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## Blood Metal Ion Levels Have Limited Utility in the Surveillance of Asymptomatic Large-Head Metal-on-Metal Total Hip Arthroplasties

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## ABSTRACT

**Background:** Blood cobalt (Co) and chromium (Cr) ion levels have been used as surveillance tools for adverse reaction to metal debris (ARMD) in metal-on-metal (MoM) articulations with varying thresholds in different countries. The aim of our study is to present the serial 12-year blood Co and Cr levels in a cohort of MoM total hip arthroplasties (THAs) with femoral head size  $\geq 36$  mm and analyze their utility in asymptomatic patients at current thresholds.

**Methods:** A total of 256 patients with unilateral MoM THA with femoral head size  $\geq 36$  mm were included in this study with data collected prospectively. The implants used were Birmingham hip resurfacing cup—Freeman stem (BHR-F) or an Articular Surface Resurfacing cup—Corail/S-ROM stem. Annual follow-up with blood Co and Cr measurements was done as per Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom guidelines. Receiver operating characteristic curve was plotted based on the sensitivity and specificity of blood metal ion values to detect ARMD. The metal ion levels in asymptomatic patients were analyzed separately.

**Results:** Receiver operating characteristic curves showed poor discriminatory ability for both Co and Cr values in predicting ARMD at 7  $\mu\text{g/L}$ . The sensitivity of Co and Cr was 82.1% and 53.5%, respectively, and their positive predictive values were 43.8% and 67.6%, respectively. After 7 years, there was no significant change in Co values, and there was a decline in Cr value after 9 years in asymptomatic patients.

**Conclusion:** To the best of our knowledge, this is the first study to describe the behavior of serial blood metal ion levels in asymptomatic large-diameter MoM THA. We suggest that annual blood Co and Cr have limited discriminant capacity in diagnosing the occurrence of metallosis and their measurement beyond 7 years is of limited utility in asymptomatic patients.

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There has been a significant decline in metal-on-metal (MoM) total hip arthroplasty (THR) and hip resurfacing arthroplasty (HRA) in all joint registries due to concerns regarding adverse reaction to metal debris (ARMD) [1–4]. The Medicines and Healthcare Products Regulatory Agency (MHRA) of United Kingdom issued guidelines regarding follow-up in these patients in 2012 [5]. They recommended annual follow-up for life with blood cobalt (Co) and chromium (Cr) metal ion level measurement in all MoM THAs with femoral head size  $\geq 36$  mm. They also recommended metal artifact

reduction sequence magnetic resonance imaging (MARS MRI) scan in all symptomatic patients and in asymptomatic patients with blood Co and Cr greater than 119 nmol/L and 134.5 nmol/L, respectively (7  $\mu\text{g/L}$  or 7 ppb). The metal ion threshold for HRA was the same.

It is vital to understand changes in metal ion levels with time. Although studies have examined the changing trends in metal ion levels in HRA [5], there has been no study, to our knowledge, that has examined serial metal ion measurements in large-head-diameter MoM THAs to support this guideline or its utility in asymptomatic patients. Hart et al [6] compared metal ion levels between HRA and MoM THA at a single point and found that failed MoM THAs had significantly higher Co level than “well-functioning” HRAs and MoM THAs. The primary aim of our study is to present the serial 12-year blood Co and Cr levels in a cohort of asymptomatic MoM THAs with femoral head size  $\geq 36$  mm and

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**Table 1**  
Demographic Parameters and Revision.

	Total	BHR	ASR
Total patients (N)	256	168 (66%)	88 (34%)
Hip type			
Corail	—	—	21 (24%)
S-ROM	—	—	67 (76%)
Gender			
Female	117 (46%)	79 (47%)	38 (43%)
Male	139 (54%)	89 (53%)	50 (57%)
Age at operation			
Median (IQR)	61 (52-70)	64 (55-71)	57 (47-66)
Revision			
No	180 (70%)	127 (76%)	53 (60%)
Yes	76 (30%)	41 (24%)	35 (40%)

BHR, Birmingham hip resurfacing; ASR, Articular Surface Resurfacing; IQR, interquartile range.

analyze their utility in these patients at current thresholds. Additionally, we evaluated the utility of the current threshold of 7 µg/L, in diagnosing ARMD.

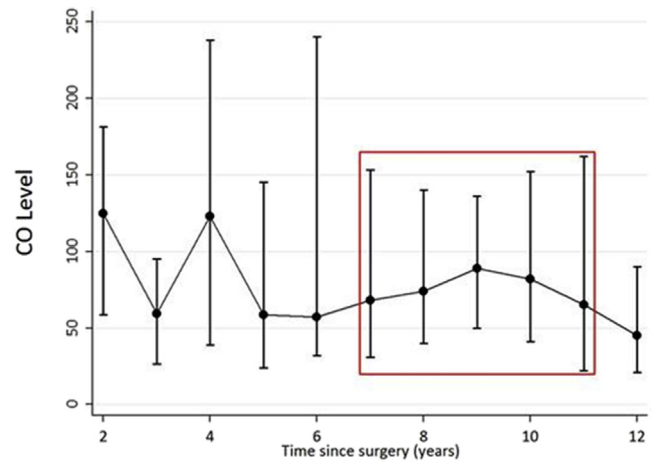
**Materials and Methods**

We maintained a database of all patients undergoing large-head MoM THAs at our unit. All patients who underwent unilateral MoM THA with femoral head size ≥36 mm between January 2004 and December 2006 were included in this prospective study. Bilateral cases and patients revised for infection were excluded to narrow the focus of the study to metal ion levels in unilateral THA and revision for ARMD. The implants used were Birmingham hip resurfacing cup with a Freeman femoral stem (BHR-F; Midland Medical Tech, West Midlands, UK) or an Articular Surface Resurfacing cup with a Corail or S-ROM stem (ASR-C/S) (DePuy, Leeds, UK). The patients were followed up annually with blood Co and Cr measurements and MARS MRI scan was performed if they were raised beyond MHRA thresholds or the patients were symptomatic. The blood metal ion levels were analyzed by coupled mass spectrometry at our hospital, which is accredited for measuring metal ion levels. Occurrence of symptoms, ARMD, and revision surgery were recorded. As per MHRA guidelines, patients with pain, stiffness, mechanical symptoms like clicking and clunking, reduction in function or difficulty in performing activities of daily living because of the operated hip were considered symptomatic. The occurrence of ARMD was determined using MARS MRI scans and was confirmed by histopathological analysis of intraoperative tissue samples.

**Table 2**  
Annual Blood Cobalt and Chromium Values in Asymptomatic Patients.

Time	Cobalt		Chromium	
	Median	IQR	Median	IQR
2 y	125	(59-181)	105	(52-125)
3 y	60	(26-95)	46	(35-68)
4 y	123	(39-238)	56	(38-148)
5 y	59	(24-145)	50	(25-107)
6 y	57	(32-240)	72	(36-157)
7 y	68	(31-153)	57	(33-90)
8 y	74	(40-140)	51	(33-78)
9 y	89	(50-136)	52	(36-82)
10 y	82	(41-152)	48	(35-80)
11 y	65	(22-162)	43	(24-70)
12 y	45	(21-90)	51	(25-72)

IQR, interquartile range.



**Fig. 1.** Blood cobalt level.

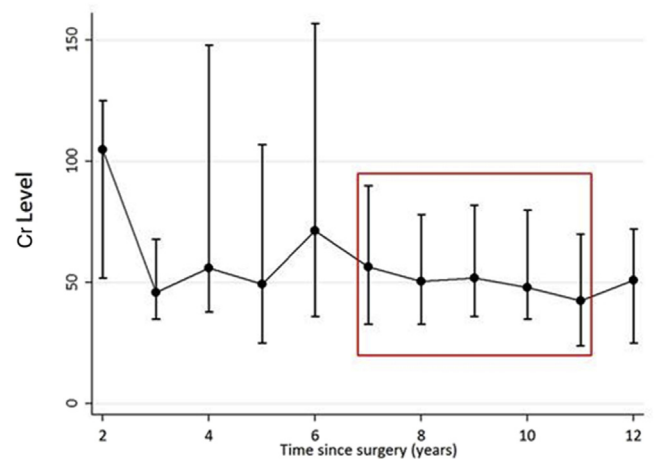
**Statistical Analysis**

Mann-Whitney test was used to analyze changes in blood Co and Cr levels as they were distributed in a nonparametric fashion. Receiver operating characteristic curve was plotted based on the sensitivity and specificity of blood ion values to detect ARMD in the cohort. Changing trends in metal ion levels in asymptomatic patients were analyzed.

**Results**

In our large-head MoM THA database, there were 294 THAs of which 4 hips were revised for infection and 17 patients had bilateral THA. After excluding them, 256 patients were included in this study. The demographic parameters and revision rates are shown in Table 1. The median Co and Cr values are shown in Table 2 and Figures 1 and 2. The patients who developed symptoms or ARMD during the study were dropped from the asymptomatic cohort. Ninety-two patients were removed from the asymptomatic cohort during the course of the study. This included 76 patients who were revised and 16 patients who developed symptoms, had high blood metal ion levels or developed ARMD and were being followed up.

There was a significant increase in blood ion values in the first 2 years. After 7 years, there was no significant change in Co values, and there was a decline in Cr value after 9 years in asymptomatic



**Fig. 2.** Blood chromium level.

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