SCIENTIFIC LETTER

Description of modern practices of percutaneous coronary intervention and identification of risk factors for adverse outcome in the French nationwide OPEN registry

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There is increasing interest in registry data to get a clear picture of contemporary practice in various fields, however many existing registries have significant limitations.[1] The OPEN registry of PCI (percutaneous coronary intervention) used a large number of centres (42% of interventional centres in France) and thus is probably truly representative of national practice. In all centres, consecutive patients were taken during a short period of recruitment to ensure they were representative of the treated population. Follow up was 98.8% and the quality of data was validated by clinical research officers at each participating centre. In OPEN the goals were to define the morbidity and mortality of contemporary PCI in France and to identify factors predictive of adverse outcome.

METHODS

This prospective, observational study was carried out in a cohort of 3109 consecutive patients who underwent PCI in 79 centres located throughout France. Treatment was entirely at the discretion of the clinician, and patients were followed up for one month. The following data were collected at inclusion in the registry: patient demographics, medical history, prescribed treatment, cardiovascular risk factors (hyperlipidaemia, hypertension, diabetes, smoking), and the clinical context of the PCI. Procedural data recorded included; treated arteries, reperfusion (thrombolysis in myocardial infarction (TIMI) flow grade), residual stenosis, number of stents, length of stents, and, if measured, creatine phosphokinase concentration. During one month follow up the following clinical events were recorded: death (vascular or non-vascular), Q wave or non-Q wave MI (myocardial infarction), repeated revascularisation of the target vessel, ischaemic or haemorrhagic stroke, peripheral or major haemorrhagic complications, and any other clinical event requiring specific treatment. All participating centres were visited several times to check source data. All data were double entered onto a database and checked for integrity and consistency.

Sample size was determined to detect a 2% event incidence with 0.5% precision (binomial exact estimation). Two sided 95% confidence intervals (CI) of incidences were determined using the Clopper-Pearson exact method.

Factors determining the occurrence of major clinical events (death or MI or revascularisation of the target vessel) were screened using univariate analysis (two sided Fisher's exact test) and logistic regression analysis was performed on a random subset of 2457 patients. The remaining 20% of patients were used to check the predictive value of the selected logistic model, given its descriptive value was sufficient. The logistic model was built using a stepwise strategy. The significance level for a variable to be entered into, or removed from, the model was set at 5%. Independence of the selected variables was checked by means of the Spearman rank correlation coefficient. In case of relevant correlation between two variables ($r > 0.60$), the first of the two variables entered into the model was retained and the second one discarded. Odds ratios (OR) and 95% CI are provided for the different variables of the model. All statistical analyses were carried out using the SAS package (SAS 6.12 for Windows, SAS Institute, Cary, North Carolina, USA).

RESULTS

The population was mainly male (79%), mean age 64 years, 23% of whom had diabetes. Acute coronary syndromes preceded revascularisation in the majority: unstable angina (38%), MI < 12 hours (11%), MI < 30 days (15%). The left anterior descending artery was the most frequently treated and 27.6% of patients received two or more stents. Arterial access related complications occurred in 2.2% (table 1). One month follow up data were obtained for 3071 registry patients (98.8%).

Using all of the demographic, clinical, and procedural characteristics, a stepwise selection logistic regression procedure was performed. Factors predictive of death/Q-MI/revascularisation were: acute MI < 12 hours (OR 4.1, 95% CI 2.3 to 7.5, p = 0.0001); cardiogenic shock (OR 8.0, 95% CI 3.0 to 21.2, p = 0.0001); procedure failure (OR 1.0, 95% CI 1.01 to 1.03, p = 0.009); number of stents (OR 1.4, 95% CI 1.1 to 1.8, p = 0.009); absence of β blockers (OR 2.0, 95% CI 1.2 to 3.3, p = 0.007); left anterior descending artery (OR 1.7, 95% CI 1.0 to 2.8, p = 0.047).

Factors predictive of bleeding complications, almost all of which related to the arterial access site were: age (OR 1.1, 95% CI 1.0 to 1.1, p = 0.0001); female sex (OR 2, 95% CI 1.2 to 3.4, p = 0.009); smoking (OR 2.6, 95% CI 1.6 to 4.3, p = 0.0002); post-procedural heparin (OR 2.0, 95% CI 1.3 to 3.1, p = 0.003); unstable angina (OR 2.3, 95% CI 1.4 to 3.9, p = 0.0007); MI < 12 hours (OR 2.4, 95% CI 1.2 to 4.6, p = 0.01); MI > 1 month (OR 2.6, 95% CI 1.1 to 6.3, p = 0.03).

DISCUSSION

Registry data are available from a number of other published series, however most have significant limitations and some are limited to specific clinical scenarios or trial exclusion

Table 1 Complications at one month follow up

	Patients (n = 3071)	
	n (%)	95% CI
Death	49 (1.6%)	1.2% to 2.1%
*Myocardial infarction	38 (1.2%)	0.9% to 1.7%
Revascularisation	39 (1.3%)	0.9% to 1.7%
Stroke	10 (0.3%)	0.2% to 0.6%
Puncture site complications	68 (2.2%)	1.7% to 2.8%
Death/Q-MI/revascularisation	91 (3.0%)	2.4% to 3.6%

*With Q wave: 20 (0.7%).

cohorts. The National Heart Lung and Blood Institute (NHLBI) registries are relatively small as a proportion of national activity, and cases are consecutive for specified operators, rather than by centre.[2 3] The German Community Hospitals series from 1992–94 had 98% follow up, however this pre-dates widespread stenting, with a stent rate of only 2.8%.[4] The European registry of cardiac catheter interventions from 1996 concerns activity rather than outcomes.[5]

The OPEN registry attempted to overcome these limitations by using a very large number of national centres, recruiting all patients, and having fully audited one month follow up. OPEN is less selective and more complete in its data collection than most other published series and it provides some of the most reliable and complete, representative outcome data available for contemporary PCI.

The OPEN registry gives an accurate image of PCI in a western country with a high stenting rate, and low IIb/IIIa inhibitor prescription. Major adverse cardiac events occur in roughly 3% of patients and are influenced by modifiable factors such as the number of implanted stents and the lack of β blocker prescription. Bleeding complications were clearly influenced by a prolonged prescription of heparin after the procedure.

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IMAGES IN CARDIOLOGY

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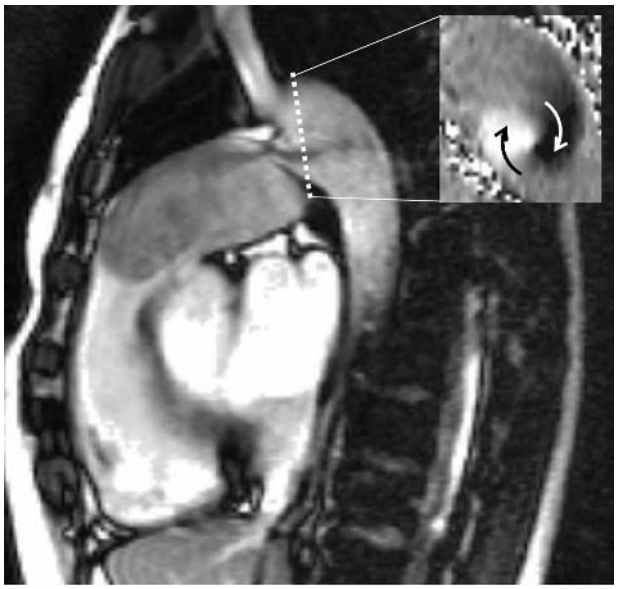
Aortic tornado

The figure shows cardiovascular magnetic resonance visualisation of flow through a patent ductus arteriosus (PDA). The study also showed evidence of a type of flow familiar at the outlet of a bath or in atmospheric storms, but which may not have been detected inside the body before: a converging, tornado-like vortex.

A 21 year old woman with a continuous murmur and pulmonary artery and left ventricular dilatation on echocardiography was imaged. An appropriately aligned cine acquisition showed a dark streak indicative of a jet from the PDA in the upper part of the pulmonary trunk (main panel). Surprisingly, however, a dark streak of signal loss also extended back from the duct into the aortic lumen during systole.

We had seen this phenomenon in a previous PDA patient and suspected the aortic signal loss was caused by gradients of velocity in the ''eye'' of a converging vortex. In the current patient, therefore, we performed phase contrast velocity mapping, encoded head-to-foot, in a plane transecting the presumed vortex, as indicated by the dotted line. The velocity map showed rotation or vorticity of flow in the aorta, clockwise as viewed from the front (inset). The highest velocities in this plane were close to the centre of rotation.

Our interpretation is that the vortex develops as flow converges on the duct from blood that has already gained rotational momentum after passing through curvatures of the arch. The rotating flow spins faster as it is drawn into the eye of the vortex towards the PDA.



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