

Serum metal ion levels after second-generation metal-on-metal total hip arthroplasty

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Abstract

Introduction Metal-on-metal bearings for total hip arthroplasty are increasing in popularity. However, metal ion toxicity, metal hypersensitivity, and metal carcinogenicity are the causes concern for patients with metal-on-metal hip replacement. We investigated serum levels of cobalt and chromium ions in patients with successfully implanted second-generation metal-on-metal total hip arthroplasty (THA) using PINNACLE-A (DePuy, Warsaw, IN, USA).

Materials and methods Thirty-three patients underwent primary cementless THA with the use of a 36-mm femoral head PINNACLE-A with a metal-on-metal articulation. Blood samples were taken preoperatively, at 3 months, and at 1 year, and levels of cobalt and chromium were determined.

Results At 3 months, levels of both cobalt and chromium had increased significantly compared with preoperative levels. There were no significant differences between levels of either metal at 3 months and 1 year.

Conclusion Patients with metal-on-metal THA had higher circulating levels of metal ions than before arthroplasty at 3 months, with no additional significant increases at 1 year in this study.

Keywords Total hip arthroplasty · Metal-on-metal · Serum metal ion level · Cobalt · Chromium

Introduction

Metal-on-metal bearings are being increasingly used in total hip arthroplasty (THA) and hip resurfacing with the understanding that reduced wear and osteolysis will improve long-term survival [1]. However, the possible complications resulting from the dissemination of metal particles and ions throughout the body are 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 [2]. We investigated serum levels of cobalt and chromium ions in patients with successfully implanted second-generation metal-on-metal THA using PINNACLE-A (DePuy, Warsaw, IN, USA) [3, 4].

Materials and methods

From December 2006 to April 2008, 85 consecutive primary THA procedures using PINNACLE-A were performed in our department. Study exclusion criteria included the presence of other metallic implants, metal allergy, pregnancy, and renal insufficiency. This resulted in 33 patients being included in the study, including 4 men and 29 women. The mean age of participants was 60 years (range, 41–83 years), and the mean body mass index was 25 (range, 18–34). The preoperative diagnosis was osteoarthritis in 30 patients and rheumatoid arthritis in 3 patients. Demographic data are shown in Table 1.

All patients underwent primary cementless THA with the use of a 36-mm femoral head PINNACLE-A with a metal-on-metal articulation [3, 4]. S-ROM-A (DePuy) was used in the femoral stem. The acetabular component was

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Table 1 Demographic data of the study population (range)

Number of patients	33
Male:female	4:29
Mean age (years)	60 (41–83)
Mean body mass index (kg/m ²)	25 (18–34)
Pre-operative diagnosis	
Osteoarthritis	30
Rheumatoid arthritis	3

made of wrought-forged, high-carbon content cobalt–chromium alloy (0.35% C) with a diametric bearing clearance of 80–120 μm . The mean diameter of the acetabular component was 54 mm (range, 52–58 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 49° (range, 32°–70°). Clinical evaluation was performed using the Japanese Orthopaedic Association (JOA) score [5]. The JOA score carries a maximum score of 100, with scales to evaluate pain (0–40 points), range of movement (0–20 points), walking ability (0–20 points), and activities of daily living (0–20 points) [5]. This study was approved by our institution's Ethics Committee, and all patients gave informed consent.

Twelve milliliters of blood samples was taken preoperatively, at 3 months, and at 1 year after surgery using cobalt-free needles and glass tubes for trace metal analysis without additives for blood collection to avoid metal contamination. Blood samples were submitted for analysis by Mitsubishi Chemistry Medicine Co., Ltd. (Tokyo, Japan), and serum samples were stored at -20°C 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 $\mu\text{g/L}$. 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 $\mu\text{g/L}$. All concentrations below that limit were defined as 0.2 $\mu\text{g/L}$ for both cobalt and chromium to allow for statistical calculation.

Statistical analysis was performed using the Wilcoxon signed rank test to compare preoperative and postoperative JOA scores. For each time-point, the median as well as the 25th and 75th percentiles of cobalt and chromium concentrations was calculated. We used the median concentrations of cobalt and chromium, and applied the

Wilcoxon signed rank test for comparisons over time. The acetabular component inclination, the cup 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

The JOA score improved significantly from 45 points (range, 22–73 points) preoperatively to 76 points (range, 56–97 points) at 3 months ($P < 0.001$) and 80 points (57–100 points) at 1 year ($P < 0.001$).

Pre- and postoperative serum concentrations of cobalt and chromium are summarized in Fig. 1. The median preoperative serum cobalt concentration was 0.3 $\mu\text{g/L}$. At 3 months, cobalt levels (0.7 $\mu\text{g/L}$) had increased

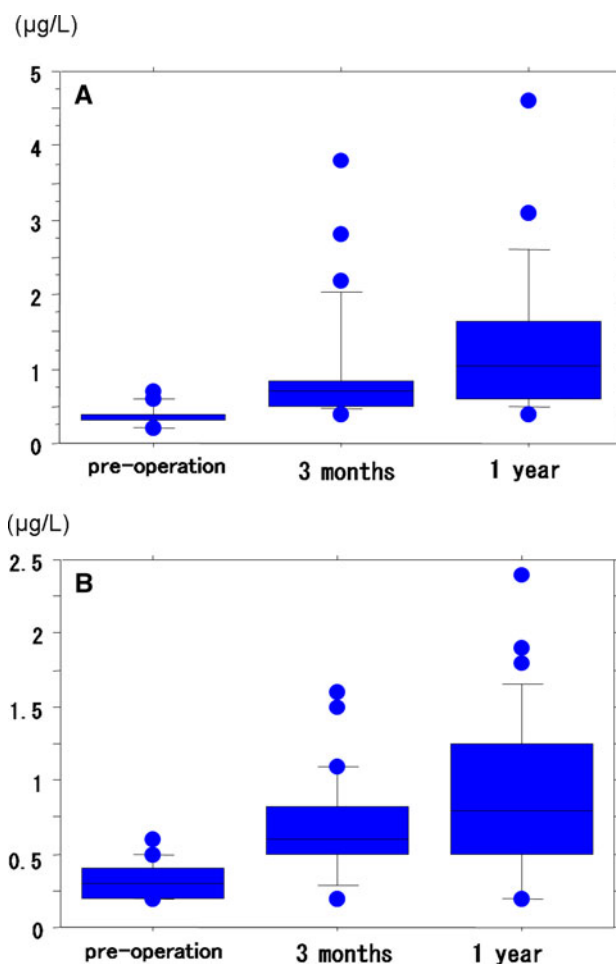


Fig. 1 Serum concentrations of cobalt (a) and chromium (b). Top, bottom, and middle lines of the graph correspond to the 75th percentile, 25th percentile, and median, respectively. Bars indicate the range of the 10th and 90th percentiles. Each circle represents an outlier

significantly compared with preoperative levels ($P < 0.001$). There was no significant difference between cobalt levels at 3 months and 1 year ($1.1 \mu\text{g/L}$; $P = 0.1301$). The median preoperative serum chromium concentration was $0.3 \mu\text{g/L}$. At 3 months, chromium levels had increased significantly ($0.6 \mu\text{g/L}$) compared with preoperative levels ($P < 0.001$). There was no significant difference between the chromium levels at 3 months and 1 year ($0.8 \mu\text{g/L}$; $P = 0.0854$).

Neither the acetabular component inclination, cup diameter, nor the age of the patient, body mass index, or JOA score showed a significant correlation with cobalt and chromium serum concentrations in the present study.

Discussion

There are limited data available on systemic metal concentrations in patients implanted with PINNACLE-A [6–8]. Antoniou et al. [6] reported a comparison of the serum metal ion levels between the 28- and 36-mm head metal-on-metal prostheses. At 6 months, serum metal levels for the 36-mm femoral head with a metal-on-metal articulation PINNACLE-A was $1.8 \mu\text{g/L}$ for cobalt and $0.25 \mu\text{g/L}$ for chromium. At 1 year, the serum metal level of cobalt was $2.3 \mu\text{g/L}$ and that of chromium was $0.4 \mu\text{g/L}$. Isaac et al. [8] measured the whole blood metal ion levels with 28-mm head metal-on-metal prostheses. The median cobalt and chromium levels were 0.83 and $0.66 \mu\text{g/L}$ at 1 year.

The levels of both cobalt and chromium in our study were lower than levels reported in previous studies of different types of metal-on-metal bearings [9–12]. In contrast, serum metal levels of cobalt and chromium for the 28-mm Metasul bearing (Zimmer, Warsaw, IN) were similar to those found in previously reported investigations for modern, second-generation metal-on-metal bearings [13, 14].

Recent study evaluated the release of metal ions after metal-on-metal total disc arthroplasty [15]. The average concentrations in the serum were $4.8 \mu\text{g/L}$ for cobalt and $1.9 \mu\text{g/L}$ for chromium after average follow-up of 15 months [15]. The levels were similar or higher than the levels shown in the literature following implantation of total hip endoprosthetics with metal-on-metal bearings [6–14].

In terms of acetabular component inclination, we found no significant correlation between cobalt and chromium serum concentrations. Vendittoli et al. [16] was also unable to draw strong conclusions regarding the acetabular inclination and levels of cobalt. On the other hand, some authors [17, 18] reported significantly higher levels of metal ions in patients with steeply inclined components. In our study, there was no significant correlation between

patient activity, as assessed using activities of daily living score of the JOA score [5] and serum metal levels. This is in agreement with recent results showing that metal ion levels are not acutely affected by patient activity [16, 17, 19]. However, another study showed a mild increase in levels of cobalt but not chromium following exercise [20].

Despite concerns regarding chromosome aberrations and translocations, the International Agency for Research on Cancer concluded that there is inadequate evidence in humans regarding the carcinogenicity of orthopaedic implants [6]. Metal-on-metal bearings often are not recommended in women of child-bearing age because of the theoretical risk of metal ion exposure to the fetus [21]. Data from Nordic registries are used to estimate adverse effects on a large scale, based mostly on metal-on-polyethylene bearings, and cancer incidence was in line with the general population [2]. Elevated ion levels have been associated with an increased prevalence of chromosomal changes, suggesting a possible carcinogenic effect [21, 22].

Our results showed that patients with metal-on-metal total hip prostheses had higher circulating levels of metal ions than before arthroplasty at 3 months, with no additional significant increases at 1 year; however, future, follow-up studies will investigate the long-term concentration of metal ions.

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