopic ISR offers more favorable benefits, fewer complications compared with open ISR. These results may have the potential to impact treatment options in low rectal cancer patients. However, as there are limitations to this meta-analysis, conclusions should be regarded with some reservations. Confidently, better designed, large trials are necessary.

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Competing interest

The authors declare they have no competing interest