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A long-lasting bisphosphonate partially protects periprosthetic bone, but does not enhance initial stability of uncemented femoral stems: A randomized placebo-controlled trial of women undergoing total hip arthroplasty

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ABSTRACT

Low bone quality may compromise the success of cementless total hip arthroplasty in high-risk patients such as elderly women. Zoledronic acid is a long-lasting antiresorptive agent, which is known to reduce short-term periprosthetic bone loss. However, its effect on femoral stem stability is not well known. Forty-nine female patients with a mean age of 68 years (range, 51–85 years) scheduled to undergo cementless total hip arthroplasty due to osteoarthritis were randomized in this double-blind, placebo-controlled trial to receive a single postoperative infusion of zoledronic acid or placebo. Patients were evaluated for up to four years postoperatively for femoral stem migration measured by radiostereometric analysis, bone mineral density (BMD) measured by dual X-ray absorptiometry, functional recovery, and patient-reported outcome scores. Implant survival was determined at nine years postoperatively. Zoledronic acid did not reduce the femoral stem migration that occurred predominantly during the settling period of the first 3–6 months. Subsequently, all femoral stems were radiographically osseointegrated. Zoledronic acid maintained periprosthetic BMD, while the expected loss of periprosthetic bone during the first 12 months was found in controls. Thereafter, periprosthetic BMD of Gruen zone 7 decreased even in the zoledronic acid group but remained 14.6% higher than that in the placebo group at four years postoperatively. Functional recovery was comparable across the groups. At nine years postoperatively, no revision arthroplasty had been performed. In conclusion, in women at high-risk for low BMD, zoledronic acid had a long-lasting, partially protective effect on periprosthetic bone loss, but the treatment did not enhance the initial femoral stem stability.

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1. Introduction

Strain-adaptive bone resorption is an inevitable biological response around uncemented femoral stems in patients with total hip arthroplasty (Kerner et al., 1999; Sumner, 2015; Yamako et al., 2017). The baseline bone mineral density (BMD) value has been found to predict subsequent periprosthetic bone loss (Engh et al., 1992; Kerner et al., 1999; Sumner, 2015). The periprosthetic bone loss process is more likely to occur in women, patients with a low cortical index, and patients with larger stems (Engh et al., 2003). However, it is difficult to avoid strain shielding by changing the implant geometry and material properties (Cilla et al., 2017).

Radiostereometric analysis (RSA) is the benchmark for in vivo evaluation of implant migration (Valstar et al., 2005). Stability of uncemented femoral stems is essential to enable biologic osseointegration through bone ingrowth. Uncemented femoral stems should preferably not migrate at all, but many femoral stems still do and the maximum time limit for subsidence appears to be one year (Kärrholm, 2012). Early stem migration has been detected in patients with a low periprosthetic BMD (Sköldenberg et al., 2011b).

Bisphosphonates, such as zoledronic acid (Black et al., 2007), are effective for diseases characterized by increased osteoclast-mediated bone resorption. Cohort studies concerning the effects of bisphosphonates in patients with hip arthroplasty have also shown promising results (Bhandari et al., 2005). Clinical trials have

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shown beneficial short-term effects of bisphosphonates on periprosthetic BMD (Venesmaa et al., 2001; Sköldenberg et al., 2011a). Moreover, bisphosphonates use may even improve the implant survival (Prieto-Alhambra et al., 2012; Teng et al., 2015; Khatod et al., 2015).

Zoledronic acid may not only inhibit periprosthetic femoral bone resorption (Scott et al., 2013), but has been shown to reduce migration of acetabular components in patients with total hip arthroplasty treated for avascular necrosis of the femoral head (Friedl et al., 2009). In pre-clinical models, zoledronic acid has promoted bone ingrowth into porous tantalum implants as a potential method for enhancement of implant fixation (Bobyn, 2005; Bobyn et al., 2009).

No previous study on the effect of zoledronic acid on RSA-measured implant migration is currently available. Aging women are ideal subjects for a study on this effect, as they frequently have low BMD (Glowacki et al., 2003; Mäkinen et al., 2007), and are prone to early migration of both components of total hip arthroplasty (Aro et al., 2012; Finnilä et al., 2016) and periprosthetic femoral bone loss (Alm et al., 2009). This study evaluated whether zoledronic acid affects femoral stem stability in women with hip osteoarthritis. Our hypothesis was that zoledronic acid would reduce the osteoclast-mediated strain-adaptive periprosthetic bone resorption and thereby enhance the early stability of uncemented femoral stems measured by RSA.

2. Material and methods

This single-center randomized, double-blind, placebo-controlled clinical trial followed the CONSORT guidelines (Schulz et al., 2010), was conducted in accordance with the ethical principles of the Declaration of Helsinki (JAVA, 2013), and was registered at ClinicalTrials.gov (NCT01218035). The study was approved by the Ethics Committee of the Hospital District of South-West Finland (decisions 4/2006 §173 and 9/2012 §270) and the Finnish Medicines Agency (191/2006, EudraCT 2006-002557-68). All study participants provided written informed consent before enrollment.

2.1. Study participants and screening

The trial included postmenopausal women with advanced degenerative hip osteoarthritis. The exclusion criteria included any inflammatory arthritis, parathyroid dysfunction, current use of drugs for osteoporosis or corticosteroids, hepatic or renal disease, skeletal disorder such as Paget's disease, malignancy within the past five years, and a history of dental infections or impending dental surgery.

During the recruitment period between March 2008 and November 2009, all new admissions were prescreened for the eligibility and willingness to participate in the study. Sixty patients were assessed for eligibility (Fig. 1), which included laboratory

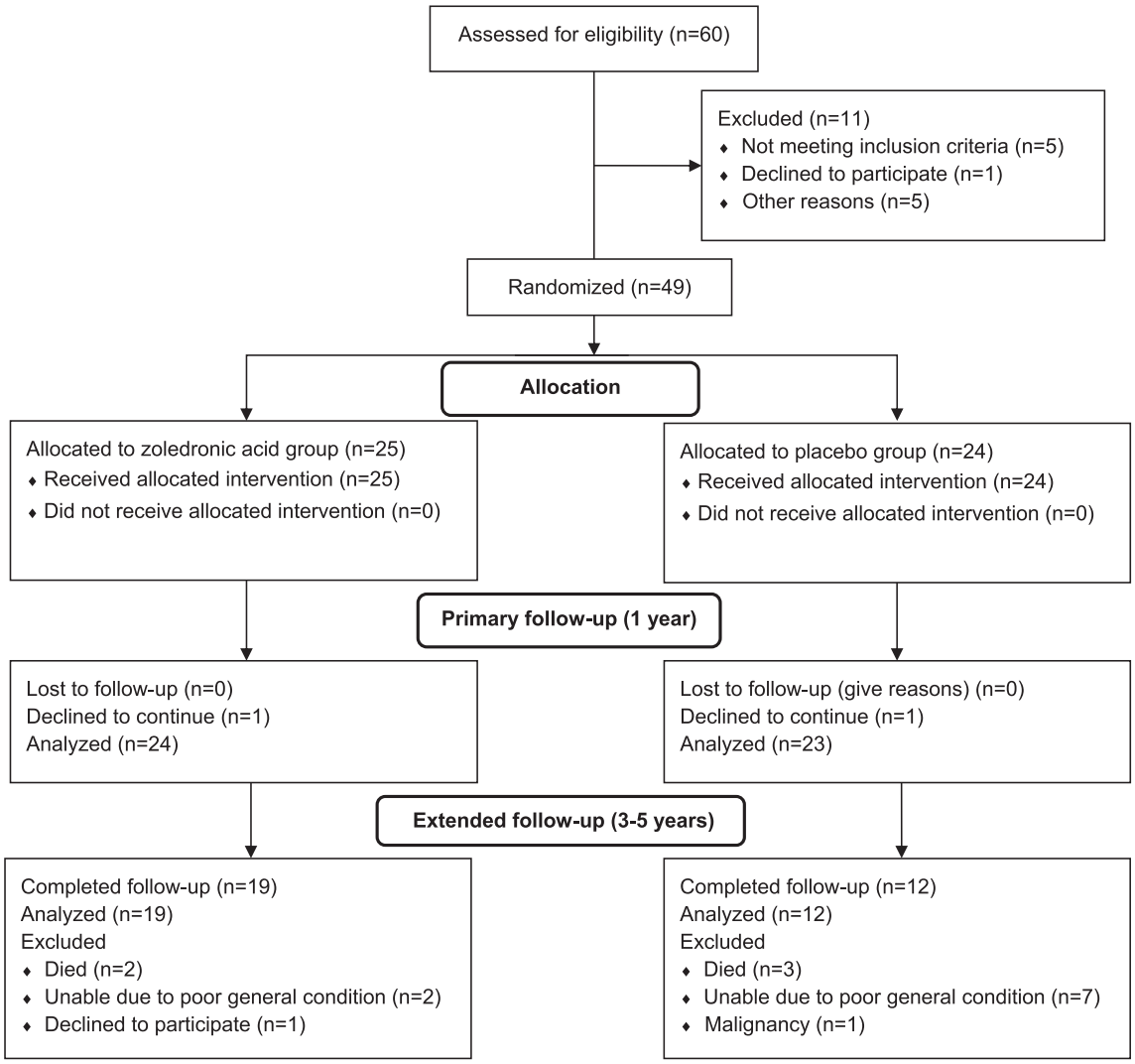

Fig. 1. Diagram of patient flow through the study.

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