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Research Article

Impella® 5.0 Microaxial Heart Pump Implementation for Prevention of Postcardiotomy Cardiogenic Shock

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Abstract

Objective: The aim of this study was to assess the efficiency of Impella® 5.0 microaxial catheter-mounted heart pump implementation in prevention of postcardiotomy cardiogenic shock in patients, operated for dilated cardiomyopathy, heart failure, NYHA class III-IV. The AKOR® extracardiac mesh implantation and mitral valve replacement were performed to all of them.

Background: Postcardiotomy cardiogenic shock (PCCS) is associated with high mortality rates of 50-80%. The results of mechanical circulatory support (MCS) in PCCS depend on proper choice of the MCS device and optimal timing of its initiation. The effectiveness of preventive use of Impella® 5.0 microaxial heart pumps after the AKOR® extracardiac mesh implantation and mitral valve replacement in patients with dilated cardiomyopathy, NYHA III-IV was tested.

Patients and Methods: The Impella® 5.0 (Abiomed, Inc.; Danvers, Mass) is a percutaneous ventricle assist device that is positioned across the aortic valve with inflow in the left ventricle (LV) and outflow in the ascending aorta. This configuration augments forward flow and directly decompresses the LV. MCS with the Impella® 5.0 microaxial heart pumps was used preventively in 9 patients (mean age was 61 ± 6 years, all males). Preoperatively all of them were evaluated as high risk of PCCS development. They had idiopathic dilated cardiomyopathy (DCM), mitral valve regurgitation: grade 3,0 ± 0,6, mean NYHA class of 3,0 ± 0,7. Mean LV ejection fraction (EF) was 31,6 ± 6,1%. LV end diastolic volume (LV EDV) was 234 ± 52 ml. Mean pulmonary artery wedge pressure was 27 ± 8 mmHg. Preoperatively cardiac index was a mean of 2,2 ± 0.1 l/min. Mitral valve replacement and the AKOR® extracardiac mesh implantation were performed in all cases. The AKOR® extracardiac mesh was implanted to prevent further dilation of heart chambers. The Impella® 5,0 catheter was inserted and initiated intraoperatively, in post bypass period, to prevent PCCS development.

Results: Cardiac index increased from 2,2 ± 0,1 l/min to 2,5 ± 0.2 l/min/m^2 (p = 0.003). Mean pulmonary wedge pressure decreased from 27 ± 8 mmHg to 17 ± 4 mmHg (p = 0.003). LV EF increased to 39,2 ± 5,2%. The mean duration of Impella® 5.0 support was 3 ± 1days. There was one case of device-related complications: hemolysis indicated by increase in plasma free hemoglobin developed at the 2d postoperative day in one patient; it was caused by suctioning of the pump and was corrected by its repositioning. No patient suffered from PCCS. All patients survived.-

Conclusions: The preventive application of Impella 5.0 is a suitable treatment modality to avoid postcardiotomy cardiogenic shock in patients with compromised myocardium.

Keywords: Postcardiotomy Cardiogenic Shock; Dilated Cardiomyopathy; AKOR® Extracardiac Mesh; Impella®; Timing of Initiation

Methods

The study was prospective, nonrandomized clinical trial. The trial protocol was approved by the local ethics committee.

All patients provided written consent before enrollment.

Enrollment criteria

Idiopathic dilated cardiomyopathy; left ventricular end diastolic dimension (LV EDD) ≥ 6,0 cm; left ventricular end diastolic volume (LV EDV) ≥ 200,0 ml; left ventricular ejection fraction (LV EF) ≤ 30%; cardiac index (CI) ≤ 2,2 l/min/m^2; NYHA class III-IV.

Exclusion criteria

Coronary artery disease; tricuspid valve regurgitation; suspected myocarditis.

Mean age of the patients was 61 ± 6 years and all of them were males (100%). All of them had idiopathic dilated cardiomyopathy (DCM), mitral valve regurgitation: grade 3,0 ± 0,6. Mean NYHA class was 3,7 ± 0,2. LV EF was 31,6 ± 6,1%. LV EDV was 234 ± 52 ml. Pulmonary artery wedge pressure was 27 ± 8 mm Hg. Preoperatively cardiac index (CI) was 2,2 ± 0,1 l/min/m^2.

	DCM n = 9	P-value
Age (years)	61 ± 6	0.222
Male/female	9/0	
NYHA class	3.0 ± 0.7	0.943
Chronic atrial fibrillation	6(66.6%)	0.060
Presence of diabetes	4(44,4%)	0.622
Creatinine (mg/dL)	1.5 ± 1.3	0.672
LV EDV (mL)	234 ± 52	0.013
LVEF (%)	30 ± 5	0.692
Cardiac Index (l/min/m^2)	2,2 ± 0,1	0.791
MV annulus (mm)	42 ± 5	0.044
MR grade	3.3 ± 0.6	0.382
PAWPs (mmHg)	27 ± 8	0.787
Mitral valve prosthesis	9/0	
CPB time interval (min)	72 ± 18	0.005
AoX clamping time interval (min)	53 ± 7	0.006

Table 1: Pre-operative demographic, clinical, echocardiographic, and surgical data.

DCM, Dilated Cardiomyopathy; NYHA, New York Heart Association; LVEDV, Left Ventricular End-diastolic Volume; LVEF, Left Ventricular Ejection Fraction; LVSI, Left Ventricular Sphericity Index; LA, Left Atrium; MV, Mitral Valve; MR, Mitral Regurgitation; TR, Tricuspid Regurgitation; PAWP, Pulmonary Artery Wedge Pressure; CPB, Cardiopulmonary Bypass; AoX, Aortic Cross.

The AKOR® extracardiac mesh was implemented to prevent further cardiac chambers' dilation.

The mesh was manufactured for each patient individually, accordingly to its heart dimensions in diastole.

The mesh was manufactured of the stripes, being done of the cutted Gelweave® vascular graft. The Sulzer Vascutec Gelweave® Vascular Graft is made of a woven polyester material that has been impregnated with an absorbable mammalian gelatin. The gelatin coating of stripes provided less damage to the epicardium.

The decision to use the Impella® 5.0 in the post cardiopulmonary bypass period was taken beforehand, during the preparation for surgery, taking in account the presence of severely compromised myocardium that could increase the risk of PCCS development.

Surgery was performed under cardiopulmonary bypass (CPB) with intermittent antegrade cold Custodiol cardioplegia. The valve was approached through the interatrial septum. Mitral valve replacement was performed in 9 patients using the MedEnge-29 double-leaf prostheses (MedEnge Ltd, Russia). The posterior leaflet was always left in place. The anterior leaflet was not resected, but split in the middle and brought to the annulus by means of prosthetic sutures. Systemic and central venous pressure monitoring, as well as pulmonary artery pressure and cardiac output measurement were done on all the patients.

Impella® 5.0 (Abiomed Inc, USA) has 21 F maximal diameter at the pump level, which can deliver up to 5.0 L min^{-1}. In all of the patients it was inserted through surgical cutdown of the femoral artery before completing the CPB. The insertion was performed under X-ray and transesophageal echocardiography (TEE) guidance. Impella® 5.0 catheter pumps were introduced to ascending aorta and advanced across the aortic valve to the left ventricle cavity. Correct delivery of the pump via the aortic valve was checked through pressure curves and TEE. After checking the positioning of the catheter the pumping was initiated. The Impella® pump flow was increased gradually up to 5,0 liters per minute. The performance of CPB was decreased in parallel. Dobutamine (5 μg/kg per min) and nitroglycerine or nipride or enoximone infusions were started and continued for a few days. The performance of Impella® 5.0 pumps and doses of cathecholamine infusion were decreased gradually, under monitoring of cardiac output and pulmonary artery pressure. The Impella® catheter pumps were explanted in the operating room, before the extubation. The rate of hemolysis was followed carefully through plasma free hemoglobin tests.

Results

MCS with Impella® 5.0 microaxial pumps was implemented preventively in 9 DCM patients, with high risk of PCCS development. The AKOR extracardiac mesh implantation and mitral valve replacement were performed in all of the patients.

The mean aortic cross-clamp time was 53 ± 7 min, mean cardiopulmonary bypass (CPB) time was 72 ± 18 min. The mean dose of dobutamine in post bypass period was 6 ± 2 μg/kg per min. Cardiac index postoperatively increased to 2,5 ± 0,2 l/min/m^2 (p = 0.003). Pulmonary artery wedge pressure postoperatively decreased to 17 ± 4 mm Hg (p = 0.003). LV EF increased to 39,5 ± 5,2% (p = 0.003). Systemic anticoagulation with a target activated clotting time of 160 to 180 s was used. Mean duration of Impella® support was 3 ± 1 days. There was one case of device-related complication: hemolysis . Hemolysis (peak free hemoglobin ≥ 100 mg/dl) was caused by pump suction and resolved after correction of catheter pump position. There had been no cases of PCCS onset and all patients survived. Mean follow-up duration was 24 ± 3 months. All the patients were alive.

Discussion

Postcardiotomy shock (PCCS) – is a life-threatening condition that may complicate surgery of patients with the compromised myocardium [1]. The reported in-hospital mortality of PCCS remains high, consistently over 50% despite full conventional treatment [2]. It is of particular value for the patients with dilated cardiomyopathy (DCM) and functional mitral regurgitation (MR) that are scheduled to the AKOR® extracardiac mesh implantation and or mitral valve replacement (MVR) as alternative treatment for DCM [9-11].

PCCS remains a clinical challenge. Conservative management with catecholamines is associated with serious limitations, including arrhythmias, increased myocardial oxygen consumption, and inadequate circulatory support.

High doses of cathecholamines could be particularly harmful for patients with compromised myocardium. The recent ESC "Guideline on Acute and Chronic Heart Failure" states: "Inotropes cause sinus tachycardia and may induce myocardial ischaemia and arrhythmias" [3]. In patients with postcardiotomy cardiogenic shock high-dose inotropes are clearly related to higher in-hospital mortality [4].

Clinicians have therefore turned to mechanical means of circulatory support and to the Impella® 5.0 (Abiomed Inc.) in particular. The Impella® 5.0 (Abiomed Inc.) is an microaxial flow pump on a pigtail catheter that is placed across the aortic valve to unload the left ventricle by delivering non-pulsatile blood flow to the ascending aorta. It provides active LV assistance and unloading, expelling aspirated blood from the left ventricle into the ascending aorta. It is especially important that Impella® 5.0 pump provide the proper LV unloading, which is essential for myocardial protection and recovery. It reduces ventricular end-diastolic pressure, increases mean arterial pressure, and decreases myocardial oxygen consumption.

Impella® 5.0 (21F motor) requires a surgical cut down, insertion of a vascular graft to the axillary or femoral artery, and use of a 23F introducer sheath.

In a multicenter, prospective, feasibility study without a control group, Impella® 5.0 was used in 16 patients with postcardiotomy cardiogenic shock with 94% survival at 30 days [12]. Engström AE., *et al*. consider mechanical circulatory support with the Impella 5.0 device as a suitable treatment modality for patients with severe PCCS [5].

However, cardiogenic shock is not a mere decrease in cardiac contractile function, but also a multiorgan dysfunction syndrome (MODS) resulting from peripheral hypoperfusion with microcirculatory dysfunction [8]. Once MODS has developed, it is difficult to improve prognosis and reduce mortality by simply increasing cardiac output with a circulatory assist device. Prevention of MODS depends on optimal timing (i.e. early initiation) of mechanical circulatory support [8]. MCS should not be considered the treatment of last resort for PCCS but should probably be initiated early in the disease course to minimize the negative effects of high-dose catecholamine therapy and before end-organ dysfunction [6].

Timing of mechanical circulatory support initiation is of a critical importance. Impella® technology is widely implemented to protect high-risk PCI, where it is initiated preventively. We decided to implement the same approach in open-heart surgery and tested the preventive use of the Impella® 5.0 pumps support in patients with a severely compromised myocardium. This group of patients was at special risk of PCCS development.

The tested approach appeared to be efficient one: there were no signs of hemodynamical instability and no need of high-dose catheholamine therapy perioperatively.

Our data coincides with the results of other authors: for patients with need for an Impella® 5.0 pump, regardless of the indication, early implantation is associated with better in-hospital and 1-year outcomes as compared to when the device is implanted late as a bailout [7,8].

It is evident that one of the limitations of the current study is that we are dealing with a small cohort. Randomized clinical trials, testing optimal timing of device therapy initiation with Impella® 5.0 are needed to establish improved outcomes in preventive Impella 5.0 implantation to obviate onset of PCCS.

Conclusions

The preventive application of Impella® 5.0 is a suitable treatment modality to avoid postcardiotomy cardiogenic shock in patients with compromised myocardium.

Conflict of Interests Statement

None declared.

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