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Effects of kidney nourishing and bone strengthening decoction on re-fracture after percutaneous vertebral augmentation in osteoporotic compression fractures

[Efectos de la decocción para nutrir los riñones y fortalecer los huesos sobre la re-fractura después del aumento vertebral percutáneo en fracturas por compresión osteoporótica]

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Abstract: Kidney Nourishing and Bone Strengthening Decoction, a traditional Chinese herbal formula, has been known for its role in regulating bone metabolism and enhancing bone density (BD). Osteoporotic compression fractures are common clinical complications in patients with osteoporosis, and percutaneous vertebral augmentation is a commonly used treatment method. This work aimed to investigate the preventive effect of the Kidney Nourishing and Bone Strengthening Decoction combined with conventional Western medicine treatment on the occurrence of vertebral re-fracture after percutaneous vertebral augmentation in osteoporotic compression fractures. Kidney Nourishing and Bone Strengthening Decoction combined with conventional Western medicine treatment was an integrated therapeutic approach that can effectively prevent vertebral re-fracture after percutaneous vertebral augmentation in osteoporotic compression fractures, regulate bone metabolism, and enhance BD.

Keywords: Traditional Chinese medicine; Vertebral fracture; Percutaneous Vertebral Augmentation; Osteoporotic compression fractures; Clinical effectiveness

Resumen: La decocción para nutrir los riñones y fortalecer los huesos, una fórmula herbal tradicional china, es conocida por su papel en la regulación del metabolismo óseo y el aumento de la densidad ósea (BD). Las fracturas por compresión osteoporótica son complicaciones clínicas comunes en pacientes con osteoporosis, y el aumento vertebral percutáneo es un método de tratamiento comúnmente utilizado. Este trabajo tuvo como objetivo investigar el efecto preventivo de la decocción para nutrir los riñones y fortalecer los huesos combinada con el tratamiento convencional de medicina occidental sobre la ocurrencia de re-fracturas vertebrales después del aumento vertebral percutáneo en fracturas por compresión osteoporótica. La decocción para nutrir los riñones y fortalecer los huesos combinada con el tratamiento convencional de medicina occidental fue un enfoque terapéutico integrado que puede prevenir eficazmente la re-fractura vertebral después del aumento vertebral percutáneo en fracturas por compresión osteoporótica, regular el metabolismo óseo y aumentar la BD.

Palabras clave: Medicina tradicional china; Fractura vertebral; Aumento vertebral percutáneo; Fracturas por compresión osteoporótica; Eficacia clínica.

INTRODUCTION

Osteoporotic Vertebral Compression Fracture (OVCF) is a common and prevalent condition in the middle-aged and elderly population. In clinical practice, conservative treatment and open surgery are commonly used. Patients typically present symptoms such as back pain, limited mobility, and spinal kyphotic deformity. Without timely treatment, patients may experience compromised organ function, reduced thoracic capacity, and kyphosis, which can severely impact their physical and mental health (Prost *et al*., 2021; Jeon *et al*., 2022).

Currently, the clinical treatment of OVCF is primarily divided into two main approaches: conservative treatment and surgical treatment. Conservative treatment mainly involves rest and activity restriction (to alleviate vertebral pressure and promote fracture healing), medication therapy (to alleviate pain and improve bone density), and rehabilitation treatment (to reduce pain and restore function). Surgical treatment mainly consists of percutaneous vertebroplasty and open surgery. Percutaneous vertebroplasty involves injecting special bone cement into the vertebral body or using balloon techniques to restore vertebral height, alleviate pain, and enhance vertebral stability. In cases of severe fractures or fractures associated with nerve compression, open surgery may be necessary, such as vertebral body resection, pedicle screw fixation, or spinal fusion, to achieve better fracture stability and nerve decompression. Vertebral augmentation procedures, including percutaneous vertebroplasty and percutaneous kyphoplasty, have emerged as minimally invasive surgical techniques in recent years. These procedures involve the injection of bone cement into the fractured vertebra to enhance its biomechanical strength (Kyriakou *et al*., 2019). Compared to traditional treatment approaches, vertebral augmentation procedures offer advantages such as simplicity, minimal trauma, and high safety, providing rapid relief of local pain, restoration of vertebral height, and improved quality of life for patients (Wang *et al*., 2018a; Li *et al*., 2021a; Dai *et al*., 2022). Combining vertebral augmentation procedures with vitamin D calcium supplementation has been used in the treatment of OVCFs, as it provides the body with calcium and promotes its absorption, thus strengthening the bones (Huang & Wu, 2020). Nevertheless, the therapeutic efficacy of using vitamin D calcium supplementation alone is not satisfactory, as it does not inhibit bone cell absorption, thereby affecting the degree of bone healing (Kong *et al*., 2019). Additionally, Western medicine treatments have certain side effects, highlighting the importance of postoperative adjunctive therapy.

Despite the advancements in the treatment methods for OVCF, there are still challenges and limitations that directly affect the recovery and treatment outcomes for patients. ① Traditional treatment methods exhibit inconsistent effectiveness and can't meet the needs of all patients. ② The postoperative recovery process is lengthy and complex, restricting patients' daily life and work abilities. After surgery, patients need to adapt to the solidification of bone cement and the process of fracture healing. During the rehabilitation period, discomfort and limitations may arise, such as pain, restricted mobility, and the requirement for extended bed rest. ③ Variations in individual patients result in issues with treatment tolerance, with some patients being unable to tolerate certain treatments or developing tolerance to medication therapies.

Traditional Chinese Medicine (TCM) has abundant experience in the treatment of OVCFs, which are considered within the scope of "bone atrophy." These fractures are primarily attributed to kidney essence deficiency and stagnation of qi and blood leading to bone deterioration (Liu *et al*., 2022). TCM treatment of OVCFs often emphasizes tonifying the kidneys and strengthening the bones, with supplementary measures to tonify the liver and kidneys, invigorate the spleen and kidneys, and promote qi circulation, blood activation, and stasis resolution (Wang *et al*., 2018b; Li *et al*., 2021b; Gao *et al*., 2023). Kidney Nourishing and Bone Strengthening Decoction is an herbal medicine formulation that exhibits no apparent toxic side effects and is beneficial for promoting fracture healing and repair (Zhang *et al*., 2013).

Rehmannia glutinosa and *Angelica sinensis* are believed to have nourishing and blood-tonifying effects, which can help improve kidney function and promote bone health. Herbs such as *Ligusticum chuanxiong, Hedyotis diffusa, and Vaccaria segetalis* have the function of promoting blood circulation and resolving stasis, which can aid in improving blood circulation, facilitating bone repair, and regeneration. Herbs like *Epimedium brevicornum*, *Chrysanthemum morifolium*, and *Cuscuta chinensis* are considered to have a warming and kidney-tonifying effect, which can enhance kidney function and improve bone density. On the other hand, herbs such as *Eucommia ulmoides*, *Epimedium grandiflorum*, *Achyranthes bidentata*, *Drynaria fortunei*, and *Cistanche deserticola* are used for supporting strong bones,

strengthening muscles, and supporting tendons and bones. The application of the Tonifying kidney Zhuanggu decoction mainly includes osteoporosis, osteoporotic compression fractures, and skeletal problems caused by insufficient kidney function. By nourishing the kidneys, improving blood circulation, and enhancing bone health, Tonifying kidney Zhuanggu decoction can help increase bone density, alleviate symptoms of osteoporosis, and promote fracture healing and recovery.

Nevertheless, there is currently limited research on the use of Kidney Nourishing and Bone Strengthening Decoction as an adjunct to vertebral augmentation procedures for the treatment of OVCFs. Hence, this study aimed to analyze the therapeutic efficacy of conventional Western medicine combined with Kidney Nourishing and Bone Strengthening Decoction for the postoperative treatment of patients with OVCFs undergoing vertebral augmentation procedures, as well as its preventive effect on recurrent vertebral fractures. It was hoped to provide a reference for improving the treatment outcomes and prognosis of patients with OVCFs undergoing surgical interventions.

MATERIAL AND METHODS

Research object

General information

A total of 86 patients with OVCFs admitted to the North China Medical&Health Group XingTai General Hospital from June 2020 to June 2022 were recruited as the study population. Based on the order of admission, the patients were rolled into treatment group (Group T) and control group (Group C), with 43 patients in each group. In Group C, there were 17 males and 26 females, with an age range of 55 to 76 years (averaging 65.1 ± 5.4 years). The duration of symptoms ranged from 1 to 15 days, averaging 5.4 ± 2.0 days. The affected vertebral segments were as follows: L1 in 14 cases, L2 in 6 cases, L3 in 9 cases, T10 in 1 case, T11 in 3 cases, and T12 in 10 cases. In Group T, there were 19 males and 24 females, with an age range of 53 to 75 years (averaging 66.2 ± 5.3 years). The duration of symptoms ranged from 1 to 15 days, averaging 5.3 ± 2.2 days. The affected vertebral segments were as follows: L1 in 15 cases, L2 in 5 cases, L3 in 10 cases, T10 in 2 cases, T11 in 2 cases, and T12 in 9 cases. The baseline characteristics differed inconsiderably between groups (p>0.05). The study received approval from the Ethics Committee of the participating hospital.

Diagnostic criteria

According to the criteria established in *Clinical Orthopedics*, the diagnosis of OVCF requires patients to have symptoms such as lumbar and back pain, tenderness, or percussion pain. The diagnosis is confirmed through imaging examinations such as computerized tomography (CT) or magnetic resonance imaging (MRI), and bone density (BD) testing reveals osteoporosis with a BD value lower than 2.5 standard deviations below the normal value.

Based on the TCM syndrome differentiation for deficiency of liver and kidney outlined in the *Guidelines for Clinical Research of New Traditional Chinese Medicine*, patients exhibit symptoms including chest, waist, and joint pain, lumbar stiffness, general fatigue, weakness and soreness in the waist and knees, aversion to cold with fever, excessive sweating, dizziness, and blurred vision. Their tongue appears pale red with a thin coating, and the pulse is deep and tight.

Inclusion and exclusion criteria

Inclusion criteria: i) patients who met the diagnostic criteria of both Western medicine and TCM; ii) compression ratio of the vertebral body between 35% and 70%; iii) patients who had undergone posterior convex deformity surgery and had residual lumbar and back pain after the surgery; iv) patients who had signed informed consent forms.

Exclusion criteria: patients with i) history of allergic reactions to the treatment drugs; ii) severe cardiac, hepatic, or renal dysfunction; iii) presence of other joint diseases such as osteoarthritis, spinal tumors, or rheumatoid arthritis; iv) long-term use of glucocorticoids, nonsteroidal anti-inflammatory drugs, or other analgesics; v) coagulation disorders, incomplete posterior edge of the vertebrae, systemic or local infections; vi) tendency for bleeding in the lumbar spine; vii) poor treatment compliance or history of mental illness.

Research methodologies

Therapeutic methodologies

All patients underwent posterior vertebral augmentation surgery, which was performed by the same group of physicians. The patients were positioned in a prone position, and fluoroscopic guidance was used to identify the puncture site. After routine disinfection, sterile surgical drapes were applied. A mixture of 10 mL of 2% lidocaine and normal saline in a 1:1 ratio was prepared and used for layered infiltration anesthesia along the puncture site until the bone periosteum of the vertebral pedicle was

reached. A 0.5 cm incision was made at the puncture site, and a puncture needle was inserted at an angle of 15-25° along the incision, aiming for the outer superior margin of the vertebral pedicle. The puncture position was confirmed using lateral fluoroscopy. Subsequently, the needle was further advanced until it reached the posterior edge of the vertebral body. After the needle was withdrawn, a puncture needle sleeve was left in place, and a guidewire was inserted through the sleeve. The sleeve was then removed, and a dilation sleeve was inserted after rotation, with the outer sheath reaching 2 mm beyond the posterior edge of the vertebral body before removing the sheath. A puncture sheath was left in place, and a fine bone drill was used to create a 3 mm hole in the anterior aspect of the vertebral body. The bone drill was then removed. The integrity of the vertebral wall was assessed using a probe. A balloon dilation catheter was inserted into the anterior one-third of the vertebral body along the sheath, and contrast medium was injected to observe the expansion of the balloon. Under continuous fluoroscopic guidance using a dynamic C-arm, bone cement was injected into the vertebral body, ensuring no leakage. After the inner core was rotated 360°, the cement was allowed to solidify for 10 minutes until complete hardening. The puncture sheath was then removed, and pressure was applied for 5 minutes. The surgical site was disinfected, and the skin was sutured and dressed. Postoperatively, the patient was observed for 10 minutes, and once their vital signs were stable and lower limb sensation and motor function were good, they were transferred back to the ward.

Group C received oral administration of calcitriol capsules (Specification: 0.5 μg × 10 capsules, Manufacturer: Henan Taifeng Biotechnology Co., Ltd., Approval Number: National Medical Product Administration H20213963) at a dosage of 0.5 μg per day. They also received chewable vitamin D calcium tablets (Specification: 1.5 g × 60 tablets, Manufacturer: Nanchang Caoshanhu Biotechnology Co., Ltd., Approval Number: China Food and Drug Administration G20050583) at a dosage of 1.5 g per day. Group T received Kidney Nourishing and Bone Strengthening Decoction in addition to the treatment received by Group C. The composition of the herbal decoction included: 12 g Prepared *Rehmannia* Root, 12 g *Angelica sinensis*, 10 g *Ligusticum chuanxiong* Hort, 12 g *Achyranthes bidentata*, 15 g *Morinda officinalis*, 15 g *Dipsaci Radix*, 12 g *Fructus corni*, 15 g *Dodder seed*, 12 g *Eucommia bark*, 15 g *Epimedium*, 20 g Salt dog spine, 10 g *Rhizoma Drynariae*, 10 g *Cistanche deserticola*. The decoction was prepared by the Chinese medicine pharmacy, with a daily dose of 1 pack (250 mL) taken once a day. The treatment started on the first day after surgery, and each treatment course lasted for 30 days. A total of 3 consecutive treatment courses were administered.

Observation indexes

I. BD. The BD at the lumbar vertebrae L1-L4 and the greater trochanter of the patients was measured using an ultrasound BD scanner at baseline (T0), 7 days after treatment (T1), 1 month after treatment (T2), 3 months after treatment (T3), and 6 months after treatment (T4).

II. Pain intensity. The pain intensity of the patients was assessed at T0, T1, T2, T3, and T4 using the visual analog scale (VAS) (Shafshak & Elnemr, 2021). The VAS score ranged from 0 to 10, with higher scores indicating more severe pain.

III. Functional impairment. The functional impairment of the patients was evaluated at T0, T1, T2, T3, and T4 using the Oswestry Disability Index (ODI) (Mannion *et al*., 2022). The ODI questionnaire consists of 10 dimensions, including traveling, social life, sexual activity, sleep quality, standing, sitting, walking, lifting, self-care, and pain intensity. The total score on the ODI scale is 50, with higher scores indicating more severe functional impairment in the limbs.

IV. Vertebral-related parameters. At T0, T1, T2, T3, and T4, measurements of the relative anterior vertebral height (fractured vertebral height/normal vertebral height × 100%) and Cobb angle were performed using X-ray images.

V. Bone metabolism. Fasting venous blood samples (3 mL) were collected from the patients at T0 and T4. After centrifugation at 3,000 rpm/min for 10 minutes, the serum was separated and analyzed for levels of bone-specific alkaline phosphatase (B-ALP), N-terminal mid-fragment of osteocalcin (N-MID-OT), total procollagen type I N-terminal propeptide (T-P1NP), and β-collagen specific sequence (β-CTX) using a fully automated electrochemiluminescence immunoassay analyzer.

VI. Quality of life. At T0 and T4, the patients' quality of life was assessed using the General Quality of Life Inventory-74 (GQOLI-74) (Yu *et al*., 2021). The GQOLI-74 questionnaire consists of four dimensions: material life, physical health, social function, and psychological well-being. It was evaluated on a percentage scale, with higher scores indicating better quality of life for the patients.

VII. Clinical efficacy. According to the

Guidelines for Clinical Research of New Chinese Medicine, the clinical treatment efficacy was evaluated based on the syndrome efficacy evaluation criteria, combined with VAS scores and ODI scores. Clinical symptom improvement of 95-100%, disappearance of pain, and normal limb function were classified as cured. Clinical symptom improvement of 70-95%, no significant tenderness, and slightly impaired limb function without affecting daily activities were classified as significantly effective. Clinical symptom improvement of 30-70%, relief of pain with mild discomfort during movement, was classified as effective. Clinical symptom improvement of 0-30%, no improvement in symptoms, pain, or limb function, was classified as ineffective. The total effective rate was calculated as (number of cured cases + number of significantly effective cases + number of effective cases) divided by the total number of cases, multiplied by 100%.

VIII. Recurrent vertebral fractures. Follow-up X-ray examinations were conducted at T3, T4, and 12 months. Complete recovery was defined as Cobb angle between 15-20°, vertebral height of the fractured vertebrae within 2-5 mm, no significant functional impairment or pain, and complete healing without separation. Recurrent vertebral fracture was defined as Cobb angle less than 15 or greater than 20°, vertebral height less than 2 mm or exceeding 5 mm, mild functional impairment and pain that allows normal daily activities and work, and slight separation of the fracture. The recurrent vertebral fracture rate was calculated as the number of recurrent vertebral fractures divided by the total number of cases, multiplied by 100%.

Statistical methodologies

Using SPSS 22.0, continuous variables were denoted as mean ± standard deviation ($\bar{x} \pm s$) and were compared using t-tests. Categorical data were presented as frequencies or rates and were compared using the chi-square test. A statistically significant difference was considered when $p<0.05$.

RESULTS

Comparison of BD before and after treatment

In Figure No. 1, both Group C and Group T patients exhibited a gradual increase in BD at the lumbar vertebrae L1-L4 and the greater trochanter after treatment. Group T demonstrated a marked increase in BD at the lumbar vertebrae L1-L4 and the greater trochanter at T2, T3, and T4 time points versus Group C ($p<0.05$).

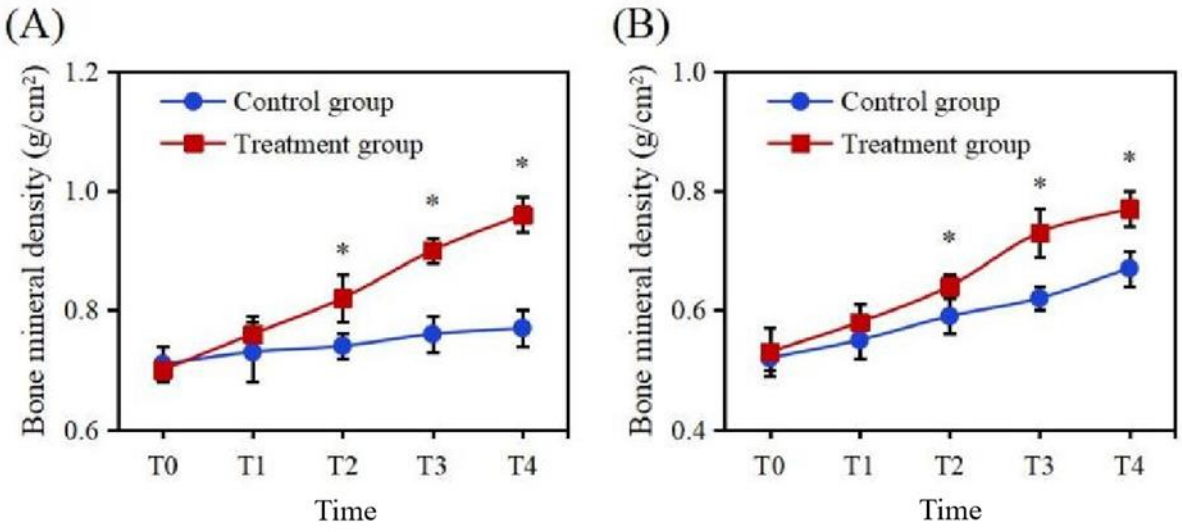

Figure No. 1
Comparison of BD between two groups. (A) BD of lumbar vertebrae L1~L4; (B) BD at greater trochanter; *$p<0.05$ vs. Group C

Comparison of pain degree before and after treatment

In Figure No. 2, both Group C and Group T patients exhibited a gradual reduction in pain intensity as indicated by the VAS scores after treatment. Relative to Group C, Group T demonstrated a notable decrease in VAS scores at T2, T3, and T4 time points (p<0.05).

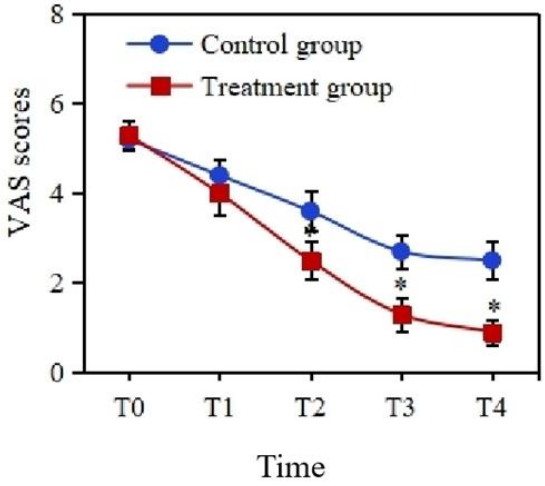

Figure No. 2
Comparison of VAS scores between groups. *p<0.05 vs. Group C

Comparison of limb dysfunction before and after treatment

In Figure No. 3, both Group C and Group T patients exhibited a gradual reduction in the degree of functional impairment as indicated by the ODI scores after treatment. Group T demonstrated a remarkable decrease in ODI scores at T2, T3, and T4 time points versus Group C (p<0.05).

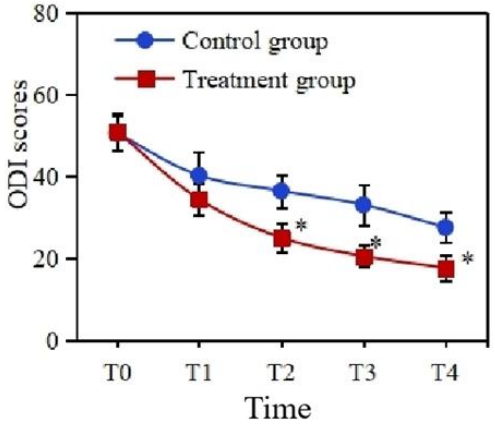

Figure No. 3
Comparison of ODI scores between groups. *p<0.05 vs. Group C

Comparison of relative height and Cobb angle of vertebral body before and after treatment

In Figure No. 4 and Figure No. 5, both Group C and Group T patients exhibited a drastic increase in relative vertebral height and a great decrease in Cobb angle after treatment. Relative to Group C, Group T demonstrated a substantial increase in relative vertebral height and a marked decrease in Cobb angle at T2, T3, and T4 time points (p<0.05).

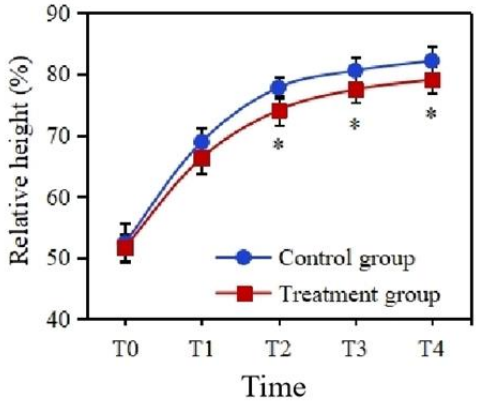

Figure No. 4
Comparison of vertebral body height between groups. *p<0.05 vs. Group C

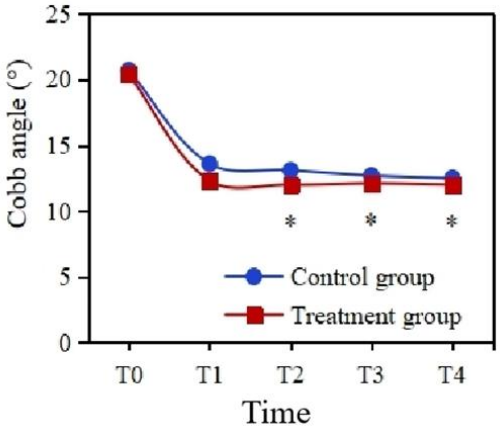

Figure No. 5
Cobb angle comparison between groups. *p<0.05 vs. Group C

Comparison of serum bone metabolism indexes before and after treatment

In Figure No. 6, relative to the pre-treatment levels within the same group, both Group C and Group T exhibited a prominent decrease in serum levels of B-ALP, N-MID-OT, T-P1NP, and β-CTX after treatment (p<0.05). Furthermore, Group T demonstrated a great reduction in serum levels of B-ALP, N-MID-OT, T-P1NP, and β-CTX after treatment relative to Group C (p<0.05).

Comparison of quality of life before and after treatment

In Figure No. 7, relative to the pre-treatment levels within the same group, both Group C and Group T exhibited a notable decrease in serum levels of B-ALP, N-MID-OT, T-P1NP, and β-CTX after treatment (p<0.05). Furthermore, Group T demonstrated a drastic reduction in serum levels of B-ALP, N-MID-OT, T-P1NP, and β-CTX after treatment versus Group C (p<0.05).

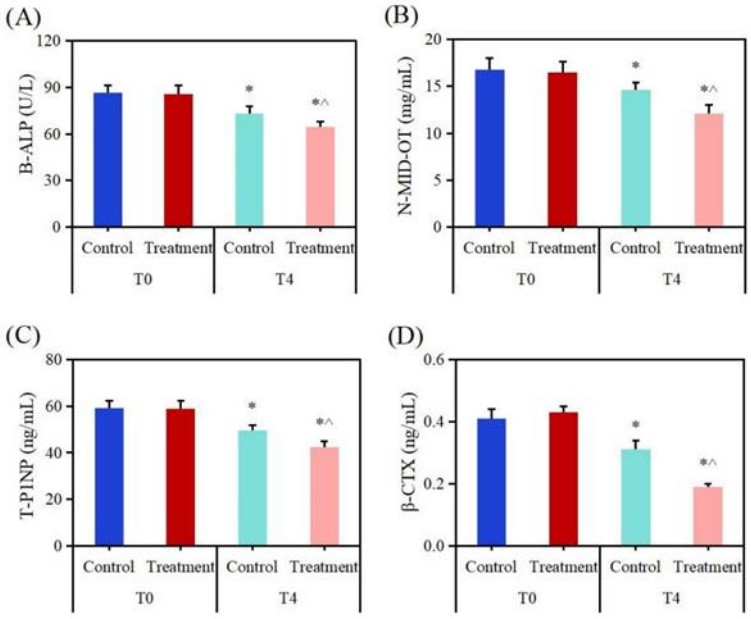

Figure No. 6

Comparison of serum bone metabolism indexes between groups. (A) Serum B-ALP; (B) serum N-MID-OT; (c) serum T-P1NP; (d) serum β-CTX; *p<0.05 vs. before treatment; ^p<0.05 vs. Group C

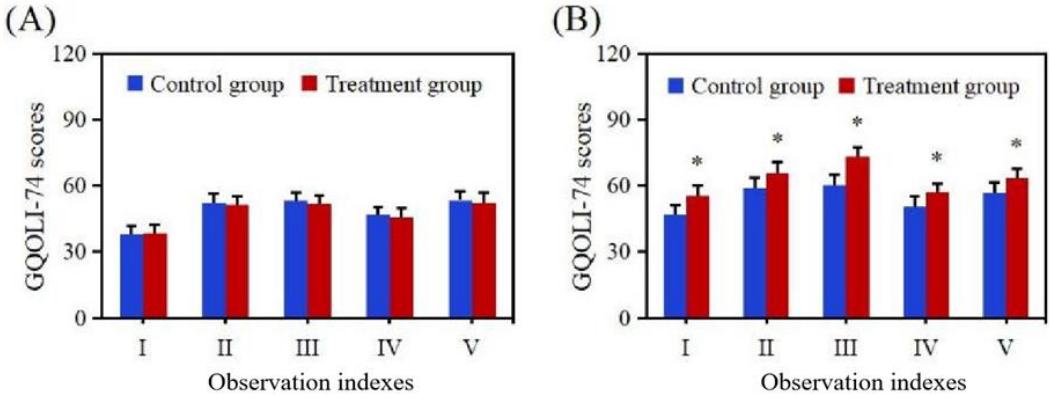

Figure No. 7

Comparison of quality of life between groups. (A) T0 before treatment; (B) T4 after treatment; *p<0.05 vs. Group C

Comparison of clinical treatment effects

In Figure No. 8, in Group C, there were 9 cases (20.93%) classified as cured, 13 cases (30.23%) as significantly effective, 16 cases (37.21%) as effective, and 5 cases (11.63%) as ineffective, resulting in a total effective rate of 88.37% (38/43). In Group T, there were 15 cases (34.88%) classified as cured, 16 cases (37.21%) as significantly effective, 10 cases (23.26%) as effective, and 2 cases (4.65%) as ineffective, resulting in a total effective rate of 95.35% (41/43). Group T exhibited a remarkably superior overall clinical effective rate after treatment to Group C (p<0.05).

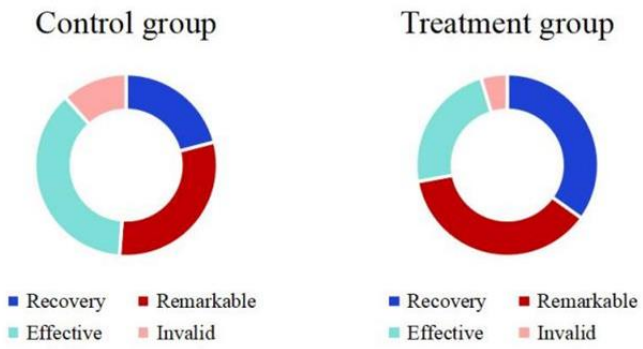

Figure No. 8
Comparison of therapeutic effects between groups

Comparison of recurrent vertebral fracture rate

In Table No. 1, the probabilities of recurrent vertebral fractures at 3 months, 6 months, and 12 months after treatment in Group C were 9.30%, 2.33%, and 0.0%, respectively, with a total incidence rate of 11.63%. In Group T, the probabilities of recurrent vertebral fractures at 3 months, 6 months, and 12 months after treatment were 2.33%, 2.33%, and 0.0%, respectively, with a total incidence rate of 4.65%. Group T exhibited a notably inferior rate of recurrent vertebral fractures after treatment to Group C (p<0.05).

Table No. 1
Comparison of recurrent vertebral fractures between groups [n (%)]

Group	n	3 months	6 months	12 months	Total
Control group	43	4 (9.30)	1 (2.33)	0 (0.0)	5 (11.63)
Treatment group	43	1 (2.33)	1 (2.33)	0 (0.0)	2 (4.65)

DISCUSSION

OVCFs are common fracture injuries, predominantly occurring in the middle-aged and elderly population, with a higher incidence in females than males (Mills *et al*., 2022). Studies have demonstrated that the probability of OVCFs in women over 50 years old is as high as 26% (Vendeuvre *et al*., 2021). The primary clinical symptoms of such patients include thoracic and back pain, limited limb mobility, or accompanying kyphotic deformity. Conservative treatment is unable to effectively correct the spinal kyphotic deformity in patients with OVCFs, nor does it alleviate lumbar and back pain. Moreover, it can exacerbate osteoporosis, leading to complications such as osteomalacia, muscle atrophy, and deep vein thrombosis (Li *et al*., 2018; Sun *et al*., 2021). Kyphoplasty is a common method for treating OVCFs, as it can rapidly alleviate patient pain, restore vertebral height, and reduce the leakage rate of bone cement (Zhang *et al*., 2021). Nevertheless, kyphoplasty is unable to improve the osteoporotic condition in patients with vertebral compression fractures and does not address the pain issues caused by soft tissue injuries such as muscles, fascia, and

ligaments surrounding the vertebrae (Park & Park, 2021). Consequently, in some patients, the degree of osteoporosis worsens after the surgery, accompanied by impaired limb mobility and a significant decline in quality of life. The injured area experiences microcirculation disorders and deposition of free radicals, while the disruption of vascular endothelial cells after injury leads to muscle fiber disarray. At this stage, pain, swelling, and bruising in the affected area worsen (Hiraga, 2019). In clinical practice, nonsteroidal anti-inflammatory drugs are commonly used for postoperative treatment; however, their effectiveness is limited in clinical settings.

TCM has achieved remarkable results in the treatment of osteoporosis, primarily attributing the key factors to kidney deficiency and spleen insufficiency. The kidney is considered the foundation of innate vitality, responsible for bone marrow production, while the spleen serves as the foundation of acquired vitality, governing the generation of qi and blood. When the kidneys and spleen become deficient, the bone lacks nourishment, leading to gradual bone degeneration. Furthermore, inadequate transformation and transportation of qi and blood due to deficiency results in qi stagnation, blood stasis, and inadequate nourishment of the skeletal system. Hence, TCM focuses on the key principles of kidney tonification, blood activation, elimination of blood stasis, and spleen invigoration to eliminate dampness in the treatment of osteoporosis (Cheng *et al*., 2022; Li *et al*., 2022; Zhuo *et al*., 2022). In this study, the Kidney Nourishing and Bone Strengthening Decoction was adopted, which contains Prepared *Rehmannia* Root, known for its functions of nourishing yin and replenishing blood, to treat symptoms of yin deficiency, blood deficiency, weak waist and knees, and fatigue-related cough and steaming bones (Wang *et al*., 2020a). Additionally, *Angelica sinensis*, a blood-tonifying herb, was included in the treatment protocol, as it possesses the effects of promoting blood circulation, lubricating the intestines, regulating menstruation, and alleviating pain (Pham *et al*., 2022). *Ligusticum chuanxiong* Hort is a blood-activating and stasis-dissipating herb, capable of promoting internal circulation of blood and qi while dispelling external wind-cold. *Achyranthes bidentata* is known for its abilities to promote bowel movement, alleviate descent, resolve stasis, regulate menstruation, tonify the liver and kidneys, and strengthen tendons and bones. *Morinda officinalis* is a tonic herb that nourishes kidney yang, strengthens tendons and bones, and dispels wind and dampness (Zhang *et al*., 2022). *Dipsaci* Radix can tonify the liver and kidneys, strengthen tendons and bones, and regulate blood circulation. It is used to treat diseases such as lumbago, weak legs and knees, and injuries from iron strikes. *Fructus corni* is an astringent herb that can tonify the liver and kidneys, constrict and consolidate, and nourish essence and marrow. *Dodder* seed belongs to the category of yang-tonifying herbs and is primarily used to tonify the liver and kidneys, consolidate essence, and reduce urination. It is commonly employed for treating symptoms of liver and kidney deficiency, lumbago, and weak waist and knees (Duan *et al*., 2022). *Eucommia* bark belongs to the category of tonic herbs that can tonify the liver and kidneys and strengthen tendons and bones. *Epimedium* belongs to the category of yang-tonifying herbs and can tonify kidney yang, strengthen tendons and bones, and dispel wind and dampness. *Salt dog spine* has warming, tonifying, and astringent properties, which can tonify the liver and kidneys, strengthen the waist and knees, and dispel wind and dampness. *Rhizoma Drynariae* is a blood-activating and stasis-dissipating herb that can promote healing, alleviate pain, tonify the kidneys, and strengthen bones. *Cistanche deserticola* is a yang-tonifying herb that can tonify kidney yang and nourish essence and blood. As a result, the Kidney Nourishing and Bone Strengthening Decoction can promote osteoblast differentiation, suppress osteoclast activity, regulate estrogen receptors and calcium-phosphorus metabolism, and exhibit antioxidant effects (Su *et al*., 2020).

B-ALP is an alkaline phosphatase secreted and synthesized by osteoblasts. It hydrolyzes pyrophosphate and regulates bone mineralization, reflecting the degree of bone calcification, osteoblast activity, and bone formation status (Llorente-Pelayo *et al*., 2020). N-MID-OT is primarily produced and secreted by osteoblasts. It maintains the normal rate of bone mineralization and serves as an important indicator of bone formation rate (Dai *et al*., 2023). The bone matrix is the structural foundation of bone tissue. T-P1NP is a specific marker of type 1 collagen deposition, reflecting the rate of osteoblast synthesis of bone collagen. It can be used to assess the clinical treatment outcomes and prognosis of patients with OVCFs (Shi *et al*., 2019). β-CTX is generated and released by osteoclasts during the bone resorption process. It is a degradation product of type 1 collagen and can be used to evaluate bone resorption status (McClung *et al*., 2018). This study found that patients receiving oral calcitriol capsules and vitamin D calcium tablets combined with surgical treatment had

higher levels of serum B-ALP, N-MID-OT, T-P1NP, and β-CTX compared to patients who were additionally treated with Kidney Nourishing and Bone Strengthening Decoction. Furthermore, the BD of lumbar vertebrae L1-L4 and the greater trochanter, Cobb angle, and anterior vertebral height were markedly greater in patients receiving oral calcitriol capsules and vitamin D calcium tablets combined with surgical treatment compared to those receiving additional Kidney Nourishing and Bone Strengthening Decoction. The Cobb angle is an indicator used to assess the severity of spinal curvature (Rrecaj-Malaj *et al*., 2020). These findings indicate that the combination of oral calcitriol capsules, vitamin D calcium tablets, and Kidney Nourishing and Bone Strengthening Decoction can effectively improve bone metabolism and BD in patients with OVCFs. Additionally, this study also found that patients receiving oral calcitriol capsules and vitamin D calcium tablets combined with surgical treatment had higher VAS and ODI scores versus those receiving additional Kidney Nourishing and Bone Strengthening Decoction. This indicates that the combination of oral calcitriol capsules, vitamin D calcium tablets, and Kidney Nourishing and Bone Strengthening Decoction can effectively alleviate the pain and degree of functional impairment in patients with OVCFs. Vitamin D calcium tablets can effectively supplement calcium in the body, promote calcium absorption in bones, and enhance bone formation, but they cannot inhibit bone resorption and bone turnover, leading to an imbalance in patients' bone metabolism (Burt et al., 2019). Modern pharmacological studies have shown that Prepared Rehmannia Root can promote the hematopoietic system and blood circulation in the bone marrow (Wang *et al*., 2020b). Active ingredients such as icariin in Epimedium can promote hematopoiesis and bone metabolism (Chen *et al*., 2022). Rhizoma Drynariae can promote bone healing, stimulate cartilage proliferation, and prevent bone and joint disorders (Hu *et al*., 2021).

In summary, the use of Kidney Nourishing and Bone Strengthening Decoction in the postoperative treatment of patients with OVCFs undergoing vertebral kyphoplasty can effectively improve the degree of pain and functional impairment, increase BD, improve anterior vertebral height and Cobb angle, enhance the quality of life in patients, and demonstrate significant clinical treatment outcomes. It also reduces the incidence of recurrent vertebral fractures after surgery. Hence, it is worth promoting and applying this treatment approach in clinical practice.

Ethics approval and consent to participate

This study was conducted with approval from the Ethics Committee of North China Medical&Health Group XingTai General Hospital. This study was conducted in accordance with the declaration of Helsinki. Written informed consent was obtained from all participants.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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