**Abstract:-**

**Background –** Adults nearly one in five have osteoporosis in India.

**Objectives -** to study the use of biologicals and conventional therapies in the management of osteoporosis

**Materials and methods –** A prospective study was conducted in Mumbai. The survey focused on the question of the management of osteoporosis for physicians.

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**Results –**

**Conclusion –**

**Introduction –**

**Osteoporosis: The Brittle Bone Disease is “**The condition in which the bone becomes weak and brittle”

“Osteo" means bone and "porosis" means porous. So, osteoporosis translates to "porous bone."

The World Health Organization defines osteoporosis as a T score less than <= 22.5

Osteoporosis can also be defined clinically as the presence of a low trauma fracture with or without BMD in the osteoporotic range.

A mechanistic definition of osteoporosis is a skeletal disorder characterized by compromised bone strength predisposing a person to an increased fracture risk.

The recent study shows that the prevalence of osteoporosis was 10.4% for men in <52.2 years category and 18.6% for men in more than 52.2 years category. In premenopausal women, the prevalence was 3.5%, 18.4% in postmenopausal women <5 YSM and 37.3% in postmenopausal women more than 5 YSM. Osteopenia was 35.1%–43.8% in men, 31%–34% in premenopausal women and postmenopausal women <5 YSM and 42.2% in postmenopausal women more than 5 YSM. At the hip, the prevalence of osteoporosis was 5.2%–6.2% in men, 2.6% in postmenopausal women <5 YSM and 16.5% in postmenopausal women more than 5 YSM. A higher prevalence of osteopenia was observed in men (50%–62%) and postmenopausal women (50%–59%) while for premenopausal women it was 32.6%.

Fractures and their complications are the relevant clinical sequelae of osteoporosis. Osteoporosis is a silent disease until the patient experiences a fracture. A recent fracture at any major skeletal site, such as vertebrae (spine), proximal femur (hip), distal forearm (wrist), or shoulder in an adult older than 50 years with or without trauma, should suggest that the diagnosis of osteoporosis needs further urgent assessment involving diagnosis and treatment.

**Objectives:-** Understanding the common therapies utilized inosteoporosis and the use of the biologicals in management of the osteoporosis

**Methodology:-**  the prospective cross-sectional study was conducted t the Mumbai. More than 40 specialized physicians

A cross-sectional study is a type of research design used in various fields like medicine, social sciences, and biology. It involves collecting data from a group of people at a single point in time, offering a snapshot of a particular situation.

We select the cross-sectional study to take the snapshot and to understand the use of the biologicals in the market for the management of osteoporosis

To gain insights specific to the Mumbai region, the target population was restricted to licensed and practicing orthopaedist in the Mumbai . Data collection was conducted through in-depth interviews with practicing orthopedic surgeons. To facilitate access to participants, collaboration was established with a medical representative familiar with the targeted physicans.

Due to limitations in accessing a broad range of participants, a convenience sampling approach was used. Collaboration with a medical representative facilitated contact with practicing orthopedic surgeons who were willing to participate in in-depth.

Include only currently practicing doctors to ensure their insights reflect up-to-date practices.

Docters with the otDoctorsher expertise were excluded to maintain the focus on the bone-related treatments.

Data collection was conducted through in-depth, semi-structured interviews

The questionnaire was made to fill the research gap some questions were open-ended so they could clearly explain their views and algorithms in management of the osteoporosis

Some questions were closed-ended for selecting the tharapy in management of the osteoporosis

**Litrature review**

Osteoporosis is the most frequent of osteometabolic diseases and its study has been especially motivated due to the important repercussions in relation to the morbidity and mortality of individuals with this condition, and for this reason it is currently considered a serious public health problem (Lanna, et al. al, 2003). With no symptoms, osteoporosis causes more than 8.9 million fractures annually worldwide, resulting in an osteoporotic fracture every 3 seconds, according to the International Federation of Osteoporosis (IOF). It is estimated that the disease affects 200 million women worldwide, across the planet, one in three women over 50 will suffer osteoporotic fractures, as well as one in five men over 50 years. The few studies carried out with men in Brazil show that the prevalence of the pathology in the male population over 65 years of age is around 15%, while the prevalence of fractures is between 12 and 20%. (Maeda, 2017). Brazil is a country with a great ethnic mixture with heterogeneous regional distribution. Thus, the prevalence of osteoporosis in Brazilian studies can range from 6 to 33% depending on the population and other variables evaluated (Marinho et al., 2015). It is known that even if osteoporosis occurs in both sexes, women stand out in the development of the disease due to aspects such as the greater number of this population, physiological issues, speed of bone loss, hormonal decrease that impacts on estrogen levels and, the consequent menopausal process (Melo, 2017). In addition, there is the natural factor of advancing age, which also contributes to the higher prevalence of osteopenia and osteoporosis in this population (Mazocco; Chagas, 2017). According to the Brazilian Society of Endocrinology and Metabolism approximately ten million Brazilians suffer from the disease and one in four women over fifty develops it (Santiago; Vieira; Nunes, 2018). Silva et al. (2018) highlight that one of the consequences of natural or induced ovarian failure is osteoporosis, thus increasing the risk of fractures. Osteoporosis is a major complication of aging in women and is strongly associated with sex hormone deficiency, but it can also be caused by alcoholism or treatment with high doses of corticosteroids. Excess caffeine also has the potential to predispose osteoporosis in postmenopausal patients. The studies by Hyassat et al. (2017) demonstrated that women at this stage of life with a daily caffeine intake greater than 300 mg/day were at greater risk of developing osteoporosis. Studies have shown that the pathophysiology of the process is based on the direct action of caffeine on osteoblasts and osteocytes, disturbing the process of differentiation, multiplication, mineralization and production of the bone matrix, leading to apoptosis of these cells (Chang, 2013; Liu, 2011). Furthermore, it is mentioned that caffeine can increase the differentiation of osteoclasts, resulting in greater loss of calcium in the urine, a fact that can predispose to the formation of urinary stones (Lacerda, 2010). All of these mechanisms can contribute to the decrease in bone density caused by high caffeine consumption. In addition to menopause, another risk factor that stands out is sarcopenia; such pathology together with osteoporosis consist of diseases that reinforce each other in terms of negative results. With the progressive senescence of the population, there has been a progressive increase in the incidence of musculoskeletal disorders, which corroborates the close association between muscle and bone; it turns out that both are not only tangent adjacent to their anatomical position, they are also known to share common endocrine and paracrine regulation, as well as the pathways that regulate their molecular signaling (Bonewald, et al., 2013; Girgis, 2015). These aspects are relevant because the loss of bone mass, muscle function and strength, when added to the senility process, is significantly enhanced with regard to the occurrence of osteoporotic fractures. Allied to this, age-related decrease in bone mass quality and composition also acts as a sarcopenia maximizer, a fact that proves that both pathologies feedback (Edwards, et al., 2015; Oliveira and Vaz, 2015). Thus, it can be seen that the increased risk of fracture in people with associated osteoporosis and sarcopenia is due to the reduction in muscle strength and mass, as well as the bone mineral density and decreased body mobility (Tarantino, et al., 2016; Steihaug et al., 2017). The work developed by Marques and Queirós (2018) and by Yeung et al. (2019) accused that elderly people with sarcopenia have a triple chance of falling, when compared to those who do not have the pathology in question. Furthermore, there is evidence that sarcopenia is closely linked to fractures, which is aggravated when it occurs in patients with some degree of osteopenia or osteoporosis. Prevention of osteoporosis consists of lifestyle measures and pharmacological therapy taking into account that bone strength reflects the integration of bone mineral density (BMD) and other bone properties that are collectively called "bone quality". Adult BMD is determined by peak bone mass and subsequent bone loss. As the BMD measured by dual energy X-ray absorptiometry (DXA) decreases, the risk of fracture increases as a continuum, without "fracture threshold". Thus, prevention of low bone mass is aimed at maximizing peak bone mass and minimizing the rate of bone loss, with the ultimate goals of maintaining bone strength and preventing fractures (Lewiecki, 2021). Some authors consider senile osteoporosis a "pediatric disease" taking into account the importance of reaching the maximum peak potential bone mass in childhood in order to lessen the effects of bone loss later in life. Preventing bone loss is preferable to treatment once established pathology has occurred, because the degradation of bone microarchitecture associated with bone loss is largely irreversible. Treatment may stabilize or increase BMD and reduce fracture risk, but is unlikely to fully restore bone quality and bone strength (Kiel, 2021). The time of peak bone mass is not known with certainty, but it probably occurs in the third decade of life in most individuals. However, for maximum bone mass to be established, good nutrition from childhood is necessary, together with regular physical activities, with the particular benefit of high-impact exercise, associated with a smoking-free life and low-tomoderate alcohol consumption. Furthermore, the administration of medications that are known to be harmful to skeletal health, such as glucocorticoids and anticonvulsants, should be avoided or minimized in dose and duration (Behringer, et al, 2014). As for pharmacological therapy, there is still no means available to maximize peak bone mass, but rather to stabilize bone mineral density and/or reduce the rate of bone loss, which is the main objective in preventing osteoporosis. Lewiecki (2021) considers that the approach to preventing osteoporosis should be done in a pyramid shape, the first level being nutrition, physical activity and prevention of falls, the second level addressing medications and diseases associated with bone loss or osteoporosis and by finally, the third level addressing pharmacological therapy. Age-related bone loss is known to begin shortly after peak bone mass for both sexes. Therefore, for most patients with low bone mass or osteopenia, it is not suggested to use pharmacological therapy to prevent bone loss. With the exception of those patients at high risk of fracture, who will, however, benefit from pharmacological therapy (Rosen; Drezner, 2021). Based on extensive experience in use, safety and proven efficacy in reducing vertebral, non-vertebral and femoral fractures, bisphosphonates are considered first-line agents in the treatment and prevention of postmenopausal osteoporosis (Caires, et al., 2017). From this class, the most used medications are: alendronate at a dose of 5 mg/day or 35 mg/week; risedronate - 5 mg/day or 35 mg/week; ibandronate - 150 mg/month and zoledronic acid - 5 mg IV once every 2 years. Among the bisphosphonates that have the best cost/benefit, in addition to greater availability of long-term safety data, are alendronate and risedronate, thus becoming the most suitable medications for the prevention of osteoporosis (Rosen, 2021). With regard to alendronate, the prevention dose used is equivalent to half the dose for the treatment, while the prevention and treatment doses are the same for the rest of the bisphosphonates. Another particularity of application is found in prevention with the use of zoledronic acid, in which the interval of doses for prophylaxis is every two years, and in treatment the dose is annual (Finkelstein; Yu, 2021). Potent antiresorptive agents increase BMD Discontinuation of bisphosphonates after 3 years (zoledronic acid) to 5 years (alendronate) is justified for patients who, at the end of this period, present a low risk of fracture. However, those who persist with a femoral T-score ≤ -2.5 after starting treatment should have this treatment continued for up to 6 (zoledronic acid) to 10 years (alendronate) (Caires et al., 2017). Medications in this class of drugs in young and elderly postmenopausal women have been shown to reduce the risk of fracture in older postmenopausal women. However, Radominski, et al. (2017), reinforce that due to the high prevalence of secondary causes of osteoporosis, many of them subclinical, it is recommended for all patients before starting any treatment a minimum laboratory evaluation that includes complete blood count, calcium, phosphorus, alkaline phosphatase, thyroid function and serum 25(OH) vitamin D measurement, 24-hour calciuria, in addition to plain lateral radiography of the thoracic and lumbar spine and measurement of BMD in the lumbar spine and proximal femur. Another way to prevent osteoporosis is with the use of calcitonin, but it is not used as a first-line therapy due to the fact that there are more effective drugs, such as bisphosphanates. Calcitonin is a 32-amino acid peptide that binds to osteoclasts and inhibits bone resorption. There are calcitonins from several species that have been shown to be compatible with those of humans, as well as human calcitonin; however, the most effective is salmon calcitonin, it has a high affinity (40 times that of human calcitonin) and a slow clearance rate. Currently, the only calcitonin used is human, but numerous clinical trials have shown the best efficacy of salmon calcitonin (Rosen, 2020). Another way to prevent bone loss, specifically in postmenopausal patients is the use of estrogen, however, it is not a first-line treatment due to concerns about adverse effects. However, in women who chose hormone replacement therapy, estrogen showed reductions in bone loss and fracture risk, in addition to benefits related to menopausal symptoms (Manson, et al, 2013). As for sarcopenia and its relationship with osteoporosis, there are effective measures that can be applied to delay or even reverse the progression of sarcopenia in the elderly. Due to the positive role of resistance exercises in human muscle mass, numerous studies have inserted resistance exercises in the treatment of sarcopenia and, consequently, osteoporosis. Authors demonstrated that a 12- to 16-week cycle of resistance training increased individuals' thigh circumference by 11.4% and muscle volume by 3.8% (Van Roie et al., 2013). Most interestingly, the authors proved that muscle growth caused by resistance exercise can occur at any age, even in the elderly (Westcott, 2009). In addition to resistance exercise, exercise in water can improve muscle balance and muscle strength, in addition to providing adequate postural mobility (Irandoust, et al., 2019). Regular physical activity can act on the clearance of body fat, improve musculoskeletal control, reduce low back pain, and improve the quality of balance and walking speed in the elderly (Irandoust, et al., 2019). Similarly, Pilates exercise can increase body fat mass and improve muscle atrophy, balance, and walking speed in middle-aged inactive women (Seghatoleslami, et al., 2018). Skeletal muscle atrophy and skeletal muscle strength have been shown to significantly improve in elderly patients with sarcopenia after adequate treatment with vitamin D and amino acids (Seeliger, et al., 2015). Authors have pointed out that combining resistance exercise with protein and vitamin D supplements is the most effective way to improve sarcopenia or myasthenia in the elderly (Eshaghi, et al., 2020). However, the complex pathogenesis of sarcopenia and several influencing factors have not been fully understood. Regarding how food can help in the osteoporotic prevention process, the Mediterranean Food Pattern or Mediterranean Diet (DM) has beneficial effects on many pathologies, including osteoporosis. The incidence of osteoporosis is lower in the Mediterranean area, which is mostly attributed to the specific dietary pattern of the area. The anti-inflammatory, antioxidant and alkalizing properties of its components contribute to the “bone-sparing” effect. Some studies demonstrate that adherence to traditional DM has been associated with high bone mineral density and reduced fracture risk. Thus, an association between key individual characteristics of the Mediterranean Food Pattern and a reduction in the incidence of osteoporosis or fracture occurrence is demonstrated, such as high consumption of fruit, vegetables and olive oil, moderate to high consumption of fish and moderate intake of alcoholic beverages (Almeida, 2017). The study by Savanelli (2017) showed a positive correlation between bone health status and adherence to DM. The results suggest that greater adherence to DM plays a beneficial role in bone health and confirm that a specific dietary approach, such as DM, can represent an important modifiable environmental factor for the prevention of osteoporosis. The same author also mentions that recent evidence has reported differences in the severity of osteoporosis in European Union countries, suggesting a lower incidence of the disease in the Mediterranean area. This effect was mainly attributed to the specific dietary pattern. In addition, Quattrini (2021) concluded, in a survey with a population of peri- and postmenopausal women, that the greater the adherence to DM, the greater the daily intake of calcium, which may, in part, explain the benefit of the diet for the pathology in question. Another point to be taken into account was highlighted by the study by Zupo (2020), in which it is argued that closer adherence to DM is independently associated with an increase in 25(OH)D, suggesting that higher levels of vitamin D may contribute to the protective effect of DM on osteoporosis.

**Statasical analysis :**

**Descriptive stastics**

Total doctors surveyed:47

Total doctors using densomab:29

Toatal doctors using teriperatide35

Total doctors using calcium:39

Total doctors using nsaids:13

Total doctors using vitamin D3:39

Total doctors using bisphosphate oral:17

Total doctors using bisphosphonate :14

**Percentage of doctors using therpy was calculated by the following formulas:**

Percent of doctors using densomab: 61.70,

Percent of doctors using densomab:74.46

Percent of doctors using calcium:82.97

Percent of doctors using nsaids:27.65

Percent of doctors using vitamin D3: 82.97

Percent of doctors using bisphosphonate oral : 36.17

Percent of doctors using bisphosphonate IV : 29.78

**Hypotheisis testing**

Null Hypothesis (*H*0​): The proportion of doctors using denosumab (*p*1​) is equal to the proportion of doctors using teriparatide (*p*2​).

*H*0​:*p*1​=*p*2​

Alternative Hypothesis (*HA*​): The proportion of doctors using denosumab (*p*1​) is not equal to the proportion of doctors using teriparatide (*p*2​)

HA​:*p*1​≠*p*2​

* **Calculate sample proprotion**
* Proportion of doctors using denosumab:

𝑝1^=29/47

* Proportion of doctors using teriparatide:

𝑝2^=35/47

**Calculate the Test Statistic:**

Use a two-proportion z-test for this analysis. The formula for the test statistic 𝑧 is:

where p̂​ is the pooled sample proportion:

*x*1​=29, 𝑛1=47

𝑥2=35, 𝑛2=47

Calculate 𝑝̂

Calculate the standard error (SE):

Calculate the z value

**Determine the p-value**

the z-value in the standard normal distribution table to find the p-value. For 𝑧=−2.175the p-value is approximately 0.0296 (two-tailed test).

p-value to the significance level (𝛼). If 𝛼=0.05:

If 𝑝≤0.05, reject the null hypothesis.

If 𝑝>0.05, do not reject the null hypothesis.

In this case, 𝑝=0.0296which is less than 0.05, so we reject the null hypothesis.

**Conculsion**

There is sufficient evidence to conclude that the proportions of doctors using denosumab and teriparatide are significantly different. Specifically, fewer doctors use denosumab compared to teriparatide.