

纳米羟基磷灰石/聚酰胺 66 融合器在颈椎前路椎间融合术中应用的中期效果

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【摘要】目的:探讨纳米羟基磷灰石/聚酰胺 66 椎间融合器(n-HA/PA66 cage)重建颈椎前中柱稳定性的中期效果。**方法:**回顾性分析 2010 年 1 月~2012 年 1 月在我院行颈椎前路减压椎间盘切除植骨融合内固定术(anterior cervical discectomy and fusion, ACDF)的患者。根据术中所用的植骨材料不同将患者分为两组:A 组采用 n-HA/PA66 cage 植骨融合, 124 例; B 组采用 PEEK cage 植骨融合, 50 例。比较两组的性别、年龄、术中出血量、手术时间、并发症发生率、术后影像学 and 临床疗效。影像学评价包括颈椎曲度、融合节段曲度、融合节段高度, 采用 Brantigan 评分判断植骨融合和 cage 下沉、移位等情况。临床疗效采用视觉模拟量表(visual analog scale, VAS)评分、日本骨科学会(Japanese Orthopaedic Association, JOA)评分和颈椎功能障碍指数(neck disability index, NDI)评价。**结果:**两组患者性别比、年龄、术前 VAS 评分、JOA 评分、NDI, 术前颈椎曲度、融合节段高度、融合节段曲度、手术时间、术中出血量等均无统计学差异($P>0.05$)。术后 B 组 2 例患者出现短暂的咽喉部不适, 术后 72h 消失, 无吞咽困难发生。所有患者均未出现脑脊液漏、血肿、切口感染等并发症。所有患者术后均获得随访, A 组随访 52.10±24.30 个月, B 组随访 49.50±26.50 个月, 两组随访时间无统计学差异($P>0.05$)。末次随访时两组患者 VAS 评分、NDI 及 JOA 评分较术前均有显著性改善($P<0.05$); 术后和末次随访时融合节段高度、融合节段曲度、颈椎曲度与术前比较均有显著性差异($P<0.05$), 两组同时时间点比较均无显著性差异($P>0.05$)。A 组 2 例患者 cage 出现下沉, B 组 3 例患者 cage 出现下沉, 两组下沉率比较有统计学差异($P<0.05$)。其他患者未发现 cage 移位、破裂以及其他内固定并发症。两组患者末次随访时均获得满意融合(Brantigan 评分均≥3 分), 融合时间分别为 4.2±1.8 个月及 4.1±2.0 个月($P>0.05$)。**结论:**应用 n-HA/PA66 cage 行颈椎前路椎间植骨融合的骨融合率与 PEEK cage 相似, 可维持融合节段高度及曲度, 是一种较理想的颈椎前中柱重建材料。

【关键词】颈椎; 脊柱融合术; 纳米羟基磷灰石/聚酰胺 66; 聚醚醚酮

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Clinical effect of the nano-hydroxyapatite/polyamide66 cage in reconstruction of cervical stability: a midterm follow-up study/LIANG Xinjie, ZHONG Weiyang, QUAN Zhengxue, et al//Chinese Journal of Spine and Spinal Cord, 2018, 28(4): 297-302

【Abstract】 Objectives: To explore the midterm outcomes of nano-hydroxyapatite/polyamide66 cage(n-HA/PA66 cage) in reconstructing the stability of anterior and middle cervical column by comparing with polyetheretherketone PEEK cage. **Methods:** A total of 174 patients who underwent the anterior cervical discectomy and fusion (ACDF) between January 2010 and January 2012 was reviewed. They were divided into two groups according to the implanted cage: 124 cases with n-HA/PA66 cage in group A, and 50 cases with PEEK cage in group B. Sex, age, intraoperative blood loss, operation time, complication rate, postoperative image and clinical effect were compared between two groups. The following radiographic measurements in all the patients were observed: cervical spine alignment, fused segments height, fused segments alignment. The rate of cage subsidence, cage displacement and bone fusion were evaluated by Brantigan score. The clinical outcomes were evaluated by visual analogue scale(VAS) score, Japan Orthopaedic Association(JOA) score and

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neck disability index(NDI). **Results:** There were no significant differences($P>0.05$) of sex, age, preoperative VAS, preoperative JOA, preoperative NDI, operation time, cervical spine alignment, fused segments height, fused segments alignment, hospitalization time and intraoperative blood loss between two groups. In group B, 2 patients showed temporary sore throat, which disappeared in 72 hours after operation without dysphagia. No cerebrospinal fluid leakage, hematoma or wound infection was found in all patients. Patients had been followed up for an average of 52.10 ± 24.30 months in group A, and 49.50 ± 26.50 months in group B, without significant difference between the two groups($P>0.05$). Cage subsidence occurred in 2 cases of group A and 3 cases of group B, there was significant difference of subsidence rate between the two groups($P<0.05$). The cervical spine alignment, fused segments height, fused segments alignment significantly improved at postoperative and final follow-up. But, there was no significant difference of cervical spine alignment, fused segments height, fused segments alignment at postoperative or final follow-up between two groups($P>0.05$). There was no cage displacement, cage breakage or other implant complication in the other patients. The Brantigan score was more than or 3 points in all the patients which showed satisfied fusion rate. The fusion time was 4.2 ± 1.8 months in group A, and 4.1 ± 2.0 months in group B, and there was no significant difference between the two groups($P>0.05$). **Conclusions:** The n-HA/PA66 cage has satisfied similar rate of osseous fusion as PEEK cage and can effectively restore and maintain the height and alignment of fused segments. The n-HA/PA66 cage is an ideal bioactive material in the reconstruction of anterior and middle cervical column.

[Key words] Cervical vertebrae; Spinal fusion; Nano-hydroxyapatite/polyamide 66; Polyetheretherketone

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颈前路减压植骨融合内固定术(anterior cervical discectomy and fusion, ACDF)是治疗颈椎疾病的经典术式^[1,2]。目前,ACDF 椎间融合植入的材料有自体髂骨、同种异体骨、钛网加自体骨等,但均存在一定的缺陷与不足^[3-5]。纳米羟基磷灰石/聚酰胺 66(n-HA/PA66)是一种新型骨修复重建材料,已应用于临床,其可通过模拟自然骨结构特性,类骨的理化及生物力学特征,取得了较好的早期临床疗效^[6-13]。近年来其已应用于颈椎稳定性的重建,短期疗效较为满意^[14,15],但中期随访报道较少。本研究对采用 n-HA/PA66 cage 行颈椎前中柱稳定性重建的颈椎病患者进行中期观察,并与应用聚醚醚酮椎间融合器(PEEK cage)的患者进行对比。

1 临床资料

1.1 一般资料

收集 2010 年 1 月~2012 年 1 月在我院行 ACDF 的患者。纳入标准:(1)患者诊断为脊髓型或神经根型或混合型(脊髓型合并神经根型)颈椎病,或颈椎过伸性损伤;(2)术前颈椎 MRI 显示单节段椎间盘退变突出或损伤,与临床表现相符;(3)严格保守治疗无效(脊髓型颈椎病除外),神经损害进一步发展。排除标准:(1)颈椎先天畸形;

(2)严重骨质疏松;(3)颈椎后方压迫脊髓或神经(如黄韧带肥厚);(4)合并孤立型后纵韧带骨化(OPLL)可能需要椎体切除和后方减压者。共有 174 例患者纳入本研究。124 例采用 n-HA/PA66 cage(A 组)植骨融合,男 60 例,女 64 例;年龄 28~78 岁(50.52 ± 25.56 岁)。50 例采用 PEEK cage 植骨融合,男 30 例,女 20 例;年龄 25~76 岁(52.50 ± 24.60 岁)。两组性别比与年龄无统计学差异($P>0.05$)。

1.2 手术方法及术后处理

术前检查未见绝对手术禁忌,术前均进行常规气管推移训练。经鼻插管全麻,患者轻度过伸仰卧位,C 型臂 X 线机定位后取颈前路横切口,沿颈内肌鞘和颈动脉鞘之间疏松结缔组织间隙钝性分离进入椎前,C 型臂 X 线机再次透视定位。适当撑开相应椎间隙,切除椎间盘及后纵韧带达到脊髓或神经彻底减压。选取合适型号的 n-HA/PA66 cage 或 PEEK cage(装有自体骨粒)置入减压椎间隙。选取合适颈前路钉板系统进行固定。术后均给予地塞米松 10mg 1 次/d、甘露醇 125ml 2 次/d、头孢呋辛 750mg 2 次/d、甲钴胺 0.5g 3 次/d 等 3d。术后患者佩戴颈托 6~8 周。

1.3 随访和评估方法

术后 1、3、6、12 个月及之后每年进行 1 次随

访,行X线片及三维CT检查。测量融合节段高度、颈椎曲度及融合节段曲度,并评估神经功能恢复情况和植骨融合情况。通过颈椎正侧位X线片、三维CT测量融合节段高度(上位椎体下终板中点至下位椎体上终板中点间的距离),并计算cage下沉的距离(术后融合节段高度与末次随访时融合节段高度的差值),下沉距离 $>2\text{mm}$ 为cage下沉。颈椎曲度通过测量颈椎Cobb角(C2与C7下终板的夹角)、融合节段曲度通过测量Cobb角(融合节段头端及尾端终板间的夹角)^[3]来判断。采用Brantigan评分^[12]判断椎体间融合情况:4分,完全融合,塑形良好;3分,融合良好,但仍有少量透光线;2分,上下部分(50%)连接,但仍有少量透光线;1分,上下部分未连接,但骨量较术后即时植骨量多;0分,上下部分未连接,高度丢失,植骨吸收。 ≥ 3 分者视为融合。临床症状改善情况采用VAS评分、颈椎功能障碍指数(NDI)及JOA评分来评价。

1.4 统计学方法

所有测量数据均采用SPSS 19.0统计软件分析,计量资料以均数 $\pm$ 标准差表示,组间比较采用单因素方差分析,两两比较采用SNK检验;术前与术后末次随访时的JOA评分、VAS评分、NDI比较采用配对 t 检验;颈椎曲度Cobb角、融合节段曲度和融合节段高度采用独立样本 t 检验,计数资料以率来表示,组间比较采用 χ^2 检验。检验水准 $\alpha=0.05$ 。

2 结果

患者均顺利完成手术,B组2例患者术后出现短暂的咽喉部不适,术后72h消失,无吞咽困难发生。所有患者均未出现神经和血管等损伤,无脑脊液漏、血肿、切口感染等并发症发生。A组随访 52.10 ± 24.30 个月;B组随访 49.50 ± 26.50 个月,两组随访时间无统计学差异($P>0.05$)。两组住院时

间、手术时间、术中出血无统计学差异($P>0.05$,表1);A组住院费用为 50513.2 ± 360.8 元,B组为 55897.20 ± 501.5 元,两组比较有统计学差异($P<0.05$)。两组术后VAS评分、JOA评分、NDI与同组术前比较均显著性改善,两组间同时间点比较均无统计学差异(表2, $P>0.05$)。两组患者术后和末次随访时融合节段高度、融合节段曲度和颈椎曲度均无统计学差异(表3, $P>0.05$)。所有患者末次随访时获得满意融合(Brantigan评分均 ≥ 3 分),融合时间分别为 4.2 ± 1.8 个月及 4.1 ± 2.0 个月,两组比较无统计学差异(表3, $P>0.05$)。A组2例患者cage出现下沉,B组3例患者cage出现下沉,但患者均无明显症状及体征,并未进一步处理。两组下沉率比较有统计学差异($P>0.05$)。随访过程中均未发现内固定出现松动、断钉及假关节和异位骨化等情况(图1、2)。

3 讨论

彻底减压是ACDF的手术关键步骤,亦是患者术后神经功能恢复的重要前提^[1,3]。椎间隙减压后,重建颈椎的稳定性同样为脊柱外科医生所关注。目前临床上使用的椎间融合材料为自体髂骨、钛网以及PEEK cage等,但是金属椎间融合器有电解、应力遮挡和过敏等不足^[5,16,17]。文献报道,虽然钛网重建的稳定性能获得较好的生物力学优势及满意的疗效,然而由于其金属特性如力学强度

表1 两组患者住院时间、手术时间和术中出血的比较
Table 1 Comparison of hospitalization time, operation time, surgical blood loss between groups

	A组(n=124) Group A	B组(n=50) Group B
住院时间(d) Hospitalization time	10.80 $\pm$ 3.75	10.58 $\pm$ 4.02
手术时间(min) Operation time	90.15 $\pm$ 30.57	95.70 $\pm$ 28.10
术中出血(ml) Surgical blood loss	60.50 $\pm$ 50.50	65.5 $\pm$ 45.0

表2 两组患者术前和末次随访时的临床评价

Table 2 Clinical outcomes of two group patients at preoperative and final follow-up

例数 Cases	JOA评分 JOA score		NDI(%)		VAS评分 VAS score	
	术前 Preoperation	末次随访 Final follow-up	术前 Preoperative	末次随访 Final follow-up	术前 Preoperation	末次随访 Final follow-up
A组 Group A 124	11.03 $\pm$ 1.23	15.02 $\pm$ 1.02 ^①	40.52 $\pm$ 15.01	16.05 $\pm$ 7.08 ^①	5.60 $\pm$ 2.30	1.70 $\pm$ 1.99 ^①
B组 Group B 50	10.70 $\pm$ 1.50	16.10 $\pm$ 0.52 ^①	41.10 $\pm$ 14.89	15.78 $\pm$ 8.20 ^①	5.90 $\pm$ 2.20	1.65 $\pm$ 2.0 ^①

注:①与同组术前比较 $P<0.05$

Note: ①Compared with preoperation at the same group, $P<0.05$

表 3 两组患者术前、术后和末次随访时的影像学评价
Table 3 Radiological outcomes of of two group patients at preoperative, postoperative and final follow-up

	A组(n=124) group A	B组(n=50) group B	t	P
融合节段高度(mm) Segmental height				
术前 Preoperative	4.65±1.1	4.42±1.20	0.154	0.632
术后 Postoperative	7.05±1.18	7.03±1.50	0.326	0.741
末次随访 Final follow-up	6.0±1.1	6.20±1.20	0.035	0.874
颈椎曲度(Cobb 角,°) Cervical spine alignment				
术前 Preoperative	10.27±6.50	11.31±5.7	0.594	0.536
术后 Postoperative	17.71±4.50	17.56±3.40	0.691	0.486
末次随访 Final follow-up	16.80±3.81	16.65±3.50	0.542	0.501
融合节段曲度(Cobb 角,°) Segmental angle				
术前 Preoperative	2.00±4.10	2.10±4.00	0.045	0.902
术后 Postoperative	6.50±2.30	6.60±2.20	0.050	0.921
末次随访 Final follow-up	5.80±2.00	5.90±2.00	0.055	0.935
融合率(%) Fusion rate	100	100	/	/
cage 下沉(≥2mm) Cage subsidence	2(1.6%)	3(6%)	3.21	0.001

大且弹性模量高,术后产生的应力遮挡可能是导致植骨融合率降低的重要原因^[18-24]。与此同时,有关术后钛网沉降等并发症并不少见,钛网沉降后可导致融合节段椎间高度、颈椎曲度的丢失、椎间孔狭窄,再次压迫颈脊髓、神经而出现相应神经症状,患者面临翻修手术的风险^[17-20]。PEEK cage 的弹性模量与骨组织十分接近,与金属材料的融合器相比,不仅可避免因应力遮挡而使骨量减少,而且在融合器与骨组织的界面不会出现应力集中,导致融合器沉陷、椎间高度和前凸曲度减小,还利于以 X 线或 MRI 影像进行术后随访;PEEK cage 还具有良好的骨诱导、骨传导及良好生物相容性,符合人体脊柱结构及内环境要求,临床应用获得了较好的临床效果^[23,25,26],但费用较高。

研究表明,羟基磷灰石拥有良好的生物相容性、生物活性和骨传导性,被视为是最有潜力的一种人体骨组织修复替代材料^[6-13]。聚酰胺具有胶原类似的结构,生物相容性好,作为外科缝线已经使用近半个世纪。国内学者通过仿生设计将纳米级

羟基磷灰石按一定比例(65%左右)均匀散布在聚酰胺基质中,使得该材料达到了与自然骨类似的理化及生物力学特征^[6,7]。前期的实验研究证明其在体内的安全性及良好的生物相容性^[8-10,27-31]。本组患者随访期间伤口愈合良好无排斥反应,亦未见明显毒性反应,示 n-HA/PA66 具有良好的生物相容性及安全性。

本研究应用的 n-HA/PA66 cage 是以 n-HA/PA66 复合物为原材料的一种新型颈椎前柱重建材料。其设计为中空长方体,长 14~16mm,宽 11~13mm,高 5~9mm。上下边缘设计为锯齿状弧形表面。前期的动物实验表明,该 cage 在维持颈椎高度、曲度、力学稳定性以及促进相邻椎体间融合等方面较其他植入物具有明显优势^[13]。有学者对 14 例颈椎病患者采用 n-HA/PA66 cage 行 ACDF,随访 3~12 个月,所有患者症状均有明显改善,JOA 改善率达到 97%,融合率为 100%,椎间高度维持良好,椎间融合器无下沉、塌陷等发生。提示应用 n-HA/PA66 cage 行 ACDF 可取得较好的临床疗效^[14]。但是,以上研究的随访时间较短。

本研究结果显示,两组患者在住院时间、手术时间、术中出血以及功能恢复均无统计学差异,末次随访时所有患者临床症状较术前有不同程度的改善,VAS 评分、JOA 评分和 NDI 较术前也有显著改善。根据融合的标准(Brantigan 评分)^[12],两组均达到满意的融合,融合率无统计学差异。提示 n-HA/PA66 cage 具有优良的生物活性及优秀的力学特性,能提供早期良好的支撑和稳定的力学环境而保障了较高的融合率,从而维持了术后颈椎前中柱重建的稳定性。提示 n-HA/PA66 cage 组与 PEEK cage 组临床疗效统计学无明显差异,中期效果满意。但两组术后并发症发生率分别为 1.6%及 10%,两组间比较有统计学差异($P<0.05$),提示 n-HA/PA66 cage 比 PEEK cage 具有优势。但 PEEK cage 组病例数仍较少,需继续随访观察。

本研究对 n-HA/PA66 cage 在颈椎稳定性重建中的中期疗效进行了临床与影像学评价,并与 PEEK cage 进行了对比,结果显示两组均获得良好的中期临床疗效,可以有效保持颈椎生理曲度和融合节段高度,但 n-HA/PA66 cage 价格远较 PEEK 低廉,cage 下沉率低。



图 1 患者女,62 岁,C4/5 ACDF+n-HA/PA66 cage **a** 术前 MRI C4/5 椎间盘突出,脊髓受压 **b** 术后 1 周 X 线片示内固定位置良好 **c** 术后 3 个月 X 线片示植骨部分融合 **d** 术后 6 个月 X 线片示植骨已融合 **e** 术后 36 个月 X 线片示内固定位置良好,植骨已融合 **f** 术后 36 个月 CT 示内固定位置良好,植骨已融合 **图 2** 患者女,45 岁,C5/6 ACDF+PEEK cage **a** 术前 MRI 示 C5/6 椎间盘突出,脊髓受压 **b** 术后 1 周 X 线片示内固定位置良好 **c** 术后 3 个月 X 线片示植骨部分融合 **d** 术后 6 个月 X 线片示植骨已融合 **e** 术后 32 个月 X 线片示内固定位置良好,植骨已融合

Figure 1 A 62-year-old female who underwent ACDF(C4/

5) with a nano-hydroxyapatite/polyamide66 cage **a** Preoperative cervical MRI showed the compression of the spinal cord **b** The immediately postoperative lateral X-ray showed C4/5 discectomy and the n-HA/PA66 cage used for reconstruction **c** The 3-month lateral X-ray showed partial bony fusion **d** The 6-month lateral X-ray showed obvious bony fusion and restoration of cervical alignment **e, f** The 36-month lateral X-ray and CT showed obvious bony fusion and good location of internal fixation **Figure 2** A 45-year-old female who underwent ACDF(C5/6) with a PEEK cage **a** Preoperative cervical MRI showed the compression of the spinal cord **b** The immediately postoperative lateral X-ray showed C5/6 discectomy and the n-HA/PA66 cage used for reconstruction **c** 3-month lateral X-ray showed partial bony fusion **d** 6-month lateral X-ray showed obvious bony fusion and restoration of cervical alignment. 32-month lateral X-ray showed obvious bony fusion and good location of internal fixation

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