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ORIGINAL PAPER

Revision of ASR hip arthroplasty: analysis of two hundred and ninety six recalled patients at seven years

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Abstract

Purpose The aim of this study is to present an algorithm for the evaluation of both symptomatic and asymptomatic patients.

Methods From November 2004 to May 2010, there were performed 296 operations: 245 total hip arthroplasty and 51 resurfacing arthroplasty with the ASR DePuy system. In April 2010, there was the first Medical Device Alert regarding all MoM hip replacements in the UK and in August 2010, DePuy recall started worldwide. In March 2012, we started our recall. All patients were invited to undergo clinical investigation, X-ray evaluations, and blood chrome and cobalt level determination. For a short period of time, there were performed second level exams and subsequently, we carried out MARS MRI hip study to all symptomatic patients and there was evidence of ALVAL lesions.

Results To the patients with ALVAL lesions were proposed surgical hip revision while the others frequent follow-up controls. One hundred patients underwent hip surgical revision.

Conclusions We recommend constant MoM THA patients monitoring and early revision if necessary.

Keywords Metal-on-metal · Total hip arthroplasty · Adverse reaction to metal debris · Aseptic lymphocytic-dominated vasculitis associated lesions · Articular surface replacement · Metal artifact reduction sequence magnetic resonance imaging

Introduction

Philip Wiles performed the first total hip arthroplasty (THA) in 1938. Subsequently, Sir John Charnley developed the use of polymethylmethacrylate cement to fix the THA. It was the gold standard type of implant fixation until the 1990s with metal-on-polyethylene interface.

The first generation of metal-on-metal (MoM) THA was introduced in 1951 by Mckee and Farrar.

Orthopaedic surgeons very soon stopped using MoM bearings because of a high rate of failure due to loosening, metallic debris, and metal hypersensitivity.

The need to reduce hip prosthesis dislocation led to an increase of the head size with a corresponding reduction in acetabular polyethylene thickness which caused an increase of the particulate wear volume.

Therefore, second-generation MoM THA was introduced in the late 1990s because they had bigger head size and low volumetric wear resulting in a low rate of aseptic loosening [1–3].

Despite this in the 2000s, adverse events caused by metal debris became apparent and led to a complete halt in the use of MoM hips. Up to that moment, one third of the prosthesis in the USA and more than one in five cases in the UK were MoM hips.

Authors used different names to describe metal debris reaction: aseptic lymphocytic-dominated vasculitis associated lesions (ALVAL), pseudotumor, adverse reaction to metal debris (ARMD), cysts, adverse local tissue reaction (ALTR), and metallosis.

In 2005, Willert et al. were the first to describe MoM bearings ALVAL in terms of specific histological reaction with

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perivascular lymphocytes aggregates with follicles of B and T cells, tissue necrosis, fibrin exudation, endothelial venules, and accumulation of macrophages.

In 2008, the Oxford group was the first to introduce the pseudotumour term as non-neoplastic, non-infected, solid or semi-liquid soft tissue periprosthetic mass communicating with hip joint in MoM THA [4].

At present, the most used term in scientific literature is ARMED as described by Langton et al. in 2010 [5].

Diagnosis and management of adverse events connected to MoM THA are difficult when compared to other bearing solutions. In 2010, all over the world the DePuy Articular Surface Replacement (ASR) recall started with the aim to investigate the threshold for revision, analyzing these criteria: poor clinical results (growing pain or mechanical symptoms), soft tissue involvement, osteolysis, and metal ion levels.

Method

In April 2010, there was the first Medical Device Alert regarding all MoM hip replacements in the UK. In August 2010, DePuy recall started worldwide. After the DePuy recall, we examined our Arthroplasty registries from November 2004 to May 2010 which contained 296 patients treated with THA (245 hips) or resurfacing ASR system (51 hips); 43% male and 57% female patients; the surgical site was right in 51%, left in 49%, 5% bilateral.

Our recall started in March 2012 in accordance with DePuy guideline. All patients were invited to undergo a clinical investigation, X-ray evaluations, and blood chrome and cobalt level determination. From 2012 to August 2017, the blood samples were sent to Imperial College Healthcare NHS Trust, Pathology report Clinical Chemistry, Ground Floor Oncology, Charing Cross Hospital LONDON Trace metal. From August 2017 up to now, the blood samples were sent to Laboratorio di Sanità Pubblica area Vasta Toscana Sud Est - Dipartimento interaziendale regionale dei laboratori di Sanità Pubblica di Area vasta Siena.

These results determined the next follow-up (FU) after three, six and 12 months. The normal value of ion metal blood level in general population is 0.3–1.5 μg/L. In MoM population, the predictable value is ≤4 μg/L, the limit level is ≤ 7 μg/L, and the risk value is >20 μg/L. High ion level was found in 106 patients at the first check-up.

The first clinical evaluation underlined pre-surgical cardiac, neurologic, and respiratory diseases, post-surgical neurological problems, hip range of motion (ROM), inexplicable local pain, implant mechanical impairment (such as swelling, squeaking).

Five patients did not undergo the recall because it was impossible to contact them, 14 patients decided to stop the FU after two years, and 15 after three years. Thirteen patients died meanwhile. For 21 patients, the recall ended after seven years; 128 patients were still in FU in 2018.

During FU, a personal algorithm based on clinical and instrumental data was developed. In case of intense pain or high metal blood level or X-ray osteolysis, the patient could receive metal artifact reduction sequence (MARS) MRI [6] or CT scan or ultrasound hip exam or scintigraphy (Table 1).

One hundred patients underwent hip surgical revision: 11 total hip revision (acetabulum and stem); in eight patients, the acetabular component was mobilized. The mean age at surgical revision was 73 years (48–90 years). All operations were performed by the surgeon-in-chief using explant Zymmer system to take off ASR component making an extensive debridement of ALVAL lesion if present (Figs. 1 and 2). In all cases, intra-operative microbiological exams were performed with negative results. The new acetabular implant used was primary or revision shell Trilogy

Table 1 Algorithm

Evidence	Indications
MRI +++, no pain, normal metal blood level	Possible mechanical malfunction, revision
MRI +++, no pain, high metal blood level	Possible mechanical malfunction, revision
X-ray +++, no pain, normal metal blood level	If MRI and scintigraphy +++ revision
	If MRI and scintigraphy −−− only FU
X-ray +++, no pain, high metal blood level	MRI +++ revision, MRI −−− only FU
X-ray −−−, high pain	MRI +++ revision
	MRI −−−, normal metal blood level suspect of local infection or allergy
No pain, high metal blood level	MRI +++ revision for mechanical malfunction
	MRI −−− revision for potential biological risk
High pain, high metal blood level	MRI +++ revision for mechanical malfunction
	MRI −−− revision for potential biological risk

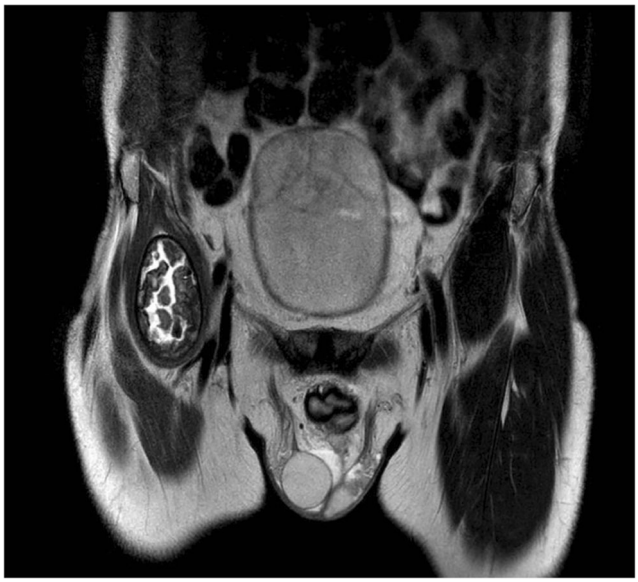

Fig. 1 MARS MRI ALVAL lesion

TMT Zymmer; cemented dual mobility acetabular component Liberty Microport was implanted if the bone stock was poor [7–10].

Clinical chart data, instrumental and blood findings on FU showed significant information (Table 2).

Results

From November 2004 to May 2010, we performed 296 MoM hip replacement operations (15 bilateral MoM THA): ASR acetabular implant (all patients), Corail femoral implant (245 hips), DePuy Resurfacing (51 hips).

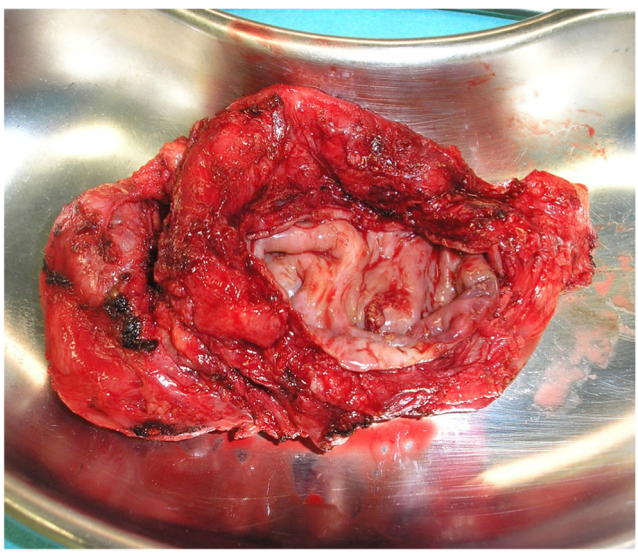

Fig. 2 Intra-operative ALVAL lesion after surgical excision

All patients, 43% male and 57% female, were contacted by letter. At the beginning, we carried out a complete clinical evaluation, blood tests for metal ion analysis, standard X-rays, and frog view X-ray exam.

One hundred six of 296 patients had elevated levels of cobalt and/or chromium (set threshold 7 μg/L). The blood levels ratio of cobalt to chromium is 1:1, but in case of taper corrosion, this ratio increased to 1.86 [11–14].

During the early recall stage, there was no evident correlation between pain, X-ray pathological findings and blood ions level. For a short period of time, we performed second level exams such as CT scan or ultrasound hip exam or scintigraphy but they did not reveal further useful information for a more accurate diagnosis. Therefore, we started to carry out MARS MRI hip study to all symptomatic patients, which allowed us to find ALVAL lesions (Figs. 1 and 2).

According to our algorithm, all these patients were advised to receive hip revision but some of them refused and continued the FU.

Patients with asymptomatic hip, high blood ion level, and no ALVAL lesion were advised to undergo complete standard control (X-rays, blood ion test, clinical evaluation) once every 12 months.

Patients with painful hip, high blood ions level, and no ALVAL lesion were performed complete standard control every six months and MARS MRI hip study every 12–18 months.

Eight patients developed growing acetabular component mobilization and were revisioned. If the pain increased or the ALVAL lesion grew, we proposed hip revision to all patients; very high blood ions level alone was an indication to revision for potential biological risk.

After a subjective evaluation, we divided patients in three categories: 0 (patients with pain), 1 (patients with good health status), and 2 (patients with very good health status). These data proved that most 0 patients had ALVAL lesions and that is statistically relevant at Wilcoxon test (0.18 value).

Patients with mean ion metal blood level 25 μg/L were revisioned (standard deviation at T-student ± 18) and those with 15 μg/L did not undergo a revision surgery (standard deviation at T-student ± 18) with a statistical significance $p = 0.0025$.

We found a second correlation between revision index and the acetabular inclination angle: it was 47° (± 7°) in revision patients and 44° (± 6°) in non- revision ones with a statistical significance $p = 0.0073$.

Third correlation was between revision index and the acetabular anteversion angle: it was 8° in revision patients and 6° in non- revision ones with a statistical significance $p = 0.0003$. There was no correlation between revision index and the acetabular component diameter or femoral component size.

Table 2 Chart data, instrumental and blood findings

	All patients (296)	Revisioned patients (100)
Median head diameter	47 mm (41–55 mm)	47 (45–56 mm)
Median acetabular diameter	52 mm (46–60 mm)	52 (50–58 mm)
Median acetabular angle		
Inclination	46° (34°–81°)	48° (38°–65°)
Version	11° (− 37°–33°)	5° (2°–9°)
ALVAL	112 patients	51 patients

Conclusions

In March 2012 in accordance with DePuy and the Italian Health Ministry guideline, we started DePuy ASR acetabular system recall. At the beginning, we followed to the letter the DePuy indications about how to conduct the investigation.

We examined 106 patients with high ions metal blood level, most of them reported significant hip pain but the X-rays did not show pathological findings so we performed second level exams CT scan or ultrasound hip exam or scintigraphy. They did not reveal useful information for a correct diagnostic evaluation of the patients therefore we started to carry out MARS MRI hip study to all symptomatic patients and they showed ALVAL lesions [15].

All the patients with ALVAL lesion were advised to undergo hip revision and those who refused continued the FU.

Patients with asymptomatic hip, high blood ions level, and no ALVAL lesion were advised to undergo complete standard control once every 12 months and those with painful hip, high blood ions level, and no ALVAL lesion were performed complete standard control every six months and MARS MR hip study every 12–18 months.

In the examined patients, we found statistically significant data between painful hip and/or high ion metal blood level and ALVAL lesion. CT scan, ultrasound hip exam, or scintigraphy are not helpful to find ALVAL lesions, only MARS MRI is able to discover it.

Our case study, on the one hand, did not find significant correlation between revision index and the acetabular component diameter or femoral component size, on the other, we found correlation between revision index and higher acetabular inclination angle and higher acetabular anteversion angle.

Inflammatory and immunological reaction to the metal debris in MoM THA is due solely to wear particles produced by different metals at the taper junction [16–18].

The revision of a MoM THA is a difficult surgical procedure because it requires to perform a complete synovectomy to debulk wear particles and to excise as much as possible ALVAL lesions with extensive soft tissue damage; this can compromise surgery outcome [19, 20]. In conclusion, we recommend constant MoM THA patients monitoring and early revision if necessary.

Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict of interest.

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