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Laparoscopic Vs Open Repair for Incisional Hernia

Meta-analysis and systematic review of laparoscopic versus open mesh repair for elective incisional hernia

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ABSTRACT

OBJECTIVES: The aim was to conduct a meta-analysis of RCTs investigating the surgical and postsurgical outcomes of elective incisional hernia by open versus laparoscopic method.

MATERIAL AND METHODS: A search of PubMed, Medline, Embase, Science Citation Index, Current Contents, and the Cochrane Central Register of Controlled Trials published between January 1993 and September 2013 identified all the prospective RCTs comparing surgical treatment of only incisional hernia (and not primary ventral hernias) using open and laparoscopic methods were selected. The outcome variables analyzed included (a) hernia diameter; (b) operative time; (c) length of hospital stay; (d) overall complication rate; (e) bowel complications; (f) reoperation; (g) wound infection; (h) wound hematoma or seroma; (i) time to oral intake; (j) back to work; (k) recurrence rate; and (l) post-operative neuralgia. The quality of RCTs was assessed using Jadad's scoring system. Random effects model was used to calculate the effect size of both binary and continuous data. Heterogeneity amongst the outcome variables of these trials was determined by the Cochran *Q* statistic and I^2 index. The meta-analysis was prepared in accordance with PRISMA guidelines.

RESULTS: Six RCTs were considered suitable for meta-analysis. A total of 378 patients underwent open mesh repair and 373 had laparoscopic repair. Statistically significant reduction in bowel complications was noted with open surgery compared to the laparoscopic repair in five studies (OR 2.56, 95% CI 1.15, 5.72, p=0.02). Comparable effects were noted for other variables which include hernia diameter (SMD -0.27, 95% CI -0.77, 0.23, p=0.29), operative time (SMD -0.08, 95% CI -4.46, 4.30, p=0.97), overall complications (OR -1.07, 95% CI -0.33, 3.42, p=0.91), wound infection (OR 0.49, 95% CI 0.09, 2.67, p=0.41), wound hematoma or seroma (OR 1.54, 95% CI 0.58, 4.09, p=0.38), reoperation rate (OR -0.32, 95% CI 0.07, 1.43, p=0.14), time to oral intake (SMD -0.16, 95% CI -1.97, 2.28, p=0.89), length of hospital stay (SMD -0.83, 95% CI -2.22, 0.56, p=0.24), back to work (SMD -3.14, 95% CI -8.92, 2.64, p=0.29), recurrence rate (OR 1.41, 95% CI 0.81, 2.46, p=0.23), and postoperative neuralgia (OR 0.48, 95% CI 0.16, 1.46, p=0.20).

CONCLUSIONS: On the basis of our meta-analysis, we conclude that laparoscopic and open repair of incisional hernia is comparable. A larger randomized controlled multicenter trial with strict inclusion and exclusion criteria and standardized techniques for both repairs is required to demonstrate the superiority of one technique over the other.

INTRODUCTION

Every surgical procedure that requires access through the abdominal wall carries a risk of development of incisional hernia. Incisional hernias are mostly related to failure of the fascia to heal and involve technical and biological factors. They may cause pain, increase in size over time, and also result in severe complications such as bowel incarceration and strangulation. A vast majority of open surgical repair of incisional hernias are achieved using a prosthetic mesh which is still associated with early or late complications such as mesh complications and the recurrence rate of approximately 32% over a 10-year follow up period [Burger et al, 2004, Teserteli et al, 2008]. LeBlanc et al in 1993 [LeBlanc & Both 1993] reported the first case of laparoscopic incisional hernia repair using a synthetic mesh to improve upon the open method. Since the introduction of this technique, a number of randomized control trials (RCTs) comparing laparoscopic and open methods have been published analyzing various aspects of these approaches. The objective of this meta-analysis was to determine the clinical outcomes, safety and effectiveness of laparoscopic repair compared with open repair for elective surgical treatment of incisional hernia only.

MATERIALS AND METHODS

Search Strategy and Data Collection

RCTs were identified by conducting comprehensive search of electronic databases, PubMed, Medline, Embase, Science Citation Index, Current Contents and the Cochrane Central Register of Controlled Trials published between January 1993 and September 2013 using medical subject headings (MESH); "hernia," "incisional," "abdominal," "randomized/randomised controlled trial," "abdominal wall hernia," "laparoscopic repair," and "open repair"; "Human"; and "English". We further searched the reference lists of all included primary studies and existing meta-analysis by hand for additional citations. Data extraction, critical appraisal and quality assessment was carried out by two authors (AA, MAM). The authors were not blinded to the source of the document or authorship for the purpose of data extraction. Standardized data extraction forms were used by authors to independently and blindly summarize all the data available in the RCTs meeting the inclusion criteria [Moher et al, 1999]. The data were compared and discrepancies were addressed with discussion until consensus was achieved. The analysis was prepared in accordance with the Preferred Reporting of Systematic Reviews and Meta-Analyses (PRISMA) statement [Moher et al, 2009]. Random effect model was used for analysis of all the variables.

The included RCTs must have reported on at least one clinically relevant outcome pertaining to the intraoperative and postoperative period. Only adult (>18 years) patients requiring elective surgical intervention purely for the repair of incisional hernia either by open or laparoscopic method were the target population for this meta-analysis. Exclusion criteria included studies that investigated the effect of open versus laparoscopic repair in a mixture of primary and incisional hernia repair and duplicate publications. The 12 outcome variables analyzed included (a) hernia diameter; (b) operative time; (c) length of hospital stay; (d) overall complication rate; (e) bowel complications; (f) reoperation; (g) wound infection; (h) wound hematoma or seroma; (i) time to oral intake; (j) back to work; (k) recurrence rate; and (l) post-operative neuralgia. We used the Jadad scoring system to evaluate the methodological quality of the identified RCT's [Haynes et al, 2006, Jadad et al, 1996].

Statistical Analysis and Risk of bias across Studies

Meta-analyses were performed using odds ratios (ORs) for binary outcome and standardized mean differences (SMDs) for continuous outcome measures. The slightly amended estimator of OR was used to avoid the computation of reciprocal of zeros among observed values in the calculation of the original OR [Agresti et al, 1996]. Random effects model based on the inverse variance weighted method approach was used to combine the data [Sutton et al, 2000]. Heterogeneity among studies was assessed using the Q statistic and I^2 index [Higgins et al, 2002, Hedges et al,1985, Cochran et al, 1954, Huedo-Medina et al, 2006, Sutton et al, 2000]. If the observed value of Q was greater than the associated x^2 critical value at a given significant level, in this case 0.05, we conclude the presence of statistically significance between-studies variation. In order to pool continuous data, mean and standard deviation of each study is required. However, some of the published clinical trials did not report the mean and standard deviation, but rather reported the size of the trial, the median and range. Using these available statistics, estimates of the mean and standard deviation were obtained using formulas proposed by Hozo [Hozo et al, 2005]. Funnel plots were created in order to determine the presence of publication bias in the present meta-analysis. Both total sample size and precision (reciprocal of standard error) were plotted against the treatment effects (OR for dichotomous variables and SMD for continuous variables) [Egger et al, 1997, Tang et al, 2000, Span et al, 2006]. All estimates were obtained using a computer program written in R [R: Language and Environment for Statistical Computing [Computer Program]. All plots were obtained using the metafor-package [Viechtbauer et al, 2010]. In the case of tests of hypotheses, the paper reports p-values for different statistical tests on the study variables. In general, the effect is considered to be statistically significant if the p-value is small. If one uses a 5% significance level then the effect is significant only if the associated p-value is ≤5%.

RESULTS

The six studies, [Asencio et al, 2009, Eker et al, 2013, Itani et al, 2010, [Navarra et al, 2007, Olmi et al, 2007, Rogmark et al, 2013] that met the inclusion criteria are detailed in Table 1, Fig 1. The pooled data for the 12 outcomes are summarized in Table 2. Statistically significant reductions in bowel complications was noted with open surgery compared to the laparoscopic repair based on five studies namely [Asencio et al, 2009, Eker et al, 2013, Itani et al, 2010, Olmi et al, 2007, Rogmark et al, 2013] (OR 2.56, 95% CI 1.15, 5.72, p=0.02) (Fig 2). Comparable effects were noted for other variables which include hernia diameter (SMD -0.27, 95% CI -0.77, 0.23, p=0.29) (Fig 3), operative time (SMD -0.08, 95% CI -4.46, 4.30, p=0.97) (Fig 4), overall complications (OR -1.07, 95% CI -0.33, 3.42, p=0.91) (Fig 5), wound infection (OR 0.49, 95% CI 0.09, 2.67, p=0.41) (Fig 6), wound hematoma or seroma (OR 1.54, 95% CI 0.58, 4.09, p=0.38) (Fig 7), reoperation rate (OR 0.32, 95% CI 0.07, 1.43, p=0.14) (Fig 8), time to oral intake (SMD -0.16, 95% CI -1.97, 2.28, p=0.89) (Fig 9), length of hospital stay (SMD -0.83, 95% CI -2.22, 0.56, p=0.24) (Fig 10), back to work (SMD -3.14, 95% CI -8.92, 2.64, p=0.29) (Fig 11), recurrence rate (OR 1.41, 95% CI 0.81, 2.46, p=0.23) (Fig 12), and postoperative neuralgia (OR 0.48, 95% CI 0.16, 1.46, p=0.20) (Fig 13). The RCTs collectively demonstrated moderate methodological quality based on Jadad score with an average score of 2.7 (out of five), with a range of 2 to 3 (Table 1).In general there was a high degree of heterogeneity detected for most of the outcomes in the included studies except for bowel complications, recurrence rate, reoperation and neuralgia (Table 2). Most of the funnel plots demonstrate asymmetry and thus suggest the presence of publication bias for a majority of outcomes (Fig 14) .

Table 1: Salient features of various RCTs

Authors/Year	Pt	Open	Lap	Follow-up	Jadad Score		
	n	n	n	months	Randomized	Blinding	Dropouts/ Withdrawals
Olmi at al/2006/	170	85	85	24	1	0	0
Navara et al/2007	24	12	12	6	2	0	0
Asencio et al/2008	84	39	45	12	2	0	1
Itani et al/2010	146	73	73	2	2	0	1
Eker et al/2013	194	100	94	35	2	0	1
Rogmark et al/2013	133	69	64	2	2	0	1

Lap= Laparoscopic, n= number, Pt= Patient

Table 2: Polled Statistics

Clinical Variable	Pt	Pooled Statistics	Overall effect Test		Test for heterogeneity		
	n	SMD or OR [CI]	Z	Pr	Q	Pr	I^2 [CI] in %
Hernia Diameter	751	-0.27 [-0.77; 0.23]	-1.06	0.29	56.88	<0.0001	90.64 [75.14; 98.37]
Operative Time	605	-0.08 [-4.46; 4.30]	-0.03	0.97	456.7	<0.0001	99.73 [NA; NA]
Bowel Complications	751	2.56 [1.15; 5.72]	2.30	0.02	1.38	0.93	0 [0; 42.56]
Complications	751	1.07 [0.33; 3.42]	0.11	0.91	47.22	<0.0001	90.64 [72.87; 98.53]
Wound Infection	751	0.49 [0.09; 2.67]	-0.83	0.41	21.11	<0.0001	74.07 [30.43; 94.84]
Wound Hematoma/Seroma	751	1.54 [0.58; 4.09]	0.87	0.38	16.99	0.0045	74.03 [25.06; 96.09]
Reoperation	411	0.32 [0.07; 1.43]	-1.49	0.14	0.91	0.82	0 [0; 73.66]
Oral Intake	108	0.16 [-1.97; 2.28]	0.14	0.89	19.45	<0.0001	94.86 [NA; NA]
LOS	751	-0.83 [-2.22; 0.56]	-1.17	0.24	226.4	<0.0001	98.64 [96.45; 99.77]
Back To Work	316	-3.14 [-8.92; 2.64]	-1.06	0.29	217.1	<0.0001	99.54 [NA; NA]
Recurrence	751	1.41 [0.81; 2.46]	1.21	0.23	0.22	0.99	0 [NA; NA]
Neuralgia	303	0.48 [0.16; 1.46]	-1.28	0.20	0.01	0.94	0 [0; 84.94]

N= number, NA= Not available, OR= Odds ratio, SMD= Standardized mean difference

Figure 1: PRISMA flow diagram

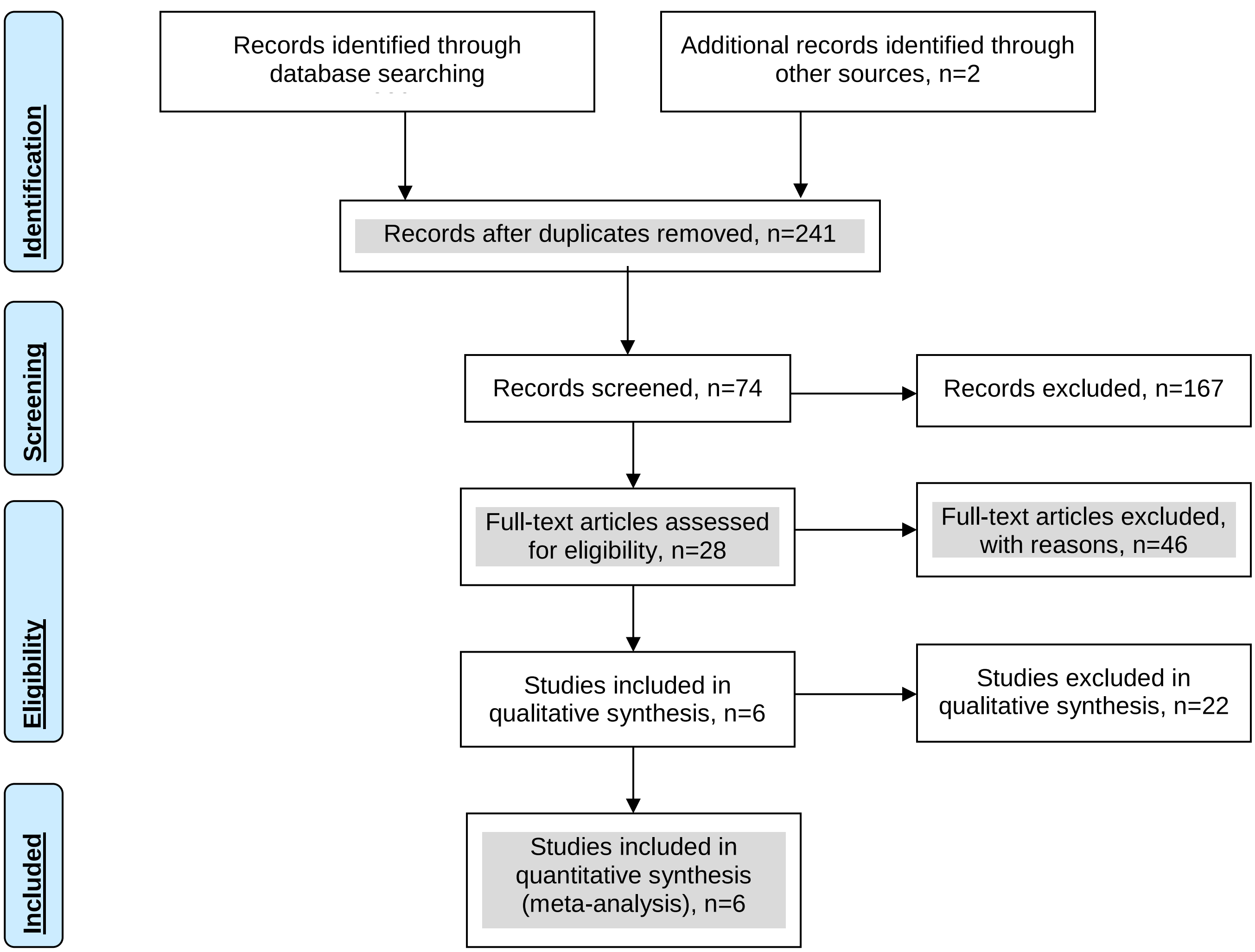


Figure 2: Forest plot of bowel complications

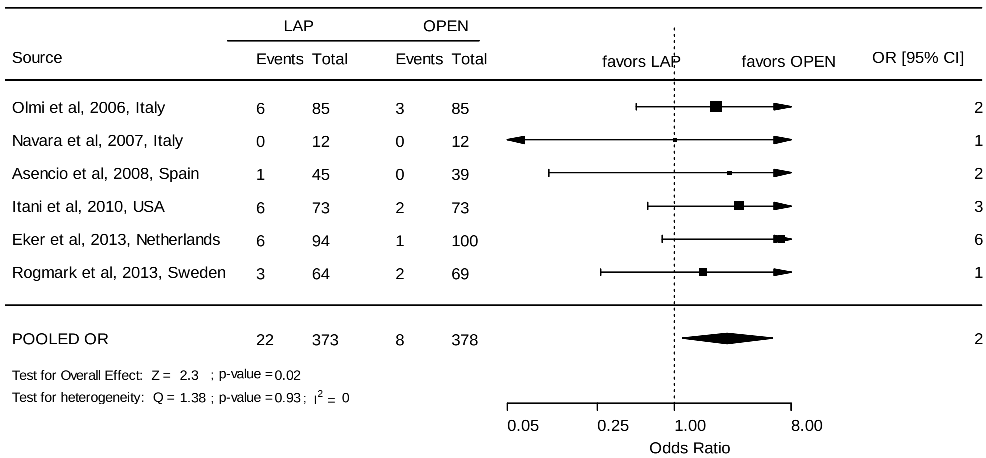


Figure 3: Forest plot of hernia diameter

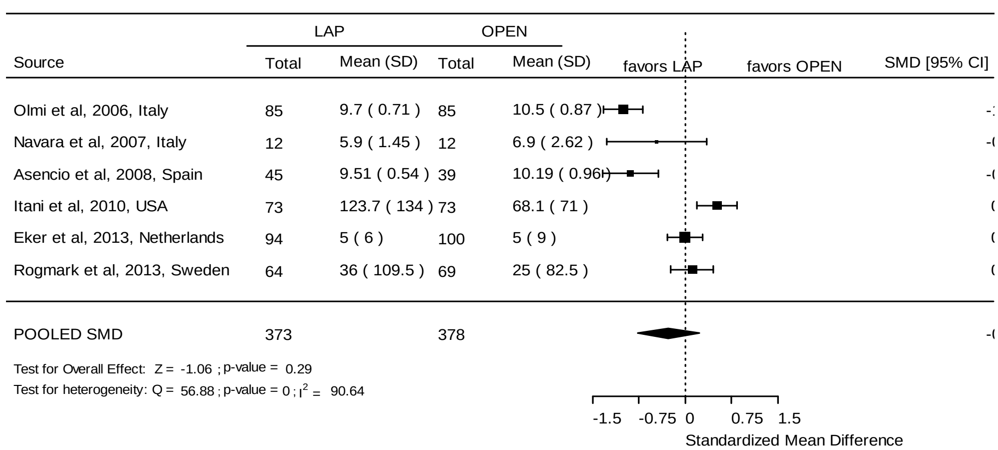


Figure 4: Forest plot of operative time

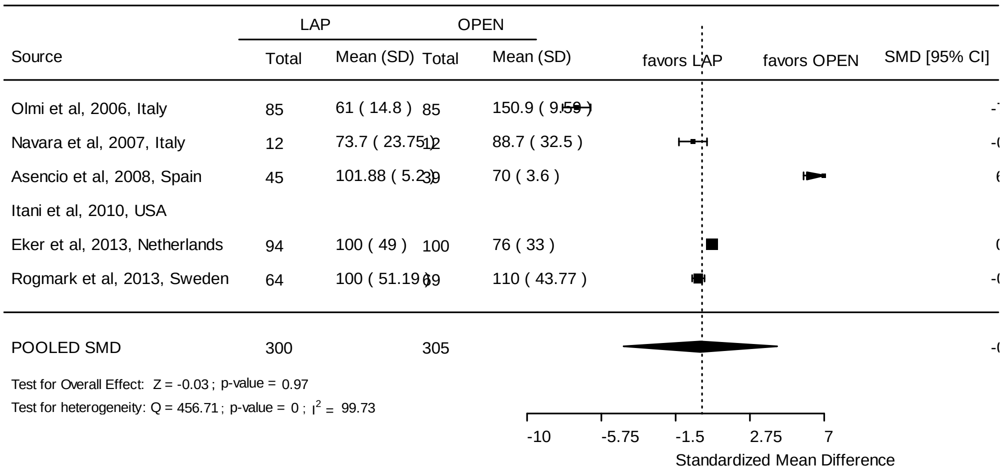


Figure 5: Forest plot of overall complications

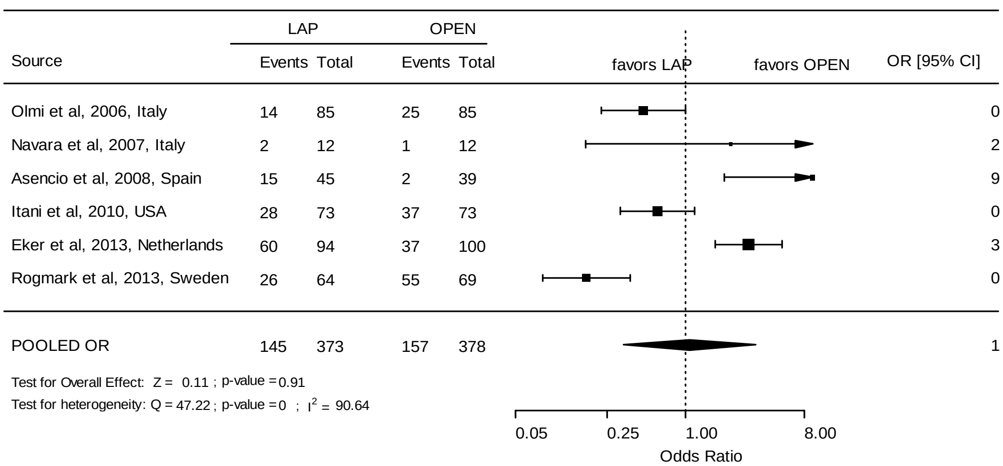


Figure 6: Forest plot of wound infection

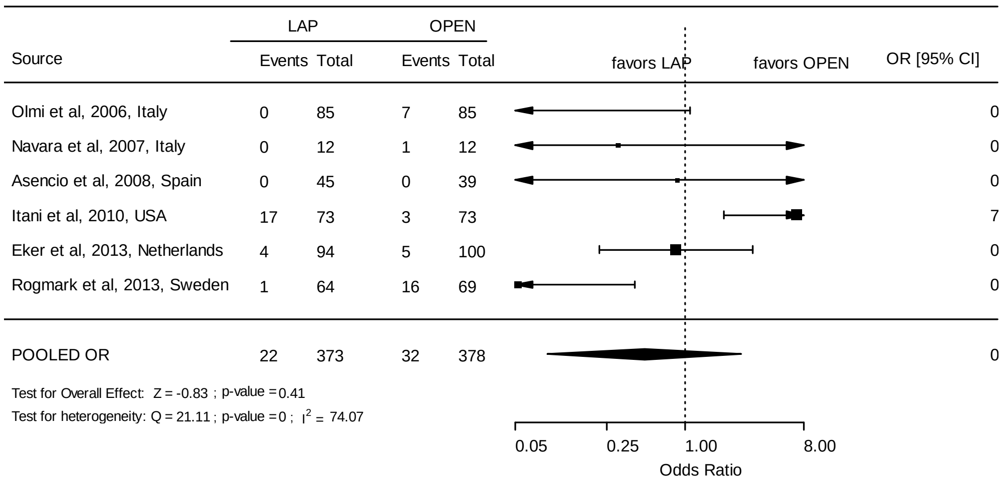


Figure 7: Forest plot of Wound haematoma or seroma

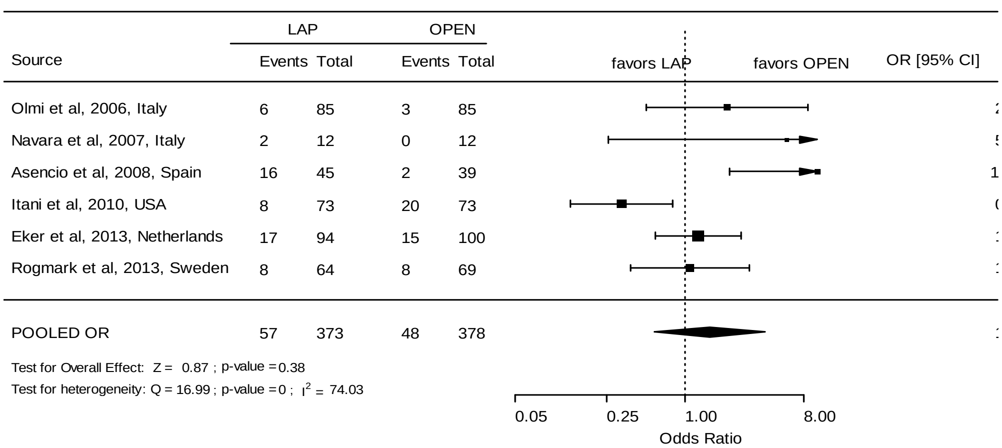


Figure 8: Forest plot of reoperation

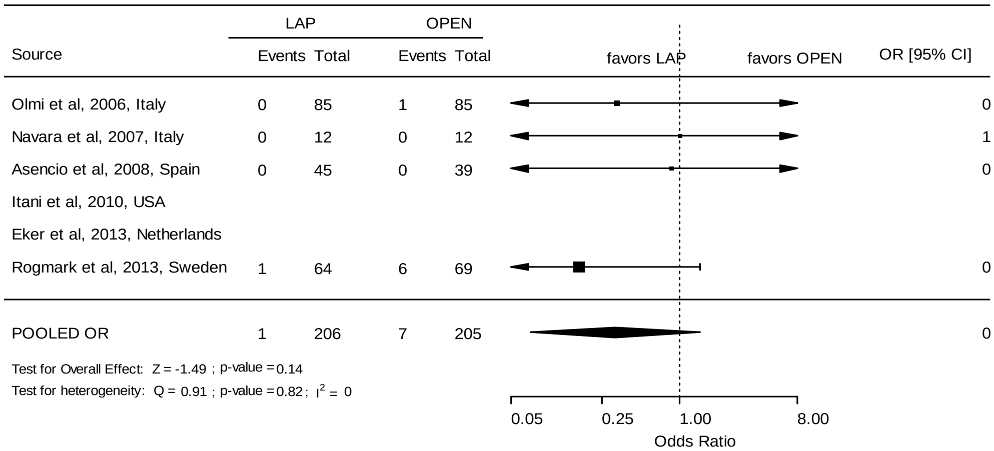


Figure 9: Forest plot of time to oral intake

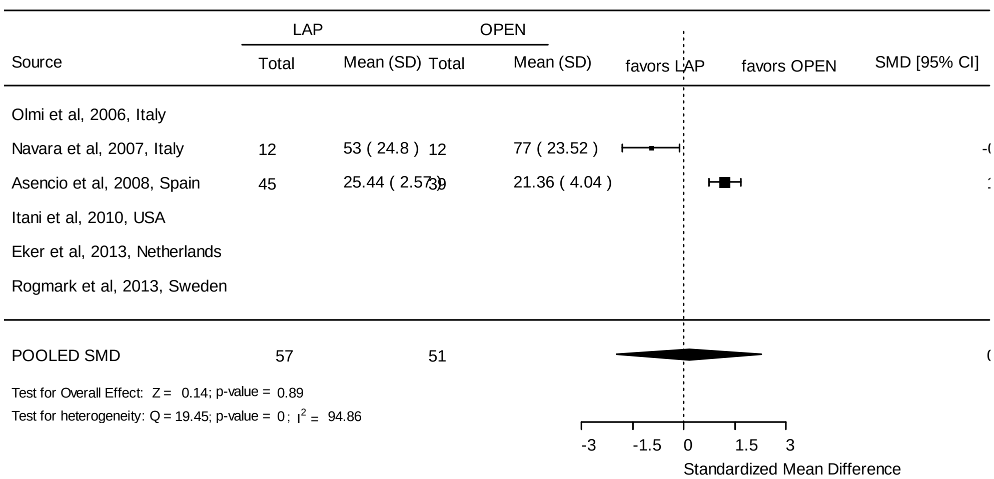


Figure 10: Forest plot of length of hospital stay

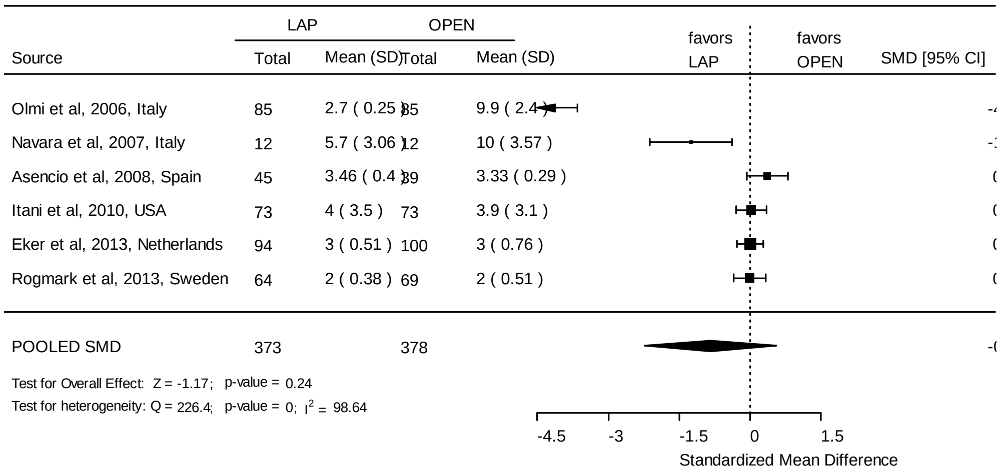


Figure 11: Forest plot of back to work

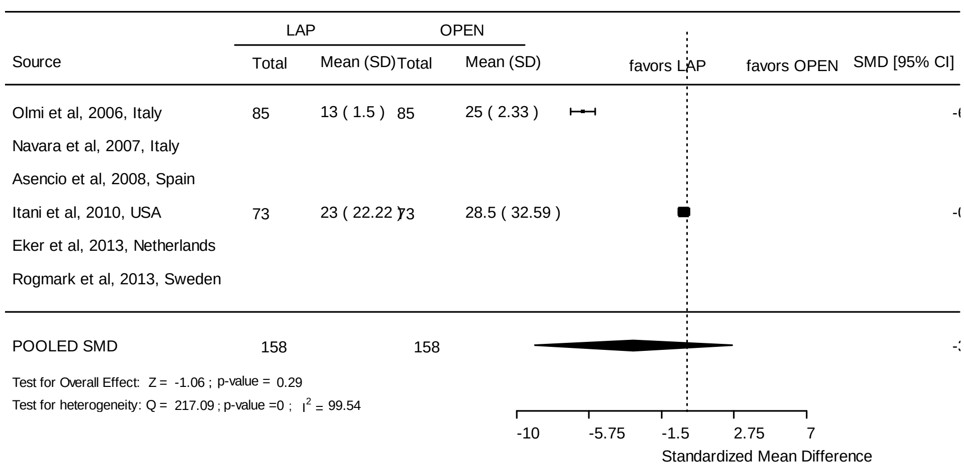


Figure 12: Forest plot of recurrence

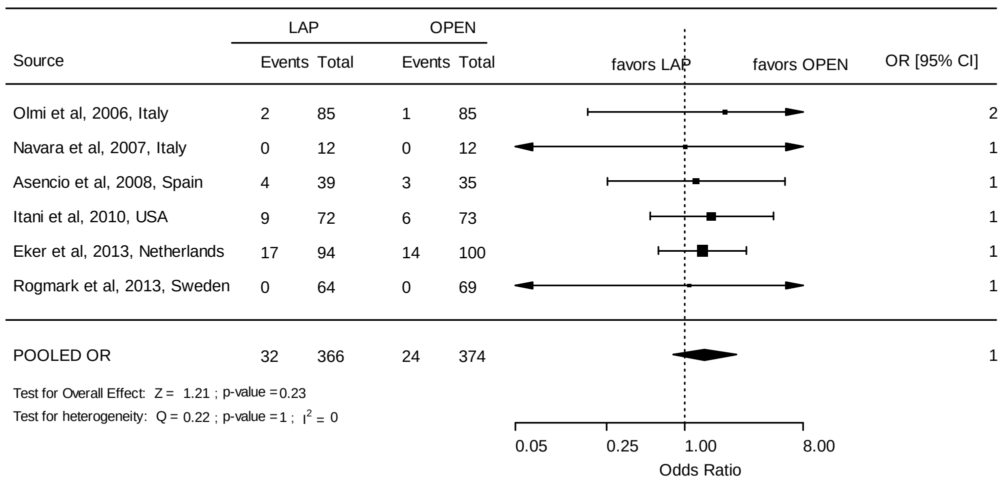


Figure 13: Forest Plot of Neuralgia

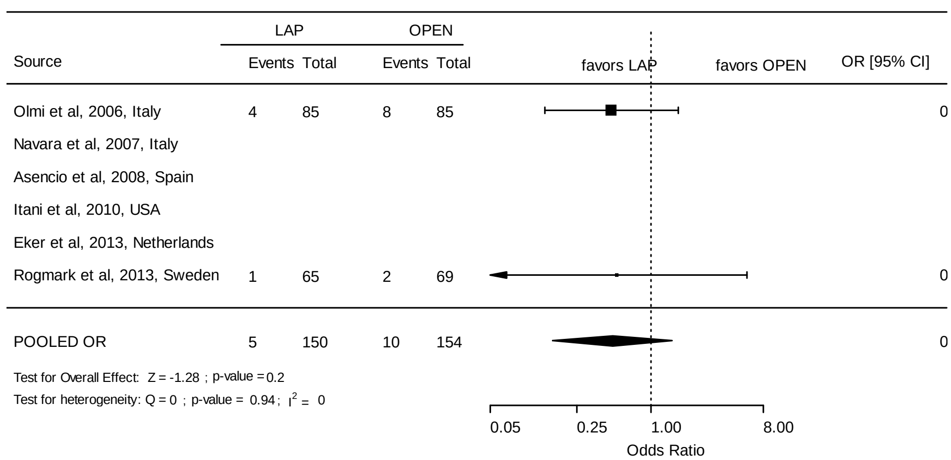
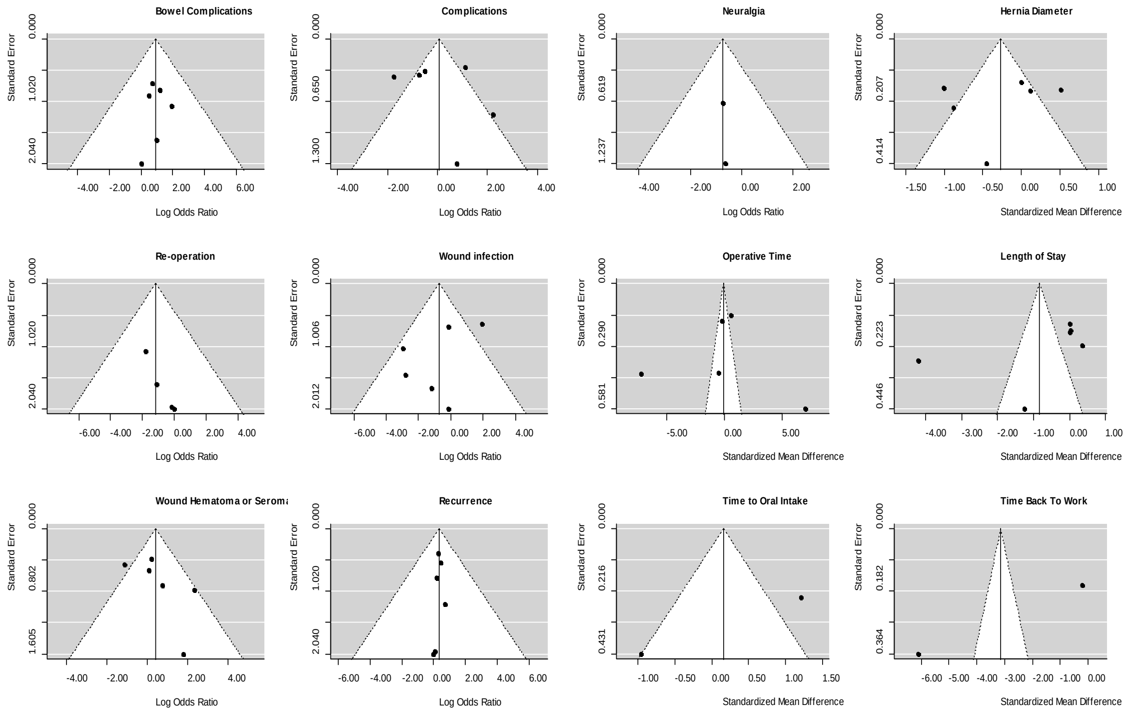


Figure 14: Funnel Plots



DISCUSSION

In the modern surgical era, laparoscopic repair has increasingly been utilized in the management of incisional hernia. First described by Le Blanc {LeBlanc et al, 1993], the technique has evolved and is now replacing open repairs where possible. Large multi-centered series [Bencini et al, 2004, Ben-Haim et al, 2002, Moreno-Egea et al, 2004, Rosen et al, 2003, Ujiki et al, 2004] have described outstanding outcomes with laparoscopic techniques citing less complications and recurrence rates of less than 10%.

We observed that laparoscopic technique was used to repair larger hernia diameters at times in our meta-analysis (Fig 3). There could be a number of explanations for this discrepancy. First of all the laparoscopic technique quite often detects more than one hernia defects whether large or small with ease. Secondly it is entirely possible that by inflating the abdomen in the laparoscopic technique, the size of these defects may become exaggerated. Therefore by measuring the size of all visible defects during laparoscopy, small or large, and documenting it as a combined defect, large diameters hernias are reported during laparoscopic repair. Whereas an open repair in a non-distended abdomen only measures the largest defect which the surgeon can feel at the time of dissecting the tissue and possibly missing the adjacent smaller defects. Itani and Rogmark's studies [Itani et al, 2010, Rogmark et al, 2013] showed markedly large hernias were repaired using laparoscopic techniques compared to their open counterpart.

The operative time taken by laparoscopic as well as the open repair was comparable in our meta-analysis based on five out of six studies [Asencio et al, 2009, Eker et al, 2013, Itani et al, 2010, Navarra et al, 2007, Rogmark et al, 2013].

Bowel complications in a variety of forms were reported by all the six RCTs [Asencio et al, 2009, Eker et al, 2013, Itani et al, 2010, Navarra et al, 2007, Olmi et al, 2007, Rogmark et al, 2013]. Pooling of this data revealed a statistically significant increase in bowel complications in the laparoscopic group. The severity of bowel injury is determined by the type of intestine injured, i.e. small or large, the time delay between the occurrence, detection and treatment, and the amount of soiling that occurs [Bishoff et al, 1999, Henniford et al, 2003]. Unrecognized enterotomies or recognized bowel injuries lead to conversion to open repair [Ascenio et al, 2009, Itani et al, 2010]. Rogmark [Rogmark et al, 2013][26] also reported bowel injuries but this did not directly lead to conversion.

The overall complication rate was comparable in the two groups based on six RCTs [Asencio et al, 2009, Eker et al, 2013, Itani et al, 2010, Navarra et al, 2007, Olmi et al, 2007, Rogmark et al, 2013] as also highlighted by other authors [Bencini et al, 2004, Ben-Haim et al, 2002]. However, surgical site infections, hematomas, seromas and superficial wound infections etc. were noted more often in the open group than the laparoscopic group. Nonetheless when all these variables (i.e wound infection, wound hematoma and seroma) were analyzed separately and the results were once again comparable for both groups. Olmi [Olmi et al, 2007][24] reported that subcutaneous drain placement was required by 97.6% of the open group patients, as was also highlighted in all the other trials [Asencio et al, 2009, Eker et al, 2013, Itani et al, 2010, Navarra et al, 2007, Rogmark et al, 2013]. However, very few drains were used in the laparoscopic group. A number of authors [Olmi et al, 2007, Itani et al, 2010, Rogemark et al, 2013] have shown significantly higher wound infection rates for open repairs compared to laparoscopic repairs.

Reoperation rate was reported by four studies [Asencio et al, 2009, Navarra et al, 2007, Olmi et al, 2007, Rogmark et al, 2013] out of six studies under consideration. Analysis showed comparable outcomes for both groups.

The time taken to oral intake was statistically insignificant for both groups based on only two studies [Asencio et al, 2009, Navarra et al, 2007]. As the number of patients analyzed for this variable is so small, any meaningful conclusion is not possible.

Only two authors [Navarra et al, 2007, Olmi et al, 2007] have documented shorter length of hospital stay following laparoscopic repair compared to the open group. However, four out of six RCTs [Asencio et al, 2009, Eker et al, 2013, Itani et al, 2010, Rogmark et al, 2013] found comparable length of hospital stay for both these procedures.

Two RCTs [Olmi et al, 2007, Itani et al, 2010] reported that patients in the laparoscopic group took less time to recover and went back to work quicker. Rogmark [Rogmark et al, 2013] on the other hand reported time taken to full recovery, instead of time taken to return to work. In our meta-analysis, only two RCTs [Itani et al, 2010, Olmi et al, 2007] reported back to work data which failed to show any difference between the two groups.

All six RCTs namely [Asencio et al, 2009, Eker et al, 2013, Itani et al, 2010, Navarra et al, 2007, [Olmi et al, 2007, Rogmark et al, 2013] reported the recurrence rate. Pooling of the data revealed no difference between the two groups. Still, the data available on the recurrence rate may be erroneous due to short follow-up in all of these RCTs. Furthermore as the number of patients recruited in all the RCTs are very small, the true recurrence rate may be underestimated.

Our analysis based on two studies [Olmi et al, 2007, Rogmark et al, 2013] showed no significant difference in the post-operative neuralgia between laparoscopic and open repair groups. This finding was not in line with other laparoscopic procedures like appendectomy or cholecystectomy where less pain is observed following laparoscopic techniques. Once again, a small number of patients analyzed for this variable may be responsible for obscuring the true difference between the two procedures.

CONCLUSIONS

On the basis of our meta-analysis, we conclude that laparoscopic and open repair of incisional hernia is comparable. We strongly feel that objective assessment is required to evaluate the long term effectiveness of the two procedures. Recurrence rates should be measured for a lengthier period of time (e.g. 5 and 10 years) and not just for two years. Also, larger RCTs recruiting greater numbers of patients with strict inclusion and exclusion criteria and standardized techniques are crucial for meaningful comparison, effectiveness of the procedures and accuracy of results.

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AUTHORS' CONTRIBUTIONS

1. AA, BM and MAM were responsible for the concept and design of this meta-analysis. Furthermore they take full responsibility for the integrity of the work as a whole, from the inception to published article.
2. AA and MAM were responsible for the acquisition and interpretation of the data.
3. SK, FR, MBH and RMY were responsible for analyzing and interpretation of the data in depth from the statistical point of view.
4. All authors were involved in drafting the manuscript and revising it critically for important intellectual content and have given final approval of the version to be published. Furthermore all authors have participated sufficiently in the work to take public responsibility for its content.

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