·临床研究·

经皮椎体支架内固定治疗骨质疏松性椎体压缩骨折的临床研究

夏坤阳,慈元,李志君,张光宇

（大连市第二人民医院,辽宁　大连　116014）

摘　要　目的:观察经皮椎体支架内固定治疗骨质疏松性椎体压缩骨折(osteoporotic vertebral compression fracture,OVCF)的临床疗效和安全性。**方法:**回顾性分析 80 例 OVCF 患者的病例资料,其中采用经皮椎体支架内固定治疗 40 例(经皮椎体支架内固定组)、采用经皮椎体后凸成形术(percutaneous kyphoplasty,PKP)治疗 40 例(PKP 组)。比较 2 组患者的骨水泥注入量、术中出血量、手术时间、胸腰椎疼痛视觉模拟量表(visual analogue scale,VAS)评分、Oswestry 功能障碍指数(Oswestry disability index,ODI)、伤椎 Beck 指数、伤椎矢状位 Cobb 角和并发症发生率。**结果:**①一般结果。2 组患者骨水泥注入量、术中出血量、手术时间比较,组间差异均无统计学意义[(2.29 ± 1.39)mL,(1.85 ± 1.25)mL,t = −1.541,P = 0.061;(6.91 ± 2.24)mL,(5.43 ± 1.12)mL,t = −0.480,P = 0.431;(33.61 ± 7.31)min,(25.76 ± 2.43)min,t = −6.59,P = 0.542]。②胸腰椎疼痛 VAS 评分。时间因素和分组因素存在交互效应(F = 44.059,P = 0.000);2 组患者的胸腰椎疼痛 VAS 评分总体比较,组间差异无统计学意义,即不存在分组效应(F = 10.250,P = 0.736);手术前后不同时间点胸腰椎疼痛 VAS 评分的差异有统计学意义,即存在时间效应(F = 88.117,P = 0.000);2 组患者胸腰椎疼痛 VAS 评分随时间变化均呈下降趋势,但 2 组的下降趋势不完全一致[(7.95 ± 0.59)分,(3.83 ± 0.53)分,(2.21 ± 0.59)分,(1.75 ± 0.55)分,F = 53.256,P = 0.000;(7.88 ± 0.57)分,(3.91 ± 0.57)分,(2.33 ± 0.88)分,(1.82 ± 0.62)分,F = 34.861,P = 0.000];2 组患者术前胸腰椎疼痛 VAS 评分比较,差异无统计学意义(t = 0.342,P = 0.731);术后 2 d、3 个月、6 个月经皮椎体支架内固定组患者胸腰椎疼痛 VAS 评分均低于 PKP 组(t = 2.556,P = 0.002;t = 3.251,P = 0.000;t = 4.101,P = 0.003)。③ODI。时间因素和分组因素存在交互效应(F = 45.476,P = 0.000);2 组患者的 ODI 总体比较,组间差异无统计学意义,即不存在分组效应(F = 11.029,P = 1.573);手术前后不同时间点 ODI 的差异有统计学意义,即存在时间效应(F = 90.952,P = 0.000);2 组患者 ODI 随时间变化均呈下降趋势,且 2 组的下降趋势完全一致[(56.65 ± 6.23)%,(20.53 ± 3.85)%,(18.27 ± 2.27)%,(17.13 ± 2.615)%,F = 52.586,P = 0.000;(55.94 ± 5.77)%,(20.51 ± 3.89)%,(18.62 ± 2.21)%,(17.31 ± 2.11)%,F = 38.366,P = 0.000];2 组患者术前及术后 2 d、3 个月、6 个月 ODI 比较,组间差异均无统计学意义(t = −0.801,P = 0.417;t = 4.772,P = 0.357;t = 3.154,P = 0.402;t = 3.904,P = 0.397)。④伤椎 Beck 指数。时间因素和分组因素存在交互效应(F = 416.582,P = 0.000);2 组患者伤椎 Beck 指数总体比较,组间差异有统计学意义,即存在分组效应(F = 34.567,P = 0.000);手术前后不同时间点伤椎 Beck 指数差异有统计学意义,即存在时间效应(F = 287.312,P = 0.000);2 组患者伤椎 Beck 指数随时间变化均呈先上升后基本保持不变的趋势,但 2 组趋势不完全一致(0.62 ± 0.06,0.95 ± 0.14,0.95 ± 0.13,0.94 ± 0.09,F = 243.085,P = 0.000;0.64 ± 0.05,0.75 ± 0.17,0.75 ± 0.14,0.74 ± 0.09,F = 44.227,P = 0.000);2 组患者术前伤椎 Beck 指数比较,差异无统计学意义(t = −2.932,P = 0.482);术后 2 d、3 个月、6 个月经皮椎体支架内固定组患者伤椎 Beck 指数均高于 PKP 组(t = 9.194,P = 0.000;t = 10.933,P = 0.000;t = 17.372,P = 0.000)。⑤伤椎矢状位 Cobb 角。时间因素和分组因素存在交互效应(F = 18.642,P = 0.000);2 组患者的伤椎矢状位 Cobb 角总体比较,组间差异无统计学意义,即不存在分组效应(F = 8.822,P = 0.639);手术前后不同时间点伤椎矢状位 Cobb 角的差异有统计学意义,即存在时间效应(F = 63.503,P = 0.000);2 组患者伤椎矢状位 Cobb 角随时间变化均呈先下降后基本保持不变的趋势,但 2 组趋势不完全一致(18.85° ± 3.32°,11.89° ± 1.84°,12.21° ± 1.34°,11.62° ± 1.55°,F = 25.137,P = 0.000;18.66° ± 3.15°,14.54° ± 4.21°,15.23° ± 3.52°,14.21° ± 2.77°,F = 38.366,P = 0.000);2 组患者术前伤椎矢状位 Cobb 角比较,差异无统计学意义(t = 0.102,P = 0.635);术后 2 d、3 个月、6 个月经皮椎体支架内固定组患者伤椎矢状位 Cobb 角均小于 PKP 组(t = 2.013,P = 0.001;t = 3.205,P = 0.000;t = 3.502,P = 0.003)。⑥并发症发生率。经皮椎体支架内固定组发生骨水泥渗漏 1 例,PKP 组发生骨水泥渗漏 10 例。2 组患者均未发生相邻椎体骨折、神经根损伤等并发症。经皮椎体支架内固定组患者并发症发生率低于 PKP 组(χ^2 = 8.538,P = 0.003)。**结论:**经皮椎体支架内固定治疗 OVCF,与 PKP 相比,二者在骨水泥注入量、术中出血量、手术时间及恢复椎体功能方面相当,但前者更有利于缓解胸腰椎疼痛、恢复椎体正常形态,且安全性高。

通讯作者:慈元　E-mail:ciyuan69@163.com

关键词　脊柱;椎体;骨质疏松性骨折;骨折,压缩性;椎体支架;骨折固定术,内;后凸成型术;临床试验

A clinical study of percutaneous vertebral body stenting internal fixation for treatment of osteoporotic vertebral compression fractures

XIA Kunyang, CI Yuan, LI Zhijun, ZHANG Guangyu

Dalian Second People's Hospital, Dalian 116014, Liaoning, China

ABSTRACT　Objective: To observe the clinical outcomes and safety of percutaneous vertebral body stenting (VBS) internal fixation for treatment of osteoporotic vertebral compression fractures (OVCFs). **Methods**: The medical records of 80 OVCFs patients were analyzed retrospectively. Forty patients were treated with percutaneous VBS internal fixation (percutaneous VBS internal fixation group) and 40 ones with percutaneous kyphoplasty (PKP) (PKP group). The consumption of bone cement, intraoperative blood loss, operative time, thoracolumbar pain visual analogue scale (VAS) score, Oswestry disability index (ODI), injured vertebrae Beck index, injured vertebrae sagittal Cobb's angle and complication incidence were compared between the 2 groups. **Results**: ①There was no statistical difference in consumption of bone cement, intraoperative blood loss and operative time between the 2 groups (2.29 ± 1.39 vs 1.85 ± 1.25 mL, $t = -1.541$, $P = 0.061$; 6.91 ± 2.24 vs 5.43 ± 1.12 mL, $t = -0.480$, $P = 0.431$; 33.61 ± 7.31 vs 25.76 ± 2.43 minutes, $t = -6.59$, $P = 0.542$). ②There was interaction between time factor and group factor in thoracolumbar pain VAS score ($F = 44.059$, $P = 0.000$). There was no statistical difference in thoracolumbar pain VAS scores between the 2 groups in general, in other words, there was no group effect ($F = 10.250$, $P = 0.736$). There was statistical difference in thoracolumbar pain VAS scores between different timepoints before and after the surgery, in other words, there was time effect ($F = 88.117$, $P = 0.000$). The thoracolumbar pain VAS scores presented a downward trend over time in the 2 groups, while the 2 groups were inconsistent with each other in the variation tendency (7.95 ± 0.59, 3.83 ± 0.53, 2.21 ± 0.59, 1.75 ± 0.55 points, $F = 53.256$, $P = 0.000$; 7.88 ± 0.57, 3.91 ± 0.57, 2.33 ± 0.88, 1.82 ± 0.62 points, $F = 34.861$, $P = 0.000$). There was no statistical difference in thoracolumbar pain VAS scores between the 2 groups before the surgery ($t = 0.342$, $P = 0.731$), while the thoracolumbar pain VAS scores decreased in percutaneous VBS internal fixation group compared to PKP group at postsurgical day 2, month 3 and month 6 ($t = 2.556$, $P = 0.002$; $t = 3.251$, $P = 0.000$; $t = 4.101$, $P = 0.003$). ③There was interaction between time factor and group factor in ODI ($F = 45.476$, $P = 0.000$). There was no statistical difference in ODI between the 2 groups in general, in other words, there was no group effect ($F = 11.029$, $P = 1.573$). There was statistical difference in ODI between different timepoints before and after the surgery, in other words, there was time effect ($F = 90.952$, $P = 0.000$). The ODI presented a downward trend over time in the 2 groups, and the 2 groups were completely consistent with each other in the variation tendency (56.65 ± 6.23, 20.53 ± 3.85, 18.27 ± 2.27, 17.13 ± 2.615%, $F = 52.586$, $P = 0.000$; 55.94 ± 5.77, 20.51 ± 3.89, 18.62 ± 2.21, 17.31 ± 2.11%, $F = 38.366$, $P = 0.000$). There was no statistical difference in ODI between the 2 groups before the surgery and at postsurgical day 2, month 3 and month 6 ($t = -0.801$, $P = 0.417$; $t = 4.772$, $P = 0.357$; $t = 3.154$, $P = 0.402$; $t = 3.904$, $P = 0.397$). ④There was interaction between time factor and group factor in injured vertebrae Beck index ($F = 416.582$, $P = 0.000$). There was statistical difference in injured vertebrae Beck index between the 2 groups in general, in other words, there was group effect ($F = 34.567$, $P = 0.000$). There was statistical difference in injured vertebrae Beck index between different timepoints before and after the surgery, in other words, there was time effect ($F = 287.312$, $P = 0.000$). The injured vertebrae Beck index presented a trend of going upward firstly and remaining basically unchanged subsequently over time in the 2 groups, while the 2 groups were inconsistent with each other in the variation tendency (0.62 ± 0.06, 0.95 ± 0.14, 0.95 ± 0.13, 0.94 ± 0.09, $F = 243.085$, $P = 0.000$; 0.64 ± 0.05, 0.75 ± 0.17, 0.75 ± 0.14, 0.74 ± 0.09, $F = 44.227$, $P = 0.000$). There was no statistical difference in injured vertebrae Beck index between the 2 groups before the surgery ($t = -2.932$, $P = 0.482$), while the injured vertebrae Beck indexes increased in percutaneous VBS internal fixation group compared to PKP group at postsurgical day 2, month 3 and month 6 ($t = 9.194$, $P = 0.000$; $t = 10.933$, $P = 0.000$; $t = 17.372$, $P = 0.000$). ⑤There was interaction between time factor and group factor in injured vertebrae sagittal Cobb's angle ($F = 18.642$, $P = 0.000$). There was no statistical difference in injured vertebrae sagittal Cobb's angle between the 2 groups in general, in other words, there was no group effect ($F = 8.822$, $P = 0.639$). There was statistical difference in injured vertebrae sagittal Cobb's angle between different timepoints before and after the surgery, in other words, there was time effect ($F = 63.503$, $P = 0.000$). The injured vertebrae sagittal Cobb's angle presented a trend of going downward firstly and remaining basically unchanged subsequently over time in the 2 groups, while the 2 groups were inconsistent with each other in the variation tendency (18.85 ± 3.32,

11.89 ± 1.84,12.21 ± 1.34,11.62 ± 1.55 degrees,F = 25.137,P = 0.000;18.66 ± 3.15,14.54 ± 4.21,15.23 ± 3.52,14.21 ± 2.77 degrees,F = 38.366,P = 0.000). There was no statistical difference in injured vertebrae sagittal Cobb's angle between the 2 groups before the surgery(t = 0.102,P = 0.635),while the injured vertebrae sagittal Cobb's angle decreased in percutaneous VBS internal fixation group compared to PKP group at postsurgical day 2,month 3 and month 6(t = 2.013,P = 0.001;t = 3.205,P = 0.000;t = 3.502,P = 0.003). ⑥The bone cement leakage was found in 1 patient in percutaneous VBS internal fixation group and 10 patients in PKP group. No complications such as adjacent vertebral fracture and nerve root injury were found in the 2 groups. The complication incidence rate was lower in percutaneous VBS internal fixation group compared to PKP group(χ^2 = 8.538,P = 0.003). **Conclusion**: The percutaneous VBS internal fixation is similar to PKP in consumption of bone cement,intraoperative blood loss,operative time and vertebral function recovery in treatment of OVCFs,while the former can be more conducive to thoracolumbar pain relief and vertebral body morphology recovery with high safety compared to the latter.

Keywords　spine; vertebral body; osteoporotic fractures; fractures, compression; vertebral body stenting; fracture fixation, internal; kyphoplasty; clinical trial

随着社会老龄化加剧,骨质疏松症已经成为一种常见病、多发病。我国 50 岁以上人群中骨质疏松症的患病率约为 19.2%,65 岁以上人群中骨质疏松症的患病率约为 32%[1-2]。骨质疏松性椎体压缩骨折(osteoporotic vertebral compression fracture,OVCF)是骨质疏松症最常见的并发症之一,具有一定的致残率和致死率,严重影响老年患者的生活质量[3]。微创手术具有创伤小、患者恢复快、卧床时间短等优点,成为临床上治疗 OVCF 的主要方法。经皮椎体后凸成形术(percutaneous kyphoplasty,PKP)是临床常用的微创手术方法,能够减轻患者疼痛、恢复椎体高度、增强椎体稳定性,提高患者生活质量[4-5]。然而,PKP 术中随着球囊撤出,部分患者发生椎体高度丢失,且该方法亦存在骨水泥渗漏等问题。经皮椎体支架内固定是在 PKP 的基础上,在椎体内置入金属支架,通过金属支架发挥支撑塌陷椎体的作用;该方法能够更好地恢复并维持椎体高度,且椎体支架撑开后形成的支架网能够发挥减少骨水泥渗漏的作用[6]。为了进一步观察经皮椎体支架内固定治疗 OVCF 的临床疗效,我们进行了此项研究,现报告如下。

1　临床资料

1.1　一般资料　选取 2020 年 1 月至 2021 年 1 月在大连市第二人民医院住院治疗的 OVCF 患者的病例资料进行研究。试验方案经医院医学伦理委员会审查通过。

1.2　纳入标准　①骨密度 T 值≤ -2.5[7];②骨折节段位于 T_5 ~ L_5,且为单节段压缩骨折;③骨折未累及椎体后壁;④骨折类型根据 OA 分型[8]为 A1 型,且根据 Genant 分型[9]为 2 级或 3 级;⑤采用经皮椎体支架内固定或 PKP 治疗;⑥病例资料完整。

1.3　排除标准　①合并其他部位骨折者;②合并严重心脑血管疾病及肝肾功能障碍者;③合并恶性肿瘤者;④病例资料存在常识性或逻辑性错误者。

2　方　法

2.1　分组方法　根据采用的手术方法,分为经皮椎体支架内固定组和 PKP 组。

2.2　手术方法

2.2.1　经皮椎体支架内固定组　采用全身麻醉,患者俯卧于手术体位垫上。C 形臂 X 线机定位伤椎,于体表标记两侧椎弓根投影位置,常规消毒铺巾。于标记处外侧 1.5 cm 处各做长度约 0.5 cm 的切口,X 线透视下沿适当角度经两侧切口依次刺入套管针,确保工作套筒末端均进入椎体约 3 mm。取出套管针,X 线透视下通过工作套管置入钻孔器向椎体前内侧钻孔,钻孔后置入钝头活塞进一步扩张通道,建立支架置入通道。结合术前测量椎体体积及术中钝头活塞的刻度槽位置,选择大小合适的椎体支架。X 线透视下,依次插入已连接合适椎体支架的球囊导管,将支架置入满意位置后[图 1(1)],连接扩张系统,两侧同时逐渐增加球囊压力,撑开支架[图 1(2)];当椎体高度恢复满意后,停止球囊扩张。当压力约为 12.12×10^5 Pa 时,支架开始扩张;撑开支架过程中注意观察扩张系统上的压力指示表,避免超过球囊的最大容积或压力,导致球囊渗漏;此外,撑开时需确保两侧支架直径一致,以实现支撑平衡。X 线透视确认椎体高度满意后,两侧同时逐步降低压力并撤出球囊导管。连接骨水泥输送装置,注入适量的聚甲基丙烯酸甲酯骨水泥[图 1(3)]。待骨水泥凝固后,取出注射用针和

工作套筒,切口止血,无菌敷料包扎。

2.2.2　PKP 组　采用局部麻醉,患者俯卧于手术体位垫上。C 形臂 X 线机定位伤椎,于体表标记两侧椎弓根投影位置,常规消毒铺巾。以标记处为中心各做长度约 0.5 cm 的切口。X 线透视下,经切口处沿伤椎两侧椎弓根穿刺进入椎体内;沿穿刺针向椎体内插入导针后,拔出穿刺针,沿导针置入工作套筒;X 线透视确认工作套筒恰好突破椎体后壁,拔出导针,沿工作套筒用手钻于椎体内攻丝、扩髓,置入扩张球囊;X 线透视确认扩张球囊位于椎体前 2/3 处,加压撑开扩张球囊,见椎体复位满意后,取出扩张球囊,透视下注入调配至拉丝期的骨水泥,待骨水泥填充良好后停止注入。骨水泥凝固后,取出工作套筒,切口止血,无菌敷料包扎。

2.3　疗效和安全性评价方法　比较 2 组患者的骨水泥注入量、术中出血量、手术时间、胸腰椎疼痛视觉模拟量表(visual analogue scale,VAS)评分、Oswestry 功能障碍指数(Oswestry disability index,ODI)[10]、伤椎 Beck 指数[11]、伤椎矢状位 Cobb 角和并发症发生率。

2.4　数据统计方法　采用 SPSS20.0 统计软件对所得数据进行统计学分析。2 组患者的性别、骨折 Genant 分型、骨折节段、并发症发生率的组间比较均采用 χ^2 检验,年龄、骨密度、骨水泥注入量、术中出血量、手术时间的组间比较均采用 t 检验,胸腰椎疼痛 VAS 评分、ODI、伤椎 Beck 指数和伤椎矢状位 Cobb 角的比较均采用重复测量资料的方差分析。检验水准 $\alpha=0.05$。

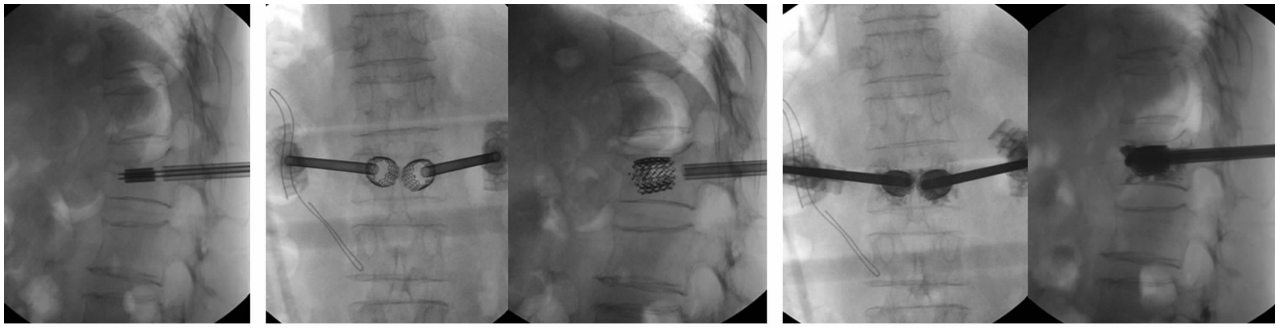
3　结　果

3.1　分组结果　共纳入 80 例患者,经皮椎体支架内固定组和 PKP 组各 40 例。2 组患者基线资料比较,差异无统计学意义,有可比性(表 1)。

3.2　一般结果　2 组患者骨水泥注入量、术中出血量、手术时间组间比较,差异无统计学意义[(2.29 ± 1.39)mL,(1.85 ± 1.25)mL,$t=-1.541$,$P=0.061$;(6.91 ± 2.24)mL,(5.43 ± 1.12)mL,$t=-0.480$,$P=0.431$;(33.61 ± 7.31)min,(25.76 ± 2.43)min,$t=-6.59$,$P=0.542$]。

3.3　疗效和安全性评价结果

3.3.1　胸腰椎疼痛 VAS 评分　时间因素和分组因素存在交互效应;2 组患者的胸腰椎疼痛 VAS 评分总



(1)　(2)　(3)

图 1　经皮椎体支架内固定治疗骨质疏松性椎体压缩骨折术中操作 X 线片

注:(1)置入椎体支架;(2)撑开椎体支架;(3)注入骨水泥。

表 1　2 组骨质疏松性椎体压缩骨折患者基线资料

组别	样本量/例	性别/例		年龄/($\bar{x}\pm s$,岁)	骨密度 T 值($\bar{x}\pm s$)
		男	女		
经皮椎体支架内固定组	40	16	24	72.3 ± 9.7	−3.75 ± 0.23
经皮椎体后凸成形术组	40	20	20	74.6 ± 9.4	−3.55 ± 0.35
检验统计量		$\chi^2=0.808$		$t=-1.000$	$t=-0.550$
P 值		0.369		0.323	0.913

组别	骨折 Genant 分型/例		骨折节段/例								
	2 级	3 级	T_9	T_{10}	T_{11}	T_{12}	L_1	L_2	L_3	L_4	L_5
经皮椎体支架内固定组	15	25	0	3	4	10	10	4	3	5	1
经皮椎体后凸成形术组	20	20	2	2	5	15	5	4	3	4	0
检验统计量	$\chi^2=1.270$		$\chi^2=6.089$								
P 值	0.260		0.637								

体比较,组间差异无统计学意义,即不存在分组效应;手术前后不同时间点胸腰椎疼痛 VAS 评分的差异有统计学意义,即存在时间效应;2 组患者胸腰椎疼痛 VAS 评分随时间变化均呈下降趋势,但 2 组的下降趋势不完全一致;2 组患者术前胸腰椎疼痛 VAS 评分比较,差异无统计学意义;术后 2 d、3 个月、6 个月经皮椎体支架内固定组患者胸腰椎疼痛 VAS 评分均低于 PKP 组(表 2)。

3.3.2　ODI　时间因素和分组因素存在交互效应;2 组患者的 ODI 总体比较,组间差异无统计学意义,即不存在分组效应;手术前后不同时间点 ODI 的差异有统计学意义,即存在时间效应;2 组患者 ODI 随时间变化均呈下降趋势,且 2 组的下降趋势完全一致;2 组患者术前及术后 2 d、3 个月、6 个月 ODI 比较,组间差异均无统计学意义(表 3)。

3.3.3　伤椎 Beck 指数　时间因素和分组因素存在交互效应;2 组患者伤椎 Beck 指数总体比较,组间差异有统计学意义,即存在分组效应;手术前后不同时间点伤椎 Beck 指数差异有统计学意义,即存在时间效应;2 组患者伤椎 Beck 指数随时间变化均呈先上升后基本保持不变的趋势,但 2 组趋势不完全一致。2 组患者术前伤椎 Beck 指数比较,差异无统计学意义;术后 2 d、3 个月、6 个月经皮椎体支架内固定组患者伤椎 Beck 指数均高于 PKP 组(表 4)。

3.3.4　伤椎矢状位 Cobb 角　时间因素和分组因素存在交互效应;2 组患者的伤椎矢状位 Cobb 角总体比较,组间差异无统计学意义,即不存在分组效应;手术前后不同时间点伤椎矢状位 Cobb 角的差异有统计学意义,即存在时间效应;2 组患者伤椎矢状位 Cobb 角随时间变化均呈先下降后基本保持不变的趋势,但 2 组趋势不完全一致;2 组患者术前伤椎矢状位 Cobb 角比较,差异无统计学意义;术后 2 d、3 个月、6 个月经皮椎体支架内固定组患者伤椎矢状位 Cobb 角均小于 PKP 组(表 5)。

表 2　2 组骨质疏松性椎体压缩骨折患者手术前后胸腰椎疼痛视觉模拟量表评分

组别	样本量/例	胸腰椎疼痛视觉模拟量表评分/($\bar{x}\pm s$,分)					F 值	P 值
		术前	术后 2 d	术后 3 个月	术后 6 个月	合计		
经皮椎体支架内固定组	40	7.95 ± 0.59	3.83 ± 0.53	2.21 ± 0.59	1.75 ± 0.55	3.97 ± 0.64	53.256	0.000
经皮椎体后凸成形术组	40	7.88 ± 0.57	3.91 ± 0.57	2.33 ± 0.88	1.82 ± 0.62	3.96 ± 0.59	34.861	0.000
合计	80	7.92 ± 0.58	3.92 ± 0.54	2.27 ± 0.74	1.79 ± 0.59	3.97 ± 0.62	88.117[1)]	0.000[1)]
检验统计量		t = 0.342	t = 2.556	t = 3.251	t = 4.101	10.250[1)]	F = 44.059[2)]	
P 值		0.731	0.002	0.000	0.003	0.736[1)]	P = 0.000[2)]	

1)主效应的 F 值和 P 值;2)交互效应的 F 值和 P 值。

表 3　2 组骨质疏松性椎体压缩骨折患者手术前后 Oswestry 功能障碍指数

组别	样本量/例	Oswestry 功能障碍指数/($\bar{x}\pm s$,%)					F 值	P 值
		术前	术后 2 d	术后 3 个月	术后 6 个月	合计		
经皮椎体支架内固定组	40	56.65 ± 6.23	20.53 ± 3.85	18.27 ± 2.27	17.13 ± 2.61	28.15 ± 3.74	52.586	0.000
经皮椎体后凸成形术组	40	55.94 ± 5.77	20.51 ± 3.89	18.62 ± 2.21	17.31 ± 2.11	28.10 ± 3.57	38.366	0.000
合计	80	56.30 ± 6.00	20.52 ± 3.87	18.45 ± 2.24	17.22 ± 2.36	28.13 ± 3.66	90.952[1)]	0.000[1)]
检验统计量		t = −0.801	t = 4.772	t = 3.154	t = 3.904	11.029[1)]	F = 45.476[2)]	
P 值		0.417	0.357	0.402	0.397	1.573[1)]	P = 0.000[2)]	

1)主效应的 F 值和 P 值;2)交互效应的 F 值和 P 值。

表 4　2 组骨质疏松性椎体压缩骨折患者手术前后伤椎 Beck 指数

组别	样本量/例	伤椎 Beck 指数($\bar{x}\pm s$)					F 值	P 值
		术前	术后 2 d	术后 3 个月	术后 6 个月	合计		
经皮椎体支架内固定组	40	0.62 ± 0.06	0.95 ± 0.14	0.95 ± 0.13	0.94 ± 0.09	0.87 ± 0.11	243.085	0.000
经皮椎体后凸成形术组	40	0.64 ± 0.05	0.75 ± 0.17	0.75 ± 0.14	0.74 ± 0.09	0.72 ± 0.11	44.227	0.000
合计	80	0.63 ± 0.06	0.85 ± 0.16	0.85 ± 0.14	0.84 ± 0.09	0.80 ± 0.11	287.312[1)]	0.000[1)]
检验统计量		t = −2.932	t = 9.194	t = 10.933	t = 17.372	34.567[1)]	F = 416.582[2)]	
P 值		0.482	0.000	0.000	0.000	0.000[1)]	P = 0.000[2)]	

1)主效应的 F 值和 P 值;2)交互效应的 F 值和 P 值。

3.3.5　并发症发生率　经皮椎体支架内固定组患者发生骨水泥渗漏 1 例，PKP 组发生骨水泥渗漏 10 例。2 组均未发生相邻椎体骨折、神经根损伤等并发症。经皮椎体支架内固定组患者并发症发生率低于 PKP 组（$\chi^2=8.538$，$P=0.003$）。

3.4　典型病例　典型病例手术前后影像图片见图 2。

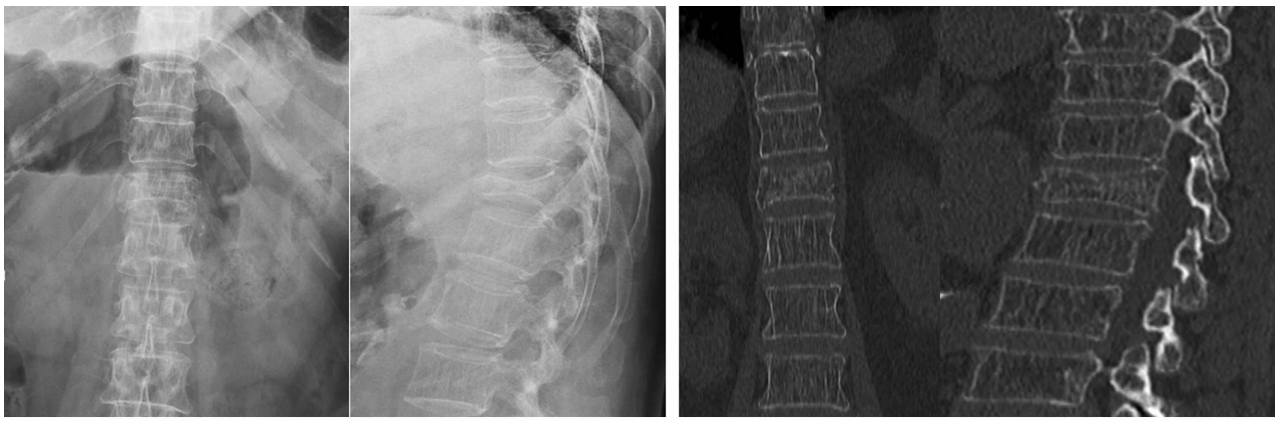
4　讨　论

椎体支架的概念于 2002 年被首次提出，其基于血管成形术支架的设计理念，通过椎体支架撑开复位压缩骨折的椎体，并联合骨水泥填充，实现恢复椎体高度和稳定性的目的[12-13]。赵鹏等[14]研究发现，经皮椎体支架内固定治疗 OVCF，能够显著缓解腰背疼痛，增强椎体的强度和稳定性。椎体支架为金属材质，具有良好的支撑作用，术中撤出球囊后，能够维持椎体复位后的高度，避免由于“回弹效应”而导致的椎体高度下降，防止椎体二次塌陷[15-16]。Alexandru 等[3]通过尸体标本试验发现，经皮椎体支架内固定恢复压缩骨折椎体形态的效果显著优于 PKP。椎体支架在椎体内展开后，形成了网格包围的空腔，一方面形成的空腔能够使骨水泥弥散效果更好，另一方面网格能够有效阻挡骨水泥渗漏[6,17]。多项研究[18-20]表明，经皮椎体支架内固定治疗 OVCF 与 PKP 比较，骨水泥渗漏发生率更低。此外，由于经皮椎体支架内固定是基于 PKP 发展而来的，操作方法与常规 PKP 无

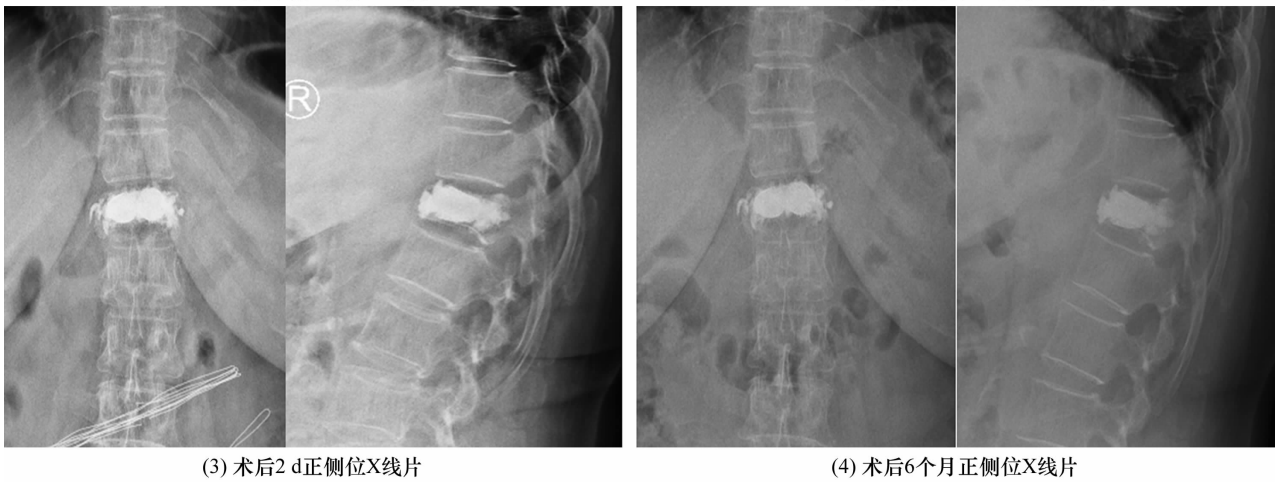
表 5　2 组骨质疏松性椎体压缩骨折患者手术前后伤椎矢状位 Cobb 角

组别	样本量/例	伤椎矢状位 Cobb 角/（$\bar{x}\pm s$，°）					F 值	P 值
		术前	术后 2 d	术后 3 个月	术后 6 个月	合计		
经皮椎体支架内固定组	40	18.85±3.32	11.89±1.84	12.21±1.34	11.62±1.55	13.64±1.84	25.137	0.000
经皮椎体后凸成形术组	40	18.66±3.15	14.54±4.21	15.23±3.52	14.21±2.77	15.66±3.4	38.366	0.000
合计	80	18.76±3.24	13.22±3.03	13.72±2.54	12.92±1.71	14.65±2.63	63.503[1)]	0.000[1)]
检验统计量		0.102	2.013	3.205	3.502	8.822[1)]	$F=18.642$[2)]	
P 值		0.635	0.001	0.000	0.003	0.639[1)]	$P=0.000$[2)]	

1）主效应的 F 值和 P 值；2）交互效应的 F 值和 P 值。



(1) 术前正侧位X线片　　(2) 术前冠状位、矢状位CT片



(3) 术后2 d正侧位X线片　　(4) 术后6个月正侧位X线片

图 2　骨质疏松性椎体压缩骨折患者经皮椎体支架内固定手术前后图片

显著差异,临床医师可快速掌握。然而,该技术仍存在一些不足:①椎体支架的尺寸固定,对于椎弓根过细的患者采用该手术方法可能会导致椎弓根损伤;②套管针直径较粗,需在全身麻醉或局部麻醉联合基础麻醉下进行穿刺;③椎体支架撑开过程中存在损伤椎体终板导致再骨折发生的可能。因此,临床上采用经皮椎体支架治疗 OVCF,术前需准确测量患者椎弓根直径,确定大小合适的椎体支架[14]。此外,对于金属支架的置入是否影响骨代谢以及可能导致的椎体二次骨折等并发症的发生情况,尚需开展大样本、长期随访的临床试验进一步探究[21-22]。

本研究结果表明,经皮椎体支架内固定治疗 OVCF,与 PKP 相比,二者在骨水泥注入量、术中出血量、手术时间及恢复椎体功能方面相当,但前者更有利于缓解胸腰椎疼痛、恢复椎体正常形态,且安全性高。

参考文献

[1] BIJLSMA A Y,MESKERS C G M,WESTENDORP R G J,et al. Chronology of age-related disease definitions osteoporosis and sarcopenia[J]. Ageing Res Rev,2012,11(2):320-324.

[2] 中华医学会骨质疏松和骨矿盐疾病分会. 骨质疏松性椎体压缩性骨折诊疗与管理专家共识[J]. 中华骨质疏松和骨矿盐疾病杂志,2018,11(5):425-437.

[3] ALEXANDRU D,SO W. Evaluation and management of vertebral compression fractures[J]. Perm J,2012,16(4):46-51.

[4] PAPANASTASSIOU I D,PHILLIPS F M,VAN MEIRHAEGHE J,et al. Comparing effects of kyphoplasty,vertebroplasty,and non surgical management in a systematic review of randomized and non-randomized controlled studies[J]. Eur Spine J,2012,21(9):1826-1843.

[5] BENNEKER L M,HOPPE S. Percutaneous cement augmentation techniques for osteoporotic spinal fractures[J]. Eur J Trauma Emerg Surg,2013,39(5):445-453.

[6] SCHÜTZENBERGER S,SCHWARZ S M,GREINER L,et al. Is vertebral body stenting in combination with CaP cement superiorto kyphoplasty[J]. Eur spine J,2018,27(10):2602-2608.

[7] 中国康复医学会骨质疏松预防与康复专业委员会. 骨质疏松性椎体压缩骨折诊治专家共识(2021 版)[J]. 中华医学杂志,2021,101(41):3371-3379.

[8] AZIMI P,MOHAMMADI H R,AZHARI S,et al. The AOSpine thoracolumbar spine injury classification system:a reliability and agreement study[J]. Asian J Neurosurg,2015,10(4):282-285.

[9] GENANT H K,WU C Y,VAN KUIJK C,et al. Vertebral fracture assessment using a semiquantitative technique[J]. J Bone Miner Res,1993,8(9):1137-1148.

[10] 蒋协远,王大伟. 骨科临床疗效评价标准[M]. 北京:人民卫生出版社,2005:119-121.

[11] 邹季,邹定斌,郭帮富. Beck 指数在脊椎压缩性骨折疗效评价中的应用[J]. 中医正骨,1992,4(3):17-18.

[12] DIEL P,RÖDER C,PERLER G,et al. Radiographic and safety details of vertebral body stenting:results from a multicenter chartreview[J]. BMC Musculoskelet Disord,2013,14:233.

[13] 张亮,高梁斌,李健,等. 椎体成形术中椎体骨密度对骨水泥弥散体积的影响[J]. 中国脊柱脊髓杂志,2011,21(11):915-918.

[14] 赵鹏,慈元,李志君,等. 经皮椎体支架成形术治疗骨质疏松性椎体压缩骨折[J]. 中国矫形外科杂志,2022,30(4):314-318

[15] HEINI P F,TEUSCHER R. Vertebral body stenting/stentoplasty[J/OL]. Swiss Med Wkly,2012,142[2021-07-16]. https://smw.ch/article/doi/smw.2012.13658.

[16] FILIPPIADIS D K,MARCIA S,RYAN A,et al. New implant-based technologies in the spine[J]. Cardiovasc Intervent Radiol,2018,41(10):1463-1473.

[17] 蔡进奎,潘和科,周健和,等. 钛网植入椎体成形术与 PKP 治疗脆性骨折疗效比较[J]. 实用医学杂志,2020,36(9):1228-1232.

[18] 周腾鹏,张顺聪,袁凯,等. 椎体支架成形术治疗骨质疏松性椎体重度压缩骨折 1 例并文献回顾[J]. 实用骨科杂志,2019,25(12):1144-1146.

[19] MARTIN-LOPEZ J E,PAVON-GOMEZ M J,ROMERO-TABARES A,et al. Stentoplasty effectiveness and safety for the treatment of osteoporotic vertebral fractures:a systematic review[J]. Orthop Traumatol Surg Res,2015,101(5):627-632.

[20] 徐响阳,罗德民,刘尚礼,等. 椎体支架系统经皮椎体后凸成形术结合唑来膦酸治疗重度骨质疏松性椎体骨折[J]. 中国骨伤,2020,33(9):827-830.

[21] 马延怀,张顺聪,袁凯,等. 经皮椎体支架成形和经皮椎体后凸成形治疗骨质疏松性椎体压缩骨折的疗效观察[J]. 中国组织工程研究,2020,24(14):2170-2176.

[22] 李佳平,李龙,李敏. 单侧入路 PKP 治疗胸腰椎骨质疏松性骨折的效果及对患者创伤应激反应、骨代谢指标的影响[J]. 临床医学研究与实践,2022,7(10):42-45.

（收稿日期:2021-08-16　本文编辑:吕宁）