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微创 ROI-C 式椎间融合器在颈椎前路中的临床应用研究*

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摘要 目的:评价应用自稳型插片式椎间融合器(Zero notch self stabilizing cervical fusion cage, ROI-C)在颈椎前路患者中的临床疗效和安全性,并进一步找寻其优缺点。**方法:**回顾性分析自 2017 年 6 月至 2018 年 6 月在我院诊断为颈椎病并行颈前路椎间盘减压植骨融合内固定手术(Anterior cervical discectomy and fusion, ACDF)的患者,共计 84 例。根据手术中使用内固定的不同,分为观察组(ROI-C 组;48 例)和对照组(常规融合器+钢板组;36 例)。比较术后 3 天、1 月、及 12 个月的 VAS、JOA 及 Macnab 评分。比较两组患者在手术中的情况(出血量,手术时间,住院时间等)的功能评分;在术后 1 年时比较两组患者的并发症情况。**结果:**在术后的各个时间截点的比较中,两组患者在 VAS、JOA 及 Macnab 评分中较术前均有显著性改善($P < 0.05$),但两组间均无显著统计学差异($P > 0.05$)。两组患者在最后一次(术后 1 年)的并发症的比较中未见显著性差异($P > 0.05$)。观察组在手术中各项指标的比较中均显著优于对照组。**结论:**与传统的常规融合器-钢板 ACDF 治疗方法相比,自稳型插片式椎间融合器能够达到相似的治疗效果及安全性。但能够有效的减少手术时间及出血量,缩短住院时间,并有效提高患者术后的舒适度,在临床中可以进一步推广。

关键词:颈椎病;ROI-C;ACDF

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Application Research on Anterior Cervical Cage Instrument of ROI-C in Anterior Cervical Discectomy and Fusion Surgery*

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ABSTRACT Objective: To evaluate the clinical efficacy of ROI-C in ACDF and to explore its advantages and disadvantages.
Methods: From 2017.06 to 2018.06, 84 cases of patients with Cervical spondylotic myelopathy included in this study, and all of the patients have received Anterior Cervical Discectomy and Fusion were divided into two groups according to different operation ways. 48 patients underwent surgery using ROI-C (experimental group), while 36 patients underwent surgery with Anterior Cervical Locking Plate System (control group). The operation time, bleeding and hospital stay were compared between the two groups, and using VAS score and JOA score to evaluate the clinical efficacy, and make a record of surgical complications, and SPSS 19.0 is used for statistical analysis.
Results: There was no significant difference in VAS, JOA and Macnab score between the two groups in 3 days, 6 months and 12 months after operation ($P > 0.05$) while it has a statistically significant difference compared with preoperative ($P < 0.01$). Surgeries in both of the two groups were successfully completed, and there were no complications such as nerve injury, hematoma and infection ($P > 0.05$). There was significant difference in the operation time, operation blood lose and hospital stay time between the two groups. **Conclusions:** Comparing the traditional system of anterior cervical locking plate in ACDF, using the ROI-C in the treatment of cervical spondylosis has a definite clinical curative effect, however, which can short operation time and the reducing postoperative swallowing discomfort and short hospital stay time, which is worth to promotion and application.

Key words: Cervical spondylosis; ACDF; ROI-C

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前言

随着生活及工作方式的改变,脊柱退行性疾病的发病率逐年提高,并且发病年龄逐年呈现年轻化,在颈椎病中更是如

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此^[1]。尽管大多数的患者通过系统的保守治疗之后,症状可以得到有效的缓解,但仍有相当一部分患者需要进行手术治疗。对于颈椎手术来讲,前路的椎管减压植骨融合内固定术(anterior cervical discectomy and fusion, ACDF)是目前最为临床应用最为广泛,也是最为经典的手术方式^[2]。这种方式可以有效的解除脊柱前方(椎间盘、骨赘等)对于脊髓的压迫,实现彻底的减压,并实现很高的安全性。但此方法也有其自身的缺陷,例如前路钛板及融合器会容易损伤到周围的神经、血管并且会导致部分患者出现吞咽不适和困难^[3]。此外,从长期来看,钛板及螺钉的松动、断裂会导致食道穿孔,融合效果不佳以及邻近节段蜕变等问题^[4]。

因此,大家一直希望寻找及发明一种新的内固定融合器,能够在保留 ACDF 各项优点的同时,尽量的避免各种上述缺陷。自稳型插片式椎间融合器(ROI-C)是由法国公司所研发的一种零切记融合器。通过其独特的双锁片结构,能够有效的实现融合的稳定,从而保证融合率。并且在操作过程中,无需暴露较大的解剖范围,从而明显减少了手术损伤及术后瘢痕的形成。并且由于此种方法无需置于颈椎的前方,从而能够有效避免对于食道和前方重要结构的干扰。在临床中,我们将自稳型插片式椎间融合器用于颈椎病患者的治疗中,取得了满意的疗效。现总结汇报如下。

1 资料和方法

1.1 研究对象

我们将 2017.06 至 2018.06 在我院就诊,结合症状、体征及相关影像学资料明确诊断为颈椎病的患者经制定好的纳入及排除标准筛选后,共选入 84 名患者。根据具体手术方法的不同,将其分为观察组(自稳型插片式椎间融合器,ROI-C 组;48 例)和对照组(常规 ACDF 组;36 例)。在上述分组中,性别比例为:观察组为男性 26;女性 22;对照组为男性 19;女性 17。观察组的平均年龄则为 43.7±9.4 岁;对照组的平均年龄则为 43.7±9.4 岁。两组患者的上述一般性资料经统计学分析后未发现显著统计学差异($P>0.05$),具有可比性。

本次研究的纳入和排除标准如下:纳入标准^[5]:① 确诊为颈椎病并行单节段手术者,且手术间隙为 C3-C6 者;② 患者年龄范围为 18-65 岁。③ 能够查阅到完整的 >1 年随访资料。排除标准^[6]:① 患者有严重骨质疏松等相关严重代谢性疾病;② 患者

为非首次手术者;③ 患者合并肿瘤、骨折或其他严重疾病。

1.2 方法

1.2.1 手术方法 所有患者均采用全身麻醉的方法。由同一主刀医生主刀进行手术的具体实施。麻醉满意后,患者均采用仰卧位,固定好头颈部后,常规消毒铺单。根据病变的节段,在患者的右侧进行横行切开,切口长约 5-6 cm。结合电刀的使用,逐层切开皮肤,皮下筋膜,颈阔肌,并暴露胸锁乳突肌。在胸锁乳突肌的内侧,沿自然解剖间隙直至椎体的前侧。拉钩沿间隙向两侧拉开,暴露椎体前缘及两侧的颈长肌。插入定位针,使用 C 臂进行定位透视。定位无误后,使用刮匙及髓核钳、椎板咬钳对椎间隙进行处理,并对椎体的后缘进行小心的磨除和刮除。对钩椎关节进行处理后,再次检查脊髓的减压情况。对终板进行再次耐心处理。生理盐水冲洗。观察组:根据具体的间隙和宽度,选择合适的试模进行预置入,满意后,选择相应的 ROI-C 椎间融合器,装入自体骨后,进行椎间隙置入。合适深度后,装入相应的插片,并按照顺序敲入。再次冲洗后放置引流管,逐层缝合。对照组:与观察组情况基本相同,唯一区别是不使用 ROI-C,而是使用前路锁定钢板和融合器进行置入。

1.2.2 术后护理 根据要求和指南进行抗生素、脱水剂及神经营养药物的使用。术后第一天即进行卧床相关功能锻炼。术后 2-3 天视情况给予拔除引流管,并开始鼓励佩戴颈托下地活动。颈托佩戴时间不长于 2 月。

1.2.3 评价方法 疼痛指标的评价使用 VAS^[7]评分进行比较。最高分为 10 分,意味着极限疼痛。疗效评价标准则使用 mJOA^[8]评分法进行评判,并得到术后改善率。影像学评判标准则使用 bobor's^[9]法进行评估,并结合椎间隙高度和三维重建结果。术后情况根据当时术中记录结果进行综合评估。

1.3 统计学分析

使用 SPSS 19.0 根据不同的样本类型采用不同的检验方法,计数资料采用卡方检验,计量资料采用 t 检验,以 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 两组患者疗效功能评分的比较

本次实验结果显示,两组患者在术后各时间点的评分较术前均有显著改善($P<0.05$)。但两组之间在术后各时间点并无统计学差异($P>0.05$)。见表 1。

表 1 两组患者的 mJOA 评分比较情况($\bar{x}\pm s$)
Table 1 The mJOA scores between 2 groups ($\bar{x}\pm s$)

Groups	before operation	6 months after operation	12 months after operation
Observe group	10.061±2.704	1.338±0.342	1.199±0.196
Control group	10.464±2.426	1.349±0.220	1.178±0.205
T	-0.496	-0.118	-0.339
P	0.623	0.906	0.737

2.2 两组患者在相关疼痛指标中的比较情况

本次研究显示,两组患者在术后 1 月及 1 年时的 VAS 指标均显著优于术前($P<0.05$)。但在术后各时间点的比较中,两组之间并无统计学差异($P>0.05$)。见表 2。

2.3 两组患者在影像学各指标中的比较

在术后 1 年时,对两组患者的融合率进行比较。其中,观察组 48 例患者中共有 46 例融合,对照组 36 例患者中,35 例出现融合。两组之间无统计学差异。术后,两组患者的责任节段的

椎间隙高度均显著优于术前,且两组之间无统计学差异 ($P>0.05$)。 见表 3。

表 2 2 组患者疼痛指标的比较($\bar{x}\pm s$)Table 2 The VAS scores between two groups ($\bar{x}\pm s$)

Groups	Before operation	6 months after operation	12 months after operation
Observe group	4.514 $\pm$ 0.922	2.295 $\pm$ 0.4496	0.953 $\pm$ 0.371
Control group	4.312 $\pm$ 0.932	2.085 $\pm$ 0.331	1.266 $\pm$ 0.059
T	0.689	1.576	-1.651
P	0.495	0.123	0.107

表 3 2 组患者椎间隙高度的比较(mm)

Table 3 The Intervertebral disc height between two groups (mm)

Groups	Before operation	6 months after operation	12 months after operation
Observe group	5.130 $\pm$ 0.775	6.689 $\pm$ 0.868	6.271 $\pm$ 0.455
Control group	4.883 $\pm$ 0.720	6.645 $\pm$ 1.007	6.346 $\pm$ 0.359
T	1.046	0.820	-0.582
P	0.302	0.417	0.564

2.4 两组患者在各手术指标及并发症等指标中的比较

通过本次研究我们发现,观察组患者在手术时间,术中出血量及住院时间等指标中均显著优于对照组。见表 4。而在并发症指标的比较中,我们发现两组患者中均未出现严

重并发症。在观察组中,有 1 例患者出现了皮肤浅层感染。经换药后,治愈。两组患者在并发症的比较中未见显著差异。而在吞咽不适的统计中,我们发现,观察组显著优于对照组 ($P<0.05$),见表 5。

表 4 2 组患者各手术指标的比较

Table 4 Comparison of Patients' Perioperative period data

	Blood lose(mL)	Operation time(min)	Hospital stay (day)
Observe group	38.148 $\pm$ 8.873	42.421 $\pm$ 14.758	5.576 $\pm$ 2.525
Control group	55.792 $\pm$ 13.155	63.506 $\pm$ 21.787	7.101 $\pm$ 1.995
T	-4.973	-3.583	-2.120
P	0.000	0.001	0.041

表 5 两组患者的吞咽不适发生率比较情况

Table 5 Comparison of Incidence of swallowing discomfort

Groups	swallowing discomfort	swallowing comfort	Incidence(%)	χ^2	p
Observe group	3	45	6.25	4.612	0.032
Control group	8	28	22.2		

3 讨论

随着生活节奏的不断加快及工作类型的转变,脊柱疾病特别是颈椎退行性疾病的发病率逐渐上升。对于大部分的局部型和神经根型颈椎病患者来讲,经过系统的保守治疗以后,能够取得比较理想的治疗效果。但对于相当一部分患者来讲,特别是脊髓型颈椎病患者来讲,手术治疗是最为合适的治疗方法。

在现阶段,颈椎退行性疾病的手术方式大约分为以下三种^[9]:前路;前后路联合;后路。其中,前路手术是应用最为广泛也是最为常见的手术方式,对于单节段的患者来讲更是如此。ACDF 是颈前路手术中最为经典的手术选择。该术式已经被应用于临床超过了 60 年的时间,并收到了良好的治疗效果^[10]。相

关研究和临床经验证实,在进行充分的减压以后,该手术方式能够有效的维持颈椎的稳定性,提高融合的概率,降低相关术后并发症的出现。但随着临床中的使用和普及,该手术方式的诸多缺陷也不断展现^[11]。例如暴露范围较大从而导致的出血较多,创伤较大,并容易损伤到周围的神经、血管甚至脊髓;由于置于颈椎的前方,容易导致患者出现吞咽困难,相邻节段假关节的形成;一旦出现螺钉松动断裂、钢板的移位,会导致食管、气道的损伤及融合的失败。因此,众多专家和学者一直致力于寻找一种新的内固定融合器械,以期既能覆盖 ACDF 的诸多优点,拥有它的各项生物力学性能,又可以避免上述缺陷,实现相对"微创化"的目标。自稳型颈椎融合器就是这样一类零切迹融合器^[12]。目前有 MC+、Zero-p、ROI-C 等多种类型^[13]。其中,

ROI-C 是应用相对广泛的一类。随着器械的不断进步以及外科医生对于此类疾病的了解,ROI-C 的手术适应症不断宽泛,目前几乎能够覆盖所有能进行 ACDF 的手术。但是由于其解剖生理学结构的限制,当相邻上下椎体出现严重骨质的破坏时,应该认为是 ROI-C 的禁忌症。

关于 ROI-C 的相关临床和实验研究,目前国内外已经有相关的证实^[14,15]。例如一个涉及 17 例患者的双节段脊髓型颈椎病实验证实,采用 ROI-C 的患者能够取得良好的治疗效果^[16]。而另一项与人工椎间盘的比较中^[17],发现 ROI-C 与人工椎间盘在临床疗效的比较中未见显著统计学差异。在影像学的相关比较中,相关文献报道^[18,19],ROI-C 组在维持颈椎的责任阶段高度以及生理曲度方面与常规前路钢板并无明显差异。而关于术后吞咽不适及相关并发症的相关研究中,更是表明,实施 ROI-C 组的患者有明显的舒适度的提高^[20,21]。在手术诸多因素的比较中(手术时间,术中出血等),由于 ROI-C 只需直接将插片进行安装固定,明显省略了相关暴露和拧入的步骤,能够显著减少了创伤和出血^[22,23]。此外,不管哪种器械,其最主要的目的是实现有效的融合^[24,25]。而融合出现障碍或者问题的原因是,置入椎间隙的骨块或者融合器同时承受轴向的直接压力和相对移动横向的剪切力,如果内固定不能实现有效的稳定,便可能出现内置物的移动和椎体的畸形^[26]。一篇超过 100 个双节段颈椎 ROI-C 的实验中显示^[27],在术后 1 年时,其确切融合率可达到 90%以上,而总融合率为 100%。

本次实验将其他的干扰因素进行排除。只专注于临床中最常见的单节段颈椎患者。并且非常重要的一点,单节段颈椎病的手术方式在临床中只会选择 ACDF。因此,使得我们的研究具有非常重要的临床价值。本次研究的结果再次证实了已有的相关研究结果^[28-30]。不论是疼痛指标还是疗效指标,ROI-C 均能取得良好的术后治疗效果,且与 ACDF 并无显著差异。而在影像学指标,特别是融合率方面,更是达到了手术的要求。在最为关注的术后舒适感以及手术相关指标的比较中,ROI-C 组的相关指标更是体现了明显的优势。

本次研究仍有较多的不足和缺陷,本次实验为回顾性实验,未能实现多中心随机双盲前瞻性的设计。此外,本次实验的患者数量仍有不足。随访时间较短,也仅限于 1 年。尽管如此,本次实验结果显示:使用 ROI-C 能够显著有效的降低手术时间和出血量,控制手术带来的创伤,提高患者的术后舒适度的同时,保证患者的手术质量和疗效。值得在临床中进一步推广应用。

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