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Usefulness of Ultrasonography for Detection of Pseudotumors After Metal-On-Metal Total Hip Arthroplasty

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ABSTRACT

We retrospectively analyzed 83 metal-on-metal total hip arthroplasties in 74 patients. Ultrasonography and magnetic resonance imaging (MRI) of each hip were performed to detect abnormal patterns and pseudotumors. We examined the reliability of ultrasonography for detecting pseudotumors in comparison with MRI. We also compared the acetabular component inclination between patients with and without pseudotumors. The mean positive and negative predictive values for pseudotumor detection by ultrasonography were 65% and 91%, respectively. The mean positive and negative likelihood ratios were 5.78 and 0.32, respectively. There was no clear association between pseudotumor presence and acetabular component inclination. We concluded that ultrasonography is a suitable technique to screen for the presence of pseudotumors. We also need to distinguish between bearing-related and taper junction corrosion-related complications.

Introduction

Several terms have been used to describe adverse soft tissue reactions in patients with metal-on-metal (MoM) bearings. Cook et al [1] suggested that the spectrum of pathologies from local tissue metallosis to bone and tissue necrosis with pseudotumor and aseptic lymphocytic vasculitis-associated lesions (ALVAL) could be covered by the term “adverse local tissue reaction” (ALTR). However, “adverse reaction to metal debris” (ARMD) was first suggested by Langton et al [2] to cover joint failures associated with pain, large sterile effusion of the hip, and/or macroscopic necrosis/metallosis. Haddad et al [3] described ARMD as an umbrella term that included metallosis, aseptic lymphocytic vasculitis-associated lesions, and pseudotumors. Pseudotumors are lesions that may be cystic, solid, or a combination of the two. They are found around MoM hip implants, as originally described by Pandit et al [4]. For the purposes of this study, “pseudotumor” is used to reflect adverse soft tissue reactions in patients with MoM bearings.

Many articles have recently been published on the subject of pseudotumors. Some reported that pseudotumors are associated with poor outcomes after revision surgery [5,6]. Others noted that pseudotumors are associated not only with a soft tissue mass and osseous changes caused by osteolysis and erosion but also with damage to the periarticular soft tissue [7]. This damage may lead to soft tissue and muscle necrosis, osseous denudation, pathological fracture, and hip dislocation [7]. Still other articles have suggested that pseudotumors occur as a result of increased metal ion levels [2,8] and that small femoral component size, female sex, and young age are associated risk factors [9].

Despite these discussions, the pathology of pseudotumors remains unclear. Recommendations from the United States Food and Drug Administration regarding this pathology include (1) routine long-term follow-up every 1–2 years for both asymptomatic and symptomatic patients with MoM hip arthroplasty; and (2) serum metal ion analyses and use of advanced imaging techniques such as magnetic resonance imaging (MRI), computed tomography, or ultrasonography for symptomatic patients with MoM hip arthroplasty. Recently, more detailed protocols for the diagnosis and management of MoM arthroplasty have been suggested [10].

Because there is evidence that pseudotumors can exist in patients with well-functioning MoM hip prostheses [11], we believe that screening for pseudotumors is important for patients' well-being regardless of their symptoms or lack thereof. Although metal artifact reduction sequence MRI is often used to detect pseudotumors [12], problems related to cost and metal artifacts have not been completely resolved [13]. Recently, ultrasonography has been performed to detect pseudotumors [14,15], although its usefulness is uncertain.

In addition, although the MoM bearing surface has been considered to be the main risk factor for pseudotumor presence in the past few years, taper junction corrosion-related complications have recently become a topic of interest [16,17]. The issue of whether an MoM bearing surface is always related to the presence of a pseudotumor remains controversial.

The primary purpose of the present study was to validate the use of ultrasonography for detecting pseudotumors. A secondary purpose was to assess whether there were correlations between the presence of a pseudotumor and the acetabular component inclination.

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Materials and Methods

Before undertaking the present study, we performed a two-proportion power analysis to determine the sample size required to detect a difference in pseudotumor prevalence between well-positioned and poorly positioned hips. To perform this analysis, we estimated that the prevalence of pseudotumors was 4% in well-positioned MoM hips and 60% in poorly positioned MoM hips, based on previous reports [18–20]. Significance was set at a *P* value of 0.05 and a power of 90%. As a result of this analysis, the minimum sample size was determined to be 26 patients (13 patients per group).

Institutional review board approval was obtained for the study. From 26 December 2006 to 24 October 2011, the senior authors performed a total of 150 MoM total hip arthroplasties (THAs) at our institution. Among these patients, we retrospectively analyzed 83 hips in 74 patients treated with MoM bearings from a single manufacturer (S-ROM-A femoral prosthesis and Pinnacle acetabular cup system; DePuy, Warsaw, IN, USA). In total, we excluded 19 hips that were lost to follow-up, 19 with high hip dislocation (Crowe type 3 or 4), 14 with MoM bearings from another manufacturer, 6 that were followed up for less than 2 years, and 9 in patients who were unwilling to undergo MRI and ultrasonography. Overall, 74 of the 83 hips were evaluated by both imaging procedures. The remaining 9 hips underwent MRI only. The patients' characteristics are presented in Table 1.

The S-ROM-A femoral stem is a modular cementless prosthesis with a 9/10 neck taper made of titanium alloy (6 A1 4V Ti). The proximal sleeve couples to the stem via a Morse taper and has a porous coating with an irregular, roughened texture. It can be coupled to the stem in any position of version.

The acetabular shell has a titanium porous-coated Pinnacle design. This Pinnacle acetabular component can accept a polyethylene liner, a ceramic liner, or an MoM insert. The metal inserts are secured with a self-locking peripheral taper and a dome contact. The MoM acetabular liners and femoral balls are composed of a wrought high-carbon alloy. The carbon content is considered to be high, at 0.15–0.35%, meeting the ASTM F1537 Alloy 2 specifications. Both the femoral heads and acetabular liners are highly polished. The 28-mm bearing surface has 60 ± 20 μm clearance, and the 36-mm bearing surface has 100 ± 20 μm clearance. The femoral heads and acetabular liners are composed of 59–68% cobalt and 27–30% chromium.

After receiving informed consent, ultrasonography of each hip was performed using a Hitachi Aloka Medical system and 7.5-MHz linear transducer (ProSound SSD-3500SX; Hitachi Aloka Medical Ltd., Tokyo, Japan) by one observer prior to MRI after a minimum follow-up of 2 years.

Kwon et al [20] reported that patients with pseudotumors displayed significantly high serum cobalt and chromium levels. Hasegawa et al [21] also reported that significant increases in both cobalt and chromium were observed within 2 years. Based on these reports, we determined that ultrasonography should be performed after a minimum follow-up of 2 years to evaluate the prevalence of pseudotumors as accurately as possible. All still images were stored in JPEG format. The ultrasonography technique and classification of its findings (joint-expansion, cystic, and mass patterns as normal or abnormal) were based on the report by Nishii et al [15]. First, longitudinal images were obtained by moving the transducer parallel to the femoral component. Second, transverse images were obtained by moving the transducer parallel to the axis of the femoral shaft. The iliopsoas muscle could be used as a guide to reach the anterior surface of the femoral component. To avoid missing lesions along the medial wall of the pelvis in our study, additional longitudinal images were obtained by moving the transducer parallel to the medial wall of the pelvis, from the anterior superior iliac spine to the anterior edge of the acetabular roof. This maneuver also helped the examiner reach the anterior surface of the femoral component, especially in obese patients. Finally, lateral areas around the greater trochanter were obtained by moving the transducer parallel and perpendicular to the femoral shaft axis. Joint-expansion, cystic, and mass patterns were defined as hypoechoic spaces of 4 mm or more between the anterior capsule and the anterior surface of the femoral component, hypoechoic lesions, and mixed hyperechoic and hypoechoic lesions, respectively. Measurements of the lesions were performed at the maximum diameter.

The procedure included evaluation from the anterior to posterolateral aspect of the hip. All ultrasonography images were evaluated at least 1 month later by two of the authors without knowledge of the clinical symptoms or radiologic findings.

After receiving informed consent, we performed MRI using a 1.5-tesla MR scanner (Achieva Nova Dual; Philips Healthcare, Best, The Netherlands) on the same day as the ultrasonography examination. Hips with pseudotumors were defined according to Hart et al [11]. The walls and contents of the lesions were characterized and used to classify the pseudotumors. Wall thicknesses of ≤ 2 and >2 mm were defined as thin and thick walls, respectively. The contents were classified according to the signal intensity on T1-weighted (T1W) and T2-weighted (T2W) images. Lesions with thin walls and typical fluid findings (hypointense on T1W and hyperintense on T2W) were classified as type 1 pseudotumors. Lesions with thick walls were classified as type 2 pseudotumors. Type 2 pseudotumors were further divided into two types depending on their contents: type 2a with typical fluid findings; and type 2b with atypical fluid findings (hyperintense on T1W and variable on T2W). Solid lesions (mixed signals) were classified as type 3 pseudotumors. The hips were divided into two groups (with and without pseudotumors). The MRI sequences were as follows: axial T1W turbo spin-echo (TSE) with an echo time (TE) of 20.4 ms and repetition time (TR) of 573 ms; axial T2W TSE with TE of 100 ms and TR of 3000 ms; coronal T1W TSE with TE of 20.4 ms and TR of 462 ms; and sagittal T2W TSE with TE of 100 ms and TR of 3000 ms. The section thickness was 5 mm, the field of view was 350×350 mm, and the pixel bandwidth ranged from 347 to 362 Hz/pixel (according to Toms et al [12]). The MRI scans were independently evaluated by two of the authors (an orthopedic surgeon and an experienced musculoskeletal radiologist) without knowledge of the clinical symptoms or radiologic findings, and a consensus was reached.

A supine anteroposterior digital radiograph of the pelvis was obtained. The tube-to-film distance was 120 cm, with the tube perpendicular to the table. The center beam was directed toward the midpoint between the upper border of the symphysis and a horizontal line connecting the bilateral anterosuperior iliac spines. The acetabular component inclination, measured using a software program (Rapideye Hyper; Toshiba, Tochigi, Japan), was defined as the angle between a line joining the tips of the bilateral teardrops and a line through the long axis of the cup ellipse. Plain radiography was shown in a previous report to be a reliable method for measuring the inclination of the acetabular components [22]. The radiographic measurements were performed by two of the authors.

Hip function was assessed in each patient using the Harris hip score (HHS) at the time of the ultrasonography and MRI examinations. Age, sex, and femoral component size were also recorded for each patient.

Table 1
Patient Characteristics.

Age (years), mean (range)	60.4 (45–82)
Sex (M/F) (no. of patients)	18/65
Time from surgery to scan (months), mean (range)	45.3 (24–68)

Statistical Analysis

The intraclass correlation coefficients (ICCs) for detecting abnormal patterns by ultrasonography were determined by calculating the kappa coefficient (κ). The ICCs for measuring acetabular component inclination on plain radiographs were also determined.