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Original Investigation

Intervention on the prescribing of alendronate in higher than recommended doses☆

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ABSTRACT

Introduction: The aim of the study is to identify patients with inappropriate prescriptions of alendronate (70 mg) and to use an educational intervention to reduce medication errors.
Methods: A quasi-experimental, prospective before and after study was conducted, without a control group, where an intervention was conducted on prescribers of patients on pharmacological treatment with alendronate 70 mg in the period from 1 July 2013 to 30 June 2014. All subjects receiving more than 4 tablets per month were included. The intervention was to provide updated information to those responsible for health care and then assess whether or not they modified the patient prescription.
Results: Out of a total of 2283 patients receiving alendronate, it was found that a mean of 105 patients per month diagnosed with osteoporosis received the presentation of 70 mg. The mean age was 66.0±5.5 years, and the large majority ($n = 159$; 95.8%) were female. A mean of 22 patients were dispensed with more than 4 tablets per month (range: 8–38 tablets/month). The intervention managed to reduce those with a higher than recommended doses to 8 patients (63.6% of cases). Insurers were paying COP $459,166 more on average each month for excess tablets dispensed, and the intervention achieved savings of COP $3,491,592 per year.
Conclusions: Educational interventions on prescribers can reduce the number of potentially inappropriate prescribing and medication errors and reduce the risk to patients and health care costs.

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Intervención sobre la prescripción de alendronato en dosis superiores a las recomendadas

Palabras clave:
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RESUMEN

Introducción: Se buscaron pacientes con prescripciones inapropiadas de alendronato de 70 mg y mediante una intervención educativa reducir los errores de medicación.

Métodos: Se realizó un estudio cuasiexperimental, prospectivo, antes y después, sin grupo control, donde se llevó a cabo una intervención en prescriptores de pacientes que se encontraban en manejo farmacológico con alendronato de 70 mg en el período comprendido entre el 1 de julio de 2013 y el 30 de junio de 2014, incluyendo todos los sujetos que recibían más de 4 tabletas por mes. La intervención consistió en suministrar información actualizada a los responsables de la atención sanitaria y evaluar, meses después, si se modificó o no la prescripción de los pacientes identificados.

Resultados: De un total de 2.283 usuarios que recibían alendronato, se hallaron, en promedio, 105 pacientes mensuales con diagnóstico de osteoporosis que estaban recibiendo la presentación de 70 mg, con edad promedio de 66,0±5,5 años y predominio femenino (n = 159; 95,8%). En promedio a 22 pacientes se les dispensaba más de 4 tabletas por mes (rango: 8-38 tabletas/mes). La intervención consiguió reducir a 8 pacientes con dosis superiores a las recomendadas, (63,6% de casos). Los aseguradores estaban pagando en promedio COP $459.166 más, cada mes, por el exceso de tabletas dispensadas y la intervención logró un ahorro de COP $3.491.592 al año.

Conclusiones: Las intervenciones educativas sobre los médicos prescriptores pueden conseguir disminuir el número de prescripciones potencialmente inapropiadas y de errores de medicación para reducir el riesgo sobre los pacientes y costes de atención en salud.

Introduction

Osteoporosis is a complex metabolic disease characterized by a decrease in the bone density and defects in bone microarchitecture that compromises the biomechanical integrity of the skeleton,[1,2] leading to an increased risk of fractures.[3,4] In the United States it was estimated that about 10 million people suffered from the disease in 2004, with the consequent increase in the risk of hip and vertebral fractures.[2,5] In Europe it is estimated that osteoporosis affects one out of every 2 women and one out of every 5 men older than 50 years.[3]

In the pharmacological management of osteoporosis have been used calcium supplements, vitamin D, estrogens, estrogen response modulators and bisphosphonates such as alendronate.[6] This drug comes in presentations of 10 mg for daily dosing and of 70 mg to be taken each week.[7,8] The administration of doses higher than 70 mg weekly does not improve the therapeutic effect but it increases the risk of adverse reactions and is considered an inappropriate prescription because it is associated with greater hypocalcemia, hypophosphatemia, and esophageal and gastric ulcers; therefore, the use of high doses of this medicine should be avoided.[6–9]

It should be considered that the Colombian healthcare system is based on the total insurance coverage of the population and it involves procedures, health technologies and drugs (including alendronate) that are contained in a plan of benefits denominated Mandatory Healthcare Plan (POS, by its Spanish initials), which is administrated by a number of insurance companies called Health Promoting Entities (EPSs, by their Spanish initials).

Since it have been observed that there is a group of patients who were receiving doses higher than 4 tablets per month of alendronate 70 mg, the objective was to identify the subjects who were receiving dispensations of alendronate at higher than recommended doses and notify those who are responsible for healthcare, in order to reduce the possible medication errors of 3 EPS, in 13 cities of Colombia.

Methods

A quasi-experimental, prospective before and after study was conducted, without a control group, where it was carried out an intervention on prescribers of patients who were under pharmacologic management with alendronate 70 mg, in the period comprised between July 1, 2013 and June 30, 2014. The information was obtained from a population database of approximately 3.5 million people affiliated to 3 EPS of the contributory regime of the General System of Social Security in Health of Colombia, in 13 different cities, including all those subjects to whom Audifarma S.A. had dispensed more than 4 tablets of this drug per month.

The variables considered in the study were: sociodemographic (age, gender, city); pharmacological (monthly number of patients that were receiving alendronate 70 mg,

number of tablets dispensed monthly and time with that prescription) and of result (number of patients that no longer received the evaluated drug).

The intervention began a month after gathering the information and consisted of 3 main strategies: (1) presentation of the cases to the medical directors of the EPS at national level, who verified that indeed the formulation was inappropriate; (2) the information was socialized in 3 occasions with the prescribing physicians so they do not confuse the 2 presentations; (3) emails with scientific literature of reference on the adequate formulation of alendronate and the risks of its use at high doses were sent to each physician.

This work was classified in the category of research without risk as defined by Resolution 8430 of 1993 of the Ministry of Health of Colombia, warranting the bioethical principles of confidentiality of the information established by the Declaration of Helsinki.

The information obtained was collected in a database in Excel 2010. Frequencies and proportions were established. The statistical package SPSS 22.0 for Windows was used for data analysis.

Results

Out of a total of 2283 users to whom bisphosphonate was dispensed in whichever of its presentations, it was found an average of 105 patients per month with diagnosis of osteoporosis who were receiving alendronate 70 mg, with a mean age of 66.0±5.5 years, and with female predominance ($n = 159$; 95.8%). Of them, a mean of 22 patients were dispensed with more than 4 tablets per month (range: 8–38 tablets/month). 67.0% of the patients claimed the drug in the city of Bogota, followed by Medellin (7.0%), Cali (7.0%) and Cartagena (5.0%). Each patient was followed up regarding the dispensation on average during 7.5±3.0 months.

After the intervention, the number of patients with higher than recommended doses was reduced to only 8, which meant a reduction of 63.6% of cases and in addition, the number of 5 patients to whom 30 or more tablets per month were dispensed, was reduced to only one, suggesting that possibly the physician mistook the presentation of the drug.

The assessment of costs showed that before the intervention the insurers were paying COP $459,166 more on average each month for the excess of tablets dispensed, which were reduced to COP $168,200 after the intervention (reduction of 63.7% of the invoiced value). This meant a cost saving for this drug of COP $3,491,592 per year for the 3 insurers.

Discussion

With this intervention related to the pharmacovigilance of the use and risks associated with alendronate it was achieved the deprescription in two-thirds of the number of patients to whom were dispensed doses higher than the recommended for the treatment of osteoporosis, a significant result, despite the fact that it is a drug that is not of widespread use. The results of this intervention are higher than those found by the same authors in interventions conducted for the inappropriate use of verapamil or for the use of angiotensin-converting enzyme inhibitors concomitantly with angiotensin II receptor blockers,[10,11] demonstrating an adequate reception of the information provided, which can avoid cost overruns for the system, and does not add any benefit to the patient and can generate some risks.

Some of the limitations found in the study involve that the information comes from a population database of dispensed drugs. In addition, it is not possible to ensure that in all cases in which the medication was suspended or changed it was due to the intervention carried out by this work team and because of the study design it is not possible to estimate which other factors could have influenced. Despite the possible limitations, it was shown that simple interventions such as sending of electronic correspondence with the list of patients with inappropriate prescriptions, accompanied by the recommendations with updated evidence and training of the healthcare staff on the proper use of the pharmaceutical resource, can be effective to improve the quality of the prescription and reduce the risk of appearance of related adverse events.[10,11]

In conclusion, a reduction of the inappropriate prescription of alendronate 70 mg was achieved in more than 60% of patients through educational strategies of updating and monitoring of the dispensation, with which is possible to modify some habits in the formulation of the physicians and to identify medication errors that could generate risks to the health of those who use them.

These results are indicators of the need to strengthen the training and updating of prescribers, through programs of continued medical education on the proper use of the drugs used in daily practice. In addition, it is necessary that clinicians adequately recognize the different presentations of the medicines in order to avoid confusions that may increase the risks and costs of healthcare.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that no patient data appear in this article.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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Conflict of interest

The authors declare that they have no conflict of interest. All authors have a contractual relationship with Audifarma S.A. but the results correspond to the findings of the intervention.

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