Atrial Septostomy for Left Atrial Decompression During Extracorporeal Membrane Oxygenation by Inoue Balloon Catheter

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**Background:** Refractory pulmonary edema is an infrequent but serious complication in patients receiving venoarterial extracorporeal membrane oxygenation (VA-ECMO) for myocardial failure. Left atrial (LA) decompression in this setting is important. Although a few methods have been reported, the experience is mostly limited to children. We aimed to evaluate the feasibility of Inoue balloon catheter in percutaneous trans-septal LA decompression in adult cardiogenic patients.

**Methods and Results:** We retrospectively analyzed 16 procedures of trans-septal LA decompression by Inoue balloon catheter in 15 VA-ECMO patients (aged 22–65 years, 6 men) with refractory pulmonary edema from May 2012 to December 2014. Mean left ventricular ejection fraction was 15%. The cause of cardiogenic shock included 7 cases of ischemic heart disease, 1 of dilated cardiomyopathy, 5 of myocarditis, and 2 of fatal ventricular arrhythmia. The procedures were performed 4.3 days after ECMO. Inoue balloon size was 24–27 mm. LA septostomy were successfully created in 14 patients. Procedure time on average was 36.8 min (range, 15–85 min). There were no procedure-related complications. Radiography on the next day showed rapid resolution of pulmonary edema.

**Conclusions:** Trans-septal LA decompression by Inoue balloon catheter is a feasible alternative method for adult patients with refractory pulmonary edema under ECMO.

**Key Words:** Atrial septostomy; Extracorporeal membrane oxygenation; Left atrial decompression; Pulmonary edema; Trans-septal catheterization

Venoarterial extracorporeal membrane oxygenation (VA-ECMO) has been used in myocardial failure caused by acute myocardial infarction, myocarditis, decompensated cardiomyopathy, or intractable arrhythmia to provide immediate cardiac and respiratory support. However, in such persistent pump failure patients, the arterial cannula can place additional afterload on the left ventricle (LV) and lead to rising LV end-diastolic pressure, and left atrial (LA) pressure. Finally, refractory severe pulmonary edema might develop. In this setting, both the wall stress and the oxygen consumption of the LV increase, and recovery of LV function and weaning from ECMO will be delayed. Although not all patients on ECMO suffer from the described vicious circle, this complex medical condition does demand a solution to avoid additional complications. LA decompression shows good results in minimizing LA/LV volume/pressure overload, chamber dilation, and resolving severe pulmonary edema. Early LA decompression was reported to enhance LV recovery. A few methods of achieving LA decompression have been reported, including balloon atrial septostomy, combined blade and balloon atrial septostomy, trans-septal/transaortic LV sheath, transaortic pigtail LV drain, surgical LA/LV vent and trans-septal cannula incorporated into ECMO. However, the experience with these is mostly limited to children. Some methods are complex and destructive. Older individuals may have much thicker atrial septal walls, so whether the percutaneous balloon dilation method is feasible has been criticized. The Inoue balloon was specially designed for percutaneous transvenous mitral commissurotomy (PTMC), and the purpose of this article is to report our single-center experience with trans-septal LA decompression using the Inoue balloon catheter.
Methods
Within May 2012 and December 2014, 124 patients suffered from cardiogenic shock and received VA-ECMO treatment at China Medical University Hospital. This retrospective study encompassed 15 ECMO patients who developed refractory severe pulmonary edema and underwent percutaneous trans-septal LA decompression. The demographic information is summarized in Table 1. Overall mean age was 48.3 years; 6 patients were men. Mean LV ejection fraction was 15%. The procedures were performed 4.3 days after ECMO under fluoroscopy.

Institutional review board approval was obtained for analyzing patient demographics, catheterization reports, angiograms, echocardiograms, chest radiographs, ECMO flow data, and inpatient charts. Before the procedure, patients were informed about procedural risks, and therapeutic benefits. Written informed consent was obtained for all procedures.

Interventional Techniques
All 15 procedures were performed in the cardiac catheterization laboratory under fluoroscopic guidance. Vascular access was via the femoral vein (ipsilateral in 12 cases, contralateral in 3 cases). Trans-septal puncture was performed using a Brockenborough needle loaded in a Mullin sheath under biplane fluoroscopic guidance (anteroposterior (AP) view and true lateral view). The position of the aortic valve was identified by its calcification (10 cases) or by the pigtail catheter (5 cases). The tip of the needle was directed posteriorly on the true lateral view and between 4 and 5 o’clock positions on AP view. After entering the LA, the Mullin sheath was advanced across the atrial septum and the needle was replaced with a stainless steel PTMC coiled guidewire. After the sheath was removed, the puncture wound, subcutaneous tissue, and the atrial septum were dilated by an 11F PTMC dilator. A 24-mm (8 cases) or 26-mm (6 cases) Inoue balloon catheter was then inserted across the atrial septum into the LA. After it was half inflated, it was pulled back until the distal balloon leaned against the atrial septum, and then it was fully inflated. Indentation of the atrial septum on the waist of the balloon was identified and then it disappeared after full inflation (Figure 1). Throughout the whole procedure, patients were under full anticoagulation for continuous ECMO without additional heparin. All patients underwent follow-up chest radiography and transthoracic echocardiography daily.

Results
Atrial septostomy was successfully performed in 14 patients with 16 procedures (Table 2). Patient 5 required a second procedure to create better inter-atrial communication because of delayed resolution of pulmonary edema. Patient
All procedures were performed in critically ill patients. For the ECMO support system, vascular access was sometimes limited. The procedures via contralateral femoral vein showed 100% success rate and median procedure time of 45 min (ipsilateral femoral vein: success rate 91.7% and 6 had the longest procedure time (85 min) because of difficulty in localizing the ideal trans-septal puncture point. Trans-septal puncture failed in patient 11 because of kinking of the device and venous cannula. The average procedure time was 36.8 min (range 15–85 min).

Table 2. Procedural Details and Clinical Outcomes of Patients Undergoing Trans-Septal Decompression of the Left Atrium

<table>
<thead>
<tr>
<th>No.</th>
<th>BW (kg)</th>
<th>Access (ipsi/contral)</th>
<th>Procedure time (min)</th>
<th>Inoue balloon size (mm)</th>
<th>Death or cause of death</th>
<th>HTx</th>
<th>ASD repair</th>
<th>LVEF F/U (%)</th>
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<tr>
<td>10</td>
<td>90</td>
<td>Contra</td>
<td>25</td>
<td>24</td>
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<td>Contra</td>
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<td>13</td>
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<td>Ipsi</td>
<td>20</td>
<td>26</td>
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<tr>
<td>4</td>
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<td>Ipsi</td>
<td>60</td>
<td>26</td>
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<tr>
<td>11</td>
<td>82</td>
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<td>Fail</td>
<td>Fail</td>
<td>IBD</td>
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<tr>
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<tr>
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<tr>
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<td>70</td>
<td>Contra</td>
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ASD, atrial septal defect; IBD, ischemic bowel disease; Contra, contralateral; HTx, heart transplantation; Ipsi, ipsilateral.

Figure 2. Supine anteroposterior chest radiography at 3 days after procedure. The refractory pulmonary edema improved after decompression of left atrium except in patients 10 and 11. Patient no.10 was complicated with pneumonia and adult respiratory distress syndrome. The transeptal puncture failed in patient no. 11 because of catheter kinking.
median procedure time 30 min). In the first 2 procedures, we performed trans-septal puncture with a pigtail catheter placed in the non-coronary aortic sinus for guidance. In the later procedures, most trans-septal punctures, except in 3 patients who were young, were completed using aortic calcification as a landmark to save additional arterial puncture. To create an adequate ASD for left-to-right shunt, in patients with a body weight >60 kg, we chose the 26-mm Inoue balloon, except in 2 cases: the patient was short in height in 1 case and there was a lack of 26-mm balloons on procedure day in the other. In such cases, despite using a smaller balloon, the pulmonary edema resolved rapidly. However, in 1 case of a patient weighing 101 kg, a second procedure with a 27-mm Inoue balloon was required to make a larger ASD.

**Follow-up**

All patients were followed up in hospital for outcomes after the procedure (Table 2). There were no procedure-related complications except for artificial ASD. Follow-up radiography in 3 days showed significant resolution of pulmonary edema (Figure 2). The oxygenation index also dropped from 9.9±5.94 to 4.6±2.99 (P<0.001 by paired t-test). Six patients were successfully weaned from mechanical ventilator and received a LV assist device (LVAD) in place of ECMO. Three of the other patients regained LV function and had ECMO successfully removed. Among the 6 patients who received LVAD, 4 underwent heart transplantation and recovered normal function. One regained LV function and was finally independent of the LVAD. In total, one of the patients who received LVAD and another 5 patients were complicated with sepsis and died. Patient 11 with an unsuccessful procedure died of ischemic bowel disease.

As to follow-up of the artificial ASD (Figure 3), 7 patients underwent ASD repair: 6 underwent the repair during LVAD implantation to avoid right-to-left shunt and the 7th patient underwent ASD repair under concerns of future complication of significant left-to-right shunt. However, among the surviving patients, 2 declined ASD repair. Echocardiography at 1 year after hospitalization still showed left-to-right shunt but neither right heart enlargement nor pulmonary hypertension. They were free of symptoms.

**Discussion**

This study is the first reported adult series of percutaneous trans-septal LA decompression with the Inoue balloon to date. Despite the small number of patients, successful creation of an efficient left-to-right shunt without complication in 14 of 15 patients demonstrated the feasibility and safety of the Inoue balloon in LA decompression. The whole procedure was performed under fluoroscopy in the catheterization laboratory with low total procedure times. Although several methods had been reported in the previous literature, the experience is mostly limited to children. Compared with surgical methods or strategies utilizing the cannula connected to the ECMO system, balloon atrial septostomy is simpler and minimally invasive. However, the feasibility of balloon dilation method in older individuals, because they have a much thicker atrial septal wall, thus a larger size balloon with good radial force might overcome this problem. In 1982 the Inoue balloon was specially designed for PTMC, because persistent ASD was a well-known complication of that procedure. With its special design, the Inoue balloon has been used in tricuspid stenosis, aortic stenosis, and, similar to our series, atrial septostomy for severe pulmonary hypertension and achieved good results.

The size of the LA drain or ASD determines satisfactory decompression. Aiyagari et al. reported a patient with the largest sheath placed had the most rapid resolution of LA hypertension; 2 unsuccessful procedures had been performed with smaller LA cannulas. The Inoue balloon was used for its unique design of a self-seating mechanism. Upsizing can be done with the same balloon or by using a graded balloon dilatation technique. This advantage can further contribute to higher procedural success rates. In our reported series, the 24- to 26-mm Inoue balloon achieved adequate LA decompression in most patients. Based on this method, we do think other large balloons, in addition to the Inoue balloon, could achieve a similar result. However, we did not directly compare the efficacy between such balloons.

The benefit of LA decompression is mainly based on 2 main mechanisms. The first, reduction of LA pressure, promotes early lung recovery and reduces the duration under sedation and ventilation. In our study, because all procedures were performed in critically ill patients, we were not able to perform routine hemodynamic measurement. Three of the study patients had LA pressure measured by trans-septal puncture needle and the average LA pressure was 29 mmHg before the procedure and reduced to 13 mmHg immediately after atrial septostomy. This suggested an adequate ASD formed a left-to-right shunt that diverted blood flow from LA back to the ECMO and finally removed the accumulated fluid from the lung parenchyma. The second, ameliorated LV wall stress, improves subendocardial perfusion, decreases myocardial oxygen consumption, and subsequently helps LV functional recovery. So far, there is no consensus with regard to the timing of LA decompression during ECMO. However, studies generally conclude earlier LA decompression may be beneficial to minimize risks related to prolonged ECMO.2

**Figure 3.** Transesophageal echocardiography 3D reconstruction for evaluation of artificial atrial septal defect (ASD). Five patients underwent transesophageal echocardiography during follow-up and 3D reconstruction was performed in 1 case. The artificial ASD was coin slot-shaped, with an area of 0.78 cm². The average ASD diameter in the 5 cases was 7.5 mm. AO, aorta; IVC, inferior vena cava; LA, left atrium; Post, posterior; RA, right atrium; RSPV, right superior pulmonary vein; SVC, superior vena cava.
In our study, we did not try to show that the Inoue balloon was superior to other existing LA decompression procedures because such head-to-head comparisons in the study patients were impossible. Based on our experience, trans-septal decompression by Inoue balloon was a simpler, minimally invasive procedure, had a short procedure time, a high procedure success rate, and the specially designed balloon was suitable for adults. We think this method may be an alternative to existing LA decompression for patients with refractory pulmonary edema under ECMO. However, despite the success of the procedure, we do not think LA decompression affected the clinical outcomes. In our study, the outcomes of the patients depended largely on the primary etiology of cardiogenic shock.

Study Limitations
First, this study was limited by its retrospective design and the small number of patients of study interest (those suffering from refractory pulmonary edema under ECMO support). We will continuously enroll patients and do further investigation. Second, because of the heterogeneous, complex, and critical medical conditions, we were unable to perform detailed hemodynamic measurements and close follow-up in each patient. Therefore, we cannot offer a strong underlying hemodynamic mechanism or molecular evidence. Third, although all patients were on ECMO for myocardial failure, this was an extremely heterogeneous group of patients with respect to age, body size, concomitant diseases, and prior cardiac disease as well as surgery. The validity of the statistical results may be affected.

Conclusions
In patients with persistent pulmonary edema after ECMO, effective LA decompression can be achieved using the Inoue balloon catheter and atrial septostomy.

Acknowledgments
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Conflict of interest
No potential conflicts of interest declared.

References