Treatment of cervical spondylosis with Bryan cervical disc arthroplasty and anterior cervical discectomy and fusion procedures: a Meta-analysis

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Abstract: Objective: To evaluate the clinical effect for postoperative of BRYAN cervical disc replacement and anterior cervical discectomy and fusion(ACDF) by Meta-analysis. **Method**: We searched Medline, PubMed, EMBASE,CBM, CNKI, et al. and searched manually the 7 relevant Chinese orthopedic journals for Articles Digital to clinical research of BRYAN cervical disc replacement and ACDF. Meta -analysis and forest plots were conducted with RevMan software. **Results**: There are 9 articles included 935 patients (452 patients for BRYAN cervical dis replacement, 483 patients for ACDF) in our Meta-analysis. At of 12 months and (or) 24 months after operation ROM, NDI, VAS, JOA, et al no statistically significant differences. **Conclusion**: Our results indicate that Bryan cervical disc replacement is superior than ACDF in maintaining the ROM. But the two operation program no difference the clinical effect.

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1.Introduction

The cervical spondylosis is a common disease in spine surgery. Anterior cervical discectomy and fusion (ACDF) have been proved to be positive efficiency for treatment of nerve root type and/or cervical spondylotic myelopathy; however, the adjacent segments showed degeneration through long-term follow-up, and the radicular symptoms appeared again (Goffin et al.,2004). Bryan cervical disc arthroplasty is implanting artificial cervical disc into vertebral interspace under decompression to replace the excision of intervertebral disc and restore the normal cervical spine biomechanics (Coffin et al., 2003). However, with the development of Bryan arthroplasty, there was controversial about its efficacy, such as the frequent occurrence of postoperative neck and shoulder pain, cervical physiological curvature decrease, etc(Sekhon 2004;Bryan 2002). The two types of surgical methods have their own advantages and disadvantages in treatment of cervical diseases, but the specific clinical effect has not yet been verified by evidence-based medicine. In this study, we will perform a Meta-analysis for clinical efficacy of treatment of cervical diseases with the two surgical methods, in order to provide evidence for clinicians to select the surgical options.

2.Materials and methods

2.1 Selection of studies

Two authors will take on the review. The search strategy described will be used to obtain titles and abstracts of studies that may be relevant to the review. Two authors will screen the search results and they will read the full text of eligible studies identified in this way. The two authors will decide on their suitability for inclusion in the review based on whether they meet the prespecified inclusion criteria. We will report disagreement and will resolve disagreement by a consensus procedure, if necessary, with a third review author.

2.2 Data extraction and management

Two review authors will extract the data independently to a self-developed data extraction form. Studies reported in non-English language journals will be translated before assessment. Where more than one publication of one trial exists, only the publication with the most complete data will be included. We will write to study authors for further information when necessary. Disagreements will be resolved by majority vote, if necessary, of a third review author. One author will enter data into Review Manager software(RevMan 5.0.20), and a second author will independently check the data entry.

2.3 Assessment of risk of bias in included studies

Two authors will independently use the GRADE criteria to assess risk of bias for all included studies.

2.4 Measures of treatment effect

For dichotomous data, results will be summarised as risk ratios(RR), with 95% confidence intervals (CI). For continuous out-comes we will use weighted mean difference (WMD) (when measures are in the same unit), or standardisedmean difference (SMD) (when different scales are used to evaluate the same outcome) with 95% CI as well.

2.5 Unit of analysis issues

Cross-over trials will not be included in this review. We will try to identify cluster-randomised trials; they will be included and analysed in accordance with section 16.3 of the Cochrane Handbook for Systematic Reviews of Interventions.

2.6 Dealing with missing data

The authors of papers withmissing data will be contacted. We will make a note of all trials that do not use intention-to-treat (ITT)analysis; we will make every attempt to analysis our data by this principal.

2.7 Data synthesis and Sensitivity analysis

A ï¬xed-effects model will be used unless significant heterogeneity with I^2> 50% among studies. In that case a random-effects model will be used.

Subgroup analysis will be used to explore possible sources of heterogeneity. Heterogeneity among studies will be estimated by the I^2 statistic. Typically, values above 50% are deemed to suggest significant heterogeneity. Values of 25% to 50% are deemed to show modest heterogeneity, and values below 25% are deemed to represent low heterogeneity.

We will perform a sensitivity analysis if we find significant heterogeneity (I^2> 50%).

3.Result

3.1 The general data

A total of 435 literatures were retrieved by computer and manual retrieve, and 11 literatures met the inclusion criteria after screening(Rabin et al.,2007; Sasso et al., 2008; Heller et al.,2009;Kim et al., 2009; Zhang et al.,2011;Li et al.,2007;Wang et al.,2008;Cao et al., 2008; Hao et al., 2011), including 5 English ((Rabin et al.,2007; Sasso et al.,2008;Heller et al., 2009; Kim et al.,2009;Zhang et al.,2011) and 4 Chinese literatures (Li et al.,2007;Wang et al.,2008; Cao et al., 2008;Hao et al., 2011), the publication year was limited from 2007 to 2011. In the total of 935 cases of cervical diseases, 452 cases were Bryan cervical disc arthroplasty and 483 cases were ACDF. There were two included studies which had the same sample(Sasso et al.,2008;Heller et al.,2009), so the number of cases will not be repeated statistics. Due to the last follow-up was not explicitly described in one literature, and the follow-up time was denoted as 24 months after surgery. Each study was carried out the baseline comparison of two groups, there was no significant difference.

3.2 Postoperative neck pain VAS

The neck pain VAS was only one literature 3 months postoperation, so it didn't make Meta-analysis. 12 and 24 months after operation, two literatures of neck pain VAS were included in the analysis (Zhang et al., 2011; Wang et al.,2008). The Meta-analysis results showed that there was no statistically heterogeneity at 12 month using a fixed effect model (*P*=0.38, Figure 1). The Meta-analysis results showed that there was also no statistically heterogeneity at 24 month using a random effect model (P=0.1, Figure 2).

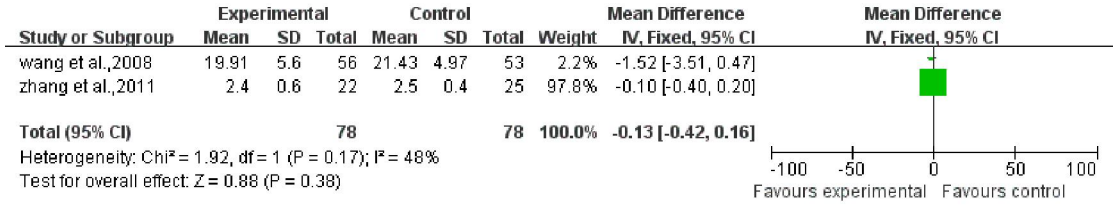

Fig 1. The neck pain VAS at 12 month.

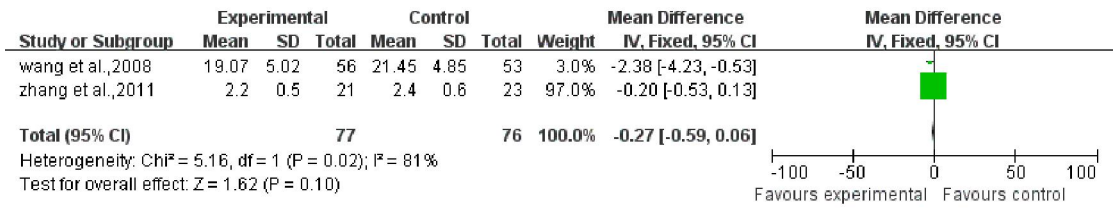

Fig 2. The neck pain VAS at 24 month.

4.Discussion

There were no recognized indicators for evaluation of the efficacy of surgical treatment of cervical spondylosis currently; however, it usually uses ROM, VAS, NDI, SF-36 and JOA score to describe the therapeutic effects.

ROM is an important indicator for evaluation of efficacy of cervical spine surgery. Many scholars have confirmed that Bryan cervical disc arthroplasty could retain the ROM of most joints, reduce the load of cervical spine and reduce the ROM of adjacent joints (Wigield et al.,2003;DiAngelo et al.,2003). Our study also showed that the ROM of Bryan arthroplasty group was better than that of ACDF group at 3rd month and 24th month. The reason might be that Bryan arthroplasty ensured the anterior decompression, and also maintained the normal height of cervical spine; therefore, the ROM wasn't influenced. And ACDF method fused the upper and lower vertebrae to change the physiological curve of cervical spine, which influenced the ROM. However, we only analyzed the ROM without considering the complications of the two surgical programs, including the prosthetic loosening, subsidence and surgical segmental vertebral kyphosis, etc; therefore, it still needs large-scale multi-center clinical trials to observe the long-term ROM.

VSA main evaluates the pain intensity of patients, from left "no pain at all" to right "unbearable pain" (Scott and Huskisssion 1975). Our results showed that there were no significant differences in neck pain VAS and upper extremity pain VAS between the two programs 12 and 24 months after surgery, which was consistent with Wang, *et al* (2008). The reason might be related to the less literatures, small number of patients, and the different pain description.

NDI is an important indicator for evaluation of cervical spondylosis efficacy in Western countries, which has good reliability and reproducibility(Ralph et al., 2007). Wang *et al* (2008)found that the NDI of Bryan arthroplasty group was better than that of ACDF group 6 weeks and 3 months after surgery, but there were no significant differences in 12, 18 and 24 months between two groups; which was associated with longer neck collar braking of ACDF group. Our study also confirmed that there was no significant difference in NDI between the two programs at 12 and 24 months (P=0.74 and P=0.06).

JOA score is used to assess the spinal cord function of patients with cervical spondylosis, including upper and lower extremity motor function, sensory disturbance and bladder function. Our study suggested that there was no significant difference in JOA score between the two programs at 24 months. Cao *et al* (2008) found that the JOA score of Bryan arthroplasty group was significantly higher than that of ACDF group through long-term follow-up (30.6 months), which might be associated with better decompression (Li et al., 2007). We believed that JOA score was affected by individual description, sample size, et al, and we believed the results of this study would be consistent with the results of further large-scale multi-center clinical cohort study.

In summary, Bryan cervical disc arthroplasty had better MOR in treating cervical spondylosis (especially nerve root type and/or cervical spondylotic myelopathy) than ACDF; however, there was no significant difference in NDI, SF-36 and JOA score between the two programs. Therefore, there was no significant difference in clinical efficacy of cervical spondylosis between the two programs.

This study had strict inclusion and exclusion criteria, widely search strategies, which bring different data of the same issue. Through Meta-analysis and reliable statistical methods, the literatures were quantitatively combined and analyzed, and a more scientific conclusion was proposed, which provide guidance for research and clinical practice.

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