Chapter 6

High incidence of pseudotumors after hip resurfacing even in low risk patients; results from intensified MRI screening protocol

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Abstract

We intensified our screening protocol for the presence of pseudotumors in a consecutive series of patients with a hip resurfacing arthroplasty (HRA), to establish whether we should be alert to the presence of 'silent' pseudotumors. Patients categorised with high risk (11 hips) and low risk (10 hips) for pseudotumor development and a control group (23 hips) were screened with Metal-Artefact Reduction Sequence (MARS) magnetic resonance imaging (MRI). The Anderson classification to grade any Metal-on-Metal (MoM) disease present on MARS-MRI images was used. In 15 out of 44 MRI scans pseudotumors were observed (34.1%), of which six were graded with mild (13.6%), eight with moderate (18.2%) and one with severe MoM disease (2.3%). Twelve pseudotumors were present in asymptomatic patients (27.3%). Metal ion levels were normal in 80% of the MARS-MRI screened patients. As a consequence of our intensified screening protocol, one patient was revised for pseudotumor formation and another patient was scheduled for revision. Silent pseudotumors were observed in all three groups. Before our intensified screening protocol was initiated, no pseudotumors were encountered in our cohort of 289 HRAs. We concluded that clinical outcomes and plain radiographs for screening MoM patients underestimates the presence of pseudotumors in MoM patients. The true clinical relevance of these pseudotumors is still unclear.

Introduction

Metal-on-Metal (MoM) bearings have been widely used in hip arthroplasty. Although wear rates are low, these bearings still release cobalt and chromium particles which may result in a periprosthetic soft tissue reaction, requiring revision surgery.[1,2] This periprosthetic soft tissue damage, known as adverse reaction to metal debris (ARMD) compromises aseptic lymphocytic vasculitis-associated lesions (ALVAL), metallosis and pseudotumor formation.[3] Revision surgery for pseudotumors is sometimes difficult and post-revision surgery clinical outcomes are less satisfying.[4] The reported incidence of pseudotumors varies, depending on patient characteristics, type of follow-up and implant design features.[5,6] Earlier MoM hip arthroplasty studies relied on clinical outcome scores and radiographs of large case series to report on good implant performance and excellent functional outcomes.[7-9] Recently published data, however, report on a much higher incidence of pseudotumors in patients with MoM implants after all patients have been screened for the presence of these adverse peri-prosthetic reactions with Metal-Artefact Reduction Sequence (MARS) magnetic resonance imaging (MRI) or ultrasound.[10,11] Suspicion arises that there may be a relatively large number of 'silent' pseudotumors present in otherwise well-functioning implants. There is reason to believe that the occurrence of pseudotumors is not solely observed with malpositioned implants with relatively high metal ion levels and poor clinical outcome.[11] From this growing unease we decided to intensify our screening protocol for the presence of pseudotumors in a consecutive series of patients with HRA. The aim of this study was to clarify whether we should be alert to the presence of 'silent' pseudotumors in our cohort of hip resurfacing patients. According to previously defined patient and implant characteristics[6,11], we categorised high and low risk patients for pseudotumor development, together with a non-stratified control group. Subsequently, in all three groups MARS-MRI screening for pseudotumors was performed.

Patients and methods

Patients

Between September 2004 and September 2010 we included 298 consecutive HRA procedures (240 patients) in a prospective cohort study. Females <60 years of age and males <65 years of age were the primary candidates for HRA if diagnosed with end stage osteoarthritis (OA) and had an active lifestyle. Older patients with

sufficient bone quality and an active lifestyle were considered for HRA on an individual basis. Dual energy X-ray absorptiometry was used to exclude patients with osteoporosis. Patients with renal failure, femoral cysts, avascular necrosis (AVN) of the femoral head and female patients trying to conceive were also excluded. Procedures were followed in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000. After informing the patient on the expected benefits and risks associated with HRA, informed consent on the surgery procedure and on study participation was obtained. Our study was approved by the Institutional Review Board (IRB nr. 08.013, 18th December 2008).

Implant system

All procedures were performed by one of two experienced hip arthroplasty surgeons (TS, HH). The ReCap hip resurfacing system (Biomet Inc, Warsaw, USA) was implanted by a posterolateral approach. The press-fit acetabular component and the cemented femoral component are manufactured from "as-cast" cobalt-chrome (Co-Cr-Mo) with a high carbon content (>0.2%) without any heat treatment. The acetabular outside is a full hemisphere design and has four pairs of small fins for initial rotational stability. It has a titanium porous plasma spray surface coating facilitating bone ingrowth. The system offers 2 mm increment sizing. The surgical technique has been described earlier by Gross and Liu.[12] All patients received antibiotic prophylaxis with a cephalosporin preoperatively and 24 hours post-operatively, fourteen days of indometacin for periarticular ossification prophylaxis, diclophenac for pain management and thrombosis prophylaxis with dalteparine 5000 units for six weeks postoperatively. Patients were rehabilitated with immediate unrestricted weight bearing according to the patient's tolerance. All bilateral procedures were staged interventions with at least a three month interval.

Study design

To evaluate the occurrence and incidence of pseudotumor formation we defined three different groups of patients. The first group had a perceived high risk for pseudotumor formation based on gender, component size and cup inclination angle.[6,11,13] Cup inclination angle was measured on the latest available standard anteroposterior radiograph using earlier described methods.[14] Eventually we

allocated 11 female patients with a cup inclination angle >45° and a femoral component size <50 mm to this 'high risk' group. Five patients in this group had bilateral HRA; one patient fulfilled all high risk criteria bilaterally, four patients only unilaterally, and therefore 12 hips were included in the high risk group for MARS-MRI screening. The 'low risk' group consisted of 10 asymptomatic male patients with a unilateral HRA, cup inclination angle <45° and femoral component size >50 mm. The third group consisted of 19 patients (22 hips) who, regardless of risk factors, were scheduled for routine follow-up between November 2011 and May 2012 and acted as a 'control' group without risk stratification (Table 6.1). In all three groups, blood serum samples were collected and assessed on cobalt and chromium concentrations. Samples were collected in metal-free vacutainers; the first 5 mL blood was discarded to eliminate metal contamination from the needle. Tubes were stored at 2-8°C and sent to an external laboratory (Ziekenhuis Groep Twente, Hengelo, Netherlands) for analysis. The metal ion levels in whole blood were determined using Atomic Absorption Spectrophotometry (AAS) analysis. Cobalt levels were classified according to guidelines by the Dutch Orthopaedic Society[15] with normal Cobalt <40 nmol/L, slightly elevated 40-85 nmol/L, elevated 85-170 nmol/L and extremely elevated >170 nmol/L. All MARS-MRI examinations were performed on a 1,5T MRI (Philips Medical Systems, Best, Netherlands). Scan parameters are listed in table 6.2. All MARS-MRI images were judged by an experienced musculoskeletal radiologist (KB) and validated by a second musculoskeletal radiologist (RH), who were both unaware of the clinical status of the patients. We used the description by Matthies et al of a pseudotumor being a sterile inflammatory lesion found in the soft tissues surrounding a MoM hip arthroplasty.[16] Grading of MARS-MRI findings was based on the method described by Anderson et al[17] (Table 6.3). Since Harris hip scores (HHS), Oxford hip scores (OHS)[18,19] and anteroposterior and lateral radiographs were collected yearly as part of routine follow-up, these were available for all patients. The OHS results were calculated using the original scoring system (12 points being best possible score, 60 points being the worst possible score).

Table 6.1, Patient characteristics			
	High ARMD risk	**Low ARMD risk**	**Routine FU group**
Patients/Hips (n)	11/12	10/10	19/22
Male/female (n)	0/11	10/0	16/3
Fem. comp. size (median)	46mm (min-max: 44-50)	52mm (min-max: 50-56)	52mm (min-max: 46-54)
Cup inclination angle (mean)	60^0 (min-max: 55-70)	41^0 (min-max: 35-44)	51.5 (min-max: 36-64)
Bilateral MoM (n)	5	0	3
HHS score (mean)	89 (min-max: 79-95)	89 (min-max: 83-91)	80 (min-max: 48-91)
HHS pain score (n)	7 none, 2 slight; 2 moderate	10 none	9 none; 8 slight; 3 moderate
Age (mean)	53.1 years (min-max: 41-61)	54 years (min-max: 40-66)	54 (min-max:28-69)
Follow up (mean)	3.8 years (min-max: 1 – 7)	4.5 years (min-max: 2.3-6.9)	4.0 years (min-max: 1.6-6.9)

Statistical analysis

Descriptive statistics were used to compare the three study groups. Metal ion data distributions were asymmetric and are expressed as a group median with range. Symmetrical data are represented by a mean and standard deviation (SD). The significant level α is defined as .05 in this study. A post hoc analysis was used to measure the statistical power of the observed difference in pseudotumor occurrence between groups. SPSS software (SPSS Statistics, version 17.0, IBM Corporation, Somers USA) was used for all statistical analyses.

Results

Patient characteristics are shown in table 6.1. Before the intensified screening protocol was implemented, no pseudotumors had been detected in our cohort of 298 HRAs. With the MARS-MRI screening completed, pseudotumors were observed in all three groups (Table 6.4). The risk for pseudotumor development in the high risk group was 0.45, 0.33 in the low risk group and 0.3 in the control group. However, the statistical power to detect a true significant difference in risk ratios between groups was low (0.11). Overall, in 15 cases of the 44 MARS-MRIs available for analysis, pseudotumor formation had occurred. In total 29 MARS-MRI images were classified as grade A, none as grade B, six as grade C1, eight as grade C2 and one grade as C3. In contrast to the MARS-MRI images, the cobalt levels were normal in 80% of the patients. Two patients had slightly elevated metal ion levels, four patients had elevated levels and two patients had extremely elevated levels. Median Cobalt level for all patients was 24 nmol/L (min-max: 11-

1897 nmol/L). Out of the 15 pseudotumors which were observed on MARS-MRI, there were 12 silent pseudotumors. These patients did not complain of any pain or other symptoms and had excellent clinical outcome scores (HHS >90, Oxford Hip Score <16) with normal radiographs. One female patient from the high risk group with severe MoM disease underwent revision surgery, and one male patient from the control group with moderate MoM disease is scheduled for revision. The revised patient had bilateral HRA: seven years after implantation on her right, six years on her left side.

Table 6.2, *MARS-MRI details*

	TE (ms)	TR (ms)	TI (ms)	Slice thickness	FOV (mm)	Matrix	BW (HZ/pixel)	Coil
Coronal PDW	30	3000		2,5	230 x 197	328 x 220	435	sense body 16 ch
Coronal STIR	40	8645	130	2,5	230 x 198	256 x 168	437	sense body 16 ch
Transverse PDW	30	3576		3	240 x 199	344 x 198	437	sense body 16 ch
Transverse	40	105000	130	3	280 x 198	280 x 152	435	sense body 16 ch
Sagittal STIR	40	9570	130	3	230 x 230	256 x 189	438	sense body 16 ch

Table 6.3, *Anderson classification for MoM disease on MARS-MRI*[13]

Grade	Description	Criteria
A	Normal or acceptable	Normal post-op appearances including seromas and small haematomas
B	Infection	Fluid-filled cavity with high signal T2 wall; inflammatory changes in soft tissues, ± bone marrow oedema
C1	Mild MoM disease	Periprosthetic soft tissue mass with no hyperintense T2W fluid signal or fluid-filled peri-prosthetic cavity; either less than 5 cm maximum diameter
C2	Moderate MoM disease	Peri-prosthetic soft tissue mass/fluid-filled cavity greater than 5 cm diameter or C1 lesion with either of following: (1) muscle atrophy or edema in any muscle other than short external rotator or (2) bone marrow edema: hyperintense on STIR
C3	Severe MoM disease	Any of the following: (1) fluid-filled cavity extending through deep fasci, (2) a tendon avulsion, (3) intermediate T1W soft tissue cortical or marrow signal, (4) fracture

Table 6.4, Incidence of and characterization of pseudotumor formation and cobalt levels			
	High ARMD risk	Low ARMD risk	Routine FU group
Patients/hips (n)	11/11	10/10	19/23
Pseudotumor (n)	5	3	7
Grade C1/C2/C3	2/2/1	3/0/0	1/6/0
Pseudotumor size (mean)	5.2cm (min-max:1.9-10.5)	3.3cm (min-max:1.8-5.0)	4.4cm (min-max: 1.9-8.0)
Cobalt median (nmol/L)	27 (min-max: 19-1897)	18 (min-max: 11-36)	24 (min-max: 12-407)

There was no pseudotumor observed on her right side but on her left side she had a pseudotumor measuring 105 mm craniocaudally, 71 mm anteroposteriorly and 80 mm mediolaterally (Figure 6.1). Her Cobalt level was extremely elevated (1897 nmol/L). Her HHS score was 91 points and she never complained of pain after HRA. She did however regularly noticed squeaking on the left side, something we had not observed in any other patient from our series. Both cups had a steep inclination angle (left 70^0, right 59^0). During revision surgery a large fluid filled cyst was excised, extending from the lateral side to the anterior part of the hip joint.

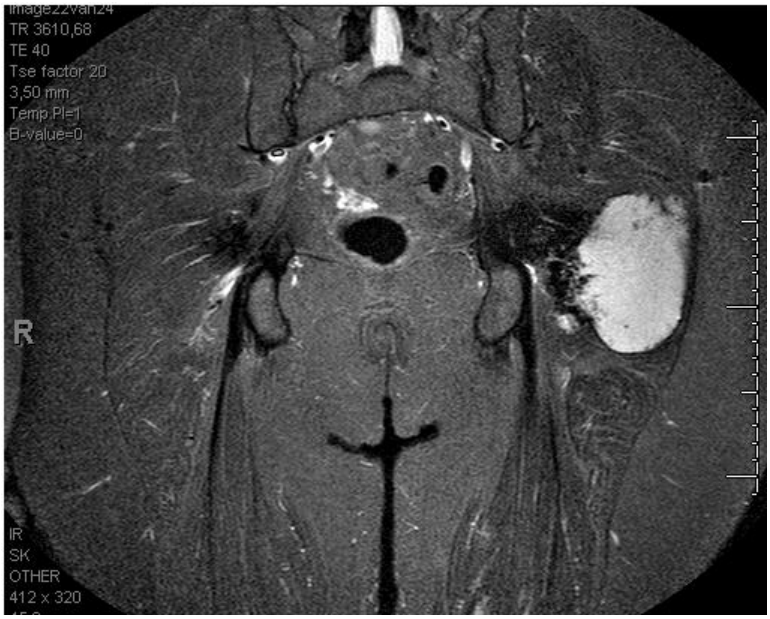

Figure 6.1, Large fluid filled cyst left hip, indicating Anderson grade 2 MoM disease. Patient was revised.

Discussion

In our study group of patients with a Recap HRA the prevalence of pseudotumors appeared to be high, with pseudotumor occurrence even in the group defined as having a low risk for ARMD. With an established pseudotumor incidence of 34.1 percent in this concise exploratory study group, we can expect another 87 pseudotumors using an intensified MARS-MRI screening protocol on our entire group of 298 resurfacing hip arthroplasties. Of these 87 pseudotumors, an expected 17 would classify as a grade C2 or C3 pseudotumor with an increased revision risk. As confirmed by other authors, pain was not a very useful indicator for pseudotumor occurrence.[20.21] Compared to the extent of damage noticed on MARS-MRI and at revision surgery, one has to wonder by which mechanism pseudotumors develop relatively pain free. Mild symptoms and relatively low metal ion levels can contribute to the difficulty of convincing patients to have their HRA revised. However, recent media attention about the negative effects of MoM bearings has scared many MoM patients, who even ask for revision surgery in absence of any symptoms. Although several authors report on pseudotumor rates, the number of studies using other imaging modalities than plain radiographs to detect pseudotumor occurrence is very limited. High rates of pseudotumor occurrence have been found in other studies which used MARS-MRI or computer tomography (CT) scanning. Wynn-Jones reported a similar pseudotumor rate of 36% using the ASR resurfacing device.[21] Compared to MoM hip resurfacing, higher pseudotumor rates are reported for MoM total hip arthroplasty. Mistry reported a 58.3% pseudotumor rate using the Ultima TPS design[20] and Bosker found a 39% pseudotumor rate in MoM THA patients who received the M2a-Magnum femoral head and ReCap acetabular component.[10] Langton described a 13.6% revision rate for ARMD with the ASR design, but use of MRI or CT scanning was not reported in this paper.[6] Malviya found a pseudotumor incidence of just 0.15% using the BHR resurfacing device, although it is not clear from his paper if all patients routinely were scanned using MARS-MRI[22] To our knowledge, there are no other studies which have investigated the prevalence of pseudotumors with this particular HRA design using imaging modalities other than plain radiographs. The studies by Baad-Hansen and Gagala were limited to 23 and 25 HRA patients respectively with a maximum follow-up of 24 months.[23,24] Gross and Liu recently published a case series of 740 consecutive procedures with the ReCap HRA design with a follow-up of seven years maximum.[25] The reported

Kaplan-Meier survivorship with any revision as an end point was 96.4% at 7 years, with only two revisions (0.3%) for adverse wear. Follow-up was limited to clinical outcomes and plain radiographs, but as the possibility of more adverse wear failures was acknowledged by the authors, they started taking metal ion samples routinely. There remains uncertainty on the risk factors for pseudotumor formation with current MoM hips. Studies have suggested that edge-loading resulting from adverse cup orientation and implant design leads to a higher wear of the components and subsequently increases blood metal ion levels.[26,27] Clinical studies and reports from arthroplasty registers also implicate smaller components in connection with increased metal ion levels.[13,28] Based on these finding, the use of MoM prostheses is supported for appropriately trained surgeons who select appropriate patients.[29] Recently, studies have debated risk factors for pseudotumor formation. Kwon et al and Mistry et al showed that pseudotumors can be observed in asymptomatic patients with well positioned and well functioning prostheses.[20,30] Recently, Matthies et al reported that pseudotumors are common in well positioned MoM prosthesis.[16] These results are confirmed by our study in which pseudotumors were commonly found in asymptomatic patients with well positioned, large components. This suggests that development of pseudotumors is more likely to be dependent on patient susceptibility than on factors such as component size, component positioning or implant design. The risk for pseudotumor formation is higher for any patient with any MoM prosthesis than previously thought. Until now, clinical signs, radiographic evaluation and metal ion levels have been used to identify patients at risk for pseudotumor formation. The best protocol for detecting pseudotumors is not yet defined, but ultrasound scans, CT or MARS-MRI scans are commonly used. Our study indicates that follow-up methods of clinical outcomes and radiographs underestimate the prevalence of pseudotumors after MoM HRA. Moreover, metal ion levels alone are also not sufficient to detect all cases of ARMD. Our findings, especially those from the low risk ARMD group, have prompted us to start using MARS-MRI scans for our whole MoM cohort. Our findings suggest that radiographic screening with MARS-MRI, CT or ultrasound on all patients with a hip resurfacing might be the only option to discover the real magnitude of pseudotumor formation after MoM arthroplasty. There are several limitations of our study. Most importantly, the number of patients is small since we report on an exploratory study at this stage. In spite of this limited number of patients we still feel the need to report on our

preliminary findings of the high number of pseudotumors found on MARS-MRI even in low risk patients with few or no symptoms. In our study group, there were quite a few patients with a steep cup inclination angle, which is considered the only risk factor for ARMD by some authors.[31] However, despite the fact that we differentiated amongst other factors between high and normal cup inclination, we still found pseudotumors with normally inclined cups. We believe that conventional radiological and clinical follow-up together with metal ion analyses will underestimate the true prevalence of MoM-disease. An intensified screening protocol for pseudotumors with MRI, CT scan or ultrasound is likely to become unavoidable. There is no consensus yet on the clinical relevance of pseudotumors and it may be possible that only some become problematic. There is increasing evidence that the incidence of pseudotumor formation with large diameter (>36 mm) MoM may be higher than assumed so far and the use of these implants has been suspended in the Netherlands.

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LARGE DIAMETER METAL-ON-METAL HIP PROSTHESIS

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