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■ HIP

The risk of cardiac failure following metal-on-metal hip arthroplasty

S. A. Sabah,
J. C. Moon,
S. Jenkins-Jones,
C. LI. Morgan,
C. J. Currie,
J. M. Wilkinson,
M. Porter,
G. Captur,
J. Henckel,
N. Chaturvedi,
P. Kay,
J. A. Skinner,
A. H. Hart,
C. Manisty

From University College London, United Kingdom

■ S. A. Sabah, MRCS, Specialist Registrar
Royal National Orthopaedic Hospital, Stanmore, Middlesex and University College London, London, UK.

■ J. C. Moon, MD, Professor of Cardiology
Institute of Cardiovascular Sciences, University College London and Barts Heart Centre, London, UK.

■ S. Jenkins-Jones, MSc, Honorary Senior Research Associate
Division of Surgery and Interventional Sciences, University College London, UK and Global Epidemiology and Medical Statistics, Pharmatelligence, Cardiff, UK.

■ C. LI. Morgan, MSc, Honorary Research Associate
Division of Surgery and Interventional Sciences, University College London, UK and Global Epidemiology and Medical Statistics, Pharmatelligence, Cardiff, UK.

■ C. J. Currie, PhD, Professor of Applied Pharmacoepidemiology
Global Epidemiology and Medical Statistics, Pharmatelligence, Cardiff, UK and Division of Population Medicine, School of Medicine, Cardiff University, Cardiff, UK.

■ J. M. Wilkinson, PhD, Professor of Orthopaedics
Department of Oncology and Metabolism, University of Sheffield, Sheffield, UK and National Joint Registry for England, Wales and Northern Ireland.

■ M. Porter, FRCS(Ed) FRCS Ed (Orth), Consultant Orthopaedic Surgeon and Medical Director NJR
Centre for Hip Surgery, Wrightington Hospital, Wigan, UK.

■ G. Captur, PhD, Specialist Registrar and Academic Clinical Lecturer

■ C. Manisty, MBBS MRCP PhD, Senior Lecturer and Consultant Cardiologist
Institute of Cardiovascular Sciences, University College London, UK and Department of Cardiology, Barts Heart Centre, London, UK.

■ J. Henckel, MRCS, Specialist Registrar
Royal National Orthopaedic Hospital, Stanmore, UK and Division of Surgery and Interventional Sciences, University College London, UK.

■ N. Chaturvedi, MD, Professor of Clinical Epidemiology, and Director, MRC Lifelong Health and Ageing Unit
Institute of Cardiovascular Sciences, University College London, London, UK.

■ P. Kay, FRCS, Orthopaedic Surgeon
Wrightington Hospital, Wigan, UK

■ J. A. Skinner, MBBS, FRCS(Eng), FRCS(Orth), Consultant Orthopaedic Surgeon, Professor of Orthopaedic Surgery

■ A. H. Hart, MA, MD, FRCS (Orth), Professor of Orthopaedics
Royal National Orthopaedic Hospital, Stanmore, Middlesex, UK.

Correspondence should be sent to C. Manisty; email: c.manisty@ucl.ac.uk

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Aims

The aim of this study was to determine whether patients with metal-on-metal (MoM) arthroplasties of the hip have an increased risk of cardiac failure compared with those with alternative types of arthroplasties (non-MoM).

Patients and Methods

A linkage study between the National Joint Registry, Hospital Episodes Statistics and records of the Office for National Statistics on deaths was undertaken. Patients who underwent elective total hip arthroplasty between January 2003 and December 2014 with no past history of cardiac failure were included and stratified as having either a MoM (n = 53 529) or a non-MoM (n = 482 247) arthroplasty. The primary outcome measure was the time to an admission to hospital for cardiac failure or death. Analysis was carried out using data from all patients and from those matched by propensity score.

Results

The risk of cardiac failure was lower in the MoM cohort compared with the non-MoM cohort (adjusted hazard ratio (aHR) 0.901; 95% confidence interval (CI) 0.853 to 0.953). The risk of cardiac failure was similar following matching (aHR 0.909; 95% CI 0.838 to 0.987) and the findings were consistent in subgroup analysis.

Conclusion

The risk of cardiac failure following total hip arthroplasty was not increased in those in whom MoM implants were used, compared with those in whom other types of prostheses were used, in the first seven years after surgery.

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Metal-on-metal (MoM) prostheses of the hip have been widely used,[1] but are now known to have unacceptably high rates of failure.[2-4] This has triggered regulatory alerts, device recalls and mandatory surveillance programs. The failure of these devices has led to many patients subsequently undergoing early revision.[5-8] Corrosion and wear of MoM implants, which are composed of cobalt-chromium alloy, can result in the release of particulate debris and metal ions into the circulation. Alongside localized effects, MoM prostheses have been associated with systemic complications such as cardiotoxicity and mortality.[9-14] Concerns have been recently raised about cobalt cardiomyopathy, particularly following the report of a three-fold increased risk in hospital admissions due to cardiac failure in a subgroup of men with MoM prostheses.[15,16] The findings have, however, been inconsistent.[13,17,18] The symptoms and signs of cardiac failure are common in patients undergoing total hip arthroplasty (THA) and any association between the type of prosthesis and cardiac failure presenting at a later date, and usually to a different clinician, could easily be overlooked.[19]

Record-linkage studies have been used to investigate the relationship between death due to cancer in patients who have undergone MoM THA, concluding that there is no increased risk.[20-22] In this study, we tested the hypothesis that MoM THA was associated with increased risk of cardiac failure compared with other types of prostheses.

Patients and Methods

This was a retrospective cohort study using linked national data sets. The United Kingdom National Joint Registry (NJR), which is the largest arthroplasty registry in the world,[23]

was the primary source of data for this study. The submission of data to the registry has been mandatory for National Health Service (NHS) hospitals in England, Wales and Northern Ireland since 1 April 2011, with > 95% of primary procedures captured in 2015 and now with information from more than two million arthroplasties.[23]

Each record describes the demographics of the patient including age, gender, American Society of Anesthesiologists (ASA) grade,[24] body mass index (BMI), the type of prosthesis including the bearing surface, size of the components and brand and surgical details. Corresponding data are generated routinely for NHS Hospital Episodes Statistics (HES),[25] which specify the reasons for admission, procedures performed and length of stay. The Office for National Statistics (ONS)[26] records death certification data on all deaths registered in England and Wales including the date and cause(s) of death.

Individual patient-level record linkage was carried out by NHS Digital (NHS, Leeds, United Kingdom), using the NHS number, date of birth, gender and postcode. Only patients consenting to inclusion in the NJR registry and to the use of their data for research purposes were included. Pseudo-anonymous data from the NJR were provided to the investigators for analysis. The study was undertaken in accordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) checklist.[27]

The inclusion criteria involved those who underwent elective, primary THA between 1 January 2003 and 31 December 2014 who had linked HES records. This provided a minimum period of six preoperative years in which to establish a record of cardiac failure at the time of THA and a minimum postoperative follow-up of six months. Patients with cardiac failure prior to or in the six months following THA, which would most likely have been attributable to pre-existing disease, were excluded from the overall analysis but included in sensitivity analyses. A step-wise process was used to remove records of insufficient quality and cases with duplicate or conflicting data. The exposure of interest was defined as the type of arthroplasty. The MoM cohort included patients with metal acetabular and femoral components which articulated directly; both resurfacing and stemmed arthroplasties were included. Exposure dated from the first primary arthroplasty. Patients with both a MoM and a non-MoM arthroplasty were excluded.

The primary outcome measure was the time to an episode of cardiac failure following arthroplasty. The secondary outcome measure was all causes of mortality. The time at risk for the outcome was measured from the day of the arthroplasty until the first hospital admission with cardiac failure, death or the end of the study period (March 2015). Cardiac failure was defined by the appropriate diagnostic codes following discharge from hospital or on a death certificate (see supplementary material). The demographics of the patients and details of the operation were extracted from NJR and comorbidities were extracted from HES data.

The study protocol was approved by the Research Subcommittee of the NJR and the Data Access Advisory Group of NHS Digital.

Statistical analysis. Cox proportional hazards models were used to estimate the hazard ratio (HR) for primary and secondary outcomes by group and were adjusted for potential confounding factors including age at the time of the operation, gender, a history of type 2 diabetes, hypertension, coronary heart disease and other indicators of comorbidity and frailty (Charlson comorbidity index,[28] ASA grade and the number and length of hospital admissions in the five years prior to arthroplasty).

In order to control for the indications available in the data set, propensity-matched analyses (adjusted and unadjusted) were performed using one-to-one matching of patients undergoing MoM arthroplasty with those undergoing a non-MoM arthroplasty. The cohort was stratified by gender before propensity matching and matched by age, history of diabetes, heart disease and hypertension, Charlson index and ASA class. A caliper of 0.2 was used for the propensity score.

Further comparisons were performed for subgroups, including those at the highest risk of cardiac failure and those at the highest risk of implant failure,[29] including those with an Articular Surface Replacement (ASR) XL Acetabular System (DePuy Orthopaedics, Warsaw, Indiana). BMI was available for approximately half of the patients (n = 278 757) and was included as a further covariate for this subset. Data processing was performed using Microsoft SQL Server 2012 (Redmond, Washington), and statistical analyses with SPSS Statistics version 22.0 (IBM, Armonk, New York). The proportional hazards assumption was tested using the correlation between survival and partial residuals.

Results

A total of 581 954 patients with a THA recorded in the NJR could be linked to HES and ONS data. Following data cleaning and the exclusion of emergency admissions, 550 589 (94.6%) THAs remained. Of these, 535 776 (97.3%) had no history of cardiac failure either before their arthroplasty or within the subsequent six months. This cohort was used in the main analysis (Fig. 1). A total of 53 529 patients (10.0%) had a MoM hip arthroplasty and were matched in the propensity analysis. Notably, the patients were younger (mean age: 58.6 years, SD 11.1) *versus* 69.2 years, SD 11.0). More were male (61.1% *versus* 38.1%) with fewer comorbidities, as measured by the prevalence of diabetes, coronary heart disease and hypertension, Charlson index and ASA grade (Table I). By design, propensity matching reduced these differences (Table I).

There were 1431 incidents of cardiac failure in the MoM cohort and 21 245 in the non-MoM cohort. The crude event rates were 3.8 and 9.7 per 1 000 person years' exposure, respectively, with a crude relative rate of 0.389 (95% confidence interval (CI) 0.368 to 0.410, Table II). Following adjustment, the adjusted hazard ratio (aHR) for the MoM cohort relative to the non-MoM cohort was 0.901

Table I. Baseline characteristics of patients with metal-on-metal and non-metal-on-metal arthroplasties: all patients and those matched by propensity score

	All patients			Propensity-matched patients		
	MoM	Non-MoM	p-value	MoM	Non-MoM	p-value
Number of patients	53 529	482 247	N/A	53 529	53 529	
Mean follow-up, yrs (SD)	7.2 (2.3)	4.6 (3.0)	< 0.001*	7.2 (2.3)	4.6 (3.1)	< 0.001*
Mean age, yrs (SD)	58.6 (11.1)	69.2 (11.0)	< 0.001*	58.6 (11.1)	58.6 (11.8)	0.004*
Gender, n (%)			< 0.001†			1†
Male	32 700 (*61.1*)	183 867 (*38.1*)		32 700 (*61.1*)	32 700 (*61.1*)	
Female	20 829 (*38.9*)	298 380 (*61.9*)		20 829 (*38.9*)	20 829 (*38.9*)	
Mean body mass index, kg/m^2 (SD)	28.4 (5.2)	28.5 (5.3)	0.170*	28.4 (5.2)	28.7 (5.2)	< 0.001*
Prior type 2 diabetes, n (%)	2034 (*3.8*)	38 575 (*8*)	< 0.001†	2034 (*3.8*)	1922 (*3.6*)	0.070†
Prior hypertension, n (%)	11 171 (*20.9*)	197 830 (*41.0*)	< 0.001†	11 171 (*20.9*)	10 436 (*19.5*)	< 0.001†
Prior coronary heart disease, n (%)	2966 (*5.5*)	53 239 (*11*)	< 0.001†	2966 (*5.5*)	2710 (*5.1*)	0.001†
Mean Charlson Index (SD)	0.2 (0.7)	0.5 (1)	< 0.001*	0.2 (0.7)	0.2 (0.6)	< 0.001*
Prior hospitalisations						
Mean total admissions (SD)	1.4 (3.2)	2.1 (7.6)	< 0.001*	1.4 (3.2)	1.4 (2.6)	< 0.001*
Mean hospitalized days (SD)	4.4 (17.6)	6.5 (20.3)	< 0.001*	4.4 (17.6)	4.3 (18.0)	< 0.001*
ASA, n (%)			< 0.001†			< 0.001†
P1 - Fit and healthy	20 892 (*39*)	79 107 (*16.4*)		20 892 (*39.0*)	19 998 (*37.4*)	
P2 - Mild disease not incapacitating	29 158 (*54.5*)	335 415 (*69.6*)		29 158 (*54.5*)	30 868 (*57.7*)	
P3 - Incapacitating systemic disease	3362 (*6.3*)	65 896 (*13.7*)		3362 (*6.3*)	2621 (*4.9*)	
P4 - Life threatening disease	100 (*0.2*)	1742 (*0.4*)		100 (*0.2*)	38 (*0.1*)	
P5 - Expected to die within 24 hrs	17 (*0*)	87 (*0*)		17 (*0*)	4 (*0*)	
Ethnicity, n (%)			< 0.001†			< 0.001†
Asian	213 (*0.4*)	1531 (*0.3*)		213 (*0.4*)	330 (*0.6*)	
Black	399 (*0.7*)	2229 (*0.5*)		399 (*0.7*)	461 (*0.9*)	
Chinese	10 (*0*)	158 (*0*)		10 (*0*)	20 (*0*)	
Mixed	98 (*0.2*)	638 (*0.1*)		98 (*0.2*)	137 (*0.3*)	
Not recorded	8686 (*16.2*)	63 900 (*13.3*)		8686 (*16.2*)	7617 (*14.2*)	
Other	201 (*0.4*)	1597 (*0.3*)		201 (*0.4*)	258 (*0.5*)	
White	40 391 (*75.5*)	398 401 (*82.6*)		40 391 (*75.5*)	42 278 (*79*)	

*Student's *t*-test
†chi-squared test
MoM, metal-on-metal; SD, standard deviation; ASA, American Society of Anesthesiologists

(95% CI 0.853 to 0.953, Table III). In unadjusted analysis, the relative rate of all-cause mortality was 0.389 (95% CI 0.376 to 0.402). Following adjustment, the HR for all-cause mortality was 0.892 (95% CI 0.862 to 0.924).

In subgroup analyses, the aHR was below unity or did not achieve significance for all groups (Fig. 2. In the age-specific subgroup analysis, there was a trend towards an increasing rate of cardiac failure with increasing age, ranging from 0.600 (0.353 to 1.019) in the youngest cohort (≤ 44 years) to 1.15 (0.908 to 1.370) in the oldest (≥ 85 years).

In the propensity-matched analysis, there were 1431 incidents of cardiac failure in the MoM cohort and 1004 in the non-MoM cohort. Due to the longer follow-up, the crude event rates were lower in the MoM cohort (3.8 events per 1000 person years *versus* 4.1 events per 1000 person years), with an unadjusted relative rate of 0.917 (95% CI 0.846 to 0.994, Table II). In adjusted analyses, the aHR was 0.909 (95% CI 0.838 to 0.987, Table III). For all-cause mortality, the aHR was 0.877 (95% CI 0.835 to 0.922, Table III). The subgroup analysis of the propensity-matched cohorts is illustrated in Figure 3. No subgroup had a significantly increased aHR.

A total of 557 patients in the MoM cohort and 14 256 in the non-MoM cohort had a previous history of cardiac failure. The respective event rates for the first subsequent admission with cardiac failure were 136.6 and 195.3 per 1000 person years (Table IV). After adjustment, the aHRs for cardiac failure and all-cause mortality were 0.997 (95% CI 0.885 to 1.122; p = 0.952) and 0.983 (95% CI 0.854 to 1.132; p = 0.814), respectively. In the analysis that included BMI as a covariate, the aHRs for cardiac failure and all-cause mortality were 0.920 (95% CI 0.831 to 1.019) and 0.879 (95% CI 0.850 to 0.909), respectively.

Additional analyses were performed on the MoM cohort by the type of device including the type of head, the brand of the acetabular component and the size of the components. For patients receiving a modular head, the aHR approximated unity (aHR = 1.013; 95% CI 0.953 to 1.078). Of these patients, the aHR for those receiving an ASR XL prosthesis was 0.970 (95% CI 0.776 to 1.213). For those having a resurfacing, the aHR was significantly lower (0.656; 95% CI 0.587 to 0.732, Table V). No brand of acetabular component or size of femoral head had an increased aHR for cardiac failure (supplementary fig a).

Discussion

In this study involving more than half a million patients with arthroplasties of the hip, there was no association between a MoM arthroplasty and an increased incidence of cardiac failure in the first seven years after surgery.

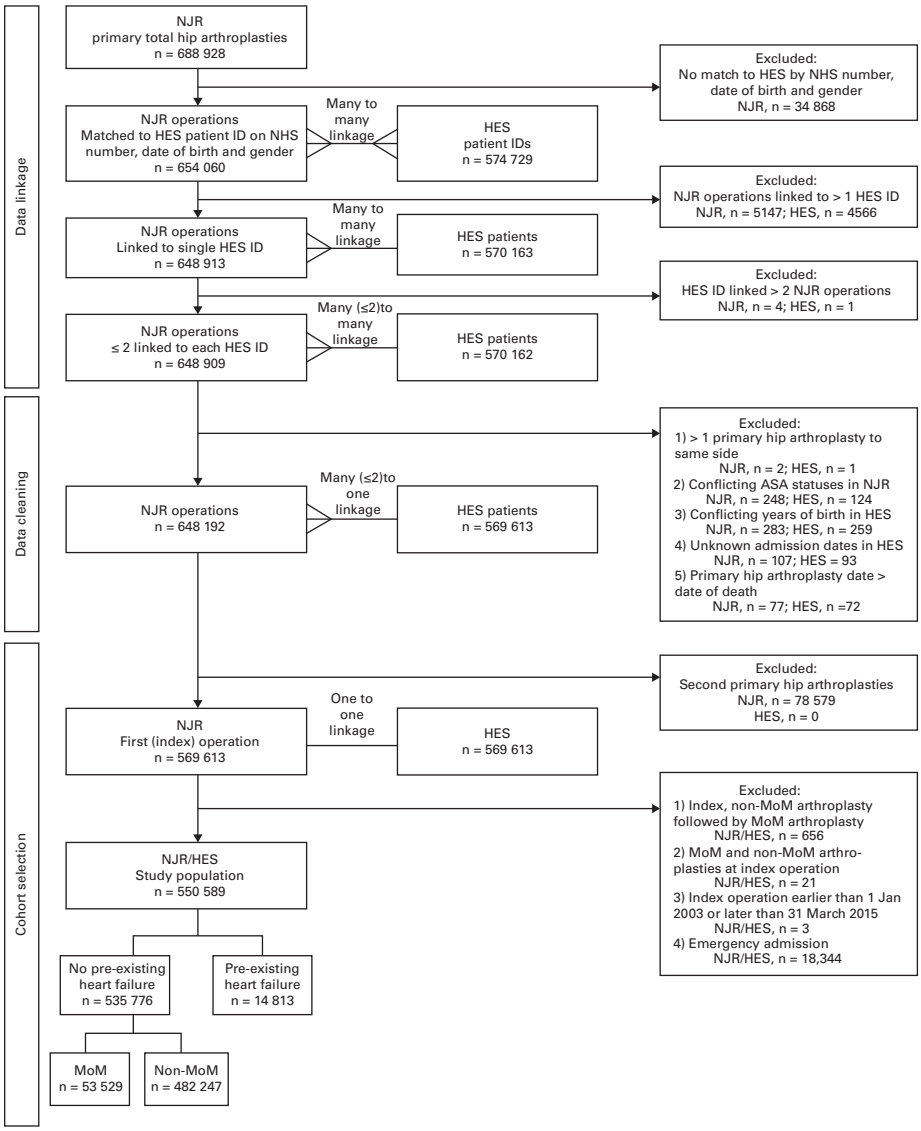


Fig. 1

Flowchart showing data linkage, data cleaning and selection of the cohorts. NJR, National Joint Registry; NHS, National Health Service; HES, hospital episode statistics, MoM, metal-on-metal

In contrast to the recent report of increased rates of admission with cardiac failure in subgroups of patients with MoM arthroplasties,[15] the risk of cardiac failure in these patients appeared to be lower than those with other types of bearing surfaces. These findings persisted after extensive adjustment for confounding factors, after matching by propensity score and even among patients at the highest risk of either cardiac failure or implant failure. Patients with pre-existing cardiac failure had, as expected, significantly higher rates of admission with cardiac failure and death due to cardiac failure. However, this was not influenced by exposure to MoM arthroplasty. In common with other studies,[20,21] we found no increase in all-causes of mortality with MoM arthroplasty.

It is however, likely that there are residual confounding factors for which we have failed to account. Our finding that the lower rate for all causes of mortality from MoM arthroplasties was markedly attenuated by multivariate adjustment and matching by propensity score, indicates that this is likely to be due to lower morbidity. These results are in line with previously published studies assessing the risk of cancer and mortality with these patients, in which similarly lower HRs were reported, particularly in patients with a MoM resurfacing.[18,21,30] Resurfacing is a bone-conserving option, sought by patients aiming to return to high levels of function. Aspects of better health which are not captured in these data such as exercise and not smoking or socioeconomic status may explain these findings.

The use of modular MoM arthroplasties was more varied, with some patients receiving them because they were deemed to be at high a risk of dislocation. This includes patients with poor musculature, neurological disorders,

Table II. Incidents, the rate of events and the crude relative risk of heart failure and all-cause mortality for patients with metal-on-metal and non-metal-on-metal arthroplasties: all patients and those matched by propensity score

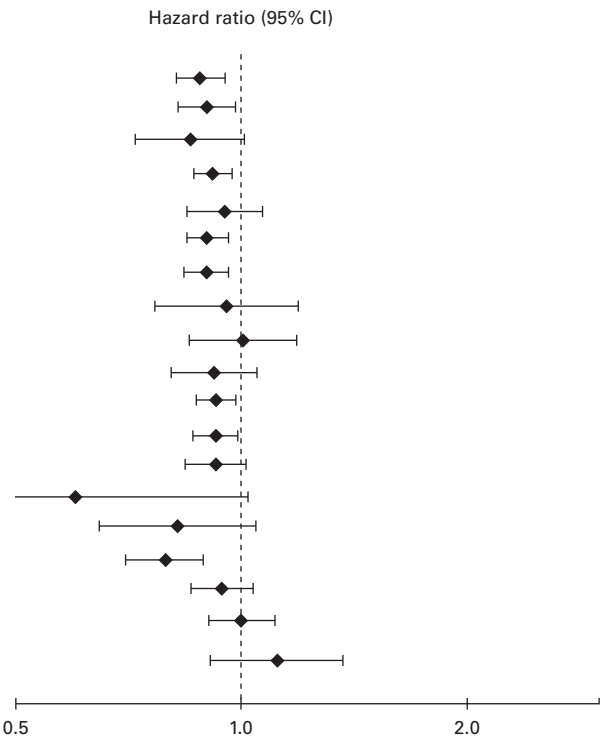
	MoM			Non-MoM			Crude relative risk (95% CI)
	Patients	Events	Rate*	Patients	Events	Rate*	
All patients							
Cardiac failure	53 529	1431	3.8	482 247	21 245	9.7	0.389 (0.368 to 0.410)
Death	53 529	3728	9.7	482 247	55 875	24.9	0.389 (0.376 to 0.402)
Propensity-matched patients							
Cardiac failure	53 529	1431	3.8	53 529	1004	4.1	0.917 (0.846 to 0.994)
Death	53 529	3728	9.7	53 529	2776	11.2	0.864 (0.823 to 0.908)

*rate per 1000 person years' exposure
MoM, metal-on-metal; CI, confidence interval

Table III. Adjusted hazard ratio of cardiac failure and all-cause mortality for patients with metal-on-metal and non-metal-on-metal arthroplasties: all patients and those matched by propensity score

	Adjusted hazard ratio (95% CI)	p-value*
All patients		
Cardiac failure	0.901 (0.853 to 0.953)	< 0.001
Death	0.892 (0.862 to 0.924)	< 0.001
Propensity-matched patients		
Cardiac failure	0.909 (0.838 to 0.987)	0.023
Death	0.877 (0.835 to 0.922)	< 0.001

*Cox PH model
CI, confidence interval

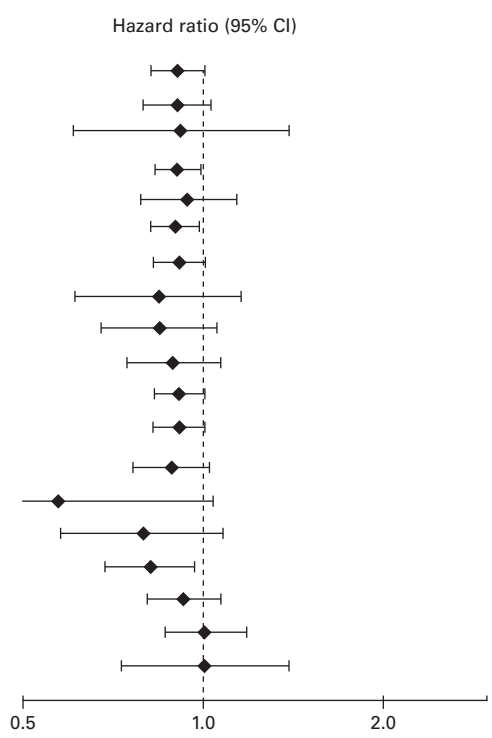


Sub-group		aHR 95% CI	Patients
Gender	Male	0.881 (0.819 to 0.947)	9694/216 567
	Female	0.899 (0.824 to 0.981)	12 982/319 209
Diabetes	Diabetes	0.853 (0.720 to 1.010)	19 760/495 167
	Non-diabetes	0.915 (0.863 to 0.971)	2916/409 609
CHD	CHD	0.951 (0.846 to 1.069)	17 067/479 571
	Non-CHD	0.900 (0.845 to 0.958)	5609/56 205
BMI	< 25	0.896 (0.838 to 0.958)	1742/62 681
	25 to 29.9	0.953 (0.764 to 1.188)	2852/112 693
	30+	1.005 (0.852 to 1.186)	3195/103 383
ASA	1	0.917 (0.803 to 1.047)	2231/99 999
	2 to 5	0.922 (0.867 to 0.98)	20 445/435 777
Charlson	0	0.923 (0.861 to 0.989)	13 486/383 187
	1+	0.925 (0.843 to 1.014)	9190/152 589
Age	12 to 44	0.600 (0.353 to 1.019)	72/18 153
	45 to 54	0.822 (0.646 to 1.045)	321/44 966
	55 to 64	0.79 (0.701 to 0.890)	1810/117 636
	65 to 74	0.941 (0.856 to 1.035)	6546/187 275
	75 to 84	1.000 (0.901 to 1.110)	10 657/140 533
	85+	1.115 (0.908 to 1.370)	3270/27 210

Fig. 2

Adjusted hazard ratio (aHR) of cardiac failure for patients with metal-on-metal (MoM) and non-MoM arthroplasties: all patients by subgroup. CI, confidence interval; CHD, coronary heart disease; BMI, body mass index; ASA, American Society of Anesthesiologists grade.

variations in anatomy and other factors that may be associated with a poorer outcome. These patients therefore have more in common with those undergoing non-MoM arthroplasty than those undergoing a resurfacing This is reflected in our findings, in which the HR for cardiac failure in patients undergoing a modular MoM arthroplasty was close to unity, and thus higher than in those undergoing a resurfacing.



Sub-group		aHR 95% CI	Patients
Gender	Male	0.908 (0.818 to 1.008)	1504/65400
	Female	0.907 (0.794 to 1.036)	931/41 658
Diabetes	Diabetes	0.919 (0.606 to 1.393)	2189/103 102
	Non-diabetes	0.910 (0.834 to 0.992)	246/3956
CHD	CHD	0.950 (0.790 to 1.142)	1934/101 382
	Non-CHD	0.898 (0.820 to 0.985)	501/5676
BMI	< 25	0.916 (0.829 to 1.012)	160/9844
	25 to 29.9	0.843 (0.613 to 1.158)	278/20 189
	30+	0.846 (0.675 to 1.061)	322/18 079
ASA	1	0.894 (0.746 to 1.072)	493/40 890
	2 to 5	0.912 (0.832 to 1.00)	1942/66 168
Charlson	0	0.914 (0.827 to 1.010)	1623/89 499
	1+	0.884 (0. 765 to 1.022)	812/17 559
Age	12 to 44	0.571 (0.313 to 1.041)	45/11 383
	45 to 54	0.793 (0.581 to 1.082)	179/24 972
	55 to 64	0.817 (0.687 to 0.973)	570/38 847
	65 to 74	0.930 (0.808 to 1.071)	822/23 010
	75 to 84	1.011 (0.864 to 1.183)	657/7768
	85+	1.010 (0. 733 to 1.391)	162/1078

Fig. 3

Adjusted hazard ratio of cardiac failure for patients with metal-on-metal (MoM) and non-MoM arthroplasties: propensity-matched patients by subgroup. CI, confidence interval; aHR, adjusted hazard ratio; CHD, coronary heart disease; BMI, body mass index; ASA, American Society of Anesthesiologists grade.

Table IV. Events, the rate of events and adjusted hazard ratio of cardiac failure and all-cause mortality for patients with a history of cardiac failure and metal-on-metal and non-metal-on-metal arthroplasties

	MoM			Non-MoM			Adjusted hazard ratio (95% CI)	p-value†
	Patients	Events	Rate*	Patients	Events	Rate*		
Cardiac failure, n	557	293	136.6	14 256	6747	195.3	0.977 (0.885 to 1.122)	0.952
Death, n	557	208	64.6	14 256	4933	96.0	0.983 (0.854 to 1.132)	0.814

*rate per 1000 person years' exposure
†Cox PH model
MoM, metal-on-metal; CI, confidence interval

MoM arthroplasties vary both in design and manufacturing process, and have different rates of failure and circulating levels of metal ions.[29,31,32] Subgroup analysis by manufacturer found no differences between devices associated with high rates of implant failure such as stemmed implants, those with a large femoral head and brands including the ASR XL and other MoM implants. The ASR XL (DePuy) is a type of large-diameter, stemmed arthroplasty with a high rate of implant failure.[33] It was subject to a worldwide device recall and was recently identified as being associated with an increased risk of cardiac failure in elderly men.[15]

Cobalt cardiomyopathy was first described in 1967 in patients with excess dietary cobalt, 'Quebec beer-drinkers' cardiomyopathy'.[33] More recently, case reports and small series have reported cardiomyopathy related to failure of MoM implants.[7,35-39] However, there were < 30 cases in total and these patients had extreme levels of circulating metal ions. Prentice et al[40] performed a cross-sectional observational study of systemic complications and found a 5% lower ejection fraction in 35 patients with MoM resurfacing implants compared with patients with conventional arthroplasties. Subsequent multimodality work[41] using both echocardiography and MRI, the benchmark measure of cardiac function, failed to replicate these findings despite including patients with high levels of metal ions in the blood (mean cobalt 30 ppb (range 8 to 118). Using epidemiological approaches, one study found lower standardized mortality ratios for cardiovascular death in a large cohort of patients with a MoM arthroplasty compared with those with a non-MoM arthroplasty.[22] Cardiac failure was not specifically studied. A recent report from Australia

Table V. Incidents, the rate of events and adjusted hazard ratio of cardiac failure for patients with either modular or resurfaced metal-on-metal and non-metal-on-metal arthroplasties

	Patients	Events	Event rate*	Adjusted hazard ratio (95% CI)	p-value†
Modular					
Cases	25 656	1084	6.1	1.013 (0.953 to 1.078)	0.675
Controls	482 247	21 245	9.6		
ASR XL					
Cases	2353	78	4.5	0.970 (0.776 to 1.213)	0.790
Controls	482 247	21 245	9.6		
Resurfaced					
Cases	27 870	347	1.7	0.656 (0.587 to 0.732)	< 0.001
Controls	482 247	21 245	9.6		

*rate per 1000 person years' exposure
†Cox PH model
CI, confidence interval

noted a three-fold increase in the risk of admissions to hospital because of cardiac failure in 63 men with an ASR XL THA with a mean age of 82 years, compared with 1502 men with a metal-on-plastic THA.[14] These patients were significantly different from our patients, both in age and risk of cardiac failure. All patients in their study had a high rate of cardiac failure; the incidence of cardiac failure in the control group was 18% at a mean of 7.2 years, and the effect was confined to men. In our study, there was no increased risk of cardiac failure in older patients with an ASR XL THA (supplementary table ii). The numbers were small (n = 786), with wide CIs.

This study is the largest epidemiological study of systemic effects (cardiac failure) after MoM arthroplasty. Given the nature of the sources of the data, case recruitment should be comprehensive and the findings can therefore be generally followed. The statistical power of the dataset enabled extensive subgroup analysis to address specific concerns such as the differences between gender and brands.[15] We accept that before 2005, the data in the NJR include less than 80% of the arthroplasties undertaken in the United Kingdom and some MoM arthroplasties may have been omitted from the analysis.[42]

Limitations include those of the HES data, where coding is not performed by clinicians and the coding of cardiac failure is imperfect, although this should introduce only analytical noise, rather than bias. Cardiac failure is mainly captured when severe, as in admission to hospital or death, missing cardiac failure diagnosed and managed in a primary care setting. Follow-up was up to seven years only. However, a systematic review suggested that recognized cases occur within a median of 19 months (up to six years) postoperatively.[7] We did not include analysis of the levels of metal ions in the blood. Any association of cardiac failure and high levels of metal ions could have been missed, but given the mandated surveillance of these levels and the association of metal ions with local symptoms, most of these patients would have had revision surgery. Retrospective analysis of registry data can rarely be definitive about causality.[13,17] There are, however, no prospective observational or sufficiently powered randomized controlled trials, nor are there likely to be in the future. There are only two previous studies, both negative and unpublished,[33,42] and no association was reported in a single, small meta-analysis.[13]

In conclusion, we found a lower incidence of cardiac failure and mortality in patients with MoM arthroplasties compared with other types of arthroplasty of the hip in the first seven years after surgery. While there may be confounding factors by indication, these results should provide reassurance to clinicians and patients alike, regarding the cardiac sequelae associated with these devices. We recommend epidemiological analysis at five-yearly intervals to investigate for any latent effects.

Take home message:

Patients with metal-on-metal hip prostheses (of any type) are not at significantly increased risk of severe heart failure in the first 7 years after elective surgery.

Supplementary material

Further information including tables and figures are available alongside the online version of this article at www.bjj.boneandjoint.org.uk

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Author contributions:
S. A. Sabah: Study design, Writing paper
J. C. Moon: Study design, Review of manuscript
S. L. Jenkins-Jones: Data preparation, Review of manuscript
C. Ll. Morgan: Statistical analysis, Review of manuscript
C. J. Currie: Study design, Statistical analysis, Review of manuscript
J. M. Wilkinson: Study design, Review of manuscript
M. Porter: Review of manuscript
G. Captur: Review of manuscript
J. Henckel: Study design, Review of manuscript
N. Chaturvedi: Study design, Review of manuscript
P. Kay: Review of manuscript
J. A. Skinner: Study design, Writing paper
A. H. Hart: Study design, Writing paper
C. Manisty: Study design, Writing paper

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