

## Original Research Article

# Expert opinion on the clinical use of calcium and vitamin D supplements in osteoporosis in Indian settings

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### ABSTRACT

**Background:** Several clinical studies demonstrated that calcium intake decreases the risk of osteoporosis and osteoporotic fractures. However, understanding the prescription practice of calcium supplements employed in Indian contexts may help in improving patient management and developing evidence-based recommendations for optimizing the treatment. So, this study aimed to gather clinicians' perspective regarding the use of calcium and vitamin D supplements for the management of osteoporosis in Indian settings.

**Methods:** The current survey involved 17 questions pertaining to current feedback, clinical observations, and clinical experience of specialists on osteoporosis management and the use of calcium and vitamin D supplements.

**Results:** According to 30%, 26%, 25%, and 19% of the experts, higher dietary sodium (salt) intake was generally associated with negative calcium balance and bone mineral loss, increased risk of fracture, decreased calcium excretion in the urine and decreased dietary calcium absorption. Calcium and vitamin D were recommended by 78% of the respondents for the management of osteoporosis. Approximately 72% of the respondents stated calcium aspartate anhydrous as the preferred calcium supplement to manage osteoporosis. Around 49% of the respondents reported a reduced risk of bone fractures among those who consume more calcium than the average amount. Further 48%, 30%, and 25% of the respondents indicated that calcium aspartate anhydrous have better absorption, better bioavailability, and better gastrointestinal tolerability.

**Conclusions:** According to the expert's opinion, both calcium and vitamin D administration in conjunction with maintaining a balanced sodium intake were recommended for managing osteoporosis.

**Keywords:** Osteoporosis, Calcium, Vitamin D, Fracture, Calcium aspartate anhydrous

### INTRODUCTION

Osteoporosis is emerging as a global epidemic due to the aging population and increased life expectancy. According to the International Osteoporosis Foundation, one in every three women over the age of 50 and one in every five males are projected to experience osteoporotic fracture throughout their lifetime.<sup>1</sup> Osteoporosis affects approximately 200 million individuals worldwide annually.<sup>2</sup> Numerous studies have revealed a prevalence of osteoporosis that spans from 8% to 62% among Indian women of various age groups and a range of 8.5% to

24.6% in men over the age of 50 years.<sup>3</sup> Osteoporosis affects one out of every eight men and one out of every three women in India, establishing the country as having the highest prevalence of this disease globally. The prevalence of osteoporosis in India reaches its peak 10-20 years earlier than in Western nations, thereby adversely affecting the country's health and economic resources.<sup>4</sup>

Osteoporotic fracture (OF) occurs every three seconds, contributing to a global total of 8.9 million OFs worldwide annually.<sup>5</sup> Compared to the rates in 1990, it was predicted that the incidence of hip fractures would increase by 240% for women and 310% for men globally by 2050.<sup>1</sup> The

lifetime risk of OFs ranges from 30% to 40%.<sup>6</sup> These fractures not only bring about severe morbidity but also elevate the risk of mortality, particularly in the case of hip and vertebral fractures.<sup>7</sup> Furthermore, osteoporosis imposes a substantial financial burden, leading to an increase in disability-adjusted life span, and a decline in overall quality of life.<sup>1</sup>

Calcium supplementations have been shown to improve bone mineral density (BMD) and reduce the morbidity associated with osteoporosis and osteoporotic fractures across various genders and age groups. In a randomized, double-blind, placebo-controlled study conducted by Reid et al involving 1,471 postmenopausal women with a 5-year follow-up, those who received 1,000 mg/d of calcium supplements demonstrated prevention of bone loss compared to an equivalent placebo group.<sup>8</sup> Furthermore, a meta-analysis study by Cumming et al reported relative risk reductions for osteoporotic fractures ranging from 25% to 70%. With an intake of around 1000 mg/day of elemental calcium, the majority of trials indicated an estimated 30% reduction in the risk of fractures.<sup>9</sup> But understanding the prescription practice of calcium supplements employed in Indian contexts may help in improving patient management and developing evidence-based guidelines and recommendations for optimizing the treatment.

The objective of the present survey-based study was to comprehend the clinicians' perspective regarding the use of calcium and vitamin D supplements for the management of osteoporosis.

## METHODS

A cross sectional, multiple-response questionnaire based survey was carried out among physicians specialized in treating osteoporosis patients in the major Indian cities from June 2022 to December 2022.

### Questionnaire

The questionnaire booklet titled opinion of experts on calcium aspartate in osteoporosis (OPERA) study was sent to the clinicians who were interested to participate. The OPERA study questionnaire consisted of 17 questions pertaining to current feedback, clinical observations, and clinical experience of specialists on osteoporosis management and the use of calcium supplements. The study was conducted after getting approval from Bangalore ethics, an independent ethics committee which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

### Participants

An invitation was sent to leading physicians in managing osteoporosis in the month of March 2022 for participation in this Indian survey. About 237 clinicians from major cities of all Indian states representing the geographical

distribution shared their willingness to participate and provide necessary data. Those who did not provide consent were excluded. Doctors were requested to complete the questionnaire without discussing with peers. A written informed consent was obtained from each clinicians before initiation of the study.

### Statistical analysis

The data were analyzed using descriptive statistics. Categorical variables were presented as percentages to provide a clear understanding of their distribution. The frequency of occurrence and the corresponding percentage were used to represent the distribution of each variable. To visualize the distribution of the categorical variables, pie, and bar charts were created using Microsoft excel 2013 (version 16.0.13901.20400).

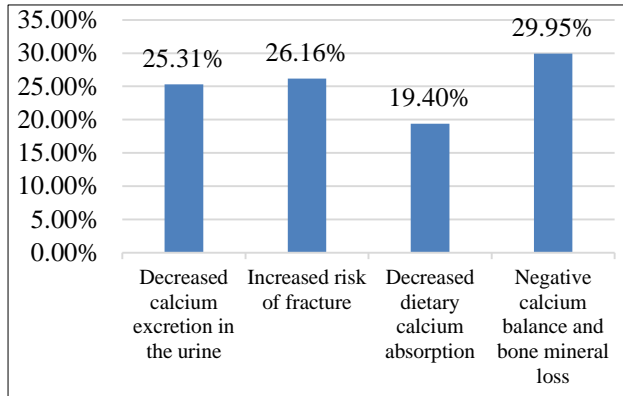
## RESULTS

According to 50% of the respondents, the monthly average number of osteoporosis cases encountered in clinical practices was 21-30. Majority (67%) of the clinicians reported that osteoporosis was more prevalent in females. According to 57% of respondents, osteoporosis was predominant in the age group of 51-60 years. Nearly 51% of respondents reported that the condition was equally prevalent in both urban and rural populations. The prevalence of osteoporosis-related fractures was 21 to 30%, as per 48% of the respondents, while 38% and 13% reported it to be 10-20% and 31-40%. Regarding T-scores, nearly 53% of respondents considered a -2.5 T-score to be common in postmenopausal osteoporosis, while 41% opted for a -3 T-score. Approximately 43% of respondents reported high body weight as a contributor to osteoporosis fractures, followed by high BMD (28%), and poor muscular strength (27%).

According to the responses, 37%, 29%, and 22% of the participants stated that yoga, swimming, and slow exercises can help prevent osteoporosis, while 13% of the respondents agreed on the benefits of all the aforementioned exercises. In terms of bone health, 36% and 30% of the respondents indicated that bone mineral accretion was rapid during the first 10 weeks of fetal life and adolescence, which predicts the risk of fractures in old age.

More than half (54%) of the respondents reported that pregnancy and lactation were known to result in bone mineral loss from the skeleton. Nearly 98% of the respondents reported that calcium aspartate was organic calcium and approximately 74% of respondents favored BMD testing to identify osteoporosis. Higher dietary sodium (salt) intake was generally associated with a negative calcium balance and bone mineral loss, an increased risk of fracture, decreased calcium excretion in the urine, and reduced dietary calcium absorption, as reported by 30%, 26%, 25%, and 19% of the respondents (Figure 1). Most (78%) of the respondents recommended

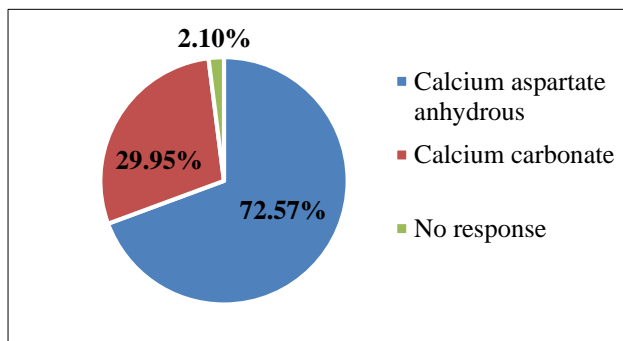
calcium and vitamin D for the management of osteoporosis (Table 1) and calcium aspartate anhydrous was preferred by 72% among the calcium salts (Figure 2).



**Figure 1: Distribution of response to clinical features associated with higher dietary sodium (salt).**

**Table 1: Distribution of response to recommended treatment for management of osteoporosis.**

Treatment	Response rate (n=237) (%)
Calcium and vitamin D	185 (78.05)
Bisphosphonates	46 (19.40)
Selective estrogen receptor modulators (SERMs)	28 (11.81)
Hormone replacement therapy (HRT)	20 (8.43)
Biosimilars	10 (4.21)



**Figure 2: Distribution of response to preferred treatment to manage osteoporosis.**

Regarding dietary calcium, 49% of the clinicians concurred with the assertion that 'consuming calcium amounts above average reduces the risk of bone fractures.' Statements such as 'activated vitamin D leads to a decrease in dietary calcium absorption,' 'the typical calcium intake for most adult's ranges between 0.5 mg and 2.0 mg per day,' and 'the efficiency of absorption varies inversely with calcium intake, resulting in higher absorption when calcium intake is low,' were affirmed by 28%, 20%, and 11% of the surveyed respondents, respectively (Table 2).

**Table 2: Distribution of response to true statements about dietary calcium.**

Statement	Response rate (n=237) (%)
Typical calcium intake in most adults is between 0.5 mg and 2 mg per day	47 (19.83)
Activated vitamin D decreases the absorption of dietary calcium	66 (27.84)
There is clear evidence that people who consume more than the average amount of calcium have a lower risk of bone fractures	117 (49.36)
Absorption efficiency is inversely related to calcium intake so that a higher proportion is absorbed when calcium intake is low	27 (11.39)

Approximately 48% of the respondents observed that calcium aspartate anhydrous has an advantage compared to other calcium salts in terms of better absorption. Additionally, 30% and 25% of the respondents reported the superiority of calcium aspartate anhydrous in terms of improved calcium bioavailability and gastrointestinal tolerability (Table 3).

**Table 3: Distribution of response to advantages of calcium aspartate anhydrous.**

Advantages	Response rate (n=237) (%)
Better absorption as compared to other calcium salts	115 (48.52)
Better gastrointestinal tolerability	60 (25.31)
Better bioavailability of calcium	72 (30.37)
All the above	35 (14.76)

**DISCUSSION**

The recommended standard of therapy for osteoporosis should incorporate sufficient calcium intake, as calcium utilization was known to enhance bone health. The present study adds to the evidence that supported the effectiveness of calcium supplementation in managing osteoporosis.

Excessive sodium intake, which was manifested through salt consumption, was recognized to exacerbate osteoporosis.<sup>10</sup> The excessive intake of sodium can lead to increased calcium excretion in the urine, thereby reducing BMD and elevating the risk of fractures.<sup>11</sup> The experts in the present study reported an association between high dietary sodium (salt) intake and several adverse effects, including negative calcium balance and bone mineral loss, an increased risk of fractures, reduced calcium excretion in urine, and diminished dietary calcium absorption. This relationship was also highlighted in a randomized controlled trial involving postmenopausal women

conducted by Teucher et al. They found that when combined with a high-calcium diet, moderately high salt consumption led to a significant rise in urine calcium excretion, significantly impacting the balance of bone calcium. Salt intake was identified as a pivotal factor responsible for the significant alteration in bone calcium balance.<sup>12</sup> Furthermore, another study conducted by Park et al which encompassed 86 postmenopausal individuals with osteopenia or osteoporosis, indicated an association between high urine calcium excretion and excessive salt consumption, as assessed through a 24-hour urine collection.<sup>13</sup>

The experts in the current study have reaffirmed the association between higher calcium intake and a reduced incidence of bone fractures. A survey by Sheth et al involving 128 orthopedic surgeons, reported that the majority of the participants favored prescribing regular calcium supplements. Among the respondents, 64% expressed that calcium supplements were effective in preventing fractures.<sup>14</sup> This aligns with the current study findings where the expert's recommended calcium and vitamin D for osteoporosis management. Similarly, a meta-analysis conducted by the National Osteoporosis Foundation revealed a statistically significant correlation between calcium and vitamin D supplements and a decrease in total and hip fractures across various populations. The study indicated that such supplementation might lead to a 15% reduction in the risk of hip fractures and a 30% reduction in the risk of total fractures, thereby potentially alleviating the burden of osteoporotic fractures on the public health system.<sup>15</sup> A meta-analysis of six randomized controlled trials (RCTs) involving 49,282 participants and 5,449 fractures, including 730 hip fractures demonstrated that the combined supplementation of vitamin D and calcium (at daily doses of 1000–1200 mg) led to a 6% reduction in the risk of any fracture and a 16% reduction in the risk of hip fracture.<sup>16</sup>

A meta-analysis by Eleni et al reported that the combined use of calcium and vitamin D has a favorable effect on reducing osteoporotic fractures.<sup>17</sup> In a study by Dawson-Hughes et al. comprising 176 men and 213 women of 65 years of age or older reported that over the course of the three-year trial period, dietary supplementation with calcium and vitamin D considerably decreased bone loss assessed in the femoral neck, spine, and whole body and decreased the risk of nonvertebral fractures.<sup>18</sup> In order to combat osteoporosis, the major dietary intervention was currently the administration of calcium and vitamin D supplements because of their relationship to decreased bone loss (associated with aging) and decreased fracture risk.<sup>10</sup>

The current study participants endorsed calcium aspartate anhydrous as the preferred calcium salt for osteoporosis treatment. They also emphasized that calcium aspartate anhydrous stands out due to its superior absorption when compared to other calcium salts. Furthermore, they

highlighted its benefits, including improved bioavailability of calcium and better gastrointestinal tolerability. A study conducted by Tang et al which involved 1,306 individuals with an initial T-score of -1.5 or lower, investigated the effects of calcium aspartate anhydrous in comparison to a placebo, as well as calcium citrate and vitamin D, or two placebos. The study findings indicated that within a period of 3 to 12 months, the administration of calcium aspartate anhydrous contributed to a significant increase in BMD.<sup>19</sup>

The current study findings underscore the significance of calcium and vitamin D supplementation, along with maintaining a balanced sodium intake, in combating osteoporosis and its associated fractures. The insights gained from this study contribute to the body of evidence that can help clinicians and individuals to make informed decisions that can ultimately lead to better bone health and reduced susceptibility to osteoporosis-related fractures. The use of a meticulously designed and validated questionnaire for gathering expert data was another major strength of the study. Since personal viewpoints and preferences might have influenced the conclusions, the dependence on expert judgments introduces the possibility of bias. Interpreting the results while keeping these limitations in mind was essential, and further research should be pursued to confirm and broaden the scope of the findings.

## CONCLUSION

There was a higher intake of dietary sodium (salt) was associated with an adverse calcium balance and the loss of bone minerals. Calcium consumption has been shown to reduce the likelihood of bone fractures. As per the expert consensus, both calcium and vitamin D along with maintaining a balanced sodium intake were recommended for managing and preventing osteoporosis in routine practice. Calcium aspartate anhydrous stands out as a preferred choice of calcium supplement due to its improved absorption, enhanced bioavailability, and better gastrointestinal tolerability.

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