Prevalence and outcome of newly detected diabetes in patients who undergo percutaneous coronary intervention

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Aims
The beneficial effect of specific measures in patients with newly detected diabetes during percutaneous coronary intervention (PCI) has been poorly studied. Here, we determined the prevalence of newly detected diabetes in a cohort of patients who underwent PCI and analysed their clinical outcome.

Methods and results
A prospective study included patients without previous diagnosis of diabetes that were referred for PCI between November 2005 and May 2006. Major cardiac events were registered after admission and during 12 months of follow-up, and oral glucose tolerance was tested at 15 days after hospital discharge. Six hundred and sixty-two consecutive patients were referred to our hospital for PCI. The distribution of the glycometabolic state of the entire population was (95% CI): known diabetes 28.8% (25.2–32.6), newly detected diabetes 16.2% (13.1–19.8), impaired glucose tolerance 24.5% (20.8–28.5), impaired fasting glucose 1% (0.4–2.4), and normal glucose regulation 29.5% (25.5–33.7). In a multivariable analysis, the presence of newly detected diabetes was not an independent predictor of cardiac events after 1 year of follow-up.

Conclusion
The prevalence of diabetes in patients who underwent PCI was very high (45%), 35% of which was patients with newly detected diabetes. In our series newly detected diabetes was not an independent predictor of outcome at 12 months. Nevertheless, this finding requires independent confirmation in other series to draw general conclusions on the whole spectrum of percutaneous interventions.

Keywords
Diabetes mellitus • Impaired glucose regulation • Oral glucose tolerance test • Coronary angioplasty

Introduction
Diabetes mellitus is an important public health problem. Its prevalence is variable and increases with age, i.e. in the USA 9.6% of the population aged over 20 years suffer from known diabetes.1 Data from European citizens show that prevalence of diabetes mellitus and impaired glucose in elderly people is 10–20% and 30–35%, respectively.2 Results from the Framingham heart study show that incidence has doubled in the last 30 years3 and an increase in prevalence worldwide is predicted for the forthcoming decades.4

In patients with coronary artery disease, a number of studies have demonstrated a greater prevalence of diabetes compared with the general population.5–7 However, limited data are available in patients who undergo percutaneous coronary intervention (PCI). Muhlestein et al.8 reported that 61% of patients showed abnormal fasting plasma glucose (FPG) and found a significant correlation between FPG and mortality. Diabetes is also known to negatively affect PCI results,9,10 so specific measures such as glycoprotein IIb/IIIa inhibitors and drug-eluting stents during PCI are recommended in these patients.

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The most effective diagnostic method to identify the abnormal glucose regulation (AGR) in patients with coronary artery disease was controversial until the European Society of Cardiology classified the oral glucose tolerance test (OGTT) as a Type I recommendation for patients with cardiovascular disease without known diabetes to detect glucose intolerance or newly detected diabetes. Oral glucose tolerance test offers higher accuracy in comparison with FPG. Here, we aimed to determine the prevalence of AGR, especially newly detected diabetes, in patients referred for PCI, to describe the clinical profile of patients with prediabetes and newly detected diabetes and analyse the in-hospital and 12-month outcome in patients with newly detected diabetes and prediabetes and to compare it with that of patients with known diabetes. The hypothesis of the study would be the possible worse outcome in patients with newly detected diabetes who undergo PCI and consequently the theoretical benefit of specific measurements of revascularization.

Methods

All consecutive patients managed with PCI in a tertiary hospital that is centre of reference of interventional cardiology and cardiac surgery for a population of 1,088,036 inhabitants were prospectively recruited from 1 November 2005 to 31 May 2006. Patients with ST-elevation myocardial infarction were excluded from the study due to the fact that in our centre the program of primary PCI is not universal and is performed only while the catheterization laboratory is opened.

Troponin levels were systematically registered 6 h post-PCI. Before hospital discharge, the following data were obtained by clinical interview: demographic data, cardiovascular risk factors, family history of early coronary disease, and diabetes, previous history of coronary artery disease, presence of peripheral artery or cerebrovascular disease, extension of previously diagnosed coronary artery disease, description of PCI, in-hospital cardiovascular events, and medications on discharge. Blood pressure, weight, height, and waist circumference were also recorded. Two weeks after discharge, patients without a previous diagnosis of diabetes underwent FPG and OGTT with 75 g of glucose. Blood samples from every patient were drawn to measure basal insulin, glycated haemoglobin A1c (HbA1c), lipid, hepatic, and renal profile and microalbuminuria. Laboratory studies were done according to the normal practice of our hospital: glycaemia were analysed by the enzymatic method from Modular Roche Diagnostics (Mannheim, Germany), HbA1c by means of quantification chromatography (ADAMS A1c, Nichols Institute Diagnostics, San Clemente, USA) and insulinemia by immunnoassay electrochemoluminescence (Elecsys 2010, Roche Diagnostics).

Clinical events of the whole population were registered during the admission and 12-month follow-up in the cardiology office or by telephone contact. The last follow-up assessment was on 2 October 2007. In-hospital major adverse cardiovascular events (MACE) included: non-fatal MI and need of percutaneous revascularization or stroke (only the patients discharged alive who performed the OGTT were included in the study). MACE at 12 months were death, non-fatal MI, and new PCI or stroke. The diagnosis of acute myocardial infarction, including the in-hospital and post-PCI, was established following the universal definition of myocardial infarction. All patients gave written informed consent before recruitment and the study was approved by the local research Ethics Committee.

Definition of glycometabolic state

Known diabetes was based on a previous diagnosis before PCI in accordance with the recommendations of the WHO 1999. FPG and OGTT were made 15 days after hospital discharge for patients without a previous diagnosis of diabetes. Plasma glucose levels were measured (mmol/L) at the start of the OGTT (FPG) and at 2 h post-challenge (2 h PC). Patients were divided according to the results of the OGTT (WHO, 1999) as follows: normal glucose regulation: FPG < 6.1 + 2 h PC < 7.8; impaired fasting glucose: FPG ≥ 6.1 and < 7.0 + 2 h PC < 7.8; impaired glucose tolerance: FPG < 7.0 + 2 h PC ≥ 7.8 and < 11.1, and newly detected diabetes: FPG ≥ 7.0 or 2 h PC ≥ 11.1.

The term AGR is used to describe the presence of impaired fasting glucose, impaired glucose tolerance, or newly detected diabetes and the term prediabetes is used to describe the presence of impaired fasting glucose or impaired glucose tolerance. The homeostasis model assessment (HOMA) index was calculated according to the formula described by Matthews et al.: insulin (μU/mL) × glucose (mmol/L)/22.5.

Statistical analysis

Results for normally distributed continuous variables are expressed as the mean value and standard deviation, and continuous variables with non-normal distribution are presented as median values (interquartile intervals). Analysis of normality of the continuous variables was performed with the Kolmogorov–Smirnov test. Categorical variables are expressed as percentages. For the purpose of this analysis, patients with impaired fasting glucose or impaired glucose tolerance were classified within the category of prediabetes. Differences among groups were analysed by means of the non-parametric Mann–Whitney U test for continuous variables. Categorical data were analysed by means of the χ2 test or Fisher’s exact test, as appropriate. Differences were considered to be statistically significant, if the null hypothesis could be rejected with 95% confidence (P < 0.05). We performed a multivariable analysis to determine whether the glycemic status, defined as newly detected diabetes, AGR, glucose levels at baseline or after 2 h were predictors of events at 12 months. The analysis was adjusted by variables that are classically considered as determinants of events (age, indication of PCI, three-vessel disease or left main disease, ejection fraction, treatment with drug-eluting stents, Ilb/Illa inhibitors, and statins). Linear trends were verified using the Cochran–Armitage test for categorical data and regression lines of the logit for each of the continuous variables. We also include a Kaplan–Meier analysis at 12 months. The SPSS 13.0 statistical software package (SPSS Inc., Chicago, IL, USA) was used for all calculations.

Results

Analysis of glycometabolic state in the entire population

Percutaneous coronary intervention was performed over a period of 7 months in 662 consecutive patients in our hospital. Eighty-two patients were excluded due to acute coronary syndrome with ST-segment elevation. Oral glucose tolerance test was not done.
in 167 patients with known diabetes and in another 75 patients without a previous diagnosis of diabetes (41 refused testing, 31 lost contact, and 3 deaths in the following 15 days post-PCI). Oral glucose tolerance test was done in the remaining 338 patients (81.8% of the eligible population). The indication for PCI was due to non-ST elevation acute coronary syndrome in 76.1% and to stable angina in 23.9% (Figure 1).

The true glycometabolic state after performing OGTT in the studied population (n = 580) which underwent PCI (95% CI) was: known diabetes 28.8% (25.2–32.6), newly detected diabetes 16.2% (13.1–19.8), impaired glucose tolerance 24.5% (20.8–28.5), impaired fasting glucose 1% (0.4–2.4), and normal glucose regulation 29.5% (25.5–33.7). No significant differences were seen in the glycometabolic distribution in patients who had undergone PCI for acute coronary syndrome compared with those for stable angina.

Cohort of patients who underwent oral glucose overload

The demographic and clinical characteristics of the population without a previous diagnosis of diabetes are shown in Table 1. The most relevant analytical data are shown in Table 2, and Table 3 shows the characteristics of their coronary disease, data related to PCI, and clinical outcome. In-hospital outcome and 12 months follow-up were successfully obtained in 100 and 95% of patients, respectively.

Follow-up of the patients who underwent the oral glucose overload

Patients with newly detected diabetes presented a trend towards more frequently in-hospital adverse events in comparison with normoglycemic patients (6.5% vs. 1.4%, P = 0.06) (Table 3). However, in the multivariable analysis, the glycemic status of the patients without known diabetes was not predictor of events at 12 months (Table 4) after having adjusted by the variables that are classically considered as determinants of the outcome of the PCI.

Clinical profile and follow-up of the patients with known diabetes

Of the 167 patients with known diabetes, there were 8 in-hospital deaths and 25 patients without complete follow-up at 12 months. Baseline characteristics of the patients were: age 70.2 (60–75), male gender 94 (70.1%), indication of PCI due to acute coronary syndrome 122 (91%), ejection fraction 62% (45–62), left main disease 11 (8.2%), multivessel disease 101 (75.4%), and utilization of drug eluting stents 64 (47.8%). At follow-up, a MACE was registered in 30.6% at 12 months (14 death, 10 myocardial infarction, 14 new PCI, and 3 stroke), a percentage that was significantly higher than in normoglycemics (10.7%, P < 0.001), prediabetics (10.7%, P < 0.001), and patients with newly detected diabetes (12.9%, P < 0.001) (Figure 2).

Discussion

Previous studies show a high prevalence of AGR in patients with coronary artery disease.6,7 In our series, 28.8% had known diabetes, 16.2% newly detected diabetes, 25.5% prediabetes, and 29.5% were normoglycemics. Our results expand previous knowledge of the glycometabolic state in patients with coronary artery disease as this is, to our knowledge, the first study to provide data based on an OGTT specifically in patients who undergo PCI that included a high rate in the performance of OGTT (81.8% of the patients). Furthermore, our series underlines the high diagnostic benefit of the OGTT and the Class I
Table 1: Clinical profile of patients without a previous diagnosis of diabetes mellitus and comparison among subgroups

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 338)</th>
<th>AGR (n = 198)</th>
<th>Normoglycaemia (n = 149)</th>
<th>Prediabetes (n = 121)</th>
<th>NDD (n = 77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66.5 (56–74)</td>
<td>70.2 (58–75)</td>
<td>63.7 (51–73)</td>
<td>67.9 (58–75)</td>
<td>70.6 (58–75)</td>
</tr>
<tr>
<td>Males</td>
<td>271 (80.1)</td>
<td>159 (80.3)</td>
<td>112 (80.0)</td>
<td>96 (79.3)</td>
<td>63 (81.8)</td>
</tr>
<tr>
<td>FH DM</td>
<td>87 (25.7)</td>
<td>58 (29.3)</td>
<td>29 (20.7)</td>
<td>33 (27.2)</td>
<td>25 (32.5)</td>
</tr>
<tr>
<td>Arterial hypertension</td>
<td>168 (49.7)</td>
<td>100 (50.5)</td>
<td>68 (47.1)</td>
<td>56 (46.3)</td>
<td>42 (54.5)</td>
</tr>
<tr>
<td>Dyslipaemia</td>
<td>164 (48.5)</td>
<td>98 (49.5)</td>
<td>66 (48.6)</td>
<td>48 (38.7)</td>
<td>33 (42.7)</td>
</tr>
<tr>
<td>Active smokers</td>
<td>96 (28.4)</td>
<td>50 (25.5)</td>
<td>29 (20.7)</td>
<td>17 (14.0)</td>
<td>17 (22.1)</td>
</tr>
<tr>
<td>Obesity (BMI &gt; 30 kg/m²)</td>
<td>120 (35.5)</td>
<td>72 (36.4)</td>
<td>48 (35.1)</td>
<td>33 (27.2)</td>
<td>17 (22.1)</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>98 (92–102)</td>
<td>98.0 (92–103)</td>
<td>97.2 (91–102)</td>
<td>97.2 (92–103)</td>
<td>98.5 (96–103)</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>134 (126–147)</td>
<td>135 (126–147)</td>
<td>132 (119–145)</td>
<td>133 (120–145)</td>
<td>140 (129–155)</td>
</tr>
<tr>
<td>Previous AMI</td>
<td>126 (37.3)</td>
<td>77 (38.9)</td>
<td>49 (35.0)</td>
<td>46 (38.1)</td>
<td>31 (40.5)</td>
</tr>
<tr>
<td>Previous revascularization</td>
<td>47 (14.3)</td>
<td>24 (12.4)</td>
<td>18 (13.6)</td>
<td>17 (14.0)</td>
<td>15 (19.5)</td>
</tr>
<tr>
<td>Previous vascular disease</td>
<td>52 (15.4)</td>
<td>34 (17.1)</td>
<td>18 (12.9)</td>
<td>15 (12.4)</td>
<td>19 (24.7)</td>
</tr>
<tr>
<td>ACS</td>
<td>257 (76.0)</td>
<td>148 (74.7)</td>
<td>109 (77.8)</td>
<td>89 (73.5)</td>
<td>59 (76.6)</td>
</tr>
<tr>
<td>b-Blockers at discharge</td>
<td>251 (74.3)</td>
<td>145 (73.2)</td>
<td>106 (75.7)</td>
<td>89 (73.5)</td>
<td>51 (67.0)</td>
</tr>
<tr>
<td>ACE-inhibitors/ARB at discharge</td>
<td>135 (39.9)</td>
<td>84 (42.4)</td>
<td>49 (35.0)</td>
<td>45 (36.7)</td>
<td>40 (51.9)</td>
</tr>
<tr>
<td>Statins at discharge</td>
<td>274 (81.1)</td>
<td>157 (73.3)</td>
<td>90 (74.0)</td>
<td>89 (73.5)</td>
<td>63 (81.8)</td>
</tr>
</tbody>
</table>

Data available for all variables in 311 patients. Categorical variables are expressed as absolute values and percentages and numerical variables as medians (lower and upper quartile). Prediabetes: includes impaired fasting glucose and impaired glucose tolerance. AGR: abnormal glucose regulation (includes prediabetes and NDD). NDD: newly detected diabetes. FH DM: family history of diabetes. BP: blood pressure. Previous revascularization: includes PCI and CABG. ACS: acute coronary syndrome.

*P-value between normoglycaemia and AGR.
**P-value between normoglycaemia and prediabetes.
***P-value between normoglycaemia and NDD.
Table 2: Analytical profile of patients without previous diagnosis of diabetes mellitus and comparison among subgroups

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 338)</th>
<th>AGR (n = 198)</th>
<th>Normoglycaemia (n = 140)</th>
<th>Prediabetes (n = 121)</th>
<th>NDD (n = 77)</th>
<th>P-value*</th>
<th>P-value**</th>
<th>P-value***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting plasma glucose (mmol/L)</td>
<td>5.4 (5.0–5.9)</td>
<td>5.6 (5.3–6.2)</td>
<td>5.2 (4.9–5.4)</td>
<td>5.5 (5.0–5.8)</td>
<td>6.2 (5.5–7.0)</td>
<td>a</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>Glycaemia 2H (mmol/L)</td>
<td>8.2 (6.9–10.7)</td>
<td>10.2 (8.6–12.1)</td>
<td>6.5 (5.6–7.2)</td>
<td>8.9 (8.2–10.0)</td>
<td>12.8 (11.8–14.9)</td>
<td>a</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>4.8 (4.5–5.1)</td>
<td>4.9 (4.7–5.2)</td>
<td>4.7 (4.5–4.9)</td>
<td>4.8 (4.6–5.1)</td>
<td>5.2 (4.9–5.5)</td>
<td>0.006</td>
<td>0.003</td>
<td>0.001</td>
</tr>
<tr>
<td>Insulinemia (µU/mL)</td>
<td>7.7 (5.1–11.1)</td>
<td>8.4 (5.3–12.2)</td>
<td>7.0 (4.5–9.9)</td>
<td>7.5 (5.1–12.1)</td>
<td>9.0 (5.8–12.6)</td>
<td>0.003</td>
<td>0.10</td>
<td>0.006</td>
</tr>
<tr>
<td>HOMA</td>
<td>1.8 (1.2–2.8)</td>
<td>2.1 (1.3–3.3)</td>
<td>1.6 (1.1–2.7)</td>
<td>1.8 (1.2–3.1)</td>
<td>2.7 (1.5–4)</td>
<td>0.001</td>
<td>0.03</td>
<td>0.001</td>
</tr>
<tr>
<td>Microalbuminuria (mg/mmol crea)</td>
<td>0.65 (0.30–1.76)</td>
<td>0.76 (0.33–2.30)</td>
<td>0.54 (0.27–0.54)</td>
<td>0.65 (0.32–2.00)</td>
<td>0.82 (0.39–3.22)</td>
<td>0.02</td>
<td>0.17</td>
<td>0.01</td>
</tr>
<tr>
<td>LDL-cholesterol (mmol/L)</td>
<td>2.3 (1.8–2.8)</td>
<td>2.2 (1.7–2.8)</td>
<td>2.3 (1.9–2.8)</td>
<td>2.3 (1.8–2.8)</td>
<td>2.2 (1.7–2.9)</td>
<td>0.31</td>
<td>0.60</td>
<td>0.31</td>
</tr>
<tr>
<td>Triglyceride (mmol/L)</td>
<td>1.3 (1.0–1.8)</td>
<td>1.3 (1.0–1.8)</td>
<td>1.1 (0.9–1.7)</td>
<td>1.3 (0.9–1.8)</td>
<td>1.5 (1.1–2.1)</td>
<td>0.08</td>
<td>0.41</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Data available for all variables in 321 patients. Numerical variables are expressed as medians (lower and upper quartile). Prediabetes includes impaired fasting glucose and impaired glucose tolerance. AGR, abnormal glucose regulation (includes prediabetes and NDD); NDD, newly detected diabetes; Glycaemia 2H, glycaemia 2 h post-challenge; HOMA, homeostasis model assessment.

aP-value is not calculated, because they are different by definition.
*P-value between normoglycemia and AGR.
**P-value between normoglycemia and prediabetes.
***P-value between normoglycemia and NDD.

Newly detected diabetes and clinical implications

Given the poor evolution after PCI in the diabetic population due to higher rate of restenosis, more frequent inflammatory complications, and a trend towards higher rate of repeat PCI, our study raises the question whether patients with newly detected diabetes present a similar risk profile to patients with known diabetes. In our series, newly diabetic patients presented a typical metabolic profile for diabetes and clearly differed from the clinical profile of normoglycemic patients, i.e. higher age and systolic blood pressure, increased triglycerides, previous coronary disease and less frequent multivessel disease, and a trend towards more frequent myocardial infarction at 2 h post-challenge, was not predictor of events at 12 months.

Our hypothesis is based on the idea that the AGR and consequently they probably did not obtain any benefit from PCI. Previous knowledge of the glycometabolic state will also influence the possibility of coronary artery by-pass grafting revascularization in these patients. Thus, the identification of patients with newly detected diabetes who are candidates for revascularization is particularly important. The results of our study raise the question whether patients with newly detected diabetes present a similar risk profile to patients with newly detected diabetes. In our series, newly diabetic patients did not present a metabolic profile for diabetes. Our series shows a trend towards higher rate of restenosis, more frequent inflammatory complications, and a trend towards higher rate of repeat PCI. New evidence from the ACC/AHA guidelines indicates that newly diabetic patients did not have any difference in the outcome of newly detected diabetes. AGR or the values of HOMA or triglycerides in patients with newly detected diabetes. However, in the presence of newly detected diabetes in comparison with patients without diabetes, the AGR may improve the risk profile of patients with newly detected diabetes. This hypothesis is based on the idea that the AGR may improve the risk profile of patients with newly detected diabetes.

The results of our study raise the question whether patients with newly detected diabetes present a similar risk profile to patients with newly detected diabetes. In our series, newly diabetic patients did not have any difference in the outcome of newly detected diabetes. AGR or the values of HOMA or triglycerides in patients with newly detected diabetes. However, in the presence of newly detected diabetes in comparison with patients without diabetes, the AGR may improve the risk profile of patients with newly detected diabetes. This hypothesis is based on the idea that the AGR may improve the risk profile of patients with newly detected diabetes.
Each score may have a particular prognosis and outcome, probably related to the time of evolution of the disease and each one with its specific treatment option. Precisely, the longer follow-up with its associated probability of progression to more severe degrees of dysglycaemia, a different population with higher percentage of patients with abnormal level of glucose at baseline and the lack of utilization of drug eluting stents and IIb/IIIa inhibitors may explain the higher incidence of events reported by Muhlestein et al. in comparison with our series. Larger series of patients followed after PCI are necessary to confirm this hypothesis.
Prediabetes, coronary artery disease, and percutaneous coronary intervention

After performing OGGT, prediabetes was present in 25.5% of our population. The clinical impact and management of prediabetes in patients with coronary artery disease are still controversial. In the follow-up of patients included in the Euro Heart Survey,24 prediabetes was not shown to be an independent prognostic risk factor. Similar results have been shown in post-menopausal females with coronary artery disease and impaired fasting glucose, according to the ADA 2003 criteria.25 In the same way, currently there is no data demonstrating worse results of PCI in prediabetes. Therefore, diagnosis of prediabetes would not imply changes in attitude towards PCI. However, other studies have demonstrated the relationship between prediabetes and cardiovascular clinical events.25,26,28 Both prediabetics and newly diabetics may benefit from other measures. A change in life style improves outcomes in both groups.23,29 and drugs such as metformin and rosiglitazone have demonstrated the ability to delay the progression towards diabetes in prediabetic patients.29,30 Thus, the diagnosis of prediabetes suggests the need for a greater emphasis on secondary prevention.

Study limitations

A limitation of the study is that the OGTT was performed 2 weeks after the hospital discharge and, although ideally it should have been done prior to the PCI, it was not possible due to logistic reasons. However, no differences were found in previous reports when the OGTT was performed in-hospital or in an outpatient basis.31 Moreover, patients in whom OGTT was not performed (75 of 413 eligible patients) were generally older, in a worse functional class and some of them died while in the hospital. As patients with ST-elevation acute coronary syndrome were also excluded, a selection bias cannot be excluded and the results may not be extrapolated to all the patients referred for PCI. Finally, in our series, the lib/llb inhibitors and drug eluting stents were underused in comparison with previous reports, and these may have modified the outcome in the newly diabetic population.

Conclusions

The prevalence of newly detected diabetes and AGR in patients with coronary artery disease who undergo PCI is very high. The presence of newly detected diabetes had no influence in the 1-year outcome. Oral glucose tolerance test performed previously to a PCI procedure may provide valuable information to modify secondary prevention measures, but data to recommend a modification in the strategy of revascularization in these patients are still lacking. Our findings should be confirmed in larger series that include the whole spectrum of patients treated with percutaneous interventions.

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Conflict of interest: none declared.

References


