



The influence of bisphosphonate on bone mineral density after total knee arthroplasty: A Randomised Controlled Trial

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ABSTRACT

Purpose: The effect of bisphosphonate on postoperative bone mineral density (BMD) is rarely reported. In the present study, the BMD change in ipsilateral hip with and without application of bisphosphonate after primary total knee arthroplasty (TKA) was evaluated.

Methods and analysis: Sixty-eight patients undergone TKA due to severe osteoarthritis were enrolled in this study. According to the application of bisphosphonate, the patients were divided into treatment group and control group. The BMD of ipsilateral hip was measured preoperatively and at the 3rd, 6th, 12th and 24th month after surgery. Independent *t*-test was conducted to compare BMD difference between two groups preoperatively and paired *t*-test was conducted to compare BMD at each time point. The significant difference was considered at $P < 0.05$.

Results: No statistical difference of preoperative BMD in femoral neck, wards triangle, greater trochanter and proximal femur between two groups was detected. BMD in all ranges of interest (ROIs) in the control group reached the lowest level at the 12th month after surgery and increased slightly at the 24th month after surgery. The BMD in all ROIs in the treatment group revealed a slight fluctuation around the baseline level.

Conclusion: The application of bisphosphonate after TKA contributes to the BMD postoperatively. Bisphosphonate is helpful in reducing complications caused by osteoporosis after TKA as well as the recovery of patients. Therefore, patients can benefit from the application of bisphosphonate.

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1. Introduction

As the largest and most complex joint, knee joint supports the whole body so that its degeneration or injury is very common. For patients with severe osteoarthritis, TKA is a very effective intervention strategy for functional recovery and pain relief when other treatments are failed. Therefore, TKA becomes one of the most widely used joint replacement surgeries. The osteoporosis after TKA operation has been reported. As one of major drugs for the treatment of osteoporosis, bisphosphonate is widely used with confirmed treatment efficacy through various studies [1,2]. However, whether its impact on bone mineral density (BMD) in patients after TKA is the same efficient is unclear, this stimulates us to explore the effect of bisphosphonate on BMD of the patients who have underwent the TKA surgeries.

2. Materials and methods

2.1. Inclusion and exclusion criteria

Patients were included in this study if they have undergone single lateral TKA surgery due to severe osteoarthritis, and have holonomic data of BMD determined at pre-operatively and at the 3rd, 6th, 12th and 24th month after surgery. Exclusion criteria included the history of total hip replacement and contralateral total knee replacement (≥ 3 months), rheumatoid arthritis, metabolic bone disease, single lateral or bilateral femoral head necrosis, and lumbar disc herniation.

All patients were assigned to the treatment group and the control group one by one alternately according to the order of operation time. The treatment group with the administration of alendronate at the dose of 70 mg once a week after surgery until the end of the study, the control group without the administration of alendronate. Postoperative rehabilitation training and other treatments in both groups were exactly same. All procedures of TKA

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surgery were completed by a same surgeon. Also the same surgeon enrolled participants, and assigned participants to interventions.

This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). A special informed consent was carefully explained to all patients and signed.

2.2. Data collection and evaluation methods

All data was collected at the hospital the authors work in. BMD in four ranges of interest (ROIs) of hip were collected and analyzed.

2.2.1. Femoral neck

The neck of femur is a bridge connecting femoral head and femoral shaft. It is one of the parts with the highest possibility of fracture in the body. BMD measurement of femoral neck is important for preventing the fracture of femoral neck.

2.2.2. Wards triangle

Between the medial bone trabecular under compressive stress and the lateral bone trabecular under tensile stress, there is a triangle called wards triangle. It is the region with the lowest BMD in proximal femur, and with high sensitivity to the change in BMD. The change of BMD in wards triangle can reflect the change in bone density in time.

2.2.3. Greater trochanter

Between femoral neck and femoral shaft, there is a hump called greater trochanter. It is the muscle attachment point such as gluteus medius and gluteus minimus muscle. Its serious osteoporosis can result in avulsion fracture, thus affecting the function of hip joint.

2.2.4. Proximal femur

The BMD in proximal femur is the average BMD of femoral neck, trochanter and intertrochanter area. Due to its accuracy, it is great meaningful in longitudinal study of BMD.

2.3. BMD measurement

BMD was measured using dual energy X-ray absorptiometry (Lunar iDEX, GE Medical, Waukesha, Wisconsin, USA). The check time points included the pre-operative point, and at the 3rd, 6th, 12th and 24th month after surgery. The BMD of ipsilateral femoral neck, greater trochanter, wards triangle and proximal femur of ipsilateral hip was measured after surgery. The preoperative data are set as the baseline level. The radiologist is blinded for the patients group.

2.4. Statistical analysis

SPSS19.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Independent *t*-test was carried out to compare the difference of pre-operative BMD between two groups, and paired *t*-test was performed to compare the difference of BMD at each point after surgery with the preoperative data. The statistically significant difference was considered at $P < 0.05$.

This work has been reported in line with the CONSORT criteria [3].

3. Results

3.1. Patient information

From June 2013 to December 2014, 96 patients who underwent

TKA in our hospital were recruitment in the study, 28 patients were excluded due to lost to follow-up or haven't holonomic data of BMD. A total of 68 patients (21 men, 47 women) were enrolled in this study finally. The average age of these patients was 65.02 ± 5.62 years old and the mean follow-up period was 24 months. The treatment group including 38 cases and the control group including 30 cases. All patients were suffered from severe pain combined with obvious dysfunction before operation. Before surgery, all knees at the operation side had radiographic Kellgren-Lawrence grade III or greater. As for the non-operation side, 50 cases had Kellgren-Lawrence grade II or less, and 18 cases had Kellgren-Lawrence grade III or more, but didn't undergo TKA surgery because the patients were considered as the non-necessity to conduct the surgery.

3.2. BMD outcomes

3.2.1. Femoral neck

Before operation, BMD of femoral neck in the treatment group was slightly lower than that in the control group, but no significant difference was observed. In the control group, in the first 6 months after surgery, BMD of femoral neck revealed a continuous decreased, and then revealed a slight increase at the 12th month and decreased again at 24th after surgery. In the treatment group, BMD reached the lowest point at the 3rd month after surgery, and almost increased to baseline level at the 6th month after surgery and kept to the 24th month after surgery.

3.2.2. Wards triangle

In the control group, the BMD continuous decreased in the first 12th month and slightly increased at 24th months after surgery. In the treatment group, its BMD at the 3rd month after surgery revealed a slight increase with the variation of 4.0%.

3.2.3. Greater trochanter

In the control group, BMD reached the bottom level at the 12th month and kept to the 24th months after surgery. In the treatment group, BMD exhibited a slight increase at the 3rd month and reversion downward to the lowest level at the 6th month and then increase slightly at the 12th month and kept to the 24th after surgery.

3.2.4. Proximal femur

In the control group, BMD of proximal femur kept decreasing trend during the 24 months' follow-up period with the max variation of -5.1% . But in the treatment group, the change of BMD in proximal femur was minimal (Fig. 4, and Tables 2 and 3) (see Figs. 1–3 and Table 1).

4. Discussion

Due to severe osteoarthritis, BMD always presents a gradually decreasing trend caused by reduced physical activity after surgery. The bone density can change with functional recovery of joints, particularly in the hip and knee joint bearing body weight, which has been reported in many studies [4,5]. In this study, the BMD of ipsilateral hip with surgery was obviously reduced after surgery without the administration of bisphosphonate. In patients with the administration of bisphosphonate, there was no obvious reduction in BMD at all follow-up time points compared with the baseline level. In consideration of annual bone mass loss of 2% due to the increasing age, the protective effect of bisphosphonate on BMD is more distinct. According to the study of Yoshinori [5], even taking into account 4% loss of bone mass due to the increased age during the 2-year follow-up, approximately half of patients have higher

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