Comparison of Outcomes in Discectomy with or without Annulus Fibrsous Repair for the Treatment of Lumbar Herniated Discs: A Systematic Review and Meta-Analysis

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Research Article

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Abstract

Objective

The aim of the study is to evaluate whether discectomy combined with annulus fibrosus repair to treat lumbar disc herniations is effective and investigate the implications of each annulus fibrosus repair method for clinical practice.

Methods

PRISMAP guidelines were followed in this review. PubMed, Embase, Cochrane, Web of Science databases and the reference list grey literature were searched for randomized controlled trials (RCTs), screened the studies according to inclusion criteria, and extracted the data and analyzed by Review Manage (version 5.4).

Results

10 RCTs with 2197 patients were included in this study. The results showed that the risk of post-operative reherniations (*RR: 0.42, 95%CI [0.30, 0.58], P < 0.00001*) and the risk of reherniation-related reoperations (*RR: 0.63, 95%CI [0.46, 0.87], P = 0.005*) were markedly lower in the discectomy with annulus fibrsous repair (DAFR) group compared with discectomy alone (DA) group. The two groups had no significant difference in ODI, VAS-back pain, VAS-leg pain, and SF-scale. The DAFR group had a longer operative time and a higher postoperative disc height than the control group. It was obtained by the subgroup analysis that the Barricaid repair method was more effective in reducing the risk of reherniations and the risk of reherniation-related reoperations compared with other repair methods relatively.

Conclusion

Discectomy with annulus fibrosus repair reduced the risk of reherniations and the risks of reherniation-related reoperations but could not reduce postoperative pain and improve overall health status better than discectomy alone. Discectomy with annulus fibrosus repair had a better ability to maintain disc height but had a longer operative time.

Introduction

Lumbar disc herniation (LDH) is considered to be one of the main causes of low back pain and leg pain[1]. 70% of the population will experience back pain in their lifetime, and before age 65, the prevalence of back pain rises with age. More than $100 billion is spent annually in the United States to treat low back pain[2, 3]. The intervertebral disc consists of three parts: the upper and lower cartilaginous endplates, the peripheral annulus fibrous, and the inner nucleus pulposus[4]. When the annulus fibrosus breaks due to various factors, the nucleus pulposus will be squeezed under pressure to form a protrusion and compress the nerve roots in the spinal canal[5]. If the protrusion occurs in the lumbar spine, symptoms such as lower back pain and leg pain could be produced. Most patients (66%) experienced complete relief within one year with a variety of conservative treatments, such as non-steroidal anti-inflammatory drugs (NSAIDs), acupuncture, and physiotherapy[6, 7]. However, the remaining patients experience no improvement or even worsening of symptoms after more than 6 months of conservative treatment[8, 9], at which point the surgeon will have to consider performing a discectomy for the patient.

Traditional discectomy only resects the nucleus pulposus protruding outside the annulus fibrosus without repairing the annulus fibrosus, and the reherniation rate after discectomy is reported to be between 3% and 18%[10]. The reason is that the defect in annulus fibrous only heals by scar tissue, which is a limited and slow self-healing process due to the lack of blood supply[11]. As a result, the annulus fibrosus can only form poor thin layers of fibrosus tissue by self-repairing[12], the

remaining nucleus pulposus in the disc after surgery is prone to protrude from the annulus fibrosus and cause reherniations[13]. Previous studies have shown a strong correlation between the risk of reherniations and the size of the annulus fibrosus defect, with the risk of reherniations increasing with larger annulus fibrosus defects[14]. The risks of reherniations and reoperations increase more markedly when the annulus fibrosus defect width reaches 6 mm or more[14]. Another type of resection is the removal of all or almost all of the nucleus pulposus, the disadvantages of this method are also significant, it has been shown that the degeneration of the spinal facet joint may be the result of excessive nucleus removal, and the degeneration of the spinal facet joint could accelerate the damage to the adjacent centrums[15]. Some studies have shown that limited nucleus pulposus removal results in better clinical outcomes and a lower risk of low back pain, but a higher risk of reherniations[16, 17]. Therefore, to avoid postoperative reherniations and reoperations, some scholars have suggested discectomy with annulus fibrosus repair[18]. In this way, not only can the pressure of the herniated disc on the nerves be relieved, but also the complications caused by the removal of too much nucleus pulposus can be avoided. However, Cauthen et al. reported that repair of the annulus fibrosus required enlarged resection of the lamina for suturing, thus increasing the incidence of complications such as low back pain in the patient postoperatively[17, 19, 20]. Therefore, the clinical efficacy of annulus fibrosus repair is still controversial.

The purpose of this study was to analyze the clinical outcomes and risk of reherniations of discectomy with or without annulus fibrosus repair for the treatment of lumbar disc herniations to evaluate whether discectomy combined with annulus fibrosus repair is effective. Comparisons were also made between the different methods of annulus fibrosus repair to explore the implications of each repair method for clinical practice.

Methods

Registration and Protocol

This systematic review and meta-analysis followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol and had been registered on the PROSPERO platform (Registration number is CRD42023460915, https://www.crd.york.ac.uk/PROSPERO/).

Data source

We systematically searched PubMed, Embase, Cochrane, Web of Science Database and the reference list grey literature for studies published from the date of creation to September 1st, 2023. Search terms were “lumber disc herniation”, “lumbar discectomy”, “annulus fibrsous repair”, “annular closure”, “reherniations”, and “recurrent herniation”, with related Medical Subject Heading. Search strategies were detailed in Supplemental Material 1.

Selection criteria and study design

Inclusion criteria were as follows: Patients required discectomy with or without fibrous annulus repair to therapy herniated discs; patients of any gender. Exclusion criteria were as follows: Patient’s age < 18 years; Repeated publications; non-clinical trials; review, systematic review, meta-analysis; follow-up time was less than six months; the contents of research were incomplete or the data was incomplete; studies reporting the same data; the full text was not available. Only randomized controlled trials (RCTs) published in Chinese or English could be included.

Outcomes

Two dichotomous variables (the risk of reherniations and the risk of reherniation-related reoperations); six continuous variables (operation time (in minutes)), post-operative visual analogue score of back pain (VAS-back pain), post-operative visual analogue score of leg pain (VAS-leg pain); post-operative Oswestry Disability Index (ODI); post-operative short-form health survey scale (SF scale); post-operative disc height (in millimeter);

Research screening and data extraction

Based on the above inclusion and exclusion criteria, two investigators (Zhao, and Cheng) searched the research separately. Endnote 20 was applied to sort out the retrieved research and eliminate the duplicate research preliminarily, the titles and abstracts were read to exclude irrelevant studies, and then the full text was read to identify the initial included studies. Finally, two investigators extracted the data from all eligible research. After completing these steps, results were exchanged and reviewed with each other, and if any disagreement was encountered, a third investigator would be arranged to participate in the discussion and consult on the inclusion.

Risk of bias

Two other researchers (Wang, and Huang) independently used Review Manager (RevMan, V.5.4, The Cochrane Collaboration, 2020)[21] to evaluate the quality of the included studies. In case of any disagreement, a third researcher will be assigned to participate in the discussion. The qualities of the included research were assessed strictly according tothe cochrane risk of bias assessment criteria (Cochrane RoB 2 tool)[22].

Statistical method

This meta-analysis was performed with RevMan 5.4. Risk ratio (RR) and 95% Confidence Interval (95% CI) were used for dichotomous variables; Standard Mean Difference (StdMD) and 95% CI were used to count different scales for continuous variables and Mean Difference (MD) and 95% CI were used to count the same scales for continuous variables. The heterogeneity of different studies was tested by the P-value of the Q-test and I^2-test. If $I^2 < 50\%$ and $P > 0.05$, the heterogeneity was suggested to be small, and a Fixed Effect model was used. If $I^2 > 50\%$ or $P < 0.05$, the heterogeneity was suggested to be large, and the reasons for heterogeneity would be analyzed by sensitivity analysis. Sensitivity analysis was performed by the one-to-one study exclusion, and if the source of heterogeneity could not be identified, the random effect model was used.

Publication bias

Limited by the number of included studies, no outcome was included in more than 10 studies, so publication bias could not be analyzed.

Result

Study selection and characteristics

According to the search strategy, a total of 130 studies were searched and 3 additional studies were added in from other sources. 57 duplicate studies were excluded; 42 studies were excluded by reading the titles and abstracts; 34 relevant studies were assessed by reading the full text. 18 non-randomized controlled trials and 6 studies reporting the same data were excluded, and 10 studies were finally included. Nine studies[23–31] were published in English and one study[32] was published in Chinese. All studies reported no differences in the basic conditions of the patients and preoperative outcomes to be researched between the two groups. The search process and results were shown in Fig. 1, and the characteristics of the studies were shown in Table 1.

Study quality and risk of bias

The quality of the included studies was assessed by the Cochrane risk of bias assessment criteria and the results were shown in Fig. 2.

Analysis results

The risk of reherniation

Six studies[23, 26, 27, 29, 30, 32] reported the risk of postoperative reherniations, and 897 patients were included. The result was (*RR: 0.42, 95%CI [0.30, 0.58], P < 0.00001*), and the heterogeneity test was $I^2 = 0\%, P = 0.47$. It was suggested that there was no heterogeneity between the studies, suggesting the result was stable, so a fixed effect was used for the analysis. The results showed that the DAFR group significantly reduced the occurrence of postoperative disc reherniations (Fig. 3).

The risk of reherniation-related reoperation

Six studies[23, 24, 27, 28, 30, 32] reported the risk of postoperative reoperations, and 1509 patients were included. The result was (*RR: 0.63, 95%CI [0.46, 0.87], P = 0.005*), and the heterogeneity test was $I^2 = 0\%, P = 0.61$. It was suggested that there was no heterogeneity between the studies, suggesting the result was stable, so a fixed effect was used for the analysis. The results showed that the DAFR group significantly reduced the occurrence of postoperative reherniation-related reoperations (Fig. 3).

Oswestry Disability Index (ODI)

Eight studies[23–26, 28–30, 32] reported the postoperative ODI, and 2117 patients were included. The heterogeneity test was $I^2 = 87\%, P < 0.00001$. It was suggested that there was heterogeneity between the studies, so a sensitivity analysis was performed. No significant data deviation and no source of heterogeneity were found, suggesting that the results were relatively stable with low sensitivity, so a random-effects model was used. The result was (*MD: -0.65, 95%CI [-2.34, 1.14], P = 0.48*). The results showed no difference in postoperative ODI between the two groups (Fig. 4).

Visual Analogue Score of back pain (VAS-back pain)

Eight studies[23–26, 28–30, 32] reported postoperative VAS-back pain, and 2067 patients were included. The heterogeneity test was $I^2 = 70\%, P = 0.001$. It was suggested that there was heterogeneity between the studies, so a sensitivity analysis was performed. The analysis revealed that a study reported by Li[28] had a greater effect on heterogeneity, and the heterogeneity test performed after excluding this study was $I^2 = 32\%, P = 0.19$, suggesting that there was no heterogeneity, so a fixed-effect model was used. The result was (*SMD: -0.06, 95%CI [-0.15, 0.02], P = 0.15*). The results showed no difference in postoperative VAS-back pain between the two groups (Fig. 4).

Visual Analogue Score of leg pain (VAS-leg pain)

Seven studies[23–26, 28–30] reported postoperative VAS-leg pain, and 2019 patients were included. The heterogeneity test was $I^2 = 82\%, P < 0.0001$. It was suggested that there was heterogeneity between the studies, so a sensitivity analysis was performed. The analysis revealed that a study reported by Li[28] had a greater effect on heterogeneity, and the heterogeneity test performed after excluding this study was $I^2 = 0\%, P = 0.42$, suggesting that there was no heterogeneity, so a fixed-effect model was used. The result was (*SMD: -0.06, 95%CI [-0.15, 0.03], P = 0.18*). The results showed no difference in postoperative VAS-leg pain between the two groups (Fig. 4).

Operation time

Five studies[25, 26, 29, 31, 32] reported the operation time, and 736 patients were included. The heterogeneity test was $I^2 = 94\%, P < 0.00001$. It was suggested that there was heterogeneity between the studies, so a sensitivity analysis was performed. No significant data deviation and no source of heterogeneity were found, suggesting that the results were

relatively stable with low sensitivity, so a random-effects model was used. The result was (*MD: 11.66, 95%CI [2.77, 20.55], P = 0.01*). The results showed that the DAFR group increased the operation time (Fig. 5).

Short-form health survey scale (SF-scale) and Disc height

Three studies[24, 26, 29] reported the postoperative SF scale, and 892 patients were included. The result was (*SMD: -0.05, 95%CI [0.19, 0.08], P = 0.45*), and the heterogeneity test was $I^2 = 0\%, P = 0.55$. Two studies[26, 29] reported postoperative Disc height, and 165 patients were included. The result was (*MD: 0.95, 95%CI [0.53, 1.38], P < 0.00001*), and the heterogeneity test was $I^2 = 0\%, P = 0.37$. It was suggested that there was no heterogeneity between the studies, so a fixed effect was used for the analysis. The results showed no difference in the postoperative SF scale between the two groups, while the disc height of the DAFR group was higher (Fig. 5).

The subgroup of the risk of reherniations and reherniation-related reoperations based on different annular fibrosus repair methods.

Three repair methods were included in the reherniation subgroup, and four repair methods were included in the reoperation subgroup. The analyses showed that the results of the Barricaid repair method were statistically significant (*P < 0.0001*), whereas the other repair methods did not (Annular Stapler (*P = 0.05*), Amniotic Membrane (*P = 0.19*) in the subgroup-reherniations. The subgroup-reherniation-related reoperations showed similar results (Barricaid (*P < 0.01*), Amniotic Membrane (*P = 0.19*), Annular Stapler (*P = 0.19*), Xclose (*P = 0.5*)). The results showed that the Barricaid repair method was more effective in reducing the risk of reherniations and the risk of reherniation-related reoperations (Fig. 6).

Discussion

In the published meta-analyses, a maximum of 6 RCTs were included[33] and some studies[34, 35] included only 2 RCTs. Furthermore, we found that different studies published with duplicate data were included in previous meta-analyses[33], which would undoubtedly make the results of the meta-analysis inaccurate and cause the results to be less credible. Compared with previously published studies, this meta-analysis increased the searched databases and used more comprehensive search terms for the search. In the end, a total of 10 RCTs of high quality were screened. Meanwhile, we performed the subgroup of the risk of reherniations and reherniation-related reoperations based on different annular fibrosus repair methods and concluded that the repair method of Barricaid was currently the most reliable repair method, which will provide indications to clinical practitioners.

The results showed that patients in the discectomy with annulus fibrsous repair (DAFR) group had 0.42 times the risk of reherniation and 0.63 times the risk of reherniation-related reoperations within 2 years after surgery. It was suggested that discectomy with annulus fibrosus repair could effectively reduce the risk of postoperative reherniations and reherniation-related reoperations. Previously, patients with annulus fibrosus defects greater than 6 mm in width or defect dimensions greater than 54 mm^2 had a higher risk of reherniations[36]. For these patients with discectomy, the surgeon would remove as much nucleus pulposus tissue as possible to avoid postoperative reherniations. However, the disadvantages of this approach were also obvious, which undoubtedly destroyed the physiology of the disc and aggravated the patient's back pain in the long run[37]. Whereas discectomy with DAFR permitted the preservation of more nucleus pulposus tissue for patients[38]. However, not all patients require DAFR. Studies reported that it was unnecessary for patients with annulus fibrosus defects less than 5 mm in width or defect dimensions less than 36 mm^2 to require DAFR because of the low likelihood of reherniations[39]. Moreover, there were some conditions for the use of repair methods. In the case of Barricaid (Intrinsic Therapeutics, Inc., Woburn, MA, USA), the height of the intervertebral disc must be greater than 5 mm to have enough space to create conditions for repairing the annulus fibrosus[40]. On top of that, DAFR could potentially reduce the costs of healthcare because reoperation was more expensive compared to primary surgery[10]. Studies had shown that primary surgery was more expensive in the DAFR group but reduced the incidence of postoperative complications, the use of

medications, and the cost of reoperation. Treatment of reherniation was reported to cost an average of $26,593 per patient, and reherniation-related reoperations cost an average of $39,836 per patient[10]. DAFR reduced the risk of reherniations and reherniation-related reoperations, thereby reducing overall health care costs. However, these conclusions above were limited within two years of postoperative follow-up, and we cannot extrapolate from existing RCTs to judge whether DAFR will continue to have these superiorities over a 5- or even 10-year follow-up period. Therefore, we suggested that the effects of DAFR should continue to be investigated in subsequent studies to explore its long-term therapeutic efficacy.

The Oswestry Disability Index (ODI) score was one of the most important measures for evaluating and measuring functional disability-related disorders associated with back pain[41, 42]. The ODI score evaluated the patient's pain, ambulation, sleep, and social activities, with lower scores indicating lower levels of pain[43]. The Visual Analogue Score (VAS) score was used as one of the common measures of pain level, with lower scores indicating less subjective pain perception[44]. For the two outcome indicators, VAS-back pain and VAS-leg pain, several studies used a 0–10 scale, and several studies used a 100 scale, so we standardized the results using StdMD before analyzing. The SF-scale was currently available in two frequently used scales, the SF-36 and the SF-12, which was a simplified version of the SF-36 scale[45]. The SF-scale was a measure of general health, an assessment of a patient's overall health status that was not specific to a particular disease, with higher scores indicating better general conditions[45–47]. The results of the analysis of the four outcome indicators, ODI score, VAS-back pain, VAS-leg pain, and SF-scale, did not show statistical significance ($p > 0.05$), suggesting that discectomy with DAFR could achieve the same good results as discectomy alone in terms of in reducing postoperative pain and improving overall health status, but could not achieve a better improvement. In a non-randomized controlled trial reported[36] by S. L. Parker, patients who underwent DAFR had lower VAS scores because the DAFR effectively maintained disc volume and disc height, allowing for an increase in foramen size, which reduced nerve root compression. However, the results of the meta-analysis were inconsistent with it. We supposed that this may be because the material used to repair was to some extent a xenobiotic that could act as a repair while also irritating the nerve root or the dural sac to some extent. Thus, the ability of ARF could achieve better improvements in clinic outcomes remained questionable.

Operative time in the DAFR group was on average 11.66 minutes longer than the control group, and there was strong heterogeneity in this outcome ($I^2 = 94\%, P < 0.00001$). By comparing the results of the included studies, we found that there was a large variation in different repair methods, with the Xclose[31] method having the shortest time and the Barricaid[26] method having the longest time. We also found a large variation in the time of the same repair method[25, 26], suggesting that the DAFR technique was in a learning phase. However, the technique was highly learnable and after a certain number of operations had been accumulated, the operating time would decrease. The results suggested that DAFR helped to better maintain the disc height. The reason for this was that DAFR effectively closed the annulus fibrosus defect, returning the pressure within the disc to normal and reducing the risk of the nucleus pulposus tissue being squeezed out of the disc. Therefore, the physician was allowed to remove less nucleus pulposus tissue in discectomy[16]. It has been reported that the removal of a larger volume of nucleus pulposus in discectomy was an important factor affecting the decrease in disc height and quality of life. In addition, maintenance of disc height had been associated with a reduced risk of reherniations and also contributed to the stability of the lumbar spine and a reduction in degeneration of the spinal facet joint[48].

In this meta-analysis, subgroup analyses of the risk of reherniations and the risk of reherniation-related reoperations with different repair methods were performed by combining the results of studies with the same repair method. The results showed that in the subgroup analyses, there was no statistical significance for the methods except Barricaid. Therefore, with the available RCTs, we could not conclude that the other repair methods have a definite therapeutic effect at this time. Barricaid consisted of a titanium anchor implanted in the vertebrae and a flexible polyester mesh[49]. The mesh polymer covered the annulus fibrosus gap and prevented the nucleus pulposus from being extruded and forming a recurrent herniation. Some studies had reported that Barricaid led to an increased incidence of cartilage endplate changes (EPC)[30, 50]. Biomechanically, the endplates act as shock absorbers, and they were one of the most important pathways for providing nutrients to the intervertebral discs, and the normal function of the nucleus pulposus cells was dependent on the functional integrity of the cartilaginous endplate cells[51]. However, Adisa Kursumovic et al. reported that during a follow-up

period of up to two years, no evidence was found to suggest that changes in EPC negatively affected clinical outcomes in patients implanted with Barricaid, although the incidence of EPC was higher[50]. Thus, longer follow-up may be needed to determine the impact of the change in cartilage endplate on the patients with DAFR. In the subgroup of postoperative reherniations, the P-value of the T-test of Annular Stapler (2020 Medical Technology Company, Beijing, China) repair method was 0.05, which can be considered statistically significant to a certain extent, but we supposed that the therapeutic efficacy of this method still needed to be determined by more RCTs to increase the sample size. In Anderson's study[23], they used discectomy with cryopreserved amniotic membrane to repair annulus fibrosus defects, which was a very meaningful attempt, although the results were not statistically significant. Repair of annulus fibrosus defects by bioremediation methods was still undesirable, but there was a huge scope for research and development in the future. Through repairing the annulus fibrosus with these mechanical methods, the annulus fibrosus could only grow slowly through scar tissue, and the intervertebral discs would not return to normal[52]. Through bioremediation method, cells with regenerative therapeutic properties and scaffolds could be combined and implanted into the damaged area of the annulus fibrosus to promote regeneration of annulus fibrosus[53].

There were some limitations to this meta-analysis: (1) The number of included studies and the total number of samples need to be further increased, and some of the included studies contained small sample sizes. (2) Although the types of included studies were all RCTs, most of the articles were not blinded, so the results may be influenced by subjective factors. (3) Publication bias could not be performed due to limitations in the number of studies; therefore, publication bias may exist.

Conclusion

Discectomy with annulus fibrosus repair decreased the risk of reherniations and the risk of reherniation-related reoperations and facilitated the maintenance of disc height. Annulus fibrosus repair could not reduce postoperative pain and improve overall health status better than discectomy alone, and the operative time was longer.

Declarations

Ethics approval and consent to participate

This declaration is not applicable.

Consent for publication

Not applicable.

Competing interests

There exists no conflict of interest.

Authors' contributions

Yize Zhao wrote the main manuscript text. Yize Zhao and Qian Cheng extracted and analyzed the data. Zhe Wang and Yong Huang prepared Figures and Tables. Ganjun Feng, Limin Liu and Yueming Song designed the materials and methods. All authors participated in data analysis, summary and discussion. All authors reviewed the manuscript.

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Availability of data and materials

All data generated or analysed during this study are included in this published article and its supplementary information files and all data and materials in this article were available.

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Table 1

Table.1 characteristics of studies; annulus fibrosus repair group (AFR group); control group (CG)

1st Author	Published year	Study design	Repair method	Sample size		Gender (Male/female)		Mean age	
				AFR	CG	AFR	CG	AFR	CG
Baile	2013	RCT	Xclose	478	249	284/194	140/109	42.4±11.3	79.5±2.6
Kursumovic	2014	RCT	Barricaid	27	23	/	/	/	/
Xu	2021	RCT	Xclose	15	15	11/4	9/6	41±9.7	42±11.5
Ren	2020	RCT	Annular Stapler	51	54	/	/	42.0±11.6	45.6±12.2
Thome	2018	RCT	Barricaid	276	278	156/120	171/107	43±11	44±10
Anderson	2017	RCT	Amniotic Membrane	40	40	12/18	20/20	44.3±13.1	47.2±9.1
Li	2021	RCT	Annular Stapler	25	25	/	/	/	/
Barth	2018	RCT	Barricaid	242	251	142/100	154/97	42.9±10.7	44±10.5
Cho	2019	RCT	Barricaid	30	30	20/10	25/5	41.37±10.86	42.63±11.51
Jiang	2017	RCT	Annular Stapler	25	23	12/13	11/12	48.68±6.00	49.91±7.01

Figures

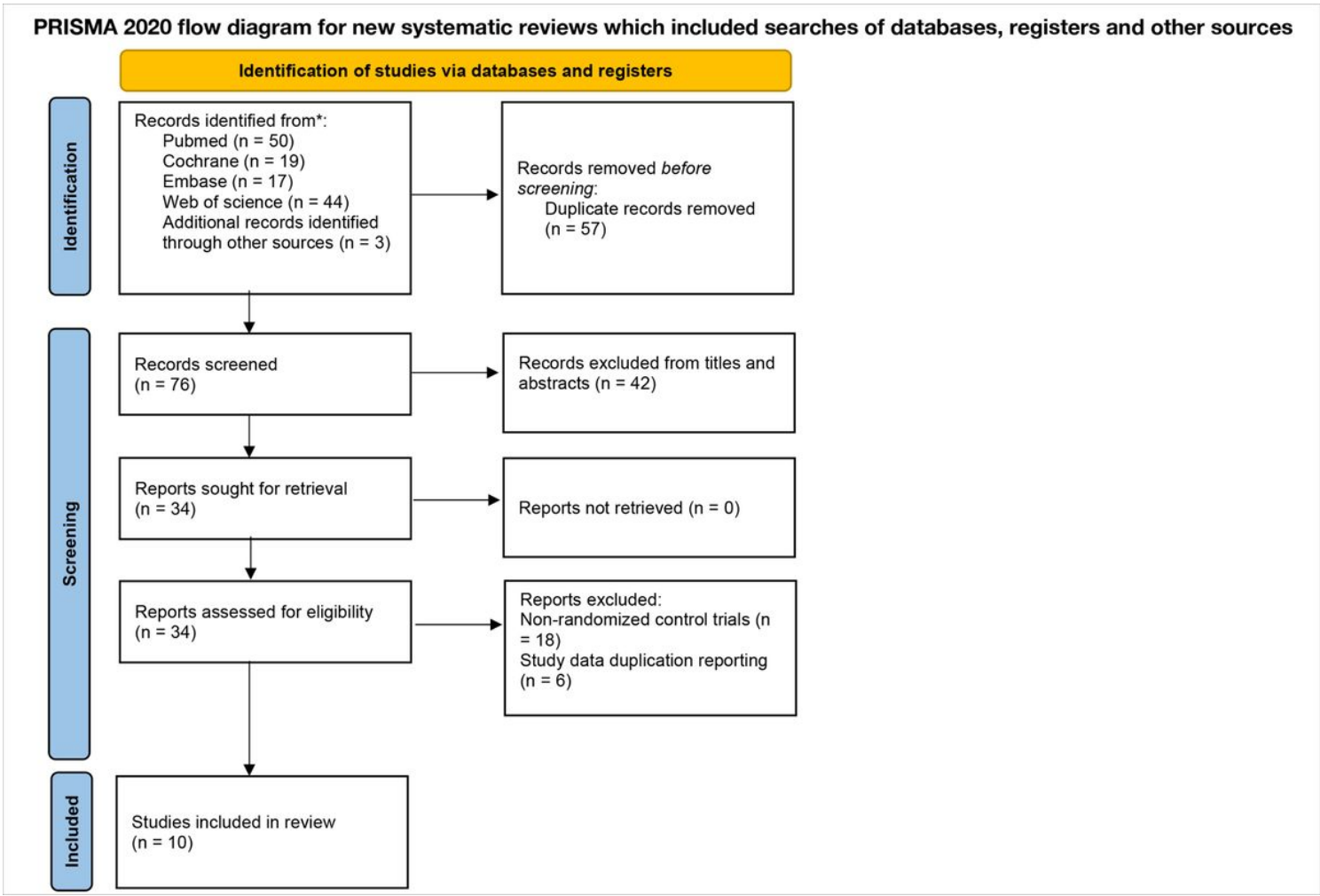

Figure 1

Flow diagram

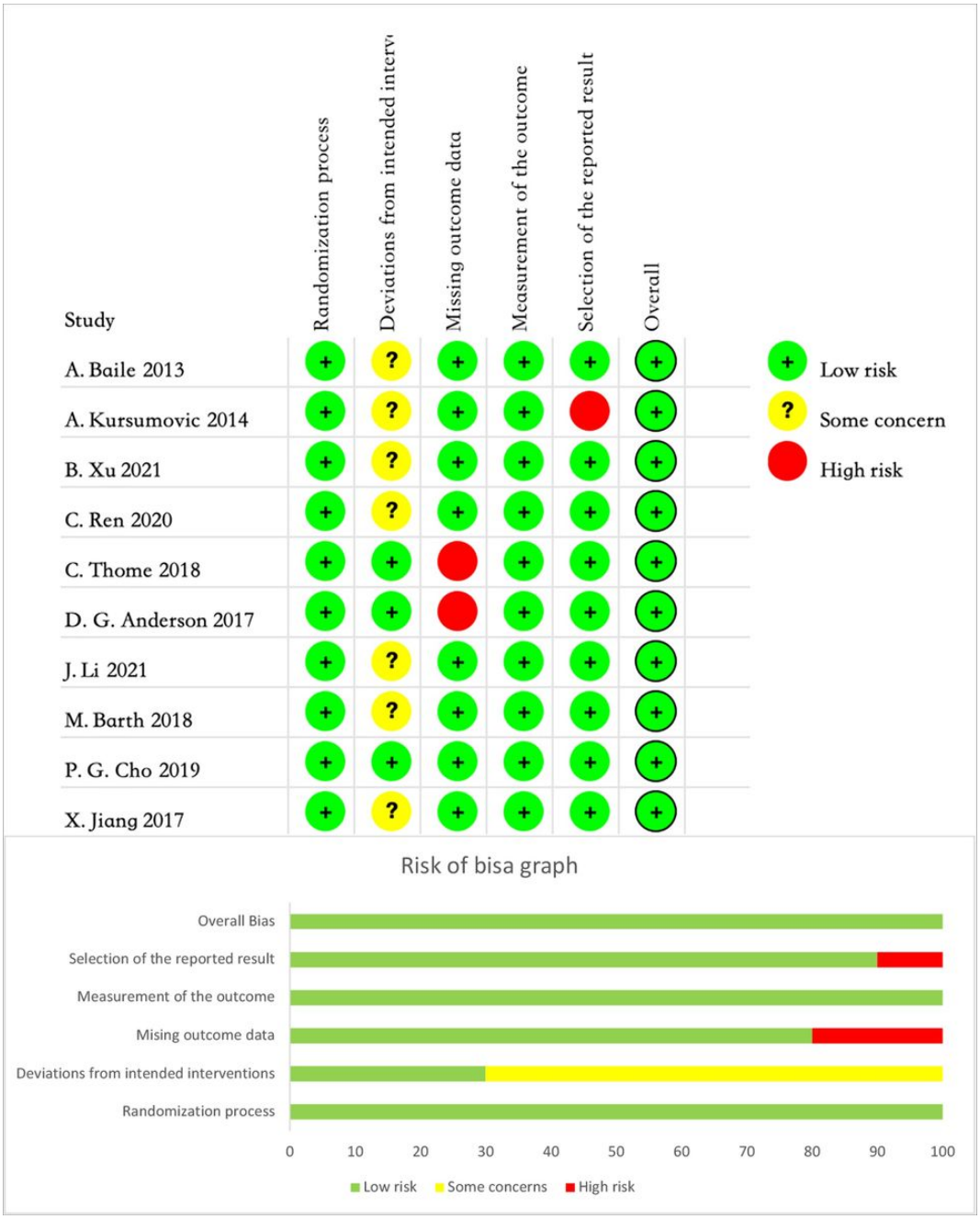

Figure 2

Risk of bias graph and Risk of bias summary

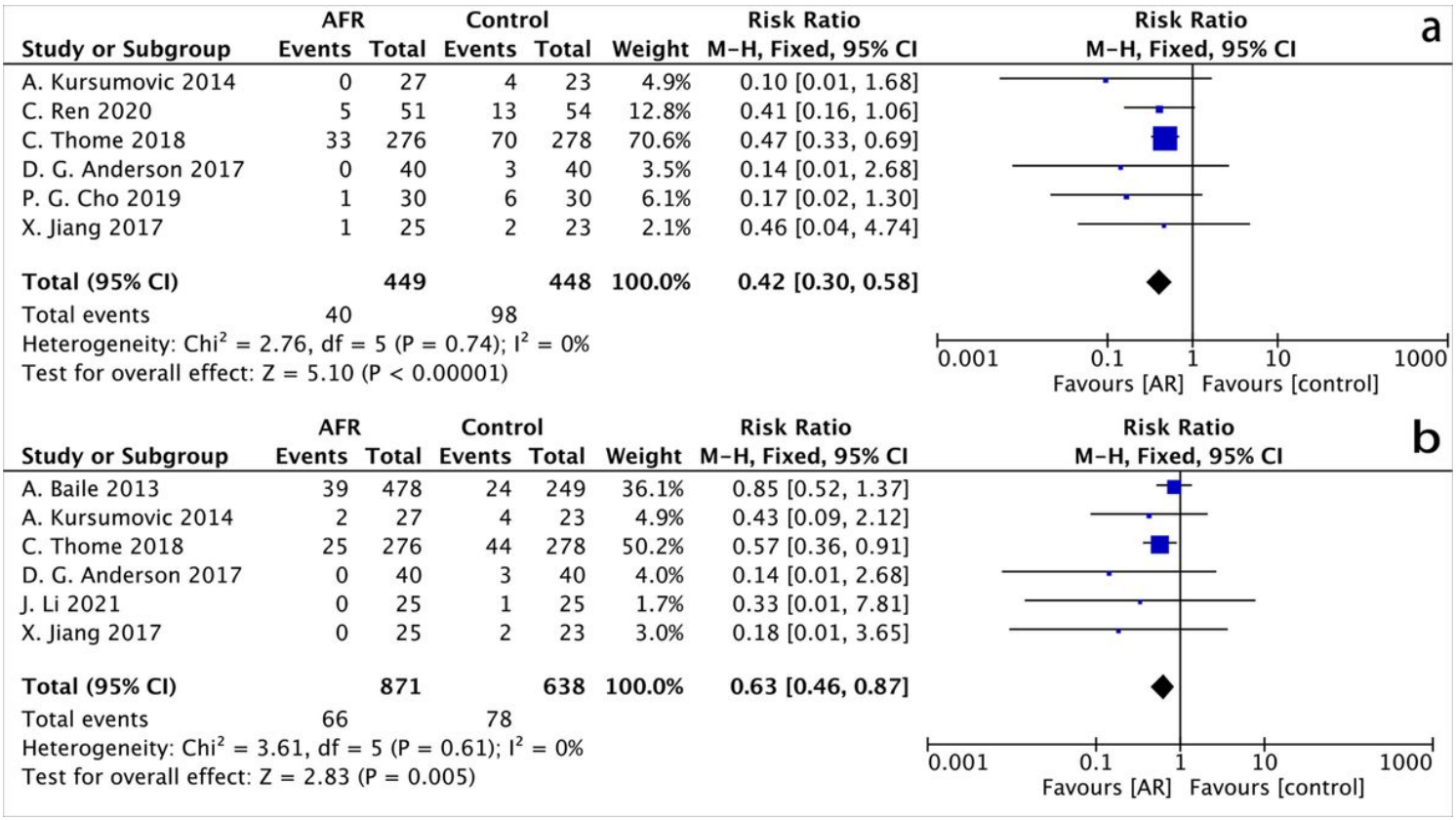

Figure 3

Reherniation (a) and Reherniation-related reoperation (b)

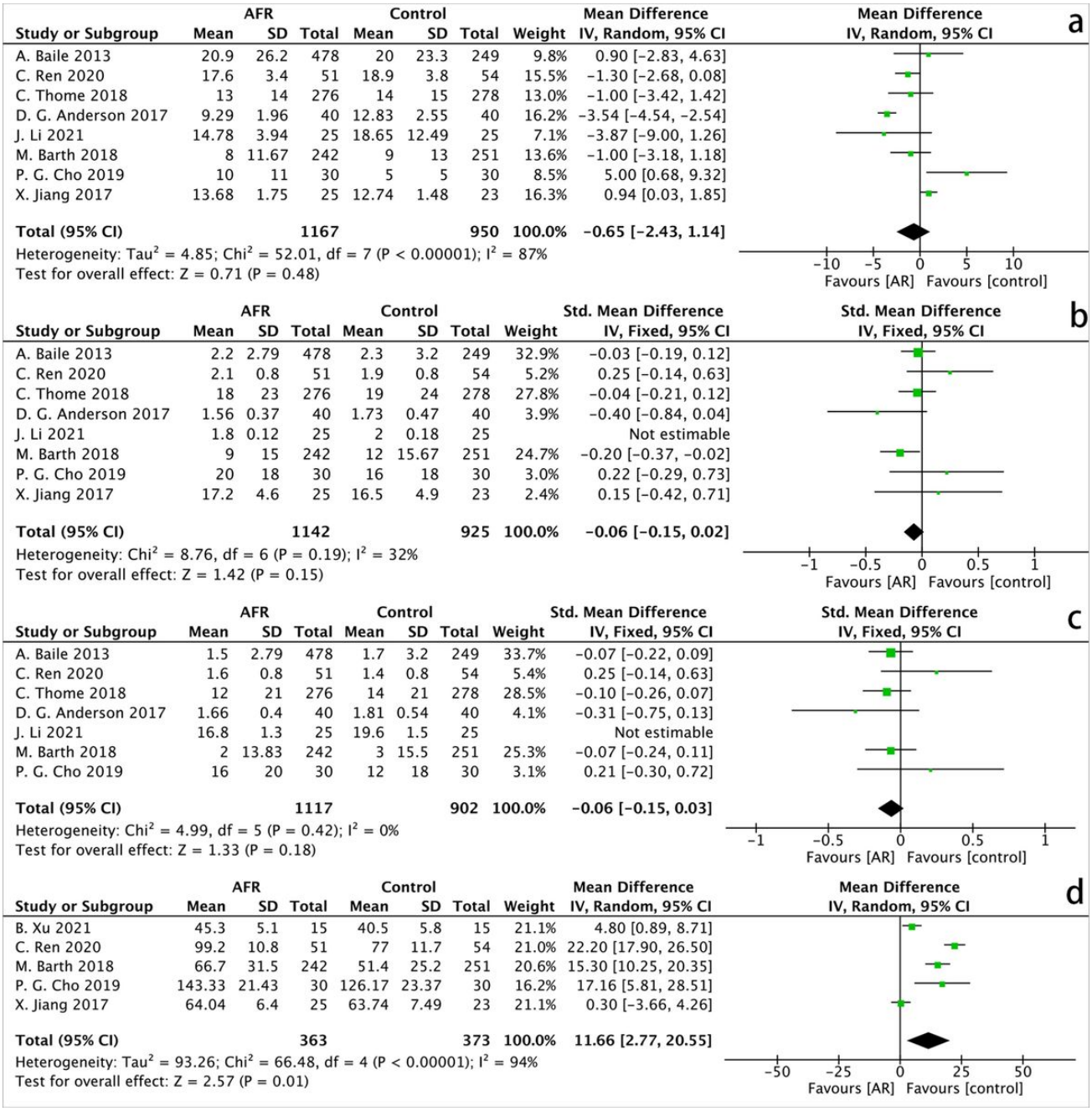

Figure 4

ODI (a); VAS-back pain (b); VAS-leg pain (c); Operation time (d)

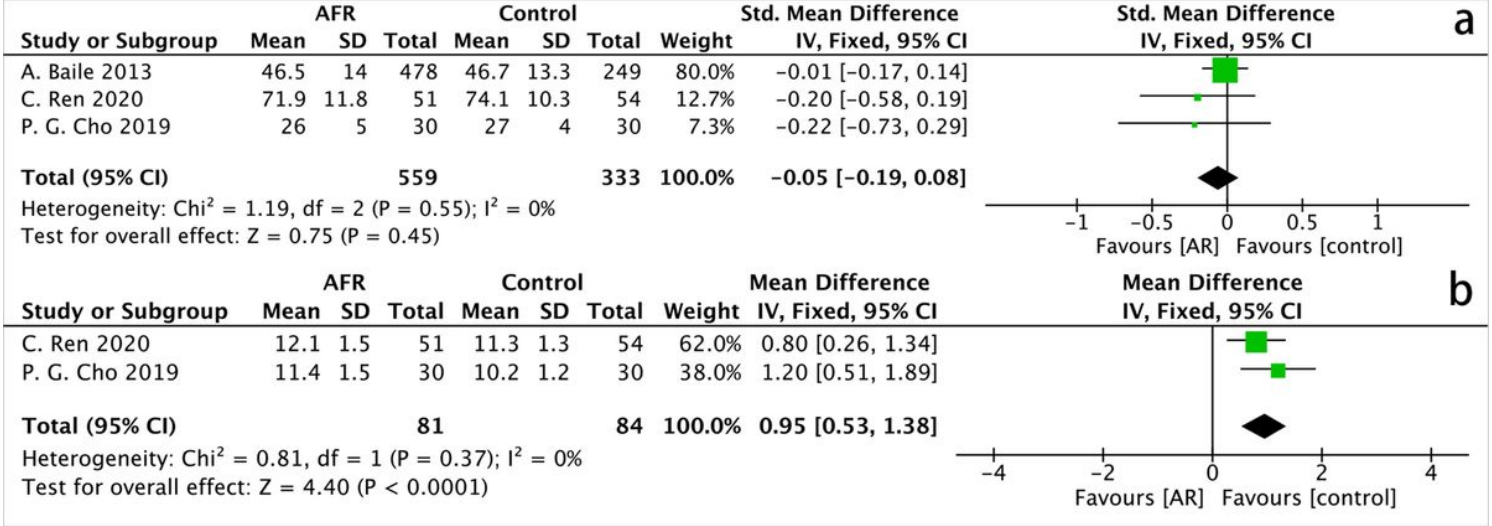

Figure 5

SF-scale (a) and Disc height (b)

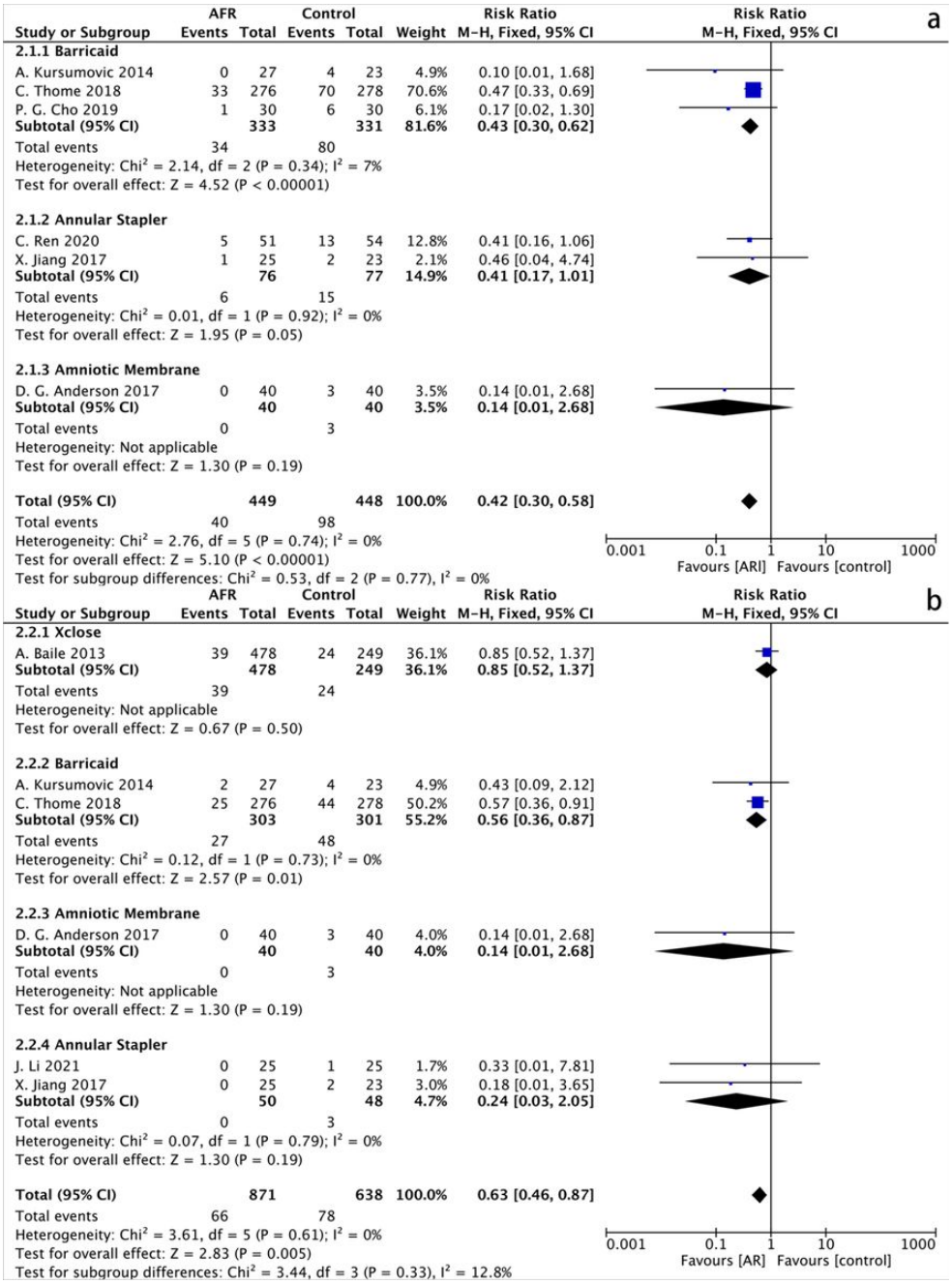

Figure 6

The subgroup of the risk of reherniations (a) and reherniation-related reoperations (b) based on different annular fibrosus repair methods

Supplementary Files

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