

Role of Registries and Observational Studies in the Continuous Quality Improvement of Health Care

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Specific clinical registries and observational studies are important elements that reveal the reality and safety of daily practice. On the other hand, clinical trials are essential to demonstrate the efficacy of a particular intervention. However, clinical trials are designed under specific conditions which introduce biases in patient and participating center selection, and in the analysis of subgroups not included in the study design. Moreover, a publication bias should also be considered, as most trials reporting positive findings are more likely to be published. (1, 2) Therefore, once trials have demonstrated efficacy of a certain clinical intervention, registries and observational studies can determine the impact of such intervention in the real world. (3)

The article by Mariani et al, "Time to and Use of Reperfusion Therapy in a Health Care Network" published in this issue of the journal, presents well-expressed objectives. (4) It tries to show the current picture of reperfusion therapy in ST-segment elevation acute coronary syndromes (STEACS) in a collaborative network of hospitals from the south of the Greater Buenos Aires. From this picture, the implementation of timely measures may improve the outcomes.

This picture highlights the main initial improvement points regarding the high percentage of patients with STEACS not receiving reperfusion therapy and the long delays to reperfusion therapy quantified in their different time intervals. After analyzing and quantifying these issues, the authors postulate specific measures of improvement which may be evaluated once they are applied in the future. From a purely orthodox point of view, the plan postulates the implementation of a continuous quality improvement cycle.

The first problem detected is the high percentage of patients who do not receive reperfusion therapy. Part of this percentage corresponds to patients whose intended primary percutaneous coronary intervention (PCI) entailed such excessive delay that no reperfusion therapy was finally performed. In this sense, the availability of a continuous registry common to all the centers belonging to the network would be very

helpful to establish mean time delays in each medium-complexity center. This would allow the development of protocols including fibrinolysis in those centers with delays longer than 90 minutes between possible thrombolytic therapy and percutaneous coronary intervention of the infarct-related artery. These protocols would be particularly useful in those patients presenting to the health care system within the first three hours and without contraindications for fibrinolysis. Subsequently, these patients could undergo a percutaneous coronary intervention within the first 24 hours, constituting a pharmacoinvasive strategy. (5-7) Registries are important to provide pictures of a situation and to elaborate improvement plans. Evidently, on many occasions the best is the enemy of the good, and promoting interventional therapies instead of fibrinolysis in areas with dispersed populations or with lack of access to medical centers with PCI capacity may lead to questionable outcomes. But together with these protocols it is necessary to establish support systems with telemedicine for physicians who make the first contact with these patients and a system of patient transportation within the network also committed with the emergency care of the patients. (8, 9)

The Andalusia experience monitored through the ARIAM-Andalusia Registry, which includes patients presenting to centers with and without PCI capabilities, shows that the implementation of provincial action plans comprising multidisciplinary teams, a center with PCI capability and a prehospital emergency system coordinating also transport of patients among the centers, has produced a progressive increase in the percentage of primary PCI over the years, a reduction of fibrinolysis and a continuous decrease in the percentage of patients who do not receive any reperfusion strategy. Moreover, pharmacoinvasive strategy (PCI the morning after successful fibrinolysis) also shows a continuous increase over the years (Table 1). These results have been achieved by considering STEACS as an integral process involving the different levels of prehospital and hospital health care and also by the presence of a public emergency system which coordinates the immediate transfer of patients to centers

ARIAM-Andalusia Registry	Year (n = 9771)				
Type of reperfusion	2008	2009	2010	2011	2012
Primary PCI	9.4%	18.6%	25.1%	33.1%	41%
Fibrinolysis	59.6%	57.2%	52.1%	46.9%	43.1%
No reperfusion	31%	24.1%	22.8%	19.8%	15.8%
Successful fibrinolysis + PCI	30.2	37.4%	43.6%	47.8%	61.6%

Table 1. Evolution of reperfusion strategies in Andalusia

Period 2008-2012 province of Granada	Hospital without cath lab n = 808	Hospital with cath lab n = 684	Total in the province of Granada n = 1492
Percentage of primary PCI	5.32%	28.5%	15.95%
Percentage with door-to-needle time < 120 min	22.2%	67.6%	64.1%

Table 2. Percentage and door-to-balloon delays in primary PCI for the province of Granada in the period 2008-2012. ARIAM-Andalusia Registry

with PCI capability.

The second problem detected in the study is the long delays to initiation of reperfusion therapy. The breakdown of the time intervals shows that time to presentation, which depends on the patient, is within acceptable ranges which are difficult to improve. Yet, after the first medical contact, there are delays in all the health care system components, particularly after deciding patient transfer to a tertiary care center for primary PCI without performing any reperfusion treatment. When this delay is greater than two hours, the advantage of primary PCI over fibrinolysis is abolished. It seems clear that the implementation of an emergency system facilitating prehospital fibrinolysis or direct transfer of patients to a center with PCI capability within 120 minutes is the best way to improve these delays. However, this measure depends mostly on the health care system organization. The ARIAM-Andalusia Registry has demonstrated that the province of Granada, which has only one center with PCI capability and four centers without it presents clear differences regarding the care of patients in hospitals without and with catheterization laboratory, with very low rates of primary PCI in the former due to excessive delays (Table 2). In these cases, either a pharmacoinvasive strategy or direct transfer of patients from the prehospital emergency system to the hospital with immediate PCI capability should be promoted.

Conflicts of interest

None declared

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