Metal Ion Levels After Revision Of Large Head Metal-on-Metal Hip Replacements With Abnormal Wear

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INTRODUCTION:
There have been recent concerns regarding high metal ion levels and adverse reaction to metal debris (ARMD) in patients with metal-on-metal (MoM) hip replacements. Both the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the Food and Drug Administration (FDA) in the United States released warnings regarding the state of MoM hip replacements, and metal ion testing has been recommended to monitor patients with MoM hip replacements. Studies have shown metal ions to correlate with component wear, and can be used as a diagnostic tool for monitoring bearing wear. High metal ions have been associated with the presence of pseudotumors, gross metallosis, and reports of cobalt toxicity have been reported. While revision of pseudotumors report poor outcomes, it has been reported in several case reports that symptoms resolve and metal ion levels decrease after revision of cobalt toxicity.

METHODS:
Patients
Twenty-eight patients with large-head MoM hip replacements were included in the study, with average femoral size of 44 mm (36–51). The study cohort included 24 females and 4 males patients, whose metal ion levels were above 7 μg/L in at least one blood fraction (serum or whole blood). 7 μg/L was chosen as the cut-off, as this was the suggested level by the MHRA where the patient may have problems associated with abnormal wear. There were 21 unilateral patients and 7 bilateral MoM patients. Eleven were total hip replacements and 17 were hip resurfacings. Serum and whole blood metal ion levels were taken pre-revision and post-revision.

Metal ion analysis
The samples were obtained using an intravenous catheter (Insyte-WTM; Becton Dickinson, Franklin Lakes, New Jersey). After the catheter had been introduced, the metal needle was withdrawn and the first 5mls of blood were discarded to avoid possible contamination from the needle. A second 5mls were collected using a vacuum tube (Venosafe VF-106SAHL; Terumo Europe NV, Leuven, Belgium). Whole blood was placed into EDTA tubes and serum samples in preservative-free tubes. Concentrations of chromium and cobalt were determined using ICPMS at the Super-regional Assay Service Trace Elements Centre at the Biochemistry Department of the Royal Surrey County Hospital, Guildford, United Kingdom. The quantification limits for both elements are less than 0.2 μg/L and within-assay reproducibility is 2% at a concentration of 8 μg/L. This laboratory demonstrates excellent accuracy in international trace elements external quality assessment schemes. Windows SPSS version 15.0 (SPSS Inc., Chicago, Illinois) was used for statistical analysis throughout.

RESULTS:
Cobalt and chromium in both serum and whole blood decreased significantly post-revision (table 1) (all p<0.0001) after an average time of 4.3 months post-revision (range: 1–41 mos). Pre-revision metal ion levels significantly correlated with the rate of cobalt and chromium ion level decrease in all blood fractions (all p<0.0001). Whole blood cobalt decreased significantly faster compared to whole blood chromium (p=0.03); however, there was no significant difference in the rate of change between serum cobalt and chromium (p=0.24). Table 1.

<table>
<thead>
<tr>
<th></th>
<th>pre revision</th>
<th>post revision</th>
<th>% change</th>
<th>rate of change</th>
</tr>
</thead>
<tbody>
<tr>
<td>serum Cr</td>
<td>43.4 μg/L (6.6-115)</td>
<td>9.5 μg/L (3.3-41.5)</td>
<td>65.70%</td>
<td>5.6 μg/L/month</td>
</tr>
<tr>
<td>whole blood Cr</td>
<td>30.6 μg/L (7.7-75.5)</td>
<td>8.48 μg/L (4.3-28.6)</td>
<td>59.50%</td>
<td>3.5 μg/L/month</td>
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<tr>
<td>serum Co</td>
<td>67.2 μg/L (2.1-228)</td>
<td>2.74 μg/L (0.8-21.2)</td>
<td>89.70%</td>
<td>7.4 μg/L/month</td>
</tr>
<tr>
<td>whole blood Co</td>
<td>60.5 μg/L (1.5-271)</td>
<td>3.0 μg/L (0.3-26.4)</td>
<td>87.30%</td>
<td>8.9 μg/L/month</td>
</tr>
</tbody>
</table>

*all values reported are medians

DISCUSSION:
Once the malfunctioning prosthesis is removed, this study shows that metal ion levels decrease significantly. Metal ion levels can be used as an indicator of in vivo wear of the prosthesis, and high levels indicate malfunctioning of the component. High metal ions have been associated with the formation of pseudotumors, metallosis, and systemic cobalt toxicity, and it is important to know whether the body is able to rid itself of the metal ions that are responsible for these reactions.

Even with a short average follow-up period of 4 months, approximately 89% of cobalt and 63% of chromium was cleared from the body. It is important to note that none of the patients in this study had renal impairment; even with a normally functioning kidney, the body was not able to eliminate the metal ions fast enough to keep at an acceptable level at which damage is not incurred on the body. This suggests that while the malfunctioning implant stays in the body, the amount of metal ion release from the component is high and constant.