

Metal-on-metal hip replacements: implications for general practice

What is the problem with metal-on-metal hip replacements?

Hip replacements with large metal-on-metal bearing surfaces were introduced in the late 1990's. These devices aimed to improve outcomes in young and active patients with hip arthritis, who had experienced poor results with conventional implants. Metal-on-metal bearings showed early promise, with 1.5 million implanted worldwide as stemmed hip replacements and hip resurfacings (non-stemmed surface replacement). Unfortunately these devices experienced unexpected high short-term failure rates and have rarely been used since 2012.¹ Furthermore concerns have been raised about the potential long-term systemic effects of metal ions in the blood. High metal ion exposure poses a theoretical risk of developing certain cancers, whilst some deaths have been reported in metal-on-metal hip patients which occurred due to cardiac failure secondary to metal ion toxicity. However large cohort studies have presently observed that metal-on-metal hip patients are not at increased risk of cancer, heart failure, or mortality compared with other hip replacement patients.

Many metal-on-metal hips have required revision surgery for abnormal reactions to metal debris generated from the implant, which can substantially damage the bone and soft-tissues.¹⁻³ These reactions can occur in patients with minimal or no symptoms, and outcomes following revision surgery have been poor.³ It was thought that outcomes could be improved by identifying problems early. Therefore since 2012 worldwide regulators, such as the Medicines and Healthcare products Regulatory Agency (MHRA), have recommended screening many metal-on-

metal hip patients,⁴ though this screening is extremely variable and very costly.⁵ In addition to clinical review (history and examination, including gait), metal-on-metal hip replacement patients can require blood metal ion testing (cobalt and chromium concentrations, which reflect implant wear), x-rays (identify signs suggestive of implant failure), and ultrasound or magnetic resonance imaging (identify soft-tissue disease, such as “pseudotumour” masses³ and muscle damage).

In the UK since the 2012 MHRA guidance was published, stemmed metal-on-metal hip replacement patients (40%-50% of all metal-on-metal hips) have been investigated annually regardless of symptoms. However patients with hip resurfacings (50%-60% of all metal-on-metal hips) have required less regular review given resurfacing failure rates have been lower compared with stemmed metal-on-metal hips.¹ Over 80% of all hip resurfacing patients are asymptomatic, with many discharged by hospitals if the initial 2012 reviews were satisfactory.^{4,5}

Why have metal-on-metal hips recently been in the news?

On 29th June 2017, the MHRA published updated follow-up recommendations for all patients with metal-on-metal hip replacements.⁶ This scheduled MHRA update recommends more intensive surveillance than previously,⁴ although recommendations may not be fully supported by evidence.^{1,7} Every patient now needs blood metal ions and patient-reported outcomes (Oxford Hip Score), with most requiring annual investigations for the implant lifetime. Imaging is performed in symptomatic patients and/or those with abnormalities, such as high ions.

This new guidance will now affect over 60,000 UK patients, most of whom are asymptomatic with well-functioning implants.^{1, 8} There has never been a medical device recall on this scale before. The costs for delivering this surveillance in the UK will increase substantially by 80% compared with using the 2012 recommendations, which cost £8.2 million/year.⁷ For these reasons the 2017 MHRA guidance has been associated with a flurry of national media interest with headlines referring to “toxic” metal-on-metal hips.^{9, 10}

How will the latest MHRA guidance impact on GPs?

The MHRA state the “Medical Device Alert is being sent to GPs for information only, in case patients ask about the contents of this notice. GPs need take no further action on receipt of this alert.”⁶ However the professional orthopaedic bodies recommend concerned patients can contact their GP.¹¹ Furthermore the NHS recommends concerned patients should consult “their doctor” if they have certain symptoms, including chest pain, shortness of breath, and fatigue.¹² This professional advice coupled with the extensive media coverage will generate many primary care consultations nationwide involving understandably concerned patients. Our experience suggests this has already started.

What are the challenges for GPs?

Hospitals are responsible for contacting patients and organising surveillance. Although GPs do not need to actively manage patients with metal-on-metal hips,⁶ many concerned and anxious patients with these devices will continue to present to primary care for advice. Some patients may even request blood tests for reassurance.

However many GPs will be unaware of the problems associated with metal-on-metal hip replacements and the implications of the new MHRA guidance, namely because GPs will have presently received limited or no correspondence from secondary care about how the new follow-up will be introduced locally. These delays have stemmed from hospitals receiving little or no warning from the MHRA about the contents or imminent publication of this scheduled surveillance update. Hospital staff (clinicians, nurses, and managers) are currently developing strategies for implementing the new guidance locally, which itself is complex. For example one local hospital implanted over 5,000 metal-on-metal hips, which will require about 100 staffed clinic days to see every patient just once. Comprehensive advice from hospitals on how to manage patients with metal-on-metal hips may therefore not be immediately forthcoming to GPs. This makes it very difficult for GPs to advise concerned patients, or to provide realistic timeframes about when they will be contacted or reviewed in hospital. However to manage the follow-up burden hospitals may request GPs undertake some investigations.

Another fundamental challenge for GPs will be to establish whether patients actually have metal-on-metal hips. Every hip replacement contains metal, however only those with a metal-on-metal bearing surface are problematic. Since 2003, 800,000 hip replacements have been implanted in the UK, with only 8% having metal-on-metal bearings.¹ Unfortunately the specific type of implant patients receive is often not recorded in primary care and patients do not always know, so the correct information must be obtained from hospitals. Many operations were done privately, which may present further challenges to obtaining this information. Therefore many concerned patients who do not even have metal-on-metal hips may present to primary care. These anxieties may persist, as these patients will never be recalled by secondary care given that

they do not have metal-on-metal hips. Without more information from hospitals, such GP consultations will be unnecessary for patients and may lead to incorrect advice and/or inappropriate referrals.

What can GPs do for patients with metal-on-metal hips?

GPs can improve the consultations they have with anxious and concerned patients in numerous ways. Our experience suggests it is important to discuss the issues around metal-on-metal hips at a practice meeting. This helps educate all staff and aids decision making on how to manage certain scenarios, e.g. concerned patients requesting blood tests. GPs have no responsibility to proactively identify patients,⁶ however when consulted GPs must initially try to establish whether the hip replacement was metal-on-metal. All hip resurfacings are metal-on-metal, but most stemmed hip replacements are not.¹ This information may help identify the implant from primary care records and/or if a patient knows they had a resurfacing. If the implant type cannot be established, patients should be advised to contact the secretary of the responsible consultant. This may also allow patients to find out about the recall.

Symptomatic patients reviewed in primary care, regardless of implant, should continue to be referred to secondary care. This includes patients with persistent pain (groin, buttock, lateral hip, or thigh), mechanical symptoms (clicking, clunking, squeaking, or instability), local swellings/masses, or in rare cases patients with nerve palsy (femoral/sciatic), vascular symptoms (claudication/venous thrombosis), or localised skin rashes.^{2, 3}

GPs can reassure asymptomatic patients that hospitals are currently developing updated follow-up protocols and that they will be recalled at some stage, although this may take time given the large numbers involved. Patients may also be concerned about the media portrayal that these implants are associated with serious problems such as cancer, heart failure, or dementia. However patients can be reassured that presently no robust population data exists to support claims that these implants cause systemic problems.

Primary care should not be expected to undertake any follow-up,⁶ however our experience suggests some hospitals ask GPs to repeat and interpret blood metal ion tests. Given the latest MHRA recommendations coupled with stretched healthcare resources it is possible hospitals may increasingly request GPs to undertake blood tests, x-rays and/or patient-reported outcomes. Any requests from hospitals and/or concerned patients for investigations in primary care should be diverted back to hospitals given the complexities with performing and interpreting tests, especially blood metal ions which can only be analysed at a few specialised centres. Similarly requests regarding compensation claims should be referred to secondary care, either by the patient or their legal representative. Litigation for metal-on-metal hip patients has been ongoing for about a decade and continues to go strong. This usually consists of group actions involving hundreds of affected patients, with the outcomes of these being variable. A large group action is going to trial in the UK High Court in October 2017, which will be “one of the largest product liability group actions in recent years”,¹³ with similar litigation continuing in the USA.

Given recent events we plan to contact our local hospitals and request an update for the surrounding Clinical Commissioning Groups, specifically relating to how hospitals plan to

organise follow-up and over what time period. We will also enquire about having a primary hospital contact, with knowledge about metal-on-metal hip problems and the latest surveillance, who could manage many of the questions or concerns from GPs and patients. We recommend other GPs consider similar strategies so that any concerned metal-on-metal hip replacement patients presenting to primary care can be advised appropriately.

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