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Clinical Study

Therapeutic observation on point-toward-point needling at points on the low back regions for residual back pain after percutaneous kyphoplasty

腰背部穴位透刺治疗经皮椎体后凸成形术术后残余痛的疗效观察

Chen Shan-shan (陈姗姗)[1,2]
1 Zhejiang Chinese Medical University, Hangzhou 310053, China
2 Traditional Chinese Medical Hospital of Zhuji, Zhejiang 311800, China

Abstract
Objective: To observe the effect of point-toward-point needling at points on the low back regions on residual back pain after percutaneous kyphoplasty (PKP), thoracolumbar function and quality of life (QOL) in patients with osteoporotic vertebral compression fracture (OVCF).
Methods: A total of 72 patients with OVCF and residual back pain after PKP were included and allocated into a treatment group (*n*=36) and a control group (*n*=36) by the random number table. Cases in the control group received salmon calcitonin injection (miacalcic), for 1 mL each time, once a day, and oral intake of calcium carbonate D_3 pill, 600 mg each time, once a day, whereas cases in the treatment group received point-toward-point needling at points on the low back regions and electroacupuncture (EA) for 30 min each time, once a day and 6 times a week on the basis of the treatment in the control group. Treatment in both groups lasted for 2 weeks. Therapeutic efficacy indicators including visual analog scale (VAS), Oswestry disability index (ODI) and Barthel index (BI) were evaluated before and after treatment and at follow-up visit (1 month after treatment).
Results: The total effective rate was 94.4% and 88.9% in the treatment group after treatment and at the follow-up visit, respectively, higher than 77.8% and 69.4% in the control group, and the between-group differences were statistically significant (both *P*<0.05). After treatment and at the follow-up visit, the VAS and ODI scores decreased, and BI scores increased in both groups, and the intra-group differences were statistically significant (all *P*<0.05). After treatment and at the follow-up visit, between-group differences of VAS, ODI and BI scores were statistically significant (all *P*<0.05).
Conclusion: On the basis of conventional medication treatment, point-toward-point needling at points on the low back regions has a good therapeutic effect in relieving residual back pain after PKP, improving thoracolumbar function and QOL, better than conventional medication treatment alone.
Keywords: Acupuncture Therapy; Point-toward-point Method; Electroacupuncture; Fractures, Compression; Osteoporosis; Low Back Pain; Pain Measurement; Visual Analog Scale

【摘要】目的：探讨腰背部穴位透刺对骨质疏松胸腰段压缩性骨折经皮椎体后凸成形术(PKP)术后残余痛、胸腰椎功能及生活质量的改善作用。**方法：**共纳入骨质疏松胸腰段压缩性骨折PKP术后存在残余痛的患者72例，根据随机数字表法将其随机分为观察组和对照组，每组36例。对照组予鲑降钙素注射液(密盖息)皮下注射，每次1 mL，1次/d；碳酸钙D_3片口服，每次 600 mg，1次/d。观察组在接受与对照组相同的用药基础上加用腰背部穴位透刺和电针治疗，每次30 min，1次/d，6次/周。两组疗程均为2周。治疗前、治疗后及随访时(治疗后1个月)进行视觉模拟量表(VAS)、改良Oswestry功能障碍指数(ODI)及Barthel指数(BI)评分，并根据以上评分评价临床疗效。**结果：**观察组治疗后及随访时的总有效率分别为94.4%和88.9%，高于对照组的77.8%和69.4%，组间差异均有统计学意义(均*P*＜0.05)。两组患者治疗后及随访时VAS和改良ODI评分下降，BI评分均升高，与本组治疗前差异均具有统计学意义(均*P*＜0.05)。治疗后及随访时观察组的VAS、改良ODI及BI评分均与对照组有统计学差异(均*P*＜0.05)。**结论：**在常规药物治疗基础上加用腰背部穴位透刺能有效减轻患者PKP术后残余痛，改善患者胸腰椎功能，提高患者生活质量，疗效优于单独常规药物治疗。

【关键词】针刺疗法；透针；电针；骨折，压缩性；骨质疏松；腰痛；疼痛测评；视觉模拟量表
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Author: Chen Shan-shan, bachelor, attending physician of traditional Chinese medicine.
E-mail: css860310@aliyun.com

Osteoporotic vertebral compression fracture (OVCF) is a common condition in the elderly population accompanied by decreased bone mineral density (BMD), which can cause acute or chronic low back pain, functional limitations of the spine, a thoracolumbar vertebral deformity, vertebral height (VH) loss, and deterioration of quality of life (QOL)[1-2]. Treatments of OVCF include conservative treatment and surgery, in which minimally invasive surgery aims to stabilize bone fracture and rebuild vertebral mechanical strength to reach the goal of preventing further compression, relieving pain and restoring the normal movement capability. Percutaneous kyphoplasty (PKP) is a common operation method. It is both safe and effective for pain, reducing bed rest time and complications, and improving QOL[3-5]. However, some patients may experience residual low back pain after PKP, which hampers the QOL. Thus, it's crucial to search for an effective treatment for residual back pain after PKP. We used point-toward-point needling at points on the low back regions [acupoints on the Bladder Meridian and Jiaji (EX-B 2) points] combining electroacupuncture (EA) to treat residual back pain after PKP, for observing the effect of such method on pain, thoracolumbar function and QOL. The results are summarized as follows.

1 Clinical Materials

1.1 Diagnostic criteria

The diagnostic criteria of osteoporosis were based on the *Expert Consensus on the Diagnosis of Osteoporosis in Chinese Population* (3rd draft, 2014)[6]: BMD of the proximal femur lower by over 2.0 standard deviations (SD) compared to normal young adults or bone mineral loss over 25%; diagnosis of lumbar compression fracture by X-ray, CT or MRI examination.

1.2 Inclusion criteria

Conforming to the diagnostic criteria above; aged between 50 and 65 years, male or female; the severity of residual back pain after PKP evaluated by visual analog scale (VAS) ≥3 points; the education level above primary school to ensure the capability of finishing the scale evaluation; signed informed consent.

1.3 Exclusion criteria

Bone fracture caused by tumor or other pathological reasons or metabolic osteoporotic patients; a history of thoracolumbar vertebral bone fracture or surgery in such region; low back pain caused by intervertebral disc herniation or muscle tension; spine deformity or accompanied with other neurogenic diseases affecting lumbar function; skin lesion or infection of local skin; medicine allergy in our study or fear of the acupuncture treatment; poor compliance during treatment and follow-up visit period.

1.4 Dropout criteria

Poor compliance or voluntarily quit the experiment; occurrence of serious adverse events or complications, and unable to follow the further treatment; incomplete clinical information which may affect therapeutic evaluation.

1.5 Statistical methods

The data processing was done using the SPSS version 21.0 software; the mean ± standard deviation ($\bar{x} \pm s$) was used to describe measurement data and compared with *t*-test; the rank-sum test was used for ranked data. A *P*-value of less than 0.05 indicated statistical significance.

1.6 General data

A total of 72 OVCF patients with residual back pain after PKP admitted to our hospital between May 2016 and October 2017 were randomly allocated into a treatment group and a control group, with 36 cases in each group. Inter-group comparisons of general data showed no statistical significance (all *P*>0.05), indicating that the two groups were comparable (Table 1).

Table 1. Comparison of general data

Group	*n*	Gender (case)		Mean age ($\bar{x} \pm s$, year)	Mean duration ($\bar{x} \pm s$, day)	Affected vertebra			Number of affected vertebra		
		Male	Female			T_{12}	L_1	L_2	1	2	3
Treatment	36	16	20	58.3±6.7	4.5±0.7	10	23	11	30	4	2
Control	36	17	19	57.6±7.2	4.2±0.6	10	24	13	26	9	1

2 Treatment Methods

2.1 Control group

Patients in the control group received salmon calcitonin injection (miacalcic) combining calcium carbonate D_3 pill. Salmon calcitonin injection (miacalcic, Swiss Novarits Pharmaceutical Co., Ltd., series number: 201603) was applied by subcutaneous injection, 1 mL every time, once a day; calcium carbonate D_3 pill (Wyeth Pharmaceutical Co., Ltd., series number: 1610234) was orally administered, 2 pills (600 mg) every time, once a day with 7 d as one course.

2.2 Treatment group

Patients in the treatment group received point-toward-point needling at points on the low back regions and EA stimulation on the basis of the treatment in the control group.

Acupoints: Back-Shu points and Jiaji (EX-B 2) points on the same level on the affected low back regions.

Methods: After routine sterilization with 75% alcohol,

disposable filiform needles (Hwato Brand, Suzhou Medical Appliance Co., Ltd., China, series number: 160241) of 0.25 mm in diameter and 40 mm in length were used. The point-toward-point needling was manipulated from the Back-Shu points on the Bladder Meridian and corresponding Jiaji (EX-B 2) points at the same level where pain primarily occurred, with the needle tip going downward where pain disappeared. Upon the needling qi arrival, Hwato brand SDZ-II EA apparatus was connected, with sparse-dense wave (2 Hz/10 Hz), to the Back-Shu points on the Bladder Meridian and corresponding Jiaji (EX-B 2) points at the top and bottom respectively of the same side, to generate a bearable stimulation. EA treatment lasted 30 min, once a day, 6 times a week with a 1-day interval as a treatment course.

Patients in both groups received 2 courses. The follow-up visit was conducted 1 month after the end of the treatment.

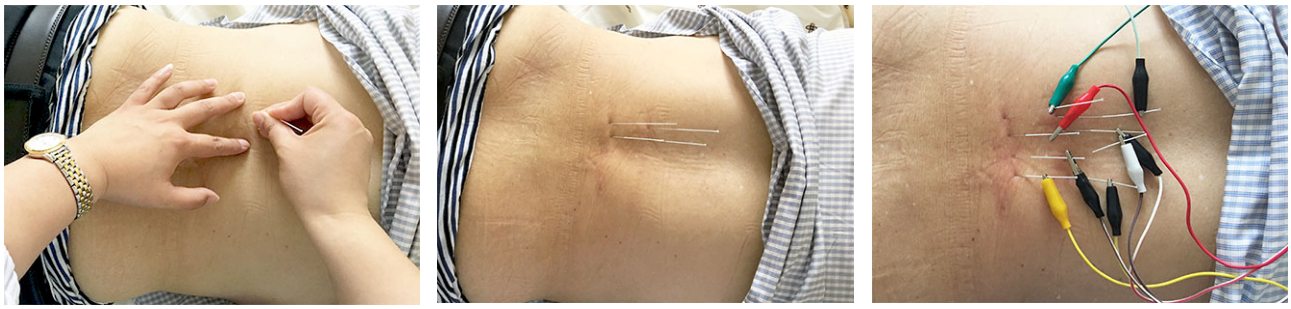

Figure 1. Point-toward-point needling manipulation

3 Therapeutic Efficacy Analysis

3.1 Observation items

Therapeutic efficacy indexes of pain severity, thoracolumbar function and QOL were evaluated before and after treatment and at the follow-up visit (1 month after treatment).

3.1.1 VAS

The pain intensity was evaluated by the VAS[7]. 0 point for painless and 10 points for extreme pain. Higher score indicated more serious pain.

3.1.2 Oswestry disability index (ODI)

Thoracolumbar function was evaluated with ODI[8]. ODI included 10 sub-items, and the score ranged from 0 to 5 in each item. The total possible score of ODI was 50 points; a higher score indicated a worse thoracolumbar function.

3.1.3 Barthel index (BI)

The QOL was evaluated with BI[9]. BI included 10 sub-items with a total possible score of 100 points; a higher score indicated a better QOL condition.

3.2 Criteria of therapeutic efficacy

Based on literature, we used VAS improvement rate as the criteria of therapeutic efficacy[10].

VAS improvement rate = (VAS score before treatment − VAS score after treatment) ÷ VAS score before treatment × 100 %.

Marked effect: VAS improvement rate ≥50%.

Effective: VAS improvement rate ≥25%, but <50%.

Invalid: VAS improvement rate <25%.

3.3 Results

3.3.1 Comparison of therapeutic efficacy

The total effective rate was 94.4% and 88.9% in the treatment group after treatment and at the follow-up visit respectively, versus 77.8% and 69.4% in the control group, and the between-group differences were statistically significant (both $P<0.05$), (Table 2 and Table 3).

Table 2. Comparison of therapeutic efficacy after treatment (case)

Group	*n*	Marked effect	Effective	Invalid	Total effective rate (%)
Treatment	36	25	9	2	94.4[1)]
Control	36	14	14	8	77.8

Note: Compared with the control group, 1) $P<0.05$

Table 3. Comparison of therapeutic efficacy at the follow-up visit (case)

Group	*n*	Marked effect	Effective	Invalid	Total effective rate (%)
Treatment	36	24	8	4	88.9[1)]
Control	36	12	13	11	69.4

Note: Compared with the control group, 1) $P<0.05$

3.3.2 Comparison of VAS score

There was no between-group statistically significant difference in VAS score between the two groups before treatment (P>0.05). After treatment and at the follow-up visit, the VAS score dropped significantly in both groups (both P<0.05), and the VAS scores in the treatment group at the two observation time points were lower than those in the control group, indicating statistical significance (both P<0.05), so it's more effective for pain relief in the treatment group (Table 4).

Table 4. Comparison of VAS score at the two different time points ($\bar{x}$ ±s, point)

Group	n	Before treatment	After treatment	Follow-up visit
Treatment	36	7.5±0.9	3.3±0.7[1)2)]	1.4±0.3[1)2)]
Control	36	7.3±1.2	4.6±0.8[1)]	3.2±0.6[1)]

Note: Intra-group comparison, 1) P<0.05; compared with the control group at the same time point, 2) P<0.05

3.3.3 Comparison of ODI score

There was no between-group statistically significant difference in ODI score before treatment (P>0.05). After treatment and at the follow-up visit, the ODI score dropped significantly in both groups (both P<0.05), and the ODI scores in the treatment group at the two observation time points were lower than those in the control group, showing statistical significance (both P<0.05), which indicated a better improvement of functional disorder in the treatment group (Table 5).

Table 5. Comparison of ODI score at the two different time points ($\bar{x}$ ±s, point)

Group	n	Before treatment	After treatment	Follow-up visit
Treatment	36	32.7±6.4	12.2±4.7[1)2)]	8.5±1.6[1)2)]
Control	36	32.3±7.8	19.8±5.5[1)]	15.2±2.9[1)]

Note: Intra-group comparison, 1) P<0.05; compared with the control group at the same time point, 2) P<0.05

3.3.4 Comparison of BI score

There was no between-group statistically significant difference in BI score before treatment (P>0.05). After treatment and at the follow-up visit, the BI score increased significantly in both groups (both P<0.05), and the BI scores in the treatment group at the two observation time points were higher than those in the control group, showing statistical significance (both P<0.05), which indicated a better improvement of QOL in the treatment group (Table 6).

Table 6. Comparison of BI score at the two different time points ($\bar{x}$ ±s, point)

Group	n	Before treatment	After treatment	Follow-up visit
Treatment	36	30.4±11.5	54.7±10.2[1)2)]	65.2±14.7[1)2)]
Control	36	31.6±12.1	45.3±13.9[1)]	53.1±11.6[1)]

Note: Intra-group comparison, 1) P<0.05; compared with the control group at the same time point, 2) P<0.05

4 Discussion

OVCF is a common disorder in orthopedics department, and usually affects the elderly population. Although this disease has a prognosis, about 30% of the patients suffer from poor outcomes with the conservative treatment[11]. PKP is an important treatment method for OVCF[12-14]. It can reset vertebral position with a percutaneous puncture balloon which can dilate in the vertebrae. Such method can not only restore vertebral body height, but also increase vertebral rigidity and strength, so as to restore a normal curve of the spine. Moreover, it can form a space in vertebral side the body, and nearly stable to decrease the incidence of leakage. During bone cement injection, the solidification process can generate much heat to destroy pain-related nerve endings of the vertebral body, which might be the pain relief mechanism of PKP method[15-16]. Generally speaking, a lot of patients experience a substantial relief of low back pain after PKP surgery, while some patients feel local pain or referred pain in the area beside operative incision location, which is usually thought to be the PKP post-surgery residual pain. Currently, treatments for residual pain include bed rest, oral intake of anti-inflammatory drug and anti-osteoporosis methods.

The clinical manifestation of OVCF residual back pain after PKP pertains to Bi-impediment syndrome or low back pain in traditional Chinese medicine (TCM). The general pathogenesis includes kidney-essence deficiency as the root cause and qi stagnation and blood stasis as the symptoms. The kidney stores essence and governs bone. Insufficient kidney essence leads to weakness of the bone and causes bone fracture easily. Bone fracture causes harm to sinews and collaterals, leads to blood loss, qi stagnation, meridian obstruction and thus generates pain. Therefore, treatment should be focused on supplementing kidney essence, facilitating qi and blood movement. The Bladder Meridian connects with the kidney and runs through low back region, governs sinews, and is the most commonly used meridian in treating low back pain. Chen H, *et al*[17] held that low back pain was closely

linked with the Bladder Meridian from the perspective of meridian route and modern anatomy. The Back-Shu points in our research can dredge meridian to stop pain on one hand, and regulate visceral functions on the other hand. Yin YH, *et al*[18] treated low back pain patients caused by lumbar disc herniation with acupuncture on the Back-Shu points on the first side line of the Bladder Meridian. The result showed a significant clinical effect. We used Jiaji (EX-B 2) points at the same level, since such points locate between the Governor Vessel and the Bladder Meridian. The Governor Vessel commands yang qi of the whole body, and the Bladder Meridian is the king of the yang meridians. Therefore, Jiaji (EX-B 2) points can dredge the Governor Vessel and the Bladder Meridian, to boost yang qi, promote blood circulation, and unblock meridians to stop pain. Zhou X, *et al*[19] observed the analgesia of EA at Jiaji (EX-B 2) points for incision pain in mice. The result showed that with the accumulation of time (24 h after withdrawing needle), the mechanical withdrawal threshold substantially rose, with heat withdrawal latency prolonged significantly, indicating that EA at Jiaji (EX-B 2) points was effective in releasing pain. To conclude, EA at Back-Shu points on the Bladder Meridian and Jiaji (EX-B 2) points has the functions of tonifying kidney essence, facilitating qi and blood flow, and unblocking meridians to stop pain.

Point-toward-point needling is a special acupuncture technique. It requires the insertion of the needle at one acupoint, with the needle tip approaching the other acupoint. Such method can stimulate more acupoints with fewer needles at one time. Fewer needle insertion can reduce patients' pain and thus promote compliance, and stimulating more acupoints can dredge more meridians simultaneously and increase stimulation, which facilitate the conduction of needle sensation[20-22]. Tang CL, *et al*[23] found point-toward-point needling at the trigger point was effective for low back pain caused by the third lumbar transverse process syndrome. Other researchers found that point-toward-point needling at yang meridian on the back (such as the Governor Vessel, the first side line of the Bladder Meridian) was effective for low back pain caused by lumbar muscle strain and back myofascitis[24-25]. In this study, we used point-toward-point needling at Back-Shu points and Jiaji (EX-B 2) points where low back pain occurred and inserted the needle downward. Such method was safe and had the function of stimulating trigger point and acupoint simultaneously. Sparse-dense wave has a better therapeutic effect than continuous wave and discontinuous wave in relieving pain and improving lumbar functions in post-surgery patients with lumbar disc herniation[26]. Therefore, we used EA together with sparse-dense wave on the basis of conventional acupuncture for analgesia and improving clinical efficacy.

Our result showed that after treatment and 1 month after the end of the treatment, the improvements in pain, functional disorder and QOL in the treatment group were superior than those in the control group, indicating that point-toward-point needling at points on the low back regions was effective in alleviating residual back pain after PKP, improving thoracolumbar functions and QOL. Therefore, it is worth clinical popularization.

Conflict of Interest

The author declared that there was no potential conflict of interest in this article.

Statement of Informed Consent

Informed consent was obtained from all individual participants included in this study.

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Translator: Jia Yi-fan (贾一凡)

