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Review

A systematic review and meta-analysis of outcomes in hybrid constructs for multi-level lumbar degenerative disc disease

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ABSTRACT

A systematic review and meta-analysis was performed to assess the effect of hybrid constructs which involve a total disc arthroplasty (TDA) with stand-alone anterior lumbar interbody fusion (ALIF) versus non-hybrid constructs including multi-level TDA, multi-level transforaminal lumbar interbody fusion (TLIF) with posterior transpedicular fixation or multi-level stand-alone ALIF as a surgical intervention for degenerative disc disease (DDD) in the lumbar spine. Primary outcomes analysed included the Oswestry Disability Index (ODI) and the Visual Analogue Scale (VAS) for back pain. A systematic search of Medline, Embase, Pubmed, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews and Google Scholar was undertaken by two separate reviewers and a meta-analysis of the outcomes was performed. Three studies met our search criteria. When comparing hybrid constructs to multi-level TDA or lumbar fusion (LF) improvements in back pain were found with a VAS back pain score reduction of 1.38 ($P < 0.00001$) postoperatively and a VAS back pain score reduction of 0.99 points ($P = 0.0006$) at 2-years follow-up. Results so far slightly favour clinically significant improved VAS back pain score outcomes postoperatively and at 2-years follow-up for hybrid constructs in multi-level lumbar DDD of the spine when compared with non-hybrid multi-level LF or TDA. It cannot however be concluded that a hybrid construct is superior to multi-level LF or TDA based on this meta-analysis. The results highlight the need for further prospective studies to delineate best practice in the management of degenerative disc disease of the lumbar spine.

1. Introduction

Lumbar fusion (LF) either with stand-alone anterior lumbar interbody fusion (ALIF) or transforaminal lumbar interbody fusion (TLIF) with transpedicular screw fixation is an acceptable approach in the operative management of degenerative disc disease (DDD) [1] and has relatively similar 'cost to quality of life improvement ratios' using the Short Form Survey – 36 (Physical Component Summary) when compared to coronary artery bypass surgery, knee and hip replacement [2]. In recent years, total disc arthroplasty (TDA) has emerged as an alternative option for patients with DDD of the lumbar spine. TDA has shown small but statistically significant differences to short term pain relief, quality of life and disability when compared to fusion in the lumbar spine for chronic low-back pain [3]. Several published meta-analyses have demonstrated at least non-inferiority at the postoperative period and at 2-years follow-up with possible physical function and back pain advantages [4–8]. Results at 10-years follow-up have also been reported to compare favourably with single and two level TDA versus LF [1].

Theoretical benefits of TDA over LF are stated as a reduction in adjacent segment disease (ASD) due to motion preservation of the spine over the mid to long term. The literature however now suggests that even though there seems to be a minor higher risk of ASD after lumbar fusion of either one or two levels, the reported ASD is not clinically meaningful as indicated by an analysis of four randomized controlled trials (RCTs) in 2014 by Mannion et al. [9–11]. Emerging evidence also suggests ASD is probably an effect of genetic predisposition rather than primarily due to fusion [12]. At this stage it is still unclear as to whether there are any cost differences between TDA as compared to LF [13–15].

One level disc arthroplasty was shown to have similar kinematics of an intact spine, whereas two level replacements tended to reduce clinical stability [16] with increases in postoperative back pain due to posterior joint structures including the facet and iliosacral joints

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[17]. Hybrid constructs were found to be a potential solution to these stability [16] and postoperative back pain issues [18,19].

Hybrid surgery with a TDA at L4–L5 and a stand-alone anterior lumbar interbody fusion (ALIF) at L5–S1 has thus been utilized by some spinal surgeons for degenerative disc disease of the lumbar spine. Few studies have focused on the comparison of hybrid versus the non-hybrid constructs for multi-level lumbar DDD. Therefore, we conducted a systematic review and meta-analysis to compare these approaches in terms of their outcomes and complications.

2. Method

2.1. Purpose

The purpose of this paper was to compare the effect of hybrid constructs as a surgical intervention for DDD in the lumbar spine on clinical outcomes including disability and back pain using the Oswestry Disability Index (ODI) [20] and Visual Analogue Scale (VAS) for back pain with non-hybrid surgical options including stand-alone ALIF, multi-level TDA and TLIF with transpedicular fixation. A systematic review and meta-analysis of outcomes in lumbar hybrid constructs for multi-level degenerative disc disease was undertaken and complication rates were analysed as a secondary outcome.

2.2. Search strategy and study selection

A systematic search of Medline, Embase, Pubmed, Cochrane Central Register of Controlled Trials (CCTR), Cochrane Database of Systematic Reviews (CDSR), Google Scholar was undertaken by two separate reviewers (A. Lackey & K. Phan). For Medline, the MESH terms "lumbar vertebrae", "arthroplasty or arthroplasty, replacement", "spinal fusion", "intervertebral disc degeneration or intervertebral disc displacement" connected by Boolean operator AND were used. The search was otherwise conducted using "lumbar fusion" and "total disc replacement" or "hybrid fusion". Papers were included if they were reporting hybrid fusion arthroplasty in the lumbar spine with ODI or VAS (back pain) reported as primary outcomes. The PRISMA statement was followed and is described within the results.

All papers were excluded if there was less than 2-years follow-up for VAS (back pain) or ODI primary outcomes and if VAS (back pain) or ODI were not reported as primary outcomes. All case series, case reports, opinions of respected authorities, descriptive studies, reports of expect committees were excluded and if the paper had a high risk of bias as per the Cochrane Back Review Group list of criteria.

2.3. Data extraction, critical appraisal and treatment effect

Relevant data was extracted from the literature through interpretation of writing, tables and figures. Data extraction was conducted and reviewed by independent authors. Risk of bias was assessed using the Cochrane Back Review Group list of criteria [21]. If the papers were graded as a high risk of bias, they were excluded from the study. The final results were reviewed by a senior investigator. The minimum clinically important difference in primary outcome was viewed as a 30% change, a value previously described by Jacobs et al. [3].

2.4. Statistical analysis

All statistical analysis was conducted with Review Manager Version 5.3.5 (Cochrane Collaboration, Software Update, Oxford, United Kingdom). The weighted mean difference (WMD) and odds ratio (OR) was used as a summary statistic. In the present study, both fixed- and random-effect 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 (as an inconsistency index), 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 statistics 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 2-sided.

A Begg's and Egger's test for publication bias was not indicated given the paucity of studies, likewise a trim and fill analysis.

3. Results

The PRISMA search strategy workflow [22] went as follows: 1015 results for the search were reviewed from Ovid Medline, Embase 1996 to present and from inception with Pubmed, Google Scholar, Cochrane Central Register of Controlled Trials (CCTR) and Cochrane Database of Systematic Reviews (CDSR). Nine papers were considered relevant and after exclusions based off predetermined criteria, three were included for meta-analysis.

3.1. Risk of bias

Risk of bias was assessed using the Cochrane Back Review Group list of criteria. The three studies being analysed consisted of one retrospective analysis and two non-blinded, RCTs and as such many of the criteria were not considered applicable. For the prospective studies assessed, if at least half of the applicable criteria rated 'yes' as opposed to 'no' or 'unsure' or 'NA', the paper was not considered to have a high level of bias and was thus included. Seven of 13 related to prospective studies and one of the criteria was related to non-surgical interventions (compliance) therefore the retrospective analysis was not scored in this way and met all five of five applicable criteria [5,21].

3.2. Cochrane back review group list of bias criteria

See Table 1.

3.3. Study characteristics and perioperative data

Study characteristics including study enrolment period, institute, country, design, comparator intervention and size are included in Table 2.

3.3.1. Study characteristics

The baseline patient parameters of all 184 patients were summarized with average age and percentage of male sex displayed in Table 3.

3.3.2. Perioperative data

Operation duration was reported in all three trials and varied between studies considerably with Chen reporting vastly longer operating times for both hybrid and non-hybrid surgeries than Hoff