BRITISH ORTHOPAEDIC ASSOCIATION

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Metal On Metal Hip Replacement and Hip Resurfacing Arthroplasty :

What does the MHRA Medical Device Alert mean?

You will be aware that the MHRA (Medicines and Healthcare products Regulatory Agency) has been investigating the incidence of adverse events associated with metal on metal (MOM) hips. An Expert Advisory Group was set up to investigate the incidence and extent of problems and to establish guidelines that would help and advise surgeons and patients. The clinicians on the group are all members of the Hip Society and include John Skinner, Martyn Porter, Keith Tucker, Paul Gregg and Peter Kay. The NJR, BOA and MHRA were all represented and Jan van der Meulen acted as statistical adviser. The NJR was used to find cases of revision of MOM and HRA . A report has now been submitted to the MHRA and the MHRA has released a Medical Device Alert for all MOM bearings.

The key points are that excellent results are reported with MOM hip resurfacing arthroplasty (HRA) and THR from many centres. It is accepted that MOM bearings have a higher incidence of painful joints. There are a small but significant number of patients who develop pain and significant tissue damage.

It is felt that pain with MOM bearings should be investigated as we are still uncertain which patients are likely to progress or develop serious soft tissue reactions. These reactions (variously referred to as ALVAL, Pseudo tumour, effusions, bursae ,tissue necrosis and ARMD (adverse reaction to metal debris)) are rare and probably have an incidence of somewhere between 1 and 9 per thousand devices implanted. It is possible that the incidence is higher in some areas and more frequent with some devices than others. The MHRA feel that there is insufficient evidence to highlight one particular device at this stage and it is fair to say that adverse reactions have been reported with all MoM devices.

The advice on a practical level is straight forward and probably just represents best practice for patients by their surgeons. It is likely that there will be media interest as the MHRA is briefing the press and that there will be a high level of enquiry by patients to trusts, hospitals and surgeons.

As the advice stands it does not constitute a formal recall of all patients. It means that all patients should probably be contacted by letter and told of the Alert. Patients can be reassured that in the absence of pain or symptoms, the serious soft tissue reactions/tissue necrosis are rare.

If patients are anxious then they may be offered a blood test to measure cobalt and chromium levels. The main purpose of this is that low levels are reassuring and strongly predict not having an adverse outcome or soft tissue reaction. Slightly elevated levels or very high levels are less certainly understood but probably correlate with high wear at the bearing. Ultimately in the presence of pain, high cup inclination angle and elevated metal ions then revision should be considered. It can be argued that in the presence of pain and high inclination angles revision should be considered anyway.

It is likely that Cobalt and Chromium levels may be useful for screening but they are not well understood at present. High levels may start as low as 7 ppb for either metal. High levels have a higher correlation with revision, pain and soft tissue reactions, but the correlation is not absolute in the short term. It may be that longer follow up will clarify this.

The alert mandates follow up at least annually, for the first five years and then as per locally agreed protocol thereafter. It may be that life-long review is appropriate for some components. Not all patients will require in person follow up. It may be that postal questionnaire or phone call is all that is required in asymptomatic stable joints and those with proven provenance. Patients should be warned to contact the surgeon/ hospital if symptoms change or function or hip scores deteriorate.

All revisions should be documented in the NJR and several centres are happy to analyse the implant for cause of failure.

It should be noted that there are several other causes of failure including impingement, psoas/adductor tendonitis, failure of fixation of components, femoral neck fracture or resorption/AVN, neurological, referred pain from spine, sacrum or adnexae, hernia. These are not generally associated with the soft tissue reactions that have triggered the MHRA intervention.

It seems that we as the Orthopaedic Profession will be called on to reassure investigate and manage the patients through this difficult time. We believe that there remains uncertainty as to the incidence of this problem and that although fluid collections around these implants may be common, severe reactions are thankfully rare. If they occur, the surgery may be complex as the soft tissue damage reported can be severe.

Pain in patients with mom bearings should be investigated and if it is associated with features such as high component inclination angles, high metal ion levels, soft tissue reactions then this should be taken seriously. It does seem to be a progressive condition and early revision in selected cases may be sensible.

It will be a long time before we know whether this is an overreaction but we all agree that patient safety is paramount. In the current climate of uncertainty the advice to follow up our patients seems sensible and may even facilitate good practice with PCT/Insurance company support.

Yours sincerely

John Skinner	Graham Gie	Peter Kay
Chair Expert Advisory Group	President	President Elect
For BHS,BOA, NJR, MHRA	British Hip Society	British Orthopaedic Association

See next page for details of Blood collection techniques

Measuring cobalt and chromium Ions

Chromium and cobalt and other metals present in surgical implants are usually measured by inductively coupled plasma mass spectrometry (ICPMS) using either quadruple (QICPMS) or high resolution mass spectrometry (HR-ICPMS). Both are capable of accurate analysis, but only HR-ICPMS instruments will allow the measurement of some other metal ions such as titanium and nickel. Electro thermal atomisation atomic absorption spectrometry may also be used, but is less common now in the leading trace element analysis laboratories.

Blood samples for trace element analysis must be collected in trace element free tubes. Tubes are available with either EDTA anticoagulant for the analysis of whole blood samples or with no additive for the analysis of serum samples. There is a small difference in results obtained from whole blood and serum, but both can be used to assess release of metals from implants. The primary advantage of whole blood for the surgeon is that samples can be sent to the laboratory without the need for separation of serum, a step which may allow potential for sample contamination. Some laboratories may advise against the use of stainless steel needles for sample collection, but the amount of contamination introduced via this route is usually low relative to the amount of chromium and cobalt released from high wear joints.

Synovial fluid samples should be collected into the same blood collection tubes or into sterile plastic 'universal' containers. Urine samples should be random collections voided directly into a plastic universal container, although in rare circumstances a timed 24-hour collection may be appropriate. In this case the laboratory should be contacted for advice before sample collection is commenced. In all circumstances glass and metal-containing containers must be avoided.

Trace element assays are available from the Supra-Regional Trace Element laboratories. In all cases the samples must be referred to the analytical laboratory via the local clinical biochemistry laboratory. Most laboratories will be unable to accept referrals from individual surgeons. All laboratories use QICPMS. HR-ICPMS is also available at London (Imperial College).

All laboratories participate in the national QC programme TEQAS, run from the School of Molecular and Biomedical Sciences, University of Surrey. This includes assessment of chromium and cobalt. Most laboratories will also participate in other international EQA schemes.

SAS Trace Element Laboratories

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