

## · 临床研究 ·

## 经皮穿刺椎体扩张球囊后凸成形术后邻近椎体再骨折相关危险因素分析

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**【摘要】** 目的: 探讨经皮穿刺椎体扩张球囊后凸成形术(percutaneous kyphoplasty, PKP)治疗骨质疏松性椎体压缩骨折(osteoporosis vertebral compression fractures, OVCFs)术后椎体再骨折相关危险因素, 为临床预防提供参考。方法: 对 2013 年 11 月 6 日至 2018 年 12 月 14 日收治的 228 例符合纳入标准的 OVCFs 患者进行回顾性分析, 男 35 例, 女 193 例, 年龄 58~91(69.70±7.03)岁。所有患者采用 PKP 手术治疗且临床资料完整, 按照术后是否发生再骨折分为再骨折组(24 例)和未再骨折组(204 例)。将可能与再骨折相关的因素(性别、年龄、手术节段、手术节段椎体数目、是否合并退行性侧弯、是否抗骨质疏松)纳入单因素研究, 再将单因素分析有统计学意义的危险因素进行多元 Logistic 回归分析, 进一步明确 PKP 术后椎体再骨折独立危险因素。再以 PKP 术后椎体再骨折时间为随访终止时间、以术后发生再骨折为终点事件, 以是否合并退行性侧弯为变量因子, 进行生存分析。结果: 228 患者均获随访, 时间 1.8~63.6(28.8±15.6)个月, 再骨折发生率为 10.5%(24/228)。两组患者在年龄、手术椎体数目、是否合并脊柱退行性侧弯、是否抗骨质疏松治疗方面差异有统计学意义( $P<0.05$ ); 单因素 Logistic 回归分析显示手术椎体数目、合并侧弯可能为 PKP 术后再骨折发生的危险因素, 将可能的危险因素纳入多元 Logistic 回归分析显示是否合并脊柱退行性侧弯是椎体再骨折的独立危险因素。生存分析时间的平均值 42.1 个月,  $P$  值为 0.00, 平均值 95% 置信区间为 34.4~49.7 个月, 表明合并退行性脊柱侧弯可能与再骨折发生有关。结论: 合并脊柱侧弯是 OVCF 椎体成形术后再骨折的独立危险因素, 亦是术后发生再骨折可能的高危因素。

**【关键词】** 椎体成形术; 椎体压缩性骨折; 再骨折; 脊柱退行性侧弯; 骨质疏松; 危险因素  
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**Analysis of related risk factors for the refracture of adjacent vertebral body after percutaneous kyphoplasty** FANG Shen-yun, MIN Ji-kang, ZENG Zhong-you, ZHANG Qiang-hua, ZHU Tao, WENG Wei, ZHANG Wei-li, SHEN Fang-ying, XIA Ying, and DING Li-ying. Orthopedics Center of Huzhou First People's Hospital, Huzhou 313000, Zhejiang, China

**ABSTRACT Objective:** To investigate the risk factors of vertebral refracture after percutaneous kyphoplasty (PKP) for osteoporotic vertebral compression fractures (OVCFs), and to provide reference for clinical prevention. **Methods:** A retrospective analysis of 228 OVCFs patients who met the inclusion criteria admitted from November 6, 2013 to December 14, 2018. There were 35 males and 193 females, with a male-to-female ratio of 3:20, and aged 58 to 91 years with an average of (69.70±7.03) years. All patients were treated with PKP and had complete clinical data. According to whether refracture occurred after operation, they were divided into refracture group (24 cases) and non-refracture group (204 cases). Factors that may be related to refracture (including gender, age, surgical segment, number of vertebral bodies in the surgical segment, whether combined with degenerative scoliosis, whether anti-osteoporosis treatment) were included in the univariate analyses, and the single factor analysis of statistically significant risk factors was carried out with multiple Logistic regression analysis to further clarify the independent risk factors for vertebral body refracture after PKP. Survival analysis was performed using the time of vertebral refracture after PKP as the end time of follow-up, the occurrence of refracture after PKP as the endpoint event, and the presence or absence of degenerative lateral curvature as a variable factor. **Results:** All 228 patients were followed up for 1.8 to 63.6 months with an average of (28.8±15.6) months, and the refracture rate was 10.5%(24/228). There were statistically significant differences between two groups in age, number of operative vertebral bodies, whether combined with degenerative scoliosis and whether anti-osteoporosis treatment ( $P<0.05$ ). Univariate Logistic regression analysis showed that the number of vertebral

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bodies in the surgical segment and whether combined with degenerative scoliosis may be risk factors for refracture after PKP. Multiple Logistic regression analysis of the above possible risk factors showed that combined scoliosis was an independent risk factor for vertebral refracture of the vertebral body. Survival analysis showed that the mean survival time was 42.1 months, the *P* value was 0.00, and the mean 95% confidence interval was 34.4–49.7 months, indicating that the combination of degenerative lateral bending might be related to the occurrence of refracture. **Conclusion:** Combined scoliosis is an independent risk factor for refracture after OVCFs vertebroplasty, and it is also a possible high-risk factor for refracture after surgery.

**KEYWORDS** Vertebroplasty; Vertebral compression fracture; Refracture; Spinal degenerative scoliosis; Osteoporosis; Risk factors

骨质疏松椎体压缩性骨折(osteoporosis vertebral compression fractures, OVCFs)近十几年呈上升趋势。成为中老年人的常见病、多发病。导致患者疼痛伴活动受限,生活质量下降,严重的导致死亡率增高<sup>[1]</sup>。经皮椎体后凸成形术(percutaneous kyphoplasty, PKP)治疗 OVCFs 的疗效已经得到认可。其止痛效果在 90%以上<sup>[2-3]</sup>。PKP 能达到即刻稳定骨折目的,从而恢复早期活动,减少并发症。随着 PKP 手术的广泛开展,PKP 术后的椎体再骨折发生也越来越多<sup>[4-5]</sup>。本研究通过对 PKP 术后再骨折相关危险因素进行分析,为进一步预防 PKP 术后椎体再骨折发生提供依据,指导临床实践。

## 1 资料与方法

### 1.1 病例选择

纳入标准:(1)术前均存在一定程度腰背痛、常伴不能翻身,或起身无力感,局部棘突扣压痛。(2)术前 X 线、CT 及 MRI 检查明确椎体压缩骨折为新鲜骨折,即 MRI 上显示 T1 信号为低信号,T2 信号为高信号或稍高信号,同时合并上述症状。(3)经双能 X 线骨密度测量仪或 QCT 测量腰椎骨密度,T 值 < -2.5 SD 或低于 80 mg/dl,合并骨折且为低能量损伤。排除标准:(1)脊椎感染或肿瘤导致的病理性骨折。(2)高能量损伤导致椎体骨折。(3)合并抑郁症等精神疾病患者。

### 1.2 一般资料

选择 2013 年 11 月 6 日至 2018 年 12 月 14 日收治的 228 例 OVCFs 行 PKP 术患者,男 35 例,女 193 例,年龄 58~91(69.70±7.03)岁。本研究纳入的骨折椎体包括单个椎体 179 例,2 个椎体 43 例,3 个椎体 6 例。按术后是否再骨折分为再骨折组和非再骨折组。24 例再骨折患者中,T<sub>10</sub>-T<sub>11</sub> 节段 1 例,T<sub>11</sub>-T<sub>12</sub> 节段 6 例,T<sub>12</sub>-L<sub>1</sub> 节段 8 例,L<sub>1</sub>-L<sub>2</sub> 节段 2 例,L<sub>2</sub>-L<sub>3</sub> 节段 1 例,T<sub>8</sub>-T<sub>12</sub> 节段 1 例,T<sub>9</sub>-T<sub>12</sub> 节段 1 例,T<sub>11</sub>-L<sub>1</sub> 节段 1 例,T<sub>12</sub>-L<sub>3</sub> 节段 1 例,T<sub>12</sub>-L<sub>2</sub> 节段 1 例,L<sub>1</sub>-L<sub>3</sub> 节段 1 例。其中骨折合并侧弯有 17 例,7 例无侧弯,但均存在退行性改变。

### 1.3 观察项目与方法

#### 1.3.1 危险因素的判定 (1)基本资料:通过医院

信息系统(Hospital Information System, HIS)病历及影像系统搜集以下因素:①性别、年龄;②手术节段;③手术椎体数目;④是否合并脊柱退变性侧弯情况,根据 Cobb 角大小,依据冠状位 >10°,定义为脊柱退变性侧弯;⑤是否抗骨质疏松情况,术后规范行抗骨质疏松治疗(降钙素针剂,50 U,肌注,每天 1 次,加钙剂和维生素 D3),出院后予长期钙剂和维生素 D3 维持治疗。条件符合患者(计算肌酐清除率 ≥ 35 ml/min,且无其他禁忌证)行唑来膦酸针 5 mg 静脉滴注。建议疗程 3 年,每年 1 次。(2)手术资料:本研究 PKP 手术均采用双侧穿刺、骨水泥均采用聚甲基丙烯酸甲酯(polymethyl methacrylic, PMMA),器械均使用上海凯利泰经皮椎体扩张球囊成形系统进行手术,手术时间 30~60 min。

**1.3.2 研究方法及再骨折判定** 将患者分为再骨折组和未再骨折组,将相关危险因素纳入单因素 Logistic 研究,经过统计学处理,筛选出危险因素。再进一步对筛选出的危险因素,进行多元 Logistic 回归分析独立危险因素。再以 PKP 术后椎体再骨折时间为随访终止时间、以术后发生再骨折为终点事件,以是否合并退行性侧弯为变量因子,进行生存分析中寿命表(life tables)过程。

本文所述再骨折是指 PKP 术后除术椎外发生在邻近椎体或邻椎(包含了骨折椎体以外上或下间隔 1~3 个正常椎体外的其他椎体再骨折)出现的椎体再骨折。定义:邻椎再骨折是指术椎节段初次骨折后一段时间内邻近或邻椎出现骨折。Cobb 后凸角测量方法:骨折椎体的上位椎体上终板和下位椎体下终板垂线的夹角为 Cobb 角。

#### 1.4 术后处理及随访

术后次日佩戴胸腰支具下床活动。门诊随访拍摄脊柱正侧位 X 线片。随访统一以末次随访时间作为随访结束时间。采用电话、门诊复查等形式进行随访,随访前制定计划表,具体内容包括是否 PKP 术后再骨折、是否继续服用钙剂及维生素 D3、是否输注唑来膦酸针剂、是否进行影像学检查。另外,对出现椎体再骨折的病例以第 2 次入院或门诊确诊时间为再骨折时间。具体为减去第 1 次确诊骨折时间,为

再骨折时间间隔,即随访结束时间。

1.5 统计学处理

采用 IBM SPSS Statistics 23 软件进行数据统计分析。定性资料(性别、年龄、手术椎体数目、是否合并脊柱退行性侧弯、是否抗骨质疏松)采用卡方检验,双侧值取 0.05。单因素 Logistic 回归分析有统计学意义的再采用多元 Logistic 回归分析与椎体再骨折发生相关的高危因素,  $P < 0.05$  为差异有统计学意义。随访时间用“month”表示。将再骨折与脊柱退行性侧弯进行生存分析。具体赋值因变量方法:是否合并退变性侧弯(Scoliosis “Y/N”),“0”表示 Scoliosis “N”,无侧弯;“1”表示 Scoliosis “Y”,合并退行性侧弯。计算再骨折(Refracture)率(“0”表示未再骨折,“1”表示再骨折)。手术目标椎体节段用“target”表示。内容包括患者年龄,性别(0=男,1=女),手术椎体节段数目(用 Vertebral “N”表示),是否抗骨质疏松(Osteoporosis “Y/N”,“0”表示 Osteoporosis “N”,骨质疏松依从性差;“1”表示 Osteoporosis “Y”,抗骨质疏松依从性好)为自变量进行分析,进一步明确独立危险因素。

2 结果

本研究有 24 例 PKP 术后发生再骨折,占 10.5% (24/228), 男女比例为 3:20, 再骨折组年龄 61~89 (75.3±7.3)岁,非再骨折组年龄 58~91 (69.0±6.7)岁。随访时间 1.8~63.6 (28.8±15.6)个月。失访 31 例,失访率 13.6%。

2.1 PKP 术后再骨折组与未再骨折组相关因素比较

两组患者在年龄、手术椎体数目、是否合并脊柱退行性侧弯、是否抗骨质疏松治疗方面差异有统计学意义 ( $P < 0.05$ );性别方面差异无统计学意义 ( $P > 0.05$ )。见表 1。

2.2 单因素 Logistic 回归分析

将有统计学意义的危险因素纳入单因素 Logistic 回归分析排除各因素间的相互影响后结果显示:手术椎体数目,合并脊柱退行性侧弯可能为 PKP 术后再骨折发生的危险因素。见表 2。

表 1 PKP 术后再骨折组与未再骨折组相关危险因素比较结果

Tab.1 Comparison of risk factors between the refracture group and the non-refracture group after PKP

危险因素	组别	再骨折组 非再骨折组		$\chi^2$ 值	P 值
		(例)	(例)		
年龄	≤65 岁组	3	65	4.45	0.04
	>65 岁组	21	139		
手术椎体数目	≤1 个组	7	172	38.71	0
	≥2 个组	17	32		
是否合并脊柱侧弯	合并脊柱侧弯组	18	28	50.06	0
	不合并脊柱侧弯组	6	176		
是否抗骨质疏松治疗	抗骨质疏松治疗组	23	79	26.06	0
	不抗骨质疏松治疗组	1	125		
性别	男性组	4	31	0	1
	女性组	20	173		

2.3 多因素 Logistic 回归分析

将单因素回归分析显示的危险因素纳入多元 Logistic 回归分析显示合并脊柱退行性侧弯 [ $OR = 0.111, 95\% CI (0.036, 0.345), P = 0.00$ ]是椎体再骨折独立危险因素。

2.4 生存分析

经统计得出,生存分析时间的平均值为 42.10,  $P$  值为 0.00, 平均值 95% 置信区间为 34.4~49.7 个月。寿命表显示中位生存时间合并侧弯组为 48.98 个月, 不合并侧弯组 63.00 个月。Wilcoxon 检验值 42.64,  $P$  值为 0.00, 表明合并脊柱退行性侧弯可能与再骨折发生有关。见图 1。典型病例见图 2。

3 讨论

3.1 PKP 术后再骨折的发生

近 10 余年来 PKP 术后邻近椎体的再骨折发生率呈增高趋势。Su 等<sup>[6]</sup>对椎体后凸成形术治疗骨质疏松性压缩骨折进行队列研究,收集 100 余例患者,再骨折发生率达 27.8%,而且 68% 发生在邻近椎体。本研究再骨折率比报道偏低。这可能与术后患者未

表 2 骨质疏松性椎体压缩性骨折 228 例患者单因素 Logistic 回归分析结果  
Tab.2 Results of univariate Logistic regression analysis in 228 patients with OVCFs

危险因素	B	标准误差	瓦尔德	显著性	Exp(B)	EXP(B) 95% 置信区间	
						下限	上限
是否侧弯	-2.128	0.647	10.82	0.001	0.119	0.034	0.423
性别	-0.432	0.712	0.369	0.543	0.649	0.161	2.618
年龄	0.041	0.040	1.093	0.296	1.042	0.964	1.126
手术椎体数目	1.016	0.447	5.159	0.023	2.763	1.149	6.640
是否抗骨质疏松	0.279	0.534	0.273	0.601	1.321	0.464	3.761

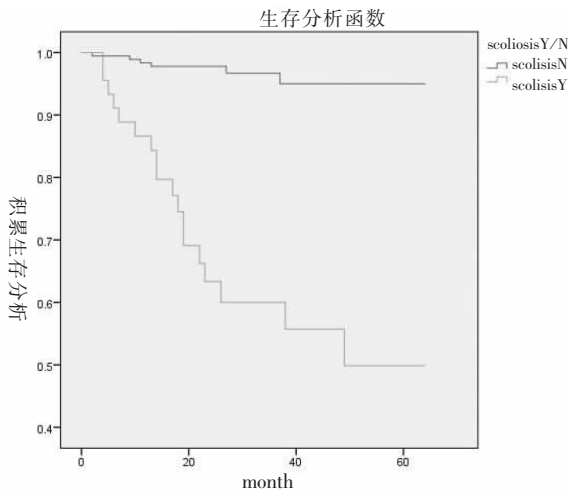


图 1 合并脊柱退行性侧弯与再骨折关系  
Fig.1 Association between combined degenerative scoliosis and refracture

及时就诊有关。而术后再骨折的原因众说纷纭,骨质疏松症自然发展、生物力学改变,与注射骨水泥的量过多及骨水泥漏入椎间盘有关等,仍颇具争议<sup>[7]</sup>。据文献报道,导致 PKP 术后再骨折发生的可能因素很多,更多文献关注高龄<sup>[8-10]</sup>,邻近椎体骨折<sup>[11]</sup>,骨水泥剂量<sup>[12-13]</sup>,骨水泥分布<sup>[14-15]</sup>,骨水泥椎间隙渗漏<sup>[10,13,16]</sup>,骨密度<sup>[9-10,13,17]</sup>,脊柱力线异常<sup>[18]</sup>等因素。

### 3.2 危险因素的统计学结果分析

本研究中得出,合并脊柱退行性侧弯是导致 PKP 术后再骨折的独立危险因素。有研究认为椎体后凸畸形<sup>[19]</sup>或脊柱力线异常<sup>[18]</sup>改变了椎体应力负重状态,导致再骨折发生。这从侧面也映证了脊柱侧弯引起力线异常,可能与再骨折存在一定关联。一般资料显示脊柱退行性侧弯大部分集中于椎体骨折数目



图 2 患者,女,78 岁,初次诊断为骨质疏松性 L<sub>1</sub> 椎体压缩性骨折(2016-11-18)、腰椎有明显退行性侧弯 2a,2b。术前腰椎正侧位 X 线片示 L<sub>1</sub> 椎体压缩性骨折,腰椎退行性侧弯 2c,2d。术后 2 个月复查腰椎正侧位 X 线平片提示 L<sub>1</sub> 椎体内骨水泥在位 2e,2f。术后 6 个月因 T<sub>12</sub> 椎体压缩性骨折再次行 PKP 手术,术后复查腰椎正侧位 X 线平片提示骨水泥分布良好 2g,2h。第 2 次 PKP 术后 1 年半因 T<sub>10</sub>、T<sub>11</sub> 椎体压缩性骨折,再次行 PKP 手术,术后复查腰椎正侧位 X 线平片提示骨水泥在位

Fig.2 A 78-year-old female patient was first diagnosed with osteoporotic L<sub>1</sub> vertebral compression fracture (2016-11-18), with obvious degenerative scoliosis 2a,2b. The AP and lateral X-ray films showed L<sub>1</sub> vertebral compression fracture and degenerative scoliosis before operation 2c,2d. The AP and lateral X-ray films showed that the bone cement in the L<sub>1</sub> vertebral body was in place at 2 months after operation 2e,2f. PKP was performed again in 6 months after operation due to compression fracture of the T<sub>12</sub> vertebral body, and the AP and lateral X-ray films showed that the bone cement was well distributed 2g,2h. PKP was performed again in the first half of the year because of compression fracture of T<sub>10</sub> and T<sub>11</sub>. After the operation, the AP and lateral X-ray films showed that bone cement was in place.

2 个(平均 1.8 个椎体)的患者,该类患者存在不同程度的脊柱退行性侧弯。结合一般资料来看,从骨折受累节段看,再骨折发生集中在 T<sub>11</sub>-T<sub>12</sub> 或 T<sub>12</sub>-T<sub>11</sub>、T<sub>12</sub>-L<sub>1</sub> 或 L<sub>1</sub>-T<sub>12</sub> 这些节段中,即胸腰椎体结合处,此处为应力集中区,亦是退行性侧弯集中分布区。其他再骨折发生在与原骨折椎体间隔 1~3 个椎体处。从生存分析进一步得出,合并脊柱退行性侧弯对再骨折有明显影响,合并侧弯组中位生存时间为 48.98 个月,明显低于不合并侧弯组患者,进一步表明合并脊柱退行性侧弯是 PKP 术后再骨折的高危因素。

总之,随着 PKP 应用普及,再骨折患者会越来越多,对于合并严重脊柱退行性侧弯患者,要警惕发生再骨折的危险,尽早进行骨质疏松防治和干预。另外,研究对象主要来自我院门诊和住院的患者,非多中心大样本研究,病例的选择面较小,且许多患者来自偏远农村,失访病例较多,还有其他一些可能相关的因素未纳入本研究中,这些因素之间的相互联系还需在以后的研究中进一步探索。

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