

· 临床研究 ·

CPC/PMMA 复合骨水泥在老年椎体后凸成形术中的初步应用研究

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【摘要】 目的:从临床应用角度分析磷酸钙骨水泥(calcium phosphate bone cement,CPC)/聚甲基丙烯酸甲酯(polymethyl methacrylate,PMMA)骨水泥在老年骨质疏松性胸腰椎骨折患者椎体后凸成形术(percutaneous kyphoplasty,PKP)治疗中的有效性及可靠性。方法:对2016年2月至2016年12月收治的单椎体胸腰段骨质疏松性压缩骨折接受PKP手术且骨密度 ≤ -3.0 SD的62例患者进行回顾性分析,其中CPC/PMMA复合骨水泥组23例,年龄为(77.6 \pm 2.2)岁,PMMA骨水泥组39例,年龄为(77.1 \pm 1.1)岁。比较两组患者手术前后疼痛、椎体前缘高度比、局部Cobb角变化、术中骨水泥渗漏及术后邻椎骨折发生情况。结果:两组患者性别、年龄、随访时间以及术前疼痛、椎体前缘高度比、局部Cobb角等基本情况差异无统计学意义($P>0.05$)。术后1d两组患者的疼痛、椎体前缘高度比、局部Cobb角均有所改善($P<0.05$),术后1d及末次随访疼痛、椎体前缘高度比、局部Cobb角组间比较差异无统计学意义($P>0.05$),同时新发邻椎骨折、骨水泥渗漏情况组间比较差异也无统计学意义($P>0.05$)。两组患者术后随访疼痛均有持续改善($P<0.05$),局部Cobb角略有增加($P<0.05$);椎体前缘高度比略有下降($P<0.05$)。随访X线片或CT影像资料无法证实CPC降解及新骨形成长入。结论:CPC/PMMA复合骨水泥用于PKP治疗老年骨质疏松性胸腰椎压缩骨折安全可靠,可以有效缓解疼痛,维持椎体稳定,和PMMA骨水泥疗效相当。但目前尚无直接临床证据支持CPC/PMMA复合骨水泥可降低邻椎骨折发生率以及CPC降解、新骨长入骨水泥中,需要进一步研究。

【关键词】 骨质疏松性椎体压缩骨折; 椎体后凸成形术; 聚甲基丙烯酸甲酯; 磷酸钙骨水泥
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Preliminary application of CPC/PMMA composite bone cement in kyphoplasty for the elderly DENG Xuan-geng, XIONG Xiao-ming, CUI Wei, GU Tao, WAN Dun, SHI Hua-gang, CHEN Xing, SONG Si-mao, HOU Wei, MEI Guo-long, and JIANG Wen-bing. Department of Spine, Sichuan Orthopedic Hospital, Chengdu 610041, Sichuan, China

ABSTRACT Objective: From the perspective of clinical application to analyze the effectiveness and reliability of CPC/PMMA bone cement in percutaneous kyphoplasty (PKP) for the treatment of elderly patients with osteoporotic thoracolumbar fractures. **Methods:** A retrospective analysis was performed on 62 patients with osteoporotic compression fracture of single-vertebral thoracic or lumbar segment who underwent PKP surgery and had a bone density less than or equal to -3.0 SD from February 2016 to December 2016. Among them, 23 patients were in CPC/PMMA group, with an average age of (77.6 \pm 2.2) years old, 39 patients in PMMA group, with an average age of (77.1 \pm 1.1) years old. The indexes between two groups were compared, including the visual analogue scale (VAS), height ratio of anterior vertebra (AVHR), local Cobb angle, cement leakage, new adjacent vertebral fracture (NAVF). **Results:** There were no significant difference in gender, age, follow-up time and preoperative VAS, AVHR, local Cobb angle between two groups ($P>0.05$), at the 1 day after operation, VAS, AVHR, local Cobb angle in all patients got obvious improvement ($P<0.05$), which was no significant difference at 1 day after operation and final follow-up ($P>0.05$). At the same time, there was no statistically significant difference in the incidence of new adjacent vertebral fracture and cement leakage ($P>0.05$). The pain in both groups continued to improve at follow-up after operation ($P<0.05$), the local Cobb angle increased ($P<0.05$) and AVHR decreased slightly ($P<0.05$). However, the images of conventional methods (X-ray or CT) could not find signs about CPC degeneration and new bone ingrowth. **Conclusion:** CPC/PMMA composite bone cement is safe and reliable in PKP for treatment of elderly patients with osteoporotic thoracolumbar fractures, which can effectively relieve pain and maintain vertebral body stability. It has the same curative effect as PMMA bone cement. It was worthy to re-

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search more in future, although no direct evidences support the CPC/PMMA composite bone cement can reduce the incidence of adjacent vertebral fracture, CPC degeneration or new bone ingrowth.

KEYWORDS Osteoporotic vertebral compression fractures; Percutaneous kyphoplasty; Polymethyl methacrylate; Calcium phosphate

经皮椎体成形(percutaneous vertebroplasty, PVP)和经皮后凸成形术(percutaneous kyphoplasty, PKP)的椎体强化术是目前治疗骨质疏松性椎体压缩骨折(osteoporotic vertebral compression fractures, OVCFs)的手段之一,尽管有争议^[1-2],但因其快捷、微创的特点且早期临床效果显著,已于国内外广泛开展。聚甲基丙烯酸甲酯(polymethyl methacrylate, PMMA)骨水泥应用最广,但其却具有无生物活性、弹性模量高等缺点;磷酸钙骨水泥(calcium phosphate cement, CPC)具有一定的强度,降解速度适中,但固化后椎体支撑能力仍有不足,主要用于非负重区骨填充。二者均非临床理想的骨水泥。实验表明 PMMA/CPC 两种材料按一定比例混合调配的骨水泥可以结合二者的优点,理论上改变了单一材料骨水泥的生物及力学性能,具有两种材料的优点,是临床具有应用潜力的填充材料^[3]。目前尚无 CPC/PMMA 复合骨水泥的临床应用报道,现对 2016 年 2 月至 2016 年 12 月收治的骨质疏松性压缩骨折接受 PKP 手术患者的临床资料进行回顾性分析,将有关复合骨水泥临床初期应用情况报告如下。

1 资料与方法

1.1 病例选择

纳入标准:知情同意选择 PKP(应用 PMMA 或 CPC/PMMA 骨水泥)的胸腰椎骨折病例;骨密度检查 T 值 ≤ -3.0 SD,骨折位于胸腰段(T₁₀-L₂)单椎体骨折;年龄 ≥ 75 岁。排除标准:新发多椎体骨折;随访时间 < 1 年;合并其他严重疾病,影响疗效判断。

1.2 一般资料

将符合上述病例选择标准的患者,根据骨水泥应用不同分为 PMMA 组和 CPC/PMMA 组。其中 CPC/PMMA 组符合纳入标准 30 例,排除 7 例(随访时间不足),共纳入 23 例,男 6 例,女 17 例,年龄 75~84(77.6 \pm 2.2)岁;PMMA 组符合纳入标准 54 例,排除 15 例(随访时间不足 14 例,1 例因病去世),实际纳入病例 39 例,男 11 例,女 28 例;年龄 75~83(77.1 \pm 1.1)岁。两组患者一般资料比较差异无统计学意义,见表 1。

1.3 治疗方法

所有患者采用 PKP 手术治疗,全麻俯卧位,单侧或双侧穿刺,具体手术穿刺方法同文献[4]。两组均在牙膏期推注骨水泥,骨水泥弥散至椎体后 1/3 时,或渗漏至椎管,或较多量椎体外渗漏时停止注射,待

体外剩余骨水泥发热后拔出穿刺针(CPC/PMMA 复合骨水泥等待时间较 PMMA 骨水泥约长 7 min),敷料压迫穿刺口止血后覆盖保护,术后 4 h 后佩戴腰围起床活动,并继续或开始骨质疏松治疗,方案同国内指南^[5]。两组典型病例影像学资料见图 1-2。

PMMA/CPC 配置方法:PMMA(Heraeus Sostopalv, 德国)、CPC(可注射型磷酸钙人工骨,上海瑞邦)干粉各 5 g 混匀,以 PMMA 液相调配成稀糊状,推入推注杆中备用。

1.4 观察项目与方法

1.4.1 一般情况观察 包括年龄、性别、随访时间。

1.4.2 影像学观察 术前、术后 1 d、末次随访时 X 线片测量局部 Cobb 角,椎体前缘高度比(height ratio of anterior vertebra, AVHR),术后 1 d 以 X 线片或 CT 片观察骨水泥渗漏情况,随访期间摄 X 线片(必要时 MRI 检查)观察邻椎新发骨折(new adjacent vertebral fractures, NAVF)。其中局部 Cobb 为伤椎上位椎上终板与下位椎下终板夹角。AVHR 按 INFINITT 系统测量值: $2 \times$ 伤椎高度/(上邻椎高度+下邻椎高度)。NAVF 通过相邻上下椎楔形改变或 MRI 椎体信号改变判断。骨水泥渗漏经 X 线或 CT 片上骨水泥弥散范围超出椎体边界为标准。

1.4.3 临床症状观察 术前、术后 1 d、末次随访时采用疼痛视觉模拟评分(visual analogue scale, VAS)对临床症状进行评定。

1.5 统计学处理

采用 SPSS 22.0 统计软件进行数据分析,年龄、VAS 评分、局部 Cobb 角、AVHR 等定量资料如满足正态分布或近似正态分布,组间比较采用两组间独立样本 *t* 检验;如不符合正态分布,组间比较采用非参数检验。性别、NAVF 等定性资料比较采用非参数检验。各组内 VAS 评分、局部 Cobb 角、AVHR 不同时间点间比较采用重复测量检验,组内两两间比较采用配对 *t* 检验。以 $P < 0.05$ 为差异有统计学意义。

2 结果

两组患者性别、年龄、NAVF、骨水泥渗漏、随访时间及 VAS 评分、局部 Cobb 角、AVHR 差异无统计学意义($P > 0.05$)。见表 1-2。术后及末次随访时患者 VAS 评分、AVHR 及局部 Cobb 角较术前均有改善,且改善与组别因素无关($F = 0.617, P = 0.438; F = 0.427, P = 0.579; F = 0.918, P = 0.371$)。

两组患者术后疼痛均缓解,术后 1 d 至末次随

访时疼痛有持续改善($t=2.729, P=0.012; t=2.806 P=0.008$), 组间差异无统计学意义(表 1)。

术后 1 d 两组病例均行 X 线及 CT 检查, 骨水泥渗漏 PMMA 组有 19 例(椎管内 3 例), 而 CPC/PMMA 组有 11 例(椎管内 2 例), 椎管内渗漏均为少量且沿后纵韧带分布, 所有渗漏病例无相应症状。术后 CT 横断面两组均可见骨水泥周边出现骨-水泥间隙(图 1e, 2e 箭头所示), 其中 PMMA 病例尤为明显。末次随访均行 X 线检查, CPC/PMMA 组行 CT 检查 16 例, PMMA 组 10 例。两组患者末次随访 X 线片未见术椎及骨水泥形态、分布变化。行 CT 检查的 CPC/PMMA 病例骨-水泥间隙模糊或消失(图 1g), PMMA 病例仍清晰可见骨-水泥间隙(图 2g)。

随访期内邻椎骨折 PMMA 组 4 例(再手术 2 例), CPC/PMMA 组 1 例(非手术治疗)。局部 Cobb 角随访期内略有增加($t=-6.992, P=0.000; t=-7.206, P=0.000$), 末次随访虽然与术前差异有统计学意义($t=6.163, P=0.000; t=9.323, P=0.000$), 但却有接近术前 Cobb 角的趋势。术椎高度末次随访较术后有下降($t=2.397, P=0.025; t=6.278, P=0.000$), 当仍较术前有改善($t=-3.274, P=0.003; t=-5.876, P=0.000$)。

3 讨论

3.1 CPC/PMMA 复合骨水泥临床应用的可能性

目前椎体强化术中最常用的骨水泥为 PMMA, 聚合固化时间短, 粘度高, 支撑强度大, 价格便宜, 可以满足早期止痛和起床活动的临床要求。但由于 PMMA 弹性模量远大于椎体骨, 可对周围骨组织形成应力遮挡, 诱发骨组织吸收; 聚合过程中局部温度

可达 44~113 °C^[3,6], 可能使周围骨细胞及微血管破坏; PMMA 材料还可促进破骨细胞活性及成骨细胞凋亡^[7], 注射后在体内呈收缩态^[8], 可能出现界面松动, 导致椎体内稳定性下降, 增大术椎再骨折风险^[9]。另一方面术椎强化后弹性模量较大幅度增高, 从而增大了相邻椎体应力, 增加了邻椎骨折发生的概率。因此降低弹性模量将更有利于疗效的持久^[10-11]。

而 CPC 具有可生物降解替代、弹性模量接近正常松质骨的优点, 研究也证实椎体强化术后 PMMA 与椎体骨质之间的结合是单纯的机械连接, 而 CPC 与骨小梁是直接生物连接^[12], 且即便是椎间盘内渗漏, CPC 较 PMMA 对间盘退变影响也相对较小^[13]。但部分实验性临床研究表明 CPC 为填充材料的 PVP 或 PKP 可以有效缓解患者疼痛, 但存在的问题是术后卧床时间较长(CPC 固化时间为 3~7 d), 随访期间椎体高度多数丢失或继发塌陷^[14-15], 因此临床并未得到广泛应用。这可能与椎体内为富血环境, CPC 固化过程中血液的沾染导致 CPC 晶体崩解及固化不全有关^[16]。

实验证实 CPC/PMMA 按一定比例混合使用, 不产生新物质, 细胞及动物实验安全性好; 1:1 比例复合骨水泥抗压强度约 40 MPa(约为 PMMA 水泥的 1/2), 抗折强度约 32 MPa(低于 PMMA 的 70 MPa), 弹性模量更接近于人体骨, 且凝固温度约为 48 °C(远低于 PMMA 的 78 °C), 对周围骨组织的影响相对较小; 且 CPC 随时间推移在体内可逐步降解, 新骨逐渐长入骨水泥内^[3], 更有利于骨水泥-骨界面结构的稳定性, 同时降低了术椎的弹性模量, 有助于远期疗

表 1 两组骨质疏松性椎体压缩骨折患者一般资料比较

Tab.1 Comparison of general data of patients with OVCFs between two groups

组别	例数	性别(例)		年龄 ($\bar{x}\pm s$, 岁)	邻椎新发骨折 (例)	骨水泥渗漏 (例)	随访时间 ($\bar{x}\pm s$, 月)
		男	女				
CPC/PMMA 组	23	6	17	77.6±2.2	1	11	15.4±3.6
PMMA 组	39	11	28	77.1±1.1	4	19	14.1±2.2
检验值		$\chi^2=-0.793$		$t=-1.067$	$\chi^2=-0.819$	$\chi^2=-0.067$	$t=1.357$
P 值		0.858		0.286	0.413	0.946	0.175

表 2 两组骨质疏松性椎体压缩骨折手术前后 VAS、AVHR、局部 Cobb 角比较($\bar{x}\pm s$)

Tab.2 Comparison of pre- and post-operative VAS, AVHR, local Cobb angle of patients with OVCFs between two groups($\bar{x}\pm s$)

组别	例数	VAS(分)			Cobb 角(°)			椎体前缘高度比(%)		
		术前	术后 1 d	末次随访	术前	术后 1 d	末次随访	术前	术后 1 d	末次随访
CPC/PMMA 组	23	7.1±0.8	1.7±0.8	1.0±0.8	16.7±4.2	11.2±2.6	14.1±2.8	68.2±7.4	72.0±5.9	71.1±5.3
PMMA 组	39	7.2±0.6	1.6±0.7	1.1±0.8	15.7±4.4	10.9±3.0	13.1±3.4	67.3±7.7	71.2±6.8	69.7±6.5
t 值		-1.077	-0.870	-0.081	-0.680	-0.636	-1.412	0.434	0.452	0.858
P 值		0.268	0.384	0.936	0.497	0.525	0.158	0.666	0.653	0.394



图 1 CPC/PMMA 组女性患者,84 岁,扭伤致 T₁₂ 压缩骨折,腰背痛 5 d 入院 **1a,1b,1c**. 术前 X 线、MRI、CT 示 T₁₂ 椎体压缩骨折(箭头所示),椎体高度降低约 1/4,椎体破裂 **1d,1e**. 术后 1 d X 线及 CT 示骨水泥充填大部分椎体,分布较均匀,椎管前壁稍渗漏,但骨水泥边缘可见骨-水泥间隙 **1f,1g**. 术后 29 个月 X 线及 CT,X 线示 T₁₂ 椎高度维持,椎体前缘与上位椎骨桥连接,上下无邻椎骨折;CT 横断面部位与 1e 近似,提示原骨折部已愈合,但骨水泥影像变化不大,骨水泥边缘骨-水泥间隙模糊或消失

Fig.1 An 84-year-old female patient in CPC/PMMA group, sprain resulted back pain for 5 days, was diagnosed T₁₂ compression fracture admission to hospital **1a,1b,1c**. Preoperative X-ray, MRI, CT showed T₁₂ vertebral compression fracture (shown by arrow), the height of the vertebral body was reduced by about 1/4, and the vertebral body ruptured **1d,1e**. On 1 day after operation, X-ray and CT showed that the cement filled most vertebral bodies, and the distribution was relatively uniform, some slightly leaked in anterior wall of the spinal canal, but bone-cement space could be found at the edge of the cement **1f,1g**. X-ray and CT at 29 months after operation, X-ray showed that T₁₂ vertebral height was maintained, the anterior edge of the vertebral body was connected to the superior vertebral bridge, and there was no adjacent vertebral fracture; the CT cross-sectional area was similar to figure 1e, indicated that the original fracture had healed, but the bone cement image did not change much, and the bone-cement space at the edge of the cement was blurred or disappeared

效的稳定且合并症较少。在现有条件下相较于 PMMA 与 CPC, PMMA/CPC 复合骨水泥理论上更适用于骨质疏松性胸腰椎骨折的椎体强化术。

3.2 CPC/PMMA 复合骨水泥的有效性和可靠性

骨疼痛的缓解依赖于骨折端的稳定,椎体强化术的主要机制是骨水泥“黏合”“支撑”骨折椎体获得椎体内稳定从而达到缓解疼痛的目的。理论上复合骨水泥 CPC/PMMA 中 PMMA 具有良好的“支撑”和“黏合”作用,而 CPC 的复合降低了复合骨水泥的弹性模量,同时可以逐步降解,允许骨组织长入 PMMA 内,从而更有效形成骨与骨水泥的“界面交锁”,是相对理想的骨水泥。

本组病例中,CPC/PMMA 复合骨水泥 PKP 术后

可以有效缓解疼痛,一定程度上恢复椎体高度及后凸角,与 PMMA 骨水泥比较临床疗效无差异。术后可完全无痛地早期下床活动,避免了 CPC 骨水泥术后需卧床 3~7 d 的情况,更符合临床要求。因此可以替代 PMMA 骨水泥在椎体强化术中的临床应用。遗憾的是由于 CPC 本身不显影,临床上常规检查(X 线及 CT)难以在后期判断是否存在 CPC 降解和骨长入情况。在临床上 CPC 后期是否降解成骨,实现复合骨水泥与骨间更紧密的连接,可能需要更精准的手段证实。两组病例术后 CT 均可发现骨-水泥间隙,其中 PMMA 组病例尤为明显,这可能为 PMMA 皱缩的结果,但也不排除骨水泥填充不足所致。CPC/PMMA 组部分病例随访 CT 间隙消失,而 PM-



图 2 PMMA 组女性患者,79 岁,滑跌伤致 L₁ 压缩骨折,腰背痛 1 周入院 **2a,2b,2c.** 术前 X 线、MRI、CT 示 L₁ 压缩骨折,椎体高度丢失约 1/4,椎体破裂 **2d,2e.** 术后 1 d X 线及 CT 示骨水泥充填大部骨折部位,主要分布于右侧椎体,骨水泥边缘可见骨-水泥间隙(箭头所示) **2f.** 术后 27 个月 X 线示术椎无塌陷,上下邻椎无塌陷(L₂ 椎体前方高密度影为体外干扰影) **2g.** 术后 27 个月 CT 横断面(与 2e 相似断面)示骨水泥稳定,水泥-骨结合面无明显变化,骨-水泥间隙仍清晰可见(箭头所示)

Fig.2 A 79-year-old female patient in PMMA group, slipping injury resulted back pain for 1 week, was diagnosed L₁ compression fracture admission to hospital **2a, 2b, 2c.** Preoperative X-ray, MRI, CT showed L₁ vertebral compression fracture, the height of the vertebral body was reduced by about 1/4, and the vertebral body ruptured **2d, 2e.** On 1 day after operation, X-ray and CT showed that the cement filled most vertebral bodies, main distribution on the right vertebral body, bone-cement space could be found at the edge of the cement (indicated by arrow) **2f.** No collapse of the operative vertebrae and the upper-lower adjacent vertebrae (the high-density shadow in front of the L₂ vertebral body was an external disturbance shadow) by X-ray at 27 months after operation **2g.** At 27 months after operation, the CT cross-section (similar to 2e) showed that the cement was stable, there was no obvious change in the cement-bone junction, and the bone-cement space was still clearly visible (indicated by arrow)

MA 病例随访 CT 横断面仍然存在骨-水泥间隙,间接证实混合骨水泥术后骨-水泥界面较 PMMA 更为友好,稳定性可能更好,不排除界面有骨组织长入。

复合骨水泥渗漏概率不高于 PMMA 骨水泥,并不额外增加渗漏风险。理论上术椎弹性模量与邻椎差距减小可一定程度上减少邻椎骨折的发生概率。文献报道 PKP 术后椎体继发骨折发病率为 10%~65.7%,主要风险因素还是高龄、低骨密度以及局部力学环境^[17-20]。本组病例选择 75 岁以上,骨密度 ≤ -3.0 SD 的胸腰段骨折病例作为研究对象,希望加大邻椎骨折或术椎塌陷的发现率。PMMA 组新发骨折率接近文献报道,仍在相对较低水平。尽管从发病率看 CPC/PMMA 组似乎再骨折情况略好,但两组差异无统计学意义,未能体现出 CPC/PMMA 可降低邻椎

骨折发生率的理论优势,也可能和病例量较小有关。值得注意的是两组随访期内疼痛的改善与后凸角和椎体高度变化无相关,即无论是否恢复椎体高度以及后凸角,手术均能有效缓解疼痛,与其他文献相似^[21]。两组病例末次随访 Cobb 角虽与术前差异有统计学意义,但和术后 1 d Cobb 角比较,已接近术前 Cobb 角水平。也即是术后 Cobb 角虽有改善,但随时间推移有回归术前水平的趋势,近年文献也有类似报道^[22],同样椎体高度也有相应变化。有限元研究显示成形术后椎体高度的维持有助于减少椎体的应力^[23],适宜的后凸角有利于脊柱力线的恢复,椎体高度与后凸角的恢复应与手术的中远期疗效相关。随时间推移后凸角加大和椎体高度部分再丢失,不排除这是中远期发生邻椎骨折的基础(局部力学环境

改变)。

3.3 本研究缺陷

本研究病例数较少,随访时间较短,末次随访仅部分病例完成 CT 检查,无法完全比较骨-水泥间隙变化情况。而且常规检查手段:X 线、CT 难以获得直接证据来证实 CPC/PMMA 复合骨水泥的理论优势是否成立。尽管实验研究可证实混合骨水泥中 CPC 降解、骨组织长入情况^[24],但临床应用还需要更直接的证据,比如穿刺取样或更为精细的无创检查。

尽管存在一些研究缺陷,初步临床研究表明:和 PMMA 比较,CPC/PMMA 复合骨水泥同样可有效缓解疼痛,维持椎体高度,尽早恢复下床活动,而且调配使用方便,不额外增加手术合并症,临床上可代替 PMMA 骨水泥。但是否具备理论上的优势:保留 PMMA 和 CPC 各自优点并弥补各自材料缺陷,提高中远期疗效,还需要进一步研究。

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