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Review

Bilateral *versus* unilateral instrumentation in spinal surgery: Systematic review and trial sequential analysis of prospective studies

Kevin Phan [a,b,c,*], Vannessa Leung [b], Daniel B. Scherman [a], Andrew R. Tan [a], Prashanth J. Rao [a,b,c], Ralph J. Mobbs [a,b,c]

[a] NeuroSpine Surgery Research Group (NSURG), University of New South Wales, Randwick, Sydney, NSW 2031, Australia
[b] University of New South Wales, Sydney, NSW, Australia
[c] Department of Neurosurgery, Prince of Wales Hospital, Sydney, NSW, Australia

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ABSTRACT

Lumbar fusion surgical intervention is often followed by bilateral pedicle screw fixation. There has been increasing support for unilateral pedicle screw fixation in an attempt to reduce complications and costs. The following study assesses the efficacy and complications of bilateral *versus* unilateral pedicle screw fixation in open and minimally invasive lumbar interbody fusion techniques. A systematic review with meta-analysis and trial sequential analysis was performed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and recommendations. In comparison with existing meta-analyses, trial sequential analysis was implemented to reduce the potential for type I error. Of the 1310 citations screened, four observational studies and 13 randomised controlled trials were used comprising 574 bilateral cases and 549 unilateral cases. Statistical analysis showed no difference in fusion rates, total complications, dural tear rates, Visual Analogue Scale (VAS) score for back pain, VAS for leg pain, Oswestry Disability Index scores, and length of stay between bilateral and unilateral instrumentation. Unilateral instrumentation was significantly shorter in duration ($P < 0.00001$) and led to significantly lower blood volume loss ($P = 0.0002$). These results were the same for both open and minimally invasive surgical approaches. Unilateral pedicle screw fixation appears to have similar post-operative outcomes as bilateral fixation and improved efficacy in regards to procedure duration and blood volume loss.

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1. Introduction

Lumbar fusion is an effective surgical intervention for various lumbar pathologies, including spondylolisthesis, canal stenosis or discogenic pain [1–3]. A diverse range of techniques are available including posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), and more recently minimally invasive surgical (MIS) approaches [4]. The main objectives of lumbar fusion include obtaining a solid arthrodesis of spinal segments whilst restoring load to anterior structures and improving disc height [5–7].

Traditionally lumbar fusion is often accompanied by additional bilateral pedicle screw fixation to provide additional posterior support, improve fusion rate and alignment [8,9]. However, an increasing number of studies have explored a unilateral pedicle screw fixation approach, the rationale being that it is an option that can potentially reduce soft tissue trauma, disruption to spinal structural integrity on the contralateral side, blood loss, operative time and costs involved [10,11]. Bilateral instrumentation was also criticised due to its excessive rigidity, which may hasten adjacent segment disease [12]. Biomechanical studies have demonstrated that unilateral screws are associated with increased stiffness, in comparison to bilateral screws which better approximate the segmental flexibility of an intact spine [13]. However, this has not been reflected in some clinical randomised studies, which have suggested equivalent fusion and complication rates between bilateral and unilateral instrumentation approaches.

While prior systematic reviews have been conducted, a common limitation is the potential for type I errors owing to increased random error when few data are collected and due to repeated significance when cumulative meta-analysis is updated with new trials [14,15]. One way to reduce type I errors is to employ trial sequential analysis (TSA), which uses adjusted significance boundaries and can help establish whether further trials are required or not to achieve a definitive conclusion. Therefore, the objective of

* Corresponding author. Tel.: +61 414 186 883.
E-mail address: kphan.vc@gmail.com (K. Phan).

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the present study is to compare the efficacy and complications of bilateral and unilateral instrumentation in spinal surgery, for both open PLIF/TLIF *versus* MIS approaches, using TSA methodology.

2. Methods

2.1. Literature search strategy

The present systematic review and meta-analysis was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and recommendations [16,17]. Electronic searches were performed using Ovid Medline, PubMed, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, American College of Physicians Journal Club, and Database of Abstracts of Review of Effectiveness from their dates of inception to September 2015. To achieve the maximum sensitivity of the search strategy, we combined the terms "bilateral", "unilateral", "instrumentation", "pedicle screw", or "spine surgery" or "spinal surgery" as either key words or medical subheading terms. The reference lists of all retrieved articles were reviewed for further identification of potentially relevant studies, assessed using the inclusion and exclusion criteria.

2.2. Selection criteria

Eligible studies for the present review were prospective studies which compared outcomes of bilateral and unilateral instrumentation in spinal surgery. Studies which did not include fusion rate or complications as endpoints were excluded. When institutions published duplicate studies with accumulating numbers of patients or increased lengths of follow-up, only the most complete reports were included for quantitative assessment at each time interval. All publications were limited to those involving human subjects and in the English language. Abstracts, case reports, conference presentations, editorials, reviews and expert opinions were excluded.

2.3. Data extraction and critical appraisal

All data were extracted from text, tables and figures. Two investigators independently reviewed each retrieved article (K.P., V.L.). Because quality scoring is controversial in meta-analyses of observational studies, two reviewers (K.P., V.L.) independently appraised each article included in our analysis and graded the evidence as either very low, low, moderate, or strong [18,19].

2.4. Statistical analysis

For conventional meta-analysis, the relative risk (RR) and weighted mean difference was used as a summary statistic. In the present study, both fixed-effect and random-effects models were tested. In the fixed-effects model, it was assumed that treatment effect in each study was the same, whereas in a random-effects model, it was assumed that there were variations between studies. χ^2 tests were used to study heterogeneity between trials. I^2 statistic was used to estimate the percentage of total variation across studies, owing to heterogeneity rather than chance, with values greater than 50% considered as substantial heterogeneity. I^2 can be calculated as: $I^2 = 100\% \times (Q - df)/Q$, with Q defined as Cochrane's heterogeneity statistic and df defined as degree of freedom. If there was substantial heterogeneity, the possible clinical and methodological reasons for this were explored qualitatively. In the present meta-analysis, the results using the random-effects model were presented to take into account the possible clinical diversity and methodological variation between studies. Specific analyses considering confounding factors were not possible because raw data were not available. All P values were two-sided.

Meta-analyses may result in type I errors due to increased risk of random error when sparse data is analysed, and also due to repeated significance testing when a cumulative meta-analysis is updated with new trials. Therefore, TSA can be conducted on included randomised trials to maintain the overall risk of type I error at 5%, whilst also reporting the information size, estimate of optimum sample size for statistical inference from a meta-analysis after accounting for heterogeneity or diversity. TSA combines an estimation of information size with adjusted threshold for statistical significance, called trial sequential monitoring boundaries. When the cumulative z-statistical curve crosses the trial monitoring boundary, a sufficient level of evidence for an intervention is deemed achieved and further trials are unlike to change conclusions. If the trial sequential monitoring boundary is not crossed, then there is insufficient evidence to support a conclusion. Thresholds for futility are also derived, and when the z-curve crosses into the futility area, future trials are unlikely show any differences between the two comparators for that outcome. For the present TSA, a 25% threshold was used for RR difference for fusion rate and 25% RR reduction for all complications. We adjusted all TSA for heterogeneity (diversity) according to type I error of 5% and power of 80%.

3. Results

3.1. Search strategy

A total of 1310 references were identified through the electronic database search as well as other sources, such as reference lists (Fig. 1). After exclusion of duplicate or irrelevant references, 1295 references remained for title and abstract screening. After the inclusion and exclusion criteria were applied, 37 studies remained for detailed assessment. After detailed evaluation of these articles, 17 studies were finally included in the present systematic review and meta-analysis, with a total of 574 cases of bilateral instrumentation and 549 cases of unilateral instrumentation.

All included studies were prospective studies. There were four observational studies [20–23] and 13 randomised controlled trials [10,24–35]. All studies included fewer than 100 patients in total with the exception of Duncan et al. [29] and Xie et al. [10]. Minimally invasive TLIF was used in six studies [20,21,25,27,30,31] whereas the remaining studies employed either open posterior or TLIF. The average follow-up ranged from 3 months to 36 months. Mean age and proportion of males for each group for each study is shown in Table 1. Assessment of the grade of evidence for each outcome is shown in Table 2.

3.2. Assessment of fusion

Fusion rate was reported in all 15 included studies, and was subgrouped according to procedure type: open PLIF/TLIF *versus* minimally invasive surgery. From nine studies reporting fusion rates for open PLIF/TLIF, there was no significant difference between fusion rates in bilateral *versus* unilateral instrumentation cohorts (95.2% *versus* 92.5%; RR, 1.01; P = 0.35). Similarly, there was also no difference when considering only minimally invasive spinal procedures (96.6% *versus* 92.6%; RR, 1.02; P = 0.38) or when considering all procedure types together (95.7% *versus* 92.5%; RR, 1.02; P = 0.21) (Fig. 2).

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