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Original article

Demographic and Clinical Characteristics of Patients With Stable Coronary Artery Disease: Results From the CLARIFY Registry in Spain

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ABSTRACT

Introduction and objectives: Coronary artery disease is associated with high morbidity and mortality. The objective of the CLARIFY registry is to study the treatment of outpatients with coronary artery disease in the setting of daily clinical practice.
Methods: The CLARIFY registry is a prospective registry conducted in 41 countries that included outpatients with stable coronary artery disease attending primary care or specialist units between October 2009 and June 2010. The present study describes the baseline characteristics of the Spanish cohort compared with the western European cohorts included in the registry.
Results: A total of 33 248 patients were included: 14 726 in western Europe and 2257 in Spain (selected by 192 cardiologists). The majority of the participants in Spain were men (81%) with a mean age of 65 years. There was a higher frequency of diabetes (34% vs 25%; $P < .0001$), coronary artery disease family history (19% vs 31%; $P < .0001$), myocardial infarction (64% vs 60%; $P < .0001$), and stroke (5% vs 3%; $P = .0007$) in the Spanish cohort than in the western European cohorts. The most common treatments in the Spanish sample were lipid-lowering drugs (96%), acetylsalicylic acid (89%), and beta-blockers (74%).
Conclusions: Patients in the Spanish cohort are similar to those in the western European cohorts and seem to be representative of the Spanish population with coronary artery disease. Therefore, they form a suitable basis for the study of prognostic factors at 5-year follow-up.

Características demográficas y clínicas de los pacientes con enfermedad coronaria estable: resultados del registro CLARIFY en España

Palabras clave:
Enfermedad arterial coronaria
Registro
Factores de riesgo

RESUMEN

Introducción y objetivos: La enfermedad arterial coronaria se asocia con elevada morbimortalidad. El objetivo de este registro es conocer la realidad de la práctica clínica diaria de pacientes ambulatorios con enfermedad arterial coronaria.
Métodos: Registro prospectivo realizado en 41 países en el que se incluyó a pacientes ambulatorios con enfermedad arterial coronaria estable que acudieron a consultas de atención primaria o especializada entre octubre de 2009 y junio de 2010. En este trabajo se describen las características de la visita basal de la cohorte española y su comparación con los demás países de Europa occidental participantes en el registro.
Resultados: Se incluyó a 33.248 pacientes, 14.726 en Europa occidental y 2.257 en España (por 192 especialistas en Cardiología). En España, la media de edad fue 65 años, la mayoría varones (81%). En la cohorte española, respecto al resto de Europa occidental, se observó mayor frecuencia de diabetes mellitus (el 34 frente al 25%; $p < 0,0001$), infarto de miocardio (el 64 frente al 60%; $p < 0,0001$) e ictus (el 5 frente al 3%; $p = 0,0007$) y menor frecuencia de antecedentes familiares de enfermedad arterial coronaria (el 19 frente al 31%; $p < 0,0001$). Los tratamientos más comunes en la muestra española fueron los hipolipemiantes (96%), el ácido acetilsalicílico (89%) y los bloqueadores beta (74%).
Conclusiones: Los pacientes de la cohorte española son similares a los de los demás países europeos participantes en el registro y parecen ser representativos de la población española con enfermedad arterial coronaria. Por lo tanto, constituyen una buena base para el estudio de los factores pronósticos que se pretende realizar a los 5 años de seguimiento.

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Abbreviations

CAD: coronary artery disease
DM: diabetes mellitus
HR: heart rate

INTRODUCTION

Coronary artery disease (CAD) remains the leading cause of death in Europe.[1] However, data released in 2008 show a recent fall in CAD mortality in most European countries, due to advances in prevention strategies and more effective treatments, whereas it has risen in some central and eastern European countries.[1] Although these advances have improved CAD outcomes, the number of CAD patients has increased, changing the clinical practice setting and leading to the high economic burden of €192 billion per year in the European Union.[1]

The high prevalence, morbidity and mortality, and economic burden of CAD have led to changes in the European guidelines on cardiovascular disease prevention.[2] These changes include new sections on risk factors, such as heart rate (HR). The importance of HR in the outcome of stable CAD patients has been supported by extensive evidence.[3]

Information on patients seen in daily clinical practice is needed to determine to what extent the recommendations are being applied and to what degree disease outcomes are improving. Patient data from clinical trials are useful for evaluating treatment, but do not represent clinical practice due to the stringent patient selection process and because patient follow-up and treatment is guided by the trial protocol. Patient registries are the ideal source of information on CAD patients. Although several CAD patient registries have recently been developed, they are limited by being restricted to a particular geographical area[4] or by only addressing certain CAD conditions, especially stable angina[5] or acute coronary syndrome.[6,7]

The CLARIFY[8,9] registry was developed with the main aim of obtaining worldwide data on the treatment of all CAD outpatients in the setting of daily clinical practice and of identifying the determinants, including HR, of long-term outcomes in this population. Even though HR has been associated with increased cardiovascular risk[10] it is not yet a routine component of cardiovascular assessment; furthermore, its prognostic value and to what extent it is applied in clinical practice remains unknown. This paper describes and compares the demographic and clinical characteristics of the Spanish cohort with other western European cohorts.

METHODS

CLARIFY is an international prospective registry, launched in 41 countries worldwide. Its main objective is to describe the demographic and clinical characteristics of stable CAD outpatients seen in daily clinical practice by the medical specialists (cardiologists, internists, and primary care physicians) in charge of managing these patients in each participating country. A secondary objective is to develop a risk prediction model by identifying long-term prognostic factors, including resting HR. The CLARIFY study is being conducted in accordance with the principles embodied in the Declaration of Helsinki. The present study was reviewed and approved by the Clinical Research Ethics Committee of the *Hospital Clínico San Carlos* in Madrid.

The CLARIFY study population consists of stable CAD outpatients attending primary care centers or specialist units (cardiology and internal medicine) worldwide. In each country, the national coordinators selected the participating centers according to the distribution of coronary patients and the health care organizational structure, such that the sample was representative of the epidemiological patterns in each country. Each selected physician included the first 10 consecutive patients attending his or her center who met the eligibility criteria. The national coordinators of the CLARIFY registry in Spain decided that only cardiologists who were based in hospitals or outpatient centers could participate because these specialists are responsible for making decisions about stable CAD patients. The list of researchers is shown in the supplementary material.

The registry includes stable CAD outpatients with at least 1 of the following conditions: documented myocardial infarction that occurred more than 3 months earlier; at least 1 coronary stenosis blocking > 50% of the artery on angiography; chest pain with myocardial ischemia confirmed by stress electrocardiogram, stress echocardiography, or myocardial imaging; coronary artery bypass graft or percutaneous coronary intervention conducted more than 3 months before inclusion. Patients were excluded if they had been hospitalized for cardiovascular disease in the last 3 months, were scheduled for revascularization, or their condition hindered their participation in the study and the 5-year follow-up period.

Patients were recruited between October 2009 and June 2010 worldwide and from April to June 2010 in Spain. All patients will be followed up for 5 years with annual visits. Data collection is by electronic forms translated into the local language. At baseline, patients were evaluated for demographic information, risk factors, lifestyle, medical history, physical examination, current symptoms, data from the most recent tests, and current chronic medical treatments. At the annual visits, this information is updated and data are collected on the patient's clinical course and cardiovascular mortality and morbidity. This is an observational study and thus all the information is collected during daily clinical practice in each center, as documented in the patients' medical history.

Based on data from previous studies,[5] the total size of the sample of the registry was determined by estimating cardiovascular mortality and mortality or cardiovascular events to be 2% and 4.5% per year, respectively. At least 31 000 participants are expected to be selected with an estimated 5% loss to follow-up per year. Thus, the expected number of cardiovascular deaths will be approximately 2300. On the basis of the analysis of HR as a categorical variable (population divided into HR quartiles), we used a conservative approach that compared the highest HR quartile to the other quartiles to establish the risk of cardiovascular mortality. This comparison resulted in a minimum statistical power of 80% to identify a 20% increase in risk for the group with the highest HR. If HR is considered a continuous variable, a power of 90% to detect an instantaneous hazard ratio of 1.06 for each 10 bpm increase in HR would be obtained at a significance level of 5%. In general, each participating country had to recruit a mean of 25 patients (range, 12.5-50) per million population to obtain a representative sample.

The *post hoc* analysis presented in this article describes the baseline characteristics of the sample in Spain and other western European countries (Germany, Austria, Belgium, Denmark, France, Greece, Ireland, Italy, the Netherlands, Portugal, Switzerland, the United Kingdom) participating in the CLARIFY registry. Continuous variables are expressed as mean (standard deviation) or median [interquartile range] according to the data distribution. Categorical variables are expressed as absolute frequencies and percentages. Continuous variables (Spanish subcohort vs western European subcohorts) were compared using simple analysis of variance (ANOVA) or the Kruskal-Wallis test according to the data

distribution. Categorical variables were compared using the chi-square test. In all cases, the results were considered significant when $P < .05$.

RESULTS

The CLARIFY registry included 33 248 participants from 41 countries, of whom 14 726 were from the western European countries included in the present analysis. A total of 192 cardiologists recruited the 2257 participants from Spain. The demographic characteristics of the patients from Spain and the rest of the sample are summarized in Table 1. The majority of the participants were men (81% in Spain and 79% in the rest of the sample) and mean age was 65 years in the Spanish sample and 66 years in the remaining sample.

Risk factors and lifestyle habits are shown in Table 2. The percentage of current smokers was lower in Spain than in the other western European countries, and the percentage of exsmokers was higher in Spain (Table 2). In the Spanish sample, 78% of patients had dyslipidemia, 68% had hypertension, 34% had diabetes mellitus (DM), and 13% had peripheral artery disease. The greatest differences between Spain and the other western European countries were in the prevalence of DM (34% vs 25%, $P < .0001$) and in having a family history of premature CAD (19% vs 31%, $P < .0001$). Myocardial infarction (64% vs 60%, $P < .0001$) and stroke (5% vs 3%, $P = .0007$) were more common in Spain than in the rest of the sample, whereas carotid artery disease was less common in Spain (5% vs 9%, $P < .0001$) (Table 3). Tables 4 and 5 show the clinical profile and baseline symptoms of the patients.

Table 6 shows the treatment the patients were receiving at the time of the baseline visit. The most common treatments in the Spanish sample were lipid-lowering drugs (96%), aspirin (89%), and beta-blockers (74%). The greatest difference between Spain and the other western European countries was in the higher frequency of specific treatments such as ivabradine, antidiabetic agents, long-acting nitrates, and proton pump inhibitors in the Spanish cohort.

DISCUSSION

The results of this study show that the sociodemographic and clinical characteristics of the stable CAD patients in the Spanish cohort of the CLARIFY registry are similar to those of patients in the other participating western European countries. These characteristics appear to be representative of the Spanish population with CAD, since they are generally similar to those reported by other studies that also included patients with CAD in both local[4] and international settings.[11,12]

More than half of the participants in the Spanish sample were men with a mean age of approximately 65 years, which is similar to the mean age previously observed in this population.[4,11,13] Some significant differences were found between the Spanish cohort and the other cohorts, although in principle these differences were not expected. The observed difference in some demographic characteristics, such as age, may have been the result of minor differences of little importance but which became statistically significant due to the large sample size. The observed differences in educational level may have been partly due to differences in the way education systems are classified in each country. There were also unexpected differences in having a family history of CAD or DM. These differences may have been due to under-reporting by the cardiologists, rather than to a real difference between groups.

Tobacco consumption was low, and the percentage of smokers (9%) was similar to that reported in other Spanish registries on coronary heart disease.[4,13] The percentage of smokers was also slightly lower than in the other western European countries, a finding that has also been reported in other international registries that included Spanish patients with coronary heart disease.[11,13] Comparative studies conducted in Europe in CAD patients show a decrease in tobacco consumption in Spain over the last 10 years (18% in Spain vs 21% in Europe).[14] This trend reflects a change in lifestyle among CAD patients in Europe; the need to decrease tobacco consumption has been demonstrated and remains a fundamental aspect for the secondary prevention of CAD.[2]

The pattern of other risk factors is consistent with that previously observed in this population.[4,11,13,14] Thus, the prevalence of DM in the Spanish cohort was similar to that observed in other registries[11,13,14] and somewhat lower than that reported in patients with high cardiovascular risk.[15,16] The rate of hypertension was also similar to that reported in other studies[11,13] and lower than that observed in patients with acute CAD.[16]

Although the differences in clinical profile between the Spanish cohort and the western European cohorts in parameters such as body mass index, diastolic blood pressure and HR were statistically significant ($P < .05$) (Table 4), the absolute value of these

Table 1
Sociodemographic Characteristics

	Spain (n = 2257)	Other countries (n = 12 469)	*P*
Age, mean (SD), y	65.3 (10.8)	66.3 (10.0)	< .0001
Men	1817 (81)	9889 (79.4)	.0756
Caucasian	2133 (94.5)	9010 (72.3)	*
Employment			< .0001
Full-time	546 (24.3)	2600 (20.9)	
Half-time	71 (3.2)	661 (5.3)	
Disabled	155 (6.9)	322 (2.6)	
Unemployed	61 (2.7)	322 (2.6)	
Retired	1329 (59.1)	8305 (66.7)	
Other	86 (3.8)	249 (2)	
Education			< .0001
Primary (or less)	1180 (52.5)	3654 (29.3)	
Secondary	739 (32.9)	6186 (49.7)	
University	329 (14.6)	2619 (21.0)	

SD, standard deviation.
* Not calculated.
Unless otherwise indicated, the data are expressed as No. (%).

Table 2
Risk Factors and Lifestyle Habits

	Spain (n = 2257)	Other countries (n = 12 469)	*P*
Family history of premature CAD	429 (19.1)	3805 (30.5)	< .0001
Treated hypertension	1518 (67.5)	8460 (67.9)	.7253
Diabetes mellitus	753 (33.5)	3138 (25.2)	< .0001
Dyslipidemia	1743 (77.5)	9520 (76.4)	.2464
Peripheral artery disease	297 (13.2)	1537 (12.3)	.2482
Smoking			< .0001
Smoker	211 (9.4)	1467 (11.8)	
Exsmoker	1323 (58.9)	6105 (49.0)	
Nonsmoker	714 (31.8)	4888 (39.2)	
Alcohol consumption (drinks/wk)			< .0001
0	980 (43.6)	3974 (31.1)	
> 0 and < 20	1129 (50.2)	7868 (63.2)	
> 20	139 (6.2)	616 (5.0)	
Stimulant drinks			< .0001
Cafe	1061 (47.2)	7693 (61.8)	
Tea	53 (2.4)	2576 (20.7)	
None	1134 (50.4)	2188 (17.6)	
Weekly physical activity			< .0001
None	338 (15.0)	2209 (17.8)	
Light physical activity most weeks	1193 (53.1)	5902 (47.4)	
Vigorous physical activity for at least 20 min, 1-2 times/wk	349 (15.5)	2350 (18.9)	
Vigorous physical activity ≥20 min ≥3 times/wk	368 (16.4)	1994 (16.1)	

CAD, coronary artery disease.
Data are expressed as No. (%).

differences was of no clinical relevance. The mean blood pressure in all the CLARIFY cohorts was within the range recommended by the clinical practice guidelines[2] and was slightly lower than that recently observed in CAD patients in Europe.[12] However, the average resting HR (65 bpm) in all the cohorts exceeded the recommended target rate (55-60 bpm).[17] Recently published data from the entire CLARIFY registry show that an HR > 60 bpm was associated with a higher prevalence and greater severity of angina.[9] These data indicate the need for improved treatment to reduce HR in patients with stable angina to the recommended target rate of 60 bpm.[17]

The most pronounced differences between the Spanish and European cohorts were related to specific treatments. Although demographic and clinical characteristics did not generally differ between cohorts, the differences observed in treatment could indicate different clinical practices in each country, thus underlining the need for an international registry similar to that presented here. Follow-up data from the registry are needed to understand the prognostic implications of these differences. To date, data from the baseline visit only show that there are specific differences in treatments between the Spanish and western European cohorts. These differences mainly involve the use of

Table 3
Medical History

	Spain (n = 2257)	Other countries (n = 12 469)	*P*
Confirmed CAD			
Myocardial infarction	1430 (63.6)	6988 (59.1)	< .0001
PCI	1388 (61.7)	7692 (61.7)	.9962
Revascularization surgery	433 (19.3)	3391 (27.2)	< .0001
Other			
Abdominal aortic aneurysm	54 (2.4)	306 (2.5)	.8809
Carotid artery disease	121(5.4)	1087 (8.7)	< .0001
Implantable cardioverter-defibrillator	48 (2.1)	228 (1.8)	.3263
Pacemaker	66 (3.0)	393 (3.2)	.5836
Stroke	101 (4.5)	386 (3.1)	.0007
Transient ischemic attack	75 (3.3)	413 (3.3)	.956
Hospitalized for CHF	116 (5.2)	459 (3.7)	.0009
Atrial fibrillation/flutter	203 (9.0)	1047 (8.4)	.3268
Asthma/COPD	235 (10.5)	1166 (9.4)	.0904

CAD, coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; PCI, percutaneous coronary intervention.
Data are expressed as No. (%).

Table 4
Baseline Clinical Profile

	Spain (n = 2257)	Other countries (n = 12 469)	*P*
BMI, kg/m²	27.8 [25.7-30.5]	27.5 [25.1-30.4]	< .0001
Waist circumference, cm	99 [91-106]	99 [90-107]	.9446
SBP, mean (SD), mmHg	131 (16)	131 (16)	.3225
DBP, mean (SD), mmHg	76 (10)	77 (9)	< .0001
HR by pulse palpation, mean (SD), bpm	66 (11)	66 (11)	.0018
HR on ECG, mean (SD), bpm	65 (11)	65 (11)	.1046
ECG			
Sinus rhythm	1942 (93)	8881(94)	.4721
Atrial fibrillation/flutter	95 (5)	387 (4)	
Paced rhythm	48 (2)	194 (2)	
LBBB	154 (7)	501(5)	.0002

BMI, body mass index; DBP, diastolic blood pressure; ECG, electrocardiogram; HR, heart rate; LBBB, left bundle branch block; SBP, systolic blood pressure; SD, standard deviation.
Unless otherwise indicated, the data are expressed as No. (%) or median [interquartile range].

cardiovascular drugs such as ivabradine and long-acting nitrates, which were more frequently used in the Spanish sample (20% and 32%, respectively) than in the other European countries (12% and 16%, respectively). However, the observed difference in the use of antidiabetic agents (30% in the Spanish cohort and 21% in the other cohorts) could be explained by the higher prevalence of DM recorded in Spain (34% in Spain and 25% in other western European countries). Furthermore, the increased use of proton pump inhibitors in the Spanish cohort is striking compared with the other cohorts and with other treatments. Although the abuse of these drugs in Spain is well known,[18,19] the marked difference between Spain and the other countries cannot be explained by differences in age or in the use of medications that increase the risk of bleeding, since both factors are similar in both groups. In the absence of additional data on comorbidities that may be associated with this increase, it can only be speculated that the use of these drugs in Spanish clinical practice must strongly differ from their use in the other western European countries in the registry.

Overall, the pattern of use of cardiovascular drugs reported in the CLARIFY registry is similar to that previously reported for the Spanish population with CAD, with the exception of specific treatments such as beta-blockers and lipid-lowering drugs, whose use is slightly higher than that reported in similar registries.[4,11,20] The number of prescriptions for beta-blockers is even higher than that previously observed in patients hospitalized with acute myocardial infarction.[21] The clinical practice guidelines recommend beta-blockers in these patients and even in patients with type II diabetes. The widespread use of antiplatelet agents was similar to that observed in the total sample and to that published by other studies,[4,12] but was slightly higher than in other registries.[20] The level of use is consistent with the clinical guidelines, which recommend antiplatelet therapy in all patients with CAD unless contraindicated.[2] The cross-sectional design of the present study does not allow assessment of the degree of nonadherence with clinical practice guidelines in drug prescription and its possible causes; however, this information can be analyzed during follow-up of the registry, which, unlike previous registries,[22] has the advantage that it will allow longitudinal and prospective data collection.

Furthermore, this prospective registry is ongoing and we expect to be able to construct a prediction model that includes factors such as DM, dyslipidemia, obesity[23] and HR,[3] with a demonstrated important prognostic role in the mortality rates of these patients. Finally, the CLARIFY registry will identify and provide patient cohorts that could be of interest to future clinical studies on improving the management of CAD. It would also be of interest to assess whether there are differences between specific subgroups, since there appear to be differences, for example, between men and women in the control of risk factors after an acute coronary episode[24] despite their receiving similar treatment.[24,25]

Strengths and Limitations

Some limitations should be considered when interpreting the results of this study, such as the use of convenience sampling

Table 5
Current Symptoms

	Spain (n = 2257)	Other countries (n = 12 469)	*P*
Angina	489 (21.8)	1565 (12.6)	< .0001
CCS I	161 (7.2)	561 (4.5)	< .0001
CCS II	283 (12.6)	760 (6.1)	
CCS III	43 (1.91)	211 (1.7)	
CCS IV	2 (0.1)	32 (0.3)	
CHF symptoms			
No symptoms	2084 (92.8)	11 581 (93.0)	.8992
With NYHA II symptoms	137 (6.1)	729 (5.9)	
With NYHA III symptoms	26 (1.2)	147 (1.2)	

CCS, Canadian Cardiovascular Society class; CHF, congestive heart failure; NYHA, New York Heart Association functional class.
Data are expressed as No. (%).

Table 6
Treatments

	Spain (n = 2257)	Other countries (n = 12 469)	*P*
Cardiovascular treatments			
Antiplatelet agents			
ASA	1994 (88.74)	10 477 (84.13)	< .0001
Thienopyridine	656 (29.27)	3184 (25.59)	.0003
Other antiplatelet agents	202 (8.99)	939 (7.55)	.0187
Anticoagulants	214 (9.52)	1191 (9.56)	.9516
Beta-blockers	1659 (73.83)	9005 (72.31)	.1373
Ivabradine	443 (19.72)	1440 (11.56)	< .0001
Calcium channel blockers	668 (29.73)	3065 (24.62)	< .0001
ACEI and/or ARB	1639 (72.94)	9419 (75.64)	.0065
Lipid-lowering drugs	2148 (95.59)	11 535 (92.63)	< .0001
Long-acting nitrates	710 (31.6)	1989 (15.97)	< .0001
Other antiangina drugs	116 (5.17)	869 (6.98)	.0016
Diuretics	651 (28.98)	3813 (30.62)	.12
Other antihypertensive drugs	126 (5.61)	897 (7.2)	.0064
Digoxin and derivatives	61 (2.71)	244 (1.96)	.0208
Amiodarone/dronedarone	63 (2.80)	373 (3)	.6221
Other antiarrhythmic drugs	15 (0.67)	137 (1.1)	.0617
Other treatments			
NSAIDs	104 (4.64)	642 (5.16)	.3025
Antidiabetic agents	682 (30.35)	2667 (21.42)	< .0001
Proton pump inhibitors	1279 (56.95)	4032 (32.38)	< .0001
THRT	69 (3.07)	772 (6.2)	< .0001
HRT in postmenopausal women	3 (0.13)	54 (0.43)	.04
Treatment for erectile dysfunction	53 (2.36)	277 (2.22)	.6936

ACEI, angiotensin-converting enzyme inhibitors; ARB, angiotensin II receptor antagonists; ASA, acetylsalicylic acid; HRT, hormone replacement therapy; NSAIDs, nonsteroid anti-inflammatory agents; THRT, thyroid hormone replacement therapy.
Data are expressed as No. (%).

rather than randomized sampling to select the centers and patients. The use of this method raises the issue of whether the sample is representative of the population under study. However, several aspects can be cited in favor of its representativeness, such as the large number of patients enrolled in the study and, in particular, the similarity of its results with those of other studies in this patient population. Despite these limitations, the registry has several strengths, including the large number of participating countries, making the results more generalizable. The CLARIFY registry is not restricted to a particular geographical area and provides information on daily clinical practice in stable CAD patients.

CONCLUSIONS

The baseline data provided by the CLARIFY registry indicate that the stable CAD patients in the Spanish sample appear to be representative of the Spanish population with CAD and are similar to stable CAD patients in other western European countries. The results of the 5-year follow-up will provide information on how these patients are managed in clinical practice and the degree of adherence to the recommendations of the clinical practice guidelines, leading to improvements in the treatment of this patient population.

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CONFLICTS OF INTEREST

None declared.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.rec.2013.10.020.

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