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Development of a Personal Formulary for Uncomplicated Osteoporosis by Residents of Pharmacology

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ABSTRACT

Osteoporosis is a chronic skeletal disorder characterized by reduced bone mass and deterioration of bone microarchitecture, leading to increased fragility fractures and significant morbidity. In India, the burden of osteoporosis is rising due to increasing life expectancy, nutritional deficiencies, sedentary lifestyle, and limited awareness. Rational drug selection is essential to optimize treatment outcomes and reduce healthcare costs. This study aimed to develop a rational personal formulary (P-drug) for osteoporosis using the World Health Organization (WHO) 6-step approach.

The study was conducted in the Department of Pharmacology at Indira Gandhi Institute of Medical Sciences, Patna, Bihar, among postgraduate residents and faculty members. Bisphosphonates available under the Janaushadhi scheme were evaluated using four parameters: efficacy, safety, cost, and convenience. Weighted scores were assigned according to predefined criteria, with efficacy receiving the highest weightage. Alendronate sodium and Ibandronic acid were compared based on published literature, adverse effect profile, affordability, and patient compliance.

Alendronate sodium achieved the highest total weighted score (7.1) compared to Ibandronic acid (5.1), primarily due to its superior efficacy, lower cost, and widespread availability. Consequently, alendronate sodium 70 mg once weekly was selected as the preferred P-drug for osteoporosis. The study highlights the importance of evidence-based and cost-effective prescribing in resource-limited settings. Application of the WHO P-drug concept can promote rational pharmacotherapy, improve adherence, and optimize patient outcomes in osteoporosis management.

Keywords: Osteoporosis, P-drug, Bisphosphonates, Rational drug use, Personal formulary.

INTRODUCTION

Osteoporosis is a chronic, progressive skeletal disorder characterized by reduced bone mass and deterioration of bone microarchitecture, resulting in increased

bone fragility and susceptibility to fractures.(1) It is a major public health concern worldwide, particularly among the elderly population, and is associated with significant morbidity, mortality, and economic burden. Fragility fractures, especially of the hip, spine, and wrist, contribute substantially to disability and reduced quality of life.

In India, osteoporosis is emerging as a silent epidemic due to increasing life expectancy, urbanization, sedentary lifestyle, and nutritional deficiencies. It is estimated that over 50 million Indians are either osteoporotic or at high risk of developing the condition. Factors such as low dietary calcium intake, widespread vitamin D deficiency, early menopause in women, and limited awareness further exacerbate the burden of disease in the Indian population.(2) Despite this, osteoporosis remains underdiagnosed and undertreated in routine clinical practice.

The management of osteoporosis includes both non-pharmacological and pharmacological interventions. Lifestyle modifications such as adequate calcium and vitamin D intake, weight-bearing exercises, and fall prevention strategies are essential components of care. Pharmacologic therapies are either antiresorptive or anabolic. The antiresorptive agents include medications that have broad effects such as hormone/estrogen therapy and selective estrogen receptor modulators (SERMS) as well as specific agents for osteoporosis treatment (bisphosphonates, denosumab and calcitonin). The anabolic agents are teriparatide, abaloparatide and romosozumab).(1,3) However, the selection of appropriate therapy often varies due to differences in patient characteristics, drug availability, cost considerations, and physician prescribing patterns.

The concept of a Personal Formulary (P-drug), introduced in the context of rational pharmacotherapy, emphasizes the selection of a limited number of drugs based on efficacy, safety, suitability, and cost for a specific condition. (4) Developing a personal formulary for osteoporosis treatment is particularly relevant in India, where healthcare resources are limited, and out-of-pocket expenditure remains high. A rational, evidence-based selection of drugs can improve treatment adherence, reduce unnecessary polypharmacy, and optimize patient outcomes.(5) Rational drug use requires that patients receive medications appropriate to their clinical needs, in adequate doses, for an appropriate duration, and at the lowest possible cost.(6)

Given the variability in clinical practice and the lack of standardized prescribing patterns in India, there is a need to develop a structured personal formulary for osteoporosis tailored to the Indian population. This study aims to evaluate commonly used drugs for osteoporosis and establish a rational personal formulary based on efficacy, safety, cost-effectiveness, and suitability in the Indian healthcare setting.

MATERIALS & METHODS

This study was carried out in the Department of Pharmacology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar (India), among the residents and faculty members of the Department of Pharmacology. A personal formulary for treatment of osteoporosis was developed after thorough discussion among the residents. In case of disagreements or doubt, senior faculty members were consulted.

P-drug for osteoporosis was selected using the WHO 6-step approach.

Step 1: Define the Diagnosis:

Osteoporosis is defined as a systemic skeletal disorder characterized by decreased bone mass and microarchitectural deterioration of bone tissue, leading to increased bone fragility and a higher risk of fractures. The diagnosis is primarily established by measuring bone mineral density (BMD) using dual-energy X-ray absorptiometry (DEXA).

According to World Health Organization (WHO) criteria:(3)

- Normal: T-score ≥ –1.0
- Osteopenia: T-score between –1.0 and –2.5
- Osteoporosis: T-score ≤ –2.5
- Severe osteoporosis: T-score ≤ –2.5 with one or more fragility fractures

In the Indian clinical setting, diagnosis may also rely on:

- History of low-trauma (fragility) fractures
- Clinical risk factors (e.g., postmenopausal status, advanced age, low body weight, long-term corticosteroid use)
- Limited access to DEXA in resource-constrained areas

Thus, both BMD assessment and clinical evaluation play crucial roles in diagnosing osteoporosis in the Indian population

Step 2: Specify the Therapeutic Objective

● Prevention of Fragility Fractures
● Increase or Maintain Bone Mineral Density
● Reduction of Bone Loss
● Relief of Symptoms
● Correction of Nutritional Deficiencies
Minimization of Drug-Related Adverse Effects
Improvement of Treatment Adherence
Prevention of Disease Progression

Step 3: Identify Effective Drug Groups

Bisphosphonates

Step 4: Compare Drugs Using P-Drug Selection Criteria

Residents were taught how to analyse and give scores (α) to drugs used for osteoporosis available in the market. Four parameters, according to the P-drug concept of Joshi and Jayawick Ramarajah (7), efficacy, safety, cost and convenience were taken into consideration for each group and their drugs.

1. Efficacy was derived according to the efficacy profile as per the published literature. Drugs with more efficacy were given a higher score.
2. Safety of a drug was described according to the side effect profile as per the published literature. Drugs with more side effects were given a lower score.
3. Janaushadhi(8) was used to determine the cost of drugs. The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is a flagship campaign launched by the Department of Pharmaceuticals, Government of India, to provide quality generic medicines at affordable prices to all citizens. Originally introduced in 2008 and revamped in 2015, the scheme operates through dedicated outlets known as Janaushadhi Kendras, which offer drugs and surgical items at prices 50% to 90% lower than their branded counterparts. By procuring medicines from WHO-GMP certified suppliers and ensuring quality through NABL-accredited laboratory testing, the initiative dispels the myth that low-priced generic drugs are inferior in efficacy. As of 2026, the scheme has expanded significantly with a target of 20,000 functional Kendras across the country, saving citizens billions in out-of-pocket healthcare expenses while simultaneously promoting entrepreneurship and self-employment for pharmacists and NGOs (8,9). A lower score was given to drugs with a higher cost. Drugs not available under the Janaushadhi scheme were excluded from the study.
   Convenience was compared according to the patient compliance, dosage form, dosage schedule and route of administration.
4. Scores were given to each four parameters from 1 to 10 for each drug. Each parameter was given a fractional numerical rating (β) according to the importance, i.e. 0.4 for efficacy, 0.3 for safety, 0.2 for cost and 0.1 for convenience. Score (α) was multiplied by fractional numerical rating (β) to get the total score ($\gamma=\alpha \times \beta$). A higher total score indicates a better value. (10)

Step 5: Select the P-Drug

Based on the total weighted score, the drug with the maximum score was selected as the personal formulary drug for osteoporosis.

Step 6: Prescribe the P-Drug

A personal formulary having details of Sample Prescription, Patient Counselling, Monitoring and Follow-up was made. Then the senior residents and postgraduate students kept a copy of the personal drug formulary.

RESULT

Bisphosphonates have become the mainstay of osteoporosis treatment globally, in part related to cost as they have become generic. Alendronate, risedronate, ibandronate, and zoledronic acid are approved for the prevention and treatment of post-menopausal osteoporosis. Alendronate, risedronate, and zoledronic acid are also approved for the treatment of glucocorticoid-induced osteoporosis, and risedronate and zoledronic acid are approved for prevention of glucocorticoid-induced osteoporosis. Alendronate, risedronate, and zoledronic acid are approved for treatment of osteoporosis in men.

Table 1 shows the price comparison of the available bisphosphonates on Janaushadhi.

Drug	Dosage Form	Dose	Frequency	Route	Duration of Treatment	Price per unit	Total cost (in rupees)
Alendronate sodium	Tablet	70 mg	Weekly	Oral	5 years	4.6875	1218.75
Ibandronic acid	Tablet	150 mg	Monthly	Oral	5 years	304.69	18281.4

Table 2 denotes the following scores of the drugs among bisphosphonates.

Drug	Efficacy (0.4)	Safety (0.3)	Cost (0.2)	Convenience (0.1)	Total Score
Alendronate sodium	9 (3.6)	5 (1.5)	8 (1.6)	4 (0.4)	7.1
Ibandronic acid	5 (2.0)	5 (1.5)	4 (0.8)	8 (0.8)	5.1

Since Alendronate sodium (Tablet 70 mg single weekly dose) has the highest total score (7.1), it is selected as the P-drug for osteoporosis. Accordingly, the following personal formulary was prepared.

Table 3 shows description of Alendronate as Personal Formulary for uncomplicated osteoporosis. Recommended alendronate dosage for uncomplicated osteoporosis and key patient-counselling points, including essential information, common side effects, contraindications, instructions, and follow-up advice.

DISCUSSION

The present study aimed to develop a rational personal formulary (P-drug) for the treatment of osteoporosis in the Indian healthcare setting using the WHO 6-step approach. Among the available bisphosphonates under the Janaushadhi scheme, alendronate emerged as the most appropriate P-drug based on a composite evaluation of efficacy, safety, cost, and convenience.

Bisphosphonates are widely recognized as the first-line pharmacological therapy for osteoporosis due to their well-established ability to inhibit bone resorption and reduce fracture risk.(11) The findings of this study are consistent with global and national treatment guidelines, which recommend bisphosphonates, particularly alendronate, as initial therapy in most patients with osteoporosis. Alendronate has demonstrated significant reductions in vertebral, non-vertebral, and hip fractures in multiple clinical trials, making it one of the most extensively studied and trusted agents in this class.

Table 3: Personal Formulary of Alendronate for uncomplicated osteoporosis

DOSAGE:
Osteoporosis: 70 mg orally once weekly
WHAT TO TELL THE PATIENT
Information:
Alendronate is a bisphosphonate used to strengthen bones and reduce the risk of fractures in osteoporosis. It works by inhibiting bone resorption, thereby increasing bone mineral density and reducing fracture risk, especially in the spine and hip.
Side Effects: Gastric irritation, esophagitis, abdominal pain, nausea, musculoskeletal pain; rarely osteonecrosis of jaw and atypical femoral fractures
Contraindications:
Esophageal disorders (e.g., achalasia, strictures), inability to remain upright for 30 minutes, hypocalcemia, severe renal impairment (CrCl <35 mL/min), hypersensitivity.
Instructions:
Take one tablet (70 mg) once weekly on an empty stomach in the morning with a full glass of plain water. Do not lie down for at least 30 minutes after taking the medication. Avoid food, beverages, or other medications for at least 30 minutes.
Next Appointment:
Review after 3 months to assess tolerance and adherence; BMD monitoring annually or as advised.
Follow-up:
Long-term therapy (3–5 years) with periodic reassessment. Monitor for side effects, calcium and vitamin D status, and fracture risk. Drug holiday may be considered based on risk profile.

In this study, alendronate achieved the highest total weighted score (7.1) compared to ibandronate (5.1), primarily due to its superior efficacy and significantly lower cost. Cost remains a critical determinant of drug selection in India, where out-of-pocket healthcare expenditure is high. The availability of alendronate at a substantially lower price through the Janaushadhi scheme enhances its accessibility and supports long-term adherence, which is essential in a chronic condition like osteoporosis.

Although ibandronate offers the advantage of monthly dosing, which may improve convenience and adherence, its higher cost and comparatively lower efficacy in preventing non-vertebral and hip fractures reduced its overall score. This highlights the importance of balancing convenience with clinical effectiveness and affordability in resource-limited settings.

It is also important to note that denosumab, a monoclonal antibody that inhibits RANKL and reduces bone resorption, is now included in the Janaushadhi scheme, improving its accessibility in the Indian population. However, despite its proven efficacy in reducing vertebral, non-vertebral, and hip fractures, denosumab is generally reserved for patients at high fracture risk or in those who are intolerant to, have contraindications to, or do not respond adequately to bisphosphonates. (12) Its use is also limited by higher cost compared to oral bisphosphonates, the need for subcutaneous administration every six months, and concerns regarding rebound bone loss after discontinuation. Therefore, while denosumab is an effective alternative, it is not typically considered a first-line agent in routine practice.

Safety is another important consideration in long-term osteoporosis therapy. Both alendronate and ibandronate have comparable safety profiles, with gastrointestinal adverse effects being the most common. However, appropriate patient counseling—such as taking the drug with water and remaining upright—can significantly minimize these risks. Rare adverse effects like osteonecrosis of the jaw and atypical femoral fractures should be monitored, especially during prolonged therapy.

The use of a structured scoring system based on efficacy (0.4), safety (0.3), cost (0.2), and convenience (0.1) provided an objective framework for drug selection. This

approach aligns with the principles of rational pharmacotherapy and ensures that clinical decision-making is evidence-based and context-specific. The involvement of residents and faculty in the selection process also enhances educational value and promotes rational prescribing habits among future clinicians.

An important strength of this study is its focus on real-world applicability in the Indian context, particularly by incorporating drug availability under the Janaushadhi scheme. However, certain limitations should be acknowledged. The study considered only a limited number of bisphosphonates available through this scheme and did not include other therapeutic classes such as teriparatide or selective estrogen receptor modulators, which may be indicated in specific patient populations. Additionally, individual patient factors such as comorbidities, fracture risk severity, and tolerance were not incorporated into the scoring system, which may influence drug selection in clinical practice.

CONCLUSION

In conclusion, this study supports the selection of alendronate as the preferred P-drug for osteoporosis in the Indian setting due to its high efficacy, acceptable safety profile, affordability, and widespread availability. While newer agents like denosumab expand therapeutic options, bisphosphonates remain the cornerstone of treatment in most patients. The application of the WHO P-drug concept provides a systematic and rational approach to drug selection and can be extended to other therapeutic areas to improve prescribing practices and patient outcomes.

Declaration by Authors

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