A novel coronary active perfusion system using a conventional intra-aortic balloon pump for off-pump coronary artery bypass grafting

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Objective: It is important for coronary active perfusion systems to avoid myocardial ischemia during off-pump coronary artery bypass grafting. We have developed a new concept for a perfusion system to pump blood based on changes in helium gas volume. This system uses a conventional intra-aortic balloon pump to activate the perfusion pump. Our study used basic and animal experiments to investigate the most suitable system for coronary perfusion using this new concept.

Methods: A conventional intra-aortic balloon pump was used to supply power. A device for perfusion was developed with a balloon placed inside a stiff syringe barrel. The device was connected to the helium gas line of the intra-aortic balloon pump. Changes in flow with changes in augmentation level were noted when volumes outside and within the balloon were changed. Six pigs with occlusion of the left anterior descending artery were used for system validation, with monitoring to identify changes in hemodynamics and cardiac enzyme levels.

Results: In the basic experiment, an 80-mL outside volume and 3.0-mL inner volume resulted in the greatest percentage change in flow rate with respect to changes in augmentation. In the animal experiment, the new coronary active perfusion system prevented myocardial ischemia during coronary occlusion.

Conclusions: We clarified the most suitable method for our new coronary active perfusion system. Using this system, safe anastomosis was consistently performed in animal experiments. Clinically, off-pump coronary artery bypass may potentially be performed more safely and easily using this new system. (J Thorac Cardiovasc Surg 2014;148:304-10)

Off-pump coronary artery bypass grafting (OPCAB) has emerged as a promising technique for the treatment of ischemic heart disease. However, the procedure requires occluding the target coronary artery to maintain a bloodless surgical field during anastomosis. Myocardial ischemia may thus occur, resulting in hemodynamic instability and arrhythmias during anastomosis. Such instability will inevitably require conversion to cardiopulmonary bypass.[1] In addition, retraction and stabilization during OPCAB often cause systemic hypotension, particularly when the heart is displaced vertically to expose the lateral and posterior vessels.[2] With OPCAB, the target vessel needs to be perfused during anastomosis.

Several clinical studies have demonstrated the effectiveness of passive coronary perfusion, intracoronary shunts, and external shunt circuits for reducing ischemic injury.[3,4] These approaches are advantageous in terms of both cost and ease of setup, but offer little benefit and may even endanger patients with severe proximal coronary artery stenosis or severe ischemic heart disease. It remains unclear how the adequacy of blood flow is affected by these passive shunts when systemic blood pressure deteriorates during retraction or compression of the heart during OPCAB.[5]

As mentioned earlier, there are some limits to passive coronary perfusion. We have therefore been studying active coronary perfusion systems since 2000. Over the course of 10 years, we developed a coronary active perfusion system (CAPS) to supply sufficient blood to the myocardium during OPCAB.[6,7] With our CAPS, oxygenated blood is supplied from the femoral artery and perfused by a pump to optimize blood flow to the myocardium, and the volume of blood supplied is independent of hemodynamic status during the procedure. However, the system requires a special pump, controller, and power supply system, making it difficult to use. For that reason, use of this procedure has not yet become popular.

We have developed a new concept for a perfusion system to pump blood based on changes in helium gas volume. This system uses a conventional intra-aortic balloon pump

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Abbreviations and Acronyms

CAPS = coronary active perfusion system
CK = creatine kinase
IABP = intra-aortic balloon pump
LAD = left anterior descending coronary artery
OPCAB = off-pump coronary artery bypass grafting

(IABP) to activate the perfusion pump, replacing our former CAPS system. Our study involved basic and animal experiments to clarify the most suitable system for coronary perfusion using this new concept.

METHODS

Basic Study of the New CAPS

Power supply. The conventional IABP (Datascope CS100; Maquet, Fairfield, NJ) used in the experiments was originally a device to assist cardiac function in synchrony with a patient's heartbeat. Augmentation changes the volume of helium gas, inflating the balloon at the end. The IABP was tested to see if flow could be adjusted by changing the level of augmentation. The IABP was set to auto mode, and synchronization was set to internal mode (at a fixed rate of 60 bpm).

Device for perfusion. A device for perfusion was developed with a balloon made of pliant, readily contracting urethane placed inside a stiff syringe barrel made of acrylic (Figure 1, *A*). The balloon pump was connected to the helium gas line of the IABP. The balloon passively deflated as a result of changes in the pressure inside the syringe that were synchronized to the patient's electrocardiogram. A tube with a directional valve was connected to each end of the balloon. Passive deflation of the balloon pumped blood in a single direction (returning drained blood) during diastole (Figure 1, *B* and *C*). We named this new device the "booster shunt."

Flow was measured with a volume of outside space (in actuality, this included the volume of the 2-m-long tube connecting the pump to the IABP) of 60 mL, 80 mL, or 100 mL. The volume of outside space is the capacity indicated in Figure 1, *B* and *C*. Changes in this volume result in changes in the pressure within the syringe barrel, causing changes in passive deflation of the balloon.

Flow was measured with a volume of the inner balloon of 1.0 mL, 2.0 mL, or 3.0 mL. Volume of the inner balloon is indicated in Figure 1, *B* and *C*. This volume is closely related to the amount by which the balloon is inflated with 1 beat of the heart.

Changes in flow in accordance with changes in augmentation level were noted when the volumes of the outside space and inner balloon were changed.

Coronary cannula. The cannula (CS150M; Forte Grow Medical, Tochigi, Japan) is the same coronary cannula used in the former CAPS at our facility, as previously reported.[6,7] The enlarged, fixed portion of the cannula can prevent back-bleeding from the arteriotomy site when it is larger than the coronary artery being perfused. Flow was measured using a cannula with an external diameter of 1.5 mm and an inner diameter of 0.6 mm, and a new cannula with an external diameter of 1.5 mm and inner diameter of 0.8 mm.

Measurement. A 30% glycerin solution (liquid temperature, 37°C) was used to simulate blood. The IABP was in auto mode with a rate of 60 bpm. Augmentation was changed from level 1 to level 9. The aforementioned volume of the outside space (60 mL, 80 mL, or 100 mL) and volume of the inner balloon (1.0 mL, 2.0 mL, or 3.0 mL) in the perfusion device were changed. Flow rate was measured using 2 different coronary cannula inner diameters (0.6 mm and 0.8 mm). Flow rate was measured at different augmentation levels. To ascertain the percentage increase in flow rate as augmentation changed, flow rate with augmentation at level 1 was set as 100%. Percent changes in flow rate with different levels of augmentation were then determined.

Animal Experiment

All animal studies were approved by the Institutional Animal Care and Use Committee at Kanazawa University School of Medicine, and were performed in accordance with the Principles of Laboratory Animal Care formulated by the National Society for Medical Research and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources of the National Research Council, published by the National Academies Press, and revised in 2010.

Six pigs with occlusion of the left anterior descending coronary artery (LAD) were used to validate the new coronary perfusion system. The 6 pigs had a mean ± standard deviation body weight of 45.3 ± 5.4 kg and a mean ± standard deviation hemoglobin level of 12.5 ± 2.4 g/dL.

Pigs were placed in the supine position, sedated by intramuscular injection of ketamine (20 mg/kg body weight), and intubated with a 7.0F endotracheal tube via tracheotomy. Anesthesia was maintained with halothane (0.5%-1.5%), and muscle relaxation was induced with pancuronium (0.1 mg/kg), administered via a peripheral intravenous route. An arterial pressure line was inserted into the right brachiocephalic artery through the right carotid artery. A 5F catheter was inserted into the right femoral artery to pump out arterial blood for the perfusion system.

Median sternotomy was performed, the pericardium was incised longitudinally, and pericardial purse-string sutures were placed to expose the heart. After systemic heparinization (200 U/kg), the LAD was snared at a point just distal to the first diagonal branch, and coronary arteriotomy was performed. A coronary perfusion cannula was then inserted through the arteriotomy site. To prevent the release of pressure from the arteriotomy site, a site distal to the arteriotomy was snared. Arterial blood was passed through extension tubes and pumped out by the booster shunt to perfuse the LAD site (Figure 2).

Coronary perfusion was performed for 60 minutes, and hemodynamic and mechanical data were recorded. Flow was measured with a flow meter (VeriQ; MediStim, Oslo, Norway) at a point 2 cm distal to the site of cannula insertion. Previous reports have cited a native coronary flow of about 25 mL/min in the distal portion of the LAD. If this flow can be maintained and cardiac function is unaffected, myocardial ischemia should not occur.[8] A cannula with an inner diameter of 0.6 mm was used, based on the results of these basic experiments. The IABP was in auto mode and synchronized with the subject's electrocardiogram. Peripheral perfusion was provided at augmentation level 9 while the LAD was ligated.

Levels of creatine kinase (CK)-MB iso-enzyme and presence of troponin T were also determined every 15 minutes to assess if distal myocardial ischemia was present.

The end point of this study was 60 minutes of observation without ventricular arrhythmia.

At the end of the experiment, all pigs were administered a lethal intravenous injection of potassium chloride.

Statistical Analysis

Statistical analyses were performed using SPSS for Windows version 19.3J software (IBM-SPSS Inc, Armonk, NY). Cumulative data are expressed as mean ± standard deviation. Repeated-measures analysis of variance (ANOVA) was used to compare flow rates among the augmentations. Two-way ANOVA was used to compare percentage increases in flow rate among the 3 groups (60 mL, 80 mL, and 100 mL; 1.0 mL, 2.0 mL, and 3.0 mL), followed by Bonferroni correction for the adjustment of multiple comparisons. The percent increase in flow rate was expressed as the ratio of the value to that with augmentation level 1. One-way ANOVA was used to analyze changes in hemodynamics, coronary perfusion flow, and CK-MB levels. All reported *P* values were 2-sided.