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ORIGINAL ARTICLE

The effectiveness and safety of annulus closure device implantation in lumbar discectomy for patients with lumbar disc herniation: a systematic review and meta-analysis

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Abstract

Objective The objective of this study was to systematically estimate the effectiveness and safety of annulus closure device (ACD) implantation in discectomy for patients with lumbar disc herniation (LDH).

Methods A systematic search was performed on PubMed, EMBASE and the Cochrane Library for randomized controlled trial (RCT) from inception until April 16, 2022. Trials which investigated comparisons between with and without ACD implantation in discectomy for LDH patients were identified.

Results In total, five RCTs involving 2380 patients with LDH underwent discectomy were included. The included patients were divided into ACD group and control group (CTL). Significant differences were found in the rate of re-herniation (ACD: 7.40%, CTL: 17.58%), reoperation (ACD: 5.39%, CTL: 13.58%) and serious adverse event (ACD: 10.79%, CTL: 17.14%) between ACD group and CTL group. No significant difference was found in VAS-BACK, VAS-LEG, ODI and SF-12 PCS between ACD and CTL. The surgical time of ACD was longer than CTL with statistical significance. In subgroup analyses based on discectomy type, significant differences were found in the rate of re-herniation (ACD: 10.73%, CTL: 21.27%), reoperation (ACD: 4.96%, CTL: 13.82%) and serious adverse event (ACD: 7.59%, CTL: 16.89%) between ACD and CTL in limited lumbar discectomy (LLD).

Conclusion Discectomy either with or without ACD implantation is considered to achieve similar clinical outcomes. Whereas, the ACD implantation in LLD is associated with lower re-herniation and reoperation rate but prolonged surgical time for LDH patients. Researches on cost-effectiveness and effect of ACD implantation in different discectomy are needed in the future.

Keywords Annulus closure device · Discectomy · Lumbar disc herniation · Meta-analysis · Systematic review

Abbreviations

ACD	Annulus closure device
LDH	Lumbar disc herniation
LLD	Limited lumbar discectomy
SCIE	Science citation index expanded
WoS	Web of Science
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
RCT	Randomized controlled trial
MED	Micro-endoscopic discectomy
PED	Percutaneous endoscopic discectomy
UBE	Unilateral biportal endoscopic discectomy
VAS	Visual analogue scale
SEA	Serious adverse event
ODI	Oswestry disability index
SF-12 PCS	Physical component summary of 12-item short-form health survey
MD	Mean difference

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95% CI	95% Confidence interval
OR	Odds ratio
ALD	Aggressive lumbar discectomy
VEPC	Vertebral endplate changes
NA	Not available
Exp	Experimental group
CTL	Control group

Introduction

Since Mixter and Barr have first reported the surgical treatment for symptomatic lumbar disc herniation (LDH) in 1934 [1], discectomy is regarded as major treatment of symptomatic LDH. With the continuous advancement of minimally invasive surgery, various surgical approaches for lumbar discectomy have been invented and proposed, such as micro-discectomy, micro-endoscopic discectomy (MED), percutaneous endoscopic discectomy (PED), full-endoscopic discectomy (FED) and unilateral biportal endoscopic discectomy (UBE) [2–6]. Whereas, the problems of postoperative re-herniation and reoperation have not been solved [7, 8], which has become a consensus of high cost and poor prognosis [9, 10]. Therefore, the reduction of recurrence rate and reoperation rate has always been a research hotspot [11].

A study reported that postoperative re-herniation could be related to annular defects due to lumbar discectomy [12]. Moreover, Miller et al. [13] suggested that patients with large postoperative annular defects (≥ 6 mm width) had a 2.5-fold higher rate of re-herniation, compared with patients who had small annular defects (< 6 mm width) after discectomy. Hence, repairing annular defects to reduce the re-herniation rate and reoperation rate has been proposed in recent years, which was performed by implantation of an annular closure device (ACD)—Barricaid™ (Intrinsic Therapeutics, Inc., Woburn, MA, USA) or Xclose Tissue Repair System (Anulex Technologies, Minnetonka, MN) [14, 15]. Many clinical studies have been published focusing on their effectiveness. Some trials suggested that implantation of ACD resulted in better clinical outcomes [16, 17] and reduced the risk of symptomatic re-herniation and reoperation [18–20]. However, Bailey et al. [14] held different opinions, suggesting that the differences of re-herniation rate between groups at all follow-up time points were not statistically significant in their study. Considering the effect of these devices for preventing re-herniation remained controversial among individual studies, we performed this study to systematically estimate the effectiveness and safety of ACD implantation in lumbar discectomy for patients with LDH.

Materials and methods

Protocol and registration

The review protocol of this study was prospectively registered (PROSPERO, CRD42022309101), following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and checklist.

Search methods and selection criteria

We performed a systematic search on PubMed, EMBASE and the Cochrane Library for randomized controlled trials (RCTs) from inception until April 16, 2022. Trials compared lumbar disc herniation (LDH) patients who underwent discectomy with and without implantation of ACD were identified. Keywords were used as annulus closure device, discectomy and lumbar disc herniation.

The selection criteria for including RCTs in this study were shown as follows: (1) performed the comparison between patients with LDH that underwent discectomy with and without the implantation of ACD; (2) participants were adults who suffer symptomatic LDH; (3) contained at least one outcome of interest. RCTs were excluded if: Interventions were different from the previous description; Or original data were not available.

Data extraction and statistical analyses

Two researchers extracted the data for meta-analysis independently. Description and outcomes of included trials were checked carefully. The primary outcomes were the rates of re-herniation and reoperation between ACD group and control (CTL) group. Secondary outcomes were visual analogue scale (VAS), oswestry disability index (ODI), physical component summary of 12-item short-form health survey (SF-12 PCS), surgical time and serious adverse event (SAE) between ACD group and CTL group. To compare the different effect of ACD between surgical techniques more precisely, subgroup analyses were performed based on the surgery type. Mean difference (MD) and 95% confidence interval (CI) were used for presenting the continuous outcomes. Dichotomous outcomes were presented by odds ratio (OR) and 95% CI. RevMan software (version 5.3) was used to perform all analyses. Between-study heterogeneity was evaluated using chi-squared test and I^2. If the P value was < 0.05, statistical heterogeneity exists. In this situation, a random-effects model was utilized. $P < 0.05$ was considered to be statistically significant.

Assessment of risk of bias

The Cochrane Collaboration's risk of bias criteria were used to evaluated the risk of bias in each included trial. The classifications of bias were based on seven items: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other bias. Each item was rated as low risk, unclear risk, or high risk.

Results

Study selection and characteristics

A total of 358 unique records were retrieved yielding 143 studies after removing duplications. One hundred and thirty studies were excluded according to the title and abstract screening. After removing duplications and full-text screening, eight trials were eliminated yielding five trials meeting the inclusion criteria for meta-analysis in this study (Fig. 1). The description and outcomes of all included trials are shown in Table 1. Five trials involving 2380 patients with symptomatic LDH underwent discectomy were included in this study [14, 21–24]. The sample size in these trials ranged from 60 to 727. All included trials contained explicit inclusion and exclusion criteria. Four trials performed discectomy with the implantation of bone-anchored annular closure device and one trials used Xclose Tissue Repair System as annular closure device. Three trials performed limited lumbar discectomy (LLD) and one trial performed limited micro-discectomy. The other trial reported that investigators performed discectomies per their standard practice, conducting with standard or tubular retractors, with or without use of an operating microscope or loupes.

Meta-analysis results

Significant differences were found in the rate of re-herniation (ACD: 7.40%, CTL: 17.58%; OR: 0.43; 95% CI [0.31, 0.58], $P < 0.001$, $I^2 = 0\%$), reoperation (ACD: 5.39%, CTL: 13.58%; OR: 0.36; 95% CI [0.24, 0.53], $P < 0.001$, $I^2 = 0\%$) and SAE

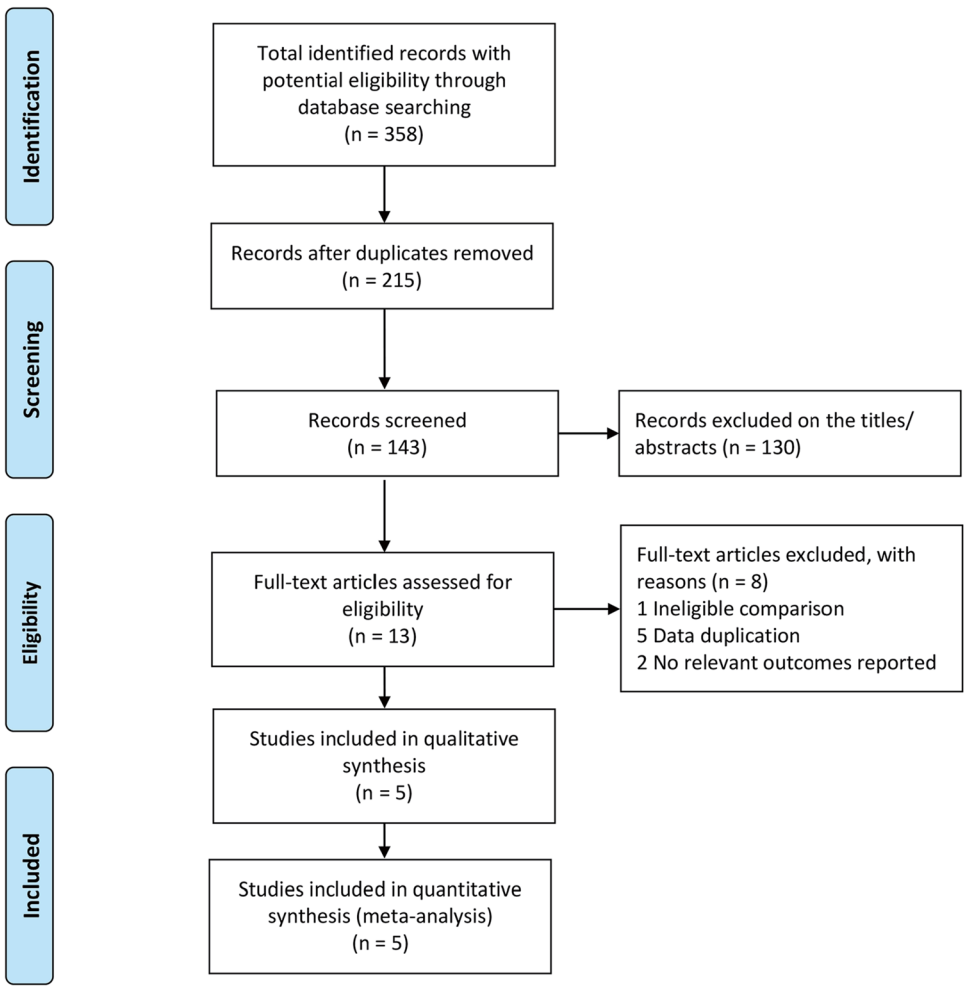


Fig. 1 Flow diagram showing the selection process of RCTs for meta-analysis

Table 1 Characteristics of the included trials

Trial	Sample size (Exp/Clt)	Mean age (Year, Exp/Clt)	Male (%, Exp/Clt)	Closure device type	Outcomes
Bailey 2013 [14]	478/249	42.4/41.9	59.4/56.2	Xclose tissue repair system	VAS, ODI, SF-12 PCS, re-herniation, reoperation
Barth 2018 [21]	242/251	42.9/44.0	61.4/58.7	Bone-anchored annular closure device	VAS, ODI, surgical time
Cho 2019 [22]	30/30	41.4/42.6	66.7/83.3	Bone-anchored annular closure device	VAS, ODI, SF-12 PCS, surgical time, re-herniation, reoperation
Kuršumović 2018 [23]	267/283	43.0/44.0	58.1/60.8	Bone-anchored annular closure device	Re-herniation, reoperation
Thomé 2018 [24]	272/278	43.0/44.0	57.0/62.0	Bone-anchored annular closure device	VAS, ODI, re-herniation, reoperation

VAS visual analog scale, *ODI* oswestry disability index, *SF-12 PCS* physical component summary of 12-item short-form health survey, *NA* not available, *Exp* experimental group, and *Clt* control group

(ACD: 10.79%, CTL: 17.14%; OR: 0.52; 95% CI [0.33, 0.83], $P=0.006$, $I^2=60\%$) between ACD group and CTL group at 24 months after surgery (Fig. 2). No significant difference was found in VAS-leg (MD, −0.23 [95% CI −0.69 to 0.23], $P=0.33$, $I^2=0\%$) and VAS-back (MD, −0.14 [95% CI −0.60 to 0.33], $P=0.56$, $I^2=0\%$) (Fig. 3). No statistical significance was found in SF-12 PCS (MD, −0.56 [95% CI −2.10 to 0.98], $P=0.48$, $I^2=0\%$) between ACD group and CTL group, and the surgical time of ACD group was longer than CTL group with statistical significance (MD, 18.11 [95% CI 13.50 to 22.72], $P<0.001$, $I^2=0\%$) (Fig. 3). There was no significant difference between ACD group and CTL group in ODI (MD, 0.59 [95% CI −1.85 to 3.03], $P=0.64$, $I^2=52\%$) (Fig. 3).

Subgroup analysis results

In subgroup analyses based on the surgery type, significant differences were found in the rate of re-herniation (ACD: 10.73%, CTL: 21.27%; OR: 0.44; 95% CI [0.31, 0.63], $P<0.001$, $I^2=0\%$), reoperation (ACD: 4.96%, CTL: 13.82%; OR: 0.33; 95% CI [0.21, 0.51], $P<0.001$, $I^2=0\%$) and SAE (ACD: 7.59%, CTL: 16.89%; OR: 0.40; 95% CI [0.27, 0.60], $P<0.001$, $I^2=0\%$) between ACD group and CTL group at 24 months after LLD (Fig. 4). The frequency of vertebral endplate changes in ACD group was superior to CTL group at 24 months after LLD (OR: 11.85; 95% CI [8.83, 15.90], $P<0.001$, $I^2=0\%$) (Fig. 4).

Risk of bias

The risk of bias in each included trial was evaluated following the Cochrane Collaboration's risk of bias criteria. The appropriate random sequence generation was reported in all five trials and the allocation concealment in four trials [14, 21–24]. One trial was double-blind randomized controlled trial where surgeons and participants were blinded [22]. Trial of Bailey et al. [14] failed in blinding of outcome assessment. There was an industry funding in three trials [21, 23, 24], which was the reason that the other bias was unclear risk (Fig. 5).

Discussion

The re-herniation rate (ACD: 7.40%, CTL: 17.58%) and reoperation rate (ACD: 5.39%, CTL: 13.58%) of ACD group were lower than CTL group with statistical significance at 24 months after surgery. Moreover, we performed a series of subgroup analyses based on surgery type. After discectomy was first reported as a surgical treatment for symptomatic LDH in 1934, O'Connell described an aggressive method for removing intervertebral disc, namely aggressive lumbar discectomy (ALD) [25]. ALD included removing the herniated disc fragment and scaling the remaining disc. Another method for disc removal described by Spengler and Williams emphasized removing the herniated disc alone without invasion of the disc space, namely LLD [26, 27]. LLD and ALD are both commonly used in clinical practice and have their own disadvantages. McGirt et al. [28] suggested that LLD was associated with lower incidence of long-term recurrent back pain but a higher incidence of re-herniation compared with ALD. In this presenting study, three trials performed LLD and one trial performed limited micro-discectomy [21–24]. The trial by Bailey et al. [14] reported that investigators performed discectomies per their standard practice, conducting with standard or tubular retractors, with or without use of an operating microscope or loupes. Sensitivity analysis showed that the data by Bailey et al. had no effect on the results. Moreover, the results of subgroup

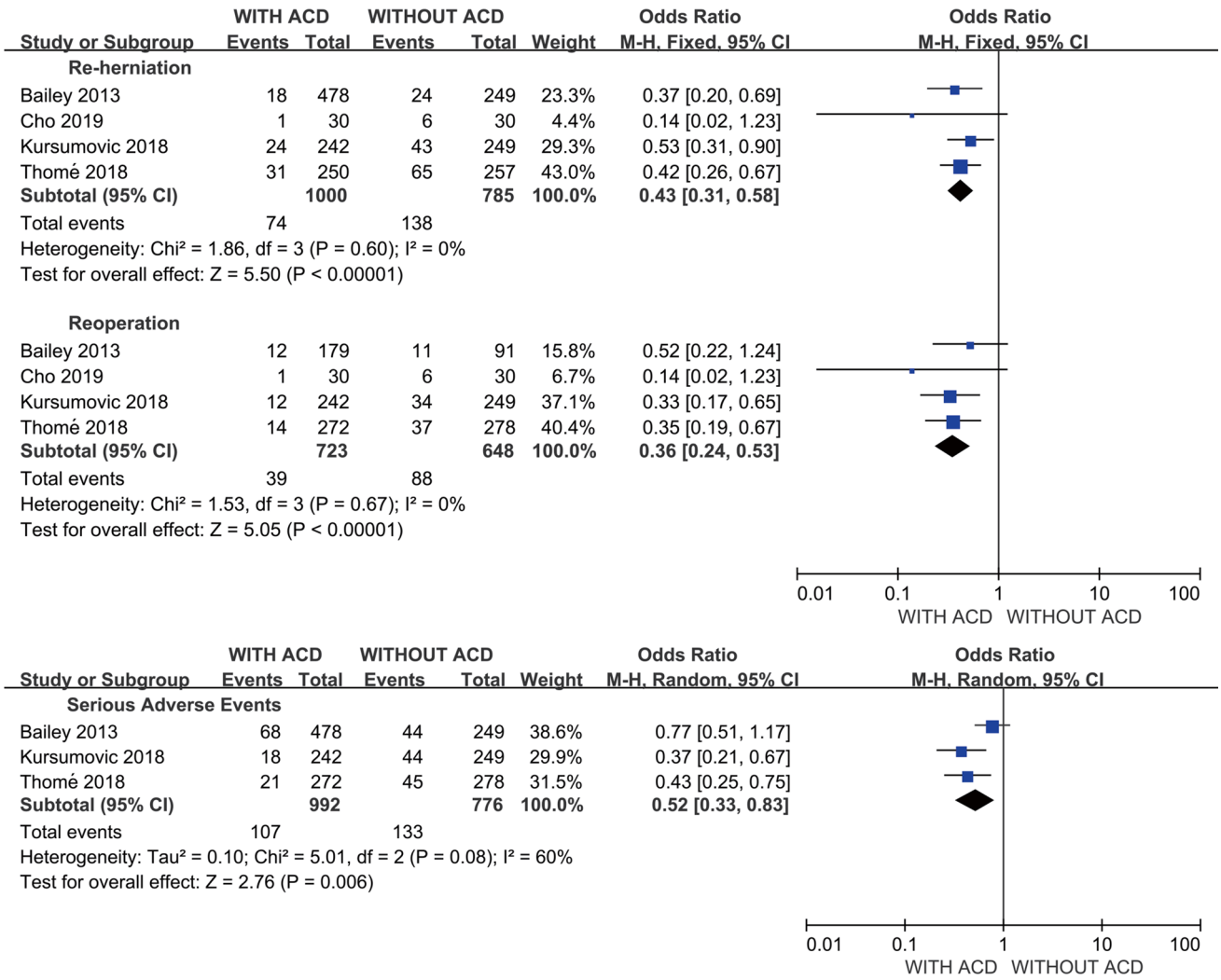


Fig. 2 Pooling results of the ACD group and the CLT group. The results were shown as follows: re-herniation rate, reoperation rate and severe adverse event rate

analyses showed that significant differences were found in the rate of re-herniation (ACD: 10.73%, CTL: 21.27%) and reoperation (ACD: 4.96%, CTL: 13.82%) at 24 months after LLD. The findings of this study suggested that the implantation of ACD was associated with lower re-herniation and reoperation rate specially for patients underwent LLD. And high-quality RCTs with sufficiently large sample sizes evaluating effect of ACD implantation in different methods of discectomy are needed in the future.

No significant difference was found in VAS-back, VAS-leg, ODI and SF-12 PCS between ACD group and CTL group in our study. Whereas, the comparison of ODI between ACD and CTL existed a high statistical heterogeneity ($I^2 = 52\%$). The number of participations in Cho's trial was lower compared to other included trials. Moreover, about 70% participations in Cho's trial was available at 2-year follow-up, which might limit the veracity of their conclusions of long-term outcome. Hence, we performed a sensitivity analysis when analyzing ODI. After omitting Cho's study, there was no statistical heterogeneity found ($I^2 = 0\%$) and the result was not affected. These findings in this study indicated that the implantation of ACD did not affect the clinical outcomes, such as pain relief and disability recovery after lumbar discectomy in 2-year follow-up. However, a few clinical trials held different opinions. Kienzler et al. and Nanda et al. [17, 19] suggested that addition of a bone-anchored ACD in lumbar discectomy was associated with better long-term (over 3 or 4 years after surgery) pain and disability relief compared to discectomy alone. Bouma et al. [16] set subgroups by age and suggested that both younger and older patients derived better benefits in clinical outcomes with bone-anchored ACD implantation compared with discectomy alone.

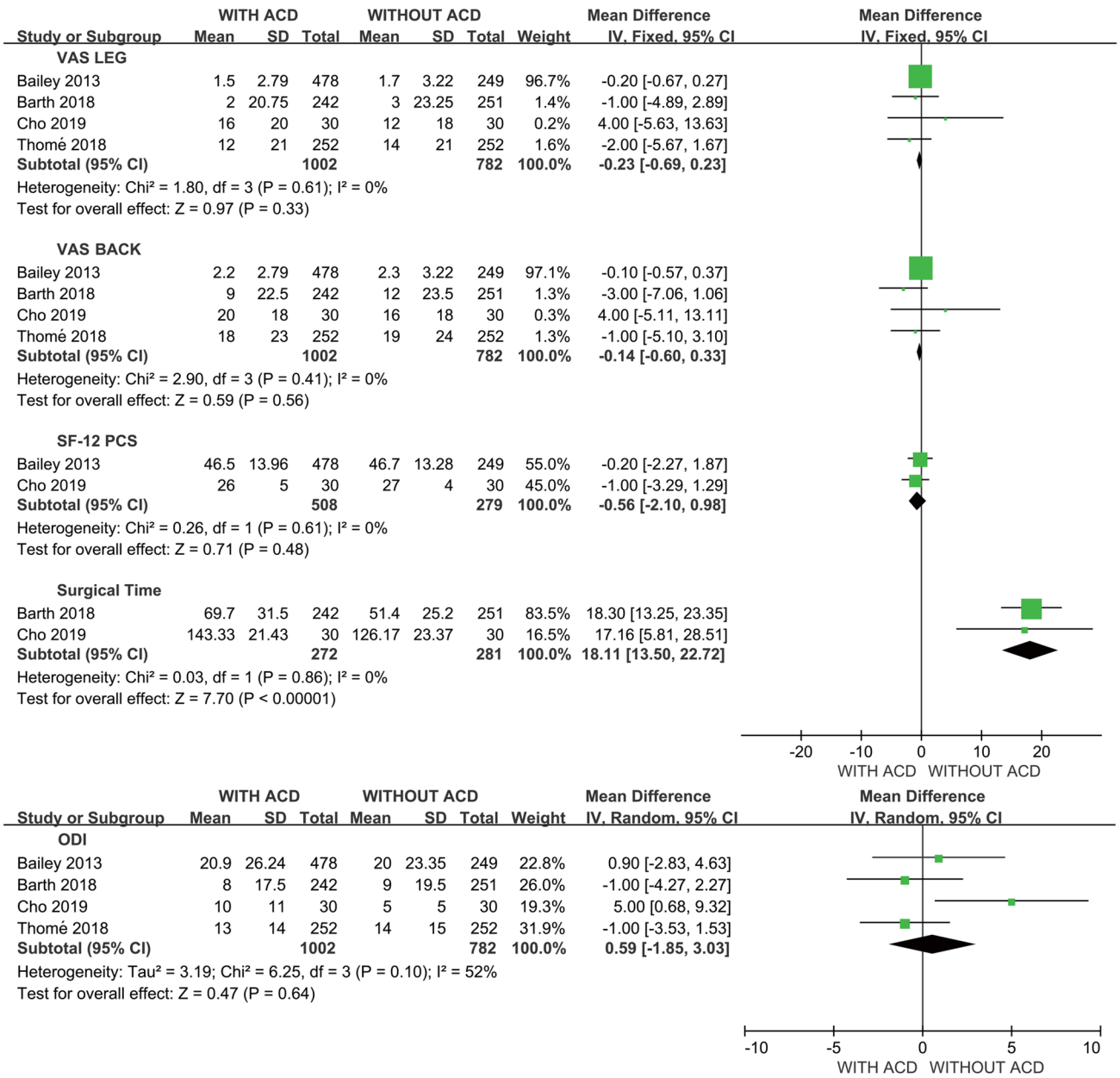


Fig. 3 Pooling results of the ACD group and the CLT group. The results were shown as follows: VAS-leg, VAS-back, SF-12 PCS, surgical time and ODI

The surgical time of ACD group was longer than CTL group with statistical significance in this study. The prolonged surgical time is associated with complications such as surgical site infection and it is a universal goal for surgeons to decreased surgical time continuously [29–31]. The introduction of a new technique into presenting surgery always requires surgeon to gain experience and overcome a learning curve to decrease the surgical time. Therefore, it is important for surgeon to weigh if the increase in surgical time caused by a new technique could be justified by the benefits it provides. The methods on reducing the additional surgical time for ACD implantation needs further research in the future.

Vertebral endplate changes (VEPC) are common in lumbar spine and could be classified as Schmorl's nodes, fracture, erosion, or calcification [32]. Brayda-Bruno et al. [33] reported that the "notched" and "Schmorl's nodes" were the most common classification of VEPC, and VEPC was found to be associated with disc degeneration and signal alterations on MRI. Moreover, Feng et al. [34] suggested that cartilaginous endplate avulsion could be associated with residual pain after lumbar discectomy. The study of Zehra et al. [35]

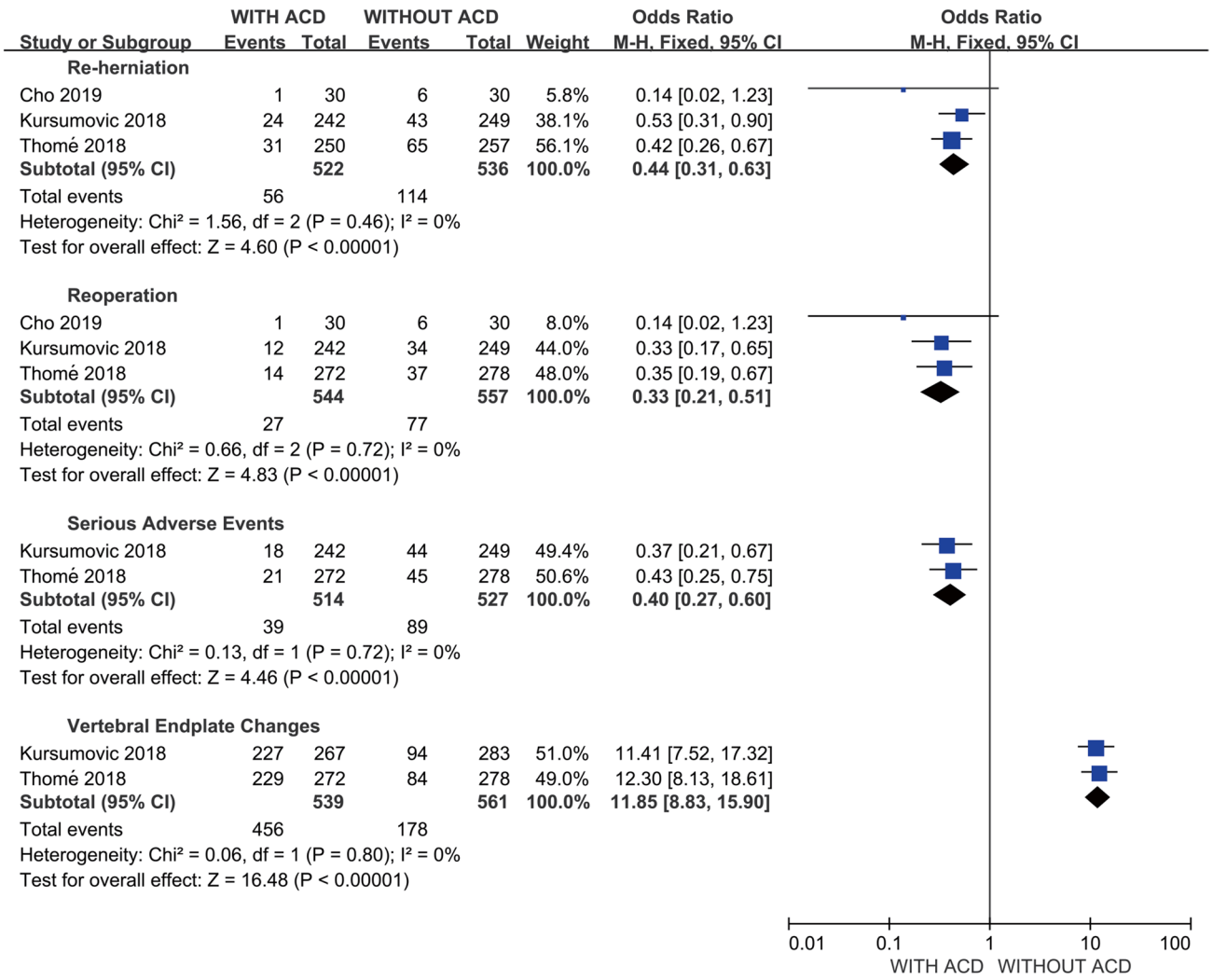


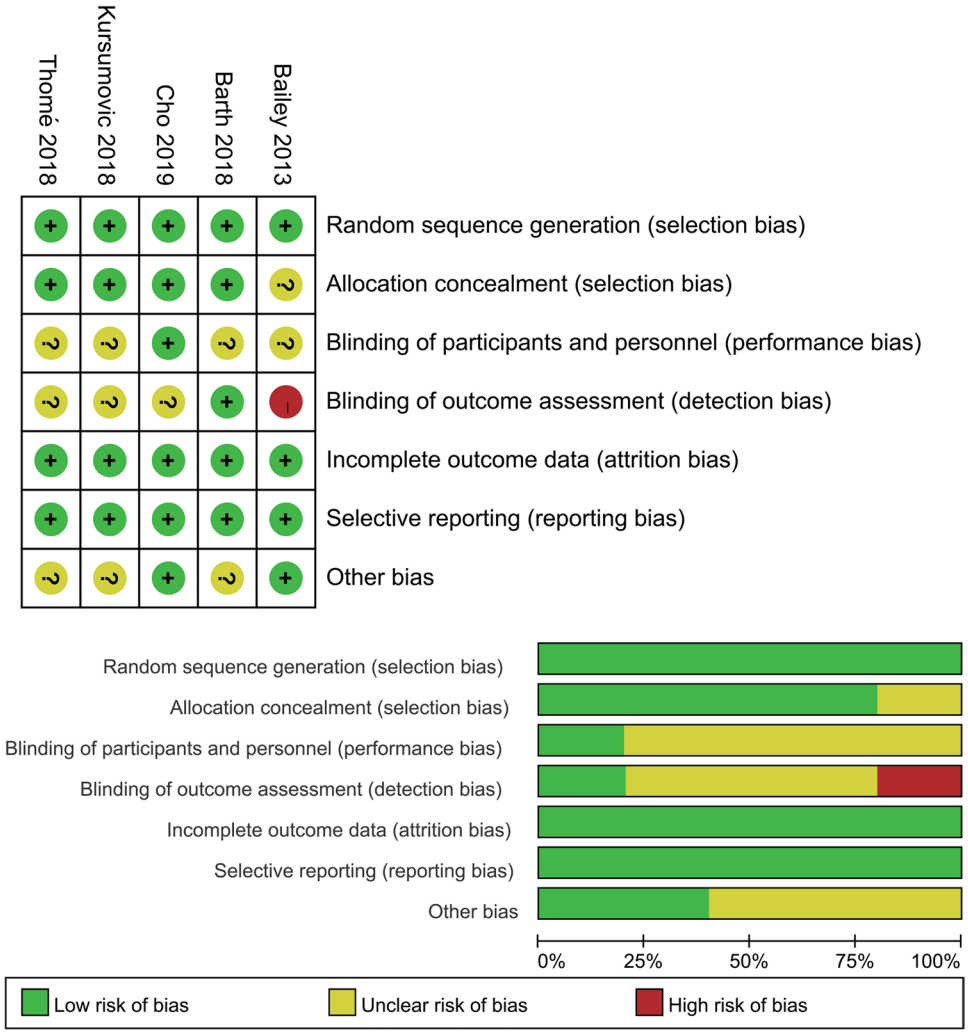
Fig. 4 Pooling results of subgroup analyses based on surgery type. The results were shown as follows: re-herniation rate, reoperation rate, severe adverse event rate and vertebral endplate changes

also noted that increased endplate defect was directly associated with facet joint changes, leading to pain. The VEPC of ACD group were superior to CTL group at 24 months after LLD in this presenting study. Whereas, VEPC had no impact on SAE rate and various clinical outcomes such as ODI, VAS and SF-12 PCS based on our results. Future studies should focus on long-term follow-up and evaluate the long-term effect of VEPC after ACD implantation on surgical outcomes.

At present, Barricaid™ is the most popular annular closing device on the market. The Xclose device is no longer available right now, and there is other solution called AnchorKnot® used in some centers [36, 37]. Ament et al. performed a cost-effectiveness analysis of ACD implantation for lumbar discectomy in 2019 [38]. They suggested that the ACD implantation was highly cost-effective compared to lumbar discectomy alone at 2 years after surgery for LDH patients with large postoperative annular defects (≥ 6 mm). According to its effect and prolonged surgical time, we suggested that ACD implantation should be treated with caution. As the results shown in this presenting study, there is currently no strong evidence suggesting that discectomy with ACD implantation is economically favorable and surgically safer compared to standard discectomy. At present, the subgroup suitable for ACD implantation could be LDH patients undergoing LLD with large annular defects (≥ 6 mm).

The objective of this study was to systematically estimate the effectiveness and safety of ACD implantation in lumbar discectomy for patients with LDH. There were two studies based on fewer number and mixed clinical trials (randomized or non-randomized) on similar topic with low credibility [39, 40]. In this meta-analysis, we recruited five RCTs which performed the comparison between ACD and CTL

Fig. 5 Risk of bias summary



after discectomy, including 2380 patients (1289 in ACD group and 1091 in CTL group). Moreover, subgroup analyses were performed based on the surgery type to compare the effect of ACD implantation between surgical techniques more precisely. Whereas, there were still several limitations in this study. First, the cost-effectiveness of ACD implantation in discectomy for patients with LDH was not available in the included trials. Second, clear allocation concealment was not presented in some included trials.

Conclusion

Discectomy either with or without ACD implantation is considered to achieve similar clinical outcomes. Whereas, the ACD implantation in LLD is associated with lower re-herniation and reoperation rate but prolonged surgical time for LDH patients. We suggested that ACD implantation should be treated with caution. More independently high-quality RCTs with sufficiently large sample sizes reporting cost-effectiveness and evaluating the effect of ACD implantation in different discectomy are needed.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00586-023-07629-0.

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Declarations

Conflict of interests The authors have no conflict of interest to disclose.

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