The RAdAC, a Welcome and Necessary Registry

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Having reached an unbelievable degree of maturity, though still in constant development, interventional cardiology is increasingly submitted to the demands of “quality assessment”, partly due to medical reasons, intended to achieve the best risk/benefit ratio and partly for economic reasons, focused to obtain the best cost/benefit relationship. Relevant scientific societies have long since introduced in their recommendations the notion of “quality control” and the procedures to achieve it. (1) Thus, the organization of a program of continuous quality improvement (CQI) in each intervention center, including participation in regional and national registries is listed as Class I, level of evidence C, in recent American recommendations. (2)

The registries, organized data collections, are a means of gathering massive amounts of information on the modality and effects of a given treatment or procedure in a population with a certain pathology. Compared with randomized studies, the registries apparently reflect more accurately “the real world”. With this information, the quality may be evaluated in terms of efficacy and security, allowing the adoption of the necessary improvement measures. Moreover, well used, registries may facilitate the prompt adoption of therapeutic advances. In this context, the RAdAC, Argentine Registry of Coronary Angioplasty, performed by Cherro et al., (3) is a fundamental contribution to the interventional cardiology quality control process at a national level.

The purpose of the data presented by Cherro et al.is to provide updated information on coronary angioplasty treatment in Argentina.

The most outstanding feature of the population included in this registry is the high percentage of acute coronary syndromes (ACS) with only 15% of patients with chronic stable angina (CSA) submitted to angioplasty. It is difficult to know whether this reflects an inclusion bias, a “COURAGE effect” (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation), (4) the controversial study that proved the absence of benefit in terms of mortality, myocardial infarction and other major coronary events when angioplasty with bare metal stents was compared with medical treatment in patients with CSA, or whether it is a random effect.

The intrahospital results informed in the RAdAC are especially worth of attention. Although the 97% primary success rate is not surprising, the intrahospital mortality figures are extremely low. Especially in patients with myocardial infarction these figures are excellent and similar to those found in the recent French registry FAST-MI 2010. (5) Since infarct results will be analyzed separately, we cannot continue with the interpretation of these 4.3% and 1.7% low mortality rates observed in ST+ and ST- myocardial infarctions, disregarding the delay between onset of pain and angioplasty, as well as other aspects of this group of patients’ management. As reported by the authors, there might have possibly been an inclusion bias.

With reference to complications, let us focus on bleeding, a well-known source of morbimortality in this context of ACS and percutaneous intervention. (6, 7) The slight percentage of hemorrhages determined in the RAdAC (0.3%) is especially surprising in this population in which most cases were performed through femoral access without using percutaneous closure systems. Although randomized studies may underestimate bleeding frequency for different reasons, including exclusion criteria, (6, 7) if we compare the RAdAC results with two randomized large studies in similar populations, (SCA), ACUITY y TRITON-TIMI 38, (8, 9) the rate of major bleeding only associated with the puncture site ranges from 0.6% in TRITON-TIMI 38 to 2.5% in ACUITY. These figures are much larger if minor bleeding and bleeding non-related to puncture site are added. Bleeding underrepresentation has also been observed in the ACC (American College of Cardiology) / NCDR (National Cardiovascular Data Registry) / Cath PCI Registry, whose data show 14% more local complications detected a posteriori in another associated database, the PCI QI (Quality Improvement) Database. Shorter hospitalization after angioplasty is one of the reasons invoked by the authors of this study to explain the difference. (10)

Regarding modalities of reperfusion, RAdAC results show that current practice, at least in the presented population corresponds to the available evidences, in the sense that in acute coronary syndrome it is convenient to treat only the “culprit” vessel, even in the worst situation, which is cardiogenic shock. (11, 12) Massive use of stents (96.8% angioplasties), as
As for the percentage of drug-eluting stents used, although the authors seem to regret the referred 33%, a target of 50% seems reasonable and achievable, given current evidence and indications. Effectively, the greatest benefit of drug-eluting stents is the reduced need for target vessel revascularization, which is approximately 8.8 events avoided per 100 treated patients, but there is little convincing evidence that their use has a beneficial effect on mortality or on the occurrence of myocardial infarction. (13) In economic terms, although the cost/benefit ratio is favorable to the use of drug-eluting stents, this ratio decreases when the more prolonged double antiplatelet aggregation cost is included.

RAdAC authors are surprised by the limited use of balloon counterpulsation, thromboaspiration systems, Cutting Balloon®, rotational atherectomy and intracoronary ultrasound. Admittedly, the percentages are low, and are expected to increase significantly, in particular the use of thromboaspiration in AMI ST+, simple to use and with undeniable and well documented benefits. (14) Similarly, a significant increase in the use of radial access can be expected, with the main advantage over the femoral access in reducing local complications, mainly in higher risk patients. (15) Let us add to this list the pressure guide, not included in the RAdAC, with well proven utility to functionally characterize lesions requiring angioplasty by measuring the relative flow fraction (RFF). (16)

Moving away from the data, we find that the overall impression left by reading and analyzing the RAdAC is a digital photograph in which there is still a lot of missing information, many “pixels”. The number of participating centers is less than half the interventional cardiology centers accredited by the Argentine College of Interventional Cardiologists, which in turn make up about 66% of the operating centers in the country (data from the ACIC), and the number of angioplasties is less than 10% of the total number performed per year in Argentina. One could argue that the number of cases is significant, and that they are “representative” of the overall activity, but, is this true? How do we know? How to ensure that data are not considered “approximate” by the same authors?

These limitations, honestly assumed by Cherro et al., not only concern the RAdAC registry but all registries which are generally characterized by the following major obstacles in their implementation: 1) participation is voluntary and therefore may not be representative, 2) the data are “self-referred” and without external auditing, 3) there is no long-term follow-up. (1) Moreover, while the construction and procurement of registries is in theory simpler than that of multicenter, randomized studies, in practice this is not so.

The collection of data at each site is a laborious and time consuming task, although nowadays greatly facilitated by the existence of software that allows the simultaneous semiautomatic execution of reports, the preparation of a database on “background work”, locally usable and exportable online, and even traceability of all the employed material, which is already mandatory in many countries, using the barcode system. In addition, items, regularly updated by those responsible for the registries, are incorporated by commercial companies to renovated versions of the software, and “injected” via the Internet to users.

The voluntary participation of the various centers is certainly difficult to obtain, for various reasons, but this is a gradual process, and rejection is not inexorable or definitive. As examples we can cite the cases of Spain, which has already published the twentieth consecutive annual edition of the interventional activity registry, involving 60% of the centers (17) and of Germany, where the QuIk (acronym for Quality Assurance in Invasive Cardiology) registry, voluntary and self-funded, currently collects data from more than 80% of private practice activity, starting with eight participating centers in 1996 to 123 at present. (18)

As for the completeness and accuracy of data collected at each center, although there may be voluntary “omissions or errors” generally this not the case, and the best way to avoid them is to acquire human and material resources to carry out this task. Ideally, however, the data should be examined by external auditors.

Finally, the performance of this type of registries should be an activity that is maintained over time, producing consecutive versions to appreciate the evolution of local, regional or national practices.

Therefore, the RAdAC, Argentine Coronary Angioplasty Registry, which retrieves and expands the previous CONARECV and CONARECX registries, should be appreciated at its full value. It is hoped that this initiative will be perpetuated, that its tenacious promoters will find sufficient arguments to involve more and more interventional cardiology centers, the human and material resources to perform it in the best conditions and the effective support of scientific societies, commercial companies and public institutions directly or indirectly related to the specialty.

Conflicts of interest
None declared.

REFERENCES