Discectomy Combined with Annulus Fibrosus Repair for the Treatment of Lumbar Disc Herniation: A Bayesian analysis of Random Controlled Trials

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Research article

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Abstract

Objective To investigate clinical effects of discectomy combined with annulus fibrosus (AF) repair for the treatment of lumbar disc herniation.

Methods We searched PubMed, Embase, Web of Science, CNKI and WanFang data for studies evaluating discectomy combined with AF repair and discectomy for the treatment lumbar disc herniation. Two reviewers selected studies, assessed quality, and extracted data. This meta-analysis was performed to calculate the weighted mean difference (WMD), risk ratios (RRs), and 95% confidence intervals (CIs).

Results Six randomized controlled trials (RCTs) were included in the meta-analysis. The pooled results suggested that the recurrence rate and reoperation rate in the non-repair group versus those in the repair group [RR= 2.64, 95% confidence interval (CI) 1.09, 6.41], [RR=1.33, CI 0.85, 2.10], respectively. The rate of Visual analogue scale (VAS) relief in the repair group was significantly better than in non-repair group [WMD=0.23, CI 0.04, 0.42], and did not increase the incidence of postoperative complications. There were no significant differences between the two surgical procedures in the Oswestry disability index (ODI) reduction [WMD=-0.18, CI -1.50, 1.14], intraoperative blood loss [WMD = -1.23, CI -4.46, 2.00] and the length of the surgical incision [WMD = 0.08, CI -0.01, 0.18]. However, the operation time of the repair group was slightly longer than non-repair group [WMD =6.73, CI 2.80, 10.66].

Conclusion Discectomy combined with AF repair is superior to discectomy regarding postoperative recurrence rate and postoperative pain relief, but the operation time is slightly longer than the latter. There is no significant difference in reoperation rate, intraoperative blood loss, length of the surgical incision, postoperative complication rate, and reduction in ODI between the two surgical procedures.

Introduction

Lumbar disc herniation (LDH) refers to a series of clinical symptoms, such as lumbar back pain, numbness, pain and weakness of one or both lower extremities. These symptoms mainly caused by the breakthrough of annulus fibrosus (AF) in the nucleus pulposus of the intervertebral disc and the stimulation or compression of adjacent spinal nerve roots. Currently, for LDH patients with mild symptoms, conventional therapy such as medicine, bed rest and physiotherapy is often used, but some patients cannot tolerate pain in the process of conservative treatment or for patients who have failed to undergo regular conservative treatment, surgery is often needed.

Surgical interventions included discectomy, lumbar fusion, and internal disc replacement. Discectomy considered a standard procedure for the treatment of LDH. [1]During the operation, some patients can feel the apparent relief of symptoms at the moment of being relieved of nerve compression. However, the amount of nucleus pulposus removal has been a controversial issue for clinicians.[2] Some studies have suggested that excessive removal of nucleus pulposus tissue to reduce the rate of recurrence lumbar disc herniation.[3,4] However, studies have shown that excessive removal of nucleus pulposus tissue could accelerate normal disc degeneration, reduce the height of the intervertebral disc after surgery, change the overall structure and biomechanics of the lumbar spine, and even lead to the risk of instability.[5,6] Afterwards, some scholars supported the limited removal of nucleus pulposus tissue and a small amount of nucleus pulposus removal, which could reduce the operation time and speed up the recovery of patients, but the surgical procedure has significantly increased the recurrence rate.[2,7] In traditional surgery, there is no solution for the ruptured AF after the removal of the nucleus pulposus tissue. Due to the inadequate nutritional supply in the intervertebral disc AF, the healing is slow, and the anti-stress strength is low, [8] thus, there is a high risk of re-protrusion of nucleus pulposus at the original rupture site.[7]

In recent years, AF repair technology has been gradually applied to repair ruptured AF after nucleus pulposus removal, and the therapeutic effect of AF repair has been evaluated and analyzed in relevant literature. However, due to the small sample size and inconsistent conclusions of a single study, it is not enough to provide a basis for clinical treatment. Therefore, we performed this meta-analysis to investigate the clinical effects of two methods for the treatment of LDH and look forward to providing evidence-based for clinicians.

Materials And Methods

We conducted this meta-analysisby the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[9] The protocol for the meta-analysis was registered with the International Prospective Register of Systematic Reviews (CRD42018110414).

Search strategy

We searched PubMed, Embase, Web of Science, CNKI and WanFang data, until August, 2019 for studies evaluating the treatment effect of lumbar disc herniation by discectomy combined with AF repair and discectomy for the treatment lumbar disc herniation, without languages restrictions. Search terms included the keywords related to discectomy, annulus, lumbar, and their variants. The details of our search strategy are available in the Supporting Information (**Appendix A**). Additionally, we manually searched the reference lists of all eligible studies to identify additional potential studies.

Study selection and eligibility criteria

Inclusion criteria: (1) Type of participant: patients with lumbar disc herniation; (2) Type of exposure: discectomy combined with annulus fibrosus repair; (3) Type of study design: randomized controlled trials; (4) Type of outcome: the primary outcomes of this meta-analysis were recurrence rate, reoperation rate, postoperative reduction of VAS and ODI, postoperative complications. Secondary outcomes were operative time (minutes), intraoperative blood loss (ml), and the length of surgical incision (cm); (5) Follow-up time is more than one year; (6) AF repair method is suture.

Exclusion criteria: (1) patients with other lumbar diseases; (2) cases, reviews, abstract, and articles with incomplete summary data; (3) articles published repeatedly or using the same database.

Data extraction

We extracted the following information from each included study: author, year, sample size, age, gender, and duration of follow-up. If there are some disagreements, we resolved by discussion to reach an agreement. All extracted data were entered into a predefined standardized Excel file (Microsoft Corporation, USA). When we found duplicate reports of the same database, we obtained data from the study with the most complete data set.

Quality assessment

The quality of the randomized controlled trial articles was used by modified JADAD.[10] The evaluation includes random sequence generation, randomization hiding, blinding, and withdrawal. The first three questions, each one is 2 points, the scores are based on appropriate, unclear, inappropriate, followed by 2 points, 1 point, 0 points, respectively; the last question is 1 point, depending on whether there are withdrawal reasons, give 1 point or 0 points. We assigned scores of 1 to 3, and 4 to 7, for low and high quality of studies, respectively.

Statistical analysis

RevMan 5.3 (The Cochrane Collaboration, Denmark) was used to statistical analyses. The I^2 statistic was used to quantify the heterogeneity of the included studies.[11] And I^2 value higher than 50% indicates significant heterogeneity, the random-effects model was used; otherwise, the fixed-effects model was used. Dichotomous data was analyzed by relative risks (RRs), and continuous data was used by the weighted mean difference (WMD). A two-sided P value less than 0.05 was considered statistically significant. Publication bias was assessed with funnel plots.

Results

Search results

Two reviewers undertook the searches independently, and a total of 972 articles were retrieved. Endnote X8 (version 18.0.0.10063) was used to remove 390 duplicate studies. Besides, we removed 455 irrelevant articles, 33 reviews, 31 conference papers, and 24 cases/comments/letters through the title and abstract. Afterward, we deleted 13 duplicate data articles (Appendix B), 13 cohort studies (Appendix C), and 7 no control group articles through the full text. Finally, 6 articles were included.[12-17] The study selection process was shown in **Figure. 1**.

Study characteristics

These included studies were published between 2013 and 2018, with sample sizes ranging from 45 to 727 subjects, and a total of 1,168 subjects. 643 subjects undergoing discectomy combined with annulus fibrosus repair surgery. All follow-up time is more than one year. The main characteristics of the included trials are summarized in **Table 1**.

Quality assessment

The average score was 4.17 (range, 4-5), suggesting that all the studies were of high quality. For the generation of random sequences, all included articles provide computer-generated random numbers or similar methods. Six articles indicate the use of random number table or other random allocation scheme, but did not provide details. One article mention the article used blind, [12] and five articles do not mentioned the blind method; all articles describe the number and reasons for withdrawal. The details of the article quality are shown in **Table 2**.

Clinical outcomes

The primary outcomes

Recurrence rate

Five articles provided available data in recurrence rates.[13-17] There was no significant heterogeneity ($P>0.1$, $I^2=0\%$), so the fixed effect model was used for analysis. The pooled outcomes demonstrated that a 2.64-fold higher risk of recurrence in the AF unrepaired group than in the repair group [RR = 2.64, 95% CI (1.09, 6.41), P < 0.00; Figure 2].

Reoperation rate

For some patients with recurrence and severe symptoms, surgery is needed again. Five studies provided available data in reoperation rate.[12-15,17] There was no significant heterogeneity ($P>0.1$, $I^2=7\%$), the fixed-effect model was used for analysis. The pooled outcomes demonstrated that a 1.33-fold higher risk of reoperation rate in the AF unrepaired group than in the repair group [RR = 1.33, 95% CI (0.85, 2.10), P = 0.21; Figure 3].

Postoperative reduction of VAS

Five articles provided information on postoperative pain relief in patients,[12,14-17] but some articles provided VAS for back pain and lower limb pain, which we combined. The data were calculated based on the difference between the mean and standard deviation of the preoperative and postoperative VAS. There is no heterogeneity ($P>0.1$, $I^2=0\%$), and the fixed-effect model was used. The combined results showed that the pain relief in the AF repaired group was better than that in the unrepaired group [WMD=0.23, 95% CI (0.04, 0.42), P=0.02; Figure 4].

Postoperative reduction of ODI

Five articles provided available data on the decrease of ODI in patients.[12,14-17] No significant heterogeneity was detected between the groups ($P>0.1$, $I^2=0\%$), a fixed effect model was selected. The pooled outcomes demonstrated that there was no significant difference between the two groups in postoperative reduction of ODI values [WMD=-0.18, 95% CI (-1.50, 1.14), P=0.79; Figure 5].

Postoperative complications

Postoperative complications mainly included wound infection, rupture of the endorhachis, intraspinal hematoma, nerve injury, cerebrospinal fluid leak, etc. Five articles provided available data on postoperative complications. [12-14, 16-17] No significant heterogeneity was detected between the studies ($P>0.1$, $I^2<50\%$; Figure 6). The combined results showed that there was no significant difference between the two groups in postoperative complications.

The secondary outcomes

Intraoperative blood loss (ml)

Five studies compared the intraoperative blood loss between the two groups.[13-17] No significant heterogeneity was detected between the studies ($P>0.1$, $I^2=0\%$), a fixed-effect model was used. The pooled outcomes indicated that there was no significant difference in intraoperative blood loss between the two groups [WMD = -1.23, 95% CI (-4.46, 2.00), P = 0.45; Figure 7].

Operative time (minutes)

Five studies provided available data in operative time.[13-17] Significant heterogeneity was detected between the studies ($P<0.1$, $I^2 = 67\%$). Therefore, the random-effects model was used to do analysis. The pooled outcomes suggested that the operation time of the AF repaired group was significantly longer than that of the unrepaired group at 6.73 mins [WMD=6.73, 95% CI (2.80, 10.66), P<0.01; Figure 8].

Length of the surgical incision (cm)

Two studies compared the length of surgical incision between the two groups.[14,15] No significant heterogeneity was detected between the studies ($P>0.1$, $I^2=0\%$), a fixed-effect model was used. The pooled outcomes indicated that there was no significant difference in length of surgical incision between the two groups [WMD = 0.08, 95% CI (-0.01, 0.18), P = 0.10; Figure 9].

Discussion

The main finding of this meta-analysis demonstrated that discectomy combined with AF repair is superior to discectomy regarding postoperative recurrence rate ,and postoperative pain relief, but the operation time is slightly longer than the latter. There is no significant difference in reoperation rate, intraoperative blood loss, length of the surgical incision, postoperative complication rate, and reduction in ODI between the two surgical procedures. Although all studies included in this meta-analysis were RCTs and the heterogeneity was low, the number of included studies and the total sample size is limited. Therefore, we extracted the data from 11 cohort studies, and analyzed it according to the statistical analysis method of the meta-analysis. The pooled outcomes were similar to ours, and further prove the stability of our research results. However, the reoperation rate was significantly lower in the annulus repair group than in the unrepaired group in no-RCTs. The combined effects of the cohort study are shown in Appendix C.

The surgical approach of LDH should aim to maximize the restoration of the stability of the intervertebral disc structure and a better balance of forces. Discectomy is an effective surgical procedure for the treatment of LDH, but the postoperative recurrence rate is 10-15%,[18-20] and similar to the total recurrence rate of AF unrepaired group in this meta-analysis. Many factors are affecting the recurrence of LDH, such as postoperative defect of the annulus fibrosus, the degree of disc degeneration, obesity, smoking, and other factors.[4,7,21-25] Lebow et al. found that recurrence after nucleus pulposus removal occurred mostly in the original nucleus.[26] Rupture of AF around with high level of phospholipase A_2, which aggravates the hyperplasia of scar tissue.[27] Hyperplastic scar tissue can compress nerve root or dural sac and increase postoperative recurrence rate. Therefore, the surgeon repairs the ruptured AF, reducing the stimulation of nerve roots.[28] The study of Carrage has shown that a significant correlation between the integrity of AF and postoperative recurrence.[29] By comparing the area of the AF rupture, McGirt et al. found that the incidence of reoperation required for patients with an AF rupture greater than 54 mm^2 was approximately 18%. In contrast, for patients with a diameter of less than 36 mm^2, the incidence of reoperation was 4.7%.[5] Bostelmann et al. performed biomechanical analysis of human corpses and found that the pressure of the intervertebral disc after AF repair was basically close to the preoperative level.[30] Our meta-analysis showed that the AF-repaired group significantly reduced postoperative recurrence rates, and the same conclusion was obtained in 9 cohort studies [RR=2.97, 95% CI (1.69, 5.21), P<0.01, Appendix C].

The rLDH patients with mild symptoms can be treated conservatively. However, some patients who cannot tolerate symptoms such as pain and numbness need to be surgery again. Lebow et al. showed that surgery was used for the rLDH patients, the postoperative treatment was not as effective as the initial postoperative rehabilitation, [26] and the reoperation would lead to biomechanical changes of the intervertebral disc and accelerate the degeneration of adjacent discs.[31] The study of Klassen has shown that patients undergoing second surgery for LDH have a postoperative ODI value of 2.9-folds, 3.6-folds incidence of lower extremity pain, and 1.4-folds incidence of back pain that of primary surgery.[32] Mainly because the second operation increased the degree of ruptured AF scar adhesion, and the removal of the nucleus pulposus tissue again caused the height of the intervertebral disc to be significantly lower than that primary surgery. In addition, with the height of the intervertebral disc and the overall structure ofthe lumbar changes, accelerates the degeneration of the facet joints, and even the instability of the lumbar spine in their remainder lifetime. [26,33]Therefore, reoperation is not an ideal choice; the important is how to reduce the recurrence rate and reoperation rate of patients after initial surgery. Whereas our study shows that there is no significant difference in the reoperation rate between the two methods, which may be due to the limited sample size.

For the secondary outcomes, there was no statistically significant difference in the intraoperative blood loss and the length of the surgical incision. It was consistent with the results obtained by the cohort study, as shown in Appendix B. However, the meta-analysis showed that the AF repair group had more operative time than the unrepaired group (6.73 mins), and the combined results of the nine cohort studies showed that the AF repair group had more operative time than the unrepaired group 3.12mins. The AF repair group can remove limited nucleus pulposus tissue than the unrepaired group, which may save some operation time, but it will increase the operation time during the repaired process. The results of the combination of RCTs and the cohort studies showed that the increased operation time of the AF repaired group within 10 minutes, which may not have clinical significance for the entire operation time.

Call for Future Studies

Materials used for AF repair is a polymer polyethylene material, which is an inert biological material and not easily degraded in the body. It is unclear that the suture knot as a foreign matter increases the formation of scar adhesion. (2) The Barricaid produced in the United States is another repair material for AF. Can the filled material be blended with the surrounding tissue in the late stage? In addition, the bone anchor fixator needs to be fixed in the endplate, which causes the endplate to deform.[34] Whether it will accelerate the degeneration of the endplate and affect the stability of the lumbar vertebrae, which needs further observation. (3) Currently, there is no guidance for AF repair of rupture; it has been unclear which kinds of patients need to be repaired. (4) In recent years, with the rapid development of biotechnology, some scholars regulate the expression of AF-derived stem cells by constructing biomaterial scaffolds,[35] which we expected better therapeutic results in the future.

Limitations

Although the study design included in the meta-analysis was RCTs, the stability of each outcome was well, and further use of the results of the cohort study confirmed the stability of the conclusions. However, the following limitations still exist: (1) Most of the articles do not adopt blind methods, so the results obtained may be influenced by the subjective factors of the researchers. (2) There was moderate heterogeneity in the operation time, and the heterogeneity source may be the medical level, and the difference in the repair materials used in different regions. (3) Quantitative methods are not used to assess the publication bias of the article due to the limited number of articles included, so there may be potential publication bias.

Conclusions

Discectomy combined with AF repair is superior to discectomy regarding postoperative recurrence rate and postoperative pain relief, but the operation time is slightly longer than the latter. There were no significant difference inreoperation rate, intraoperative blood loss, length of the surgical incision, postoperative complication rate and reduction in ODI between the two surgical procedures. However, due to the small number of studies and the small sample size, we expect a multi-center, large sample, high quality, double-blind RCT study to to update our conclusions further..

Abbreviations And Acronyms

LDH: Lumbar disc herniation; AF: Annulus fibrosus; VAS: Visual analogue scale; ODI: Oswestry disability index; RCTs: Randomized controlled trials; WMD: Weighted mean difference; CI: Confidence interval; RR: Rate ratio; rLDH: Recurrent lumbar disc herniation.

Declarations

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Availability of data and materials

All data are fully available without restriction.

Author contribution

HW, JLH and JZB conceived of the design of the study. JLH, XQS and WYF participated in the literature search, study selection, data extraction, and quality assessment. JZB and JLH performed the statistical analysis. JZB and JLH finished the manuscript. All authors read and approved the final manuscript.

Authors' information

The author information can be found in the title page.

Ethics approval and consent to participate

This article does not contain any studies with human participants or animals performed by any of the authors

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1. Characteristics of the included studies

Author	Year	Research time	Group	Sample size	Gender (M/F)	Age （Year）	Follow-up （Month）
Bailey	2013	2007-2011	Repair	478	284/194	42.4±11.3	24
			Non-repair	249	140/109	41.9±11.6	24
Li	2014	2011-2013	Repair	51	30/21	38.8±11.7	18
			Non-repair	168	92/76	37.7±12.4	18
Jiang	2017	2013-2015	Repair	25	12/13	48.68±6	12
			Non-repair	23	11/12	49.91±7.01	12
Zhang*	2017	2014-2015	Repair	28	11/17	46.1±11.4	14.5
			Non-repair	28	9/19	44.9±12.5	14.5
Zhang	2017	2013-2016	Repair	36	19/17	45.2±4.7	25
			Non-repair	33	19/14	43.8±5.1	25
He	2018	2015-2016	Repair	21	12/9	35±10	12
			Non-repair	24	13/11	34±11	12

*Zhang Liang

ble 2. Methodological Quality Assessment of Included Studies by Modified JADAD

Study	Random sequence production	Allocation concealment	Blind method	Withdrawal	Total score
Bailey 2013	Adequate	Unclear	Unclear	Description	5
i 2014	Adequate	Unclear	Inadequate	Description	4
Jiang 2017	Adequate	Unclear	Inadequate	Description	4
hang* 2017	Adequate	Unclear	Inadequate	Description	4
Zhang 2017	Adequate	Unclear	Inadequate	Description	4
e 2018	Adequate	Unclear	Inadequate	Description	4

quate is 2 point, Unclear is 1 point, Inadequate is 0 point, Description is 1 point, Indescription is 0 point, 1-3 as low quality, 4-7 as high quality,* Zhang L

Figures

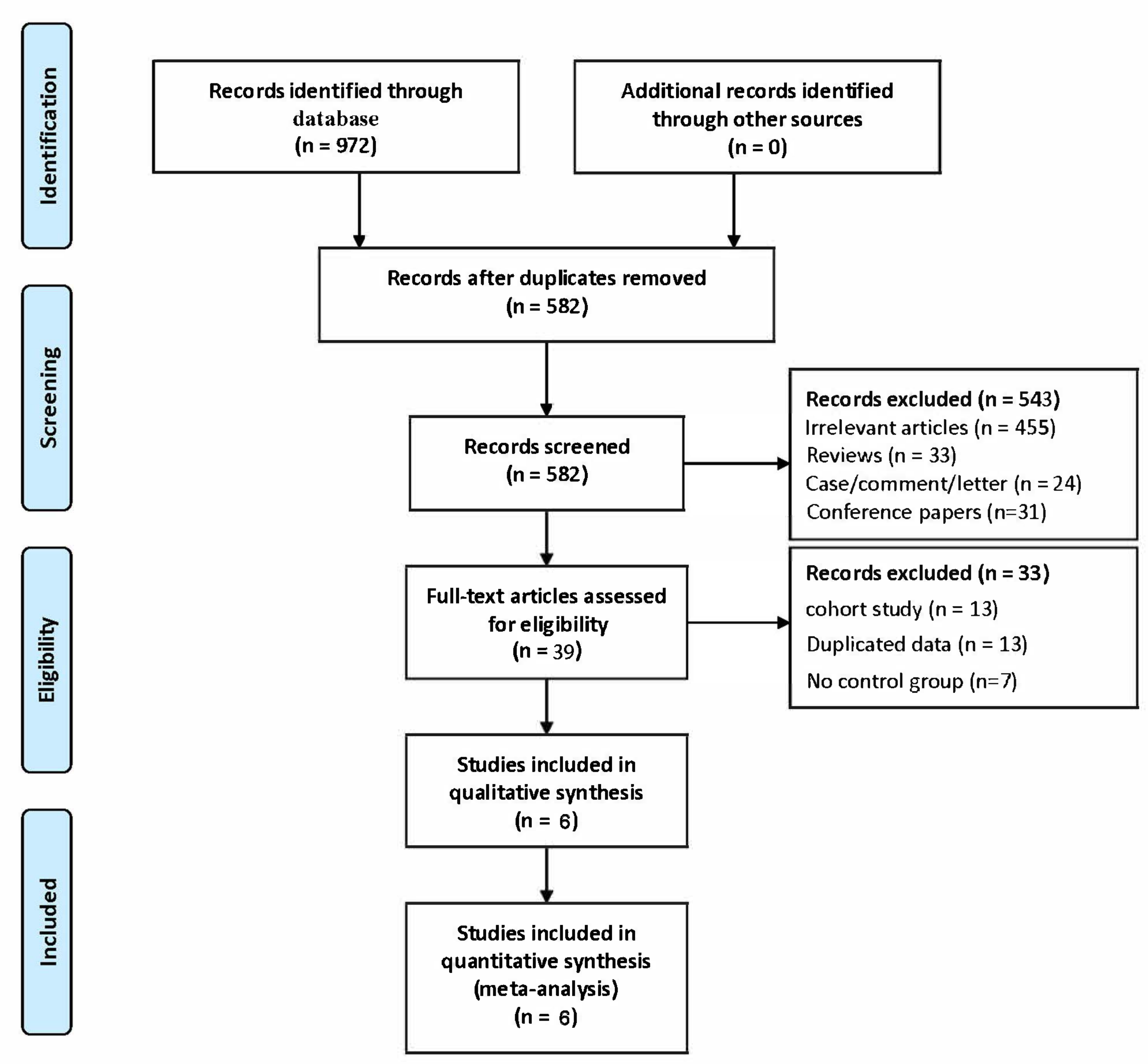

Figure 1

The flow chart of studies selecting.

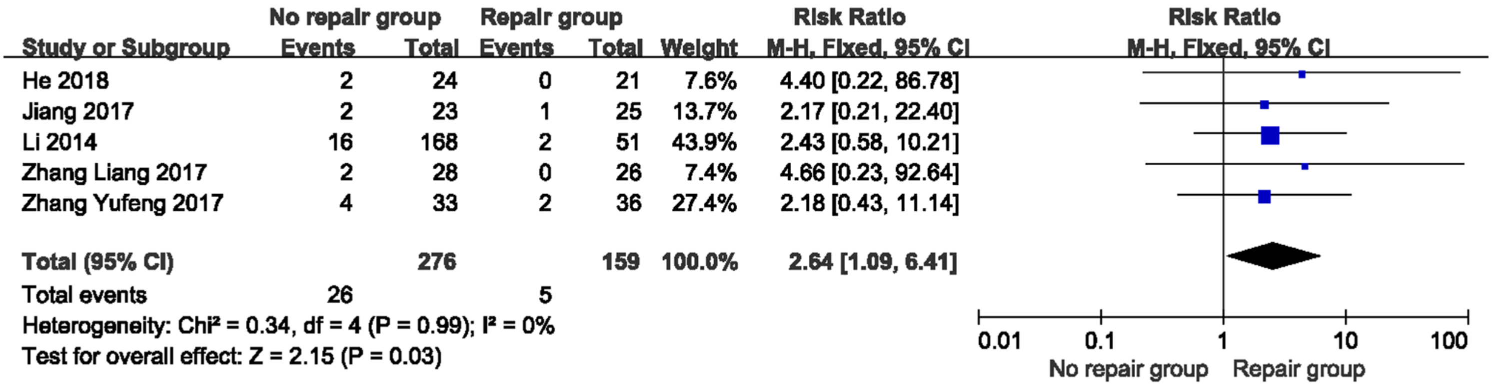

Figure 2

The forest plot for recurrence rate between the two groups.

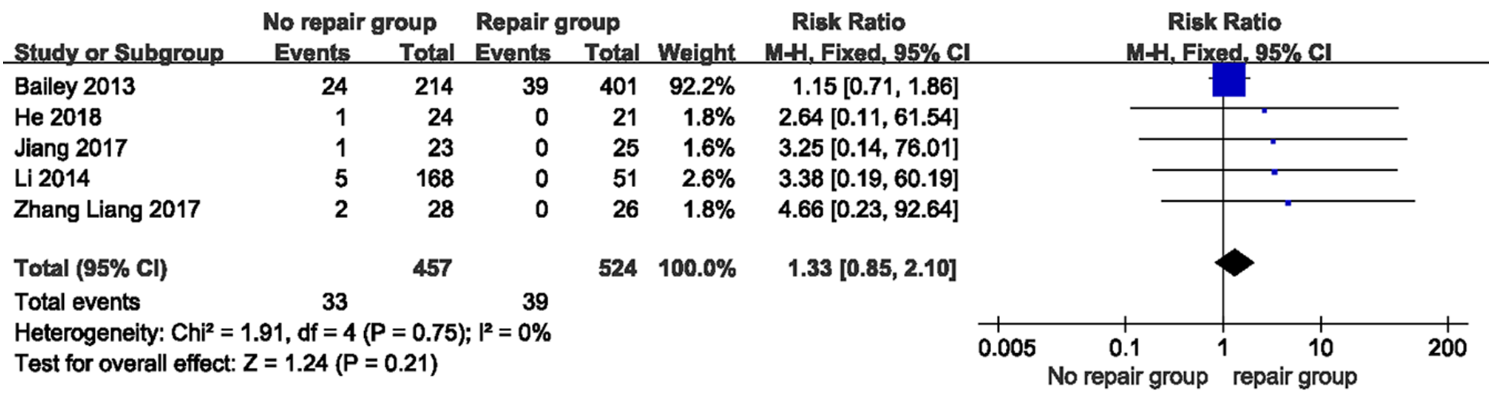

Figure 3

The forest plot for reoperation rate between the two groups.

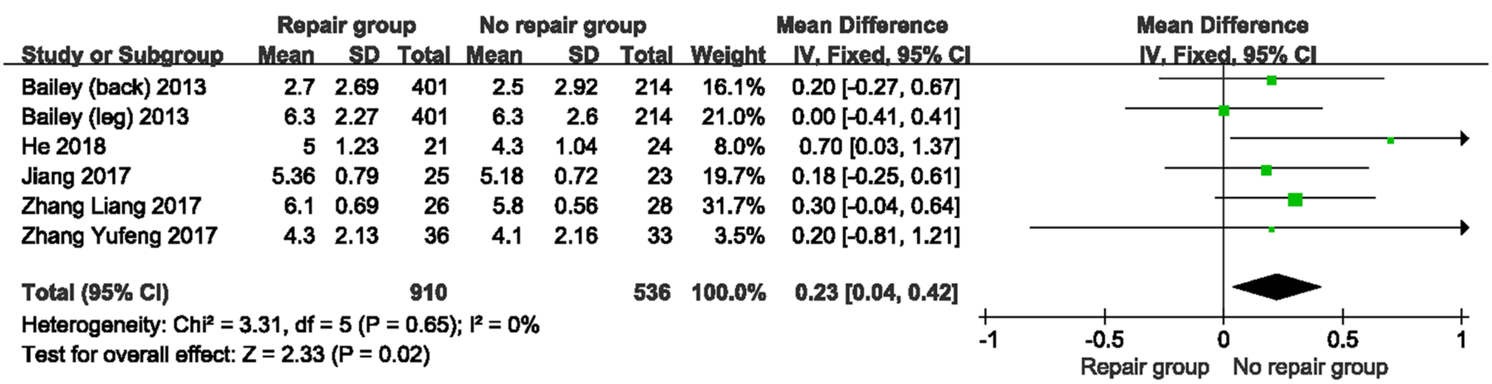

Figure 4

The forest plot for postoperativse reduction of VAS between the two groups.

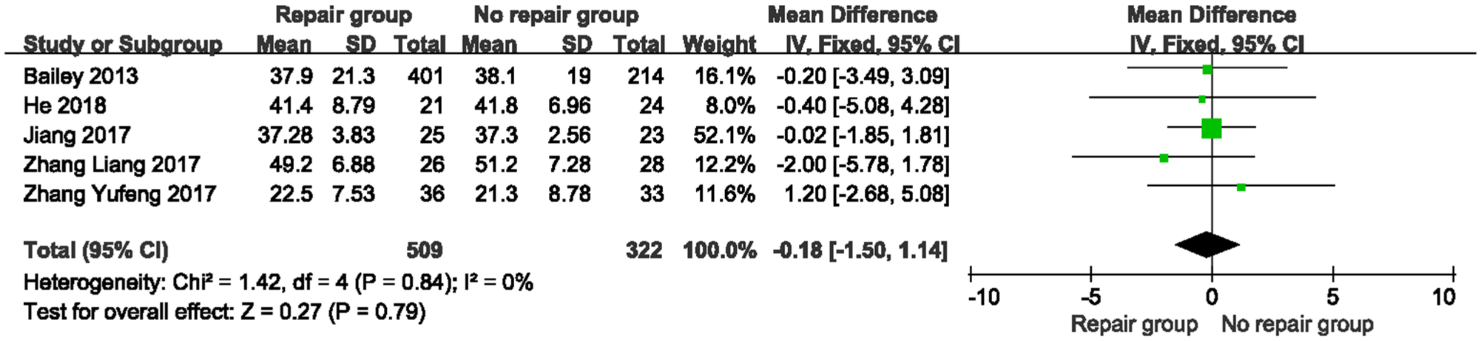

Figure 5

The forest plot for postoperative reduction of ODI between the two groups.

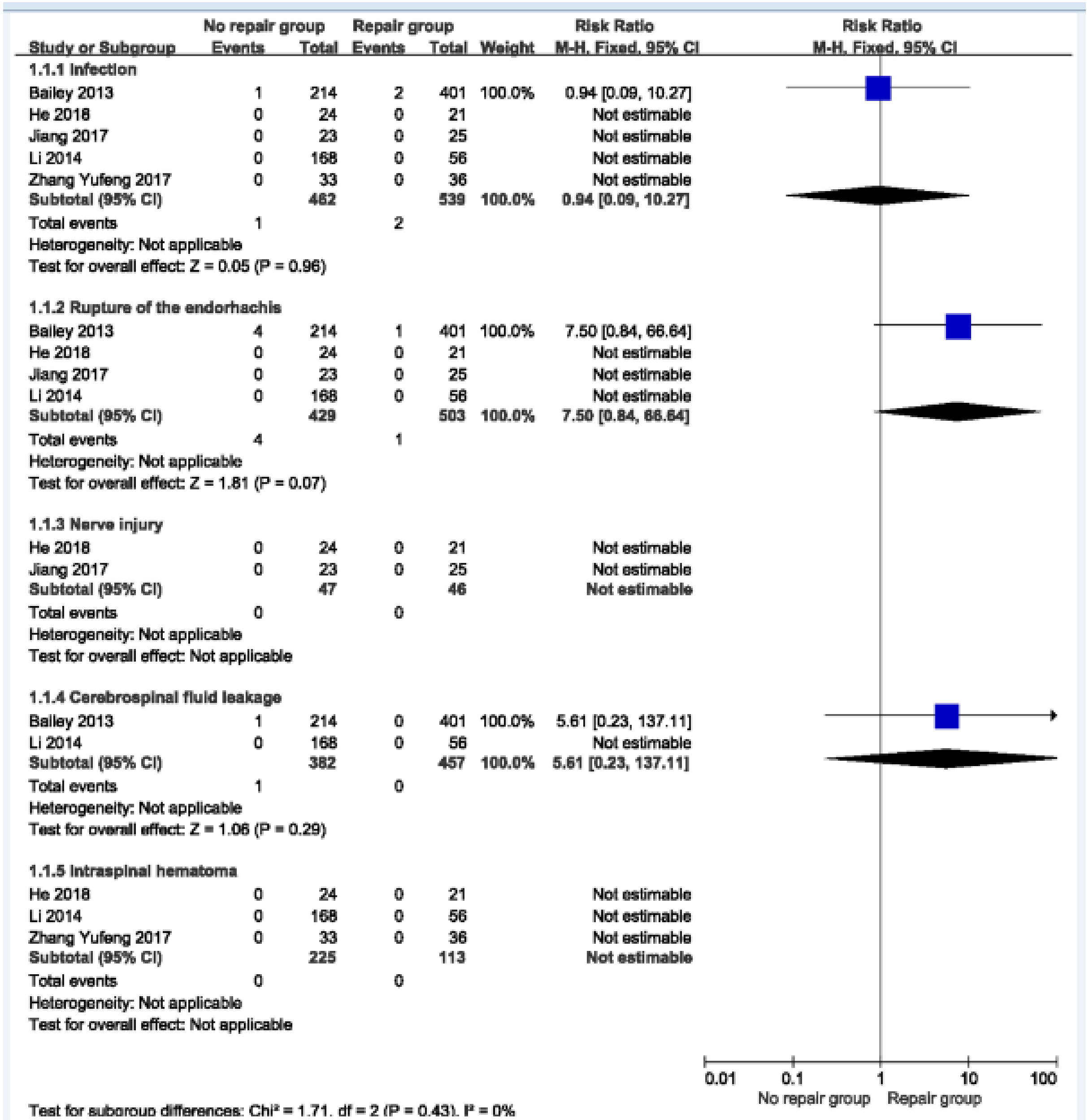

Figure 6

The forest plot for postoperative complications between the two groups.

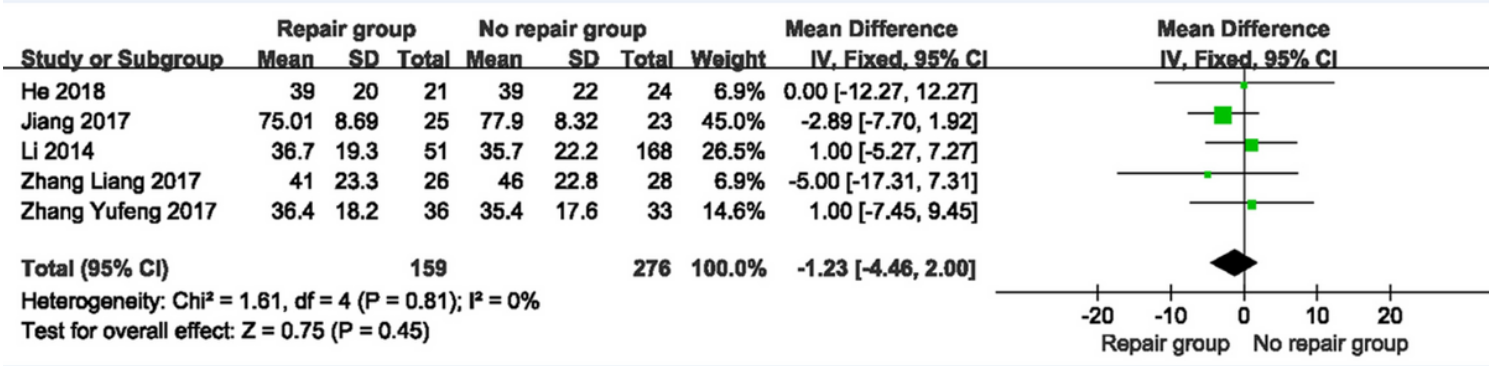

Figure 7

The forest plot for intraoperative blood loss (ml) between the two groups.

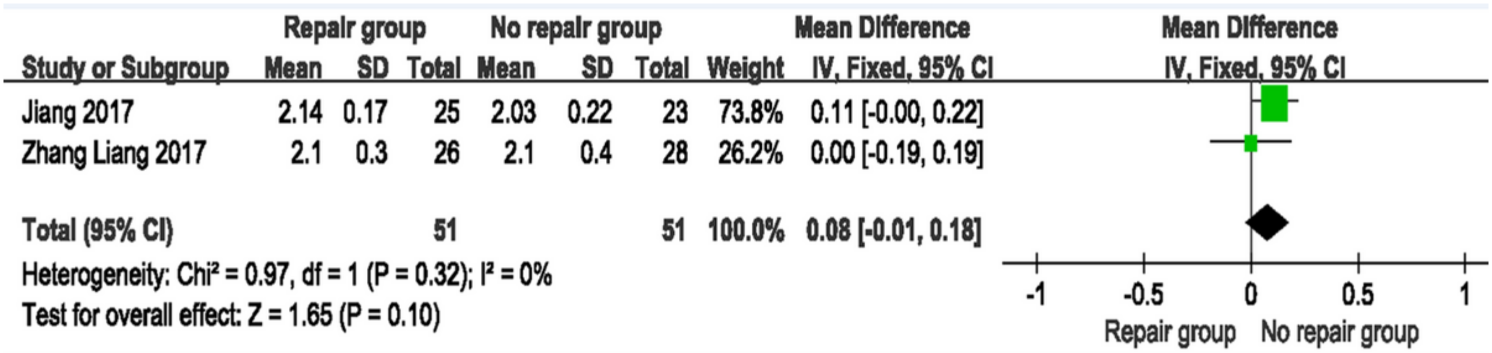

Figure 8

The forest plot for operative time (minutes) between the two groups.

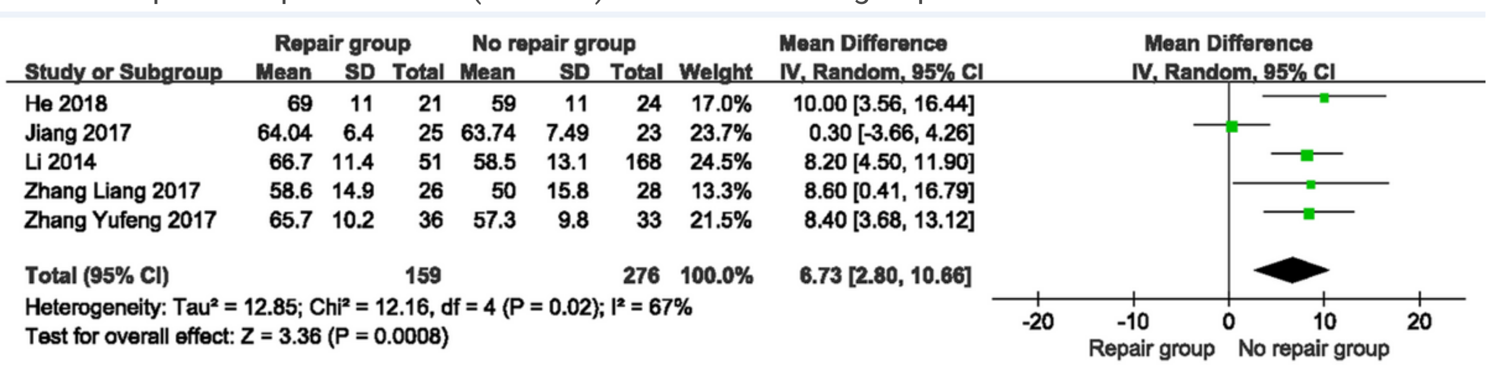

Figure 9

The forest plot for length of surgical incision (cm) between the two groups.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AppendixC.docx
- AppendixB.docx
- PRISMAchecklist.doc
- AppendixA.docx