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ORIGINAL RESEARCH

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Clinical efficacy of romosozumab in the treatment of elderly male patients of osteoporotic with hip fractures: a retrospective study

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Abstract

Background: This study aims to evaluate the efficacy and safety of romosozumab in elderly male patients with osteoporosis-associated hip fractures. **Methods**: A retrospective analysis was conducted using medical records from 94 elderly male patients with hip fractures who received treatment at our institution between October 2021 and March 2023. The patients were divided into two groups based on their treatment regimens: the observation group (n = 47) received monthly subcutaneous injections of 210 mg romosozumab for 12 months, and the control group (n = 47) was administered 10 mg of alendronate sodium orally each morning. **Results**: The results showed that the total effective rate was significantly higher in the observation group ($p < 0.05$), with a marginally greater rate of significant effectiveness in the observation group. Post-treatment assessments indicated significantly lower Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores in the observation group than the control group ($p < 0.05$). Bone mineral density (BMD) in the observation group was markedly higher, with significantly reduced levels of osteocalcin (OSC) and bone-specific alkaline phosphatase (BALP) ($p < 0.05$). Quality of life scores improved significantly in the observation group ($p < 0.05$), and there was no significant difference in adverse event incidence between the two groups ($p > 0.05$). Follow-up evaluations at 3, 6 and 12 months revealed that the observation group maintained higher BMD, osteocalcin, procollagen type 1 N-terminal propeptide (P1NP), and C-terminal telopeptide of type 1 collagen (CTx) levels, alongside a reduced incidence of fractures and adverse events compared to the control group ($p < 0.05$). After one year, the fracture healing rate was significantly higher in the observation group ($p < 0.05$). **Conclusions**: These findings suggest that romosozumab provides a substantial therapeutic benefit in elderly male patients with osteoporotic hip fractures, with no notable increase in adverse reactions and favorable follow-up outcomes.

Keywords

Romosozumab; Osteoporosis; Hip fracture

1. Introduction

Osteoporosis is a metabolic disorder characterized by reduced bone mass and deteriorated bone microstructure, commonly observed among elderly males. Clinically, osteoporosis manifests through symptoms such as fatigue, lumbar discomfort and diffuse bone pain, symptoms that mainly impact the aging population [1, 2]. The prevalence of osteoporosis has been increasing in China, underscoring its public health relevance [3]. A serious complication of osteoporosis is hip fracture, which is associated with intense pain, impaired mobility and diminished physical activity, substantially reducing patients' quality of life [4]. In clinical practice, hip fractures are often managed through surgical reduction followed by postoperative pharmacological therapy [5]. However, given the advanced age of many patients, the side effects of pharmacological treatments can be particularly challenging [6]. Presently, the standard management for patients with osteoporotic hip fractures includes a combination of pharmacotherapy, surgical intervention and rehabilitation training [7]. Although these approaches provide certain rehabilitative benefits, their overall efficacy remains limited, especially in high-risk elderly male patients [8]. Therefore, there is an urgent need for exploring new and effective treatment options to improve outcomes in this population.

Despite ongoing research on osteoporotic hip fractures, substantial knowledge gaps remain, particularly regarding gender-specific aspects of the condition. Most studies have focused on female patients, with limited research addressing osteoporotic hip fractures in males, thereby overlooking the distinct clinical

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needs of this demographic [9]. Furthermore, the pathogenesis and treatment responses associated with male osteoporosis are not fully understood, indicating a pressing need for further investigations for novel pharmacological options for this population remain necessary. Romosozumab, a monoclonal antibody targeting sclerostin, represents a promising advancement in osteoporosis treatment [10]. By inhibiting the interaction between sclerostin and low-density lipoprotein receptor-related proteins 5 and 6 (LPR5/6) as well as frizzled proteins, romosozumab enhances the Wnt signaling pathway, which then promotes osteoblast activity and reduces bone resorption [11, 12], contributing to its therapeutic role in reducing fracture risk among osteoporosis patients. However, studies specifically evaluating its efficacy and safety in elderly male patients with osteoporotic hip fractures remain limited. Therefore, targeted research to verify its therapeutic potential and safety in this population is warranted.

Research on romosozumab's effects in elderly male patients with osteoporotic hip fractures is essential due to its dual mechanism in increasing bone density, offering the potential for improved treatment outcomes in this population [13], as it could guide clinical practice and facilitate the development of personalized treatment plans, ultimately enhancing patient outcomes and quality of life. The findings from this study aim to provide foundational data to support larger clinical trials and further research on managing osteoporotic hip fractures in elderly male patients.

The primary objective of this study is to evaluate the clinical efficacy of romosozumab in elderly male osteoporotic hip fracture patients by assessing its clinical significance in improving quality of life, reducing the psychological and economic burdens associated with fractures, and providing scientific evidence to inform clinical decision-making. Additionally, potential risks will be analyzed. Although romosozumab has demonstrated good safety in clinical trials, some side effects and adverse reactions remain, especially in elderly patients [14]. Thus, this study also collects data on adverse events to comprehensively assess the safety of romosozumab in the elderly male population. Given the increased incidence of osteoporosis and hip fractures in older adults, studying this demographic is crucial to understanding the impact of osteoporosis on the health of elderly males [15]. Overall, this research aims to fill existing gaps in the literature on osteoporotic hip fractures in elderly males and to improve our understanding of male osteoporosis. By focusing on elderly male osteoporotic hip fracture patients, this study contributes significantly to the academic and clinical research of the disease, ultimately improving health management and treatment outcomes for this population.

2. Materials and methods

2.1 Patient and general information

Sample size calculation and grouping method:

The sample size was calculated using the formula: $n = \pi_t \times (1 - \pi_t) \times \pi_c \times (1 - \pi_c)/[(\pi_t - \pi_c - \Delta)] \times (\mu_{\alpha/2} + \mu_\beta)^2$.

This retrospective cohort study aimed to evaluate fixed variables as primary efficacy outcome indicators. An equal (1:1) superiority design was applied, with parameters set to $\alpha = 0.025$ (one-sided), $\beta = 0.20$ (one-sided) and $\Delta = 5\%$. Based on these parameters and the primary efficacy outcome indicators, a required sample size of 39 patients per group was determined through public disclosure calculations. Considering a 20% dropout rate, 47 patients were required per group, leading to a total inclusion of 94 patients across both groups. Lastly, the study included 47 patients in the observation group and 47 patients in the control group, who were assigned to their study groups according to the recorded treatment methods they underwent. This study was approved by our hospital's ethics committee.

From existing case records, a retrospective analysis was conducted on the clinical data of 94 male patients diagnosed with osteoporotic hip fracture in our hospital from October 2021 to March 2023. Based on different treatment regimens recorded, the study included 47 patients in the observation group and 47 patients in the control group.

The inclusion criteria for this study required that (1) all patients provided informed consent and were fully aware of the study's purpose and procedures, (2) each patient met the 2020 ESCEO guidelines for osteoporosis [16] and (3) had undergone surgical intervention for hip fracture.

Exclusion criteria included patients with (1) any mental disorders, (2) those with severe dysfunctions affecting the heart, liver or kidneys, (3) had significant endocrine or metabolic disorders, (4) a prior history of glucocorticoid, calcitonin, or other osteoporosis-related treatments or (5) presence of malignant tumors.

2.2 Interventions

As this was a retrospective study, the treatment protocols were obtained from the patients' case records.

Patients in the control group received a daily dose of 10 mg of alendronate sodium, administered orally each morning for a period of 12 months. In contrast, patients in the observation group received monthly subcutaneous injections of 210 mg of romosozumab, also for a duration of 12 months. Romosozumab was administered according to standard subcutaneous injection procedures, as specified in the recorded treatment protocols.

2.3 Primary outcome

The outcome indicators results were retrieved from the patients' records.

2.3.1 Evaluation criteria for curative effect

Curative effects were classified as significantly effective, effective or ineffective. The total effective rate was calculated as follows: Total effective rate = ([Significantly effective + Effective]/total number of cases) × 100%. A treatment was considered significantly effective if the patient experienced no pain or functional impairment, with computed tomography (CT) scans confirming complete fracture healing. An effective outcome was considered if a patient's pain had improved, allowing partial self-care and CT scans showed a blurred fracture line, suggesting healing progression. Ineffective treatment was considered for no significant pain relief, continued difficulty

with self-care, and poor healing on CT review.

2.3.2 Bone mineral density and bone metabolism markers

Bone mineral density (BMD) and bone metabolism markers, including osteocalcin (OSC) and alkaline phosphatase (BALP), were measured before and after treatment. BMD was assessed at the femoral neck using a dual-energy X-ray densitometer. Fasting venous blood samples (5 mL) were collected from all patients before and after treatment in Ethylenediaminetetraacetic Acid (EDTA) anticoagulant tubes. Samples were centrifuged at 3000 RPM for 10 minutes to separate serum, which was then used to measure OSC and BALP levels through enzyme-linked immunosorbent assay (ELISA).

2.3.3 Pain degree and functional activity

Pain levels in both groups were assessed using the Visual Analogue Scale (VAS) [17], which ranges from 0 to 10, with higher scores indicating more intense pain. Functional activity was evaluated using the Oswestry Disability Index (ODI) [18], which ranges from 0 to 50, where higher scores reflect greater disability.

2.3.4 Quality of life

The quality of life for patients in both groups was evaluated before and after treatment using the World Health Organization Quality of Life Brief Questionnaire (WHOQOL-BREF) [19]. The WHOQOL-BREF comprises 26 items distributed across four domains: physical health, psychological health, social relationships and environmental factors. Each item is scored on a Likert scale from 1 to 5, with higher scores indicating a better quality of life and the total possible score being 100 points.

2.3.5 Adverse reactions

Adverse reactions, including vomiting, diarrhea and arrhythmia, were systematically monitored and recorded throughout the study period. Routine follow-ups involved both clinical examinations and patient self-reports to identify any adverse events, such as their type, severity, timing, duration and management. Additionally, laboratory tests, such as blood tests, were regularly conducted to monitor biochemical indicators and detect potential adverse effects. Patients were advised to report any discomfort or unusual symptoms promptly to facilitate the early identification and management of adverse reactions.

2.3.6 Follow-up

The patients were followed for 12 months to evaluate the long-term clinical efficacy and safety of the treatment.

(1) BMD: BMD was assessed at 3, 6 and 12 months post-treatment using dual-energy X-ray absorptiometry (DXA) to monitor changes in bone density over time.

(2) Biochemical Markers: serum biochemical markers were measured to assess bone metabolism. Markers of bone formation (*e.g.*, osteocalcin, P1NP) and bone resorption (*e.g.*, CTx) were analyzed. Blood samples were collected from fasting patients, typically in the morning, and allowed to sit at room temperature before centrifugation to isolate serum. Osteocalcin levels were measured via enzyme-linked immunosorbent assay (ELISA), while P1NP (procollagen type I N-terminal propeptide) levels were quantified using antibodies in colorimetric or fluorescence-based assays. CTx (C-terminal telopeptide of type I collagen) concentrations were determined by ELISA, involving sample dilution, antibody reactions, washing, and substrate addition for color development. Absorbance readings were taken using an ELISA reader (typically a spectrophotometer), and concentrations were calculated from a standard curve.

(3) Fracture Incidence: the occurrence of new fractures during the follow-up period was recorded, including hip, vertebral and other fracture types, to evaluate the effectiveness of romosozumab in fracture prevention.

(4) Adverse Event Incidence: adverse events, particularly cardiovascular events and allergic reactions, were documented throughout the follow-up period to assess the safety profile of romosozumab.

(5) Imaging Evaluation: imaging studies, including X-rays or Magnetic Resonance Imaging (MRI), were performed to evaluate fracture healing status, providing further insights into the treatment's long-term impact.

2.4 Statistical analysis

Data analysis was conducted using SPSS version 22.0 (IBM, Armonk, NY, USA) and GraphPad Prism version 8.0.2 (GraphPad Software, Inc, San Diego, CA, USA). For normally distributed data, the results are expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$). Independent sample t-tests were used to compare differences between groups, while paired t-tests were used for within-group comparisons. For data that did not follow a normal distribution or had unequal variances, the Mann-Whitney U test was applied, with results reported as median (M) and interquartile range (M (P25, P75)). Categorical data are expressed as case counts and percentages (%), with between-group comparisons conducted using chi-square (χ^2) tests or Fisher's exact test as appropriate. Statistical significance was defined as $p < 0.05$.

To account for the multiple outcome measurements (*e.g.*, changes in bone density, fracture incidence), Bonferroni correction or the Holm-Bonferroni method was applied to adjust significance levels across multiple comparisons, thereby controlling the false-positive rate. This approach ensured that the significance level for each outcome was adjusted according to the number of comparisons, thereby reducing the likelihood of Type I errors.

3. Results

3.1 Treatment efficacy

The observation group demonstrated a significantly higher total effective rate compared to the control group ($p < 0.05$). Specifically, the rate of significantly effective outcomes in the observation group exceeded that in the control group, with a marginal difference observed between the groups (Table 1).

TABLE 1. Comparison of clinical efficacy (n (%)).

Groups	n	Significantly effective	Effective	Ineffective	Total effective rate
Control group	47	22 (46.81)	11 (23.40)	14 (29.79)	33 (70.21)
Observation group	47	30 (63.83)	12 (25.53)	5 (10.64)	42 (89.36)
χ^2		2.755	0.058		5.343
p		0.097	0.810		0.021

3.2 VAS score and ODI score

After treatment, the observation group exhibited significantly lower scores in both the VAS and ODI values compared to the control group ($p < 0.05$), indicating improved pain management and functional outcomes (Table 2).

3.3 BMD and bone metabolism markers

Following treatment, patients in the observation group showed a significantly greater increase in BMD compared to the control group. Additionally, the observation group exhibited significantly lower levels of OSC and bone BALP than the control group ($p < 0.05$, Tables 3,4).

3.4 Quality of life

After the intervention, the quality of life scores of patients in the observation group were significantly higher than those in the control group ($p < 0.05$, Table 5).

3.5 Adverse reactions

There was no statistically significant difference in the incidence of adverse reactions between the two groups ($p > 0.05$, Table 6).

3.6 Follow-up

During the follow-up period at 3, 6 and 12 months post-treatment, the observation group exhibited significantly higher levels of BMD, OSC, P1NP, and CTx compared to the control group ($p < 0.05$, Table 7). Additionally, the observation group showed a significantly lower fracture incidence rate and adverse event rate. After one year, the fracture healing rate in the observation group was notably higher than that in the control group ($p < 0.05$, Tables 8,9,10).

TABLE 2. Comparison of VAS score and ODI score ($\bar{x} \pm s$, score).

Groups	n	VAS		ODI	
		Before intervention	After intervention	Before intervention	After intervention
Control group	47	6.40 ± 1.99	3.28 ± 1.16	31.23 ± 4.70	25.74 ± 2.90
Observation group	47	6.32 ± 1.84	2.47 ± 1.00	32.94 ± 5.73	23.11 ± 3.10
t		0.215	3.633	1.575	4.260
p		0.830	<0.001	0.119	<0.001

VAS: Visual Analog Scale; ODI: Oswestry Disability Index.

TABLE 3. Comparison of bone mineral density ($\bar{x} \pm s$).

Groups	n	Before intervention	After intervention
Control group	47	0.620 ± 0.042	0.631 ± 0.034
Observation group	47	0.661 ± 0.043	0.724 ± 0.048
t		0.617	6.829
p		0.163	<0.001

TABLE 4. Comparison of bone metabolic markers ($\bar{x} \pm s$).

Groups	n	OSC (ng/mL)		BALP (ng/mL)	
		Before intervention	After intervention	Before intervention	After intervention
Control group	47	15.59 ± 3.97	12.09 ± 2.69	20.42 ± 5.09	16.34 ± 3.33
Observation group	47	15.10 ± 3.73	10.35 ± 3.10	21.17 ± 4.67	14.06 ± 2.36
t		0.617	2.908	0.748	3.501
p		0.539	0.005	0.456	0.001

OSC: osteocalcin; BALP: bone-specific alkaline phosphatase.

TABLE 5. Comparison of quality of life after intervention ($\bar{x} \pm s$).

Groups	n	Before intervention	After intervention
Control group	47	47.04 ± 6.87	57.21 ± 6.59
Observation group	47	47.55 ± 7.31	70.79 ± 8.94
t		0.349	8.377
p		0.728	<0.001

TABLE 6. Comparison of the incidence of adverse reactions (n (%)).

Groups	n	Vomiting	Diarrhea	Arrhythmia	Total
Control group	47	2 (4.26)	2 (4.26)	1 (2.13)	5 (10.64)
Observation group	47	3 (6.38)	2 (4.26)	3 (6.38)	8 (17.02)
χ^2					0.803
p					0.370

TABLE 7. Comparison of bone density and biochemical indicators ($\bar{x} \pm s$).

Groups	n	BMD (g/cm^3)		
		3 months after treatment	6 months after treatment	12 months after the treatment
Control group	47	0.65 ± 0.03	0.71 ± 0.04	0.79 ± 0.06
Observation group	47	0.76 ± 0.05	0.85 ± 0.08	0.96 ± 0.12
t		12.911	10.065	7.831
p		<0.001	<0.001	<0.001
Groups	n	OSC (ng/mL)		
		3 months after treatment	6 months after treatment	12 months after the treatment
Control group	47	12.25 ± 3.62	18.65 ± 4.37	15.32 ± 3.25
Observation group	47	15.30 ± 3.86	23.08 ± 4.87	20.64 ± 4.02
t		3.959	4.646	7.052
p		<0.001	<0.001	<0.001
Groups	n	P1NP (ng/mL)		
		3 months after treatment	6 months after treatment	12 months after the treatment
Control group	47	25.67 ± 6.89	45.68 ± 10.30	34.60 ± 8.37
Observation group	47	35.40 ± 7.98	55.30 ± 12.57	40.68 ± 9.32
t		6.334	4.060	3.329
p		<0.001	<0.001	0.001
Groups	n	CTx (ng/mL)		
		3 months after treatment	6 months after treatment	12 months after the treatment
Control group	47	0.20 ± 0.03	0.18 ± 0.06	0.15 ± 0.07
Observation group	47	0.45 ± 0.08	0.40 ± 0.10	0.38 ± 0.12
t		18.886	13.602	12.037
p		<0.001	<0.001	<0.001

BMD: bone mineral density; OSC: osteocalcin; P1NP: procollagen type 1 N-terminal propeptide; CTx: C-terminal telopeptide of type 1 collagen.

TABLE 8. Fracture incidence (n (%)).

Groups	n	Fracture of hip	Fracture of vertebral body	Fractures of the other sites	Total
Control group	47	2 (4.26)	4 (8.51)	3 (6.38)	9 (19.15)
Observation group	47	0	1 (2.13)	0	1 (2.13)
χ^2					7.162
p					0.007

TABLE 9. Occurrence of adverse events (n (%)).

Groups	n	Cardiovascular events	Anaphylactic reaction	Joint pain and muscle pain	Necrosis of the jaw	Upper gastrointestinal adverse reactions	Total
Control group	47	1 (2.13)	1 (2.13)	4 (8.51)	2 (4.26)	1 (2.13)	9 (19.15)
Observation group	47	1 (2.13)	0	1 (2.13)	0	0	2 (4.26)
χ^2							5.045
p							0.025

TABLE 10. Rate of fracture healing (n (%)).

Groups	n	Complete healing	Healing poor
Control group	47	39 (82.98)	8 (17.02)
Observation group	47	45 (95.74)	2 (4.26)
χ^2		4.029	
p		0.045	

4. Discussion

Bone calcium loss and absorption disorders are prevalent among patients with osteoporosis, and severe cases can lead to microstructural bone damage and traumatic fractures, with the hip being a common site of injury [20]. Osteoporosis substantially diminishes the quality of life, particularly among elderly males, by impairing overall body function and reducing organ capacity, which further compromises bone calcium absorption, accelerates bone loss, increases fracture risk and delays the healing process [21].

Currently, alendronate sodium is widely used in clinical practice for osteoporosis management [22]. As a bone metabolism regulator, alendronate has a high affinity for hydroxyapatite in bone tissue, where it is gradually released. By inhibiting osteoclast activity, alendronate helps prevent further bone loss and reduces the risk of vertebral compression fractures [23]. However, alendronate sodium is associated with gastrointestinal side effects, including diarrhea, abdominal pain, nausea and vomiting, which may limit tolerability for some patients [24]. In severe cases, it can cause esophagitis and digestive tract ulcers, adversely affecting patient quality of life and adherence to treatment [25]. In 2019, the US Food and Drug Administration approved romosozumab, a humanized monoclonal antibody, for osteoporosis treatment in postmenopausal women [26]. Clinical studies have demonstrated that romosozumab promotes bone formation while inhibiting bone resorption, effectively reducing fracture rates in osteoporosis patients across multiple trials [27]. Additionally, romosozumab has been shown to enhance bone density and is now prescribed in several countries for patients at high risk of fractures.

Our study found that the therapeutic efficacy of romosozumab was significantly greater than that of alendronate sodium. Patients in the observation group exhibited marked increases in BMD, significant reductions in bone metabolic markers, and substantial improvements in both VAS and ODI scores. These findings suggest that romosozumab exerts a robust effect on osteoporotic hip fractures, aligning with the results of most clinical studies [28, 29]. Furthermore, romosozumab was associated with significant improvements in patients' quality of life. However, romosozumab also demonstrated some adverse effects, which included allergic reactions, injection-site redness and edema, and joint pain [30]. There is also evidence linking romosozumab to an increased risk of cardiovascular events [31]. Despite these safety concerns, the overall safety profile of romosozumab appears acceptable, with only a slight increase in adverse events compared to the control group.

Romosozumab, a monoclonal antibody used to treat osteoporosis, primarily functions by inhibiting bone resorption and promoting bone formation, resulting in increased BMD [32]. While romosozumab has demonstrated substantial benefits in increasing BMD and reducing fracture risk, clinical trials have reported an associated increase in the risk of Cardiovascular Events (CVEs), including myocardial infarction, cardiovascular death and stroke, among other related conditions [33]. Several mechanisms may explain this elevated cardiovascular risk. First, romosozumab works by inhibiting sclerostin, a protein that suppresses bone formation. This inhibition activates

the Wnt signaling pathway, which enhances bone formation and inhibits bone resorption. However, research has shown that the Wnt signaling pathway also plays an essential role in cardiovascular health, potentially influencing myocardial cell function and endothelial cell integrity, both of which are essential for cardiovascular stability [34]. Another potential mechanism involves calcium metabolism. Romosozumab may impact blood calcium levels, which could be associated with cardiovascular risk. Elevated calcium levels or hypercalcemia, can lead to vascular calcification, a condition that may increase susceptibility to cardiovascular events [35]. Moreover, many patients receiving romosozumab are elderly and often have comorbidities such as diabetes and hypertension, conditions that independently heighten cardiovascular risk. Additionally, patients with a history of cardiovascular disease may face an even higher risk of CVEs when undergoing treatment with romosozumab, as pre-existing cardiovascular issues may exacerbate adverse effects. Lastly, romosozumab may interact with other medications commonly taken by elderly patients, potentially adversely affecting cardiovascular health.

To minimize potential cardiovascular risks associated with romosozumab treatment, comprehensive cardiovascular risk assessments should be conducted prior to initiation, followed by regular monitoring throughout treatment. Encouraging patients to adopt a healthy lifestyle, alongside careful management of concomitant medications and heightened awareness of cardiovascular events, can further reduce the risk of complications and enhance patient safety. In addition to cardiovascular concerns, romosozumab may induce other adverse effects, including allergic reactions such as urticaria, itching and rashes, as well as injection site pain, redness, and itching. Patients may also experience headaches, joint pain, and muscle pain, all of which should be promptly managed by healthcare professionals.

Retrospective studies, which rely on existing records rather than prospectively gathered data, offer several advantages. They are generally cost-effective, as they utilize pre-existing data, making them less expensive than randomized controlled trials (RCTs). Additionally, they are time-efficient, as outcomes can be assessed more rapidly without the need to wait for events such as disease progression or treatment response. Retrospective studies are also well-suited for examining rare diseases, where sufficient case numbers can be accumulated more easily than in prospective studies.

However, retrospective studies are vulnerable to several biases. Recall bias may arise due to reliance on medical records or patient recollections, which may omit or inaccurately capture details, potentially compromising result accuracy. Selection bias can occur if the sample is unrepresentative, particularly if selection criteria are inconsistent or limited to a single data source, such as a single hospital, which may reduce generalizability. Information bias may be introduced due to variability in the quality of medical record-keeping, impacting the accuracy of outcomes. Additionally, confounding bias is a limitation, as retrospective studies lack the ability to control for confounding variables through random assignment, potentially distorting true associations.

In contrast, RCTs offer distinct advantages. Randomization minimizes confounding bias by assigning participants randomly, and the standardization of data collection and interventions enhances the reliability and accuracy of results.

However, RCTs also face limitations, including high costs and extended timelines, making them generally more expensive and time-consuming than retrospective studies. RCTs are also bound by stringent ethical and practical requirements, which may restrict their feasibility, particularly when studying harmful factors.

While retrospective studies can yield valuable preliminary insights, it is essential to recognize their limitations and inherent biases, especially in comparison with prospective studies or RCTs. Findings from retrospective studies should be interpreted cautiously, particularly regarding causality and generalizability, and acknowledging and discussing these biases can enhance the transparency of the research and assist other researchers in understanding the scope and applicability of the findings.

5. Conclusions

In summary, romosozumab has shown favorable therapeutic efficacy in middle-aged and elderly patients with osteoporotic hip fractures, positioning it as a promising treatment option for this population.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

YCJ and FZ—designed the study and carried them out, analyzed the data, interpreted the data, prepared the manuscript for publication and reviewed the draft of the manuscript. YCJ—supervised the data collection. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of the Fourth Affiliated Hospital of Soochow University (Suzhou Dushu Lake Hospital) (Approval no. 2020-062). Written informed consent was obtained from a legally authorized representative for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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