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Modern prescribing practices and perspectives among Indian Orthopaedicians on Denosumab in osteoporosis: a cross-sectional survey

S. K. Mahendra[1], Sucheta Mehta[2], Devika Dhonde[2], Krishna Shriram Dhanasekaran[2]*

[1]Department of Orthopaedics, Matru Multispecialty Hospital, Bengaluru, India
[2]Medical Affairs, Cipla Ltd., Mumbai, India

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***Correspondence:**
Dr. Krishna Shriram Dhanasekaran,
E-mail: krishnashriram.d@cipla.com

ABSTRACT

Background: Denosumab reduces vertebral, hip and nonvertebral fracture risk by improving bone mineral density (BMD) in Osteoporosis. This survey aimed to understand the prescribing patterns and perspectives of Denosumab Indian Orthopaedic practice.
Methods: This cross-sectional survey was conducted among Indian Orthopaedicians for insights on Denosumab prescription patterns, patient profile, treatment duration, adherence, safety and efficacy. Data were analysed descriptively by cross-tabulation.
Results: Among 91 Orthopaedicians prescribing Denosumab for Osteoporosis (T-score<-2.5), 63.74% prescribed for fragility fractures, 60.44% to prevent recurrent fractures and 57.14% in patients without fragility fractures. Denosumab was preferred considering better patient compliance (56.04%), safety (54.95%), efficacy (51.65%) and dosing frequency (49.45%). Patient adherence for up to three years was reported by 79.13%. Teriparatide was the most common drug prescribed in combination (55%) or sequential manner (60% pre and 30.43% post-denosumab). Calcium and Vitamin D were supplemented by 94.51% of doctors. Denosumab drug holiday was not recommended by 62.64%. Approximately 52.7% and 66.7% of doctors reported 10% and 20% BMD increases after 12 and 12-24 months of therapy, respectively. Highest improvements were reported in the lumbar spine and hip. Myalgia (60.44%) and musculoskeletal pain (26.37%) were the most common side effects. Among all, 82.4% prescribed Denosumab in elderly osteoporotic patients with co-morbidities like diabetes (85.33%), cardiovascular disorders (62.67%), renal (54.67%) and hepatic impairment (21.33%).
Conclusions: Our findings underscore the significance of Denosumab in Osteoporosis with insights into the prescribing patterns of Indian Orthopaedicians. It highlights the need for strategies to improve patient adherence for optimizing therapeutic outcomes.

Keywords: Bone mineral density, Bisphosphonates, Denosumab, Fracture risk, Osteoporosis, Postmenopausal osteoporosis

INTRODUCTION

Osteoporosis, an emerging concern for public health causes substantial morbidity, reduced productivity and higher healthcare costs, affecting life across social and economic domains.[1] It is characterized by low bone mass and micro-architectural deterioration of bone tissue, consequently causing bone fragility and fracture susceptibility, significantly increasing morbidity and mortality.[2] Global osteoporosis prevalence was reported to range between 18.3-19.7%.[3]

Its global prevalence in women and men was reported to be 23.1% and 11.7%, respectively.[3] One in three women

>50 years of age experience osteoporotic fractures, as will one in five men >50 years.[2] An osteoporotic fracture occurs every three seconds causing more than 8.9 million fractures annually.[4] Overall Indian osteoporosis prevalence was reported to be 18.3%, slightly more common in females than males (19.4% vs. 17.3%).[5] In India, increasing life expectancy, urbanization and population >50 years of age increase the incidence of osteoporosis.[6] Additionally, the Bone Mineral Density (BMD) is influenced by various factors, of which genetic factors account for 50–85% of the normal variance in bone mass.[7]

The discovery of key pathways regulating bone metabolism has identified new treatment approaches with distinctive mechanisms of action to prevent fractures.[7] In India, currently, recommended drugs for osteoporosis and fracture risk reduction include bisphosphonates (BPs) (alendronate, ibandronate, risedronate and zoledronic acid), salmon calcitonin, denosumab, romosozumab and teriparatide whereas abaloparatide and romosozumab is also approved for use in other countries.[2,8]

Denosumab, a fully human monoclonal antibody against the receptor activator of nuclear factor kappa-B ligand (RANKL), is an antiresorptive agent that reduces osteoclastogenesis.[9] It is shown to reduce the vertebral, hip and nonvertebral fracture risks in postmenopausal and male osteoporosis.[10] After a critical literature search, to the best of our knowledge, it was found that no studies were available on the patterns of Denosumab use in Indian clinical practice. This survey aimed to understand the prescription patterns and perspectives of Indian Orthopaedicians on Denosumab for treating osteoporosis.

METHODS

Study design and population

This cross-sectional, descriptive, questionnaire-based study was conducted for three months from July 2023 to September 2023 to understand the prescribing practices of DENosumab in OsTEoporosis (DENOTE) among Orthopaedicians in India. Convenience sampling was employed and Orthopedicians were approached through the hospitals from 16 states and a union territory.

The Orthopedicians who had a minimum of five years of experience and were willing to participate in the study were included. Informed consent was obtained from all the participants before initiating the survey. All participants consented to the publication of the generated data.

Study tools

Data were collected using a pre-designed questionnaire with 20 questions which were self-structured, reviewed, validated and approved by the Institutional Ethics Committee of Anand Multispecialty Hospital, Vadodara. The questionnaire was distributed digitally. The doctors provided insights about their prescription pattern for Denosumab 60 mg in osteoporosis with closed-ended or dichotomous questions. Their perspective on the side effects and patient adherence were also recorded.

Statistical analysis

All the responses were recorded and double-checked for errors. Categorical variables expressed in numbers (n) and frequencies (%) were analyzed descriptively by cross-tabulation using Microsoft Excel.

RESULTS

A total of 100 Orthopaedicians across the country were approached out of which 91 participated. Most of them (76.82%) were aged between 30-49 years and a majority (39.56%) had 11-20 years of experience.

Osteoporosis prevalence in practice

In terms of osteoporosis type, 48.35% of doctors reported the prevalence of post-menopausal osteoporosis (PMO) to be 20-50%, 48.35% reported 10-30% prevalence for osteoporosis in elderly males and glucocorticoid-induced osteoporosis (GIOP) prevalence was reported as <5% by 45.05%.

Prescription patterns

According to their day-to-day practice, 60.43% of doctors opined that Denosumab was mostly prescribed to patients aged between 60-70 years (Table 1). A total of 92.3% (n=84/91) doctors were prescribing Denosumab for PMO, followed by 57.14% (n=52/91) and 52.75% (n=48/91) for male and GIOP, respectively.

Most of the doctors chose Denosumab considering its better patient compliance (56.04%) followed by its safety (54.95%), efficacy (51.65%) and dosing frequency (49.45%). Overall, 32.97% of doctors preferred administering Denosumab themselves to their patients, while 29.67% preferred it to be administered at home by a paramedic professional. A total of 62.64% of doctors reported not recommending a Denosumab drug holiday for their patients (Table 1).

Patient profiles

A total of 63.74% of doctors reported prescribing Denosumab in osteoporotic patients with fragility fractures (T-score<-2.5), whereas 60.44% prescribe it to prevent recurrent fractures, followed by 57.14% in treating osteoporotic patients without fragility fractures (T-score<-2.5). They also prescribed Denosumab as the drug of choice for patients unable to comply with administration, intolerant and unresponsive to other anti-resorptive drugs, as well as in surgical cases (like Total Joint Arthroplasties) requiring BMD improvement (Figure 1).

Table 1: Prescription pattern of denosumab.

Variable			N (%)
Denosumab prescription in different age groups (in years)	50-60		23 (25.27)
	60-70		55 (60.43)
	>70		13 (14.28)
Indications	Osteoporosis	Post-menopausal	84 (92.3)
		Male	52 (57.14)
		Glucocorticoid induced	48 (52.75)
Reasons for choosing Denosumab	Better patient compliance		51 (56.04)
	Safety		50 (54.95)
	Efficacy		47 (51.65)
	Dosing frequency		45 (49.45)
	Cost		39 (42.86)
	Route of administration		21 (23.08)
	Class of drug		20 (21.98)
Convenience of administration	At hospital/clinic	By doctor	30 (32.97)
		By paramedics	25 (27.47)
	At home	By paramedics	27 (29.67)
		By self/ caregiver	9 (9.89)
Drug holiday	Yes		34 (37.36)
	No		57 (62.64)
Calcium and Vitamin D Supplementation	Yes		86 (94.51)
	No		5 (5.49)

Treatment duration and patient adherence

Denosumab was commonly prescribed for two (32.97%), three (25.27%) and four (16.48%) years. A total of 37.36% of doctors opined that 51-75% of patients adhere to Denosumab therapy, whereas only 18.68% reported 76-100% patient adherence. A majority (79.13%) reported that their patients adhere to Denosumab therapy for up to three years (Table 2).

Combination and sequential regimen

A total of 65.93% (n=60/91) practitioners prescribed Denosumab in combination or sequential regimen (combination (n=60) and sequential (n=38)). Among the drugs combined with Denosumab, the most common drug was Teriparatide (55%) (Figure 2A). In a sequential regimen, Teriparatide was commonly prescribed before and after Denosumab therapy.

Alendronate and Risedronate were the most preferred BPs pre- and post-Denosumab therapy (Figure 2B). The duration of anti-osteoporotic drugs prescribed post-denosumab discontinuation varied; Alendronate (12-24 months), Risedronate (24 months), Zoledronic acid (24-36 months), Ibandronate (12 months) and Teriparatide (6-12 months).

Efficacy

Most of the doctors (56.04%) reported a 10% increase in BMD while 27.47% and 16.48% of doctors reported a 5% and 20% increase in BMD, respectively. Among them, a majority (56%) reported observing a 5% BMD increase in 12 months. A total of 52.94% and 66.66% reported a 10% and 20% BMD increase after 12 and 12-24 months of therapy, respectively (Figure 3A). Among all, 57.26% and 38.46% of doctors opined that the highest improvement in BMD was observed at the lumbar spine (LS) and the total hip (TH), respectively (Figure 3B).

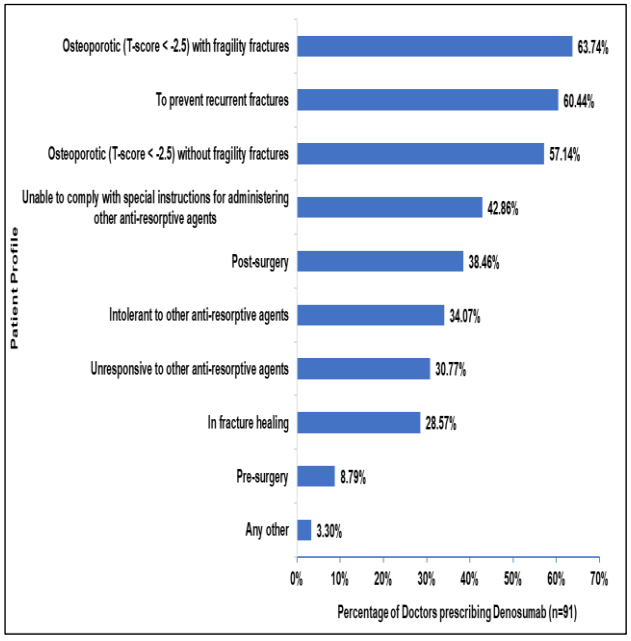

Figure 1: Patient profiles for prescribing Denosumab.

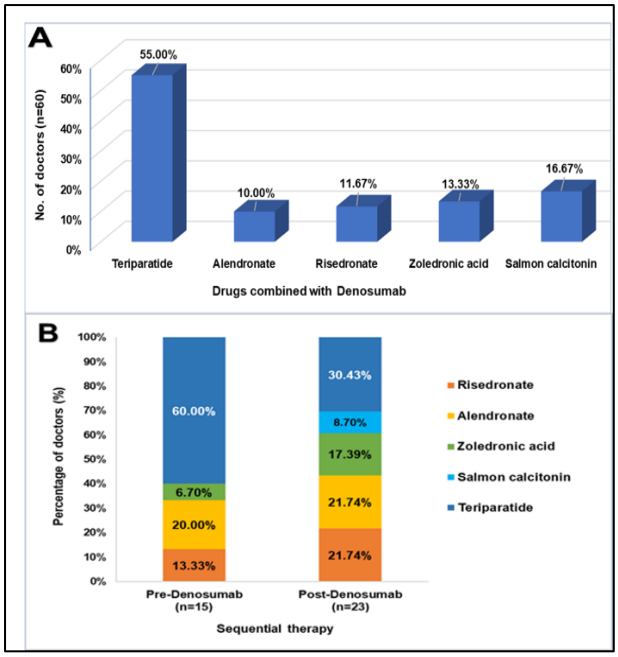

Figure 2: (A) Combination therapy with Denosumab and (B) Sequential therapy pre- and post-Denosumab.

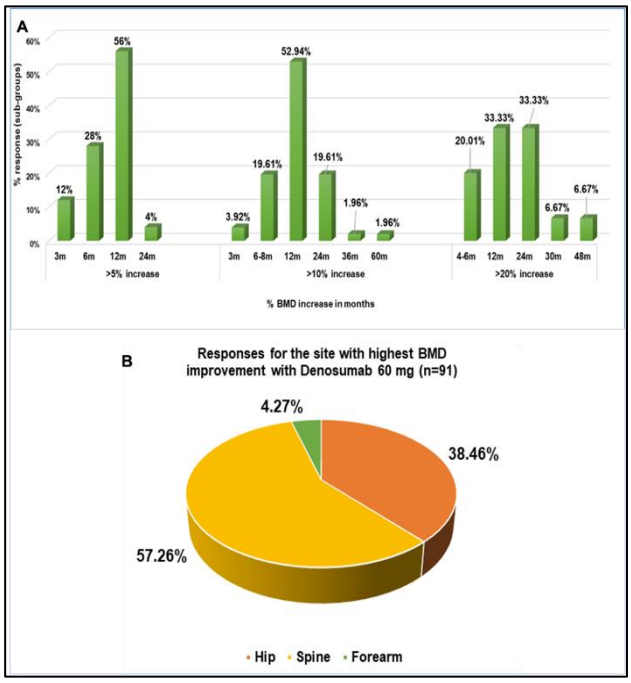

Figure 3: (A) Observed percentage increase in BMD and (B) Site with highest BMD improvement with Denosumab therapy.

Side effects

Myalgia (60.44%) and musculoskeletal pain (26.37%) were the most cited side effects with Denosumab. Other side effects reported were fever (21.98%), gastrointestinal disorders (12.09%), back pain (12.09%), hypersensitivity reactions (8.79%) and osteonecrosis of the jaw (ONJ) (6.59%). A doctor reported mortality in three of his patients (reasons undisclosed, hence causality unknown).

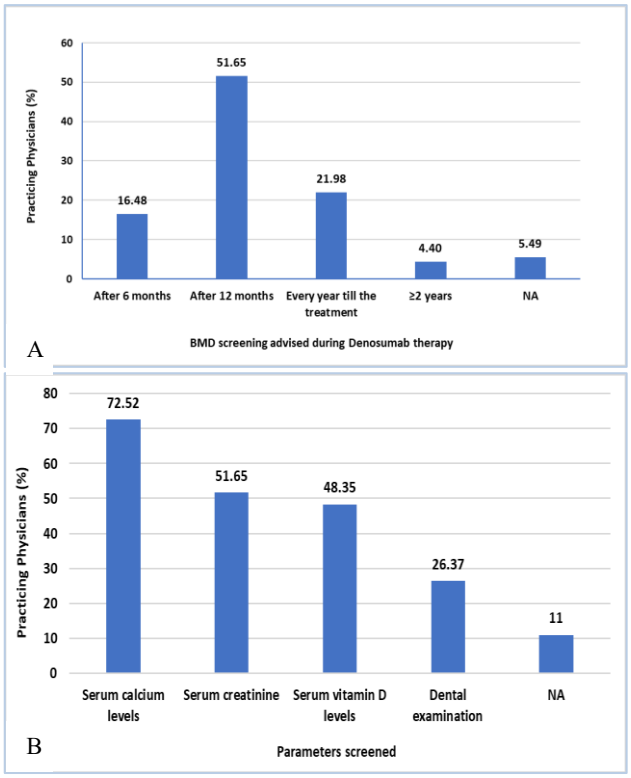

Figure 4: (A) Frequency of BMD screening during Denosumab therapy and (B) Clinical parameters screened during Denosumab therapy.

Monitoring parameters

Almost half of the doctors (51.65%) were screening BMD in their patients after 12 months of Denosumab therapy, whereas 21.98% were screening BMD every year till the patient was on Denosumab therapy (Figure 4A).

Around three-fourth of doctors (72.52%) reported monitoring serum calcium levels while ~50% monitored serum creatinine and vitamin D and 26.37 % for dental examination. However, 11% (n=12) reported monitoring none of these parameters (Figure 4B).

Use in special populations

Among all, 82.4% were using Denosumab to treat osteoporosis in elderly patients with co-morbidities. Among them a majority (85.33%) responded for prescribing it in patients with diabetes, followed by 62.67% for patients with cardiovascular diseases.

Nearly half (54.67%) of the doctors were prescribing Denosumab in patients with renal impairment, while 21.33% were prescribing it in patients with hepatic impairment.

Table 2: Denosumab treatment duration and patient adherence.

Variables			N (%)
Denosumab treatment duration (in years)	<1		6 (6.59)
	<2		30 (32.97)
	<3		23 (25.27)
	<4		15 (16.48)
	<5		2 (2.20)
	≥5		15 (16.48)
Patient adherence	Compliance to Denosumab (%)	10-25	16 (17.58)
		26-50	24 (26.37)
		51-75	34 (37.36)
		76-100	17 (18.68)
	Persistence to Denosumab (in years)	<1	12 (13.19)
		1-<2	39 (42.86)
		2-<3	21 (23.08)
		3-<4	6 (6.59)
		4-<5	4 (4.4)
		≥5	9 (9.9)

DISCUSSION

Osteoporosis is a chronic disease requiring chronic treatment. Although evaluation of the long-term safety and efficacy of osteoporosis medications is essential, understanding the rationality of prescribing patterns and patient profiling is vital.[11] This study focused on the usage patterns and perspectives of Indian Orthopaedicians for Denosumab in Osteoporosis. Over the past decade, there has been a progressive increase in the number of Denosumab prescriptions over other anti-resorptives and anabolic in clinical practice.[12] This may be due to improved patient compliance with Denosumab, recommendations by various societies and the FREEDOM (Fracture Reduction Evaluation of Denosumab in Osteoporosis Every 6 Months) trial evidencing progressive BMD improvement at the LS, TH and femoral neck (FN) with 10 years safety data on Denosumab.[13] Guidelines from the American Association of Clinical Endocrinologists (AACE) and the Indian Society for Bone Mineral Research (ISBMR) recommend Denosumab as a first-line agent to treat postmenopausal women and men with osteoporosis at high risk for fracture.[1,2]

In our study, the prevalence of PMO in practice was reported to be ranging between 20-50%. It was comparable to the findings of a pan-Indian study by Babhulkar et al in which osteoporosis prevalence was 19.4% for females.[5] In our study, patients between 60-70 years of age were the most prescribed with Denosumab. Similarly, in a study by Erra A et al, the average age range was 60-91 years.[14]

The AACE guidelines recommend using Denosumab to treat severe osteoporosis and associated vertebral fractures.[1] In our study, most of the doctors were prescribing Denosumab in severely osteoporotic patients with or without (high risk) fragility fractures (T-score<-2.5) to prevent recurrent fractures. In a Taiwanese study, the cohort persistent to Denosumab experienced relative risk reductions of the hip (38%), clinical vertebral (37%) and nonvertebral (38%) fractures, with a mean (± SD) on-treatment follow-up time of 16±11 months.[15] It was also commonly used in patients who are intolerant/ unresponsive/ unable to comply with administering other anti-resorptives. It was also observed that Denosumab was used in surgical cases. In elderly patients, Denosumab or teriparatide significantly prevented periprosthetic bone loss, improving BMD after total knee arthroplasty (TKA) thus, effectively reducing the risk of periprosthetic fractures.[16,17] In a study by Tani et al, Denosumab achieved strong pedicle screw fixation with an increase in BMD in elderly patients with spine fusion surgeries.[18]

In the FREEDOM Trial, Denosumab showed "broad-spectrum" anti-fracture efficacy as early as 12 months after starting it in PMO.[1,10] Studies showcasing Denosumab treatment duration of up to 10 years indicate persistent fracture protection with a good safety profile.[1,11] In our study, commonly reported treatment durations were up to two (32.97%) and three years (25.27%). Whereas 16.48% reported prescribing Denosumab for more than four and five years each.

Adherence can be defined as a composite of being both compliant and persistent with therapy.[19] Only 18.68% of doctors opined having the highest patient medication adherence (76-100%) to Denosumab followed by 37.36% of doctors opined having 51-75% adherence in our study. The persistence levels towards Denosumab therapy in PMO women were 86% and 76% at one year and two years in a French study.[20] Similarly, a Danish study reported higher persistence in osteoporotic patients under Denosumab (84% at one year and 71.9% at two years).[21]

In this study, 42.86% and 23.1% of doctors opined for 1-2 and 2-3 years of patient persistence, respectively. Doctors preferred Denosumab mostly due to its good patient compliance (56.04%) followed by safety (54.95%), efficacy (51.65%) and dosing frequency (49.45%). Good compliance might be because patients adhere better to less frequent dosing regimens.[22]

In this study, most of the doctors preferred administering Denosumab to their patients in the clinic, while some opined for its administration at home by a paramedic professional. The administration route for Denosumab is likely to influence patient adherence. Denosumab requires subcutaneous (SC) administration by healthcare professionals (HCPs), giving them a greater role in ensuring patient adherence. It also provides HCPs with direct evidence of patient adherence and an opportunity to communicate with the patient about the importance of not missing scheduled treatments rather than relying on patient recall about their treatment adherence.[22]

In the FREEDOM Trial, the highest BMD improvement in PMO women was at the LS (9.2%) and TH (6.0%) at 12 months of Denosumab.[10] Whereas in the FREEDOM extension trial, the highest BMD improvement was in the LS in both long-term (21.7% from FREEDOM baseline) and cross-over (16.5% from extension baseline) groups.[11] Comparably in our study, 57.26% and 36.7% doctors opined for BMD increase in the LS and TH. Whereas 56% opined observing a 5% BMD increase in 12 months followed by 52.94% and 66.66% reporting 10% and 20% BMD increase between 12 to 24 months, respectively.

In this study, myalgia, musculoskeletal pain and fever were the common adverse events reported for Denosumab. Other reported events were gastrointestinal effects, back pain, hypersensitivity and ONJ. However, in the FREEDOM extension study, the incidence of adverse events such as serious infection, cellulitis, eczema and malignancy remained low and less frequent for hypocalcemia and fatal adverse events (like ONJ and atypical femoral fractures).[11]

Although the fracture prevention data isn't available, studies suggest Teriparatide and Denosumab combination results in a larger BMD increase in the LS and TH than either agent alone in the high-risk patients (T-score≤-2.5).[1,2] Denosumab and Teriparatide were reported to be the most preferred combination, in our study. Also, teriparatide was mostly preferred pre-and post-Denosumab therapy followed by alendronate and other anti-resorptives. Many studies suggest teriparatide pre-Denosumab to be more effective than teriparatide post-Denosumab therapy.[23,24] In a study by Leder et al, a two-year Denosumab regimen post-teriparatide led to 9.4% and 4.8% BMD gains in LS and TH, whereas four-year gains were 18.3% and 6.6%, respectively. These results surpass those typically seen with the use of BPs post-teriparatide.[23,24] Transition from Denosumab to teriparatide should be avoided because of the resultant accelerated bone turnover and sustained bone loss.[23]

Discontinuation of Denosumab may potentially be risky, leading to rapid reversal causing a rebound bone turnover with subsequent bone loss and the possibility for multiple vertebral fractures. BPs preserve the BMD gains and reduce fracture risk after discontinuing Denosumab. Current evidence supports transition to short-term BP therapy with close monitoring of BMD and bone turnover markers (BTMs) as a viable option to mitigate bone loss and multiple vertebral fracture risk.[25] The United Kingdom (UK) clinical guidelines recommend maintaining optimum serum calcium (especially in the initial two weeks) and 25-hydroxyvitamin D levels.[26] Calcium and vitamin D supplementation enhance BMD gains in osteoporotic patients under Denosumab. It also helps in reducing hypocalcemia risk associated with Denosumab therapy.[27] The Delhi Vertebral Osteoporosis study (DeVOS) findings from India suggest that the odds of osteoporotic fractures are low in subjects consuming calcium and vitamin D supplements with anti-osteoporotic drugs.[2] In our study, 94.5% of the doctors supplemented their patients with calcium and vitamin D. However, 5.5% didn't, which should be intervened.

Studies on Denosumab follow periodic monitoring of BMD, serum calcium, vitamin D and BTM levels to ensure adherence and analyze the clinical outcomes.[2,10,11] In the FREEDOM extension trial, PMO women treated with Denosumab for up to 10 years had an overall safety profile consistent over time, with low fracture incidence, sustained reduction of BTMs and continued BMD gains.[11] Fifty-one percent of doctors in our study reported for screening BMD following a year of Denosumab, while 21.98% opined for annual BMD screenings throughout the entire Denosumab course. However, 11% reported monitoring none of these in their patients which should be highly concerned to be intervened.

In this study, 85.33% of doctors were prescribing Denosumab to osteoporotic patients with diabetes, followed by 62.67% for patients with cardiovascular diseases. Nearly half (54.67%) of the doctors were prescribing Denosumab to osteoporotic patients with renal impairment. It was almost like the patient characteristics of a Japanese study by Hayashi et al in which 71.7% of Denosumab-treated patients had existing co-morbidities like osteoarthritis (30.3%), hypertension (23%), diabetes mellitus (14.7%), heart disease (6.4%) and chronic renal failure and liver dysfunction (3.7% each).[28] Denosumab is safe in patients with pre-existing co-morbidities except infectious diseases.

Denosumab was associated with a markedly higher incidence of severe and very severe hypocalcemia in female dialysis-dependent patients aged≥65 years compared with oral BPs.[29] As per the findings of Bird et al the Food and Drug Administration (FDA) updated the label with a warning that before starting Denosumab,

chronic kidney disease (CKD) patients should be checked for serum calcium levels and associated mineral bone disease (MBD) which may lead to severe hypocalcemia and further worsen the condition.[29] So, Denosumab should be used judiciously in CKD patients with a Nephrologist's opinion.

The preference for Denosumab to treat severe osteoporosis and its application in pre-operative period to improve BMD demonstrates its adaptability and clinical importance. Low levels of patient persistence can be increased by patient education and perhaps more nuanced study designs to provide more granular data. Combining Denosumab with Teriparatide or alternate agents represents dual-action therapies, especially in cases where single-agent therapy may not be sufficient. Holistic care and management include judicious supplementation with calcium and vitamin D as well as regular surveillance of bone health parameters. Addressing differences in dosing practices and improving adherence remain important areas to maximize Denosumab treatment for osteoporosis.

Despite the available consistent evidence on Denosumab's safety and efficacy, to the best of our knowledge studies on its prescription patterns in varying patient profiles are very limited. So, our DENOTE study focused on a comprehensive understanding of usage patterns and perspectives for Denosumab among Indian Orthopaedicians.

One of the limitations of the study is the smaller sample size. Additionally, the study focuses only on prescribing patterns of Indian Orthopaedicians, which may limit the generalizability of the findings to other specialties. Moving forward, continued research and collaborative efforts are warranted to further refine osteoporosis management strategies and improve patient outcomes in clinical practice.

CONCLUSION

This study provides significant information about the changing scenario of osteoporosis practice in the era of Denosumab among Indian Orthopaedicians. It highlights the need for holistic patient care concerning calcium and vitamin D supplementation, monitoring of bone health parameters and co-morbidities along with treatment decisions. Resolving dosing discrepancies and improving strategies for patient adherence are identified as potential targets for intervention to optimize Denosumab therapy and its outcomes.

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