Direct Implantation of Self-expandable Aortic Valve

To the Editor

I congratulate the authors of the study "Outcome of direct implantation of self-expandable aortic valve prosthesis for severe aortic stenosis" (1) published in RAC, as they attempt to solve the problem of embolism or its prevention with the technique of direct transcatheter aortic valve implantation (TAVI). The subject is of great relevance in the area of TAVI, because even though this technique has shown decreased mortality and non-inferiority compared to conventional surgery in contraindicated or high risk populations in the multicentric PARTNER A and B studies, many issues remain unsolved 10 years after the first TAVI performed by Prof. Cribier. (2)

Incidence of stroke, according to the Valve Academic Research Consortium (VARC) definitions in the literature, would be 6.7% (Partner inoperable B cohort) or 5.5% (Partner high risk A cohort), mainly during the first 30 days post-TAVI; (3) however, causes of stroke are multifactorial. One of them is associated prosthesis migration in highly calcified aorta, porcelain aorta, at pre-dilation with balloon aortic valvuloplasty, at prosthesis deployment and during post-dilation (both for the Core Valve as for the Edwards SAPIEN valve). Moreover, contrary to what was previously assumed for the transapical access, the selected access would have no impact on the prevention of embolism. (4) Kahlert et al observed the greatest number of intracranial high intensity transient signals (HITS) at the moment of valve positioning and deployment (both for the Core Valve as for the Edwards SAPIEN valve). (5) The advantage of direct TAVI without pre-dilation as strategy for prevention of embolism would be speculative as Grube et al reported 5% stroke incidence and 16.7% need of post-dilation with this technique (similar to randomized studies without this strategy). (6)

As stated by the authors, even though the sample is small, at least 30% (6/20 patients) required balloon post-dilation, leading to a second problem of direct TAVI: bad apposition and paravalvular leak, which, as postulated by Rodes Cabau, would impact on population survival. Bad apposition of the CoreValve prosthesis is frequent, even more in valves with excess calcium, which, according to Schulz, is observed in 30% of the cases at any level: aortic, valvular or ventricular. (7)

Implementation of cerebral protection systems would be one of the solutions to stroke, as the Claret CE Pro System device (Claret medical, Santa Rosa, CA, USA) with detritus capture in 50% of TAVI cases recently described by Naber et al. (8)

Evidently, there is still a lot of improvement to be done on TAVI and durability is not a lesser aim, but the current population is too elderly to extend follow-up beyond 5 years. A moderate risk population should be analyzed in which strokes, paravalvular leaks and device recapture need to be solved.

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Antiplatelet Therapy Guided by Platelet Function Tests in Patients Undergoing Successful Coronary Angioplasty

To the Editor

In the recently published article "Antiplatelet Treatment guided by platelet function tests in patients undergoing successful coronary angioplasty", (1) the authors have been very careful in their approach and layout and have precisely delineated its usefulness, all of which speaks about their seriousness.

Today we have numerous and powerful antithrombotic drugs, the limit of their use being bleeding.

Thus, when encountered with the need for revascularization in our patients, we are obliged to be very meticulous in choosing the best method based on two aspects: factors favoring stent thrombosis (2) and factors predisposing to bleeding. This is achieved with a complete and thorough medical history. We have learnt this in cancer patients, in whom frequent surgeries, prothrombotic states, chemotherapy, etc. make us very careful specially in stent selection and in the duration of dual antithrombotic therapy. (3)

Given the dramatic situation involving early or late stent thrombosis and the variable resistance to clopidogrel (5-20%), a laboratory method that allows us to measure platelet function in terms of residual hyperreactivity and inhibition is extremely useful, giving us the possibility of a more rational use of the drug, although, as the authors claim, it is true that there is still no evidence of outcome improvement.

According to the TRITON-TIMI 38 study (4) the greatest benefit of prasugrel was achieved in the group of AMI patients with ST segment elevation. If we exclude patients older than 75 years with bleeding predisposing factors, we would increase the benefits in patients with ACS without ST elevation and in diabetics

By knowing platelet activity, we would add to the indications patients with resistance or poor response to clopidogrel and patients with complex coronary lesions with stent implantation, which is more than welcome news.

In these years of medical practice, measuring coagulation and platelet aggregation has given us some security in the management of our patients, both in their follow-up as in the development of complications and the conducts that should be applied. What the authors postulate seems consistent with this thinking.

We will see if the development of new drugs which apparently need no laboratory control maintain the results.

The final conclusions are, I believe, of great clinical utility.

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Endoleak: Complication of Endovascular Treatment After Abdominal Aortic Aneurysm

To the Editor

I have read the article "Endoleak: complication of endovascular treatment after abdominal aortic aneurysm" published in your journal by Dr. Agostino, Souto y Beigelman. (1) The term "endoleak" was first postulated by G. White and J. May in 1996. (2) I do not know if the Spanish translation is presently scientifically recognized by Spanish speaking societies. The second point to establish is if type II endoleak is actually a complication. This endoleak, secondary to the retrograde flow from collateral branches of the aorta has a relatively benign outcome. In my Doctoral Thesis, recently presented at the University of Buenos Aires, only persistent type II endoleaks which continued one year after treatment were significantly dangerous. They were dangerous because they were accompanied by aneurysmal growth. However, from a ratio of almost 50% intraoperative type II endoleaks, only 6% required some kind of treatment for aneurysmal growth, specifically because they were associated with at least one year evolution. Therefore, considering type II endoleak as a "complication" may bring serious academic and clinical consequences. It would then be more appropriate to categorize as complication the type II endoleak associated with aneurysmal growth. But, since this article recommends the echo-Doppler as follow-up method, I believe it is more important to show, in this brief letter, the current follow-up protocols. One of the main pillars for the success of endovascular treatment of aortic aneurysm (ETAA) is its correct follow-up. What are the American Society of Vascular Surgery (SVS) follow-up recommendations? (3)

Surveillance during the first year after ETAA should be a contrast angio-CT at one month and at 12 months post-treatment (Recommendation grade: strong. Quality of evidence: high).

If a type II endoleak or another important anomaly is detected at the one month post-treatment tomography, a new tomography is recommended at the sixth month (Recommendation grade: strong. Quality of evidence: high).

If in the one-year angio-CT no endoleak is detected, color echo-Doppler is a CT alternative for postoperative annual surveillance (Recommendation grade: weak. Quality of evidence: low).

Presence of a type II endoleak must initially indicate continuous CT surveillance to monitor aneurysm size. If the aneurysm is reducing or remains with a stable size, echo-Doppler follow-up is suggested as an alternative to systematic CT (Recommendation grade: weak. Quality of evidence: low).

A new endoleak detected after previous imaging studies have suggested complete exclusion of the aneurysmal sac should involve an evaluation to rule out type I or type III endoleak (Recommendation grade: strong. Quality of evidence: high).

An echo-Doppler and a CT without contrast are recommended as angio-CT substitutes for surveillance of patients with renal failure (Recommendation grade: strong. Quality of evidence: high).

A CT without contrast of the entire aorta is recommended at five year intervals after ETAA or open surgery (Recommendation grade: strong. Quality of evidence: high).

Similar recommendations were published by the European Society for Vascular and Endovascular Surgery in 1911. (4)

There is no present recommendation that justifies replacing the information provided by angio-CT, especially in the first year after treatment. The evidence to support a change in the current protocols is insufficient. There is, in a selected group of patients, the possibility of echo-Doppler follow-up, doubtless related to lower invasiveness and cost.

L. Mariano Ferreira

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Authors' response

We have carefully read the comment submitted by Dr. L. M. Ferreira to whom we are grateful for his interest. We also underline the contributions of his recent thesis, and therefore consider it is necessary to clarify three points:

a) The term endoleak is vastly used in the English literature (1, 2) and thus we have only mentioned it in the title translated to English. As can be seen, in the Spanish text we have used the term "end ofuga".

b) Any type of endoleak is considered a complication in the literature, (3-7) though they must not necessarily be treated, as mentioned by Dr. Ferreira, and can be monitored along time. Before taking a decision, the treating physician should be familiar with the subject or consult the vascular surgeon. Thus, we assume that the article title does not induce conducts, but only mentions what is described in the literature, and hence, does not lead to "important academic or clinical conse quences". Effectively, the adopted conduct in the patient presented in the article was expectant. We have not found in our literature review any article claiming that the endoleak is not a complication.

c) In accordance with Dr. Ferreira's contribution, we reconsider and agree that the American Society of Vascular Surgery recommends endoleak follow up with angio-CT, but on the other hand, he ac knowledges that "in a selected group of patients, there is the possibility of echo-Doppler follow-up, doubtless related to lower invasiveness and cost".

In addition, the Hispanic American Consensus for the Endovascular Treatment of Abdominal Aorta Aneurysm (Cartagena 2009) mentions that " in patients with contraindication for computed to mography and in qualified facilities to perform echo-Doppler studies, this method may be routinely applied, preserving computed tomography for cases in which the echo-Doppler establishes the presence of a "*complication*". (8)

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Cost-effectiveness of Drug-Eluting Stents (Des) Versus Bare-Metal Stents (Bms)

To the Editor

I have read with interest the article in the previous issue of the Journal on the cost-effectiveness of drug-eluting stents (DES) versus bare-metal stents (BMS) in the management of symptomatic coronary disease. (1)

First, I would like to stress the importance of this type of analysis in the practice of modern medicine: on one hand, the physician faces the duty of ensuring the best quality care for his patients and, on the

other hand, the social responsibility of preserving limited resources. Funding used for any program or new technology to treat a pathology is "lost" because it cannot be used for other strategies that may have greater impact on health (e.g., the incorporation of new technologies for the treatment of a disease results in fewer resources for prevention). This opportunity cost should be taken into account, as it is not enough to get cost-effective treatments, but their budgetary impact should be also measured.

Some aspects of the work are worth mentioning. Most patients come from two cohort studies with a prolonged follow-up where neither the cost-effectiveness threshold was established nor discount was made (in the case of Neyt et al) and in which the sensitivity analysis was performed considering very few variables (stent cost, lesion severity and diabetes), making it difficult to assess the robustness of the conclusions on the possible variation of any of the evaluated aspects.

In four of the included studies (25%) no sensitivity analysis was performed and in those in which it was conducted variables such as discount rate, number of procedures of the center and incidence of restenosis were not included, which might perhaps modify the final decision. Four of the six studies where no discount was performed have a follow-up of more than one year, which would justify its implementation. The fact that the cost-effectiveness threshold is established by the authors (especially in piggy-back studies or on top of randomized controlled trials, -RCS-) prevents an easy comparison between the obtained results. It is sometimes interesting to determine the willingness to pay in terms of country gross domestic product (how many GDP they are willing to pay for a new technology or treatment, or per QALY gained), or using international dollars.

Finally, I wish to highlight the importance of appropriate clinical judgment to determine when to place a stent in patients with coronary disease where the potential benefit does not result in reduction of hard events such as death or reinfarction, but in terms of new target vessel revascularization with an incidence which is also highly variable (from 3.3 to 18%).

Different studies and clinical practice guidelines (2, 3) emphasize the good outcome of adequate medical treatment in low-risk patients with stable coronary disease and those selected cases that should be preserved for endovascular treatment with drug-eluting stents.

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