

CASE REPORT Intra Aortic Balloon Pumping 8Fr Short Type

Use of 8Fr Short Balloons at Our Facility

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• Patient's Background

The patient was a 67-year-old woman, 148 cm in height and weighing 50 kg. Her risk factors were hypertension and hyperlipidemia. She had previously been aware of chest pain during exertion. She had felt a sudden compressive sensation in her chest, extending through the left shoulder. She was transported by ambulance to our hospital. Upon arrival, electrocardiography revealed ST elevation in leads II, III and aVF. She was suspected of having acute coronary syndrome and underwent emergency coronary angiography (CAG).

• Information on the disease

CAG revealed complete obstruction of the right circumflex artery (RCA) and intense stenosis of the left anterior descending artery (LAD) and the left circumflex artery (LCX), i.e. the involvement of three branch lesions. Because she was already hemodynamically unstable during CAG, percutaneous coronary intervention (PCI) of the RCA was carried out via the right femoral artery under support with an intra-aortic balloon pump (IABP).

Due to intense calcification, passage of the device through the affected area was difficult, but stenting provided favorable blood flow, allowing PCI to be completed without loss of hemodynamic stability. Complete vascular reconstruction was subsequently performed successfully to deal with the LAD and LCX lesions.

• Operative Procedure and Methods

An 8Fr 35mL short IAB was inserted through a sheath via the left femoral artery to begin support employing an IABP. The Datascope System 98 was used as a console. IABP was begun at the maximum augmentation level, and balloon unwrapping was confirmed. After unwrapping had been confirmed, augmentation was set at the lowest level achieving the maximum augmentation while monitoring the balloon pressure patterns displayed on the console. In the present case, the augmentation level was set at 9/10.

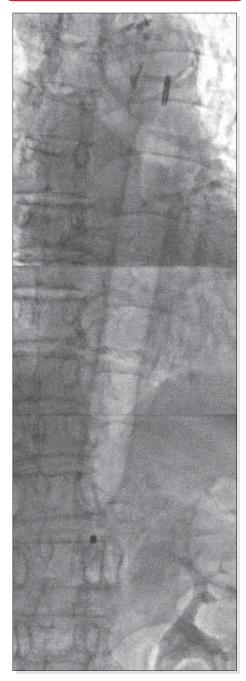
• Results and Discussion

For patients returning from this type of surgery to the intensive coronary care unit, our hospital makes it a rule to guide the patient to change his/her body position once every two hours and to lift the bed backrest (to an angle of 10 degrees at maximum) to prevent bedsores. During the 2 days by the time of the IAB removal, there were no problems such as IAB shaft kinking, migration of the IAB or leg ischemia. It was thus possible to carry out IABP in this case without difficulty.

• System specifications							
Sheath introducer	8Fr 17.5cm (a kit component)						
Guide wire	0.032 inch × 150 cm hydrophilic type Tip form angle type (a kit component)						
Console	System 98 (a product of Datascope Corp.)						



• After IABP insertion



• Selection of IAB at our facility

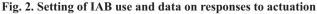
Previously, we selected an optimum IAB for a given patient on the basis of the patient's height, body weight, etc. from three alternatives, i.e., 35mL (8Fr), 30mL (8Fr) and 25mL (7Fr) IABs. Since the 8Fr 35mL Short IAB became available for clinical use, we have been using this device as the first-choice IABP regardless of height, body weight and so on.

Before the 8Fr 35mL Short LAB was adopted as the first-choice IAB, we compared its efficacy for IABP with that of the 35mL Normal IABP and analyzed its balloon diameter and length.

• Comparison efficacy as a means of IABP

The experiment used a mock circuit generating pulsatile flow, with a Ventricular Assist Device (VAD) serving as an actuator. The mock diameter for the IAB-inserted portion was set at either 20 mm or 25 mm. The integral value of the augmented areas of the pressure pattern (an indicator of IABP efficacy) was compared between the 8Fr 35mL Short IAB and the 8Fr 35mL Normal IAB (fig. 1 and 2). Regardless of mock diameter and heart rate, IABP efficacy was significantly higher with the 8Fr 35mL Short IAB than with the 8Fr 35mL Normal IAB (Fig. 3 and 4).





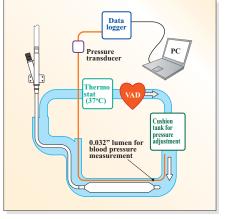


Fig. 1. Mock circuit for the experiment

Pseudo-blood:	50% glycerin solution,	
	warmed to 37°C (viscosity 4 cps)	
Blood pressure:	100/50 mmHg, heart rate 100 bpm	
Console:	Xemex IABP Console 908	
Assist ratio:	1:4	

_	Vol.	Inf. ¹	Def. ²	Inf.+Def. ³	Balloon length	Balloon diameter
	(mL)	(msec)	(msec)	(msec)	(mm)	(mm)
30mL normal IAB 30mL short IAB (manufactured on a trial basis)	30 30	71 72	91 90	162 162	210 180	14.1 15.1
35mL normal IAB	35	86	97	183	214	15.1
35mL short IAB	35	89	96	185	162	17.1
			1 Inflation tim	e 2 Deflation tin	ne 3 Inflation ti	me + Deflation time

Inflation time 2 Deflation time 3 Inflation time +

Fig. 3. IABP efficacies at various mock diameters

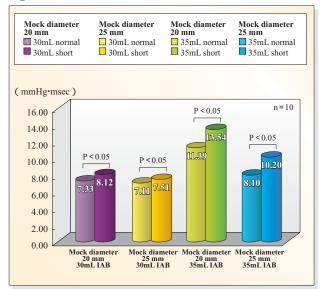
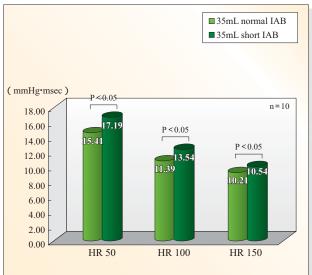


Fig. 4. IABP efficacies at various heart rates



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• Analysis of IAB balloon length and balloon diameter

In 100 patients who underwent PCI and contrast-enhanced CT of the thoracic/abdominal aorta, we measured the distance from the left subclavicular artery to the renal artery as well as the inner diameter of the descending aorta, subphrenic segment of the aorta and abdominal aorta below the renal artery on CT images (Fig. 5) and analyzed IAB length and diameter. The vascular diameter tended to become smaller at portions below the renal artery, and about 30% of all cases showed calcification or tunica intima thickening. When the 8Fr 35mL Normal IAB was used, it was positioned in the vicinity of the area below the renal artery in some cases, raising the possibility of balloon rupture and other complications. Thus, in terms of safety, the 8Fr 35mL Short IAB seemed to be superior (Fig. 6). In the analysis of balloon diameter, the inner diameter of the artery was larger than the balloon diameter of the Short IAB at the site of Short IAB insertion. However, since the descending aorta begins to follow a tortuous course near the subphrenic region, there is a possibility of the IAB coming into contact with the vascular wall in this tortuous region, suggesting the necessity of checking balloon pressure patterns and setting the augmentation level so as not to expose the vascular wall to excessive stress. On the basis of these results, we adopted the 8Fr 35mL Short IAB as the first-choice device for IABP.

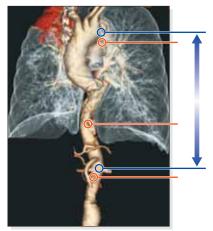


Fig. 5. Sites of measurement

	Male	Female	Total
No. of patients	60	40	100
Mean age (years)	66.5	72.6	68.5
Mean height (cm)	163.2	148.5	157.5
Distance from left subclavicular artery to aorta below renal artery (mm)	231.6	211.0	224.9
Minor diameter of descending aorta(mm)	25.3	23.2	24.6
Minor diameter of subphrenic aorta(mm)	22.6	21.2	22.2
Minor diameter of aorta below renal artery (mm)	17.1	14.0	15.9

Fig. 6. Results of measurement

• Use of this device at our facility

To date, the 8Fr 35mL Short IAB has been used for 31 patients at our hospital, including 3 sheathless cases. Twenty-five patients were male. Mean height was 163.3 cm (minimum: 148 cm) and mean duration of actuation was 61.4 hours (maximum: 160 hours). Ease of IAB insertion and manipulation with this product did not differ from those of the previously used product. In terms of response performance of the IAB, pursuit was possible without difficulty even at high heart rates. Tip pressure monitoring revealed no attenuation of pressure patterns, etc. Stability during insertion was favorable, with no downward migration of the IAB being noted. No problems such as leg ischemia were noted during IABP actuation. Satisfactory IABP efficacy was obtained in all cases. Observation of the IAB after use under an electron microscope revealed partial whitening of the surface in some cases, but this change was not severe enough to reduce the durability of this device.

Manufactured	by:
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