

## Review Article

# Incidence of postoperative dysphagia/dysphonia between cervical disc replacement and anterior cervical discectomy and fusion: a comprehensive evaluation

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**Abstract:** The aim of this study is to compare the incidence of postoperative dysphagia/dysphonia between anterior cervical discectomy and fusion (ACDF) with an anterior plate and cervical disc replacement (CDR). PubMed, EMBASE, Web of science, Ovid, Cochrane library and China Knowledge Resource Integrated Database (until March 1, 2016) were searched. RCTs that reported the number of patients who suffered from dysphagia/dysphonia after CDR and ACDF were included. Relative risk (RR) with 95% confidence interval (95% CI) was calculated for dichotomous outcomes. Sensitivity analyses and publication bias were performed. Finally 12 RCTs with a total of 1948 patients who underwent CDR and 1552 patients who underwent ACDF were included in this meta-analysis. No statistically significant difference concerning the incidence of postoperative dysphagia/dysphonia between CDR and ACDF was observed (RR = 0.809, 95% CI [0.610, 1.073],  $z = 1.47$ ,  $P = 0.142$ ). A significant lower incidence of postoperative dysphagia in CDR group compared with patients in ACDF group was observed (RR = 0.751, 95% CI [0.588, 0.960],  $z = 2.29$ ,  $P = 0.022$ ). No statistically significant difference concerning the incidence of postoperative dysphonia between CDR and ACDF was observed (RR = 0.435, 95% CI [0.133, 1.423],  $z = 1.38$ ,  $P = 0.169$ ). CDR may reduce the incidence of postoperative dysphagia but not dysphagia/dysphonia as a whole part and dysphonia compared with ACDF with an anterior plate. Since lack of gold standard diagnostic criteria and details of dysphagia or dysphonia in the included original studies, results of this meta-analysis should be validated by future RCTs which use gold standard diagnostic criteria and specially focused on details of postoperative dysphagia and dysphonia.

**Keywords:** Dysphagia, dysphonia, ACDF, cervical disc replacement, meta-analysis, deglutition, deglutition disorders

## Introduction

Since the 1960s anterior cervical discectomy and fusion (ACDF) with or without anterior cervical plate has been regard as the golden standard method for the treatment of many cervical spinal diseases [1]. With potential advantages of preservation of motion, decreased rate of adjacent segment degeneration and less work stoppage, cervical disc replacement (CDR) has been widely applied in recently years [2]. A great deal of studies including randomized controlled trials (RCT), non-randomized prospective studies and retrospective studies have compared the clinical and radiographic results between ACDF and CDR [3-12]. From 2006 to

2016 numerous meta-analyses have been conducted and published online but these studies often focused on operation time, mean blood loss, hospital stay duration, Japanese Orthopedic Association (JOA) score, neck and arm visual analog scale (VAS), neck disability index (NDI), adjacent segment degeneration, range of motion (ROM), instrumental complications, work stoppage and cost-effectiveness [13-21]. One of the most valuable advantage of CDR is the potential decreased rate of adjacent segment degeneration which have been specially focused by many spinal surgeons and lots of RCTs and meta-analyses concerning adjacent segment degeneration have been conducted since the artificial cervical disc was developed

[18, 22-25]. However, dysphagia/dysphonia, one of the most common early complaints after anterior cervical surgery, has not been specially investigated in previous meta-analyses.

Dysphagia, commonly regarded as a “multi-factorial” result, has not been fully investigated. Many factors were reported to be associated with postoperative dysphagia and one of them is anterior plate [26]. If an anterior cervical plate is placed directly posterior to the esophagus, the plate may have an influence on the incidence of postoperative dysphagia as any mechanical irritation or impingement against the esophagus may make a contribution to postoperative dysphagia. A new zero-profile, standalone device (Zero-P, Synthes GmbH, Switzerland) for ACDF has been developed and reported to be able to reduce the incidence of dysphagia compared to anterior plate [27-29]. Similarly the artificial disc prosthesis can also be regarded as “low-profile” or “non-profile” but whether CDR can reduce the incidence of postoperative dysphagia still remains controversial. Dysphonia, similar with dysphagia, is a common complication (prevalence ranges from 1% to 51% by previous studies) of anterior cervical spine surgery [30-32]. Dysphonia is one potential manifestation of a recurrent laryngeal nerve palsy and other symptoms such as postoperative airway obstruction, persistent cough, or aspiration can be found in patients with severe injuries. More extensive dissection, aggressive retraction, longer cuff inflation time, and elevated endotracheal tube pressures were reported to be associated with postoperative dysphonia [33, 34]. Theoretically ACDF with an anterior plate often means a more extensive dissection and a more aggressive retraction compared with CDR; however whether this difference will have an impact on postoperative dysphonia still remains controversial. Meta-analysis, a good statistical method to combine the results from multiple studies, is able to increase statistical power, improve estimates of the magnitude of an effect and resolve uncertainty across conflicting reports [35-37]. Based on the most available and up-to-date information, a meta-analysis was performed to compare the incidence of postoperative dysphagia/dysphonia between ACDF and CDR. To the best of our knowledge, this is the first meta-analysis concerning dysphagia/dysphonia after ACDF and CDR.

### Patients and methods

Ethical approval for this study was not required because it was a meta-analysis of existing literature and did not involve any collection or handling of individual patient data. This study was performed and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [38].

#### *Search strategy*

PubMed, EMBASE, Web of science, Ovid, Cochrane library and China Knowledge Resource Integrated Database (until March 1, 2016) were searched using search algorithm as “cervical” and (“arthroplasty” or “total disc replacement” or “artificial disc replacement”) or (“total disc replacement” or “artificial disc replacement”) and (“dysphagia” or “dysphonia” or “Deglutition disorders”) or (“complications” or “outcomes” or “adverse events”). Additional related references from identified articles were also searched to identify other relevant publications. Only studies published in English or in Chinese language were included. The literature search was performed by two authors independently.

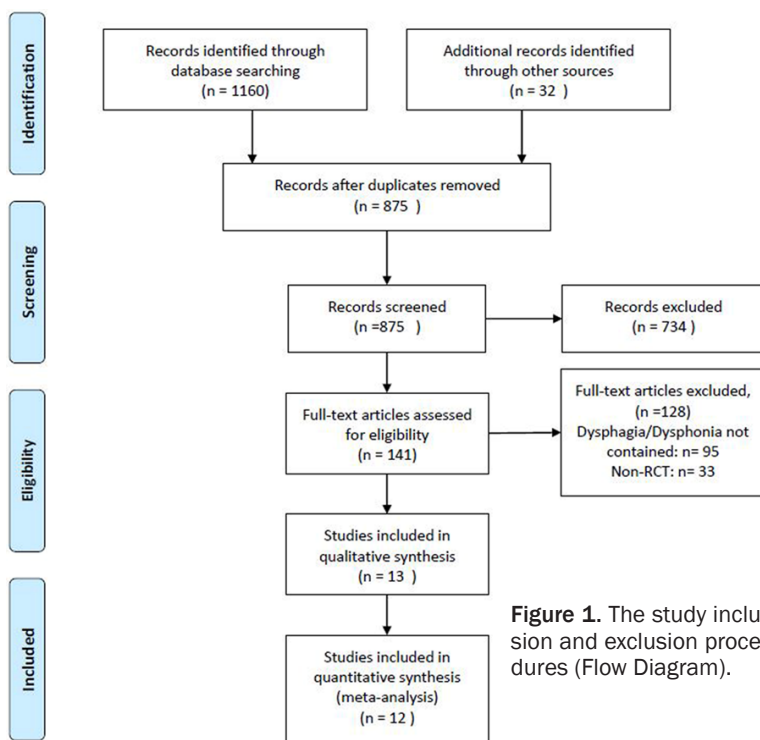
#### *Inclusion and exclusion criteria*

We included studies that were eligible for the following criteria: RCTs that reported the number of patients who suffered from dysphagia and (or) dysphonia after CDR and ACDF; the individual patients were older than 18 years. There was no limit placed on the follow-up duration or on the type of artificial disc prosthesis, anterior plate or cage/bone graft. Patients underwent single level or multi-level surgery were not limited. The exclusion criteria included: studies with patients who had acute spinal fracture, infection, tumor, osteoporosis, ankylosing spondylitis, or rheumatoid arthritis; studies with patients who had a history of disorders in the central nervous system such as stroke and traumatic brain injury, previous neck surgery and esophageal diseases; duplicate reports of earlier trials; reviews, letters, case reports, or comments.

#### *Data extraction and quality assessment*

Two investigators independently extracted the data from all qualified studies according to the

## Dysphagia/dysphonia after CDR and ACDF



**Figure 1.** The study inclusion and exclusion procedures (Flow Diagram).

inclusion and exclusion criteria listed above. Discrepancies were solved through discussion until agreement was reached. The information retrieved from the studies included the first author, publication year, mean age in CDR and ACDF groups, number of operated levels, follow-up duration, type of artificial disc prosthesis, type of fusion method in the control group, events of postoperative dysphagia/dysphonia, and number of patients in CDR and ACDF groups. The modified JADAD scale was used to assess the quality of included RCTs [39, 40]. This 7-point assessment includes the following categories: randomization, concealment of allocation, double blinding, withdrawals, and dropouts.

### Statistical analysis

The STATA software (version 13.0; StataCorp, College Station, TX) was used for all statistical analyses. Two-sided *P* values less than 0.05 were considered statistically significant. Relative risk (RR) with 95% confidence interval (95% CI) was calculated for dichotomous outcomes. Cochran's *Q*-statistic and the  $I^2$  metric were conducted to assess heterogeneity between studies [41]. We classified heterogeneity into three categories: high ( $I^2 > 50\%$ ), middle ( $25\% < I^2 < 50\%$ ), and low ( $I^2 < 25\%$ ). If the heterogene-

ity test result returned  $P > 0.1$ , the pooled ORs were analyzed using the random-effects model, or else, the fixed effects model was used [42]. Sensitivity analyses were also performed after sequential removal of each study. Lastly, publication bias was investigated by both Beggar's funnel plot and Egger's linear regression test [43].

## Result

### Characteristics of included studies

One thousand one hundred and sixty citations were initially retrieved from PubMed, EMBASE, Web of science, Ovid, Cochrane library and China Knowledge Resource Integrated Database. After duplicates removed, eight hundred and seventy-five citations were screened. 734 citations were excluded after title screen and 141 articles were reviewed for full-text. In these 141 articles: 95 articles did not report the incidence of dysphagia/dysphonia after CDR and ACDF; 33 articles were non-randomized prospective controlled trials, cohort studies, retrospective studies, case series and reviews. 13 RCTs reported the incidence of dysphagia/dysphonia after CDR and ACDF met the eligibility criteria were included in qualitative synthesis. One study [6] which reported the dysphagia/dysphonia as mean value and standard deviation according to the 0-100 VAS score was excluded and 12 RCTs were included in quantitative synthesis. The study inclusion and exclusion procedures are summarized in **Figure 1** (Flow Diagram).

Finally 12 RCTs with a total of 1948 patients who underwent CDR and 1552 patients who underwent ACDF were included in this meta-analysis [5, 44-54]. Nine studies were conducted in USA, one study was conducted in China, one study was conducted in Switzerland and one study was conducted in Sweden. Nine studies just include patients who underwent single level surgeries, two studies included patients who underwent two-level surgeries and one study included patients who under-

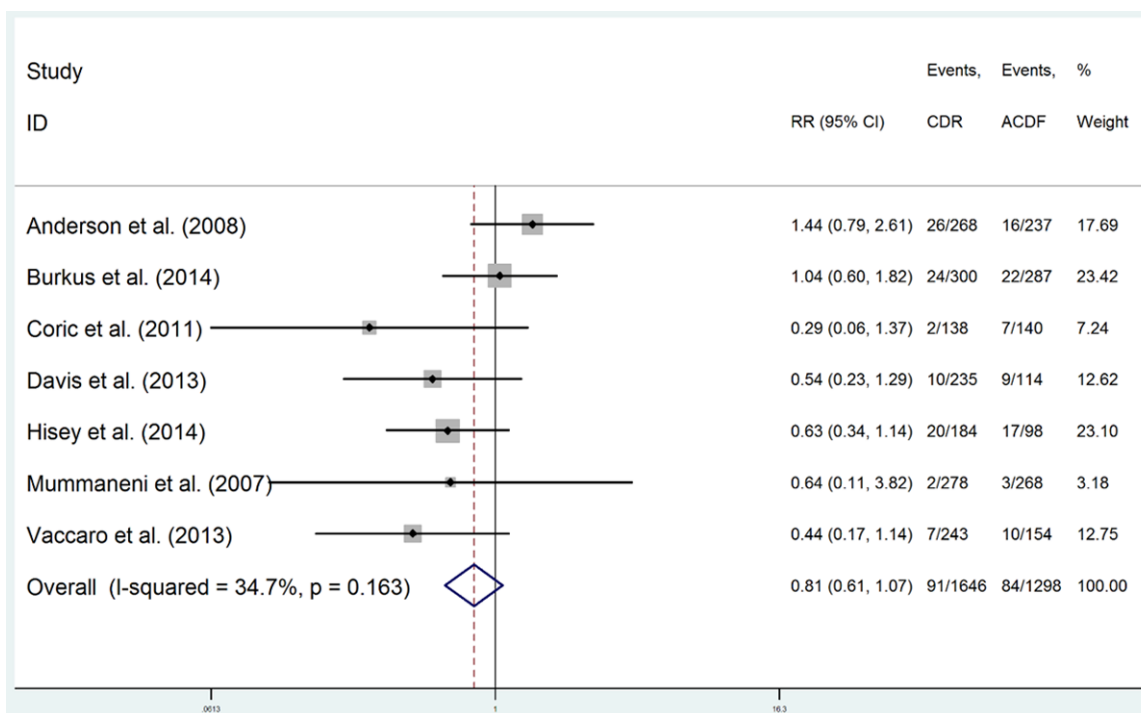
## Dysphagia/dysphonia after CDR and ACDF

**Table 1.** The main characteristics of the included studies

Author	Year	Country	Mean age (CDR)*	Mean age (ACDF)	Number of levels	Follow-up time*	Prosthesis of CDR	Fusion method	Study design	Dysphagia and (or) Dysphonia	Dysphagia Measurement	CDR Events	Sample size (CDR)	ACDF Events	Sample size (ACDF)	Quality#
Anderson et al.	2008	USA	Unclear	Unclear	Single-level	2	Bryan	Allograft and Plate	RCT	Dysphagia/ Dysphonia	WHO Grade	26	242	16	221	7
Burkus et al.	2014	USA	43.3	43.9	Single-level	7	Prestige	Allograft with plate	RCT	Dysphagia/ Dysphonia	Unclear	24	276	22	265	7
Cheng et al.	2008	China	45	47	Two-level	2	Bryan	Autograft and plate	RCT	Dysphagia	Unclear	0	31	1	34	7
Coric et al.	2011	USA	43.7	43.9	Single-level	2	Kineflex  C	Allograft and Plate	RCT	Dysphagia/ Dysphonia	Unclear	2	136	7	133	7
Davis et al.	2013	USA	45.3	46.2	Two-level	2	Mobi-C	Allograft and Plate	RCT	Dysphagia/ Dysphonia	Unclear	10 (9/1)	225	9 (8/1)	105	7
Hisey et al.	2014	USA	43.3	44	Single-level	2	Mobi-C	Allograft and Plate	RCT	Dysphagia/ Dysphonia	Unclear	20 (19/3)	164	17 (15/3)	81	7
Janssen et al.	2015	USA	42.1	43.5	Single-level	7	ProDisc-C	Plate	RCT	Dysphagia	The Bazaz grading scale	0	103	2	106	7
McAfee et al.	2010	USA	45	44	Single-level	2	PCM	Allograft and Plate	RCT	Dysphagia	Unclear	62	151	48	100	7
Mummaneni et al.	2007	USA	43.3	43.9	Single-level	2	Prestige ST	Allograft and Plate	RCT	Dysphagia/ Dysphonia	Unclear	2	276	3	265	7
Porchet et al.	2004	Switzerland	44	43	Single-level	2	Prestige II	Autograft	RCT	Dysphagia	Unclear	1	27	0	28	7
Skeppholm et al.	2015	Sweden	46.7	47	Mixed Levels	2	Discover	Autograft and plate	RCT	Dysphagia	the Dysphagia Short Questionnaire	9	81	12	70	7
Vaccaro et al.	2013	USA	53.6	48.6	Single-level	2	SECURE-C	Allograft and plate	RCT	Dysphagia/ Dysphonia	Unclear	7 (6/1)	236	10 (8/2)	144	7

CDR, cervical disc replacement; ACDF, anterior cervical discectomy and fusion; RCT, randomized controlled trial. \*Years. #RCTs were assessed by the modified JADAD scale.

## Dysphagia/dysphonia after CDR and ACDF



**Figure 2.** Forest plot of the risk ratio of the incidence of dysphagia/dysphonia after anterior cervical discectomy and fusion (ACDF) and cervical disc replacement (CDR).

went single level or two level surgeries. The mean follow-up duration of each study ranged from 2 to 7 years and the publication year of each study ranged from 2004 to 2015. Seven studies reported the total incidence of dysphagia/dysphonia, eight studies reported the incidence of dysphagia and three studied reported the incidence of dysphonia. The prostheses in CDR patients included Bryan, Prestige, Kineflex|C, Mobi-C, ProDisc-C, PCM, Prestige ST, Prestige II, Discover, and SECURE-C while the patients in ACDF group received allograft and anterior plate or autograft and anterior plate. The main characteristics of the included studies are listed in **Table 1**.

### Meta-analysis of dysphagia/dysphonia

Seven studies with a total of 1555 patients who underwent CDR and 1214 patients who underwent ACDF reported the whole incidence of dysphagia and dysphonia. Meta-analysis of all these studies revealed no statistically significant difference concerning the incidence of postoperative dysphagia/dysphonia between CDR and ACDF (RR = 0.809, 95% CI [0.610, 1.073],  $z = 1.47$ ,  $P = 0.142$ , **Figure 2**).

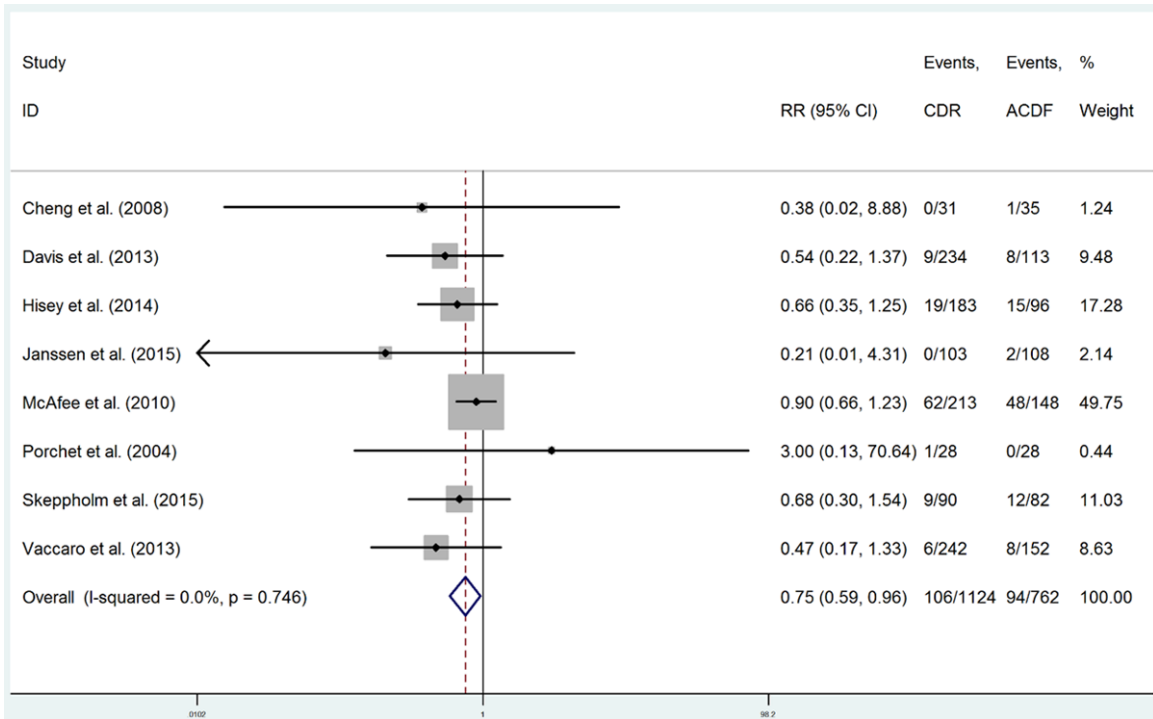
Eight studies reported the incidence of postoperative dysphagia and there were 1018 patients in CDR group and 668 patients in ACDF group. Meta-analysis of all these studies showed a significant lower incidence of postoperative dysphagia in CDR group compared with patients in ACDF group (RR = 0.751, 95% CI [0.588, 0.960],  $z = 2.29$ ,  $P = 0.022$ , **Figure 3**).

Three studies with 625 patients in CDR group and 330 patients in ACDF group reported the incidence of postoperative dysphonia. Meta-analysis of these studies revealed no statistically significant difference concerning the incidence of postoperative dysphonia between CDR and ACDF (RR = 0.435, 95% CI [0.133, 1.423],  $z = 1.38$ ,  $P = 0.169$ , **Figure 4**).

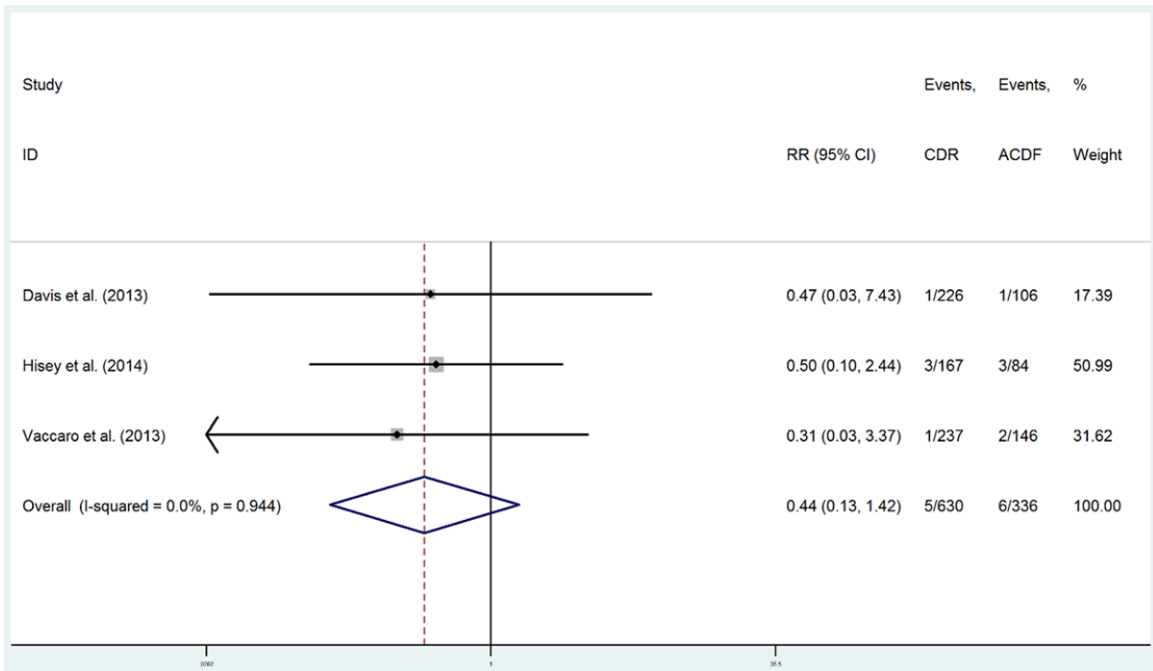
### Test for heterogeneity

No significant heterogeneity was detected in our study and the fixed effects model was used in our study. For meta-analysis of dysphagia/dysphonia, heterogeneity chi-squared = 9.18 (d.f. = 6),  $P = 0.163$ , I-squared (variation in RR attributable to heterogeneity) = 34.7%. For meta-analysis of dysphagia, heterogeneity chi-

## Dysphagia/dysphonia after CDR and ACDF



**Figure 3.** Forest plot of the risk ratio of the incidence of dysphagia after anterior cervical discectomy and fusion (ACDF) and cervical disc replacement (CDR).

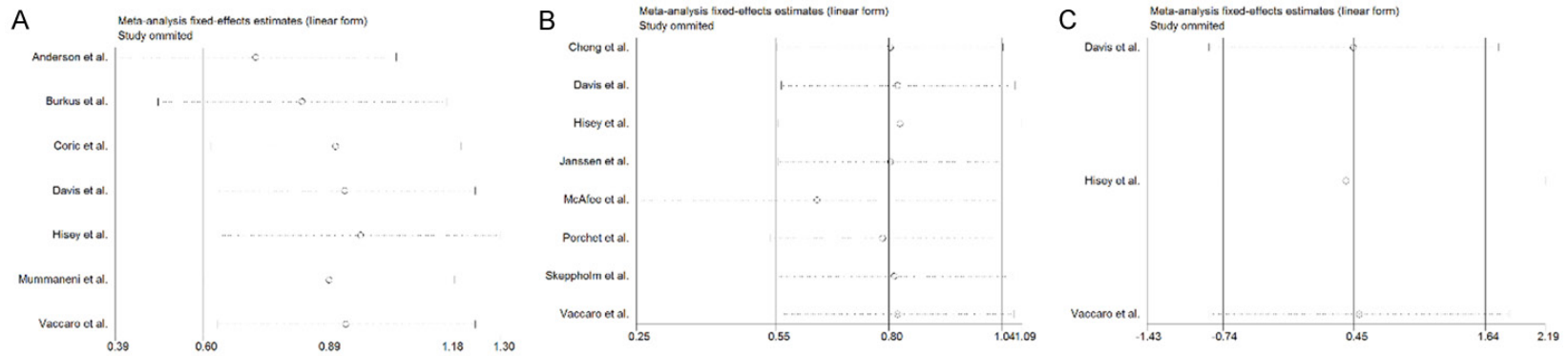


**Figure 4.** Forest plot of the risk ratio of the incidence of dysphonia after anterior cervical discectomy and fusion (ACDF) and cervical disc replacement (CDR).

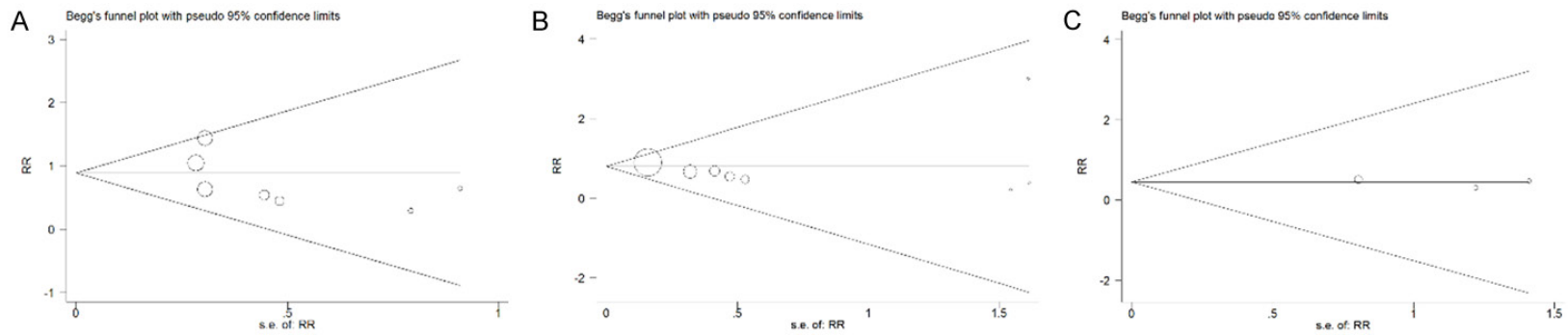
squared = 4.29 (d.f. = 7), P = 0.746, I-squared (variation in RR attributable to heterogeneity) =

0.0%. For meta-analysis of dysphonia, heterogeneity chi-squared = 0.12 (d.f. = 2), P = 0.944,

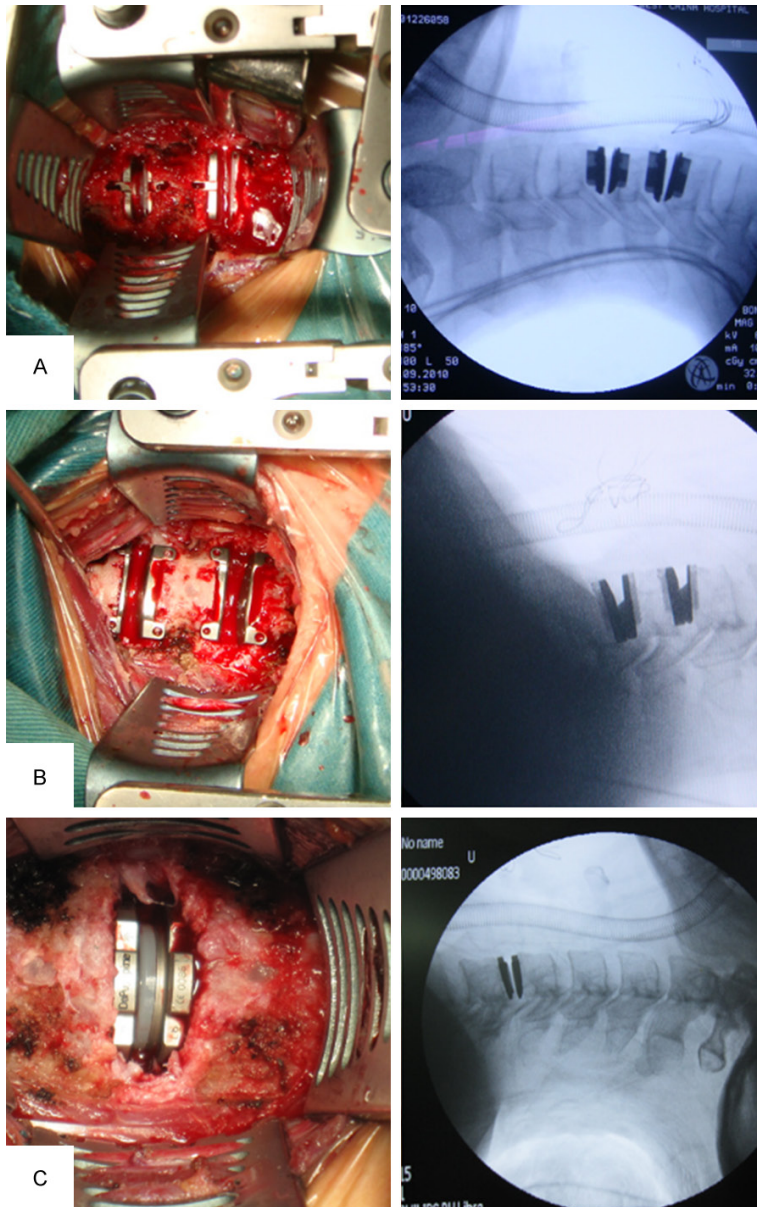
## Dysphagia/dysphonia after CDR and ACDF



**Figure 5.** Sensitivity analysis for meta-analysis of dysphagia/dysphonia (A), meta-analysis of dysphagia (B) and meta-analysis of dysphonia (C).



**Figure 6.** Publication bias test for meta-analysis of dysphagia/dysphonia (A), meta-analysis of dysphagia (B) and meta-analysis of dysphonia (C).



**Figure 7.** Intraoperative images and lateral X-rays showed the “non-profile” artificial disc prosthesis (A: ProDisc-C prosthesis; B: Prestige LP prosthesis; C: Discover prosthesis).

I-squared (variation in RR attributable to heterogeneity) = 0.0%.

#### *Sensitivity analysis and publication bias*

Sensitivity analyses were conducted and the data showed that no individual study had a marked effect on the results of meta-analyses (Figure 5A-C). A Funnel plot was generated to assess publication bias (Figure 6A-C). Begg’s and Egger’s tests were performed to statistically evaluate funnel plot symmetry. The results from Begg’s and Egger’s tests showed no evi-

dence of publication bias. For meta-analysis of dysphagia/dysphonia: Begg’s test ( $Pr > |z| = 0.881$ ) and Egger’s test ( $Pr > |z| = 0.218$ ), for meta-analysis of dysphagia: Begg’s test ( $Pr > |z| = 0.805$ ) and Egger’s test ( $Pr > |z| = 0.704$ ) and for meta-analysis of dysphonia: Begg’s test ( $Pr > |z| = 0.602$ ) and Egger’s test ( $Pr > |z| = 0.601$ ).

#### **Discussion**

Previous studies have reported that the incidence of postoperative dysphagia can reach up to 71% and the incidence of persistent dysphagia can reach up to 35.1% even at 7.2 years after ACDF with an anterior cervical plate [55, 56]. Dysphonia, similar with dysphagia, is a common complication of anterior cervical spine surgery. Dysphonia and dysphagia are reported to be persistent problems in a significant proportion of patients, even beyond 5 years after anterior cervical spine surgery [56]. Previous studies have demonstrated that the use of a smaller profile plate can reduce the incidence of dysphagia after ACDF [26]. Recently a meta-analysis based on 30 studies have concluded that the zero-profile implant can reduce the incidence of dysphagia after ACDF [29]. Similarly, the artificial disc

prosthesis can also be regarded as “low-profile” or “non-profile”. Theoretically ACDF with an anterior plate often means a more extensive dissection and a more aggressive retraction compared with CDR which may also have an impact on postoperative dysphonia and dysphagia. To the best of our knowledge, this is the first meta-analysis concerning dysphagia/dysphonia after ACDF and CDR.

12 RCTs with a total of 1948 patients who underwent CDR and 1552 patients who underwent ACDF were included in this meta-analysis.



Dysphonia and dysphagia are reported as a whole incidence in 7 RCTs. So 3 meta-analyses were conducted in this study in fact: meta-analysis of dysphagia/dysphonia, meta-analysis of dysphagia and meta-analysis of dysphonia. The results from meta-analysis of dysphagia indicated that CDR may reduce the incidence of postoperative dysphagia: RR = 0.751, 95% CI [0.588, 0.960]. In fact, ACDF with an anterior cervical plate or CDR are both performed using a classic Smith-Robinson approach. The surgical approach, decompression method and scraping off the cartilaginous endplate are all similar in two kinds of surgeries. However, when discectomy, decompression and preparation of endplate completed, the anterior plate incorporated with allograft or autograft were used in ACDF patients but a “low-profile” or “non-profile” artificial disc prosthesis was implanted into intervertebral space in CDR patients (Figure 7). First, the “non-profile” or “low-profile” artificial disc prosthesis, similar as the Zero-P Implant System, can avoid or reduce the mechanical irritation or impingement against the esophagus which anterior plate may cause [27, 28, 57]. Second, in ACDF with an anterior plate, a more powerful traction and more resection of pre-vertebral tissue may be needed to get a much larger exposed space in order to place the plate and insert the screws more easily but this may also make a contribution to postoperative dysphagia [58]. Third, patients underwent ACDF often used a cervical orthosis after surgery which restricted the movement of the cervical spine during swallowing and changed swallowing physiology which may also have an impact on postoperative dysphagia [59]. Future studies are needed to deny or support such explanations.

Results from meta-analysis of dysphonia showed no significant difference between ACDF and CDR group concerning the incidence of postoperative dysphonia: RR = 0.435, 95% CI [0.133, 1.423]. Dysphonia is one potential manifestation of a recurrent laryngeal nerve palsy and more extensive dissection, aggressive retraction, longer cuff inflation time, and elevated endotracheal tube pressures were reported to be associated with postoperative dysphonia. We think that the effect of “non-profile” or “low-profile” may not have a significant impact on postoperative dysphonia as the plate thickness is not as high as the huge ante-

rior cervical osteophytes [60-62]. However, we should be aware of the hypothesis considering no significant difference between two groups concerning the incidence of postoperative dysphonia merely on the basis of the negative results in this study as the number of studies and sample size is relatively small. Although meta-analysis can increase the statistical power by combining all eligible studies, it is limited in its effect estimation owing to the small number of studies included. Thus, more evidence is needed to support, or deny, such a conclusion. We also observed no significant difference concerning the incidence of postoperative dysphagia/dysphonia between CDR and ACDF (RR = 0.809, 95% CI [0.610, 1.073]). Even some researchers were accustomed to regard the dysphagia and (or) dysphonia as a whole complication and often reported the total incidence of dysphagia and (or) dysphonia as dysphagia/dysphonia, we strongly recommend future studies report the incidence of dysphagia and dysphonia respectively. Putting two kinds of multifactorial complications together may not make a contribution to investigating them clearly and deeply.

The primary limitation of this meta-analysis is the lack of gold standard diagnostic criteria of dysphagia or dysphonia in the included original RCTs studies, this greatly decrease the level of evidence in this meta-analysis. Different methods for dysphagia evaluation are available at present: patient-reported dysphagia outcomes measure, clinician-based outcome measures, and complementary examinations such as barium swallow test, video fluoroscopic swallow evaluation, or fiberoptic endoscopic evaluation [63]. Even the Bazaz grading scale for dysphagia, the Dysphagia Short Questionnaire and the Eating Assessment Tool were widely used in previous studies, gold standard diagnostic methods such as video fluoroscopic swallow evaluation, or fiberoptic endoscopic evaluation are greatly recommended in future studies [64-68]. The Voice Handicap Indices is a frequently used patient self-reported dysphonia evaluation index [69], however, Dysphonia Severity Index is recommended in future studies as this index has been reported to be a better index which can measure the severity [70]. The second limitation of this meta-analysis is the lack of details of dysphagia and dysphonia in the included original studies. Generally the inci-

dence of dysphagia and dysphonia decreases during the following months after surgery and evaluation at different time can lead various incidences across the different studies. This study failed to evaluate the severity of dysphagia/dysphonia at different follow-up time, and future studies should not only focus on the severity of dysphagia/dysphonia but also on the duration time of dysphagia/dysphonia after ACDF and CDR. The third limitation is the patients population differences in the included original studies as dysphagia/dysphonia were reported to be multi-factors' results and many confounding factors may have an impact on the results. Future studies should make the baseline comparable as much as possible and multi-factor analysis was recommended. The fourth limitation is that we failed to perform subgroup analysis stratified by ethnicity, gender, number of operated levels, kinds of plates and kinds of artificial disc prosthesis considering the limited studies included in our study. At last although the funnel plot and Begg's test showed no publication bias, selection bias may have occurred because only studies in English or Chinese were selected.

Extensive literature was searched and reviewed across multiple data-base resources, our meta-analysis has some clear advantages: (1) this is the first meta-analysis that compared the incidence of postoperative dysphagia/dysphonia between ACDF and CDR; (2) all included studies were RCTs; (3) three meta-analyses were conducted in this study in fact: meta-analysis of dysphagia/dysphonia, meta-analysis of dysphagia and meta-analysis of dysphonia; (4) results from sensitivity analysis did not show any single study strongly affecting the combined results; (5) no significant heterogeneity was detected in our study; (6) the well-designed search and selection method significantly increased the statistical power of this meta-analysis; (7) no publication bias was detected, indicating that our pooled results are likely to be reliable.

### Conclusion

Based on the most available and up-to-date information, results of this meta-analysis indicate that CDR may reduce the incidence of postoperative dysphagia compared with ACDF with an anterior plate. However, the incidence of dysphagia/dysphonia as a whole part and

the incidence of postoperative dysphonia were not observed significantly different in CDR and ACDF with an anterior plate. Since lack of gold standard diagnostic criteria and details of dysphagia or dysphonia in the included original studies, results of this meta-analysis should be validated by future RCTs which use gold standard diagnostic criteria and specially focused on details of postoperative dysphagia and dysphonia.

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### Disclosure of conflict of interest

None.

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