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## Assessment of Calcium Supplements and Teriparatide Usage in Osteoporosis among Orthopedic Surgeons



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### ABSTRACT

Osteoporosis is a “silent disease” because it progresses without symptoms until a fracture occurs. Because of larger skeletons and no period of rapid hormonal change, osteoporosis progresses more slowly in men than in women. The fractures caused by osteoporosis have a great impact on public health, as they are often associated with increased morbidity, mortality, and high economic cost. This study seeks to assess the Calcium supplements and Teriparatide usage in osteoporosis among orthopedic surgeons, identify the choice of drug by orthopedic surgeons in the treatment of osteoporosis, and it help to identify Criteria by which orthopedic Surgeons prescribed drugs for Osteoporosis. Along with It can help a pharmaceutical company to understand the need of the customer (Surgeons) prior launching any new molecule. It can help a pharmaceutical company to make strategies and make a foothold through creative marketing to acquire a good market share for their product.



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## 1. INTRODUCTION

Osteoporosis is a multifactorial progressive skeletal disorder characterized by reduced bone mass and deterioration of bone microarchitecture, predisposing it to increased fracture risk. The capacity of bone to resist mechanical forces and fractures depends not only on the quantity of bone tissue but also on its quality.

Osteoporosis is a “silent disease” because it progresses without symptoms until a fracture occurs. Because of larger skeletons and no period of rapid hormonal change, osteoporosis progresses more slowly in men than in women. The fractures caused by osteoporosis have a great impact on public health, as they are often associated with increased morbidity, mortality, and high economic cost.<sup>[1]</sup>

### 1.1 Osteoporosis in India:

The population of India projected to increase to 1,367 million by 2020 and 1,613 million by 2050 among them 9.8% (134 million) and 19.6% (315 million), respectively, will be adults over 60 years. These staggering numbers give some idea of the population at risk for osteoporosis in India in the years to come.<sup>[2]</sup>

Osteoporosis is becoming a serious problem for the public economy and health, because of the increase in elderly population in the near future. Conservative estimates in a study suggest that 20% of women and about 10-15% of men are osteoporotic in India. Another highly conservative estimate by a group of experts suggested that 26 million Indians suffer from osteoporosis, and this number expected to reach 37 million by 2020.<sup>[3]</sup>

In developing countries like India, hip fractures are a major health problem. Hip fractures cause mainly physical impairment and mortality in the elderly patients. A survey carried out by the Indian Society for Bone and Mineral Research (ISBMR) among orthopedic surgeons across the country, revealed that in government hospitals about 80%-85% hip fractures are surgically treated whereas in private hospitals almost 100% receive surgical treatment.<sup>[4]</sup>

### 1.2 Diagnosis:

**Before any symptoms develop:**

A risk calculator is available to determine your risk of developing osteoporosis, depending on the number of risk factors that you have. There are two commonly used risk calculators. One is FRAX®, and the other is Q Fracture. You may be referred DEXA scan if you found to be at increased risk, or your risk is uncertain. DEXA stands for dual energy X-ray absorptiometry. A scan uses special X-ray machines to check your bone density. A DEXA scan can confirm osteoporosis.<sup>[5]</sup>

### **After symptoms develop:**

Osteoporosis often first diagnosed when you break a bone after a minor bump or fall. Even after the first fracture has occurred, treatment can help to reduce your risk of further fractures. You may be referred DEXA scan to look for signs of osteoporosis if you are thinking to have sustained a fragility fracture. However, sometimes women of 75 or older who have a fracture are assuming to have had a fragility fracture. In this group of women, treatment of osteoporosis may be started without having a DEXA scan first. This is because osteoporosis is so common in this age group.<sup>[5]</sup>



### **1.3 Treatments:**

Various medicines are available that can help to prevent and treat bone loss. Options used to treat 'thinning' of the bones include the following.

#### **1.3.1 Calcium and vitamin D:**

As a combination therapy, calcium and vitamin D is the accepted baseline treatment for osteoporosis. For elderly patients treatment with Vitamin D may have additional benefits, because vitamin D therapy increases muscle strength and thus may reduce the possibility of fractures.<sup>[6]</sup>

#### **1.3.2 Bisphosphonates:**

Bisphosphonates are a group of medicines that include alendronate, risedronate and etidronate. They are the most commonly used medicines to treat osteoporosis. They work on the bone-making cells. They can help to restore some lost bone and help to prevent further bone loss.

Research studies have shown that the risk of bone fracture may be reducing by taking one of these medicines if you have osteoporosis. They may also help to reduce the chance of a second fracture if you have already had a fragility fracture. Alendronate is the medicine that is usually used first. Risedronate or etidronate may be considered in certain people who are not able to tolerate alendronate or in whom alendronate is not suitable.

A rare side effect of bisphosphonates is a condition called osteonecrosis of the jaw. This condition can result in severe damage to the jawbone. So, if you take a bisphosphonate and you experience pain, swelling or numbness of the jaw, a 'heavy jaw feeling' or loosening of a tooth, you should tell your doctor.<sup>[7]</sup>

### **1.3.3. Calcitonin:**

Another anti-resorptive agent approved for treatment of osteoporosis is calcitonin. Calcitonin acts like the endogenous form of the hormone on the calcitonin receptor on osteoclasts to decrease their activity. Out of all recombinant or synthetic calcitonins that have been used for medical purposes, the salmon calcitonin preparation is the most widely used. As a desirable additional effect, calcitonin has been noted to reduce the pain of clinical vertebral fractures.<sup>[8]</sup>

### **1.3.4. Estrogen replacement therapy:**

Treatment of osteoporotic women with estrogen replacement therapy to prevent fracture has been controversial. The Women's Health Initiative trial on estrogen replacement therapy was the first large-scale, randomized, controlled study of healthy women aged 50-79 years. The results of this study showed that there was 34% risk reduction for hip and vertebral fractures and by the end of the study, the incidence of osteoporotic fractures was reduced by 24%. Estrogen therapy has long-term side effects including vascular events and breast cancer, which limit its widespread use.<sup>[9]</sup>

### **1.3.5 Parathyroid hormone peptide medicines:**

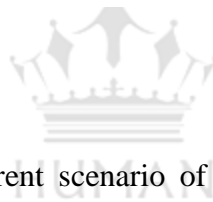
These medicines are sometimes suggested for people who have already had a fragility fracture. There are two of these medicines available: Teriparatide (brand name Forsteo®) and parathyroid

hormone (brand name Preotact®). They gave by an injection under the skin every day for two years. Studies have shown that they can reduce the risk of some osteoporotic fractures.

**Lifestyle:** Medication will not restore all lost bone. In addition, medication may not be suggested for all people with 'thinning' of the bones (osteoporosis). Therefore, there are a number of lifestyle measures that are also important in treating osteoporosis. They include:

- Weight bearing exercise,
- Muscle strengthening exercises,
- Not smoking,
- Keeping any alcohol drinking to within the levels as described earlier.

Following this, where appropriate, some people's offered suggestions such as a muscle strengthening and balance program, or recommendations on how to reduce potential hazards in their home. <sup>[10]</sup>



## 2. Need For Study:

The study helps to determine the current scenario of Calcium supplements and Teriparatide usage in Treatment of Osteoporosis and overall market potential of the Calcium supplements and Teriparatide. The study helps to determine the current prescribing trend of doctors for osteoporosis. It gives an idea of current market coverage of competitor brands.

It can help a pharmaceutical company to understand the need of the customer (Surgeons) prior launching any new molecule. It can help a pharmaceutical company to make strategies and make a foothold through creative marketing to acquire a good market share for their product.

## 3. Objective:

- ✓ Assessment of Calcium supplements and Teriparatide usage in osteoporosis among orthopedic surgeons,
- ✓ Identify the choice of drug by orthopedic surgeons in the treatment of osteoporosis,
- ✓ To identify Criteria by which orthopedic Surgeons prescribed drugs for Osteoporosis.

#### **4. The significance of the study:**

The study designed for assessment of usage of calcium supplement and Teriparatide and brand preference of orthopedic surgeons in osteoporosis; the results of this study are believed to be of great benefit to Pharmaceutical Manufacturing Company.

#### **5. Research Methodology:**

The design of the study was Descriptive study. The researcher used Non-Probability (Convenience) sampling to get the data. Total sample sizes were 250 and the target population included the orthopedic surgeons from cities of Chhattisgarh i.e. Raipur, Durg, Bhilai, Rajnandgaon, Bilaspur and Jagadapur.

The research involved data collection from primary and secondary sources. The primary data was collected through questionnaires (Mixed) and unstructured interviews. Personal interviews gave an in depth into the information and eliminated misinterpretation. The secondary data obtained from published material, journals, and internet sources.

#### **6. Data Analysis, Finding and Interpretation:**

For pictorial presentation, bar graphs and pie charts were drawn to enable users to conceptualize the results. From the sample size that was selected, the returned questionnaires whose response were used in further processing of the data to come up with the research findings included :

6.1. Total no of patients examine suffering from osteoporosis by Orthopedic surgeons daily:

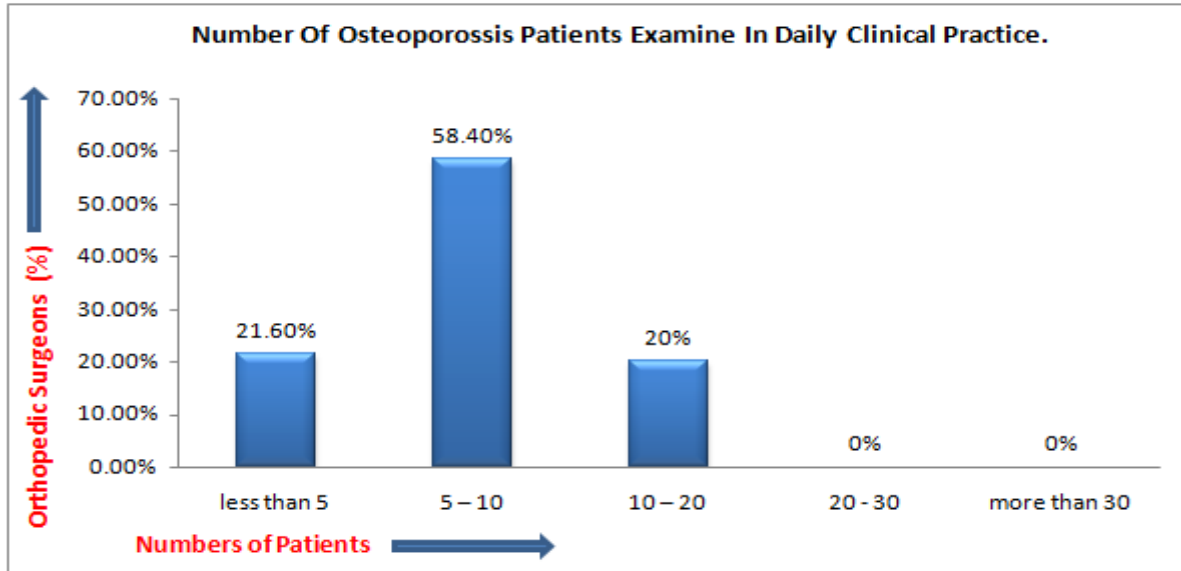


Figure 1: Number Of Patients Examine In Daily Clinical Practice.

Among the total respondents 21.60%, 58.40%, 20% surgeons examine less than 5, 5-10, 10-20 respectively Osteoporosis patients daily.

**Inference:** It found that data taken from most of the doctors have a strong prescribing base with 5-10 patients / day.

6.2. Gender mostly analyzed by Orthopedic Surgeons:

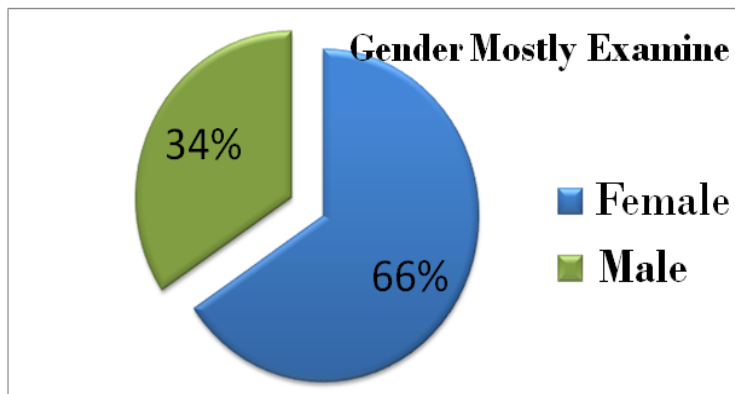
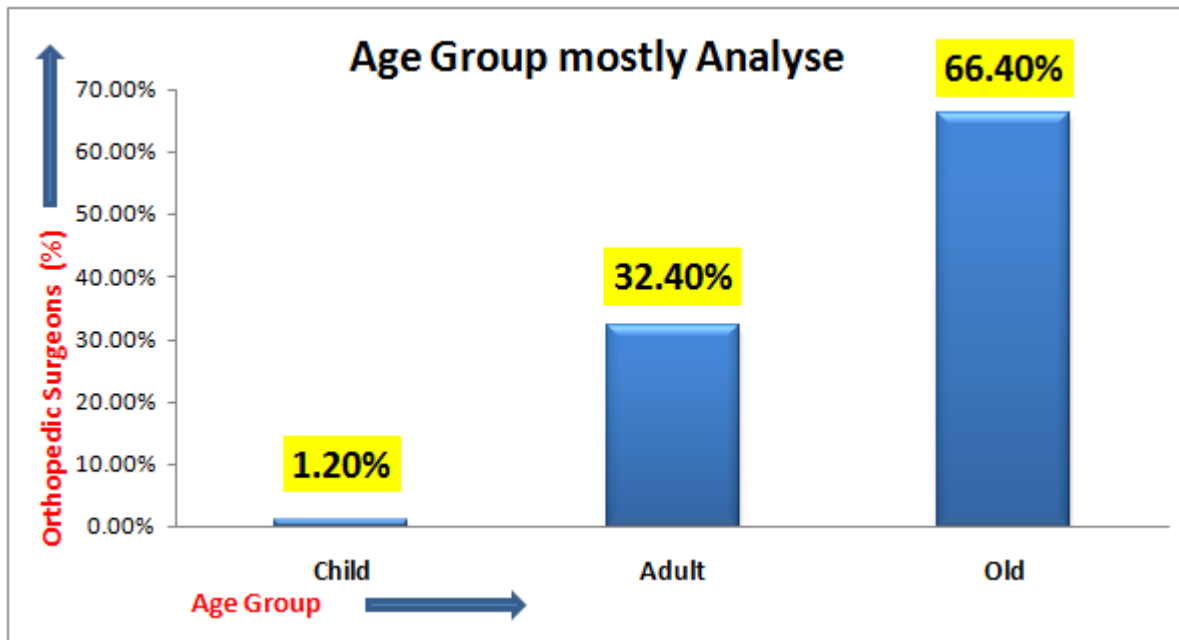


Figure 2: Gender mostly examines by Orthopedic Surgeons.

When the question asked by a researcher from orthopedic surgeons during an interview about to whom (Gender) they examine resulting, among them, 34% of orthopedic surgeons mostly examine to male daily and 66% of surgeons respond as they mostly examine female patient daily.

**Inference:** From above surgeons responds it found that mostly female were suffering from osteoporosis as compared to male and the ratio was almost 2:1. Female are most prone to suffer Osteoporosis, the reason being Hormonal changes, Less BMD as compare to males.

### 6.3. Age group mostly analyzed by Orthopedic Surgeons:



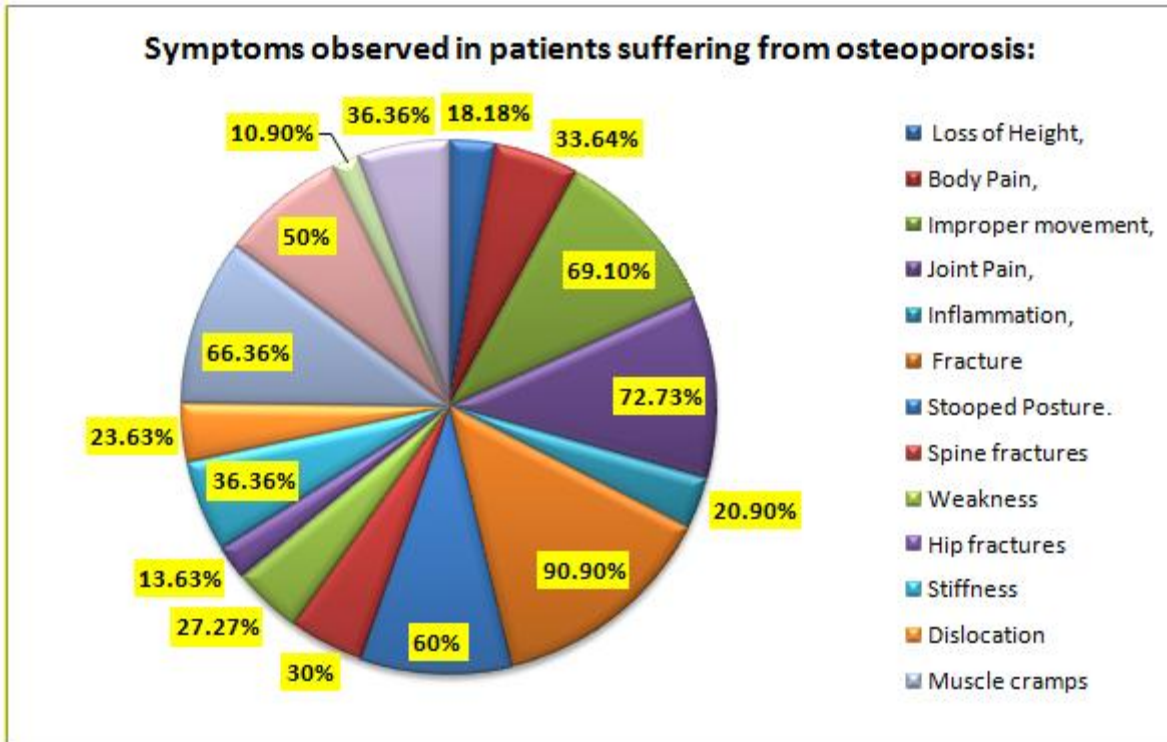
**Figure 3: Age Group mostly analyzed by Orthopedic Surgeons.**

When the question asked by are searched from orthopedic surgeons during an interview about to which age group they mostly examine resulting, among them 1.20 % of orthopedic surgeons mostly examine to Child Patient, 32.40 % of surgeons mostly examine the adult patient and 66.40 % of surgeons respond as they mostly examine old patient daily.

**Inference:** Among three-group age, it found that mostly old people prone to suffer from osteoporosis as compared to adult and child were negligible.



#### 6.4. Symptoms observed in patients suffering from osteoporosis:



**Figure 4: Symptoms observed in patients suffering from osteoporosis.**

When asked to orthopedic surgeons about the symptoms of osteoporosis they indicate some kind of symptoms that are as:

- ✓ Loss of Height,
- ✓ Body Pain,
- ✓ Improper movement,
- ✓ Joint Pain,
- ✓ Inflammation,
- ✓ Fracture,
- ✓ Stooped posture, etc.

**Inference:** Body pain, Joint pain and Fracture are main common symptoms in osteoporosis.

### 6.5. First line treatment of Osteoporosis:

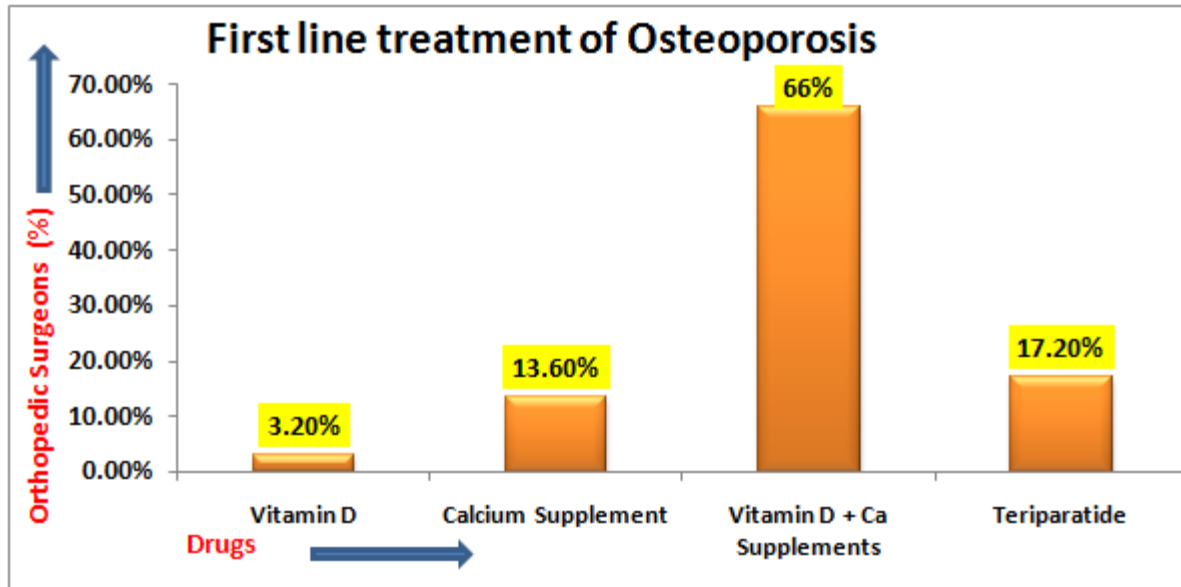


Figure 5: First line treatment of Osteoporosis

Through closed-ended Questionnaire when researcher asked about first line treatment of Osteoporosis among all respondents 13.60 % of orthopedic surgeons indicate calcium supplements, 66 % of surgeons indicate vitamin D3 and Calcium Supplement combination, 17.20% of surgeons indicate Teriparatide drug for the treatment of Osteoporosis and among them 3.20% of orthopedic surgeons preferred single Vitamin D for treatment of Osteoporosis.

**Inference:** It found that most of the surgeons preferred Vitamin D and Calcium supplement combination as first-line treatment of Osteoporosis. Teriparatide preferred less as compared to calcium and Vitamin D combination because of its competitive price of treatment whereas Calcium and Vitamin D combination preferred more because of supportive treatment and it fits with a pocket of osteoporosis patients.

6.6. Duration of prescribing drug for treatment of Osteoporosis:

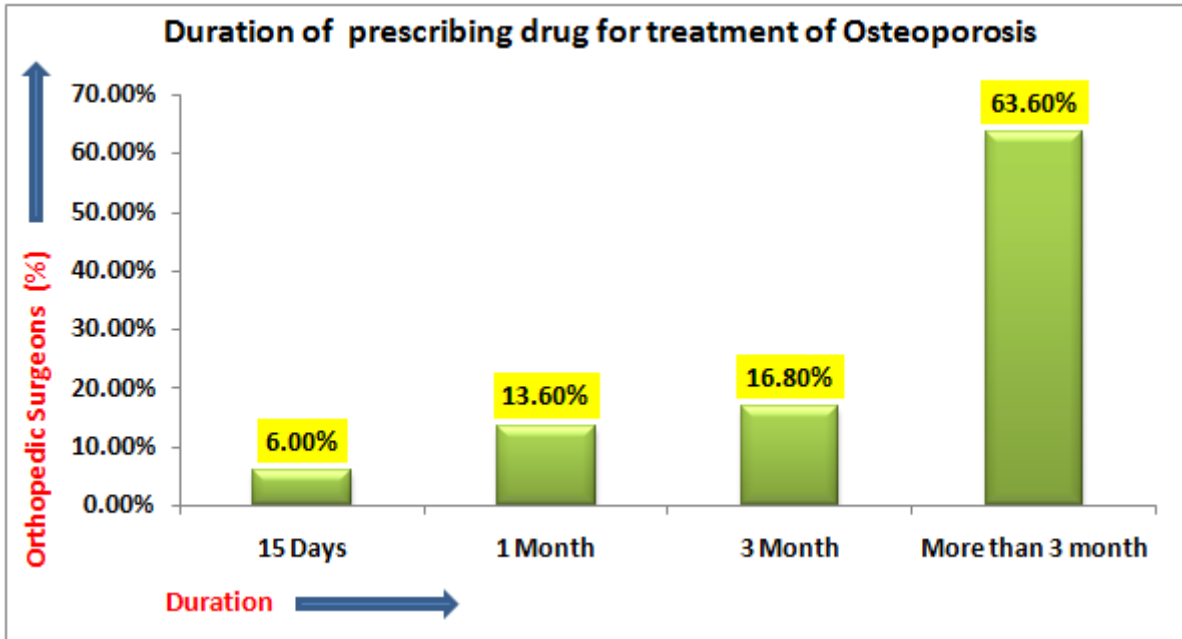


Figure 6: Duration of prescribing the drug for treatment of Osteoporosis.

Among all respondents 6.00% of surgeons prescribed the drug for 15 days, 13.60% surgeons prescribed for 1 month, 16.80% of surgeons prescribed and 63.60%, orthopedic surgeons prescribed more than 3-month medicine for treatment of Osteoporosis.

**Inference:** It found that mostly orthopedic Surgeons prescribed medicine for more than 3 months for the treatment of Osteoporosis because of the bone healing process is quite slow it takes the time to recover.

### 6.7. Brand preference for treatment of Osteoporosis:

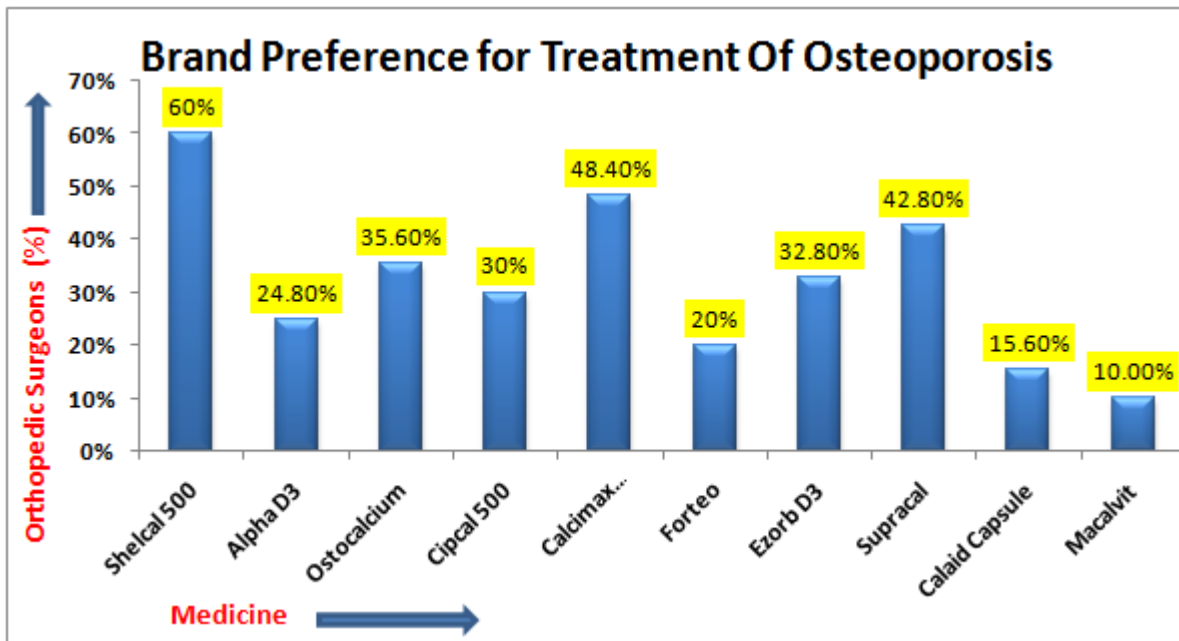


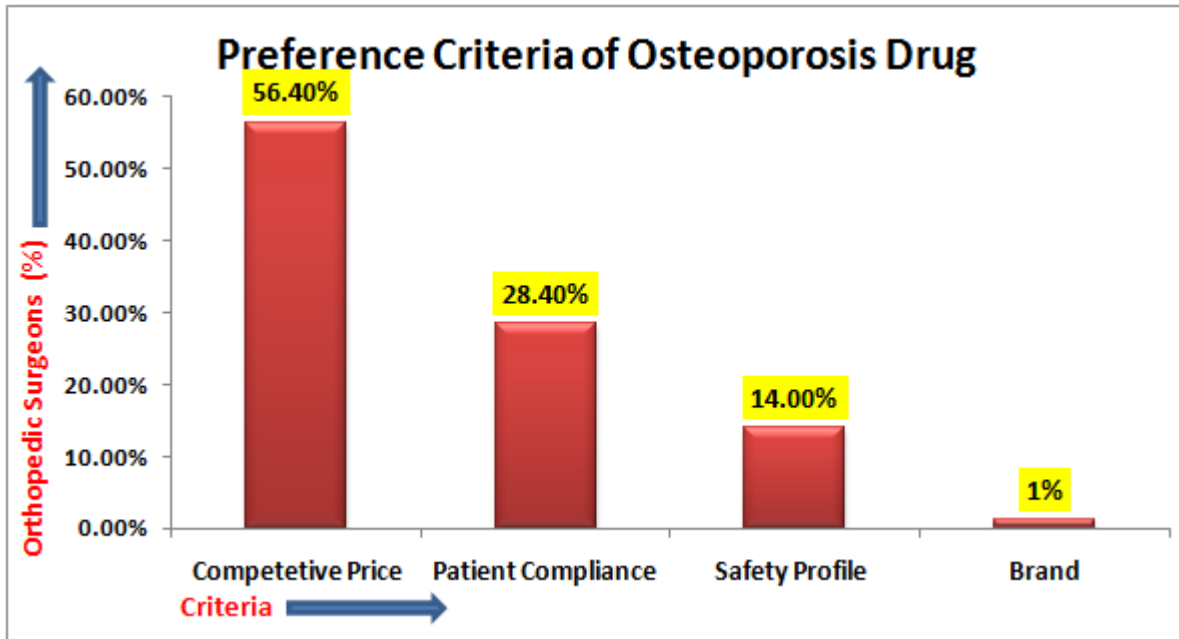
Figure 7: Brand preference for treatment of Osteoporosis.

After taking responds about brand preference researcher, scale up the top 10 most preferred brands Shelcal 500, Alpha D3, Ostocalcium, Cipcal500, Forteo, Ezorb D3, Supracal, Calaid Capsule and Macalvit.

#### Inference:

- Among all brands, Shelcal mostly preferred by the orthopedic surgeons followed by Calcimax fort and Supracal having second and third position respectively.
- It found that there is tough competition between Ostocalcium and Ezorb D3.
- Among All brands, Forteo was a single which mostly preferred by Surgeons in a
- Therapeutic segment of Osteoporosis.

### 6.8. Preference Criteria for Prescribing Osteoporosis Drug:



**Figure 8: Preference criteria for Prescribing Osteoporosis Drug.**

Among all respondents, 56.40%, 28.40%, 14.00% and 1% of orthopedic surgeons gave the first rank to Competitive price, Patient compliance and Safety profile respectively as their preference criteria for prescribing the osteoporosis drug.

#### **Inference:**

Most of the orthopedic surgeons gave first preference criteria to competitive price for prescribing osteoporosis drug.

Among all orthopedic surgeons, none of them gave first preference to brand for prescribing osteoporosis drug.

#### **7. Limitations of the study:**

- Due to personal attitudes, individual values and organizational policies, practitioners' in the medical profession keep most of their undertaking secret.

- The researcher received minimal cooperation from some respondents. The Unavailability of target respondents due to their busy schedules was a major challenge. Therefore, accessibility of records was limited; hence limiting the availability of more information that would have permit elaborate research.
- Resource constraints also posed a great limitation; with constrained finances and very busy schedules, therefore the researcher having limited time to carry out the research.

## 8. CONCLUSION

Osteoporosis, though one of the most common diseases with patient frequency 5 to 10 patient daily, mostly affecting both elderly men and women, is also one of the most neglected diseases. The lack of overt symptoms at the initial stages of the disease and unavailability of economical diagnostic tools to aid in early diagnosis, on a common treatment regime, makes the situation grim. As more anti-osteoporosis molecules become widely available in India, it is imperative for surgeons to select appropriate therapy for their patients.

In the present study, Orthopedic Surgeons mostly prescribe calcium and vitamin D supplementation like SHELCAL, CALCIMAX and SUPRACAL in Chhattisgarh along with Calcium Supplements some of them Orthopedic Surgeons also prescribe Teriparatide like FORTEO. Orthopedic surgeons preferred economic condition and safety compliances of the patient to prescribing the osteoporosis drug. Teriparatide prescribed very less because of its costly medication,

Treatment of Osteoporosis with Teriparatide is costly but more effective in cases of severe osteoporosis. Some doctors said that it shows better results. For the use of Teriparatide, the factors like cost of treatment might have long-term implications for the treatment of osteoporosis and thus need to be addressed.

## 9. Suggestion for Further Research:

- Mostly females are affecting with osteoporosis, so early diagnosis (frequent checking of bone density) and proper maintenance of diet is better than long-term treatments with potent drugs.

- Proper care should take in post-menopausal women's and old people, as themselves are most susceptible to osteoporosis.
- Shelcal is the leading brand (Region: Chhattisgarh) so the company should focus on best promotional activities to acquire the good market share.
- Calcium and vitamin D mostly used in combinations. So instead of releasing single molecules, afford should be made on combinations along with good promotional strategies.
- Teriparatide used for effective treatment in the late phases of osteoporosis. Rather than the high cost, low cost of Teriparatide will acquire a good market share.
- Calcium used for long-term treatment so gives more preference to safety profile and should be cost effective.
- There is a need for a study to increase the data collection area and population size to get the accurate date and result about the market scenario of osteoporosis and their drug for treatment.

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