

Drug administration and clinical pharmacy column

Availability and affordability of osteoporosis treatment drugs in Wuhan based on the WHO/HAI standard survey method

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Abstract: In the present study, we aimed to investigate the availability and affordability of osteoporosis (OP) treatment drugs in Wuhan and provide references for policymakers. We used the WHO/HAI standardization method to investigate the OP drug in Wuhan and collected drug information for statistical analysis to evaluate the availability and affordability. The results showed that the availability of bisphosphonates, active vitamin D, and their analogs was relatively high; the availability of denosumab, salmon calcitonin, and teriparatide was general; and the availability of calcitonin, raloxifene, and strontium ranelate was low. In terms of affordability, alendronate generic drugs had good affordability, while the other 10 OP treatment drugs had poor affordability. Generally, the overall availability of OP treatment drugs in Wuhan was average, and the affordability was poor. As China's aging problem intensified, relevant government departments might consider including more OP treatment drugs in the medical insurance catalog and concentrating their quantities in the procurement process to further improve the availability and affordability of OP treatment drugs.

Keywords: WHO/HAI; Osteoporosis treatment drugs; Availability; Affordability

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1. Introduction

Osteoporosis (OP) is the most common skeletal disease in clinical practice. It is characterized by damage to the microstructure of bone tissue and low bone mass, resulting in increased bone fragility and increased risk of fracture^[1]. The incidence of OP is closely related to age^[2]. In 2018, the National Health Commission conducted an epidemiological survey on OP, the results showed that the prevalence of OP in people over 50 years old in China was 19.2%, and in people over 65 years old was 32.0%. Among those

over 65 years old, the prevalence rate of women was as high as 51.6%, which was significantly higher than that of European and American^[3,4]. As of 2020, China's population over the age of 65 was nearly 176 million (about 12.6% of the total population), making it the country with the largest absolute number of elderly people in the world, while the proportion was only 6.9% in 1999^[5]. As the problem of population aging becomes more and more serious, OP greatly threatens the health and quality of life of middle-aged and elderly people in China, bringing a heavy economic burden to the patient's family and society. Moreover, it has become a serious public health problem and challenge for China at present and in the future^[6]. Therefore, continuous early screening and standardized drug treatment are crucial.

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OP treatment drugs mainly include bisphosphonates, calcitonin, vitamin D and its analogs, and parathyroid hormone analogs. Effective drug therapy can improve patients' bone quality, increase bone density, and significantly reduce fracture risk^[4–6]. However, whether patients can obtain drugs for the treatment of OP and whether they can afford the corresponding medical costs are the key factors for effectively reducing the incidence of OP. The World Health Organization (WHO) and Health Action International (HAI) have developed the WHO/HAI standardized survey methodology^[7] to study the price, availability, and affordability of medicines in public and private institutions in different countries and regions. To date, the availability and affordability of OP treatment drugs have not been reported in China. Based on the WHO/HAI standardization method, we aimed to investigate the price, availability, and affordability of OP treatment drugs in medical institutions and retail pharmacies in Wuhan and provide a reference for the formulation and improvement of medical and health policies.

2. Methods

2.1. WHO/HAI standardization method

The WHO/HAI standardization method used to evaluate the price, availability, and affordability of OP treatment drugs in Wuhan is a scientific and reasonable research method, and many published studies have applied this method to investigate and analyze the price, availability, and affordability of medicines in many countries and regions^[8–11]. China is the largest developing country and the second-largest economy in the world. It is also a big country for generic drugs. Drugs with the same International Nonproprietary Names for Pharmaceutical Substances (INN) often exist in different dosage forms and specifications from multiple

manufacturers. Therefore, in order to more accurately reflect the availability of the investigated drugs, for drugs with the same INN, regardless of the specifications and dosage forms, all available price information on marketed drugs was recorded.

2.2. The choice of institutions

According to the introduction of the second edition of the WHO/HAI survey manual^[7], combined with the scale of the hospital, firstly, a major public hospital in Wuhan (usually a tertiary hospital) was selected and taken as the center. With a 3-h drive as a radius, the other two public secondary hospitals and three primary hospitals were selected, and then the nearest retail pharmacy around each medical institution was selected. Meanwhile, the corresponding candidate survey units were selected near the target survey hospital or pharmacy, and when the drug availability of the target survey institution was less than 50%, the candidate institution was investigated.

2.3. The selection of drugs

According to the Guidelines for the *Diagnosis and Treatment of Primary Osteoporosis* (2017 Edition), OP treatment drugs can be divided into bone resorption inhibitors, bone formation promoters, and other mechanism drugs based on their mechanism of action. Considering the comprehensiveness and representativeness of drug coverage, and combined with the guideline recommendations and the National Essential Drugs List (2018 Edition), this study selected seven types of drugs, with a total of 11 kinds of OP treatment drugs. The detailed drug information is shown in Table 1.

In addition, this study evaluated the originator brands (OBs) and lowest-priced generic drugs (LPGs) when examining the availability and affordability of OP treatment drugs in healthcare facilities and retail pharmacies.

Table 1. Specifications and dosage forms of 11 OP treatment drugs.

Drugs	INN	Dosage form	Specification
Bisphosphonates	Alendronate	70 mg	Tablet
	Zoledronic acid	100 mL:5 mg	Injection
	Ibandronic acid	2 mL:2 mg	Injection
Calcitonins	Calcitonin	1 mL:20 U	Injection
	Salmon calcitonin	1 mL:50 IU/2 mL:4400 IU	Injection/spray
Selective estrogen receptor modulators	Raloxifene	60 mg	Tablet
Parathyroid hormone analogs	Teriparatide	20 µg	Injection
Strontium salt	Strontium ranelate	2 g	Suspension
Active vitamin D and its analogs	Alfacalcidol	0.25 µg	Tablet/capsule
	Calcitriol	0.25 µg	Capsule
RANKL inhibitors	Denosumab	60 mg (1.0 mL)	Injection

Note: INN, International Nonproprietary Names for Pharmaceutical Substances; RANKL, receptor activator of NF-κB ligand.

OBs refer to the investigated drugs produced by the original patent holders, regardless of whether the patent has expired or not. The LPGs refer to the generic drug with the lowest unit price that can be found in the research institution on the day of the survey. The unit price means the price of each unit of medicine, such as tablet, grain, press, gram, and milliliter.

2.4. Evaluation indicators

2.4.1. Availability

Based on the introduction of the second edition of the WHO/HAI survey manual^[7], the availability of each drug was reported as the percentage of institutions in which the medicine was found on the day of data collection. If one institution had at least a specific dosage or strength of one medicine, this drug was denoted as available in this institution. Availability is equal to the number of institutions that can provide the drug divided by the total number of research institutions multiplied by 100%.

The availability of original and generic drugs with the same INN name was evaluated separately. For generic drugs, the drug was considered available at the institution when a specification was available. The following ranges were applied for describing availability: not available

(availability = 0), very low (0–25%), low (25%–50%), fairly high (50%–75%), and high (> 75%).

2.4.2. Affordability

According to the WHO/HAI organization, the index for evaluating affordability is a relative ratio that is based on the standard treatment guidelines of medicines, how many times the total drug costs of using the standard dose to treat a disease is compared with the local minimum daily wage standard within a certain course of treatment. According to the WHO/HAI standardization method, when the ratio is less than 1, it can be considered that the affordability of the investigated drug is good. This study estimated the affordability of each investigated drug based on the first-grade minimum wage standard of 2010 Yuan/month (about 67 Yuan/d) promulgated in the city of Wuhan in 2021^[12].

2.5. Data collection and statistics

In the present study, two data collectors carried out the survey with the designed drug information collection form and visited the selected survey hospitals and retail pharmacies. After each survey, the project leader reviewed the data. After the survey, the data statistician used Excel software to conduct a statistical analysis of the data.

3. Results

3.1. The availability of drugs for OP

Table 2 shows that the availability of alendronate, zoledronic acid, alfacalcidol, and calcitriol was relatively high, and the availability of strontium ranelate was zero in both medical institutions and retail pharmacies. The availability of denosumab and raloxifene LPGs was zero, and the availability of calcitonins and teriparatide was moderate.

Table 3 reveals that for original brands, there were eight kinds that could be obtained in public medical institutions and retail pharmacies. For generic drugs,

seven kinds were available in public medical institutions, and five kinds were available in retail pharmacies. In public medical institutions, the availability of two original brands and one generic drug was greater than 50%. In retail pharmacies, the availability of four original brands and four generic drugs was greater than 50%.

3.2. The affordability of drugs for OP

Table 4 shows that the affordability of OP treatment drugs was not optimistic. Except that the affordability of alendronate generic drugs was 0.6 times of daily salary, the cost of the drugs was higher than one time

Table 2. The availability of OP treatment drugs (%).

INN	Drug type	Public medical institutions	Retail pharmacies	Average
Alendronate	OBs	100.0	83.3	91.7
	LPGs	0.0	66.7	33.3
Zoledronic acid	OBs	33.3	66.7	50.0
	LPGs	33.3	83.3	58.3
Ibandronic acid	OBs	0.0	0.0	0.0
	LPGs	16.7	0.0	8.4
Calcitonin	OBs	16.7	0.0	8.4
	LPGs	33.3	0.0	16.7
Salmon calcitonin	OBs	50.0	33.3	41.7
	LPGs	16.7	16.7	16.7
Raloxifene	OBs	0.0	16.7	8.4
	LPGs	0.0	0.0	0.0
Teriparatide	OBs	16.7	66.7	41.7
	LPGs	16.7	0.0	8.4
Strontium ranelate	OBs	0.0	0.0	0.0
	LPGs	0.0	0.0	0.0
Alfacalcidol	OBs	16.7	33.3	25.0
	LPGs	66.7	83.3	75.0
Calcitriol	OBs	83.3	83.3	83.3
	LPGs	50.0	83.3	66.7
Denosumab	OBs	16.7	50.0	33.4
	LPGs	0.0	0.0	0.0

Note: INN, International Nonproprietary Names for Pharmaceutical Substances; OBs, originator brands; LPGs, lowest-priced generic drugs.

Table 3. The availability of OP treatment drugs in public medical institutions and retail pharmacies ($n = 11$).

Availability	Public medical institutions		Retail pharmacies	
	OBs	LPGs	OBs	LPGs
0%	3	4	3	6
< 25%	4	3	1	1
25%–50%	2	3	3	0
50%–75%	0	1	2	1
> 75%	2	0	2	3

Note: OBs, originator brands; LPGs, lowest-priced generic drugs.

of daily salary in both original brands and generic drugs from public medical institutions and retail pharmacies, which would cause a huge economic burden for patients with OP. In addition, generic drugs were generally more affordable than original drugs. If generic drugs could ensure drug efficacy and safety, the economic situation of patients could be improved. Besides, the treatment cost of teriparatide was much greater than one times the daily salary. The unit price of the teriparatide was relatively high, and the dosage was once a day, which brought great economic pressure on patients. Denosumab was 1.6 times the daily salary, and the affordability was better than other original OP treatment drugs.

This study conducted a statistical analysis of drug prices in all surveyed public hospitals and retail pharmacies, and their respective median prices were calculated. Table 5 shows that compared with retail pharmacies, the affordability of public hospitals was good, especially the affordability of original brands. Retail pharmacies were faced with the dilemma of sales and profitability, and drug prices were higher than public hospitals, resulting in the poor affordability of medicines. In addition, this study also conducted a statistical analysis of the drug prices of all the original brands and generic drugs. Table 6 shows that the overall affordability of generic drugs was better than that of original brands.

Table 4. Affordability of OP treatment drugs (unit: times).

INN	Drug type	Public medical institutions	Retail pharmacies
Alendronate	OBs	3.5	3.7
	LPGs	–	0.6
Zoledronic acid	OBs	3.2	3.7
	LPGs	2.0	2.1
Ibandronic acid	OBs	–	–
	LPGs	3.1	–
Calcitonin	OBs	4.2	–
	LPGs	3.8	–
Salmon calcitonin	OBs	20.4	3.4
	LPGs	3.1	3.6
Raloxifene	OBs	4.5	4.7
	LPGs	–	–
Teriparatide	OBs	2390.4	2390.4
	LPGs	58.2	–
Strontium ranelate	OBs	–	–
	LPGs	–	–
Alfacalcidol	OBs	9.2	6.1
	LPGs	2.0	1.4
Calcitriol	OBs	4.9	5.0
	LPGs	3.4	3.6
Denosumab	OBs	1.6	1.6
	LPGs	–	–

Note: OBs, originator brands; LPGs, lowest-priced generic drugs; –, Not obtained.

Table 5. Comparison of the overall affordability of OP treatment drugs in public hospitals and retail pharmacies.

	Drug type	Median price (Yuan)	Times
Public medical institutions	OBs	58.49	0.87
	LPGs	43.95	0.66
Retail pharmacies	OBs	310.00	4.63
	LPGs	46.50	0.69

Note: OBs, originator brands; LPGs, lowest-priced generic drugs.

Table 6. Comparison of overall affordability of OBs and LPGs.

Drug type	Median price (Yuan)	Times
OBs	72	1.07
LPGs	44	0.66

Note: OBs, originator brands; LPGs, lowest-priced generic drugs.

4. Discussion

4.1. The availability of OP drugs with different mechanisms

The current survey showed that the availability of classic bisphosphonates, active vitamin D, and its analogs was relatively high. The availability of strontium ranelate was zero. The European Medicines Agency issued an evaluation announcement for strontium ranelate in 2014, pointing out that the marketing authorization of strontium ranelate was maintained, while the use of the drug was restricted only for those who suffered from severe OP, and the original manufacturer stopped production. The availability of generic drugs for denosumab was zero, which was a receptor activator of NF- κ B ligand (RANKL) inhibitor developed in the past 10 years. Denosumab is still in the patent protection period, and its core patent is expected to expire in 2025. At present, Qilu Pharmaceutical, Luye Pharma Group, and other companies have applied for clinical trials of denosumab and preparations for listing. The availability of raloxifene generic drugs was zero. It was only produced by Hengrui Pharmaceutical in China and approved for marketing on August 31, 2020, and has not yet entered the market in Wuhan.

The overall availability of OP treatment drugs was moderate, and the possible reasons included the following two aspects. On the one hand, the problem of population aging in China was becoming more and more serious, and OP greatly threatens the quality of life of middle-aged and elderly people. The national level should pay more attention to the harm of OP.

On the other hand, domestic drug manufacturers were limited by their own scale and capital and had the insufficient motivation to develop and produce high-quality and cheap generic drugs. It was suggested that government departments should formulate corresponding support policies, strengthen the enthusiasm of drug manufacturers, and further improve accessibility.

4.2. The affordability of OP treatment drugs

4.2.1. The poor affordability of OP treatment drugs

The affordability of both original brands and generic drugs was poor, while the affordability of generic drugs was better than that of original brands. In recent years, the Chinese government has successively issued the “Announcement of the State Food and Drug Administration on Carrying out Self-inspection and Verification of Drug Clinical Trial Data” (No. 117 of 2015) and “Opinions on Carrying out Consistency Evaluation of Generic Drug Quality and Efficacy” (No. 8 of 2016) to ensure the safety and effectiveness of generic drugs and clarified the consistency of generic drugs and original brands. The state could consider increasing the support and capital investment for the pharmaceutical industry and supporting domestic pharmaceutical companies to produce safe, effective, high-quality, and inexpensive generic drugs, further improving the affordability of OP treatment drugs.

4.2.2. The affordability and pharmacoeconomics of OP treatment drugs

Economic factors should also be considered in the clinical drug treatment plan for OP. Our research group has previously conducted an economic evaluation of

alendronate^[13], and the results show that alendronate has a good cost-effectiveness benefit. Further research^[14] has found that compared with the cost and effectiveness of oral alendronate, zoledronic acid for injection is an advantageous solution. There are differences in the economics of different treatment options, and pharmacoeconomic research can provide a reference for clinical treatment decisions and health system policymakers. In recent years, multiple studies have recommended sequential therapy^[15,16]. For example, sequential bisphosphonates after denosumab, since the discontinuation of denosumab may instead increase the risk of vertebral fractures, and the potential risks of long-term bisphosphonate use include osteonecrosis of the jaw and atypical femoral fractures, sequential treatment of both would increase patient benefit and reduce the potential risk^[17–19]. Mori et al.^[20] have compared the cost-effectiveness of sequential teriparatide/alendronate and alendronate in female OP patients in Japan, and the results show that sequential teriparatide/alendronate is not an economical treatment option. However, for 75-year-old women, sequential teriparatide/alendronate is more cost-effective if the price of teriparatide is reduced by 50%. Reducing prices will increase the affordability of OP treatment drugs and further affect the results of pharmacoeconomic evaluations. Therefore, government departments could implement relevant inclusive policies to reduce the price of OP treatment drugs, thereby improving the affordability of OP treatment drugs and making OP treatment drugs more economical.

Generally, future research should conduct more in-depth investigations on the availability, affordability, and pharmacoeconomics of different types and regimens of OP treatment drugs to provide information for the formulation of medical and health policies, clinical drug regimens, and patients' economic expenditures^[21,22].

4.3. Limitations and advantages

This study has some limitations. First of all, due to the diversity of the medical insurance system, the different types of patient insurance coverage in different regions, and the circumstances in which retail pharmacies cannot use medical insurance to pay, this study failed to consider the medical insurance payment situation. Future research can consider the type of medical insurance, as well as the proportion of medical insurance reimbursement and self-payment, to evaluate the affordability of drugs more objectively. Second, although the time horizon of this study was 1 month, the price of medicines was mainly affected by policies, per capita GDP levels, and so on^[23,24], and it fluctuated less in the short term. Therefore, this paper did not consider the mistake of the time horizon. Finally, this paper only sampled some OP treatment drugs in Wuhan and then evaluated their availability and affordability. The policies and economic levels vary across China, and the results and conclusions should be cautiously applied to other regions and cities.

Despite the limitations, to the best of our knowledge, this was the first time in China to evaluate the availability and affordability of OP treatment drugs. In addition, this study included almost all types of OP treatment drugs, evaluated them comprehensively, and provided a reference for medical and health policymakers.

5. Conclusions

In general, the availability of OP treatment drugs in Wuhan was moderate, and the affordability was poor. With the intensification of the aging problem in China, it was recommended that relevant government departments should increase policy support, consider more types of OP treatment drugs in the medical insurance catalog and the centralized procurement plan with volume,

continue to optimize the drug structure and the reasonable reimbursement ratio of medical insurance, and further improve the availability and affordability of OP treatment drugs in China.

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基于WHO/HAI标准调查方法的武汉市骨质疏松治疗药物的可获得性及可负担性分析

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摘要: 本研究分析了武汉市骨质疏松治疗药物的使用情况, 可为相关政策的制定提供参考。研究采用WHO/HAI标准化法, 对武汉市骨质疏松治疗药物进行调研, 并收集药品信息进行统计分析, 对可获得性和可负担性进行评价。结果显示, 在可获得性方面, 双膦酸盐类、活性维生素D及其类似物的可获得性相对较高; 地舒单抗、鲑降钙素以及特立帕肽可获得性一般; 依降钙素、雷洛昔芬及雷奈酸锶可获得性较低。在可负担性方面, 阿仑膦酸仿制药的可负担性较好, 其余10种骨质疏松治疗药物的可负担性均较差。研究表明, 武汉市骨质疏松治疗药物的总体可获得性一般, 并且可负担性较差。随着中国老龄化问题的加剧, 相关部门可考虑将更多种类的骨质疏松治疗药物纳入医保目录以及集中带量采购工作中, 进一步提高骨质疏松治疗药物的可获得性和可负担性。

关键词: WHO/HAI; 骨质疏松治疗药物; 可获得性; 可负担性