Summer Training at
Zydus Cadila Health Care Ltd., Ahmedabad, Gujrat
(April 3 to June 2, 2017)

Assessment of Calcium Supplements Usage in Osteoporosis Among Orthopedic Surgeons

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CERTIFICATE

This is to certify that **Mr. Ankit Khandelwal** has undergone summer training at **Zydus Cadila Healthcare Ltd., Ahmedabad(Gujrat)** from **3rd April 2017 to 2nd June 2017**.

The candidate himself completed the project assign to him during summer training. His approach to the project was sincere and proactive. This summer training is in partial fulfillment of the course requirement recommended for the award of MBA in Pharmaceutical Management.

I wish him success in all his future endeavors.

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TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Mr. Ankit Khandelwal** from **Indian Institute of Health Management Research, Jaipur** has successfully completed his training from **21st April to 31st May 2017** in our Organization. During his training, he underwent practical training on project titled **"Assessment of Calcium supplements usage in osteoporosis among orthopaedic surgeons"**

During his training, we found him very sincere, hardworking, co-operative and full of enthusiasm.

We wish him all success in his future endeavors.

For, CADILA HEALTHCARE LTD

AMIT AJMERA
DIVISION HEAD

Place → Ahmedabad

Date → 08.06.2017

ACKNOWLEDGEMENT

First and foremost, I venerate to the God whose mercy, compassion and benediction have guided me in each step during the course of my life and this study as well.

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ANKIT KHANDELWAL

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Abbreviations

RCPA	**:**	**Retail Chemist Prescription Audit**
BMI	**:**	**Body Mass Index**
IOF	**:**	**International Osteoporosis Foundation**
DXR	**:**	**Digital X-ray radiogrammetry**
PTH	**:**	**Parathyroid Hormone**
BMD	**:**	**Bone mineral density**
IU	**:**	**International Unit**
IOF	**:**	**International Osteoporosis Foundation**
HRT	**:**	**Hormone replacement therapy**

Executive summary

"Osteoporosis is a one of the most public health problem leading to an increased risk of developing spontaneous and alarming fracture.in all over world, osteoporosis causes more than 9 million fractures annually."

"Osteoporosis is estimated to affect 200 million women worldwide - approximately one-tenth of women aged 60, one-fifth of women aged 70, two-fifths of women aged 80 and two-thirds of women aged 90"

"Osteoporosis is a chronic, progressive bone disease in which bone resorption exceeds bone formation, leading to a reduction in bone mineral density and disruption of bone microarchitecture. Patients with osteoporosis have an increased risk of fractures that occur with stresses which would not normally cause fracture in a non-osteoporotic individual."

The project assigned was Market Research on Calcium Supplements with primary objective being:

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

This project was carried out in 3 stages:

First stage was to carry out by RCPA (retail chemist prescription audit) and preparation of questionnaire followed by second stage which involved meeting with orthopedic surgeons and conducting the survey at Ahmedabad, Delhi, Jaipur. The final stage was data analysis and conclusion.

Company profile

Zydus Cadila Pharmaceuticals Ltd. is one of the largest privately held pharmaceutical companies in India, headquartered at Ahmedabad, in the state of Gujarat.

Vision:

Zydus shall be a leading global healthcare provider with a robust product pipeline; Opening up new pathway through innovation and quality excellence, we shall be a research – based company by 2020

Mission:

"Zydus cadila is enthusiastic to life ..in all its dimension. zydus world is shaped by a passion for new innovation, commitment to partners and concern for people in an effort to create healthier communities, worldwide."

"Over the last six decades, the Zydus has been developing and manufacturing plant of pharmaceutical products in India and selling and distributing these in more than eighty-five other countries around the world. Zydus strongly Focused on innovation and research". Zydus group has built strong positions in key segments of:

- Cardiovascular
- Gastrointestinal,
- Women's Healthcare
- Respiratory,
- Dermatology
- Pain Management
- Anti-infectives

At," Zydus Cadila pharmaceuticals, research and development is at the core of all its initiatives, be it biotechnology, Active pharmaceutical ingredient's, Formulations, lot of scientists in its various research and development steps reinforce the competitiveness of research in the therapeutic areas which have high unmet medical needs."

Global presence:

"Worldwide, Zydus has a very solid presence in the controlled pharma markets of the United State, Europe (France & Spain) and the high-profile markets of Latin America and South Africa. It also has a presence in 25 other developing markets of pharma in all over world"

Manufacturing Plants:

A wide range of capabilities have helped the group create a robust manufacturing infrastructure. Zydus cadila develop and manufacture an enormous range of pharmaceuticals as well as diagnosis, skin care product and other Over the counter product. Spread over five states of India, the group has eight state-of-the-art manufacturing facilities, creating a strong global manufacturing hub for the group.

- Moraiya (Ahmedabad), Baddi, Sikkim and Goa (formulations manufacturing plants)

- Brazil (finished dosage plant)
- Dabhasa and ankleshwar, Navi Mumbai (API manufacturing plant)
- Ahmedabad (Oncology API manufacturing plant)
- Cytotoxic Injectable, Zydus Hospira, Ahmedabad
- Cytotoxic Injectables, Zydus BSV, Ahmedabad

Osteoporosis:

"Osteoporosis is a chronic, liberal bone disease characterized by declining in bone mineral density(BMD) and disruption of bone microarchitecture". Patients who suffering from osteoporosis have a bigger risk of fractures that occur with pressures which would not normally cause fracture in a non-osteoporotic individual.

Osteoporosis is also known as a 'silent disease' because it figures on without any symptoms and remains unobserved for a long time as bone resorption process in early stages is almost asymptomatic and at later stages typically presents with a fracture due to unimportant shock.

Osteoporosis in worldwide:

"In all over world, osteoporosis cause more than 9 million fracture per year, resulting in an osteoporotic fracture every 3 second. Osteoporosis is estimated to affect 200 million women worldwide – approximately one – tenth of women aged 60, one – fifth of women aged 70, two – fifth of women aged 80 and two thirds of women aged 90. For the year 2000, there were an estimated 9 million new Osteoporosis fractures, of which 1.6 million were at the hip, 1.7 million were at the forearm and 1.4 million were clinical vertebral fracture."

Osteoporosis in India:

- On the basis of 2001 census, around 170 million Indians are above the age of 50, & expected to increase to 230 million by 2015. Even conservative estimates suggest that of these, 20 per cent of women and about 15-20 % of men would be suffer from osteoporotic**. It is expected that more than about 50% of all osteoporotic hip fractures will occur in Asia by the year 2050**

What causes osteoporosis?

There are many risk factors may cause bone loss and osteoporosis. Some of these things you cannot change and others you can change.

Risk factors that you cannot change such as:

- **Sexual category**: As compare to men Women get osteoporosis more.
- **Age**: The older people mostly suffer from osteoporosis.
- **Body frame** people who have Small in Hight more likely to develop osteoporosis, thin women are at greater risk.
- **Ethnicity**: "Asian women are at highest risk. Black and Hispanic women have a lower risk of osteoporosis"

Other risk factors are:

- **Sex hormones: "**Sex hormones may decrease estrogen levels due to missing menstrual periods can cause osteoporosis in females. Low testosterone levels can cause osteoporosis in men."
- Eating disorders such as anorexia nervosa
- **Ca^{+2} and vitamin D intake:** A low food in Ca^{+2} and vitamin D makes you more prone to bone loss & result is osteoporosis.
- **Medication:** Some drugs are also raise the risk of osteoporosis.
- **Physical action:** Deficiency of workout & physical work or long-term bedrest can cause weak bones.

Diagnosis & treatment of osteoporosis

Diagnosis

Earlier any symptoms diagnose:

"The idealistic situation is that 'thinning' of the bones should be forbidden in the first place. If this is not possible than the next best thing is for diagnosis and treatment of osteoporosis before any symptoms or fracture occur"

There are two mains normally used risk calculators, such as

1. **FRAX**
2. Q fracture.

"If you are found to be at substantial risk, you may be referred for a DEXA scan. DEXA exist for **dual-energy X-ray absorptiometry**. DEXA is a scanning machine that uses special X-ray to check your bone density. A DEXA scan can confirm that you are suffering or not from osteoporosis."

After symptoms develop:

"Osteoporosis is frequently first time diagnosed when your bone break after a slight bump or fall. Even after the first fracture has occurred, treatment can help to reduce your risk of further fractures."

After 65, In this age group of women, treatment for osteoporosis may be started without having a DEXA scan because at This stage of age osteoporosis is so common.

Treatment

Various medicines are available that can use in osteoporosis. drugs used to treat 'thinning' of the bones include the following:

Calcium supplementation:

Vitamin C is used as an antioxidant and a nutrient that can boost immunity, among other benefits. But vitamin C is also preventing bone loss associated with osteoporosis.

Vitamin D supplementation:

"Vitamin D is progressively being well known as a key element in overall bone health and muscle function. It plays a key role in bone health, calcium absorption, balance and muscle performance." "The minimum daily requirement in patients with osteoporosis is 800 IU of vitamin D3. Vitamin D is also available as ergocalciferol (vitamin D2) and cholecalciferol (vitamin D3). Vitamin D is metabolized to active metabolites. These metabolites promote the active absorption of calcium and by the small intestine."

Bisphosphonates:

In Bisphosphonates, there are a cluster of medicines such as alendronate, risedronate and etidronate. They are the most widely used drug in the treatment of osteoporosis. Bisphosphonate work based on bone-making cells. Bisphosphonates can support to reestablish some lost bone and help to stop further bone loss. Bisphosphonate may similarly help to reduce the chance of a second fracture. Alendronate is choice of drug in bisphosphonate class of drug

Calcitonin:

"Calcitonin is widely use in the treatment of osteoporosis. **calcitonin** produces modest increases in bone mass because it slows the rate at which osteoclasts absorb bone. Only women who are at least five years past menopause can take **calcitonin**.

Hormone replacement therapy

Hormone replacement therapy (HRT) was once measured a first-line therapy for the prevention and treatment of osteoporosis in women. Now a days HRT is not recommended for the treatment of osteoporosis, it is important to mention because many osteoporosis patients still use it for controlling postmenopausal symptoms

Teriparatide:

Teriparatide is a synthesis form of human parathyroid hormone(PTH). PTH is secreted from parathyroid glands. Teriparatide is an anabolic agent. "Parathyroid hormone increases the

concentration of calcium in serum by mobilizing calcium from bone. Pharmacologically, when PTH is administered intermittently at low doses, it has been shown to have mostly anabolic effects on osteoblasts. PTH initiates bone formation first. Teriparatide is the only drug that cause bone formation only."

Methodology

- **Research Design:** Descriptive study
- **Sample population**: Orthopedic Surgeons
- **Sample Area**: Ahmedabad, Delhi, Jaipur
- **Sample Size** 194
- **Sampling Technique**: Non-probability sampling technique
- **Collection of Data:** The research involved data collection from primary sources. The primary data collected through questionnaire.
- **Data Analysis:** The data collected from questionnaire analyzed by MS- EXCEL and table, graph, chart, were used to present findings

Findings & interpretation

Question 1. As an orthopedic surgeon how much percentage of osteoporotic patients examined in a day?

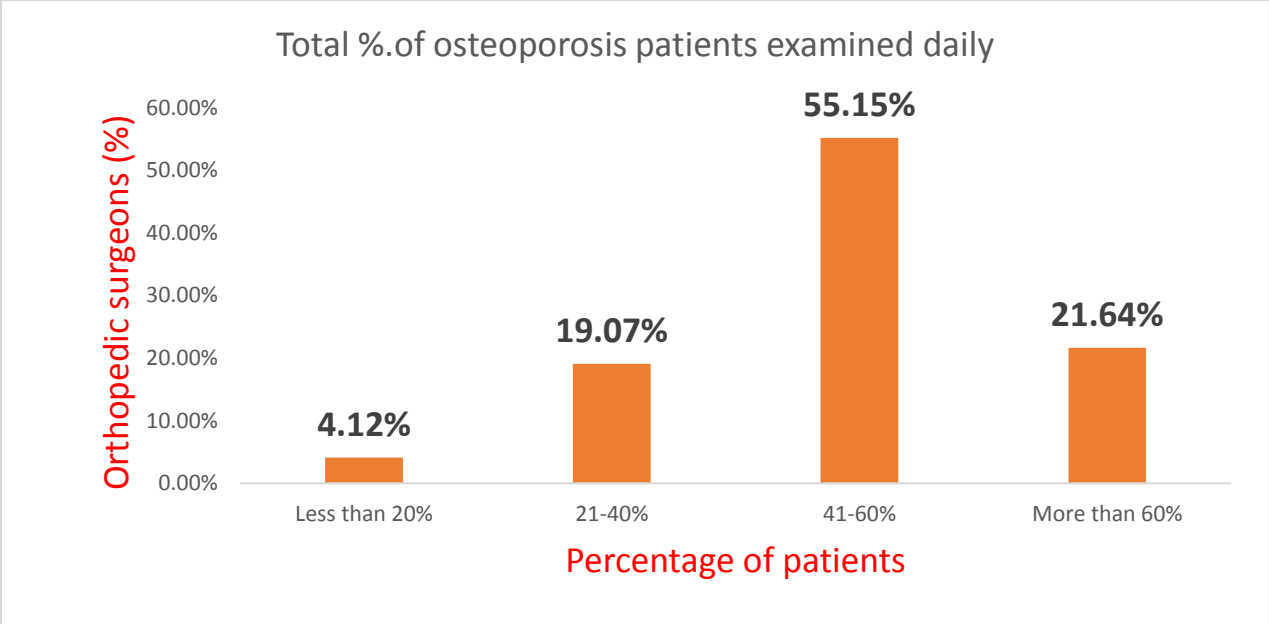

Figure 1: Percentage of osteoporosis patients examined in a day

Inference: It was found that most of the doctors have strong prescribing base with 40-60 % patients / day

Question 2. In your practice, which age group is frequently affected with osteoporosis?

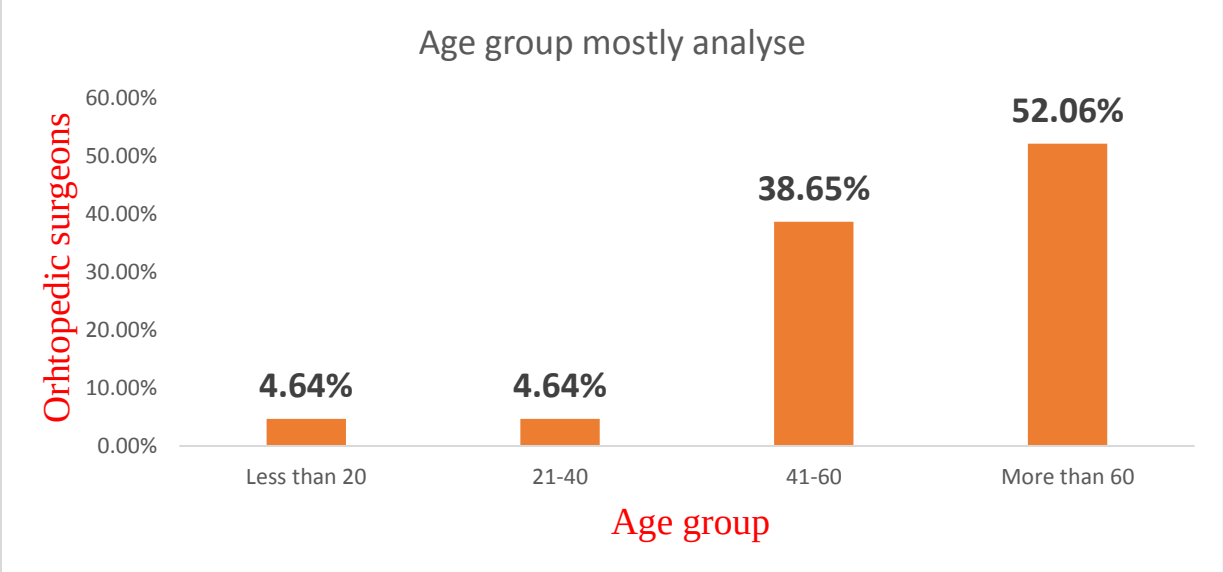

Figure 2: Age group mostly examined by orthopedic surgeons

Inferences: It was found that mostly old people more than 60 age suffer from osteoporosis as compare to adult or child was negligible.

Question 3. Which are the initial symptoms in your osteoporosis patients that help you in diagnose?

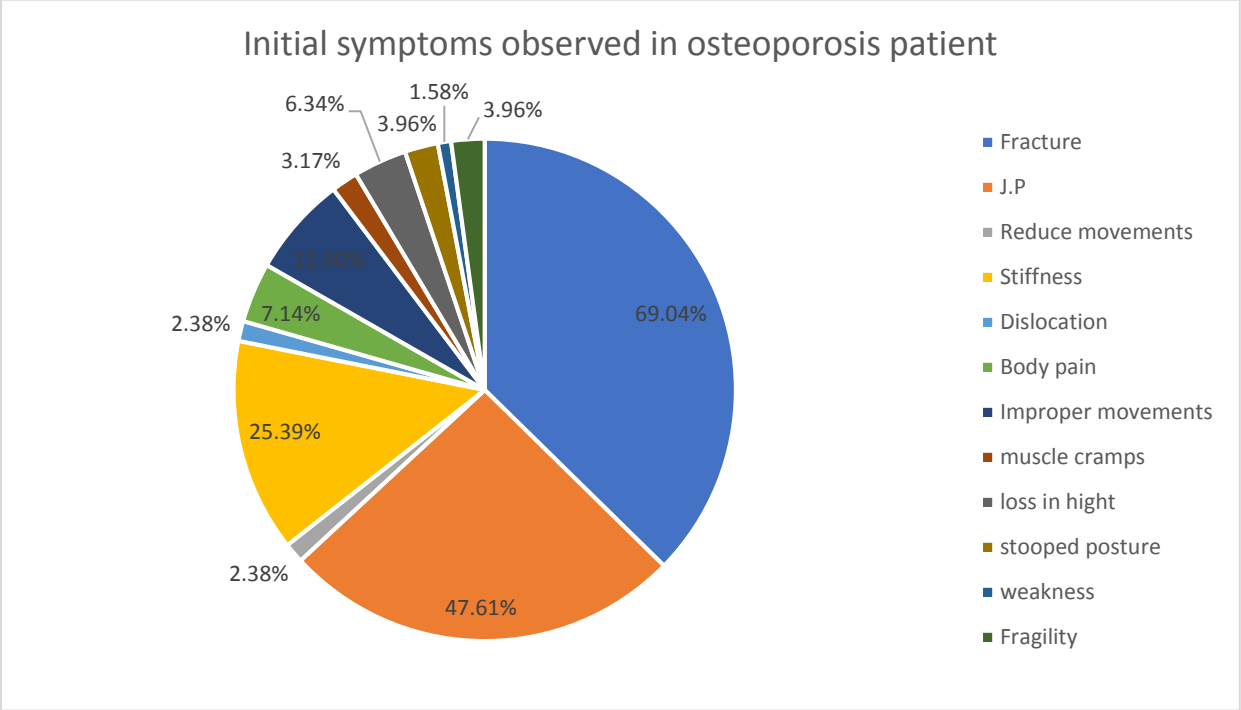

Figure 3: Initial symptoms in osteoporosis patients

Inferences: Orthopedic surgeons indicate some kind of initial symptoms among them Joint pain, Fracture and stiffness are main common symptoms in osteoporosis.

Question 4. As a first line treatment of osteoporosis, which treatment would you recommend?

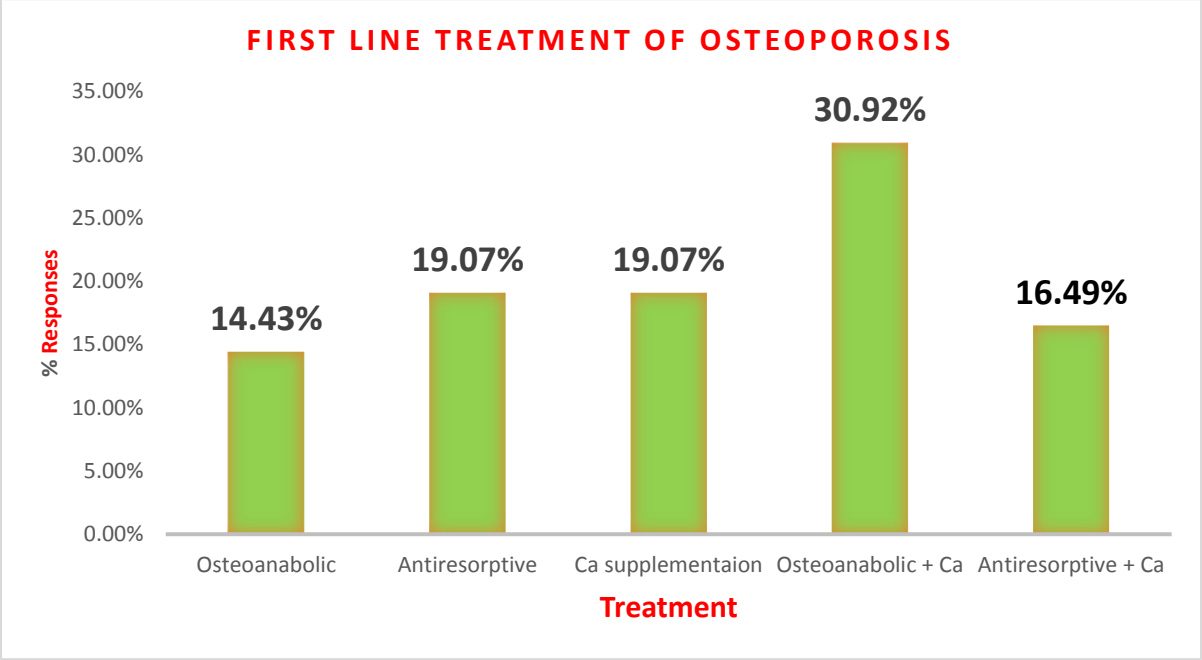

Figure 4: First line treatment of osteoporosis

Inference: It was found that most of surgeons preferred Osteoanabolic & Calcium supplement combination as a first line treatment of osteoporosis. Combination preferred more as compare to single drug.

Question 5: Among calcium salt which calcium would you recommend?

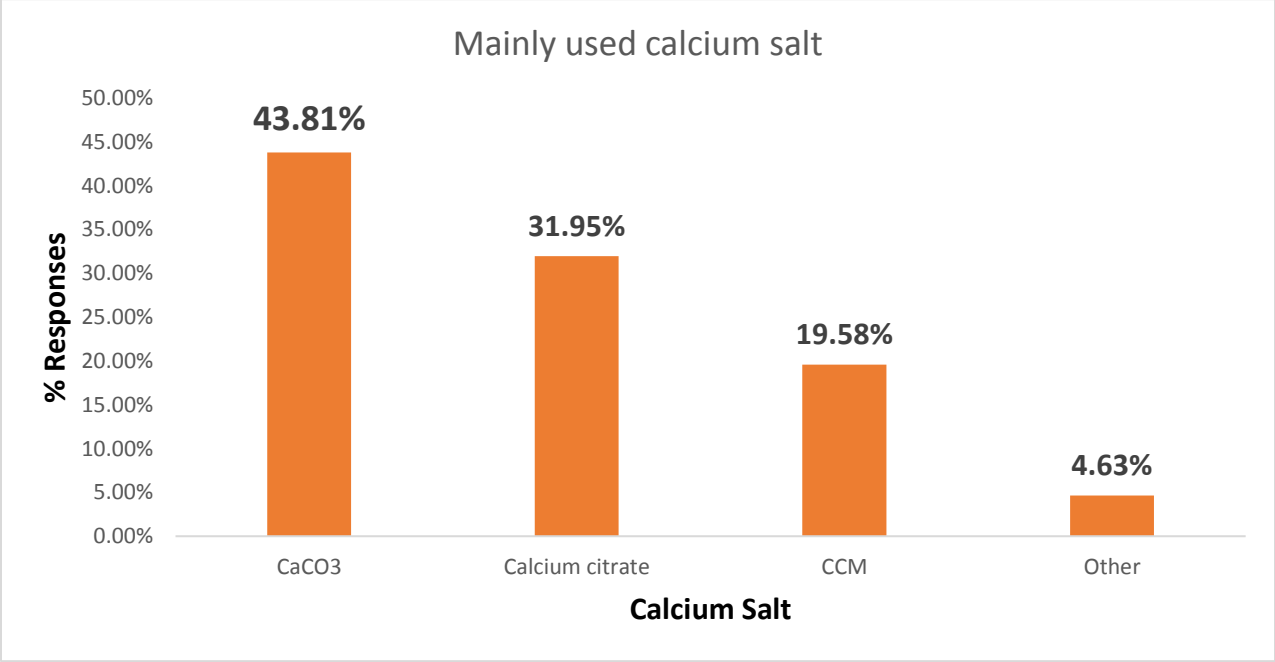

Figure 5: Mainly used calcium salt by orthopedic surgeons

Inferences: It was found that most of the surgeons preferred Calcium Carbonate as a Calcium salt. Calcium citrate preferred less a compare to Calcium Carbonate because of its competitive price. Calcium Carbonate preferred more because of it fits with the pocket of osteoporosis patients.

Question 6. How much elemental calcium would you recommend to your patients daily?

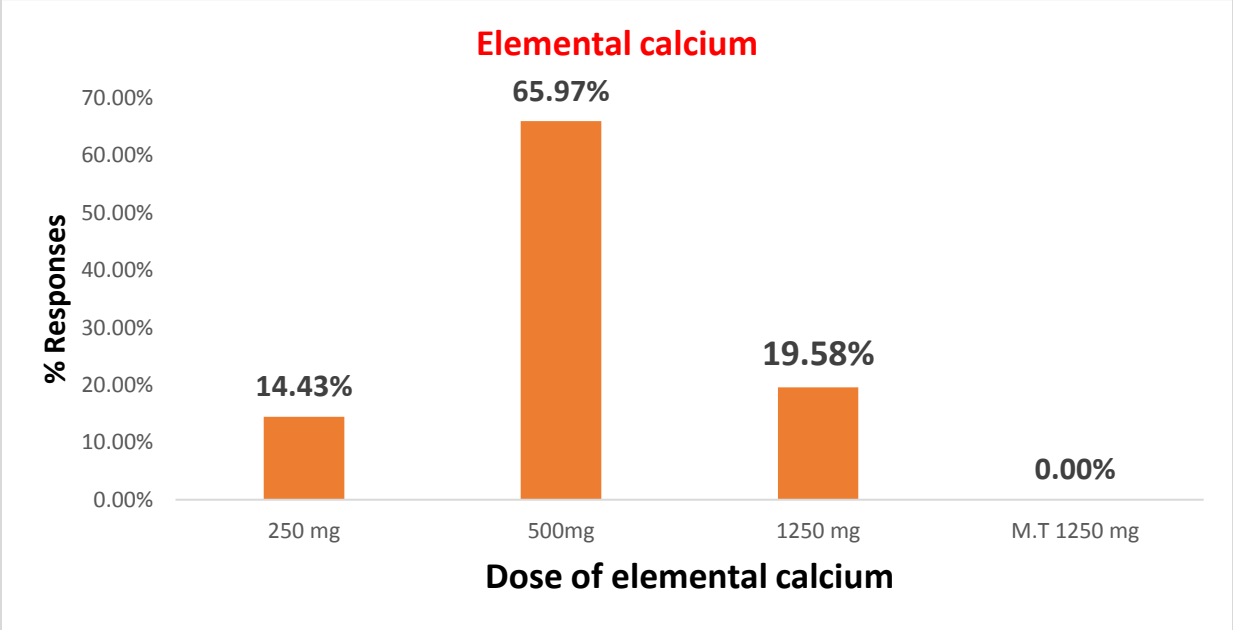

Figure 6: How much elemental calcium prescribed by orthopedic surgeons

Inferences: It was found that most of surgeons prescribed 500 mg elemental calcium in the treatment of osteoporosis because calcium is absorbed best when taken in amount of 500 – 600 mg or less (according to National Osteoporosis Foundation).

Question 7: In a calcium combination, how much vitamin D would you recommend?

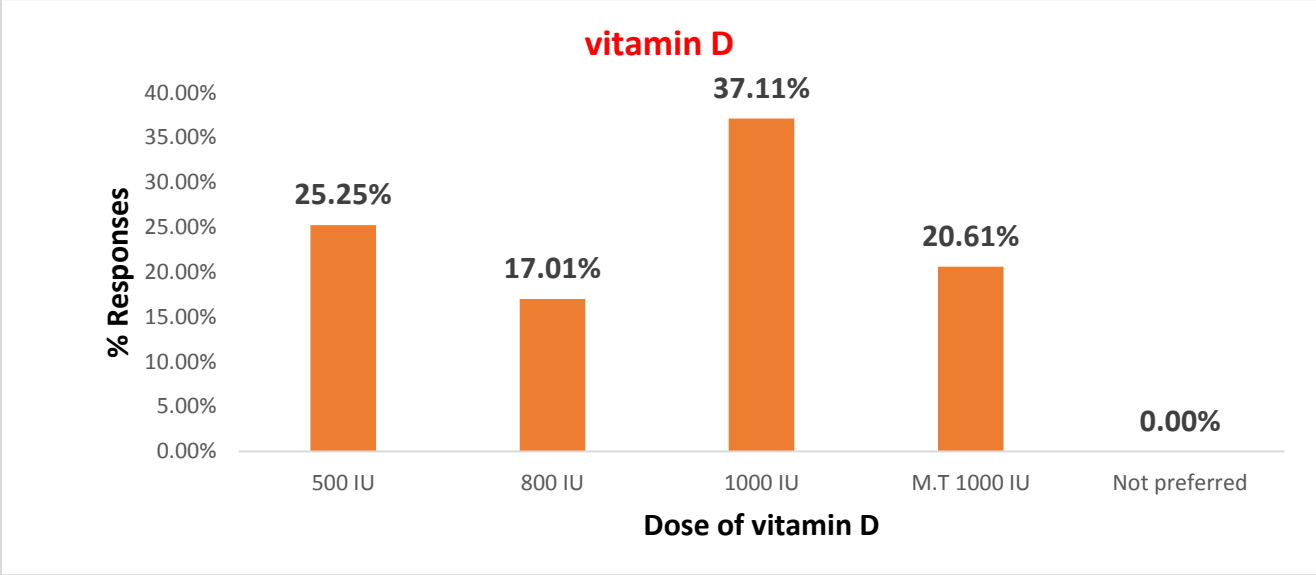

Figure 7: How much vitamin D prescribed by orthopedic surgeons

Inferences: It was found that most of surgeon prescribed 1000 IU vitamin D with Calcium combination.

Question 8: Do you recommend other mineral's?

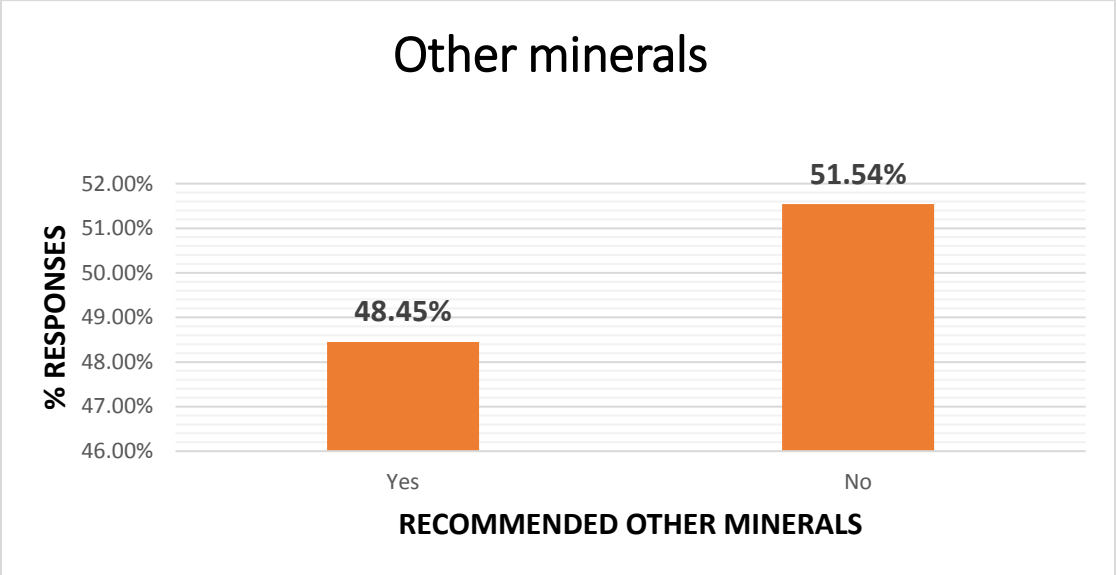

Figure 8: Other minerals recommended by surgeons

Inferences: It was found that most of the surgeons not preferred any minerals along with Calcium + vitamin D.

Question 9: If yes, then Along with calcium + Vitamin D3 which elements would you recommend to your patients?

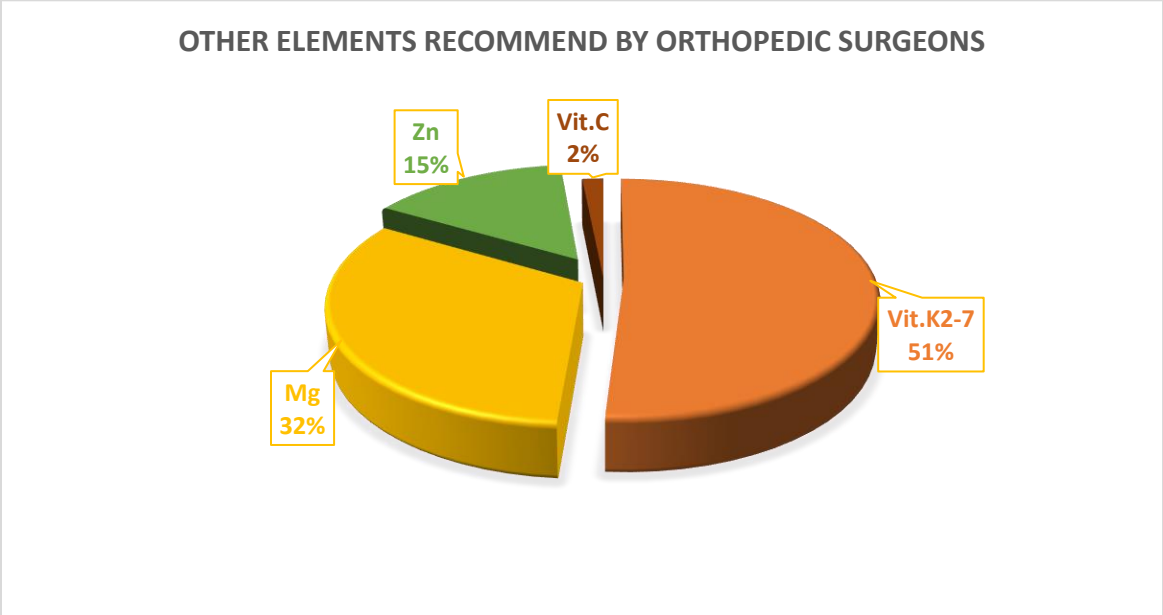

Figure 9: Other elements prescribed by orthopedic surgeons

Inferences: It was found that most of the surgeons preferred Vitamin k2-7 along with Calcium+ vitamin D.

Question 10. What are the preference criteria for Calcium Supplementation?

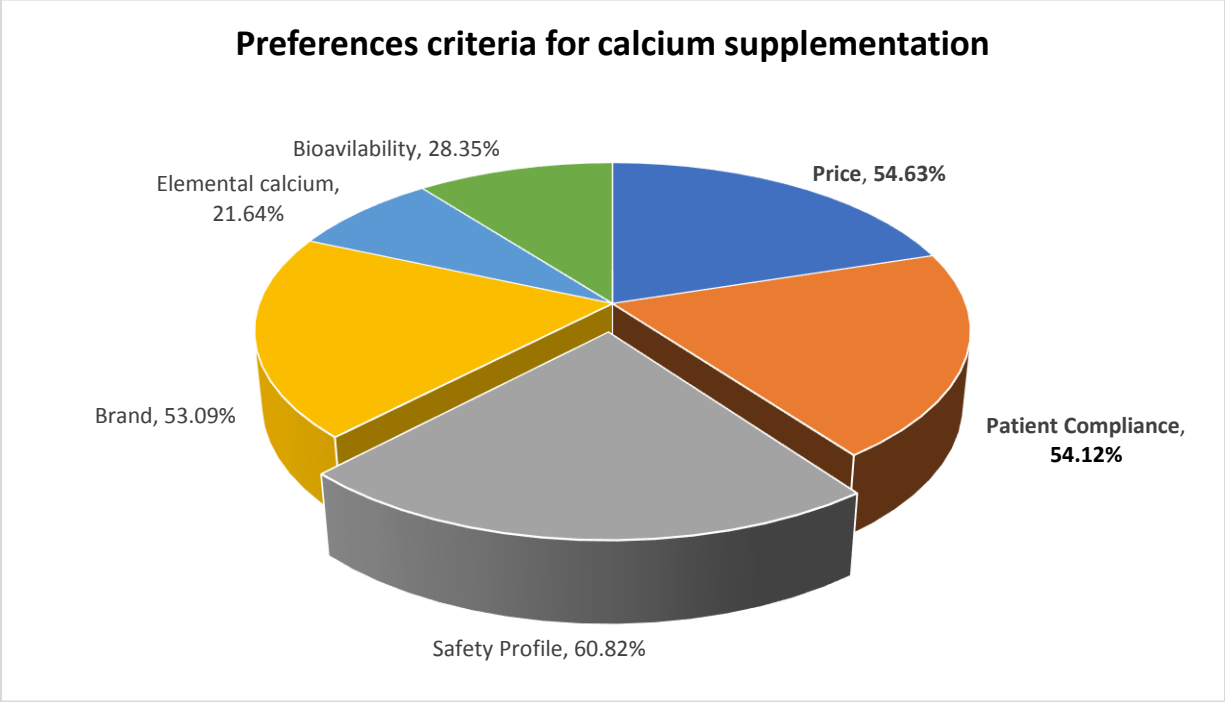

Figure 10: Preferences criteria for calcium supplementation

Inferences: Most of the Orthopedic surgeons gave first preference criteria to Safety profile for prescribing osteoporosis drug.

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

Conclusion's

Osteoporosis, though one of the most common diseases with patient frequency 41% to 60% osteoporosis patient in a day, mostly affecting more than 60 years people is also one of the

most neglected diseases. Lack of overt symptoms in 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 Osteoanabolic & Calcium supplement combination as a first line treatment in osteoporosis. Orthopedic surgeons preferred $CaCO_3$ as a calcium supplement mostly. Orthopedic surgeons preferred economical condition and safety compliances of patient to prescribing the osteoporosis drug.

Most of the Orthopedic surgeons prescribe 1000 IU as a dose of Vitamin D & not preferred any minerals with combination.

Limitation of study

- The researcher received minimal cooperation from some respondents. The Unavailability of target respondent's 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.
- Due to personal attitudes, individual values and organizational policies, practitioners' in the medical profession keep most of their undertaking secret.

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