

## 临床论著

# 颈椎间盘置换术与颈前路椎间融合术治疗双节段颈椎间盘退变性疾病疗效的 Meta 分析

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**【摘要】目的:**系统评价颈椎间盘置换术(TDR)与颈前路椎间盘切除椎间植骨融合术(ACDF)治疗相邻两个节段颈椎间盘退变性疾病的疗效。**方法:**检索 Pubmed、Medline、Embase 等数据库,筛选应用两种手术方式治疗相邻两个节段颈椎间盘退变性疾病的前瞻性临床对照研究;各研究中观察组术式为 TDR(TDR 组),对照组术式为 ACDF(ACDF 组);两组病例数均不少于 10 例;随访时间均不少于 2 年;术后疗效评价指标至少包括以下指标中的一项:颈痛及上肢痛 VAS 评分(VAS),颈部功能障碍指数(NDI),健康调查简表 SF-36 评分(SF-36),术后不良事件(AE)等指标。采用 Doowns-Black 评分及 NOS 评分评价纳入研究的质量。**结果:**共纳入 5 篇英文文献,2 篇为随机对照研究(RCT),3 篇为前瞻性队列研究,研究质量 Doowns-Black 评分均在 18 分及以上,NOS 评价前瞻性队列研究质量均为 6 星。共纳入 593 例患者,其中 TDR 组 314 例,ACDF 组 279 例。经 Meta 分析合并效应指标,末次随访时颈痛 VAS 评分标准化均数差(SMD)及不良事件发生相对危险度(RR)两组比较无显著性差异( $P>0.05$ );TDR 组上肢痛 VAS 评分、NDI 评分、邻近上节段和下节段屈伸 ROM、邻近节段退变低于 ACDF 组( $P<0.05$ ),SF36-PCS 躯体健康评分及手术节段屈伸 ROM SMD 高于 ACDF 组( $P<0.05$ )。**结论:**相邻两个节段颈椎间盘退变性疾病行 TDR 的疗效较 ACDF 具有优势,安全性较高,但需要更多大样本随机对照研究以及更长时间的随访结果来验证。

**【关键词】**颈椎间盘置换术;颈前路椎间盘切除椎间植骨融合术;双节段;Meta 分析

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**[Abstract]** **Objectives:** To assess and compare the effectiveness and safety of total cervical disc replacement (TDR) and anterior cervical discectomy and fusion (ACDF) for double-segment cervical disc disease. **Methods:** The search was made in PubMed, Medline, Embase. The criterion of articles needed for system assessment should have included: (1) clinical control trials with application of two kinds of surgical treatment with double-segmental cervical spondylosis; (2) the treatment group received cervical disc replacement, while the control group received ACDF; (3) the number of patients must be more than 10 both in treatment group and control group; (4) the evaluation of postoperative effects must include visual analog scale (VAS) neck disability index (NDI) and the range of motion (ROM) of targeted levels etc. Doowns-Black score grade and NOS were applied to evaluate the quality of included studies. **Results:** There were 5 studies which included 593 patients (314 patients for Bryan cervical disc replacement, 279 patients for ACDF) in our system assessment. All articles were from English literature, among them 2 were random controlled trials while the rest were prospective cohort studies. The scores of Doowns-Black score system were 18 and above, the scores of NOS system were 6 stars and above. The meta-analysis showed that the standardized mean differences (SMD) of neck pain VAS score and relative risk (RR) of adverse events in the two groups were not significantly different ( $P>0.05$ ); For

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the standardized mean differences(SMD) of upper limb pain VAS score, NDI score, ROM of flexion and extension of adjacent segment and relative risk(RR) of adjacent segment degeneration, those in TDR group were lower than those in ACDF group( $P<0.05$ ). SF36 PCS body health score and ROM of flexion and extension of operated segment in TDR group were higher than those in ACDF group( $P<0.05$ ). **Conclusions:** Our results indicate that total cervical disc replacement for double-segment cervical disc disease is safe and superior than ACDF in therapeutic effectiveness. But this needs more large sample randomized controlled trials and longer follow-up study.

**[Key words]** Total cervical disc replacement; Anterior cervical discectomy fusion; Two-level; Meta-analysis

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颈前路椎间盘切除椎间植骨融合术(anterior cervical discectomy and fusion,ACDF)作为治疗因椎间盘退变引起的脊髓型和神经根型颈椎病的标准手术方式<sup>[1,2]</sup>,已经广泛应用多年。但因该术式消除了融合节段的活动度,邻近节段的活动代偿增加,有许多研究报道ACDF会加速邻近节段的退变<sup>[3-5]</sup>。为了防止邻近节段的活动度乃至整个颈椎的生物力学被破坏,椎间盘置换术(total disc replacement,TDR)被应用于临床<sup>[6,7]</sup>。目前,已有大量研究证实,单节段颈椎间盘置换手术的疗效确切,相对于ACDF,手术及邻近节段的活动度显著得到保护,不良事件、异位骨化发生率及二次手术率均更低<sup>[8]</sup>。循证医学证据也支持上述结论<sup>[9-11]</sup>。然而,对于连续两个节段的颈椎间盘置换术与ACDF的疗效比较少有报道。本研究对两个节段行TDR与ACDF比较的文献进行合并与Meta分析,以获得循证医学证据。

## 1 资料与方法

### 1.1 纳入及排除标准

纳入标准:(1)研究类型为多中心研究的随机对照试验(randomized controlled trials,RCT)或前瞻性队列研究;(2)研究对象为年满18岁,对保守治疗无效的连续双节段退变性颈椎间盘疾病患者;(3)干预措施观察组(TDR组)采用前路椎间盘摘除、减压和人工椎间盘置换,对照组(ACDF组)采用前路椎间盘摘除、减压、自体骨移植或融合器行内固定,其余治疗相同;(4)纳入的研究至少包括本分析评价指标中的一项,并提供全面的数据。排除标准:(1)骨折、感染、肿瘤、骨质疏松、代谢性疾病等疾病;(2)随访时间小于24个月;(3)有颈椎前路手术史。

### 1.2 文献检索及筛选

对数据库Pubmed、Embase、Cochrane进行检索,采用(((two level) OR double level) OR bi level)) AND (((artificial cervical disc replacement) OR total disc replacement) OR cervical artificial disc replacement) OR cervical spine arthroplasty)检索式进行检索,同时对纳入文献的参考文献列表进行手工检索。如对文献的选择和评价发生分歧,可通过讨论协商解决或第三方(通讯作者)仲裁决定。

### 1.3 评价指标的选取

由两名评价者对纳入文献的以下指标进行提取:颈痛及上肢痛VAS评分(visual analog scale, VAS),颈部功能残障指数(neck disability index, NDI),健康调查简表SF-36评分(the MOS item short from health survey,SF-36),术后不良事件(adverse event,AE)、手术节段、邻近上节段和下节段屈伸ROM、Hilibrand退变评价标准评定下邻近节段退变发生率。各项指标均是至少2年随访时的结果。

### 1.4 文献质量评价

采用Doowns-Black评分及NOS评分评价纳入文献的质量<sup>[12]</sup>,即针对同时有前瞻性队列研究与RCT研究时的评分标准,分别以16分以上及5星以上为文献质量高。

### 1.5 统计学方法

采用Stata 12.0软件进行Meta分析,Q检验( $P<0.10$ )或者 $P>50\%$ 表明显著异质性,采用随机效应模型进行Meta分析,反之使用固定效应模型进行Meta分析。由于纳入研究的相关指标测定标准存在差异,定性指标的效应量合并采用相对危险比(risk ratio,RR),定量指标采用标准化均数差(standard mean difference,SMD)进行合并。

## 2 结果

### 2.1 检索结果及质量评价结果

共检索出 327 篇文献, 删去重复文献后余下 266 篇文献, 删去综述、信件、个案报道等余下 199 篇文献, 按照排除标准再次筛选, 共有 5 篇文献纳入本研究<sup>[13~17]</sup>, 全部为英文文献, 2 篇<sup>[15, 16]</sup>为 RCT 研究, 3 篇<sup>[13, 14, 17]</sup>为前瞻性队列研究。纳入研究基本特征见表 1, 质量评价见表 2, Downs-Black 评分研究质量均在 18 分及以上, NOS 评价前瞻性

队列研究质量均为 6 星。

### 2.2 Meta 分析结果

**2.2.1 颈痛 VAS 评分** 5 篇文献均报道了末次随访时的颈痛 VAS 评分。异质性检验  $P=0$ , 采用固定效应模型进行合并, 合并末次随访颈痛 VAS 评分标准化均数差  $SMD=-0.167(95\%CI,-0.340 \sim 0.006)$ ,  $P>0.05$ , 两组比较无显著性差异(图 1)。

**2.2.2 上肢痛 VAS 评分** 5 篇文献均报道了末次随访时的上肢痛 VAS 评分。异质性检验  $P=0$ ,

表 1 纳入研究基本情况

Table 1 Characteristics of the included studies

作者 Author	发表年份 Year	研究类型 Study design	病例数 Cases		性别比(男/女) Sex(male/female)		平均年龄 Average age		假体类型 Prosthetic type	随访时间(月) Follow-up (months)	结局指标 Outcome
			TDR	ACDF	TDR	ACDF	TDR	ACDF			
Cheng 等 <sup>[15]</sup> Cheng L, et al	2009	随机对照 Randomized controlled trial	31	34	16/15	17/17	45	47	Bryan	24	SF-36/VAS/NDI/Odom
Davis 等 <sup>[16]</sup> Davis RJ, et al	2014	随机对照 Randomized controlled trial	225	105	113/ 112	45/60	45.3	46.2	Mobi-C	48	SF-36/VAS/NDI/ROM/
Fay 等 <sup>[14]</sup> Fay LY, et al	2013	前瞻性队列研究 Prospective cohort study	37	40	28/9	26/14	52.1	63	Bryan	39.6±6.7	VAS/NDI/JOA/ROM/
Kim 等 <sup>[17]</sup> Kim SW, et al	2009	前瞻性队列研究 Prospective cohort study	12	28	8/4	17/11	47	51	Bryan	24	VAS/NDI/ROM/FSU/
Hou 等 <sup>[13]</sup> Hou Y, et al	2013	前瞻性队列研究 Prospective cohort study	32	88	20/12	38/55	46.3	51.2	Discover	24	VAS/NDI/ROM/FSU/

注: TDR, 颈椎间盘置换术; ACDF, 颈前路减压椎间融合术; SF-36, 生活质量评分; VAS, 疼痛视觉模拟评分; Odom, Odom 评分; NDI, 颈椎功能障碍指数; JOA, 日本骨科学会评分; ROM, 颈椎活动度; FSU, 脊柱功能单位

Note: TDR, total cervical disc replacement; ACDF, anterior cervical discectomy and fusion; SF-36, short form 36 health survey; VAS, visual analog scale va; Odom, Odom score; NDI, neck disability index; JOA, Japanese Orthopaedic Association score; ROM, Range of motion; FSU, Functional spinal unit

表 2 纳入研究质量评分

Table 2 Quality score of included study

作者 Author	研究类型 Study design	证据级别 Level of evidence	研究质量评分 Quality score of study					匹配 Matching	
			Downs-Black 评分 Downs-Black score		NOS 评分 NOS scale				
			选择 Selection	可比性 Comparability	暴露 Expose	总分 Total score			
Cheng 等 <sup>[15]</sup> Cheng L, et al	随机对照 Randomized controlled trial	II	20	—	—	—	—	1, 2, 3, 4, 5, 6	
Davis 等 <sup>[16]</sup> Davis RJ, et al	随机对照 Randomized controlled trial	II	21	—	—	—	—	1, 2, 3, 4, 5, 6	
Fay 等 <sup>[14]</sup> Fay LY, et al	前瞻性队列研究 Prospective cohort study	III	18	***	**	**	*****	3, 4, 5, 6	
Kim 等 <sup>[17]</sup> Kim SW, et al	前瞻性队列研究 Prospective cohort study	III	19	***	**	**	*****	1, 3, 4, 5, 6	
Hou 等 <sup>[13]</sup> Hou Y, et al	前瞻性队列研究 Prospective cohort study	III	19	***	**	**	*****	1, 3, 4, 5, 6	

注: 1, 年龄; 2, 性别比; 3, 术前疾病类型; 4, 同一术者; 5, 术后结局指标; 6, 随访时间

Note: 1, Age; 2, Gender; 3, Type of preoperative disease; 4, One surgeon; 5, Out come after operation; 6, Follow-up time

采用固定效应模型进行合并,上肢痛 VAS 评分 SMD= -0.229 (95%CI, -0.402~ -0.056), $P=0.01$ , TDR 组较 ACDF 组有更低的 VAS 评分(图 2)。

**2.2.3 NDI** 5 篇文献均报道了末次随访时的 NDI。异质性检验  $I^2=43.6\%$ ,采用固定效应模型进行合并,NDI 评分 SMD=-0.303 (95%CI, -0.477~-0.129), $P=0.001$ ,TDR 组较 ACDF 组有更低的 NDI(图 3)。

**2.2.4 手术节段屈伸 ROM** 3 篇文献<sup>[13,14,17]</sup>报道了末次随时访手术节段的屈伸 ROM,异质性检验  $I^2=84.9\%$ ,有显著异质性,采用随机效应模型进行合并,手术节段颈椎屈伸 ROM SMD=6.153 (95% CI, 4.482~7.824), $P<0.05$ ,TDR 组手术节段 ROM 显著性大于 ACDF 组 ROM(图 4)。

**2.2.5 邻近上节段屈伸 ROM** 2 篇<sup>[13,17]</sup>文献报道了末次随访时邻近上节段的屈伸 ROM,异质性检验  $I^2=0$ ,采用固定效应模型进行合并,邻近上节段颈椎屈伸 ROM SMD=-0.657 (95%CI, -1.012~-0.302), $P<0.05$ ,ACDF 组上节段 ROM 显著性大于 TDR 组上节段 ROM(图 5)。

**2.2.6 邻近下节段屈伸 ROM** 2 篇文献<sup>[13,17]</sup>报道了末次随访时邻近下节段的屈伸 ROM,异质性检

验  $I^2=1.6\%$ ,采用固定效应模型进行合并,邻近下节段颈椎屈伸 ROM SMD=-1.958 (95%CI, -2.369~-1.547), $P<0.05$ ,ACDF 组下节段 ROM 显著大于 TDR 组下节段 ROM(图 6)。

**2.2.7 SF-36 评分** 2 篇文献<sup>[15,16]</sup>报道了末次随访时的 SF-36 评分,异质性检验  $I^2=47\%$ ,采用固定效应模型合并,SF-36 PCS 评分 SMD=0.323 (95%CI, 0.099~0.546), $P=0.005$ ,TDR 组较 ACDF 组有更高的 SF-36 PCS 评分(图 7)。

**2.2.8 不良事件发生相对危险度** 3 篇文献<sup>[13,15,16]</sup>报道了不良事件发生率,异质性检验  $I^2=0$ ,采用固定效应模型进行合并,RR=0.66 (95%CI, 0.373~1.168), $P>0.05$ ,两组比较无显著性差异(图 8)。

**2.2.9 Hilibrand 标准邻近节段退变发生相对危险度** 2 篇文献<sup>[13,17]</sup>报道了应用 Hilibrand 标准评价邻近节段退变的发生率,异质性检验  $I^2=0$ ,采用固定效应模型进行合并,RR=0.441 (95%CI, 0.239~0.814), $P=0.009$ ,TDR 组较 ACDF 组有更低的邻近节段退变发生率(图 9)。

### 3 讨论

颈椎间盘置换术(TDR)因其具有保护手术节

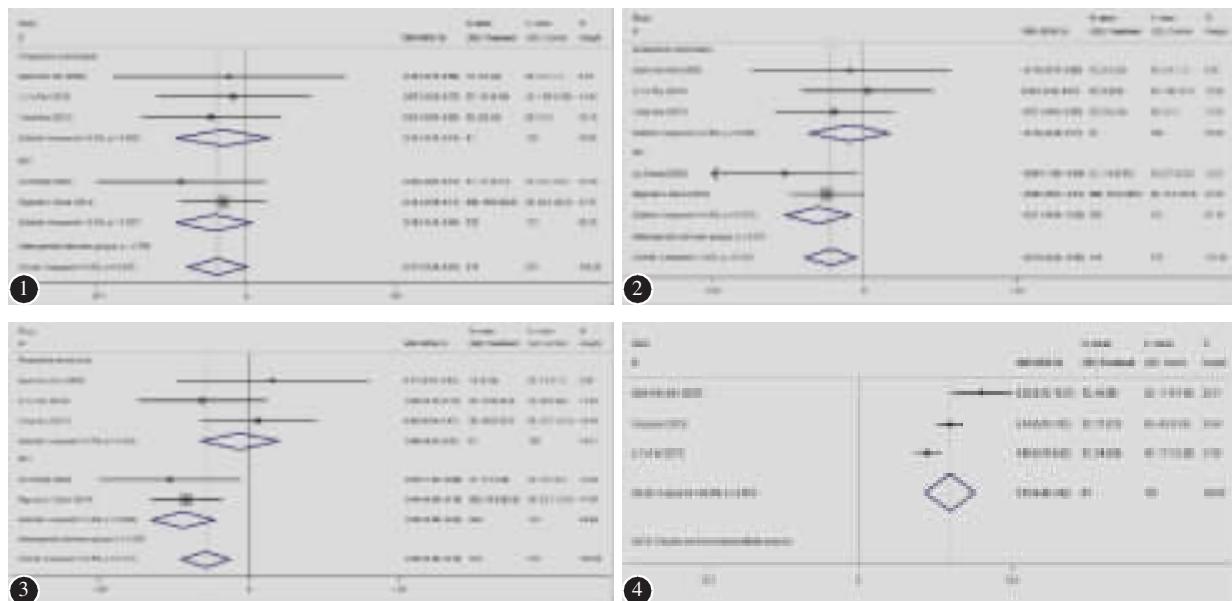


图 1 末次随访颈痛 VAS 评分比较 图 2 末次随访上肢痛 VAS 评分比较 图 3 末次随访 NDI 评分比较 图 4 末次随访手术节段屈伸 ROM 比较

**Figure 1** Meta-analysis of VAS score of neck pain between TDR and ACDF for last follow-up ( $P>0.05$ ) **Figure 2** Meta-analysis of VAS score of upper limb pain between TDR and ACDF for last follow-up ( $P=0.01$ ) **Figure 3** Meta-analysis of NDI score between TDR and ACDF for last follow-up( $P=0.001$ ) **Figure 4** Meta-analysis of ROM of operative level between TDR and ACDF for last follow-up( $P<0.05$ )

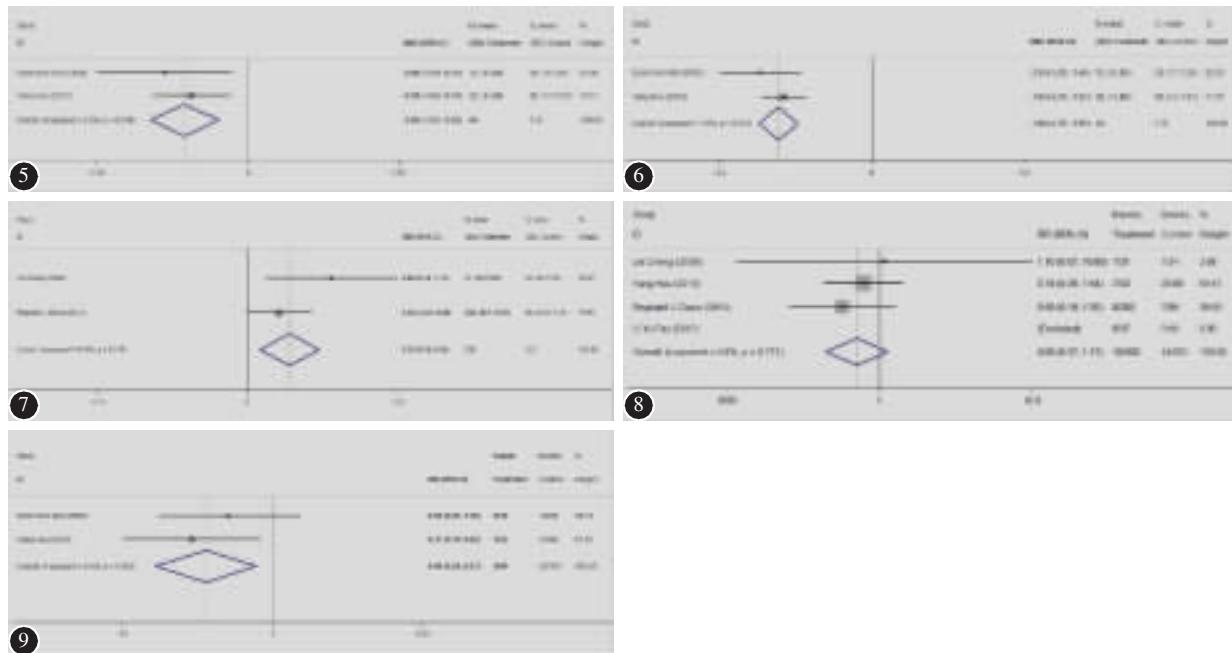


图5 末次随访邻近上节段屈伸ROM比较 图6 末次随访邻近下节段屈伸ROM比较 图7 末次随访SF-36 PCS比较  
图8 末次随访不良事件发生相对危险度比较 图9 末次随访邻近节段退变发生相对危险度比较

**Figure 5** Meta-analysis of ROM of upper level between TDR and ACDF for last Follow-up( $P<0.05$ ) **Figure 6** Meta-analysis of ROM of under level between TDR and ACDF for last Follow-up( $P<0.05$ ) **Figure 7** Meta-analysis of SF-36 PCS score between TDR and ACDF for last Follow-up( $P=0.005$ ) **Figure 8** Meta-analysis of adverse event between TDR and ACDF for last follow-up ( $P>0.05$ ) **Figure 9** Meta-analysis of relative risk of degeneration for adjacent segment between TDR and ACDF for last Follow-up( $P=0.009$ )

段活动度进而减少邻近节段椎间盘压力而发挥减少邻近节段退变的效果<sup>[18]</sup>,维持手术节段的生理活动度,防止应力增加,是TDR相对于ACDF术式最大的优势。与此同时,TDR术后避免了长时间的颈托固定,缩短患者返回工作和学习时间,而异位骨化、假关节形成等发生率显著降低,已被成功地应用于临床,并且被大量研究证实相对于ACDF术式具有疗效优势<sup>[19]</sup>。然而,少有关于双节段应用TDR疗效及安全性的报道,尽管在体外研究中<sup>[19,20]</sup>证实双节段TDR可以为手术及邻近节段提供接近正常的生理活动度,并且邻近节段的椎间盘承受的压力显著低于ACDF手术组,但尚无针对临床研究的循证医学证据。因此,我们对已有文献进行了Meta分析,在本研究中,纳入的3篇文献合并末次随访的TDR组手术节段屈伸ROM显著高于ACDF组,而邻近上下节段的屈伸ROM低于ACDF组,可以认为ACDF组邻近节段活动度的代偿增加,是潜在的导致退变的因素之一。关于单节段TDR的手术疗效,已有大量报道证实优于ACDF手术,而在对比单节段与双节段置换的

研究中<sup>[21]</sup>证实双节段TDR的手术疗效优势与单节段手术疗效优势是一致的。在本研究中,双节段TDR术后末次随访时上肢痛VAS评分、NDI低于ACDF组( $P<0.05$ ),SF36-PCS躯体健康评分高于ACDF组;末次随访时颈痛VAS评分及不良事件发生率两组比较无明显差异,证实双节段TDR具有安全性。但只有Hou等<sup>[13]</sup>单独报道了两种术式在术后吞咽困难的发生率,TDR组为3/32、ACDF组为10/88,TDR组显著低于ACDF组。邻近节段退变的评价方法目前尚无统一的标准,纳入研究中,仅2篇文献<sup>[13,17]</sup>采用了Hilibrand标准进行邻近节段退变的评价:出现新的骨赘或者原有骨赘增大,出现新的椎间隙变窄(>30%)或者原有变窄间隙加重,前纵韧带骨化加重。然而影像学上的退变如果未表现出临床症状,其意义还存在争议<sup>[21]</sup>。在本研究中合并退变发生相对危险度RR=0.441,(95%CI,0.239~0.814), $P=0.009$ ,TDR组较ACDF组有更低的邻近节段退变发生率。而关于双节段TDR术后与ACDF组术后的手术节段或是邻近节段二次手术率,纳入的5篇研究均未报道,可能

与样本量大小及随访时间有关。

综上所述,双节段TDR具有安全性,其疗效较ACDF术式具有优势,并且可以降低邻近节段退变发生率。但本研究纳入的文献较少,样本量有差异,研究类型不完全一致,以及作为TDR植入材料的人工椎间盘存在差异,均可能在合并结果时发生偏倚。结论仍需要大样本、多中心随机对照研究以及更长的随访结果进行验证。

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