

· 临床研究 ·

零切迹自稳型颈椎融合器治疗双节段脊髓型颈椎病的中期临床疗效

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【摘要】目的 评价应用零切迹自稳型颈椎融合器(ROI-C)行颈前路椎间盘切除融合术(ACDF)治疗双节段脊髓型颈椎病的中期临床疗效。方法 2012年3月—2014年3月,本院采用ROI-C行ACDF治疗的双节段脊髓型颈椎病患者22例,男16例,女6例;年龄45~76岁,平均58.1岁;C₃/C₄/C₅ 3例,C₄/C₅/C₆ 11例,C₅/C₆/C₇ 5例,C₆/C₇/T₁ 1例,C₃/C₆及C₇/T₁ 1例,C₃/C₄及C₅/C₆ 1例。采用疼痛视觉模拟量表(VAS)评分评价颈部疼痛程度,日本骨科学会(JOA)评分评价神经功能,MacNab标准评价疗效优良率。颈椎侧位X线片测量颈椎生理曲度和融合节段椎间高度,过伸过屈位X线片评价融合相邻节段的椎间活动度(ROM),并对术前及随访时数据进行比较。结果 所有手术顺利完成。所有患者随访29~53个月,平均35.3个月。术后3个月VAS和JOA评分均较术前明显改善,差异有统计学意义($P<0.05$);末次随访时VAS评分和JOA评分较术后3个月进一步改善,且差异有统计学意义($P<0.05$)。术后3个月颈椎曲度和融合节段椎间隙高度均较术前明显改善,差异有统计学意义($P<0.05$);末次随访时与术后3个月时相比,差异无统计学意义($P>0.05$),颈椎曲度和融合节段椎间隙高度维持良好。末次随访时融合器沉陷率为11.4%。术后3个月相邻节段ROM较术前增加,差异有统计学意义($P<0.05$);末次随访时相邻节段ROM较术后3个月进一步增加,且差异有统计学意义($P<0.05$)。末次随访时有1例融合上位相邻节段发生椎间隙不稳,但无临床症状。根据MacNab标准,疗效优良率为90.9%。随访中未发生术后颈部轴性疼痛、融合器松动等其他并发症。结论 应用ROI-C行ACDF治疗双节段脊髓型颈椎病中期随访临床疗效可靠,颈椎生理曲度和融合椎间高度得以有效维持。

【关键词】颈椎; 颈椎病; 椎间盘切除术; 脊柱融合术; 内固定器

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Mid-term clinical evaluation of zero-profile anchored spacer for treatment of double-segmental cervical spondylotic myelopathy

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【Abstract】Objective To evaluate the mid-term clinical efficacy of double segmental cervical spondylotic myelopathy treated by anterior cervical discectomy and fusion (ACDF) with zero-profile anchored spacer (ROI-C). Methods From March 2012 to March 2014, 22 cervical spondylotic myelopathy patients (16 males, 6 females, average age 58.1 years, ranging 45-76 years old) who underwent double segmental ACDF with ROI-C were evaluated. The visual analogue scale (VAS) score was used to assess the degree of neck pain, and the Japanese Orthopaedic Association (JOA) score was used to assess neurological function. MacNab standard was used to evaluate the rate of excellent and good therapeutic efficacy. The cervical curvature, intervertebral space height of fusion segment and range of motion (ROM) of adjacent segments were also evaluated on roentgenograph. The preoperative and follow-up data were compared. Results All operations were completed successfully. The patients were followed up for 29-53 months, mean 35.3 months. Compared with preoperative, the VAS and JOA scores were improved significantly at postoperative 3 months, and the differences were statistically significant ($P<0.05$); Compared with postoperative 3 months, the VAS and JOA scores were improved significantly at final follow-up, and the differences were statistically significant ($P<0.05$). Compared with preoperative, the cervical curvature and intervertebral space height of fusion segment were improved significantly at postoperative 3 months, and the differences were statistically significant ($P<0.05$); but

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there was no significant difference between the final follow-up and postoperative 3 months ($P>0.05$). The cervical curvature and intervertebral space height of fusion segment were maintained well, and the cage subsidence rate was 11.4%. Compared with preoperative, ROM of adjacent segments was increased at postoperative 3 months, and the difference was statistically significant ($P<0.05$); Compared with postoperative 3 months, ROM of adjacent segments was increased at final follow-up, and the difference was statistically significant ($P<0.05$). At final follow-up, there was 1 patient with intervertebral instability at adjacent segments, but no clinical symptoms. According to MacNab standard, the excellent and good rate was 90.9%. No other complications such as cervical axial pain and loosening of the fusion cage occurred in the follow-up. **Conclusion** Double-segmental cervical spondylotic myelopathy treated by ACDF with ROI-C has a good mid-term clinical efficacy, and patient's cervical physiological curvature and the height of the fusion segment could be effectively maintained.

【Key Words】Cervical vertebrae; Cervical spondylosis; Discectomy; Spinal fusion; Internal fixators

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双节段脊髓型颈椎病, 由于颈脊髓受压较重, 脊髓神经可出现不可逆损伤, 严重者可致瘫痪, 手术解除脊髓神经压迫是首选方案之一。对于压迫因素主要来自脊髓腹侧者, 颈前路手术可进行直接彻底减压, 并重建颈椎生理曲度和椎间高度, 较颈后路椎管扩大成形术更有优势^[1]。近来, Wang等^[2]通过Meta分析发现颈前路椎间盘切除融合术(ACDF)与颈前路椎体次全切除融合术(ACCF)治疗多节段脊髓型颈椎病均可获得良好的临床疗效, 但ACDF的手术并发症发生率更低。零切迹自稳型颈椎融合器(ROI-C)已在ACDF中广泛应用, 本研究组前期研究已证实了应用ROI-C治疗颈椎病的早期临床疗效可靠, 有助于重建颈椎生理曲度、恢复椎间高度, 且并发症较少^[3-4]。本研究通过进一步随访, 观察应用ROI-C治疗双节段脊髓型颈椎病的中期临床疗效, 并评价术后中期颈椎生理曲度、融合器沉降以及融合相邻节段的退变情况, 现报告如下。

1 资料与方法

1.1 一般资料

2012年3月—2014年3月, 本院采用ROI-C行ACDF治疗的双节段脊髓型颈椎病患者22例, 男16例, 女6例; 年龄45~76岁, 平均58.1岁; C₃/C₄/C₅ 3例, C₄/C₅/C₆ 11例, C₅/C₆/C₇ 5例, C₆/C₇/T₁ 1例, C₅/C₆及C₇/T₁ 1例, C₃/C₄及C₅/C₆ 1例。患者均以四肢乏力麻木、双手精细活动障碍为主要临床表现, 伴有行走踩棉花感, 锥体束征阳性, 伴/不伴有颈部疼痛, 手术前经过规范非手术治疗4~6周效果欠佳或症状进行性加重。本组病例患者既往均无颈椎手术史。术前、术后3个月和末次随访时均在本院拍摄颈椎正侧位和过伸过屈位X线片。

1.2 手术方法

患者全身麻醉后取仰卧并头高脚低约15°体位,

取颈右侧颈横纹做一横切口, 长4~5 cm, 切开皮肤、皮下组织、筋膜, 沿皮下分离皮瓣, 切开颈阔肌。沿胸锁乳突肌内侧缘将胸锁乳突肌及颈动脉鞘向外拉开, 并将气管、食管向内侧牵开。显露颈长肌及椎体前缘, 剥离椎前筋膜, C形臂X线机定位准确后切开责任节段前纵韧带, 在距离病变节段上下终板约8 mm处安装Caspar撑开器, 撑开椎间隙。切除椎间盘, 并清理椎体后缘骨赘, 切开后纵韧带, 探查并确认脊髓硬膜囊压迫解除。处理软骨终板至骨面渗血, 试模, 取大小合适的ROI-C融合器, 以自体髂骨或同种异体骨填充其间, 将其置入病变椎间隙, 距离椎体前缘约2 mm, 缓慢松开Caspar, 使用专用弧形嵌片打入器将自锁嵌片打入上下位椎体内, 再次透视确认内置物位置良好。冲洗伤口并彻底止血, 放置负压引流管, 逐层关闭伤口。术后常规予营养神经、预防感染等对症处理, 术后2~3 d根据引流量拔除引流管, 术后第1天佩戴颈托下床活动。

1.3 评价指标

采用疼痛视觉模拟量表(VAS)评分^[5]、日本骨科学会(JOA)评分^[6]评价患者临床疗效和神经功能。根据MacNab标准^[7]评价疗效优良率。颈椎曲度测量采用Harrison法^[8]: 颈椎侧位X线片上测量C₂与C₇椎体后缘切线间的锐角。融合相邻节段稳定性评价: 过伸过屈位X线片上测量融合节段相邻椎间隙的上位椎体下缘和下位椎体上缘夹角(Cobb角), 过伸位和过屈位Cobb角之差为该节段活动度(ROM), ROM>13°定义为不稳。融合器沉降评价: 末次随访时融合节段椎间隙高度较术后早期减少>3 mm定义为融合器沉降^[9]。

1.4 数据处理

2016年8月通过电话和门诊随访, 进行VAS评分、JOA评分和MacNab评价结果的收集, 由影像科专业医师摄取标准颈椎正侧位和过伸过屈位X线片, 后由本课题组2位骨科医师在华海医学影像系

统上进行融合节段的椎间隙高度和 Cobb 角测量。

应用 SPSS 13.0 软件对数据进行统计学分析, 数据用 $\bar{x} \pm s$ 表示。先进行正态性检验, 术前和末次随访时的 VAS 评分、JOA 评分、椎间隙高度和 Cobb 角的比较采用配对 t 检验, 以 $P < 0.05$ 为差异有统计学意义。

2 结 果

所有患者随访 29~53 个月, 平均 35.3 个月。术后 3 个月 VAS 和 JOA 评分均较术前明显改善, 差异有统计学意义 ($P < 0.05$); 末次随访时 VAS 评分和 JOA 评分较术后 3 个月进一步改善, 且差异有统计学意义 ($P < 0.05$, 表 1)。根据 MacNab 评价标准, 末次随访时优良率为 90.9% (优 16 例, 良 4 例, 中 2 例)。术后 3 个月颈椎曲度和融合节段椎间隙高度均较术

前明显改善, 差异有统计学意义 ($P < 0.05$); 末次随访时与术后 3 个月时相比, 差异无统计学意义 ($P > 0.05$, 表 1), 颈椎曲度和融合节段椎间隙高度维持良好。末次随访时 44 个融合节段中, 椎间隙高度丢失 > 3 mm 共 5 个节段, 融合器沉陷发生率为 11.4%。术后 3 个月相邻节段 ROM 较术前增加, 差异有统计学意义 ($P < 0.05$); 末次随访时相邻节段 ROM 较术后 3 个月进一步增加, 且差异有统计学意义 ($P < 0.05$, 表 1)。末次随访时 1 例患者融合上位节段出现不稳, 但无临床症状。本研究前期报道本组病例术后 6 个月融合率为 96.2%, 12 个月已全部获得骨性融合^[3], 且发现融合节段椎间隙前方均出现不同程度的骨桥连接。随访中未发生术后颈部轴性疼痛、融合器松动等其他并发症。典型病例影像学资料见图 1。

表 1 统计数据
Tab. 1 Statistical data

项目 Item	<i>n</i>	术前 Pre-operation	术后 3 个月 Postoperative 3 months	末次随访 Final follow up
VAS 评分 VAS score	22	3.86 ± 0.77	1.41 ± 0.50*	1.05 ± 0.65* [△]
JOA 评分 JOA score	22	9.09 ± 1.77	12.95 ± 1.33*	14.23 ± 1.34* [△]
颈椎曲度 / (°) Cervical curvature / (°)	22	12.63 ± 9.75	17.28 ± 7.79*	16.75 ± 7.50*
融合节段椎间隙高度 / mm Intervertebral space height of fusion segment / mm	44	4.95 ± 0.78	6.25 ± 0.68*	6.03 ± 0.65*
融合相邻节段 ROM / (°) ROM of adjacent segment / (°)	46	5.07 ± 1.26	6.14 ± 1.27*	7.07 ± 1.98* [△]

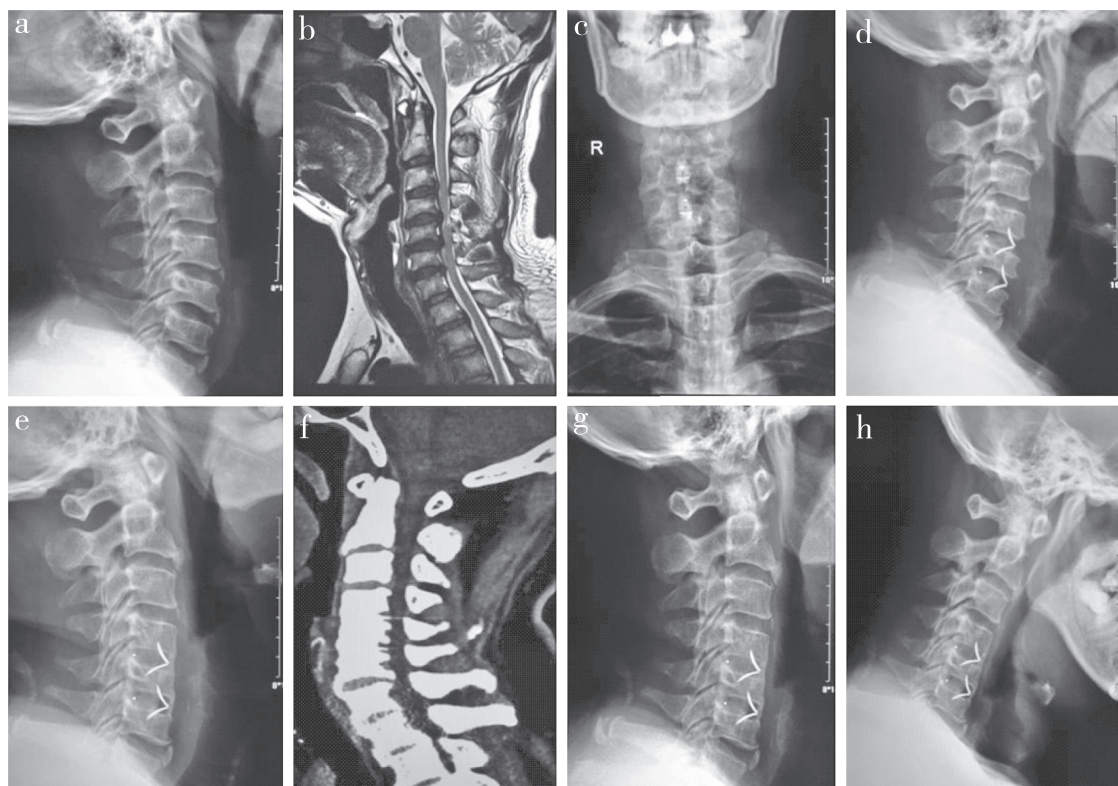
注: *与术前相比, $P < 0.05$; [△]与术后 3 个月相比, $P < 0.05$

Note: * $P < 0.05$, compared with pre-operation; [△] $P < 0.05$, compared with postoperative 3 months

3 讨 论

脊髓神经功能的病理生理特点决定了症状性双节段脊髓型颈椎病大多需要外科干预, 而颈椎前路手术通过直接减压解除脊髓压迫而减少神经的进一步损伤, 其改善患者脊髓神经功能的效果是明确的^[10-11]。Scholz 等^[12]应用零切迹颈椎融合器 (Zero-P) 行 ACDF 治疗 45 例颈椎病患者, 随访 > 2 年, 中期临床疗效满意, 融合率达到 97.0%。Grasso 等^[13]报道了应用 ROI-C 治疗 32 例颈椎病患者, 术后 2 年时患者 VAS 评分和 NDI 较术前明显改善, 颈椎生理曲度和椎间隙高度得到有效维持。Chen 等^[14]对比了应用 Zero-P 和锁定钢板行 ACDF 的中期疗效, 平均随访 30.8 个月 (24~36 个月), 发现两组的 NDI 和 JOA

评分改善程度相近。Zero-P 组邻近节段退变 (ASD) 发生率为 12.1% (4/33), 而钢板组为 15.8% (6/38)。Liu 等^[15]报道应用 ROI-C 行 ACDF 治疗多节段脊髓型颈椎病, 并与钢板联合 PEEK 融合器组进行对比, 随访 (23.8 ± 6.6) 个月, 发现两组之间在 JOA 评分和 NDI 改善程度方面无明显差异, 但 ROI-C 组手术时间更短, 出血量更少, 且术后吞咽不适发生率更低, 故认为 ROI-C 的中期临床疗效和对颈椎生理曲度的改善效果可靠。本研究组认为 ROI-C 的主要优点在于减少对椎前软组织和食管的影响, 有利于减少术后吞咽困难的发生; 且 ROI-C 的应用操作相对于钢板螺钉置入简化了手术步骤, 减少了术中出血量^[3,4]。本研究随访结果表明, 应用 ROI-C 行 ACDF 治疗双节段脊髓型颈椎病的中期临床疗效满意, 术



男, 57岁, 脊髓型颈椎病采用ROI-C行双节段ACDF a: 术前X线片示颈椎退行性改变 b: 术前MRI示C₄/C₅/C₆脊髓受压明显 c, d: 术后1周X线片示C₄/C₅/C₆水平椎前增生骨赘已被清理 e, f: 术后30个月X线片和CT示C₄/C₅/C₆椎间隙前方骨桥形成, 与椎体前缘相平齐, 融合器未见明显沉陷 g, h: 术后30个月过伸过屈位X线片示融合相邻节段无明显不稳

Male, 57 years old, cervical spondylotic myelopathy treated by double-segmental ACDF with ROI-C a: Preoperative roentgenograph shows cervical degeneration b: Preoperative MRI shows significant C₄/C₅/C₆ spinal cord compression c, d: Roentgenograph at postoperative 1 week show hyperplasia of osteophytes at C₄/C₅/C₆ level has been cleared e, f: Roentgenograph and CT at postoperative 30 months show bone bridge formation in anterior space of C₄/C₅/C₆ intervertebral space, aligned with anterior edge of vertebral body, and there is no obvious subsidence in fusion cage g, h: Hyperflexion and hyperextension roentgenograph at postoperative 30 months show adjacent segments without significant instability

图1 典型病例影像学资料

Fig. 1 Imaging data of a typical case

后未出现严重的颈部轴性疼痛症状, 且脊髓神经功能较术后早期进一步改善, 疗效优良率较高。

ACDF术中置入融合器或钛网, 术后中远期可能面临内置物沉陷的风险, Park等^[9]回顾性分析了77例行ACDF治疗的患者, 发现中远期融合器沉陷率为33.8%(26/77), 该研究同时发现了发生融合器沉陷的病例骨性融合率(96.2%, 25/26)比未发生沉陷者更高(92.2%, 47/51)。本组病例融合器沉陷率为11.4%, 较文献报道的更低。ACDF术后导致融合器沉陷的主要因素包括颈椎曲度、融合节段数、融合器材料和患者骨质量等, 术前颈椎生理曲度不良、多节段融合以及严重骨质疏松者, 融合器下沉的风险增大^[16]。本研究组前期研究发现应用ROI-C有助于恢复颈椎的生理曲度和椎间高度, 本次随访时发现颈椎生理曲度虽然较术后早期略有减小, 但改善度得到有效维持, 这与Grasso等^[13]的研究结

果相似。Lim等^[17]认为保留终板对防止融合器下沉有重要作用, 但若软骨终板上仍附着软组织也将影响骨性融合, 本研究组认为术中用刮匙将终板刮至微微渗血比较合适, 既有利于融合, 又可降低融合器塌陷下沉的风险。既往单嵌片零切迹融合器的支撑强度和稳定性曾受质疑, 本研究发现融合器节段前方骨桥的形成不仅增加了融合节段的稳定性, 也有助于阻止融合器沉陷, 且骨桥与椎体前缘相平齐, 不会造成对椎前软组织的压迫。

ACDF术后中远期ASD的发生已引起广泛关注, 有研究报道ACDF术后症状性ASD的发生率可高达26.0%^[18], 需要手术翻修的症状性ASD发生率约为6.0%(1.0%~11.9%)^[19]。融合节段相邻运动单元术后应力增大可能是其退变加速的主要原因, Eck等^[20]通过生物力学研究表明, ACDF术后颈椎活动时融合相邻节段椎间盘内压力增大。本研究结

果表明,应用ROI-C治疗双节段脊髓型颈椎病术后中期随访时影像学提示融合相邻节段不稳的发生率为4.5%(1/22),但尚未发现症状性ASD,可能是由于随访时间尚短,仍需要进一步长期跟踪随访。

总体而言,应用ROI-C行ACDF治疗双节段脊髓型颈椎病的中期临床疗效尚好,颈椎生理曲度和融合节段椎间隙高度得到有效维持,未发现内置物松动及症状性ASD等并发症,影像学观察到大部分融合节段椎体前缘骨桥形成,增加了融合节段的稳定性。本研究的局限性在于为单中心回顾性中期随访研究,样本量相对较少,尚需多中心大样本长期随访数据进一步分析远期疗效及其并发症。

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