

assess its incremental value relative to the existing markers of SCD risk in HCM.

APPENDIX. SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at <http://dx.doi:10.1016/j.rec.2020.02.008>

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REFERENCES

- van der Bijl P, Podlesnikar T, Bax JJ, Delgado V. Sudden cardiac death risk prediction: the role of cardiac magnetic resonance imaging. *Rev Esp Cardiol.* 2018;71:961–970.
- Weng Z, Yao J, Chan RH, et al. Prognostic Value of LGE-CMR in HCM: A Meta-Analysis. *JACC Cardiovasc Imaging.* 2016;9:1392–1402.
- Almaas VM, Haugaa KH, Strøm EH, et al. Noninvasive assessment of myocardial fibrosis in patients with obstructive hypertrophic cardiomyopathy. *Heart.* 2014;100:631–638.
- Aletras AH, Tilak GS, Hsu LY, et al. Heterogeneity of intramural function in hypertrophic cardiomyopathy: mechanistic insights from MRI late gadolinium enhancement and high-resolution displacement encoding with stimulated echoes strain maps. *Circ Cardiovasc Imaging.* 2011;4:425–434.
- Hinojar R, Fernández-Golfín C, González-Gómez A, et al. Prognostic implications of global myocardial mechanics in hypertrophic cardiomyopathy by cardiovascular magnetic resonance feature tracking. *Relations to left ventricular hypertrophy and fibrosis Int J Cardiol.* 2017;249:467–472.
- Nucifora G, Muser D, Gianfagna P, et al. Systolic and diastolic myocardial mechanics in hypertrophic cardiomyopathy and their link to the extent of hypertrophy, replacement fibrosis and interstitial fibrosis. *Int J Cardiovasc Imaging.* 2015;31: 1603–1610.

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Awake VA-ECMO in cardiogenic shock: an experience with future potential



Awake ECMO-VA en shock cardiogénico: una experiencia prometedora

To the Editor,

The current guidelines from the European Society of Cardiology for the treatment of cardiogenic shock (CS) put circulatory support with venoarterial extracorporeal membrane oxygenation (VA-ECMO) as the last therapeutic step after inotropes and invasive mechanical ventilation; in emergency situations, it is a suitable option.¹ In respiratory disease, there is increasing use of support with venovenous ECMO implanted in conscious patients who therefore have spontaneous breathing (awake ECMO). This modality aims to avoid intubation, invasive mechanical ventilation, and the associated sedation and immobility, and there is evidence of better postoperative outcomes in terms of complications and mortality.^{2,3} In the current literature, there is very limited evidence on VA-ECMO in CS. So far, only isolated cases and 3 small series (2 in adults and 1 in children) have shown that it is viable and has good outcomes as a rescue for acute CS (23 patients; 6-month survival, 70.8%)⁴ and in patients with advanced heart failure and INTERMACS profile 1 who require support as a bridge to device implantation (19 patients; 1-year survival, 84.2%).⁵

We present the positive experience from our hospital with a group of patients with CS treated with awake VA-ECMO. Of the 73 VA-ECMO implantations for CS between 2010 and 2018, 10 (13.7%) were implanted in patients with spontaneous breathing; 70% of these were in men, with a median [interquartile range] age of 50 [47–57] years. The median APACHE-II score was 16 [9–19], and the SAPS-II score, 30 [25–32]. The most common cause of CS was decompensation of advanced heart failure in patients awaiting transplant (7 patients; 71% in INTERMACS 1 and 29% in INTERMACS 2) and the rest were: 1 acute myocardial infarction

in Killip class IV, 1 septic cardiomyopathy, and 1 acute myocarditis (all 3 were in INTERMACS 1). The aim of circulatory support in the first 8 patients was as a bridge to transplant (7) or to decision on definitive treatment (1); 6 (75%) of these patients finally received a transplant and 2 died while on circulatory support (1 due to malignant cerebral infarction and 1 due to refractory multiorgan failure). In the patients with septic myocardopathy and acute myocarditis, the aim was as a bridge to recovery. Eight patients had implantation of an intra-aortic balloon pump: 5 had already had this implanted prior to ECMO support (those in INTERMACS 1), and 3 required it while on support to offload the left ventricle (table 1).

All ECMO implantations were performed in the intensive care unit with a femorofemoral configuration, except 1 which was implanted in the operating room with a femoroaxillary configuration. The median duration of support was 8 [6.5–11.9] days. Weaning was possible in 80% of the patients (all except the 2 who died), and the overall survival in the intensive care unit was 60%, while survival to discharge from hospital was 50%, similar to that of our general VA-ECMO series.⁶ While on ECMO, 3 patients required intubation and invasive mechanical ventilation due to acute pulmonary edema (2) or stroke (1) (table 2), with a median duration of invasive mechanical ventilation of 84 [57–96] hours; in our general series, this was 312 [126–564] hours. Prior to their intubation, these patients had been on awake ECMO for 6, 60, and 64 hours. The median stay in ICU was 16 [14–18] days and the median hospital stay was 37 [28–59] days.

Regarding complications, 9 patients (90%) had at least 1 complication associated with their circulatory support or clinical condition, with a distribution similar to that published in the literature. The most common complication was pericannular bleeding (5), followed by lower limb ischemia (4), other nonintracranial hemorrhage (n), stroke (1), and oxygenator failure (1). Other complications included acute kidney injury in 60% (5 before starting support and 1 after, who required renal replacement therapy, with complete recovery in 100%), infections

Table 1
Summary of patients and clinical course

| Patient | Age | Sex | Underlying disease | IABP implantation | Support (h) | Complications related to ECMO | Other complications during ECMO |
|---------|-----|-----|-------------------------------|-------------------|-------------|---|--------------------------------------|
| 1 | 50 | M | Valvular DCM | Pre-ECMO | 146 | Lower limb ischemia and gastrointestinal bleeding | Stroke |
| 2 | 58 | M | Idiopathic DCM | Pre-ECMO | 312 | Oxygenator failure | Acute confusional state and CAB |
| 3 | 52 | F | ARVD | No | 134 | Pericannular bleeding | |
| 4 | 47 | F | Familial DCM | No | 192 | No | AKI |
| 5 | 57 | M | Chronic DCM after myocarditis | Post-ECMO | 355 | Lower limb ischemia | |
| 6 | 49 | M | Familial DCM | Pre-ECMO | 190 | Pericannular bleeding | Acute confusional state, CAB and UTI |
| 7 | 39 | M | Idiopathic DCM | Pre-ECMO | 86 | Pericannular bleeding | |
| 8 | 29 | M | Septic cardiomyopathy | Post-ECMO | 194 | Pericannular bleeding and lower limb ischemia | Acute confusional state |
| 9 | 41 | F | Acute viral myocarditis | Post-ECMO | 214 | Lower limb ischemia | |
| 10 | 61 | M | AMI Killip IV | Pre-ECMO | 336 | Pericannular and minor ENT bleeding | Acute confusional state and CAB |

AKI, acute kidney injury; AMI, acute myocardial infarction; ARVD, arrhythmogenic right ventricular dysplasia; CAB, intravascular catheter-associated bacteremia; DCM, dilated cardiomyopathy; ECMO, extracorporeal membrane oxygenator; ENT, ear nose and throat; F, female; IABP, intra-aortic balloon pump; IMV, invasive mechanical ventilation; M, male; UTI, urinary tract infection.

Table 2
Summary of ventricular support used

| Cause of cardiogenic shock | Aim of ECMO support | Reason for stopping ECMO | Final outcome of patients weaned from ECMO | Indication for subsequent IMV |
|--|--|---|---|---|
| Decompensation of advanced CHF (7): 5 INTERMACS 1 2 INTERMACS 2 | Bridge to transplant (6) Bridge to decision (1) | Transplant (5) Death (2): 1 malignant cerebral infarction 1 refractory MOF | Alive (3) Died (2): 1 invasive aspergillosis 1 postoperative mediastinitis | Surgical intervention* (5) Neurological decline (1) APE (1) |
| AMI Killip IV INTERMACS 1 (1) | Bridge to transplant | Transplant | Death (postoperative aortic rupture) | Surgical intervention* |
| Septic cardiomyopathy INTERMACS 1 (1) Acute myocarditis INTERMACS 1 (1) | Bridge to recovery (2) | Recovery (2) | Alive (2) | APE IMV not required |

AMI, acute myocardial infarction; APE, acute pulmonary edema; CHF, chronic heart failure; ECMO, extracorporeal membrane oxygenation; IMV, invasive mechanical ventilation; MOF, multiorgan failure.

* Patients who received transplant required intubation and IMV to allow them to undergo surgery in the operating room.

in 40% (3 associated with the intravascular catheter and 1 urinary), acute confusional state in 4, and stroke (table 1). However, it should be noted here that there were no incidences of respiratory infection or weakness in the critically ill patient (in our general series on VA-ECMO, the incidences were 23% and 20%, respectively, similar to the current literature). Mortality in the patients weaned from ECMO after cardiac transplant related to postoperative mortality.

We present the first published series of awake VA-ECMO in patients with CS in Spain, and the results are promising. In conclusion, and taking into account the limitations of a case series, our results are consistent with the limited international literature. This series demonstrates that VA-ECMO implantation—at least in hospitals with sufficient experience in the management of extracorporeal support in awake patients with spontaneous breathing as circulatory support in CS—is a viable therapeutic option with good outcomes: fewer complications associated with sedation and invasive mechanical ventilation and good morbidity and mortality outcomes. However, more studies are needed to reinforce this practice and optimize appropriate patient selection.

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REFERENCES

- Díez-Villanueva P, Sousa I, Núñez A, et al. Early treatment of refractory cardiogenic shock with percutaneous veno-arterial ECMO implanted in the cardiac catheterization laboratory. *Rev Esp Cardiol.* 2014;67:1059–1061.
- Fuehner T, Kuehn C, Hadem J, et al. Extracorporeal membrane oxygenation in awake patients as bridge to lung transplantation. *Am J Respir Crit Care Med.* 2012;185:763–768.

3. Benazzo A, Schwarz S, Frommlet F, et al. Vienna ECLS Program. Twenty-year experience with extracorporeal life support as bridge to lung transplantation. *J Thorac Cardiovasc Surg.* 2019;157:2515–2525e10.
4. Sommer W, Marsch G, Kaufeld T, et al. Cardiac awake extracorporeal life support-bridge to decision? *Artif Organs.* 2015;39:400–408.
5. Mori M, McCloskey G, Geirsson A, et al. Improving outcomes in INTERMACS 1 category 1 patients with pre-LVAD, awake venous-arterial extracorporeal membrane oxygenation support. *ASAIO J.* 2019;65:819–826.
6. García-Gigorro R, Renes-Carreño E, Pérez-Vela JL, et al. Mechanical support with venoarterial extracorporeal membrane oxygenation (ECMO-VA): Short-term

and long-term prognosis after a successful weaning. *Med Intensiv.* 2017;41:513–522.

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Current clinical outcomes of tricuspid regurgitation and initial experience with the TricValve system in Spain



Resultados clínicos actuales en insuficiencia tricúspide y experiencia inicial con el sistema TricValve en España

To the Editor,

Tricuspid regurgitation (TR) is classified as either primary or secondary according to the underlying mechanism. Moderate/severe TR has been associated with greater mortality than mild insufficiency, even in the absence of pulmonary hypertension or right ventricular dysfunction.¹ Nevertheless, less than 18% of patients with severe TR are referred to tricuspid valve surgery.² In the current era, technology has brought us the opportunity to treat those deemed at high risk for surgical valve replacement with the development of various tricuspid transcatheter valve interventions.³ We aimed to appraise the current management of TR $\geq 2+$ in our center, with special attention to the safety and feasibility bicaval valve implantation (CAVI).

In the first semester of 2018, of 3620 consecutive patients who underwent transthoracic echocardiography, a total of 97 (2.7%) had TR $\geq 2+$ and were followed up for 1 year to determine their outcomes. Of these, TR was severe in 41.7%, massive in 17.7%, and torrential in 2.1%.⁴ Mean age was 75.9 ± 11.2 years, 65% were women and the most common etiology was secondary TR. Echocardiography determined a mean size of the tricuspid annulus (4 chambers) of 48.3 ± 9.3 mm, with an estimated tricuspid annular plane systolic excursion of 16.9 ± 4.2 mm. Mean pulmonary artery systolic pressure was 53.6 ± 14 mmHg and left ventricular ejection fraction was $54.2 \pm 13.3\%$. At a mean follow-up of 323.9 ± 101.4 days, 37.1% of the patients required hospital admission mainly due to heart failure (HF) (58.3%) and at least 7% had multiple readmissions. Overall, the most common strategy was medical treatment (93.8%) and 13 patients (13.5%) died mostly because of refractory HF (61.5%). Two patients underwent uneventful surgical repair with improvement but there was 1 periprocedural death due to right ventricular failure. One more patient, with suitable anatomy for edge-to-edge repair and lack of retrograde large V wave in the caval veins, underwent MitraClip (Abbott Vascular, United States) implantation in the tricuspid position without any clear improvement as a result of residual unchanged TR, despite immediate procedural success. Finally, 2 patients underwent CAVI as compassionate therapy after approval by competent authorities, including Tricento (NVT, Germany) and the first reported case in Spain with TricValve (Products&Features, Austria) systems.

The first CAVI case was a 58-year woman with a mitral mechanical prosthesis (Carbomedics n.25 valve, LivaNova, United Kingdom) implanted 11 years earlier, functional TR, dyspnea in New York Heart Association (NYHA) class III-IV, and multiple

admissions due to HF. Transthoracic echocardiography showed massive TR due to secondary impaired coaptation of the leaflets because of right ventricular dilation with preserved function (51% according to magnetic resonance). After discussion by the Heart Team, it was decided to perform percutaneous implantation of Tricento. The patient was discharged 24 hours after a successful procedure and at 30 days showed NYHA class I, improvement in the 6-minute walk test (6-MWT) from 408 to 475 meters, and reduction in TR to grade 2+.

The second CAVI case was a 74-year woman who had undergone surgical mitral (Carbomedics n.25) and aortic (ATS n.18, Medtronic, United States) valve replacement 8 months previously. At that time, TR was moderate and there was no annular dilation, but after surgery severe TR developed leading to several readmissions due to decompensated right-HF with progression to massive TR. Therefore, the Heart Team decided to implant compassionate TricValve. Transfemoral venous approach implantation of the device was performed under transesophageal echocardiography, and hemodynamic evaluation demonstrated an abolished V wave in both the superior and inferior vena cava (figure 1). The patient was discharged 3 days later after blood transfusion due to pre-existing anemia. At 30 days, functional status improved to NYHA class II, 6-MWT from 158 to 239 meters, and TR persisted as severe but with reduction of pulmonary artery systolic pressure from 68 to 49 mmHg.

In general, the CAVI systems try to abate the backward blood flow into the caval veins,⁵ which are usually dilated at end-stage TR for damping HF symptoms. Its indication requires careful hemodynamic assessment (retrograde V wave and wedge pressure) and its correlation with the etiology of the dyspnea. Compared with orthotopic valves, there is a lower risk of cardiac injury or acute right ventricular failure; nevertheless, atrial and ventricular volume overload status remains because the structure of the native valve is not modified. The question of whether further dilation of the caval system might occur causing periprosthetic leakage and minimizing the clinical positive impact of this heterotopic strategy remains unanswered, but this initial experience reflects positive remodeling in the right heart and venous system in the short-term. Interestingly, the TricValve system offers standardized sizes and less interplay with the atrium as opposed to the Tricento device, which requires customize sizing. In addition, TricValve can be implanted in patients with a short distance from the inferior vena cava to the suprahepatic veins (< 10 mm) because the sealed segment is shorter than with Tricento.⁵

In summary, TR is associated with high mortality in the short-term with medical treatment. Assessment of potential prognostic benefit by bicavally implanted heterotopic prosthesis requires longer term studies, but our initial experience suggests safe and effective procedural and short-term outcomes.