Metal ion levels in patients with a lumbar metal-on-metal Total Disc Replacement:

Similar concerns compared to metal bearing Total Hip Arthroplasties?

EuroSpine 2011, Milan

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Introduction

• Increased use of metal-on-metal (MoM) articulating prostheses, induced by the introduction of Resurfacing Hip Arthroplasty (RHA).

• In spine surgery: MoM Total Disc Replacement (TDR).

• Advantage MoM: low volumetric wear.

• Disadvantage MoM: high number of wear particles which measure 6-834 nm in diameter.

→ systemic metal particles (Cobalt and Chromium) +

→ metal (particles) + corrosion = metal ions
Introduction

• Increasing concern in Hip Arthroplasty literature about the correlation between elevated metal ion levels and
  • pseudotumours
  • hypersensitivity reactions
  • osteolysis
  • focal periprosthetic soft tissue necrosis

→ What about metal ion levels in patients with a MoM TDR?

Patients and methods

- Built-up out of 3 ongoing trials:
  1. RCT: Analysis of metal ion levels in patients with a THA and RHA. Levels of the control group are preoperative metal ion levels.
  2. Cohort with exclusively metal ion analysis in patients with a RHA.
  3. Cohort with exclusively metal ion analysis in patients with a TDR.

(THA: conventional MoM Total Hip Arthroplasty)

- Inclusion:
  - Age RHA and THA: <65 years; TDR 25-55 years
  - Follow-up > 1 year

- Exclusion:
  - Environmental or medical exposure to metals
  - Bilateral or bi-segmental RHA/THA/TDR
Patients and methods

• Blood analysis:
  • THA and RHA: 12 months postoperative according to study protocol.
  • TDR: median 34.5 months postoperative during regular follow-up.
  • A minimum interval of 12 months was chosen because of a running-in phase in metal ion release.
  • Identical blood collection and analysis protocols, using inductively-coupled plasma mass spectrometer (ICP-MS).

• Determination of Chromium and Cobalt in both whole blood and serum.
Patients and methods

Metal-on-Metal articulations:

- **RHA: Conserve plus®** (Wright Medical Technology, Arlington, Tennessee, USA)

- **THA: Zweymuller with a 28mm Metasul® head** (Zimmer Orthopaedics, Warsaw, Indiana, USA)

- **TDR: Maverick™ TDR** (Medtronic Sofamor Danek GmbH, Köln, Germany)
Results

$\alpha = \text{significant difference compared to the control group}$
## Results

### Metal ions in TDR versus THA and RHA.

<table>
<thead>
<tr>
<th></th>
<th>Control (N=81)</th>
<th>TDR (N=10)</th>
<th>RHA (N=36)</th>
<th>THA (N=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobalt whole blood</td>
<td>0.1 (0.1-0.8)</td>
<td>0.6 (0.1-1.2)</td>
<td>1.3 (0.6-11.5)</td>
<td>1.1 (0.1-2.2)</td>
</tr>
<tr>
<td>Cobalt serum</td>
<td>0.1 (0.1-2.6)</td>
<td>0.1 (0.1-1.1)</td>
<td>1.1 (0.1-7.7)</td>
<td>0.8 (0.1-1.9)</td>
</tr>
<tr>
<td>Chromium whole blood</td>
<td>0.1 (0.1-1.2)</td>
<td>0.1 (0.1-1.1)</td>
<td>1.0 (0.1-6.0)</td>
<td>0.5 (0.1-1.9)</td>
</tr>
<tr>
<td>Chromium serum</td>
<td>0.1 (0.1-2.9)</td>
<td>0.1 (0.1-0.9)</td>
<td>1.8 (0.1-10.2)</td>
<td>0.9 (0.1-2.9)</td>
</tr>
</tbody>
</table>

- **Only chromium levels in the TDA group in whole blood are *not* significantly different compared to the THA group.**
- **However, both levels are low.**
Results

- Motion is required to induce metal ion release, so this was verified in the TDR group.
- Range of motion of the TDR in sagittal plane.
  - Median 15.5 degrees
  - Range 10-22 degrees
Discussion

• Metal ions in patients with TDR:
  1. Similar to the control group.
  2. Lower metal ion levels compared to THA and RHA.

• Difference can be explained by range of motion and load.
  • Wear TDR: 0.38-0.44mm³/year \(^{(1)}\)
  • Wear MoM THA/RHA: 1-5mm³/year \(^{(2)}\)

• Limitation of this study:
  • small TDR population: n=10.
  • postoperative period of blood analysis between TDR and THA/RHA different.

Conclusion

• Only limited reason for concern about elevated metal ion levels in patients with TDR, however, spine surgeons using a MoM TDR should still be aware of concerns expressed in the hip replacement literature about toxicity from elevated metal ion levels.

• Case report:

A Granulomatous Mass Surrounding a Maverick Total Disc Replacement Causing Iliac Vein Occlusion and Spinal Stenosis
A Case Report
By Michael R. Berry, MD, Brian G. Peterson, MD, and Dirk H. Alander, MD
Investigation performed at the Saint Louis University School of Medicine, St. Louis, Missouri
Disclosure information

Financial support for the metal ion measurements was obtained from Wright Medical Technology (Arlington, Tennessee). No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

Original:
Bisseling P, Zeilstra DJ, Hol A, Van Susante JLC. Metal ion levels in patients with a lumbar metal-on-metal Total Disc Replacement; similar concerns compared to metal bearing Total Hip Arthroplasties? JBJS (Br.) 2011;93-B:949-54