REV BRAS REUMATOL. 2016;xxx(xx):xxx–xxx

SOCIEDADE BRASILEIRA DE REUMATOLOGIA

REVISTA BRASILEIRA DE REUMATOLOGIA

www.reumatologia.com.br

Original article

Use of pamidronate for osteoporosis treatment in public health care in Brazil

Leila Bianchet Zanatta[a], *Cristina Marcatto*[a], *Cassio Slompo Ramos*[a], *Nadila Mañas*[a], *Carolina Moreira*[a,b], *Victoria Borba*[a,b,*]

[a] *Serviço de Endocrinologia e Metabologia (SEMPR), Hospital de Clínicas, Universidade Federal do Paraná, Curitiba, PR, Brazil*
[b] *Department of Internal Medicine, Division of Endocrinology, Universidade Federal do Paraná, Curitiba, PR, Brazil*

ARTICLE INFO

Article history:
Received 26 August 2015
Accepted 1 May 2016
Available online xxx

Keywords:
Pamidronate
Bone mineral density
Osteoporosis

ABSTRACT

Purpose: The use of bisphosphonates for osteoporosis is effective in reducing the risk of fractures. However, oral formulations are sometimes not well tolerated or are contraindicated. Due to its availability in Brazilian public health system, pamidronate is frequently prescribed for osteoporosis, despite the lack of studies demonstrating its anti-fracture efficacy and the absence of FDA or EMEA approval for this purpose. The aim of this study was to evaluate the bone mineral density (BMD) response to pamidronate in a group of women with osteoporosis in a tertiary care hospital.

Patients and methods: The medical records of women with osteoporosis who received pamidronate for up to two years of treatment were reviewed. Patients were stratified at high or intermediate risk of fracture.

Results: A total of 70 women were in treatment with pamidronate. Among them, 74% were at high risk of fracture. A significant gain in spine BMD after 24 months of treatment was observed ($p = 0.012$). There was no difference between the groups of high and not high risk of fracture. At the femur, no significant increase in BMD was present, though, a strong negative correlation with high PTH levels ($r = -0.61$; $p = 0.003$) was seen. In the multivariate analysis BMI at 12 months had impact in the response to the treatment.

Conclusion: The intravenous pamidronate in a group of postmenopausal women with predominant high risk of fracture promoted an isolated gain in the spine BMD, even though, clinical randomized trials are needed to confirm its anti-fracture efficacy.

* *Corresponding author.*
E-mail: vzcborba@gmail.com (V. Borba).

http://dx.doi.org/10.1016/j.rbre.2016.07.005

Please cite this article in press as: Zanatta LB, et al. Use of pamidronate for osteoporosis treatment in public health care in Brazil. Rev Bras Reumatol. 2016. http://dx.doi.org/10.1016/j.rbre.2016.07.005

Uso de pamidronato para o tratamento da osteoporose no sistema público de saúde no Brasil

Palavras-chave:
Pamidronato
Densidade mineral óssea
Osteoporose

RESUMO

Justificativa: O uso de bisfosfonatos para a osteoporose é eficaz na redução do risco de fraturas. No entanto, as formulações orais às vezes não são bem toleradas ou são contraindicadas. Em razão da sua disponibilidade no sistema público de saúde brasileiro, o pamidronato é frequentemente prescrito para a osteoporose, apesar da falta de estudos que demonstrem a sua eficácia antifratura e da ausência de aprovação da *Food and Drug Administration* (FDA) ou da *European Medicine Agency* (Emea) para essa finalidade. O objetivo deste estudo foi avaliar a resposta da densidade mineral óssea (DMO) ao pamidronato em um grupo de mulheres com osteoporose em um hospital terciário.

Pacientes e métodos: Revisaram-se os prontuários médicos de mulheres com osteoporose que receberam pamidronato por até dois anos de tratamento. As pacientes foram estratificadas em risco alto ou intermediário de fratura.

Resultados: Estavam em tratamento com pamidronato 70 mulheres. Entre elas, 74% tinham alto risco de fratura. Observou-se um ganho significativo na DMO da coluna vertebral após 24 meses de tratamento (p = 0,012). Não houve diferença entre os grupos de risco de fratura alto e não alto. No fêmur, não foi encontrado aumento significativo na massa óssea; contudo, observou-se uma forte correlação negativa com altos níveis de PTH (r = -0,61; p = 0,003). Na análise multivariada, o IMC aos 12 meses teve impacto na resposta ao tratamento.

Conclusão: O pamidronato intravenoso em um grupo de mulheres na pós-menopausa predominantemente com alto risco de fratura promoveu um ganho isolado na DMO da coluna vertebral, embora sejam necessários ensaios clínicos randomizados para confirmar sua eficácia antifratura.

Introduction

Bisphosphonates represent the major drugs in the therapeutic arsenal of osteoporosis. They are powerful anti-resorptive agents, deposited in mineral bone, and their diversity in action and anti-fracture efficacy may be clinically warranted depending on the strength of connection and detachment to the bone tissue.[1] Among the four bisphosphonates approved for osteoporosis treatment, based on double-blind randomized controlled trials, zoledronate has the greatest affinity for bone, followed respectively by alendronate, ibandronate, and risedronate.[2]

Pamidronate is a nitrogen-containing bisphosphonate with an intermediary potency to inhibit bone reabsorption, and it was initially indicated for preventing bone metastasis growth in different types of cancer.[1,3] The efficacy of pamidronate has been demonstrated in the treatment of lytic bone metastasis; to control hypercalcemia of malignancy in multiple myeloma; in the prevention of osteoporosis induced by glucocorticoids or secondary to chemotherapy or immunosuppressive drugs after solid organ and stem cell transplantation.[4–13]

The pamidronate has been extensibly used since 1991 and became standardized by the public health agency for osteoporosis treatment. It started to be widely used due to its availability in the public health care system and the lack of other formally approved parenteral anti-resorptive drugs for osteoporosis treatment at that time. It is important to note that this is the only non-oral medication for osteoporosis treatment available in our public health care system. However, pamidronate has never been approved for osteoporosis treatment and, despite its frequent use in daily practice for many patients with intolerance to oral bisphosphonates, prospective studies are lacking in evidence to support pamidronate's anti-fracture efficacy.

Objectives

Primary

The aim of this study is to evaluate the therapeutic response to pamidronate in the BMD gain of spine and total femur, in a group of postmenopausal women with osteoporosis, followed in an osteoporosis outpatient clinic for a treatment period of up to 36 months.

Secondary

To evaluate the influence of clinical aspects such as age, fracture risk, and dose of pamidronate administered per year on the response to the treatment.

Methods

Study design and patients

In 2006, due to the availability of intravenous pamidronate in the Hospital de Clinicas da UFPR, the Bone Metabolism Unit started its application in patients with osteoporosis.

Please cite this article in press as: Zanatta LB, et al. Use of pamidronate for osteoporosis treatment in public health care in Brazil. Rev Bras Reumatol. 2016. http://dx.doi.org/10.1016/j.rbre.2016.07.005