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Oncologic outcomes of minimally invasive versus open distal pancreatectomy for pancreatic ductal adenocarcinoma: A systematic review and meta-analysis

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ABSTRACT

In the absence of randomized trials, uncertainty regarding the oncologic efficacy of minimally invasive distal pancreatectomy (MIDP) remains. This systematic review aimed to compare oncologic outcomes after MIDP (laparoscopic or robot-assisted) and open distal pancreatectomy (ODP) in patients with pancreatic ductal adenocarcinoma (PDAC). Matched and non-matched studies were included. Pooled analyses were performed for pathology (e.g., microscopically radical (R0) resection and lymph node retrieval) and oncologic outcomes (e.g., overall survival). After screening 1760 studies, 21 studies with 11,246 patients were included. Overall survival (hazard ratio 0.86; 95% confidence interval (CI) 0.73 to 1.01; $p = 0.06$), R0 resection rate (odds ratio (OR) 1.24; 95%CI 0.97 to 1.58; $p = 0.09$) and use of adjuvant chemotherapy (OR 1.07; 95%CI 0.89 to 1.30; $p = 0.46$) were comparable for MIDP and ODP. The lymph node yield (weighted mean difference (WMD) −1.3 lymph nodes; 95%CI -2.46 to −0.15; $p = 0.03$) was lower after MIDP. Patients undergoing MIDP were more likely to have smaller tumors (WMD -0.46 cm; 95%CI -0.67 to −0.24; $p < 0.001$), less perineural (OR 0.48; 95%CI 0.33 to 0.70; $p < 0.001$) and less lymphovascular invasion (OR 0.53; 95%CI 0.38 to 0.74; $p < 0.001$) reflecting earlier staged disease as a result of treatment allocation bias. Based on these results we can conclude that in patients with PDAC, MIDP is associated with comparable survival, R0 resection, and use of adjuvant chemotherapy, but a lower lymph node yield, as compared to ODP. Due to treatment allocation bias and lower lymph node yield the oncologic efficacy of MIDP remains uncertain.

Introduction

The implementation of minimally invasive (laparoscopic or robot-assisted) distal pancreatectomy (MIDP) into surgical practice has increased over the last decade. Several meta-analyses of retrospective cohort studies have shown that MIDP is associated with a reduced length of hospital stay and less morbidity compared to open distal pancreatectomy (ODP) [1,2].

Most literature on MIDP vs. ODP, however, mainly focuses on short-term outcomes in patients with benign and pre-malignant tumors [3–7]. Current concerns regarding the oncologic outcomes of MIDP are illustrated by two recent international surveys where 19–31% of surgeons expected MIDP to be inferior to ODP in patients with pancreatic ductal adenocarcinoma (PDAC) [8,9]. Only few studies have specifically focused on oncologic outcomes (survival, radical (R0) resection and lymph node retrieval) after MIDP in PDAC [10–12]. Most of these studies are small single-center studies

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Abbreviations

MIDP	minimally invasive distal pancreatectomy
ODP	open distal pancreatectomy
PDAC	pancreatic ductal adenocarcinoma
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
RAMPS	radical antegrade modular pancreatosplenectomy
WMD	weighted mean difference
OR	Odds ratio
E-MIPS	European consortium on minimally invasive pancreatic surgery

presenting outcomes without adjustment for baseline differences and are therefore prone to treatment allocation bias.

A 2016 Cochrane review including 12 studies in patients with PDAC showed a comparable rate of tumor negative resection margins (R0), recurrence and survival of MIDP as compared to ODP [13]. However, this review did not report on perineural- and lymphovascular invasion and amount of resected and tumor positive lymph nodes. Critical appraisal in this Cochrane review showed that all included studies were of very low quality [13].

Recently, several large multicenter and (propensity) matched cohort studies were published on this topic [14–16]. We performed a systematic review and meta-analysis on the oncologic efficacy of MIDP vs. ODP in patients with PDAC, including assessment of perineural- and lymphovascular invasion and lymph node retrieval.

Methods

This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines and Cochrane Handbook for Systematic Reviews of Interventions [17,18]. The PRISMA checklist is shown in Appendix A. The protocol of this systematic review was registered in the PROSPERO international prospective register of systematic reviews (registration number: CRD42017077609).

Literature search

A systematic literature search was performed using the PubMed, Cochrane and Embase databases focusing on studies comparing MIDP and ODP for patients with PDAC published before March 9, 2018. Consistent combinations of the following search terms were used: pancreatic neoplasms (MeSH), pancreatic adenocarcinoma, pancreatectomy (MeSH), distal pancreatectomy, left pancreatectomy, laparoscopy (MeSH), robotic surgery and minimally invasive surgery. The full literature search is shown in Appendix B. Additionally, the World Health Organization International Clinical Trial Registry was searched for ongoing trials. All references of included studies were manually screened.

Eligibility criteria

Studies were included if they reported on oncologic outcomes of both MIDP and ODP with more than 10 patients with PDAC per group and were written in English. Reviews, conference abstracts and studies that were not available in full text were excluded from the systematic review.

Study selection

All identified studies were independently screened based on title and abstract by two reviewers (J.H. and M.K.) and either included or excluded for full-text evaluation. Full-text selection based on eligibility was independently performed by two reviewers (J.H. and M.K.). Any conflicts between the reviewers were resolved using discussion until consensus was reached.

Risk of bias

All studies were critically appraised independently by 2 authors (J.H. and M.K.) individually according to the ROBINS-I tool for assessing risk of bias in non-randomized studies of interventions [19]. This tool was chosen since the inclusion of any randomized controlled trial was not expected. Included studies were scored as to have an overall low, moderate, serious, or critical risk of bias based on the judgement for the individual 7 domains.

Data extraction

Data extraction was performed according to a predefined evidence table and cross-checked by 2 authors (J.H. and M.K.) individually. Collected data included study characteristics (design, study period, sample size, use of definition for PDAC, and definition for margin status), patient characteristics (age, body mass index, ASA physical status, neo-adjuvant chemotherapy, and radiotherapy) intra-operative outcomes (duration, blood loss, splenectomy, additional organ resection, and radical antegrade modular pancreatosplenectomy (RAMPS)), pathology outcomes (tumor size, resection margin involvement (R − status), lymph nodes, perineural invasion, and lymphovascular invasion) and postoperative outcomes (length of hospital stay, postoperative pancreatic fistula, 30-day mortality, adjuvant chemotherapy, time to adjuvant chemotherapy, local recurrence, and survival).

Statistical analyses

All analyses were performed using Review Manager (RevMan, version 5.3. Copenhagen: The Nordic Cochrane Center, The Cochrane Collaboration, 2014). When median and range or interquartile range (IQR) were reported, mean and standard deviations (SD) were calculated using calculation algorithms as described by Hozo et al. [20] and Bland [21]. Continuous data were analysed using the inverse variance method and dichotomous (categorical) data were analysed using the Mantel-Haenszel method. Continuous data were expressed as weighted mean difference (WMD) and dichotomous (categorical) data were expressed as odds ratio (OR), both with their corresponding 95%CI and p-value. Time-to-event outcomes were analysed with use of the extracted Hazard Ratios (or if not available these were calculated based on the recommendations by Tierney et al. [22]). Statistical significance was defined as $p < 0.05$. When both unadjusted and adjusted ORs were presented, the adjusted ORs were included. All analyses were performed with use of the random-effects model based on the expected heterogeneity of the included studies [23]. Publication bias for R0 resection and survival were assessed with a funnel plot. To assess the impact of treatment allocation bias on the first meta-analyses, a sensitivity analysis excluding studies which reported non-adjusted ORs or non-matched ORs was performed.

Results

Search results

In total, 1760 studies were identified (after removal of duplicates). After screening of titles and abstracts, 61 studies remained for full-text assessment of which 21 studies with a total of 11,246 patients met the eligibility criteria for this systematic review. No additional studies were identified during screening of the references of included studies. The PRISMA study selection flow-chart is shown in Fig. 1 and the characteristics of all included studies are shown Table 1. No completed randomized trials were identified and searching the World Health Organization International Clinical Trial Registry revealed no relevant ongoing or completed trials.

Methodological quality

Critical appraisal showed that half of the included studies had a critical risk of bias in at least one domain [16,24–32], 8 studies were judged to be at serious risk of bias in at least one domain [11,12,15,33–38] and 2 studies were classified as having a moderate risk of bias [14,39]. None of the studies had a low risk of bias. Results of the critical appraisal, for each of the 7 domains and the total score for each study are shown in Table 1. Outcomes adjusted for baseline characteristics were reported in 14 studies [11,12,14,15,27,29–31,33–35,37–39], type of adjustment and included variables are shown in Appendix C.

Patient characteristics

Of 11,246 patients, 3013 patients underwent MIDP (2488 laparoscopic, 525 robot-assisted) and 8233 underwent ODP. Meta-analyses showed that age (WMD 0.47 years; 95%CI -1.25 to 2.19; $p = 0.59$), body mass index (WMD 0.21 kg/m^2; 95%CI -0.51 to 0.93; $p = 0.57$) and ASA-score ≥ 3 (OR 1.15; 95%CI 0.89 to 1.48; $p = 0.30$) were comparable between both groups (Appendix D). In the MIDP group, fewer patients received neoadjuvant chemotherapy (OR 0.30; 95% CI 0.14 to 0.64; $p = 0.002$) and neoadjuvant radiotherapy (OR 0.45; 95% CI 0.28 to 0.72; $p < 0.001$) (Appendix D).

Intra-operative outcomes

Conversion from MIDP to ODP was reported in 285 out of 1267 patients (22%, range: 0–27%). Blood loss was lower for patients undergoing MIDP compared to ODP (WMD -227 mL; 95% CI, −347 to −106; $p < 0.001$) and operative time comparable for both groups (WMD -10 min; 95% CI -21 to 1; $p = 0.07$) (Appendix E). The number of patients who received splenectomy (OR 0.52; 95% CI 0.13 to 2.07; $p = 0.35$) and an additional organ resection (beyond splenectomy) (OR 0.82; 95% CI 0.40 to 1.69; $p = 0.59$) were comparable for MIDP and ODP (Appendix E). Only one study reported the use of radical antegrade modular pancreatosplenectomy (RAMPS) for

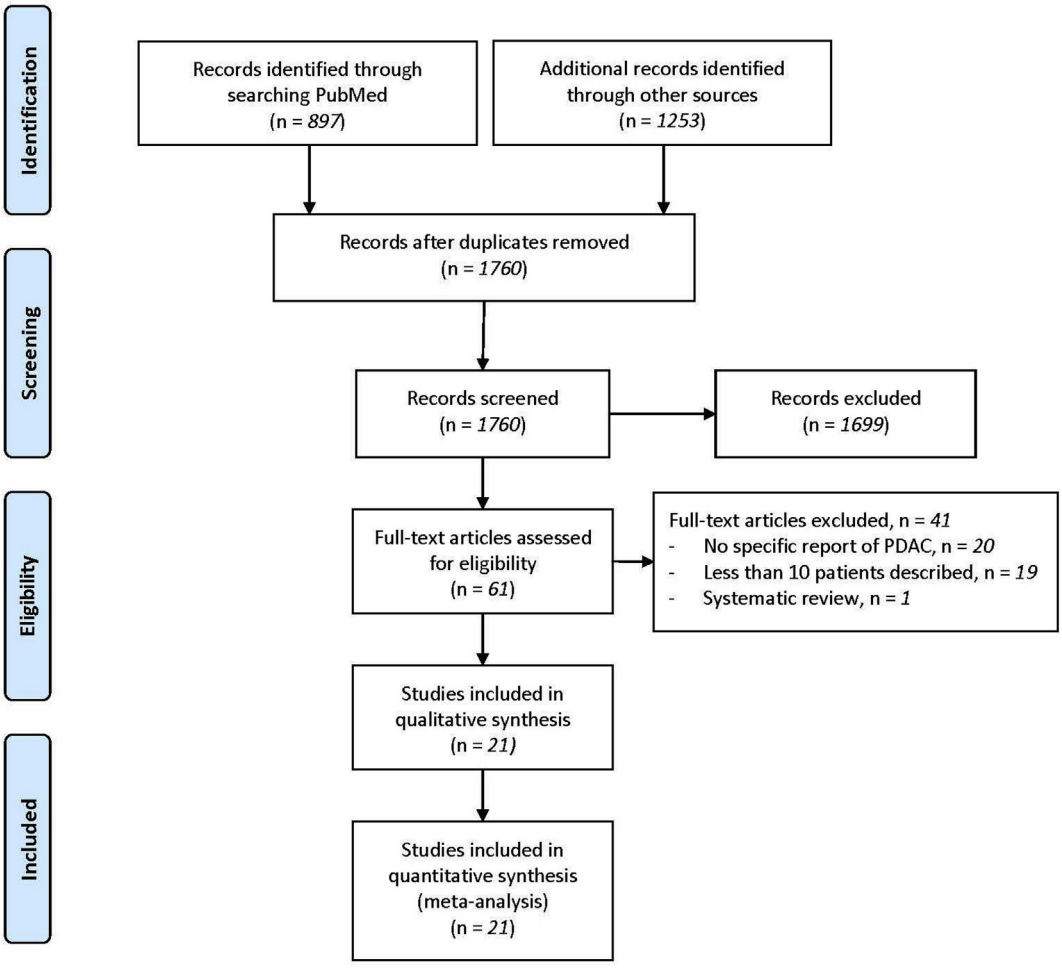

Fig. 1. Preferred reporting items for systematic reviews and meta-analyses study selection flow diagram.

Table 1
Study characteristics.

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Author	Study period	No. of patients		Type of MIDP	Study design	Adjusted outcomes	Follow-up	Risk of bias							
		MIDP (= 3013)	ODP (= 8233)	LDP / RDP				1	2	3	4	5	6	7	C*
Adam[33]	2010 – 2011	267	708	LDP	Retrospective	Partially	1 month								
Anderson[15]	2010 - 2012	505	1302	LDP (51) / RDP (454)	Retrospective	Partially	17 months*								
Bauman[24]	2005 - 2014	33	46	LDP (28) / RDP (5)	Prospective	No	11 months*								
Braga[34]	2007 - 2010	30	34	LDP	Prospective	Matched	1 month								
Hu[49]	2007 - 2011	11	23	LDP	Retrospective	No	12-72 months								
Joliat[26]	2000 - 2015	10	22	LDP	Retrospective	No	2 months								
Kantor[27]	2010 - 2013	349	1205	LDP	Retrospective	Partially	21 months**								
Kooby[11]	2000 - 2008	23	70	LDP	Retrospective	Matched	10 months*								
Lee[35]	2007 - 2010	10	40	LDP (8) / RDP (4)	Retrospective	Matched	39 months*								
Lee[28]	2000 - 2013	23	249	LDP (19) / RDP (4)	Retrospective	No	3 months								
Magge[12]	2002 - 2010	28	34	LDP (20) / RDP (8)	Retrospective	Matched	21 months*								
Plotkin[16]	2011 - 2014	166	335	LDP (130) / RDP (36)	Prospective	No	1 month								
Raoof [38]	2010 – 2013	563	563	LDP	Retrospective	Matched	27 months								
Sharpe[29]	2010 - 2011	144	625	LDP	Retrospective	Partially	1 month								
Shin[30]	2006 - 2013	70	80	LDP	Prospective	Matched	NA								
Stauffer[50]	1995 - 2014	44	28	LDP	Prospective	No	NA								
Sulpice[37]	2007 - 2012	347	2406	LDP	Retrospective	Partially	NA								
van Hilst[51]	2007 - 2015	340	340	LDP (324) / RDP (16)	Retrospective	Matched	13 months*								
Wellner[39]	2013 - 2016	11	13	LDP	Prospective	Matched	1 month								
Zhang[31]	2010 - 2014	22	76	LDP	Retrospective	No	NA								
Zhang[52]	2003 - 2013	17	34	LDP	Retrospective	Partially	6 months								

LDP = Laparoscopic distal pancreatectomy; RDP = robot-assisted distal pancreatectomy* indicates median follow-up; ** indicates mean follow-up; partially indicates that for several outcomes an adjustment for patient characteristics was made; C = conclusion

= critical risk of bias; = serious risk of bias; = moderate risk of bias; = low risk of bias

both groups: 74% for MIDP and 48% for ODP [30].

Pathology outcomes

In the MIDP group, tumor size was smaller (WMD -0.46 cm; 95% CI -0.67 to −0.24; $p < 0.001$) and lower incidences of perineural invasion (OR 0.48; 95% CI 0.33 to 0.70; $p < 0.001$) and lymphovascular invasion (OR 0.53; 95% CI 0.38 to 0.74; $p < 0.001$) were reported, as compared to the ODP group. R0 resection rate was comparable between MIDP and ODP (OR 1.24; 95% CI 0.97 to 1.58; $p = 0.09$), but the number of retrieved lymph nodes was lower after MIDP (WMD -1.3 lymph nodes; 95% CI -2.46 to −0.15; $p = 0.03$). Meta-analyses of pathology outcomes are shown in Fig. 2.

Postoperative outcome and survival

MIDP was associated with a shorter length of hospital stay compared to ODP (WMD -2.09 days; 95% CI -2.51 to −1.67; $p < 0.001$). Postoperative pancreatic fistula (OR 0.97; 95% CI 0.70 to 1.35; $p = 0.87$) and 30-day mortality (OR 0.74; 95% CI 0.37 to 1.49; $p = 0.40$) (Appendix F) and the number of patients receiving adjuvant chemotherapy (OR 1.07; 95% CI 0.89 to 1.30; $p = 0.46$) were comparable for MIDP and ODP. The time between surgery and start of chemotherapy (−2.82 days; 95% CI -5.29 to −0.35; $p = 0.03$) was shorter after MIDP compared to ODP. Local tumor recurrence (OR 0.78; 95% CI 0.43 to 1.41; $p = 0.41$) and overall survival (HR 0.86; 95% CI 0.73 to 1.01; $p = 0.06$) were comparable after MIDP and ODP. Forest plots are shown in Fig. 3.

Sensitivity analysis

Exclusion of non-matched and non-adjusted studies did not influence blood loss, operative time, splenectomy, additional organ resections and R0 resection. This sensitivity analysis only influenced tumor size (WMD -0.54; 95% CI -1.37 to 0.30; $p = 0.21$), number of harvested lymph nodes (WMD -0.74; 95% CI -4.00 to 0.51; $p = 0.13$) and time between surgery and start of chemotherapy (WMD -2.48; 95% CI -6.00 to 1.05; $p = 0.17$). Which were in the sensitivity analysis comparable for MIDP and ODP. All reports included in the meta-analysis on overall survival were studies presenting adjusted hazard ratios. Forest plots of all sensitivity analyses are shown in Appendix G.

Publication bias

Based on funnel plots (Fig. 4) on the R0 resection rate and overall survival there was low suspicion of publication bias.

Discussion

This systematic review and meta-analysis of 21 cohort studies comparing MIDP and ODP in over 11,000 patients with PDAC showed comparable overall survival and R0 resection rates for both procedures. Treatment allocation bias was present since in the

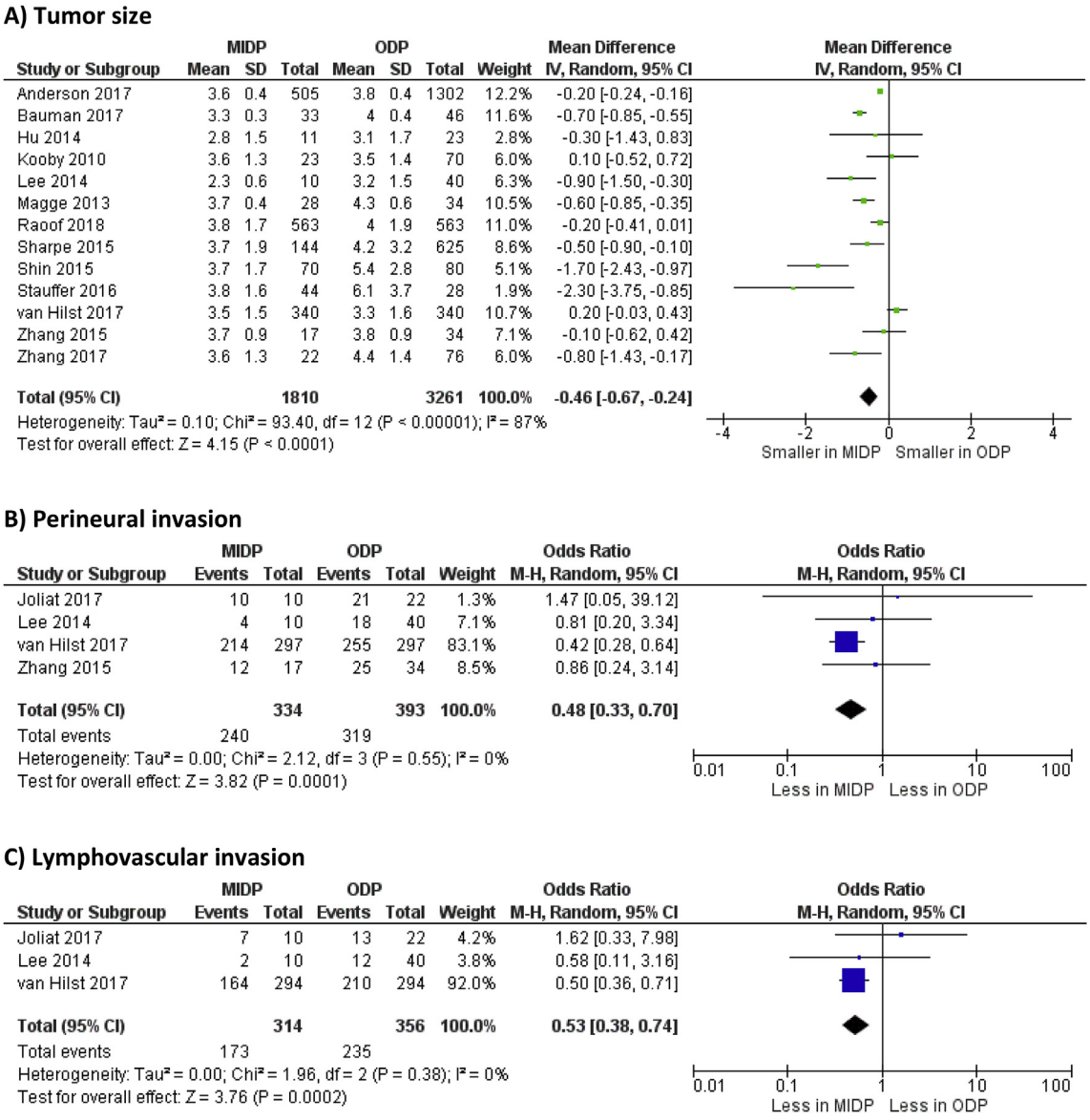


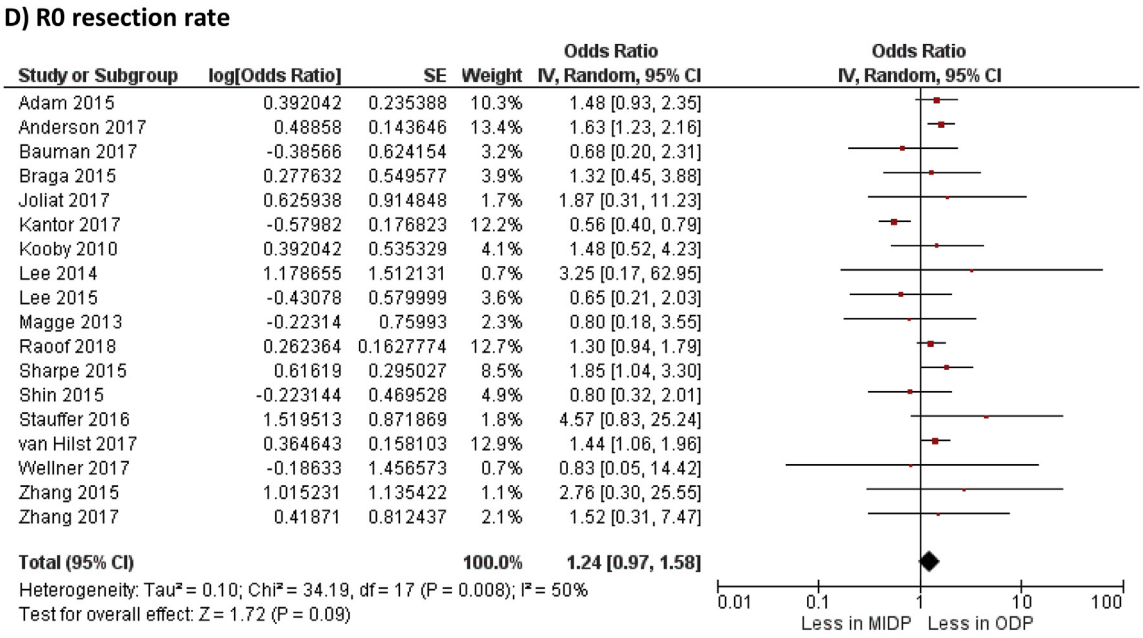
Fig. 2. Pathology outcomes
Fig. 2. Forest plots of pathology outcomes. A. Tumor size (mm), B. Perineural invasion, C. Lym phovascular invasion, D. R0 resection, E. Total number of harvested lymph nodes.

MIPD group fewer patients received neoadjuvant chemo- or radiotherapy, and tumors were smaller with a lower incidence of perineural and lymphovascular invasion. When non-adjusted and non-matched studies were excluded, tumor size was comparable, indicating less treatment allocation bias. Lymph node yield and R0 resection rate were comparable between the groups.

Two previous systematic reviews on MIDP in PDAC were considerably smaller as they only included 5 and 12 studies with a total of 261 and 1506 patients, respectively [13,40]. Both studies reported comparable survival and R0 resection rates, and concluded that the available evidence was of low quality and that randomized controlled trials are necessary. The presence of treatment allocation bias was also illustrated in both studies by the presence of smaller tumors in the MIDP group. In contrast to the present study, both these reviews did not report on other characteristics related to survival (neoadjuvant treatment and perineural and lymphovascular invasion). Therefore, the total extent of treatment allocation bias and its influence on the outcomes remained unclear.

In 2016, the first International State-Of-the-Art Conference on Minimally Invasive Pancreatic Resection was held in Sao Paulo [41]. It was concluded that MIDP was performed in smaller tumors, and R0 resection rates were comparable to OPD [42]. In the present study, after excluding non-matched and non-adjusted studies, both tumor size and R0 resection rates were comparable between MIDP and ODP. This finding supports the need for randomized studies.

Large tumors with vascular involvement or additional organ involvement are often considered as relative contra-indications for performing MIDP in patients with PDAC. In a worldwide survey amongst pancreatic surgeons, 66% considered involvement of other organs a contra-indication for MIDP [33,35,43]. Despite these results, in the present systematic review additional organ resections were reported in 7 out of 20 studies (774 patients) and no trend regarding fewer additional organ resections in MIDP was observed



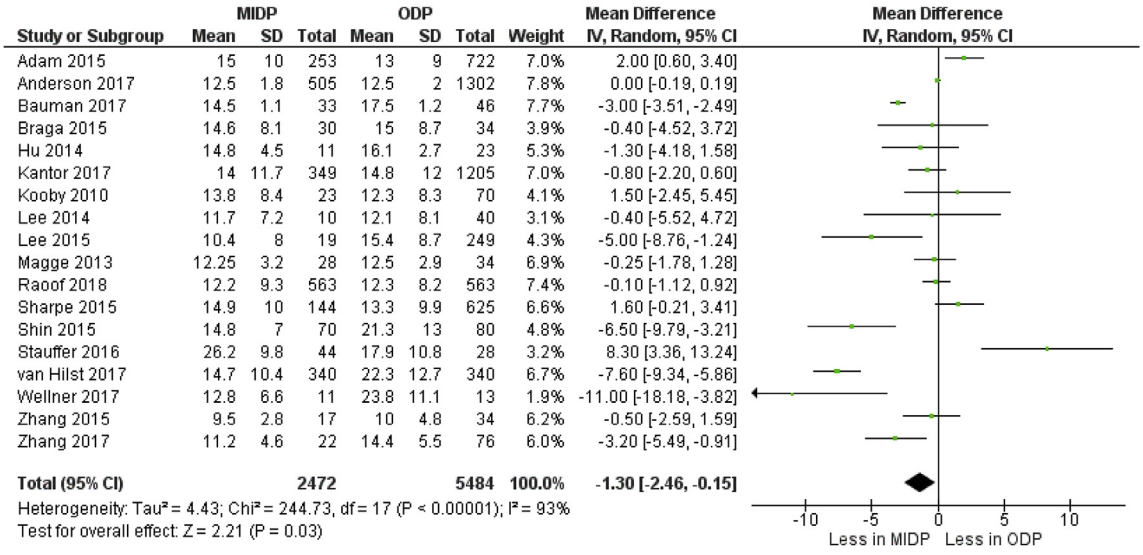


Fig. 2. (*continued*).

[9]. Information on the extent of the additional organ resections performed was not available as were the oncologic outcomes in this group. Further evidence is needed to determine the oncologic results of extended MIDP for PDAC.

This systematic review has some limitations. First, no randomized controlled trials were available. The World Health Organization International Clinical Trial Registry revealed one completed multicentre Dutch randomized trial [44] and one ongoing monocenter Swedish randomized trial [45] on minimally invasive vs. open distal pancreatectomy, but both trials include patients for all indications (benign, pre-malignant and malignant). Second, only 2 studies in this present meta-analysis reported the definition for R1 resection (i.e. 0 or 1 mm free margin) that was used. Strobel et al. clearly showed a difference in survival when different definitions of R0 are applied [46]. A previous systematic review of randomized controlled trials of patients with PDAC showed that reported R0 resection rates in these trials range from 17 - 100% [47]. The lack of accurate reporting in the included studies could therefore have influenced the meta-analysis and efforts should be made to increase uniform assessment and reporting of resection margins. Third, the overall risk of bias in the included studies was substantial with 10 studies considered to have a critical risk. Only a minority of studies presented outcomes adjusted for differences in patient characteristics. In a sensitivity analysis, excluding non-adjusted and non-matched studies, the comparability of the MIDP and ODP group improved (comparable tumor size) but also decreased the available studies for meta-analyses, which could have influenced results. Perineural and lymphovascular invasion was only reported in respectively 4 and 3 studies. These limited data showed that these important predictors of worse survival occurred less in the

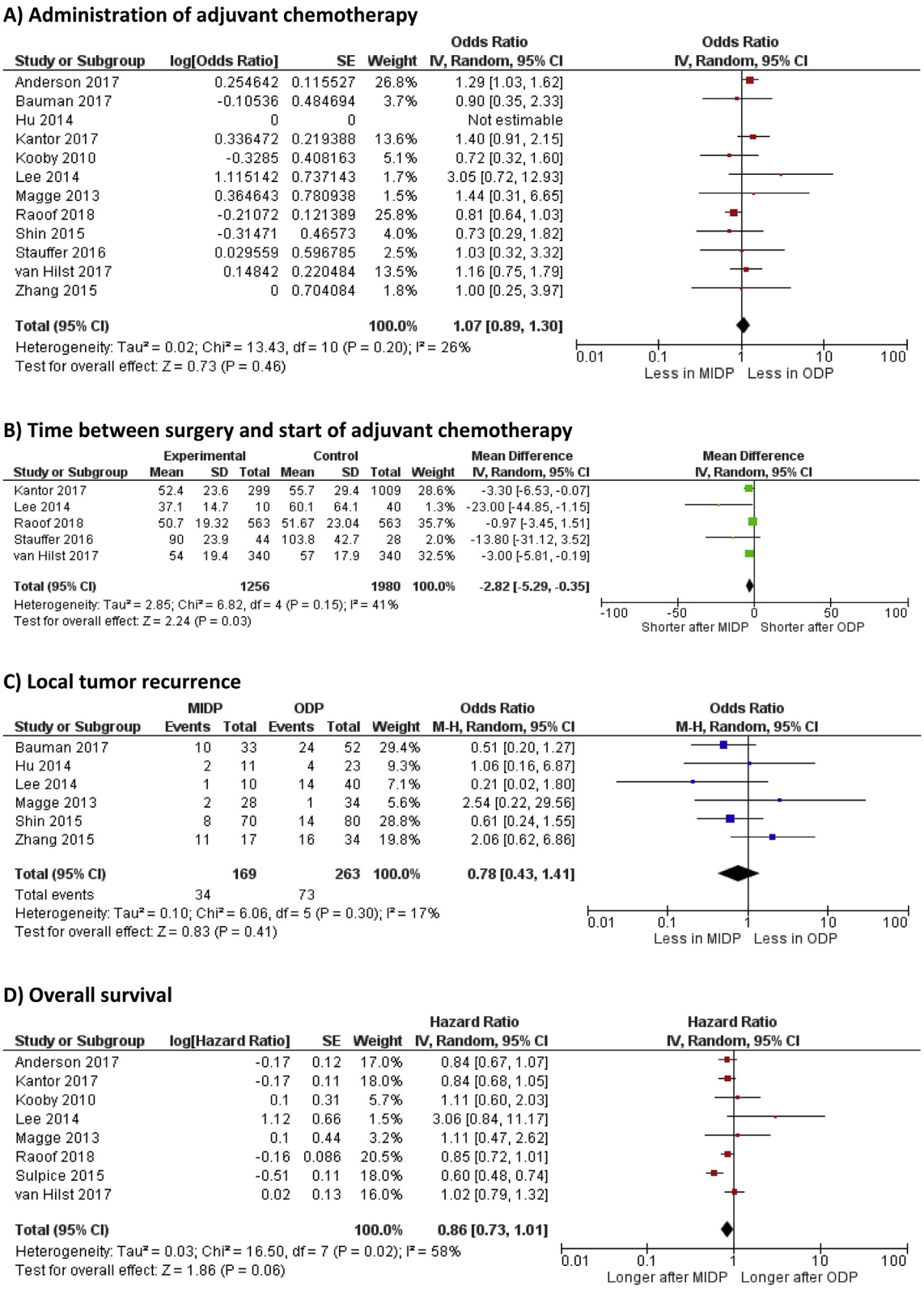
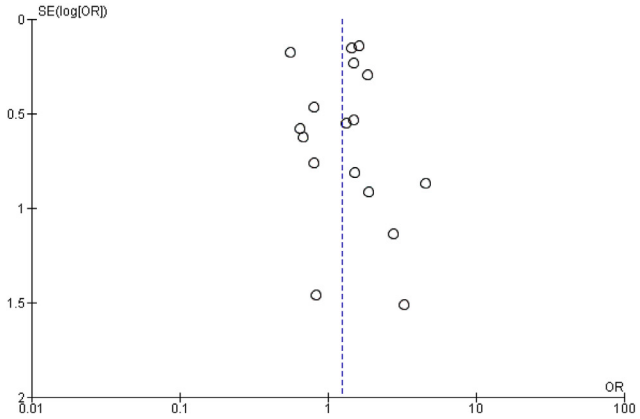


Fig. 3. Postoperative oncologic outcomes
Fig. 3. Forest plots of postoperative outcomes. A. Administration of adjuvant chemotherapy, B. Time until start adjuvant chemotherapy, C. Local recurrence, D. Overall survival.

MIDP group compared to ODP. Therefore, these predictors may have influenced study outcomes [11,48].

Selection criteria for minimally invasive surgical techniques are commonly associated with patient outcome. Younger patients with a lower BMI, without previous abdominal surgery and with smaller tumors are more often selected for MIDP. Despite efforts

A. Funnel plot of studies reporting on R0 resection after minimally invasive versus open distal pancreatectomy



B. Funnel plot of studies reporting on overall survival after minimally invasive versus open distal pancreatectomy

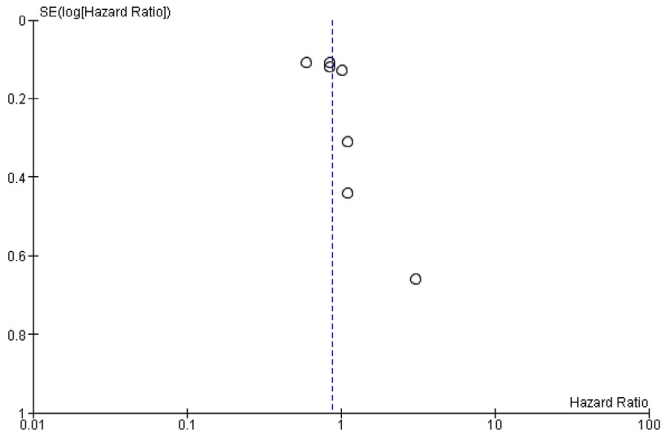


Fig. 4. Funnel plots on R0 resection and overall survival after minimally invasive versus open distal pancreatectomy.

to present more comparable data, for example, using propensity score matching, randomized controlled trials remain mandatory to determine the true effect of MIDP in patients with PDAC. The European consortium on minimally invasive pancreatic surgery (E-MIPS), consisting of over 40 international high-volume pancreatic centers, has started randomizing patients in the DIPLOMA trial (Registered under ISRCTN44897265). This trial includes standardized surgical technique and pathology reporting.

Conclusion

This systematic review and meta-analysis in over 11,000 patients showed comparable overall survival, R0 resection rate, and use of adjuvant chemotherapy after MIDP and ODP. Due to clear treatment allocation bias (MIDP performed in smaller tumors with a lower incidence of perineural and lymphovascular invasion) and the lower lymph node yield after MIDP, the oncologic efficacy of MIDP remains uncertain and a randomized controlled trial remains indicated.

Conflicts of interest

Authors declare to have no conflicts of interest regarding the submitted manuscript.

Conflicts of interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejso.2018.12.003.

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