

· 临床研究 ·

骨填充网袋椎体成形术与经皮球囊后凸成形术
治疗骨质疏松性椎体压缩性骨折

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【摘要】 目的:探讨骨填充网袋椎体成形术治疗骨质疏松性椎体骨折的临床疗效。方法:对 2015 年 12 月至 2017 年 6 月符合纳入与排除标准的 127 例(145 椎)骨质疏松性胸腰椎体骨折患者的临床资料进行回顾性分析,通过临床表现、X 线、CT、MRI 明确责任椎体,其中 95 例(110 椎)采用经皮椎体后凸成形术治疗(PKP 组),男 34 例(42 椎),女 61 例(68 椎),年龄(73.92±7.14)岁,胸椎 47 节(T₈-T₁₂),腰椎 63 节(L₁-L₅);另外的 32 例(35 椎)采用骨填充网袋椎体成形术治疗(网袋组),男 11 例(12 椎),女 21 例(23 椎),年龄(71.56±7.89)岁,胸椎 16 节(T₉-T₁₂),腰椎 19 节(L₁-L₅)。观察患者术后 3 d 疼痛改善、椎体高度恢复、功能改善情况,并通过 X 线片观察骨水泥弥散及渗漏情况。结果:所有患者顺利完成手术,术中未出现并发症。骨填充网袋椎体成形术治疗的 32 例患者手术时间为(31.75±4.99) min,术后 3 d 的 VAS 评分,椎体前缘、中部高度,腰部 ODI 评分分别为(2.38±0.94)分、(19.54±2.36) mm、(18.16±2.65) mm 和(25.19±5.49)分,各项目与术前比较明显改善($P<0.01$),与 PKP 组比较差异无统计学意义($P>0.05$)。术后 3 d 的 X 线片显示两组患者的骨水泥均呈斑片状、团块状或少量弥散状分布,网袋组的渗漏率为 2.86%(1/35),PKP 组的渗漏率为 16.36%(18/110),多为“拖尾征”,两组比较差异有统计学意义($P<0.05$)。结论:骨填充网袋椎体成形术治疗骨质疏松性椎体骨折具有类似经皮椎体后凸成形术的疗效,能够缓解疼痛,恢复部分椎体高度,并且明显减少渗漏率,是一种简单、快速、有效的治疗方法。

【关键词】 脊柱骨折; 骨质疏松; 经皮球囊后凸成形术; 骨填充网袋椎体成形术

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Observation of the clinical efficacy of the bone filling bag vertebroplasty for the treatment of osteoporotic vertebral compression fractures XU Bing, WANG Xiao-feng, YE Xiao-yu, YANG Yi-yu, WANG Guan-hua, and MA Guang-xi. Department of Spinal Surgery, Integrated Traditional Chinese and Western Medicine Hospital of Wenzhou Affiliated to Zhejiang Chinese Medicine University, Wenzhou 325000, Zhejiang, China

Abstract Objective: To explore the clinical effects of bone filling bag vertebroplasty in treating osteoporotic vertebral compression fractures. Methods: The clinical data of 127 patients (145 vertebrae) with osteoporotic vertebral compression fractures who corresponded the criteria of inclusion and exclusion from December 2015 to June 2017 were retrospectively analyzed. Responsible vertebral bodies were identified by clinical situation, X-rays, CT scan, MRI. Among them, 95 cases (110 vertebrae) were treated by percutaneous kyphoplasty (PKP group), there were 34 males (42 vertebrae) and 61 females (68 vertebrae), with an average age of (73.92±7.14) years, 47 thoracic vertebra (T₈-T₁₂) and 63 lumbar vertebra (L₁-L₅). Other 32 patients (35 vertebrae) were treated by bone filling bag vertebroplasty (bone filling bag vertebroplasty group). There were 11 males (12 vertebrae) and 21 females (23 vertebrae), with an average age of (71.56±7.89) years, 16 thoracic vertebra (T₉-T₁₂) and 19 lumbar vertebra (L₁-L₅). Postoperative pain after 3 days, vertebral body height, improvement of lumbar function were recorded and bone cement diffusion and leakage were observed by X-rays. Results: All operations were successful and no complications were found. In bone filling bag vertebroplasty group, operation time was (31.75±4.99) min, postoperative VAS score at 3 days was (2.38±0.94) points, anterior and middle height of the vertebral body were (19.54±2.36) mm and (18.16±2.65) mm, respectively; ODI score was (25.19±5.49) points, all above items after operation were better than preoperation ($P<0.01$), but there was no significant difference between two groups ($P>0.05$). Bone cement was patchy, clumpy or slightly dispersed by X-rays at 3 days after operation, the leakage rate of bone cement in bone filling bag vertebroplasty group was 2.86% (1/35), while was 6.36% (18/110) in PKP group, all of them were “trailing sign”, there was significant difference between two

ABSTRACT Objective: To explore the clinical effects of bone filling bag vertebroplasty in treating osteoporotic vertebral compression fractures. **Methods:** The clinical data of 127 patients (145 vertebrae) with osteoporotic vertebral compression fractures who corresponded the criteria of inclusion and exclusion from December 2015 to June 2017 were retrospectively analyzed. Responsible vertebral bodies were identified by clinical situation, X-rays, CT scan, MRI. Among them, 95 cases (110 vertebrae) were treated by percutaneous kyphoplasty (PKP group), there were 34 males (42 vertebrae) and 61 females (68 vertebrae), with an average age of (73.92±7.14) years, 47 thoracic vertebra (T₈-T₁₂) and 63 lumbar vertebra (L₁-L₅). Other 32 patients (35 vertebrae) were treated by bone filling bag vertebroplasty (bone filling bag vertebroplasty group). There were 11 males (12 vertebrae) and 21 females (23 vertebrae), with an average age of (71.56±7.89) years, 16 thoracic vertebra (T₉-T₁₂) and 19 lumbar vertebra (L₁-L₅). Postoperative pain after 3 days, vertebral body height, improvement of lumbar function were recorded and bone cement diffusion and leakage were observed by X-rays. **Results:** All operations were successful and no complications were found. In bone filling bag vertebroplasty group, operation time was (31.75±4.99) min, postoperative VAS score at 3 days was (2.38±0.94) points, anterior and middle height of the vertebral body were (19.54±2.36) mm and (18.16±2.65) mm, respectively; ODI score was (25.19±5.49) points, all above items after operation were better than preoperation ($P<0.01$), but there was no significant difference between two groups ($P>0.05$). Bone cement was patchy, clumpy or slightly dispersed by X-rays at 3 days after operation, the leakage rate of bone cement in bone filling bag vertebroplasty group was 2.86% (1/35), while was 6.36% (18/110) in PKP group, all of them were “trailing sign”, there was significant difference between two

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groups ($P < 0.05$). **Conclusion:** The clinical effect of bone filling bag vertebroplasty in the treatment of osteoporotic vertebral compression fractures is similar to percutaneous kyphoplasty, it can effectively relieve the pain, restore part vertebral body height and obviously reduce the leakage rate, with safer, it is a simple, rapid and effective therapeutic method.

KEYWORDS Spinal fractures; Osteoporosis; Percutaneous kyphoplasty; Bone filling bag vertebroplasty

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随着人口老龄化,骨质疏松症的发生率逐年增加,主要并发症骨折带来的风险逐渐增大,其中骨质疏松性椎体压缩性骨折(osteoporotic vertebral compression fracture, OVCF)亦逐渐成为危害老年人生命的主要并发症。近年来随着骨水泥技术在脊柱外科的使用,椎体成形术或经皮椎体后凸成形术逐渐成为微创治疗 OVCF 的首选方式,但该手术方式的骨水泥渗漏问题一直困扰临床医生^[1]。随着外科技术的发展,骨填充网袋技术逐渐应用于临床治疗 OVCF^[2],因此我院自 2015 年 12 月起亦采用骨填充网袋椎体成形术治疗骨质疏松性椎体压缩性骨折,取得了满意的疗效。

1 资料与方法

1.1 病例选择

1.1.1 纳入标准 (1)年龄>60岁,低能量外伤史出现胸腰部疼痛。(2)骨密度检测符合骨质疏松症的诊断。(3)X线片、MRI影像学检查确定新鲜椎体压缩性骨折。(4)无椎管内明显骨块占位和神经症状,CT示压缩椎体后壁无明显后凸,椎管无占位。(5)合并有其他系统疾病但不影响短时间耐受手术者。(6)患者对治疗及风险均知情同意。

1.1.2 排除标准 60岁以下;不符合骨质疏松症的诊断;X线片、MRI影像学检查为陈旧性压缩骨折;椎体压缩爆裂性骨折,或椎管内明显占位,或有神经症状表现者;合并有其他系统疾病不能耐受手术者;合并神经系统疾病或医患关系紧张不能很好的配合治疗者。

1.2 一般资料

自 2015 年 12 月至 2017 年 6 月在我院住院治疗符合纳入与排除标准的骨质疏松性椎体压缩性骨折患者 127 例(145 椎),采用经皮椎体后凸成形术治疗(PKP 组)95 例(110 椎),其中男 34 例(42 椎),女 61 例(68 椎),年龄(73.92±7.14)岁,胸椎 47 节(T₈-T₁₂),腰椎 63 节(L₁-L₅)。采用骨填充网袋椎体成形术治疗(网袋组)32 例(35 椎),其中男 11 例(12 椎),女 21 例(23 椎),年龄(71.56±7.89)岁,胸椎 16 节(T₉-T₁₂),腰椎 19 节(L₁-L₅)。本组所有患者通过临床表现、X线、CT、MRI明确责任椎体,知情同意后行椎体成形术治疗。两组患者的性别、年龄等一般资料经统计学处理,差异无统计学意义($P > 0.05$),具有可比性,见表 1。

表 1 两组骨质疏松性压缩骨折患者一般资料比较

Tab.1 Comparison of general data of patients with osteoporotic vertebral compression fractures between two groups

组别	例数	性别(例)		年龄($\bar{x} \pm s$, 岁)	伤椎(节)	
		男	女		胸椎	腰椎
PKP 组	95	34	61	73.92±7.14	47	63
网袋组	32	11	21	71.56±7.89	16	19
检验值	-	$\chi^2=0.021$		$t=-1.569$	$\chi^2=0.096$	
P 值	-	0.885		0.119	0.756	

1.3 治疗方法

手术操作均由本院脊柱外科同组副主任及主任医师共同完成,采用的是山东冠龙医疗用品有限公司的椎体成形成套手术器械,包括穿刺针、实心椎体钻、骨填充网袋、骨水泥注入器等。

术中通道建立过程:俯卧位,腹部悬空,使胸腰背部适当处于过伸位,术前 C 形臂 X 线定位责任椎的体表位置,术中注意确保良好的球管方向。标准为:前后位椎体位于 C 形臂 X 线的等量点上;C 形臂 X 线与责任椎体终板保持一致,终板投影呈一线影;两侧椎弓根的形状对称,并与棘突间距相同。常规消毒铺巾,采用 1%利多卡因浸润麻醉后行椎弓根入路,根据术前评估结合术中定位再次确定穿刺进针点、矢状位和冠状位穿刺角度。一般将穿刺针针尖置于椎弓根影的外上缘(即左侧为 10 点钟位,右侧为 2 点钟位),再行椎弓根穿刺。当正位显示针尖达椎弓根中线,侧位显示针尖进椎弓根影的 1/2 处时,表明进针正确,继续 C 形臂 X 线侧位下进针;当侧位显示针尖达椎体后缘,正位显示针尖达椎弓根影内缘时,退出穿刺针内芯,插入实心椎体钻缓慢旋转进针,当侧位超过椎体 2/3,正位在椎弓根中线时,拔出椎体钻即工作通道建立完成(此过程需 C 形臂 X 线连续透视监测,避免损伤造成椎体移位)。

经皮椎体后凸成形术:通过工作通道置入扩张球囊,X 线侧位透视见球囊位于椎体中前下方,由后上向前下倾斜,缓慢向球囊内注入对比剂使囊内压力逐步升高,一般压力在 150~175 kPa,并且采用“扩张-放松-再扩张”的渐进式复位方法(此过程需要在 C 形臂 X 线连续透视下监测气囊位置、大小、形状和椎体恢复高度)。再将调匀后的骨水泥在牙膏期后期



图 1 经皮椎体后凸成形术 (球囊扩张后注入骨水泥)
图 2 骨填充网袋椎体成形术 (骨填充网袋置入后注入骨水泥)

Fig.1 Percutaneous kyphoplasty (Implantation of bone cement after balloon dilation insertion) **Fig.2** The bone filling bag vertebroplasty (Implantation of bone cement after bone filling bag insertion)

时用骨水泥注入器经工作通道缓慢注入椎体 (图 1)。一般每个椎体 4.5~9.0 ml (此过程需在 C 形臂 X 线连续透视下监测骨水泥渗透情况), 并且时刻询问患者感觉, 待骨水泥适当凝固后抽出工作通道, 无菌辅料包扎伤口完成手术。

骨填充网袋椎体成形术: 通过工作通道置入骨填充网袋 (此过程在 C 形臂 X 线连续透视下监测网袋置入椎体超过 2/3), 再将调匀后的骨水泥在牙膏期后期时用骨水泥注入器经工作通道缓慢注入椎体 (图 2)。一般每个椎体 2.4~4 ml (此过程需在 C 形臂 X 线连续透视下监测骨水泥渗透情况), 并且时刻询问患者感觉, 待骨水泥适当凝固后抽出工作通道, 无菌辅料包扎伤口完成手术。

1.4 观察项目与方法

所有患者术后 3 d 在腰围保护下负重活动并行 X 线片复查, 观察手术前后相关指标: (1) 疼痛采用视觉模拟评分 (visual analogue score, VAS)^[3], 范围为 0~10 分, 0 分表示无痛, 10 分表示剧烈疼痛。(2) 腰部功能采用 Oswestry 功能障碍指数问卷 (ODI) 进行评定^[4], ODI 由疼痛强度、生活情况、提物、行走、坐位、站立、睡眠、性生活、社交生活及出游等 10 项组成, 每项有 6 个选择, 每项的最高得分为 5 分, 计分为 0~5 分, 5 分表示情况最严重, 分数越高功能障碍越严重。(3) 通过术后 X 线片观察椎体高度恢复及骨水泥在椎体中的填充渗漏情况。

1.5 统计学处理

采用 SPSS 17.0 软件进行统计学分析, 计数资料采用 χ^2 检验, 定量资料以均数 \pm 标准差 ($\bar{x}\pm s$) 表示, 组间比较采用单因素分析, 组内比较采用配对 t 检验。以 $P<0.05$ 为差异有统计学意义。

2 结果

本组患者顺利完成手术, 术中均未出现并发症。手术时间 PKP 组为 (32.13 \pm 4.73) min, 网袋组为 (31.75 \pm 4.99) min, 两者差异无统计学意义 ($P>0.05$)。

2.1 两组患者的 VAS、椎体高度及 ODI 评分情况

两组患者术前的 VAS 评分, 椎体前缘、中部高度和腰部 ODI 功能评价比较差异无统计学意义 ($P>0.05$)。术后 3 d VAS 评分, 椎体前缘、中部高度, 腰部 ODI 功能评价 PKP 组分别为 (2.21 \pm 0.96) 分、(20.17 \pm 2.09) mm、(18.71 \pm 2.12) mm、(24.8 \pm 5.16) 分, 网袋组分别为 (2.38 \pm 0.94) 分、(19.54 \pm 2.36) mm、(18.16 \pm 2.65) mm、(25.19 \pm 5.49) 分, 两组患者各项指标与术前比较差异均有统计学意义 ($P<0.01$), 但两组间比较差异无统计学意义 ($P>0.05$)。见表 2~3。

2.2 两组患者术后骨水泥渗漏情况

术后 3 d 所有椎体 X 线基本显示骨水泥呈斑片状、团块状或弥散状分布, 其中网袋组的骨水泥多呈现在网袋中心, 较集中, 周边渗出扩散较少。PKP 组中发生骨水泥渗漏共有 18 节椎体, 其中有 13 节是“拖尾征”, 有 3 节是椎间盘渗漏, 有 2 节是前壁渗漏, 透漏率为 16.36% (18/110)。网袋组中发生骨水泥渗漏仅有 1 节椎体, 为“拖尾征” (术中骨水泥注射完拔出时造成的椎弓根处骨水泥渗漏^[5]), 透漏率为 2.86% (1/35), 两者比较差异有统计学意义 ($\chi^2=4.254, P<0.05$)。

3 讨论

3.1 OVCF 的治疗选择

OVCF 以楔形骨折最常见, 以往对于 OVCF 的治疗多采用保守治疗, 主要包括卧床休息、适当的镇痛药物使用、支具的佩戴及逐步的康复锻炼等, 有创伤小、治疗风险低的优势, 但由于卧床时间较长, 发生坠积性肺炎、褥疮、泌尿系感染、下肢静脉血栓等并发症的概率高, 同时长期卧床会导致骨量再次丢失, 进一步加剧骨质疏松, 引发二次骨折, 使患者进入骨质疏松的“骨松-骨折-制动-更骨松-再骨折”的恶性循环。有研究认为保守治疗不能早期改善疼痛症状及功能, 并且椎体高度恢复概率偏低, 容易发生脊柱畸形, 形成陈旧性 OVCF, 使患者的腰背痛更

表 2 两组骨质疏松性椎体压缩性骨折患者的手术时间、VAS 及 ODI 评分比较 ($\bar{x}\pm s$)

Tab.2 Comparison of operation time, VAS, ODI scores of patients with osteoporotic vertebral compression fractures between two groups ($\bar{x}\pm s$)

时间	例数	手术时间 (min)	VAS 评分 (分)		ODI 评分 (分)	
			术前	术后 3 d	术前	术后 3 d
PKP 组	32	32.13±4.73	7.45±0.98	2.21±0.96	50.48±4.58	24.80±5.16
网袋组	95	31.75±4.99	7.53±0.98	2.38±0.94	50.25±4.68	25.19±5.49
t 值	-	-0.384	0.393	0.885	-0.249	0.361
P 值	-	0.702	0.695	0.378	0.804	0.718

表 3 两组骨质疏松性椎体压缩性骨折患者的椎体高度比较 ($\bar{x}\pm s$)

Tab.3 Comparison of anterior and middle height of the vertebral body of patients with osteoporotic vertebral compression fractures between two groups ($\bar{x}\pm s$)

时间	例数	椎体前缘高度 (°)		椎体中部高度 (°)	
		术前	术后 3 d	术前	术后 3 d
PKP 组	32	16.14±2.77	20.17±2.09	15.05±2.73	18.71±2.12
网袋组	95	16.90±2.57	19.54±2.36	15.95±2.59	18.16±2.65
t 值	-	1.376	-1.429	1.639	-1.192
P 值	-	0.171	0.156	0.104	0.236

加持久,甚至出现神经症状。并且病椎愈合差,形成假关节,造成脊柱不稳,更加严重影响患者生活,不利于患者的康复和生存。因而有学者采用椎弓根钉棒内固定系统治疗 OVCF,能恢复椎体高度,纠正脊柱畸形,具有较强的稳定性,提高脊柱的承载力。但 OVCF 患者本身存在骨质疏松,椎弓根螺钉固定的牢固程度与患者的骨密度呈负性相关性,脊柱承载负荷和活动范围较大,使钉棒内固定的强度和把持力减弱,容易出现椎弓根螺钉的松动和脱出,并且钉棒内固定系统的手术创伤大,时间长,相对老年人风险较大,因此目前临床对于椎弓根钉棒内固定系统的选择都比较慎重^[6-7]。近年来随着脊柱外科微创技术的发展,经皮椎体成形术(PVP)和椎体后凸成形术(PKP)逐渐成为世界公认的能够有效治疗 OVCF 的微创治疗方法,这两种方法能够恢复椎体高度,有明确的止痛效果,远期能够预防骨折塌陷,避免了长期卧床,实现了早期下地负重活动,从而改善了患者生存质量,减少了骨折相关并发症的发生^[8]。

3.2 骨水泥渗漏的因素分析

PVP 是将骨水泥直接注入弥散在椎体内,使骨水泥块与骨小梁嵌插交错从而加强椎体刚度,但不能很好地恢复椎体高度和椎体压缩前的排列及分散负荷能力,而且注射骨水泥时灌注压力大,容易发生渗漏或进入周围组织或血管,造成栓塞等并发症。PKP 是改良的 PVP,通过球囊扩张后注入骨水泥,不

但可以恢复椎体刚度和强度,还能够使椎体复位并形成空腔,利于灌注骨水泥,使椎体高度恢复、相对减少渗漏,但球囊扩张撑开椎体和骨水泥灌注是分步进行,而含空腔的椎体力学性能较差,球囊抽出时易出现椎体“回弹”,可能再次丢失椎体高度,并且大量临床病例报道仍有较高的渗漏率(8%~40%)等并发症^[9-11]。其中骨水泥渗漏是最常见的并发症,其发生渗漏的主要因素大致包括:(1)伤椎因素。伤椎皮质破损明显,压缩爆裂性骨折存在,椎体血管沟更是血管性渗漏的解剖基础。(2)穿刺扩张技术。穿刺点的选择不当,多次反复穿刺破坏椎体结构,球囊扩张过度再次损伤椎体均能够造成医源性渗漏。(3)骨水泥因素。合适黏度的骨水泥在拉丝期时机、注射骨水泥的量、压力及速度把握不当均能造成渗漏的发生^[12-13]。因此减少骨水泥的渗漏是脊柱微创治疗 OVCF 需要解决的重要临床问题。

3.3 骨填充网袋技术的原理及应用

为了弥补 PKP 的缺陷临床开发了能够放置于椎体内的骨填充网袋,它是由聚对苯二甲酸乙二醇酯(PET)材料制成,不影响细胞,具有良好的生物相容性,能够通过网孔分次缓慢弥散至椎体骨小梁间隙,形成骨水泥与骨组织的绞索结合,能够稳定弥散形态,有效控制骨水泥渗漏,并且骨水泥逐渐填充网袋使之膨胀,能够逐步抬高终板,并直接留置椎体内,骨水泥与椎体高度恢复是同步进行,不会出现“回弹”现象,从而改善椎体高度^[14-16]。笔者亦采用骨填充网袋椎体成形术治疗骨质疏松性椎体骨折,结果显示:具有与椎体后凸成形术相同的临床疗效,患者疼痛均得到明显缓解,椎体前缘、中部高度明显恢复,改善了腰部功能,X 线显示骨水泥均成团块状或少量弥散状分布,并且椎体骨水泥渗漏率极低,提高了安全性。笔者认为采用骨填充网袋椎体成形术治疗 OVCF 具有疗效肯定、创伤小、手术时间短、易耐受、容易操作、极低的渗漏率等优势,值得临床应用。

当然笔者在应用骨填充网袋椎体成形术的临床

观察中也注意到骨填充网袋一些问题,如骨水泥仅在骨填充网袋周围渗透,无法弥漫到椎体周围皮质,总体弥散效果欠佳,骨水泥的填充量有限,部分椎体高度恢复不理想等,值得临床应用时引起重视并进行总结改进,以便更好的提高临床疗效。

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