doi: 10.13241/j.cnki.pmb.2014.30.038

Coflex 固定加椎板开窗减压在腰椎管狭窄症的疗效观察 *

陈学明 罗 平 漆建鑫 杨 帆 王 科

（湖南株洲市三三一医院脊柱科 湖南 株洲 412002）

摘要 目的：观察 Coflex 固定加椎板开窗减压在腰椎管狭窄症的疗效。**方法**：选择 2009 年 8 月至 2012 年 8 月在我院治疗，经 CT 诊断为腰椎椎管狭窄的患者 82 例，随机分为观察组和对照组，每组各 41 例。观察组行 Conflex 固定加椎板开窗减压治疗，对照组行常规手术治疗。观察和比较两者患者 1 年后的健康情况、术后满意程度、VAS 评分及 Barthel 指数。**结果**：观察组术后满意度 90.2%，对照组为 65.9%，与对照组比较，观察组满意度更高，差异有统计学意义（X^2=16.8,P<0.001）；两组患者健康情况的比较：观察组优良率（82.9%）较对照组（56.1%）高，两组健康情况相互比较差异有统计学意义（X^2=17.1, P<0.001）；观察组随访 VAS 评分 2.34± 1.02，对照组 VAS 评分 4.31± 1.33，两组 VAS 评分比较差异均有统计学意义（t=7.43, P<0.0 01）；观察组 Barthel 指数（92.3± 5.1）优于对照组（81.2± 4.2），差异有统计学意义（t=5.31, P<0.0 01）。**结论**：Conflex 固定加椎板开窗减压对腰椎管狭窄症的疗效确切，不良反应少，值得在临床上推广。

关键词：椎管狭窄症；腰椎；疗效；减压；椎板

中图分类号：R683 **文献标识码**：A **文章编号**：1673-6273（2014）30-5941-03

Clinical Efficacy of Coflex Fixed Lamina Windowing Decompression in the Treatment of Lumbar Spinal Stenosis*

CHEN Xue-ming, LUO Ping, QI Jian-xin, YANG Fan, WANG Ke

（Zhuzhou 331 hospital, Zhuzhou, Hunan, 412002, China）

ABSTRACT Objective: To observe the clinical efficacy of Coflex fixed Lamina windowing decompression in the treatment of lumbar spinal stenosis. **Methods:** 82 patients who were diagnosed with lumbar spinal stenosis and treated between August 2009 and August 2012 in our hospital were divided into two groups randomly and equally. The treatment group had Coflex fixed Lamina windowing decompression while the control group had regular operation. During the one-year treatment, observe and compare the patient's health, postoperative satisfaction degree, VAS score and Barthel index of the two groups were observed and compared. **Results:** The postoperative satisfaction degree of the treatment group (90.2%) was higher than that (65.9%) of the control group, with statistical difference (x^2=16.8, P<0.001). The treatment group had a good-health rate of 82.9%, higher than that of 56.1% for the control group, and the difference was statistical (x^2=17.1,P<0.001). The VAS score was 2.34± 1.02 for treatment group, and was 4.31± 1.33 for control group, also with statistical difference (t=7.43, P<0.001). The Barthel index of the treatment group was 92.3± 5.1, higher than that (81.2± 4.2) in the control group, and there was statistical difference (t=5.31, P<0.0 01). **Conclusion:** The Coflex fixed Lamina windowing decompression had convincing and reliable curative effect in treating lumbar spinal stenonis, with less adverse reactions, and is worth promoting in clinic.

Key words: Spinal stenosis; Lumbar vertebra; Curative effect; Decompression; Vertebral plate

Chinese Library Classification(CLC): R683 Document code: A

Article ID: 1673-6273(2014)30-5941-03

前言

腰椎管狭窄症是指腰椎椎骨和软组织发生形态和结构的变化，导致椎管、椎间孔狭窄，压迫或刺激神经根、马尾神经，而引起腰腿痛等马尾神经症状或神经根症状[1,2]。常见于中老年人，随着人口老龄化，此病有增加的趋势，患者常伴有慢性臀部、腰背部、大腿、小腿疼痛，约 70%-80%患者常表现下肢疼痛，约 60%的患者表现为背痛，腰椎管狭窄症影响人们的日常生活，可导致患者生活不能自理[3,4]。腰椎管狭窄症手术以改善患者症状，提高生活质量为目的，通过椎管减压消除或减轻神经根和(或)马尾神经的压迫以达到缓解症状[5,6]。Conflex 非融合动态固定方法在获得一定稳定性的同时保留了部分腰椎节段运动，近年来临床应用逐渐增多[7-9]。本研究旨在探讨 Conflex 固定加椎板开窗减压治疗腰椎管狭窄症的治疗效果，现报道如下。

1 资料与方法

1.1 一般资料

* 基金项目：卫生部科技计划项目（W2012ZT72）

作者简介：陈学明(1976-)，男，副主任医师，研究方向：脊柱退行性疾的诊断与治疗研究，

电话：13973345560, E-mail:cicicxm@sina.com

（收稿日期：2013-10-21 接受日期：2013-11-28）

选取我院 2009 年 8 月至 2012 年 8 月入院，经 CT 诊断为腰椎椎管狭窄的患者 82 例，随机分为观察组和对照组各 41 例。其中观察组男 28 例，女 13 例；年龄 49~76 岁，平均年龄 60± 5.4 岁，狭窄节段分布：L12 例、L25 例、L39 例、L412 例、L513 例，单节段腰椎椎管狭窄 31 例，双节段腰椎管狭窄 6 例，三节段腰椎椎管狭窄 4 例；对照组男 25 例，女 16 例；年龄 48~73 岁，平均年龄 62± 4.6 岁，狭窄节段分布：L13 例、L27 例、L38 例、L413 例、L510 例，单节段腰椎椎管狭窄 30 例，双节段腰椎管狭窄 5 例，三节段腰椎椎管狭窄 6 例。所有患者无骨折、先天性脊柱畸形等疾病，且均经过 4 个月以上保守治疗无效。两组患者在性别、年龄、狭窄节段分布和狭窄节段数目上比较无明显差异(P>0.05)，具有可比性。

1.2 方法

1.2.1 手术方法 观察组患者全身麻醉后取俯卧位，保持腰椎轻度后凸。以病变腰椎节段为中心做后正中切口，长 5～7 cm，切开皮肤、分离皮下组织和筋膜，剥离椎旁肌至上、下关节突平面，剥离骶棘肌暴露椎板，切除黄韧带，咬除椎板。摘除突出的椎间盘组织，探查并松解神经根，修整棘突间骨面，选取试模植入合适型号的 Conflex 固定，于透视下观察椎间隙前后缘高度达到一致即用棘突夹植入，深度距硬脊膜 2-5mm，依次缝合伤口，术后予以抗炎药，留置引流管一周；对照组行常规手术治疗，术后处理与观察组一致。

1.2.2 观察指标 患者于术后 1 年，行腰椎 x 线片、CT 检查，并调查问卷随访。收集患者术后满情况(满意度 = 很满意 + 满意 / 例数)。SF-36 健康调查评分表，包括患者术后健康状况、躯体功能、肌体疼痛等方面评价术后疗效[10]。疼痛视觉模拟量表(VAS)评分评估疼痛、Barthel 指数评估日常生活。

1.3 统计学分析

采用 SPSSl8.0 统计学软件，所有数据以均数± 标准差($\bar{x}$± s)表示，计量资料采用 t 检验，计数资料采用 x^2 检验，以 P<0.05 表示差异有统计学意义。

2 结果

2.1 两组患者术后满意程度的比较

观察组十分满意 14 例、满意 23 例、不满意 4 例，满意度 90.2%；对照组很满意 10 例、满意 17 例、不满意 16 例，满意度 65.9%。与对照组比较，观察组满意度更高，差异有统计学意义(x^2=16.8, P<0.001)(见表 1)。

表 1 两组患者满意程度的比较[n/(%)]

Table 1 Comparison of the satisfaction degree between two groups[n/(%)]

Group	n	Quite satisfied	Satisfaction	Not satisfied	Total satisfaction
Treatment group	41	14(34.1%)	23(56.1%)	4(9.8%)	37(90.2%)*
Control group	41	10(24.4%)	17(41.5%)	16(39%)	27(65.9%)

Note: Compared with the control group, *P<0.001.

2.2 两组患者健康情况的比较

SF-36 评分结果显示：观察组术后疗效优 13 例、良 21 例、可 5 例、差 2 例，优良率 82.9%(34/41)，对照组优 8 例、良 15 例、可 10 例、差 8 例，优良率 56.1%(23/41)，两组健康情况相互比较差异有统计学意义(x^2=17.1,P<0.001)(见表 2)。

表 2 两组患者健康情况的比较[n/(%)]

Table 2 Comparison of the healthy condition between two groups[n/(%)]

Group	n	Excellence	Favorable	General	Poor	Total favorable
Treatment group	41	13(31.7%)	21(51.2%)	5(12.2%)	2(4.9%)	34(82.9%)**
Control group	41	8(19.5%)	15(36.6%)	10(24.4%)	8(19.5%)	23(56.1%)

Note: Compared with the control group, **P<0.001.

2.3 两组患者 VAS 评分及 Barthel 指数的比较

VAS 评分包括进食、行走、洗澡、穿衣、拿碗、小便、上楼梯等，观察组随访 1 年，VAS 评分 2.34± 1.02；对照组 VAS 评分 4.31± 1.33。两组 VAS 评分比较差异均有统计学意义(t=7.43, P<0.0 01)；观察组 Barthel 指数(92.3± 5.1)较对照组(81.2± 4.2)高，两组相互比较差异有统计学意义(t=5.31，P<0.0 01)(见表 3)。

3 讨论

腰椎管狭窄症是常见的骨科疾病，关节突内聚、椎间盘突出、椎管狭窄等病理性退行性改变可导致腰椎管有效容量减少，管腔内径狭窄，压迫神经根、马尾神经而出现的一组临床综

表 3 两组患者 VAS 评分及 Barthel 指数的比较比较[$\bar{x}$± s]

Table 3 Comparison of the VAS score and Barthel index between two groups[$\bar{x}$ ± s]

Group	n	VAS	Barthel
Treatment group	41	2.34± 1.02	92.3± 5.1***
Control group	41	4.31± 1.33	81.2± 4.2

Note: Compared with the control group, ***P<0.001.

合症。相邻椎骨的连接部位,如椎间盘、关节突关节、黄韧带等,是最易发生退变的部位。流行病学研究表明腰症患病率约为30%,65岁以上人群中患病率更高。腰椎管狭窄分为中央狭窄、侧隐窝狭窄及椎间孔狭窄, 治疗的目的是扩大椎管狭窄部,解除神经根压迫[11-13]。常规的手术方法需要广泛剥离椎骨两侧的软组织,切除椎板、棘突及其韧带,因而创伤大、出血多,大量破坏腰椎后部结构[14]。因此,患者术后因脊柱的稳定性降低而不利于术后恢复[15]。

近年来Coflex系统在退行性腰椎椎管狭窄手术中的应用受到重视,其特点是可以使脊柱前突局部增加,限制不稳定节段的运动幅度,通过限制腰椎后伸,避免黄韧带褶皱,适当撑开棘突,扩大椎间孔,增加椎间隙距离,为脊柱提供稳定性,并能保留脊柱运动功能,从而达到解除压迫,缓解疼痛的目的[16-19]。椎间盘突出节段不稳、退变性腰椎管狭窄、椎间盘源性腰痛均可选用Coflex,尤其是退变性腰椎管狭窄症疗效更显著[20]。

本研究采用Conflex固定加椎板开窗减压治疗腰椎管狭窄症,术后一年复查随访,发现患者对治疗的健康评分、满意度、Barthel指数较传统手术高,(VAS)评分要低于常规手术。表明Conflex固定加椎板开窗减压对腰椎管狭窄症有较好的临床疗效,且手术出血少、安全性高。Coflex治疗退变性腰椎管狭窄症具有手术简单安全、创伤小、出血少、一定程度上保留椎骨节段运动;椎板开窗减压与标准的全椎板切除术相比,开窗减压术损伤小、并发症少,且尽量保持脊柱的稳定性,对术后脊柱的稳定性影响较小[21, 22]。两者联合对腰椎管狭窄症的疗效更显著,值得在临床上推广应用。

参 考 文 献(References)

[1] Xu C, Tian N F, Li F, et al. Complications in degenerative lumbar disease treated with a dynamic interspinous spacer (Coflex) [J]. Int Orthop, 2013, 37(11): 2199-2204

[2] 刘汝落. 腰椎管狭窄症[J]. 中国矫形外科杂志, 2004(19): 72-74
Liu Ru-luo. Lumbar spinal stenosis [J]. Orthopedic Journal of China, 2004(19): 72-74

[3] Xu D, Xu H Z, Chen Y H, et al. Discectomy and discectomy plus Coflex fixation for lumbar disc herniation, a clinical comparison study [J]. Chinese Journal of Surgery, 2013, 51(2): 147-151

[4] Zhou S Y, Chen X S, Jia L S, et al. Short-term clinical results of interspinous dynamic fixation of Coflex for the prevention of adjacent segment degeneration after lumbar fusion[J]. Chinese Journal of Surgery, 2012, 50(9): 772-775

[5] Liu J, Liu H, Song Y M,et al. The mid-term follow-up of Coflex non-fusion internal fixation in the treatment of degenerative lumbar disease [J]. Chinese Journal of Surgery, 2013, 51(2): 142-146

[6] Chad, DA. Lumbar spinal stenosis [J]. Neurol Clin, 2007,25 (2): 407-418

[7] Zang L, Hai Y, Su Q S, et al. Device implanted complications of Coflex interspinous dynamic stabilization [J]. Chinese Journal of Surgery, 2012, 50(9): 782-787

[8] 李志琳, 甄平, 钱济先, 等. Coflex植入术与Quadrant通道下TLIF结合经皮Sextant椎弓根螺钉治疗退行性腰椎管狭窄症的疗效对比[J]. 现代生物医学进展, 2012, 12(30): 5902-5906
Li Zhi-lin, Zhen Ping, Qian Ji-xian, et al. Comparison of Short Term Outcome in the Treatment of Degenerative Lumbar Stenosis between Coflex Interspinous Implant and TLIF via MAST Quadrant Retractor Combine with Mini-invasive Percutaneous Pedicle Screw Fixation Sextant System [J]. Progress in Modern Biomedicine, 2012, 12(30): 5902-5906

[9] 梁冰,何伟涛,周金贤,等. Coflex治疗老年退变性腰椎管狭窄症16例[J]. 中国中医骨伤科杂志, 2011,21(01): 40-41
Liang Bing, He Wei-tao, Zhou Jin-xian, et al. 16 patients with elderly degenerative lumber spinal stenosis treated by Coflex[J]. Chinese journal of traumatology, 2011, 21(01): 40-41

[10] Jenkinson C, L Wright, A Coulter. Criterion validity and reliability of the SF-36 in a population sample[J]. Qual Life Res, 1994, 3(1): 7-12

[11] Du F T. Clinical analysis of interspinous dynamic internal fixation with the Coflex system in treating lumbar degenerative disease [J]. China Journal of Orthopaedics and Traumatology, 2011, 24 (4): 291-294

[12] Arrotegui I. Coflex interspinous spacer. Use in degenerative lumbar disc herniation[J]. Acta Ortop Mex, 2010, 24(3): 187-190

[13] 黄隆, 何立江. 后路减压内固定术治疗腰椎管狭窄100例[J]. 中国老年学杂志,2012,32(5): 1059-1060
Huang Long, He Li-jiang. 100 patients with lumbar spinal stenosis treated by posterior decompression internal fixation[J]. Chinese Journal of Gerontology,2012,32(5): 1059-1060

[14] Mao Z X, Jiang J M, Yan H B, et al. Effect of Coflex interspinous stabilization and vertebral arch pedicle screw implantation on the stability of three-dimensional motions of the lumbar spine [J]. Journal of Southern Medical University, 2010, 30(4): 863-866

[15] Tsai K J, Murakami H, Lowery GL, et al. A biomechanical evaluation of an interspinous device (Coflex) used to stabilize the lumbar spine[J]. J Surg Orthop Adv, 2006, 15(3): 167-172

[16] Yasar B, Er U, Simsek S, et al. Functional and clinical evaluation for the surgical treatment of degenerative stenosis of the lumbar spinal canal[J]. J Neurosurg Spine, 2009, 11(3): 347-352

[17] Mao Z G, Wu Q X, Zhu J M, et al. Surgical treatment for degenerative lumbar scoliosis associated with spinal stenosis[J]. China Journal of Orthopaedics and Traumatology, 2008, 21(11): 860-862

[18] 管华清,杨惠林,徐耀增,等. 腰椎棘突间置入动态内固定Coflex系统治疗中年腰椎旋转不稳:近期腰椎稳定性评价[J]. 中国组织工程研究与临床康复. 2011, 17(09): 1575-1578
Guan Hua-qing, Yang Hui-lin, Xu Yao-zeng, et al. Coflex interspinous process dynamic internal fixation for the treatment of middle-aged lumbar rotation instability: Short-term lumbar stability evaluation [J]. Chinese Journal of clinical rehabilitation and tissue engineering research. 2011, 17(09): 1575-1578

[19] Richter, A, Schutz C, Hauck M, et al. Does an interspinous device (Coflex) improve the outcome of decompressive surgery in lumbar spinal stenosis One-year follow up of a prospective case control study of 60 patients[J]. Eur Spine J, 2010,19(2): 283-289

[20] Cong ML, Gong W M, Zhong Q G, et al. Urodynamic study of bladder function for patients with lumbar spinal stenosis treated by surgical decompression[J]. J Int Med Res, 2010, 38(3): 1149-1155

[21] Li Z H, Wang S Y, Tang H, et al. Spinal fusion combined with dynamic interspinous fixation with Coflex system for lumbar degenerative disease [J]. China Journal of Orthopaedics and Traumatology, 2011, 24(4): 277-281

[22] Villarejo F, Carceller F, Budke M, et al. Experience with coflex interspinous implant[J]. Acta Neurochir Suppl, 2011, 108: 171-175