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.
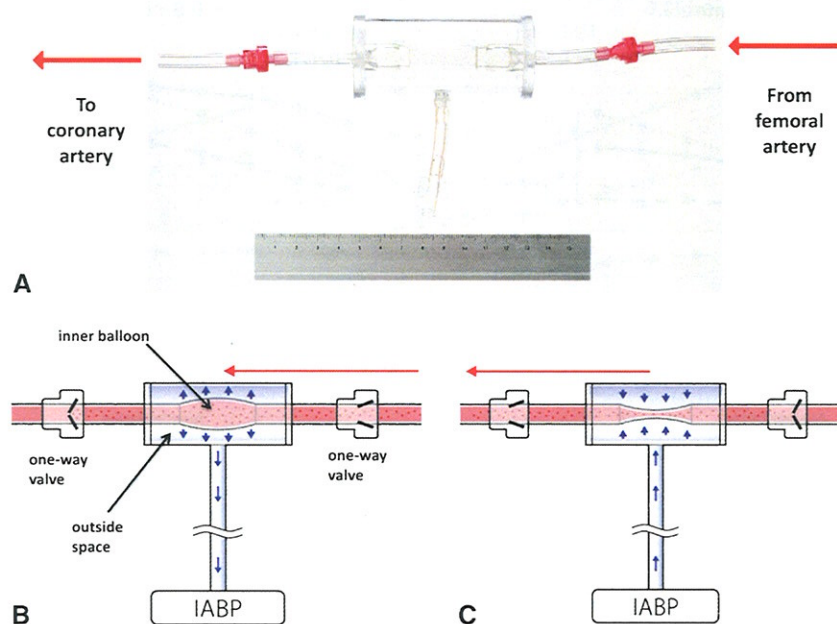
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FIGURE 1. Schema of the newly developed perfusion device (booster shunt). A, The booster shunt. B, Schema of the systolic phase. C, Schema of the diastolic phase. *IABP*, Intra-aortic balloon pump.

RESULTS

Basic Study of the Booster Shunt

Figure 3 shows changes in flow rate due to increased or decreased augmentation when the volume of outside space was changed. Changes in flow rate and percent increases in

FIGURE 2. Schema of the animal experiment. *IABP*, Intra-aortic balloon pump.

flow rate were seen when a cannula with inner diameter of 0.6 mm (Figure 3, *A* and *C*) or 0.8 mm (Figure 3, *B* and *D*) was used.

Repeated-measures ANOVA showed that in both instances, volumes of outside space of 80 mL resulted in significantly greater changes in flow rate with respect to increased augmentation than those seen with a 60- or 100-mL volume of outside space (Figure 3, *A* and *B*). In both instances, flow rate did not alter with changes in augmentation when the volume of outside space was 100 mL. Two-way ANOVA showed that with augmentation levels 5 through 9, both cannulae with inner diameters of 0.6 mm and 0.8 mm resulted in significantly greater flow rates with an 80-mL volume of outside space than with 60- and 100-mL volumes (Figure 3, *C* and *D*).

Figure 4 shows changes in flow rate due to increased augmentation when the volume of the inner balloon was changed. Measurements of flow rate and percent increase in flow rate are indicated for the cannulae with an inner diameter of 0.6 mm (Figure 4, *A* and *C*) and 0.8 mm (Figure 4, *B* and *D*).

Repeated-measures ANOVA showed that in both instances, flow rate was significantly greater with respect to increased augmentation with a 2.0-mL volume of inner balloon than with a 1.0-mL volume; the same was true for a volume of 3.0 mL compared with a volume of 2.0 mL. Flow rate did not alter in accordance with changes in augmentation with a 1.0-mL volume of inner balloon (Figure 4, *A* and *B*).

Two-way ANOVA showed that with an augmentation level ≥5, a 3.0-mL volume of the inner balloon with an
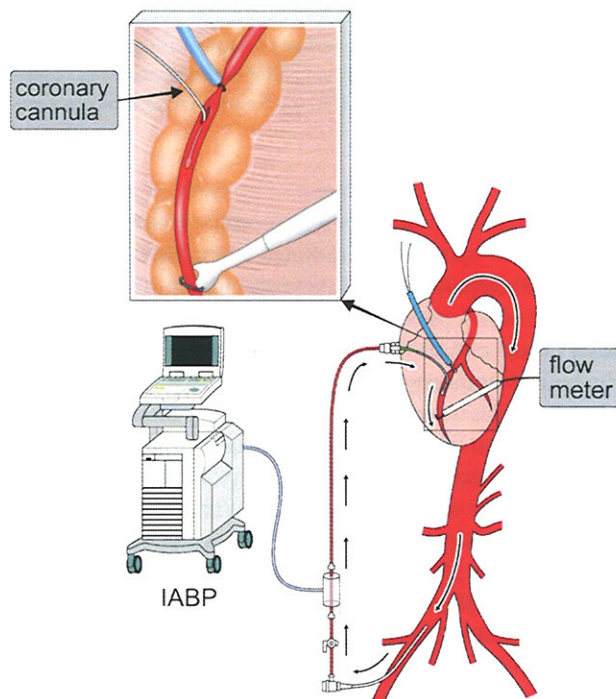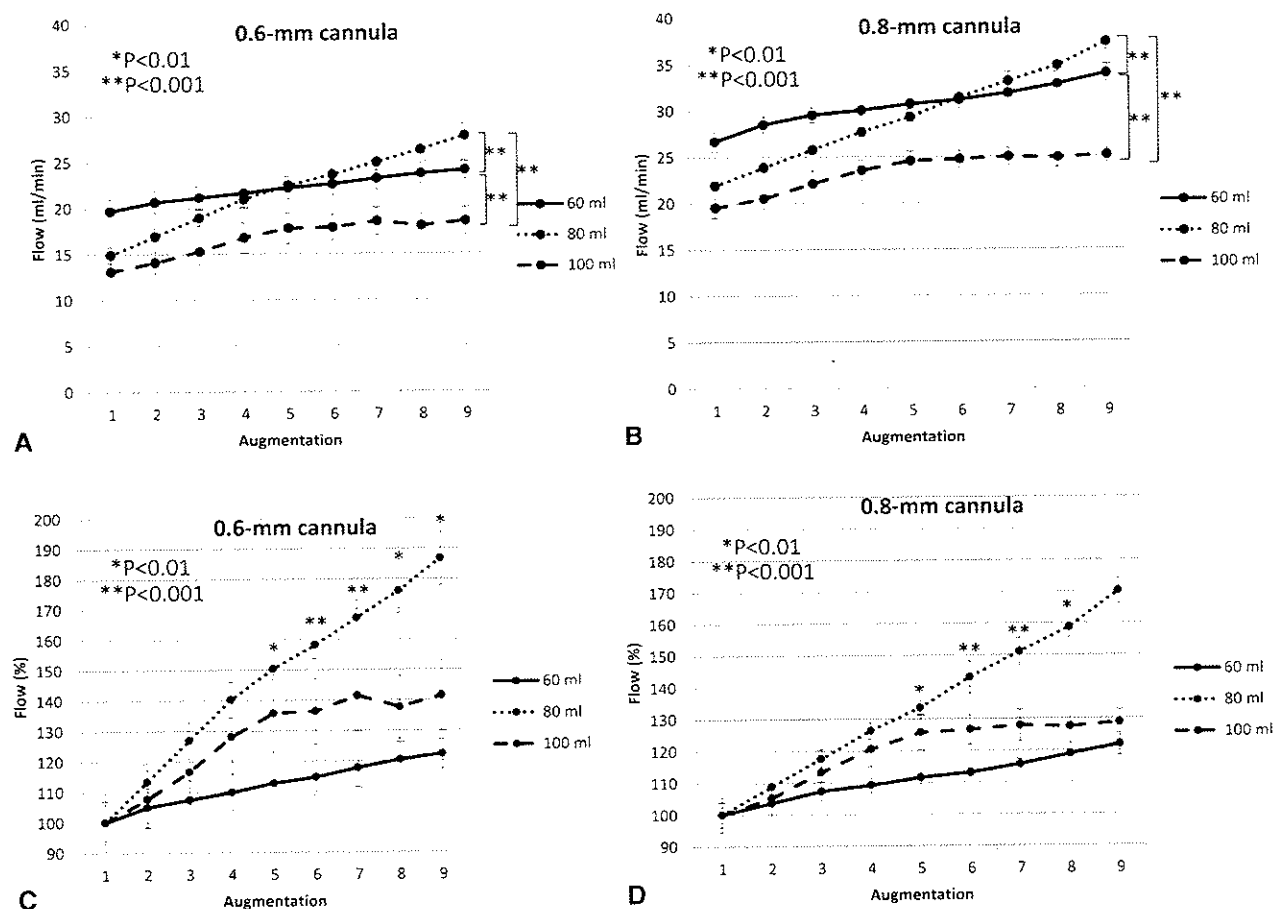
FIGURE 3. Change in flow rate for each volume of the outside space. A. Relationship between flow rate and augmentation for each volume of outside space using a cannula with inner diameter of 0.6 mm. B. Relationship between flow rate and augmentation for each volume of outside space using a cannula with inner diameter of 0.8 mm. C. Relationship between percentage increase in flow rate and augmentation for each volume of outside space using a cannula with inner diameter of 0.6 mm. D. Relationship between percentage increase in flow rate and augmentation for each volume of outside space using a cannula with inner diameter of 0.8 mm. *Significant difference between groups from baseline at $P < .01$. **Significant difference between groups from baseline at $P < .001$.

inner diameter of 0.6 mm resulted in a significantly greater percent increase in flow rate than did the other 2 inner balloon volumes of 1.0 and 2.0 mL. With an augmentation level ≥ 7, an inner balloon of 3.0 mL with an inner diameter of 0.8 mm resulted in a significantly greater percent increase than did the other 2 inner balloon volumes of 1.0 and 2.0 mL (Figure 4, C and D).

Animal Experiment

As mentioned earlier, an 80-mL volume of outside space and a 3.0-mL volume of the inner balloon resulted in the greatest percent change in flow rate with respect to changes in augmentation. To adequately encompass the flow rates regulated with our current CAPS, we selected the booster shunt that used an 80-mL volume of outside space and a 3.0-mL volume of the inner balloon.

Hemodynamics. No significant changes in heart rate were found at each measurement time point. Heart rate was 85.8 ± 7.1 bpm before coronary artery ligation, 85.6 ± 6.6 bpm at 30 minutes after, and 88.3 ± 6.9 bpm at 60 minutes after. Likewise, no significant changes in aortic blood pressure were seen during the 60-minute observation period. Blood pressure was 96.3 ± 4.2 mm Hg before coronary artery ligation, 92.3 ± 3.0 mm Hg after 30 minutes, and 91.5 ± 3.8 mm Hg after 60 minutes. No fatal ventricular arrhythmia was observed within the 60-minute observation period in any of the pigs. Native coronary flow was 21.8 ± 3.3 mL/min, compared with 20.6 ± 1.5 mL/min at the start of perfusion, 20.3 ± 1.9 mL/min after 30 minute, and 19.9 ± 1.7 mL/min after 60 minutes. No significant changes in flow over time were noted. During the experiment, none of the animals displayed disrupted hemodynamics.

The pattern of the booster shunt during the experiment is shown in Figure 5. A flow pattern predominated in the diastolic phase.
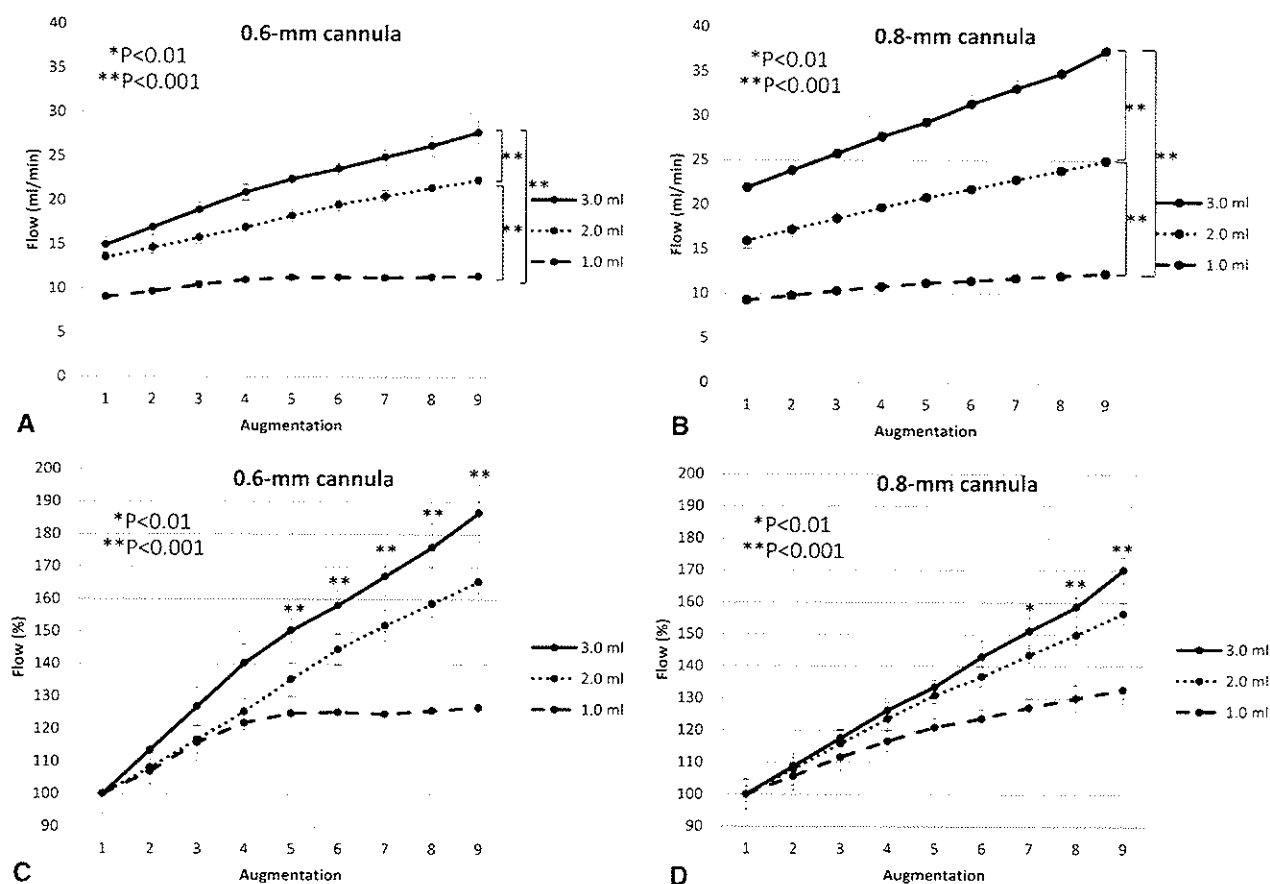
FIGURE 4. Changes in flow rate with each volume of the inner balloon. A, Relationship between flow rate and augmentation for each volume of inner balloon using a cannula with inner diameter of 0.6 mm. B, Relationship between flow rate and augmentation for each volume of inner balloon using a cannula with inner diameter of 0.8 mm. C, Relationship between percentage increase in flow rate and augmentation for each inner balloon volume using a cannula with inner diameter of 0.6 mm. D, Relationship between percentage increase in flow rate and augmentation for each inner balloon volume using a cannula with inner diameter of 0.8 mm. *Significant difference between groups from baseline at $P < .01$. **Significant difference between groups from baseline at $P < .001$.

CK-MB levels were not found to be more elevated at each measurement time point, with 5.6 ± 1.3 ng/mL before the experiment, 5.7 ± 1.2 ng/mL after 30 minutes, and 5.7 ± 1.4 ng/mL after 60 minutes. Negative results for troponin T test were obtained at every measurement. None of the patients developed myocardial ischemia as a result of coronary perfusion using the booster shunt.

DISCUSSION

Our study suggests the potential effectiveness of the booster shunt using a conventional IABP according to our concept for coronary perfusion. This new device for perfusion, with an 80-mL outside space volume and 3.0-mL inner balloon volume, was suitable to provide coronary flow of 15 to 37 mL/min during diastole, sufficient to prevent distal myocardial ischemia. The ability of this booster shunt was comparable to that of the old version, while also allowing adjustment of the perfusion rate by augmentation of the IABP. In an animal experiment,

hemodynamics were satisfactorily maintained, indicating that the system is highly useful for providing cardioprotection during distal anastomosis in OPCAB.

The conventional IABP used in our study was the Datascope CS series, the most popular IABP worldwide. IABPs can already be found in facilities performing heart surgery, so our system can immediately be fashioned just by procuring the booster shunt and associated circuit. The booster shunt has a simple structure and can be manufactured inexpensively. Furthermore, using an existing IABP to supply power, the system is easily and readily constructed, representing a key advantage for the new CAPS using a booster shunt.

Several techniques have been developed to perfuse the coronary arteries and avoid myocardial ischemia during OPCAB. At present, the most popular technique uses an intracoronary shunt tube.[8] However, this approach may not be able to provide adequate perfusion in patients with low blood pressure or severe proximal coronary artery
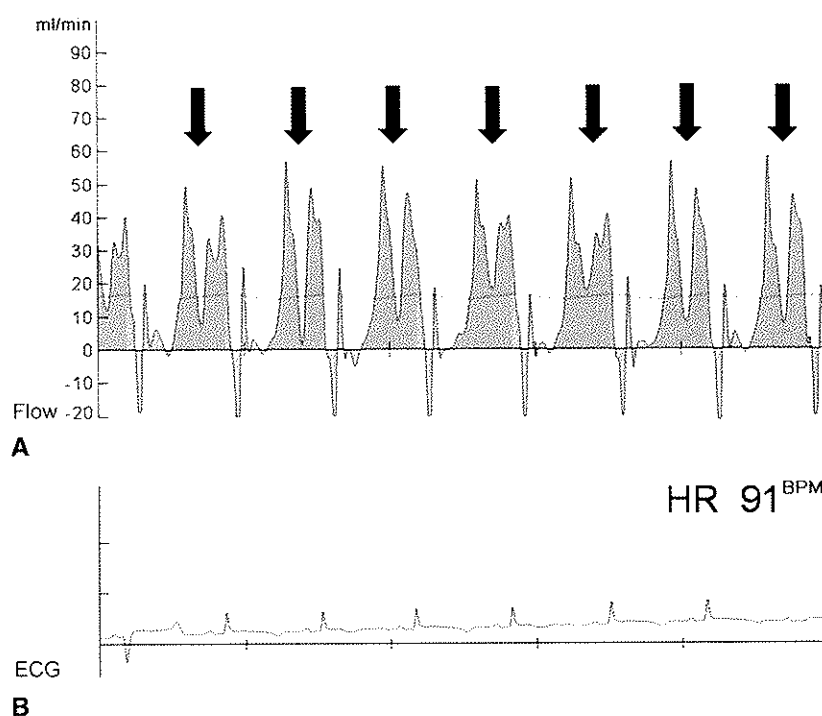
FIGURE 5. Waveform of coronary perfusion flow and electrocardiogram. A, Pattern of the coronary active perfusion system. A flow pattern predominated in the diastolic phase (*arrow*). B, Electrocardiogram (*ECG*).

stenosis.[9] In addition, blunt insertion or extraction of a stiff intraluminal shunt at both proximal and distal sites can cause endothelial denudation or sometimes cause catastrophic endothelial damage in the presence of diffuse calcified coronary artery vessels.[10] Some active perfusion systems are thus required to provide stable flow.

Many active perfusion systems also reportedly prevent myocardial ischemia during OPCAB. One is perfusion-assisted direct coronary artery bypass, as described by Cooper and colleagues.[11] Another is the coronary-assisted perfusion system of Walker and colleagues[12] These techniques provide nonpulsatile flow using a servocontrolled pump during anastomoses. However, these active perfusion systems have a number of disadvantages in that they require large, expensive, and complicated components, so they have not yet gained widespread acceptance among cardiac surgeons. We have previously undertaken experimental investigations of our former CAPS perfusion-assisted system,[13] known as the SAFE System.[7]

Like the other systems, our formerly employed CAPS provides coronary flow independent of systemic blood pressure, but differs fundamentally from other systems in 2 ways. First, the flow produced by our former CAPS is pulsatile, synchronized with the diastolic phase of the native cardiac cycle from the syringe pump, whereas other systems generate a steady flow. Second, coronary perfusion pressure stays within the physiologic range of 50 to 65 mm Hg,

whereas other systems require suprasystemic perfusion pressure.[13] This CAPS is profoundly effective, and distal myocardial ischemia can be avoided in many cases.[7] However, the system has several disadvantages because of its size, expense, and the difficulty of flow volume control, like other active perfusion systems, and likewise has yet to gain widespread acceptance among cardiac surgeons. We therefore developed the system for a booster shunt activated by an IABP.

During anastomosis, overperfusion can result in endothelial cell damage, whereas underperfusion can lead to myocardial ischemia.[14,15] It is important to be able to adjust blood volume in active coronary perfusion systems to a level adequate for the artery size. To obtain this function, we tried to change the pressure of the outside space of the booster shunt by augmenting the IABP. Among all 60-, 80-, and 100-mL models of the outside space, the perfusion volume of the 80-mL model was the most variable according to the change in augmentation. Likewise, the 3.0-mL inner balloon was the most likely to achieve a suitable perfusion volume among the 1.0-, 2.0- and 3.0-mL inner balloons.

Our study involved an experiment with pigs that presented a heart rate of around 80 bpm, somewhat faster than that normally encountered during OPCAB in human beings. The booster shunt was able to adequately synchronize with this heart rate and provide adequate flow to the distal myocardium. The system maintained a flow

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rate commensurate with that in basic experiments. Incidentally, reports have indicated that flow exceeding 40 mL/min can cause intimal injury due to the increased pressure in the coronary arteries, and can lead to signs of myocardial edema.[14,15] Larger flow may be required in some instances, such as during bypass to treat severe stenosis of the main trunk of the right coronary artery. In such instances, using a cannula with a large inner diameter allows adequate response without exceeding the physiologic pressure inside the coronary arteries. During anastomosis of the circumflex branch, the appropriate coronary perfusion supplied from the active perfusion system is useful to maintain hemodynamics.

The cannula used here was the same coronary cannula used in our former CAPS. We have handled many cannulae during OPCAB, but have yet to encounter fatal vascular injuries caused by the cannula. The actual insertion process is extremely easy and is performed very smoothly. The cannula is designed to be useful as a suture guide during anastomosis. The operative field can be visualized easily by handling the cannula, and accidental miss-stitching of the posterior coronary wall can be prevented. The cannula includes an enlarged portion at the tip that can also prevent back-bleeding from the arteriotomy site by selecting a suitable size for the individual coronary artery.[7] Based on our experience, we believe that the booster shunt, as a further development of the above system, can be used more effectively and conveniently than the traditional device.

Several limitations must be considered when interpreting our findings. The main limitation of our study was that an in vivo animal model was used in place of human patients. Assurance that the same results would be observed in human patients is therefore required. Although we used pigs with normal coronary function in our study, we believe that a greater flow rate is necessary in high peripheral vascular resistance conditions such as diabetes, and that this is an important point in the clinical setting. To confirm the effectiveness of our booster shunt in terms of cardioprotection, access to regional wall functions, such as by echocardiography, is thought to be important. Furthermore, we did not have a control group in our study and if our booster shunt offers satisfactory cost performance remains unclear. To resolve these issues, we plan to verify the extent of myocardial protective effects in groups with other perfusion devices in the future.

CONCLUSIONS

Our study clarified the effectiveness of a booster shunt activated by a conventional IABP, and flow volume was easily adjustable depending on artery size. Using this booster shunt system, safe anastomosis was performed in animal experiments. Clinically, OPCAB can be expected to be performed more safely and easily using this booster shunt.

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