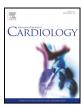
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# Effect of part-time cardiac catheterization facilities in patients with acute myocardial infarction

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#### ABSTRACT

*Background:* Although the easy availability of invasive cardiac care facilities is associated with an increase in their use, their influence on outcomes is not clear. We sought to investigate whether a newly available cardiac catheterization laboratory (CCL) performing percutaneous coronary intervention (PCI) on a part-time (PT) basis might improve outcomes in patients with acute myocardial infarction (AMI).

*Methods*: This was an observational cohort study that included all consecutive patients with AMI admitted to a secondary-level hospital in Spain before and after the PT-CCL opened in January 2006: during 1998–2005 and 2006–2014, respectively. All-cause in-hospital and long-term mortality were the co-primary endpoints. In-hospital complications and length of stay were secondary endpoints. For the analyses, patients were stratified according to propensity-score (PS) quintiles.

*Results*: A total of 5339 patients were recruited, and 50.3% were managed after the opening of the PT-CCL. The PT-CCL was associated with greater use of PCI (81.2 vs. 32.5%, p < 0.001) and guidelines-recommended medication (all p < 0.001), lower risk of recurrent angina (PS-adjusted RR = 0.160, 95% CI 0.115–0.222) and shorter length of hospital stay (PS-adjusted RR for length of stay <8 days = 0.357, 95% CI 0.301–0.422). In patients with NSTEMI, PT-CCL was associated with improved long-term survival (PS-adjusted HR = 0.764, 95% CI 0.602–0.970).

*Conclusions:* In patients with AMI, a new PT-CCL was associated with greater use of PCI and guideline-recommended medication, lower risk of recurrent angina and shorter length of hospital stay. In a subset of patients with NSTEMI, PT-CCL was associated with improved long-term survival.

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#### 1. Background

During the last decade it has been consistently shown that in patients with moderate to high risk non ST-segment elevation acute coronary syndrome (ACS) and ST-segment–elevation myocardial infarction (STEMI), timely revascularization with percutaneous coronary intervention (PCI) improves the prognosis by reducing the likelihood of death and reinfarction [1,2]. However, not all hospitals treating patients with ACS are capable of performing PCI. In a recent report, only 41.7% of hospitals in the United States have PCI capabilities [3]. Further, PCI centers are not evenly distributed throughout the United States [3] and estimates indicate that up to 16% of all hospital are only capable of providing the service on a part-time basis (Monday to Friday, 7 am to 5 pm) [4]. In Spain, authors participating in the RECALCAR project promoted by the Spanish Society of Cardiology report that only 67% of National Health Service (NHS) hospitals are PCI capable and 16% of them provide the service part-time [5].

Notably, the PCI capability and the condition of full-time (24 h per day/7 days per week) or part-time service might be factors accounting for differences in the likelihood to receive revascularization in a timely manner [6]. Further, having a cardiac catheterization laboratory on site is a critical factor that determines the use of angiography and angioplasty [7–9]. However, authors have shown that the expansion in hospital PCI capability in the United States might not always increase access to care

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Abbreviations: ACS, acute coronary syndrome; AMI, acute myocardial infarction; CI, confidence interval; CKMB, creatine-kinase MB isoform; HR, hazard ratio; MI, myocardial infarction; NHS, National Health Service; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; PT-CCL, part-time cardiac catheterization laboratory; RR, relative risk; STEMI, ST-segment elevation myocardial infarction.

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[4]. Although the easy availability of invasive cardiac care facilities is associated with an increase in their use, their influence on outcomes is not clear [6,9–15]. Consequently, research is urgently needed on the relationship between changes to PCI capability and outcomes of interest such as patients' outcomes and population health [4].

In the present study, we sought to investigate whether a newly available cardiac catheterization laboratory performing PCI on a parttime basis (PT-CCL) in a secondary hospital might improve outcomes in patients with acute myocardial infarction (AMI).

#### 2. Methods

Prospective observational study that recruited all consecutive patients with AMI admitted to the Coronary Care Unit of Hospital Universitario de Santa Lucia de Cartagena (Secondary-level teaching Hospital), in the Murcia region (Spain) from January 1998 to March 2014. Inclusion criteria were: (1) patients aged  $\geq$ 18 years with confirmed acute MI; (2) admitted within 24 h to the Coronary Care Unit and (3) agreed to participate. The exclusion criteria were: (1) MIs occurring during bypass surgery or coronary angioplasty; (2) MI diagnosis later invalidated in favor of another diagnosis. The diagnosis was established using at least two of the following criteria: typical precordial pain lasting >30 min, a deviation of >0.1 mV in ST-segment in >2 leads and an increase in the creatine kinase fraction MB (CK-MB) to a minimum of twice the normal level. AMI was classified into ST-segment or non-ST segment elevation (STEMI, NSTEMI).

#### 2.1. Management by type of MI

From the beginning of the study (January 1998) to January 2006 patients were managed as follows: STEMI patients within the first 12 h received immediate thrombolysis as first choice (if no contraindication). If contraindication or no reperfusion criteria at 90 min, they were transferred by mobile Intensive Care Unit to a PCI-capable Hospital (Hospital Universitario Virgen de la Arrixaca, Murcia; transfer time by highway around 1 h). After the intervention, the patient was transferred to the Coronary Care Unit of the reference hospital, unless the hemodynamic or clinical situation made it inadvisable. NSTEMI patients were managed conservatively unless high risk criteria were present according to guidelines [16].

In January 2006, a newly available cardiac catheterization laboratory was opened that was capable of performing primary PCI and angioplasty to NSTEMI patients on a part time basis (Monday to Friday, 8 am to 3 pm). STEMI patients attending to our hospital from 3 pm to 8 am (or weekend) were proposed for consideration of primary PCI to the interventional cardiologist on call (Hospital Universitario Virgen de la Arrixaca). If it was denied, patient received immediate thrombolysis (if no contraindication). If contraindication or no reperfusion criteria at 90 min, they were transferred by mobile Intensive Care Unit to a PCI-capable Hospital (Hospital Universitario Virgen de la Arrixaca). NSTEMI patients requiring cardiac catheterization should wait till the PT-CCL was opened.

#### 2.2. Study endpoints

The co-primary study endpoints were all-cause in-hospital and postdischarge long-term mortality (median follow-up 6.0 years, interquartile range 3.5–9.1). Secondary endpoints were the following complications during hospitalization: heart failure, angina or reinfarction, ventricular tachycardia or fibrillation, major hemorrhage or free-wall rupture. As exploratory analysis we additionally assessed the relation between PT-CCL and 1-year risk of readmission due to cardiac causes (i.e. new acute coronary syndrome, heart failure or ventricular tachycardia/fibrillation).

Recurrent angina was defined as typical chest pain lasting  $\geq$  10 min that relieves with nitrates and/or associates electrocardiographic signs of ischemia. Reinfarction was defined as recurrent ischemic symptoms

lasting >15 min after resolution of symptoms of the index MI and a second elevation of cardiac enzymes to over the normal upper limit or by a further 20% if already over the upper limit. Major hemorrhage was defined as intracranial bleeding, evidence (imaging) of retroperitoneal bleeding, or any overt hemorrhage causing hemodynamic instability and/or requiring  $\geq$ 1 packed red blood cells or whole blood. Heart failure was defined as that present on admission or which developed during the hospitalization.

The study protocol was approved by The Clinical Investigation Committees of our institution.

#### 2.3. Statistical analysis

Categorical variables are presented as numbers and percentages, and compared using the chi-square test or the Fisher exact test. Continuous variables were expressed as mean and SD. Continuous variables were compared using the Student *t*-test or Wilcoxon rank sum test. We used the Kaplan-Meier method to estimate cumulative incidence and assessed the differences with the log-rank test.

We developed a full non-parsimonious logistic regression model to derive a propensity-score for the management with PT-CCL with 27 independent variables (age, gender, hypertension, diabetes mellitus, current smoking, dyslipidemia, peripheral artery disease, chronic obstructive pulmonary disease, previous atrial fibrillation, chronic renal disease, previous New York Heart Association (NYHA) class  $\geq 2$ , neoplasm, previous ischemic heart disease, previous cerebrovascular accident, time from symptom onset to admission, heart rate, systolic blood pressure, Killip class, ST-segment elevation myocardial infarction/new left bundle branch block, peak CKMB, left ventricular ejection fraction and in-hospital/ discharge medical treatment, i.e. aspirin, thienopyridines, betablockers, angiotensin converting enzyme inhibitor/angiotensin receptor blocker, lipid lowering medication and IIb-IIIa inhibitors). Our propensity score analysis attempted to compare outcomes for patients with AMI managed with PT-CCL vs. without PT-CCL who had similar distribution of measured covariates, and in this was approximated the condition of random assignment [17]. The C statistic of the propensity score was 0.921 (95% CI 0.903-0.920) for PT-CCL. We then divided subjects into five equal-size groups using the quintiles of the estimated propensity score. Two hundred and thirty four (4.4%) patients were excluded from multivariable and propensity scores analyses because of missing values. Exclusion of these patients from the analyses did not modify the estimates of mortality rates or the hazard ratios of mortality associated with PT-CCL. The effect of treatment (PT-CCL) was determined using the estimated regression coefficient from the fitted regression models, thus we conducted adjusted analyses using binary logistic regression and Cox proportional hazard models. Proportional hazards and linear assumptions for the risk-adjusting variables were verified by log-log curves and the examination of Schöenfeld residuals and were acceptable. Discrimination and calibration of the binary logistic model were assessed with the C-Statistic and the Hosmer-Lemeshow test, respectively. Risks of the clinical events were expressed as relative risks (RRs) and hazard ratios (HRs) and their 95% confidence intervals (Cls). The 95% CI of study endpoints was calculated by a bootstrapping method with 3000 replications. A pos hoc Bonferroni correction was applied for the multiple comparisons of each composite of the study endpoints (n = 7), providing a *p*-value of 0.0071 for the comparison of period with PT-CCL vs. without PT-CCL. To test for consistency, CIs were calculated with a 3000-iterations bootstrapped method. Analyses were performed with SPSS v.20 (IBM, Armonk, NY, USA).

#### 3. Results

A total of 5339 patients were recruited, and 50.3% were managed after the opening of the PT-CCL. Baseline characteristics were significantly different between patients managed with PT-CCL versus those without (Tables 1 & 2). Patients in the PT-CCL group were slightly but

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