

· 临床研究 ·

单侧固定联合经椎间孔椎间融合术治疗腰椎退行性疾病 5 年以上随访的疗效评价

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【摘要】 目的:评价单侧固定联合经椎间孔椎间融合(TLIF)治疗腰椎退行性疾病 5 年以上随访的临床疗效。**方法:**对 2007 年 3 月至 2009 年 10 月采用单侧椎弓根螺钉联合经椎间孔椎间融合治疗的 24 例腰椎退行性疾病患者进行回顾性分析,其中男 13 例,女 11 例;年龄 34~68 岁,平均 52 岁。采用视觉模拟评分(VAS)评估患者术前、术后疼痛情况,Oswestry 功能障碍指数(ODI)评价疗效,通过影像学测量不同部位椎间隙高度,并评估末次随访时椎体间融合情况,观察相关并发症。**结果:**24 例患者均获随访,时间访 5~8 年,平均 6.7 年。VAS 腰痛评分由术前的 7.82 ± 0.71 下降到末次随访时的 1.87 ± 0.81 ($P < 0.05$),VAS 腿痛评分由术前的 8.42 ± 1.24 下降到末次随访时的 2.23 ± 1.62 ($P < 0.05$)。ODI 由术前的 $(53.42 \pm 8.26)\%$ 下降到末次随访时的 $(12.45 \pm 7.67)\%$ ($P < 0.05$)。术后手术节段不同部位的椎间隙高度均较术前提高 ($P < 0.05$),但是末次随访时手术节段椎间隙高度较术后 3 个月相比下降 ($P < 0.05$)。术后不同时间点手术侧椎间隙高度与对侧高度比较,差异无统计学意义,但是末次随访时手术对侧椎间隙高度丢失程度较大。末次随访时椎体间总融合率为 95.8%。通过影像学检查相邻节段退变发生率为 45.8%,多裂肌纤维化发生率为 8.3%。未发现继发性脊柱侧弯,cage 移位及螺钉松动、断裂等情况。**结论:**在严格把握手术适应证的前提下,单侧固定联合经椎间孔椎间融合术作为腰椎退行性疾病的一种治疗方法,5 年以上随访疗效满意。但是单侧固定存在手术侧椎间隙高度的丢失及相邻节段退变等问题,需进一步临床研究去证实。

【关键词】 腰椎; 脊柱融合术; 单侧椎弓根螺钉; 退行性疾病

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ABSTRACT Objective:To evaluate the clinical effects of over 5-year follow-up of unilateral pedicle screw fixation with transforaminal lumbar interbody fusion (TLIF) in treating lumbar degenerative diseases. **Methods:**The clinical data of 24 patients with lumbar degenerative disease underwent unilateral pedicle screw fixation with transforaminal lumbar interbody fusion from March 2007 to October 2009, were retrospectively analyzed. There were 13 males and 11 females, aged from 34 to 68 years old with an average of 52 years. Postoperative pain and functional results were analyzed by the visual analogue scale (VAS) and Oswestry Disability Index (ODI). Radiological examination was obtained for each patient to assess the height of intervertebral space, postoperative intervertebral fusion conditions and general complications. **Results:**All patients were followed up from 5 to 8 years with an average of 6.7 years. VAS scores of low back pain and leg pain decreased from preoperative 7.82 ± 0.71 , 8.42 ± 1.24 to postoperative 1.87 ± 0.81 , 2.23 ± 1.62 , respectively ($P < 0.05$). ODI decreased from preoperative $(53.42 \pm 8.26)\%$ to postoperative $(12.45 \pm 7.67)\%$ ($P < 0.05$). Postoperative intervertebral space height in different segments were improved than preoperative ($P < 0.05$), but in final follow-up it was decreased than 3 months after operation ($P < 0.05$). There was no significant difference in the postoperative intervertebral space height between the operated side and non-operated side. But at final follow-up, the intervertebral space height of non-operated side was obviously loss. At final follow-up, the fusion rate was 95.8%. The incidence of adjacent segment degeneration was 45.8%. The paraspinal muscle fibrosis incidence was 8.3%. No complications such as secondary scoliosis, intervertebral height loss, cage slippage, screw loosening and internal fixation breakage were found. **Conclusion:**Unilateral pedicle screw fixation with TLIF is a satisfactory method and can obtain good effects in treating lumbar degenerative diseases according to over 5-year follow-up, however, its indications should be well considered. But the problems such as intervertebral space height of operated side loss and adjacent segment degeneration after unilateral pedicle screw fixation need further clinical study.

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1911 年, 脊柱融合方法被运用于脊柱手术中^[1], 随后, 脊柱融合术广泛运用于临床。随着椎弓根螺钉器械的不断发展, 椎弓根螺钉固定联合脊柱融合在脊柱手术中已广泛应用。20 世纪 90 年代有学者尝试采用单侧椎弓根螺钉固定以降低内固定应力、减少手术创伤并降低医疗费用^[1-2]。之后国内外许多学者对单侧固定的临床疗效进行了研究, 部分学者认为单侧固定具有简化手术操作, 缩短手术时间, 减少术中出血, 创伤相对较少等优点^[3-5]。但是, 也有不少学者对单侧固定能否提供手术节段融合所需的生物力学稳定性心存疑虑^[6]。目前对其临床研究主要集中在 5 年以下的疗效观察, 对 5 年以上的疗效报道较少。2007 年 3 月至 2009 年 10 月, 笔者采用单侧固定联合经椎间孔椎间融合 (TLIF) 治疗 24 例腰椎退行性疾病患者, 再对其临床资料进行回顾性分析, 报告如下。

1 资料与方法

1.1 一般资料

本组 24 例, 男 13 例, 女 11 例; 年龄 34~68 岁, 平均 52 岁。均为单节段手术, 术前临床表现为腰痛及单侧下肢放射痛, 至少经过 3 个月保守治疗无效。术前诊断: 腰椎间盘突出极外侧突出 9 例, 腰椎间盘突出后外侧突出 11 例 (其中伴有腰椎终板 Modic 改变 2 例, 伴有腰椎轻度退变性滑移 6 例, 临床表现为腰痛 3 例), 腰椎间盘突出症单纯髓核摘除术后复发 4 例。L_{3,4} 5 例, L_{4,5} 11 例, L₅S₁ 8 例。脊柱肿瘤及感染、严重的骨质疏松不纳入本研究。所有病例影像学检查可证实腰椎退行性改变。

1.2 治疗方法

1.2.1 手术方法 采用全身麻醉, 取俯卧位, 术前 C 形臂 X 线定位融合节段上下椎弓根, 并作标记, 在症状侧后正中中线旁开长约 3 cm 行纵行手术切口, 于多裂肌与最长肌之间钝性分离至手术节段, 在 C 形臂 X 线透视下置入椎弓根螺钉, 切除手术节段部分椎管、黄韧带及关节突关节, 打开神经根管, 牵开硬膜囊和神经根, 对椎管、侧隐窝狭窄及椎间盘突出做到充分减压, 同时对神经根加以保护。切除椎间盘及软骨终板, 取适量术中切除的碎骨, 填充于椎间隙前 1/3 并斜行置入合适大小融合器 (cage) 1 枚, C 形臂 X 线透视确认 cage 位置。最后安装连接杆, 加压固定, 创口放置引流管 1 条, 逐层缝合创口。

1.2.2 术后处理 术后常规使用抗生素 3 d, 应用脱水剂和激素 3 d, 术后 48 h 内拔除引流管。术后第

1 天即开始腰背肌及直腿抬高功能训练, 1 周内下床活动, 3 个月内避免过度弯腰及负重活动。

1.3 观察项目与方法

1.3.1 临床疗效的观察 所有病例术后 3、6、12 个月及末次随访时门诊复查。术前、术后 3 个月及末次随访时采用疼痛视觉模拟评分 (visual analogue scale, VAS)、Oswestry 功能障碍指数 (Oswestry Disability Index, ODI)^[7] 进行临床疗效评价。Oswestry 功能障碍指数项目包括疼痛程度、日常生活自理能力、提物、行走、坐、站立、性生活、睡眠、社会活动和旅行情况, 每个问题 6 个选项, 最高得分 5 分, 最低得分 0 分, 满分 50 分。假如 10 个问题都作答, 记分方法: [实际得分/50(最高可能得分)]×100%, 假如有 1 个问题没回答, 则记分方法: [实际得分/45]×100%。

1.3.2 影像学观察 腰椎 X 线片上测量的指标包括手术节段椎间隙手术侧高度及对侧高度, 椎间隙腹侧高度及背侧高度^[8]。在腰椎动力位 X 线片根据 Suk 等^[9]融合评价标准评价椎体间融合情况, 同时行 CT 检查来观察融合节段, 以终板界面的桥接骨小梁穿越融合器来判断是否融合^[10]。末次随访均行腰椎 MRI 检查, 观察手术节段多裂肌、相邻节段退变情况以及椎管内结构。多裂肌纤维化的判断主要根据手术前后多裂肌横截面积及脂肪化程度^[11]。相邻节段退变性疾病的诊断标准, 腰椎 MRI 上采用 Pfirrmann 等^[12]的腰椎间盘退变分级标准评价椎间盘退变情况, 椎间盘信号 I、II 级为正常椎间盘, III、IV、V 级为退变椎间盘, 椎间盘信号由术前 I、II 级变为术后 III 级及以上定义为退变, 或术前信号为退变椎间盘等级, 术后退变加重 1 级或 2 级亦定义为出现退变^[13]; 腰椎 X 线椎间隙高度丢失 >10%、椎体前后滑移 >3 mm、骨赘形成 >3 mm, 出现终板硬化、退变性侧凸等^[14], 并根据加州大学洛杉矶分校分级标准^[15]进行分级: 0 级, 未退变; I 级, 轻度退变; II 级, 中度退变; III 级, 严重退变。并观察患者有无相应的临床症状。

1.4 统计学处理

采用 SPSS 19.0 统计软件对数据进行分析。手术前后 VAS 评分、ODI 及影像学测量结果用均数±标准差 ($\bar{x} \pm s$) 表示, 采用配对 *t* 检验进行统计学分析, 以 *P*<0.05 为差异有统计学意义。

2 结果

所有患者获得随访, 时间 5~8 年, 平均 6.7 年。术后的 VAS 评分、ODI 较术前明显改善 (*P*<0.05), 末

次随访与术后 3 个月差异无统计学意义 ($P>0.05$)。见表 1-2。

表 1 腰椎退行性疾病 24 例患者手术前后 ODI 比较($\bar{x}\pm s$)

Tab.1 Comparison of ODI of 24 patients with lumbar degenerative disease between preoperation and postoperation($\bar{x}\pm s$)

项目	术前	术后 3 个月	末次随访
疼痛程度(分)	3.22±1.28	1.22±0.34	1.02±0.60
生活自理能力(分)	2.24±0.73	0.42±0.25	0.38±0.71
提举重物状况(分)	3.17±1.51	1.46±1.27	1.26±1.35
行走状况(分)	4.15±1.20	1.07±0.12	1.04±0.35
坐(分)	2.31±1.65	0.42±0.51	0.37±0.95
站立(分)	3.40±0.75	1.09±0.71	1.07±0.84
睡眠状况(分)	3.48±0.63	0.52±0.98	0.37±0.73
性生活状况(分)	1.17±0.42	1.05±0.53	1.04±0.88
社会生活状况(分)	2.03±0.84	0.18±0.59	0.17±0.72
旅行(分)	2.35±1.15	1.32±1.12	1.18±0.85
总评(%)	53.42±8.26	14.58±7.28 ^a	12.45±7.67 ^b

注:与术前比较,^a $t=15.624, P=0.000$; ^b $t=14.975, P=0.000$ 。^a与^b比较, $t=1.272, P>0.05$

Note: Compared with preoperative data, ^a $t=15.624, P=0.000$; ^b $t=14.975, P=0.000$ 。 ^avs^b, $t=1.272, P>0.05$

术后手术节段不同部位的椎间隙高度均较术前提高($P<0.05$)。但是末次随访时椎间隙高度与术后 3 个月比较下降($P<0.05$), 较术前仍明显提高($P<0.05$)。术后不同时间点手术侧椎间隙高度与对侧高度比较, 差异无统计学意义($P>0.05$), 而且末次随访

时手术侧椎间隙高度丢失程度与对侧椎间隙高度丢失程度差异无统计学意义, 但是手术侧椎间隙高度丢失程度较大。见表 2。

所有患者术后行腰椎 X 线、CT 及 MRI 检查, 根据融合判断标准, 上下两个骨面均融合者有 23 个节段, 一侧骨面未融合者 1 个节段, 融合率为 95.8% (23/24)。根据邻近节段退变性疾病的诊断标准, 11 例相邻节段出现退变, 发生率为 45.8% (11/24), 并根据加州大学洛杉矶分校分级标准, I 级 7 例, II 级 3 例, III 级 1 例, 大部分患者集中在轻度退变。3 例患者伴有轻度腰腿痛, 多数患者未出现相应的临床症状。多裂肌纤维化的发生率为 12.5% (2/24)。术后随访未发现继发性脊柱侧弯, cage 移位及螺钉松动、断裂等情况。典型病例见图 1。

3 讨论

经椎间孔腰椎间融合术已被证实可以缓解腰部疼痛^[16]。TLIF 能恢复椎间隙高度、减压神经根及保持脊柱前方的载荷传递^[17]。

3.1 单侧椎弓根螺钉固定的可行性

许多生物力学研究显示, 双侧固定在抗轴向旋转和侧屈方面较单侧固定稳定^[18-20]。但是 Wetzel 等^[21]研究证实, 关节突关节对腰椎稳定性尤其是抗旋转功能起着重要作用, 所以相对双侧固定而言, 单侧固定保留了对侧椎板和小关节、棘突、棘上及棘间韧带等, 保护腰椎后部张力带结构, 从最大程度上维持脊柱的稳定性。而且 Chen 等^[22]体外生物力学研究结果认为单侧椎弓根螺钉固定结合单枚 cage 与完整标本提供的生物力学稳定无显著差异。因此目前生物力学上对椎间融合所需的内固定强度争议仍很

表 2 腰椎退行性疾病 24 例患者手术前后 VAS 评分及椎间隙不同部位高度比较($\bar{x}\pm s$)

Tab.2 Comparison of VAS scores and intervertebral space height of 24 patients with lumbar degenerative disease between preoperation and postoperation($\bar{x}\pm s$)

观察项目	术前	术后 3 个月	末次随访
VAS-腰痛评分(分)	7.82±0.71	3.31±0.68 ^{a1}	1.87±0.81 ^{b1}
VAS-腿痛评分(分)	8.42±1.24	3.78±1.05 ^{a2}	2.23±1.62 ^{b2}
椎间隙腹侧高度(mm)	13.78±2.31	19.62±3.94 ^{a3}	16.74±2.78 ^{b3}
椎间隙背侧高度(mm)	9.29±1.71	12.87±3.61 ^{a4}	11.43±2.26 ^{b4}
椎间隙手术侧高度(mm)	10.06±3.01	14.83±4.61 ^{a5}	13.32±4.32 ^{b5}
椎间隙手术侧对侧高度(mm)	9.71±3.23	14.17±3.86 ^{a6}	12.51±3.72 ^{b6}

注:与术前比较, ^{a1} $t=25.684, P=0.000$; ^{b1} $t=23.208, P=0.000$; ^{a2} $t=21.272, P=0.000$; ^{b2} $t=22.187, P=0.000$; ^{a3} $t=-6.757, P=0.000$; ^{b3} $t=-5.892, P=0.000$; ^{a4} $t=-7.329, P=0.000$; ^{b4} $t=-6.582, P=0.000$; ^{a5} $t=-4.268, P=0.000$; ^{b5} $t=-3.127, P=0.000$; ^{a6} $t=-5.618, P=0.000$; ^{b6} $t=-4.625, P=0.000$ 。^{a1}与^{b1}比较, $t=1.85, P>0.05$; ^{a2}与^{b2}比较, $t=1.25, P>0.05$; ^{a3}与^{b3}比较, $t=0.795, P>0.05$; ^{a4}与^{b4}比较, $t=0.954, P>0.05$; ^{a5}与^{b5}比较, $t=1.012, P>0.05$; ^{a6}与^{b6}比较, $t=0.843, P>0.05$

Note: Compared with preoperative data, ^{a1} $t=25.684, P=0.000$; ^{b1} $t=23.208, P=0.000$; ^{a2} $t=21.272, P=0.000$; ^{b2} $t=22.187, P=0.000$; ^{a3} $t=-6.757, P=0.000$; ^{b3} $t=-5.892, P=0.000$; ^{a4} $t=-7.329, P=0.000$; ^{b4} $t=-6.582, P=0.000$; ^{a5} $t=-4.268, P=0.000$; ^{b5} $t=-3.127, P=0.000$; ^{a6} $t=-5.618, P=0.000$; ^{b6} $t=-4.625, P=0.000$ 。 ^{a1}vs^{b1}, $t=1.85, P>0.05$; ^{a2}vs^{b2}, $t=1.25, P>0.05$; ^{a3}vs^{b3}, $t=0.795, P>0.05$; ^{a4}vs^{b4}, $t=0.954, P>0.05$; ^{a5}vs^{b5}, $t=1.012, P>0.05$; ^{a6}vs^{b6}, $t=0.843, P>0.05$



图 1 患者,女,47岁, $L_{4,5}$ 椎间盘退变伴突出,行单侧椎弓根螺钉固定椎间融合术 **1a**. 术前腰椎矢状位 MRI 示 $L_{4,5}$ 椎间盘退变伴突出 **1b,1c**. 术前腰椎正侧位 X 线测量; $L_{4,5}$ 椎间隙腹侧高度为 12.7 mm,背侧高度为 8.6 mm,手术侧椎间隙高度为 10.3 mm,手术对侧高度 9.8 mm **1d,1e**. 术后 3 个月复查腰椎正侧位 X 线 $L_{4,5}$ 椎间隙腹侧高度为 17.7 mm,背侧高度为 13.6 mm,手术侧椎间隙高度为 13.7 mm,手术对侧高度 13.1 mm **1f,1g**. 术后 7 年复查腰椎正侧 X 线 $L_{4,5}$ 椎间隙腹侧高度为 16.4 mm,背侧高度为 12.1 mm,手术侧椎间隙高度为 13.2 mm,手术对侧高度 11.8 mm **1h,1i**. 术后 7 年复查腰椎冠状位和矢状位 CT 显示 $L_{4,5}$ 已完全融合,但是手术对侧椎间隙高度显著下降 **1j,1k,1l**. 术后 7 年复查腰椎矢状位及横断位 MRI(1k,1l)显示椎管内减压彻底,无椎间盘突出复发,其邻近的 L_5S_1 椎间盘信号降低,提示存在退变发生可能,多裂肌未见明显纤维化

Fig.1 A 47-year-old female patient with degenerative intervertebral disc complicated with protrusion at $L_{4,5}$ was treated by unilateral pedicle screw fixation with transforaminal lumbar interbody fusion **1a**. Preoperative sagittal lumbar sagittal MRI showed the degenerative intervertebral disc complicated with protrusion at $L_{4,5}$ **1b,1c**. Preoperative AP and lateral X-rays measurement at $L_{4,5}$, ventral height of intervertebral space was 12.7 mm, dorsal height was 8.6 mm, intervertebral space height of operated side was 10.3 mm, non-operated side was 9.8 mm **1d,1e**. AP and lateral X-rays measurement at 3 months after operation, ventral height of intervertebral space was 17.7 mm, dorsal height was 13.6 mm, intervertebral space height of operated side was 13.7 mm, non-operated side was 13.1 mm **1f,1g**. AP and lateral X-rays measurement at 7 years after operation, ventral height of intervertebral space was 16.4 mm, dorsal height was 12.1 mm, intervertebral space height of operated side was 13.2 mm, non-operated side was 11.8 mm **1h,1i**. Postoperative at 7 years, coronal and sagittal CT showed the $L_{4,5}$ got complete fusion with continuous trabeculae bridging the disk space, the intervertebral space height of non-operated side was obvious loss **1j,1k,1l**. Postoperative at 7 years, sagittal and transverse MRI showed spinal canal decompression was complete, no recurrent disc herniation, the adjacent L_5S_1 disc signal was decreased, suggesting the presence of degeneration, no obvious fibrosis in multifidus muscles

大,所以需要更多的临床研究去证实。刘良乐等^[23]研究显示发现单侧和双侧椎弓根螺钉固定腰椎退行性疾病的应用中疗效无明显差异,且单侧组在手术时间、出血量、住院时间和住院费用等指标上均优于双侧组。Hu 等^[24]对 7 篇研究单侧与双侧椎弓根螺钉固定的随机对照试验文章进行了 Meta 分析,结果显示单侧椎弓根螺钉固定临床疗效及融合率与双侧固定无显著差异,单侧固定具有缩短手术时间、减少术中失血量及降低植入物成本的优点。本组患者术后经过 5~8 年的随访(平均 6.7 年),末次随访时 VAS 评分、ODI 均较术前明显改善 ($P<0.05$),总融合率为 95.8%,末次随访时未发现继发性脊柱侧弯,cage 移位及螺钉松动、断裂等情况,说明单侧固定的 TLIF 治疗腰椎退行性疾病取得了满意临床疗效。

由于传统开放 TLIF 常联合双侧固定,需要对椎旁肌肉进行广泛的剥离,从而损伤了椎旁肌的供应血管及其支配的神经,导致椎旁肌水肿、变性和瘢痕形成,使发生腰椎术后综合征风险增大^[25]。而本组患者采用后中线旁开做小切口,经肌间隙入路,进行 TLIF 操作,术中最大程度的保护了椎旁肌,而且通过普通拉钩牵拉,在透视下即可完成椎弓根螺钉内固定的操作,无须使用各种复杂的器械。由于不行椎旁肌的剥离,末次随访时椎旁肌纤维化发生率仅为 8.3%。

3.2 单侧椎弓根螺钉固定存在的问题

本组患者术后随访椎间隙高度较术前明显增加,末次随访时椎间隙高度术后 3 个月相比有所下降,但仍高于术前($P<0.05$),而且术后不同时间点手术侧椎间隙高度与对侧高度比较差异无统计学意义,说明如果植骨融合满意,单侧椎弓根螺钉固定足以有效的维持脊柱的稳定性。但是笔者也发现末次随访时手术对侧椎间隙高度丢失程度较大,虽然没有统计学意义($P>0.05$),但是也不能排除这是因单侧固定引起手术对侧的椎间隙高度丢失,因为有研究认为单侧融合固定术中无法直接对手术对侧椎间隙进行撑开,导致单侧固定时融合节段手术对侧椎间隙高度的恢复差于手术侧^[26]。

相邻节段退变性疾病是腰椎融合术后常见的并发症。有研究认为过强的内固定固定可引起植骨区的应力遮挡,从而使邻近节段的应力传导发生改变,导致邻近节段活动度代偿增加,应力也随之增大,从而继发了邻近节段退变,也可导致移植骨的吸收和固定椎体出现骨质疏松,从而影响椎体间融合^[27-29]。但是 Kumar 等^[30]随访结果发现后外侧融合联合椎弓根螺钉内固定并没有提高邻近节段退变的发生率。Toyone 等^[31]5 年的随访研究中发现单侧椎弓根螺钉

固定联合后路椎体间融合术邻近节段退变性疾病的发生率较双侧固定低。本组患者经过较长时间的随访(平均 6.7 年),相邻节段退变发生率为 45.8%,大部分为 I 度退变,所以不能排除年龄的增长对相邻节段退变的影响,因为有研究认为随着年龄的增大相邻节段退变性疾病的发生率就越高^[32]。

3.3 单侧椎弓根螺钉固定的手术适应证

单侧固定的手术适应证与传统 TLIF 手术相似,但是单侧固定不适用于巨大的中央型椎间盘突出伴钙化或有双侧症状患者。一般认为单侧固定不适用于多节段(2 个以上节段)。为获得有效的内固定并且提供足够的脊柱稳定,要求非手术侧解剖结构完整,特别是小关节的完整及不存在峡部不连,真性滑移亦不是单侧固定的适应证。

虽然本组患者经 5~8 年的随访取得了满意的临床疗效,但样本量太少、随访时间不够长,还需要高质量、大样本和更长期随访的随机对照试验进一步证实这一结论。

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