doi:10.11659/jjssx.07E019077

·临床研究·

新型可注射骨水泥螺钉在治疗腰椎滑脱合并骨质疏松症中的应用

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[摘 要] **目的** 评价新型可注射骨水泥螺钉(CICPS)治疗腰椎滑脱合并骨质疏松症中的中长期疗效。**方法** 回顾性分析我院2011年5月至2017年5月采用CICPS治疗的56例腰椎滑脱合并骨质疏松症患者的临床资料,通过观察术前及术后疼痛视觉模拟评分(VAS)、功能障碍指数(ODI),分析VAS、ODI变化情况,通过术前及术后腰椎正侧位X射线、CT等影像学检查评估螺钉有无松动、椎间隙高度变化及椎间融合情况。**结果** 术中共植入CICPS 176枚,其中9枚发生渗漏,渗漏率5.1%。56例患者均获得随访,随访时间17~75个月,平均(29.91±14.78)个月。患者术前VAS(4.34±1.65)分,末次随访时(0.95±0.64)分,二者比较差异有统计学意义($P<0.05$);ODI评分术前(50.40±17.34)%,末次随访时(6.03±6.72)%,二者比较差异有统计学意义($P<0.05$)。患者椎间隙高度术前为(7.85±2.75)mm,术后即刻为(12.43±2.13)mm,二者比较差异有统计学意义($P<0.05$);末次随访时椎间隙高度为(11.89±2.80)mm,与术后即刻比较差异无统计学意义($P>0.05$)。所有患者融合节段腰椎动力位变化小于5°,CT平扫提示融合节段可见连续性骨痂通过。无螺钉松动、断裂及拔出病例。**结论** 新型可注射骨水泥螺钉独特的侧空设计能够确保其在腰椎滑脱合并骨质疏松症患者中的力学稳定性,中长期疗效安全可靠。

[关键词] 可注射骨水泥螺钉;可膨胀椎弓根螺钉;空心侧孔椎弓根螺钉;腰椎滑脱;骨质疏松

[中图分类号] R681.5;R681.5+7 [文献标识码] A [收稿日期] 2019-07-16

Application of a new bone cement injectable cannulated pedicle screw in lumbar spondylolisthesis combined with osteoporosis

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Abstract: Objective To evaluate the medium and long-term effects of a new bone cement injectable cannulated pedicle screw (CICPS) in lumbar spondylolisthesis complicated with osteoporosis. **Methods** Totally 56 cases of lumbar spondylolisthesis combined with osteoporosis treated by CICPS from May 2011 to May 2017 were retrospectively analyzed. The clinical efficacy of the patients was evaluated by the improvement of preoperative and postoperative pain visual analogue scale (VAS) and oswestry disability index (ODI). The loosening of screws, loss of intervertebral space height and intervertebral fusion were assessed by preoperative and postoperative lumbar imaging examination, including anterior and lateral position X-ray examination, CT and other imaging examinations. **Results** A total of 176 CICPSs were implanted intraoperatively, 9 cases of which had leakage, with a leakage rate of 5.1%. All the 56 patients were followed up for 17 to 75 months, with an average follow-up time of (29.91±14.78) months. The VAS score was (4.34±1.65) points before operation, and it was (0.95±0.64) points at the last follow-up, the difference was significant ($P<0.05$). ODI score was (50.40±17.34)% before operation, and it was (6.03±6.72)% at the last follow-up, the difference was significant ($P<0.05$). The height of the intervertebral space of the patients was (7.85±2.75) mm before operation, and it was (12.43±2.13) mm after operation, the difference was significant ($P<0.05$), and it was (11.89±2.80) mm at the last follow-up, there was no significant difference compared with the height immediately after operation ($P>0.05$). In all patients, the change of lumbar dynamic position at the fusion segment was less than 5 degrees, and plain CT scan suggested that continuous callus could be seen at the fusion segment. There was no loose, break nor pull out of screws. **Conclusion** The unique lateral cavity design of CICPS can ensure its mechanical stability in patients of lumbar spondylolisthesis combined with osteoporosis, and the medium and long-term efficacy is safe and reliable.

Keywords: bone cement injectable cannulated pedicle screw; inflatable pedicle screw; hollow lateral hole pedicle screw; lumbar spondylolisthesis; osteoporosis

腰椎滑脱症是临床上引起中老年人慢性腰腿痛的常见病因之一,多见于L_4~L_5节段,临床上手术治疗的最终目的通常是解除神经根压迫,重建脊柱结构的稳定性[1-2]。椎弓根螺钉固定是脊柱外科的标准操作,其贯穿脊柱前、中、后三柱结构,具有三维矫形力量强大,可大幅度提高融合率等优势,是目前维持脊柱稳定性和改善脊柱疾病生物力学特征的主要技术[3]。随

[基金项目] 军事医学与战创伤救治临床新技术计划(SWH2016YSCXZD-04)

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着我国人口进入老龄化社会,骨质疏松的发病率逐年增高,2008 年我国约有七千万骨质疏松患者,预计 2020 年我国骨质疏松和骨量减少患者将达到 2.87 亿[4]。可见,未来腰椎滑脱合并骨质疏松患者也将有所增加。腰椎滑脱术中椎体提拉复位及术后椎体稳定性的维持对椎弓根螺钉的抗拔出力提出了严格要求,加之患者合并骨质疏松症,螺钉把持力下降,螺钉松动风险增高[5-6],因此,研发出一种适合此类患者的椎弓根螺钉很有必要。

改变椎弓根螺钉长度及螺纹等设计,可提高椎弓根螺钉生物力学稳定性,但鉴于解剖等因素,其提高椎弓根螺钉力学稳定性的作用有限。当前国内外研究多集中于可膨胀椎弓根螺钉(expandable pedicle screw, EPS)和空心侧孔椎弓根螺钉(fenestrated pedicle screw,FPS),但上述螺钉在腰椎滑脱,尤其是重度滑脱中运用的相关报道少见,且缺乏中长期疗效的观察[7-14]。本课题组前期自主研发可注射骨水泥螺钉(bone cement-injectable cannulated pedicle screw, CICPS),采用了独特的渐变侧孔和单向、万向两种钉头设计。通过前期临床试验证实了 CICPS 具有优越的生物力学稳定性,并取得相关国家专利[15]。本研究旨在通过对 56 例患者的回顾性分析,进一步观察 CICPS 的中长期疗效。

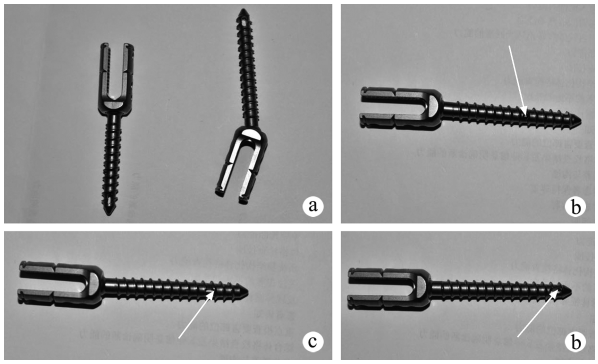
1 资料与方法

1.1 临床资料

回顾性分析 2011 年 5 月至 2017 年 5 月在陆军军医大学第一附属医院采用 CICPS 治疗的腰椎滑脱合并骨质疏松症患者 56 例,其中男 10 例,女 46 例;年龄 46 ~ 76 岁,平均(61.07 ± 7.74)岁;骨密度值 -2.5 ~ -5.0 SD,平均(-3.10 ± 0.5)SD。L_3 滑脱 3 例,L_4 滑脱 31 例,L_5 滑脱 27 例;Ⅰ度滑脱 21 例,Ⅱ度滑脱 25 例,Ⅲ度滑脱 9 例,Ⅳ度滑脱 1 例。所有患者术前经 X 射线、CT 及 MRI 检查提示不同程度的腰椎滑脱,相应节段的腰椎管狭窄、腰椎间盘突出,并伴有不同程度的腰骶部疼痛及一侧或者双侧下肢症状。所有患者术前签署了知情同意书。纳入标准:①术前腰椎滑脱诊断明确,且经过 3 ~ 6 个月保守治疗症状未见缓解,影响生活质量;②合并骨质疏松症,术前双光子骨密度检查提示 T < -2.5 SD;③术前无明显手术禁忌。

1.2 CICPS 的设计

本课题组自主研发的 CICPS 直径 5.0 ~ 6.0 mm,长度 45 ~ 50 mm,钉头采用单向万向设计两种,螺钉纵向中空,骨水泥流出道直径 2.2 mm,远端封闭。其中万向钉头设计的 CICPS 可以在水平 ±20°方向旋转,单向钉头可水平方向 360°旋转。在螺钉前 2/5 设计 3 个侧孔,由小到大纵向分布。靠近钉头的侧孔为圆形,直径 2 mm;对侧间隔 1 个螺纹为椭圆形侧孔,长径 3 mm,短径 2 mm;尖端为贯穿的 U 型侧孔长 4 mm,宽 2 mm(图 1)。



a:螺钉实物图设计;b:螺钉侧面从小到大渐变孔设计;c、d:渐变测引的设计 白色箭头示系侧孔位置

图 1 CICPS 螺钉设计

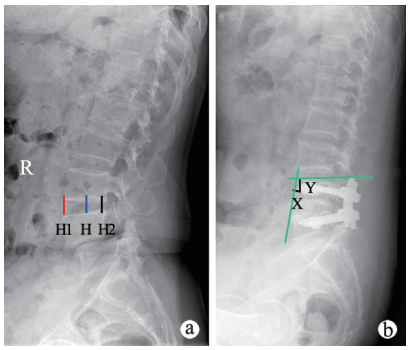
1.3 方法

手术采用后侧入路,常规暴露滑脱节段椎体及下位椎体的进针点,为降低骨水泥渗漏率,CICPS 置钉角度稍大于常规椎弓根螺钉,置钉过程中确保椎弓根及椎体皮质骨完整性。置钉完毕,C 型臂 X 射线机透视下通过特制的注射装置,将预先调制好的骨水泥在“牙膏期”注入 CICPS。结合前期研究,常规注入骨水泥 1.5 mL,如有骨水泥泄露或可疑泄露,应立即停止注射,同时观察患者生命体征[15]。待骨水泥凝固,在双侧螺钉间置入预弯合适的钛棒并撑开椎间隙,根据患者术前症状常规行一侧或双侧椎板切除、椎间盘摘除减压,而后将塞满自体骨的型号合适的椎间融合器置入椎间隙。术后 24 h 常规给予预防性抗感染治疗,术后第 2 天下地活动,3 个月内佩戴腰椎支具制动,术后常规行抗骨质疏松治疗。

1.4 观察指标及测量方法

临床指标测定上,记录患者手术时间、出血量、术后并发症,所有患者术前常规行疼痛视觉模拟评分(VAS)、Oswestry 功能障碍指数评分(ODI),比较患者术前、术后及末次随访时 VAS、ODI 变化情况。影像指标测定上,测量患者术前、术后及末次随访时手术节段椎间隙高度,采取 X 射线侧位片测量椎间隙前缘高度(H1),椎间隙后缘高度(H2),记录两者的平均值(H),见图 2a。记录术后及末次随访时 CICPS 尖端距离椎体前缘变化值(X)及距离椎体上终板距离变化值

(Y),术后值记录 X-p、Y-p,末次随访时记录 X-f、Y-f,相应差值绝对即为 X、Y(图 2b)。记录患者末次随访时动力位融合节段角度变化值 A。螺钉松动评定标准为腰椎侧位片 CICPS 位移(X、Y)大于1 mm且腰椎 X 射线正位片未见明显双环征[16]。椎间隙融合成功判定标准动力位片融合节段角度变化值A <5°,且患者 CT 平扫提示融合节段椎间隙有连续性骨痂通过。所有数据在我院影像归档和通信系统(picture archiving and communication systems,PACS)上测量。



a:椎间隙高度的测量;b:螺钉位移距离测量

图 2 CICPS 相关指标测量方法

1.5 统计学分析

应用 SPSS 25.0 统计软件进行分析,同一指标前后测量配对采用配对 t 检验,同一指标多点测量采用单因素方差分析,方差齐性采用 LSD 检验,方差不齐采用秩和检验。P <0.05 表示差异有统计学意义。

2 结果

2.1 手术及随访情况

手术时间 150 ~341 min,平均(238.27 ±79.97)min,出血量 100 ~2 300 mL,平均(505.36 ±403.70)mL。术中共植入 CICPS 176 枚,其中 9 枚发生渗漏,均为椎前静脉渗漏,渗漏率 5.1%,术中患者未见明显血流动力学障碍。51 例患者术后诉症状明显缓解,3 例未见明显缓解,2 例患者诉术后下肢疼痛或麻木加重,经静脉输入甘露醇后消肿、甲钴胺营养神经后缓解。术后发生 2 例切口感染,1 例清创后愈合,1 例经常规抗感染治疗切口愈合。术后所有患者均得到随访,随访时间 17 ~75 个月,平均(29.91 ±14.78)个月。

2.2 临床评定结果

患者术前 VAS 为(4.34 ±1.65)分,末次随访时为(0.95 ±0.64)分,较术前明显降低,差异具有统计学意义(P <0.05)。患者术前 ODI 为(50.40 ±17.34)%,末次随访时为(6.03 ±6.72)%,较术前明显降低,差异具有统计学意义(P <0.05)。

2.3 影像评定结果

患者术前椎间隙高度为(7.85 ±2.75)mm,术后即刻为(12.43 ±2.13)mm,术后椎间隙高度明显恢复,差异有统计学意义(P <0.05),末次随访时椎间隙高度为(11.89 ±2.80)mm,与术后即刻相比,椎间隙高度虽有一定程度的丢失,但差异无统计学意义(P >0.05)。术后即刻 CICPS 距离椎体前缘(5.02 ±2.35)mm,末次随访时为(5.07 ±2.31)mm,差异无统计学意义(P >0.05);术后 CICPS 距离上终板(7.39 ±2.56)mm,末次随访时为(7.49 ±2.50)mm,差异无统计学意义(P >0.05),X、Y 绝对值均小于 1 mm,术后随访正位片未见明显双环征(图 3)。所有患者术后末次随访时腰椎动力位融合节段角度变化值 A <5°,且 CT 平扫提示融合节段椎间隙有连续性骨痂通过。

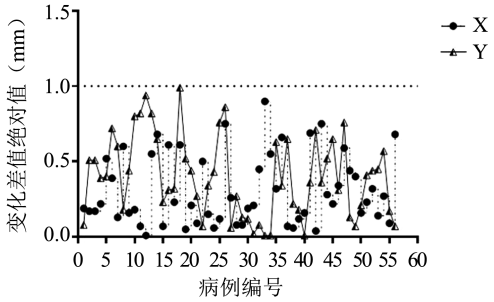


图 3 CICPS 位移情况

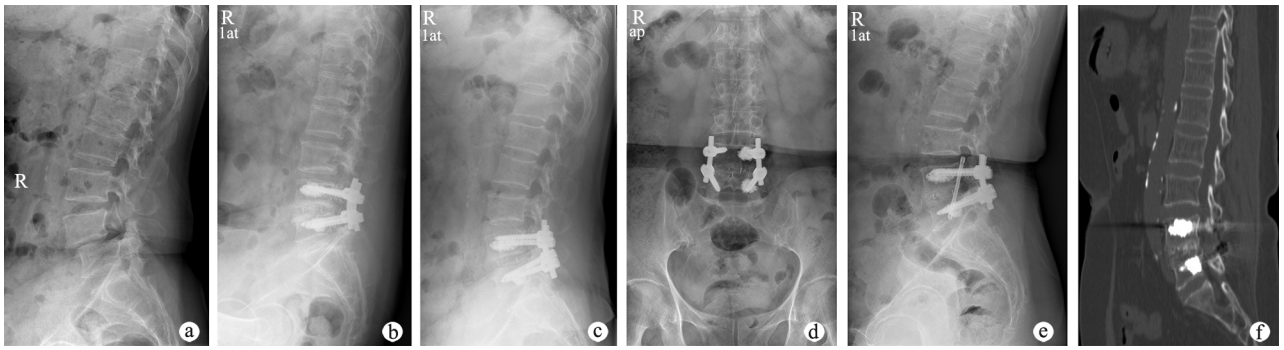
2.4 典型病例

患者,女,59 岁。反复腰痛 9 年,加重伴左下肢疼痛 1 年,双光子骨密度 -2.7 SD,腰椎侧位提示Ⅱ度滑脱,于我院全身麻醉下行后路腰椎滑脱复位、椎管减压、椎间植骨融合、骨水泥螺钉强化内固定术,术后提示滑脱复位良好,骨水泥弥散均匀无渗漏;术后 6 个月随访未见螺钉松动,术后 49 个月随访提示螺钉 X 射线正位片未见明显双环征,螺钉无断裂,CT 提示融合节段椎间隙可见连续性骨痂通过(图 4)。

3 讨论

腰椎滑脱症是引起中老年人腰腿痛的常见病因之一,手术复位滑脱的椎体不仅能重建脊柱稳定性,而且可以增加椎间植骨床的面积及改变椎间融合器的局部应力,从而促进椎间植骨融合的成功率[17-19]。腰椎滑脱合并骨质疏松症无疑增加了患者术中滑脱椎体复位的难度,同时也增加了内固定失败的风险,因此腰椎滑脱合并骨质疏松症中如何确保骨水泥螺钉术中及术后长期的生物力学稳定性是螺钉设计的焦点所在。

Chen 等[12]的研究结果显示,骨水泥主要从螺钉近端侧孔流出。本课题组自主研发的CICPS采用渐



a:术前腰椎X射线侧位;b:术后X射线显示骨水泥弥散均匀无渗漏;c:术后6个月X射线未见螺钉松动;d、e、f:术后49个月X射线及CT提示融合节段椎间隙可见连续性骨痂通过

图4 典型病例影像资料

变孔设计,由螺钉近端向远端依次设计为从小到大的3个渐变侧孔,远端侧孔对穿,确保了骨水泥从流出道流出时压力均匀分散,从而均匀弥散于椎体内,保证了CICPS的最大抗拔出力。本课题组前期通过生物力学试验证明,CICPS纵向抗拔出力可增加323.8%,明显高于当前文献所报道的96%~262%[15,20]。随访发现,术后即刻与末次随访时椎间隙高度差异无统计学意义,CICPS距离椎体前缘变化值及CICPS距离上终板变化值小于1 mm,X射线正位片未见双环征提示螺钉未见松动,间接证实了CICPS在腰椎滑脱合并骨质疏松症患者中优越的生物力学稳定性。融合率是目前国内外公认的内固定疗效评价指标[21]。本研究末次随访时,所有患者动力位片融合节段角度变化值A<5°,且患者CT平扫提示融合节段椎间隙有连续性骨痂通过,提示患者手术节段融合成功,进一步证实了CICPS的有效性。

骨水泥螺钉的渗漏率一直是广大学者关注的焦点。本研究中置入176枚CICPS,其中9枚发生渗漏,均为椎前静脉渗漏,无椎管内渗漏,渗漏率5.1%,低于其他学者的研究报道[22-28]。这与CICPS的独特设计有关,CICPS的3个侧孔集中在螺钉远端的前2/5,骨水泥流出道远离椎体后壁,且CICPS独特侧孔设计确保了骨水泥的均匀弥散,分散了骨水泥注射时的局部压力,从而降低了骨水泥渗往椎管及椎体外渗漏的风险。既往有学者报道,术中骨水泥的使用量与渗漏率呈正相关[25]。本研究中,每个螺钉仅使用骨水泥1.5 mL,低于现有文献报道的使用量[24,26],这可能也是CICPS渗漏率低于其他类型骨水泥螺钉的原因之一。本研究渗漏患者的中长期随访结果显示,患者VAS和ODI改善显著,未出现明显临床不适,进一步验证了CICPS的远期安全性。

本研究发现,患者术后末次随访时椎间隙高度存在一定程度的丢失,但患者至末次随访时VAS和ODI均获得明显改善,且影像学评估显示所有融合节段均获得骨性融合,提示患者椎间隙高度虽有一定程度的丢失,但并未影响CICPS治疗的中长期疗效。

此外,针对滑脱椎体不在同一个平面或部分滑脱严重患者钛棒卡进钉槽困难,CICPS的单向头和万向头设计可确保钉头在相应方向进行旋转,使钛棒顺利卡入钉槽,在一定程度上降低了手术难度,节省了手术时间,提高了患者的手术耐受性。

综上所述,CICPS在腰椎滑脱合并骨质疏松症患者中具有可靠的生物力学稳定性,中长期疗效安全、可靠,不失为治疗该类疾病的一种优良选择。但本研究亦存不足,首先作为回顾性研究,证据等级水平存在一定弱化;其次,缺乏严格的对照试验,样本数量较少,后续需加大样本量,设计前瞻性临床对照研究,为临床提供更加可靠的借鉴。

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(编辑: 左艳芳)