

· 临床研究 ·

定向骨水泥导向器治疗胸腰椎压缩骨折的疗效分析及影像学研究

周晓吉^{1,2}, 刘永涛¹, 李宏², 曹晓建¹

(1. 南京医科大学第一附属医院, 江苏南京 210000; 2. 中国人民解放军联勤保障部队第 904 医院, 江苏无锡 214000)

【摘要】 目的: 应用定向骨水泥导向器行单侧椎体后凸成形术(PKP)治疗骨质疏松性椎体压缩骨折, 观察骨折椎体内骨水泥分布规律及临床疗效。方法: 回顾性分析 2016 年 7 月至 2018 年 7 月收治的 211 例(211 椎)骨质疏松性椎体压缩骨折(OVCFs)患者的临床资料, 所有患者采用 PKP 治疗, 其中 102 例应用定向骨水泥导向器(观察组), 男 30 例, 女 72 例, 年龄(68.4 ± 8.9)岁; 109 例应用常规骨水泥导向器(常规组), 男 32 例, 女 77 例, 年龄(70.4 ± 9.2)岁。观察两组患者手术时间、骨水泥量、疼痛视觉模拟评分(VAS)、Oswestry 功能障碍指数(ODI)、骨水泥的分布及渗漏情况、病椎 Cobb 角改善率。结果: 两组患者性别、年龄及病椎分布比较差异均无统计学意义($P>0.05$)。两组患者手术时间、骨水泥量、VAS 评分、ODI 评分、Cobb 角改善率组间相比差异无统计学意义($P>0.05$)。观察组渗漏 10 个椎体, 渗漏率为 9.80%, 常规组渗漏 11 个椎体, 渗漏率为 10.09%, 两组差异无统计学意义($P>0.05$)。观察组中椎体骨水泥 I~IV 度分布比例分别为 60.78%、19.61%、9.80%、9.80%, 常规组中椎体骨水泥 I~IV 度分布比例分别为 39.45%、22.93%、22.93%、14.68%, 观察组中骨水泥 I 度分布率明显优于常规组($P<0.05$); 两组骨水泥 II 度分布率差异无统计学意义($P>0.05$)。自 T₁₀ 至 L₅ 骨水泥 I 度分布率两组均呈递减趋势, 观察组 L₁~L₅ 节段骨水泥 I 度分布椎体数占比为 50%, 高于常规组的 30.23%, 差异有统计学意义($P<0.05$)。结论: 定向骨水泥导向器可控骨水泥弥散方向, 达到单侧穿刺、双侧骨水泥有效分布, 手术效果满意, 用于单侧 PKP 治疗 OVCFs 是可行且有效的。

【关键词】 骨质疏松性椎体压缩骨折; 单侧椎体后凸成形术; 骨水泥分布; 定向骨水泥导向器

中图分类号: R683.2

DOI: 10.3969/j.issn.1003-0034.2019.07.008

开放科学(资源服务)标识码(OSID): 

Therapeutic effect and imaging study of directional bone cement guide for the treatment of thoracolumbar vertebral compression fractures ZHOU Xiao-ji, LIU Yong-tao, LI Hong, and CAO Xiao-jian*. *The First Affiliated Hospital of Nanjing Medical University, Nanjing 210000, Jiangsu, China

ABSTRACT Objective: To evaluate the therapeutic effects and bone cement distribution of unilateral percutaneous kyphoplasty (PKP) with oriented bone cement injector for thoracolumbar osteoporotic vertebral compression fractures (OVCFs).

Methods: The clinical data of 211 patients (211 vertebrae) with thoracolumbar osteoporotic compression fractures underwent PKP between July 2016 to July 2018 were retrospectively analyzed. All punctures were performed unilaterally: 102 patients in observation group used oriented bone cement injector including 30 males and 72 females with an average age of (68.4 ± 8.9) years old; 109 patients in regular group used traditional bone cement injector including 32 males and 77 females with an average age of (70.4 ± 9.2) years old. The two groups were compared in terms of duration of operation, cement volume, visual analogue scale (VAS), Oswestry Disability Index (ODI), distribution of bone cement, bone cement leakage and Cobb angle modified rate. **Results:** There were no significant difference in gender, age and fracture vertebra between the two groups ($P>0.05$). No significant difference was found between two groups in duration of operation, cement volume, VAS, ODI and Cobb angle ($P>0.05$). In observation group, 10 cases occurred cement leakages, with leakage rate of 9.80%; and in regular group, 11 cases occurred cement leakage, with leakage rate of 10.09%. There was no significant difference in the cement leakage rate between two groups ($P>0.05$). In observation group, proportion rate of I~IV degree in cement distribution was 60.78%, 19.61%, 9.80%, 9.80%, respectively; while 39.45%, 22.93%, 22.93%, 14.68% in regular group. The I degree of cement cross-filling rate was better in observation group than in regular group ($P<0.05$). There was no significant difference between two groups in II degree distribution rate of bone cement ($P>0.05$). From T₁₀ to L₅, I degree bone cement distribution rate of both groups showed decline trend. The I degree cement cross-filling rate in L₁~L₅ was 50% in observation group and 30.23% in regular group ($P<$

0.05). **Conclusion:** Oriented bone cement injector can control the direction of bone cement dispersion and achieve effective distribution of bilateral bone cement using unilateral puncture and satisfactory surgical results. It is feasible and effective for unilateral PKP treatment of OVCFs.

KEYWORDS Osteoporotic vertebral compression fractures; Unilateral percutaneous kyphoplasty; Bone cement distribution; Oriented bone cement injector

经皮椎体后凸成形术(PKP)是目前治疗骨质疏松性椎体压缩骨折(OVCFs)的可靠且有效的微创方法,和经皮椎体成形术(PVP)相比,其具有椎体高度恢复满意、骨水泥渗漏率低等优势。标准的PKP为双侧入路,因考虑到手术时间、辐射对健康的影响,单侧入路近年来更受医患的欢迎^[1]。但是鉴于单侧穿刺入路影响骨水泥在椎体中的分布,故其手术效果和安全性有争论。因此,本研究通过对2016年7月至2018年7月行PKP治疗的211例OVCFs患者(211个椎体)的临床资料回顾性分析,观察应用定向骨水泥导向器行单侧PKP治疗OVCFs患者的临床疗效及安全性,并与常规骨水泥导向器行单侧PKP进行比较。

1 资料与方法

1.1 病例选择

纳入标准:骨质疏松性椎体压缩骨折,疼痛持续不能缓解或长期卧床可能引发并发症;非爆裂性椎体骨折,椎体后壁基本完整,椎管内无占位,硬膜囊无明显受压,患者无受损平面以下神经功能障碍;局部压叩痛,与影像学表现一致。排除标准:脊柱非特异性感染或结核;脊柱三柱均累及的骨折。

1.2 一般资料

本组共纳入211例(211个椎体),其中102例患者采用定向骨水泥导向器(观察组),109例患者采用常规骨水泥导向器(常规组),两组患者性别、年龄及骨折椎体分布等术前资料比较,差异无统计学意义,具有可比性($P>0.05$),见表1。

1.3 治疗方法

所有患者采取俯卧位。术中心电监护及吸氧,C形臂X线透视辅助定位手术椎体及病椎椎弓根体表投影。

观察组:采用单侧椎弓根入路,进针点位于椎弓根外上方(左侧为10点钟位置,右侧2点钟位置),当针尖在正位片上位于椎弓根内侧缘,侧位片超过椎体后缘时,退出穿刺针建立工作通道,球囊扩张,调制骨水泥,待骨水泥处于拉丝期晚期或团状期早期时推注骨水泥。采用定向骨水泥导向器(图1),先将开口对准塌陷的终板下方灌注,C形臂X线透视监测骨水泥量及弥散,随时旋转导向器调整弥散方向(360°),待骨水泥凝固后拔出工作套管。



图1 定向骨水泥导向器:远端封闭,开口位于侧方,通过旋转可控制骨水泥推注方向

Fig.1 Oriented bone cement injector. The distal end is closed, the opening is located on the side, the bone cement push direction can be controlled by rotation

常规组:体位、麻醉、工作通道建立均同前,骨水泥推注时采用常规前端开口骨水泥导向器,通过调整骨水泥导向器的深浅来控制骨水泥的弥散,C形臂X线透视监测骨水泥量及弥散,待骨水泥凝固后拔出工作套管。

1.4 观察项目及方法

1.4.1 一般情况观察 包括手术时间及骨水泥注入量。

表1 两组骨质疏松性椎体压缩骨折患者性别、年龄及骨折椎体分布

Tab.1 Comparison of gender, age and fracture vertebra between two groups with osteoporotic vertebral compression fractures

组别	例数	性别(例)		(x±s,岁)	椎体(例)								
		男	女		T ₁₀	T ₁₁	T ₁₂	L ₁	L ₂	L ₃	L ₄	L ₅	
观察组	102	30	72	68.4±8.9	10	12	16	20	15	11	11	7	
常规组	109	32	77	70.4±9.2	10	13	17	21	16	12	12	8	
检验值		$\chi^2=0.006$				$t=-1.603$				$\chi^2=0.048$			
P值		0.938				0.110				1.000			

1.4.2 临床症状观察 包括疼痛 (VAS 评分^[2])、Oswestry 功能障碍指数(ODI)。

1.4.3 影像学观察 包括骨水泥分布及渗漏、伤椎 Cobb 角改善率。(1)根据充填在 2 个椎弓根间骨水泥的比例来评价骨水泥的分布^[3]。(2) I -IV 度骨水泥充填评价标准见图 2,3。(3)骨水泥渗漏按 Yeom 等^[4]提出的方法进行分类:B 型,骨水泥沿椎基底静脉渗漏至椎体后缘;C 型,骨水泥沿骨皮质缺损渗漏,主要渗漏到椎间盘、椎体旁;S 型,骨水泥沿椎间

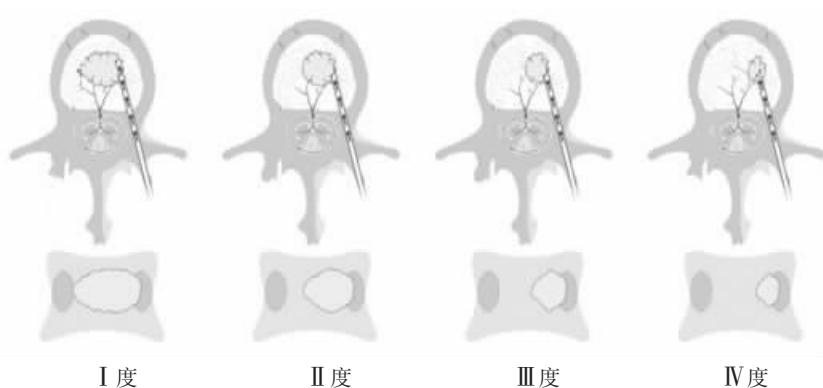


图 2 I -IV 度骨水泥充填评价标准示意图

Fig.2 Schematic diagram of I -IV degree cement cross-filling standard

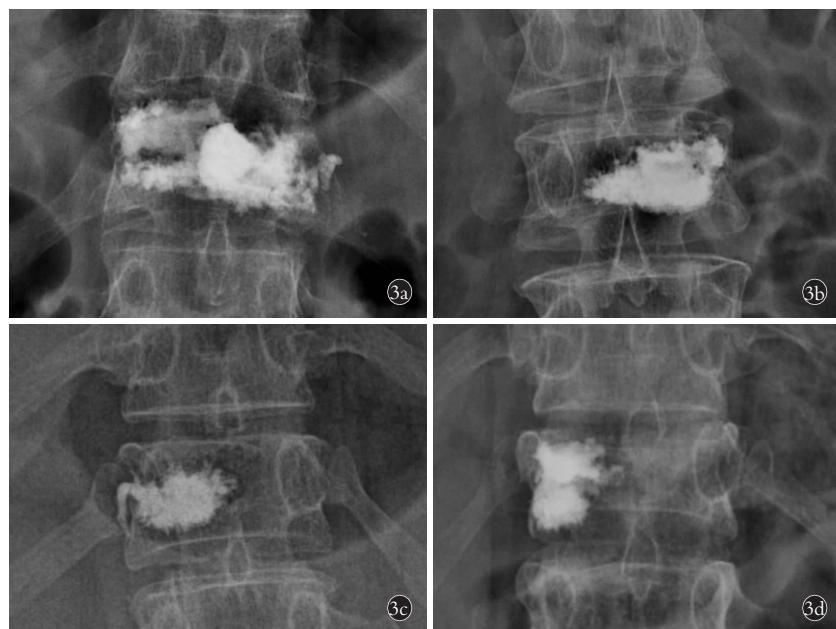


图 3 I -IV 度骨水泥充填评价标准 X 线片 3a. I 度骨水泥充填在 2 个椎弓根间的比例 $\geq 75\%$ 3b. II 度骨水泥充填在 2 个椎弓根间的比例 $<75\%$ 且 $\geq 50\%$ 3c. III 度骨水泥充填在 2 个椎弓根间的比例 $\geq 25\%$ 且 $<50\%$ 3d. IV 度骨水泥充填在 2 个椎弓根间的比例 $<25\%$

Fig.3 Standard X-ray of four different grades of cement cross-filling 3a. The proportion of I degree cement distribution between pedicles was greater than or equal to 75% 3b. The proportion of II degree cement distribution between pedicles was less than 75% but greater than or equal to 50% 3c. The proportion of III degree cement distribution between pedicles was less than 50% but greater than or equal to 25% 3d. The proportion of IV degree cement distribution between pedicles was less than 25%

静脉渗漏, 主要渗漏到椎体周围。侧位 X 线片上压缩骨折椎体上下终板垂线交角即为椎体后凸角度 (Cobb 角), Cobb 角改善率=[(术前 Cobb - 术后 Cobb)/术前 Cobb]×100%。

1.5 统计学处理

采用 SPSS 13.0 软件进行统计学分析。两组患者年龄、手术时间、骨水泥量、VAS 评分、ODI 评分及 Cobb 角改善率等定量资料以均数±标准差 ($\bar{x}\pm s$) 表示, 采用独立样本 t 检验进行分析。两组性别、骨折椎体分布、骨水泥渗漏率及骨水泥分布采用 χ^2 检验。以 $P<0.05$ 为差异有统计学意义。

2 结果

所有手术顺利完成, 术后患者疼痛均明显减轻, 术中、术后无感染、神经脊髓损伤、骨水泥过敏等并发症发生。两组患者的手术时间、骨水泥量及术后 Cobb 角改善率差异无统计学意义(表 2);观察组术中 10 例发生骨水泥渗漏 (C 型 8 例,S 型 2 例), 渗漏率为 9.80%, 常规组 11 例发生骨水泥渗漏(C 型 9 例,S 型 2 例), 渗漏率为 10.09%, 差异无统计学意义 ($\chi^2=0.005, P=1.000$)。两组患者术后临床症状均明显改善, 同一组内术后 1 个月时的 VAS 评分、ODI 评分与术前比较差异有统计学意义(见表 3);两组患者术前、术后 3 d、术后 1 个月的 VAS 评分、ODI 评分组间比较差异均无统计学意义 ($P>0.05$), 见表 3。

在 T₁₀-T₁₂ 节段两组椎体骨水泥均主要为 I 度分布;在 L₁-L₂ 节段观察组主要为 I 度分布, 常规组主要为 II 度分布;在 L₃-L₅ 节段观察组 4 种分布差异不明显, 常规组主要为 III-IV 度分布;各椎体骨水泥分布情况见表 4。观察组所有骨水泥 I 度分布椎体所占比例 60.78%(62/102), 常规组所有骨水泥 I 度分布椎体所占比例 39.45%(43/109), 两组比较差异有统计学意义 ($\chi^2=9.594, P=0.002$), 见表 4。自 T₁₀ 至 L₅ 骨水泥 I 度分布率两组均呈递减趋势, 在

表 2 两组骨质疏松性椎体压缩骨折患者手术时间、骨水泥注射量及 Cobb 角改善率比较 ($\bar{x} \pm s$)

Tab.2 Comparison of operation time, cement volume, cement leakage rate and Cobb angle modified rate between two groups with osteoporotic vertebral compression fracture

($\bar{x} \pm s$)

组别	例数	手术时间(min)	骨水泥量(ml)	Cobb 角改善率(%)
观察组	102	41.1±9.8	4.6±1.3	5.1±4.2
常规组	109	42.6±8.7	4.5±1.9	4.9±5.7
P 值		0.241	0.658	0.773
t 值		-1.177	0.443	0.289

$T_{10}-T_{12}$ 节段两组骨水泥 I 度分布率相比差异无统计学意义 ($\chi^2=0.681, P=0.412$), 在 L_1-L_5 节段观察组椎体 I 度骨水泥分布率优于常规组 ($\chi^2=5.140, P=0.023$)。典型病例见图 4。

3 讨论

OVCFs 治疗方法主要包括卧床静养、药物、功能锻炼及手术。长期卧床静养会导致骨量急性丢失、骨质疏松加重、坠积性肺炎、褥疮、下肢深静脉血栓形成、泌尿系感染等并发症,降低生活质量,甚至危及生命^[5-6]。

椎体后凸成形术可以快速缓解 OVCFs 引起的胸腰部疼痛,维持脊柱力学平衡稳定,改善生活质

量,被患者及临床医师广泛认可^[7-8]。经典的 PKP 通过双侧椎弓根穿刺实现骨水泥对称分布及弥散,恢复椎体强度及刚度,有满意的脊柱生物力学性能及远期疗效,但其有接触 X 线时间长、手术时间长等缺点。近年来单侧穿刺 PKP 开始广泛应用于临床,有不少研究证明单侧 PKP 的生物力学性能和临床疗效与双侧 PKP 相比差异不明显^[9-12]。也有许多学者反对单侧椎体后凸骨水泥成形术,认为:(1)单侧 PKP 中骨水泥不易达到双侧均匀分布,影响椎体刚度^[13],椎体刚度是评价脊柱力学稳定重要指标之一,椎体内骨水泥分布会影响病椎的刚度,双侧骨水泥分布比单侧骨水泥分布可获得更好的刚度恢复,随访发现骨水泥分布与术后疼痛的缓解也有一定的相关性^[14-15]。(2)追求双侧骨水泥均匀分布需增大穿刺角度,椎弓根内壁穿破及神经损伤风险增大。

研究中观察组采用侧开孔定向骨水泥导向器,实现单侧穿刺入路骨水泥可控 360°方向弥散,实现骨水泥分布填充过中线,随访临床症状及手术情况与常规组相比差异无统计学意义,影像学指标中 I 度骨水泥分布率明显优于常规组,尤其对于腰椎骨折,和常规组相比,观察组定向骨水泥导向器的优势更为明显。但是两组腰椎椎体内骨水泥的分布均没有胸椎($T_{10}-T_{12}$)理想,可能因为腰椎解剖形态粗大,单侧球囊扩张范围比较局限,所以笔者认为对于

表 3 两组骨质疏松性椎体压缩骨折患者手术前后 VAS 及 ODI 评分比较 ($\bar{x} \pm s$, 分)

Tab.3 Comparison of pre-and post-operative VAS, ODI between two groups with osteoporotic vertebral compression fractures ($\bar{x} \pm s$, score)

项目	例数	VAS 评分			ODI 评分		
		术前	术后 3 d	术后 1 个月	术前	术后 3 d	术后 1 个月
观察组	102	7.9±1.1	2.2±1.4	2.0±0.8 [▲]	85±3.4	30.9±3.9	24.4±1.1 [△]
常规组	109	7.7±0.9	2.5±1.2	2.2±0.9 ^{▲▲}	83±3.0	31.9±3.5	25.3±1.5 ^{△△}
t 值		1.449	-1.674	-1.702	1.689	-1.877	-1.856
P 值		0.149	0.096	0.090	0.093	0.062	0.065

注:与术前比较,[▲] $t=-3.429, P=0.001$,^{▲▲} $t=-2.389, P=0.019$;[△] $t=-2.395, P=0.018$;^{△△} $t=-2.981, P=0.004$

Note: Compared with preoperative data, [▲] $t=-3.429, P=0.001$, ^{▲▲} $t=-2.389, P=0.019$;[△] $t=-2.395, P=0.018$;^{△△} $t=-2.981, P=0.004$

表 4 两组骨质疏松性椎体压缩骨折患者椎体骨水泥分布情况比较 [例(%)]

Tab.4 Comparison of distribution of cement cross-filling between two groups with osteoporotic vertebral compression fractures [case(%)]

椎体	观察组(例数=102)				常规组(例数=109)			
	I 度	II 度	III 度	IV 度	I 度	II 度	III 度	IV 度
$T_{10}-T_{12}$	31(81.58)	4(10.53)	2(5.26)	1(2.63)	30(75)	5(12.5)	2(5)	3(7.5)
L_1-L_2	24(68.57)	7(20.01)	2(5.71)	2(5.71)	11(29.73)	15(40.54)	8(21.62)	3(8.11)
L_3-L_5	7(24.14)	9(31.03)	6(20.69)	7(24.14)	2(6.25)	5(15.63)	15(46.88)	10(31.25)
$T_{10}-L_5$	62(60.78)	20(19.61)	10(9.8)	10(9.8)	43(39.45)	25(22.93)	25(22.93)	16(14.68)



图 4 患者,女,71岁,T₁₂椎体压缩骨折,应用定向骨水泥导向器行T₁₂椎体单侧PKP。4a.术前X线侧位片显示T₁₂椎体压缩骨折 4b. MRI矢状位T2加权图像,椎体内表现为高信号 4c,4d,4e.术中C形臂X线透视球囊扩张及骨水泥弥散情况 4f,4g.术后1d腰椎正侧位X线片显示T₁₂椎体骨水泥充填满意 4h,4i,4j.术后1d T₁₂椎体三维CT,显示骨水泥在椎体分布满意

Fig.4 A 71-year-old female patient with compression fracture of T₁₂ was treated by unilateral percutaneous kyphoplasty (PKP) with oriented bone cement injector 4a. Preoperative lateral X-ray showed vertebral compression fracture of T₁₂ 4b. MRI sagittal T2WI showed high signal within the vertebral body 4c,4d,4e. The intraoperative C-arm X-ray showed image of balloon dilation and bone cement filling 4f,4g. AP and lateral X-rays at 1 day after operation showed well distribution of bone cement within the T₁₂ vertebral body 4h,4i,4j. Three-dimensional CT images of T₁₂ at 1 day after operation showed well distributed bone cement on the vertebral body

腰椎骨折,尤其下腰椎的骨折,最好需要双侧球囊扩张,这也为我们进一步改进骨水泥导向器和工作通道实现单侧入路下双侧球囊扩张提供了思路。

观察组采用的定向骨水泥导向器不需过分追求穿刺角度即可完成病椎定向骨水泥灌注。本研究中胸腰椎采用的穿刺角度均低于既往所报道的单侧入路安全穿刺范围^[16~17](T₁₀~T₁₂:5°~10°,L₁~L₂:10°~15°,L₃~L₅:15°~20°),说明应用定向骨水泥导向器行单侧PKP在安全穿刺角度范围内能到达预期的骨水泥弥散效果。

骨水泥渗漏是椎体骨水泥成形术常见的并发症之一,骨水泥一旦渗漏至椎管内会导致灾难性的后果。骨水泥主要通过椎体裂缝或者脊椎的静脉丛向病椎周围渗漏。笔者认为使用常规的骨水泥导向器注射骨水泥时,压力集中在导向器末端,骨水泥向前方四周弥散,若出现骨水泥渗漏迹象时术者只可暂停推注骨水泥,导致椎体内骨水泥分布不均,影响手术疗效。定向骨水泥导向器有360°推注方向,可控制骨水泥弥散方向,避开椎体易发生渗漏的位置。若出现骨水泥渗漏迹象时,术者不必暂停推注,可调整方

向继续推注骨水泥,不仅可以减少渗漏,而且不影响骨水泥灌注量及骨水泥的分布。也有类似文献报道采用侧方开口的骨水泥导向器可实现骨水泥的双侧分布,且降低了骨水泥渗漏风险^[18]。本研究中观察组渗漏率为 9.80%,与常规组比较差异无统计学意义,且低于既往文献报道^[19]。

综上所述,通过两组患者的临床疗效及术后影像学对比,定向骨水泥导向器通过旋转导向器调整骨水泥弥散方向,达到单侧穿刺、双侧分布,减少手术时间,缩短医师和患者 X 线暴露时间,是治疗 OVCFs 患者的安全有效方法。但尚未纳入双侧椎体骨水泥成形术作为对照并缺少长期随访的研究,更多工作正在进一步开展中。

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