Serum Ion Level After Metal-on-metal THA in Patients With Renal Failure

Chang Ich Hur MD, Taek Rim Yoon MD,
Sang Gwon Cho MD, Eun Kyoo Song MD,
Jong Keun Seon MD

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Abstract We retrospectively reviewed cementless THAs with metal-on-metal bearings in five patients with chronic renal failure and investigated the relations between renal failure and elevated serum cobalt and chromium levels and the side effects of these elevations. Serum cobalt and chromium levels were measured by atomic absorption spectrophotometry at a minimum followup of 2.7 years (mean, 3.9 years; range, 2.7–6.2 years) in five patients with chronic renal failure and in six patients with normal renal function after THA. Mean serum cobalt concentration was 12.5 µg/L in patients with chronic renal failure; this was more than 100-fold higher than in patients with the same prosthesis type and similar followup period, but with no known renal disease. However, the mean serum chromium concentration was 5.1 µg/L, which was within the normal range in all 11 study patients. Side effects related to elevation of serum cobalt or serum chromium concentration were not identified and overall clinical results were good 4 years after surgery. The serum cobalt level was higher in patients with chronic renal failure. Longer followup is necessary to determine any clinical effects.

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Each author certifies that his or her institution has approved or waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

C. I. Hur, T. R. Yoon (✉), S. G. Cho, E. K. Song, J. K. Seon
Department of Orthopaedics, Center for Joint Disease, Chonnam
National University Hwasun Hospital, Chonnam National
University School of Medicine, 160 Ilsimri, Hwasun-eup,
Hwasun-gun, 519-809 Hwasun, Jeonnam, Korea
e-mail: tryoon@chonnam.ac.kr

Introduction

Metal-on-metal (MOM) at articulation in THA is generally accepted to be more resistant to wear than metal- or ceramic-on-polyethylene THA devices [4, 6, 11–13]. Some investigators have reported excellent results for MOM bearing components in primary THA [6, 11]. Several reports have questioned elevation of serum ion concentration in patients with renal failure [2, 4, 9]. One study reported high serum cobalt and chromium levels in two patients with renal failure with MOM THA prostheses [3]. The authors recommended not using MOM THA prostheses in patients with renal failure.

When ceramic-on-ceramic bearing THA was not available, we used MOM THA in young patients with renal failure rather than metal-on-polyethylene THA to reduce wear and osteolysis and to decrease further revision surgery rates.

We asked whether serum cobalt and chromium levels after MOM THA are higher in patients with renal failure than in patients with normal renal function. We also examined the side effects attributable to elevated serum ion levels.

Materials and Methods

We retrospectively reviewed serum ion levels in two groups treated with the same type of THA prosthesis and with similar followups but with markedly different renal functions. Group 1 consisted of six patients (four males, two females) with renal failure, and all were treated using cementless Metasul[®] (Centerpulse Orthopaedics, Baar, Switzerland) MOM THA prostheses between 1999 and 2002 (Table 1). Two of these patients (Patients 2 and 5)

Table 1. Serum cobalt and chromium concentrations for patients with renal failure

Patient number	Gender	Age at operation (years)	Side	Diagnosis	Followup (years)	Blood urea nitrogen/creatinine (mg/dL)		Serum cobalt (µg/L) (Normal: 0.1–2)	Serum chromium (µg/L) (Normal: 0–10)
						Preoperative	Recent		
1	Female	57	Right	Osteoarthritis	4.0	42.5/5.8	70.3/8.3	51.6	3.5
2	Male	41/41	Right/left	Osteonecrosis	2.7/2.8	48.4/8.6	62.2/9.0	8.0	9.0
3	Male	33	Right	Osteonecrosis	6.2	37.2/2.6	45.0/9.8	0.0	7.1
4	Male	67	Left	Neck fracture	3.8	39.1/2.5	56.9/3.3	0.5	2.8
5	Male	62/62	Right/left	Osteonecrosis	3.9/3.9	20.4/2.6	23.0/2.2	2.3	3.0
Average		52			3.9	37.1/5.4	44.4/5.4	12.5	5.1

Table 2. Serum cobalt and chromium concentrations for patients with normal renal function

Patient number	Gender	Age at operation (years)	Side	Diagnosis	Followup (years)	Blood urea nitrogen/creatinine (mg/dL)		Serum cobalt (µg/L) (Normal: 0.1–2)	Serum Chromium (µg/L) (Normal: 0–10)
						Preoperative	Recent		
1	Female	58	Left	Osteonecrosis	6.0	14.0/0.7	11.8/0.7	0.0	3.3
2	Female	65	Left	Osteonecrosis	5.8	13.2/1.0	11.7/0.8	0.0	13.9
3	Male	66	Right	Osteonecrosis	5.6	9.4/1.0	11.1/1.0	0.4	4.3
4	Male	41	Right	Osteoarthritis	4.7	13.3/0.7	15.8/0.9	0.0	10.3
5	Male	58	Right	Osteonecrosis	5.3	13.3/1.0	18.6/0.8	0.0	2.3
6	Male	24	Right	Osteonecrosis	2.5	18.5/0.9	10.9/1.0	0.0	4.6
Average		52			5.0	13.6/0.9	13.2/0.9	0.07	6.4

underwent bilateral THAs. In Group 1, one patient was excluded because she underwent kidney transplantation after THA. Group 2 consisted of six patients (four males, two females) with normal renal function; they also were treated between 1999 and 2002 (Table 2). The minimum followup was 2.7 years (mean, 3.9 years; range, 2.7–6.2 years) in Group 1 and 2.5 years (mean, 5.0 years; range, 2.5–6.0 years) in Group 2.

After planning this study, we obtained whole blood specimens from all patients at the last followup. Blood was obtained using a stainless-steel hypodermic needle attached to a plastic collecting tube (needles and collecting tubes were from the same batches). All samples were obtained by one registered nurse and were forwarded to a laboratory for analysis. The serum levels of cobalt were measured by atomic absorption spectrophotometry (Varian, Victoria, Australia) with a detection limit of 0.1 µg/L and serum chromium levels by atomic absorption spectrophotometry (PerkinElmer, Inc, Boston, MA) with a detection limit of 0.1 µg/L.

The change of renal function was evaluated by measuring creatinine levels preoperatively and at the last followup.

We obtained anteroposterior and frog leg lateral radiographs of the hip preoperatively, immediately postoperatively, at 3, 6, and 12 months postoperatively, and then annually.

We (TRY, SGC) used the classification of Engh et al. [7] to evaluate femoral stem stability, the classification of Gruen et al. [8] to evaluate femoral stem osteolysis and acetabular component, and the classification of DeLee and Charnley [5] to evaluate acetabular osteolysis. Complications were checked at each followup.

Preoperative and postoperative blood urea nitrogen/creatinine were analyzed by Wilcoxon matched-paired signed-ranks test, and serum cobalt and chromium concentrations between Group 1 and Group 2 were analyzed by the Mann-Whitney U test, which also was used to compare unilateral and bilateral THAs in Group 1.

Results

Average serum cobalt concentration in Group 1 was 12.5 µg/L (range, 0.0–51.6 µg/L) (Table 1), whereas in Group 2, it was 0.1 µg/L (range, 0.0–0.4 µg/L) (Table 2). The mean serum cobalt concentration was more than 100-fold higher ($p = 0.03$) in Group 1 than in Group 2. However, one patient in Group 1 and five patients in Group 2 had serum cobalt concentrations below the detection limit (0.1 µg/L).

Average serum chromium concentrations were similar in both groups ($p = 0.66$): 5.1 µg/L (range, 2.8–9.0 µg/L)

Fig. 1A–C (A) A preoperative radiograph of the hip of a 41-year-old man with chronic renal failure shows osteonecrosis of the femoral head. (B) An anteroposterior radiograph taken 3 months

after bilateral THAs is shown. (C) An anteroposterior radiograph taken 2 years 9 months postoperatively shows bone ingrowth and no loosening.

in Group 1 (Table 1) and $6.4 \mu\text{g/L}$ (range, $2.3\text{--}13.9 \mu\text{g/L}$) in Group 2 (Table 2). The mean serum chromium concentrations were within the normal range (range, $0\text{--}10 \mu\text{g/L}$) in all patients.

The two patients (Patients 2 and 5) with renal failure who underwent bilateral THA had serum cobalt levels of 8.0 and 2.3, respectively. These levels were not elevated compared with those of other patients with renal failure ($p = 0.80$). On the contrary, the levels were lower than the average value of the renal failure group. The serum chromium levels were 9.0 and 3.0, respectively, which were within normal ranges (normal serum level, $0\text{--}10 \mu\text{g/L}$).

Renal function did not change after THA in both groups. In both groups, postoperative serum creatinine levels were not different from preoperative levels ($p = 0.705$) (Group 1: preoperative average of $5.2 \mu\text{g/L}$ [range, $2.5\text{--}8.6 \mu\text{g/L}$] versus postoperative average of $5.4 \mu\text{g/L}$ [range, $2.2\text{--}9.8 \mu\text{g/L}$]; Group 2: preoperative average of $0.9 \mu\text{g/L}$ [range, $0.7\text{--}1.0 \mu\text{g/L}$] versus postoperative average of $0.9 \mu\text{g/L}$ [range, $0.7\text{--}1.0 \mu\text{g/L}$]).

Final followup radiographs showed bone ingrowth into all femoral components. No loosening of either femoral or acetabular components was detected, and thus, no revision surgery was required (Fig. 1).

We detected no side effects related to elevation of serum cobalt and chromium concentration. There were no skin problems (such as dermatitis) or occurrence of malignancy.

Discussion

Potential problems of MOM THA include local toxicity, hypersensitivity, malignant transformation, inflammation, bone loss, prosthetic loosening, and deleterious effects on renal function. Because of these potential problems, the use of MOM THA in patients with renal failure is debatable [1, 2]. Nevertheless, we performed six MOM THAs in patients with renal failure. We asked whether serum cobalt and chromium levels after MOM THA were higher in patients with renal failure than in patients with normal renal function and whether there were any side effects attributable to elevated serum ion levels.

This study is limited by the small number of patients (five patients in the first group and six patients in the second group). Also, the variability in ion concentrations was substantial, as in other studies. The variability increased the means in this small group of patients.

However, the data for the cobalt ion concentrations were elevated in three of the five patients with renal failure. The serum chromium concentrations were less variable. Nonetheless, the data should be considered preliminary and require confirmation by larger studies.

Back et al. [1] reported no adverse effects of serum cobalt and chromium levels after new-generation MOM hip resurfacing in 20 consecutive patients with normal renal function. Brodner et al. [3] observed maximum cobalt levels more than 100-fold higher in two patients who had cementless MOM THAs as compared with reported mean serum cobalt levels in patients with the same prosthesis type and normal renal function. Thus, they considered chronic renal failure a relative contraindication to using MOM THA. We also observed a mean cobalt concentration 100-fold higher in patients with renal failure than in patients with normal renal function, whereas mean serum chromium concentrations were within the normal range in all patients. However, this mean was affected greatly by the values of one patient.

Our study included two patients with renal failure who underwent bilateral THAs. Their ion levels were not higher than those of the other patients with renal failure. Witzleb et al. [14] described the ion levels 2 years after MOM THA, comparing ion levels of bilateral THAs with those of unilateral THA. They found the chromium ion level after bilateral THAs was higher than that of unilateral THA until 1 year, but thereafter the chromium ion level was not different. Furthermore, the cobalt ion levels were similar at all times. Our results concur with theirs.

There is a running-in wear period for MOM bearings; some authors have suggested this period is within 2 years [2, 10]. We can assume, after the running-in wear period, the metal ion level of bilateral THAs becomes equal to that of unilateral THA.

As for side effects of elevated ion levels, our patients had no complaints of local toxicity and hypersensitivity or occurrence of malignancy. As described in the radiographic results, there was no bone loss or prosthetic loosening. Also, there was no deleterious effect on renal function.

Our data further suggest high serum cobalt levels occur after MOM THA in patients with renal failure, but the serum chromium levels were not elevated. Therefore, we believe MOM THA in patients with renal failure probably is not advisable, even though we found no side effects related to elevated cobalt level during the followup. After 2 years, the serum ion levels of bilateral MOM THAs were similar to those of unilateral MOM THA. Longer followup

in larger groups of patients is necessary to monitor serum cobalt and chromium concentrations and renal function in patients with renal failure who have undergone MOM THA.

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