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不同黏度骨水泥治疗骨质疏松性椎体压缩性骨折疗效比较 *

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摘要 目的:探讨不同黏度骨水泥治疗骨质疏松性椎体压缩性骨折的临床疗效。**方法:**选择2016年1月~2018年6月滁州市第一人民医院收治的骨质疏松性椎体压缩性骨折患者90例,按照随机数字表法分为高黏度组42例和低黏度组48例,分别采用高黏度骨水泥经皮椎体后凸成形术和低黏度骨水泥经皮椎体后凸成形术治疗。比较两组单个椎体手术时间、骨水泥注入量、骨水泥渗漏发生情况。所有患者术后随访3个月,比较两组术前、术后3个月疼痛数字评分量表(NRS)评分、Oswestry功能(ODI)评分、椎体中间高度和Cobb角变化。**结果:**高黏度组单个椎体手术时间少于低黏度组($P<0.05$),两组骨水泥注入量、骨水泥弥散体积比较无统计学差异($P>0.05$)。高黏度组骨水泥总渗漏率低于低黏度组($P<0.05$)。两组患者术前NRS评分、ODI评分、椎体中间高度和Cobb角比较差异无统计学意义($P>0.05$);术后3个月两组NRS评分、ODI评分和Cobb角较术前降低,椎体中间高度较术前升高,且高黏度组NRS评分、ODI评分和Cobb角低于低黏度组,椎体中间高度高于低黏度组($P<0.05$)。**结论:**高黏度骨水泥经皮椎体后凸成形术治疗骨质疏松性椎体压缩性骨折的疗效较黏度骨水泥更佳,术后总渗漏率更低,脊柱畸形矫正、脊柱功能恢复更佳,同时疼痛也明显降低,适于临床推广。

关键词:经皮椎体后凸成形术;骨质疏松椎体压缩性骨折;高黏度骨水泥;低黏度骨水泥;疗效;比较

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Comparison of Different Viscosity Bone Cement in the Treatment of Osteoporotic Vertebral Compression*

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ABSTRACT Objective: To explore the clinical effect of different viscosities bone cement in the treatment of osteoporotic vertebral compression fractures. **Methods:** 90 patients with osteoporotic vertebral compression fractures who were treated in The First People's Hospital of Chuzhou from January 2016 to June 2018 were selected, they were divided into high viscosity group (42 cases) and low viscosity group (48 cases) according to the method of digital random table. Percutaneous kyphoplasty with high-viscosity bone cement and percutaneous kyphoplasty with low-viscosity bone cement were used respectively. The operation time, cement injection volume and bone cement leakage of two groups were compared. All patients were followed up for 3 months. The changes of NRS score, Oswestry function (ODI) score, vertebral height and Cobb angle before and after operation were compared between the two groups. **Results:** The operation time of single vertebral body in the high viscosity group was less than that in the low viscosity group ($P<0.05$). There was no significant difference between the two groups in the bone cement injection volume and the bone cement dispersion volume ($P>0.05$). The total bone cement leakage rate of high viscosity group was significantly lower than that of low viscosity group, there were statistical differences between the two groups ($P<0.05$). There were no significant differences in preoperative NRS score, ODI score, intervertebral height and Cobb angle between the two groups ($P>0.05$). The NRS score, ODI score and Cobb angle of the two groups at 3 months after operation were lower than those before operation, the intervertebral height was higher than that before operation. The NRS score, ODI score and Cobb angle of the high viscosity group were lower than those of the low viscosity group, The intervertebral height was higher than that of low viscosity group ($P<0.05$). **Conclusion:** Percutaneous kyphoplasty with high-viscous bone cement is better than percutaneous kyphoplasty with low-viscous bone cement. The total leakage rate is lower, spinal deformity correction and spinal function recovery is better, while the pain is also significantly reduced, which is suitable for clinical promotion.

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前言

近年来,随着我国社会人口老龄化进程的加剧,我国骨质疏松性椎体压缩性骨折的发生率显著升高。骨质疏松性椎体压缩性骨折可以引起持续性的胸腰背疼痛、脊柱畸形及功能障碍,不仅影响患者脊柱功能,还会对患者生活质量造成巨大影响,严重者可能因椎体塌陷而使患者发生生命危险^[1]。经皮椎体后凸成形术是一种微创手术方法,具有治疗时间短、对患者创伤小、患者术后恢复快等优点,已成为临床上治疗骨质疏松性椎体压缩性骨折的重要方法^[2]。经皮椎体后凸成形术需要应用骨水泥进行填充,比较常用的是 Confidence 高黏度骨水泥和 PMMA 低黏度骨水泥^[3]。已有研究表明,两种黏度的骨水泥在缓解患者腰背疼痛、修复压缩椎体中间高度等方面均具有很好的治疗效果^[4,5],但目前仍缺乏对两种黏度的骨水泥用于治疗骨质疏松性椎体压缩性骨折的系统评价。鉴于此,本研究对我院收治的骨质疏松性椎体压缩性骨折患者进行了随机对照研究,观察并对比两种方法的应用效果,旨在为骨质疏松性椎体压缩性骨折的治疗方案的选择提供依据,现报道如下。

1 资料与方法

1.1 临床资料

选择 2016 年 1 月~2018 年 6 月滁州市第一人民医院收治的骨质疏松性椎体压缩性骨折患者 90 例,纳入标准:(1)所有患者均符合中华医学会骨科学分会制定的《中国骨质疏松性骨折诊疗指南》中骨质疏松性椎体压缩性骨折的诊断标准^[6],并经影像学检查确诊;(2)病程 <14 d 的新鲜骨折患者;(3)经骨密度测量仪检测骨密度 ≤ 2.5 SD;(4)患者及家属对研究内容知情同意,并签署同意书。排除标准:(1)合并神经功能障碍者;(2)合并椎体或椎间隙感染者;(3)合并肝、肾等脏器功能障碍者;(4)长期服用激素类药物者;(5)合并精神系统疾病及认知功能障碍者。按照随机数字表法将患者分为高黏度组(应用 Confidence 高黏度骨水泥填充)42 例和低黏度组 48 例(应用 PMMA 低黏度骨水泥填充)。高黏度组:男 14 例,女 28 例;年龄 55~78 岁,平均 (65.34 ± 6.74) 岁;病程 1 d~12 d,平均 (8.23 ± 2.53) d。低黏度组:男 15 例,女 33 例;年龄 56~77 岁,平均 (66.42 ± 6.23) 岁;病程 1 d~13 d,平均 (8.17 ± 2.58) d。两组性别、年龄、病程比较差异无统计学意义($P>0.05$),具有可比性,本研究经医院伦理委员会同意。

1.2 手术方法

1.2.1 高黏度组 采用高黏度骨水泥经皮椎体后凸成形术治疗,患者取仰卧位,在髂前上棘及肩部各垫一个软垫,使胸腰椎处于过伸状态,在 C 型臂 X 线机下确认骨折椎体,常规皮肤消毒,应用 1%利多卡因局部麻醉。选择骨折椎体的椎弓根外上侧部位作为进针点,套管进针,在 C 型臂 X 线机下确认穿刺针部位,当穿刺针位于椎弓根的外侧壁、中线处和内侧缘时提示进针方向正确,并继续钻入,进入椎体 2 mm 左右时拔出针芯,取

出穿刺套管,更换工作通道,应用手钻扩张周围组织,放置球囊,同时应用注射器向球囊内注入对比剂,观察压力变化和椎体中间高度恢复情况,向压力泵内充填 0.9%氯化钠溶液,并连接好,然后用骨水泥搅拌器将调制好的 Confidence 高黏度骨水泥注入充填器,将骨水泥充填器拧紧,当骨水泥处于拉丝期时在 C 型臂 X 线机下将骨水泥注入伤椎内,至骨水泥要超过椎体边缘时停止加压,严密观察是否有骨水泥渗漏,当骨水泥即将凝固时术者缓慢旋转穿刺针,然后等待骨水泥完全凝固,拔出穿刺针,进行加压止血并包扎伤口。

1.2.2 低黏度组 采用低黏度骨水泥经皮椎体后凸成形术治疗,手术准备、麻醉方法同高黏度组。在 C 型臂 X 线机下确认穿刺针部位,经皮穿刺,沿着椎弓根进入伤椎,进入椎体 2 mm 左右时拔出针芯,取出穿刺套管,更换工作通道,应用手钻扩张周围组织,放置球囊,同时应用注射器向球囊内注入对比剂,观察压力变化和椎体中间高度恢复情况,并将调试好的 PMMA 低黏度骨水泥推入充填器,在 C 型臂 X 线机下将骨水泥注入伤椎内,一旦发生渗漏应立即停止注入,然后改变穿刺针方向继续推注,直至骨水泥沿着骨小梁间隙浸润,C 型臂 X 线机显示骨皮质呈现毛刺状为止,拔出穿刺针,进行加压止血并包扎伤口。

1.3 观察指标

(1)比较两组单个椎体手术时间、骨水泥注入量、骨水泥弥散体积、骨水泥渗漏情况。骨水泥弥散体积的计算方法为^[7]:在 64 排螺旋 CT 下获得 0.25 mm 图像,按照全部体层图像勾画出弥散边界,计算弥散面积,将弥散面积乘以层高可得骨水泥弥散体积。(2)所有患者术后随访 3 个月,比较两组患者术前、术后 3 个月疼痛数字评分量表(Numeric Pain Rating Scale, NRS),NRS 评分用 0~10 分来描述疼痛强度,0 分为无痛,10 分为剧烈疼痛,评分越高说明疼痛情况越剧烈^[8]。(3)比较两组患者术前、术后 3 个月 Oswestry 功能评分(Oswestry disability index, ODI),该 ODI 评分包括步行、站立位、坐立位、睡眠、提物、自理能力、性生活、社会活动、旅游、疼痛等 10 项内容,每项内容有 6 个选项,每项分值为 0~5 分,最高评分为 50 分,评分越高表明功能障碍越严重^[9]。(4)比较两组患者术前、术后 3 个月椎体中间高度和 Cobb 角变化,分别于术前、术后 3 个月进行 X 线检查,在侧位 X 线片上测量椎体中间高度和 Cobb 角。

1.4 统计学处理

采用 SPSS 20.0 软件对数据进行统计处理,采用 $n(\%)$ 表示计数资料,行 χ^2 检验;采用 $(\bar{x} \pm s)$ 表示计量资料,行 t 检验; $P<0.05$ 为差异具有统计学意义。

2 结果

2.1 两组手术时间、骨水泥注入量、弥散体积比较

高黏度组单个椎体手术时间少于低黏度组($P<0.05$),两组骨水泥注入量、骨水泥弥散体积比较无统计学差异($P>0.05$),见表 1。

表 1 两组单个椎体手术时间、骨水泥注入量、骨水泥弥散体积比较($\bar{x} \pm s$)Table 1 Comparison of operative time, bone cement injection volume and bone cement dispersion volume of two groups of single vertebrae($\bar{x} \pm s$)

Groups	n	Operation time of single vertebral body(min)	Bone cement injection volume (mL)	Bone cement dispersion volume(cm^3)
High viscosity group	42	30.23 $\pm$ 3.78	2.71 $\pm$ 0.75	8.73 $\pm$ 0.93
Low viscosity group	48	43.78 $\pm$ 3.67	2.63 $\pm$ 0.78	8.84 $\pm$ 0.88
t		3.428	1.034	0.463
P		0.035	0.098	0.832

2.2 两组术后骨水泥渗漏情况比较

统计学差异($P < 0.05$), 见表 2。

高黏度组骨水泥总渗漏率低于低黏度组, 两组数据比较有

表 2 两组术后骨水泥渗漏情况比较[n(%)]

Table 2 Comparison of postoperative cement leakage between the two groups [n(%)]

Groups	n	Intraspinal leakage	Leakage of intervertebral space	Paravertebral leakage	Peripheral vascular leakage	Total leakage
High viscosity group	42	0(0.00)	1(2.38)	1(2.38)	0(0.00)	2(4.76)
Low viscosity group	48	1(2.08)	3(6.25)	5(10.42)	2(4.17)	11(22.92)
χ^2						5.974
P						0.015

2.3 两组术前、术后 3 个月 NRS、ODI、椎体中间高度和 Cobb 角比较

NRS 评分、ODI 评分和 Cobb 角较术前降低, 椎体中间高度较术前升高, 且高黏度组 NRS 评分、ODI 评分和 Cobb 角低于低黏度组, 椎体中间高度高于低黏度组($P < 0.05$)。见表 3。术前, 两组患者 NRS 评分、ODI 评分、椎体中间高度和 Cobb 角比较差异无统计学意义 ($P > 0.05$); 术后 3 个月两组表 3 两组术前、术后 3 个月 NRS、ODI、椎体中间高度和 Cobb 角比较($\bar{x} \pm s$)Table 3 Comparison of NRS, ODI, intervertebral height and Cobb angle between the two groups before operation and 3 months after operation($\bar{x} \pm s$)

Groups	NRS(scores)		ODI(scores)		Intervertebral height(mm)		Cobb angle($^{\circ}$)	
	Before operation	3 months after operation	Before operation	3 months after operation	Before operation	3 months after operation	Before operation	3 months after operation
High viscosity group(n=42)	6.54 $\pm$ 2.25	2.06 $\pm$ 0.54*	34.54 $\pm$ 3.45	14.35 $\pm$ 3.63*	18.56 $\pm$ 3.24	24.25 $\pm$ 3.64*	23.24 $\pm$ 3.54	11.54 $\pm$ 2.43*
Low viscosity group(n=48)	6.48 $\pm$ 2.28	4.35 $\pm$ 0.65*	34.78 $\pm$ 3.52	23.64 $\pm$ 4.25*	18.24 $\pm$ 3.55	20.12 $\pm$ 3.24*	23.53 $\pm$ 3.65	17.54 $\pm$ 2.26*
t	0.135	2.667	0.142	2.672	0.128	2.682	0.122	2.654
P	0.825	0.034	0.802	0.033	0.921	0.032	0.932	0.035

Note: compared with before operation, * $P < 0.05$.

3 讨论

骨质疏松症是一组以骨组织中无机盐成分减少, 骨脆性增加为主要病理特征的病变, 具有较高的发病率和患病率^[10,11]。有报道显示, 全球约有 2 亿人患有骨质疏松症, 发病率居全部疾病的第 7 位^[12]。目前我国骨质疏松症患病率约为 7.2%~9.6%, 严重影响人们健康^[13,14]。骨质疏松症可降低椎体力学强度, 易诱发椎体压缩性骨折, 患者表现为剧烈的腰背疼痛、腰椎后凸畸形, 从而导致生活质量下降甚至影响其自理能力。经皮椎体后凸成形术是经皮椎体成形术的改良术式, 该术式通过扩张的球囊撑开伤椎内被压缩的骨组织, 使之形成相对“真空”的腔隙,

并向伤椎腔隙内注入骨水泥, 从而有效的恢复椎体中间高度, 矫正脊柱后凸畸形^[15]。有报道显示, 相对与传统的经皮椎体成形术, 经皮椎体后凸成形术注入骨水泥更加安全、简便, 保证了椎体复位的有效性^[16]。Confidence 高黏度骨水泥和 PMMA 低黏度骨水泥是目前经皮椎体后凸成形术中常用的两种骨水泥, 两种骨水泥的物理特性存在较大区别。由于高黏度骨水泥在我国的应用时间较短, 因此目前国内对不同黏度骨水泥弥散程度差异、注入体积、对椎体中间高度恢复等研究仍较少, 比较不同黏度骨水泥治疗骨质疏松性椎体压缩性骨折的疗效对于指导临床治疗具有重要意义。

本研究对我院收治的 90 例骨质疏松性椎体压缩性骨折患

者进行随机对照研究,结果显示,高黏度组单个椎体手术时间少于低黏度组,两组骨水泥注入量、骨水泥弥散体积比较无统计学差异,与刘洋等和黄晓楠等报道相符^[17,18]。分析原因主要是由于高粘度骨水泥具有瞬间高粘度、聚合温度低的特点,且不会增加手术操作难度、骨水泥注入量,因此单个椎体手术时间少。本研究结果还显示,高黏度组骨水泥总渗漏率低于低黏度组。在经皮椎体后凸成形术治疗中可能出现骨水泥渗漏,从而将导致患者神经根、血管损伤,甚至肺栓塞,进而导致治疗失败。影响骨水泥渗漏的主要因素包括:骨折特点、穿刺技术和骨水泥的特性等^[19-21]。有学者研究发现,当骨水泥混合后呈面团状的高黏度状态可以大大降低骨水泥的渗漏量,由于高粘度骨水泥没有湿砂期和粘丝期,聚合温度只有 55℃,因此大大降低了渗漏率,同时也提高了手术的安全性^[22-24]。本研究结果显示,术后 3 个月两组 NRS 评分、ODI 评分和 Cobb 角较术前降低,椎体中间高度较术前升高,且高黏度组 NRS 评分、ODI 评分和 Cobb 角低于低粘度组,椎体中间高度高于低粘度组,提示高黏度组患者术后椎体中间高度恢复更好,脊柱畸形矫正、脊柱功能恢复更佳,同时疼痛也明显降低。分析其原因主要是:(1)高黏度骨水泥凝固温度较低粘度水泥低,在注射过程中对周围组织损伤较小,因此患者术后恢复更佳^[25,26];(2)高黏度骨水泥降低了术后渗漏率,手术后患者恢复更好^[27,28];(3)高黏度骨水泥在椎体内分布更加均匀,因此能够提供更好的生物力学强度,术后椎体负载能力更大^[29,30]。同时本研究也存在样本数量较少,随访时间仍较短的缺点,今后有待于进一步扩大样本量、延长随访时间进行深入研究。

综上所述,高黏度骨水泥具有瞬间高粘度、聚合温度低、可注射时间长等优点,单个椎体手术时间较低黏度骨水泥少,总渗漏率低于低黏度骨水泥,术后患者椎体中间高度恢复更好,脊柱畸形矫正及脊柱功能恢复更佳,同时患者疼痛也明显降低,适于临床推广。

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