Appendix 1: details of MIPDO and surgical procedures

MIPDO procedure

Patients had a preoperative fasting and water time of 5 to 6 hours and received general anesthesia with endotracheal intubation in a standard operating room. The TEE probe was inserted, and the procedure was performed under TEE guidance. The location, size, flow direction of the pmVSD, valvular regurgitation, and distance between the pmVSD and the aortic valve were measured intraoperatively by TEE. Antibiotics and heparin (80 IU/kg) were administered intravenously before the operation. A median thoracic skin incision of 1 to 2 cm was made. Then, the subcutaneous tissue was dissected to the left fourth parasternal intercostal space. The intercostal muscles were dissected to establish the surgical approach. The free wall of the right ventricle was exposed by opening and suspending the pericardium. A purse-string suture was placed on the right ventricular free wall directly facing the direction of the pmVSD shunt. The right ventricle was punctured within the purse-string suture with a trocar. A 0.035-inch guide wire was placed in the trocar. After the guide wire was passed through the pmVSD, the trocar was removed and the dilator and delivery sheath were advanced through the pmVSD to the left ventricle along the guide wire. The size of the occluder was 1 to 2 mm larger than the diameter of the pmVSD. After removing the guide wire and dilator sheath, the selected occluder was deployed through the delivery sheath under the guidance of TEE. The TEE was used to reassess the shape and position of the occluder, the presence of a residual shunt, and valvular regurgitation before and after occluder release. Finally, the delivery sheath was withdrawn, and the purse-string suture was tied using the knotter. After completing the operation, the patient was sent to the intensive care unit where the endotracheal tube was removed. Echocardiography and electrocardiogram were performed to confirm that there was no obvious RS or server arrhythmia after the operation right in the operation room.

Devices and delivery system:

The symmetric occluders (used for pmVSDs with a distance of more than 2 mm from the aortic valve) were of following manufacturers: (I) Shanghai Shape Memory Alloy Co, Ltd, Huangpu, Shanghai, China; (II) Lifetech scientific Co, Ltd, Shenzhen, China; (III) Beijing Huayi Shengjie Science&Technology Co, Ltd, Beijing, China. The asymmetric occluders (used for pmVSDs with a distance of less than 2 mm from the aortic valve) were all from Shanghai Shape Memory Alloy Co, Ltd, Huangpu, Shanghai, China.

The entire delivery system includes a trocar, 0.035-inch guide wire, dilator and delivery sheath, and a loading sheath. The size of the delivery sheath (5 to 9 Fr) is chosen according to the size of the occluder. Thoracoscopic instruments, including a retractor and a knotter, were used to perform the procedures through a 1 to 2 cm surgical incision.

Surgical procedure

Patients had a preoperative fasting and water time of 5 to 6 hours and received general anesthesia with endotracheal intubation in a standard operating room. A mid-line sternotomy incision thoracotomy of 10 to 20 cm in length was made by using moderate hypothermia at 32–34, CPB, aortic cross-clamping and cold crystalloid cardioplegic arrest. The defect was reached using an incision in the right atrium. Intraoperative temporary detachment of the tricuspid valve increased the exposure of the defect. Depending on the size of the defect and surgeon preference, the VSD was closed by direct suture or with a Dacron patch using an interrupted suture. Careful examination was needed to confirm that there was no obvious residual shunt, tricuspid valve regurgitation or server arrhythmia after the heart resuscitation. Protamine was given intravenously (2.0 mg/kg) following the termination of CPB.

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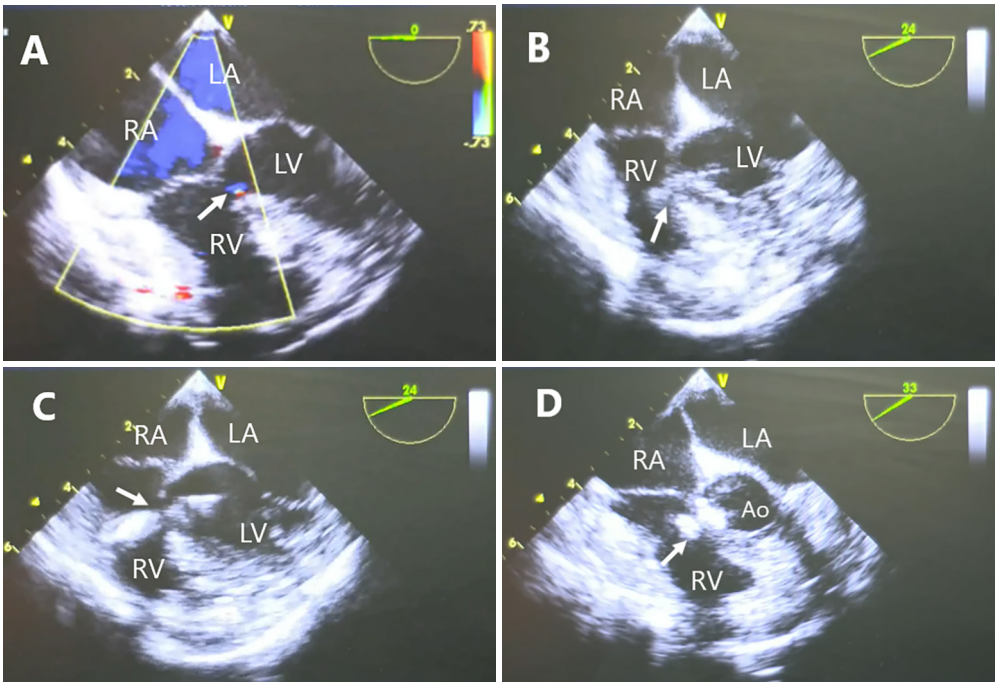

Figure S1 Transesophageal echocardiogram views of the MIPDO procedure. (A) Perimembranous ventricular septal defects (pmVSDs) before MIPDO procedure (arrow). (B) The guide wire (arrow) was inserted through the pmVSD to the left ventricle (LV). (C) The delivery sheath (arrow) was inserted through the pmVSD. (D) Occluder (arrow) and aortic valve under the long axis view of the aorta. Ao, aorta; LA, left atrium; LV, left ventricle; RA, right atrium; RV, right ventricle.

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Appendix 1: measurement and calculation formulas of the echo data

Parameters including LA, RV, IVS, LVPW, EF, MDG, TDG, ASG, PSG were measured directly with the echocardiography. The HR was measured with the simultaneous electrocardiography. CI was calculated using original indexes of weight, LVEDD and HR with the following formulas:

CI [L/(min·m^2)] =LVEDV (mL) * EF (%) *HR (bpm)/(BSA (m^2)*100000);

LVEDV (ml) =7 * LVEDD $(cm)^3$/(2.4+LVEDD (cm));

BSA (m^2) = weight (kg)*0.035+0.1, when weight <30 kg;

BSA (m^2) = (weight (kg)-30)*0.02+1.05, when weight ≥30 kg.

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Appendix 1: calculation of sample size

We used the sample size formula as follows:

$$n = \frac{\left[\mu_{1-\alpha}\sqrt{2\bar{p}(1-\bar{p})} + \mu_{1-\beta}\sqrt{p_T(1-p_T) + p_C(1-p_C)}\right]^2}{(\Delta - (p_T - p_C))^2} \quad [1]$$

Definitions and values used (decided according to the clinical consensus and articles reviewed) in the formula: p_T:estimated successful rate of MIPDO group (98%); p_C: estimated successful rate of surgical group (98%); $\bar{p}=(p_T + p_C)/2$; Δ: non-inferiority margin (8%); μ: The quantile corresponding to a standard normal distribution, α: Type I error levels for statistical tests (0.025 one-sided); β: Type II error levels for statistical tests (0.2 one-sided).

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