

Comparison of the adverse events of anterior cervical disc replacement versus anterior cervical discectomy and fusion

Citation

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Review question

1. Our current research aims to compare adverse events between artificial cervical disc replacement and anterior cervical discectomy and fusion.
2. To evaluate which surgical procedure is more safety for the treatment of cervical spondylosis.
3. Vital evidence-based guidance will be provided for spine surgeons and designers to evaluation of prognosis and improvement of dynamic devices.

Searches

The electric database of PubMed, MEDLINE, Embase, Google Scholar and The Cochrane Library will be systematically searched without language restriction in Dec. 2017 by 2 independent authors.

The keywords will be defined as follows: anterior cervical disc replacement, cervical disc arthroplasty, cervical dynamic device, cervical artificial disc; anterior cervical decompression and fusion, anterior interbody fusion; randomized controlled trial, randomized trial, and controlled clinical trial; the keywords will be combined with Boolean operators of AND, OR, and NOT.

A search strategy developed with comprehensive use of keywords is shown. Related articles listed in previous systematic reviews, meta-analysis, and other clinical research articles will be manually searched to avoid original misses.

Types of study to be included

Only randomized controlled trials with no limits on language, date or form of publication.

Condition or domain being studied

Cervical degenerative disc diseases are common in spinal disorders, and features with neck and arm pain, sometimes, associated with numbness of upper limbs, loss of function. The therapeutic methods include nonoperation, anterior cervical discectomy and fusion (ACDF), Anterior cervical disc replacement (ACDR), and others.

Participants/population

Patients who suffered from cervical spondylosis were required surgical intervention, either ACDR or ACDF.

Intervention(s), exposure(s)

Any anterior artificial device that was used to perform the ACDR will be included, such as ProDisc-C, Prestige disc, Bryan disc, KineflexIC, Modic-C, and PCM. The control group was treated by standard ACDF.

Comparator(s)/control

A control group (ACDF) is required.

Primary outcome(s)

- (1) Adjacent segment degeneration (ASD)
- (2) Subsequent Surgical Intervention
- (3) Gastrointestinal

Secondary outcome(s)

- (1) Dysphagia/dysphonia
- (2) Neck /or arm pain
- (3) Neurological

Data extraction (selection and coding)

Risk of bias (quality) assessment

The risk of bias of the included studies will be assessed according to the Furlan checklist, which includes 7 items: (A) Was the method of randomization adequate? (B) as the treatment allocation concealed? (C) Was knowledge of the allocated interventions adequately prevented during the study? (D) Were incomplete outcome data adequately addressed? (E) Are reports of the study free of suggestion of selective outcome reporting? (F) Other sources of potential bias. The overall quality of this systematic review and meta-analysis will be summarized and evaluated with GRADE pro (<http://www.gradepro.org>).

Strategy for data synthesis

The meta-analysis will be performed with the statistic software RevMan 5.3 software (Cochrane Collaboration, Oxford, UK). Fixed-effects models ($I^2 < 50\%$) or random-effects models ($I^2 \geq 50\%$) will be chosen according to the heterogeneity of the included articles. For dichotomous outcomes, RR and 95% confidence intervals (CIs) were calculated, For continuous outcomes, weighted mean difference and 95% confidence intervals (CIs) were calculated.

Analysis of subgroups or subsets

Subgroup meta-analysis will be performed on articles from different countries, patients with 1 or 2 or more pathological segments, different cervical artificial discs and different follow-ups. Other factors such as age, gender, and race will also be conducted.

Contact details for further information

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Anticipated or actual start date

10 December 2017

Anticipated completion date

31 January 2018

Funding sources/sponsors

National 12th five-year science and technology support plan (2012BAI18B05).

Conflicts of interest

Language

PROSPERO
International prospective register of systematic reviews

English

Country

China

Stage of review

Review_Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Discectomy; Humans; Total Disc Replacement

Date of registration in PROSPERO

20 December 2017

Date of publication of this version

20 December 2017

Details of any existing review of the same topic by the same authors**Stage of review at time of this submission**

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Versions

20 December 2017

PROSPERO

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