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Review Article

The effect of Mobi-C cervical total disc replacement versus ACDF in symptomatic degenerative disc disease: a meta-analysis of randomized controlled trials

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Abstract: Introduction: The efficacy of total disc replacement (TDR) using Mobi-C cervical artificial disc for treating symptomatic degenerative disc disease remained controversial. We conducted a systematic review and meta-analysis to compare the efficacy and safety of Mobi-C cervical artificial disc versus anterior cervical discectomy and fusion (ACDF) in symptomatic degenerative disc disease. Methods: We searched PubMed, EMbase, Web of science, EBSCO, and Cochrane library databases through September 2017 for randomized controlled trials (RCTs) assessing the effect of Mobi-C versus ACDF on symptomatic degenerative disc disease. Meta-analysis was performed using the random-effect model. Results: Six RCTs involving 731 patients were included in the meta-analysis. Overall, compared with ACDF treatment for symptomatic degenerative disc disease, TDR using Mobi-C resulted in significantly increased NDI score (Std. mean difference =0.33; 95% CI=0.18 to 0.49; P<0.0001) and NDI success rate (RR=1.36; 95% CI=1.16 to 1.61; P=0.0002), decreased reoperation (RR=0.25; 95% CI=0.16 to 0.39; P<0.00001) and adverse events than ACDF treatment (RR=0.53; 95% CI=0.38 to 0.73; P=0.0001), but demonstrated no significant influence on pain scores (Std. mean difference =0.11; 95% CI=-0.05 to 0.27; P=0.19), blood loss (Std. mean difference =-0.78; 95% CI=-1.89 to 0.32; P=0.16), duration of surgery (Std. mean difference =0.17; 95% CI=-0.27 to 0.60; P=0.45), hospital stay (Std. mean difference =-0.14; 95% CI=-0.32 to 0.04; P=0.13). Conclusions: Mobi-C treatment resulted in a significantly improved NDI score and NDI success rate, decreased reoperation and adverse events compared to ACDF surgery in symptomatic degenerative disc disease.

Keywords: Mobi-C, total disc replacement (TDR), anterior cervical discectomy and fusion (ACDF), symptomatic degenerative disc disease, meta-analysis

Introduction

Anterior cervical discectomy and fusion (ACDF) is widely accepted as the standard surgical procedure for cervical disc decompression for symptomatic degenerative disc disease and can decompress affected neural components, provide mechanical stability and lordosis, and preserve intradiscal height [1-3]. However, ACDF has some limitations such as the increase in motion, shear strain, and intradiscal pressure in adjacent vertebrae [4-6]. Patients treated with ACDF are reported to result in increased rates of adjacent-segment degeneration because of force and motion translocation [4, 7-9].

Cervical total disc replacement (TDR) is a treatment option for symptomatic radiculopathy and myelopathy. Many studies have reported that TDR is a safe and effective alternative to ACDF for one-level and two-levels cervical decompression [10-14]. The Mobi-C cervical artificial disc (LDR Medical; Troyes, France) consists of 2 cobalt-chromium-molybdenum alloy endplates and an ultra-high-molecular-weight polyethylene mobile insert and allows 5 independent degrees of freedom [15, 16]. Some RCTs have reported cervical TDR using Mobi-C is able to significantly improve neck disability index (NDI) score, patient satisfaction, and reoperation compared to ACDF in symptomatic degenerative disc disease [16-18].

However, the use of Mobi-C has not been well established. Recently, several studies on the topic have been published, and the results have been conflicting [17, 19, 20]. With accumulating evidence, we therefore performed a systematic review and meta-analysis of RCTs to compare the efficacy and safety of Mobi-C versus ACDF in symptomatic degenerative disc disease.

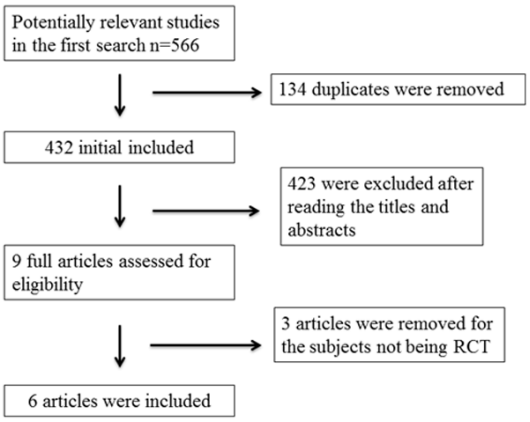

Figure 1. Flow diagram of study searching and selection process.

Materials and methods

Ethical approval and patient consent were not required because this was a systematic review and meta-analysis of previously published studies. The systematic review and meta-analysis were conducted and reported in adherence to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [21].

Search strategy and study selection

Two investigators independently searched the following databases (inception to September 2017): PubMed, EMbase, Web of science, EBSCO, and Cochrane library databases. The electronic search strategy was conducted using the following keywords: Mobi-C or total disc replacement, and anterior cervical discectomy and fusion or ACDF. We also checked the reference lists of the screened full-text studies to identify other potentially eligible trials.

Inclusive selection criteria were as follows: (i) population: patients with symptomatic degenerative disc disease; (ii) intervention: TDR using Mobi-C; (iii) comparison: ACDF; (iv) outcome measure: neck disability index (NDI) score and NDI success rate; and (v) study design: RCT.

Data extraction and outcome measures

We extracted the following information: author, number of patients, population, age of patients, setting, type of control, and the experience of operators. Data were extracted independently by two investigators, and discrepancies were resolved by consensus. We contacted the corresponding author to obtain the data when necessary. No simplifications and assumptions were made. The primary outcomes were NDI score and NDI success rate. Secondary outcomes included reoperation, pain scores, blood loss, duration of surgery, hospital stay, and adverse events.

NDI success was defined as an improvement of at least 30 points for patients with a baseline NDI score of at least 60 or as an improvement of at least 50% from baseline for patients with a baseline NDI score less than 60 [22].

Quality assessment in individual studies

Methodological quality of the included studies was independently evaluated using the modified Jadad scale [23]. There was 3 items for Jadad scale: randomization (0-2 points), blinding (0-2 points), dropouts and withdrawals (0-1 points). The score of Jadad Scale varied from 0 to 5 points. An article with Jadad score ≤ 2 was considered to be of low quality. If the Jadad score ≥ 3, the study was thought to be of high quality [24].

Statistical analysis

We estimated the relative risk (RR) with 95% confidence interval (CI) for dichotomous outcomes (NDI success rate, reoperation, pain scores, adverse events), and standard Mean differences (Std. MDs) with 95% CI for continuous outcomes (NDI score, blood loss, duration of surgery, hospital stay). A random-effects model was used regardless of heterogeneity. Heterogeneity was reported using the I^2 statistic, and $I^2 > 50\%$ indicated significant heterogeneity [25]. Whenever significant heterogeneity was present, we searched for potential sources of heterogeneity via omitting one study in turn for the meta-analysis or performing subgroup analysis. Publication bias was not evaluated because of the limited number (<10) of included studies. All statistical analyses were performed using Review Manager Version 5.3 (The Cochrane Collaboration, Software Update, Oxford, UK).

Results

Literature search, study characteristics and quality assessment

A detailed flowchart of the search and selection results was shown in **Figure 1**. 566 potentially

Table 1. Characteristics of included studies

NO.	Author	Mobi-C group						ACDF group						Surgical level	Follow-up	Jada scores
		NO.	Ethnicity, hispanic or latino/not hispanic or latino	Age (years)	BMI, kg/m^2	Able to work No.	Able to drive No.	NO.	Ethnicity, hispanic or latino/ not hispanic or latino	Age (years)	BMI, kg/m^2	Able to work No.	Able to drive No.			
1	Hou 2016, China	51	-	46.3±7.8	21±3.2	-	-	48	-	48.5±8.3	22±2.5	-	-	One-level	5 y	3
2	Hisey 2016, USA	164	3/161	43.3±9.2	27.3±4.4	108 (65.9%)	155 (94.5%)	81	2/79	44.0±8.2	27.4±4.2	46 (56.8%)	79 (97.5%)	One-level	5 y	4
3	Reginald 2015, USA	225	14/211	45.3±8.1	27.6±4.5	141 (62.7%)	210 (93.3%)	105	7/98	46.2±8.0	28.1±4.2	64 (61.0%)	102 (97.1%)	Two-level	4 years	4
4	Hisey 2014, USA	164	3/161	43.3±9.2	27.3±4.4	108 (65.9%)	155 (94.5%)	81	2/79	44.0±8.2	27.4±4.2	46 (56.8%)	79 (97.5%)	One-level	2 years	4
5	Davis 2013, USA	225	14/211	45.3±8.10	27.625±4.4697	141 (62.7%)	210 (93.3%)	105	7/98	46.2±7.99	28.102±4.1953	64 (61.0%)	102 (97.1%)	Two-level	2 years	4
6	Park 2008, Korea	21	-	45 (31-61)	-	-	-	32	-	47 (26-63)	-	-	-	One-level	1 year	3

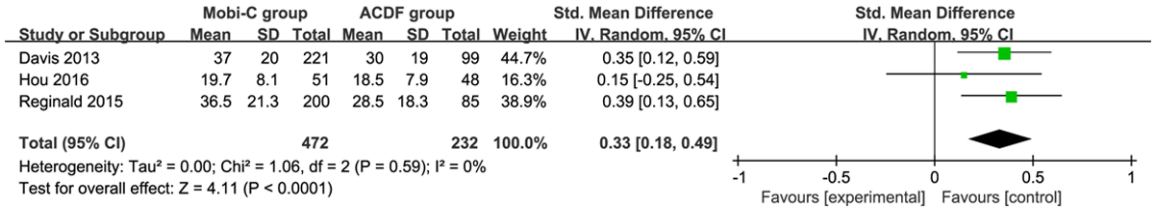

Figure 2. Forest plot for the meta-analysis of NDI score.

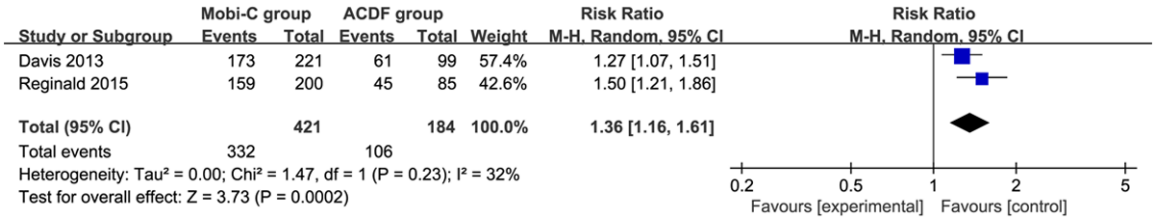

Figure 3. Forest plot for the meta-analysis of NDI success rate.

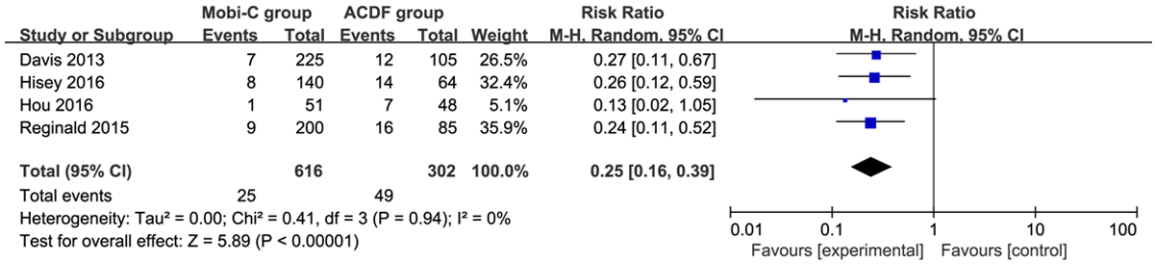

Figure 4. Forest plot for the meta-analysis of reoperation.

relevant articles were identified initially. Finally, six RCTs that met our inclusion criteria were included in the meta-analysis [16-20, 26].

The baseline characteristics of the six eligible RCTs in the meta-analysis were summarized in **Table 1**. The six studies were published between 2008 and 2016, and sample sizes ranged from 53 to 330 with a total of 731. Two same patient samples were studied in different follow-up time and published by Hisey [18, 20] and Davis [16, 17]. There were similar age, BMI, work status and driving status in patients at baseline. Of these six RCTs, four studies reported one-level total disc [18-20, 26] and two studies reported two-level total disc [16, 17] for analysis. And the follow-up time varied from 1 year to 5 years.

Among the six studies included here, three studies reported the NDI score [16, 17, 19], two studies reported the NDI success rate [16, 17], four studies reported the reoperation [16-19], two studies reported the pain scores [17, 19], three studies reported the blood loss, duration of surgery and hospital stay [16, 19, 20], five studies reported the adverse events [16-18, 20, 26].

Primary outcomes: NDI score and NDI success rate

These two outcome data were analyzed with a random-effects model, and the pooled estimate of the three included RCTs suggested that compared to ACDF, Mobi-C treatment could significantly improve NDI score (Std. mean difference =0.33; 95% CI=0.18 to 0.49; P<0.0001) for symptomatic degenerative disc disease, with no heterogeneity among the studies (I^2= 0%, heterogeneity P=0.59) (**Figure 2**). Consistently, TDR using Mobi-C resulted in significantly increased NDI success rate (RR=1.36; 95% CI=1.16 to 1.61; P=0.0002), with low heterogeneity among the studies (I^2=32%, heterogeneity P=0.23) (**Figure 3**).

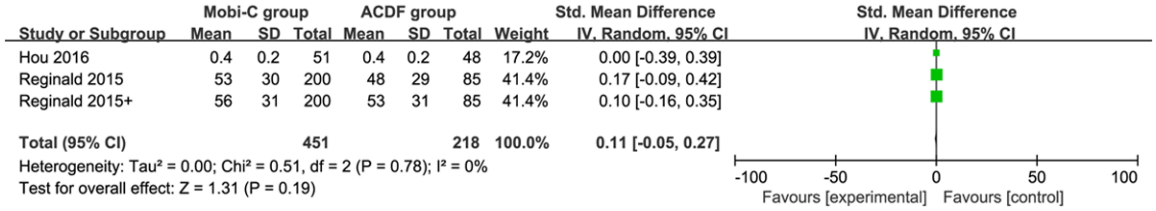

Figure 5. Forest plot for the meta-analysis of pain scores.

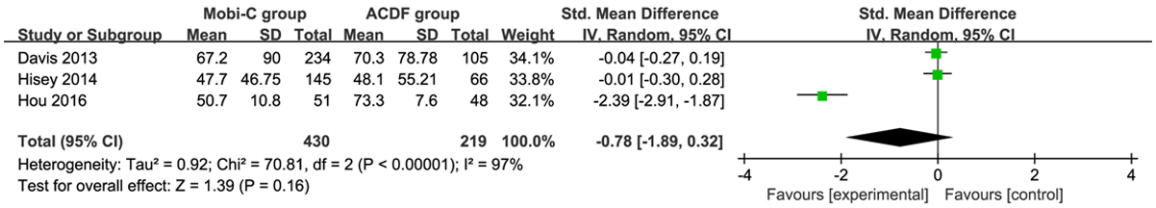

Figure 6. Forest plot for the meta-analysis of blood loss (ml).

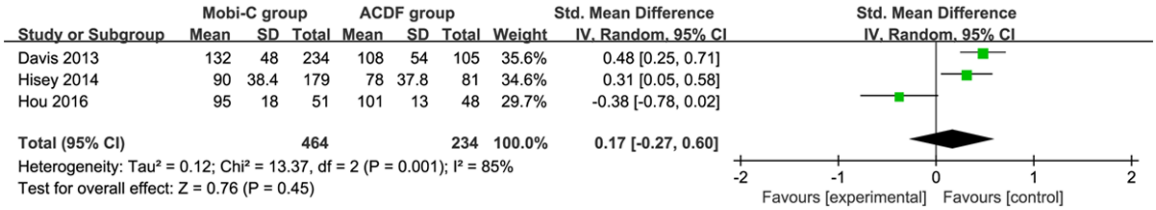

Figure 7. Forest plot for the meta-analysis of duration of surgery (min).

Sensitivity analysis

Low heterogeneity or no heterogeneity was observed among the included studies for NDI score and NDI success rate. Thus, we did not perform sensitivity analysis by omitting one study in each turn to detect the source of heterogeneity.

Secondary outcomes

Compared with ACDF in symptomatic degenerative disc disease, TDR using Mobi-C resulted in significantly decreased reoperation (RR= 0.25; 95% CI=0.16 to 0.39; P<0.00001; **Figure 4**), but showed no notable influence on pain scores (Std. mean difference =0.11; 95% CI=-0.05 to 0.27; P=0.19; **Figure 5**), blood loss (Std. mean difference =-0.78; 95% CI=-1.89 to 0.32; P=0.16; **Figure 6**), duration of surgery (Std. mean difference =0.17; 95% CI=-0.27 to 0.60; P=0.45; **Figure 7**), hospital stay (Std. mean difference =-0.14; 95% CI=-0.32 to 0.04; P=0.13; **Figure 8**). In addition, Mobi-C treatment led to remarkably reduced adverse events than ACDF treatment (RR=0.53; 95% CI=0.38 to 0.73; P=0.0001; **Figure 9**).

Discussion

Short- and long-term studies have reported greater improvements in NDI, neck pain, and arm pain in TDR populations compared to ACDF, but the significance of these results remain controversial [12, 27-30]. Single-level TDR clinical trials indicate that TDR may result in a lower incidence of secondary operations [12, 29, 31]. For example, a 2-fold increase in secondary surgery rates in patients with one-level ACDF was revealed compared with Bryan cervical disc replacement [32]. Our meta-analysis suggested that compared to ACDF treatment for symptomatic degenerative disc diseases, TDR using Mobi-C was able to significantly improve NDI score and NDI success rate, reduce reoperation and adverse events, but with no notable influence on pain scores, blood loss, duration of surgery and hospital stay.

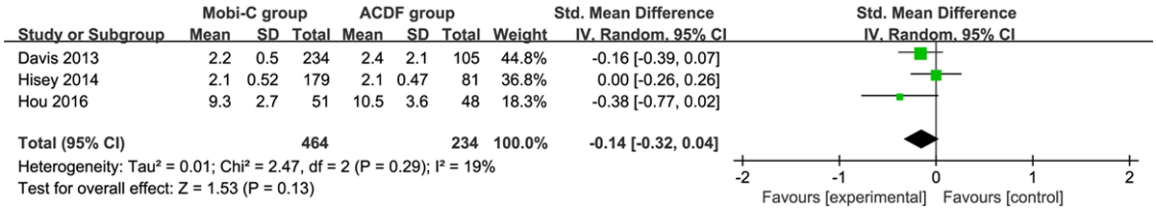

Figure 8. Forest plot for the meta-analysis of hospital stay (days).

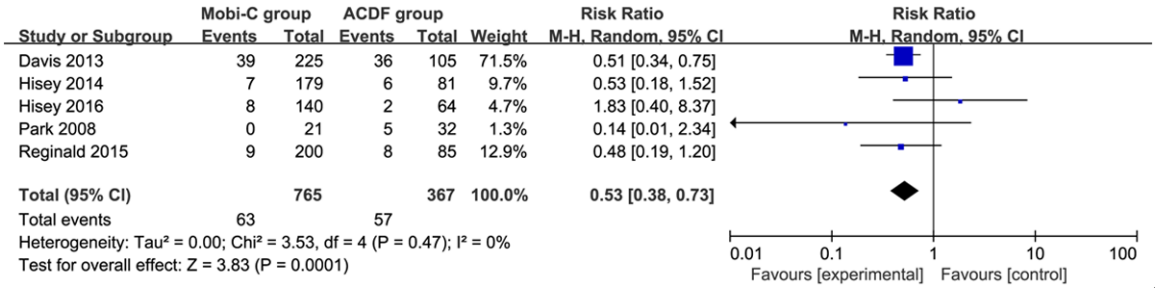

Figure 9. Forest plot for the meta-analysis of adverse events.

The safety and effectiveness of TDR has been proved based on many studies at different follow-up periods [12, 32]. TDR has an important advantage over ACDF with regard to motion preservation. ACDF eliminates motion at treated levels, while TDR has preserved segment mobility with high success [29, 32]. TDR may reduce the incidence of adjacent-segment degeneration compared with ACDF due to maintain segmental motion and stress profiles [33-35]. In one RCT involving one-level arm, there were 4 times fewer TDR patients requiring a subsequent operation at adjacent levels after Mobi-c treatment than ACDF [16].

Similar results were revealed in the 2-level arm for adjacent-level surgeries. In a long-term TDR study with the Prestige artificial cervical disc, TDR patients resulted in a lower rate of secondary surgeries involving adjacent segments compared with ACDF controls (TDR 2.9% versus ACDF 4.9%) [12]. Mummaneni et al. also reported that TDR population demonstrated a statistically significant decrease in secondary operations because of adjacent segments (TDR 2/276 versus ACDF 9/265) [29]. One included RCT reported a significantly greater rate of adjacent-segment degeneration at both the inferior and superior index levels for 2-level ACDF compared with TDR using Mobi-C for symptomatic degenerative disc disease at 4 years [17]. The rate of adjacent-level operations was similar between one-level and two-level ACDF or TDR groups.

This meta-analysis has several potential limitations that should be taken into account.. Firstly, our analysis is based on only four RCTs and two of them had a relatively small sample size (n<100). Overestimation of the treatment effect is more likely in smaller trials compared with larger samples. Next, pooling results may be affected by different follow-up periods (ranging from 1 year to 5 years) and longer follow-up time is needed to confirm the efficacy of Mobi-C treatment. Finally, although there is no heterogeneity among the reviewed studies, different operation levels may have a potential impact on our results.

Conclusions

TDR patients with Mobi-C demonstrated significantly increased function and reduced reoperation and adverse events for symptomatic degenerative disc disease. TDR using Mobi-C was recommended to be administrated in clinical work.

Disclosure of conflict of interest

None.

Abbreviations

TDR, Total disc replacement; ACDF, Artificial disc and anterior cervical discectomy and fusion; RCTs, Randomized controlled trials; NDI, Neck disability index; Std. MDs, Standard mean differences.

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