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Observation of the Therapeutic Effect of Fu's Subcutaneous Needling on Residual Lower Back Pain in Elderly Patients after PVP Surgery

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Abstract: *This prospective randomized controlled trial aimed to evaluate the efficacy and safety of Fu' s Subcutaneous Needling (FSN) for residual pain in patients with osteoporotic vertebral compression fractures (OVCFs) after percutaneous vertebroplasty (PVP). Fifty patients with residual low back pain occurring after PVP in the Department of Orthopedics of Bazhong City Hospital of Traditional Chinese Medicine were prospectively included, and were divided into the control group and the FSN group according to the randomized numerical table method, with 25 patients in each group. The control group received oral alfacalcidol, calcium carbonate, and alendronate in accordance with the 2022 Chinese Guidelines for Primary Osteoporosis. In addition to these treatments, the FSN group received FSN. Outcome measures, including Visual Analog Scale (VAS), Oswestry Disability Index (ODI), and Modified Japanese Orthopedic Association (M-JOA) scores, were assessed at baseline (t0), immediately post-intervention (t1), and at multiple follow-up time points: 2 days (t2), 3 days (t3), 4 days (t4), 1 week (t5), 1 month (t6), and 3 months (t7) post-intervention. Compared with the control group, the FSN group demonstrated significantly higher total efficacy (68.0% vs. 95.8%, $P < 0.05$), lower VAS scores at t1–t3, t5–t6 ($P < 0.05$), and improved ODI and M-JOA scores ($P < 0.05$). FSN alleviates residual post-PVP pain, enhances functional recovery, and improves quality of life.*

Keywords: *Fu' s Subcutaneous Needling; Osteoporotic vertebral compression fractures; Percutaneous vertebroplasty; Residual pain*

1. Introduction

Osteoporotic vertebral compression fractures (OVCFs), a prevalent complication of osteoporosis, exhibit a substantial disease burden in aging populations, affecting approximately 33.3% of women and 20.0% of men over 50 years of age [1]. In China, osteoporosis prevalence exceeds 90 million cases, further amplifying the clinical significance of OVCFs management [1]. OVCFs are strongly associated with severe pain, functional impairment, diminished quality of life [2], and secondary complications including deep vein thrombosis and pulmonary infections [3]. Percutaneous vertebroplasty (PVP), the current gold-standard minimally invasive intervention for OVCFs [4], demonstrates notable limitations: 15.6% of patients develop residual low back pain postoperatively [5], which not only exacerbates psychological distress (e.g., anxiety and depression) but also impedes early postoperative mobilization. Conventional pharmacological management relying on nonsteroidal anti-inflammatory drugs (NSAIDs) carries significant risks, particularly gastrointestinal hemorrhage [6], underscoring the urgent need for safer alternatives. Fu' s Subcutaneous Needling (FSN), a non-pharmacological intervention, demonstrates rapid analgesic efficacy and favorable safety profiles in chronic nonspecific low back pain [7]. To address these gaps, this prospective randomized controlled trial aimed to evaluate both the therapeutic effectiveness of FSN in alleviating post-PVP residual pain .

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2. Information and methods

2.1 Participants and Randomization

Fifty patients (60–89 years) with residual pain (VAS ≥ 4 at postoperative day 1) after PVP at Bazhong Hospital of Traditional Chinese Medicine (March 2023–June 2024) were randomized into control (n=25) and FSN (n=25) groups using R software (v3.5.1). The study was approved by the hospital ethics committee (Approval No. 2022-007).

2.2 Inclusion criteria

(1) Meets the diagnostic criteria for both osteoporotic pathologic fracture and residual low back pain after PVP [8]. Diagnostic criteria for osteoporosis-induced fractures in the Primary Osteoporosis Guidelines (2022): low back pain, spinal deformity, fragility fracture, and T-value of midshaft bone measured by DXA ≤ -2.5. Diagnostic criteria for residual post-PVP low back pain: residual pain in the same area of the low back on the 1st day after PVP with VAS score ≥ 4, and the clinical manifestations of pain in lying position or pain worsened by standing up. Aggravation. (2) Age 60-89 years old. (3) Willingness to participate in the study [9].

2.3 Exclusion criteria

(1) Rheumatic immune diseases affecting bone metabolism, drugs affecting bone metabolism, or long-term use of glucocorticoids, etc.; (2) Combination of other diseases that can cause low back pain, such as stones, etc.; (3) Pathological fracture treated with PVP; (4) New fracture after PVP; (5) Post-operative imaging suggesting cement leakage: (6) Combination of severe hepatic and renal insufficiency; (7) Combination of neurological and psychiatric diseases.

2.4 Sample size calculation

The sample size calculation was based on the results of the pre-test, in the pre-test, the total effective rate of the control group was 50.0%, the total effective rate of the FSN group was 91.7%, the Power was set to be 0.9, the Alpha to be 0.05, and the sample size was calculated to be 23 cases in each group by using the PASS15.0, and taking into account the 10% loss-of-visit rate, the final 25 patients were included in each group respectively, for a total of 50 patients.

2.5 Interventions

2.5.1 Control Group

Patients received standard anti-osteoporosis therapy according to the 2022 Chinese Guidelines for the Diagnosis and Treatment of Primary Osteoporosis. Starting on postoperative day 1, oral medications included: Alfacalcidol tablets (Chongqing Yaoyou Pharmaceutical Co., China; NMPA approval no. H10950135; 0.25 μg/tablet): 0.5 μg once daily. Caltrate D (Wyeth Pharmaceuticals; NMPA approval no. H10950030; 0.3 g/tablet): 600 mg once daily. Alendronate sodium tablets (Shiyao Group Ouyi Pharmaceutical Co., China; NMPA approval no. H10980109; 10 mg/tablet): 10 mg once daily.

2.5.2 FSN Group

In addition to the control regimen, FSN was administered as follows: Daily for the first 3 days, then every 3 days for two consecutive courses (3 sessions per course).

The specific operation of FSN is as follows:

(1) Patients Positioning: Patients were positioned in a lateral or prone posture to fully expose the lumbar region. Affected muscles (characterized by palpable tension, rigidity, or nodularity) were identified via palpation. Insertion points were selected 5–8 cm from the affected muscle boundaries.

(2) Operational Protocol: The patient is placed in the auto-comfort side or prone position and areas of scarring, nodules, and joints are avoided. After standard disinfection, a disposable floating needle (Nanjing Paifu Medical Technology Co., China; Medical Device Registration No. Su 20152200832; batch no. 20230215) was mounted onto an inserter. The needle tip was advanced subcutaneously at a 10–15° angle toward the affected muscle until the soft catheter fully entered the subcutaneous loose connective tissue. The catheter hub was secured into the needle seat. A fan-shaped sweeping motion

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(150–200 repetitions) was performed while patients engaged in reperfusion exercises (e.g., resisted leg/hip lifting, "swallow" posture). Post-procedure, patient pain relief, the needle core was removed, and the catheter remained subcutaneously for 4–6 hours before extraction.

2.6 Observation indicators

2.6.1 Visual Analog Scale (VAS)

Pain intensity was quantified using a 10-cm ruler (0 = no pain; 10 = worst pain imaginable). Assessments occurred at baseline (t0), immediately post-intervention (t1), and days 2 (t2), 3 (t3), 4 (t4), week 1 (t5), month 1 (t6), and month 3 (t7). Scores were aggregated by the same healthcare professional.

2.6.2 Oswestry Disability Index (ODI)

Scoring consisted of 10 items: intensity of pain, lifting, sitting, standing, disturbed sleep, walking, sex life, social life, self-care, and travel in 10 areas, with a maximum score of 5 and a minimum score of 0 for each item. ODI scoring index = (actual score/highest possible score) × 100%. Higher values indicated greater dysfunction. Scores are tallied by the same health care provider, and the evaluation time point same as VAS [10].

2.6.3 Modified Japanese Orthopedic Association (M-JOA) Score

The M-JOA assay consists of 4 items, ranging from 6 to 29 points, with higher scores indicating that the patient's lumbar spine is functioning better.

2.7 Efficacy Criteria

Clinical efficacy was evaluated using the Nimodipine method [11]. Efficacy index (%) = [(pre−treatment VAS score − post−treatment VAS score)/pre−treatment VAS score] ×100%. Classification: Cure: ≥90% improvement; Marked improvement: 70–89%; Effective: 30–69%; Ineffective: <30%. Total efficacy rate = (Cure + Marked improvement + Effective)/Total cases] ×100%. Finally, the clinical efficacy of the two groups of patients 1 week after the intervention was evaluated according to the above methods.

2.8 Statistical Analysis

Data were analyzed using SPSS 25.0. Continuous variables (mean ± SD) were compared via independent t-tests or repeated-measures ANOVA with Bonferroni correction. Nonparametric tests and χ^2/Fisher's exact tests were used for skewed and categorical data, respectively. $P < 0.05$ indicated significance.

3. Results

In the FSN group, one patient withdrew due to new fractures after PVP, and 49 patients were included in statistical analysis.

3.1 Baseline Characteristics

The differences in age, gender, BMI and bone mineral density between the two groups were not statistically significant. ($P > 0.05$, Table 1).

Table 1 Comparison of general data between the two groups

variable	Control (n=25)	FSN (n=24)	t/x^2	P-value
Age (years)	72.16±5.26	72.33±4.94	0.119	0.906
Sex			0.214	0.644
Male	11 (44.0%)	9 (37.5%)		
Female	14 (56.0%)	15 (62.5%)		
BMI(kg/m²)	23.95±2.76	23.29±2.21	0.917	0.364
Bone density	3.14±0.62	3.42±0.22	0.561	0.421

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3.2 Clinical Efficacy

After the intervention, the clinical efficacy of the two groups of patients was statistically analyzed, and the total effective rate of the patients in the FSN group was 95.8%; the total effective rate of the patients in the control group was 68%, and the difference was statistically significant ($P < 0.05$), as shown in Table 2.

Table 2 Comparison of clinical outcomes between the two groups of patients

Groups	Cure	Marked improvement	Effective	Ineffective	*P*-value
Control(n=25)	0(0 %)	1(4.0 %)	16(64.0 %)	8(32.0 %)	0.023*
FSN(n=24)	3(12.5 %)	8(33.3 %)	12(50 %)	1(4.2 %)	

Note: Comparison with control, *$P<0.05$

3.3 Comparison of VAS scores between the two groups of patients

Compared with t0, VAS scores in both groups showed a decreasing trend at t1-t7 time points. Compared with the control group, the FSN group showed a significant decrease in VAS scores at t1-t3, t5-t6 time points, and the difference was statistically significant ($P < 0.05$), as shown in Table 3.

Table 3 VAS pain scores of patients in both groups at each time point before and after the intervention

Times	Control (n=25)	FSN (n=24)	Z-value	*P*-value
pre-intervention	6 (5, 6)	6 (5, 6)	-0.574	0.566
Immediately after intervention	5 (4, 5)	2 (2, 3)	-6.161	< 0.001**
24 h	5 (5, 6)	5 (4, 5)	-3.787	< 0.001**
48 h	5 (4, 5)	4 (4, 5)	-1.994	0.046
72 h	4 (3, 4)	2 (2, 3.5)	-3.746	< 0.001**
1st week	4 (3, 4)	2 (2, 3)	-3.675	< 0.001**
1st month	3 (2, 4)	2 (2, 3)	-3.565	< 0.001**
3rd month	1 (1, 2)	1 (0, 1)	-1.595	0.111

Note: Comparison with control group, **$P<0.001$.

3.4 Comparison of ODI index (%) between the two groups of patients

Compared with the control group, the ODI index of the FSN group was significantly lower at the time points of t2-t4, t6-t7, and the differences were all statistically significant ($P < 0.001$), as shown in Table 4.

Table 4 ODI index (%) at each time point before and after the intervention in both groups

Times	Control (n=25)	FSN (n=24)	t-value	*P*-value
pre-intervention	91.00±1.97	90.50±2.02	-0.875	0.386
24 h post-intervention	85.28±3.10	80.58±3.61	-4.890	< 0.001**
48 h	78.08±2.47	64.67±3.71	-14.952	< 0.001**
72 h	69.12±3.23	56.25±3.19	-14.018	< 0.001**
1st week	46.88±3.63	37.17±2.70	-10.592	< 0.001**
1st month	34.64±2.89	27.17±2.69	-10.472	< 0.001**
3rd month	17.84±2.76	14.67±2.33	-4.333	< 0.001**

Note: Comparison with control group, **$P<0.001$.

3.5 Comparison of M-JOA scores between the two groups of patients

Compared with the control group, M-JOA scores were significantly higher in the FSN group at the t2-t7 time points, and the differences were all statistically significant ($P < 0.05$), as shown in Table 5.

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Table 5 M-JOA scores at each time point before and after the intervention in both groups of patients

Times	Control (n=25)	FSN (n=24)	t-value	*P*-value
pre-intervention	8.6±0.71	8.58±0.88	-0.730	0.942
24 h post-intervention	9.96±0.94	11.25±0.99	4.694	< 0.001**
48 h	10.52±1.09	14.33±1.05	12.498	< 0.001**
72 h	13.04±1.37	18.00±1.69	11.296	< 0.001**
1st week	15.40±1.44	20.71±1.08	14.516	< 0.001**
1st month	20.56±1.33	22.71±1.08	6.199	< 0.001**
3rd month	24.44±1.36	25.67±1.31	3.221	0.02*

Note: Comparison with control group, *P<0.05, **P<0.001.

3.6 Incidence of adverse reactions

Minor gastrointestinal reactions (control: 3; FSN: 2) and headaches (control: 1; FSN: 2) resolved with symptomatic treatment. No severe adverse events occurred. There were no adverse events such as bleeding at the puncture site, infection, or worsening of pain in the patients during and after the FSN.

4. Discussion

In this study, a prospective randomized controlled trial found that for patients with residual pain after PVP for OVCF, the FSN group had lower VAS scores than the control group at the immediate post-intervention (t1), day 2 (t2), day 3 (t3), week 1 (t5), and month 1 (t6), and the postoperative ODI index (%) and M-JOA scores were significantly improved. This result suggests that FSN has a significant effect in relieving postoperative residual pain after PVP and can effectively reduce patients' pain perception, which is consistent with the findings of Hu Kaixia et al [8]. Most of the current studies on residual pain after PVP have focused on the assessment of pain and treatment effects in the short term, and this study only assessed the VAS score and ODI index (%) score on the 3rd day after treatment. However, there is a lack of sufficient data and research on the assessment of pain relief and treatment effects in the long term. The results of this study found that the patients in the FSN group had better long-term efficacy than the control group at 1 week, 1 month, and 3 months after treatment.

According to Chinese medicine theory, post-PVP residual back pain belongs to the category of "paralysis" [12]. Most of these patients have a history of lumbar sprain, contusion, fracture, or surgery, or are directly attacked by wind, cold, and dampness, resulting in localized qi and blood stagnation, blockage of meridians, and dysfunction of internal organs, which are interrelated and interact with each other, and jointly lead to the occurrence and development of post-PVP residual pain [13].

Chinese medicine classic "Suwen - soup mash sweet theory" pointed out that the disease at the beginning of the disease, the evil is very fine and micro, the first invasion of the skin, manifested as muscle nodules or strips, which is consistent with the floating needle muscle theory of palpation of the affected muscle, "tight, stiff, hard, slippery" characteristics. In addition, "Su Wen - Skin Department Theory" mentions: "Where the twelve meridians and channels, the skin of the Department also", the lesions will be in accordance with the skin → channels → meridians → viscera → organs of the hierarchy of development. By stimulating the loose connective tissue closely related to the skin, FSN plays a role in relaxing the meridians and regulating qi and blood [14]. In Chinese medicine theory, meridians are the channels through which qi and blood run, and the smoothness of qi and blood is directly related to the state of health of the body. After PVP, due to surgical trauma and local qi and blood stagnation, the smoothness of meridians and channels is affected, which in turn triggers pain [13]. Peng Congjun et al [15] concluded that FSN can effectively dredge the meridians and promote the operation of qi and blood as well as the metabolism of pain-causing substances by applying special needles to the loose connective tissues under the skin and carrying out horizontal sweeping movements, which can produce strong mechanical stimulation to the fascial structures, thus relieving pain. FSN is applied to the affected muscle area, reflecting the TCM treatment principle of "pain as loss" [16]. At the same time, FSN is combined with reperfusion activities to further promote qi and blood circulation and tissue repair [17]. The reperfusion activity effectively improves tissue ischemia and promotes metabolism and tissue repair by continuously stretching and contracting the local muscles or joints and intermittently squeezing the blood vessels with external force or its own force. In conclusion, the Chinese medicine theory of FSN for the treatment of postoperative residual pain after PVP is mainly reflected in shujing and activating collaterals, regulating qi and blood, using pain as infusion and promoting tissue repair. Modern medical research [18] suggests that FSN can reduce pain by stimulating the opioid peptide receptors in local nerve endings to

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produce analgesic substances, relieve muscle tension and spasm, improve blood circulation, and promote the removal of inflammatory mediators and the repair of local tissues. However, the specific mechanism of FSN for the treatment of postoperative residual pain after PVP is still unclear and needs to be further explored in future studies.

However, this study has some limitations. Due to the objective conditions, the sample size was small, which may affect the generalizability of the results.

In summary, FSN can significantly relieve residual pain after PVP, improve patients' postoperative dysfunction and enhance quality of life. As a non-pharmacological therapeutic technique, FSN is easy to operate, safe and has high clinical promotion value.

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References

[1] Guidelines for the diagnosis and treatment of primary osteoporosis (2022)[J]. Chinese Journal of Osteoporosis and Bone Mineral Salt Diseases,2022,15(06):573-611.
[2] Luthman S, Widén J, Borgström F. Appropriateness criteria for treatment of osteoporotic vertebral compression fractures)[J]. Osteoporos Int. 2018;29(4):793-804.
[3] Hinde K, Maingard J, Hirsch J A, et al. Mortality Outcomes of Vertebral Augmentation (Vertebroplasty and/or Balloon Kyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis)[J]. Radiology. 2020;295(1):96-103.
[4] Rabei R, Patel K, Ginsburg M, et al. Percutaneous Vertebral Augmentation for Vertebral Compression Fractures: National Trends in the Medicare Population (2005-2015))[J]. Spine (Phila Pa 1976). 2019;44(2):123-133.
[5] Li Q, Shi L, Wang Y, et al. A Nomogram for Predicting the Residual Back Pain after Percutaneous Vertebroplasty for Osteoporotic Vertebral Compression Fractures)[J]. Pain Res Manag. 2021; 2021:3624614.
[6] Yuan W J, Xu P A, Liang Z, et al. Effect of ketorolac on postoperative analgesic effect and safety analysis of patients undergoing percutaneous transluminal vertebroplasty[J]. Chinese Pharmacist, 2023,26(12):449-455.
[7] Shao Y J, Xie H L, Wang X C, et al. A randomized controlled study of floating needle therapy for chronic non-specific lower back pain[J]. Hubei Journal of Traditional Chinese Medicine, 2021,43(07):45-48.
[8] Hu K X. Effect of floating needle in treating residual pain after PVP for osteoporotic vertebral compression fracture[J]. Chinese and foreign medicine research,2021,19(03):45-47.
[9] Yu Y A, Wang Z G, Mao T, et al. Floating needle treatment of residual pain after percutaneous vertebroplasty in 30 cases[J]. Chinese Journal of Orthopedics and Traumatology,2021,29(09):74-76+80.
[10] Cheng J W, Wang Z L,Liu W, et al. Improvement of Oswestry dysfunction index and reliability and validity test[J]. Chinese Spinal Cord Journal,2017,27(03):235-241.
[11] Yan H M, Jiang Y, Hu L H, et al. Key issues in the design of efficacy indexes for clinical trials of symptomatic new Chinese medicines[J]. Drug Evaluation Research,2023,46(09):1833-1840.
[12] Shen F, Li W, Ye B S, et al. Progress of rehabilitation of chronic pain after osteoporotic vertebral compression fracture kyphoplasty[J]. Chinese Journal of Orthopedics and Traumatology, 2024, 32(07):91-96.
[13] Huang W T, Wan S M, Wang Z G, et al. Progress of Chinese and Western medicine treatment of residual low back pain after percutaneous vertebroplasty[J]. Journal of Jiangxi University of Traditional Chinese Medicine,2024,36(03):115-119+123.
[14] Yang J X, Fu Z H. Analyzing the theory and clinical research of floating needle[J]. Western Chinese medicine,2015,28(06):156-158.
[15] Peng Y J, Zhu B M, Wu X. Acupuncture depth and systems biology[J]. World Science and Technology-Modernization of Traditional Chinese Medicine,2019,21(03):444-448.
[16] Fu Z H. Reperfusion and reperfusion activity - on the method of activity while treating in external treatment[J]. Chinese Acupuncture and Moxibustion,2015,35(S1):68-71.

ISSN 2616-5791 Vol. 6, Issue 3: 1-7, DOI: 10.25236/AJMHS.2025.060301

[17] Liu N, Fu Z H, He Q T, et al. Introduction to floating needle reperfusion activity[J]. Chinese medicine introduction,2018,24(23):93-95.
[18] Tao J L, Fu Z H, Zhang H R. Analysis of the action mechanism of floating needle therapy[J]. Shizhen Guomian Guomian,2014,25(12):3006-3008.