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动态中和固定系统与后路椎间融合术治疗退变性椎管狭窄的近期疗效对比研究*

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摘要 目的:对比动态中和固定系统(Dynesys)与后路椎间融合术治疗退变性椎管狭窄的近期疗效。**方法:**70例椎管狭窄伴或不伴椎间盘突出患者,随机分为Dynesys组与后路椎间融合术组。前者行椎板减压并Dynesys内固定,后者行减压术并椎间融合术,术后随访24个月,对比两组术后功能恢复情况、椎间隙高度、活动度及邻近节段退变情况。**结果:**①两组患者术后随访结束时ODI指数、VAS评分均较术前明显下降($P<0.05$),两组ODI指数与VAS评分无显著性差异($P>0.05$)。②术后两组固定节段间隙均较术前明显增加($P<0.05$),Dynesys组L4-5节段、L5-S1节段活动度大为下降($P<0.05$),融合术组相应节段均融合良好,无活动度。③Dynesys组头侧相邻节段活动度与术前无明显变化,融合术组头侧相邻节段较术前活动度明显增加($t=2.286, P=0.026$),两组术侧相邻节段活动度差异有统计学意义($t=3.125, P=0.003$)。④随访结束时Dynesys组有1例(2.6%)患者S1节段出现1根螺钉松动,邻近节段未见退变病例;融合组有4例(12.5%)邻近节段出现I-II度退变,两组邻近节段退变率差异有统计学意义(fisher $p=0.039$)。**结论:**Dynesys动态固定植入手术与传统后路椎间融合术治疗退行性椎管狭窄术后短期内效果相当,前者对邻近节段活动性的影响小于融合术。

关键词:退行性变;椎管狭窄;动态中和固定系统;后路椎间融合术;活动度

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Comparative Study on Short Term Efficacy between Dynamic Neutralization System and Posterior Intervertebral Fusion for Degenerative Spinal Stenosis*

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ABSTRACT Objective: To compare short term efficacy between dynamic neutralization system and posterior interior intervertebral fusion for degenerative spinal stenosis. **Methods:** 70 Patients with intervertebral disc herniation with spinal canal stenosis or not were randomly divided into dynesys group ($n=38$) and posterior intervertebral fusion group ($n=32$), the former group was applied with vertebral decompression and dynesys internal fixation, and the latter was given decompression and posterior intervertebral fusion, follow-up for 24 months, and postoperative function recovery, intervertebral space height, motion range and degeneration of adjacent segment were compared between the two groups. **Results:** ① All patients were successfully operated and followed up for 24 months. At the end of follow-up, ODI and VAS scores of patients in two groups were significantly decreased compared with preoperation ($P<0.05$), but there was no significant difference between the ODI score and VAS score ($P>0.05$). ② The fixed segment spaces of the two groups were significantly increased compared with preoperation ($P<0.05$), Range of motion of L4-5 segment and L5-S1 segment of dynesys group was significantly decreased ($P<0.05$). However, the fusion segment of Fusion group fixed good and there was no activity. ③ Cranial adjacent segment activity of pre&post treatment had no obvious change in dynesys group, cranial adjacent segment activity of fusion group increased significantly compared with preoperation ($t=2.286, P=0.026$), the difference was statistically significant between the two groups ($t=3.125, p=0.003$). ④ At the end of follow-up, One case (2.6%) in dynesys group had one screw loosening at S1 segment, no other adjacent segment was found degeneration; fusion group had four cases (12.5%) had I - II degree adjacent segment degeneration, The difference was significant between the two groups ($P=0.039$). **Conclusions:** The short term effect of dynesys dynamic fixation operation and traditional posterior interior intervertebral fusion for degenerative spinal whose short-term efficacy postoperatively were similar, but adverse influence of the former on adjacent segment activity is less than fusion method.

Key words: Degeneration; Spinal stenosis; Dynamic neutralization system; Posterior interior intervertebral fusion; Range of motion

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前言

腰椎退变可引起腰椎间盘突出、椎管狭窄、腰椎滑脱等,常引发腰腿疼痛,影响患者运动,保守治疗往往收效甚微,常借助于手术治疗。在手术治疗退变性椎管狭窄中,在减压的同时需要进行腰椎固定才能保持手术节段的稳定性。后路椎间融合术长期以来被认为是治疗腰椎退变性疾病的标准术式,但该术式虽能保持融合节段的长期稳定性,但是融合后由于脊柱节段力矩的重新分配会加速邻近节段的退变,导致其他节段的病变^[1]。动态中和固定系统(dynamic neutralization system, Dynesys)是一种非融合型经腰椎后路椎弓根动态稳定治疗技术,近年来已在临床广泛应用。笔者选取部分病例资料对两种不同固定术式的近期疗效进行 24 个月随访观察,现将研究结果报道如下。

1 资料与方法

1.1 临床资料

资料来自本院脊柱外科 2008 年 1 月 -2010 年 12 月间收治并入选的退变性椎管狭窄患者 70 例。其中男 37 例,女 33 例,年龄 34-55 岁,平均(41.6± 6.9)岁。病例入选标准:X 线或脊椎 MRI 明确诊断且保守治疗无效者。排除标准:脊柱退变性侧弯 >10° 者、腰椎峡部退变性滑脱达 II 度及以上者、2 节段以上狭窄者、骨质疏松者、脊柱肿瘤或结核患者、体重指数(BMI) ≥ 30 者及二次脊柱手术者。70 例患者均有椎管狭窄典型表现,例如腰部疼痛,单侧或双侧下肢疼痛或麻木,间歇性跛行等,支腿抬高试验阳性;入选患者中单阶段狭窄 58 例,2 节段狭窄 12 例,具体为 L4-5 狭窄 30 例,L4-5 伴 L5-S1 狭窄 12 例,L5-S1 狭窄 24 例;伴椎间盘突出者 18 例。所有患者按照随机数字表分为 Dynesys 组(n=38 例)与后路椎间融合术组(n=32 例)。两组患者年龄、性别、责任节段椎间隙高度及活动度等指标对比情况见表 1。

1.2 手术方法

Dynesys 固定组:全身静脉麻醉,取俯卧位,后正中切口,

表 1 两组患者基本信息对比情况
Table 1 The characteristics between the two groups

Index	Dynesys Group(n=38)	Fusion group(n=32)	T-value	P-value
Age	40.7± 5.7	42.3± 6.8	1.055	0.295
Gender				
Male	21(55.3)	16(50.0)	0.193	0.660
Female	17(44.7)	16(50.0)		
Narrow segment				
Single	31(81.6)	27(84.4)	0.096	0.757
Double	7(18.4)	5(15.6)		
Slipped disc				
Yes	11(28.9)	7(21.9)	0.455	0.500
No	27(71.1)	25(79.1)		
ODI score(%)	58.4± 18.8	60.2± 20.1	0.384	0.702
VAS score				
Lumbago	6.1± 1.9	6.3± 2.0	0.426	0.671
Skelalgia	6.8± 1.8	7.0± 2.2	0.411	0.682
L4/5 space*				
Height(mm)	7.5± 1.5	7.6± 1.4	0.230	0.819
Activity(°)	10.2± 2.2	9.8± 2.4	0.572	0.570
L5/S1space**				
Height(mm)	7.6± 1.9	7.8± 1.5	0.358	0.723
Activity(°)	10.3± 2.4	10.1± 2.5	0.245	0.808
Cranial adjacent segmental activity(°)	9.8± 2.4	10.4± 2.8	0.953	0.344

注:*Dynesys 组 26 例、融合组 19 例;**Dynesys 组 21 例、融合组 16 例。

Note:*Dynesys Group(26 cases), Fusion Group(19 cases);**Dynesys Group(21 cases), Fusion Group(16 cases).

Dynesys 椎弓根螺钉进钉点较常规椎弓根螺钉进钉点偏外侧,尽量将螺钉头置入小关节外侧的窝内,置入后并 X 线透视确认;据术前确定的责任椎间隙行单侧或双侧椎板开窗减压,咬除增厚或钙化的黄韧带及小关节突内侧增生部分,至少保留外侧关节突 1/2,治疗侧隐窝狭窄、中央椎管狭窄,伴椎间盘突出者采用半椎板切除髓核摘除、对侧潜行扩大减压。完成减压后检查神经根移动度。确认减压充分后,在保持腰椎正常生理前凸位下,测量左右两侧上下椎弓根螺钉间距离,按所测得长度截取聚氨基甲酸酯套管(PCU)管,最后将聚对苯二甲酸乙酯(PET)绳索套入 PCU 管和上下椎弓根螺钉间,收紧 PET 绳索后予小螺钉锁牢,手术完成后,放置引流管,严密缝合两侧的骶棘肌。术后卧床,常规抗感染、抗凝、脱水处理,术后 24-48 h 或引流量少于 50 mL 时拔除引流管,术后 1 周-1 个月佩戴腰椎支具下床活动。

后路椎间融合术组:气管插管全麻,取俯卧位,后正中切口,按标准操作常规植入椎弓根螺钉并 X 线透视确认,减压术同 Dynesys 组,减压术完成后用神经根拉钩保护好硬脊膜与神经根,摘除椎间盘及融合节段残余的髓核、纤维环及终板软骨面,保留骨性终板,椎间融合器试模后,用铰刀再次清除软骨终板,将切下的部分棘突、椎板的软组织咬成细颗粒状,填充于椎间融合器内,植入融合器,行椎间加压后锁固,置入引流管,严密缝合切口。术后处理同 Dynesys 组。

1.3 观察指标

Oswestry 功能障碍指数 (Oswestry Disability Index, ODI):通过 Oswestry 功能障碍指数问卷测量患者术前及术后 24 个月 ODI 得分。问卷共 10 项指标,共 50 分,ODI 指数=ODI 得分/50*100%,得分越高表示功能障碍越严重。

疼痛视觉模拟量表评分(Visual Analogue Scale, VAS):术前及术后 24 个月由患者自评评价主观疼痛程度,评分范围 0-10 分,得分越高,主观疼痛程度越高。

影像学指标:术前与术后 24 个月经 X 线及腰椎 MRI 测量手术节段椎间隙高度(背侧高度)、前屈后伸位活动度(range of motion, ROM)及上侧邻近关节活动度。

邻近节段退变等级^[2]:术后 24 个月采用 UCLA(University of California at Los Angeles Grading Scale)法评价邻近节段退变程度,UCLA 根据椎间隙是否变窄、是否有骨赘形成、是否出现终板硬化等三个方面分 I-IV 等级评判退变程度,级别越高,退变程度越高。

1.4 统计学方法

椎间隙高度、ODI、VAS、ROM 等计量资料用 $\bar{x} \pm s$ 表示,计量资料的比较采用 t 检验,构成比的比较采用 χ^2 检验或 Fisher 精确概率法,所有数据经 SPSS17.0 软件进行统计学处理, $P < 0.05$ 视为差别有统计学意义。

表 2 两组患者随访结束时观察指标对比情况

Table 2 The comparison of the observational index after follow-up between the two groups

Index	Dynesys Group(n=38)				Fusion Group(n=32)				T-value▲	P-value
		T-value△	P-value		T-value△	P-value				
ODI score(%)	18.9± 9.5	11.560	0.000	20.0± 8.7	10.383	0.000	0.505	0.615		
VAS score										
lumbago	2.7± 1.4	8.881	0.000	2.9± 1.5	7.693	0.000	0.573	0.569		
skelalgia	2.1± 1.2	13.393	0.000	2.2± 1.2	10.835	0.000	0.347	0.730		
L4-5 space*										
Height(mm)	8.9± 1.3	3.596	0.000	9.1± 1.4	3.472	0.001	0.488	0.628		
Activity(°)	3.3± 1.2	14.040	0.000	-	-	-	-	-		
L5-S1 space**										
Height(mm)	8.6± 1.0	2.134	0.039	8.8± 1.1	2.150	0.040	0.570	0.573		
Activity(°)	3.1± 1.3	12.418	0.000	-	-	-	-	-		
The upper adjacent segmental activity(°)	10.1± 2.5	0.534	0.595	12.1± 2.8	2.286	0.026	3.125	0.003		

注:*Dynesys 组 26 例、融合组 19 例;**Dynesys 组 21 例、融合组 16 例。

△与手术前比较;▲随访结束时比较。

Note:*Dynesys Group(26cases),Fusion Group(19cases);**Dynesys Group(21cases),Fusion Group(16cases).

△ Compared with preoperation; ▲ Compare with after follow-up.

2 结果

两组患者均顺利完成手术,未出现脊髓神经损伤、硬脊膜撕裂等术中并发症,术后也未出现感染、下肢深静脉血栓等并发症。术后患者均完成 24 个月随访观察,随访结束后两组患者

ODI 指数、VAS 评分均较手术前明显下降,差异具有统计学意义 ($P < 0.05$), 术后两组 ODI 指数与 VAS 评分无显著性差异 ($P > 0.05$)。术后两组固定节段间隙均较手术前明显增加 ($P < 0.05$),Dynesys 组 L4-5 节段、L5-S1 节段活动度大为下降 ($P < 0.05$),融合术组相应节段均融合固定,无活动度。Dynesys 手术

组头侧相邻节段活动度与术前无明显变化,融合术组头侧相邻节段较术前活动度明显增加,差异具有统计学意义($P < 0.05$),两组术后 24 个月头侧相邻节段活动度组差异有统计学意义。见表 2。

随访结束时 Dynesys 组有 1 例(2.6%)患者 S1 节段出现 1 根螺钉松动,邻近节段经 MRI 检查未见退变病例,融合组有 4 例(12.5%)出现 I-II 度退变,主要是头侧椎间隙高度降低,未见骨赘形成与终板硬化,两组邻近节段退变率差异有统计学意义(fisher $P = 0.039$)

3 讨论

对退变性椎管狭窄或椎间盘突出症常规的手术治疗方法是实施脊柱减压并植骨融合内固定手术。脊柱融合术后,其在改善神经功能与确保融合节段的稳定性方面疗效确切,但融合节段由于丧失了运动功能而导致脊柱的活动度重新分配,导致邻近节段的运动力度增加,而加速其退变^[3]。文献报道腰椎融合术后邻近节段出现退变的比例可高达 52.5%^[4]。

Dynesys 是一种经椎弓根固定的动态固定系统,与传统融合术相比最大不同是通过使用 PCU 套管和 PET 绳索将椎弓根螺钉桥接起来而不是金属连接棒坚强连接^[5]。Dynesys 系统设计之初是为在维持脊柱稳定性的同时保留一定的椎间活动度,减小卸载退变性椎间盘的内压力及小关节突关节的负荷,同时适度撑开后柱有利于增加椎间孔容积,减轻神经压迫导致的炎症及腰痛。从手术操作角度看,Dynesys 内固定较之融合术保留了腰椎正常解剖结构与椎间盘及小关节、韧带功能,在限制腰椎异常活动的同时留存了一定的活动度,避免融合术带来的脊柱僵硬等并发症,此外减少了骨融合中的植骨步骤。由此得出 Dynesys 的适应证是:轻度退变性滑脱或退变性椎间盘疾病伴脊柱不稳、椎间盘突出症伴脊柱屈曲不稳和需行广泛椎板切除减压的退变性椎管狭窄^[6]。

Di Silvestre M 等^[7]对 29 例老年椎间孔狭窄病例实施 Dynesys 内固定治疗,研究结果表明后柱轻度撑开使得腰椎前屈时椎管容积扩大 11%,椎间孔容积增加 19%。Hoppe S 等^[8]对 39 例 L4/5 节段退行性变致椎管狭窄患者行 Dynesys 内固定,随访 5-11.2 年,总体结论认为 Dynesys 治疗手段远期疗效肯定,二次手术率同其他固定手段相近,且患者满意度高,但也存在螺钉松动、装置位移等并发症。王华东等^[9]通过 Dynesys 治疗 42 例腰椎退变性疾病患者,ODI 指数由术前的 (60.4 ± 21.5)% 降至术后的 (23.9 ± 13.5)%,VAS 腰腿疼评分均显著下降,10-36 个月随访期内疗效满意。本研究中,两组患者术后 24 个月 ODI 指数与 VAS 评分均较术前明显下降,L4-5 和 L5-S1 间隙高度均较术前显著增加,且以上指标随访结束时差异均无统计学意义,也说明两种手术方法在确保患椎的稳定性,解除疼痛方面疗效相近,相比较而言 Dynesys 组固定节段和头侧相邻节段活动度更为接近。因此,笔者认同 Dynesys 能维持椎间一定的生理活动,创造接近于正常脊柱力学分配的相对适宜环境,有利于退变椎间盘的减负和预防椎间盘再突出发生的论断^[10]。

Dynesys 系统虽然能保持手术椎间隙限制性的活动度,但长期过大负荷的作用下仍可能出现局部的不稳^[11]。Putzier M 等^[12]通过 Dynesys 内固定治疗 35 例椎间盘突出症患者,22 例软

骨病或关节炎患者和 9 例退行性脊柱前移患者,随访 33 个月,结果判定髓核摘除后椎间盘突出与软骨病患者腰椎责任节段未进一步退变,退行性脊柱前移患者中 3 例邻近节段退变明显,并据此认为 Dynesys 不适用于骨畸形和需要广泛减压患者。故本组资料在入组时将过度肥胖者予以排除,尽可能剔除肥胖对手术的干扰。此外,Vaga^[13]等研究结果表明 Dynesys 系统虽能部分逆转固定节段椎间盘的退变,但由于邻近节段负荷增加,力学环境发生改变,可能会增加相邻节段退变的风险。国内张阳^[14]等的研究结果表明 Dynesys 内固定能导致相邻节段活动度增大,导致近端相邻节段负荷增加,增加相邻节段退变的风险。与之向左意见者则认为邻近节段退变是腰椎疾病自然发展的结果而不能简单归因于实施了 Dynesys 手术^[15-17]。本研究结果中 Dynesys 组头侧相邻节段活动度与术前无明显变化,且头侧邻近节段未发现有退变病例,而融合术组头侧相邻节段较术前活动度明显增加($P < 0.05$),出现 4 例邻近节段退变病例,至少说明术后 24 个月 Dynesys 组对邻近关节的负性影响要远小于传统融合组。本研究 Dynesys 组中有 1 例患者 S1 节段出现 1 根螺钉松动,笔者分析可能与 S1 椎弓根螺钉较其他节段椎弓根的螺钉短而影响到螺钉的把持力有关^[18-20]。

综上所述,Dynesys 内固定治疗退变性椎管狭窄较之传统融合术能保留脊柱固定节段的限制性运动,二者在稳定手术节段、减轻神经压迫方面近期效果相当,前者对邻近节段的退变影响要小于融合术。

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