

· 临床研究 ·

颈椎特异性短杠杆微调手法治疗神经根型颈椎病的多中心临床研究

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摘要 目的:评价应用颈椎特异性短杠杆微调手法治疗神经根型颈椎病的价值。**方法:**从 4 家医院选取神经根型颈椎病患者 120 例, 随机分期为 3 组, 每组 40 例。宣教组通过健康教育指导患者纠正以往各种可能诱发颈椎病的不良习惯, 长杠杆手法组按照《推拿学》中颈椎病推拿手法操作规范进行手法治疗, 短杠杆手法组采用颈椎特异性短杠杆微调手法治疗。3 组患者均治疗 4 周, 然后分别采用颈椎功能障碍指数(the neck disability index, NDI)、颈椎病治疗成绩评分、简明健康状况调查表(short form 36 health survey questionnaire, SF-36)评分评价临床疗效, 并根据患者的颈椎病治疗成绩评分和治疗费用计算疗效费用比。**结果:**治疗前 3 组患者的 NDI 比较, 差异无统计学意义[(39.80 ± 4.31)%, (39.90 ± 4.31)%, (39.45 ± 4.53)%, $F = 0.122$, $P = 0.885$]。治疗结束后 3 组患者的 NDI 比较, 差异有统计学意义[(32.40 ± 5.62)%, (11.45 ± 6.49)%, (7.75 ± 4.94)%, $F = 216.088$, $P = 0.000$]; 短杠杆手法组的 NDI 低于宣教组和长杠杆手法组($P = 0.000$, $P = 0.013$), 长杠杆手法组的 NDI 低于宣教组($P = 0.000$)。3 组患者治疗前后 NDI 差值比较, 差异有统计学意义[(7.40 ± 4.18)%, (28.45 ± 4.16)%, (31.70 ± 3.09)%, $F = 470.802$, $P = 0.000$]; 短杠杆手法组治疗前后 NDI 差值大于宣教组和长杠杆手法组($P = 0.000$, $P = 0.001$), 长杠杆手法组治疗前后 NDI 差值大于宣教组($P = 0.000$)。治疗前 3 组患者的治疗成绩评分比较, 差异无统计学意义[(57.33 ± 7.07)%, (57.50 ± 8.32)%, (58.10 ± 6.41)%, $F = 0.124$, $P = 0.884$]。治疗结束后 3 组患者的治疗成绩评分比较, 差异有统计学意义[(66.47 ± 5.95)%, (88.28 ± 6.19)%, (91.03 ± 8.90)%, $F = 142.267$, $P = 0.000$]; 短杠杆手法组和长杠杆手法组治疗结束后的治疗成绩评分均高于宣教组($P = 0.000$, $P = 0.000$); 短杠杆手法组和长杠杆手法组治疗结束后的治疗成绩评分比较, 差异无统计学意义($P = 0.199$)。3 组患者治疗前后治疗成绩评分差值比较, 差异有统计学意义[(9.13 ± 7.79)%, (30.78 ± 8.98)%, (32.93 ± 8.18)%, $F = 99.672$, $P = 0.000$]; 短杠杆手法组和长杠杆手法组治疗前后治疗成绩评分差值均大于宣教组($P = 0.000$, $P = 0.000$); 短杠杆手法组和长杠杆手法组治疗前后治疗成绩评分差值比较, 差异无统计学意义($P = 0.482$)。治疗前 3 组患者的 SF-36 评分比较, 差异无统计学意义[(98.09 ± 7.84)分, (98.02 ± 10.94)分, (99.48 ± 11.78)分, $F = 0.253$, $P = 0.777$]。治疗结束后 3 组患者的 SF-36 评分比较, 差异有统计学意义[(106.76 ± 6.21)分, (113.30 ± 8.75)分, (118.14 ± 8.26)分, $F = 21.367$, $P = 0.000$]; 短杠杆手法组治疗结束后的 SF-36 评分高于宣教组和长杠杆手法组($P = 0.000$, $P = 0.018$), 长杠杆手法组治疗结束后的 SF-36 评分高于宣教组($P = 0.001$)。3 组患者治疗前后 SF-36 评分差值比较, 差异有统计学意义[(8.67 ± 5.69)分, (15.28 ± 7.46)分, (18.66 ± 7.19)分, $F = 22.151$, $P = 0.000$]; 短杠杆手法组和长杠杆手法组治疗前后 SF-36 评分差值均大于宣教组($P = 0.000$, $P = 0.000$); 短杠杆手法组和长杠杆手法组治疗前后 SF-36 评分差值比较, 差异无统计学意义($P = 0.073$)。短杠杆手法组的疗效费用比高于长杠杆手法组[(37.86 ± 7.99)%, (33.21 ± 8.63)%, $t = -2.331$, $P = 0.035$]。**结论:**颈椎特异性短杠杆微调手法治疗神经根型颈椎病, 疗效优于单纯宣教和长杠杆手法, 疗效费用比优于长杠杆手法治疗。

关键词 颈椎病; 神经根病; 手法; 整骨; 特异性微调手法; 临床试验; 多中心研究

A multicenter clinical study of cervical specific short – lever fine – regulation manipulation for treatment of cervical spondylotic radiculopathy

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ABSTRACT Objective: To evaluate the applied values of cervical specific short – lever fine – regulation manipulation in the treatment of cervical spondylotic radiculopathy (CSR). **Methods:** One hundred and twenty patients with CSR were selected out from four hospitals and were randomly divided into education group, long – lever manipulation group and short – lever manipulation group, 40 cases in each group. The patients in education group got health education and were guided to correct all kinds of previous bad habits that might induce cervical spondylosis. The patients in long – lever manipulation group were treated with manipulation therapy according to the operation specification of TUINA manipulation of cervical spondylosis which was extracted from TUINA Science. The patients in short – lever manipulation group were treated with cervical specific short – lever fine – regulation manipulation. All patients in the 3 groups were treated for 4 weeks, and the clinical curative effects were evaluated and compared between the 3 groups by using neck disability index (NDI), treatment outcome score of cervical spondylosis and short form 36 health survey questionnaire (SF – 36) score respectively, and the effectiveness – cost ratio was calculated according to patients' treatment outcome scores of cervical spondylosis and cost of treatment. **Results:** There was no statistical difference in NDI between the 3 groups before the treatment ($39.80 \pm 4.31, 39.90 \pm 4.31, 39.45 \pm 4.53\%$, $F = 0.122, P = 0.885$). There was statistical difference in NDI between the 3 groups after the end of the treatment ($32.40 \pm 5.62, 11.45 \pm 6.49, 7.75 \pm 4.94\%$, $F = 216.088, P = 0.000$). The NDI was lower in short – lever manipulation group compared to education group and long – lever manipulation group ($P = 0.000, P = 0.013$), and was lower in long – lever manipulation group compared to education group ($P = 0.000$). There was statistical difference between the 3 groups in the differences of NDI between pretreatment and posttreatment ($7.40 \pm 4.18, 28.45 \pm 4.16, 31.70 \pm 3.09\%$, $F = 470.802, P = 0.000$). The difference of NDI between pretreatment and posttreatment was larger in short – lever manipulation group compared to education group and long – lever manipulation group ($P = 0.000, P = 0.001$), and was larger in long – lever manipulation group compared to education group ($P = 0.000$). There was no statistical difference in the treatment outcome scores between the 3 groups before the treatment ($57.33 \pm 7.07, 57.50 \pm 8.32, 58.10 \pm 6.41\%$, $F = 0.124, P = 0.884$). There was statistical difference in the treatment outcome scores between the 3 groups after the end of the treatment ($66.47 \pm 5.95, 88.28 \pm 6.19, 91.03 \pm 8.90\%$, $F = 142.267, P = 0.000$). The treatment outcome scores were higher in short – lever manipulation group and long – lever manipulation group compared to education group ($P = 0.000, P = 0.000$) and there was no statistical difference in the treatment outcome scores between short – lever manipulation group and long – lever manipulation group ($P = 0.199$) after the end of the treatment. There was statistical difference between the 3 groups in the differences of treatment outcome scores between pretreatment and posttreatment ($9.13 \pm 7.79, 30.78 \pm 8.98, 32.93 \pm 8.18\%$, $F = 99.672, P = 0.000$). The differences of treatment outcome scores between pretreatment and posttreatment were larger in short – lever manipulation group and long – lever manipulation group compared to education group ($P = 0.000, P = 0.000$). There was no statistical difference between short – lever manipulation group and long – lever manipulation group in the differences of treatment outcome scores between pretreatment and posttreatment ($P = 0.482$). There was no statistical difference in SF – 36 scores between the 3 groups before the treatment ($98.09 \pm 7.84, 98.02 \pm 10.94, 99.48 \pm 11.78$ points, $F = 0.253, P = 0.777$). There was statistical difference in SF – 36 scores between the 3 groups after the end of the treatment ($106.76 \pm 6.21, 113.30 \pm 8.75, 118.14 \pm 8.26$ points, $F = 21.367, P = 0.000$). The SF – 36 scores were higher in short – lever manipulation group compared to education group and long – lever manipulation group ($P = 0.000, P = 0.018$), and were higher in long – lever manipulation group compared to education group after the end of the treatment ($P = 0.001$). There was statistical difference between the 3 groups in the differences of SF – 36 scores between pretreatment and posttreatment ($8.67 \pm 5.69, 15.28 \pm 7.46, 18.66 \pm 7.19$ points, $F = 22.151, P = 0.000$). The differences of SF – 36 scores between pretreatment and posttreatment were larger in short – lever manipulation group and long – lever manipulation group compared to education group ($P = 0.000, P = 0.000$). There was no statistical difference between short – lever manipulation group and long – lever manipulation group in the differences of SF – 36 scores between pretreatment and posttreatment ($P = 0.073$). The effectiveness – cost ratio was higher in short – lever manipulation group compared to long – lever manipulation group (37.86 ± 7.99 vs $33.21 \pm 8.63\%$, $t = -2.331, P =$

0.035)。Conclusion: The curative effect of cervical specific short-lever fine-regulation manipulation is better than that of health education and that of long-lever manipulation in the treatment of CSR, and it is superior to long-lever manipulation in effectiveness-cost ratio.

Keywords cervical spondylosis; radiculopathy; manipulation, osteopathic; specific spine adjustment technique; clinical trial; multicenter study

颈椎特异性短杠杆微调手法来源于上海中医药大学附属岳阳中西医结合医院推拿科沈国权创立的脊柱微调手法。该手法自 20 世纪 90 年代开始应用于临床,并通过国家级继续教育学习班在国内推广。从已有的研究来看^[1-6],应用该手法治疗颈椎病安全有效,但这些研究中缺乏多中心的临床研究。为此,本研究拟从临床疗效及卫生经济学角度探讨颈椎特异性短杠杆微调手法治疗神经根型颈椎病的价值,现总结报告如下。

1 临床资料

1.1 一般资料 纳入研究的患者为 2012—2013 年上海中医药大学附属岳阳中西医结合医院推拿科、上海中医药大学附属曙光医院骨伤科、上海交通大学医学院附属瑞金医院推拿科和上海市第一人民医院推拿科收治的神经根型颈椎病患者。试验方案经各医院医学伦理委员会审查通过。

1.2 诊断标准 采用《第二届颈椎病专题会议座谈会纪要》中神经根型颈椎病的诊断标准^[7]。

1.3 纳入标准 ①符合上述诊断标准;②年龄 30 ~ 50 岁;③自愿加入本研究,签署知情同意书。

1.4 排除标准 ①合并高血压、冠心病、动脉粥样硬化、贫血、骨质疏松症、精神疾病及肝、肾、消化系统严重病变者;②目前正在接受其他相关治疗者。

2 方法

2.1 样本量测算、随机分组及盲法实施 将纳入研究的患者分为宣教组、长杠杆手法组和短杠杆手法组。综合文献资料,非特异性长杠杆手法和特异性短杠杆手法治疗颈椎病的有效率分别为 80% 和 90%。设定 $\alpha = 0.05$, $U_{\alpha} = 1.96$, $\pi = 0.8$, $\delta = 0.08$, 根据样本量计算公式: 样本量 = $U_{\alpha}^2 \times \pi \times (1 - \pi) / \delta^2 = 96.04$, 以此估计所需样本量为 100 例,考虑到 20% 的病例脱落率,实际纳入的病例数应为 120 例,每组应纳入病例为 40 例。根据随机方案产生的各分中心的随机编码,由项目负责人以密件形式发放给各研究分中心项目负责人,安排专人保管。对疗效评估人员和数据统计人员设盲。

2.2 临床干预 宣教组定期对患者进行健康教育,消除患者日常工作、学习及生活中各种诱发颈椎病的因素,并为每位接受健康教育的患者发放颈椎病健康教育资料。长杠杆手法组按《推拿学》中颈椎病推拿手法操作规范^[8]进行操作。患者坐位,医者先按揉其风池、肩井、肩外俞、肩髃、曲池、合谷等穴,然后立于患者背后,用揉法放松颈肩部 5 ~ 10 min (揉法力量 4 kg, 频率每分钟 120 次)。软组织推拿结束后施以颈椎斜扳手法,听到局部响声提示操作成功 (但不可以强求,操作动作到位即可)。再用拿法拿揉颈项部,最后提拿两侧肩井,并搓患侧肩部至前臂。每周治疗 3 次。短杠杆手法组软组织推拿手法同长杠杆手法组,然后施以特异性短杠杆手法,以病变脊柱节段棘突、横突为接触点,拇指或食指掌指关节桡侧着力,实施快速小幅度推扳,调整成功时可闻及关节弹响或触及松动感。3 组均每周治疗 3 次,2 周为 1 个疗程,共治疗 2 个疗程。

2.3 临床观察 采用颈椎功能障碍指数 (the neck disability index, NDI) 调查问卷表^[9] 计算患者的 NDI, $NDI = [\text{每个项目得分的总和} / (\text{受试对象完成的项目数} \times 5)] \times 100\%$ 。采用四川大学华西医院康复中心制定的颈椎病治疗成绩评分表^[10] 计算治疗成绩评分, 治疗成绩评分 = $[(29 - \text{实际得分}) / 29] \times 100\%$ 。采用简明健康状况调查表 (short form 36 health survey questionnaire, SF-36) 评定患者的生活质量。根据患者的颈椎病治疗成绩评分和治疗费用计算疗效费用比, 疗效费用比 = $(\text{治疗前后颈椎病治疗成绩评分差值} / \text{治疗费用}) \times 100\%$ 。

2.4 数据统计 采用 SPSS13.0 软件进行数据统计分析。3 组患者年龄、体质量、病程、NDI、颈椎病治疗成绩评分、SF-36 评分的组间整体比较均采用单因素方差分析,组间两两比较采用 LSD-*t* 检验;短杠杆手法组和长杠杆手法组疗效费用比的组间比较采用 *t* 检验。检验水准 $\alpha = 0.05$ 。

3 结果

3.1 分组结果 纳入研究的患者共 120 例,宣教组、

长杠杆手法组和短杠杆手法组各 40 例。3 组患者的基线资料比较,差异无统计学意义,有可比性(表 1)。

表 1 3 组神经根型颈椎病患者基线资料比较

组别	样本量(例)	年龄($\bar{x} \pm s$, 岁)	体质量($\bar{x} \pm s$, kg)	病程($\bar{x} \pm s$, 周)
宣教组	40	37.95 \pm 5.43	66.18 \pm 9.62	2.64 \pm 1.77
长杠杆手法组	40	37.48 \pm 4.78	64.25 \pm 8.05	2.73 \pm 1.78
短杠杆手法组	40	38.63 \pm 5.07	64.98 \pm 9.26	2.69 \pm 1.84
F 值		0.514	0.467	0.024
P 值		0.600	0.628	0.976

3.2 疗效及卫生经济学指标观察结果 治疗前 3 组患者的 NDI 比较,差异无统计学意义。治疗结束后 3 组患者的 NDI 比较,差异有统计学意义;短杠杆手法组的 NDI 低于宣教组和长杠杆手法组($P=0.000$, $P=0.013$),长杠杆手法组的 NDI 低于宣教组($P=0.000$)。3 组患者治疗前后 NDI 差值比较,差异有统计学意义;短杠杆手法组治疗前后 NDI 差值大于宣教组和长杠杆手法组($P=0.000$, $P=0.001$),长杠杆手法组治疗前后 NDI 差值大于宣教组($P=0.000$)。见表 2。

治疗前 3 组患者的治疗成绩评分比较,差异无统计学意义。治疗结束后 3 组患者的治疗成绩评分比较,差异有统计学意义;短杠杆手法组和长杠杆手法组治疗结束后的治疗成绩评分均高于宣教组($P=0.000$, $P=0.000$);短杠杆手法组和长杠杆手法组治疗结束后的治疗成绩评分比较,差异无统计学意义($P=0.199$)。3 组患者治疗前后治疗成绩评分差值比较,差异有统计学意义;短杠杆手法组和长杠杆手法组治疗前后治疗成绩评分差值均大于宣教组($P=0.000$, $P=0.000$);短杠杆手法组和长杠杆手法组治疗前后治疗成绩评分差值比较,差异无统计学意义($P=0.482$)。见表 3。

治疗前 3 组患者的 SF-36 评分比较,差异无统计学意义。治疗结束后 3 组患者的 SF-36 评分比较,差异有统计学意义;短杠杆手法组治疗结束后的 SF-36 评分高于宣教组和长杠杆手法组($P=0.000$, $P=0.018$),长杠杆手法组治疗结束后的 SF-36 评分高于宣教组($P=0.001$)。3 组患者治疗前后 SF-36 评分差值比较,差异有统计学意义;短杠杆手法组和长杠杆手法组治疗前后 SF-36 评分差值均大于宣教组($P=0.000$, $P=0.000$);短杠杆手法组和长杠杆手法组治疗前后 SF-36 评分差值比较,差异无统计学意义($P=0.073$)。见表 4。

短杠杆手法组的疗效费用比高于长杠杆手法组[(37.86 \pm 7.99)%, (33.21 \pm 8.63)%, $t=-2.331$, $P=0.035$]。

4 讨论

尽管对脊柱推拿的安全性关注日益增强,但仍然存在从业人员水平参差不齐、技术粗糙等问题。近年来,一些业界的领跑者开始把脊柱推拿研究的重心放到规范化、标准化、安全性等方面,脊柱生物力学研究也逐渐成为热点^[11]。根据近年来有关脊柱推拿的临床和实验研究进展,沈国权教授对现存脊柱推拿理论和方法进行了反思,提出了将生物力学原理融入脊柱

表 2 3 组神经根型颈椎病患者治疗前后颈椎功能障碍指数 $\bar{x} \pm s$

组别	样本量(例)	治疗前	治疗结束后	治疗前后差值
宣教组	40	(39.80 \pm 4.31)%	(32.40 \pm 5.62)%	(7.40 \pm 4.18)%
长杠杆手法组	40	(39.90 \pm 4.31)%	(11.45 \pm 6.49)%	(28.45 \pm 4.16)%
短杠杆手法组	40	(39.45 \pm 4.53)%	(7.75 \pm 4.94)%	(31.70 \pm 3.09)%
F 值		0.122	216.088	470.802
P 值		0.885	0.000	0.000

表 3 3 组神经根型颈椎病患者治疗前后颈椎治疗成绩评分 $\bar{x} \pm s$

组别	样本量(例)	治疗前	治疗结束后	治疗前后差值
宣教组	40	(57.33 \pm 7.07)%	(66.47 \pm 5.95)%	(9.13 \pm 7.79)%
长杠杆手法组	40	(57.50 \pm 8.32)%	(88.28 \pm 6.19)%	(30.78 \pm 8.98)%
短杠杆手法组	40	(58.10 \pm 6.41)%	(91.03 \pm 8.90)%	(32.93 \pm 8.18)%
F 值		0.124	142.267	99.672
P 值		0.884	0.000	0.000

表 4 3 组神经根型颈椎病患者治疗前后简明健康状况调查表评分 $\bar{x} \pm s$, 分

组别	样本量(例)	治疗前	治疗结束后	治疗前后差值
宣教组	40	98.09 ± 7.84	106.76 ± 6.21	8.67 ± 5.69
长杠杆手法组	40	98.02 ± 10.94	113.30 ± 8.75	15.28 ± 7.46
短杠杆手法组	40	99.48 ± 11.78	118.14 ± 8.26	18.66 ± 7.19
F 值		0.253	21.367	22.151
P 值		0.777	0.000	0.000

手法的思路,应用短杠杆微调手法治疗脊柱源性疾病,并取得了满意的疗效。

上世纪 90 年代,沈国权教授在继承传统推拿手法的基础上结合现代生物力学研究成果创立了特异性短杠杆微调手法。脊柱微调手法操作精巧、细腻、柔和,可控性强、安全性高。脊柱微调是以中医整体观念为指导思想的整体最优脊柱调整观念,以中医理论、现代解剖知识及生物力学理论为依据^[12-13]。临床上,对颈椎病中医特异性手法的规范性、多中心的研究较少,存在的主要问题有单个技术应用范围小、覆盖人群少,规范化水平低,临床疗效未经过系统评价、证据不足、推广困难等^[14],因此进行多中心的临床研究十分必要。

治疗结束后,3 组患者的 NDI 均较治疗前有所降低,短杠杆手法组的降低程度最明显、长杠杆手法组次之、宣教组最低;3 组患者的治疗成绩评分和 SF-36 评分均较治疗前有所增加,短杠杆手法组和长杠杆手法组的增加程度相当,且均大于宣教组。说明短杠杆手法和长杠杆手法均能有效治疗神经根型颈椎病,短杠杆手法治疗的效果更好。从卫生经济学指标的观察结果来看,短杠杆手法治疗神经根型颈椎病的疗效费用比更高。

综上所述,颈椎特异性短杠杆微调手法治疗神经根型颈椎病,疗效优于单纯宣教和长杠杆手法,疗效费用比优于长杠杆手法治疗。

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