

Outcomes After Coronary Stent Implantation in Patients With Metal Allergy

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Background—Clinical outcomes after stent placement in patients with a history of metal allergy remain incompletely understood. We performed a single-center retrospective study to evaluate such outcomes.

Methods and Results—Twenty-nine allergic patients who underwent coronary stent implantation were compared with a nonallergic group (n=250) matched for demographics and a propensity score for allergy to metal. Hypersensitivity to nickel was reported in 26 of 29 and chromium in 9 of 29. Patch testing performed in 11 of 29 patients was positive in all. Comparing allergy versus control subjects, there were no differences in number of segments treated (1.4 ± 0.7 versus 1.5 ± 0.7), stents placed (1.7 ± 1.1 versus 1.6 ± 0.9), and frequency of drug-eluting stent usage (52% versus 60%). In-hospital death (0% versus 0%), myocardial infarction (MI, 4% versus 3%, $P=0.27$), and 30-day death (3% versus 0%, $P=0.53$) and MI (3% versus 4%, $P=0.71$) were statistically similar. There were no differences in 4-year death (12% versus 13%), target lesion revascularization (TLR, 13 versus 17%, $P=0.54$), or death/MI/TLR (24% versus 34%, $P=0.20$). Clinically driven repeat angiography in 12 of 29 allergy patients revealed binary restenosis rates of 27% in bare metal stents and 0% in drug-eluting stents, with mean diameter in-stent restenosis of 36% and 8%, respectively. There was no change in circulating eosinophil and lymphocyte counts after stenting in the allergy group (0.19 – 0.20 , $P=0.67$, and 1.90 – 1.79 , $P=0.59$, respectively).

Conclusions—A history of metal allergy was not associated with adverse early or late outcomes in this single-center study. (*Circ Cardiovasc Interv.* 2012;5:220–226.)

Key Words: coronary stent ■ restenosis ■ allergy

The most common manifestation of metal hypersensitivity is contact dermatitis to nickel. Hypersensitive skin reactions to other metals such as cobalt, chromium, molybdenum, and gold also occur, but much less frequently.¹ In allergic individuals, release of metal ions on skin contact induces a type IV hypersensitivity reaction mediated by allergen-specific T-cells, manifesting as a red pruritic rash with areas of vesiculation.² The prevalence of nickel hypersensitivity in the general population is estimated at 8%, being more prevalent in females, and typically relating to repeated exposure to consumer items such as jewelry, zip fasteners, and cell phones.³

Whether there may be deleterious immune-mediated reactions to noncutaneous metal implants remains uncertain. For example, reports have demonstrated peri-implant T-lymphocytic inflammation occurring after joint replacement surgery in patients with a history of metal contact dermatitis.⁴ However, studies evaluating the association between metal hypersensitivity and orthopedic implant failure have yielded conflicting results.^{4,5} Similarly, there have been reports of severe systemic symptoms occurring after placement of metallic patent foramen ovale closure devices that have resolved with device re-

moval.^{6,7} In a study of 47 patients who underwent patent foramen ovale closure with an Amplatzer device ($\approx 50\%$ nickel), 8 were subsequently identified as nickel-allergic by patch testing at the time of follow-up.⁸ Of these, 5 patients reported an increase in the frequency of migraine headaches, chest pain, and palpitations after device placement, significantly more frequent than reported by nonallergic control subjects. However, there were no detectable differences in device performance in the allergy group compared with control subjects and no evidence of implant failure.

Coronary stents used in the United States since 1997 have been constructed using 316L stainless steel, cobalt-chromium alloy, or platinum-chromium alloy platforms. In varying amounts, all such stents contain nickel (10% to 35%), chromium as chromate (18% to 20%), and, aside from the Multi-link vision stent, molybdenum (2.7% to 9.7%). Conceptually, any stent component may have the propensity to induce immune-mediated thrombosis or restenosis in hypersensitive individuals. Antiproliferative and polymer coatings of drug-eluting stents have been postulated to induce such a detrimental response in some individuals,⁹ but it remains

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uncertain whether stent metal components may induce local implant failure when implanted in patients with metal allergy. In this regard, clinical studies have suggested a higher risk of restenosis or re-restenosis in patients who were found to be patch-test positive for metal allergy after stent placement.^{10–12} However, these studies were limited by small sample sizes of allergic groups and the possibility that stent placement may have influenced the subsequent patch result through sensitization.

Despite limited data, it is notable that Food and Drug Administration–approved Instructions for Use for all currently available US coronary stents warn against stent implantation in patients with a history of metal allergy. However, clinical outcomes after stent placement in patients with a history of metal allergy remain incompletely understood. To address this, we retrospectively evaluated outcomes in patients with a history of metal contact allergy who subsequently underwent coronary stent placement, hypothesizing adverse short- and long-term outcomes compared with a matched control group.

WHAT IS KNOWN

- Concern exists regarding the safety of coronary stent placement in patients with a history of metal allergy.
- Earlier studies suggested an increased risk of restenosis in patients who were identified as metal-allergic after stent placement.

WHAT THE STUDY ADDS

- A history of metal allergy was not associated with adverse clinical outcomes, restenosis, or acute allergic response after coronary stent placement in this single-center study.

Methods

Patient Population

This single-center study was approved by the Mayo Clinic Institutional Review Board. Medical records containing any of the terms nickel, manganese, chromium, chromate, or molybdenum were cross-referenced with the percutaneous coronary intervention (PCI) registry between 1997 and 2009. Patients who refused authorization of their records for research were excluded. Individual medical record review was then performed to identify patients with a history of metal contact allergy who subsequently underwent index coronary stent implantation. Only those identified as allergic before index stent placement were included. Patients undergoing PCI at the Mayo Clinic in Rochester, MN, are prospectively followed in a registry that includes demographic, clinical, angiographic, and procedural data. Immediate and in-hospital events are recorded, and each patient is surveyed by telephone using a standardized questionnaire at 6 months, 1 year, and then annually after the procedure. Ten percent of all records are randomly audited by the supervisor for data integrity. All adverse events are confirmed by reviewing the medical records of the patients followed at our institution and by contacting the patients' physicians and reviewing the hospital records of patients followed elsewhere.

Matching

Two control groups were identified for analysis. The first comprised the 13 796 remaining (nonallergic) patients who underwent coronary

stent implantation between December 1, 1997, and May 31, 2009. The second was a cohort of nonallergic patients (n=250) matched to the allergy cohort. Matching was accomplished by matching on age within 5 years, sex, PCI date within 2 years, drug-eluting stent use, and a propensity score (within one-fourth of its standard deviation) for allergy to metal. The propensity score was based on age, PCI date, sex, family history of coronary artery disease, diabetes mellitus, history of cholesterol >240 mg/dL, prior PCI, prior coronary artery bypass grafting (CABG), history of myocardial infarction (MI), chronic renal disease, congestive heart failure, smoking status, tumor, preprocedural Thrombolysis In Myocardial Infarction flow, drug-eluting stent use, history of stroke or transient ischemic attack (TIA), number of stents placed, urgency of procedure, an interaction between age and sex, and an interaction between drug-eluting stents and sex. As many as 25 control subjects were allowed to be matched to an allergic patient.

Variables and Definitions

Demographic features, angiographic variables, in-hospital, and long-term outcomes were studied. Comparisons of allergy versus matched control subjects and allergy versus entire remaining PCI population were performed. Eosinophil and lymphocyte counts were evaluated in the allergic group before and after stent implantation. Quantitative coronary angiography using automated edge detection (Paeon Realizing Cardiac Imaging system IC-PRO version 3.2.1.51, Paeon, Inc, New York, NY) was performed in those allergic patients who underwent clinically driven implantation repeat coronary angiography ≥ 6 months after index stent placement. After guide catheter calibration, the stent, proximal reference, and distal reference segments were studied in 2 orthogonal projections to obtain mean diameter in-stent restenosis.

The number of diseased coronary arteries was defined by the number of major arteries with $\geq 50\%$ stenosis, provided at least 1 of the major arteries had $\geq 70\%$ stenosis. Patients with $\geq 50\%$ stenosis in the left main coronary artery were considered to have 2-vessel disease if there was right dominance and 3-vessel disease if there was left dominance. MI was diagnosed in the presence of at least 2 of 3 criteria: (1) typical chest pain for at least 20 minutes; (2) elevation of serum creatine kinase levels (or the MB fraction) $>2\times$ normal; and (3) a new Q-wave on the ECG. Severe renal dysfunction was defined as a creatinine of >3.0 mg/dL or a history of dialysis or renal transplant. Cardiogenic shock was defined as a prolonged systolic arterial pressure <95 mm Hg or systolic arterial pressure <110 mm Hg while on inotropes or with intra-aortic balloon pump support. Procedural success was defined as a reduction of residual luminal diameter stenosis to $\leq 20\%$ without in-hospital death, Q-wave MI, or need for emergency CABG. A history of stroke or TIA was defined as a documented history of stroke or TIA that resulted in abnormalities in vision, speech, sensation, or motor function or a history of cerebrovascular (carotid) surgery. Congestive heart failure was defined as any documentation in the medical record.

Statistical Analysis

All data are presented as mean $\pm$ SD and frequency (percentage) unless indicated otherwise. Comparisons between unmatched groups were tested using Student *t* test for continuous data and Pearson χ^2 test for categorical data. Fisher exact test was used for variables with low frequency counts. For the matched cohort of allergic and nonallergic patients, conditional logistic regression was used to test group differences. For in-hospital outcomes, probability values were calculated from exact conditional logistic regression. For summary statistics of the matched control group, we weighted control subjects so that all control subjects matched to a single case would have equal weight summing to the weight of an allergic patient. In this way, the summary statistics would not be skewed toward the cases that had more matches. These weights were also used for constructing Kaplan-Meier survival estimates. Cox proportional hazards models were used to compare survival between allergic patients and their matched control subjects, with separate baseline strata for each allergic case and its set of matched nonallergic patients. Paired *t* tests were used to test differences

in circulating differential white cell counts from pretest to late follow-up within the allergic patient cohort.

Results

Baseline Clinical Characteristics

Twenty-nine patients were identified with a history of allergy to stent metal components. Of these, 26 (90%) reported sensitivity to nickel and 9 (31%) to chromium. Molybdenum allergy was reported in 1 patient who was also allergic to nickel. Patch testing had been additionally undertaken in 11 of 29 patients and was positive in all cases. None of the patients were referred to an allergist for evaluation before stenting and none were administered medication with the specific goal of suppressing an allergic response. However, 2 of 29 did receive immunosuppressive treatment in the peristent period: chronic methotrexate 2.5 mg once weekly for rheumatoid arthritis (n=1) and prednisone 30 mg daily for 2 weeks commenced 14 days after stent placement for chronic obstructive pulmonary disease exacerbation (n=1).

Compared with the remaining nonallergic stented population (n=13 796), patients with a history of metal allergy were more likely to be female (69% versus 30%, $P<0.001$), whereas other demographic and clinical characteristics were statistically similar (Table 1). By matching for age, sex, PCI date, drug-eluting stent use, and a propensity score for allergy to metal, a matched control group of 250 nonallergic patients was generated. Table 2 illustrates that baseline demographic and clinical characteristics were similar between allergic and matched control groups.

Procedural Characteristics

Baseline angiographic and procedural characteristics were compared between allergic patients and their matched control subjects (Table 3). The majority of parameters were similar between groups, although fewer interventions were performed in the left anterior descending artery of allergic patients and more in the right coronary artery, compared with control subjects. The total number of segments treated (1.4 ± 0.7 versus 1.5 ± 0.7) and mean number stents placed (1.7 ± 1.1 versus 1.6 ± 0.9) was not different between groups. The stents that were placed used 1 of 3 metal platforms: 316L stainless steel (n=35), L605 cobalt chromium (n=11), and MP35N cobalt chromium (n=4). Details of stent type and metal composition¹³ are provided in online-only Data Supplement Table I.

In-Hospital and 30-Day Outcomes

In-hospital outcomes of allergic and matched control groups are illustrated in Table 4. There were no in-hospital deaths, Q-wave MIs, or emergency CABG in either group after stent placement and there were no statistically significant differences in in-hospital rates of MI, shock, or target vessel revascularization between groups. Emergency postprocedural requirement for intra-aortic balloon pump support, however, occurred significantly more frequently in allergic patients (n=2) and was unrelated to the presence of metal allergy. A single episode of acute femoral arterial thrombosis occurred in the allergy group. This patient with severe peripheral arterial disease presenting with a ST-elevation—MI had an

Table 1. Baseline Clinical Characteristics: Metal Allergy Patients Versus Nonallergic Control Subjects

Variable	Control Subjects (n=13 796)	(n=29)	P Value
Age, y	66.7 $\pm$ 12.2	63.9 $\pm$ 11.9	0.23
Male sex	9663 (70%)	9 (31%)	<0.001
Preprocedural shock	536 (4%)	0 (0%)	0.63*
Unstable angina	7420 (54%)	15 (52%)	0.82
CHF status			0.35
Never	11 192 (85%)	23 (79%)	
Previous	422 (3%)	1 (3%)	
Current	1510 (12%)	5 (17%)	
Diabetes	3389 (25%)	10 (34%)	0.22
Hypertension	9499 (72%)	23 (82%)	0.24
Body mass index, kg/m ²	29.7 $\pm$ 5.7	30.5 $\pm$ 5.9	0.43
History of cholesterol $\geq$ 240 mg/dL	9768 (78%)	22 (85%)	0.42
Family history of CHD			0.95
No	5781 (42%)	14 (48%)	
Unknown	5063 (37%)	6 (21%)	
Yes	2952 (21%)	9 (31%)	
Smoking status			0.10
Never	4814 (36%)	5 (17%)	
Former	6045 (45%)	18 (62%)	
Current	2546 (19%)	6 (21%)	
History of MI >7 d	3349 (25%)	8 (29%)	0.64
Peripheral arterial disease	1134 (10%)	2 (7%)	0.59
History of stroke/TIA	1434 (11%)	3 (10%)	0.97
Moderate/severe renal disease	481 (4%)	2 (7%)	0.48
Tumor/lymphoma/leukemia	1666 (12%)	5 (17%)	0.41
Metastatic cancer	118 (1%)	0 (0%)	1.00*
EF $\leq$ 40%	1416 (10%)	5 (17%)	0.52

Values are shown as n (%) or mean $\pm$ SD.

CHF indicates congestive heart failure; CHD, coronary heart disease; MI, myocardial infarction; TIA, transient ischemic attack; EF, ejection fraction.

*Fisher exact test.

intra-aortic balloon pump placed with difficulty. Femoral arterial occlusion occurred 1 hour later, making it unlikely that metal allergy played a causative role. Comparing allergy versus matched control groups, 30-day rates of death (3% versus 0%, $P=0.53$) and MI (3% versus 4%, $P=0.71$) were statistically similar. The single death that occurred in the allergy group shortly after dismissal was in the aforementioned patient with multiple comorbidities who underwent emergency femoral repair and subsequently developed pneumonia as the cause of death. We additionally compared outcomes of the allergic group with the entire remaining PCI population and found no significant differences in in-hospital outcomes aside from femoral thrombosis relating to the single event in the allergy group described above (online-only Data Supplement Table I).

Long-Term Outcomes

Comparing allergic and matched control groups, long-term follow-up indicated no significant difference in 4-year rates

Table 2. Baseline Clinical Characteristics: Metal Allergy Patients Versus Matched Control Subjects

Variable	Control Subjects (n=250)		Control Subjects, Weighted (n=29)		Allergic (n=29)		P Value
	n	%	n	%	n	%	
Age, y	65.5±10.6		63.6±4.0		63.9±11.9		0.56
Male	127	51	9	31	9	31	
Preprocedural shock	0	0	0	0	0	0	
Unstable angina	126	50	16	56	15	52	0.86
CHF status							0.61
Never	204	85	22	80	23	79	
Previous	11	5	2	7	1	3	
Current	26	11	3	13	5	17	
Diabetes	73	29	9	32	10	34	0.72
Hypertension	188	78	21	77	23	82	0.71
Body mass index, kg/m ²	30.3±6.4		30.9±2.5		30.5±5.9		0.67
History of cholesterol ≤240 mg/dL	209	86	22	82	22	85	0.80
Family history of CHD							0.36
No	99	40	11	38	14	48	
Unknown	88	35	9	31	6	21	
Yes	63	25	9	31	9	31	
Smoking status							1.00
Never	68	28	7	25	5	17	
Former	122	50	12	43	18	62	
Current	54	22	9	32	6	21	
History of MI >7 d	67	27	8	27	8	29	0.88
Peripheral vascular disease	30	12	3	10	2	7	0.45
History of CVE	24	10	2	7	3	10	0.51
Moderate/severe renal disease	13	5	2	8	2	7	0.97
COPD	24	10	3	11	2	7	0.53
Tumor/lymphoma/leukemia	44	18	5	17	5	17	0.98
Metastatic cancer	0	0	0	0	0	0	
EF ≤40%	28	11	4	12	5	17	0.23

CHF indicates congestive heart failure; CHD, coronary heart disease; MI, myocardial infarction; CVE, cardiovascular event; COPD, chronic obstructive pulmonary disease; EF, ejection fraction.

of death (12% versus 13%, $P=0.72$; hazard ratio, 1.08; 95% confidence interval, 0.52, 3.69), target lesion revascularization (TLR, 13% versus 17%, $P=0.54$; hazard ratio, 0.76; 95% confidence interval, 0.25, 2.26) or death, MI, or TLR (24% versus 34%, $P=0.20$; hazard ratio, 0.82; 95% confidence interval, 0.38, 1.76) between groups. Given that drug-eluting stents could in theory suppress an allergically mediated proliferative response thereby masking a clinically important effect, the subgroup of allergic patients who received bare metal stents was compared with matched control subjects. There were no differences in rates of death ($P=0.32$), TLR ($P=0.46$), or death, MI, or TLR ($P=0.34$) between groups. Finally, a comparison of the allergic group with the entire remaining PCI population also revealed no significant difference in 4-year rates of death (12% versus 15%), TLR (13 versus 16%, $P=0.70$), or death, MI, or TLR (24% versus 34%, $P=0.18$).

Subclinical Parameters of Allergic Response

Differential white cell counts were available before and after stenting (mean, 91 days) in 24 of 29 metal-allergic patients. There was no significant change in total white count ($6.5\text{--}6.3\times 10^9/\text{L}$), eosinophil count ($0.19\text{--}0.20\times 10^9/\text{L}$), or lymphocyte count ($1.90\text{--}1.79\times 10^9/\text{L}$) after coronary stent placement. Clinically driven repeat angiography was performed in 12 of 29 allergy patients at a mean of 832 days after index stent placement. Of these, the binary in-stent restenosis rate was 27% in bare metal and 0% in drug-eluting stents, with mean diameter in-stent restenosis of 36% and 8%, respectively, by quantitative coronary angiography.

Discussion

This study suggests a benign outcome after coronary stent implantation in patients with a history of metal allergy. There

Table 3. Angiographic and Procedural Characteristics: Metal Allergy Patients Versus Matched Control Subjects

Variable	Control Subjects (n=250)		Control Subjects, Weighted (n=29)		Allergic (n=29)		P Value
	n	%	n	%	n	%	
Diseased vessels, n, 70/50							0.96
Single	74	34	10	39	10	40	
Double	94	43	10	42	7	28	
Triple	50	23	5	19	8	32	
Worst lesion type							0.95
B1	50	20	8	26	6	21	
B2	80	32	8	26	10	36	
C	117	47	14	48	12	43	
Thrombus in any lesion	36	15	6	20	7	25	0.49
Prophylactic IABP	0	0	0	0	0	0	
Maximum device size, mm	3.3±0.6		3.4±0.2		3.3±0.4		0.64
Urgency of PCI							0.40
Elective	121	48	13	44	12	41	
Urgent	108	43	14	50	14	48	
Emergency	21	8	2	6	3	10	
Segments treated, n	1.5±0.7		1.5±0.2		1.4±0.7		0.61
Total vessels treated, n							0.31
1	204	82	24	82	26	90	
2	46	18	5	18	3	10	
Total stents placed, n	1.6±0.9		1.7±0.3		1.7±1.1		0.74
Use of DES	149	60	15	52	15	52	
GP IIb/IIIa use	146	58	17	59	16	55	0.98
PCI vessel							
LAD	135	54	16	56	10	34	0.037
LM	7	3	0	1	1	3	0.51
RCA	71	28	9	30	14	48	0.06
LCx	73	29	8	26	6	21	0.51
Vein graft	10	4	1	4	1	3	0.80

IABP indicates intra-aortic balloon pump; PCI, percutaneous coronary intervention; DES, drug-eluting stent; LAD, left anterior descending; LM, left main; RCA, right coronary artery; LCx, left circumflex.

were no differences in early or late major adverse cardiovascular outcomes in comparison with a matched control group of nonallergic patients. Moreover there was no evidence of clinically relevant systemic or local immune-mediated responses after stent placement. Along these lines, a study of dermatitis patients in Denmark recently identified 17 patients with allergy to nickel or chromium who had undergone stenting.¹⁴ Of these, 2 patients had the single end point of repeat coronary intervention (any vessel), statistically similar to nonallergic patients.

In general, prior clinical studies have suggested an increased propensity for restenosis or re-restenosis in metal-allergic patients. Specific concern was raised in regard to gold. Placement of gold-containing stents appeared to induce systemic sensitization,^{15,16} and rates of restenosis were found to be higher in gold-allergic versus nonallergic patients.¹²

Such stents are no longer in use. Regarding nongold stents, Koster et al¹⁰ performed patch testing for metal allergies on 131 patients undergoing repeat angiography for suspected restenosis approximately 6 months after bare metal stenting. Of these, 10 patients (8%) had positive patch reactions, all of whom were found to have binary in-stent restenosis. In contrast, of the remaining 121 patients who were patch-negative, only 79 (65%) had restenosis, a statistically significant difference. The authors interpreted these findings to suggest an allergic reaction to implanted metal was a trigger for restenosis. A similarly designed study identified patch positivity in 2 of 20 (10%) patients with restenosis and 8 of 89 (9%) without, a nonsignificant difference.¹¹ However, patch positivity was significantly more frequent in a group with recurrent restenosis (9/23) compared with a nonrecurrence group (5/42), leading the authors to postulate an allergic

Table 4. In-Hospital Outcomes After Stent Placement in Metal Allergy Patients and Matched Control Subjects

Variable	Control Subjects (n=250)		Control Subjects, Weighted (n=29)		Allergic (n=29)		P Value*
	n	%	n	%	n	%	
Procedural success	250	100	29	100	29	100	
Death/Q-wave MI/CABG	0	0	0	0	0	0	
Any MI	9	4	3	9	1	3	0.68
MI/TVR	11	4	3	9	1	3	0.68
Emergency use of IABP	0	0	0	0	2	7	0.025
Femoral occlusion	0	0	0	0	1	3	0.10
Hematoma	7	3	1	5	1	3	1.00
Cardiac arrest/shock	4	2	0	1	1	3	0.32
Heart block	2	1	0	1	0	0	1.00
Renal failure	2	1	0	1	0	0	1.00

MI indicates myocardial infarction; CABG, coronary artery bypass graft; TVR, target vessel revascularization; IABP, intra-aortic balloon pump.

*Fisher exact test.

mechanism behind recurrent rather than de novo restenosis. It is also notable that in the larger of these studies, where patch testing was performed in consecutive patients suspected to have restenosis,¹⁰ there was no overall difference in mean diameter in-stent restenosis in allergic versus nonallergic groups. Moreover, a hypersensitivity-mediated reaction in allergic patients might be expected to produce a diffuse rather than focal stent reaction. However, in this study, 3 of the 10 allergic patients exhibited a focal pattern of in-stent restenosis; excluding these patients might then affect the study's interpretation.

Our study differed from prior studies in 3 major aspects. First, we evaluated clinical rather than angiographic outcomes. Related to this, the prior studies by design did not include patients who had clinical events without undergoing angiography. Second, we defined metal allergy by history rather than patch testing. The purpose was to specifically address the clinical dilemma of whether to place a stent when encountered with a patient who offers a history of allergy to metal components. Eleven patients had positive patch tests (there were no patch-negative patients), and there were no adverse early or late outcomes in this subset, either. Third, we only included patients who had a documented history of metal allergy before coronary stent placement. In prior studies, patch testing was performed many months after coronary intervention, raising the possibility that sensitization had occurred directly as a result of stent placement. These differences in patient selection criteria may have contributed to the contrasting findings of the current and prior studies.

Sample size and the small number of observed events remain an important statistical limitation. In this regard, a tempered interpretation of the data might be that there is no clear evidence of harm. Given the frequency of metal contact allergy reported in the general population and the lack of systematic specific enquiry regarding metal allergy in all PCI patients in this study, it is inevitable that a number of patients

with allergy were not included. Acknowledging this, it could be argued that the study group (comprising those with a documented clinical history) may have included those with the most severe allergies and thereby of most clinical interest, but this remains speculative. An additional limitation of the present study is that it is a retrospective analysis from a single institution, which may limit its broad applicability. A large-scale, prospective study might address these limitations.

Conclusions

This single-center, retrospective study suggests that coronary stent implantation in patients with a history of metal allergy is not associated with adverse early or late cardiovascular outcomes.

Disclosures

None.

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Outcomes After Coronary Stent Implantation in Patients With Metal Allergy

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Supplementary Table 1

Type and percentage metal composition of stents placed in metal allergy patients

Metal Platform	Number	Stent type (n)	Ni (%)	Co (%)	Cr (%)	Mb (%)	Fe (%)	Ti (%)
316L Stainless Steel	35	Cypher DES (15) BX-Velocity (11) Liberté (2) Multilink (7)	14	-	18	2.7	64	-
L606 Cobalt Chromium	11	Xience DES (7) Vision (4)	10	50	20	-	-	15
MP35N Cobalt Chromium	4	Endeavor DES (4)	35	34	20	9.7	-	-

Cypher drug eluting and BX-velocity bare metal (Cordis Corporation, Bridgewater NJ); Liberté bare metal (Boston Scientific Corporation, Natick MA); ACS Multilink bare metal (Guidant Corporation, Santa Clara CA); Xience drug eluting and Vision bare metal (Abbott Laboratories, Abbott Park IL); Endeavor drug-eluting (Medtronic Incorporated, Minneapolis MN)

Supplementary Table 2

In-hospital outcomes after stent placement in metal allergic and entire remaining PCI population

Variable	Controls n=13,796 No. (%)	Allergic n=29 No. (%)	P
Death	209 (2%)	0 (0%)	1.00
Any MI	628 (5%)	1 (3%)	1.00
Q-wave MI	38 (0%)	0 (0%)	1.00
In-hospital CABG	64 (0%)	0 (0%)	1.00
Death/MI/CABG/TVR	872 (6%)	1 (3%)	1.00
Emergency use of IABP	270 (2%)	2 (7%)	0.11
Femoral occlusion	9 (0%)	1 (3%)	0.021
Femoral bleed	106 (1%)	0 (0%)	1.00
Cardiac arrest	137 (1%)	0 (0%)	1.00
Shock	298 (2%)	1 (3%)	0.47
Heart block	154 (1%)	0 (0%)	1.00
Renal failure	154 (1%)	0 (0%)	1.00

* Fisher's exact test

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