

· 基础研究 ·

椎体后凸成形术中灌注不同凝固状态骨水泥对骨质疏松性椎体压缩性骨折绵羊椎体生物力学的影响

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【摘要】目的 探讨椎体后凸成形术中灌注不同凝固状态骨水泥对骨质疏松性椎体压缩性骨折(OVCF)绵羊椎体强度和刚度的影响。**方法** 选取成年绵羊8只, 获得L₁₋₅椎体40个, 随机分为4组, 每组10个。采用3%稀盐酸浸泡和双侧椎弓根微泵灌注法制作骨质疏松椎体模型, 再将骨质疏松椎体置于衡翼生物力学机上并压缩其高度的1/4制作压缩骨折椎体模型。制备骨水泥灌注通道后, 用球囊经双侧椎弓根复位骨折椎体, 在C形臂X线机透视下, 对照组(A组)不灌注骨水泥, 其余各组分别在聚甲基丙烯酸甲酯(PMMA)骨水泥粉液混合后2 min(骨水泥稀薄期, B组)、4 min(骨水泥黏稠期, C组)、6 min(骨水泥凝固期, D组)灌注骨水泥。室温放置24 h待骨水泥凝固。分别于术前和术后测量各组椎体的强度和刚度。**结果** 术前4组椎体强度和刚度组间比较, 差异均无统计学意义($P>0.05$)。A组术后椎体强度低于术前, B、C、D组术后椎体强度均高于术前, 差异有统计学意义($P<0.05$)。4组术后椎体刚度均低于术前, 差异有统计学意义($P<0.05$)。B、C、D组术后椎体强度和刚度均高于A组, 差异有统计学意义($P<0.05$); B、C组术后椎体强度和刚度均高于D组, 差异有统计学意义($P<0.05$); B组和C组术后椎体强度和刚度差异无统计学意义($P>0.05$)。**结论** OVCF绵羊采用椎体后凸成形术治疗, 注入稀薄期和黏稠期骨水泥的椎体强度和刚度均高于注入凝固期骨水泥的椎体。注入不同凝固状态骨水泥均可增强椎体强度, 但椎体刚度均恢复不到未骨折时期状态。

【关键词】 腰椎; 骨折, 压缩性; 骨质疏松; 椎体后凸成形术; 骨代用品; 绵羊

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Biomechanical effects of different coagulated bone cements on osteoporotic vertebral compression fractures during kyphoplasty in sheep

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【Abstract】Objective To investigate the effect of bone cement in different coagulation states on the vertebral strength and stiffness of sheep with osteoporotic vertebral compression fracture(OVCF) during kyphoplasty. **Methods** Eight adult sheep were selected to obtain L₁₋₅ vertebral bodies. The 40 vertebral bodies were randomly and equally divided into 4 groups. The osteoporotic vertebral body model was made by 3% dilute hydrochloric acid immersion and bilateral pedicle micro-pump perfusion. Then the vertebral bodies were placed on a balanced wing biomechanical machine to compress 1/4 of their height, so as to make a compression fracture vertebral body model. After preparing the bone cement perfusion channel, the fractured vertebral body was reduced by bilateral pedicles with a balloon. Under C-arm roentgenography, the control group(group A) was not infused with bone cement, and the other groups were infused with bone cement 2 min(bone cement in thinning stage, group B), 4 min(bone cement in viscous stage, group C) and 6 min(bone cement in solidification stage, group D) after PMMA bone cement powder and liquid was mixed. The bone cement was set at room temperature for 24 h. The strength and rigidity of the vertebral bodies in the 4 groups were measured before and after operation. **Results** There were no significant differences in the preoperative strength and rigidity of the vertebral bodies

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between the 4 groups ($P > 0.05$). The postoperative vertebral strength of group A was lower than those before operation, and those of groups B, C and D were all higher than that before operation, and the postoperative vertebral stiffness of the 4 groups were all lower than that before operation, all with a statistical significance ($P < 0.05$). The postoperative vertebral strength and stiffness of groups B, C and D were higher than those of group A, all with a statistical significance ($P < 0.05$). The postoperative vertebral strength and stiffness of groups B and C were higher than those of group D, all with a statistical significance ($P < 0.05$). There was no significant difference in vertebral strength and stiffness between group B and group C ($P > 0.05$). **Conclusions** OVCF sheep are treated with kyphoplasty, the vertebral body strength and stiffness of bone cement injected in thinning and viscous stages are higher than those injected in solidification stage. Bone cement injected in different stage could enhance the strength of compressive vertebral body, but the stiffness of vertebral body could not restored to the unfractured state.

【Key Words】 Lumbar vertebrae; Fractures, compression; Osteoporosis; Kyphoplasty; Bone substitutes; Sheep

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随着我国人口老龄化趋势的加剧,骨质疏松性椎体压缩性骨折(OVCF)的发生率逐年上升,给社会和家庭带来不小的经济压力^[1-2]。手术是目前治疗OVCF的主流方法,主要有椎体成形术和椎体后凸成形术。椎体成形术不经球囊扩张椎体而直接向骨折椎体内灌注聚甲基丙烯酸甲酯(PMMA)骨水泥,能够迅速缓解腰背痛,但灌注压力较大,如灌注的骨水泥较稀薄,易发生渗漏^[3-4]。椎体后凸成形术先经球囊扩张骨折椎体,恢复骨折椎体高度并使骨折部分椎体复位后再向其内部灌注骨水泥,骨水泥渗漏风险较小,并可改善Cobb角^[5-6],目前在临的应用较普遍。

PMMA骨水泥为椎体后凸成形术中较常用的骨水泥,其凝固过程分为稀薄期、黏稠期和凝固期,不同凝固状态的骨水泥灌注对椎体强度和刚度的影响目前尚无定论。本研究通过向OVCF绵羊骨折椎体灌注不同凝固状态的骨水泥,并对灌注前后椎体强度和刚度进行测试,了解骨水泥灌注的最佳凝固状态,为临床骨水泥灌注时期的选择提供依据。

1 材料与方法

1.1 实验标本

从同一牧场选取同一饲养方式养殖的成年绵羊8只,(30.3±1.7)月龄,体质量为(49.8±2.5)kg。获取绵羊L₁₋₅椎体共40个,X线扫描排除骨折、先天畸形、肿瘤、骨质疏松等病变,切除椎体两侧3/4横突,保留1/4横突以便行椎弓根钻孔时解剖定位,去除周围软组织、韧带、棘突及椎体上下椎间盘、终板。将准备好的椎体按随机数字表法随机分为4组,每组10个。

1.2 仪器和材料

双能X线骨密度仪购自美国通用公司,游标卡

尺(精确度为0.02 mm)购自上海精密科学仪器有限公司,衡翼生物力学实验机(型号:HY-3080)购自上海衡翼精密仪器有限公司。包裹椎体上下端的自凝牙托粉(批号:2018-04-25)购自安阳市鹰牌齿科有限公司。实验所用的注射用PMMA骨水泥[国食药监械(准)字2014第3650624号(更)]购自天津市合成材料工业研究所有限公司。微量注射泵(型号:KL-702)购自北京科力医疗有限公司。

1.3 骨质疏松椎体模型制备

将4组椎体经双侧椎弓根入路,以直径3 mm的骨钻钻入距离椎体前壁1/3处。4组椎体均浸泡入3%稀盐酸中,经双侧椎弓根插入输液管,以60 mL/h的速率微泵匀速灌注3%稀盐酸,确保椎体内外均匀脱钙。脱钙4 h后取出椎体,以生理盐水冲洗椎体表面及椎弓根通道,直至盐酸冲尽。分别于脱钙前后用双能X线骨密度仪测量4组椎体骨密度并记录。

1.4 压缩骨折椎体模型制备

用游标卡尺测量4组椎体的前缘高度并记录。将每个椎体的上下端用牙托粉包裹,包裹厚度为2 mm。将每个椎体置于衡翼生物力学机上,使椎体纵轴与力学机压缩轴线在一条直线上,首先以200 N/min进行预加载,消除椎体的蠕变和时间效应。再以10 mm/min的加载速率进行椎体压缩,压缩椎体高度的1/4。用图形记录仪记录椎体压缩过程中载荷-位移曲线,椎体的强度值即为载荷-位移曲线的峰值,刚度值为载荷-位移曲线的斜率。将制备好的压缩骨折模型椎体予以湿润生理盐水纱布包裹,装入塑料袋后置于-6℃的冰箱中保存。

1.5 标本分组制备

将椎体从冰箱取出后放在室温(23℃)下解

冻6 h, 每个椎体以直径3 mm的丝锥经双侧椎弓根入路制备骨水泥灌注通道, 插入工作套管, 放入Kyphon球囊, 连接带压力表的注射器, 球囊压力控制在200 Pa以内。C形臂X线机透视下扩张球囊使压缩骨折椎体复位, 球囊扩张后对照组(A组)不灌注骨水泥, 其余各组分别在PMMA骨水泥粉液室温(23℃)下2:1混合后2 min(骨水泥稀薄期, B组)、4 min(骨水泥黏稠期, C组)及6 min(骨水泥凝固期, D组)灌注骨水泥, 并记录骨水泥使用剂量。4组椎体于室温(23℃)下放置24 h, 用游标卡尺测量椎体前缘高度, 衡翼生物力学机测试各组椎体强度和刚度。

1.6 统计学处理

采用SPSS 23.0软件对数据进行统计分析。计量资料以 $\bar{x} \pm s$ 表示, 组间数据比较采用单因素方差分析, 组内术前和术后数据比较采用配对t检验; 计数资料以个数表示; 以 $P < 0.05$ 为差异有统计学意义。

2 结 果

2.1 骨密度、骨水泥注入量和渗漏情况

脱钙前和脱钙后, 4组椎体骨密度组间比较, 差异均无统计学意义($P > 0.05$, 表1)。4组椎体脱钙后骨密度均比脱钙前降低, 差异有统计学意义($P < 0.05$, 表1), 表明骨质疏松模型成功制备。B、C、D 3组骨水泥注入量差异无统计学意义($P > 0.05$, 表1)。B组3个椎体发生骨水泥渗漏, C组1个椎体发生骨

水泥渗漏, D组无骨水泥渗漏椎体。

表1 各组脱钙前后骨密度及骨水泥注入量

Tab. 1 Bone mineral density before and after decalcification and bone cement injection volume of each group

$n=10, \bar{x} \pm s$			
组别 Group	骨密度/($\text{g} \cdot \text{cm}^{-3}$) Bone mineral density/($\text{g} \cdot \text{cm}^{-3}$)		骨水泥注入量/mL Bone cement injection volume/mL
	脱钙前 Before decalcification	脱钙后 After decalcification	
A	1.10 ± 0.05	0.74 ± 0.06*	—
B	1.12 ± 0.06	0.73 ± 0.05*	3.31 ± 0.08
C	1.11 ± 0.06	0.74 ± 0.07*	3.28 ± 0.09
D	1.11 ± 0.04	0.70 ± 0.04*	3.26 ± 0.10

注: *与脱钙前比较, $P < 0.05$ 。

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

2.2 椎体强度和刚度

术前4组椎体强度和刚度组间比较, 差异均无统计学意义($P > 0.05$, 表2)。A组术后椎体强度低于术前, B、C、D组术后椎体强度均高于术前, 差异有统计学意义($P < 0.05$, 表2)。4组术后椎体刚度均低于术前, 差异有统计学意义($P < 0.05$, 表2)。B、C、D组术后椎体强度和刚度均高于A组, 差异有统计学意义($P < 0.05$, 表2); B、C组术后椎体强度和刚度均高于D组, 差异有统计学意义($P < 0.05$, 表2); B组和C组术后椎体强度和刚度差异无统计学意义($P > 0.05$, 表2)。

表2 各组手术前后椎体强度和刚度比较

Tab. 2 Comparison of vertebral strength and rigidity pre- and post-operation of each group

$n=10, \bar{x} \pm s$

组别 Group	强度/N Strength/N		刚度/($\text{N} \cdot \text{mm}^{-1}$) Rigidity/($\text{N} \cdot \text{mm}^{-1}$)	
	术前 Pre-operation	术后 Post-operation	术前 Pre-operation	术后 Post-operation
A	3 378.16 ± 555.31	1 615.89 ± 311.55*	227.45 ± 59.84	120.77 ± 12.06*
B	3 468.59 ± 637.15	5 213.52 ± 734.60*△▲	250.43 ± 52.65	198.80 ± 34.52*△▲
C	3 263.88 ± 716.64	4 714.75 ± 681.07*△▲	265.07 ± 43.40	184.49 ± 36.06*△▲
D	3 396.65 ± 599.77	3 905.08 ± 472.62*△	246.26 ± 53.12	150.61 ± 10.72*△

注: *与术前比较, $P < 0.05$; △与A组比较, $P < 0.05$; ▲与D组比较, $P < 0.05$ 。

Note: * $P < 0.05$, compared with pre-operation; △ $P < 0.05$, compared with group A; ▲ $P < 0.05$, compared with group D.

2.3 椎体前缘高度

原始高度和骨折后高度各组间比较, 差异无统计学意义($P > 0.05$, 表3)。4组骨折后高度均低于原

始高度, 差异有统计学意义($P < 0.05$, 表3)。4组术后高度均高于骨折后高度, 但仍低于原始高度, 差异有统计学意义($P < 0.05$, 表3); B、C、D组术后

高度均高于A组, 差异有统计学意义($P<0.05$, 表3), B、C、D组之间术后高度差异无统计学意义($P>0.05$, 表3)。

表3 各组椎体前缘原始高度、骨折后高度及术后高度
Tab. 3 Original, post-fracture and postoperative vertebral anterior height of each group

组别 Group	原始高度/cm Original height/cm	骨折后高度/cm Post-fracture height/cm	$n=10, \bar{x} \pm s$	
			术后高度/cm Postoperative height/cm	
A	4.02 ± 0.08	2.94 ± 0.07*	3.30 ± 0.04*△	
B	4.05 ± 0.07	2.95 ± 0.05*	3.67 ± 0.08*△▲	
C	4.03 ± 0.07	2.95 ± 0.05*	3.72 ± 0.11*△▲	
D	4.04 ± 0.08	2.94 ± 0.04*	3.70 ± 0.09*△▲	

注: *与原始高度比较, $P<0.05$; △与骨折后高度比较, $P<0.05$;

▲与A组比较, $P<0.05$ 。

Note: * $P<0.05$, compared with original height; △ $P<0.05$, compared with height after fracture; ▲ $P<0.05$, compared with group A.

3 讨论

脊柱可分为前、中、后三柱, 前2/3椎体、前1/2纤维环和前纵韧带构成前柱, 后纵韧带与后1/3椎体、后1/2纤维环构成中柱, 黄韧带、棘间韧带、棘上韧带与整个椎弓、棘突构成后柱^[7-9]。OVCF主要发生于椎体的前柱和中柱, 且通常是前柱压缩程度更重、中柱压缩程度次之, 后柱较少受累, 因此, 椎体压缩性骨折在矢状位X线片上一般呈现由前向后的楔形变^[10]。当椎体发生楔形变, 脊柱Cobb角势必发生相应改变, 由于Cobb角是上位椎体上缘延长线的垂直线与下位椎体下缘延长线的垂直线间的夹角, 上位椎体楔形变越重, Cobb角增加越大, 脊柱后凸改变越显著^[11-13]。若不手术恢复压缩椎体高度、纠正楔形变, 则椎体压缩骨折后脊柱力学传导异常将进一步加重, 导致患者腰背部疼痛持续并加重, 骨折椎体的上位椎体逐渐向前滑脱, 甚至出现脊髓和神经根的损伤等并发症^[14-15]。椎体后凸成形术是目前治疗OVCF的主要手术方式之一, 可较快地减轻患者腰背部疼痛, 恢复椎体高度, 纠正脊柱后凸畸形, 改善脊柱力学传导, 减少中远期并发症的发生^[16]。

椎体后凸成形术的主要目的除了恢复压缩椎体原有高度之外, 还要尽可能恢复椎体的强度和刚度^[17]。强度是评估椎体所能承受最大压缩力的指标, 达到或超过骨折前椎体原有抗压强度才能使椎体术后更好地承受载荷^[18-20]。刚度是椎体在承受压

力后的一个形变指标, 刚度越高则在承受相同载荷下发生的形变越小^[21-22]。但是椎体不同于一般的金属材料, 并不是刚度越大对人体越有利。若骨折椎体的刚度远超过邻近椎体, 则因为术后生物力学改变和下位椎体的应力集中, 相邻椎体会发生退行性变加速或出现应力性骨折^[23-25]。因此, 如何使压缩骨折椎体的强度和刚度恢复到最有利于人体的状态对于预后具有重要意义^[26-27]。椎体后凸成形术中PMMA骨水泥注入状态的不同对椎体强度和刚度的影响目前尚无定论。根据PMMA骨水泥凝固状态的不同, 可将其分为稀薄期、黏稠期和凝固期。稀薄期和黏稠期骨水泥呈液态或半黏稠状态, 流动性和弥散性较好; 进入凝固期后, 骨水泥由半黏稠状态逐渐转变为固态, 流动性和弥散性逐渐丧失, 需要较大压力才能推注进入椎体。不同凝固状态的骨水泥在骨质疏松椎体内弥散分布状态不同对椎体强度与刚度的影响需要生物力学实验进一步验证。

本研究中4组椎体骨密度和椎体前缘原始高度差异均无统计学意义, 使用完全相同的脱钙方案和脱钙时间制备骨质疏松模型后, 4组椎体脱钙后骨密度差异无统计学意义; 在制作压缩骨折模型时, 将骨质疏松模型放于衡翼生物力学机上压缩掉其原始高度的1/4, 测量压缩前后椎体前缘高度, 4组椎体压缩后前缘高度差异无统计学意义; 行椎体后凸成形术时, 4组的球囊压力均控制在200 Pa; 经双侧椎弓根通道灌注骨水泥, B、C、D组骨水泥剂量差异无统计学意义, 保证了研究结果的可比性。A组因球囊扩张后未灌注骨水泥, 术后椎体前缘高度小于B、C、D组, 而B、C、D组术后椎体前缘高度组间差异无统计学意义, 说明球囊扩张后骨折椎体内无骨水泥支撑, 椎体会逐步塌陷; 不同凝固状态的骨水泥注入椎体后都能对压缩骨折椎体起到有效的支撑作用。

本研究结果显示, 术前4组椎体强度差异无统计学意义, 术后A组因未灌注骨水泥其椎体强度小于术前, B、C、D组术后椎体强度均高于术前, 说明不同凝固状态的骨水泥均能增强椎体强度, 对脊柱起到良好的支撑作用。本研究结果还显示, 不同凝固状态的骨水泥注入椎体后均能增强椎体刚度, 但刚度均小于术前, 说明骨水泥虽能增强椎体的形变能力, 但术后椎体的弹性形变依然恢复不到未骨折状态。B、C组术后椎体强度和刚度均高于D组, 而B、C组椎体强度和刚度相当, 说明PMMA骨水泥在稀薄期和黏稠期注入椎体能显著增强椎体强度和刚度, 效果优于凝固期。推测可能原因为稀薄期和黏

稠期骨水泥灌注入椎体后在椎体内弥散较均匀, 能使整个椎体的强度得到全面有效的增强, 形变能力也增强; 而凝固期骨水泥注入椎体后, 迅速在球囊扩张开的空间内凝固, 不能有效经过骨折间隙和骨小梁进行弥散, 对椎体整体的支撑作用和形变能力减弱。

虽然稀薄期骨水泥对椎体强度和刚度的增强效果较好, 但10个椎体中有3个出现了骨水泥渗漏, 其渗漏率不容忽视。而黏稠期骨水泥除了能较好增强椎体的强度和刚度, 渗漏率也较低, 10个椎体中仅1个出现骨水泥渗漏。凝固期骨水泥灌注的10个椎体虽均未出现渗漏, 但对椎体强度和刚度的增强效果有限。权衡利弊, 本研究组建议行椎体后凸成形术时, 选择黏稠期骨水泥灌注, 既能增强椎体的强度和刚度, 也能减少渗漏的发生。

本研究的不足: ①采用的标本是离体绵羊椎体, 虽然绵羊椎体与人的椎体有很高的相似性, 但由于人是直立行走, 而绵羊为四肢行走, 因此, 在椎体发育过程的应力传导上存在明显差异, 势必在椎体的结构上存在一定差异, 而此结构差异对研究是否有明显的影响仍有待进一步探讨。②为离体的动物椎体力学实验, 脱离了生物体的内环境, 因此, 尚不能完全阐明内环境状态下的生物力学变化。

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