



Article Survey on Cardiogenic Shock and the Use of ECMO and Impella in Spanish Cardiac Critical Care Units

Manuel Martínez-Sellés ^{1,2,3,*}, Jorge García Carreño ¹, Jorge Martínez-Solano ¹, Iago Sousa ¹ and Miriam Juárez-Fernández ¹

- ¹ Cardiology Department, Hospital General Universitario Gregorio Marañón, CIBERCV, 28007 Madrid, Spain; jgc.fire@gmail.com (J.G.C.); jorge92ms@gmail.com (J.M.-S.); mijufernandez@secardiologia.es (M.J.-F.)
- ² School of Biomedical and Health Sciences, Universidad Europea, 28670 Madrid, Spain
- ³ School of Medicine, Universidad Complutense, 28040 Madrid, Spain
- * Correspondence: mmselles@secardiologia.es; Tel.: +34-915-868-293

Abstract: Background: Previous studies suggest variability in the management of cardiogenic shock (CS). Methods: An anonymous survey was sent to Spanish hospitals. Results: We obtained 50 answers, mainly from cardiologists (36–72%). The annual average of ECMOs is 16.7 ± 11.3 applications in CS patients and of Impellas is 8.7 ± 8.3 applications in CS patients. Intra-aortic balloon counterpulsation is used in the majority of CS ECMOs (31–62%), and Impella is used in 7 (14%). In 36 (72%) cases, ECMO is used as a treatment for cardiac arrest. In 10 cases, ECMO removal is percutaneous (20%). In 25 (50%) cases, age is a relative contraindication; 17 have a mobile ECMO team (34%); and 23 (46%) have received ECMO patients from other centers in the last year. Pre-purged ECMO is only used in 16 (32%). ECMO implantation is carried out under ultrasound guidance in 31 (62%), only with angiography in 3 (6%) and with both in 11 (22%). The Swan–Ganz catheter is used routinely in 8 (16%), only in doubtful cases in 24 (48%), and in most cases in 8 (16%). The ECMO awake strategy is used little or not at all in 28 (56%), in selected cases in 17 (34%), and routinely in 5 (10%). Conclusion: Our study shows a huge variation in the management of patients with CS.

Keywords: cardiogenic shock; ECMO; Impella; survey

1. Introduction

Cardiogenic shock (CS) is a state of end-organ hypoperfusion related to cardiac dysfunction. The prognosis of CS continues to be poor, despite the development of mechanical circulatory support (MCS) [1]. The scarce evidence obtained with randomized clinical trials in this setting might explain inter-center variation in the management of patients with CS. Current guidelines recommend consideration of inotrope therapy in patients with CS; however, no robust data support their use [2]. In the case of MCS, the evidence is also scarce [3,4]. Impella and venoarterial extracorporeal membrane oxygenation (ECMO) are the most commonly used MCS for the treatment of patients with CS. Their results are not easy to compare, as ECMO is usually preferred in more advanced types of CS with severe respiratory failure and/or biventricular ventricular systolic dysfunction. Therefore, recent data that have suggested a benefit of Impella compared to ECMO [5,6] are difficult to interpret as ECMO-treated patients frequently have a more severe CS and are more prone to infections and other complications [7]. In addition, the newest anticoagulation strategies, both for ECMO [8–10] and Impella [11–13], can also affect the complication rate in these patients.

Intra-aortic balloon counterpulsation is frequently used in ECMOS implants due to left ventricular dysfunction. Moreover, the peculiarities of each hospital and region, the structure of the professional teams and their logistics, and the availability and type of MCS have a profound effect on the management of CS patients [14].



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Copyright: © 2023 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). The management of these patients and devices requires specialist training and expertise. A close relationship between the volume of cases and in-hospital mortality in patients with CS receiving short-term MCS has been described [15]. Variations in expertise and clinical practice may also influence outcomes, but there is almost no evidence regarding CS intercenter variations [16], particularly in the cases of medical CS and patients managed by cardiologists.

The aim of this study was to identify clinical practice differences through an anonymous survey sent to Spanish academic hospitals.

2. Materials and Methods

2.1. Study Design

A prospective electronic survey of CS practice in Spain was conducted from 1 May to 31 May 2023. The original survey was in Spanish; given that the primary target audience was Spanish medical doctors, in Appendix A, the English translation of the questionnaire is shown. The idea of performing this survey came up during the meetings of the expert panel in charge of the manuscript regarding CS in Spain [17], a manuscript endorsed by the following institutions: the Scientific Associations of the Spanish Society of Cardiology (Interventional Cardiology, Heart Failure, Ischemic Heart Disease, and Acute Cardiovascular Care), the Spanish Society of Pediatric Cardiology and Congenital Heart Disease, the Spanish Society of Anesthesiology, Critical Care and Pain Therapy, the Spanish Society of Cardiovascular and Endovascular Surgery, the Spanish Society of Intensive and Critical Care Medicine and Coronary Units, the Spanish Society of Emergency Medicine, and the Spanish Association of Perfusionists. Items included in the survey were selected following a literature review and expert opinions. A first preliminary questionnaire based on the input from this multidisciplinary group was completed by the authors (intensive care cardiologists and, in the case of JGC, interventional cardiologists). A second questionnaire with small changes proposed by the authors on data points that required clarification was developed. Finally, we performed a subsequent item reduction to ensure the survey contained a manageable number of questions that were clinically relevant. The Consensus-Based Checklist for Reporting of Survey Studies (CROSS) checklist [18] was used to report our results.

2.2. Participant Population

Inclusion criteria for survey participants: all authors of the recent expert document regarding CS in Spain [17] were contacted and asked to answer the questionnaire and provide contact data for additional expert clinicians with large experience managing CS. At least one survey was completed per participating site; in some cases, two surveys per site were registered, but only if filed by specialists working in different settings/departments. Exclusion criteria: (1) having answered the survey previously; (2) a survey already answered by a member of the same department; (3) two surveys already answered by members of the same center; (4) no experience managing CS in a Spanish center. The list of Spanish regions and institutions represented by the participants is as follows: (1) Andalucía:-Córdoba: Reina Sofía;—Sevilla: Virgen Rocío; Virgen Macarena; (2) Asturias:—Oviedo: Central de Asturias; (3) Cantabria:—Santander: Marqués de Valdecilla; (4) Canarias:—La Laguna: Santa Cruz de Tenerife;—Gran Canaria: Doctor Negrín; (5) Castilla la Mancha:—Albacete: General;—Toledo; (6) Castilla y León:—Salamanca: Clínico;—Valladolid: Clínico; (7) Cataluña:—Barcelona: Santa Creu i Sant Pau; Bellvitge; del Mar; Vall d'Hebron;—Girona: Doctor Josep Trueta; (8) Comunidad de Madrid:—Madrid: Gregorio Marañón; Puerta de Hierro; La Princesa; Doce de Octubre; La Paz; Clínico San Carlos; (9) Comunidad Valenciana:--Valencia: General; Politécnico la Fe; (10) Galicia:-Santiago de Compostela: Clínico;-A Coruña: Complejo; (11) País Vasco:—Barakaldo: Cruces; (12) Región de Murcia:—Murcia: Virgen de la Arrixaca. The sample size was not calculated as this is an observational study that aimed to obtain the maximum number of answers. Continuous variables are expressed as the mean \pm standard deviation. Categorical variables are presented as frequencies and percentages. All analyses were performed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA).

All items were mandatory, and filling out the answer to a question was only possible after filling out the previous one. Due to this reason, there was no missing information from the survey forms. As previously stated, no double entry was possible as, although the survey was anonymous, the first item was the center and the second one was the department. The survey only permitted two answers from each center and one from each department.

3. Results

3.1. Participants and Centers

We obtained 50 answers from 28 hospitals. Participant physicians had a mean age of 46.2 ± 11.0 years, and 13 (26%) were women. Most participants were cardiologists (36–72%) (Figure 1). The main setting of work was adult patients (2 exceptions), centers with cardiac surgery (2 exceptions), senior consultants (3 exceptions), ECMO/Impella availability 24/7 (8 exceptions), and distal perfusion cannulas usually used to avoid ischemia (7 exceptions). A regionally structured cardiogenic shock code was present in 5 cases (10%).

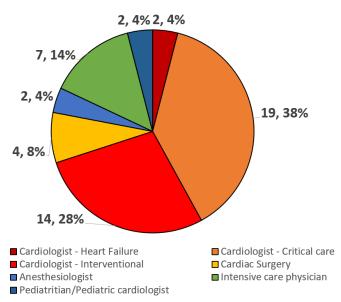


Figure 1. Type of medical specialization of the participants.

3.2. MCS Volume, Type, and Logistics

The annual average of ECMOs was 16.7 ± 11.3 applications in CS patients and of Impellas was 8.7 ± 8.3 applications in CS patients (Figure 2). Specific and paid on-call alerts for CS were available in 6 (12%), in 14 there was a non-specific or non-paid on-call alert (18%), and in the rest, code infarction or similar on-call alerts were used (30–60%). Intra-aortic balloon counterpulsation is used in the majority of ECMOs implanted due to left ventricular dysfunction (31–62%), Impella is used in 7 (14%), and no unloading is carried out in 12 (24%). The type and timing of MCS devices are decided by cardiologists (22–44%), multidisciplinary teams (17–34%), intensive care physicians (9–18%), and cardiac surgeons (2–4%). ECMO implants are mainly carried out by cardiac surgeons (34–68%), interventional cardiologists (13–26%), or with a similar frequency by both specialists (5–10%). In 26 (52%) cases, ECMO is used as a treatment for cardiac arrest. In 7 patients, ECMO removal is usually percutaneous (14%), in 40 with surgery (80%), and in 3 patients,

both are used in a similar number of patients (6%). In 25 answers, age is not a relative contraindication for ECMO/Impella (50%), in 12 answers, age 65–70 years is a relative contraindication (24%), and in 13 answers (26%) the threshold is 75–80 years. In 19 (38%), Impella 5.5 is available in stock. In 24 (48%), it is not and 7 were not sure (14%). In 17 there is a mobile ECMO team (34%) and 23 (46%) received ECMO patients transferred from other centers in the last year. Pre-purged ECMO was only used in 16 (32%).

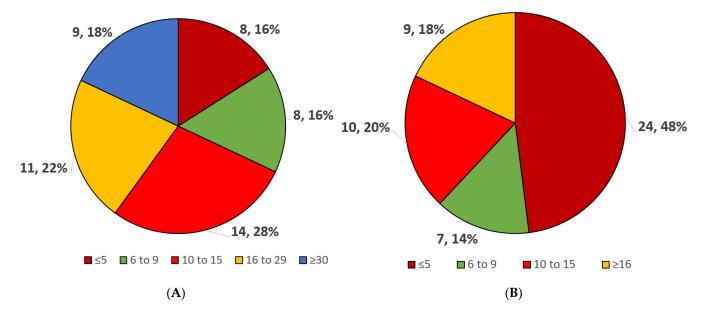


Figure 2. (**A**) Annual average of venoarterial extracorporeal membrane oxygenation implantation in patients with cardiogenic shock; (**B**) annual average of Impella implantation in patients with cardiogenic shock.

3.3. Protocols and Training

The decision regarding an MCS implant is based on protocol with a standardized approach (22–44%) or is carried out by a physician on an individual basis (28–56%). A total of 35 (70%) carry out continuous training on ECMO/Impella (33 for physicians and nurses, 2 only for nurses), and 41 (82%) have written protocols (35 for physicians and nurses, 3 only for nurses, and 2 only for physicians). Data have been collected systematically in 44 cases (88%), and they have been published in 21 (42%). Data regarding specific CS training outside their center and of professionals received from other centers to be trained on CS are depicted in Table 1. Figure 3 shows the professional that is usually in charge of ECMO circuit management (purge, air, thrombus, hybrid configurations, and cannulas).

Table 1. Specific cardiogenic shock (CS) training outside their center and professionals received from other centers to be trained on CS.

Specific CS Training in Other Center	Receptors of Professionals to Be Trained on CS
No (3–6%)	No (24–48%)
Only physicians (17–34%)	Only physicians (13–26%)
Only nurses (1–2%)	Only nurses (1–2%)
Both (29–58%)	Both (12–24%)

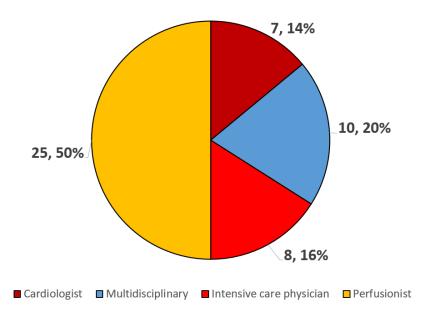


Figure 3. A professional that is usually in charge of venoarterial extracorporeal membrane oxygenation circuit management (purge, air, thrombus, hybrid configurations, cannulas).

3.4. Patient Management and Drugs

ECMO implantation is carried out under ultrasound guidance in 31 (62%), only with angiography in 3 (6%), with both in 11 (22%), and in 5 cases (10%) no guidance is used. The most common anticoagulation management is guided by activated partial thromboplastin time (aPTT) and antifactor Xa (anti-Xa) assays 46 (92%). The Swan-Ganz catheter is used routinely in 8 (16%), only in doubtful cases in 24 (48%), and in most cases in 18 (36%). Levosimendan is used little/never in 5 (10%), only at weaning in 27 (54%), and both at the acute moment and at weaning in 18 (36%). Ivabradine is used in 14 (28%). A total of 26 (52%) patients in CS undergo unloading before primary angioplasty. The ECMO-awake strategy is used little or not at all in 28 (56%), in selected cases in 17 (34%), and routinely in 5 (10%).

3.5. Pulmonary Thromboembolism

Patients with shock are usually managed by intensive care physicians (30–60%), cardiologists (11–22%), and multidisciplinary teams (6–12%); other options are less common (1 cardiac surgeon and 1 anesthesiologist). Most can perform scheduled and urgent thrombectomy (34–68%), 10 only schedule (20%), and 6 do not have this option (12%).

4. Discussion

Our study shows that there is a huge variation in the treatment of CS patients between Spanish hospitals. The main differences include the presence of site-specific clinical protocols, volume (only 18% are considered high-volume ECMO centers, reporting more than 30 ECMO patients admitted per year), management (particularly in the case of Swan-Ganz catheters and drugs), training practices, and logistics. Our data suggest a need to report CS management in a prospective national registry to measure complications, resource utilization, and outcome.

The staff required to care for CS patients can vary and include cardiologists, intensive care physicians, cardiac surgeons, anesthesiologists, perfusionists, and nurses. The best way to organize this multidisciplinary team is unknown and probably depends on specific center characteristics. Previous data have suggested cost savings through training ICU staff to care for and manage ECMO patients compared with patients managed by perfusionists [16], but the extrapolation of that experience to other hospitals is unclear.

Our study has generated important insights about CS clinical practice in Spain. The survey results align with previous data, showing that there is considerable variation in

clinical practice and CS patient volume. Guidelines from the Extracorporeal Life Support Organization (ELSO) recommend the successful and safe management of CS patients with a sufficient volume (at least six cases per year). In our survey, this threshold was not achieved by 16%. This is relevant, as a close relationship between the volume of cases and in-hospital mortality in patients with CS receiving short-term MCS has been recently described [15]. In addition, the protocolization of CS management and MCS implantation is essential, as frequently decisions are needed during the night or on weekends, and off-hours implantation is common [19]. Therefore, the fact that protocols are not available in some centers is a cause for concern and should be changed as soon as possible. These protocols might include, among other variables, age. Age is a predictor of poor outcomes in CS patients [20], but should not be used as the only variable in the decision-making process. Data regarding the use of MCS in elderly patients with CS are scarce, but a benefit is suggested even in octogenarians [21].

In our survey, venoarterial ECMO use was double that of Impella. Although recent data that have suggested a benefit of Impella compared to ECMO [5,6] are difficult to interpret as ECMO-treated patients usually have a more severe CS. In addition, cost might also be a reason for the lower use of Impella, although recent studies have suggested that Impella is cost-effective [22].

Regarding drugs, our survey found relevant differences among centers. Ivabradine reduces sinus heart rate without affecting inotropism, making it an attractive drug for performing heart rate control in CS patients. Tachycardia is a frequent compensatory mechanism in response to hypotension and low cardiac output or a side effect related to inotropic drugs. A small non-randomized series of patients with CS has suggested safety and benefit, even in patients with veno-arterial ECMO [23], but the absence of strong evidence to support ivabradine in CS patients might explain the differences we found. With levosimendan, the situation is similar. In fact, although current guidelines recommend inotrope therapy in patients with CS, no robust data support their use [2]. A recent meta-analysis found that, in patients receiving veno-arterial ECMO, levosimendan seemed to raise the weaning success rate and reduce mortality [24]. However, most of the evidence comes from retrospective studies, and randomized multicenter trials would be required to verify this benefit. Finally, the type and optimal therapeutic target for anticoagulation during ECMO and Impella treatments are unclear. In our survey, over 90% of anticoagulation management was guided by aPTT and anti-Xa assays. Previously published studies regarding anticoagulation management in CS treated with ECMO and Impella are limited by retrospective, observational design, small cohorts, patient heterogeneity, and, in the case of ECMO, the inclusion of data from venovenous and venoarterial ECMO [8-12]. Randomized controlled trials of anticoagulation strategies for patients undergoing venoarterial ECMO and Impella for CS would be welcome.

CS in patients with pulmonary embolism has specific peculiarities and management. Composite scores to more effectively stratify these patients and select those that might benefit from mechanical thrombectomy are needed [25].

Strengths and Limitations

Our study includes information from a large number of centers that reflects real-life clinical practice regarding the management of CS patients in Spain. It includes both high- and low-volume sites, but there may be CS patients admitted to other hospitals that were not captured in this survey. The fact that our results are based on a national survey is also a limitation, as the situation in other countries might be different. In addition, most of the physicians that answered our survey were adult cardiologists, so extrapolations to other settings or specialties might be difficult. Finally, practices within the same department might have variations.

5. Conclusions

Our survey confirms that there is a huge variation in the treatment of CS patients between Spanish hospitals. Differences were found in site-specific clinical protocols, volume, resources, and training practices. There is a need to report CS management in a prospective national registry to measure complications, resource utilization, and outcome.

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Conflicts of Interest: The authors declare no conflict of interest.

Appendix A

1. Specialty Cardiology—Critical care Interventional cardiology Intensive care Cardiac surgery Anesthesia Cardiology: heart failure and heart transplant 2. Age 3. Sex 4. Type of physician Senior clinician Fellow Resident 5. Hospital name 6. Setting Adults **Pediatrics** 7. Number of VA ECMOs per year in your department in CS patients 8. Number of Impellas per year in your department in CS patients 9. In my center there is Cardiac surgery and Interventional cardiology Interventional cardiology only None 10. CS code alert 24/7, different from the heart attack code and with remuneration Cardiogenic shock code alert but the previous premises are not met None 11. In my center when VA-ECMO is implanted for LV dysfunction, LV unloading: Is usually not conducted Usually Intra-aortic balloon counterpulsation Usually Impella 12. In my center the implantation of MCS in CS is decided: By protocol

Decision of the physician in charge 13. In my center, the type and timing of MCS implantation in medical CS is usually decided by: Cardiology Intensive Care physician Anesthesia Cardiac surgery 14. In my center, VA-ECMOs are usually implanted in medical patients by Interventional Cardiology Surgery Both similar 15. In my center the ECMO circuit management (purge, air, thrombus, hybrid configurations, cannulas) is usually carried out by: Cardiologist Intensive care physicians Anesthesia Perfusionist 16. In my center, a distal perfusion cannula is usually used to avoid ischemia. Yes No 17. ECMO-CPR is available at my center Yes No 18. In my center, the removal of MCS is usually carried out: Percutaneous (interventional cardiology) Surgical intervention 19. In my center there is an age limit as a relative contraindication for mechanical support No Yes 50-55-60-65-70-75-80 20. My center has Impella 5.5 available in stock Yes No I do not know 21. My center has a "mobile ECMO-VA" program Yes No 22. My department has received patients with VA-ECMO implanted in another center in the last year Yes No 23. In my department, pre-purged VA-ECMO is used Yes No, purging is performed at the time of implantation 24. In my department, ECMO-VA/Impella continuing educational sessions are held at least once a year Yes, for physicians and nurses For physicians only For nurses only No 25. In my department there are written protocols for the management of patients with ECMO-VA/Impella Yes, for physicians and nurses For physicians only For nurses only

No 26. My department collects data from patients with CS treated with VA-ECMO/Impella Yes and some have been published Yes, but they have not been published No 27. In my department there are professionals who have undergone specific training in the management of VA-ECMO/Impella outside the hospital Yes, physicians and nurses Physicians only Nurses only No 28. In my department there are professionals from other centers who come to train in ECMO/Impella with us Yes, physicians and nurses Physicians only Nurses only No 29. In my department, the assessment of vascular access for VA-ECMO/Impella implantation is usually performed: Echo-guided Angiography-guided Both None 30. In my department, anticoagulation in patients with VA-ECMO is usually: Adjusted by APTT/antiXa Premembrane UFH Prolonged times without anticoagulation 31. In my department the use of Swan-Ganz catheter in CS: Routine, in almost all cases Only in a few cases In most patients with MCS 32. In my department levosimendan in CS is used: Little/not at all Frequently, but only at weaning Frequently, both at the acute moment and as weaning 33. Ivabradine is used in my department in CS: Yes No 34. In my center, ventricular unloading is usually performed before primary angioplasty with IAoB/Impella in patients with code myocardial infarction and CS. Yes No 35. In my center ECMO-awake is used: Little/not used Selected cases Frequently 36. In my center, the management of high-risk pulmonary embolism in which thrombolysis, ECMO and/or thrombectomy are considered usually falls on: Cardiology Intensive Care Physicians Anesthesia Cardiac surgery

37. My center is available to perform percutaneous thrombectomy Yes, urgent and scheduled Not urgent, only scheduled None

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