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Original Article

Which is the most effective treatment for lumbar spinal stenosis: Decompression, fusion, or interspinous process device? A Bayesian network meta-analysis

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SUMMARY

Objective: To compare the clinical efficacy, complications, and reoperation rates among three major treatments for lumbar spinal stenosis (LSS): decompression, fusion, and interspinous process device (IPD), using a Bayesian network meta-analysis.

Materials and methods: Databases including Pubmed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science were used for the literature search. Randomized Controlled Trials (RCTs) with three treatment methods were reviewed and included in the study. R software (version 3.6.0), Stata (version 14.0), and Review Manager (version 5.3) were used to perform data analysis.

Results: A total of 10 RCTs involving 1254 patients were enrolled in the present study and each study met an acceptable quality according to our quality assessment described later. In direct comparison, IPD exhibited a higher incidence of reoperation than fusion (OR = 2.93, CI: 1.07–8.02). In indirect comparison, the rank of VAS leg (from best to worst) was as follows: IPD (64%) > decompression (25%) > fusion (11%), and the rank of ODI (from best to worst) was: IPD (84%) > fusion (13%) > decompression (4%). IPD had the lowest incidence of complications; the rank of complications (from best to worst) was: IPD (60%) > decompression (27%) > fusion (14%). However, for the rank of reoperation, fusion showed the best results (from best to worst): fusion (79%) > decompression (20%) > IPD (1%). Consistency tests at global and local level showed satisfactory results and heterogeneity tests using loop text indicated a favorable stability.

Conclusion: The present study preliminarily indicates that non-fusion methods including decompression and IPD are optimal choices for treating LSS, which achieves favorable clinical outcomes. IPD exhibits a low incidence of complications, but its high rate of reoperation should be treated with caution.

The translational potential of this article: For the treatment of LSS, several procedures including decompression, fusion, and IPD have been reported. However, each method has its own advantages and disadvantages. To date, the golden standard treatment for LSS is still controversial. In this network meta-analysis, our results demonstrate that both decompression and IPD obtain satisfactory clinical effects for LSS. IPD is accompanied with a low incidence of complications, however, its high rate of reoperation should be acknowledged with discretion.

Introduction

Lumbar spinal stenosis (LSS) is a common degenerative disease in elders and often requires surgery to relieve symptoms when conservative treatments fail. In the past, the standard procedure for treating LSS was open decompression and fusion [1]. Most patients achieve satisfactory

Abbreviations: LSS, lumbar spinal stenosis; IPD, interspinous process device; VAS, visual analogue scale; ODI, oswestry disability index.

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effects due to adequate decompression. However, because of its impairment to soft tissue, fusion surgery has been associated with a high rate of complications such as bleeding, soft tissue impairment, mortality, and adjacent segment degeneration (ASD) [2].

With the rapid development of minimal surgery, most surgeons propose that decompression alone without fusion may be a feasible method to treat LSS [3]. Prior studies have indicated its favorable effects on improving painful symptoms [4]. Additionally, most decompression-alone surgeries are performed via a minimally invasive channel, which decreases the damage to muscles and bone structure [5]. Nevertheless, decompression alone has its disadvantages, such as insufficient decompression of spinal stenosis and subsequent spondylolisthesis caused by spinal instability [6].

In the past two decades, interspinous process devices (IPD) such as Coflex, X-Stop, and DIAM are designed and applied for LSS. Such posterior segmental distractions obtain symptom improvement by indirect decompression of neural structures [7]. LSS related symptoms, including neurogenic claudication, can be alleviated by limiting lumbar extension mechanically and enlarging the spinal canal by increasing flexion [8]. Compared with the two procedures mentioned above, IPD is reported to have less invasive destruction and lower rates of complications that may make it more suitable for older population [9].

In summary, the optimal procedure for the treatment of LSS is still unclear. The purpose of this study is to compare the clinical outcomes, complications, and reoperation rate among three common surgical methods by performing a network meta-analysis.

Material and methods

Study design

The present study was conducted using Bayesian model for network meta-analysis and complied with the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) and PRISMA extension statement for incorporating a network meta-analysis [10,11]. No patients were involved in this study, thus Ethical approval and informed consent were not required.

Eligibility criteria

Studies were included in this network meta-analysis if they met the criteria as follows: (1) randomized controlled trials (RCTs); (2) patients diagnosed as single or multiple lumbar spinal stenosis; (3) patients underwent surgical treatment including fusion, decompression, or IPD; (4) comparison among two or three treatments with each other; (5) consisted of interested outcomes (VAS of back, VAS of leg, ODI, complications, and reoperation rate).

Studies were excluded from this network meta-analysis when they conformed to the following criteria: (1) case reports, abstracts, or meeting paper; (2) patients received previous surgeries; (3) published by the same authors or from the same project; (4) lack of adequate follow-up duration (less than 12 months).

Search strategy

Pubmed, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science were used to search for articles published before April 2019. The keywords and Mesh terms for retrieval were: “lumbar spinal stenosis”, “fusion”, “decompression”, “‘interspinous distraction’ or ‘interspinous device’ or ‘dynamic device’”. The additional studies from the reference list of the identified studies were also viewed. The language of included studies was restricted to English. Two researchers (Y Z and W J) examined the studies independently and conflicts of opinions were discussed and resolved with the help of the third investigator (H Y).

Quality assessment

According to the Cochrane Risk of Bias Tool, the risks of bias of each study were reviewed and evaluated. The content of the assessment included selection bias (random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcomes assessment), attrition bias (incomplete outcome data), reporting bias (selective reporting) and other bias. Each item was regarded as “low risk”, “unclear risk”, and “high risk” based on the evaluation criterion.

Data extraction

Information from the original articles were extracted by two researchers (Y Z and W J), which included study characteristics (authors, design, sample size, gender, age, intervention of treatment, and follow-up). Outcome measures such as VAS of back, VAS of leg, ODI, complications, and rate of reoperation were collected from each study for calculating.

Statistical analysis

The statistical analysis of the present study was performed with R software (version 3.6.0), Stata (version 14.0), and Review Manager (version 5.3). On the first step, we performed regular pairwise meta-analysis under random effects. OR with 95% CI will be applied for dichotomous variables, while Mean difference (MD) with 95% CI will be estimated for continuous outcomes. On the second step, Bayesian random effects model was conducted to incorporate the estimates of direct and indirect treatment comparisons and rank the interventions in order. Then, the Markov Chains Monte Carlo (MCMC) method was applied to calculate the results using WinBUGS (version 1.4.3) based on R software. The rank of interventions from each outcome was performed through the consistency model that is based on 100,000 iterations for each three MCMC chains with a burn-in period of the initial 50,000 iterations. Global consistency was estimated by inconsistency model in STATA. Node-splitting method was used to assess the local inconsistency by comparing the direct evidence with the indirect evidence. Heterogeneity of each study was evaluated based on the closed loop test with $p > 0.05$ indicating a substantial heterogeneity. According to the rank order of the treatment method in each iteration of the Markov chain, each outcome was assessed with the probability of which is the best (superior to all other interventions), second best, and third best.

Results

Study characteristics

A total of 1363 studies from searching databases and 79 studies from other sources were searched at first. After elimination of duplicated studies, 158 studies were screened for title and abstracts. Then, 110 studies were excluded for one or more of the following reasons: not RCT, abstract, animal or meeting studies; 48 remained for full text reviewing. Next, 38 articles were eliminated for one or more of the following reasons: lack of comparative data, short follow-up, and insufficient sample size. Ultimately, 10 studies [12–21] were enrolled in this network meta-analysis (Fig. 1). Among these studies, 1254 patients with mean follow-up of 34.8 months were analyzed. All 10 RCTs published between 2010 and 2016 were conducted as direct comparison between one and the other treatment: IPD versus Fusion (2 studies), Fusion versus Decompression (3 studies), and IPD versus Decompression (5 studies). Demographic data including gender, age, and follow-up were parallel in

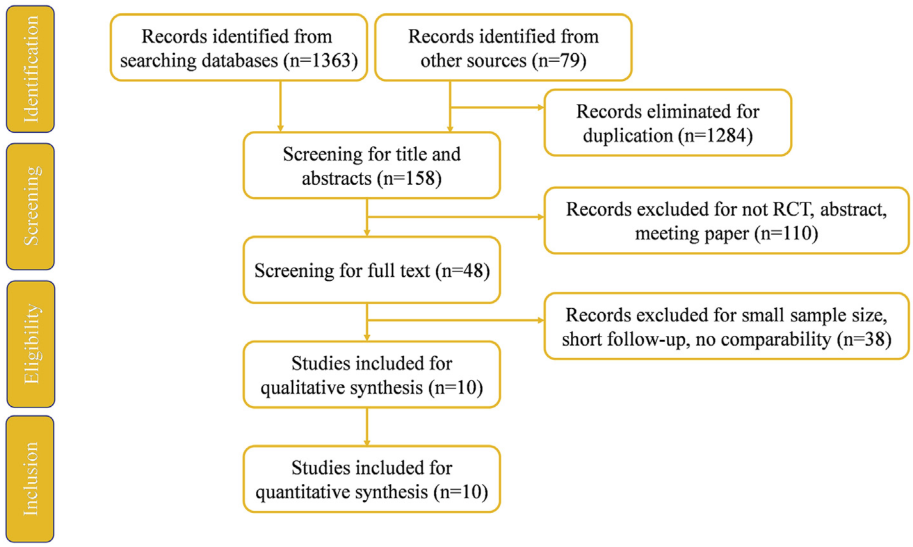

Fig. 1. The flow gram of the searching of identified studies.

Table 1
Characteristics of the identified studies in network-meta analysis.

Study	Year	Design	Groups	Sample size	Gender (male %)	Age (Mean ± SD, mean and range)	Follow-up
Azzazi et al.	2010	RCT	IPD (X-stop)	30	36.7	56.3 (27–79)	24 months
			Fusion	30	26.7	57.0 (82–78)	
Cabak et al.	2014	RCT	Fusion	50	Not available	57.74 ± 9.22	120 months
			Decompression	50	Not available	51.28 ± 12.08	
Davis et al.	2013	RCT	IPD (Coflex)	215	Not available	62.1 (41–81)	24 months
			Fusion	107	Not available	64.1 (41–82)	
Forsth et al.	2016	RCT	Fusion	111	37.8	67	24 months
			Decompression	117	29.1	66	
Galarza et al.	2014	RCT	IPD (DIAM)	45	51.1	38.5	24 months
			Decompression	47	46.8	42.5	
Ghogawala et al.	2016	RCT	Fusion	31	16.1	66.7 ± 7.2	48 months
			Decompression	35	22.9	66.5 ± 8.0	
Lonne et al.	2015	RCT	IPD (X-stop)	40	42.5	67 ± 8.8	24 months
			Decompression	41	63.4	67 ± 8.7	
Moojen et al.	2015	RCT	IPD (distraXion)	70	62.9	66 (45–83)	24 months
			Decompression	75	46.7	64 (47–83)	
Richter et al.	2010	RCT	IPD (Conflex)	30	53.3	68.3 (49–79)	12 months
			Decompression	30	60	68 (52–79)	
Stromqvist et al.	2013	RCT	IPD (X-stop)	50	60	64 (49–89)	24 months
			Decompression	50	52	71 (57–84)	

each study. As for the types of IPD, X-stop, Coflex, DIAM, distraXion, and Aperius were applied in 7 studies. The specific descriptions of included studies are listed in Table 1.

Risk of bias

Details about the risk of bias of the10 included studies are shown in Fig. 2. For random sequence generation, one study was at a high risk and one study was at an unclear risk. For allocation concealment, three studies were at an unclear risk. For blinding of participants and personnel, high risk was detected in three studies and unclear risk was found in four studies. For blinding of outcome assessment, four studies were found at an unclear risk. Two studies were identified at an unclear risk for other biases. Apart from these, no unclear or high risk was observed in other items of included studies.

VAS of back

For VAS of back, three studies consisted of 337 patients and reported IPD versus Decompression, one study consisted of 248 patients and reported IPD versus Fusion, and two studies consisted of 328 patients and reported Fusion versus Decompression Fig. 3A. There was no significant difference in VAS of back among the three treatments (Fig. 4A). Based on the treatment ranking, Decompression exhibited the highest probability of being the best one (57%), followed by IPD (34%) and fusion (9%) (Figs. 5A and 6A).

VAS of leg

For VAS of leg, two studies consisted of 245 patients and reported IPD versus Decompression, one study consisted of 248 patients and reported IPD versus Fusion, and one study consisted of 228 patients and reported Fusion versus Decompression Fig. 3B. No significant difference was observed in VAS of leg among the three treatments (Fig. 4B). Based on the treatment ranking, IPD exhibited the highest probability of being the best one (64%), followed by decompression (25%) and fusion (11%) (Figs. 5B and 6B).

ODI

For ODI, one studies consisted of 81 patients and reported IPD versus Decompression, one study consisted of 248 patients and reported IPD

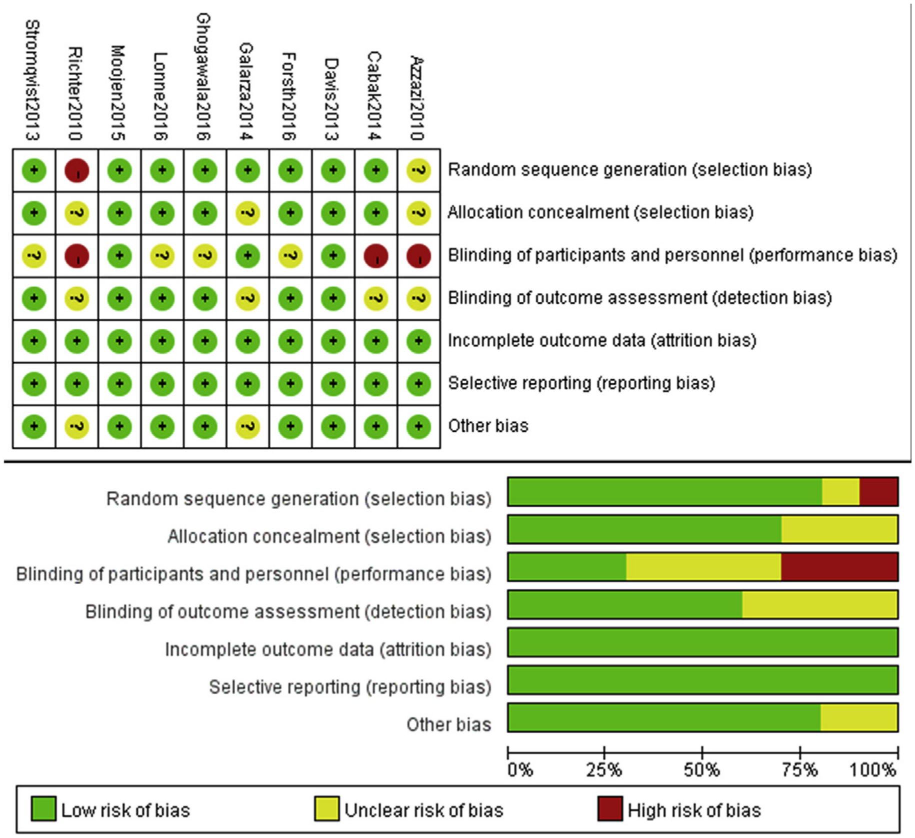

Fig. 2. Quality assessment of each RCT. Three bias levels: high risk of bias, low risk of bias, and unclear risk of bias are labeled with different color.

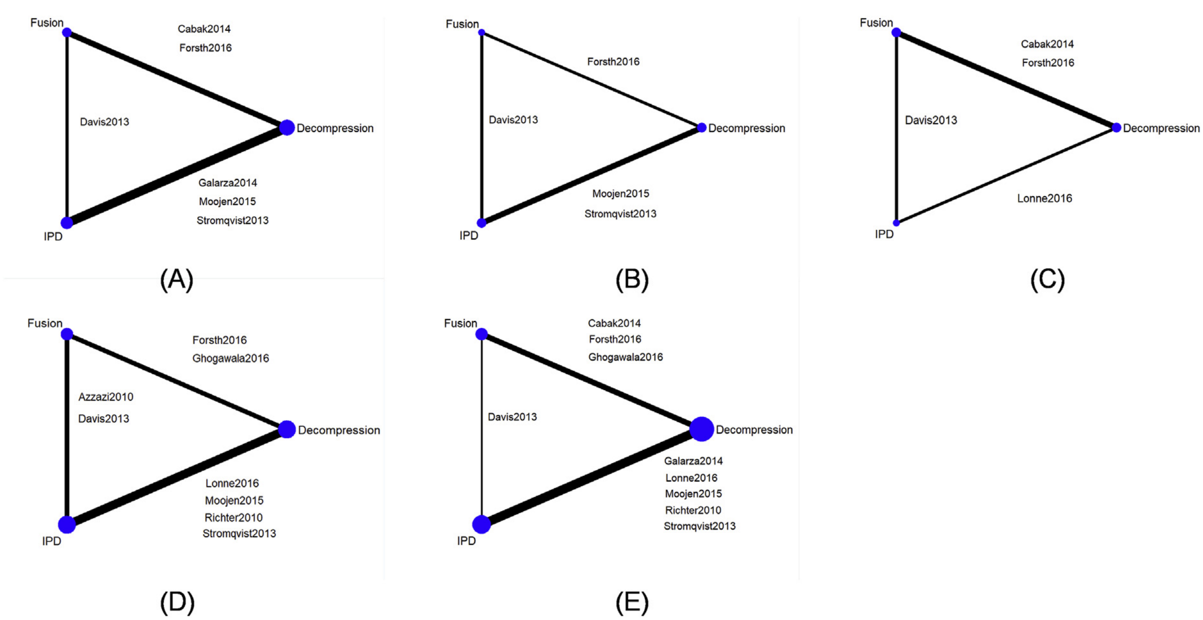

Fig. 3. Network of different treatments. (A) comparison for VAS of back; (B) comparison for VAS of leg; (C) comparison for ODI; (D) comparison for complications; (E) comparison for reoperation.

versus Fusion, and two studies consisted of 328 patients and reported Fusion versus Decompression Fig. 3C. No significant difference was detected in ODI among the three treatments (Fig. 4C). Based on the treatment ranking, IPD exhibited the highest probability of being the best one (84%), followed by fusion (13%) and decompression (4%) (Figs. 5C and 6C).

Complications

For complications, four studies consisted of 386 patients and reported IPD versus Decompression, two study consisted of 382 patients and reported IPD versus Fusion, two studies consisted of 299 patients and reported Fusion versus Decompression Fig. 3D. No significant difference

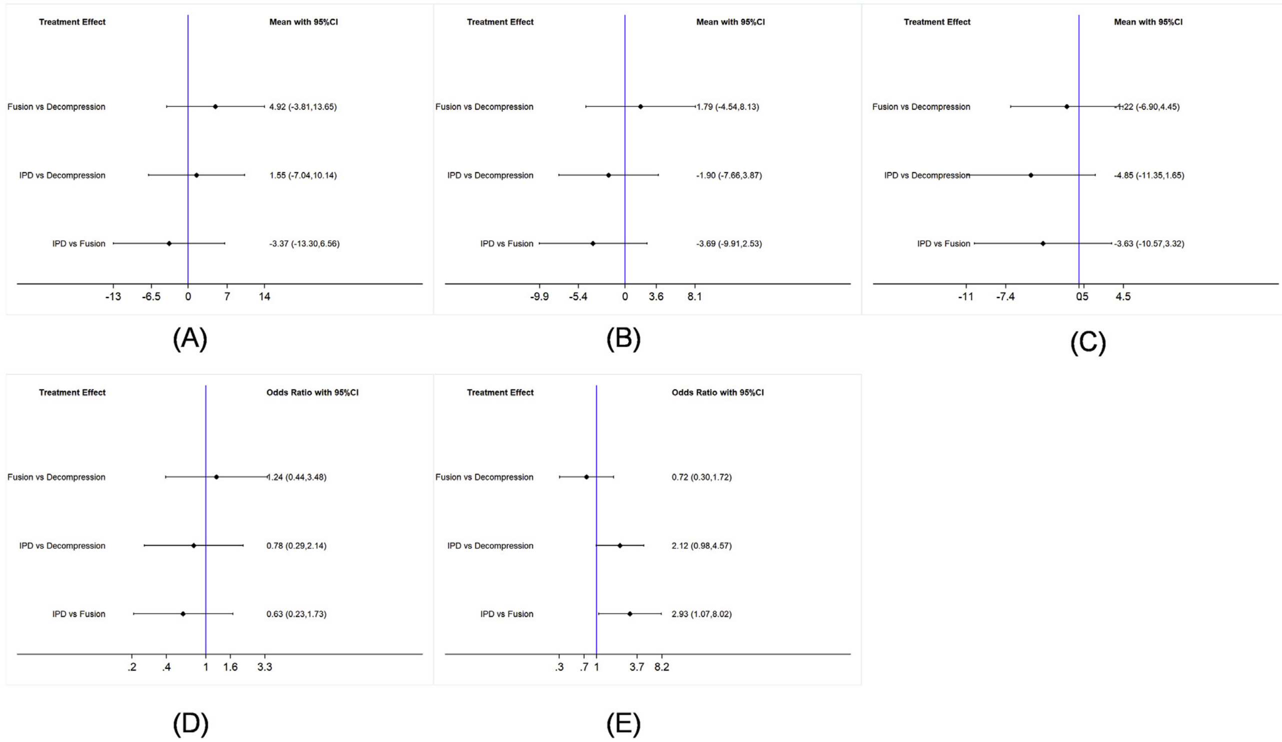

Fig. 4. Forest plot of direct comparison between different treatments. (A) comparison for VAS of back; (B) comparison for VAS of leg; (C) comparison for ODI; (D) comparison for complications; (E) comparison for reoperation.

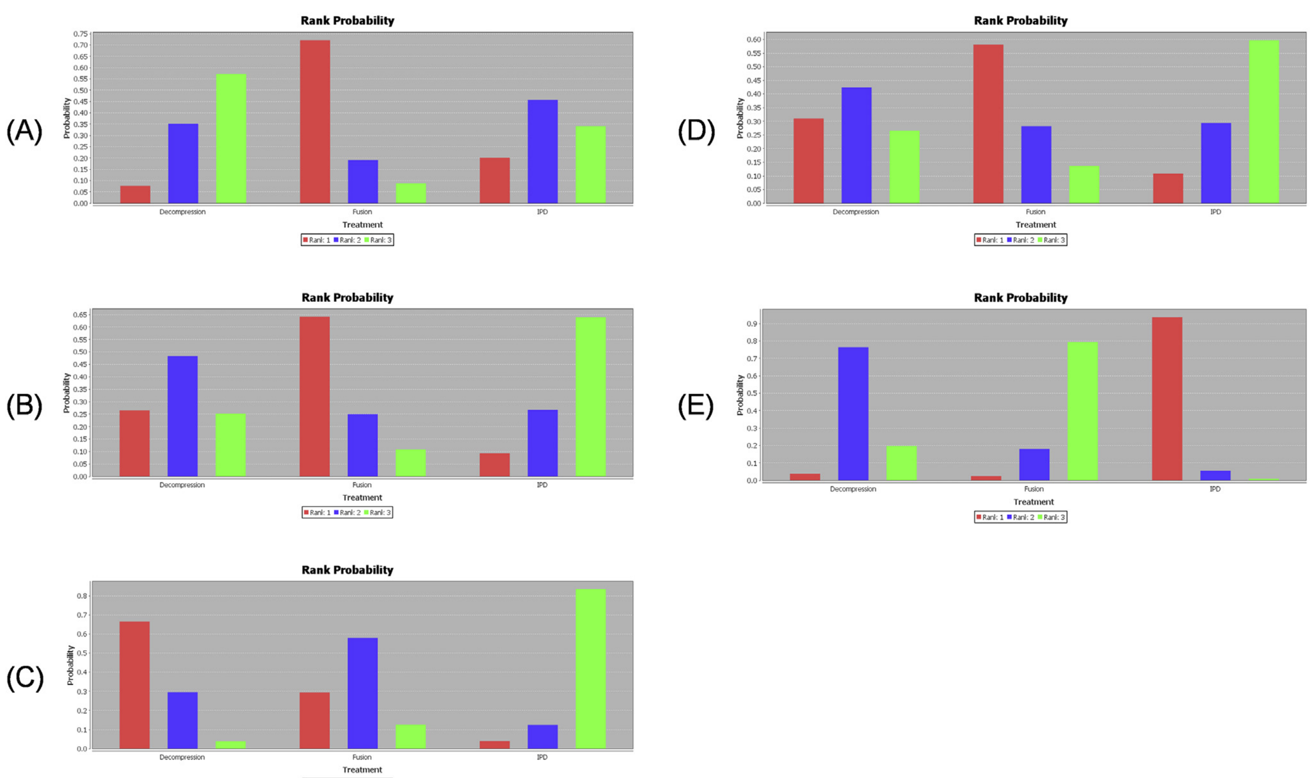

Fig. 5. Bar graph of the rank probabilities among different treatments: (A) comparison for VAS of back; (B) comparison for VAS of leg; (C) comparison for ODI; (D) comparison for complications; (E) comparison for reoperation. Among the three treatments (decompression, fusion, and IPD), of which the rank is the first reflect the maximum VAS and ODI scores or highest incidence of complications and reoperation. Rather, whose rank is the last represent the minimum VAS and ODI or lowest incidence of complications and reoperation.

(A)

Treatment	Rank 1	Rank 2	Rank 3
Decompression	0.08	0.35	0.57
Fusion	0.72	0.19	0.09
IPD	0.20	0.46	0.34

(B)

Drug	Rank 1	Rank 2	Rank 3
Decompression	0.27	0.48	0.25
Fusion	0.64	0.25	0.11
IPD	0.09	0.27	0.64

(C)

Drug	Rank 1	Rank 2	Rank 3
Decompression	0.67	0.30	0.04
Fusion	0.29	0.58	0.13
IPD	0.04	0.12	0.84

(D)

Drug	Rank 1	Rank 2	Rank 3
Decompression	0.31	0.42	0.27
Fusion	0.58	0.28	0.14
IPD	0.11	0.29	0.60

(E)

Drug	Rank 1	Rank 2	Rank 3
Decompression	0.04	0.76	0.20
Fusion	0.02	0.18	0.79
IPD	0.94	0.05	0.01

Fig. 6. Percentage plot of the rank probabilities among different treatments: (A) comparison for VAS of back; (B) comparison for VAS of leg; (C) comparison for ODI; (D) comparison for complications; (E) comparison for reoperation.

was found in complications among the three treatments (Fig. 4D). Based on the treatment ranking, IPD exhibited the highest probability of being the best one (60%), followed by decompression (27%) and fusion (14%) (Figs. 5D and 6D).

Reoperation

For reoperation, five studies consisted of 478 patients and reported IPD versus Decompression, one study consisted of 322 patients and reported IPD versus Fusion, two studies consisted of 399 patients and reported Fusion versus Decompression Fig. 3E. In comparison with IPD, fusion treatment decreased the rate of reoperation significantly (Fig. 4E). Based on the treatment ranking, fusion exhibited the highest probability of being the best one (79%), followed by decompression (20%) and IPD (1%) (Figs. 5E and 6E) (Supplementary 1 and 2).

Consistency test and heterogeneity analysis

To evaluate the consistency or inconsistency for the interested outcomes, both global and local consistency analyses were performed. In the

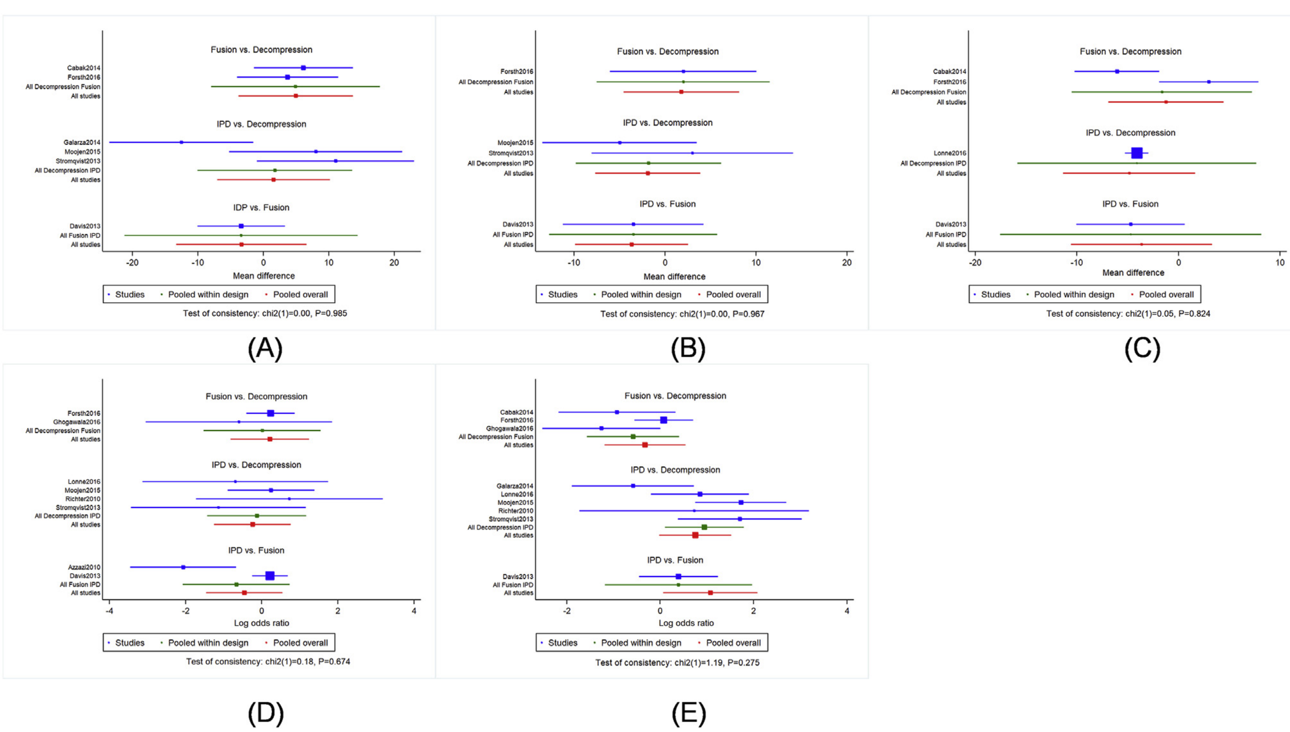

Fig. 7. Global consistency model test between different treatments: (A) comparison for VAS of back; (B) comparison for VAS of leg; (C) comparison for ODI; (D) comparison for complications; (E) comparison for reoperation.

(A)

Name	Direct Effect	Indirect Effect	Overall	P-Value
Decompression vs Fusion	4.87 (-8.25, 17.90)	5.01 (-16.81, 26.13)	4.89 (-5.08, 15.29)	1.00
Decompression vs IPD	1.63 (-10.06, 13.55)	1.42 (-21.36, 23.52)	1.36 (-7.84, 11.12)	0.98
Fusion vs IPD	-3.68 (-21.39, 14.45)	-3.39 (-20.84, 14.73)	-3.51 (-14.95, 7.82)	0.99

(B)

Name	Direct Effect	Indirect Effect	Overall	P-Value
Decompression vs Fusion	2.21 (-7.88, 12.25)	1.60 (-10.82, 14.24)	1.84 (-5.50, 9.71)	0.93
Decompression vs IPD	-2.43 (-9.58, 5.98)	-1.11 (-15.39, 12.19)	-1.74 (-8.54, 5.06)	0.92
Fusion vs IPD	-3.52 (-13.23, 6.75)	-3.79 (-17.05, 9.23)	-3.60 (-11.33, 4.23)	0.98

(C)

Name	Direct Effect	Indirect Effect	Overall	P-Value
Decompression vs Fusion	-1.72 (-8.28, 5.15)	0.45 (-13.08, 13.94)	-1.29 (-7.06, 4.66)	0.74
Decompression vs IPD	-4.08 (-12.87, 4.64)	-6.37 (-18.62, 6.03)	-4.73 (-11.40, 1.83)	0.72
Fusion vs IPD	-4.58 (-14.61, 5.44)	-2.10 (-13.48, 8.66)	-3.43 (-10.83, 3.55)	0.72

(D)

Name	Direct Effect	Indirect Effect	Overall	P-Value
Decompression vs Fusion	-0.02 (-2.15, 1.91)	0.54 (-1.78, 3.10)	0.22 (-1.18, 1.60)	0.67
Decompression vs IPD	-0.17 (-1.79, 1.33)	-0.69 (-3.64, 1.85)	-0.27 (-1.66, 0.92)	0.71
Fusion vs IPD	-0.69 (-2.71, 0.95)	-0.10 (-2.65, 2.51)	-0.50 (-1.93, 0.79)	0.66

(E)

Name	Direct Effect	Indirect Effect	Overall	P-Value
Decompression vs Fusion	-0.60 (-1.98, 0.52)	0.57 (-1.74, 2.78)	-0.39 (-1.51, 0.65)	0.29
Decompression vs IPD	0.98 (-0.05, 1.98)	-0.20 (-2.70, 2.10)	0.79 (-0.12, 1.71)	0.29
Fusion vs IPD	0.43 (-1.56, 2.44)	1.66 (0.11, 3.23)	1.18 (-0.04, 2.46)	0.27

Fig. 8. Local consistency model test between different treatments: (A) comparison for VAS of back; (B) comparison for VAS of leg; (C) comparison for ODI; (D) comparison for complications; (E) comparison for reoperation.

global consistency test, the p value in five parameters were over 0.2, which indicated a favorable transferability (Fig. 7). In the local consistency test, node-splitting analysis was used to compare the results between direct and indirect effects. The estimated effects from direct or indirect were similar in each variable, indicating a good consistency (Fig. 8). Furthermore, to determine the heterogeneity of each outcome, loop test was conducted. The results showed that each IF value was less than 3 and a 95% CI contained the zero, indicating satisfactory stability (Supplementary 3). It is worth noting that studies with small sample sizes may introduce substantial bias or increase the heterogeneity of some variables. Initially, an article with small samples was included in this analysis, but the homogeneity and consistency showed poor outcomes. By excluding this study, both above two evaluation indexes achieved ideal results.

Discussion

Though multiple procedures have been reported and explanted, the optimal treatment of LSS remains unclear. Previous studies demonstrate that adequate decompression via surgery improves LSS related clinical outcomes effectively [22]. However, for patients with combined lumbar instability, decompression alone may not change or may even aggravate back pain, thus additional fusion is recommended for these patients [23,24]. On the other hand, fusion may result in excessive tissue dissection and long surgical duration due to the insertion of implants, thereby increasing the risk of complications [25]. As a new device, IPD has been applied widely around the world in the past several years [26,27]. The design philosophy of IPD is dynamic stabilization, which relieves clinical symptoms via the alteration of movement and the transmission of spinal motion unit [28]. Compared with traditional fixation, IPD permits multi-directional motor of lumbar spine except for the pain-derived plane (for example restriction of extension), which maintains a natural motion of the lumbar. Likewise, IPD has some disadvantages such as poor control of axial rotation and lateral bending [29].

Therefore, to draw a conclusion, the authors conducted a study by integrating results from several published meta-analysis. According to our results, IPD or decompression showed better improvements in VAS and ODI scores compared with fusion. Interestingly, for two variables: VAS of leg and ODI, IPD ranked the best among the three treatments. Thomas et al. reported that decompression alone exerted a greater performance in several clinical outcomes than plus fusion for claudication secondary to LSS [30]. Davis et al. found that the Conflex Interlaminar Stabilization device led to similar perioperative outcomes as posterolateral spinal fusion (PSF) for treating degenerative spondylolisthesis [31]. Based on the above results, non-fusion procedures including decompression and dynamic devices provide similar and even better pain alleviation when compared with fusion. We hypothesized that additional blood loss and tissue stripping in fusion inevitably increase the risk of damage at the adjacent structure, thereby resulting in poor pain relief in some patients. However, our traditional paired meta-analysis did not detect any significant differences in these parameters between any two methods, revealing the need to interpret the discrepant results with caution.

Considering the safety of each treatment, our pooled results indicated that IPD showed the best impact on decreasing complications but was associated with the highest risk of reoperation. Conversely, fusion exhibited the greatest outcome in reducing the incidence of reoperation but had an unsatisfactory complication rate. Interestingly, paired meta-analysis results also showed that IPD had a higher incidence of reoperation than fusion. We assumed that such polarized results may be attributed to the following reasons: For complications, there is no doubt that muscle damage and interference of ligament introduced by open fusion procedure would increase the formation of pseudarthrosis, implant failure, and accelerate the degeneration of adjacent levels [32]. Comparatively, due to its minimal incision and mild injury to surrounding tissue, decompression and IPD decrease the occurrence of perioperative complications. Furthermore, insertion of IPD is not accompanied with the resection of lamina, which signally reduces the risk of lumbar instability after surgery [33]. With regards to reoperations, decompression or IPD seemed to be a short-term treatment; this limits the movement of responsible segments without substantial decompression, which may contribute to recurrent stenosis [34]. Biomechanical reasons played an important role in the high reoperation rate of IPD; specifically, the gain of cross-sectional area of the spinal canal is lower in IPD than fusion, which leads to a shorter service life of these devices [35]. However, in the fusion procedure, the inserted cages or bone provide an immediate support as well as long-term stability and thus avoid the need for reoperation.

Unlike lumbar disc herniation (LDH) in which the prolapsed disc must be removed for symptom relief, LSS related symptoms, particularly intermittent claudication, can be ameliorated by increasing the dimensions of the foraminal and spinal canal [36,37]. Because of this, a variety of surgical options are attempted for LSS. Based on the results of our study and clinical experiences of the authors, we considered that surgical procedures should be differed according to the type of LSS. For LSS patients combined with high-grade spondylolisthesis or evidenced dynamic instability, fusion surgery should be chosen to acquire a stable spinal sequence [38]. For stable LSS, decompression or IPD may obtain equivalent outcomes with a low rate of complications. Further, for patients with relative stability or low-grade spondylolisthesis, IPD is a preferred method that shows better effects on achieving stabilization and reducing complications [39].

The present study has some limitations: (1) our study only included 10 RCTs and the sample size is inadequate; (2) due to limited reported outcomes in included studies, we only collected and analyzed 5 parameters. Some important factors like radiological restoration, comorbidities, and mortality were not studied; (3) based on insufficient published studies for the treatment of LSS, we only studied three major treatments in this article. Larger sample sizes and more detailed studies are required to verify the therapeutic effects of different methods for LSS in the future.

Conclusion

In summary, the present network meta-analysis discovers that for the treatment of LSS, non-fusion procedures including decompression and IPD achieve parallel pain alleviation compared with fusion. IPD may be a superior procedure with a low incidence of complications. However, considering its high rate of reoperation, IPD needs to be applied prudently in clinical practice.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and material

All data generated or analyzed in this work are included in the published version.

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Conflict of interest

The authors have no conflicts of interest to disclose in relation to this article.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jot.2020.07.003.

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