

临床论著

颈前路减压 Zero-P 融合固定术后椎间隙高度变化对临床疗效和影像学参数的影响

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【摘要】目的:分析颈前路减压 Zero-P 融合固定术后椎间隙高度(intervertebral height,IH)变化对临床疗效和影像学参数的影响。**方法:**收集 2014 年 5 月~2017 年 12 月在我院行颈前路减压 Zero-P 融合固定术且随访时间 1 年以上的 123 例脊髓型和神经根型颈椎病患者的资料。记录术前、术后 1 周及末次随访时的手术节段 IH, 并按术后平均 IH 变化值(术后 1 周 IH 与末次随访的差值)将所有患者分为 IH 维持组(IH 变化值<平均 IH 变化值)和 IH 丢失组(IH 变化值≥平均 IH 变化值)。比较两组患者的性别、年龄、手术节段, 术前、术后 1 周及末次随访时的日本骨科学会 (Japanese Orthopedics Association, JOA) 颈椎功能评分、颈痛视觉模拟评分(visual analogue score, VAS)、颈椎功能障碍指数(neck disability index, NDI)、C2~7 Cobb 角及手术节段曲度, 术后 3 周内的吞咽困难发生率, 术后 3 个月、6 个月及末次随访的融合率及末次随访时的邻近节段退变(adjacent segment degeneration, ASD)发生率。两组间定量变量的差异采用独立样本 *t* 检验, 定性变量差异进行卡方检验。**结果:**根据所有患者术后平均 IH 变化值(2.08 ± 0.94 mm), 将 123 例患者分为 2 组, 其中 IH 维持组 64 例, 随访时间为 15.95 ± 3.39 个月; IH 丢失组 59 例, 随访时间为 16.95 ± 2.87 个月。两组的性别、年龄、手术节段及随访时间均无统计学差异($P > 0.05$), 术前、术后 1 周及末次随访时的 JOA 评分、VAS 评分、NDI、C2~7 Cobb 角和手术节段曲度两组间比较均无统计学差异($P > 0.05$), 吞咽困难发生率及末次随访时的融合率两组间比较均无统计学差异($P > 0.05$)。IH 维持组术前 IH 为 5.65 ± 1.69 mm, 术后 1 周为 8.33 ± 0.78 mm, 末次随访为 6.89 ± 0.98 mm, 平均变化量为 1.44 ± 0.79 mm; IH 丢失组术前 IH 为 5.31 ± 1.58 mm, 术后 1 周为 8.25 ± 0.76 mm, 末次随访为 5.50 ± 1.01 mm, 平均变化量为 2.75 ± 0.52 mm。IH 维持组末次随访时 IH 和 IH 变化值显著高于 IH 丢失组($P < 0.001$)。术后 3 个月时 IH 维持组融合率为 64.06%, IH 丢失组为 42.37%($P = 0.019$); 术后 6 个月时 IH 维持组融合率为 81.25%, IH 丢失组为 54.24%($P = 0.002$)。末次随访时 IH 维持组下邻近节段退变发生率为 12.5%, 显著低于 IH 丢失组的 28.81%($P = 0.027$)。IH 维持组假体下沉发生率为 3.13%, 显著低于 IH 丢失组的 13.56%($P = 0.047$)。**结论:**颈前路减压 Zero-P 融合固定术后手术节段 IH 丢失发生率较高;若 IH 丢失 ≥ 2 mm 可能会降低术后早期融合率, 并增加 ASD 及假体下沉等并发症的发生率。

【关键词】 颈椎病; 颈前路椎间盘切除融合术; Zero-P 椎间融合固定系统; 椎间隙高度

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[Abstract] **Objectives:** To analyze the effect of changes in intervertebral height (IH) of surgical level on clinical outcomes and imaging parameters after anterior cervical decompression and fusion with the Zero-Profile implant system (Zero-P). **Methods:** The data of 123 patients with cervical spondylosis of cervical myelopathy or radiculopathy who underwent anterior cervical decompression and fusion with the Zero-P in our hospital from May 2014 to December 2017 and were followed up for at least 1 year were retrospectively analyzed. The IH of operative segment before surgery, at 1 week after surgery and at final follow-up was recorded, and according to the mean IH change value after surgery (difference between IH at 1 week after

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surgery and final follow-up) the patients were divided into IH maintaining group (IH change < mean IH change) and IH loss group (IH change ≥ mean IH change). The gender, age, surgical segment, and preoperative, 1 week after operation, and final follow-up Japanese Orthopedics Association (JOA) cervical function score, visual analogue scale(VAS) of neck pain, neck disability index(NDI), C2-C7 Cobb angle, and operated segment curvature, dysphagia at 3 weeks after surgery, fusion rate at 3 months and 6 months after surgery, and final follow-up, and adjacent segment degeneration(ASD) incidence at final follow-up were compared between the two groups. Differences in quantitative variables between the two groups were analyzed by independent sample *t*-test, and differences in qualitative variables were analyzed by chi-square test. **Results:** Based on the mean postoperative IH change value(2.08 ± 0.94 mm) in all patients, 64 cases were included in the IH maintaining group with a mean follow-up time of 15.95 ± 3.39 months and 59 cases were included in the IH loss group followed-up for 16.95 ± 2.87 months. There was no statistical difference between the two groups in terms of gender, age, surgical segment, or follow-up time($P > 0.05$), nor was there significant difference between the two groups in preoperative, postoperative 1 week, and final follow-up JOA scores, VAS, NDI, C2-C7 Cobb angle, or surgical segment curvature($P > 0.05$). Besides, no significant difference was found in dysphagia incidence or final follow-up fusion rate between the two groups($P > 0.05$). In the IH maintaining group, the IH was 5.65 ± 1.69 mm at preoperation, 8.33 ± 0.78 mm at 1 week after surgery, and 6.89 ± 0.98 mm at the last follow-up, with a mean change of 1.44 ± 0.79 mm. In the IH loss group, IH was 5.31 ± 1.58 mm preoperatively, 8.25 ± 0.76 mm 1 week postoperatively, and 5.50 ± 1.01 mm at the last follow-up, with a mean change of 2.75 ± 0.52 mm. The IH and IH change at the last follow-up were significantly higher in the IH maintaining group than those in the IH loss group ($P < 0.001$). The fusion rate was 64.06% in the IH maintaining group and 42.37% in the IH loss group at 3 months postoperatively($P=0.019$), and 81.25% in the IH maintaining group and 54.24% in the IH loss group at 6 months postoperatively ($P=0.002$). At the final follow-up, the inferior ASD incidence was 12.5% in the IH maintaining group, which was significantly lower than the 28.81% in the IH loss group ($P=0.027$). In addition, the incidence of implant subsidence was significantly lower in the IH maintaining group(3.13%) than that in the IH loss group(13.56%)($P=0.047$). **Conclusions:** The incidence of IH loss of operative segments after anterior cervical decompression and fusion with Zero-P implant system is high, and the early postoperative fusion rate may decrease and the incidence of complications such as ASD and prosthesis subsidence may increase if IH loss ≥ 2 mm.

[Key words] Cervical spondylosis; Anterior cervical discectomy and fusion; Zero-Profile implant system; Intervertebral height

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颈椎退行性疾病 (cervical degenerative disease,CDD) 是一种在中老年人群常见的脊椎疾病, 导致颈部不适、上肢放射痛和运动感觉功能障碍。颈椎前路减压融合术 (anterior cervical discectomy and fusion, ACDF) 是治疗颈椎病经典的手术方式, 常采用椎间融合器并钛板固定, 以增加减压节段的稳定性、提高融合率等^[1]。然而, 术后轴性疼痛和相邻节段退行性变导致的生物力学不稳定是传统 ACDF 术后常见的并发症, 也有报道认为这些并发症与术中椎间隙高度不佳有密切关系^[2-5]。新型零切迹椎间融合器(Zero-P)作为另一种有效的 ACDF 手术置入物, 可以减少相邻节段的退变, 避免置入物与颈椎前部的软组织接触, 从

而可以降低术后吞咽困难的发生^[6-8]。椎间隙高度 (intervertebral height,IH) 的术中有效撑开及术后良好维持是影响 ACDF 手术疗效的重要因素。以往的研究主要集中在 IH 术中撑开的重要性, 比如有文献报道术中 IH 撑开与颈椎手术轴性症状、邻近节段退变及临床疗效有关等^[5]。相对于术中 IH 的撑开, 较少研究报道采用 Zero-P 行 ACDF 术后 IH 维持与影像学参数及临床疗效之间的关系。因此, 本研究旨在探究颈前路减压 Zero-P 融合固定术后 IH 变化对临床疗效和影像学参数的影响, 为临床工作提供参考。

1 资料与方法

1.1 纳入与排除标准

纳入标准:①年龄 18~80 岁,单节段脊髓型颈椎病或神经根型颈椎病,临床症状、体征和影像学检查结果相符,系统保守治疗治疗 3 个月以上无效;②融合节段间隙适合行 ACDF,融合节段内置物采用 Zero-P;③具有完善的术后影像学及临床资料。排除标准:①年龄<18 岁和年龄>80 岁;②多节段脊髓型或神经根型颈椎病,或症状、体征与影像学表现不符者;③行翻修手术、发生过颈部外伤或存在颈部手术史;④合并颈椎畸形、肿瘤、严重骨质疏松、强直性脊柱炎、类风湿性关节炎等疾病;⑤接受颈椎间盘置换术(CDR)或混合手术(ACDF+CDR)的患者;⑥影像学资料不完善、失访或随访时间不足 1 年的患者。

1.2 一般资料

根据纳入与排除标准,选取 2014 年 5 月~2017 年 12 月在我院行颈前路减压 Zero-P 融合固定术的 123 例患者作为研究对象。手术均在本院骨科由同一教授团队进行,患者均知情同意,研究经伦理委员会审批。记录术前、术后 1 周及末次随访时的 IH,并以术后平均 IH 变化值(术后 1 周 IH 与末次随访 IH 的差值)将所有患者分为 IH 维持组(IH 变化值<平均 IH 变化值)和 IH 丢失组(IH 变化值≥平均 IH 变化值)。

1.3 手术方法

所有患者均采用全麻后仰卧位,颈部垫圆枕稍过伸,行标准的右侧 Smith-Robinson 手术入路,逐层解剖分离充分显露。术中 C 型臂 X 线机透视再次确认手术间隙,切除病变椎间盘的髓核和纤维环组织,咬除椎体前缘和后缘增生的骨赘,彻底减压后打磨终板至有鲜血渗出,注意保留骨性终板的完整性。在 C 型臂 X 线机透视下进行试模以确定假体的大小和高度,根据试模结果选择合适大小的填充人工骨的 Zero-P 假体置入椎间隙,再次透视调整假体位置后拧入 4 枚螺钉固定,置入相应规格的 Zero-P 假体及螺钉后,C 型臂 X 线机透视置入位置良好,仔细止血,再次用大量生理盐水冲洗椎间隙及整个手术野,缝合关闭椎前筋膜、皮下组织及皮肤,伤口内放置血浆引流管 1 根。

术后常规 1~2d 拔除引流管。户外活动时常规带颈托保护 6~8 周,去颈托保护后加强颈部及项背肌功能锻炼。

1.4 观察指标

分别记录两组性别、年龄、手术节段、随访时间,术前、术后 1 周及末次随访的日本骨科学会(Japanese Orthopedics Association,JOA)颈椎功能评分、颈部疼痛视觉模拟评分(visual analogue scale,VAS)、颈椎功能障碍指数(neck disability index,NDI),术后吞咽困难发生情况。VAS 评分用于评估颈部疼痛情况,JOA 评分和 NDI 评估神经功能情况。术后吞咽困难判断标准:术后进食时出现的吞咽功能障碍(吞咽干性、液体或大块食物障碍、无力、呛咳等)、吞咽时不适感(哽咽、异物、灼热感等),并排除术后早期食管水肿、颈前血肿等因素所致的进食疼痛、不适等,且至少持续 3 周以上。

采用 PACS(4.0 版)在中立位颈椎侧位 X 线片上测量术前、术后 1 周及末次随访手术节段的 IH、颈椎整体及手术节段曲度,观察邻近节段退变(adjacent segment degeneration,ASD)和假体下沉发生情况。在功能位(过伸-过屈位)颈椎侧位 X 线片中观察融合情况。具体测量方法如图 1 所示。(1)IH:手术节段上位椎体下终板中点与手术节段下位椎体上终板中点之间的连线,IH 变化值=(术后 1 周 IH 与末次随访 IH 的差值);(2)颈椎整体曲度:C2~7 Cobb 角,椎体下终板连线与 C7 椎体下终板连线的夹角;(3)手术节段曲度:手术节段上位椎体的下终板与下位椎体的下终板形成的夹角^[9];(4)假体下沉:定量标准为椎间融合器(cage)陷入下位椎体上终板超过 2mm^[10];(5)骨融合:指在过伸过屈位片上运动≤2°或棘突间距≤2mm^[11];(6)ASD:被定义为邻近节段新出现的或范围明显扩大的前纵韧带骨化、骨赘、终板硬化或者邻近节段椎间隙狭窄>30%^[12]。上述影像学指标由 2 名研究助理分别测量记录,2 人记录的数据平均值作为最终值。

1.5 统计学分析

使用 SPSS 22.0 软件处理数据,定量变量以均数±标准差的形式表示,两组间差异采用独立样本 t 检验;定性变量以比例的形式表示,组间差异进行卡方检验。 $P<0.05$ 为差异有统计学意义。

2 结果

所有患者平均 IH 由术前的 $5.49\pm1.64\text{mm}$ 增加至术后 1 周的 $8.30\pm0.77\text{mm}$,术后 1 周后 IH 逐

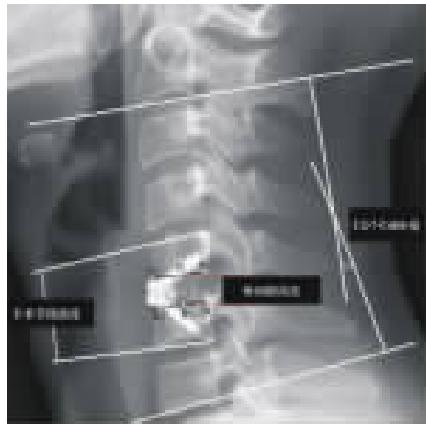


图 1 影像学参数的测量方法。(1)椎间隙高度:手术节段上位椎体下终板中点与手术节段下位椎体上终板中点之间的连线,a 为手术节段上位椎体下终板连线(a1-a2)中点,b 为手术节段下位椎体上终板连线(b1-b2)中点;(2)C2-7 Cobb 角:C2 椎体下终板与 C7 椎体下终板形成的夹角;(3)手术节段曲度:手术节段上位椎体的上终板与下位椎体的下终板形成的夹角

Figure 1 Measurement methods of radiological parameters. (1)Intervertebral height: the connection line between the midpoint of the inferior endplate of the superior vertebral body of the operative segment and the midpoint of the superior endplate of the inferior vertebral body of the operative segment. a is the midpoint of the inferior endplate line(a1-a2) of the superior vertebral body of the operative segment and b is the midpoint of the superior endplate line (b1-b2) of the inferior vertebral body of the operative segment; (2)C2-7 Cobb angle: angle formed by the inferior endplate of the C2 vertebral body and the inferior endplate of the C7 vertebral body; (3)Operated segment curvature: the angle formed by the upper endplate of the superior vertebral body and the lower endplate of the inferior vertebral body of the operated segment

渐降低,末次随访时降低到 6.23 ± 1.21 mm,术后平均 IH 变化值为 2.08 ± 0.94 mm。将所有患者分为两组,即 IH 维持组(IH 变化 <2 mm)和 IH 丢失组(IH 变化 ≥ 2 mm)。123 例患者中,IH 维持组 64 例,IH 丢失组 59 例。两组患者性别、年龄、手术节段、随访时间等一般资料之间差异无统计学意义 ($P > 0.05$,表 1)。术前、术后 1 周及末次随访的 JOA 评分、NDI 及 VAS 评分两组间比较差异均无统计学意义 ($P > 0.05$,表 2)。

术前 IH、C2-7 Cobb 角及手术节段曲度两组间比较均无统计学差异 ($P > 0.05$);术后 1 周和末次随访时的 C2-7 Cobb 角及手术节段曲度两组间比较均无统计学差异 ($P > 0.05$),术后 1 周 IH 两组间比较无统计学差异 ($P > 0.05$),末次随访时 IH 维持组的 IH 显著高于 IH 丢失组 ($P < 0.001$,表 3)。术后 3 个月、6 个月时 IH 维持组的融合率明显高于 IH 丢失组 ($P < 0.05$),末次随访时的融合率两组间比较无统计学差异 ($P > 0.05$,表 3)。术后吞咽困难发生率两组间比较无统计学差异 ($P > 0.05$),而末次随访时 IH 维持组的下邻近节段退变发生率及假体下沉发生率均显著低于 IH 丢失组 ($P < 0.05$,表 4)。

3 讨论

术中有效的 IH 撑开和术后良好的 IH 维持是颈椎手术取得良好预后的重要基础,有文献报道,术后过大或过小的 IH 都会增加术后颈痛和 ASD 的发生^[13]。因此,IH 有效撑开和术后良好维持至关重要。然而,相对于术中椎间隙撑开,较少

表 1 两组患者基本情况对比

Table 1 Comparison of basic information between the two groups

	IH 维持组($n=64$) IH maintaining group	IH 丢失组($n=59$) IH loss group	P 值 <i>P</i> value
年龄(岁) Age(yrs)	50.21 ± 9.19	47.59 ± 8.24	0.057
性别(<i>n</i>) Gender			0.281
男性 Male	29	33	
女性 Female	35	26	
手术节段(个) Surgery segments			0.145
C3/4	1	5	
C4/5	11	15	
C5/6	43	30	
C6/7	9	9	
随访时间(月) Follow-up period	15.95 ± 3.39	16.95 ± 2.87	0.082

研究关注颈前路减压 Zero-P 融合固定术后 IH 维持与临床和影像学之间的关系。

本研究中,所有患者的平均 IH 由术前的 5.49 ± 1.64 mm 增加至术后 1 周的 8.30 ± 0.77 mm,术后 1 周后 IH 逐渐降低,末次随访为 6.23 ± 1.21 mm。本研究结果显示,IH 维持组的临床结果与 IH 丢失组比较无统计学差异。Basques 等^[14]也评估了 ACDF 术后 IH 对临床及影像学结果的影响,他们纳入了 37 例单节段手术、50 例双节段手术和 13 例三节段手术的患者,发现术后 12 个月 IH 平均值从术前的 5.49 ± 1.17 mm 变为 6.62 ± 1.12 mm(IH 平均变化为 1.13 ± 1.33 mm)。而本研究中,为了避免邻近手术节段导致的生物力学改变

影响 IH 和其他影像学参数, 我们只纳入了单节段颈前路减压 Zero-P 融合固定术患者。

Truumees 等^[15]在 17 具尸体上进行了一项生物力学研究, 评估不同大小的 IH 和应力对颈椎模型的影响, 该研究发现, IH 过长或过短, 置入物与椎体终板之间产生的压载荷均增加。我们发现 IH 维持组在术后前 6 个月的融合率明显高于 IH 丢失组, 可能是由于 IH 丢失组的 IH 在短时间内下降太多, 这可能使压缩负荷集中在椎间隙最窄的终板上, 对骨融合产生负面影响。后期研究可能还需要通过有限元或生物力学实验分析在不同 IH 的 ACDF 模型上应力分布对骨融合的影响, 从而进一步验证本研究得出的结果。

据报道, 颈前路减压 Zero-P 融合固定术后假体下沉的发生率为 7%~25%^[16]。本研究中, 所有患者术后假体下沉的发生率为 8.13%(10/123), 其中 IH 维持组为 2 例, IH 丢失组为 8 例, IH 丢失组的假体下沉率明显高于 IH 维持组。既往研究认为^[16,17], 假体下沉危险因素包括 Cage 大小、置入位置、接触面积、椎体骨质及术中撑开程度等。因

表 2 两组患者不同时间点的 JOA 评分、VAS 评分及 NDI 对比

Table 2 Comparison of JOA score, VAS and NDI between groups

	IH 维持组 (n=64) IH maintaining group	IH 丢失组 (n=59) IH loss group	P 值 P value
JOA 评分 JOA score			
术前 Preoperation	10.80±2.07	10.47±1.79	0.360
术后 1 周 One week after surgery	12.56±1.58	12.62±1.55	0.822
末次随访 Final follow-up	15.53±1.50	15.56±1.41	0.915
VAS 评分 VAS score			
术前 Preoperation	5.84±1.12	5.80±1.08	0.937
术后 1 周 One week after surgery	2.84±0.98	2.75±1.04	0.592
末次随访 Final follow-up	1.97±0.84	1.92±0.93	0.658
NDI(%)			
术前 Preoperation	28.24±7.07	27.89±7.33	0.748
术后 1 周 One week after surgery	19.15±4.85	19.96±4.33	0.321
末次随访 Final follow-up	14.47±4.79	15.08±4.32	0.442

表 3 两组患者影像学指标及融合率对比

Table 3 Comparison of radiological indicators and fusion rate between groups

	IH 维持组 (n=64) IH maintaining group	IH 丢失组 (n=59) IH loss group	P 值 P value
椎间隙高度(mm) Intervertebral height			
术前 Preoperation	5.65±1.69	5.31±1.58	0.252
术后 1 周 One week after surgery	8.33±0.78	8.25±0.76	0.549
末次随访 Final follow-up	6.89±0.98	5.50±1.01	<0.001
变化值 Change value	1.44±0.79	2.75±0.52	<0.001
C2~7 Cobb 角(°) C2~7 Cobb angle			
术前 Preoperation	10.81±7.58	11.14±7.68	0.812
术后 1 周 One week after surgery	11.72±7.99	13.32±6.22	0.219
末次随访 Final follow-up	11.29±8.85	10.41±8.48	0.575
手术节段曲度(°) Operated segment curvature			
术前 Preoperation	3.07±1.85	3.18±1.97	0.741
术后 1 周 One week after surgery	3.02±1.70	3.39±1.50	0.202
末次随访 Final follow-up	3.16±1.62	2.92±1.67	0.428
融合率(%) Fusion rate			
术后 3 个月 Three months after surgery	64.06% (41/64)	42.37% (25/59)	0.019
术后 6 个月 Six months after surgery	81.25% (52/64)	54.24% (32/59)	0.002
末次随访 Final follow-up	98.44% (63/64)	96.61% (57/59)	0.607

表 4 两组患者并发症对比

Table 4 Comparison of complications between groups

	IH 维持组 (n=64) IH maintaining group	IH 丢失组 (n=59) IH loss group	P 值 P value
吞咽困难 Dysphagia	6.25% (4/64)	5.08% (3/59)	0.546
假体下沉 Implant subsidence	3.13% (2/64)	13.56% (8/59)	0.047
邻近节段退变 Adjacent segment degeneration			
上邻近节段退变 Degeneration of the upper adjacent segment	7.81% (5/64)	11.86% (7/59)	0.549
下邻近节段退变 Degeneration of the lower adjacent segment	12.5% (8/64)	28.81% (17/59)	0.027

此,不能简单地认为IH丢失组假体下沉由单一因素(IH丢失)导致,但结合本研究结果,我们认为椎间隙过度丢失与假体下沉密切相关,可能是潜在的危险因素。因此,有必要通过生物力学或动物实验进一步分析IH丢失所导致的生物力学改变对假体下沉的影响。

本研究存在如下局限性及不足:①本研究属回顾性研究,纳入患者过程中难免出现偏倚,有待前瞻性随机对照研究进行进一步验证。②以IH变化2mm作为分组界值可能不够严谨,且容易引起测量误差。但由于以往研究中没有IH丢失的统一定义和可参考的分组界值,我们基于所有患者术后平均IH变化值作为分组标准。③本研究中,ASD的评价手段为X线片,相比MRI等结果可能会不够全面。④由于本研究主要观察ACDF术后IH变化对临床和放射学结果的影响,因此未涉及术中及术后如何维持良好IH的有效方法,在今后的研究里我们会探讨颈前路减压Zero-P融合固定术后如何维持IH的有效措施。

综上所述,颈前路减压Zero-P融合固定术后手术节段IH丢失发生率较高。若IH丢失超过2mm可能会降低术后早期融合率,并可能会增加ASD及假体下沉等并发症的发生率。

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