Impella®, Percutaneous Left Ventricular Assist Device for Cardiogenic Shock: Our Experiences

Mitsuru Iida¹,²,³ and Tomoki Shimokawa¹

We report the outcome of patients supported with the Impella device at our institution. Similar to the interim analysis of J-PVAD registry presented at the 84th Annual Scientific Meeting of the Japanese Circulation Society, we observed a worse outcome in patients with AMI cardiogenic shock who received late Impella support. It is also important to highlight that only one patient of this cohort received Impella support before reperfusion at our institute. A door to unloading strategy as opposed to one emphasizing door to balloon combined with earlier initiation of Impella support seems promising¹ and it the creation of a system that embraces door to unloading which is both our institute's challenge and opportunity to improve outcomes.

KEY WORDS: cardiogenic shock, Impella, percutaneous left ventricular assist device

¹Department of Cardiovascular Surgery, Teikyo University Hospital, Tokyo, Japan,
²Department of Cardiovascular Surgery, The Cardiovascular Institute, 3-2-19 Nishiazabu, Minato-ku, Tokyo, 106-0031, Japan,
³Department of Circulatory Dynamics, National Cerebral and Cardiovascular Center Research Institute, Osaka, Japan
E-mail: m-iida@med.teikyo-u.ac.jp
doi: 10.7793/jcad.27.001
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spective study of all Impella use in Japan conducted by the Japan Impella Committee, comprised of 10 related medical societies. Our institutes first experience using Impella was to treat a patient with myocarditis in April 2018 and subsequently a total of 30 patients by June 2020. In this paper, we present the representative Impella cases (summarized in Table 1) including details on the initiation of Impella program, procedural techniques and patient management at our institute.

III. Initiation of Impella program

The first Impella supported patient at our institute was a 68-year-old male who was hospitalized for exacerbation of heart failure symptoms complicated by infectious myocarditis at 10 PM. Despite initial treatment the patient continued to fail, and the decision was made to initiate Impella support at 8 AM the next morning. Since this was the first case of Impella in our institute the institutional committee for highly difficult new medical technologies was called and the committee authorized Impella use at 1 PM with informed consent being obtained from the patient’s family at 2 PM. In this case, Impella support was initiated 6 hours after the decision was made putting the patient at risk of the downward spiral so common in such emergent scenarios. Therefore, the process of authorization for Impella use was discussed by the committee and resulted in a 1-call step for authorization in emergent situations that enabled future patients to benefit from rapid initiation of Impella support.

IV. Device selection

We also developed a standard strategy to guide selection of Impella pump type; for patients suffering from acute myocardial infarction, fulminant myocarditis and cardiomyopathy complicated with cardiogenic shock, Impella 2.5 or Impella CP is inserted from femoral artery by the interventional team to stabilize as early as possible and then Impella 5.0 is considered to escalate the level of support if necessary. Impella 5.0 is also considered as first-line strategy in urgent cases. For patients with post-cardiomyotomy cardiogenic shock (PCCS), Impella 5.0 is initiated immediately after cardiac surgery in the same procedure. At our institute, a primary physician is responsible to take care of patients admitted to the ICU, therefore a patient supported with Impella 5.0 is cared for by a cardiac surgeon. We experienced 3 cases of fulminant myocarditis treated with Impella (case #1, 13, 17) and all patients were successfully weaned from Impella support and discharged. Based on individual patients’ hemodynamic deficit and body surface area (BSA), Impella 2.5 was selected in case #1, Impella 5.0 in case #13 and Impella CP in case #17 respectively. A patient with a BSA of 1.6 m² requires > 3.5 L/min flow to support fully and achieve a cardiac index of 2.2 L/min/m² so at our institute Impella 5.0 is the first choice for patients with a BSA > 1.6 m².

V. Procedural consideration and timing of Impella initiation

Case #3 was a 45-year-old female with suspected dilated cardiomyopathy (DCM) who developed stroke during detailed examination of DCM. After intracardiac thrombus at LV apex was detected the patient was transferred to our institution. She developed recurrent stroke, and the decision was made to perform an emergent thrombectomy. Preoperative LVEF was 27% and we anticipated difficulty to wean her from cardiopulmonary bypass. Subclavian approach was considered to insert Impella 5.0 when failing the wean from CPB but the diameter of right and left subclavian artery was only 5.8 mm which would make Impella 5.0 insertion from the subclavian artery difficult. Cardiopulmonary bypass was deployed using the femoral artery and vein. After thrombectomy via left ventricle incision, weaning from CPB was attempted with two catecholamines but it was difficult to maintain blood pressure when the CPB flow went below 1 L/min. The decision was made to insert Impella 5.0 with direct aorta approach and the vascular graft anastomosis to the ascending aorta with > 9 cm of distance between the anastomosis and the aortic valve was achieved. The vascular graft was tunneled and fixed through the right thoracic cavity and the right third intercostal space, and Impella 5.0 was implanted successfully through the graft. When advancing Impella 5.0 through the graft, we followed the company’s guidance to carefully manipulate the catheter over the graft without touching the device’s differential sensor on the outlet cage. After confirming improvement of hemodynamics, Impella was weaned and explanted in...
| Diagnosis                        | age | gender | type | approach | remove | discharge | 30days mortality | assist days | hosp. days | cause | complications                      |
|---------------------------------|-----|--------|------|----------|--------|------------|------------------|-------------|------------|-------|-------------------------------------|
| Fulminant myocarditis          | 68  | M      | 2.5  | F        | ○      | ○          | 7                | 58          |            |       |                                    |
| AMI (LMT)/CGS                  | 81  | M      | 2.5  | F        | ×      | ×          | 1                | 1           | LOS        |       | bleeding                            |
| DCMLV thrombus/PCCS            | 45  | F      | 5    | DA       | ○      | ○          | 3                | 33          |            |       | bleeding                            |
| AMI (LAD #6)/CGS               | 48  | M      | 2.5  | F        | ○      | ×          | 2                | 64          | MOF        |       |                                    |
| VSP                            | 76  | M      | 5    | S        | ○      | ○          | 14               | 28          |            |       |                                    |
| ICM/MR                         | 78  | M      | 2.5  | F        | ×      | ×          | 13               | 13          | MOF        |       |                                    |
| Drug induced acute cardiomyopathy | 49  | M      | 5    | S        | ×      | ×          | 6                | 6           | MOF, bleeding | bleeding |
| ICM/VT/LV thrombus/PCCS        | 44  | M      | 5.0  | S        | ○      | ○          | 10               | 36          |            |       | bleeding, hemolysis                |
| ICM/NSTEMI/CGS                 | 71  | M      | 2.5  | F        | ○      | ○          | 2                | 31          |            |       | pneumonia                           |
| AMI/CGS                        | 75  | M      | 2.5  | F        | ○      | ×          | 5                | 35          | LOS        | pneumonia |
| DCM                            | 65  | F      | 2.5  | F        | ○      | ○          | 7                | 47          |            |       | pneumonia                           |
| AMI/CGS                        | 78  | M      | 2.5  | F        | ○      | ×          | 9                | 43          | pneumonia, LOS | pneumonia |
| Fulminant myocarditis          | 16  | M      | 5    | S        | ○      | ○          | 5                | 23          |            |       |                                    |
| ICM                            | 66  | M      | 2.5  | F        | ×      | ×          | 7                | 7           | MOF        |       |                                    |
| Drug induced acute cardiomyopathy | 67  | F      | 2.5  | F        | ○      | ○          | 11               | 17          |            |       | MOF                                |
| AMI/CGS                        | 60  | M      | 5    | S        | ○      | ×          | 20               | 33          | MOF        |       |                                    |
| Fulminant myocarditis          | 22  | M      | 3.5  | F        | ○      | ○          | 7                | 18          |            |       |                                    |
| AMI (LMT)/CGS                  | 66  | M      | 3.5  | F        | ×      | ×          | 10               | 10          | MOF        |       |                                    |
| AMI (RCA), DCM                 | 55  | M      | 3.5  | F        | ○      | ○          | 7                | 24          |            |       |                                    |
| VSP, Pneumonia                 | 69  | M      | 5    | S        | ×      | ×          | 11               | 13          |            | Pulmonary, hemorrhage, bleeding   |
| AMI (LAD #6)/CGS               | 80  | M      | 3.5  | F        | ○      | ○          | 1                | 9           |            | hemolysis |
| AMI (LAD #7)/VAP, CPA          | 74  | M      | 5    | S        | ×      | ×          | 1                | 1           | LOS        |       |                                    |
| AMI (LAD #6)/CGS, LV thrombus, PCCS | 66  | M      | 5    | S        | ○      | ○          | 10               | 20          |            |       |                                    |
| AMI (LAD #6)/CGS, LV thrombus, PCCS | 66  | M      | 5    | S        | ○      | ○          | 5                | 22          | MOF        | bleeding |
| AMI (LMT)/CGS                  | 52  | F      | 5.0  | rt. F    | ○      | ×          | 22               | 22          | MOF        |       |                                    |
| AS, CGS                        | 70  | F      | 3.5  | rt. F    | ○      | ○          | 7                | 63          |            |       |                                    |
| AMI (#6 #11)/CGS/Vf storm      | 58  | M      | 5    | rt. F    | ×      | ×          | 10               | 10          | MOF        |       |                                    |
| AMI (LAD #6)/CGS               | 70  | M      | 3.5  | rt. F    | ×      | ×          | 2                | 2           | LOS        |       |                                    |
| AMI (LMT)/CGS                  | 54  | M      | 3.5  | rt. F    | ○      | ○          | 4                | 31          |            |       |                                    |
| MR CGS                         | 89  | F      | 3.5  | rt. F    | ○      | ○          | 3                | 22          |            |       |                                    |
conjunction with hematoma removal of the right thoracic cavity on POD 3.

As demonstrated in the previous studies including RECOVER I trial\(^7\), the increased dose of catecholamines administered and the delayed initiation of Impella support lead to less favorable outcomes and therefore preoperative planning of Impella usage after CPB wean failure and rapid decision making is preferred in high risk patients. Table 2 shows the best practice for PCCS. Following case #3, we experienced two cases of PCCS (case #8, 23) and all were successfully supported and discharged to home.

Careful consideration and modification of anticoagulation is needed in postoperative cases including PCCS. As described previously, with 20 units/ml of heparin in purge solution we observed hematoma in the right thoracic cavity requiring hematoma removal operation on POD 3 in case #3. Therefore, since then heparin is fully reversed with protamine after surgical operation and no heparin is administered in purge solution until ACT goes below 150 sec. After ACT drops below 150 sec or 24 hours after Impella initiation the administration of 5 units/ml of heparin in purge is considered. Even in patients with PCCS careful

Table 2  Post-cardiotomy cardiogenic shock impella best practice

1. Identify post-cardiotomy cardiogenic shock prior to ICU admission to minimize the duration of shock
   • Identification of high-risk patient and preoperative planning of Impella usage after CPB wean failure
   • Device selection and preparation (Impella CP vs 5.0)  
   • Access site planning and evaluation (Subclavian vs femoral)  
   • Identification of post-cardiotomy cardiogenic shock
     • Criteria: Low cardiac output and elevated filling pressure after weaning from CPB despite stable infusion of 1 high-dose inotrope or two medium dose of inotrope  
       • CI < 2.2 L/min/m\(^2\) and PCWP > 20 mmHg or dPAP > 25 mmHg  
       • CPO < 0.6

2. Avoid multiple attempt of CPB weaning and increased infusion of inotropes / pressors

3. Standardized and quantitative hemodynamic-guided decision making by using protocol
   • Early Impella Initiation
   • Wean off Inotropes / Pressors
   • Hemodynamic-Guided Decision Making
     • Recovery and weaning
     • Escalation (need to increase LV support? need to add RV support?)

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monitoring of ACT is needed and we prefer to start heparin in purge from 5 units/ml and titrate up to 20 units/ml.

When explanting Impella from the vascular graft, considering thrombus formation in the vascular graft and outflow (Figs. 3 and 4) careful maneuver of Impella without excessive manipulation is needed to avoid peripheral embolization with thrombus and it is important to remove the catheter promptly. It is known that Impella insertion from subclavian artery is useful and allows patients to rehabilitate. The patient of case #8 was extubated and enabled to ambulate on POD 5 (Fig. 5). The shorter length of catheter implanted in a vessel reduces the chance of Impella malposition compared to femoral approach and we observed no issue in rehabilitation under Impella support. Therefore, we felt encouraged to rehabilitate other patients implanted via the subclavian artery.

VI. Effectiveness of Impella in patients with VSP

Case #5 was a patient with ventricular septal perforation (VSP) following myocardial infarction. The patient was resuscitated from cardiopulmonary arrest and transferred to our institute with severe end organ dysfunction. Due to multiple high doses of catecholamines being administered and worsening systemic condition, surgical repair was not an option and the decision was made to support the patient with Impella and bridge to surgical repair. After stabilization of the patient and support with Impella for two weeks, worsening hemolysis was observed and then surgical closure of VSP and concomitant CABG was performed. To detect right-to-left shunt flow through VSP, the right radial artery PaO2 was monitored. Even if right-to-left shunt flow is observed the systemic oxygenation should not be affected as far as the right radial artery PaO2 is maintained. In fact, no right-to-left shunt flow was observed by echocardiography and the patient was successfully bridged to surgery. At our institute an emergent surgical repair was the first option to treat patients with VSP but in cases of patients with severe systemic condition or unknown neurological status we wait and assess before deciding to operate. Several cases of Impella for VSP were published14) and we have previously reported the case described above15).

Conflicts of interest

None.

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