



Osteoporosis: Overview of Disease and the Current Market

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Abstract

Osteoporosis is a chronic metabolic bone disease that is projected to grow in both diagnosis and market size as the global age rises. It is defined as any significant loss in bone mass that can lead to higher fracture risk and morbidity among patients. Current diagnostic standards use fracture risk assessments tools and x-ray absorptiometry to determine a patient's risk profile. Healthy lifestyle choices such as regular exercise and dieting can limit a person's risk of osteoporosis. 90% of all bone growth occurs during infancy and puberty, creating a driving importance in developing healthy habits early. Primary and secondary osteoporosis are defined by their causes with primary osteoporosis being a result of aging or menopause while secondary osteoporosis is a wider categorization that holds all other osteoporosis causes. Because osteoporosis risk rises with age, the global market CAGR is expected to rise between 2025 to 2034 globally. North American, Asian-Pacific, and European markets are all expected to rise following this trend due to both the global population age averages increasing as well as favorable regulatory policies and awareness campaigns. Drugs are the current dominant product on the market, but research looks to new tissue engineering solutions both as drug delivery scaffolds and repair grafts.

Keywords: Osteoporosis; Disease Market; Tissue Engineering; Market Analysis

Abbreviation

CAGR: Compound Annual Growth Rate.

Introduction

Osteoporosis is the most common chronic metabolic bone disease which occurs in an estimated 200 million people globally [1]. It can affect a wide range of ages and races though it is more prevalent in older women [1]. Early detection of osteoporosis is difficult as most manifestations are undetected until a fracture occurs, making the disease clinically silent until it has already progressed [2]. Osteoporosis is defined by a systemic impairment of bone mass and architecture that results in fragility [3]. This

impairment is caused by a signaling miscommunication between osteoclasts and osteoclasts which results in a net bone density loss [1]. This bone density loss can then lead to future fractures and lead to a drop in mobility and the quality of life [3]. Other factors such as age, low body-mass index, a family history of fractures, as well as specific risk factors like the use of glucocorticoids lead to osteoporosis related fractures [1]. Treatments for osteoporosis include but are not limited to calcium and vitamin D supplements, balance and exercise programs, and vertebroplasty and kyphoplasty [2]. More novel though fewer common techniques for treating more advanced states of the bone disease include the use of autologous bone grafts [4]. Tools such as the fracture-risk

assessment tool (FRAX) evaluate an individual's 10 year-risk of sustaining a hip fracture or other major osteoporotic fractures based on bone-mineral density information taken with a dual x-ray absorptiometry [3]. Evaluating an individual's risk profile is an important step in modulating their treatment [3]. It is expected that cases of osteoporosis will rise across several countries as an aging population and longer lifespan heighten this epidemic [1]. Therefore, this review analyzes current osteoporosis market trends, existing products and therapies, and concludes with preclinical trials and studies.

Healthy tissue

Bone is a connective tissue that is among the hardest tissues in the body [27]. Healthy bones are maintained by a balance of bone-forming cells, osteoblasts, and bone degradation cells, osteoclasts, which play important roles in determining bone growth [27]. This bone growth can be further moderated by a combination of environmental and genetic factors including but not limited to hormonal effects, diet, and mechanical factors [28]. Lifestyle choices that can promote healthy bones include eating a well-balanced diet including calcium and vitamin D, exercising regularly, and avoiding smoking and excessive alcohol use [30]. It is important that these factors be taken into consideration early because 90% of peak bone mass density is determined by the age of 18 [31]. The highest rates of bone formation occur during early infancy and puberty during which healthy bones are either established or compromised [31].

Diving deeper into bone formation, different cell lineages will contribute to different parts of the mammalian skeleton [29]. The initiation of skeletogenesis begins with the migration of mesenchymal cells derived from those lineages (neural crest cells, prechordal mesodermal cells, and paraxial mesoderm cells) to sites of future bones [29]. From there, they can differentiate into chondrocytes or osteoblasts [29]. Differentiation into chondrocytes results in a process known as endochondral bone formation whereas differentiation into osteoblasts will begin intramembranous bone formation [29].

Endochondral bone formation

Chondrocytes will form cartilage models of the future bones while osteoblasts will contribute directly to bone formation [29]. The replacement of cartilage with mineralized bone is triggered by

the differentiation of proliferating chondrocytes followed by the addition of osteoblast progenitors and endothelial cells [29]. The osteoblast progenitors then differentiate into the bone-forming osteoblasts while the endothelial cells establish the bone marrow which will later become the primary ossification center [29]. While this occurs, chondrocytes and cartilage will continue to grow the ends of the bone, increasing its length and forming the secondary ossification center in one or both ends of the developing bone [27].

Intramembranous bone formation

An ossification center appears in the fibrous connective tissue membrane where mesenchymal cells differentiate into osteoblasts [27]. Osteoblasts produce osteoid tissue and a bone fibrous matrix called the osteoid [27]. Woven bone forms and encapsulates cells and blood vessels [27]. This eventually results in the formation of osteocytes from cells encapsulated by the osteoid [27]. The spongy bone interior is replaced by red marrow while the woven bone collar is replaced by mature lamellar bone [27].

Diseased tissue

Osteoporosis is a very common disease primarily determined by measuring peak bone mass [31]. It is defined as a loss in bone density which often results in injuries such as fractures and an increase in mortality [32]. There are two kinds of osteoporosis, primary and secondary osteoporosis, which are classified based on the types of factors affecting the metabolism of the bone [33]. Primary osteoporosis results primarily as a result of aging or menopause-related bone demineralization [33]. Secondary osteoporosis is caused by pathological conditions other than aging that result in osteoporosis, such as medications or other disorders [33]. Due to the generalization of all other causes of osteoporosis as secondary, this has resulted in an overly broad guidelines that point to secondary causes of osteoporosis [34]. Current guidelines point to the use of glucocorticoids, smoking, alcohol intake, hypogonadism, endocrine disorders, gastrointestinal diseases, genetic disorders, and certain medications [35]. The vast potential sources for secondary osteoporosis pose serious challenges for health care providers who must apply appropriate investigations before treatment [35]. As an example, treating parathyroidectomy for primary hyperparathyroidism can improve bone mineral density over the years [35]. However, failure to properly identify a secondary cause may result in the failure of antiresorptive or anabolic treatment of osteoporosis [35].

Market size

The global osteoporosis market is valued at 13.43 billion USD and is predicted to grow at a CAGR of 5.00% from 2025 to 2034 [5]. This puts estimates at a total market value of 20.83 billion by 2034 [5]. Contributors to this growth are the rapidly increasing elderly population since osteoporosis is more prevalent in people over 65 [6]. Additionally, new drug therapies, increasing research, and approvals for launches of treatments have also led to an inflation of the market prediction [6]. This includes better diagnostic technologies which improve early detection and monitoring, leading to a larger patient pool, favorable policies in markets such as the U.S., E.U. and Japan, and a growing public awareness promoting screening [6].

North American market

North America holds the largest portion of the osteoporosis market with an estimated 41% [5]. Within the US specifically, this remarkable market size is driven by an advanced healthcare infrastructure with widespread access to medical services which enable timely diagnosis and treatment [5]. For the US market, growth projections estimate that the annual fractures are projected to increase from 1.9 million to 3.2 million between 2018 and 2040 [8]. In addition, favorable reimbursement policies and programs and the presence of major pharmaceutical powers allows for North America's dominance within the global market [7].

Asia-Pacific market

The Asia-Pacific market is the fastest expanding market for osteoporosis with an estimated CAGR of 6.1% [5]. This can be attributed to countries like China and Japan having a growing middle class, expanded access to healthcare, and rapidly aging population, all factors that increase awareness of the disease and expansion of the market [5]. In India, the International Osteoporosis Foundation (IOF) performed an audit that found lower bone mineral densities in women ages 30 – 60 than their western counterparts [9]. On average, the IOF found that through all ages in India, widespread vitamin D deficiency, lower calcium consumption, and lifestyle changes were contributing factors towards an increase in fractures and osteoporosis [9]. However, awareness about the disease remained low with only 10% - 15% of the urban population before familiar with osteoporosis [9]. This is a key insight about diagnosis and the why the Asia-Pacific Market is expected to outpace the North American market. By 2050, more than 50% of the world's

osteoporotic fractures are expected to occur in Asia [10]. This indicates that the current market in the Asia-Pacific is not limited by cases of osteoporosis or osteoporosis related fractures, but by the healthcare infrastructure which is expected to bloom [11]. Japan offers universal coverage that includes osteoporosis drug regimens, China includes osteoporosis drugs on its National Reimbursement Drug List, and India's private sector hospitals offer packages that include osteoporosis drugs [11].

Europe

The European market for osteoporosis remains steady with a CAGR of 3.6% [12]. Europe holds the second largest osteoporosis market with about 25% of the market [12]. Like other nations, its growth is primarily driven by a combination of factors such as expanding treatment options and an expanding elderly population [12].

Existing products

Treatments for osteoporosis can be broken into two primary categories: antiresorptive and anabolic [13]. Currently on the market, the predominant treatment for osteoporosis are drugs [13]. For bone antiresorptive agents, these drugs operate by inhibiting the activity of osteoclasts [14]. Antiresorptive agents include calcitonin, bisphosphates, estrogen, selective estrogen-receptor modulators, and denosumab [14]. Anabolic drugs include Teriparatide, Abaloparatide, and Romosozumab [17]. Vitamin D supplements have also been used for the treatment of osteoporosis, though meta-analysis shows that supplements alone cannot reduce risk fracture and therefore will not be the focus of this review [14].

Antiresorptive Agents

Antiresorptive agents are split into 5 principal classes: bisphosphonates, estrogens, selective estrogen receptor modulators, calcitonin, and monoclonal antibodies such as denosumab [18]. Alendronate (Fosamax®) is one of the most common bisphosphonate drugs in the world. It has a high affinity to bone, and its effects have a longer duration [14]. It does not appear to have deleterious effects on bone mineralization and instead can increase total bone mass in the total body of postmenopausal women [15]. Risedronate (Actonel®) is another common bisphosphonate used to treat osteoporosis [16]. It is a potent inhibitor of osteoclasts and shows increased bone density

in the spine and hip [16]. It is a popular drug used for the treatment of elderly women and has been demonstrated to reduce the risk of vertebral fractures by up to 49% [16].

Estrogen replacement therapy (ERT) has been suggested as a treatment for osteoporosis due to the link between bone loss during menopause [14]. Drugs such as Tibolone can be used though these treatments are not recommended for long periods of time due to higher risk of venous thromboembolic disorders, breast cancer, cardiac events, and stroke [14]. Selective estrogen receptor modulators may be considered over estrogen replacement therapies for both sexes [14]. Raloxifene is the first of this class of drugs to be used which shows improved safety over longer periods compared to ERTs [14]. However, bisphosphates are preferred as treatments to prevent osteoporosis in postmenopausal women due to having greater non-skeletal effects [14]. Calcitonin products are Fortical® and Miacalcin® [14]. These products are used after BPs, ERTs, and SERMs have failed to treat osteoporosis [14]. The primary reason for this is that its longer-term side effects are not well known and they appear to have less effectiveness than BPs [14]. The FDA continues to monitor Calcitonin products and their recommendations to patients by doctors [14]. The last class of antiresorptive drugs is Denosumab which is a human monoclonal RANKL antibody that inactivates osteoclasts and reduces their differentiation [14]. This treatment is used for patients who have poor tolerance to BPs or renal failure [21]. This treatment demonstrated benefits for high fracture risk patients such as older men and women [14]. Its most notable side effect is skin irritation and infection, and long-term studies do not show sufficient link between Denosumab and cancer [14].

Anabolic agents

Anabolic agents operate by promoting new bone formation [17]. Unlike antiresorptive agents which can be used to prevent osteoporosis, anabolic agents should only be considered for individuals with severe osteoporosis, failure of alternative agents, or glucocorticoid-induced osteoporosis [17]. Anabolic agents work by binding to the PTH1 receptor intermittently which results in enhanced bone formation [21]. Currently, only two anabolic products are available: Teriparatide and Abaloparatide.

Teriparatide demonstrated significantly reduced risk of vertebral and nonvertebral fractures in postmenopausal women,

osteoporotic men, and glucocorticoid-induced osteoporosis with 18 to 36 months of treatment [17]. Abaloparatide showed similar results [17].

Products in clinical and preclinical trials

There are currently no products on the market for the treatment of osteoporosis that are tissue engineering based. All available products are drugs. However, one preclinical trial was conducted in Switzerland looked at the effectiveness of adipose tissue derived mesenchymal stem cells as a component for grafts [23]. This study proposed that autologous bone-grafts, the current gold standard, were questionable in osteoporotic patients due to their poor harvesting sites [23]. They proposed that stromal vascular fraction (SVF) cells could be harvested in high numbers and be successfully used to generate osteogenic grafts [23]. In their study, planned a randomized controlled trial with 270 patients [23]. Cells would be isolated and wrapped around hydroxyapatite microgranules after embedding in a fibrin-gel for augmentation of the bone void [23]. Follow up would be at the 6 week, 12 week, 6 month, and 9-month marks [23]. The results of this study are yet to be published [23].

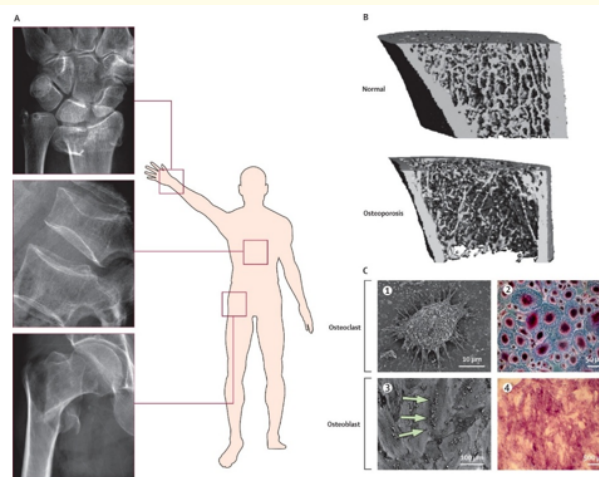


Figure 1: Overview of osteoporosis involving osteoclast overactivity and in a microscopic view [3].

This image shows common fragility fractures, common in the hips, vertebrae, and wrists, as well as a microscopic view of osteoclasts and osteoblasts.

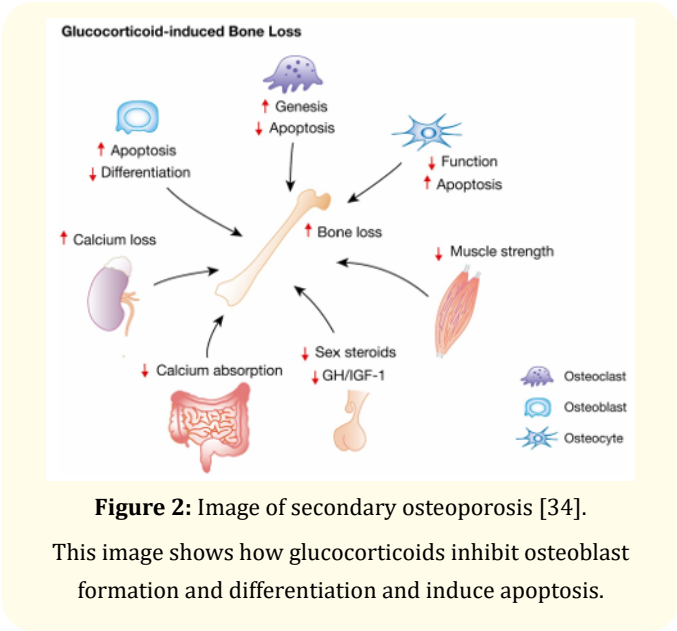


Figure 2: Image of secondary osteoporosis [34].

This image shows how glucocorticoids inhibit osteoblast formation and differentiation and induce apoptosis.



Figure 5: Image of Fosamax, a biphosphate drug recommended to treat osteoporosis [42].

This image shows Fosamax. Fosamax is a common biphosphate drug prescribed to postmenopausal women to increase bone mass and reduce fracture incidence.



Figure 3: Current global osteoporosis market predictions for a 10-year period [41].

This image shows the osteoporosis market is expected to rise to a market size of over \$20 billion by 2034. This rise comes as the global population ages in addition to favorable regulatory policies.

Brand Name	Generic Name	Dosage	Indications
Actonel	Risedronate sodium	5 mg/day; or 35 mg per week	Prevent and manage osteoporosis in postmenopausal women, and men with osteoporosis; Paget disease of bone
Atelvia	Risedronate sodium	35 mg tablet once weekly.	Treatment of osteoporosis in post-menopausal women.
Bonifos	Clodronate disodium	400 mg capsules (Canada); 800 mg capsules (Europe)	Prevent and manage osteoporosis in postmenopausal women; hypercalcemia and osteolysis from malignancy; reduce bone metastasis in primary breast cancer
Boniva	Ibandronate sodium	2.5 mg/day, or 150 mg per month	Prevent and treat osteoporosis in postmenopausal women
Didronel	Etidronate disodium	400 mg tablet	Paget disease of bone; hypercalcemia of malignancy; heterotopic ossification
Fosamax	Alendronate sodium	10 mg/day, or 70 mg per week	Prevent and treat osteoporosis in postmenopausal women; increase BMD in men with osteoporosis; Paget disease of bone
Fosamax Plus D	Alendronate sodium/cholecalciferol	70 mg tablet, 70 mg oral solution	Treat osteoporosis in post-menopausal women; increase BMD in men with osteoporosis
Alendronate	Alendronate sodium	10 mg/day, or 70 mg per week	Prevent and treat osteoporosis in postmenopausal women; increase BMD in men with osteoporosis; Paget disease of bone.
Skelid	Tiludronate disodium	240 mg tablets	Paget disease of bone

Figure 6: Table comparing different antiresorptive drugs and their management in osteoporosis [19].

This image shows a comparison of antiresorptive drugs, their dosage, and their indications.



Figure 4: Image of the osteoporosis market size for North America [7].

This image shows the osteoporosis market trends within the North American market within the last 10 years.



Figure 7: Image of Prolia from Mountainside Medical [43].

This image shows Prolia. Prolia is an injection medication prescribed to treat osteoporosis for those at a high risk of fractures such as postmenopausal women and those undergoing certain cancer treatments.

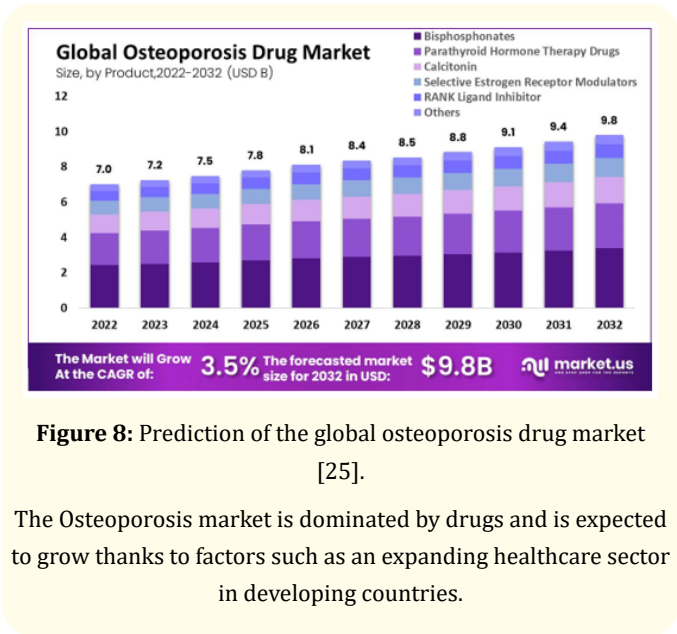


Figure 8: Prediction of the global osteoporosis drug market [25].

The Osteoporosis market is dominated by drugs and is expected to grow thanks to factors such as an expanding healthcare sector in developing countries.



Figure 9: Image of Abaloparatide [22].

The image shows Abaloparatide. Abaloparatide is one of the only approved anabolic products for osteoporosis management.

Conclusions

Osteoporosis is a growing global crisis that will affect an estimated 50% of women and 20% of men over the age of 50 in their life [4]. These fractures result in deceased mobility, impaired quality of life, and a medical burdens [4]. Current market drugs show effectiveness in early-stage treatment though there is growing concern about their long-term safety and use [26]. Biphosphates are the market’s current best, most cost-effective treatment option for early cases of osteoporosis, though new novel trends are under research [26]. Among these new options, bone tissue scaffold is

being observed for their significance in managing osteoporotic bone defects by providing mechanical support, facilitating bone regeneration and repair, and serving as vehicles for drugs [24]. The goal of all of these treatments is to minimize systemic side effects by enabling local release of pharmaceutical agents [24]. While none of this research has resulted in a market ready product, the studies are still ongoing [24].

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Conflict of Interest

Authors declare that there is no conflict of interest.

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