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Research Article

Maintaining A Temporary Mechanical Circulatory Support Program During A Year of COVID-19 Pandemic

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Abstract

Background: The Coronavirus disease 19 (COVID-19) pandemic has impacted clinical practice with important changes in the most affected areas, resulting in increased mortality from heart disease (myocardial infarction). Our objective was to analyze the feasibility of continuing a temporary mechanical circulatory support (MCS) program survival during COVID-19 pandemic.

Methods: Retrospective study including all veno-arterial extracorporeal membrane oxygenation (VA-ECMO) and Impella CP® implants in a referral hospital since March 2020 to February 2021. They were compared to previous implants results.

Results: Out of 175 short-term MCS implanted from 2013, 33 (18.9%) were conducted during the time of COVID-19 pandemic: 24 VA-ECMO and 9 Impella CP®. Compared to preCOVID-19 implants, patients in COVID-19 era presented worst left ventricular ejection fraction (16.5 [21]% vs 25 [21]%, p=0.018), more frequently right ventricular dysfunction (72.7% vs. 48.6%, p=0.022), without other significant

differences regarding the baseline situation and implant technique. Post anoxic encephalopathy was more frequent in COVID-19 era. Survival at discharge was similar in the pre-COVID era (43.7%) and during pandemic (39.4%) (p=0.700).

Conclusions: Survival after temporary MCS did not get worse significantly during the COVID-19 pandemic. The possibility of short-term MCS should be maintained for cardiogenic shock and other cases of hemodynamic instability.

Keywords: Mechanical circulatory support; ECMO; COVID-19; cardiogenic shock

1. Introduction

The Coronavirus disease 19 (COVID-19) pandemic has impacted clinical practice with important changes in the most affected areas, resulting in increased mortality from heart disease such as acute myocardial infarction (AMI) [1]. The severe pneumonia and acute respiratory distress syndrome (ARDS) in the infected patients has required veno-venous extracorporeal membrane oxygenation (VV-ECMO) therapy in up to 1% of cases[2-3], with more than 4500 cases registered in Extracorporeal Life Support Organization (ELSO) registry[4-5], assuming the overuse of this resource, usually available for both circulatory and respiratory support. The feasibility of continuing a temporary mechanical circulatory support (MCS) program for cardiogenic shock and other situations of hemodynamic instability for non COVID-19 patients is unknown. Our objective was to analyze the admission characteristics and survival of patients requiring short-term MCS during the COVID-19 pandemic.

2. Materials and methods

Prospective registry analysis including all short-term MCS devices implanted in a referral hospital from March 2020 to February 2021 in the intensive cardiac care unit (ICCU). Patients under MCS during the pandemic were compared to previous implants results regarding demographic and clinical variables, complications during the admission and survival at discharge. The devices available in our center before the pandemic were 3 ECMO (Cardiohelp system, Maquet, Rastatt, Germany), available for veno-arterial (VA) and VV therapy; 2 Impella CP® (Abiomed, Inc., Danvers, Massachusetts) and 2 Centrimag-Levitronix® (Levitronix LLC, Waltham, MA, USA). We expected the need for an average 33 short-term MCS implants per year (trend of the previous three years in our center), as well as an increase in the need for ECMO-VV due to ARDS in COVID-19 patients. Thus, during the pandemic, 2 new ECMO devices (Permanent Life Support -PLS-system, Maquet, Rastatt, Germany) and oxygenators to provide ECMO therapy intercalated in the Centrimag-Levitronix® circuit were acquired. During two months the ICCU was relocated by transforming 2 of the 4 catheterization laboratories of the cardiology department due to intensive care units (ICUs) saturation in the first pandemic wave. Half of the cardiologists were referred to other services to care for COVID-19 patients, keeping specialists in cardiovascular critical care in the Cardiology service in order to ensure assistance in the non-COVID ICCU. The alert for implantation of MCS devices (cardiologist, interventional cardiologist or cardiac surgeon depending on the implant, nurses and perfusionist) remained unchanged during the pandemic. Widespread testing for severe acute

respiratory syndrome coronavirus 2 (SARS-CoV-2) was available for all patients before admission and during hospitalization. Patients requiring emergent attention were treated with the usual infection control measures recommended for COVID-19 patients until the results of their tests were known. The possibility of short-term MCS for COVID-19 patients with hemodynamic instability was offered as well. The study conformed to the principles outlined in the Declaration of Helsinki. Statistical analysis was performed using the IBM SPSS, version 22 (IBM Corp., Armonk, N.Y., USA) using a Chi-Square or Fisher's exact test and student's T test or Mann-Whitney U test, according to their adjustment to normality. A p value of <0.05 was considered statistically significant for all analysis.

3. Results

Out of 175 short-term MCS implanted from 2013, 33 (18.9%) were conducted during the time of the COVID-19 pandemic: 24 VA-ECMO and 9 Impella CP®. Two of the patients who required VA-ECMO presented concomitant COVID-19, and the rest of the patients who required MCS were non-infected. Baseline characteristics, situation at the MCS implant, type of support, and complications during the admission are resumed in Table. The MCS device implantation rate remained similar to the previous three years (mean 25.7 VA-ECMO and 9 Impella CP® implants per year) during the COVID-19 pandemic. At the same time, during the pandemic year we observed a significant increase in the use of VV-ECMO (pre-pandemic mean 2 implants per year vs 14 implants during COVID-19 era).

Table: Comparison MCS before and during the COVID-19 outbreak

		Time of implant		P value
		Pre-COVID-19 2013-Feb 2020 (n=142)	**COVID-19 time March 2020-Feb 2021 (n=33)**	
Baseline characteristics (n,%)	Age (years) (mean+ SD)	62±10	66±10	0.084
	Male (n, %)	108 (76.1%)	22 (66.7%)	0.275
	Arterial hypertension	80 (56.3%)	19 (57.6%)	0.177
	Diabetes mellitus	51 (35.9%)	12 (36.4%)	1
	Dyslipidemia	67 (47.2%)	16 (48.5%)	1
	Smoking (previous or current)	80 (56.3%)	14 (42.4%)	0.205
	Previous cardiopathy	65 (45.8%)	18 (54.5%)	0.440
	Chronic kidney disease	8 (5.6%)	2 (6.1%)	0.808
	Chronic obstructive lung disease	6 (4.2%)	1 (3.0%)	0.620
	Cerebrovascular disease	7 (4.9%)	1 (3.0%)	0.577
	Peripheral artery disease	13 9.2%)	3 (0.1%)	0.656

Situation at the admission	Indication (n,%)			0.519
	Cardiogenic shock	63 (44.4%)	15 (45.5%)	
	Refractory cardiac arrest	16 (11.3%)	5 (15.2%)	
	Electrical storm	9 (6.3%)	2 (6.1%)	
	High-risk PCI	17 (12%)	6 (18.2%)	
	Postcardiotomy shock	36 (25.4%)	5 (15.2%)	
	Others	1 (0.7%)	0 (0%)	
	Blood test			
	pH (mean+SD)	7.26±0.2	7.21±0.2	0.153
	lactate (mmol/L) (mean+SD)	6.32±5	7.1±5	0.467
	Creatinine (mg/dl) (mean+SD)	1.3 [0.77]	1.2 [0.97]	0.759
	Hemoglobine (g/dl) (mean+SD)	11.8±2.9	10.7±2.9	0.049
	Platelets (x 10^3/µL) (mean+SD)	172±93	164±85	0.630
	Bilirrubin (mg/dl) (median, range)	0.78 [0.87]528 [640]	0.61 [0.53]	0.328
	LDH (U/L) (median, range)		640 [824]	0.494
	LVEF (%) (median, range)	25 [21]	16.5 [21]	**0.018**
	RV dysfunction (n,%)	69 (48.6%)	24 (72.7%)	**0.022**
	Preimplant cardiac arrest (n,%)	69 (48.6%)	16 (48.5%)	0.424
	Cardiac arrest duration (min) (n,%)	11 [39]	9 [50]	0.558
MCS characteristics (n,%)	Bridge to			**0.018**
	Recovery	106 (74.7%)	18 (54.5%)	
	Transplant	8 (5.6%)	1 (3.0%)	
	Ventricular assist device	8 (5.6%)	2 (6.1%)	
	Decision	4 (2.8%)	7 (21.2%)	
	Elective High-risk PCI	16 (11.3%)	5 (15.2%)	
	Support type			
	VA-ECMO (n=142)	118 (83.1%)	24 (72.7%)	0.301
	Impella CP® (n=33)	24 (16.9%)	9 (27.3%)	
	Percutaneous implant	100 (70.4%)	27 (81.8%)	0.162
	Femoral-femoral	119 (83.8%)	30 (90.9%)	0.071

	Intraaortic balloon pump added to ECMO (n=142)	52 (44.1%)	9 (37.5%)	0.124
	Impella CP® added to ECMO (n=142)	4 (3.4%)	1 (4.2%)	1
	Drugs at the implant			
	Noradrenaline	116 (81.7%)	28 (84.8%)	0.426
	Dobutamine	115 (80.9%)	26 (78.8%)	0.357
	Adrenaline	51 (35.9%)	8 (24.2%)	0.257
	eCPR (n=142)	26 (22.0%)	6 (25.0%)	0.810
	Endotracheal intubation	120 (84.5%)	25 (75.8%)	0.190
	Time at MCS (days) (median, range)	4 [6]	3±6	0.176
Evolution (n,%)	Complications			
	Vascular (bleeding, ischemia)	36 (25.4%)	7 (21.2%)	0.171
	Bleeding (minor or major)	60 (42.3%)	12 (36.4%)	0.165
	Critical care infections	69 (48.6%)	13 (39.4%)	**0.027**
	Ischemic/hemorragic stroke	9 (6.3%)	3 (9.1%)	0.108
	Renal replacement therapy	36 (25.4%)	6 (18.2%)	**0.038**
	Tracheostomy (prolonged MV)	23 (16.2%)	9 (27.3%)	0.283
	Encephalopathy	14 (9.8%)	7 (21.2%)	**0.039**
	Cause of death during admission			0.502
	Refractory CS/irreversible MODS	39 (27.5%)	5 (15.2%)	
	Anoxic encephalopathy	14 (9.9%)	5 (15.2%)	
	Bleeding complication	6 (4.2%)	2 (6.1%)	
	Other	19 (12.4%)	5 (15.2%)	

Compared to preCOVID-19 implants, patients requiring MCS in the COVID era presented worst left ventricular ejection fraction (LVEF) (16.5 [21]% vs 25 [21]%, p=0.018) and more frequently right ventricular dysfunction (72.7% vs. 48.6%, p=0.022), without other significant differences regarding the baseline situation and implant technique (Table). We did not find significant differences in the MCS indication, but bridge to decision MCS intention

increased significantly during the COVID-19 pandemic (p=0.018) (table).

Post anoxic encephalopathy was more frequent in the COVID-19 era, but infections associated with critically ill patients (throughout hospitalization) and the need for renal replacement therapy were greater in the pre-COVID time, with no differences in other complications (Table). Survival at discharge was 43.7% in the pre-COVID era vs 39.4% during COVID-19 pandemic, without finding statistically significant differences (p=0.700). Nor did we find differences regarding the causes of death during admission (table).

4. Discussion

Our study highlights a real world practical challenge in providing timing MCS during pandemic. Adapting a short-term MCS program during the COVID-19 pandemic is challenging, and we describe our experience and results compared to previous practice. This has been a challenge while ICUs saturation[6], overuse of VV-ECMO and changes in hospital practice, but we showed similar results to pre-COVID time despite adversities.

Short-term MCS should be available for selected patients in cardiogenic shock and other situations of hemodynamic instability, both for patients with COVID-19 as well as for non-infected [7]. Regarding the MCS indication, given the anticipated limitation of resources during the COVID-19 pandemic, it is reasonable to prioritize those younger patients with less comorbidity that may limit their prognosis, concentrate implants in experienced centers, and plan provision of devices, as recommended by the ELSO and other reviews[8-12]. And these criteria should be considered in the case of both COVID-19 and non-infected patients, since the limited resources of circulatory and respiratory support devices must be indicated ensuring the maximum benefit of all patients. Although we did not find significant differences in the indication for MCS, most of them because of cardiogenic shock, the number of implants in postcardiotomy shock was reduced.

This fact was probably related to the reduction of elective cardiac surgery interventions during the pandemic. The increase in the use of VV-ECMO for COVID-19 patients forced us to acquire older and less compact devices than the one we usually use for VA-ECMO (PLS system or Centrimag with oxygenator instead of Cardiohelp system). The versatility of the equipment allowed the expansion and adaptation of resources at a time with a clear overuse of ECMO in our center.

On the other hand, the need to start a MCS is emerging on many occasions, when COVID-19 status history may be limited and a result of test for SARS-COV-2 is not yet available. This is an added difficulty since it requires the use of personal protective equipment (PPE), minimizing the personnel in contact, and all infection control measures, which can hinder and delay the start of support, as occurs with the delay of door-to-ballon times in the primary percutaneous coronary intervention (PCI) in ST-elevation myocardial infarction (STEMI)[13].

In addition, it should be taken special precautions for high droplet components of the procedures that are usually required in these patients (i.e. intubation and

cardiopulmonary resuscitation –CPR-). The possible delay caused in the implantation of the MCS due to the difficulties caused by the pandemic could influence the higher rate of encephalopathy, despite the fact that the patients had similar cardiac arrest duration.

Furthermore, the saturation of ICUs by COVID-19 patients has also posed a challenge to maintain beds for uninfected patients requiring MCS, using extended ICUs in different locations as in our case. The management of critically ill patients in support with VA-ECMO or Impella is complex, and carrying it out in extended ICU spaces can be challenging[14]. It should be taken into consideration that an ICU bed for a patient under MCS requires advanced monitoring, oxygen ports, compressed air supply, clean water and drainage systems.

An increase in mortality due to AMI has been observed around the world during the pandemic[1], which is the main cause of cardiogenic shock. This fact, together with a decrease in the number of STEMI consultations observed during the pandemic[1,15], could lead to a late admission of the patient in a situation of shock or cardiac arrest. The delay in the medical contact of patients and in the treatment of STEMI has also been able to influence the worse biventricular function observed in patients who required MCS during the year of the pandemic.

It could be assumed that the mortality of patients under MCS would increase. However, in our experience, we did not observe significant differences in the survival of patients who required MCS during the outbreak, despite having worse characteristics (lower LVEF and more right ventricular dysfunction) to those patients who used MCS in preCOVID time.

Similar to what is recommended in preserving the primary PCI for the STEMI, the shock team formed in each referral center should be maintained to provide the best care for cardiogenic shock and other situations of hemodynamic instability[13]. In patients with refractory cardiac arrest, the use of VA-ECMO for extracorporeal CPR during the COVID-19 pandemic could be considered for highly selected patients in expert centers, due to the lower probability of survival in these cases[8].

Among the limitations of our work are that it is a single-center study, with a small population, but it is an experienced and referral center for MCS. The organization described aimed at maintaining the MCS program during the pandemic could help in similar epidemiological situations in the future. In conclusion, survival after temporary MCS did not get worse significantly during the COVID-19 pandemic despite the difficulties related to it. The possibility of short-term MCS program should be maintained for cardiogenic shock and other cases of hemodynamic instability. Planning and provision are essential in this situation.

Acknowledgments

None

Abbreviations:

CS=cardiogenic shock, COVID-19=Coronavirus disease 19, ECMO= extracorporeal membrane oxygenation, eCPR=Extracorporeal cardiopulmonary resuscitation, LVEF=left ventricular ejection fraction,

MCS=mechanical circulatory support, MV=mechanical ventilation, PCI=percutaneous coronary intervention, RV=right ventricle.

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Conflicts of Interest

No conflict of interest exits in the submission of this manuscript.

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