Metal ion concentration after Cormet THA

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Introduction

Limited data are available on systemic metal concentrations in patients with metal-on-metal total hip arthroplasty (THA) using a large-diameter head. However, possible complications resulting from the dissemination of metal particles and ions throughout the body are a likely cause of patient anxiety. The particles are nanometers in size and high in number, and their dissolution results in measurable increases in cobalt and chromium ions in serum, urine, and red blood cells of patients with a metal-on-metal bearing. Many concerns still remain regarding the effects of prolonged exposure to increased metal ion levels, such as hypersensitivity, carcinogenicity, and fetal exposure to metallic ions in pregnant women.[1] We investigated serum levels of cobalt and chromium ions in patients with successfully implanted large-diameter metal-on-metal THA.

Methods

From May 2008 to September 2009, 113 consecutive primary THA procedures were performed in our department. Study exclusion criteria included the presence of other metallic implants, metal allergy, pregnancy, and renal insufficiency. This resulted in 74 patients being included in the study (10 men and 64 women). The mean age of participants was 65 years (range, 40 to 84 years), and the mean body mass index was 23.6 kg/m^2 (range, 18.3 to 34.9 kg/m^2). The preoperative diagnosis was osteoarthritis in 72 patients and idiopathic osteonecrosis of the hip in 2 patients.

All patients underwent primary cementless THA using a large-diameter head (40, 44, or 48 mm) with a Cormet cup and CTi II stem (Corin, Cirencester, UK) with a metal-on-metal articulation. The Cormet cup and large-diameter head were both made of a cast, high-carbon content cobalt-chromium alloy (0.35% C), which was subject to hot-isostatic pressing and solution annealing (double heat treatment) before the machining process. The mean diameter of the acetabular component was 51 mm (range, 46 to 56 mm). The acetabular component inclination angle was measured on anteroposterior pelvic radiographs. The inclination angle was defined as the angle between the line joining the inferior teardrop points and the axis of opening of the acetabular component. The mean inclination angle was 42° (range, 27 to 55°). Clinical evaluation was performed using the Japanese Orthopaedic Association (JOA) score. The JOA score results in a maximum score of 100, with scales to evaluate pain (0 to 40 points), range of movement (ROM; 0 to 20 points), walking ability (0 to 20 points), and activities of daily living (ADL; 0 to 20 points). All patients gave informed consent.

Blood samples were taken preoperatively, and at 3 months, 1 year, and 2 years after surgery using cobalt-free needles and glass tubes for trace metal analysis without additives for blood collection to

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avoid metal contamination. Blood samples were submitted for analysis by Mitsubishi Chemistry Medience Co., Ltd. (Tokyo, Japan), and serum samples were stored at -20℃ in inert polystyrene tubes until assayed. Levels of cobalt were determined by Inductively Coupled Plasma Mass Spectrometry (Perkin-Elmer SCIEX Elan 6100 DRC ICP-MS system; Perkin-Elmer Instruments, Norwalk, CT, USA) at Mayo Medical Laboratories. The detection limit of the method was estimated to be 0.2 μg/L. Levels of chromium were determined using a graphite furnace atomic absorption spectrometer (Z-5700; Hitachi Ltd., Tokyo, Japan) with polarization-Zeeman absorption. The detection limit of the method was estimated to be 0.2 μg/L. All concentrations below that limit were defined as 0.2 μg/L for both cobalt and chromium to allow for statistical calculations.
Pseudotumor occurred in one patient. The patient was switched to a metal on polyethylene articulation 2 years postoperatively.
Statistical analysis. For each time point, the median as well as the twenty-fifth and seventy-fifth percentiles of cobalt and chromium concentrations were calculated. The Wilcoxon signed-rank test was used to compare median concentrations of cobalt and chromium over time. Differences in metal concentrations between genders were examined using the Mann-Whitney U test. Preoperative and postoperative JOA scores were compared using the Wilcoxon signed-rank test. The acetabular component inclination, the head diameter, the age of the patient, body mass index, and JOA score were correlated with serum concentrations of cobalt and chromium using the Spearman correlation coefficient. Statistical significance was set at $p<0.05$.

Results

Pre- and postoperative serum concentrations of cobalt and chromium are shown in Table 1. Significant increases in both cobalt and chromium were observed at 3 months compared with preoperative values ($p<0.001$). At 1 year, levels of both cobalt and chromium had increased significantly compared with levels at 3 months ($p<0.001$). There were no significant differences between levels of either metal at 1 and 2 years (cobalt, $p=0.065$ and chromium, $p=0.409$).

Table 1. Median levels of cobalt and chromium

	Pre	3 M	1 Y	2 Y
Cobalt (μg/L)	0.3	1.4	2.3	2.5
Chromium (μg/L)	0.2	1.4	2.0	1.9

In the patient with pseudotumor, serum levels of cobalt and chromium at 1 year were 6.4 μg/L and 7.8 μg/L, respectively. These levels were approximately 3 times compared with median levels.
Cobalt levels at 3 months were significantly higher in men than women ($p=0.024$), and the level correlated with the JOA score ($R=0.296$, $p=0.012$). The JOA score improved significantly from 43 points (range, 10 to 73 points) preoperatively to 78 points (range, 45 to 98 points) at 3 months ($p<0.001$ compared with preoperatively), 83 points (44 to 99 points) at 1 year ($p<0.001$ compared with 3 months), and 91 points (73 to 98 points) at 2 years ($p=0.052$ compared with 1 year). For JOA score, scores for ROM and ADL were positively correlated with cobalt level 3 months postoperatively ($R=0.478$, $p<0.001$ for ROM and $R=0.326$, $p=0.001$ for ADL). There were no significant differences in cobalt levels at 1 and 2 years between men and women ($p=0.061$ at 1 year and $p=0.192$ at 2 years). No correlations were found between cobalt levels and JOA score at 1 or 2 years ($R=-0.048$, $p=0.727$ at 1 year and $R=-0.019$, $p=0.949$ at 2 years). Neither the acetabular component inclination, cup diameter, age of the patient, nor body mass index showed a significant correlation with cobalt or chromium serum concentrations.

Discussion

The present study measured cobalt and chromium ion levels over a 2-year period; levels reached a steady state at 1 year. Allan et al[2] reported serum metal ion levels following hip resurfacing with the Cormet cup up to 3 years. Peak levels were observed at 1 year and levels at 3 years were showing a downward trend, but this decrease was not statistically significant. To our knowledge, the present study is the first to evaluate metal ion levels in patients with THA using the Cormet cup with a large-diameter head.

Women typically have higher circulating metal ion levels than men;[3] however, some studies showed no difference in metal ion levels between men and women.[4] Another study demonstrated that women showed a higher chromium release, whereas men had a higher cobalt release after more than 1 year.[5] In the present study, men had a higher cobalt level 3 months postoperatively, and there were no differences in cobalt levels after 1 year. Chromium levels showed no difference at any time point between men and women.

In terms of acetabular component inclination, we found no significant correlation between cobalt and chromium serum concentrations. Vendittoli et al[3] was also unable to draw any conclusions regarding the acetabular inclination and levels of cobalt. On the other hand, some authors have reported significantly higher levels of metal ions in patients with steeply inclined components.[6]

Our study showed a significant correlation between cobalt level and patient activity, as assessed using the ADL score of the JOA score. This is in agreement with a study showing an increase in levels of cobalt but not chromium following exercise.[7] However, another study showed that metal ion levels were not acutely affected by patient activity.[3,6]

It is still controversial if larger femoral head diameters decrease wear rates in patients with metal-on-metal THA. Antoniou et al[8] showed that cobalt and chromium levels 6 months postoperatively were significantly lower in patients with 36-mm metal-on-metal THA compared with patients with 28-mm metal-on-metal THA. However, neither the median cobalt levels nor the median chromium levels were significantly different between groups at 1 year. Smaller femoral head diameters and an acetabular abduction angle of 55° can increase the risk of rim contact, impingement, and edge loading. The present study demonstrated no correlation between metal ion levels and the head size. Our study showed that good ROM was associated with elevated cobalt levels at 3 months. Impingement might be likely to occur in the patients with good ROM. In the study by Vendittoli et al,[4] who evaluated metal levels after large-diameter metal-on-metal THA (Durom large-diameter head system; Zimmer, Warsaw, IN, USA) at 1 year, patients implanted with a femoral head greater than or equal to 50 mm showed significantly higher cobalt levels than patients with a femoral head less than or equal to 48 mm. Femoral heads with diameters of 50 mm and larger have an open design, whereas heads with diameters of 48 mm and smaller have a closed design. The open femoral head design showed higher cobalt concentrations than the closed design.

In conclusion, our results showed that patients with large-diameter metal-on-metal THA had higher circulating levels of metal ions at 3 months and 1 year than before arthroplasty, with no additional significant increases at 2 years after surgery. Future, follow-up studies will investigate the long-term concentration of metal ions.

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