TRANSTROCHANTERIC FRACTURES: POSTOPERATIVE USE OF ALENDRONATE

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ABSTRACT

Objective: To evaluate the results of the use of alendronate sodium in postoperative transtrochanteric femoral fractures. Method: Over a six-month period, 75 patients were treated at the Orthopedic Service for transtrochanteric femoral fractures, undergoing surgery with 135 degree DHS plate fixation. We selected 19 patients who were healthy, cooperative, previously unable to walk, classified as type III according to Tronzo, whose contralateral hips had not undergone any previous surgery, enabling the evaluation of bone mineral density (BMD) in the immediate postoperative period and after six months. The patients were divided into groups I and II, with and without the use of alendronate sodium in the immediate postoperative period, respectively. The minimum follow-up was six months. After four weeks, the patients were evaluated according to the Visual Analogue Scale for Pain (VAS) in order to verify the rate of bone resorption, bone mass and radiological consolidation of the fracture. Results: There was a statistical trend of earlier radiological consolidation and lower bone resorption in patients with the use of alendronate sodium in post-fracture with established osteoporosis. Conclusion: We concluded that radiologically, patients using alendronate sodium showed faster bone consolidation, with a lower rate of resorption.

Keywords: Post-surgery. Transtrochanteric femoral fracture, Alendronate sodium. Osteoporosis. Radiography. Consolidation.

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INTRODUCTION

Transtrochanteric fractures occur in an area between the greater trochanter and the lesser trochanter and are extracapsular. In surveys from 1941 to 1971 cited by DeLee,[1] the mean age ranged between 66 and 76 years. The female gender predominates in the ratio of 3,3:1,[2] with an increase in frequency tied to age increase. The mortality rate 12 months after the fracture is approximately 11.7%.[3]

This kind of fracture remains a major challenge to orthopedists these days, not only because of the high morbi-mortality, but also due to the technical difficulties of stabilization. With the increase in the life expectancy of the population, the number of cases of fractures in elderly people with osteoporosis has increased considerably, generating excessive medical and hospital expenses and socio-family problems. The combination of the diminished resistance of the skeleton with the impact of the trauma is the cause of this type of fracture in the senile population, together with predisposition to falls.[4] The resistance of a bone is directly related to its bone mineral density, varying with the decrease of daily activity, bone remodeling and the formation of bone callus after fractures.[5]

In 1974, Tronzo[6] subdivided transtrochanteric fractures into five types, where in type III (unstable) the diaphysis is medialized and the proximal spur fits into it; with fracture of the greater trochanter as well, it is classified as type III variant. For the fixation of this type of fracture, one of the implants used is the DHS, with an angle of 135°, as its entry point is more cranial and the risk of weakening the lateral cortical of the femur through the entrance orifice of the pin is lower than with the 150° pin, even though the latter has greater telescoping ease.[7]

Nowadays, we define osteoporosis as a metabolic disorder characterized by the decrease of bone mineral density, with deterioration of the bone microarchitecture, leading to an increase of the skeletal fragility and of the risk of fractures.[8-11] It is believed that 75% of the fractures that occur in men and women over 45 years of age are related to osteoporosis.[4] Primary osteoporosis is subdivided into type I (postmenopausal) and type II (senile). Riggs and Melton[12] related type II osteoporosis

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to the occurrence of hip fractures. The Bone Mineral Densitometry (BMD) performed by DEXA technique (dual energy X-ray absorptiometry) is today the exam of reference for the diagnosis of osteoporosis and provides reproducible values at sites of fractures associated with osteoporosis.[9-13]

Drugs considered effective for the pharmacological treatment of osteoporosis are those that primarily reduce the risk of fractures, which are classified in two groups: bone formation stimulators (PTH) and the bone tissue antiresorptive agents, which are drugs that inhibit osteoclastic activity, such as the Bisphosphonates. Nevertheless, up to 20% of patients may still lose bone mineral density in the first year after the start of treatment with antiresorptive agents.[9] Randomized studies and placebo controlled with cyclic etidronate, alendronate and risedronate revealed an increase in the bone mass in the spine and femur and reduction in the risk of vertebral fractures from 30% to 50%.[9] The dose of alendronate sodium recommended by the FDA (Federal Drug Administration) is 10 mg/day or 70 mg/week administered orally, with no consensus yet regarding the appropriate time of use of the medication.[8-14]

The aim of this study was to evaluate the clinical and radiological bone consolidation time, the loss of bone mass and the degree of reabsorption at the focal point of the fracture in patients with and without the postoperative use of alendronate sodium.

MATERIALS AND METHODS

Between May and September 2005, seventy-five patients with transtrochanteric fracture of the femur were admitted to and surgically treated in the Orthopedics Service. The service is part of the Health Regional Division 18 (DIR-18), receiving patients regulated by the Center for Medical Regulation, according to the vacant beds available in each hospital.

The procedures complied with the rules of the Ethical Committee on Human Experiences of Hospital Beneficência Portuguesa de Ribeirão Preto.

Of these 27 patients seen in the service, 19 patients (25.3%) were consulted and selected for the performance of the study, considering those that were healthy and cooperative, previously able to walk, classified according to Tronzo as type III, and whose contralateral hips had not been submitted to any prior surgery, allowing the performance of the Mineral Bone Densitometry, according to the protocol employed. In the initial appointment, they underwent a radiological study with anteroposterior and lateral view of the pelvis of affected hip with evaluation by the Singh classification for osteoporosis in contralateral hip.

The mean age of the selected patients was 73 years (ranging from 53 to 93 years); with five males (26.32%) and fourteen females (73.68%). The right side was affected in eleven patients (57.9%) and the left side in eight patients (42.1%).

The patients were submitted to surgical reduction on an orthopedic table with the aid of radioscopy, through longitudinal traction and internal rotation of the affected limb, with the surgery performed by the same team, striving to execute the most anatomical reduction possible, following the methods of the AO placement of the DHS plate, with angulation of 135º, without the use of the anti-rotation pin. The surgery lasted for one hour and thirty minutes on average. The patients were granted hospital discharge on the second postoperative day, after performance of Mineral Bone Densitometry on the contralateral hip. They received instructions regarding the use of an anti-inflammatory drug for five days, antibiotic for seven days, prophylaxis medication for deep venous thrombosis and active and passive movement of the lower limbs without load.

Two groups were divided at random for the performance of the study: group I, in which the patients made use of alendronate sodium in the oral dose of 70 mg/week starting in the immediate postoperative period, and group II (control), in which the patients did not make use of the medication. The medication was provided to the patients free of cost during the complete treatment.

All the patients were followed up over a minimum period of six months, with periodic radiological control in weeks 2, 4, 6, 8, 12, 16 20 3 24. The radiological exam was carried out with the patient in supine, with the ampoule centered on the pelvis at a distance of one meter from it. All of them underwent the other Mineral Bone Densitometry in week 24 in the postoperative period. Partial load with walking frame was allowed in the week 4, with the physician in charge, and the patients were evaluated by the Visual Analogue Scale for Pain (VAS) at the time of the load. (Figure 1)

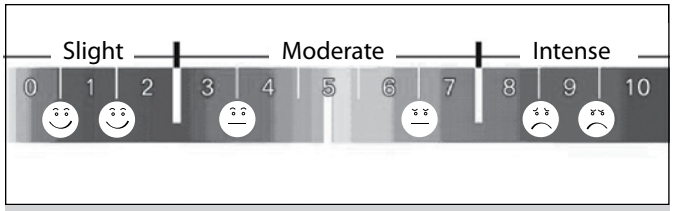

Figure 1. *Visual Analogue Scale – VAS.*

An analysis was conducted of the sliding of the screw in the plate barrel (extrusion) in the radiographies with evidence of bone consolidation, measuring the distance from the edge of the DHS plate to the head of the cotter pin. (Figure 2)

All the parameters and data encountered were evaluated statistically by the Student's t-test method.

RESULTS

Nineteen patients were separated into two study groups: nine patients were selected in group I, receiving alendronate sodium in the postoperative period with an oral dose of 70mg once a week. The mean age was 76.6 years, with 20.2% male patients and 79.8% female patients, with a diagnosis of osteoporosis in 100% of the patients. The surgical treatment was carried out according to the protocol established by this study. In this group, one patient discontinued treatment, another died due to cardiopulmonary complications and a third had another fall, evolving with a refracture. The mean radiological consolidation time was 7.6 weeks, with the mean value on the visual analogue scale for pain (VAS) of 1.57 points, a variation of densitometric bone mass with decrease of 1.04%, having a mean fracture focus resorption value of 2.3mm. (Table 1)

In group II ten patients were selected that did not make use

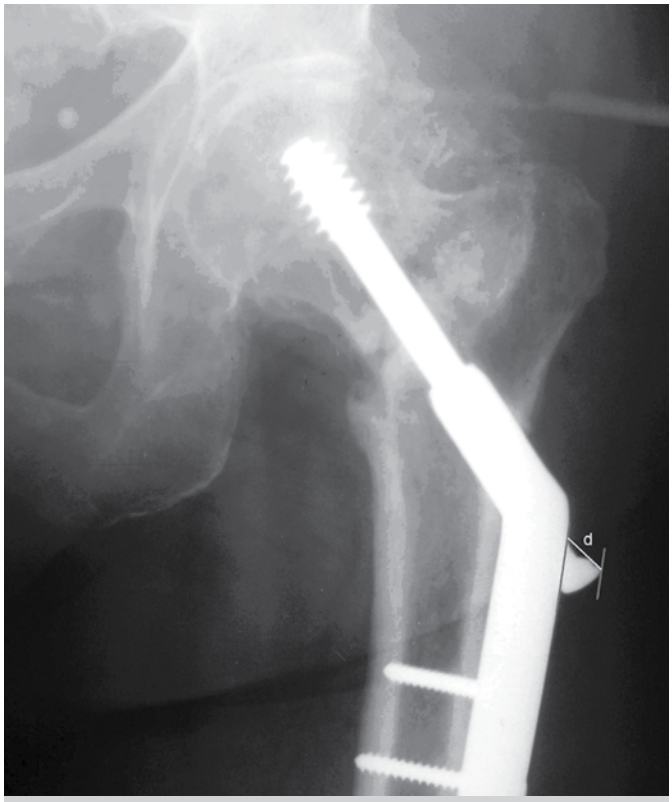

Figure 2. *Distance of the sliding of the screw in the plate barrel (d).*

of alendronate sodium in the postoperative period, with 30% of the male gender and 70% of the female gender, and mean age of 75.6 years. The diagnosis of osteoporosis was established in 70% of the patients and the surgical treatment was performed according to the protocol established by this study. In this group, three patients died in the postoperative period. The mean radiological consolidation time was 11 weeks, with the mean value on the visual analogue scale for pain (VAS) of 1.57 points, a variation of densitometric bone mass with decrease of 1.6%, having a mean fracture focus resorption value of 2.57mm. (Table 2)

DISCUSSION

The transtrochanteric fracture is an important cause of morbidity and mortality in the elderly, and is responsible for a high percentage of surgeries and occupancy of hospital beds in orthopedic conditions.

The mortality rate of the patients under analysis, after 12 months of follow-up, was 20%, with 11.1% in group I, and 30 % in group II. This mortality rate is similar to those found in literature, which reports a variation of 12 to 24% in the first year.[15] Dementia, delirium and depression increase the mortality risk in the two years after femoral fracture, reaching 30% in 24 months.[16,17]

The absolute values of bone mass, obtained with the performance of two BMD exams with the DEXA technique, are used comparatively to monitor changes of bone mineral density over time, evaluating disease evolution and therapeutic efficacy. The patients from group I, who made use of alendronate sodium as from the immediate postoperative period, experienced mean loss of bone mass of 1.04% compared with 1.60% in group II, which did not make use of the substance. These values were not statistically significant ($p>0.05$), even though the patients from group I lost a smaller quantity of bone mass. The changes in bone mass resulting from therapeutic interventions are considered modest in literature, since the response to the therapeutic approach is not uniform in all individuals. Studies show that up to 20% of patients may present reduction of bone mass in the first year after starting the treatment; considering as therapeutic efficacy a reduction in the resorption speed, which is on average 4% per year.[9]

Based on the radiological exams, the bone resorption rate was evaluated according to the established protocol and group I obtained a lower resorption rate (2.33mm) in comparison with the 2.57mm of group II, yet these data were not statistically significant ($p>0.05$). It is appropriate to emphasize that there was a complication with a patient from group I, who had another fall, and was submitted to a second surgical intervention, whereas the measurement of the cotter pin extrusion was not included in this comparative study. With a basis on the study

Table 1. *Measurements of group I, which corresponds to the patients that made use of Alendronate Sodium.*

Patient	1	2	3	4	5	6	7	8	9
Age	85	76	72	88	66	82	85	53	92
Gender	F	F	F	F	M	F	F	M	F
Side	R	R	R	L	R	L	R	R	L
Singh	II	II	III	II	II	III	IV	IV	II
Initial T-score	-4.52	-4.66	-4.17	-2.9	-2.67	-3.42	-3.27	-3.13	-3.81
Initial B.M.D.	0.432	0.416	0.474	0.627	0.725	0.565	0.583	0.665	0.518
B.M.D 6 months	#	0.433	#	0.59	0.689	0.541	0.589	0.693	0.512
Bone Mass	#	>4%	#	<6%	<5%	<4.3%	>1%	>4.2%	<1.2%
RC	#	8s	#	12s	12s	8s	6s	6s	6s
VAS	#	2	#	2	0	4	0	2	1
Resorption	#	5 mm	#	0 mm	9 mm	2 mm	3 mm	0 mm	4 mm

B.M.D. – Bone mineral density. RC– Radiological consolidation. VAS – Visual Analogue Scale

Table 2. *Measurements of group II, which correspond to the patients that did not make use of alendronate sodium.*

Patient	10	11	12	13	14	15	16	17	18	19
Age	61	93	89	85	75	63	76	59	74	81
Gender	M	F	F	F	F	F	F	M	F	M
Side	R	R	R	L	L	L	L	R	R	L
Singh	III	II	II	III	II	IV	I	III	II	I
Initial T-score	-3.06	-4.92	-3.62	-3.59	-2.05	-3.33	-3.32	-1.81	-4.2	-2.38
Initial B.M.D	0.674	0.384	0.541	0.544	0.729	0.576	0.577	0.836	0.56	0.762
B.M.D 6 months	0.656	#	#	#	0.657	0.534	0.614	0.816	#	0.763
Bone Mass	<2%	#	#	#	<9%	<1%	>4%	<2%	#	0
RC	8s	#	#	#	14s	12s	8s	12s	#	12s
VAS	1	#	#	6	4	0	0	0	#	0
Resorption	4 mm	#	#	0 mm	0 mm	0 mm	11 mm	3 mm	#	0 mm

B.M.D. – Bone mineral density. RC – Radiological consolidation. VAS – Visual analogue scale

by Canto et al.16, who quantified the sliding of the screw in the plate barrel, we obtained 100% of telescoping between zero and five millimeters in group I, and 75% in group II.

The patients were submitted to periodic radiological control, according to the methodology, for consolidation evaluation. The mean radiological consolidation of group I was 7.6 weeks if compared to group II, with a mean value of 11 weeks. These data appear to be statistically significant ($p=0.086$), considering $p>0.05$.

The Visual Analogue Scale for Pain (VAS),[18] executed with facial expressions correlated to a numerical scale from zero to ten, was used for pain quantification. It is important to emphasize that pain is a symptom, which is subjective, and that it was not discriminated by gender due to the low percentage of male patients in the sample group. The parameter was used to correlate an earlier radiological consolidation with pain of less intensity upon starting to walk (four weeks), with no significant change in groups I and II, and without data in literature for comparative analysis of this parameter.

CONCLUSION

We concluded that radiologically the patients using alendronate sodium had faster bone consolidation with a lower rate of reabsorption.

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