Cobalt and Chromium Ion Levels Following Metal-on-Metal Hip Resurfacing Arthroplasty

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INTRODUCTION:
Metal-on-metal (MOM) hip resurfacing has emerged as an important alternative to total hip replacement for many younger patients as it is bone preserving on the femoral side and the use of a large head may allow for increased stability and function. Wear with subsequent osteolysis and aseptic loosening is the biggest cause of failure of metal-on-polyethylene total hip replacements.

Although MOM hip articulations have lower wear rates than metal-on-polyethylene, the debris produced contains metal ions that are disseminated throughout the body. Modern MOM surgical bearings are typically made from a cobalt-chromium alloy (29 - 69% cobalt and 19 - 30% chromium) and elevated cobalt and chromium ion levels have been documented in the blood, serum, and urine of patients who have received MOM hip articulations. The clinical significance of these elevated ions is not clear.

The aim of the present study was to prospectively examine the serum, erythrocyte, and urinary levels of cobalt and chromium in patients who underwent metal-on-metal total hip resurfacing with the Conserve Plus implant, and to determine if there are any correlations between ion levels and clinical and radiographic outcomes.

METHODS:
This study was approved by, and carried out in accordance with the guidelines of the institutional review board. Informed consent was obtained from all patients included in this analysis.

This single centre prospective assessment enrolled 90 patients who received the Conserve Plus metal-on-metal hip resurfacing arthroplasty (Wright Medical Technology Inc.). The mean age of the sample was 47.3 years (sd=8.9; range = 16 to 65), and the mean BMI was 27.3 (sd=4.3; range = 19.1 to 37.7). 77% of the sample was male.

Serum, erythrocyte and urinary levels of cobalt and chromium were measured pre-operatively, at 3 and 6 months post-operatively, and yearly thereafter. Blood and urine samples were analyzed for cobalt and chromium levels.

Patient activity level was measured using the UCLA activity score pre-operatively and at 6, 12, and 24 months after surgery. Cup inclination and radiological angles (neck and stem antero-posterior and lateral angles) were measured pre-operatively and at 3, 6, 12, and 24 months after surgery. Patients also completed a health survey at their 6, 12 and 24 month post-operative visits. Correlations between blood and urine ion levels and the WOMAC, Harris Hip scores, RAND General Health measure, cup inclination, stem shaft angle and radiolucencies were investigated.

RESULTS:
The serum cobalt level had increased from 1.5ug/l at three months to 1.9 and 3.3ug/l at one and two years respectively, the erythrocyte cobalt level changed from 1.3ug/l at three months to 1.2 and 1.25ug/l at one and two years, and the urinary chromium levels were 2.3, 3.2 and 4.3ug/l at three months, one and two years respectively.

The serum cobalt levels were 0.93, 1.07 and 1.56ug/l at three months, one year and two years, the erythrocyte cobalt level was 0.62, 0.77 and 1.08ug/l at three months, one and two years, and the urinary cobalt measured 7.4, 8.7 and 8.3ug/l.

The median pre-operative urinary cobalt level was 0.27µg/L (range: 0.03 to 3.48µg/L). The post-operative median urinary cobalt levels at 3, 6, 12 and 24 months were significantly elevated compared to the pre-operative levels (Wilcoxon p=0.0001). The median levels of urinary cobalt at 1 and 2 years were about 31 and 32-fold higher than pre-operative levels, respectively.

The median pre-operative urinary chromium level was 0.18ug/L (range: 0.01-1.26 µg/L). The post-operative median levels of chromium in urine were significantly elevated at all the follow-up intervals (Wilcoxon p=0.0001) The median urinary chromium levels at 1 and 2 years were 19 and 20-fold higher than pre-operative levels, respectively.

Correlation analysis demonstrated a strong relationship between serum cobalt and urinary cobalt levels at 1 and 2 years after surgery (Spearman ρ=0.7, p<0.0001 at 1 year; ρ=0.8, p<0.0001 at 2 years). A similar correlation was present between serum and urinary chromium levels at 1 year (Spearman ρ=0.5, p=0.0007) and 2 years (Spearman ρ=0.8, p=0.0001) after surgery. A strong correlation was also present between erythrocyte and urinary cobalt levels at 1 year (Spearman ρ=0.5, p=0.0002), and 2 years (Spearman ρ=0.7, p=0.0002) after surgery. However, no such relationship was present between erythrocyte and urinary chromium levels.

No significant correlation was found between ion levels and other individual factors, including demographic factors (age, height, weight and BMI), activity level, shell size (outside diameter), and cup inclination. There was no correlation found between clinical outcome measures or radiographic analysis and ion levels in this study population.

DISCUSSION:
Overall, the relative increase in post-operative serum ion levels in the present study tended to be higher in magnitude when compared to that observed with other resurfacing implants and total hip replacement devices. In addition, median serum ion levels continued to increase after the first year in the present study (non-significant, p<0.05) in contrast to most studies that documented a decline in ion levels at an earlier stage ranging from 3 months to 1 year after surgery. The continued increase in urinary and serum chromium levels in the present study indicates continuing ion release even after the so called run in period. Hip simulator and retrieval studies suggest that wear from MOM articulations decreases during a running in period to a lower steady state by about one million cycles. In our group of young patients this steady state should have been easily reached by one, if not two years post-operatively. This could be a concern for accumulation of metal ions over time. Daniel et al. also found that an early expected decline in ion levels did not occur with the Birmingham implant but levels did eventually reduce with a longer follow up of four years. We observed a strong correlation between serum cobalt and chromium levels. However, the correlation between erythrocyte ion levels and urinary ion levels was strong only for cobalt. This may indicate differences in the metabolic pathways and biokinetics for cobalt and chromium ions. Systemic chromium in its hexavalent form is readily taken up by erythrocytes and converted to its trivalent (less toxic) form. The lower concentrations of erythrocyte chromium may suggest the satisfactory elimination of the carcinogenic hexavalent form of chromium in blood.

It is clear from the results of this and previously conducted studies that serum and erythrocyte levels of chromium and cobalt are elevated in patients who have undergone hip replacement surgery with prostheses made from these metals. Epidemiological studies with a long-follow up period are required to obtain a better understanding of the clinical implications of elevated cobalt and chromium concentrations in hip arthroplasty patients with a metal on metal articulation. In addition, the role of the metal implant treatments and optimal articulation clearances remain to be determined.

REFERENCES:
Brodnner et al. (2003). J Bone Joint Surg Am. 85A