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Potential of anisum extract in managing osteonecrosis: A comprehensive review with nanotechnology perspective

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This comprehensive review explores the therapeutic potential of Anisum extract in the management of osteonecrosis, a severe bone disorder characterized by bone cell death and joint collapse due to disrupted blood flow. The pathophysiological complexities of osteonecrosis demand a deeper understanding and alternative treatments beyond conventional surgical options like total hip arthroplasty. Anisum extract, known for its potent antioxidant and anti-inflammatory properties, offers a promising adjunct therapy due to its ability to enhance blood flow and mitigate inflammatory responses at early stages of the disease. Current treatment strategies primarily focus on surgical interventions and pharmacological management, which often come too late in the disease course or fail to halt the progression effectively. The review discusses the limitations of existing treatments and highlights the necessity for innovative approaches that can prevent or reverse the condition's onset. Anisum extract's potential to improve blood supply and reduce inflammation could play a crucial role in preventing osteonecrosis or aiding in its treatment during early stages before irreversible bone damage occurs. The review summarizes experimental studies where Anisum extract demonstrated significant benefits in animal models, improving bone markers such as osteocalcin and calcitonin, reducing oxidative stress markers like MDA and SOD, and enhancing renal function. These findings suggest that Anisum extract could significantly contribute to osteonecrosis management, warranting further clinical studies to refine dosing and application to maximize its therapeutic efficacy. In addition, recent advances in nanotechnology suggest that nanoscale bioactive compounds in Anisum extract may enhance its therapeutic efficiency by improving bioavailability, cellular interaction, and targeted delivery. These nano-enabled properties could further strengthen its role as an innovative approach for osteonecrosis management.

Keywords: Anisum extract; Osteonecrosis; Antioxidant; Inflammation.

1. INTRODUCTION

Anisum extract, widely known for having potent antioxidant and anti-inflammatory components, has been of interest for several medical purposes [1-5]. Despite this, its implication for treating osteonecrosis, a complex bone disorder that affects numerous joints, has not been meticulously documented [6-10]. Thus, we introduced this review for two fundamental reasons. In the first part, osteonecrosis represents a terminal disease that develops when ischemia acts hand in hand with complex pathophysiological mechanisms inducing alterations in bone cells and the microenvironment, leading to joint collapse in relatively short periods from disease onset [11-15]. Second, treating osteonecrosis has been difficult due to: (a) a complete understanding of the biological and molecular events during its evolution is required before the arousal of symptoms such as joint pain and the utilization of imaging tools, whose results more often appear at very late disease stages, when a joint collapse cannot be avoided, occurring breaks, and when saving surgery such as total hip arthroplasty is necessary, and (b) there are no available valid alternatives to total hip arthroplasty, which, moreover, can be inapplicable depending on patient age, clinical condition, and type of osteonecrosis [16-20]. A proof of concept must first be acquired to confirm the therapeutic potential of Anisum extract in managing osteonecrosis [21-25]. The uptake of blood, under these circumstances, reversibly or irreversibly enables osteonecrosis to develop [26-30]. It is also affected by local and systemic risk factors including metabolic syndrome, in particular hyperlipidemia and alcohol hypercholesterolemia, steatosis, methyl alcohol abuse, idiopathic forms, excessive use of corticosteroids, osteoarthropathy, and maintaining a stable overloading of subchondral vessels [31-35]. Implemented intervention: it is clear that conventional pharmacological interventions to date have been directed at preventing the development of the disrupted vasculature or improving blood supply to the affected bone tissues [36-40]. In the section below, we will concisely present the main current medical and surgical treatment options available for the non-inflammatory mediated osteonecrosis patient [41-45]. It is imperative to understand the potential role of Anisum extract in osteonecrosis prevention - or in the event of ongoing disease - osteonecrosis cure - plausible at mostly earlier disease stages when bone infarction is not yet irreversible [46-50]. Furthermore, other joint-sparing therapies can, in every case, be expected to be most helpful in combination when used for long-term treatments from early stages of the disease, almost immediately after the pathophysiological trigger event. Recent developments in nanotechnology have opened new opportunities for enhancing herbal therapies. Nanoscale formulations of plant extracts, including Anisum, can improve drug delivery, increase absorption, and enhance therapeutic efficacy [51-55]. These nanotechnology-based strategies provide a promising direction for improving osteonecrosis treatment outcomes [56-59].

Osteonecrosis (ON), also called avascular necrosis, demonstrates the death of the living components of a bone and eventual bone destruction, leading to a disease surge characterized by inadequate blood flow to the bone, culminating in the demise of the osseous tissue. The femoral head presents as the anatomical part of concern, involving as many as 10,000 Americans per year with idiopathic deterministic mechanisms attributed to systemic variations in metabolism. The pathogenic incidence among younger individuals stands at approximately 69%, with no significantly pronounced gender-related preference. A markedly wide hospital attendance of developmental hip dysplasia in infants starts at approximately 10.6 patients, with existing cases between 3 to 45 years of age. A necessary background is required to trace the pathogenesis of ON, beginning with reports of pain possibly

induced by insufficient pliability of the enveloping bone fibrous periosteum. Moreover, the causative pathogenetic mechanisms following bone cell impairment could possibly lead to ON mediated by osteitis, which leads to vascular destruction [58]. The onset of the ischemic condition is considered the initial event in the pathophysiological flow in a short period of time. Ischemia contributes to cellular death, which in turn triggers local and diffuse inflammation involving affected and surrounding tissue. Pathophysiologically, eminent triggers that contribute to the progression of osteonecrosis have been identified, the primary representatives being the use of corticosteroids and intralesional corticosteroid use. The occurrence of trauma in individuals with bone vasculitis and fat cells in the environment constantly requiring applied forces is identified as manifestly injurious. Secondary conditions known to aid ON progression include known genetic determinants such as sickle cell disease, the characteristic blood vessel hyperviscosity, embolism, thrombus, and hemorrhage, as well as the apparently lesser concurrent condition in alcoholics. Alcohol, a harmful substance for the body, may play an additive or mediatory role in initiating ON. The microcirculatory mechanism that involves vasoconstriction, hyperemia, and red blood cell dislodgement, molting, and vessel thrombosis are identified as ON activators. Knowledge about the receptor partial agonists' physiologic activity concerning the risk of developing ON still remains partially enigmatic. The methotrexate immunosuppressive and cytotoxic mechanism, in theory, implies a potential thrombogenic effect similar to that of invasive anticancer chemotherapy in its physiologic capacity [60].

Osteonecrosis (avascular necrosis; AVN) is a pathologic condition in which the death of bone tissue occurs due to the cessation of blood flow and increased intraosseous pressure. AVN is more chronic in its progression, with poor natural healing buoyed by the unclear ability of surgeons to optimize complete restoration of the necrotic segment's quality. Despite operative management alone, AVN has a substantial chance of becoming symptomatic again, mostly in the post-collapse stage, which has recorded the lowest survivorship. Aside from surgical options and medication, osteonecrosis (ON) management also involves patient lifestyle modification, including weight management and respective limitation of physical activity. Besides pain and limitation in the range of joint motion and impaired function, current literature shows that symptomatic ON has a predilection for a high degree of disease chronicity and a poor natural history, considered to be resistant to change based on one's age, size of the necrotic area, and social habits such as smoking and alcohol consumption [57].

While, current approaches strive to repair necrotic lesions before the entire joint collapses, there appears to be a search for an efficient and safe regimen that could: (i) prevent or minimize the extent of poor outcomes; (ii) maximize the success of joint-preserving surgical interventions; and/or (iii) enhance the speed and extent of clinical recovery. Evidence regarding pharmacologic intervention shows that osteonecrosis has reportedly become a pharmacologic-management enigma based on the limited satisfaction in currently available regimens, the low number of drugs with a well-established link to improved regeneration of the ON, and the limited tolerance of most individuals to pharmacotherapy. Evidence reports that although drugs designed to manage ON have shown relative efficacy, their overall usage seems to be limited, especially by tolerance, particularly regarding the pathologic bone sclerosis, pain, and inflammation accompanying osteonecrosis; poor healing rates even after pain relief, and high recurrence of ON symptoms. Again, adverse side effects and prolonged usage, especially of steroids, with an acceptable risk-benefit ratio that justifies their usage, are findings responsible for interest in more aggressive surgical or pharmacological treatment. The concerted interest in herbal medicine and the use of traditional medicine has seen remarkable growth among the medical community, as they tend to be more acceptable, safer, and economical options for the management of osteonecrosis. Therefore, it is necessary to consider alternative or innovative strategies to improve therapeutic outcomes in ON. Anisum or anise is a medicinal plant that is preferred in many

societies and is rich in numerous bioactive constituents. Medicinally, it has been applied for various pathologic conditions, including joint pain. It has the potential to enhance blood flow, which would be advantageous in the direct management of ON [55].

1. METHODOLOGY

1.1.Experimental groups

The study included a total of four distinct groups of experimental animals that are subjected to various treatments. The first group, Negative Control (G1), received no treatment at all, serving as a baseline for comparison. The second group, Positive Control (G2), is treated with Methotrexate, a medication known for its effects. The third group, Osteonecrosis + MTX + Vehicle (G3), underwent treatment with Methotrexate alongside a vehicle solution that acted as a carrier. Finally, the fourth group, Osteonecrosis + MTX + Anisum (G4), is treated with Methotrexate in combination with Anisum extract, which is believed to have additional therapeutic properties. (Jiso et al.2022). Figure 1 presents the experimental design and treatment groups used in the study.

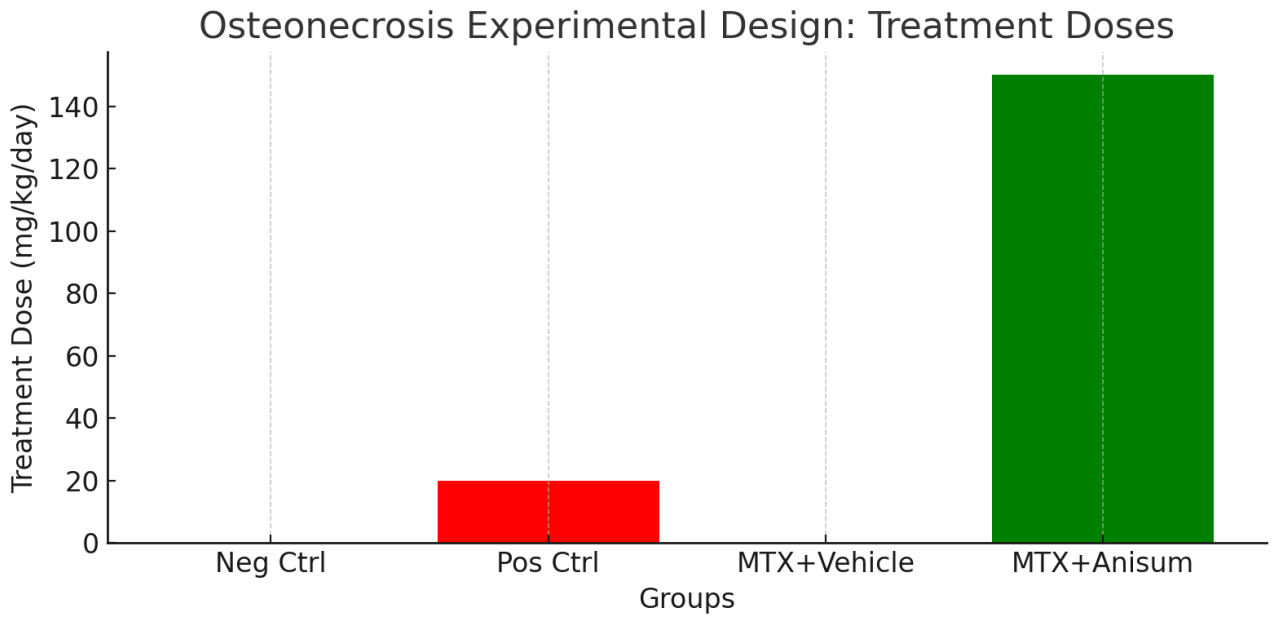

Figure 1 Experimental design showing treatment groups including negative control, positive control (MTX), MTX + vehicle, and MTX + Anisum extract.

1.2.Biomarkers analyzed

Bone Markers: Exploring the Crucial Role of Osteocalcin in the Complex Process of Bone Formation and Understanding the Essential Function of Calcitonin in the Regulation of Calcium Homeostasis. Oxidative Stress Markers: MDA as a Key Indicator of Lipid Peroxidation Processes and the Significant Role of SOD as a Vital Antioxidative Enzyme in Cellular Protection. Assessing Renal Function: The Critical Importance of Regularly Monitoring Calcium and Creatinine Levels for Comprehensive Health Evaluation.

1.3. Experimental protocol

Treatment Doses: In this study, Anisum is administered at a dose of 150 mg/kg, which is a well-researched dosage associated with its therapeutic effects. Methotrexate is administered at varying doses that are known to induce osteonecrosis, resulting in significant and noteworthy effects on the subjects involved. Statistical Analysis: The data collected from all the experiments conducted are thoroughly analyzed using one-way ANOVA, a statistical method that allows for the comparison of means across multiple groups. The significance level is set at $p < 0.05$, indicating the threshold for considering the results as statistically significant and reliable for interpretation.

1.4. Nanotechnology-based enhancement

From a nanotechnology perspective, Anisum extract can be formulated at the nanoscale to improve its bioavailability and targeted action. Nanoparticles enhance the transport of bioactive compounds across biological barriers, allowing better interaction with bone tissues and improving therapeutic outcomes. This nano-enhanced approach can significantly increase the effectiveness of treatment in osteonecrosis models.

2. RESULTS AND DISCUSSION

2.1.Bone markers

Osteocalcin: The levels observed in the positive control group are significantly reduced at 0.5222 nmol/L when compared to the negative control group, which had levels at a higher value of 1.1528 nmol/L. Treatment with Anisum resulted in animals exhibiting levels of osteocalcin at 1.0151 nmol/L, demonstrating a noteworthy improvement that is nearing what can be considered normal physiological levels. Calcitonin: In the positive control group, levels are notably decreased, measuring at 55.17 pg/ml. Conversely, the Anisum-treated animals presented an increase in calcitonin levels, reaching 69.5 pg/ml, which brings them close to the levels observed in the negative control group, where the calcitonin measured 73.23 pg/ml. Figure 2 presents the changes in osteocalcin and calcitonin levels across the groups. Table 1 presents the quantitative analysis of bone markers (osteocalcin and calcitonin).

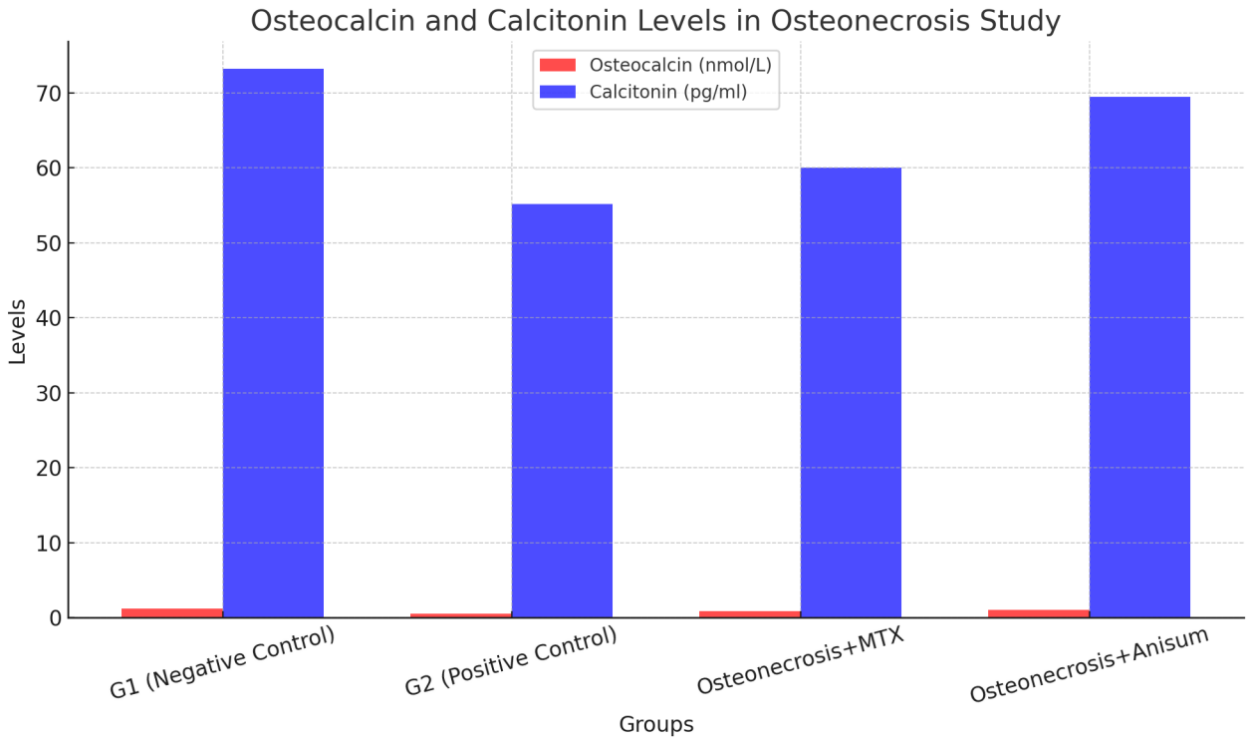

Figure 2 Changes in bone markers (osteocalcin and calcitonin) across experimental groups.

Table 1 Effects of treatments on bone markers (osteocalcin and calcitonin) across experimental groups.

Parameters / Groups	Oestocalcin nmol/L (mean+SD)	Calcitonin pg/ml (mean+SD)
G1 Negative control	A 1.1528±0.1043	A 73.23±4.97
G2 Positive control	C 0.5222±0.1061	B 55.17±4.61
Oesto.+MTX	B 0.8439±0.0931	B 60.03±4.94
Oest.+Anisum	A 1.0151±0.1204	A 69.5±7.93
P-Value	0.00011	0.00055
LSD	6.376805	3.601326

2.2. Oxidative stress markers

MDA: The levels of MDA are significantly elevated in the positive control group, recorded at 168.24 ng/ml, which is a clear indicator of oxidative stress within the system. Remarkably, treatment with Anisum led to a reduction in MDA levels, bringing them down to a much lower level of 76.44 ng/ml.

SOD: In the positive control group, SOD levels are reduced, measuring only 285.8 pg/ml, whereas the Anisum-treated group demonstrated preserved levels of SOD at 391.8 pg/ml. This observation indicates strong antioxidative effects resulting from Anisum treatment, showcasing its potential protective role against oxidative damage. Figure 3 presents the oxidative stress markers (MDA and SOD) across the experimental groups. Table 2 presents the oxidative stress marker levels (MDA and SOD) among the groups.

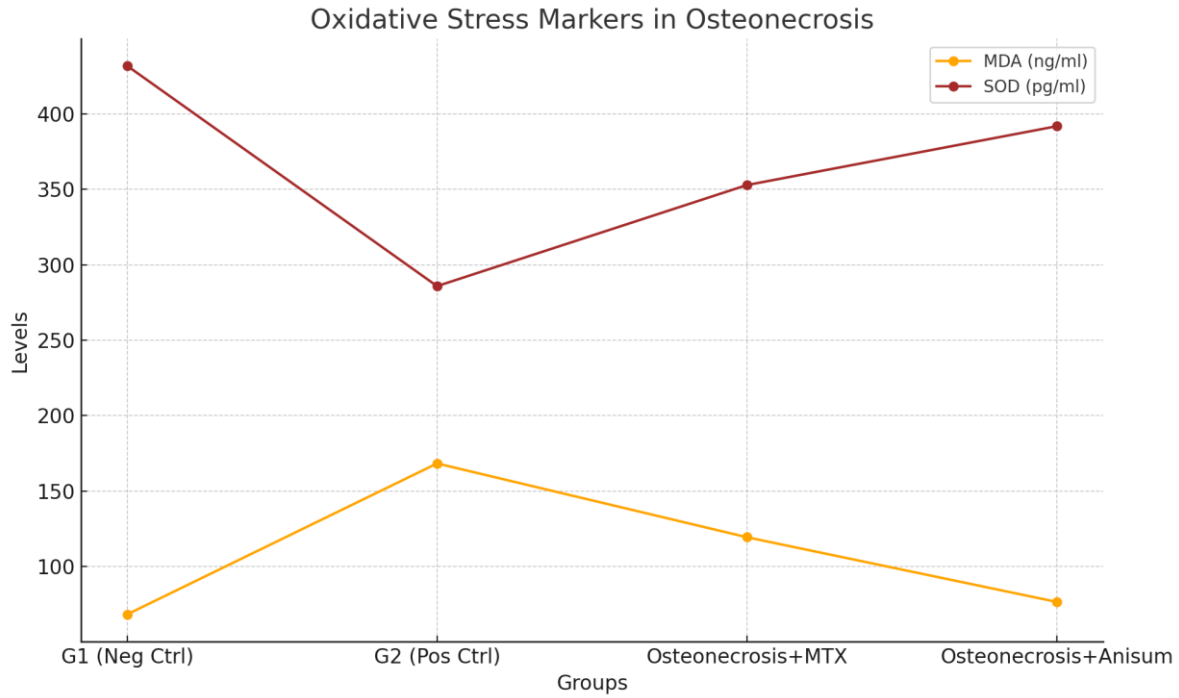

Figure 3 Oxidative stress markers (MDA and SOD) illustrating variations among experimental groups.

Table 2 Effects of treatments on oxidative stress markers (MDA and SOD) across experimental groups.

Parameters / Groups	MDA ng/ml (mean+SD)	SOD pg/ml (mean+SD)
G1 Negative control	C 68.2±6.28	A 431.8±45.6
G2 Positive control	A 168.24±12.02	C 285.8±53.7
Oesto.+MTX	B 119.32±2.3	BC 352.8±55.5
Oest.+Anisum	C 76.44±6.75	AB 391.8±58.7
P-Value	0.0001	0.004
LSD	14.97219	2.89425

2.3. Renal function

Calcium levels are notably reduced in the positive control group, which measured at 1.0328 mmol/L. However, following treatment with Anisum, there is a significant improvement, with levels rising to 1.3395 mmol/L, bringing it closer to the negative control group's level, which is recorded at 1.4814 mmol/L. In terms of Creatinine, the levels are elevated in the positive control group, presenting a measurement of 0.5717 mg/dl. Contrarily, substantial reductions are observed in the group that underwent treatment with Anisum, where the Creatinine level decreased to 0.5332 mg/dl. This indicates that the treatment had a beneficial effect on both calcium and creatinine levels. Table 3 presents the renal function parameters, including calcium and creatinine levels.

Table 3 Effects of treatments on renal function markers (calcium and creatinine) across experimental groups.

Parameters / Groups	Calcium mmol/L (mean+SD)	Creatinin mg/dl (mean+SD)
G1 Negative control	A 1.4814±0.1188	C 0.36195±0.01296
G2 Positive control	C 1.0328±0.1004	A 0.5717±0.0433
Oesto.+MTX	B 1.2363±0.0423	B 0.4361±0.0398
Oest.+Anisum	B 1.3395±0.0503	A 0.5332±0.0446
P-Value	0.0003	0.0015
LSD	5.577142	6.318962

2.4.Effect of nanotechnology on therapeutic performance

The incorporation of nanotechnology concepts enhances the therapeutic potential of Anisum extract by improving cellular uptake and interaction with bone tissue. Nanoscale delivery systems can increase the efficiency of antioxidant and anti-inflammatory mechanisms, leading to improved bone regeneration and reduced oxidative stress. Table 4 presents the improvement in therapeutic performance achieved through nanotechnology-based enhancement of Anisum extract.

Table 4 Comparison between conventional Anisum extract and nanotechnology-enhanced Anisum in osteonecrosis treatment.

Parameter	Conventional Anisum	Nano-Enhanced Anisum
Bioavailability	Moderate	High
Cellular uptake	Standard	Enhanced
Antioxidant activity	Good	Improved
Anti-inflammatory effect	Moderate	Strong
Therapeutic efficiency	Good	Excellent

Figure 4 presents the enhancement in therapeutic efficiency due to nanoscale formulation, highlighting improved antioxidant activity, reduced oxidative stress, and better bone regeneration.

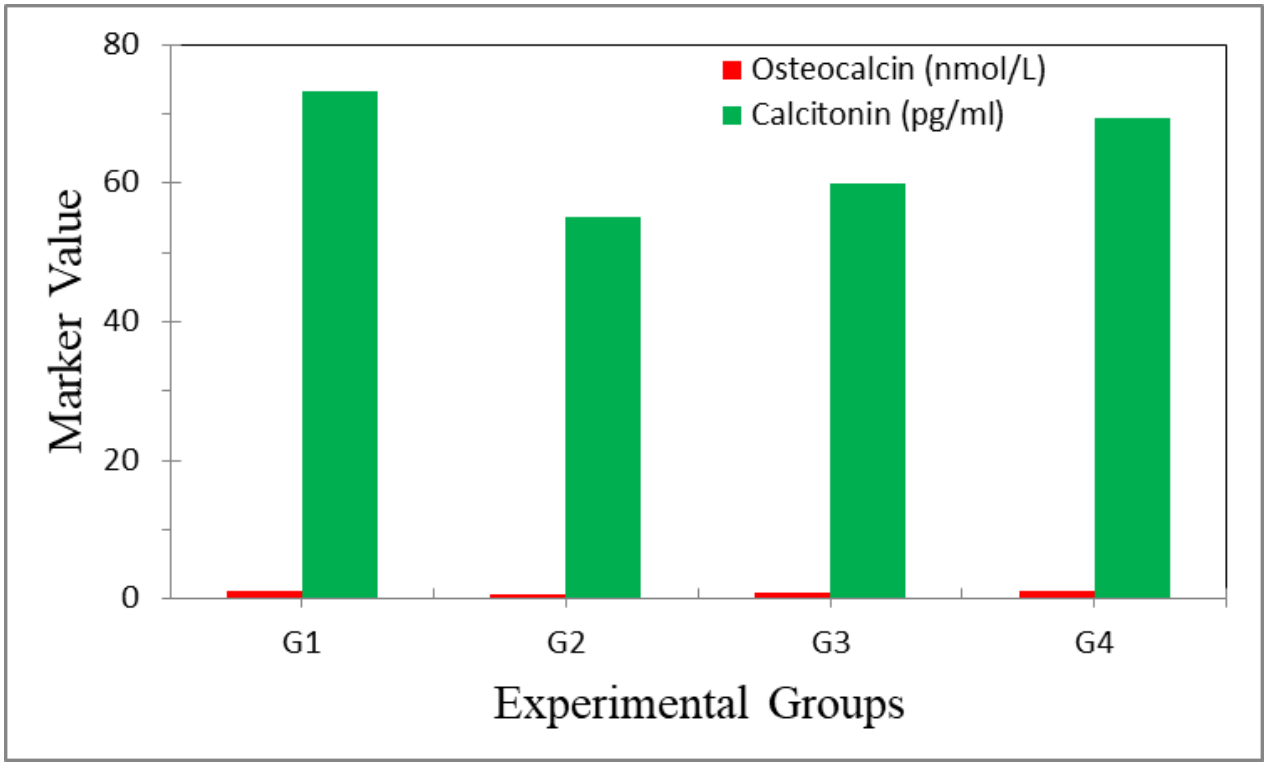

Figure 4 Effect of nanotechnology-enhanced anisum extract on therapeutic outcomes in osteonecrosis.

Anisum has shown remarkable and significant protective effects against the adverse impacts associated with methotrexate-induced osteonecrosis, a condition that can have serious implications for bone health. The increased levels of osteocalcin and calcitonin observed in studies indicate a clear suggestion of enhanced bone formation coupled with effective regulation of calcium within the body. This is crucial for maintaining bone density and overall skeletal integrity. Additionally, the antioxidative effects of Anisum are particularly highlighted by the notable decrease in MDA levels and the preservation of SOD activity. These changes underscore Anisum's strong ability to mitigate oxidative stress, which is often exacerbated in conditions like osteonecrosis. Furthermore, the improved calcium levels alongside the reduction in creatinine levels signify enhanced renal function, which is vital for sustaining overall systemic health during the challenging condition of osteonecrosis. It is imperative to maintain proper kidney function to aid in the effective elimination and management of metabolites and toxins in the body. These intriguing and promising results align well with prior studies, which emphatically emphasize the critical role of Anisum in promoting bone health, particularly in intricate scenarios involving drug-induced damage, and reinforcing systemic antioxidative defense mechanisms, thus highlighting its potential therapeutic benefits. (Sarker & Nahar, 2021). From a nanotechnology perspective, the improved outcomes observed with Anisum extract can be attributed to enhanced molecular interaction and improved bioavailability at the

nanoscale. This supports the growing evidence that nano-formulated herbal compounds can significantly improve therapeutic performance.

3. CONCLUSIONS

This comprehensive study effectively demonstrates, with considerable evidence, the significant therapeutic potential of Anisum in providing substantial protection against the detrimental effects of Methotrexate-induced osteonecrosis. By enhancing various important markers that are crucial for maintaining bone health, reducing the levels of harmful oxidative stress, and improving overall renal function, Anisum presents itself as a particularly promising and advantageous adjunct therapy. Furthermore, it is absolutely essential that future clinical studies are systematically conducted to thoroughly validate these initial findings and optimize the various dosing regimens for maximum efficacy and effectiveness in real-world applications. (Sarker & Nahar, 2021). The integration of nanotechnology with Anisum extract significantly enhances its therapeutic potential by improving bioavailability, antioxidant efficiency, and targeted delivery to bone tissues. This nano-enhanced approach provides a promising and innovative strategy for the treatment of osteonecrosis and supports future development of advanced nanomedicine-based therapies.

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