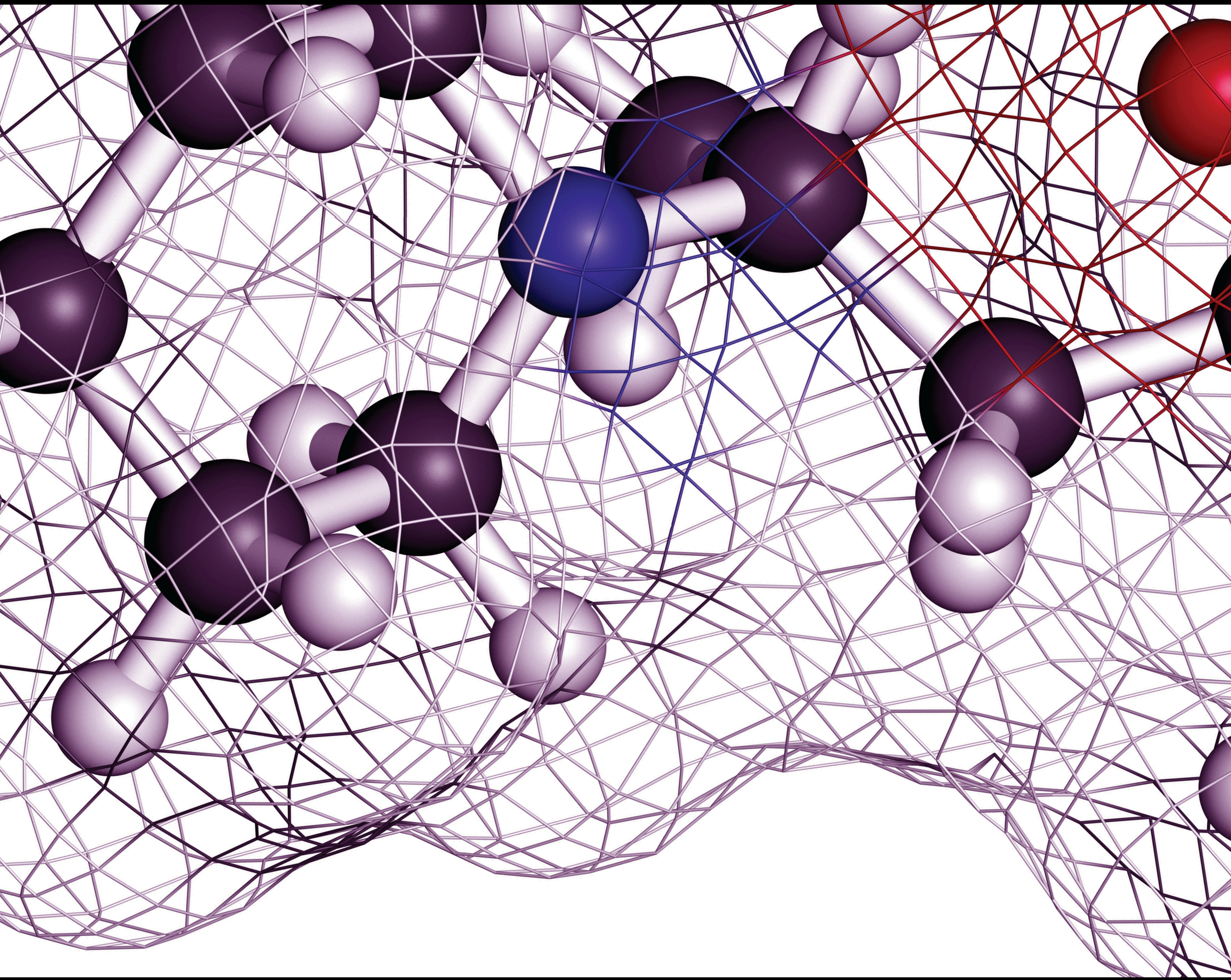
Pain Research and Management

Assessment and Management of Pain in Patients with Osteoporotic Fragility Fracture

Lead Guest Editor: Nan Jiang
Guest Editors: Willem-Jan Metsemakers, Wei Ji, and Min Yan



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Editorial

Assessment and Management of Pain in Patients with Osteoporotic Fragility Fracture

Nan Jiang,[1] **Wei Ji**,[2] **and Min Yan**[3]

[1]*Division of Orthopaedics and Traumatology, Department of Orthopaedics, Nanfang Hospital, Southern Medical University, Guangzhou 510515, China*
[2]*Division of Spine Surgery, Department of Orthopaedics, Nanfang Hospital, Southern Medical University, Guangzhou 510515, China*
[3]*Department of Anesthesiology, The Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou 310052, China*

Correspondence should be addressed to Nan Jiang; hnxyjn@smu.edu.cn

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Fragility fractures are fractures caused by mechanical forces, known as low-level or low-energy trauma that would not ordinarily lead to fractures. Such forces, quantified by the World Health Organization (WHO), are as forces equivalent to a fall from a standing height or less. As both a sign and a symptom of osteoporosis [1], fragility fractures most frequently occur in the vertebrae, proximal femur, and distal radius [2]. Currently, fragility fractures have become a major public health problem, resulting in high socioeconomic impacts [3–6]. For individuals, fragility fractures often lead to chronic pain, loss of autonomy, deterioration in quality of life, and need for care [5]. Risk factors of fragility fractures include increasing age, postmenopausal females, decreased bone mineral density (BMD), systemic corticosteroid therapy, rheumatoid arthritis (RA), and family history of osteoporosis [2].

Although great advances have been achieved in surgical techniques and instruments for the treatment of fragility fractures, current information of fragility fracture-related pain remains limited. Therefore, we organized this special issue, with the aim of conveying the updated knowledge in the field of evaluation and management of fragility fracture-associated pain.

In this special issue, the readers will find six articles, including three focused on vertebral fractures, two on geriatric hip fractures, and one on foot fractures: "Effect of Preoperative Zoledronic Acid Administration on Pain Intensity after Percutaneous Vertebroplasty for Osteoporotic Vertebral Compression Fractures" by Hu et al.; "Percutaneous Vertebroplasty and Facet Blocking for Treating Back Pain Caused by Osteoporotic Vertebral Compression Fracture" by Cheng et al.; "Advances in Vertebral Augmentation Systems for Osteoporotic Vertebral Compression Fractures" by Long et al.; "Effects of Orem's Self-Care Model on the Life Quality of Elderly Patients with Hip Fractures" by Xu et al.; "Fascia Iliaca Compartment Block for Perioperative Pain Management of Geriatric Patients with Hip Fractures: A Systematic Review of Randomized Controlled Trials" by Wan et al.; and "Prophylaxis of Pain and Fractures within Feet in the Course of Osteoporosis: The Issue of Diagnosing" by Bitenc-Jasiejko et al.

In the field of vertebral fractures, Hu et al. investigated the effects of preoperative administration of zoledronic acid (ZOL) on pain intensity after percutaneous vertebroplasty (PVP) for osteoporotic vertebral compression fractures (OVCFs). Based on a randomized controlled trial (RCT) of 242 patients, the authors concluded that intravenous infusion of ZOL before PVP can effectively decrease the postoperative pain intensity, reduce bone loss, increase bone density, reduce the risk of refracture, and improve the quality of life of the patient. However, the incidence of adverse events in the ZOL group was higher than in the controlled group.

In a retrospective study, Cheng et al. compared the efficacy of PVP plus facet blocking (FB) with PVP alone in relieving postoperative back pain in patients with OVCFs.

Based on an analysis of 204 patients, they concluded that PVP combined with FB could provide better pain relief than PVP alone in the short term (1 day and 3 months) after surgery, with similar outcomes at 1-year follow-up time. However, patients receiving the combination method had a longer operation time and more fluoroscopic exposure.

In a review article, Long et al. introduced recent advances on vertebral augmentation systems for the management of OVCFs, including PVP, percutaneous kyphoplasty (PKP), the OsseoFix® system, the SpineJack® system, radiofrequency kyphoplasty (RFK), and the Kiva system. Each technique has advantages and disadvantages, and orthopedists should be familiar with the indications and contraindications of each technique.

Regarding geriatric hip fractures, Xu et al. analyzed the effects of Orem's self-care program on the life quality of senile patients with hip fractures. Based on a RCT of 130 participants, the authors concluded that the self-care program based on Orem's model for geriatric patients with hip fractures could significantly improve life quality and reduce perioperative complications. Whether this nursing program can be routinely applied in this field requires more future studies.

In a systema review, Wan et al. summarized the current evidence of fascia iliaca compartment block (FICB) for perioperative pain management of geriatric patients with hip fractures. Based on comprehensive analyses of 27 RCTs with 2478 cases, the authors concluded that FICB is a safe, reliable, and easy-to-conduct technique, which is able to provide adequate pain relief during perioperative management of geriatric patients with hip fractures. However, as indicated by the authors, due to the still existing flaws of the current RCTs (limited sample size, inconsistency of the outcome parameters, and detailed FICB strategies), future RCTs are warranted.

It is interesting that Bitenc-Jasiejko and colleagues explored the roles of examination of posture and pressure distribution during standing, postural balance, and gait in the prevention of foot fatigue fractures during osteoporosis. Based on the literature review and examples of their clinical patients, they indicated that detailed posture diagnostics and gait estimation, along with the analysis of pressure distribution within the feet, are an essential aspect for the prevention of structural degradation and fatigue fractures within the feet. In addition, they also provided helpful recommendations, which need to be testified in the future.

In this issue, we did not receive submissions on distal radius fragility fractures, which never means the incidence of such a fracture is low. Actually, distal radius fragility fractures possess unique characteristics and treatment [7]. Future studies with a high level of evidence should also focus on this disease.

Conflicts of Interest

The Guest Editors declare that they have no conflicts of interest.

Acknowledgments

We would like to thank the Guest Editor, Willem-Jan Metsemakers, for his consent to join our editorial team. Due to the pandemic of COVID-19, Dr. W.J. Metsemakers did not participate in processing submissions.

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Wei Ji
Min Yan

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Review Article

Advances in Vertebral Augmentation Systems for Osteoporotic Vertebral Compression Fractures

Yufeng Long,[1] **Weihong Yi**,[2] **and Dazhi Yang**[1,2]

[1]*Health Science Center, Shenzhen University, Shenzhen 518071, Guangdong Province, China*
[2]*Department of Spine Surgery, The 6th Affiliated Hospital of Shenzhen University Health Science Center, Shenzhen 518052, Guangdong Province, China*

Correspondence should be addressed to Dazhi Yang; dazhiyang@email.szu.edu.cn

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Osteoporotic vertebral compression fracture (OVCF) is a common cause of pain and disability and is steadily increasing due to the growth of the elderly population. To date, percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) are almost universally accepted as appropriate vertebral augmentation procedures for OVCFs. There are many advantages of vertebral augmentation, such as short surgical time, performance under local anaesthesia, and rapid pain relief. However, there are certain issues regarding the utilization of these vertebral augmentations, such as loss of vertebral height, cement leakage, and adjacent vertebral refracture. Hence, the treatment for OVCF has changed in recent years. Satisfactory clinical results have been obtained worldwide after application of the OsseoFix System, the SpineJack System, radiofrequency kyphoplasty of the vertebral body, and the Kiva VCF treatment system. The following review discusses the development of the current techniques used for vertebral augmentation.

1. Introduction

Osteoporosis is characterized by decreased bone mass that leads to increased bone fragility and diminished structural support of the skeleton. The factors that lead to osteoporosis mainly include age, gender, lifestyle, drug effects, and autoimmune diseases, which disrupt the balance between osteogenesis and osteoclasts. Vertebral fractures secondary to osteoporosis are called osteoporotic vertebral fractures (OVCFs). One of the features that cause OVCFs is low energy damage. Because of the ascent of the ageing population, OVCFs, which are mainly caused by osteoporosis, have become one of the most major health problems worldwide. Approximately 20% of the elderly population is older than 70 years, and 16% of postmenopausal women worldwide experience OVCFs [1]. Furthermore, several complications of OVCFs, such as persistent pain, kyphotic deformity, weight loss, depression, reduced quality of life, and even death, have been reported [2]. Osteoporosis and its associated fractures are serious health issues in the ageing population. Indeed, vertebral compression fracture secondary to osteoporosis is a cause of morbidity and even mortality in older adults. Conservative therapies include bed rest, medications, bracing, physical therapy, exercise, and nerve root blocks. Conservative treatments are routinely used for OVCF patients; however, in cases of failed conservative treatment with insufficient pain relief after three weeks, vertebral augmentation should be considered. Moreover, it is inconclusive whether, based on current knowledge, conservative management is the best method for patients with OVCFs [3]. Conservative treatment, in addition, is ineffective in a large portion of patients [4]. Meanwhile, infectious diseases of the respiratory and urinary systems have been observed during the administration of conservative care, and hyperkyphosis is a common problem following OVCFs [5]. All of these elements have terrible impacts on patients with OVCFs. Since the introduction of minimally invasive surgery with its lower injury, shorter time, and rapid symptom relief, spinal surgeons, interventional radiologists, and others have become interested in vertebral augmentation techniques in recent years. These techniques mainly include percutaneous vertebroplasty (PVP), percutaneous kyphoplasty (PKP), and the Spine-Jack® System. The aim of this review is to analyse these devices that have been applied in recent years and to identify the differences among these new techniques.

Table 1 shows the comparison of several vertebral augmentation techniques, and Table 2 shows the summary of study characteristics [6–13]. Selection inclusion criteria and exclusion criteria: studies with the following criteria were included: (1) patients with osteoporotic lumbar and thoracic vertebra fractures; (2) random control trials or prospective or retrospective comparative studies; (3) moreover, studies which reported at least one of the following outcomes: vertebral height, cement leakage, adjacent vertebral fracture, visual analogue score, and Oswestry Disability Index. Studies were excluded in this article if they had neoplastic etiology, neurocompression, infection, traumatic fracture, neurologic deficit, spinal stenosis, severe degenerative diseases of spine, previous surgery at the involved vertebral body, and vertebral augmentation with other semi-invasive intervention treatments.

2. The Development of Vertebral Augmentation Systems

2.1. Percutaneous Vertebroplasty (PVP). In 1984, PVP was first introduced by Galibert and Deramond for treating haemangiomas at the C2 vertebra [14]. PVP has been used in patients with OVCFs who have failed conservative treatments to alleviate back pain and correct the deformity (Figure 1). The main predictors of favourable outcome among patients who have persistent and intense pain after OVCFs include early intervention and the absence of intravertebral clefts at 1 month after vertebroplasty [15].

Since its application in the treatment of OVCFs, various complications of PVP have been observed, such as neuraxial anaesthesia, severe cement embolism, new vertebral fractures, and infection after PVP. Cement leakage is one of the most common complications of this technique. The risk factors for cement leakage include the severity grade of the vertebral fracture, low viscosity of the polymethyl methacrylate bone cement, and the presence of intravertebral clefts; cortical disruption is also a risk factor for cement leakage [16–18]. One reason for cement leakage is early application of cement that has not reached its optimum viscosity. One of the efficient ways to detect cement leakage at an early stage is based on thorough fluoroscopic monitoring. The risk of cement leakage is approximately 30% since the cement extends beyond the confines of the bone because the low-viscosity cement is injected at a high pressure during the operation. Although the detected rate of cement leakage was found to be approximately 82% by using computed tomography (CT) [19], studies have indicated that most leakages are asymptomatic, among which, however, serious complications of nerve root or spinal cord compression and pulmonary embolism cannot be ruled out [16, 20, 21]. Moreover, adjacent vertebral fracture is one of the complications after PKP and cement leakage into the disc is considered the main factor increasing the risk of adjacent fracture [22].

The bipedicular approach was carried out as the standard technique of PVP. However, considering several aspects, such as operation time, cement volume, and radiation dose, a unipedicular approach was reported and advocated, as it reduced the operating time, limited X-ray exposure, and decreased the risk of cement leakage. The complications caused by vertebral pedicle puncture were decreased [23]. A meta-analysis conducted in 2016 indicated that there was no significant difference in the visual analogue score (VAS), the Oswestry Disability Index (ODI), or the rate of cement leakage. In addition, the operation time of unilateral PVP was shorter than that of bilateral PVP and this technique needed less cement [23]. Comparing the two surgery methods, these methods showed significant differences in pain relief, improvement of life quality, and radiological outcomes [23–25]. However, one study reported that the unipedicular approach might be associated with more nerve root stimulation [24].

PVP seems to be efficient and safe during the treatment of patients with OVCFs, and it can be performed at a reasonable cost with minimal complications [12]. For the time being, however, PVP should be cautiously considered for patients who have not yet received conservative therapy [26].

2.2. Percutaneous Kyphoplasty (PKP). PKP is an improved technique based on PVP, which is applied to reduce the rate of bone cement leakage, better restore vertebral height, and stabilize the fractured vertebra at present. In addition, PKP is a safe and effective technique for the treatment of OVCFs (Figure 2). It was reported that compared with conservative medical care, balloon kyphoplasty significantly improved patient outcomes [27]. Furthermore, a randomized controlled trial (RCT) with a 24-month follow-up demonstrated that PKP relieved pain and improved motor function and quality of life more effectively than nonsurgical therapy without increasing the risk of additional vertebral fractures [28].

Both PKP and PVP are safe and effective surgical procedures for treating OVCFs [29]. However, in terms of restoring vertebral height and local kyphotic corrections, PKP is relatively better than PVP [30]. Studies of PKP have indicated that the procedure duration of PKP is short and this technique yields fewer cement leakages with better pain relief, improvements of ODI, and a trend towards a longer fracture-free survival [31, 32].

Although bone cement leakage is one of the most common complications of PKP as well, because balloon kyphoplasty forms a space in the fractured vertebra within the vertebral body, the bone cement can be injected under low pressure and the rate of bone cement leakage can be reduced to 1–8% [33]. However, the problem of bone cement leakage has not been completely solved. Although cement extravasation may lead to severe complications such as pulmonary cement embolism, PKP is superior to PVP because of the lower cement leakage rate [29]. Published

Table 1: The outcome comparison of different vertebral augmentation techniques.

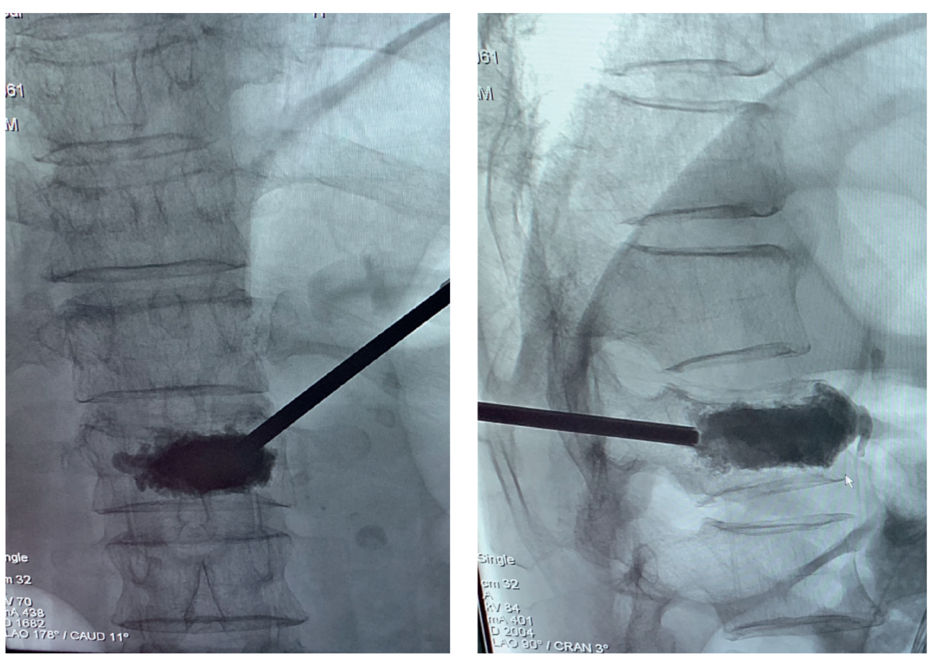
	PVP		PKP		OS		SJS		RFK		KVT	
	Pre	Po	Pre	Po	Pre	Po	Pre	Po	Pre	Po	Pre	Po
MVH	8.5 ± 1.1	8.6 ± 1.1	8.6 ± 1.1	12.4 ± 2.8	8.3 ± 1.1	13.1 ± 1.8	8.4 ± 1.1	12.9 ± 1.8	8.3 ± 1.3	12.5 ± 1.4	8.4 ± 2.1	12.7 ± 1.6
KA	15.9 ± 5.5	11.3 ± 3.8	16.7 ± 7.8	8.8 ± 5.4	11.7	10.4	14.3	8.5	13.9	8.1	15.7	7.9
CL	—	20–70%	—	4–13.4%	—	4%	—	5.00%	—	6%	—	0.03%
AF	—	0–7.8%	—	25–26%	—	11.40%	—	12.50%	—	0–10%	—	13.8%
VAS	8.2 ± 1.8	4.1 ± 1.4	8.4 ± 1.0	3.8 ± 2.0	7.7	3.4	7.4 ± 1.3	4.1 ± 2.1	8.0 ± 1.1	3.5 ± 2.7	8.2 ± 1.5	3.9 ± 1.9
ODI	67.1 ± 16.2	36.8 ± 11.3	65.6 ± 15.8	36.4 ± 10.7	70.6%	30.6%	82.5%	25.7%	83.2%	23.6%	81.4%	24.5%

PVP, percutaneous vertebroplasty; PKP, percutaneous kyphoplasty; OS, OsseoFix® System; SJS, SpineJack® System; RFK, radiofrequency kyphoplasty; KVT, Kiva VCF Treatment System; MVH, middle vertebral height; KA, kyphotic angle; CL, cement leakage; AF, adjacent fracture; VAS, visual analogue score; ODI, Oswestry Disability Index; Pre, preoperative; Po, postoperative.

Table 2: Summary of study characteristics (population, gender, and etiology).

Techniques	Gender (*n*) Male	Gender (*n*) Female	Mean age (year)	Fractured vertebral sites (*n*)
PVP	11	26	71.3 ± 10.0	T10–L5 (40)
PKP	10	17	64.6 ± 9.1	T4–L5 (32)
OS	5	9	75.2 ± 9.8	T11–L5 (15)
SJS	5	8	75.4 ± 8.4	T10–L5 (13)
RFK	3	6	75.3 ± 8.5	T12–L5 (11)
KVT	4	7	66.5 ± 9.1	T12–L5 (11)

PVP, percutaneous vertebroplasty; PKP, percutaneous kyphoplasty; OS, OsseoFix® System; SJS, SpineJack® System; RFK, radiofrequency kyphoplasty; KVT, Kiva VCF Treatment System.

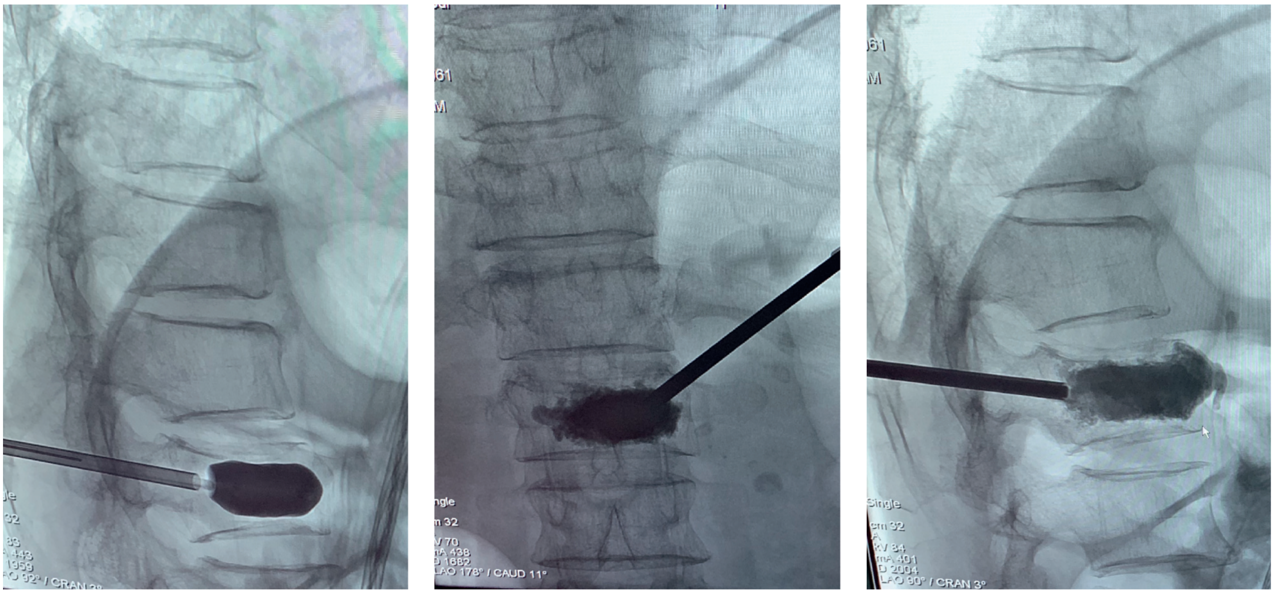


(a) (b)

Figure 1: Male patient with back pain due to osteoporotic fracture of the L1 vertebral body. The frontal and the lateral fluoroscopy view—needles were placed in the anterior third of L1 vertebral bodies and cement injection was finished under continuous fluoroscopy.

research has indicated a cement leakage rate of approximately 9% in the PKP technique, while the cement leakage rate in PVP is as high as 41% [34]. Notably, in the treatment for bone cement leakage, no significant difference was found between PKP and PVP [35].

Both unilateral and bilateral PKP procedures show effectiveness for OVCFs. In addition, the unilateral puncture technique is reportedly superior to the bilateral puncture technique in several aspects: shorter operation time, lower radiation dose, and less injected bone cement [25]. One of



(a) (b) (c)

Figure 2: (a) The balloon was inflated to restore the height of the fractured vertebra and to create a cavity within the vertebra. (b) Frontal fluoroscopy view when bone cement was injected into the fractured vertebra. (c) Lateral fluoroscopy view when bone cement was injected into the fractured vertebra.

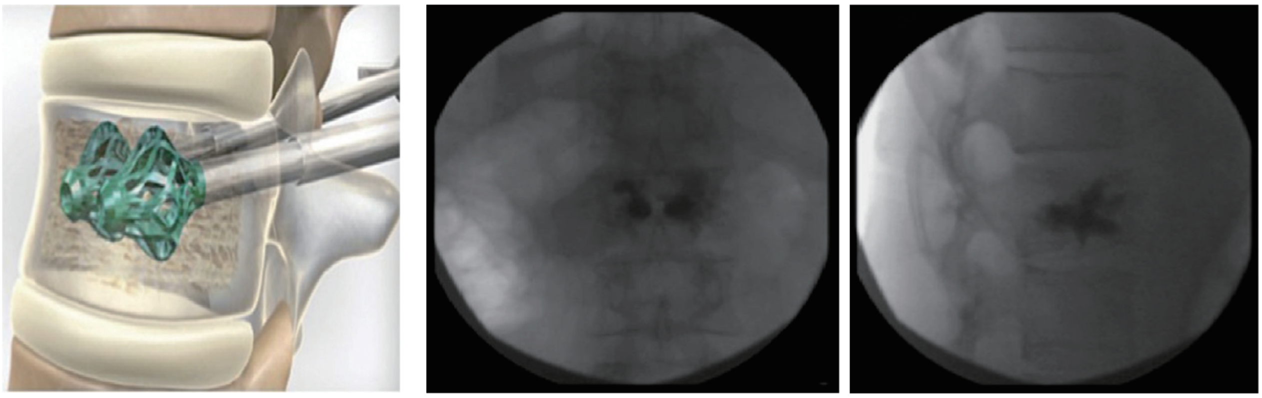
the limitations of PKP, however, is that this technique produces significant displacement of the vertebra and damage to the trabeculae in the fractured vertebral body. Another problem is the loss of the fractured vertebral height between the period of removing the balloon and the period of injecting the cement. Moreover, studies have indicated that the influence of bone cement leakage caused by PKP is small and that there are no clinical symptoms among patients with cement extravasation [36, 37].

Both PVP and PKP increase bone strength as well as relieve pain caused by OVCFs, and both techniques rely on injecting polymethyl methacrylate (PMMA) cement into the fractured vertebra for mechanical stabilization of the OVCFs. Currently, mineralized collagen-modified PMMA (MC-modified PMMA), a kind of new bone cement that does not change the beneficial properties of PMMA, has better biocompatibility than normal PMMA. It has been reported that this new bone cement forms a stable structure in the vertebral body as well as improves the prognosis of patients who have OVCFs by reducing pain and reoperation [30]. With the development of biomaterials, it is possible to obtain new types of bone cement with bioactivity, excellent biomechanics, and even osteogenesis and appropriate degeneration.

2.3. OsseoFix® System. The OsseoFix® System (Alphatec Spine Inc., Carlsbad, California, USA) (Figure 3) is an expandable titanium mesh cage that is applied in the treatment of OVCFs and prevents kyphotic deformity by compacting the surrounding trabecular bone [38]. The cage is implanted into the anterior third of the vertebral body and then expanded slowly. The height of the fracture vertebra is restored because of the compaction of the trabecular bone by the titanium mesh cage. Subsequently, the cement is injected into the cage. Moreover, compared with the cement volume applied in PKP, significantly less cement is required in the utilization of the OsseoFix® System [39].

The OsseoFix® System has been available since 2009 and is a new percutaneous stabilization method for osteoporotic thoracolumbar vertebral compression fractures [40]. The OsseoFix® System has been applied for vertebral compression fractures among patients with T6 to L5 stable vertebral fractures (type A1.1 to A1.3 or A3.1, according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification). It has been reported that the OsseoFix® System is also useful in treating acute stable traumatic vertebral fractures of the same type among young patients. Moreover, the OsseoFix® System is well suited for stabilizing tumourous VCFs as well as osteoporotic VCFs. Several studies have indicated that vertebral fractures with intraspinal bone fragments, spinal cord compression, and previous treatment at the same level are the main contraindications for treatment with the OsseoFix® System [6, 39, 41].

A study of the clinical and radiological outcomes among patients with OVCFs showed that both the mean VAS (7.7–1.4) and mean ODI (70.6%–30.1%) showed significant improvements after treatment with the OsseoFix® System. Furthermore, according to the measurement of Cobb's angle, the mean kyphotic angle after the operation showed improvement (from 11.7° to 10.4° after 12 months). Meanwhile, despite one case of loss of height in a stabilized vertebral body (3.1%) [6], no complications, including adjacent vertebral fractures, were observed. The OsseoFix® System, which required less cement and provided significant



(a) (b)

Figure 3: (a) OsseoFix® System. (b) Osteoporotic vertebral fracture lateral fluoroscopy view [39].

height maintenance in vitro, was biomechanically similar to PKP [40]. It was suggested that the OsseoFix® System had an indirect mechanism of increasing vertebral body height and that the implant might be applied as a cement-free implant in future operations because of the special structure of the OsseoFix® System [6].

2.4. SpineJack® System. The SpineJack® System, a titanium implant, is mainly designed to restore the height of the vertebral body and is applied to treat OVCFs. It consists of a mechanical working system that allows controlled reduction of the vertebral fracture; the feature facilitates the recovery of collapsed vertebrae and provides 3D support to the structure, which is required to mechanically stabilize the vertebral body in axial compression [42]. After the reduction, PMMA is injected into the vertebral body to stabilize the reduction. This technique may now reduce the amount of cement injected, and this new augmentation method could also be a useful approach for treating traumatic fractures in young and middle-aged patients by using the combination of a permanent implant plus cement [43].

In a trial with an over 3-year follow-up, the results of percutaneous treatment performed with the SpineJack® System among patients with OVCFs indicated good long-term clinical efficiency and safety, especially in maintaining vertebral height and decreasing the risk of adjacent vertebral fracture; additional studies showed that compared with PKP, the SpineJack® System was more able to reduce mechanically compressed vertebral bodies and maintain height restoration than balloon kyphoplasty [44–49]. The bone cement volume was reduced to 10% with the SpineJack® System, while PKP required a 30% cement volume in the treatment of traumatic wedge fractures. It was reported that the SpineJack® System yielded positive function among patients with acute OVCFs. Furthermore, the treatment was performed after a mean delay of 5.8 months and showed that the effectiveness in correcting the structural damage was preserved in patients with chronic OVCFs [44–49].

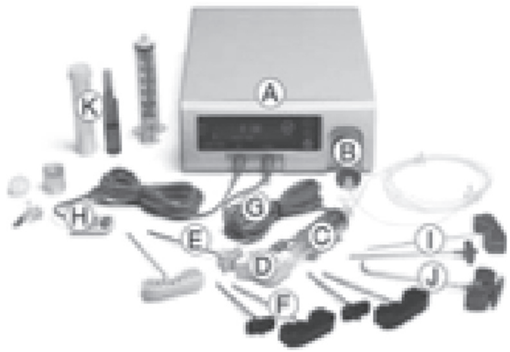
Considering the short-term follow-up, the results and function of the SpineJack® system need to be studied in a larger series, and future studies should focus on long-term clinical and radiological outcomes.

2.5. Radiofrequency Kyphoplasty (RFK). Radiofrequency kyphoplasty, a kind of vertebral augmentation system, was introduced in Germany in 2009 with a unipedicular approach. With the help of an articulating osteotome, multiple channels are created within the cancellous bone of fractured vertebra, which preserves more intact cancellous bone than inflation of a balloon does (Figure 4) [50]. Then, ultrahigh viscosity cement is injected into the vertebral body. The procedure is accomplished by using the energy of radiofrequency to warm the cement and accelerate its polymerization.

The indications for RFK mainly include painful OVCFs in elderly patients (65 years of age) after conservative therapy failure, painful aggressive primary tumours of the spine, or osteolytic metastases to the spine with a high risk of vertebral fracture in the palliative care setting [51].

A study indicated that there was a significant reduction in VAS and that the improvement in ODI was approximately between 65% and 96%; furthermore, pain reduction and minimization of daily handicap were effectively achieved [11]. It was reported that RFK improved pulmonary function, especially when the fractures were in the main spinal region of the diaphragm [11]. Further study showed that FEV1 values improved after radiofrequency kyphoplasty. Thus, according to the inverse relationship between FEV1 and mortality risk, RFK may well reduce the risk of mortality [11]. In an in vitro study, compared with PKP, RFK achieved similar outcomes in both stabilizing and restoring the height of the fractured vertebra. In addition, the operational time was shorter and there was less damage to the trabecular bone [12]. RFK was effective for pain relief, and the risk of cement leakage was reduced. Moreover, in postoperative fractures and the secondary loss of high restoration, RFK performed better than PKP [8, 13].

However, more large-sample multicentred RCT studies are required in the future to validate this new surgical system.



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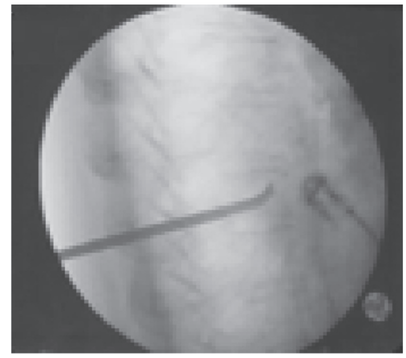


(b)

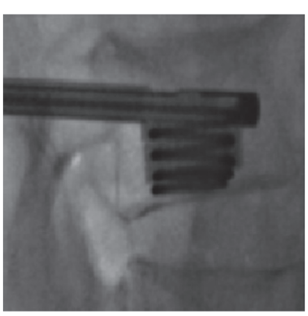
Figure 4: (a) Radiofrequency device and application system: (A) multiplex controller, (B) hydraulic assembly, (C) master syringe, (D) activation element, (E) locking delivery cannula, (F) StabiliT introducer-working cannula and stylet, (G) activation element cable, (H) hand switch cable, (I) straight line osteotome, (J) power curve navigating osteotome, and (K) StabiliT ER2 bone cement [52]. (b) Intraoperative X-ray of L1 vertebra (lateral view) using RFK [52].

(a)

(b)

(c)

(d)



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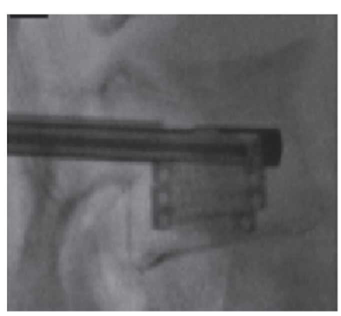

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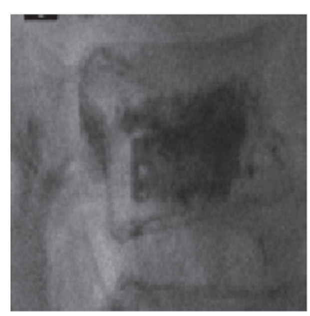
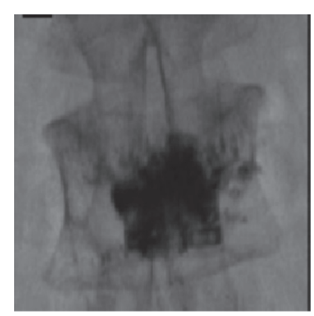


(g)



(h)

Figure 5: A percutaneous nitinol coil guidewire (a) is coiled within the cancellous portion of the fractured vertebral body. (b) Afterwards, a radiopaque PEEK implant is delivered incrementally via the nitinol coil guidewire (c) and then a nesting, cylindrical column is formed that provides vertical displacement, which may restore the height of the fractured vertebra (d) [10]. Fluoroscopic images illustrating the procedure of using the Kiva VCF treatment system (e). After removing the coil, a radiopaque PEEK implant was implanted (f) to provide structural support to the vertebral body and then bone cement was injected through the implant, as shown by lateral (g) and anteroposterior (h) fluoroscopic images [10].

2.6. Kiva VCF Treatment System. The Kiva System is a novel alternative surgical equipment for treating OVCFs. In the procedure for utilizing this new technique, a nitinol Osteo Coil guidewire is advanced through a deployment cannula percutaneously. After correct placement of the nitinol coil in the cancellous portion, a polyether ether ketone (PEEK) implant (the implant contains 15% barium sulfate for radiopacity and forms a nesting, cylindrical column) is implanted incrementally over the coil until the desired restoration of the fractured vertebral height is achieved. Subsequently, the guidewire is removed and bone cement is injected through the pipe of the implant until the column is filled with cement (Figure 5).

The Kiva System was applied to patients with painful A1.1, A1.2, or A1.3 (AO spine fracture classification) OVCFs at the thoracic and lumbar spine or at an age at entry of 50 years or greater; 1–3 symptomatic OVCFs were considered [53]. Furthermore, a VAS score of 5 or greater, fracture age of less than 6 months, and an ODI score of 30% or greater were required [10].

The restoration of vertebral height could be maintained with both procedures for 6 months, and the Kiva group had fewer complications, such as adjacent fractures, than the PKP group had [53]. A previous study established that the rate of adjacent-level fracture with Kiva was reduced; therefore, the cost of treating OVCFs was reduced [2]. A study on the Kiva System showed that the mean back pain score on the VAS decreased by approximately 66% ($P < 0.0001$), and the improvement of the mean ODI score was approximately 63% at 12 months after operation. In addition, approximately 8% of cement extravasation was identified radiographically; however, no clinical symptoms were observed [10].

Compared with PKP, a study suggested that the Kiva System had identical outcomes, including the effective relief of pain. Kiva was shown to be noninferior to PKP and revealed a positive trend in several secondary endpoints [54]. Meanwhile, the Kiva System was found to be similar to PKP with respect to VAS and ODI, while less bone cement was needed via the Kiva System [2]. A comparison of the PKP and the Kiva System for OVCFs at 6 months after surgery indicated that the improvement in VAS in the Kiva group was significantly better than that in the PKP group ($P < 0.0001$), and the mean ODI scores in both groups also improved from $68.7\% \pm 15.8\%$ to $24.8 \pm 18.6\%$ in the Kiva group and from $80.6\% \pm 8.6\%$ to $33.2 \pm 6.3\%$ in the PKP group 6 months later. Furthermore, the mean operation time in the Kiva group was shorter than that in the PKP group, in which 12.7 ± 3.7 minutes per vertebra was observed in the Kiva System group and 34.1 ± 7.0 minutes per vertebra was observed in the PKP group [10].

The Kiva System can be effective for painful vertebral fractures [2, 10, 53, 55]. Longer observation, however, is needed to confirm whether the Kiva System provides positive functional improvement, and further randomized prospective studies with larger patient samples are necessary to predict long-term outcomes after the intervention [53, 56].

3. Conclusion

The principles of vertebral augmentation include improvements in functionality and back pain that promote the social life and independence of patients with OVCFs. Since not all vertebral compression fractures are the same, a tailored-based approach is necessary for optimum efficacy and safety [57]. Moreover, the surgical instruments, including balloons, the OsseoFix® System, the SpineJack® System, radiofrequency kyphoplasty, and the Kiva VCF system, have been improved. All of these techniques are utilized in clinics.

By comparing the outcomes of several vertebral augmentation techniques (Tables 1 and 2), these do have differences. According to our clinic experience, unilateral PKP has satisfied effects on vertebral augmentation, with less complications and medical cost. Although novel techniques have attractive effects on treatment of vertebral fracture, there is no clear indication that guides what kind of techniques we shall use. Besides, the outcomes of these novel techniques needed more clinical observation.

In addition, with the utilization and development of virtual reality (VR) and digital navigation in the field of spine surgery, the procedure and even the outcomes of the operation can be simulated in vitro. Before the real operation of vertebral augmentation, doctors can receive abundant training and practice in techniques such as finding the best angle and direction to inject bone cement. This approach could significantly shorten the operation time, reduce the pain of patients during the operation procedure, and avoid complications. Therefore, with the development of vertebral augmentation systems, the operation will be more efficient and safe. Moreover, with the application of novel theories, such as enhanced recovery after surgery (ERAS) and bone cement with compatible biomechanical properties and bioactivities, patients with OVCFs can achieve the maximum improvements in functionality as well as life ability and quality. Vertebral augmentation systems will likely undergo greater development than any other technical aspects.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Review Article

Prophylaxis of Pain and Fractures within Feet in the Course of Osteoporosis: The Issue of Diagnosing

Aleksandra Bitenc-Jasiejko,[1] **Krzysztof Konior**,[2] **Kinga Gonta**,[3] **Magdalena Dulęba**,[3] **and Danuta Lietz-Kijak**[1]

[1]*Department of Propaedeutic, Physical Diagnostics and Dental Physiotherapy, Pomeranian Medical University in Szczecin, Szczecin, Poland*
[2]*Doctoral Study Department of Propaedeutic, Physical Diagnostics and Dental Physiotherapy, Pomeranian Medical University in Szczecin, Medical Center in Nowogard, Szczecin, Poland*
[3]*College of Physiotherapy in Wroclaw, Ortogenic Rehabilitation and Podology Center in Wroclaw, Wroclaw, Poland*

Correspondence should be addressed to Aleksandra Bitenc-Jasiejko; abj@posturologia.pl

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Background. Considering the enormous risk of fractures in the course of osteoporosis in the area of the feet, an important aspect of prophylaxis is periodic and, in special cases, ongoing monitoring of defects and deformations as well as pressure distribution. The purpose of this article is to indicate the role of the examination of posture and pressure distribution during standing, postural balance, and gait, in the prevention of fatigue fractures in the course of osteoporosis, based on the literature review and examples of patients. *Methods*. The manuscript consists of two parts; it has a review-analytical character. The first part reviews the literature. The data were obtained using the MEDLINE (PubMed), as well as Cochrane and Embase databases. The database review was carried out focusing mainly on English-language publications, while taking into account the topicality of scientific and research works in the area of osteoporosis. The problem of multiaspects in the area of bone density was pointed out. Considering the above, in the second part, the authors analyzed 11 exemplary patients with osteoporosis, referring to the assessment of foot and lower limb defects using traditional posturological methods and including pedobarography to diagnostic procedures that are used in the assessment of pressure distribution, standing and moving, and an attempt to balance. *Results*. Analysis of the research and scientific literature proved the lack of unambiguous diagnostic procedures of the locomotor system recommended for the prevention of fatigue fractures in the course of osteoporosis. The main diagnostic recommendations are imaging tests (most often X-ray), which are recommended in the case of specific clinical symptoms. The analysis of exemplary patients with osteoporosis showed numerous disorders in the distribution of pressure in the plantar part of the feet, which are related, among other things, with their individual defects and lower limbs. *Conclusions*. Detailed posture diagnostics and gait estimation, along with the analysis of pressure distribution within the feet are a very important aspect of the prevention of structural degradation and fatigue fractures within the feet. An important postulate for further research and scientific work is the elaboration of the procedures that will serve the preventive diagnostics of the locomotor system, aimed at early detection of threats of fatigue fractures.

1. Introduction

Osteoporosis is defined by the World Health Organization (WHO) as a reduction in the bone density index, which affects about 30% of women and 12% of men [1]. The issue of osteoporosis depends mainly on its differentiation, especially on the problem of bone osteomalacia, which has similar causes. Equally, in osteoporosis and osteomalacia, as well as in osteopenia, the most common element of these diseases is vitamin D deficiency, which leads to impaired phosphate and calcium concentrations. Vitamin D is produced inside the skin due to the influence of sunlight and supplied to the body with nourishment. Osteomalacia may also be caused by calcium and phosphate insufficiencies, for reasons unrelated to vitamin D (e.g., dietary deficiencies), lack of exposure to the sun, and malabsorption of vitamin D from the digestive tract or kidney and liver failure [2–5]. The analysis of osteomalacia usually detects decreased concentrations of calcium (may also be regular), phosphates, and the active form of vitamin D (25-OH-D), as well as an elevated concentration of alkaline phosphatase (ALP) [6]. In the definition of osteoporosis, WHO defines a reduced T-score of bone mineral density (BMD) as-2.5 (T-score < -2.5), diagnosed by X-ray imagining double emission (measured by dual-emission X-ray) [7–11]. Innovative medical engineering methods, the so-called Nanoindentation, indicate that there are significant contrasts in bone hardness in patients with osteoporosis, which affects their load resistance, deformation possibilities, and flexibility, while reducing microhardness in relation to the control group [12, 13].

Bone fragility and, as a result, fractures of the distal part of the foot, pelvic bone, sacral bone, head of the proximal tibial bone, and ribs may be a manifestation of osteomalacia, with a deficiency of vitamin D3 and an equally abnormal absorption of calcium ions and phosphates. These issues should be differentiated from fractures due to osteoporosis in which there is a rupture of the femoral neck, spine vertebrae, or spondylopathy by reducing bone mineral density, which are determined by densitometric examination. The fracture risk increases with age [1, 14, 15].

Since 2001, osteoporosis has been ultimately defined as a disorder within the skeletal system, in which the risk of bone fracture increases, not only due to their reduced density, but also in the course of their fragility, which rises with age [16]. The lack of calcium or phosphates leads to decreased bone mineralisation, while a deficiency of vitamin D leads to weakened muscle receptors [17, 18]. Hypophosphatemia is also induced by drug intake, for example, neutralising phosphates or diuretics, and also, although less frequently, by hereditary diseases and paraneoplastic production of phosphatonins. Additionally, this may be caused by conditions such as prostate cancer and bronchial cancer [19–22]. Therefore, it should be noted that osteoporosis is often a secondary disease in patients with chronic kidney, liver, and lung diseases, often resulting from ageing. Idiopathic osteoporosis also represents an essential aspect of considerations regarding the prevention of bone fractures and, as a consequence, the therapeutic challenge of an unknown etiological factor [23].

Osteoporosis is more common in women, and an additional factor determining its occurrence is menopause and the postmenopausal period (PMOP: postmenopausal osteoporosis), which is related to the impact of oestrogen on osteoclasts [24–29]. It has also been demonstrated that the number of pregnancies, age, and body mass index increase the risk of osteoporosis [30]. However, a much more important determinant of the fractures arising in the course of osteoporosis is advanced age [31]. Microlesions of tissues develop over time; nonetheless, in elderly women, fractures and overload cracks are more frequent [15, 32, 33]. It has been proven that age, BMI, and number of pregnancies are important determinants of the development of postmenopausal osteoporosis [34]. The fundamental and recurrent causes of decreased BMD index in the elderly, apart from systemic diseases and medications intake, include the improper supply of nutrients and a lack of physical activity [35–37].

Osteoporosis is a significant issue in diabetic patients, especially in terms of the prevention of diabetic foot syndrome and defragmentation, as well as bone fractures in the course of Charcot neuroosteoarthropathy. In the course of type I diabetes mellitus, a mild reduction of bone mineral density is noticed, whereas in type II diabetes mellitus, which is more frequent in older people, a regular or increased BMD index is observed. An enhanced risk of fractures in individuals with diabetes is associated with peripheral neuropathy and weakened muscle capacity, which in consequence affects local structural instability caused by hyperglycaemia, particularly glycosylation in collagen fibres [38]. Permanent degradation of the osteoarticular structures of the foot is commonly caused by chronic, often multiple joint inflammation. An additional factor is the instability of the body's balance, which increases the danger of falling. As a result, osteoporosis in diabetic patients is a secondary disease in coexisting kidney diseases, angiopathy, and so on. Research in patients with type I diabetes indicates an elevated number of fatigue fractures [39–44].

Furthermore, it should be noted that the relationship between diabetes mellitus and osteoporosis is imprecise, while bone density studies in the course of diabetes often do not present clear outcomes [45]. Nevertheless, considering the great importance of fracture prophylaxis in diabetic patients, which is strongly influenced by bone mineralisation, bone density, and elasticity, the authors believe that taking into account individual assessments of the coexistence of osteoporosis is a crucial priority. The studies show that over 50% of the general population with diabetes and 20% of younger people (aged 20–56) burdened with the disease fulfil the criteria of osteoporosis [46, 47]. The examination of patients at risk of Charcot's neuro-osteoarthropathy is of particular importance, as, in these individuals, the bone mineral density has been significantly reduced [48]. It should be noted that within the feet there are relatively few cross-sectional studies on bone density, mineralisation, and so on.

On the internal level, the function of mechanical load detection is carried out by osteocytes [49–52]. Biomechanisms, aimed at the reconstruction of the bone structure and repair of microdamage, cause periodic bone-weakening at the resorption site. During healing, this particular bone area (adhesion process) shows a periodically elevated fracture risk [53, 54].

On the external level, the key issue in the elimination of biomechanical abnormalities will be the diagnosis of body posture, including diagnostic methods aimed at the early detection of defective pressure distribution during standing, body balancing, and locomotion. As a consequence, these actions are aimed at defect correction, relief, and amortization. As a part of the prevention of fractures, pharmacological treatment, supplementation of vitamin D and calcium, and diet therapy are mainly recommended [55–57].

An important aspect is also the monitoring and treatment of comorbidities, that is, those that constitute the main cause of osteoporosis [58, 59]. Diagnostics of the musculoskeletal system is recommended mainly to patients at risk, mainly the elderly [60] and women in the postmenopausal age [61, 62]. However, for younger people, routine tests are recommended [60]. Detailed imaging diagnostics is performed in the event of emerging clinical symptoms (pain, inflammation, and swelling). The most frequently recommended examination is X-ray, which, unfortunately, in the initial phase shows a low diagnostic sensitivity, increasing after about 3 months from the appearance of the first symptoms [63–68].

However, research and the scientific literature do not indicate detailed noninvasive diagnostic procedures. There are also no scientific and research reports in the area of foot assessment, including in particular the procedures for assessing the distribution of pressure within the feet.

From the authors' experience, the diagnosis of postural and functional defects of structures allows the early detection of the risk of fatigue fractures in patients with osteoporosis. Consequently, periodic tests allow the early implementation of effective measures to prevent fatigue fractures. Such activities are of particular importance in the prevention of foot fractures, mainly due to the significant gravitational overloads arising during locomotion. Considering the above, the authors made a detailed diagnosis of posture in 11 exemplary patients with osteoporosis, indicating at the same time diagnostic methods for the assessment of foot defects and deformities, and the analysis of pressure distribution during standing, walking, and body balancing.

The effects of the analysis of exemplary patients.

All figures and images have been prepared by the authors and are their property.

The analysis of patients included 11 exemplary patients with osteoporosis, aged 27–86, including eight men and 3 women with pain in the feet, ankle joint, and/or shin, with a limited range of mobility. Two patients additionally suffer from diabetes; four of them have a history of fatigue fractures. In all these patients, postural diagnostics was performed, with particular emphasis on the assessment of foot and lower limb defects using traditional posturological methods, including pedobarography in diagnostic procedures, which is used to assess the distribution of pressure in the standing and locomotion position and the balance test.

Table 1 presents the results of tests of 11 patients, indicated in this publication, and photogrammetric research, which were accompanied by anthropometry of the foot and podoscopic tests in individual sectors of the foot including the following:

Arch height measurements that have been combined with the plantar part assessment

Goniometric assessment of the walk angle and toes position

The results of the examinations of the feet performed in patients with osteoporosis indicate that 9 out of 11 suffer from tarsal valgus. Seven patients presented hallux valgus and defects of the toes from II to V. However, the comparison of the results of the X-ray with the outcomes of the tests indicates that each patient has a different problem and, as a consequence, a different cause of pain and distortion. The clinical exemplary patients presented in this publication show asymmetrical and chaotic dysfunctions of the foot and structural instability. Given the fact that patients have individually specific changes, the diagnostic procedure indicated by the authors points to the necessity of individual determination of the needs in terms of relief, shock absorption, and correction to be performed in patients with osteoporosis.

Below are photographic documentation of 9 patients, that is, X-ray, magnetic resonance imaging, and podoscopic research, which used selected elements of functional diagnostics and anthropometry.

During X-ray tests, hallux valgus with an overload of the metatarsophalangeal joint in the area of MTP I and frequent subluxation of sesamoid bones was observed in five patients. Among four patients, enthesopathy of the plantar fascia was detected. In the case of 4 exemplary patients, fractures within the foot bone were observed, in one exemplary patient case tibial, and fibula bone fractures occurred. The analysis of X-rays shows numerous overload changes in the region of the foot, which is manifested by calcifications and osteophytes in the joints and defective trabeculation.

The assessment of the pressure on the arch of the foot when standing and walking will be crucial in the early detection of increased pressure. For this purpose, a pedobarographic test was carried out under both static and dynamic conditions (Figure 10(a). Evaluation of pressure during standing/Figure 10(b): assessment of pressure during walking).

The analysis included the values of pressure in individual metaplanes, determined according to the model, and markings indicate pressure on individual sectors of the foot:

MH—internal part of the tarsus/LH—external part of the tarsus: allows the reading of pressure, with the correlation of results based on the outcomes of anthropometric tests of valgus/varus tarsus deformity/tarsus instability, both while standing and walking

MF—metatarsus: allows the pressure on the metatarsus to be assessed; this is especially important in assessing pressure during walking

M 1-5—pressure on the metatarsophalangeal joints: allows conclusions to be drawn on the functionality of the transverse arch

T1—pressure on the great toe and T2-5—pressure on the toes 2–5

The results of the examination show a significant overload of the forefoot, with fractures and degradation of the 3rd metatarsal head (M3 meta surface). It is noteworthy

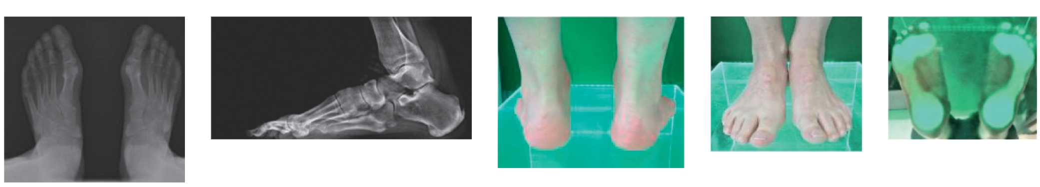
Table 1: Summary of general information, defects, and ailments of the feet of patients included in the study, together with an assessment of functionality in individual areas of the foot (foot, longitudinal arch, transverse arch, and toes).

Patient no./ figure no.	Medical history			Diagnosed foot defects while standing			
	Age (years)	Weight (kg)	Medical history, complaints	Tarsus	Longitudinal arch	Transverse arch	Toes
No. 1 Figures 1(a)–1(e)	69	70	Pain in the forefoot, both right and left. Limited mobility in the upper ankle joint	L-valgus R-normal	L-reduced R-normal (planovalgus foot in the gait assessment of both feet-pedobarography)	L-reduced R-reduced	L-normal R-normal
No. 2 Figures 2(a)–2(f)	86		Comminuted fracture of the fibula, tibia	L-post fracture valgity R-valgity	L-reduced R-reduced	L-reduced R-reduced	L-hallux valgus R-hallux valgus
No. 3	66	65	Ankle swelling, foot pain	L-valgity R-valgity	L-normal R-normal (planovalgus foot in the gait assessment of both feet-pedobarography)	L-reduced R-reduced	L-normal R-normal
No. 4 Figures 3(a)–3(f)	55	85	Pain of the whole foot hindering walking, venous insufficiency	L-varus deformity R-varus deformity	Varus forefoot-instability at the level of the tarsometatarsal joints	L-reduced R-reduced	L-hallux valgus, II-V-hammer toes R-hallux valgus, II-V varus toes (fixed lesions-X-ray)
No. 5 Figures 4(a)–4(c)	58	95	Foot pain	L-valgity R-valgity	L-normal R-normal (planovalgus foot in the gait assessment of both feet-pedobarography)	L-reduced R-reduced	L – hallux valgus, flexible hammer toes–hallux valgus, flexible hammer toes
No. 6 Figures 5(a)–5(e)	71	91	Pain in the area of the first metatarsophalangeal joint, limitation of mobility. Diabetes II, renal failure, psoriasis, prostate hypertrophy, hypertension, heart failure, fatty liver, lymphoedema	L-valgity R-valgity	L-normal R-normal (planovalgus foot in the gait assessment of both feet-pedobarography)	L-reduced R-reduced overload change (callus) in the area of II and III metatarsophalangeal joint	L-hallux valgus/rigid II, IV varus toes/II hammer toe P-II-IV flexible hammer toes
No. 7 Figures 6(a)–6(g)	27	87	Fracture of the calcaneus with fragmentation in 2015	L-valgity R-valgity	L-normal P-normal (planovalgus foot in the gait assessment of both feet-pedobarography)	L-reduced R-reduced	L-normal R-normal
No. 8. Figures 7(a)–7(e)	79	68	Pain of the left foot, of the great toe, psoriasis	L-valgity R-valgity	L-reduced R-reduced (planovalgus foot in the gait assessment of both feet-pedobarography)	L-reduced R-reduced	L-hallux valgus, dislocation of the sesamoid bones (X-ray) R-hallux valgus

Table 1: Continued.

Patient no./ figure no.	Medical history			Diagnosed foot defects while standing			
	Age (years)	Weight (kg)	Medical history, complaints	Tarsus	Longitudinal arch	Transverse arch	Toes
No. 9.	82	94	Significant valgity and pain of the ankle of the left limb; in the right limb, the condition is complicated by surgery due to hallux valgus, lymphoedema, no X-ray-the patient does not agree to the X-ray image	L-valgity (the lack of X-ray image prevents making diagnosis) R-valgity	L-reduced R-reduced(pedobarography)	L-reduced R-reduced	L-hallux valgus, II-IV hammer toesR-significant deformities of the toes (postoperative complications)
No. 10. Figures 8(a)–8(e)	33	87	Pain of the II metatarsophalangeal joint of the left foot, instability of the III toe, microfractures within the head of the III metatarsal bone; medical history revealed numerous microfractures in the right hand, radius, fibula-during activities of daily living (e.g. abnormal body position)	L-normal R-normal	L-normal R-normal Adduction of the metatarsal bones, distortion at the level of the line of lisfranc joints (X-ray, pedobarography indicates significant pressure on the base of the V metatarsal bone). When standing, varus forefoot in relation to the tarsus (pedobarography)	L-reduced R-reduced in both feet, significantly increased pressure on the II metatarsophalangeal joint (pedobarography) degradation of the head of the II metatarsal bone of the left foot (X-ray)	Toes (L and R) apparent features of the Morton's foot caused by adduction of the forefoot (X-ray)II-V flexible hammer toes. Significant instability of the II toe of the left foot
No. 11 Figures 9(a)–9(f)	66	82	L-amputation of the toes I-IV, the metatarsophalangeal joints, as a result of necrosis (circulatory disorders), with an episode of coma, pain of the plantar surface			L-reduced R-reduced	L-amputation of toes I-IV, varus fifth toe (X-ray) P-hallux valgus, II-V flexible hammer toes

L: left limb; R: right limb.



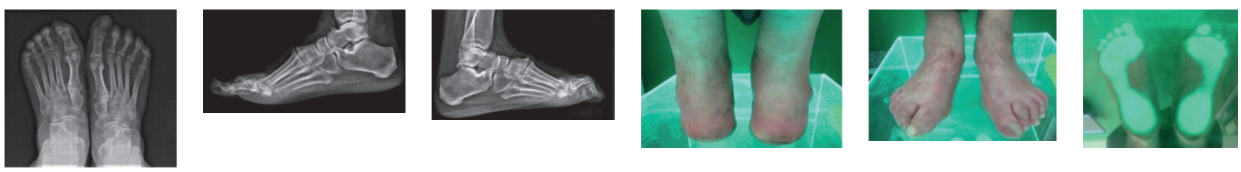
(a) (b) (c) (d) (e)

Figure 1: (a–e) Results of imaging tests (X-ray) and podoscopic tests: patient no. 1. (a). Dorsal-plantar foot X-ray: hallux valgus, subluxation of sesamoid bones, overloaded cuneometatarsal joint, and osteophytes in the area of navicular bone.(b) Lateral X-ray: Achilles tendon enthesopathy and numerous calcifications. (c) Posterior picture: ankle joint and hindfoot evaluation. (d) Anterior picture of the feet: assessment of toe positioning and deformation. (e) Plantar photo on the podoscope: evaluation of plantar part of the foot and height measurement of the longitudinal arch.

that the compensatory processes that reduce pain while standing do not activate while walking (despite persistent pain), while standing the foot is stabilized by the tarsometatarsal joints (TMTJ), which consequently makes the second and third metatarsal bones susceptible to fractures as a result of stress [69–71].

(a) (b) (c) (d) (e) (f)

Figure 2: (a– f) Results of imaging tests (X-ray) and podoscopic tests: patient no. 2. (a) Posterior-anterior X-ray; fracture of the medial ankle and fracture of the distal end of the fibula. (b) Anterior-posterior X-ray: fracture of the medial ankle, fracture of the distal end of the fibula, overload changes in the phalangeal joints, and inflammation in the metatarsal joints. (c) Lateral X-ray: microfractures of the heel bone and enthesopathy of the plantar fascia: calcaneal spur. (d) Posterior picture: ankle joint and hindfoot evaluation. (e) Anterior picture of the feet: assessment of toe positioning and deformation. (f) Plantar photo on the podoscope: assessment of plantar part of the foot, height measurement of the longitudinal arch.

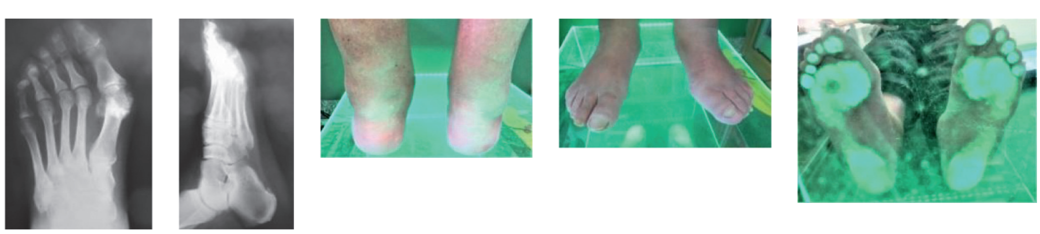


(a) (b) (c) (d) (e) (f)

Figure 3: (a–f) Results of imaging tests (X-ray) and podoscopic tests: patient no. 4. (a) Dorsal-plantar foot X-ray: phalangeal valgity, degeneration of the interphalangeal joints, and additional navicular bone in the left foot. (b) Lateral X-ray: coronoid talus bone and degradation lesions in the phalangeal joints. (c) Lateral X-ray: coronoid talus bone and degradation lesions in the phalangeal joints. (d) Posterior picture: ankle joint and hindfoot evaluation. (e) Anterior picture of the feet: assessment of toe positioning and deformation. (f) Plantar photo on the podoscope: assessment of plantar part of the foot and height measurement of the longitudinal arch.

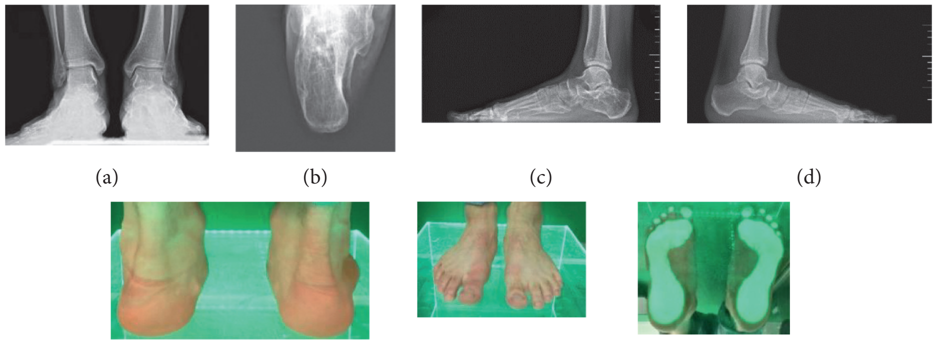
(a) (b) (c)

Figure 4: (a–c) Podoscopic tests: patient no. 5. (a) Posterior picture: ankle joint and hindfoot evaluation. (b) Anterior picture of the feet: assessment of toe positioning and deformation. (c) Plantar photo on the podoscope: assessment of plantar part of the foot and height measurement of the longitudinal arch.



(a) (b) (c) (d) (e)

Figure 5: (a–f) Results of imaging tests (X-ray) and podoscopic tests: patient no. 6. (a) Dorsal-plantar foot X-ray: degeneration of the I head of metatarsal bones, phalangeal valgity, and overload lesions in metatarsophalangeal joints. (b) Lateral foot X-ray: enthesopathy of the plantar fascia and inflammation in the metatarsophalangeal joints. (c) Posterior photo: ankle joint and hindfoot evaluation. (d) Anterior picture of the feet: assessment of toe positioning and deformation. (e) Plantar photo on the podoscope: assessment of plantar part of the foot and height measurement of the longitudinal arch.

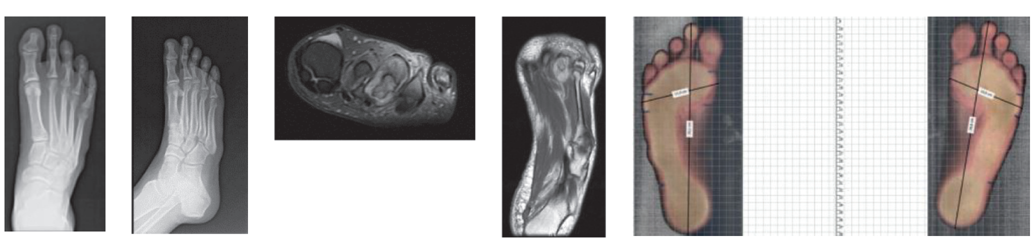


(a) (b) (c) (d)
(e) (f) (g)

Figure 6: (a–g) Results of imaging tests (X-ray) and podoscopic tests: patient no. 7. (a) Anterior-posterior X-ray, numerous overload changes in the upper ankle joints, tarsometatarsal joints, and calcifications. (b) Axial X-ray: heel bone fracture. (c) Lateral X-ray: numerous overload changes and calcifications. (d) Lateral X-ray: numerous overload changes and calcifications. (e) Posterior photo: ankle joint and hindfoot evaluation. (f) Anterior picture of the feet: assessment of toe positioning and deformation. (g) Plantar photo on the podoscope: assessment of plantar part of the foot and height measurement of the longitudinal arch.

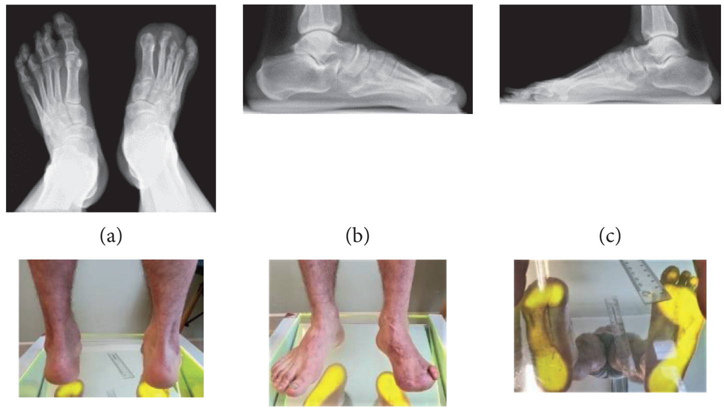
(a) (b) (c) (d) (e)

Figure 7: (a–e) Results of imaging tests (X-ray) and podoscopic tests: patient no. 8. (a) Dorsal-plantar X-ray: hallux valgus, subluxation of sesamoid bones, and overloaded cuneometatarsal joint. (b) Diagonal foot X-ray (lateromedial): enthesopathy of the plantar fascia and Achilles tendon, numerous calcifications, and overloads in the upper ankle joint. (c) Posterior picture: ankle joint and hindfoot evaluation. (d) Anterior picture of the feet: assessment of toe positioning and deformation. (e) Plantar photo on the podoscope: assessment of plantar part of the foot, height measurement of the longitudinal arch.



(a) (b) (c) (d) (e)

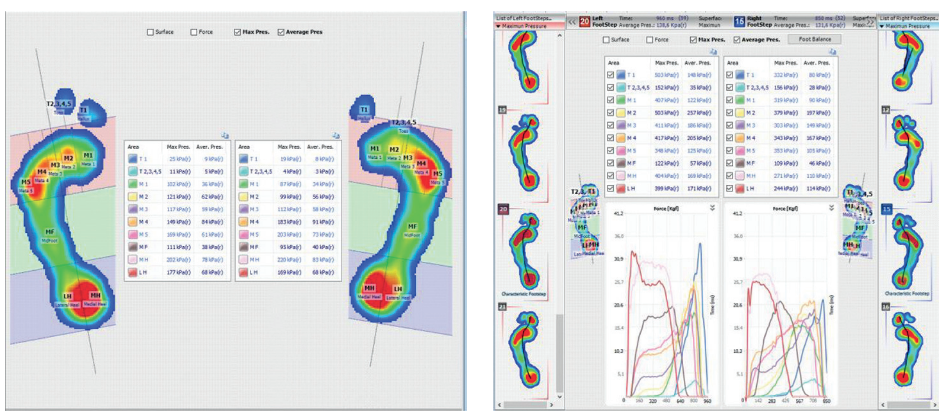
Figure 8: (a–e) Results of imaging tests (X-ray, MRI) and foot scanning: patient no. 10. (a) Dorsal-plantar X-ray: degradation lesion of the III head of the metatarsal bone and numerous transverse calcifications. (b) Diagonal X-ray of foot 45: degradation lesion of the III head of metatarsal bone and numerous calcifications. (c) Magnetic resonance imaging with contrast: degradation lesion of the III head of the metatarsal bones and medial plantar nerve neuralgia. (d) Magnetic resonance imaging with contrast: degradation lesion of the III head of the metatarsal bone and medial plantar nerve neuralgia. (e) Plantar photo from 2D Scanner: assessment of plantar part of the foot and measurement of foot length and width.



(a) (b) (c)

(d) (e) (f)

Figure 9: a–f) Results of imaging tests (X-ray) and podoscopic tests: patient no. 11. (a) Dorsal-plantar foot X-ray: fatigue fracture of the III metatarsal bone, amputation of toes I–IV in the left foot. (b) Lateral X-ray: amputation of toes I–IV, overload in the area of ankle joints, and talonavicular. (c) Lateral X-ray: overload in the area of ankle joints and talonavicular. (d) Posterior photo: ankle joint and hindfoot evaluation. (e) Anterior picture of the feet: assessment of toe positioning and deformation. (f) Plantar photo on the podoscope: assessment of plantar part of the foot and height measurement of the longitudinal arch.



(a) (b)

Figure 10: (a) The result of pedobarographic test when standing. (b) While walking, patient no. 10, increased pressure on the M1-M5 metaplanes.

Patient no. 10 presented adduction and varus deformity of the forefoot at the level of the line of Lisfranc joints. This is also illustrated by the result 10a, in the left foot:

Increased pressure on the heel in the MH area (which is confirmed by the diagnosis of valgity made in a physical examination).

Increasing pressure on the head of the 1st (M1) to the 5th (M2) metatarsal bone. This may be due to the fact that metatarsal bones, including the arch of the foot, are exposed to fatigue fractures.

The pedobarographic examination also allowed the assessment of spatial and temporal parameters during foot shunting. Figure 11 presents the results of the examination of the distribution of forces, pressure, and acceleration for patient no. 7 suffering from a fracture of the calcaneus.

The pressure distribution curve is repeatable, an increased pressure is observed on the forefoot of both feet, and this may be associated with a significant dispersion of the values of forces in individual footprints. This result may indicate instability of the structures of the upper and lower ankle.

The functionality of the longitudinal arch is assessed using pedobarography. A degree of arch arcing while standing is determined using the Biomech Studio software and the AI (Arch Index). The results presented in Figures 12(a) and 12(b) for patient no. 7 confirm instability of the foot structures, because selected traces while walking show asymmetrical and unique overpronation of the foot.

Comparative analysis of the results of foot arch examinations during standing and walking is used to assess the functionality of the feet. Six patients who are presented in this publication have overpronation of the foot, which allows a conclusion of planovalgus foot during walking to be drawn (i.e., lowering of the arch of the foot during the phase of push off and no lateral edge contact, i.e., no supination of the feet).

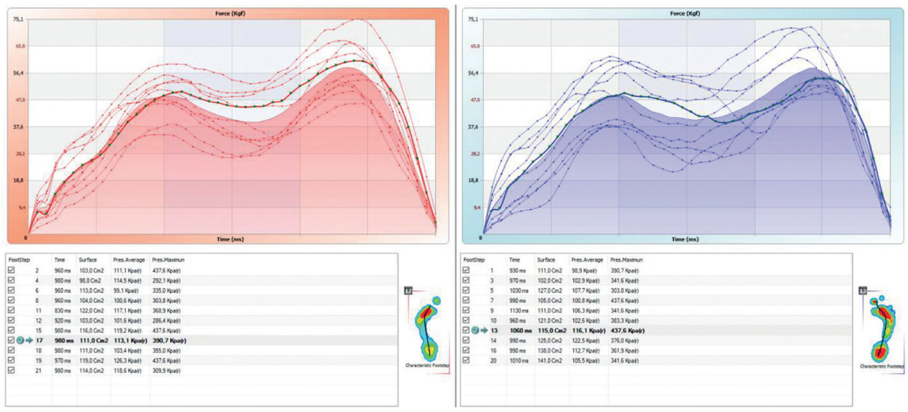
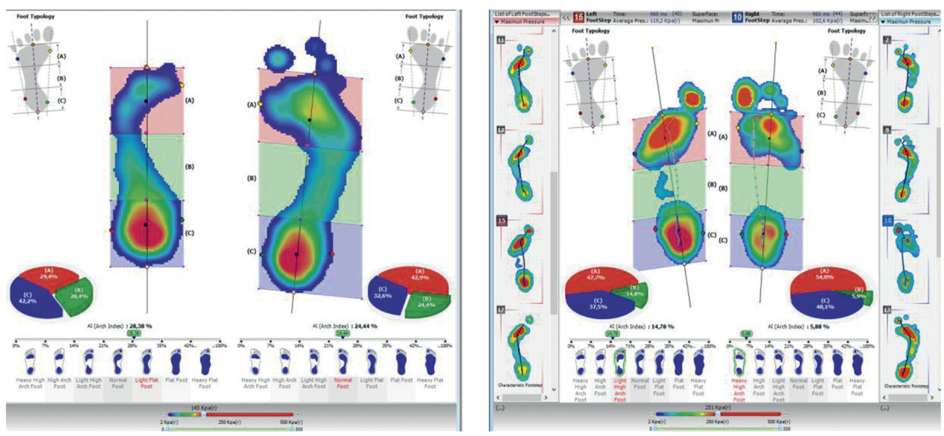


FIGURE 11: The results of the examination of the distribution of forces and time-space parameters while walking, patient no. 7.



(a) (b)

FIGURE 12: (a) The result of the foot arch examination when standing. (b) The result of foot arch examination while walking: patient no. 7.

The push off curve was also observed by pedobarography, as illustrated in Figure 13.

The ability to maintain balance, which is also assessed during a pedobarographic examination, is also important in assessing the distribution of pressure on the feet. Figure 14 shows the result of the balancing test in patient no. 7. The result indicates a significant imbalance, especially for the lateral oscillations of the COP (Figure 14).

The pedobarography has a very wide diagnostic spectrum, while both standing and walking. Therefore, it is widely used in the prevention of fractures resulting from overloads. These include, in particular, osteoporosis.

2. Discussion

In the prophylaxis of secondary fractures, which occur during the curing process, it is essential to create the appropriate conditions through two factors:

(I) Elimination of improper pressure, through depreciation and relief

(II) Targeting of its accurate distribution

These factors are strategic goals in the process of reducing clinically visible changes [37, 72]. In the course of the diagnostics and therapy, the time periods of the applied procedures should be taken into account. This emphasises the fact that after the reconstruction phase in patients with osteoporosis, the bone structure has an extended mineralisation time [12, 73].

Reduced bone density and weakened mechanisms of its reconstruction, repair of microdamage, defects in the microarchitecture of the trabeculae, and the porosity and thinning of the cortical layer require rapid prophylactic actions, starting at the level of loads arising in the course of everyday life [74–77]. However, this does not indicate the exclusion from activity, as it has been proven that immobilisation does not promote bone remodelling [78–80]. The skeletal system has an autoprogramme, targeted at the thinning of unused bone, which was observed in military workers as well as professional athletes. Thus, raising the load on the bone raises its weight. Nevertheless, it should be emphasised that improper pressure distribution may promote the local accumulation of microdamage. In the case of an incorrect tension level, the process of decreasing/increasing of bone mass may result in microdamage and, in the long term, may cause morphological changes of bones, which through a loss of elasticity may often result in noticeable fractures [51, 81–83]. This phenomenon particularly

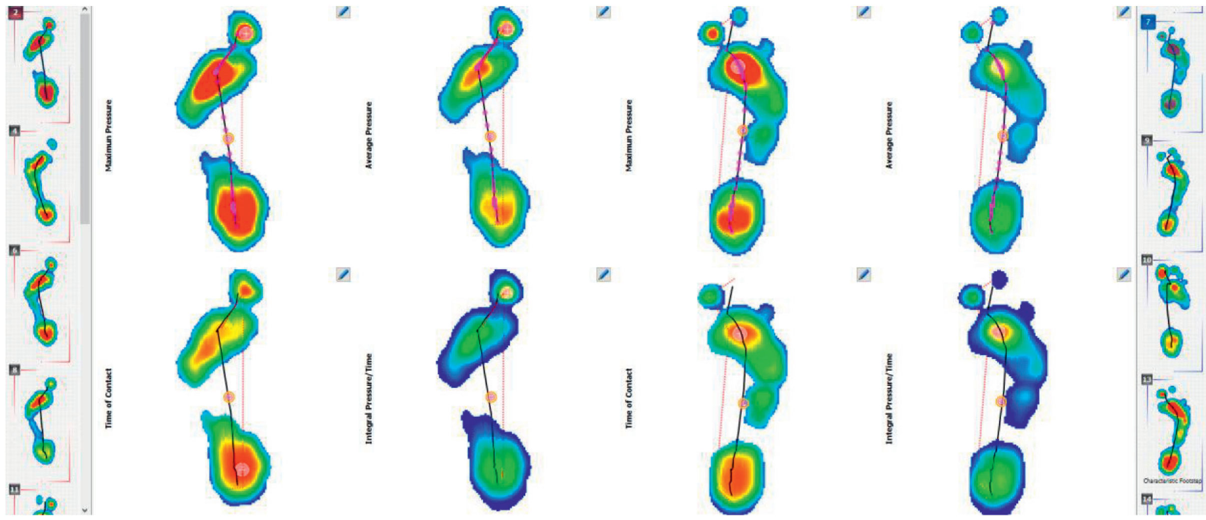


Figure 13: The assessment of the progression of the condition for patient no. 7: push off curve; the thin red line depicts overpronation propulsion of the left foot.

concerns the foot, because its function, apart from locomotion, is postural stabilisation when standing and walking. The feet accommodate to the surface changes and movements performed by a person, changing the length of soft structures and the arrangement of hard ones and then subsequently returning to their architecture at the moment of relief. Another function of the foot is to act as a shock absorber, which not only exposes it to numerous overload changes but also to microinjuries resulting from excessive impacts and stress pressure [84–86].

In the assessment of the foot's condition, and especially in the activities focused on the prevention of overload changes, the diagnosis of its dynamic parameters and support function has a significant role. Adjusting the pressure distribution, carried out in the process of microdamage prophylaxis, should, therefore, be a process of balancing between the motor activity and simultaneous elimination of excessive load, arising during everyday life activities [87–91]. In a physical activity schedule, an essential role of rest, as well as periodic breaks in training, was indicated, as part of fatigue fracture prevention [92]. Antigravitational exercises, such as swimming, will play a significant function in the time of demand for periodical relief and in individuals at risk of fracture formation [93, 94]. The return to regular activity should be strictly supervised and based on an accurate diagnostic-rehabilitation plan [69, 95].

The recommended treatment, as a component of fracture prophylaxis, mainly involves the initiation of pharmacological treatment, after prior bone density diagnosis and/or X-ray examination. Diet therapy, healthy lifestyle, and vitamin D and calcium supplementation reduces the fracture risk; nevertheless, it is suggested to estimate the intake of calcium due to controversies related to its supply and risk of cardiovascular diseases [55–57]. In the therapy of osteoporosis, bisphosphonates are the fundamental pharmacological agents. The remaining drugs are aimed at reducing the risk of nonvertebral and hip fractures, as well as treating systemic diseases that are the main cause of osteoporosis [58, 59]. International guidelines and recommendations for the pharmacological treatment of osteoporosis indicate minor differences, particularly in the age range of patients [11, 61, 96–98]. There are few reports in the research and scientific literature that would indicate an important role in the prevention of fractures and therapy through the use of individual orthopaedic insoles, specialist footwear, orthopaedic cushioning, and relieving elements. In the opinion and recommendations of the authors, it should be extended and include a significant role of relieving, amortization and correcting defects and dysfunctions of the foot, manifested during walking, running, standing, and other life activities.

The research and scientific literature indicates that, in the area of locomotor system diagnostics, as well as in the investigation of fractures in the course of osteoporosis, a highly specialised imaging diagnostic examination remains the golden means (most often, these are X-ray examinations). This is performed in the majority of cases when the patient already reports specific clinical symptoms, such as pain during normal life functions [69]. This situation is frequently the case when a fracture has already occurred. However, there is no fatigue fracture classification system that can be applied to all bones. The estimation schemes, commonly quoted by Fredericson et al. [64], Aredt at al. [65], and Nattiv et al. [66], do not include any recommendations for foot assessment. Although X-ray examinations are easy to perform and relatively inexpensive, they show a low sensitivity (15%–35%) in the initial phase of lesions, which increases about 3 months after the first symptoms appeared [67, 68].

The scientific and research literature does not indicate specific diagnostic procedures. The studies of patients with osteoporosis, reviewed in this publication, showed a chaotic and asymmetrical and highly individualized course of dysfunctions in the area of defects and diseases of the lower extremities. According to the authors, individual differences are closely related to coexisting diseases, in particular to postural defects, with a very individualized course. This is an

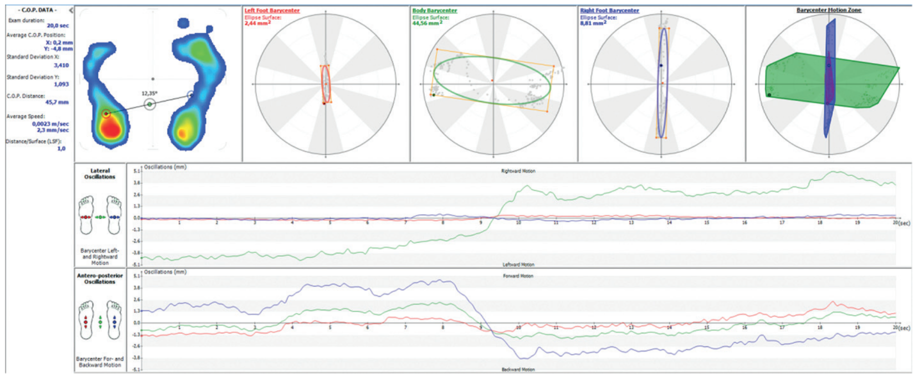


Figure 14: The result of the balance test for patient no. 7.

important postulate for further research aimed at the creation of diagnostic procedures, which are procedures applicable in the prevention of fractures in the course of osteoporosis. The imaging diagnostics recommended so far, due to its intended use, obviously do not constitute preventive procedures for the early detection of fatigue fracture threats. According to the authors, early detection of defects, distortions, gait disturbances, and mobility of structures (including in particular structural instability) will be an important aspect of preventing osteoporotic (and other fractures arising in the course of low bone density) fractures.

In the course of prophylaxis, screening is recommended, including women aged over 65 and men aged over 75, among patients at risk. Recommendations are population studies of older people; younger ones should be routinely assessed [60] and all women after menopause [61, 62]. Within the field of foot diagnostics, the interdisciplinary role of the medical team is crucial [99]. According to the authors, considering only the elderly in the screening diagnosis, and thus examining younger people only in the case of emerging clinical symptoms, significantly reduces the effectiveness of preventive measures.

Preventive actions in the area of fractures in the course of osteoporosis should be focused on precise feet screening diagnostics and, also, due to the fact of a close relationship between the action of forces during everyday life activities and the formation of microfractures, breakages, and a lack of adhesions, in patients with reduced bone density (BMD) [100, 101]. It is estimated also that the occurrence of osteoporotic fractures in the foot is rising, mainly due to the fact of the ageing of the population and the increase within the number of people exercising above 50 years [63]. Another important element determining microdamage and bone fractures is the body mass index (BMI), which applies to each age group, that is, both elderly and adolescents [102–104].

According to the researchers, the diagnosis of pressure distribution through pedobarography is crucial for the prevention of tissue destruction within the foot. The assessment of defects and functions of the feet, especially during locomotion, serves for the precise detection of the causes of faulty distribution of the tensions. The essence is to differentiate the pressure that occurs while standing and walking, mainly due to the compensatory processes that maintain balance [105–107]. Pedobarography also allows for the assessment of the average time-space parameters and pressure forces especially during walking. This is a very important diagnostic aspect; it was assumed that considering that the heel stroke accounts for 110% of body weight and increases to 250% of body weight during running, the pressure distribution on the forefoot increases by about 40%–50% [108, 109]. The prevention of fatigue fractures should include monitoring pressure forces over time and measuring the values of acceleration of the foot during the phase of push off. Disturbances in the distribution and directions of forces are an absolute determinant of overload fractures. Drawing conclusions on pressure distribution disorders is of key importance, in particular in the assessment of the average obtained for a large number of samples, acquired in one patient. As a result of the pedobarographic examination, the result is obtained regarding the foot arch, pronation and supination functions, so it is also possible to infer about the foot structure and function during walking. All these aspects constitute important conclusions regarding the stability of structures, locally and globally (i.e., the balance of the body when standing). Instability of the foot structures not only can cause imbalance during walking, which promotes injury during a fall, but also can be manifested as imbalance when standing. The prevention of fractures should include the prevention of falls, in particular in patients with bone density deficits [11, 61]. In addition, patients at increased risk of falling should be given high doses of vitamin D [57]. The development of osteoporosis is promoted by an overload of the musculoskeletal system, body weight transfer during locomotion (movement), and losing and regaining balance. The lower limbs are particularly overloaded in the exemplary patient [110].

The balance test is an important aspect of functional diagnostics of the musculoskeletal system; combined in one device (i.e., a pedobarograph), it significantly reduces the cost of biomechanical diagnostics [111–118]. Also, when bone structures are injured, both crushing and microfractures are noticed; current observations through noninvasive diagnostic methods and the implementation of relieving measures are of great importance in the prevention of complications, including the avoidance of secondary fractures.

It seems evident that deformities in the feet and lower limbs, and generally defects in posture, will encourage the formation of defective pressure distribution and a point increase in its value. At the same time, whereas the structural instability induced by osteoporosis will favour the occurrence of defects, structural inefficiencies, and balance disorders, we may speak of a kind of "vicious circle" of events. Therefore, according to the authors, the screening of patients with osteoporosis will also be crucial within the following:

Initial assessment of foot defects, for example, valgus/varus deformity of the tarsus, height of the vault, and deformations of the toes (mallet toes, claw toes, hallux valgus, and varus toes)

Reliable estimation of pressure distribution under static conditions

Evaluation of foot progression during walking, running, and other types of locomotion

Disturbances of the gait determination in terms of defective pressure distribution, including particularly the relationship of increased tension during prolonged contact of the foot with the ground

The importance of patient education in the field of foot observation and fast intervention in case of local pain, redness, and local body temperature increase [119–121]

Screening tests of feet should consist of the assessment of skin condition for hyperkeratosis, since the first symptoms of increased pressure within the feet are calluses and blisters, formed in the soles of the feet [122, 123]. The analysis of pressure distribution is not only important in prevention and screening, but also an important aspect in planning relief procedures and individual orthopaedic supply [124]. Measurable and precise diagnostic methods of pressure (in point and global terms) and the assessment of time and contact surface of the plantar part of the feet with the ground should be used to design individual orthopaedic insoles and footwear [125, 126]. It has been proven that orthopaedic insoles with individually designed elements of the foot arch (i.e., longitudinal and transverse arch) significantly improved body balance in older women with osteoporosis and were an important aspect of preventing falls, sprains, and so on [127].

The lack of ability to relieve the feet and no autocorrection during gait (supination/pronation) is one of the most important problems of patients with diabetes and its complications, for example, Charcot neuroosteoarthropathy [128]. This is an important aspect due to the fact that osteoporosis quite often statistically coexists with diabetes. It is necessary to implement targeted rehabilitation measures and appropriate relief, corrective and shock-absorbing supply in particular in the prevention of microfractures, ligament damage, and muscle atrophy in the course of sensory neuropathy [129]. The supply should take into account, first of all, important parameters showing foot dysfunction, gait disturbances, defects, and deformations [130–132]. Patient education and support in the selection of footwear with an individual orthopaedic insole are also necessary in the holistic prevention of fractures in osteoporosis. For the exemplary patient, footwear should be tailored to the needs of patients. This is particularly important in the prevention of fractures in patients with severe foot deformities in osteoporosis. These are also important postulates for further research and scientific works planned by the authors.

3. Conclusions

(1) The analysis of the literature showed that, apart from the diagnosis of bone density and the assessment of vitamin D levels, calcium levels, and so on, highly specialised imaging tests (mainly X-ray), used in the event of clinical symptoms, are the recommended diagnostic procedures in the area of the musculoskeletal system.

(2) Patients with osteoporosis show numerous individual deformities (defects), dysfunctions, and structural changes in the feet, which results in various disorders of pressure distribution. Extending diagnostics by periodic and screening tests, focused on assessing foot defects, balance disorders, and monitoring time-space parameters during gait will be an important aspect in the prevention of fractures in the course of osteoporosis.

(3) Pedobarography has a wide range of uses in periodic screening and ongoing foot diagnostics when the first symptoms of overload (e.g., corns, calluses, pain, and redness) have appeared.

(4) Instability and locally increased pressure are observed especially during locomotion; therefore, it is an important aspect to conduct a detailed analysis of patients while walking.

(5) In addition to supplementation and pharmacotherapy, the prevention of osteoporotic fractures should include the use of orthopaedic insoles, taking into account the patient-tailored design of elements to relieve and absorb shocks and correct deformations and defects.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this article.

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Review Article

Fascia Iliaca Compartment Block for Perioperative Pain Management of Geriatric Patients with Hip Fractures: A Systematic Review of Randomized Controlled Trials

Hao-yang Wan,[1] Su-yi Li,[2] Wei Ji,[3] Bin Yu ,[1] and Nan Jiang [1]

[1]*Division of Orthopaedics & Traumatology, Department of Orthopaedics, Nanfang Hospital, Southern Medical University, Guangzhou 510515, China*
[2]*Department of Medical Quality Management, Nanfang Hospital, Southern Medical University, Guangzhou 510515, China*
[3]*Division of Spine Surgery, Department of Orthopaedics, Nanfang Hospital, Southern Medical University, Guangzhou 510515, China*

Correspondence should be addressed to Bin Yu; smuyubin@163.com and Nan Jiang; hnxyjn@smu.edu.cn

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Background. With continuous increase of the aging population, the number of geriatric patients with fragility hip fractures is rising sharply, and timely surgery remains the mainstay of treatment. However, adequate and effective pain control is the precondition of satisfactory efficacy. This systematic review aimed to summarize the use of fascia iliaca compartment block (FICB) as an analgesic strategy for perioperative pain management in geriatric patients with hip fractures. *Methods*. PubMed and Embase databases were searched for English published randomized controlled trials (RCTs) reporting application of FICB for pain control of the older adults with hip fractures between January 1st, 2000, and May 31st, 2020. The modified Jadad scale was used to evaluate quality of the RCTs included. Primary outcomes of the eligible RCTs were presented and discussed. *Results*. A total of 27 RCTs with 2478 cases were included finally. The present outcomes suggested, after admission or in the emergency department (ED), FICB can provide patients with equal or even better pain relief compared with the conventional analgesia methods, which can also reduce additional analgesic consumptions. While, before positioning for spinal anesthesia (SA), FICB is able to offer superior pain control, facilitating SA performance, after surgery FICB can effectively alleviate pain with decreased use of additional analgesics, promoting earlier mobilization and preventing complications. *Conclusions*. FICB is a safe, reliable, and easy-to-conduct technique, which is able to provide adequate pain relief during perioperative management of geriatric patients with hip fractures.

1. Introduction

Hip fracture, an important and debilitating condition in the older adults, represents a worldwide challenge [1]. With the progressive aging population, hip fracture has become a significant public health issue worldwide. It is estimated the absolute number of hip fractures is expected to increase from 1.6 million in 2000 to 6.3 million by the year 2050 [2]. Besides, hip fracture ranks among the top 10 of disability [3]. Furthermore, the increasing number of patients with hip fractures and the great risk of limb disability aggravate the economic burdens, both personally and socially. The estimated annual cost of hip fracture treatment in the US had increased from approximate 10.3 to 15.2 billion dollars in 1990 [4] to 17 billion in 2002 [5]. Nowadays, hip fracture has become a widely concerning social problem.

Geriatric patients with hip fractures without adequate pain control are reluctant to mobilize, thus increasing the potential risk of complications and slows the recovery [6]. It is known that cognitive impairment has been widely reported in geriatric patients with hip fractures, which is partly attributed to the untreated or not-well-controlled pain. A previous study indicated that cognitively intact patients with hip fractures with untreated pain were nine times more likely to develop delirium than those with effective pain control [7]. Thus, adequate analgesia is of great significance.

In addition, patients with hip fractures are at high risks of many complications, and even some are fatal, such as pneumonia [8], pressure ulcer [9], urinary tract infection [10], and deep venous thrombosis [11]. Hence, timely surgery remains the mainstay of treatment [12]. In order to achieve satisfying clinical efficacy and lower the risk of adverse events, appropriate analgesic methods play a vital role.

Current strategies for pain management include oral and parenteral systemic analgesia, such as paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, epidural and spinal anesthesia (SA), and peripheral nerve blocks [13]. Although opioids have been widely applied, they can provide effectively static pain relief, but they may be inadequate for dynamic pain [14]. Besides, opioids may bring side effects, especially for the older adults, such as delirium, drowsiness, constipation, nausea, and even respiratory depression, which may affect prognosis of the patients [15–17]. In order to lower the risk of adverse events and also guarantee the treatment efficacy, different analgesia strategies have been investigated and compared.

Considering the particularity of this cohort, recently, peripheral nerve blockade or regional anesthesia has become an increasingly attractive option in delivering effective pain relief, with fascia iliaca compartment block (FICB) as a representative. FICB or fascia iliaca block (FIB), first proposed by Dalens et al. in 1989, is a means of blocking the three principal lumbar plexus nerves of the thigh with a single injection of local anesthetic delivered immediately dorsal to the fascia iliaca [18, 19]. Indications of FICB are surgical anesthesia to the lower extremity, management of cancer pain and pain owing to inflammatory conditions of the lumbar plexus, and amelioration of acute pain following trauma, fracture, and burn [20], while contraindications of FICB are few, including patients with coagulopathy, those who are taking antithrombotic medications, infection at the injection site, or history of femoral bypass surgery [21, 22]. Besides, allergies to the anesthetic agents and crush injury at or near the injection site are set as absolute contraindications [21, 22].

Recently, as the number of studies investigating the use of FICB as a new analgesia strategy in the treatment of geriatric patients with hip fractures is rising, it is necessary to summarize current experience of this technique. Here, we conducted a systematic review aiming to review the present knowledge regarding the use of FICB for pain management during perioperative treatment of geriatric patients with hip fractures.

2. Methods

Literature search was performed by two independent authors in the PubMed and Embase databases to identify English published randomized controlled trials (RCTs) regarding the use of FICB as a pain relief strategy in perioperative management of geriatric patients with hip fractures between January 1st, 2000, and May 31st, 2020. The following search strategy was used: "(hip fracture OR femur fracture) AND (Fascia iliaca block OR Fascia iliaca nerve block OR Fascia iliaca compartment block OR Fascia iliaca compartment nerve block OR Fascia iliac block OR Fascia iliac nerve block OR Fascia iliac compartment block OR Fascia iliac compartment nerve block OR FICB OR FIC OR FIB)."

Only RCTs evaluating the application of FICB for perioperative pain management in geriatric patients with hip fractures were considered. Exclusion criteria were FICB applied in nonhip fracture or nongeriatric patients. In addition, studies that did not provide adequate information for quality assessment or data analysis were also excluded.

Two authors independently screened the titles, abstracts, and even full texts to make sure that the retrieved RCTs should strictly meet the inclusion criteria. Two authors independently evaluated the quality of the RCTs included using the modified Jadad scale [23], an eight-item scale designed to assess randomization, blinding, withdrawals and dropouts, inclusion and exclusion criteria, adverse effects, and statistical analysis (Table 1). The score for each study could range from 0 (lowest quality) to 8 (highest quality). Scores of 4 to 8 denote good to excellent quality and 0 to 3 poor to low quality. Disagreement was resolved by discussion, and if necessary, a third author's opinion was consulted for final decision.

3. Results

Altogether, 440 publications were identified initially. After limiting study type to RCTs, removing the duplicates, screening the titles, and evaluating the abstracts and/or full texts, we finally included 27 RCTs studies [24–50] with 2478 cases. The eligibility selection process is shown in Figure 1.

According to the modified Jadad scale, 26 RCTs were rated as good (Table 2). However, only two studies [33, 44] gave a clear description on the method used to assess adverse effects. In addition, 9 studies [25, 30, 40–44, 46, 49] were not designed as blinded. Although another 5 studies [24, 29, 36, 39, 50] were designed as blinded, they did not describe the blinding method in detail.

The RCTs included were mainly divided into three groups according to the stage of FICB use and the primary outcomes reported, including preoperative use (12 RCTs), application before surgical anesthesia (4 RCTs), and postoperative use (8 RCTs). Table 3 provides general information, comparison details, FICB strategy, primary outcome parameters, and conclusions of the RCTs included. The visual analog scale (VAS) pain score, additional analgesia use, and adverse effects were the most frequently reported outcome measures.

4. Discussion

4.1. FICB for Pain Management before Surgery. During the acute phase following hip fractures, it is essential and important to provide geriatric patients with adequate pain relief, which assists them in moving about in bed, using a bedpan, and receiving preoperative preparations [24]. The frequently used methods for pain relief include NSAIDs and opioids, while NSAIDs increase potential risk of bleeding and can exacerbate underlying gastrointestinal problems in

Table 1: The modified Jadad scale with eight items.

Item assessed	Response	Score
Was the study described as randomized?	Yes	+1
	No	0
Was the method of randomization appropriate?	Yes	+1
	No	−1
	Not described	0
Was the study described as blinded?*	Yes	+1
	No	0
Was the method of blinding appropriate?	Yes	+1
	No	−1
	Not described	0
Was there a description of withdrawals and dropouts?	Yes	+1
	No	0
Was there a clear description of the inclusion/exclusion criteria?	Yes	+1
	No	0
Was the method used to assess adverse effects described?	Yes	+1
	No	0
Was the method of statistical analysis described?	Yes	+1
	No	0

*Double-blind obtains 1 score; single-blind obtains 0.5 score.

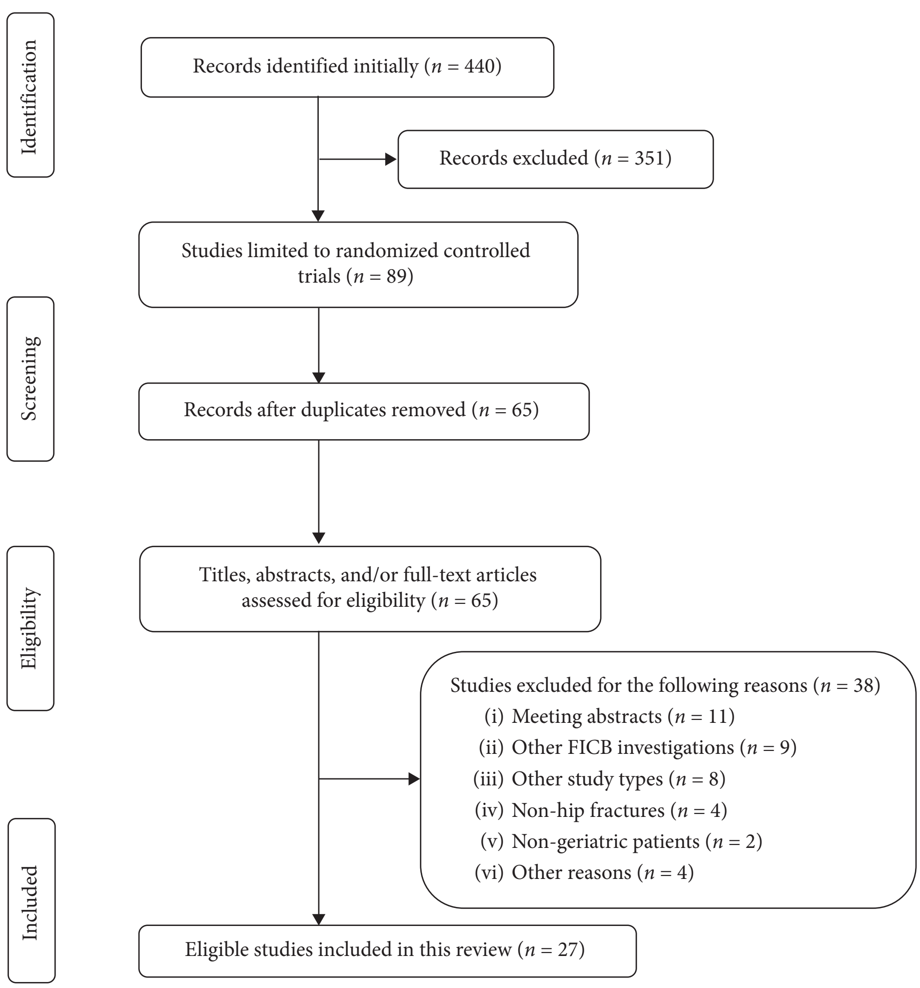

Figure 1: Preferred reporting items for systematic reviews and meta-analyses flow diagram.

Table 2: Methodological assessment of the RCTs included.

Study	Random description	Random method	Blinding description	Blinding method	Withdrawals/ dropouts description	Inclusion/ exclusion criteria	Adverse effects assessment	Statistical methods description	Total score
Foss et al. 2007 [24]	Yes	Yes	Yes	ND	Yes	Yes	No	Yes	6
McRae et al.2015 [25]	Yes	Yes	No	ND	Yes	Yes	No	Yes	5
Wennberg et al. 2019 [26]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	7
Pasquier et al. 2019 [27]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	7
Godoy Monzón et al. 2010 [28]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	7
Ma et al. 2018 [29]	Yes	Yes	Yes	ND	Yes	Yes	No	Yes	5.5
Newman et al. 2013 [30]	Yes	Yes	No	ND	Yes	Yes	No	Yes	5
Zhou et al. 2019 [31]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	6
Cooper et al. 2019 [32]	Yes	Yes	Yes	Yes	Yes	Yes	No	No	6
Reavley et al. 2015 [33]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	7.5
Aprato et al. 2018 [34]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	6.5
Wennberg et al. 2019 [35]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	7
Yun et al. 2009 [36]	Yes	Yes	Yes	ND	No	Yes	No	Yes	4.5
Diakomi et al. 2014 [37]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	6.5
Madabushi et al. 2016 [38]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	5.5
Kacha et al. 2018 [39]	Yes	Yes	Yes	ND	No	Yes	No	Yes	5
Temelkovska-Stevanovska et al. 2014 [40]	Yes	ND	No	ND	No	Yes	No	Yes	3
Deniz et al. 2014 [41]	Yes	ND	No	ND	Yes	Yes	No	Yes	4
Bang et al. 2016 [42]	Yes	Yes	No	ND	Yes	Yes	No	Yes	5
Mostafa et al. 2018 [43]	Yes	Yes	No	ND	Yes	Yes	No	Yes	5
Yamamoto et al. 2019 [44]	Yes	Yes	No	ND	Yes	Yes	Yes	Yes	6
Thompson et al. 2020 [45]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	6.5
Schulte et al. 2020 [46]	Yes	Yes	No	ND	Yes	Yes	No	Yes	5
Diakomi et al. 2020 [47]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	7
Mouzopoulos et al. 2009 [48]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	6.5
Nie et al. 2015 [49]	Yes	Yes	No	ND	Yes	Yes	No	Yes	5
Hao et al. 2019 [50]	Yes	Yes	Yes	ND	Yes	Yes	No	Yes	5.5

ND: not described.

Table 3: RCTs evaluating FICB in pain management in geriatric patients with hip fracture.

Study	Country	Comparison and no. of the included patients	FICB strategy	Outcome parameters	Primary conclusions
Preoperative use					
Foss et al. 2007 [24]	Denmark	FICB = 24 vs IM morphine = 24	40 mL 1.0% mepivacaine	VRS (rest/movement), total morphine consumption	FICB provided better pain relief at all times and at all measurements compared to IM morphine
McRae et al.2015 [25]	Australia	FICB = 11 vs standard care (IV morphine) = 13	15–20 mL 2% lidocaine, weight-dependent	NRS, adverse events	FICB group had a greater reduction in pain than those who received standard care
Wennberg et al. 2019 [26]	Sweden	FICB = 66 vs placebo (saline) = 61 (adjunctive therapy)	30 mL 0.2% ropivacaine	VAS	Low-dose FICB improved pain management as a pain-relieving adjuvant to other analgesics
Pasquier et al. 2019 [27]	Switzerland	FICB = 15 vs placebo (saline) = 15 (adjunctive therapy)	30 mL 0.5% bupivacaine	NRS (rest/movement), total morphine consumption	Anatomic landmark-based FICB did not help reduce pain after prehospital morphine
Godoy Monzón et al. 2010 [28]	Argentina	FICB = 62 vs IV NSAIDs (Diclofenac or Ketorolac) = 92	0.3 mL/kg 0.25% bupivacaine	VAS	FICB can provide equally effective analgesia as NSAIDs for up to 8 h
Ma et al. 2018 [29]	China	CFICB = 44 vs oral drugs (tramadol and paracetamol) = 44	50 mL 0.4% ropivacaine, 5 mL/h 0.2% ropivacaine continuously	VAS (rest/movement), patients' satisfaction, side effects, length of hospital stay	Patients treated with CFICB received better analgesia both at rest and at movement compared to traditional analgesia
Newman et al. 2013 [30]	UK	FICB = 56 vs FNB = 51	20–30 mL 0.5% levobupivacaine, weight-dependent	VAS, opioid consumption	Patients treated with FNB had better pain control and less morphine requirement
Zhou et al. 2019 [31]	China	FICB = 77 vs FONB = 77	35 mL 0.4% ropivacaine	VAS (rest/exercise), requirement for analgesic drugs, postoperative complications	Both FONB and FICB were effective in acute pain control. FONB performed better in reducing pain and function recovery
Cooper et al. 2019 [32]	Australia	FICB = 52 vs FNB = 48	20 mL 0.5% levobupivacaine	NRS	FICB can provide equivalent analgesia effect as FNB for femur fracture patients
Reavley et al. 2015 [33]	UK	FICB = 88 vs "3-in-1"block = 90	2 mg/kg 0.5% bupivacaine	VAS	FICB was as effective as "3-in-1" block for immediate pain relief
Aprato et al. 2018 [34]	Italy	FICB = 70 vs IAHI = 50	40 mL 0.25% ropivacaine	NRS (rest/movement), additional analgesic drug, adverse events	IAHI provided better pain management and reduced systemic analgesia consumption compared with FICB
Wennberg et al. 2019 [35]	Sweden	FICB = 65 vs control = 60	30 mL 2 mg/mL ropivacaine	Changes of cognitive status	FICB did not affect cognitive status in this study
Application before surgical anesthesia					
Yun et al. 2009 [36]	Korea	FICB = 20 vs IV alfentanil = 20	30 mL 0.375% ropivacaine	Time to achieve SA, VAS, quality of patient positioning, patient acceptance	FICB was more efficacious than IV alfentanil with better pain control during positioning and shorter time to achieve SA as well

Table 3: Continued.

Study	Country	Comparison and no. of the included patients	FICB strategy	Outcome parameters	Primary conclusions
Diakomi et al. 2014 [37]	Greece	FICB = 21 vs IV fentanyl = 20	40 mL 0.5% ropivacaine	Time needed and quality of position, NRS, postoperative analgesia, morphine consumption, patient satisfaction	Patients who received FICB showed significantly lower pain score, shorter spinal performance time, and better quality of position
Madabushi et al. 2016 [38]	India	FICB = 30 vs IV fentanyl = 30	30 mL 0.375% ropivacaine	VAS, sitting angle, positioning quality, time to perform SA, postoperative analgesic requirement	Patients who received FICB needed less time for SA and had better quality of positioning accompanied by superior analgesia
Kacha et al. 2018 [39]	India	FICB = 50 vs placebo (normal saline) = 50	30 mL 0.25% ropivacaine	VAS, time of positioning SA, total duration of analgesia	FICB effectively provided analgesia during positioning for SA and significantly extended the total duration of analgesia
Postoperative use					
Temelkovska-Stevanovska et al. 2014 [40]	Macedonia	FICB = 30 vs FNB = 30	40 mL 0.25% bupivacaine	VDS (rest/movement), additional analgesia, and duration for the first time, side effects	FNB provided superior postoperative pain relief versus FICB, and lower amount of supplemental analgesia
Deniz et al. 2014 [41]	Turkey	FICB = 20 vs "3-in-1" block = 20 vs control = 20	30 mL 0.25% bupivacaine	VAS, opioid consumption, adverse effects, and cortisol and ACTH levels	Both FICB and "3-in-1" block can bring superior analgesia and reduction in opioid consumption. The two blocks also showed a suppression of stress hormones
Bang et al. 2016 [42]	Korea	FICB = 11 vs. Non-FICB = 11	40 mL 0.2% ropivacaine	Postoperative VAS scores, opioid consumption, and adverse events	The FICB had a significant opioid-sparing effect in the first 24 hours after hemiarthroplasty
Mostafa et al. 2018 [43]	Egypt	FICA = 30 vs. IV fentanyl = 30	35 mL 0.125% levobupivacaine + PC-FICA*	Postoperative VAS scores, additional analgesia requirement, and total additional analgesia assumption	PC-FICA provided a better quality of analgesia and decreased postoperative rescue analgesic requirement without increased side effects compared to PCA IV fentanyl
Yamamoto et al. 2019 [44]	Japan	FICB = 25 vs IV acetaminophen = 28	40 mL 0.25% levobupivacaine	VAS (rest/movement), total number of rescue analgesics required, incidence of delirium	Patients treated with FICB received better pain control compared to IV NSAIDs without increasing the complication rate
Thompson et al. 2020 [45]	America	FICB = 23 vs control = 24	30 mL 0.25% ropivacaine	Pain medication consumption, functional recovery, patient satisfaction	FICB significantly decreased postoperative consumption of morphine for breakthrough pain while increasing patient satisfaction

Table 3: Continued.

Study	Country	Comparison and no. of the included patients	FICB strategy	Outcome parameters	Primary conclusions
Schulte et al. 2020 [46]	USA	FICB = 57 vs control = 40	45 to 60 mL 0.375% ropivacaine	VAS, MME, postoperative ambulatory distance	A single perioperative FIB for patients with hip fractures undergoing surgery may decrease opioid consumption and increase the likelihood that a patient is discharged home
Diakomi et al. 2020 [47]	Greece	FICB = 91 vs sham FICB = 91	40 mL 0.5% ropivacaine	Incidence, intensity, and severity of CPSP at 3 and 6 months after hip fracture surgery	FICB in the perioperative setting may reduce the incidence, intensity, and severity of CPSP at 3 and 6 months after hip fracture surgery, providing safe and effective postoperative analgesia
Other benefits of FICB					
Mouzopoulos et al. 2009 [48]	Greece	FICB = 102 vs placebo (water for injection) = 105	0.25 mg dose of 0.3 mL/kg bupivacaine	Perioperative delirium, mean duration of delirium	Severity and incidence of delirium were significantly lower in intermediate-risk patients treated with FICB, along with shorter mean duration of delirium
Nie et al. 2015 [49]	China	CFICB = 51 vs PCIA (IV fentanyl) = 53	20–30 mL 0.5% ropivacaine, 0.1 mL/kg/h 0.25% ropivacaine continuously	Postoperative pain and complications (delirium, nausea and vomiting, and pruritus)	FICB showed a stronger effect on reducing postoperative nausea and vomiting, and pruritus, but with a higher incidence of developing delirium
Hao et al. 2019 [50]	China	CFICB = 44 vs placebo (normal saline) = 46	30 mL 0.45% ropivacaine, 6 mL/h 0.25% ropivacaine continuously	Postoperative delirium, change in preoperative and postoperative pain scores, opioid consumption	The incidence of post-op delirium was lower for patients who received CFICB

RCTs: randomized controlled trials; FICB: fascia iliaca compartment block; VRS: verbal rating scale; IM: intramuscular; IV: intravenous; NRS: numerical rating scale; VAS: visual analogue scale; NSAIDs: non-steroidal anti-inflammatory drugs; CFICB: continuous fascia iliaca compartment block; FNB: femoral nerve block; FONB: femoral obturator nerve block; IAHI: intra-articular hip injection; SA: spinal anesthesia; VDS: verbal descriptive scale; ACTH: adrenocorticotropic hormone; PCIA: patient-controlled intravenous analgesia; FICA: fascia iliaca compartment analgesia; PC-FICA:: patient-controlled fascia iliaca compartment analgesia; MME: morphine milligram equivalents; CPSP: chronic postsurgical pain. *Protocol: a continuous basal infusion of 4 mL/h levobupivacaine 0.125% and demand boluses of 2 ml with a lockout interval of 15 min.

geriatric patients. Improper opioids use may also cause a high risk of adverse events, such as hypotension, sedation, and even respiratory depression [51]. How to balance between adequate pain control and minimum risk of adverse events remains a great challenge. Recent RCTs reported the efficacy of using FICB technique for preoperative pain management in geriatric patients with hip fractures (Table 3).

Outcomes of several RCTs indicated that the analgesic effect of FICB is better than that of the opioids. A 2007 RCT [24] compared the efficacy of FICB with intramuscular injection of 0.1 mg/kg morphine in patients suspected of hip fracture before radiograph test in the emergency department (ED). Outcomes showed patients who received FICB achieved maximum pain relief both at rest and on movement, with a significantly less morphine consumption, and a decreased proportion of patients who required sedation. In a subsequent 2015 RCT, McRae et al. [25] compared FICB with intravenous morphine and also obtained better efficacy after FICB disposition, without immediate adverse events. These outcomes demonstrate that FICB may provide better pain control in hip fracture than morphine, administered either intramuscularly or intravenously. However, the sample sizes of the two studies are limited. In addition to the comparisons between FICB and morphine, two RCTs also investigated potential efficacy of FICB as an adjuvant therapy to routine preoperative analgesics (e.g., morphine and paracetamol); however, their conclusions differed [26, 27]. Wennberg et al. [26] concluded that low-dose FICB was an effective pain-relieving adjuvant to other analgesics, while Pasquier et al. [27] failed to find any significant effect of FICB as an adjuvant therapy. Their different conclusions may be associated with several possible factors. First, FICB strategies including anesthesia types and concentrations differed between the two studies. Second, outcome measures and detection time points were also different. Third, different sample sizes may also influence the outcomes, especially for the study by Pasquier et al. [27], which only included 15 participants for each group. It also should be noted that in the study by Wennberg et al. [26], aside from morphine, paracetamol was also applied; the single use of paracetamol in controlled group may be another source for explanation of different conclusions between the two studies.

NSAIDs are first-line analgesics as an alternative to opioids, and recent studies also compared the analgesic effect of FICB with NSAIDs. A 2010 RCT [28] showed that the mean VAS score of patients at 15 min following NSAIDs injection was significantly lower than those by FICB. However, the scores of patients who received FICB at 2 h and 8 h were lower than those who received NSAIDs, despite no statistical differences. They concluded that FICB is nearly as effective for up to about 8 h after administration and can effectively control post-hip fracture pain, with a rapid onset. Later in 2018, Ma et al. [29] evaluated the use of FICB in the very older adults (over 80 years) with hip fractures, with a traditional method (50 mg tramadol plus 500 mg paracetamol, orally, three times a day) set as controls. Outcomes revealed that the VAS pain scores under different phases in patients who had received FICB were significantly lower than those of the controls, including scores at rest and in the morning of the day of surgery, as well as passive movement scores at 1 h after analgesia at the time of admission and in the morning of the day of surgery. Aside from RCTs, a non-RCT also indicated the definite efficacy of FICB as an effective pain relief strategy for patients with proximal femur fractures, as compared with NSAIDs [52].

In addition to the comparisons of FICB with opioids and NSAIDs, previous RCTs also compared efficacy of FICB with other different analgesic methods achieved by local injections, including femoral nerve block (FNB), “3-in-1” block, and even intra-articular hip injection (IAHI). In an RCT published in 2013, Newman et al. [30] performed comparisons between FICB and FNB guided by nerve stimulator in patients with femoral neck fractures. Outcomes revealed that patients who underwent FNB had better analgesic effect than those who received FICB, with less morphine consumption following FNB. Similarly, although outcomes of a 2019 RCT revealed that both FICB and FNB were effective in pain control, patients managed by FNB showed better analgesic efficacy, with lower incidences of nausea and vertigo [31]. However, another 2019 RCT did not find significant difference regarding the reduction in pain scores between FICB and FNB, suggesting their similar efficacy [32]. Several factors may account for the differed outcomes, such as drug dose and concentration, experience of the physicians, and detection points as well. As for the “3-in-1” block, it was first described by Winnie et al. in 1973 [53] and shares similarities with FICB, as both are single-injection anterior thigh approach techniques aiming at blocking the femoral, obturator, and lateral femoral cutaneous nerves [33]. Outcomes of a 2015 RCT revealed similar efficacy between the two techniques in relieving the immediate pain following femur fractures [33]. Apart from FNB and “3-in-1” block, even a study evaluated the efficacy of FICB versus IAHI. In this RCT, Aprato et al. [34] found better efficacy following IAHI treatment, with less supplement of systemic analgesia. However, considering many possible confounding factors, such as the limited number of such reports and safety and handleability of this technique, more future studies are necessary.

It is known that impaired cognition is one of the major risk factors for perioperative delirium in geriatric patients with hip fractures. A recent double-blind RCT [35] investigated the effects of preoperative FICB use on cognition. However, they failed to find a positive association between preoperative pain relief by FICB and the cognition status of the included patients. Considering a low-dose FICB administered as a supplement to regular analgesia in this study, this discrimination requires to be addressed in future studies.

As mentioned previously, feasibility of technique conducting is also of great importance, especially in the ED. In fact, conducting of FICB does not require complicated equipment or assistance and even can be performed by junior doctors [16] and trained paramedics [25], which greatly improves the efficiency in the ED and pre-hospital settings. Høgh et al. [54] analyzed the efficacy of FICB technique performed by junior registrars (JR) in preoperative pain management for patients with hip fractures. Outcomes demonstrated that FICB performed by JR is feasible, which requires minimal introduction and no expensive equipment and is connected with a minimal risk approach. Similarly, a recent study also conveyed that conducting FICB by junior doctors and specialist nurses in the ED is feasible and safe and improves the proportion of patients receiving blocks [55].

In general, most RCTs found that FICB displays better analgesic effect than opioids and NSAIDs. However, controversy exists with regard to the comparisons of FICB with other nerve block techniques. Despite this issue, FICB has been confirmed to be a feasible, safe technique, with most patients achieving satisfactory efficacy in pain relief prior to surgery.

4.2. FICB as an Adjuvant to Surgical Anesthesia. It is known that, for geriatric patients with hip fractures, spinal anesthesia (SA) is a widely accepted anesthetic strategy, which reveals a lower mortality and lower risks of adverse events compared with general anesthesia [56]. However, positioning for SA is a great challenge for both patients and anesthesiologists as movement is extremely painful, resulting in major patient distress. In addition, inadequate pain relief may cause physiological sequelae, such as tachycardia, hypertension, and increased cardiac work that may compromise high-risk cardiac patients [37]. Therefore, it is important to conduct effective management of pain, not only for patient comfort, but also for easier performance of the central nervous blockades. Recent RCTs investigated the efficacy of FICB as an adjuvant to surgical anesthesia (Table 3).

In a 2009 RCT, Yun et al. [36] compared the efficacy of FICB with a continuous infusion of alfentanil prior to SA for geriatric patients with femoral neck fracture. Outcomes revealed that patients who received FICB had a lower mean VAS score during positioning and a shorter mean time to achieve SA, with better patient acceptance than the controls. Later in 2014, another RCT [37] evaluated FICB versus intravenous fentanyl for positioning hip fracture patients for SA; aside from the above parameters, they also found that FICB implementation was associated with a lower morphine consumption after surgery and a longer duration to the first dose demand. In a 2016 RCT, Madabushi et al. [38] once again confirmed the superiorities of FICB before positioning for SA; in addition to the above issues, they also reported significantly improved sitting angle in FICB group. A recent double-blinded RCT [39] found that the mean total duration of analgesia after SA predisposed with FICB was significantly longer, which may help explain the previous findings that patients who received FICB had a lower morphine consumption and a longer duration to the first dose requirement [37].

In short, although the number of RCTs reporting FICB as an adjuvant prior to SA remains limited, current RCTs, based on different outcome parameters, suggested that conducting FICB before positioning for SA in geriatric patients with hip fractures can provide superior pain management compared with traditional methods, facilitating SA performance, yielding satisfactory postoperative analgesia with wide acceptance, thus improving the overall quality and efficiency of care [37].

4.3. FICB for Pain Management after Surgery. After hip surgery, adequate pain relief is also important, which can facilitate earlier mobilization, restore limb function, and prevent complications. Recent RCTs also assessed the efficacy of FICB in postoperative pain management from different perspectives (Table 3).

A 2014 RCT compared the postoperative analgesia effect of FNB with FICB in patients with hip fractures, and outcomes showed better efficacy following FNB intervention, with a lower amount of additional analgesia and a lower rate of side effects [40]. It is reasonable to understand these outcomes, as in this study FNB was provided continuously, whereas FICB was performed only once. At the same year, another RCT compared FICB with 3-in-1 block for postoperative pain control in patients who received prosthesis surgery as a result of hip fracture. Results showed similar efficacy of FICB and 3-in-1 block, also with similar tramadol consumption between the two [41]. A 2016 prospective RCT [42] evaluated the efficacy of FICB after hemiarthroplasty, and outcomes revealed a significant opioid-sparing effect in the first 24 h after surgery with FICB supplement. Later in 2018, an RCT [43] compared the effect of patient-controlled FICB with patient-controlled intravenous fentanyl (PC-IVF) for pain management after surgery. Outcomes showed satisfactory efficacy following FICB with decreased additional analgesia use and side effects. Later in 2019, Yamamoto et al. evaluated the effect of FICB versus intravenous acetaminophen on improvement of postoperative pain on movement, and they concluded that FICB achieved better efficacy without increasing the risk of complications [44]. However, they also indicated that no significant differences were found between the two regarding the total number of rescue analgesics required and the time to first standing. A new 2020 RCT showed that patients who received preoperative FICB had a statistically reduced postoperative morphine consumption and an increased proportion in patient-reported satisfaction [45], which is also supported by another 2020 RCT [46]. Aside from the definite efficacy of FICB in the alleviation of postoperative acute pain, it may also play an active role in the relief of chronic postsurgical pain (CPSP). Diakomi et al. [47] examined the impact of FICB on the development of CPSP after hip surgery, and they found that FICB group presented with lower hip-related characteristic pain intensity scores at 3 months postoperatively, with a lower percentage of patients with high-grade CPSP at 3 and 6 months after surgery. This investigation is novel and interesting, which implies that FICB may also have a positive effect on CPSP. Considering that only one RCT addressed this issue, more future studies are necessary.

In summary, although the outcome measures differed, most RCTs revealed benefits of FICB in postoperative pain relief. However, the number of such RCTs is few, with limited sample size; therefore, more future RCTs are warranted to more comprehensively assess the effect of FICB in postoperative pain management.

4.4. Other Benefits of FICB Application in Geriatric Patients with Hip Fractures. In addition to the above advantages, FICB technique may also bring other benefits in geriatric patients with hip fractures. Many studies reported that the use of FICB could reduce the risk of perioperative complications, such as delirium, pruritus, nausea, and vomiting [48–50], decrease the length of hospital stay, and accelerate functional recovery [29, 57, 58] (Table 3).

In a 2009 RCT, Mouzopoulos et al. [48] investigated the prophylaxis of FICB on perioperative delirium, and the patients included were divided into three different groups based on delirium risk (low, intermediate, and high). Although the prophylactic effect of FICB on high-risk patients was not obvious, it significantly decreased the incidence of delirium in patients in an intermediate risk. Thus, they concluded that FICB may be beneficial for perioperative delirium, especially for those in intermediate risk. Subsequently, a 2015 RCT [49] indicated the definite efficacy of FICB in alleviating postoperative pain, together with lower rates of postoperative nausea and vomiting (PONV) and pruritus, as compared with the patient-controlled intravenous analgesia (PCIA) using fentanyl. Interestingly, they observed a higher incidence of postoperative delirium in FICB group, implying that, aside from pain, many other factors may also influence the occurrence of delirium. In a recent double-blind RCT, Hao et al. [50] indicated that preoperative continuous FICB use was effective in reducing the risk of postoperative delirium. In addition to RCTs, a recently published meta-analysis [59], comprising 11 RCTs with 937 patients, indicated that FICB could reduce the total consumption of morphine and the incidence of nausea. One of the possible explanations for the decreased risk of delirium following FICB may be attributed to the reduced supplementary analgesics. However, as mentioned above, occurrence of delirium is affected by multiple factors, especially in such a cohort at a higher risk to develop delirium.

Aside from RCTs, still other studies evaluated the influence of FICB on cognitive performance. Callear and Shah [60] found that the rate of patients who had experienced postoperative delirium following SA was twice that by FICB. In a synthesis analysis of 21 RCTs assessing the efficacy of additional peripheral nerve blockade for hip fracture surgery, Rashiq et al. [61] compared FICB, FNB, and lumbar and sacral plexus block in prophylaxis of delirium. Outcomes showed that FICB had the highest probability of being the most effective against delirium. In a retrospective study comprising 959 patients aged over 65 years with a femoral neck fracture, Odor et al. [62] investigated potential influence of FICB on postoperative abbreviated mental test scores (AMTS). Outcomes revealed that FICB use at admission was linked to significantly higher adjusted odds for a higher AMTS relative to lower AMTS than conventional analgesia method. Thus, they suggested that FICB use at patient admission may help improve early postoperative cognitive performance.

In addition to the decreased risk of complications, FICB can also help reduce the length of hospital stay and accelerate the functional recovery. A previous RCT [29] reported that the mean length of hospital stay in patients that received FICB was significantly shorter than that of the controls. Similarly, Lees et al. [57] found the acute length of hospital stays in patients managed by FICB decreased to an average of 9.9 days, compared with 15 days of the control group. Similar outcome was also found in another pilot study [58]. Moreover, even one study [57] reported that the inpatient mortality in the FICB group was statistically lower than that in the control group (5.5% vs. 15%), whereas another one failed to find any statistical significance [63]. Of course, it should be noted that the mortality of such cohort of patients is influenced by multiple factors apart from analgesic methods, such as age, underlying disease, comorbidity, and treatment strategy. Therefore, cautious attitude should be taken towards the results.

4.5. Limitations and Future Perspectives. Although, in recent years, the number of RCTs investigating FICB as an analgesic strategy in the treatment of geriatric patients with hip fractures is rising, the sample size of most studies is limited. Thus, the outcomes and conclusions should be interpreted with caution. Then, the outcome parameters reported by different studies varied, making it more difficult to draw a conclusion with consistent results. Moreover, the detailed strategy of FICB (e.g., anesthetic type and dose, and interval between FICB and SA) as well as the control group settings also differed from each other, rendering it unavailable for data synthesis analysis. Although several systematic reviews and meta-analyses tried to sum up findings from published RCTs, such a high heterogeneity among RCTs may lead to a higher risk of bias.

Therefore, in order to achieve more accurate and reliable conclusions, high-quality RCTs with a larger sample size are essential. In addition, the standard reporting items of FICB investigation may be established, and if possible, standard FICB procedure should be considered. Furthermore, in-depth analyses should be performed to optimize the application of FICB in pain management in the older adults with hip fractures.

5. Summary

Growing evidence suggests that FICB is an effective and reliable strategy for preoperative pain relief in geriatric patients with hip fractures. After admission or at the ED, FICB use can provide adequate pain control, which can also decrease additional analgesics consumption. Prior to positioning for SA, FICB can facilitate conducting SA, yield satisfactory postoperative analgesia, and improve the overall quality and efficiency of care, while after surgery FICB can also provide adequate pain relief with decreased supplementary analgesics, promoting earlier hip mobilization, restoring limb function, and preventing postoperative complications. In the future, more high-quality RCTs should be conducted to more comprehensively evaluate and optimize the FICB technique for perioperative pain management in geriatric patients with hip fractures.

Data Availability

The data used to support the findings of this systematic review are from previously published studies, which have been cited.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this article.

Authors' Contributions

Hao-yang Wan and Su-yi Li contributed equally to this study.

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Clinical Study

Percutaneous Vertebroplasty and Facet Blocking for Treating Back Pain Caused by Osteoporotic Vertebral Compression Fracture

Yongquan Cheng, Xiaoliang Wu, Jiawei Shi, and Hui Jiang

Division of Spine Surgery, Department of Orthopedics, Nanfang Hospital, Southern Medical University, Guangzhou, China

Correspondence should be addressed to Hui Jiang; jiangh1975@126.com

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Background and Objectives. Back pains associated with osteoporotic vertebral compression fractures (OVCFs) may arise not just from vertebral body but also from posterior elements. Percutaneous vertebroplasty (PVP) and facet blocking (FB) combined therapy would relieve pain better, but it has not been elucidated. The purpose of this retrospective study was to compare the treatment effects of PVP and FB combined therapy with PVP alone in OVCFs patients. *Methods*. Clinical and radiological data of 204 patients were reviewed. The patients were divided into Group A (PVP alone) and Group B (PVP and FB combined therapy) according to treatments. Back pain was evaluated with Visual Analog Scale (VAS) and Oswestry Disability Index (ODI). The operation, fluoroscopic exposure time, and bone cement leakage were recorded. The χ^2 test, Student's t-test, and repeated measures analysis of variance were used to compare the differences between the two groups. *Results*. There were 125 patients in Group A and 79 patients in Group B. Their baseline characteristics were similar ($P > 0.05$). The mean VAS scores of Group A and Group B were 7.03 and 7.21 at admission, 4.7 and 3.2 at 1 day after operation, 4.0 and 3.0 at 3 months, and 2.2 and 2.2 at 12 months after operation, respectively. The mean ODI scores of Group A and Group B were 30.9 and 29.8 at admission, 17.6 and 17.7 at 3 months, and 10.5 and 10.9 at 12 months after operation, respectively. The mean operation time and fluoroscopic exposure time of Group A (35.6 minutes and 7.2 seconds, respectively) was significantly shorter than that of Group B (45.7 minutes and 11.7 seconds, respectively, $P < 0.01$). The incidence of bone cement leakage and new fractures after operation did not have statistically significant difference between groups. *Conclusion*. PVP and FB combined therapy could provide better pain relief than PVP alone in short term after operation in patients with OVCFs associated back pains.

1. Introduction

Osteoporotic vertebral compression fractures (OVCFs) are a major complication of osteoporosis and are becoming more prevalent as population aging. Back pain associated with OVCFs will limit the mobility of patients and cause several problems such as deep vein thrombosis, decubitus ulcer, and hypostatic pneumonia [1].

There are several verified treatments for OVCFs, including conservative treatment, open surgery, and percutaneous vertebroplasty (PVP). PVP was first introduced for treating vertebral hemangioma in 1987 [2]. Shortly thereafter it has been adopted by many authors for treating symptomatic OVCFs as a minimal invasive surgery [3–5]. It could provide rapid pain relief and improvement of life quality. Although PVP is effective in most patients, someone still has back pain after PVP or its effectiveness had been doubted [6]. It is postulated that pains associated with OVCFs may arise not just from vertebral body but also from posterior elements [7]. Therefore, facet blocking (FB) and medial branch blocking would be beneficial for alleviating back pain associated with OVCFs [8, 9]. A prospective study showed that PVP produced better pain relief than FB in the short term, but the difference in pain relief between these two techniques was insignificant in the long term (1 month to 12 months) [10]. Kim et al. investigated PVP and FB combined therapy and found that it was a profitable method for OVCFs [3]. But no one has compared the efficacy of PVP and FB combined therapy with PVP alone in English literature.

Thus, this study is conducted to compare the clinical and radiologic outcomes of these two therapies.

2. Methods

This retrospective study had been approved by the Ethics Committee of Nanfang Hospital and written form of consents had been provided by all participants. All patients who were diagnosed as OVCFs with back pain and admitted for percutaneous vertebroplasty from January 1, 2017, to December 31, 2018, were enrolled. XR and MRI were performed to confirm newly onset of OVCFs. Exclusion criteria included neurologic deficit, coagulation dysfunction, spinal infection, and loss to follow-up.

Among the 225 enrolled patients, 204 were included in this study while 21 were excluded due to loss to follow-up. The medical records including charts and radiological findings were collected. Patients were divided into two groups according to treatments: PVP alone (Group A) and PVP and FB combined therapy (Group B). Clinical data including age, sex, bone mineral density (BMD) measured by dual energy absorptiometry (DEXA), Visual Analog Scale (VAS), and Oswestry Disability Index (ODI) scores except sex item were collected. For VAS rating, the subject is asked to place a mark somewhere on a 10 cm line to assess present pain. The two extremes are labeled to correspond to the absolute minimum (0 cm) and the absolute maximum pain (10 cm) that could ever be experienced [11]. ODI is a 10-item questionnaire scoring 0 to 5 to assess patient's home and work life and analgesic requirements. Then it is calculated as percentage, with a high score indicating high level of disability [12]. In this study, one item (sex activity) was omitted because the patients were old and sexually inactive. The time points of VAS were at admission, 1 day, and 3 and 12 months after treatment, while the time points of ODI were at admission and 3 and 12 months after treatment. Radiographs at admission, 1 day, and 3 and 12 months after treatment were collected.

The PVP was performed through bilateral transpedicular approach in the prone position. After localization of the fractured vertebral body and local anesthesia with 1% lidocaine (v/v), an 11-gauge needle was inserted into the pedicle under the guidance of anterior-posterior and lateral fluoroscopic views. After the needle tip was placed into the anterior one-third or one-fourth of the fracture vertebral body, the inner needle was taken out and 3–5 ml of high-viscosity polymethyl methacrylate (PMMA) bone cement was injected under continuous fluoroscopic guidance until the bone cement was close to the cortical margin or spinal canal.

The FB was performed just after PVP in Group B. A 23-gauge needle was used for FB bilaterally. Under guidance of fluoroscope, the needle was inserted into the facet capsules of the adjacent vertebral bodies above and below the fractured one. The mixture solution was composed of 20 ml of 2% lidocaine, 20 ml of normal saline, and 2 ml of betamethasone. Then 2 ml of mixture solution was injected into each capsule. The operation time, fluoroscopic exposure time, blood loss during operation, and leakage of bone cement were recorded for both groups.

Calcium carbonate 600 mg and calcitriol 0.25 μg were administered daily to patients of both groups after operation. Two hours after operation, patients were mobilized to walk around bed without brace. Cox-2 inhibitors such as Celecoxib or Parecoxib would be given as required if patients had surgical site pain within 3 days after operation. Back muscle exercise was taught by nurses before discharge.

Statistical analysis was performed with SPSS software (version 23.0). Quantitative results were presented as mean ± standard deviation. The χ^2 test, Student's t-test, and repeated measures analysis of variance were used to compare the differences between the two groups. A multivariate logistic regression model with a backward stepwise method was used to evaluate the risk factors of new fractures after treatment. $P < 0.05$ was considered as statistically significant.

3. Results

Group A had 125 patients, while Group B had 79 patients. The demographic characteristics of patients are shown in Table 1. The male-to-female patient ratio was 37 : 167. The mean age of patients was 71.8 ± 9.1 years (range, 50–98 years; median 71 years). The mean T-score of BMD was 3.0 ± 0.46. The VAS and ODI score at admission were 7.10 ± 1.12 and 30.51 ± 7.18, respectively. These baseline features of two groups had no statistically significant differences.

The mean operation time of Group A (35.6 ± 5.9 minutes) was significantly shorter than that of Group B (45.7 ± 5.9 minutes, $P < 0.01$). Similarly, the mean fluoroscopic exposure time of Group A (7.2 ± 3.2 seconds) was significantly shorter than that of Group B (11.7 ± 6.3 seconds, $P < 0.01$). There was no significant difference in blood loss during operation between the two groups (4.8 ± 2.2 ml vs. 5.3 ± 3.1 ml, $P = 0.33$). Student's t-test was used for comparing these parameters.

The mean VAS scores of Group A and Group B were 4.7 ± 1.0 and 3.2 ± 0.8 at 1 day, 4.0 ± 0.8 and 3.0 ± 0.7 at 3 months, and 2.2 ± 0.6 and 2.2 ± 0.7 at 12 months after operation, respectively (Figure 1). For both groups, the VAS scores after operation significantly decreased when compared with baseline data (repeated measures analysis of variance, $P < 0.01$). The VAS scores showed greater improvement in Group B at 1 day and 3 months after operation compared with Group A, but there was no statistically significant difference at 12 months after operation (Student's t-test, Figure 1).

The mean ODI scores of Group A and Group B were 17.6 ± 4.6 and 17.7 ± 5.5 at 3 months and 10.5 ± 2.6 and 10.9 ± 3.2 at 12 months after operation, respectively (Table 2). The improvement of ODI scores between groups did not differ significantly (repeated measures analysis of variance).

The leakage of bone cement occurred in 10 and 8 patients of Group A and Group B, respectively. The incidence of this complication had no statistically significant difference between groups (χ^2 test, $P = 0.764$). All of these patients were asymptomatic. None of them needed further treatment. For new fractures confirmed by XR after operation during follow-up, 16 occurred in Group A and 12 occurred in Group B. The incidence of new fractures was not statistically

Table 1: Baseline demographic and clinical data of the two groups.

Characteristics	Group A ($n = 125$)	Group B ($n = 79$)	P value
Age, years	70.8 ± 8.9	72.9 ± 9.3	0.966
Sex			0.458
Male	25	12	
Female	100	67	
BMD	3.04 ± 0.45	2.94 ± 0.47	0.143
VAS score	7.0 ± 1.1	7.2 ± 1.1	0.256
ODI score	30.9 ± 7.0	29.8 ± 7.3	0.285

BMD, bone mineral density; VAS, Visual Analog Scale; ODI, Oswestry Disability Index. Age, BMD, VAS score, and ODI score were analyzed with Student's t-test, while sex was analyzed with χ^2 test.

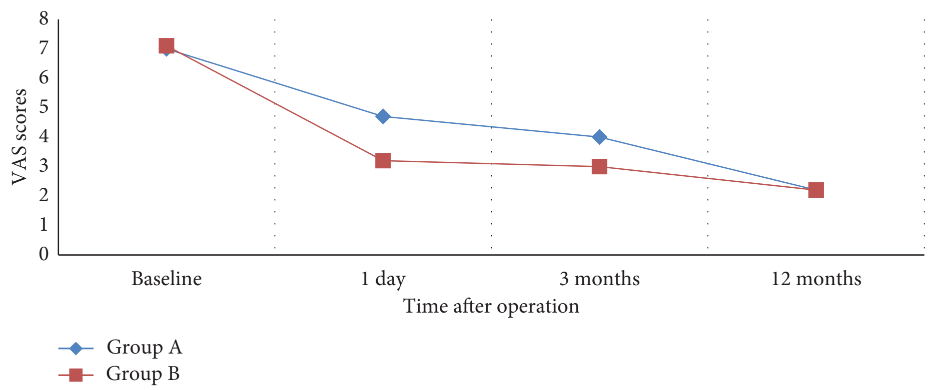

Figure 1: Comparison of Visual Analog Scale scores in two groups after operation.

Table 2: Comparison of Oswestry Disability Index scores in two groups after operation.

Time after operation	Group A ($n = 125$)	Group B ($n = 79$)	P value
3 months	17.6 ± 4.6	17.7 ± 5.5	0.863
12 months	10.5 ± 2.6	10.9 ± 3.2	0.321

significant different between groups (χ^2 test, $P = 0.655$). A multivariate logistic regression model with a backward stepwise methods showed that low BMD at admission was the only risk factor for new fractures after treatment even after adjusting confounding factors ($P < 0.05$).

4. Discussion

Osteoporosis is becoming more and more prevalent as population aging. In elderly over 70 years old, the prevalence of osteoporosis is about 40% in China [13]. OVCFs are one of the most common and severe complications resulting from osteoporosis. It was estimated that there were 700,000 OVCFs every year in the United States [14]. Back pain associated with OVCFs would cause loss of mobility, depression, and pulmonary dysfunction [4]. The concurrent treatment strategies of OVCFs include conservative therapy, open surgery, and minimal invasive cement augmentation surgeries, namely, PVP or balloon kyphoplasty [10].

Cement augmentation can provide immediate, significant, and sustained pain relief in OVCFs patients. It can also rapidly improve physical function and quality of life [15, 16]. Therefore, PVP surgeries have been performed extensively. But the very benefit of cement augmentation itself was doubted by two studies published in 2009. They compared vertebroplasty with a sham procedure. Surprisingly, both improvement in pain and disability from osteoporotic compression fractures were similar in patients treated with vertebroplasty and those treated with simulated vertebroplasty [6, 17]. These studies raised ardent debates about the effectiveness of vertebroplasty. Another concern is that some OVCFs patients still have back pain after vertebroplasty [9].

One possible explanation for these questions is that back pain of OVCFs may have multiple generators. The pain can be derived from acute fracture and inflammation proximal to the fracture site. Vertebroplasty can reduce the micromovement in the fracture site as well as neurolysis within the vertebral body due to heat generated by PMMA [18]. But in some patients with OVCFs, the back pain may also arise from posterior elements rather than fracture alone. The facet joints may be abnormally stressed due to overflexion after thoracic compression fracture, which may serve as a secondary pain generator [15]. A biomechanics model confirmed that the posterior elements of the vertebral column must subluxate cephalad or caudad in response to deformity of a vertebral body [7]. A radiologic study has demonstrated associated facet signal change on MRI in acute/subacute vertebral compression fractures, further supporting this theoretical model [19].

Thus medial branch blocking and FB were introduced to treat OVCFs related back pain. Kim et al. found that physical examination after FB was the most reliable method to confirm the most painful level among multiple OVCFs sites, and PVP and FB combined treatment had the advantages of low risk and short duration of procedure with a high chance to result in pain relief and early mobilization [3]. But they did not compare the combined treatment with PVP alone in terms of efficacy and efficiency. In a retrospective study, 53 patients with axial back pain from OVCFs were treated with medial branch block. The medial branch block provided significant pain relief and functional recovery to the patients with OVCFs complaining of continuous facet joint pain after vertebroplasty or conservation treatment [9]. A third of patients technically suitable for vertebroplasty responded beneficially to facet joint injection [8]. A prospective randomized controlled trial compared PVP with FB for severe pain due to OVCFs in 206 patients. The results showed that PVP produced better pain relief than facet blocking in the short term, but the difference in pain relief between these two techniques was insignificant in the long term [10]. Those results showed the extensive existence of soft tissue injury in OVCF patients, and the relative advantage of PVP and FB combined therapy. But it is unknown whether PVP and FB combined therapy could provide more benefit than PVP alone in OVCFs patients with back pain. This single center retrospective study was performed to elucidate this matter.

The mean VAS scores of Group A (PVP alone) and Group B (PVP and FB combined therapy) were 7.03 and 7.21 at admission, 4.7 and 3.2 at 1 day after operation, 4.0 and 3.0 at 3 months, and 2.2 and 2.2 at 12 months, respectively. The improvement of VAS scores for 1 day and 3 months after operation in Group B was statistically greater than that in Group A. This result confirmed that PVP and FB combined therapy can provide better pain relief in OVCFs patients in short term. Further studies focusing on quality of life after PVP and FB combined therapy would reveal more benefit of it, like study conducted by Imai et al. [20]. A retrospective study published in Chinese also found similar short-term benefits of PVP and FB combined therapy, but the sample size was smaller and there was lack of long-term follow-up [21]. Our study found that, after 1 year of operation, there was no statistically significant difference in VAS and ODI scores between groups. This could be attributed to the stabilization of spinal column and short-term effectiveness of local anesthetic agents and steroids [22–25]. The mean ODI scores of Group A and Group B were 30.9 and 29.8 at admission, 17.6 and 17.7 at 3 months, and 10.5 and 10.9 at 12 months after operation, respectively. These results also suggested the similarity of long-term pain relief between groups.

In our study, the mean operation time of Group A (35.6 minutes) was significantly shorter than that of Group B (45.7 minutes). The mean fluoroscopic exposure time of Group A (7.2 seconds) was also shorter than Group B (11.7 seconds). This was reasonable because FB took some time in addition to PVP. In the prospective study performed by Wang et al., the mean operation time of FB group and PVP group was 22.5 and 35.3 minutes, respectively [10]. FB would slightly increase the operation time and fluoroscopic exposure to patients and surgeons. This should be informed to OVCFs patients before operation and weighed against better pain relief in short term after operation.

The most common complication of PVP is cement leakage, which includes leakage into surrounding tissue, paravertebral vein embolism, intradiscal leakage, and leakage into spinal canal. The cumulative incidence could be as high as 40%, although majority of them do not produce any clinical symptoms [26]. In this study, the incidence of this complication did not differ significantly in statistics between groups, and none of these patients were symptomatic. Intravertebral cleft, cortical disruption, low cement viscosity, and high volume of injected cement may be the risk factors of cement leakage [27].

New fractures after PVP would occur in more than 10% of patients and could be symptomatic requiring further treatment [28]. The incidence in this study was about 14%, which was close to literature reports, and the incidences in the two groups were similar. Low BMD at admission was found to be the risk factor for new fractures in this study. A meta-analysis also demonstrated that low bone mineral density, the presence of multiple treated vertebrae, and a history of steroid usage were associated with the new OVCFs after vertebroplasty [29]. These risk factors should be considered in further analysis of our data. PVP would increase the incidence of new vertebral fractures. This might be explained by a shift in mechanical load of the spine after the bone cement was injected, increasing stress in adjacent vertebral bodies [28, 30].

There are a few limitations in this study. First, as a retrospective study, there might be several biases that affect treatment effects between groups. Further prospective controlled trial comparing PVP and FB combined therapy with PVP alone is required. Second, control group treated with FB only was lacking in this study. Third, PVP and FB slightly increased the operation time and medical cost, which should be informed to patients. Fourth, the follow-up was only 12 months, which would not be long enough to detect new fractures. Nonetheless, this study is the first large size one to investigate the benefit of PVP and FB combined therapy compared with PVP alone for managing back pain of OVCFs patients.

5. Conclusion

In patients with back pain due to OVCFs, PVP and FB combined therapy could provide better pain relief than PVP alone in short term after operation. Although FB would slightly increase operation time and fluoroscopic exposure, it is still worth to perform together with PVP if back pains generating from posterior elements are suspected.

Data Availability

The data used to support this study can be made available from the corresponding author upon request.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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Research Article

Effect of Preoperative Zoledronic Acid Administration on Pain Intensity after Percutaneous Vertebroplasty for Osteoporotic Vertebral Compression Fractures

Weiran Hu,[1,2] Hongqiang Wang,[1,2] Xinge Shi,[1,2] Yuepeng Song,[1,2] Guangquan Zhang,[1,2] Shuai Xing,[1,2] Kai Zhang,[1,2] and Yanzheng Gao[1,2]

[1]*Department of Spinal Cord Surgery, Henan Provincial People's Hospital, Zhengzhou, Henan 45003, China*
[2]*People's Hospital of Zhengzhou University, Zhengzhou, Henan 45003, China*

Correspondence should be addressed to Yanzheng Gao; doctorgao63@163.com

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Introduction. This study aimed to compare and analyze the effect of preoperative zoledronic acid (ZOL) administration on pain intensity after percutaneous vertebroplasty (PVP) for osteoporotic vertebral compression fracture (OVCF). *Methods.* The study included 242 patients with OVCFs who underwent PVP in our hospital between January 2015 and June 2018. The patients were randomly assigned to either a ZOL group ($n = 121$) or a control group ($n = 121$). The patients in the ZOL group were treated preoperatively with intravenous infusion of 5 mg ZOL. Those in the control group were treated without ZOL. All the patients were followed up for 1 year. *Results.* No statistically significant differences in age, sex, weight, and body mass index (BMI) were found between the two groups. During the follow-up period, the visual analog scale score and Oswestry dysfunction index score in the ZOL group were lower than those in the control group. The bone mineral density at 6 or 12 months after treatment was significantly higher and the levels of the bone metabolism markers were significantly lower in the ZOL group than in the control group ($P < 0.05$ for both). Two patients in the treatment group had new vertebral fractures, whereas 13 patients in the control group had new vertebral fractures, which translate to recompression vertebral fracture incidence rates of 1.7% and 10.7%, respectively. The incidence rate of mild adverse reactions was significantly higher in the ZOL group than in the control group, but all the cases were endurable. *Conclusion.* Intravenous infusion of ZOL before PVP can effectively reduce postoperative pain intensity, reduce bone loss, increase bone density, reduce the risk of refracture, and improve patient quality of life.

1. Introduction

Osteoporotic vertebral compression fracture (OVCF) is one of the most common fractures in patients with osteoporosis. However, most OVCFs are stable and asymptomatic vertebral fractures that do not require open surgical therapy. Compared with the traditional conservative treatment, percutaneous vertebroplasty (PVP) is characterized by fewer complications, positive efficacy, and less trauma. Immediate analgesia can be achieved by fixing the broken end of the fracture, and the operation can enhance the strength and stiffness of the vertebral body, restore the height of the vertebral body, and correct the deformity in kyphosis.

However, PVP still has some problems such as postoperative residual pain in the lower back and the development of new vertebral fractures, which may cause other problems in patients. A study by Zhong et al. suggested that 12.9% of patients had new fractures within 1 year after PVP [1]. Zoledronic acid (ZOL) administration can effectively increase lumbar bone density and reduce the risk of vertebral fracture in patients with osteoporosis, which has been reported in the literature [2]. Thus, it may have great significance in consolidating the surgical treatment effect of PVP and preventing new vertebral fractures.

To test this hypothesis, our department adopted the use of ZOL in combination with PVP surgery to improve the treatment of OVCF. To verify the effectiveness of this method, 242 patients who underwent PVP between January 2015 and June 2018 were randomly divided into two groups. In the treatment group, ZOL and calcium supplements were administered 2 days before the PVP surgery. In the control group, PVP was performed after calcium supplementation only. All the patients were followed up for 1 year, and the changes in visual analog scale (VAS) score, Oswestry dysfunction index (ODI) score, lumbar bone density, and bone metabolism index scores were observed and calculated.

2. Materials and Methods

2.1. General Information. The patient inclusion criteria for the study were as follows: patients with a clear medical history and clinical diagnosis of OVCF, patients who underwent imaging examination to assist diagnosis, and patients whose radiography and computed tomography findings suggested the presence of osteoporosis and changes in vertebral volume compressibility. Magnetic resonance imaging revealed a high signal intensity on the T2-weighted image of the diseased vertebral body, which confirmed the diagnosis of fresh vertebral compression fracture. Bone mineral content was determined in accordance with the *American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis 2016* [3]. According to the reference standard, osteoporosis was diagnosed when the T value of the femoral neck was <-2.5, and osteopenia, when the T value was between −1.0 and −2.0.

The exclusion criteria were as follows: patients with vertebral blowout fractures, intraspinal occupation, or neurological symptoms; patients with severe neurological and psychiatric disorders, who were lost to follow-up, and who were incapable of undergoing follow-up tests; patients with chronic liver and kidney function damages; patients with severe digestive diseases; patients with thyroid gland and parathyroid gland diseases; and patients with malignant tumor metastasis and long-term use of glucocorticoid drugs.

2.2. Grouping and Methods. After hospital admission, 242 patients, including 125 men and 117 women, were randomly divided into two groups. The mean age was 69.5 ± 6.8 years. The affected vertebrae were located at the $T5$–$L5$ levels, with a total of 367 vertebral bodies. According to the location of the fractured vertebrae, 89 fractures involved the thoracic vertebrae and 57 involved the lumbar vertebrae in the ZOL group, whereas 101 fractures were in the thoracic vertebrae and 51 were in the lumbar vertebrae in the control group. No statistically significant differences in baseline characteristics such as sex, age, height, and physical signs were found between the two groups.

Both groups received oral calcium carbonate/vitamin D3 tablets (600 mg/d; Wyeth Pharmaceuticals) since hospital admission until after surgery continuously. The ZOL group was treated with ZOL injection (5 mg/100 ml; Aclasta, Novartis Pharma Schweiz AG) 2 days before surgery, and no postoperative analgesia was used in both groups. The follow-up time points were 3 days, 1 month, 6 months, and 1 year after the operation (Table 1).

2.3. Observation Indicator. The observation indicators were as follows: (1) visual analog scale (VAS) score, where the patients rated their pain level on the relevant scale (0–10), with 0 indicating no pain and 10 indicating the most severe pain; (2) bone mineral density, where a dual-energy X-ray bone mineral density detector was used to detect the bone mineral density and the orthotopic bone mineral density and salt content of the femoral neck were measured; (3) Oswestry disability index (ODI) score, where the ODI, a specific scoring system for low back pain, has been widely used in the field of spinal surgery to investigate the degree of dysfunction according to 10 categories; and (4) bone markers, where β-CTX (β-isomerized C-terminal telopeptide of type I collagen) and P1NP (N-terminal propeptide of type I collagen) as bone markers were detected using the Cobas6000 E601 automatic immunoluminescence analyzer (Roche).

2.4. Statistical Analyses. The SPSS 18.0 statistical software was used for the statistical analysis. Quantitative data were expressed as $x \pm s$. A t-test was used for comparison between groups, and a paired t-test was used before and after treatment. Results with P values of <0.05 were considered significantly different.

3. Results

3.1. Pain Improvement. No significant difference in pretreatment VAS score was found between the ZOL and control groups ($P < 0.05$). However, the VAS score significantly differed between the two groups ($P < 0.01$) during the follow-up period. In the ZOL group, the postoperative VAS score significantly decreased gradually from that before operation ($P < 0.01$). The VAS score of the control group after the 6-month follow-up was slightly higher than that of the ZOL group but lower than that before operation (Figure 1).

3.2. Changes in ODI Score. No statistically significant differences in ODI scores before treatment and 3 days after surgery were found between the two groups ($P < 0.05$). At 1 month and 6 months after operation, all the activity functions of the patients in the two groups were improved as compared with those before the operation, and the differences were statistically significant ($P < 0.01$). The ODI score of the ZOL group was still significantly decreased 6 months after surgery as compared with 1 month after surgery ($P < 0.01$). In the control group, the ODI score showed no statistically significant difference between 1 month and 6 months after surgery ($P < 0.05$; Figure 2).

3.3. Changes in Bone Density. The comparison between the two groups showed no significant difference in left femoral neck bone mineral density before treatment ($P < 0.05$). All the patients were followed up at 6 and 12 months after surgery. The results showed that bone density increased in

Table 1: Baseline characteristics of each group.

Variable	ZOL	Conservative	P value
Number	121	121	
Gender (female/male)	72/49	81/40	0.27
Age (years)	62.60 ± 7.20	67.45 ± 4.12	0.65
Weight (kg)	67.73 ± 5.11	69.62 ± 6.70	0.46
BMI (kg/m^2)	26.15 ± 3.21	26.79 ± 5.49	0.96
Fracture levle			
Thoracic	89	101	
Lumbar	57	51	

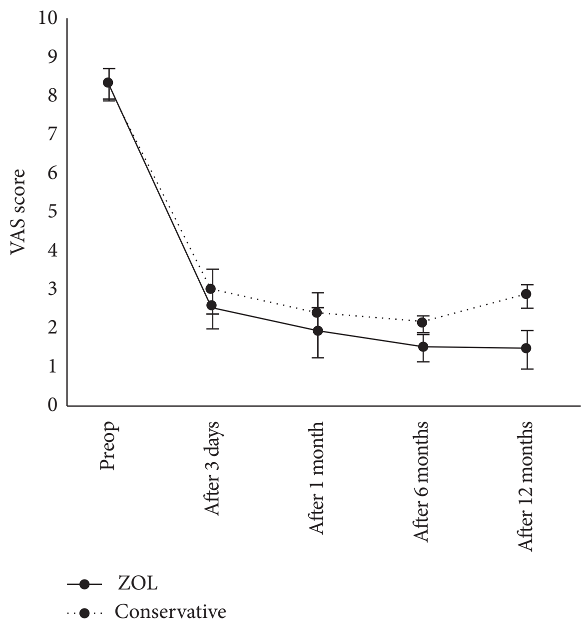

Figure 1: Visual analog scale (VAS) scores before and after percutaneous vertebroplasty (PVP) and/or zoledronic acid (ZOL) infusion. Data are presented as mean ± SD.

both groups but was statistically significantly higher in the ZOL group than in the control group at 6 or 12 months after treatment. The intragroup comparison revealed that, in the treatment group, the femoral neck mineral density at the 12-month follow-up was significantly higher than those at 6 months and before operation ($P < 0.01$; Table 2).

3.4. Changes in Bone Metabolic Factors. No significant difference in serum P1NP and β-CTX levels was found between the two groups before treatment ($P < 0.05$). Continuous monitoring after treatment revealed that the serum β-CTX and P1NP levels decreased and were significantly lower in the ZOL group than in the control group during follow-up ($P < 0.01$). In the ZOL group, the PINP and β-CTX levels decreased during the first 6 months after operation and increased 6 months after operation but remained at lower levels than those in the control group (Table 3).

3.5. New Vertebral Fracture. According to the statistical data at 12 months of follow-up, 2 patients (1 man and 1 woman) in the treatment group had new vertebral fractures in a total

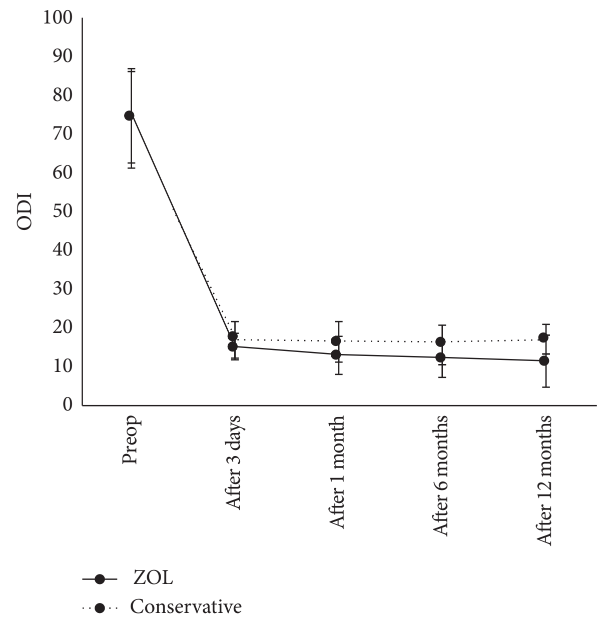

Figure 2: Oswestry dysfunction index (ODI) before and after percutaneous vertebroplasty (PVP) and/or zoledronic acid (ZOL) infusion. Data are presented as mean ± SD.

of 3 vertebral bodies, whereas 13 patients (4 men and 9 women) in the control group had new vertebral fractures in a total of 17 vertebral bodies.

3.6. Complications. Twenty-three patients complained of discomfort after ZOL administration, including 21 cases (17.4%) of fever, 17 cases (14.0%) of influenza-like symptoms, and 9 cases (7.4%) of muscle and soft tissue pain. Eight cases of bone cement leakage occurred in the experimental group; and 10 cases, in the control group, all of which showed no invasion of the spinal canal. We found no statistically significant difference in bone cement leakage rate between the two groups ($P < 0.05$; Table 4).

4. Discussion

Osteoporotic fracture (OF) has become an international public health problem and is the most severe complication of osteoporosis, characterized by high morbidity, disability, mortality, and medical costs. Among all of cases, OVCF accounts for the largest proportion. Without positive intervention, vertebral lesions may lead to imbalance in the sagittal plane of the spine, causing a chain fracture reaction in other vertebral bodies, accelerate the hump, and ultimately lead to severe kyphosis, which seriously affect patient quality of life. Previous studies reported that >39% of women aged >65 years had OVCFs [4–7].

PVP is mainly used in the treatment of patients with osteoporotic VCF. This technology has the advantages of immediate analgesic effect, limited increase in vertebral height, improvement of spinal deformity, and increased vertebral stability. It has become the currently recommended treatment method for OVCF. Through a cohort study, Yang

Table 2: Comparison of bone mineral density of the left femoral neck between the two groups before and after the treatment.

	N	Before treatment	6 months after treatment	12 months after treatment
ZOL	121	0.41 ± 0.05	0.45 ± 0.05	$0.58 \pm 0.05^{*}$
Conservative	121	0.41 ± 0.05	0.43 ± 0.04	0.44 ± 0.05
P		0.76	<0.01	<0.01

$^{*}P < 0.05$ ZOL group vs conservative group 6 month after treatment.

Table 3: Comparison of PINP and β-CTX levels between the two groups before and after the treatment.

	N	Before treatment	After treatment		
			1 months	6 months	12 months
P1NP					
ZOL	121	38.85 ± 2.01	28.77 ± 1.89	$14.79 \pm 1.01^{*}$	$16.53 \pm 5.23^{**}$
Conservative	121	39.76 ± 2.76	34.12 ± 5.41	32.11 ± 4.71	32.76 ± 2.31
β-CTX					
ZOL	121	0.47 ± 0.02	0.37 ± 0.01	$0.19 \pm 0.01^{*}$	$0.27 \pm 0.06^{**}$
Conservative	121	0.48 ± 0.01	0.45 ± 0.02	0.44 ± 0.04	0.45 ± 0.04

$^{*}P < 0.05$ ZOL group vs conservative group 6 month after treatment; $^{**}P < 0.05$ 12 months after treatment.

Table 4: Complications of the ZOL group and conservative group.

Variable	ZOL	Conservative
New vertebral body fracture n (%)	2 (1.7)	13 (10.7)
Bone cement leakage n (%)	8 (6.6)	10 (8.3)
Fever	21	
Flu-like symptoms	17	
Myalgia	9	

et al. found no significant difference in VAS and ODI scores between the PVP and conservative treatment groups after 6 months, but PVP could rapidly reduce pain and restore daily life activities at an early date [4]. In a meta-analysis of 13 randomized controlled trials with 1624 patients, Lou et al. concluded that PVP is safe and effective for rapid pain relief in patients with acute OVCF [5]. A study by Wang et al. suggested that PVP can significantly improve postoperative pain in patients with OVCF as compared with facet arthroplasty [6]. In a meta-analysis, Zhang et al. also concluded that compared with conservative treatment, PVP significantly reduced pain and improved the quality of life of patients while reducing the risk of re-fracture [7].

In this study, VAS score was reduced, pain was relieved, and quality of life was significantly improved after PVP surgery in both groups. However, with the extended follow-up time, the increasing trend of the VAS score was more obvious in the control group than in the ZOL group. We believe that this may be related to the residual pain caused by osteoporosis and the new vertebral fracture after surgery. Tan et al. conducted a prospective study on chronic pain caused by OVCF. After 1 year of follow-up after PVP treatment, the patients' back pain symptoms were significantly relieved. We believe that PVP is effective for relieving chronic pain caused by OVCF [8]. Zhang et al. reported that the VAS score of the patients with OVCF decreased from 7.6 ± 0.78 to 2.45 ± 0.51 after PVP treatment, indicating satisfactory surgical results [9].

The main mechanisms thereby PVP relieves low back pain are as follows. (1) Bone cement polymerization and solidification release a large amount of heat that cauterizes nerve endings. (2) Bone cement solidifies the fracture pieces together, increases the stability of the vertebral body, and reduces the stimulation of fracture tablets. (3) Bone cement can embolize local blood vessels, resulting in peripheral nerve ischemia and necrosis and thereby achieving an analgesic effect. Postoperative low back pain was significantly relieved in all the patients, and the postoperative VAS score was significantly reduced in both groups. A study by Ma et al. showed that PVP could alleviate pain in patients with OVCF in the early stage, partially restore the vertebral height, and significantly improve the VAS score in the first 1–3 months after surgery [10]. Ge et al. proposed that after 36 months of follow-up, radiography and VAS scores were used to evaluate patient prognosis. The authors believed that PVP treatment of OVCF was safe and effective and could quickly relieve low back pain, restore the height of fractured thoracic vertebrae, correct kyphosis, and improve the quality of life of patients [11]. Wang et al. retrospectively evaluated 35 patients with severe OVCF and found that pain was significantly relieved after PVP treatment. The authors believe that PVP for OVCF is a safe and effective treatment that can significantly restore vertebral height, reduce the kyphosis angle, significantly relieve pain, and improve limb function [12]. Clarençon retrospectively analyzed the safety and clinical efficacy of PVP in 173 patients aged >80 years who had OVCFs. They found that 79.3% of the elderly patients attained pain relief after PVP and thus concluded that PVP is a safe treatment option for elderly patients [13].

However, most patients still have mild residual pain after surgery. Some scholars believe that PVP only relieves acute pain caused by the fracture but fails to relieve the pain caused by osteoporosis. At the same time, some scholars believe that the postoperative strength of the vertebral body with compression fracture increases, changing the mechanical structure and transmission mechanism of the normal vertebral bodies, aggravating the load of the adjacent vertebral bodies, and thus increasing the risk of fracture of the adjacent vertebral bodies or causing occult trabecular bone fractures in the adjacent vertebral bodies, which will result in postoperative residual pain [14]. Yang et al. performed a statistical analysis for 1316 patients treated with PVP, among which 60 complained of postoperative discomfort, with a prevalence of 4.6%. The analysis result suggested that low bone density, lumbar fascia injury, multisegment PVP, insufficient injection volume of bone cement, unsatisfactory distribution of bone cement, and depression were important factors of postoperative residual pain in patients with OVCF [15]. A prospective cohort study led by Yan et al. included 133 elderly patients with OVCF. VAS score and ODI were used to evaluate postoperative efficacy, and fascia injury was identified as an important cause of postoperative residual lumbago and back pain [16].

The special double nitrogen side chain structure of ZOL has a high affinity for bone tissue, which can selectively act on osteoclasts, inhibit the activity of osteoclasts, inhibit bone absorption, slow down bone loss, and increase bone mass [17]. ZOL has the advantages of long-acting, obvious, and fast-acting effect, and significantly improving bone density. A multicenter, randomized, double-blind, controlled trial that administered ZOL and placebo at 6, 12, 18, and 24 months ultimately concluded that ZOL administration reduced bone mass loss and pain [18]. Cai et al. conducted a trial in patients aged >40 years who had low back pain and vertebral modic changes for 6 months. Compared with that of the placebo group, the VAS score of the ZOL group decreased significantly [19]. Liu et al. analyzed the clinical data of 482 elderly patients with osteoporotic fractures. The VAS score, bone mineral density, and incidence of recurrent fracture were better in the ZOL group after 24 months of ZOL treatment than in the control group. The authors believe that ZOL administration can reduce postoperative bone mass loss and recurrent fracture in patients with osteoporotic fractures [20]. In this study, the bone mineral density in the ZOL group was significantly improved at 12 months after surgery. However, the VAS scores in the control group increased. Therefore, in this study, we concluded that PVP combined with ZOL administration was superior to PVP alone in terms of pain relief, and the difference in pain relief between the two groups increased gradually during follow-up.

No significant difference in ODI measured at 3 days after surgery was found between the two groups, indicating that the immediate postoperative pain relief was the same between the two groups. However, with the increase in follow-up time, the ODI score of the ZOL group continued to decline, indicating that the patients' waist function continued to recover, whereas that of the control group did not continue to improve, and the difference between the two groups gradually emerged. In the experimental group, after intravenous ZOL administration, osteoporosis continued to improve and effectively relieved the postoperative residual pain caused by osteoporosis. In the control group, only the broken ends of the fractures were fixed through surgery, but no other treatment was performed for osteoporosis. Hu et al. examined 72 patients aged >60 years who had OVCFs. After measuring their spinopelvic parameters, they concluded that the spinal sagittal imbalance and ODI score were higher in the patients with OVCF than in the control group, seriously affecting quality of life [21]. Wang et al. followed up the clinical efficacy of postoperative PVP. During the follow-up of 43 patients, the mean ODI score of the patients decreased from 40 to 8 at 6 months after surgery [22].

Among the bone metabolism markers, β-CTX, a carboxy-terminal degradation product of collagen type I, is released into the blood circulation during osteoclast absorption of the bone matrix, which is a good indicator of bone resorption activity. P1NP is a bone-forming marker that reflects changes in newly synthesized collagen type I. The decrease in β-CTX level in our study suggested that ZOL had a stable long-term inhibitory effect on bone resorption and could effectively inhibit the activity of osteoclasts [23]. The P1NP level was lower after ZOL treatment, which suggests that ZOL could inhibit osteoclasts and reduce the levels of bone resorption markers [24]. In this study, the serum concentrations of PINP and β-CTX in the treatment group were lower than those in the control group within 12 months after treatment, which suggests that compared with those in the control group, bone formation and bone absorption were reduced in the ZOL group. Although the concentrations of PINP and β-CTX in the ZOL group increased after 3 months, they still remained low and, at the end of follow-up, were still less than half of the preoperative concentrations. This indicates that, after 1 year of administration, ZOL treatment still had a good inhibitory effect on bone conversion. From the pathophysiological perspective, this also explains that the relief of low back pain in the ZOL group was better than that in the control group. Our experimental results were similar to those reported by Zhang et al. [25]. The authors retrospectively evaluated 101 patients with OVCF. After the use of ZOL, the concentrations of PINP and tab-CTX decreased from 39.98 ± 1.79 g/L and 0.55 ± 0.14 g/L to 15.40 ± 1.40 g/L, and 0.34 ± 0.05 g/L, respectively, after 6 months of follow-up.

New vertebral fracture after PVP is also an important factor of pain, and a study reported that the incidence of new vertebral refracture after PVP surgery reached 10% [26]. Takahara et al. reported that the incidence of new vertebral fracture after PVP even reached 22.9% [27]. Many factors cause refracture after PVP, among which osteoporosis is the most important factor. The prevention of osteoporotic fractures should include guidance on appropriate exercise, proper diet, adjustment of lifestyle, and rational medication. In this study, 2 new vertebral fractures (3 vertebral bodies in total) occurred in the ZOL group (Figure 3), while 13 new vertebral fractures (17 vertebral bodies in total) occurred in the control group. This also partly explains the reason why the postoperative VAS score of the ZOL group was lower than that of the control group. The incidence of new vertebral fracture in the two groups was statistically significant ($P < 0.05$). The results showed that ZOL administration before surgery can effectively reduce the incidence of new vertebral fractures. Through a retrospective analysis, Yang et al. divided the time of surgery into within and after the 30 days after injury, analyzed the postoperative situation of new vertebral fractures, and found that the probability of new fractures in patients undergoing surgery within 30

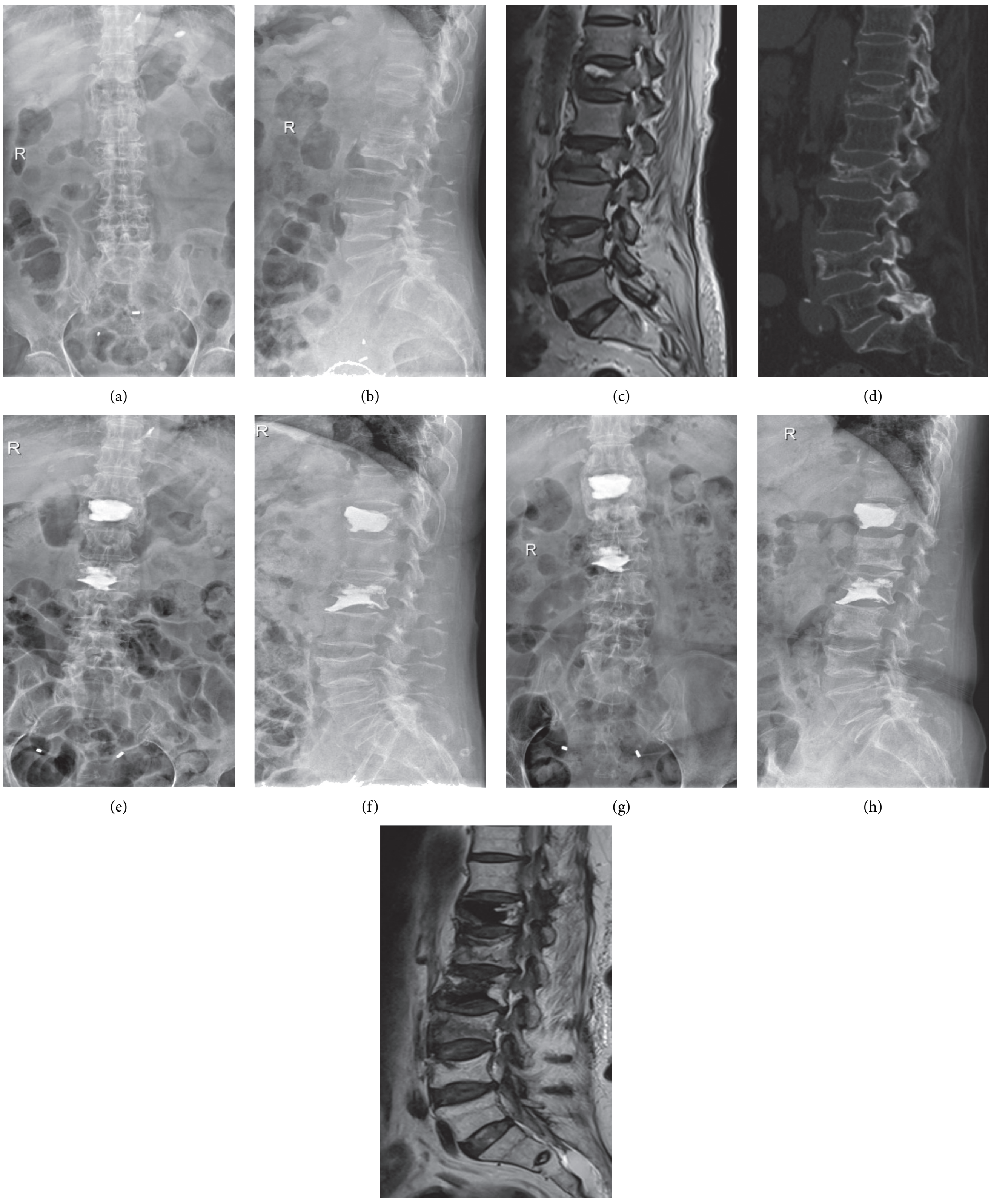

Figure 3: A 70-year-old woman. (a, b) Radiographs obtained in positive and lateral positions, showing a T12–L2 osteoporotic vertebral compression fracture. (c) Lumbar magnetic resonance image showing T12 and L2 vertebral body morphology changes. (d) Lumbar computed tomographic image showing T12 and L2 osteoporotic vertebral compression fractures. (e, f) Radiographs obtained in the positive and lateral positions after the first PVP operation for the T12 and L2 osteoporotic vertebral compression fractures. (g–i) At 8 months after the first treatment, the radiograph obtained in the positive and lateral positions and lumbar magnetic resonance image show new osteoporotic vertebral compression fractures at L1 and L3.

days after injury was significantly lower than that in the control group [28]. Zhong et al. established a risk prediction model to simulate the risk factors of new vertebral fracture after PVP surgery and concluded that the independent risk factors of new vertebral fracture were intervertebral cement leakage and previous vertebral compression fracture [1]. Lee et al. conducted a retrospective cohort study that followed up 198 patients after PVP surgery, analyzed the risk factors of new vertebral fractures, and concluded that the osteoporosis treatment and improvements in BMD and BMI were the most important factors for reducing the risk of new vertebral fracture [29]. This is highly consistent with the conclusions of our study, and the incidence of vertebral fracture after PVP can be effectively reduced by improving bone density. In their recent study, Li et al. reached a similar conclusion. Patients received PVP with combined ZOL and rosuvastatin therapy. Between-group comparisons of bone density, type I procollagen peptide (CTX) and bone-specific alkaline phosphatase (BAP) levels, VAS score, ODI score, and adjacent centrum refracture were performed before and after treatment. Bone density was higher, and BAP and CTX levels, ODI score, and VAS score were lower in the observation group than in the control group. The refracture rate in the observation group was lower than that in the control group [30].

Complications of ZOL treatment, such as flu-like symptoms, fever, and fatigue, have been widely reported [31–33], which generally lasts around 3–7 days. At the same time, the side effects of ZOL administration are generally tolerable and can be quickly relieved by self-regulation. A multicenter study from China observed and analyzed the acute side effects of ZOL infusion in patients with osteoporosis. The incidence of fever within 7 days after ZOL infusion was 28.65% (740/2583), of which 98.34% (727/740) occurred within 5 days after infusion. Among the other side effects were pain in 312 patients (26.28%) or pain aggravation in 144 patients (10.18%), most of which occurred within 3 days of ZOL administration. These symptoms are usually mild to moderate, with a short duration, which makes ZOL treatment generally safe [33]. The same conclusion was reached in this study. Although the patients in the experimental group had side effects, the follow-up observation did not show serious damage in the patients, and the complications were eventually cured in all the patients. Therefore, the safety of ZOL treatment is reliable.

Compared with long-term oral drugs, ZOL only needs to be injected once a year, which not only avoids digestive tract adverse reactions caused by oral bisphosphonates, salmon calcitonin, and other drugs but also makes the medication administration more convenient, thereby greatly improving patients' medication compliance. Moreover, with the significant relief of back pain, patients' medication compliance will be further improved.

5. Conclusion

In terms of relieving postoperative pain in patients with OVCF, the preoperative ZOL administration combined with PVP surgery was significantly better than the control treatment. Preoperative intravenous infusion of ZOL can reduce bone loss, increase bone density, reduce the risk of refracture, and improve patient quality of life.

Data Availability

All data are included in the manuscript. The datasets used and/or analyzed in the present study are available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors have no conflicts of interest regarding this paper.

Authors' Contributions

Weiran Hu and Hongqiang Wang contributed equally to this work as co-first authors.

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Research Article

Effects of Orem's Self-Care Model on the Life Quality of Elderly Patients with Hip Fractures

Xiaodong Xu,[1] Jun Han,[2] Yajia Li,[3] Xichun Sun,[4] Peng Lin,[1] Ying Chen,[1] Fuqiang Gao,[1] Zirong Li,[1] Shuai Zhang,[5] and Wei Sun[1]

[1]*Department of Orthopedics, China-Japan Friendship Hospital, Beijing 100029, China*
[2]*Department of Orthopedic Surgery, Peking University China-Japan Friendship School of Clinical Medicine, Beijing 100029, China*
[3]*Department of Dermatology, Xiangya Hospital, Central South University, Changsha 410008, China*
[4]*Department of Orthopedics, People's Hospital of Ningxia Hui Autonomous Region, Yinchuan 750001, China*
[5]*Department of Neurology, Affiliated Hospital of Yangzhou University, Yangzhou University, Hanjiang Road, Yangzhou 225100, China*

Correspondence should be addressed to Peng Lin; zryylp@163.com and Ying Chen; zryycsgk@126.com

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Background. Hip fractures of elderly patients are a public health problem worldwide, mostly lying in bed for a long time; therefore, the importance of life quality in such patients is an issue beyond question. Orem's self-care model is a nursing pattern which is introduced with the purpose of improving the self-care ability of individuals, especially the patients suffering from diseases with limits on activity. *Objective*. The aim of this study was to determine the effects of Orem's self-care program on life quality of senile patients with hip fractures. *Methods*. A randomized clinical trial study was conducted on 130 eligible old patients suffering from hip fractures who were selected using easy sampling methods and allocated randomly into two groups of experiment and control. The data were collected through validated questionnaires including visual analogue scale (VAS) and Barthel index for them. The experiment group was treated according to Orem's self-care model, and the control group was treated on the basis of the traditional care model. The data of complications including pneumonia, deep venous thrombosis, urinary infection, wound problem, and bedsore were also gathered. *Results*. As revealed, mean scores of VAS and Barthel index one week after operation in the experiment group were significantly different from the control one ($P < 0.05$, $P \leq 0.001$). The changes of VAS and Barthel index six weeks postoperatively of the two groups were also statistically significant ($P < 0.05$, $P \leq 0.001$). Compared with the control group, the difference of complications reduced significantly in the experiment group ($P < 0.05$). Accordingly, educational intervention according to Orem's self-care model seemed to be effective in promoting self-care ability for these senile patients. *Conclusions*. According to the obtained results, a self-care program based on Orem's model for elderly patients with hip fractures can improve life quality and reduce perioperative complications significantly. Therefore, it is recommended that this nursing program should be taken into account as a part of treatment measures for these patients.

1. Introduction

Fractures due to fragility of the bone around hip joints have become a major public health issue, presenting with an increasing incidence due to the growth of elderly population [1]. The annual incidence of hip fractures worldwide is estimated to increase from 1.6 million in 2000 to at least 4.5 million by 2050 due primarily to population aging [2]. Nowadays, hip fractures have become a uniquely challenging global health problem with significant socioeconomic consequences and health care budgets, with considerable risks of dependence in activities of daily living, complications, and mortality [3, 4]. Many healthy and active senile individuals suffering from hip fractures lose their independent mobility, whereas the weaker patients may lose their ability of independent living at home; the weakest patients with already-distressing health status become further debilitated by pain, anxiety, lying in bed, and inability to take care of themselves [5, 6]. Also, a lot of physical, psychological, social, and economic complications occurring in the perioperative period, such as pneumonia, deep venous thrombosis and pulmonary embolus, urinary retention, wound problem, pressure ulcers, and pain have been reported to have negative impacts on patients [7]. They undergo considerable difficulties in returning to their prefracture living situation and in achieving full recovery of function and living quality [8]. Although nursing teams provide them with information about treatment measures and complications in the form of brochures, the initial surveys and interviews with patients and their families have shown that they seriously need to learn more about severity degree of the fracture, specific operation methods, complications and possible preventive measures, and self-care knowledge [9]. Orem's theory was presented in 1959, and the application of this self-care model has had positive effects on patients with different diseases [10–13]. However, we found no studies that applied this model to orthopedic patients such as those with hip fractures. Therefore, the present study aims to examine the effects of educational interventions according to Orem's self-care theory on the life quality of elderly patients with hip fractures including femoral neck fractures and intertrochanteric fractures.

2. Patients and Methods

2.1. Trial Design and Participants. This study was a randomized clinical trial in which the effect of application of Orem's self-care program on life quality of elderly patients with hip fractures admitted in the orthopedics departments had been investigated. Two groups of patients were selected and randomly assigned to experiment and control groups.

130 patients were enrolled in the study including 65 patients for the experiment group and 65 patients for the control one. Experiment group comprised 30 cases of femoral neck fractures and 35 cases of intertrochanteric fractures, with an average age of 77.6 years old (Table 1). Control group consisted of 29 cases of femoral neck fractures and 36 cases of intertrochanteric fractures (Table 1), whose average age was 76.6 years old.

2.2. Selection Criteria. The inclusion criteria were as follows: (1) over 60 years of age; (2) isolated unilateral hip fractures including femoral neck fractures and intertrochanteric fractures; (3) fresh closed fractures (<14 days); (4) the vital signs and hemodynamics were stable; (5) no diagnosis of pneumonia, deep venous thrombosis, urinary infection, wound problem, and bedsore when admitted to the hospital; (6) be able to communicate face to face normally; and (7) undergoing the orthopedic surgery for the first time.

Exclusion criteria consisted of failure to complete the consent forms, giving up the study, and inability to participate in all the educational sessions with varying degrees of disturbance of consciousness and mental changes.

Table 1: Baseline characteristics of patients in the two groups.

	Variables	Exp.	Con.	P value
Gender	M.	24	27	0.551
	F.	41	38	
Age		77.6 ± 4.8	76.6 ± 4.1	0.197
BMI		23.9 ± 2.9	24.1 ± 3.6	0.120
Fracture type	Neck.	30	29	0.878
	Inter.	35	36	

Exp., experiment group; Cont., control group; M., male; F., female; BMI, body mass index; Neck., femoral neck fractures; Inter., femoral intertrochanteric fractures.

2.3. Instrument Design. Data collection tool was a valid and reliable questionnaire based on Orem's self-care model including visual analogue scale (VAS) and Barthel index. Visual analogue scale is a simple and frequently used method for assessment of variations in intensity of pain. VAS is designed to present to the respondent a rating scale with minimum constraints. Respondents mark the location on the 10-centimeter line corresponding to the amount of pain they experienced. This gives them the greatest freedom to choose their pain's exact intensity. It also gives the maximum opportunity for each respondent to express a personal response style [14]. Barthel index is another tool used in the study (Table 2). The Barthel index is a scale that measures disability or dependence in activities of daily living of patients including ten indices: feeding, bathing, grooming, dressing, bowel control, bladder control, toilet use, transfers, mobility, and stairs. The Barthel index is scored from 0 to 100, with 5-point increments. We considered anyone with a score <100 as having some disability [15]. Barthel index is a very simple tool and can be easily administered by the health care professional [16]. Informed consent was obtained from all patients participating in the study.

2.4. Interventions and Data Collection. Patients were randomly allocated to either the experiment group or the control one. Patients in the experiment group received education, support, and counseling on the basis of Orem's model, while patients in the control group received no intervention except the traditional routine orthopedic nursing care. Once we confirmed the experiment and control groups, we must obtain their consent forms and ensure that no significant difference existed between them in terms of demographic features, and Orem's model-based self-care questionnaires were completely filled. The educational content was prepared based on provided data by the participants and literature reviews. The experiment group received education in self-care based on Orem's model until six weeks after operation. The educational program included oral interpretation, action modeling, and distributing educational package. For different periods of different patients, we developed different nursing plans, including wholly compensatory nursing, partially compensatory nursing, and supportive education, to provide a number of special nursing care interventions. These measures consisted of making an individualized brochure of health education to promote the knowledge of fracture, setting up a schedule for less pain, relieving the patient's

Table 2: Barthel index: rank the patient's independence in the following areas.

Feeding	Independent	10
	Needs help	5
	Unable	0
Bathing	Independent	5
	Unable	0
Grooming	Independent	5
	Unable	0
Dressing	Independent	10
	Needs help	5
	Unable	0
Bowel control	Continent	10
	Occasional accident	5
	Incontinent (or needs to be given enemas)	0
Bladder control	Continent	10
	Occasional accident	5
	Incontinent (catheterized, unable to manage alone)	0
Toilet use	Independent	10
	Needs help	5
	Unable	0
Transfers (bed to chair and back)	Independent	15
	Needs minor help (verbal or physical)	10
	Needs major help (1-2 people, physical), can sit	5
	Unable	0
Mobility on level surfaces	Independent (but may use any aid, e.g., stick), >50 yards	15
	Walks with help of one person (verbal or physical), >50 yards	10
	Wheelchair independent, including corners, >50 yards	5
	Immobile or <50 yards	0
Stairs	Independent	10
	Needs help (verbal, physical, carrying aid)	5
	Unable	0

anxiety by listening and providing mental support, and enhancing the patient's knowledge about the ability to control their discomfort. Educational sessions were held every day during the stay in the hospital, and guiding patients by using telephone was continued after leaving the hospital. Partial specific measures on the base of Orem's model against complications are shown in Table 3. One week and six weeks after surgery, Orem's model-based self-care questionnaires were filled by the two groups, respectively. The data of complications including pneumonia, deep venous thrombosis, urinary infection, wound problem, and bedsore were also collected, and the data were compared.

2.5. Statistical Analysis. Statistical analyses were performed with SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA). All data are presented as mean ± standard deviation (SD). Differences between two groups were examined using an independent samples *t*-test in quantitative data. Chi-square tests were used to compare differences between groups in categorical data. A P value <0.05 was considered statistically significant.

3. Results

In Table 1, the self-care model components in the two groups were compared using independent samples *t*-test or Chi-squared test. As revealed, no significant difference was evident prior to intervention in terms of gender ($P = 0.551$), age ($P = 0.197$), BMI ($P = 0.120$), and fracture type ($P = 0.878$), respectively.

Also, data analysis of one week after operation showed that values of VAS in experiment and control groups were 4.4 ± 1.6 and 4.8 ± 1.9, and Barthel index of the two groups was 47.2 ± 11.9 and 43.4 ± 13.3, respectively (Table 4). The difference of two indicators in the two groups was statistically significant. And six weeks after operation, VAS and Barthel index in the experiment group were 1.9 ± 0.9 and 86.2 ± 12.8, while the control one showed 2.4 ± 1.5 and 81.3 ± 11.9. Mean scores of VAS and Barthel index one week after operation in the experiment group were significantly different from the control one ($P = 0.009$, $P \leq 0.001$, respectively). The changes of VAS and Barthel index six weeks after operation of the two groups were also statistically significant ($P = 0.016$, $P \leq 0.001$) (Table 4).

The patients suffering from pneumonia, deep venous thrombosis, urinary infection, wound problem, and bedsore were 4, 2, 1, 2, 1 and 8, 5, 2, 2, 2 in the experiment and control groups, respectively. There was a statistically significant difference of complications between the two groups (Table 5).

4. Discussion

Femoral neck fractures and intertrochanteric fractures are the most common types of hip fragility fractures, which are related to osteoporosis and have a dramatic influence on the

Table 3: Partial specific measures against complications of wholly compensatory nursing, partially compensatory nursing, and supportive educative nursing in the experiment group.

Against pneumonia	Systematic respiratory function exercise; encouraging deep breathing; effective coughing up phlegm; blowing a balloon or application of breath training devices; sitting up more and earlier; back-patting for sputum excretion; aerosol inhalation.
Against deep venous thrombosis	Counseling and encouraging; observing the swelling and pain of the limbs; replenishing blood volume appropriately such as drinking more water; monitoring clotting function; application of painkillers; anticoagulant drugs; continuous active motion of the lower limbs; physical measures (continuous passive motion; intermittent pneumatic compression; venous foot pump; graduated compression stockings); going to the ground earlier.
Against urinary infection	No catheterization for short operation time; drinking more water; urethral mouth care on time; strict asepsis procedure of catheterization; keeping the catheter unobstructed; bladder function exercise before withdrawal of the catheter; pulling out the catheter as soon as possible; fomenting the lower abdomen.
Against wound problem	Cold compresses; covering wound with dressing completely; keeping wound dressing dry and clean; disinfection completely and changing fresh dressing on time; encouraging a high-protein diet; proper application of antibiotics.
Against bedsore	Antidecubitus mattress; defecation care and keeping clothes and skin clean; changing the position frequently; turnover on time; covering with soft dressing; doing local massage; physical therapy.

Table 4: Comparison of VAS and Barthel index one week and six weeks after operation in both experiment and control groups.

	VAS 1	Barthel 1	VAS 2	Barthel 2
Exp.	4.4 ± 1.6	47.2 ± 11.9	1.9 ± 0.9	86.2 ± 12.8
Con.	4.8 ± 1.9	43.4 ± 13.3	2.4 ± 1.5	81.3 ± 11.9
P value	0.009	≤ 0.001	0.016	≤ 0.001

Exp., experiment group; Cont., control group; VAS 1, VAS of one week after operation; VAS 2, VAS of six weeks after operation; Barthel 1, Barthel index of one week after operation; Barthel 2, Barthel index of six weeks after operation.

Table 5: Comparison of complications in both experiment and control groups.

Complication	Exp.	Con.	P value	X^2
Pneumonia	4	8	0.363	0.826
Deep venous thrombosis	2	5	0.437	0.604
Urinary infection	1	2	—	—
Wound problem	2	2	—	—
Bedsore	1	2	—	—
Total	9	19	0.033	4.552

Exp., experiment group; Cont., control group.

elderly people, and they are associated with excess mortality and morbidity resulting in costly hospital and lengthy rehabilitation procedures. These patients experience considerable difficulties in returning to their prefracture living situation and in achieving full recovery of function [8]. Due to the low life quality of these patients, taking some measures to improve survival quality is quite essential [17]. Orem's self-care theory can help health care providers identify and satisfy patients' self-care needs since it has been proved that self-care could show immeasurable potential and practicability on the theory and practice [13]. With the socialization and familiarization of the current nursing services, self-care is becoming a developing trend nowadays. The patients necessitate long-term self-care skills, so teaching people the knowledge and technology will be a new requirement for nursing. It is required that doctors and nurses should pay attention to cultivating patients' self-care ability, mobilizing their subjective initiative, and promoting patients to take the responsibility of self-care.

The present study is the first to adopt Orem's self-care nursing theory to investigate the effects of educational intervention of aged patients of hip fractures. The traditional orthopedic routine nursing program with many deficiencies does not take into account the self-care ability of patients since nursing measures are dogmatic, and patients are accustomed to passive nursing. As a result, the nursing measures for patients who cannot take care of themselves are not very effective, which are not conducive to the rehabilitation. However, according to the specific patients and disease conditions, the self-care theory dynamically evaluates their self-care ability, adopts different nursing measures, and formulates the self-care model suitable for different individuals and stages. Moreover, nursing at all levels can be valued, and the corresponding compensation measures can be obtained according to their self-care ability. The supportive educational intervention can improve their self-care ability in and out of hospital and obviously affect public health outcomes [13].

The changes of VAS and Barthel index six weeks after operation of the two groups were also statistically significant ($P = 0.016$, $P \leq 0.001$) since patients in the experiment group had higher levels of self-care knowledge, motivation, and skills compared with the control one. All the patients of the experiment group were provided counseling services and began to participate in their nursing decisions from the time of admission. The measures encouraged them and their family members to participate in nursing activities together, mobilized their enthusiasm, explored their self-care potential, and maximized their self-care ability. It enabled the patients to correctly understand the diseases and master relevant self-care knowledge, so as to reduce the occurrence of complications and improve hip function postoperatively.

Also, we made great efforts to enhance the patients' confidence, enabled them to correctly treat and accept the changes in the internal and external environment, and improved the living quality. At the same time, it enhanced the communication and understanding between medical staff and patients and promoted the harmonious development of our relationship. The results showed that designing and implementing a training program based on Orem's theory can be effective in satisfying patients' requirements and improving their life quality.

Partial specific measures according to Orem's theory were formulated and implemented in the experiment group. Detailed nursing interventions were performed which included different measures to prevent pneumonia, deep venous thrombosis, urinary infection, wound problem, and bedsore (Table 3). Wholly compensatory nursing, partially compensatory nursing, and supportive education were implemented depending on the patient's condition. According to our study, compared with the control group, the difference of complications reduced significantly in the experiment group ($P = 0.033$). Complications may occur during as many as 20% of all hospitalizations for hip fractures, and a few postfracture complications are potentially modifiable [18]. Different nursing decisions may influence the care of these frail elders, so high-quality nursing may have less pneumonia and delirium. These complications may be modifiable; nursing is so important to cause marked variations in the incidence such as pneumonia and pressure ulcer. Aggressive preventive measures and skin management strategies might reduce the complications among patients with hip fractures and ultimately lead to improve survival of the vulnerable population [19]. Therefore, educational intervention according to Orem's self-care model seems to be effective in decreasing complications.

Therefore, a comprehensive, well-designed, and appropriate program based on Orem's model can decrease discomfort and complications, improve quality of care, help the patients to reduce dependency, and achieve the optimal health. The Orem-based self-care model program along with routine nursing care can be a useful tool to improve life quality in hip fractures. Thus, medical staff can design and train a self-care program as a part of the therapeutic process and prevent a lot of mental and psychosocial problems [8, 20].

There are limitations remained in this study. First, the sample size was relatively limited, especially the subgroups; a larger sample size might be better to find a significant difference between different groups. Second, despite the selection of variables and data collection tools which was considered and justified based on the extensive literature review, there might have been other important variables or tools which have not been selected for this study. Third, there was also one limitation due to the clinical condition that the follow-up time was not so long, which should be researched in the future.

5. Conclusion

Generally, a self-care program based on Orem's model for elderly patients with hip fractures can improve life quality and reduce perioperative complications significantly. The result was owing to the careful design and implementation of appropriate care measures catering to the needs, interests, individualism, and problems of these patients. An educative and supportive nursing system is feasible and useful in hip fractures. Therefore, designing a self-care nursing program based on Orem's self-care model should be considered to reduce complications and problems closely related to hip fragility fractures.

Data Availability

All data included in this study are available upon request by contacting with the corresponding authors.

Disclosure

Xiaodong Xu and Jun Han are joint first authors.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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