Is There a Place for Rapid-Deployment Valves for Older Intermediate-risk Patients?

¿Hay lugar para las válvulas de rápido implante en pacientes mayores de riesgo intermedio?

IULIA COTI[1], PAUL WERNER[1], DANIEL ZIMPFER[1], MAREK EHRLICH[1]

Transcatheter aortic valve replacement (TAVR) is the treatment of choice in patients older than 75 years of age, irrespective of surgical risk. However, in some health care systems the costs associated with transcatheter valve procedures might be prohibitive and prevent older higher risk patients of receiving treatment for severe aortic stenosis. Compared with conventional valves, rapid-deployment (RD) surgical aortic valve replacement demonstrated better procedural time, cardiopulmonary bypass and cross-clamp times in multiple studies and favored minimally invasive approaches, which were also associated with a reduction in ventilation and intensive care unit (ICU) times, as well as in hospital stay length, and an improved quality of life. (1) Fortunato and colleagues compared the early outcomes of a small group of older intermediate-risk patients receiving either a rapid-deployment valve, RD-V, (n=65) or a conventional surgical aortic valve replacement (n=140). (2) In this retrospective analysis, RD-V demonstrated a trend to lower-in-hospital mortality and was associated with reduced procedural times and improved valve hemodynamics; moreover, minimally invasive approaches were favored. However, a higher number of patients receiving a conventional prosthesis had an indication for urgent treatment or received concomitant procedures, both factors being usually associated with higher early mortality. A recent meta-analysis from Salmasi et al. including almost 10 000 patients (RD-V n=3686 and conventional AVR n=6310) found no significant difference in terms of operative mortality, stroke or bleeding. Despite the reduced operative and length of ICU stay times in the RD-V group, the need for permanent pacemaker implantation and the occurrence of paravalvular regurgitation was higher in this group. (1) Another analysis from the German Registry (GARY) which included more than 16 000 patients who underwent isolated AVR with current generation RD valves (n=1743) or transfemoral TAVR with current generation transcatheter heart valves (n=14 730) revealed higher risk of stroke, need for blood transfusions or postoperative renal replacement therapy in the RD-V group; in-hospital mortality was also higher in this group after propensity score matching compared with the TAVR group. (3)

In the light of present evidence, individualized directed treatment decision is important, especially in situations in which transcatheter valve therapy options are limited, in order to provide optimized medical care with reduced perioperative events in patients requiring aortic valve replacement. As bravely pointed out by Fortunato et al., RD-V represents an important tool in the arsenal of the modern cardiac surgeon, facilitating less-invasive surgical procedures and reducing procedural times while providing optimal hemodynamic performance.

Ethical considerations

Not applicable.

Conflicts of interest

None declared.

(See authors' conflict of interests forms on the web).

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Rev Argent Cardiol 2024;92:313-314. http://dx.doi.org/10.7775/rac.v92.i4.20788

Correspondence: Marek Ehrlich. E-mail: marek.ehrlich@meduniwien.ac.at

[1] Department of Cardiac Surgery, University of Vienna

AUTHORS' REPLY

We gratefully acknowledge the comments on our work of Dr. Marek Ehrlich and the University of Vienna cardiac surgery team. In this article preoperative risk stratification was made using STSprom% to employ universally recognized factors when comparing similar populations considered as "intermediate risk".

In contrast to the study by Salmasi et al., (1) in which a higher percentage of postoperative leaks was observed with rapid implantation prostheses, in our series we did not find this trend (conventional AVR 5% vs. rapid implantation 4.6%). However, we identified what we consider to be the "Achilles heel" of these new prostheses: the need for pacemakers.

In response to this challenge, we have implemented several changes in recent years that have improved this situation and reduced the rate of postprocedural atrioventricular block. These modifications include: 1. No prosthesis oversizing (always opting for the smallest size available), 2. Avoid excessive decalcification, and 3. Carefully select patients, avoiding those with a history of first- or second-degree atrioventricular block and bundle branch block.

Our aim with this article is to present our results with complete honesty. This prosthesis is not intended to replace either transcatheter valves or conventional valves, but, as the Vienna team rightly points out, to act as an additional tool in our practice. Personally, we consider that it has radically changed the way we plan surgeries.

Germán Fortunato

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New Surgical Options for Aortic Stenosis

Nuevas opciones quirúrgicas para la estenosis aórtica

TOMÁS MUSELI[1],

Aortic valve disease treatment has changed radically with the advent of transcatheter aortic valve implantation (TAVI). It is part of the daily practice of our services to have to choose between surgical or hemodynamic treatment of our patients. This decision, based on each particular case, contemplates risk scores, anatomical characteristics, costs and coverage by insurance companies, experience of the center and patient preferences.

Cardiovascular surgery began to offer less invasive approach options and new types of "sutureless" valve prostheses. At present, there are two such valve platforms: the totally sutureless Perceval (Corcym) and the Edwards Intuity rapid deployment valve (Edwards Lifesciences). Both valves, approved by the FDA in 2016, share similar technology to TAVI: Perceval as self-expandable and Intuity as balloon expandable with three points of anchorage to the aortic annulus.

The appeal of the sutureless valve surgical approach and its potential advantages over TAVI are based on the possibility of complete excision of the native valve, decalcification of the aortic annulus, or debridement of potentially infected material. (1) Other advantages of the surgical approach include the possibility of revascularizing complex coronary anatomies unsuitable for angioplasty or reducing surgical times in combined procedures.

Despite the aforementioned theoretical advantages, the debate about the benefits of sutureless valves versus conventional aortic valve replacement (cAVR) or TAVI still persists. The published data come mostly from retrospective observational studies and are inconclusive regarding mortality benefits with the less invasive surgical modality. (2-4)

In their article Rapid deployment valves versus conventional valves in aortic valve replacement in intermediate-risk patients (Rev Argent Cardiol 2024; 92: 198-204) , Fortunato et al. compared a retrospective cohort of patients with severe aortic stenosis who underwent conventional AVR vs. rapid deployment

Rev Argent Cardiol 2024;92:314-315. http://dx.doi.org/10.7775/rac.v92.i4.20811

Correspondence: Tomás Museli. General Güemes 395. Salta Capital. E-mail: muselitomas@gmail.com

[1] Cardiology Service - Sanatorio Altos de Salta. City of Salta.

valve replacement (RD-V) with Intuity valve. (5) The results replicate, to a large extent, those published internationally: RD-V has a higher proportion of mini-invasive approach, shorter surgical times (cardiopulmonary bypass and aortic clamping), a better hemodynamic profile and a trend towards greater pacemaker implantation with respect to TAVI.

The indication for sutureless surgical techniques seems to be reserved for those patients who are in a gray zone between conventional AVR and TAVI. Certain anatomical features, such as the relationship of the annulus to the coronary ostia, or the need for a combined procedure, given by complex coronary artery disease or multivalvular involvement, could determine a possible benefit of less invasive surgical techniques. (1)

The publication of Hospital Italiano de Buenos Aires outcomes with RD-V in intermediate-risk patients is a valuable contribution to local cardiology. There is still lack of information on the long-term behavior of these valves, their impact on the conduction system, as well as cost-effectiveness studies, so necessary for decision making in our setting.

Ethical considerations
Not applicable.

Conflicts of interest
None declared.

(See authors' conflict of interests forms on the web).

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AUTHORS' REPLY

Thank you very much, Dr. Museli, for your valuable comments and feedback on our work.

In relation to indications, I would like to highlight the advantages that rapid-deployment prostheses (RD-V) offer in small aortic annuli. Since we started using them, we have observed a radical decrease in the need to enlarge the aortic annulus. This not only avoids prosthesis-patient mismatch, but also mitigates the negative effects associated with annulus enlargement, such as longer aortic clamp time, prolonged extracorporeal circulation, increased surgical complexity, and risk of bleeding.

The long-term follow-up of these valves is still under development. As mentioned in our article, the system is based on Carpentier-Edwards Perimount valves. Bourguignon et al. (1) showed, at 15 years, freedom from reoperation due to structural damage of 82.7±2.9% in patients over 60 years of age, and 98.1±0.8% in patients over 70 years of age. Truly excellent results for a bioprosthetic aortic valve.

Recently, the TRANSFORM study by Malaisrie et al. was published. (2) This prospective multicenter nonrandomized study showed 95.5% and 96.1% freedom from all types of reintervention for RD-V in isolated or combined aortic valve replacement at 7 years, respectively. As Dr. Museli mentions, longer term results remain to be demonstrated.

Germán Fortunato

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Cardiologic Involvement in an Experimental Model of Reperfused Ischemic Stroke

Compromiso cardiológico en un modelo experimental de accidente cerebrovascular isquémico reperfundido

FERNANDO J. VERDUGO[1, 2]

Patients with ischemic stroke (IS) have a high incidence of cardiological complications, including myocardial injury, acute coronary syndrome, left ventricular dysfunction, electrocardiographic abnormalities, arrhythmias and sudden death. (1) Although these complications are mostly transient, they are associated with worse short-term prognosis. (1) It is important to implement experimental models of IS that reproduce cardiac complications to better understand the underlying pathophysiological mechanisms and to evaluate the potential impact of therapies.

In the Argentine Journal of Cardiology, Barbieri et al. report the implementation of a cerebral ischemia and reperfusion (I/R) model in FVB mice, showing significant neurological and histological deficit of the right hemisphere (with insular territory involvement) and, concomitantly, electrocardiographic and echocardiographic alterations. (2)

Mice subjected to I/R were evaluated electrocardiographically at baseline, at 60-minute ischemia and at 24-hour reperfusion, showing relevant repolarization alterations: prolongation of the QT interval in ischemia, prolongation of the QT interval in reperfusion with respect to ischemia, and prolongation of the T wave peak-to-end interval (TPEI) only in reperfusion. (2) The observations of the experimental model are interesting if we consider the clinical background. QT interval prolongation is observed in 20-65% of patients with IS, and its highest incidence occurs in patients with insular IS or severe neurological damage. (1,3) A prospective study of patients with IS, excluding those with heart disease, reported QT and TPEI prolongation during the first 24 hours of IS, with decreases at 72 hours. (3) In patients with IS, mortality triples in the presence of prolonged QT versus normal QT interval. (1) TPEI prolongation is associated with a higher risk of torsade de pointes in patients with acquired prolonged QT. (4)

Echocardiography was performed 24 hours post-surgery in the I/R group and in a sham group, and statistically significant differences were observed in left ventricular ejection fraction (LVEF) and shortening fraction (SF). (2) Mild systolic dysfunction secondary to I/R is assumed, although LVEF and SF values in the I/R group were similar to those reported as normal for healthy FVB mice, (5) and the sham group evidenced higher averages, suggesting a hyperdynamic state. It would have been useful to compare these parameters of systolic function at baseline to establish causality. QT prolongation is a criterion in clinical scores of Takotsubo syndrome, so it would be relevant to investigate whether the mice subjected to I/R presented segmental motility disorders indicative of this condition, although assessment in mice by echocardiography may be technically challenging.

The experimental model implemented by Barbieri et al. is noteworthy for the study of repolarization alterations secondary to IS. It would be interesting to evaluate the presence of repolarization abnormalities in IS generated in other territories, as well as their association with biomarkers mentioned in their discussion. From the clinical point of view, it seems relevant to determine whether the temporal pattern of QT and TPEI changes are replicated in humans with right IS undergoing reperfusion therapy and whether these observations would modify routine practice

Ethical considerations

Not applicable.

Conflicts of interest

None declared.

(See authors' conflict of interests forms on the web).

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Correspondence: Fernando J. Verdugo. Av. Salvador 364, Santiago, Chile. E-mail: fdoverdugo@gmail.com

[1] Hospital del Salvador, Santiago, Chile.
[2] Adjunct Assistant Professor, Universidad Finis Terrae, Santiago, Chile

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AUTHORS' REPLY

First of all, we express our gratitude to Dr. Fernando J. Verdugo for his critical reading and thorough analysis of the results presented in our article "Modifications in left ventricular function and electrocardiogram in mice due to cerebral ischemia and reperfusion", recently published in the Argentine Journal of Cardiology. (1) We also appreciate his dedication in preparing a commentary that enriches and enhances the value of our research. His reflection on the importance of having well-defined preclinical experimental models, which allow a deeper understanding of the mechanisms underlying cardiac complications that worsen prognosis in stroke patients, has fully captured the essence of our work.

Having established this experimental model and obtained relevant results, our aim is to further extend the study of the various mechanisms of cardiac damage in the context of cerebral ischemia and reperfusion. In this sense, Dr. Verdugo's suggestions are valuable to strengthen the importance of our current working hypotheses, especially with regard to the regionality of cardiac injury, cerebral anatomical topography and its relationship with cardiovascular damage, and the use of biomarkers, among other aspects.

We do not agree with Dr. Verdugo's statement that mice in the sham group present echocardiographic data suggesting a hyperdynamic state. Previous studies in conscious mice have shown that the left ventricular ejection fraction under normal conditions ranges from 80% to 85%. (2) At the same time, these values can be differentially reduced depending on the type of anesthesia used during the study. (2) In our case, the sham group showed an ejection fraction of 74.3±0.9%, (1) a value lower than that of a conscious animal, (2) but consistent with what is observed in mice anesthetized with the same type and dose of anesthesia used in our study. (2) Although some papers have reported lower values, (3) and others even higher, (4, 5) than those we present, most have shown similar values. (2, 6) A comparable pattern was observed in the left ventricular shortening fraction. (7)

Therefore, although it is important to take into account the reference values reported by other authors, it is essential to compare the results obtained in the group with the study variable intervention versus their own sham group. This approach minimizes the possibility of introducing methodological errors derived from potential differences in the control of variables such as temperature, type, dose and form of administration of anesthesia, duration of the study, strain, age and sex of the animals, operator experience and type of equipment used, among other factors.

Among Dr. Verdugo's comments, a particularly relevant aspect that enriches the discussion and exchange of ideas is the consideration of the use of control and sham groups. Previous studies in anesthetized mice, but not subjected to surgery, have shown that the values of ventricular function assessed by echocardiography are similar to those we found in our mice subjected to sham surgery. (2, 6) Moreover, in previous investigations performed in our laboratory with control mice without surgery, or sham mice with long evolution, we obtained results comparable to those of the sham group in the current study. (8, 9) Therefore, we lack sufficient biological arguments to ethically justify the sacrifice of animals in order to create an additional control group. In fact, such a protocol would have a very low probability of being approved by our Institutional Committee for the Care and Use of Laboratory Animals, since it would not meet the ethical standards for reducing the use of animals in scientific research.

On the other hand, the aim of our study was not to evaluate the impact of surgery on cardiac function. On the contrary, although our own previous evidence suggests that this does not occur, (9) any alteration that the surgical intervention could generate in the heart would represent a confounding variable, introducing possible biases in the interpretation of the results on the impact of cerebral ischemia on cardiac function. This becomes particularly relevant given that these are acute protocols in which a carotid artery is manipulated and occluded. For this reason, we consider the use of a sham group rather than a control group to be essential.

In summary, methodological, scientific and ethical reasons support the decision to use a sham group and not to include a control group without surgery.

Again, we stress the relevance of these points and sincerely thank Dr. Verdugo for taking the time to write this reader's letter, which contributes to the exchange of ideas and enriches the scientific discussion.

Ignacio P. Barbieri,
Verena B Franco Riveros,
Bruno Buchholz

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Response in Cardiac Resynchronization Therapy: is it Still Uncertain?

Respuesta en la terapia de resincronización cardíaca: ¿continúa siendo incierta?

DANIELA M. RUBIRA[1], ALEJANDRA FERRO[1], FEDERICO SALAZAR[2]

Cardiac resynchronization therapy (CRT) is an electrical treatment that was initially applied as the last therapeutic option for patients with advanced heart failure (HF) associated with left bundle branch block (LBBB). (1)

It is an effective treatment if adequately directed. However, translating consensus guidelines into "real-world" practice is often incomplete. Cardiac resynchronization therapy is underutilized and there is great heterogeneity in its implementation and response; therefore, unequivocally estimating the actual benefit of its use remains a major challenge. (2)

The definition of response to CRT varies across clinical trials. There are two main definitions: the echocardiographic and the functional response. The former is defined as a reduction in left ventricular (LV) end-systolic volume greater than or equal to 15% or an improvement in LV ejection fraction greater than or equal to 5%. Functional response refers to an improvement of at least one dyspnea class category in the NYHA classification. (3) In a study by Nakai et al. in 260 patients, response to CRT at 6 months after implantation was evaluated based on each definition, and the relationship between response and clinical outcomes was investigated. Non-responder status was associated with higher all-cause mortality. (4)

This difference in the response to a widely validated therapy was analyzed in an extensive study by María E. Santillán et al. (5) in 343 patients with heart failure and CRT. These two responses were analyzed, using clinical and echocardiographic parameters, and a predominant positive response to CRT was identified at 24-month follow-up for the first time in Argentina, with statistical significance in terms of hospitalization events, cardiac transplantation and appropriate therapies, and at the limit of significance for all-cause death. In this model, the presence of LBBB and longer QRS duration, as well as a non-ischemic etiology, stand out among the possible positive predictors. Contrary to what was presented in other trials, female sex predominated in the group of non-responders.

The similarity in the standard medical treatment of both groups and the lower incidence of adverse events among responders highlights indirectly the importance of electromechanical synchronization, and reverse remodeling as the main detectable phenomenon in daily clinical practice.

The contribution of the present work, by identifying factors related to suboptimal response to CRT and the waiting times required for its detection, encour-

Rev Argent Cardiol 2024;92:318-319. http://dx.doi.org/10.7775/rac.v92.i4.20812

Correspondence: Daniela Magali Rubira, Matheu 3146, Mar del Plata. Province of Buenos Aires. E-mail: magalidrubira@gmail.com

[1] Heart Failure, Private Community Hospital, Mar del Plata. Province of Buenos Aires.
[2] Cardiology Department, Hospital Privado de Comunidad, Mar del Plata. Province of Buenos Aires.

ages us to a wider and more targeted implementation of this type of therapeutic tool.

Although this is a retrospective analysis and sensitive to unidentified potential confounders, this study, like many others, highlights the importance of not delaying the indication of CRT in a substantial group of patients with an unfavorable prognosis who are left to standard medical treatment alone.

Ethical considerations

Not applicable.

Conflicts of interest

None declared.

(See authors' conflict of interests forms on the web).

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AUTHORS' REPLY

Cardiac resynchronization therapy (CRT) is indicated in patients with heart failure (HF) and QRS >120ms, who despite receiving optimal medical treatment persist in functional class II-IV and left ventricular ejection fraction < 35%. (1) It is an effective treatment, which has been shown to improve the long-term prognosis of this subgroup of patients. However, there is a percentage, varying between 20-40% depending on the study analyzed, that does not respond to therapy.

Over time, factors related to the lack of response have been identified and there are clear guidelines for effective therapy, among which we can highlight: 1) correct indication of the device; 2) placement of the catheter in the coronary sinus, lateral branch; 3) avoid pacing in areas of necrosis or use of quadripolar catheters to bypass the eschar using different pacing vectors; 4) programming of the optimal AV and V-V intervals to obtain the best VTI; 5) biventricular pacing > 95-97%.

Taking all these criteria into account, our division has created a work system to maintain strict follow-up of all patients with CRT. Six-monthly check-ups are performed, including clinical and electrocardiographic evaluation and device control, including follow-up with remote monitoring of selected patients.

This has allowed us to perform a broad analysis of the response according to clinical and echocardiographic parameters, identifying that the number of responding patients in our population has been high compared to other published series, and that the response has an effect on the reduction of moderate/severe functional mitral regurgitation (2) and also on the reduction of total mortality, appropriate therapies, cardiac transplantation and hospitalization for HF. (3)

Thanks to these results, we emphasize the importance of a timely indication for CRT in selected patients, as well as the importance of a strict control and follow-up that allows us to identify potential predictors of non-response and worse long-term prognosis.

María Eugenia Santillán

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