SCIENTIFIC ARTICLE

Comparison of One versus Two Cages in Lumbar Interbody Fusion for Degenerative Lumbar Spinal Disease: a Meta-analysis

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Objective: To systematically compare the fusion rate and safety of lumbar interbody fusion using one cage versus two cages for the treatment of degenerative lumbar spinal diseases.

Methods: All randomized controlled trials (RCTs) and comparative observational studies written in English comparing the outcome of lumbar interbody fusion using one or two cages in patients with degenerative lumbar spinal diseases were identified by a comprehensive search of PubMed Central, MEDLINE, EMBASE, BIOSIS and the Cochrane Central Registry of Controlled Trials. An exhaustive electronic search up to July 2013. The quality of the methodology was assessed and relevant data retrieved independently by two reviewers, after which the resultant data were subjected to meta-analysis. All meta-analyses were performed using Review Manager 5.0, which is recommended and provided by the Cochrane Collaboration.

Results: Our systematic search yielded 745 studies from the selected databases. After duplicate studies had been identified and the titles and abstracts screened, 736 studies were excluded because they were irrelevant to our topic. The full texts of the remaining nine potentially relevant references were comprehensively evaluated and four excluded for the following reasons: two studies involved co-interventions and the other two lacked control groups. Two relevant RCTs and three comparative observational studies involving 384 patients and 501 spinal segments with at least one year follow-up were identified. Analysis of the pooled data demonstrated no significant difference in fusion rate between the one-cage and two-cage groups. However, intraoperative blood loss and operating time were less and the complications rate lower in the one-cage group.

Conclusion: In patients with degenerative lumbar spinal diseases, lumbar interbody fusion using one cage has an equal fusion rate and is safer compared with using two cages. However, because this meta-analysis had some limitations, more high quality RCTs are needed to strengthen the evidence.

Key words: Cage; Fusion rate; Lumbar interbody fusion; Meta-analysis

Introduction

Lumbar interbody fusion techniques have been used for more than 50 years to treat a variety of degenerative lumbar spinal diseases, such as spondylolisthesis, instability, spinal stenosis, and degenerative disc disease^{1,2}. The original

objective of lumbar interbody fusion procedures was to remove all or most of the disc that was responsible for pain and stabilize the operated segment with bone graft to restore normal biomechanics to the spine and avert the consequences of collapse of an unsupported space.

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To improve the chances of successful fusion, avoid graft resorption or disc space collapse, and achieve intraoperative stability of operated segments, different types of fusion cages have been developed^{3,4}. Lumbar interbody fusion using cages has become a widely accepted means of managing degenerative lumbar spinal diseases in recent years. Except when the disc space size is too small, or there are nerve root anomalies that may block access to the disc space, epidural scarring and so on⁵, lumbar interbody fusion with insertion of bilateral interbody cages is routinely recommended.

This form of treatment has become standard because it predictably restores segmental alignment and balance and achieves fusion. What is interesting is that several biomechanical studies have shown that posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF) with insertion of a single cage achieve adequate biomechanical stability equal to that achieved by insertion of two cages⁶⁻⁹.

Several surgeons have reported excellent outcomes from lumbar interbody fusion using one cage in patients with degenerative lumbar spinal diseases¹⁰⁻¹². Moreover, these surgeons reported that one cage insertion decreases the operating time, intraoperative blood loss and complication rate associated with fusion cages. With the development of TLIF and endoscopic techniques, quite a few reports on this subject have been published^{3,10,11}; however, there is still lack of conclusive evidence that insertion of one cage in lumbar interbody fusion is the optimal treatment. Whether insertion of one cage insertion achieves acceptable balance, strength, and fusion and whether it is necessary to use two cages in lumbar interbody fusion has not been adequately clarified. The objective of this study was to systematically compare the fusion rate and safety of lumbar interbody fusion using one or two cages for the treatment of degenerative lumbar spinal diseases.

Materials and Methods

Search of Published Reports and Inclusion Criteria

All randomized controlled trials (RCTs) and comparative observational studies written in English comparing the outcome of lumbar interbody fusion using one or two cages in patients with degenerative lumbar spinal diseases were identified. An exhaustive electronic search up to July 2013 of PubMed Central, MEDLINE (since 1966), EMBASE (since 1980), BIOSIS (since 2004), and the Cochrane Central Registry of Controlled Trials, was performed. Keywords used in the search were: cage, intervertebral spacer, fusion and lumbar; these keywords were also used as MESH headings. References cited in retrieved articles and relevant overview articles were checked to identify additional studies.

Inclusion and Exclusion Criteria

Randomized controlled trials and comparative observational studies written in English were considered eligible for inclusion if they fulfilled all of the following:

1. The study subjects have degenerative lumbar spinal diseases (including spondylolisthesis to a maximum of grade II,

instability, spinal stenosis, degenerative disc disease), have failed to respond to an adequate trial of conservative treatment and have been treated by lumbar interbody fusion using one or two cages.

2. At a minimum, the study has reported the fusion rate; in addition, the rate of complications, operative times, and intraoperative blood losses were used to evaluate the safety of the surgery.
3. All included trials had followed up their patients for at least 1 year after surgery.

Exclusion criteria were active infection, osteopenia and neoplasm. Studies without control groups or including co-interventions were excluded.

Assessment of Quality of Methodology

Two reviewers (L.J. and T.J.) checked all titles and abstracts from the databases and evaluated the full texts of all the relevant studies independently. Disagreements were eliminated by discussion between the reviewers and, if necessary, consulting a third colleague (L.H.). The checklist of Furlan and colleagues¹³ was used to evaluate the risk of bias of RCTs. The list of criteria of the Dutch Cochrane Centre Quality Assessment was used to assess the comparative observational studies¹⁴. This check list identifies bias in studies related to selection, performance, attrition, detection and so on. The items were scored with "yes", "no", or "unsure". A score of 50% or more is considered to reflect "high methodological quality".

Data Extraction

Data were extracted independently by two reviewers (L.J. and T.J.) and consensus achieved by discussion and consultation with a third reviewer (L.H.). The data extracted from the eligible studies included study design, characteristics of participants, intervention details, number of participants allocated to each intervention group, follow-up rate and duration and outcomes (Table 1). The outcomes pooled in this analysis included fusion rate, complication rate, intraoperative blood loss and operative time.

Data Analysis

All meta-analyses were performed using Review Manager 5.0, which is recommended and provided by the Cochrane Collaboration. The results are presented as mean difference or standardized mean difference (SMD) for continuous outcomes. Dichotomous data were compared using an odds ratio (OR). For each outcome, the 95% confidence intervals (CI) were calculated; these are presented as forest plots. The pooled OR or SMD is represented by a solid diamond in the forest plots; this is the best estimate of the true pooled outcome; its width represents the 95% CI.

Statistical heterogeneity in the results of the trials was identified by the X^2 test, and expressed by the I^2 index, which was directly calculated from the Q statistic, as defined by Higgins and colleagues²⁰. I^2 ranges from 0 to 100%, 0 indicating the absence of any heterogeneity. When I^2 was <50%, low heterogeneity was assumed. Conversely, when I^2 > 50%,

TABLE 1 Characteristics of the included studies

Study	Zhao et al. 2002 ¹⁵	Suh et al. 2008 ¹⁶	Molinari et al. 2003 ¹⁷	Lee et al. 2008 ¹⁸	Kroppenstedt et al. 2008 ¹⁹
Methodology	R: simple randomization C: unclear	R: simple randomization C: sealed envelope	Comparative observational study	Comparative observational study	Comparative observational study
Participants	B: the out- come assessor was blinded 25 patients with lumbar spondylolisthesis, failed ≥6 months of conservative treatment F/M 13:12; mean age: 49 years (38–59 years); follow-up ≥24 months Follow-up rate 100.0% (25/25) Exp: 13 patients Ctl: 12 patients	B: the patients were blinded until after surgery 91 patients with a low-grade single level lumbar spondylolisthesis, failed ≥6 months of conservative treatment F/M 37:10; mean age 52.3 years (39–63 years); follow-up ≥24 months Follow-up rate 94.0% (47/50) Exp: 47 Patients; Ctl: 44 Patients; F : M 34:10; mean age 53.8 years (38–62 years); follow-up rate 88.0% (44/50)	Prospective?/retrospective? 35 patients with lumbar spondylolisthesis or a single level lumbar disc degeneration; failed 12 months of conservative treatment F/M 35:0; mean age: 36 years (22–55 years); follow-up 15 months Follow-up rate 100.0% (35/35) Exp: 19 patients Ctl: 16 patients	Retrospective 187 patients with spinal stenosis, spondylolisthesis, or herniated nucleus pulposus F:M 63:25; mean age 60.5 years (29–75 years); follow-up ≥18 months Follow-up rate 91.7% (88/96) Exp: 88 patients (151 levels); Ctl: 99 patients (153 levels); F : M 63:36; mean age 54.4 years (22–77 years); follow-up rate 90.8% (99/109)	Retrospective 46 patients with recurrent disc disease, foraminal or spinal stenosis with instability, or symptomatic spondylolisthesis F/M 17:29; follow-up ≥7 years Follow-up rate 61.0% (36/76) Exp: 22 patients; mean age 50 years (32–68 years) Ctl: 24 patients; mean age 48 years (31–67 years)
Interventions	Exp: PLIF with one cage Ctl: PLIF with two cages	Exp: PLIF with one cage Ctl: PLIF with two cages	Exp: PLIF with one cage Ctl: PLIF with two cages	Exp: PLIF with one cage Ctl: PLIF with two cages	Exp: PLIF with one cage Ctl: PLIF with two cages
Outcomes	Surgical data; clinical outcomes Fusion rate Complications; costs for both groups	Surgical data; clinical outcomes Fusion rate Complications	Surgical data; clinical outcomes Fusion rate Complications, costs for both groups	Surgical data; clinical outcomes Fusion rate Radiographic out- comes; complications	Radiographic out-comes Fusion rate Complications
B, double blinding; C, concealment of allocation; Ctl, control group; Exp, experimental group; F/M, female/male; R, randomization.

Fig. 1 Flow chart of searches for eligible articles.

heterogeneity was thought to be present, meaning that the effect was random; possible explanations for this were pursued.

Results

Study Selection

The process of identifying relevant studies is summarized in Fig. 1. Our systematic search yielded 745 studies from the selected databases. After duplicate studies had been identified and the titles and abstracts screened, 736 studies were excluded because they were irrelevant to our topic. The full texts of the remaining nine potentially relevant references were comprehensively evaluated and four excluded for the following reasons: two studies involved co-interventions^{21,22} and the other two lacked control groups^{23,24}. Thus, only two RCTs^{15,16} and three comparative observational studies^{17–19} were included in this review and assessed for the quality of their methodology. These five studies involved 384 patients and 501 operating spinal segments, reported varying durations of follow-up or contained itemized results.

Description of Characteristics of Eligible Studies

No systematic reviews or meta-analyses were found; however, two reports of RCTs^{15,16} and three comparative observational studies^{17–19} were identified. The characteristics of these five studies are summarized in Table 1.

In all eligible studies, all patients had symptomatic degenerative lumbar spinal diseases, including spondylolisthesis to a maximum of grade II, instability, spinal stenosis and degenerative disc disease. The sample sizes ranged from 25 to 187 patients. All patients had undergone instrumented lumbar interbody fusion using unilateral or bilateral cages. In four of

the studies^{15–18}, autologous morselized bone grafts had been packed into cages and introduced into the disc space, the remaining study by Kroppenstedt *et al.* was unclear on use of bone grafts¹⁹. Suh *et al.* used non-threaded interbody cages¹⁶, as did Molinari *et al.* (Brantigan [DePuy Spine, Raynham, MA, USA] or Harms [DePuy Spine])¹⁷. Zhao *et al.* used threaded-cages (BAK, Spine Tech, Minneapolis, MN, USA)¹⁵. Kroppenstedt *et al.* used a solid rectangular-shaped titanium block coated with Plasmapore (Prospace, B. Braun Aesculap AG, Tuttlingen, Germany)¹⁹. Lee *et al.* used polyetheretherketone cages (PEEK OIC Cages; Stryker, Allendale, NJ, USA) and, in contrast with the single operating segment in the other four studies, in this study there were two operating segments, which did not affect the outcome analysis and synthesis¹⁸.

Results of Assessment of Quality of Methodology

The scores for methodological quality of the studies were all more than 50% of the total possible score. According to the Furlan and Van Tulder criteria¹³, both of the RCTs^{15,16} had methodological quality scores of 9 (high quality study). One study¹⁶ used a sealed envelope technique to conceal allocation; the other one¹⁵ used a random number table. According to the Dutch Cochrane Centre Quality Assessment scale¹⁴, all three comparative observational studies^{17–19} had methodological quality scores of 11/14 (reflecting high quality). However, two of these studies^{18,19} were retrospective and the remaining one¹⁷ is unclear in this respect. None of the included studies provided information about intention-to-treat analysis. Overall, these trials were classified as of high methodological quality; however, the comparative observational studies had relatively higher risk of bias.

Fig. 2 Results of meta-analysis of fusion rates for one and two cages.

Results of Meta-Analysis

Fusion Rate

The fusion rate was main outcome we aimed to assess. In our meta-analysis, four studies^{15,16,18,19} defined fusion in terms of a relative lack of motion at the operated segment as measured on flexion/extension radiographs, whereas the other study¹⁷ defined fusion by the presence of bridging bone across the disc space on anteroposterior or lateral radiographs. All five trials reported fusion rates and calculated them based on the segment level. In all, these studies enrolled 384 patients (501 segments), 189 patients (252 segments) of whom were assigned to the one-cage group and the other 195 patients (249 segments) to the two-cage group. The fusion rate was 92.9% (234/252) in the one-cage group and 94.0% (234/249) in the two-cage group. These five studies were found to have no heterogeneity ($I^2 = 0\%$, $P = 1.00$), accordingly, a fixed effect model was used. Analysis of the pooled data revealed no significant difference in fusion rate between the two groups (OR 0.85; 95% CI 0.42–1.72, $P = 0.65$) (Fig. 2).

Intraoperative Blood Loss and Operating Time

Both intraoperative blood loss and operating time were reported by the same three trials^{15,16,18}, in which 204 patients were enrolled in all, 89 patients being assigned to the one-cage group and the other 115 to the two-cage group. Obviously, intra-operative blood loss and operating time are affected by

the scope of surgery. The study reported by Lee *et al.*¹⁸ provided data on intraoperative blood loss and operating time only for patients who had undergone single segment surgery. These three trials were found to have significant heterogeneity for both blood loss and operating time ($I^2 = 88\%$, $P = 0.0003$; $I^2 = 87\%$, $P = 0.0005$; respectively); accordingly, a randomized effect model was used. Overall, there was a significant trend toward less blood loss in patients with one cage than in patients with two cages (SMD -127.65 ; 95% CI -231.87 to -23.42 , $P = 0.02$). Meanwhile, the pooled data showed that the one-cage group had a shorter operating time than the two-cage group (SMD -34.70 ; 95% CI -57.50 to -11.91 , $P = 0.003$) (Figs 3,4).

Complication

The complications analyzed in this review were those that occur most frequently in lumbar interbody fusion procedures using cages: dural tears, neurologic problems, infections and cage migration. The complication rate was reported by three trials^{15–17} in which 151 patients were enrolled, 79 of whom were assigned to the one-cage group and the other 72 patients to the two-cage group. The complication rate was 5.1% (4/79) in the one-cage group and 15.3% (11/72) in the two-cage group. These three studies had no heterogeneity ($I^2 = 0\%$, $P = 0.58$); accordingly, a fixed effect model was used. A significant trend toward a lower complication rate in the one-cage group was identified (OR 0.30; 95% CI 0.10–0.95, $P = 0.04$) (Fig. 5).

Fig. 3 Results of meta-analysis of intraoperative blood loss for one and two cages.

Fig. 4 Results of meta-analysis of operating time for one and two cages.

Discussion

This meta-analysis of the best evidence from two RCTs^{15,16} and three comparative observational studies^{17–19} was performed to compare the fusion rate and safety between insertion of one and two cages in lumbar interbody fusion for degenerative lumbar spinal diseases. To our knowledge, no systematic review or meta-analyses have previously been published on this subject. The combined data showed no difference in the global assessment of fusion rate. Although achievement of bony union does not always mean a favorable clinical outcome²⁵, the fusion rate is nevertheless surgeons' most important concern. Bony fusion is regarded as one of the most important requirements for defining a fused level or spine as stable. In our meta-analysis, the pooled fusion rates of the five studies were 93% and 94% in the one-cage and two-cage groups, respectively, which is in agreement with the 90–100% reported elsewhere^{5,26,27}. This provides strong evidence that these two groups have equally satisfactory outcomes in terms of fusion.

However, insertion of a second cage was associated with a significantly higher complication rate, longer operating time and greater intra-operative blood loss, all of which reflect adverse outcomes, than occurred in the one-cage group. Three of the trials, including two RCTs^{15,16} and one comparative observational study¹⁸, reported the operative time and intra-operative blood loss separately for one-cage groups and two-cage groups, these outcomes were clearly worse in the latter. In addition, the two RCTs^{15,16} and one comparative observational

study¹⁷ reported fewer complications in the one-cage groups than the two-cage group. The explanation for these findings is self-evident, more operating time is needed to implant a second cage, and this is accompanied by more blood, even if the surgery is performed by skilled surgeons. In addition, of course a second cage results in more intraoperative complications associated with fusion cage^{28–30}.

In this meta-analysis, we did not synthesize the data concerning clinical outcomes because the authors used a variety of outcome measures, some of which have not been validated. Kroppenstedt *et al.* did not report the clinical efficacy of the two interventions separately¹⁹. Molinari *et al.* rated pain, function and patient satisfaction by using questionnaires from the American Academy of Orthopaedic Surgeons MODEMS version and the Scoliosis Research Society outcomes¹⁷. Zhao *et al.* allocated the patients' clinical symptoms to one of four categories: excellent, good, fair, and poor; they devised this assessment tool themselves¹⁵. Both Suh *et al.*¹⁶ and Lee *et al.*¹⁸ used a visual analog scale and the Oswestry disability scores questionnaire to assess clinical efficacy; however, Suh *et al.*¹⁶ did not provide the standard deviations of these scores. Despite a lack of pooled data concerning clinical outcome, the data from these studies all showed the same tendency; namely for patients in one-cage and two-cage groups to experience similar improvements in clinical symptoms, no significant differences between the two groups in terms of clinical results being reported.

Fig. 5 Results of meta-analysis of complication for one and two cages.

In addition to the fusion rate, Kroppenstedt *et al.*¹⁹ and Lee *et al.*¹⁸ reported some other radiographic outcomes, including segmental height, foraminal height and segmental lordotic and scoliotic angle; they found no significant differences between the two groups in these radiographic indexes. Of note, Lee *et al.*¹⁸ reported that in three patients in the unilateral cage group, the scoliotic angles of the fused level were worsened by 5°–10°. Furthermore, Zhao *et al.*¹⁵ and Molinari *et al.*¹⁷ compared the cost effectiveness between the two interventions, one cage is less expensive than two cages. In the study reported by Zhao *et al.*¹⁵, the average costs in the one and two cage groups were \$1460 ± 146 and \$2398 ± 445, respectively. Molinari *et al.* reported that the costs were higher in the two cage group by \$1728 per patient¹⁷.

The main deficiencies of this study were that it included only two RCTs^{15,16}, and the sample sizes in these two trials were small: 25 and 91 patients, respectively. However, the follow-up time was mainly about two years, which is enough time to accurately assess bone fusion^{31–33}. In Suh *et al.*'s trial¹⁶, nine patients lost to follow-up were excluded, rather than carrying out an intention-to-treat analysis.

In meta-analysis, which is the statistical analysis of data extracted from several different trials on the same problem, outcomes are pooled to achieve a more unbiased and scientific conclusion based on the larger sample provided by the pooled data^{34,35}. In this meta-analysis, we identified two RCTs^{15,16}, and three comparative observational studies^{17–19}; our findings inevitably have some limitations. Firstly, there was potential publication bias because we only retrieved published studies

from the selected databases. Because only trials reported in English were eligible, there may have been language bias. Secondly, Zhao *et al.*¹⁵ did not clearly describe their means of allocation concealment and there was inadequate blinding in both of the RCTs^{15,16}, which may have introduced some measurement bias. The weakest aspect of the observational studies was that patients may have been allocated to designated treatment groups according to their diagnosis. In addition, because of the retrospective design of these studies, relevant patient data may have been unavailable, which could have introduced selection bias. Thirdly, heterogeneity was caused by differences in technical expertise of surgeons and variations in specific types of fusion cages, internal fixation devices and interbody grafts. For example, the results for intraoperative blood loss and operating time were significantly heterogeneous. More RCTs of high quality are needed to strengthen the quality of evidence and contribute further information to complement these findings.

Conclusions

We found no significant differences in the global assessment of fusion rate between the one and two cage groups in lumbar interbody fusion for degenerative lumbar spinal disease. Both groups achieved satisfactory fusion rates. However, in the two-cage group, insertion of the second cage increased operating time, amount of blood loss and complication rate, and the procedure was more costly. Because this study has inevitable limitations, the combined results need to be assessed with caution.

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