

Registries as a Fundamental Tool to Improve Quality of Care

Registros como herramienta indispensable en la mejora de la calidad asistencial

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*“What cannot be defined cannot be measured.
What cannot be measured cannot be improved.
What cannot be improved is always degraded”.*

WILLIAM THOMSON KELVIN
(1824-1907)

Randomized clinical trials (RCTs) are fundamental to demonstrate the efficacy of a particular intervention, but are subject to a design based on ideal conditions, with the resulting introduction of selection biases of patients in the participant centers, biases in the use of subgroup analyses that were not originally planned and publication bias. (1, 2) Therefore, once clinical trials have demonstrated the efficacy of a clinical intervention, the path is open for registries and observational studies to test the impact of such intervention in real practice. (3) Thus, registries are essential to verify if health care is delivered according to the recommendations of Clinical Practice Guidelines (CPG), completing the loop between clinical research (CR), guideline development and their implementation into clinical practice. In summary, RCTs demonstrate efficacy, while registries show effectiveness, efficiency and safety, and constitute a tool of inestimable value towards continuous quality improvement. This happens with the treatment of STEMI using primary percutaneous coronary intervention (PCI), which has proved to be the most effective reperfusion strategy when it is performed within a determined time interval.

However, CPG cannot disregard the responsibility of professionals to make the appropriate decisions in the setting of any particular patient, shifting from the emphasis placed on diagnosis-based medicine to prognosis-based medicine due to the advances that will allow the individualization of what is now considered the standard. In the case of STEMI, the benefits of reperfusion strategies should be evaluated according to the time from the onset of symptoms, counterbalancing the benefits with the potential risks.

In order for measurement of clinical variability to become more credible to professionals and stimulate them towards this goal, information systems should be

more precise, incorporating more reliable estimations about the severity and complexity of cases than those currently available.

The article by Charask et al. (4) published in this issue of the Argentine Journal of Cardiology (4) aims to analyze the rate of transfer of ST-segment elevation myocardial infarction (STEMI) patients to centers with PCI capabilities, the reperfusion strategies adopted and the time delays of the system, two key points for the therapeutic success and mortality reduction of STEMI patients. (5)

The study is based on the National Survey of ST-segment Elevation Myocardial Infarction (ARGEN-IAM-ST). (6) With the participation of 1,661 patients and 247 centers (60% with PCI capabilities) and despite the limitation of a low representation, the registry provides valuable information that was not available so far.

The results show that patients treated in situ have a high reperfusion rate (86%), particularly with primary PCI (83%). On the contrary, patients transferred to centers with PCI capabilities were 35% less likely to receive any reperfusion treatment and 49% less likely to undergo primary PCI. In patients transferred who underwent primary PCI, time delays were higher than those recommended, particularly due to delays related to transportation (the door-to-balloon time was 85 minutes, but with a delay in transfer of approximately 2 hours), placing the primary PCI benefit in a marginal situation. Moreover, only 16% of the patients received thrombolytic therapy before being transferred, with a door-to-needle time of 48 minutes. These data would support the idea of adopting a plan to optimize reperfusion strategy in patients transferred, such as the implementation of pharmacoinvasive treatment.

According to the 2012 CPG of the European Society of Cardiology (ESC), (7) delays to treatment are the most readily available, measurable index of quality of care in STEMI and should be recorded in every hospital providing care to STEACS patients. When targets are not met, interventions would be needed to improve performance.

In our environment, the ARIAM (Analysis of the

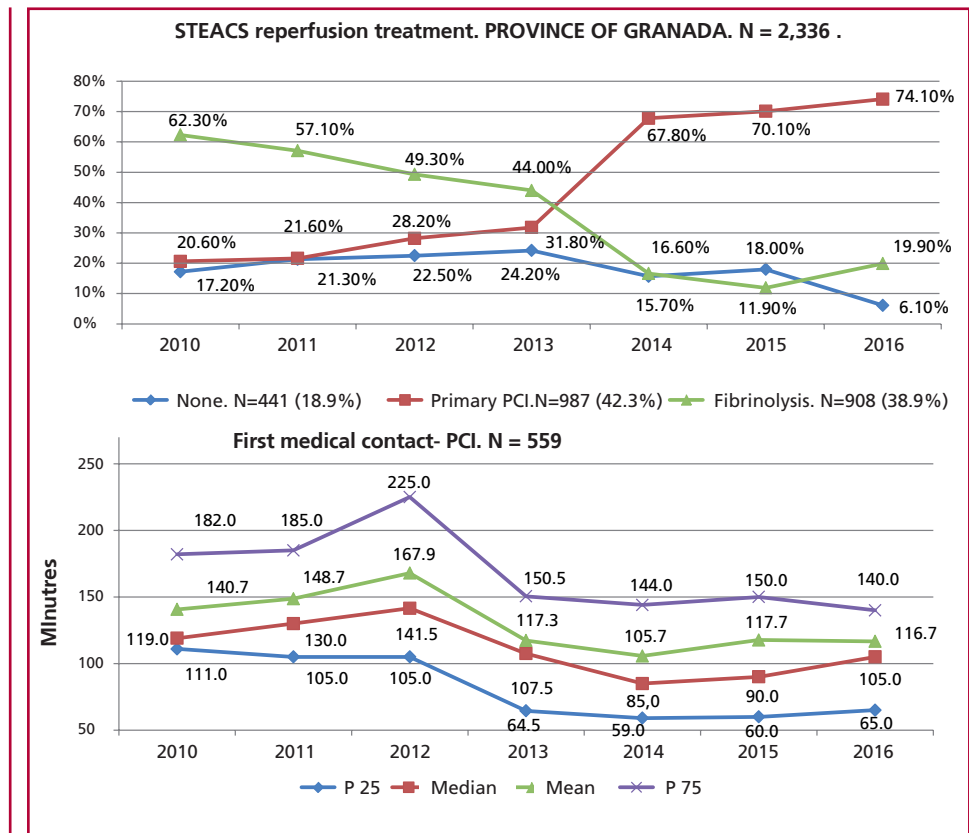
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Fig. 1. Evolution of the annual reperfusion rate in the province of Granada and of the delays between the first contact with the health care system and balloon inflation, monitored by the ARIAM-Andalusia Registry.



Delay in the Treatment of Acute Myocardial Infarction project was born in 1994 with this orientation. (8) Nowadays, the ARIAM-Andalusia Project, supported by the Health Council of the Regional Government of Andalusia, (9) is incorporated to daily clinical health care as a tool for professionals and for the Andalusian Public Health System. This continuous registry is independent of the industry and focuses on the investigation about health results and their extrapolation to daily clinical practice, with the main purpose of improving the quality of care of the processes included, with a multidisciplinary approach at the different levels and clear management of the information.

In 2012 an improvement group for the treatment of ST-segment elevation acute coronary syndrome was created in our province (Granada 12,635 Km², 919,455 inhabitants, 25% in the capital city), based on the data provided by the ARIAM-Andalusia Registry, which detected differences in the type of treatment received by patients depending on whether they consulted in hospitals with or without PCI capabilities. (10, 11) Granada has only one hospital with catheterization laboratory and primary PCI capabilities, and four centers without this resource. The aim of this project was to achieve adequate reperfusion rates in due time and proper form for all the population (we cannot forget that the entire public health care system must warrant equity of access to the best possible care). The development of

a prehospital-intrahospital Multidisciplinary Provincial Protocol, whose results have also been monitored by the ARIAM-Andalusia Project, showed a progressive increase in overall reperfusion (particularly due to primary PCI) since its implementation in 2013. However, despite a sustained improvement was seen in time delays after the first medical contact with the health care system (FCHS), it has still been insufficient, evidencing time delays longer than the standards, (7, 12) with a FCHS-balloon time > 116 minutes in > 50% of the patients undergoing primary PCI (Figure 1). Thus, an opportunity for improvement was detected, and we established different strategies according to the location of the FCHS and to the estimated delays in patient transfer to centers with primary PCI capabilities, such as the implementation of a pharmacoinvasive strategy when the delay between the first medical contact and the arrival to a center with PCI capabilities was > 120 minutes, as recommended by recent publications. (13)

The findings of the ARGEN-IAM-ST registry demonstrate that although most patients with STEMI undergo a high rate of reperfusion strategy, in the particular case of patients transferred from other centers this strategy does not meet the standards recommended by the main scientific societies, (7, 12) and suggests as improvements the use of a pharmacoinvasive strategy and better patient transfer. The dispersion of the population and the impossibility to perform primary PCI

in due time in patients who need to be transferred to centers with catheterization laboratories demand the creation of improvement working groups to elaborate their own algorithms for patient transfer according to their geographic characteristics.

This is a clear demonstration that registries visualize the gap between the evidence and the real clinical practice of a strategy. Monitoring and comparing personal results with the standards allow the detection of difficulties and show the opportunities for improvement.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/Supplementary material).

REFERENCES

- Hernández AV, Boersma E, Murray GD, Habbema JD, Steyerberg EW. Subgroup analyses in therapeutic cardiovascular clinical trials: Are most of them misleading? *Am Heart J* 2006;151:257-64. <http://doi.org/bx33q6>
- Granger CB, Gersh BJ. Clinical trials and registries in cardiovascular disease: competitive or complementary? *Eur Heart J* 2010;31:520-1. <http://doi.org/dwvj4n>
- Gitt AK, Bueno H, Danchin N, Fox K, Hochadel M, Kearney P, et al. The role of cardiac registries in evidence-based medicine. *Eur Heart J* 2010;31:525-29. <http://doi.org/bvccp7>
- Charask AA, Castillo Costa YB, D'Imperio H, Perna ER, Zapata G, Tajer CD y cols. Pacientes con infarto agudo de miocardio con elevación del ST trasladados a centros con hemodinamia. Encuesta Nacional de Infarto Agudo de Miocardio con Elevación del ST en la República Argentina (ARGENT-IAM-ST). *Rev Argent Cardiol* 2017;85:90-102.
- Pinto DS, Kirtane AJ, Nallamothu BK, Murphy SA, Cohen DJ, Laham RJ, et al. Hospital delays in reperfusion for ST-elevation myocardial infarction: implications when selecting a reperfusion strategy. *Circulation* 2006;114:2019-25. <http://doi.org/d5bk4v>
- Gagliardi J, Charask A, Perna E, D'Imperio H, Bono J, Castillo Costa Y y cols. Encuesta nacional de infarto agudo de miocardio con elevación del ST en la República Argentina (ARGEN-IAM -ST). *Rev Argent Cardiol* 2016;84:548-57. <http://doi.org/b63n>
- Steg PG, James SK, Atar D, Badano LP, Lundqvist CB, Borger MA, et al. Task Force on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology (ESC). ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. *Eur Heart J* 2012;33:2569-619. <http://doi.org/zkn>
- Ruiz Bailén M, Rucabado Aguilar M, La Rosa Salas FJ, Galindo Rodríguez S, Castillo Rivera AM; GRUPO ARIAM. Proyecto ARIAM: décimo aniversario. *Med Intensiva* 2005;29:434-6. <http://doi.org/bjr7jm>
- Boletín Oficial de la Junta de Andalucía. Número 192, de 30 de Septiembre de 2009.
- Reina Toral A, Maza Rodríguez B, Manzano Manzano F. ¿Cuál es el escenario actual de la reperfusión en el tratamiento del infarto agudo de miocardio con elevación del ST? *CardiCore* 2011;46:49-52. <http://doi.org/dd4s64>
- Reina Toral A, Colmenero Ruiz M, García Pérez C, Expósito Ruiz M, De Antonio Martín E, Bermúdez Tamayo C, et al. En representación del grupo Ariam-Andalucía. Diferencias en los resultados de la atención a los pacientes con Síndrome Coronario Agudo con Elevación del Segmento ST (SCACEST) en función del acceso inicial a hospitales con o sin sala de hemodinámica en Andalucía. *Emergencias* 2014;26:101-8.
- O'Gara PT, Kushner FG, Ascheim DD, Casey DE, Chung MK, De Lemos JA, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013;61:e78-140. <http://doi.org/mn9>
- Armstrong PW, Gershlick AH, Goldstein P, Wilcox R, Danays T, Lambert Y, et al. Fibrinolysis or primary PCI in ST-segment elevation myocardial infarction. *N Engl J Med* 2013;368:1379-87. <http://doi.org/mb9>