



## Zero Fluoroscopy Transcatheter Device Closure in Subaortic Ventricular Septal Defect

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### Abstract

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**Background :** For the last decade, transcatheter closure of ventricular septal defect (VSD) has been the treatment of choice, using fluoroscopy as a guide. However, the risk of radiation and/or contrast agent exposure has been an issue, especially in young patients. We would like to highlight the first case of zero fluoroscopy transcatheter VSD closure in Central Java.

**Case Illustration :** A 27-year-old female was referred to outpatient department due to worsening shortness of breath in the last 3 months before admission. She had a history of recurrent respiratory tract infections, feeding difficulty, and failure to thrive. Her vital signs were stable, 99% oxygen saturation, and grade 3/6 pansystolic murmur in the lower left sternal border. Transoesophageal echocardiography showed 3 mm subaortic VSD, left to right shunt. Transcatheter VSD closure was successfully done using Konar-MF™ VSD Occluder No. 8/6 mm retrograde approach without fluoroscopy.

**Conclusion :** The first zero fluoroscopy transcatheter device closure in Central Java has been successfully done in a 27-year-old female with subaortic VSD. Zero fluoroscopy transcatheter VSD closure is a feasible, safe, and effective procedure.

**Keywords :** Ventricular septal defect closure, zero fluoroscopy, echocardiography-guided

## INTRODUCTION

Ventricular septal defect (VSD), as one of acyanotic congenital heart defect, is common in children and transcatheter closure has been the treatment of choice for the last decade.<sup>1</sup> Even though the gold standard for transcatheter placement is a fluoroscopy-guided procedure, it may expose patient to radiation as much as 5 to 6.5 millisieverts.<sup>2</sup>

Therefore, the risk of radiation has always been an issue, especially in younger patients because the effects are cumulative and may cause serious complication such as malignancy.<sup>2,3</sup> Contrast agent used in fluoroscopy has several side effects as well. The iodinated contrast agent may cause acute contrast reactions such as mild allergic reaction (nausea, vomiting, rash) or more serious anaphylactic shock. Another common adverse effect of contrast agent is contrast-induced nephropathy (CIN).<sup>4,5</sup> Thus, reducing or eliminating radiation and/or contrast agent exposure is a crucial matter in congenital defect closure.

The first zero fluoroscopy transcatheter atrial septal defect closure in Indonesia was successfully done in 2018, followed by Medan, Makassar, Bandung, Malang, and Bali. We would like to highlight this case as the first zero fluoroscopy transcatheter VSD closure in Central Java.

## CASE ILLUSTRATION

A 27-year-old female was referred to the outpatient department due to worsening shortness of breath in the last 3 months before admission. She complained of recurrent cough and fever since she was a child. She also complained of feeding difficulty and low body weight. About 8 years ago she felt shortness of breath triggered by heavy physical activity. The shortness of breath got worse when she had cough & fever. She denied neither bluish on lips and nails, history of seizure, nor drugs consumption of her mother during pregnancy. Her routine medication was bisoprolol 1.25 mg OD.

In January 2024 she had fever, cough, and shortness of breath. She was hospitalised and chest X-ray showed cardiomegaly, later she was consulted to cardiologist and was diagnosed to have congenital heart disease. She was referred to Dr. Kariadi General Hospital (RSDK) for further assessment and treatment. Echocardiography in RSDK showed ventricular septal defect (VSD) and she was admitted to get VSD device closure.

In the ward, her blood pressure, heart rate, and respiratory rate were 103/61 mmHg, 83 beats per minute, and 18 breaths per minute respectively. Her peripheral oxygen saturations were 99% in all extremities and she had no fever. Her height & weight were 155 cm & 55 kg. Physical examination revealed regular 1<sup>st</sup> & 2<sup>nd</sup> heart

sound and a grade 3/6 pansystolic murmur in the lower left sternal border. She had normal sinus rhythm of 60 beats per minute in electrocardiogram. Chest X-ray did not show cardiomegaly. Laboratory test results were unremarkable. Transthoracic echocardiography (TTE) showed 4 mm subaortic VSD, left to right shunt, and 87 mmHg trans-VSD pressure gradient (PG).

## PROCEDURE

She was scheduled to get transcatheter VSD device closure under general anaesthesia. Transoesophageal echocardiography (TEE) showed 3 mm subaortic VSD left to right shunt and mild aortic insufficiency due to right coronary cusp (RCC) prolapse. We decided to close the VSD using TEE-guided-retrograde technique.

A 5F sheath was inserted into right femoral artery, then JR-3.5 5F guiding catheter was inserted through the sheath guided by 0.035" guidewire. She was given injection of unfractionated heparin 5000 IU and ampicillin 1375 mg intravenous. Guiding catheter was pushed through the descending aorta, aortic arch, ascending aorta, and then to left ventricle. Later, guiding catheter successfully crossed into right ventricle through the VSD.

Konar-MF™ VSD Occluder No. 8/6 mm was inserted into JR-3.5 5F guiding catheter using classical technique and pushed into right ventricle through the VSD. The low-pressure disk was deployed in right ventricle, then the whole system was pulled into left ventricle, then the high-pressure disk was deployed in left ventricle, so the VSD was closed completely. The device was successfully deployed and there was no residual shunt, then the device was detached from the wire. Follow-up TTE was done the next day and showed the device was stowed in place. There was no residual shunt, left ventricle (LV), or right ventricular outflow tract obstruction (RVOT). She got acetylsalicylic acid 80 mg OD and bisoprolol 1.25 mg OD. Her clinical condition was good at follow-up in outpatient department the following week and the shortness of breath had decreased. Follow-up TTE showed the device was stowed in place, no residual shunt, LVOT, nor RVOT obstruction was seen.

## DISCUSSION

Table 1 shows the management of VSD based on 2020 guidelines for the management of adult congenital heart disease by European Society of Cardiology.<sup>6</sup>

Percutaneous VSD closure has been performed in the last 20 years. It is more preferred by patients and families because of less length of stay, scarring, pain, and no intensive care needed.<sup>7</sup>

In 2023 Singab *et al.* conducted a comparative study including 72 patients and divided to transcatheter

**TABLE 1**  
**Recommendation for Intervention in Ventricular Septal Defect<sup>6</sup>**

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>
In patients with evidence of LV volume overload <sup>c</sup> and no PAH (no non-invasive signs of PAP elevation or invasive confirmation of PVR <3 WU in case of such signs), VSD closure is recommended regardless of symptoms.	I	C
In patients with no significant L–R shunt, but a history of repeated episodes of IE, VSD closure should be considered.	IIa	C
In patients with VSD-associated prolapse of an aortic valve cusp causing progressive AR, surgery should be considered.	IIa	C
In patients who have developed PAH with PVR 3–5 WU, VSD closure should be considered when there is still significant L–R shunt (Qp:Qs >1.5).	IIa	C
In patients who have developed PAH with PVR ≥5 WU, VSD closure may be considered when there is still significant L–R shunt (Qp:Qs >1.5), but careful individual decision in expert centres is required.	IIb	C
VSD closure is not recommended in patients with Eisenmenger physiology and patients with severe PAH (PVR ≥5 WU) presenting with desaturation on exercise. <sup>d</sup>	III	C

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AR = aortic regurgitation; IE = infective endocarditis; L–R = left-to-right; LV = left ventricle/ventricular; PAH = pulmonary arterial hypertension; PAP = pulmonary artery pressure; PVR = pulmonary vascular resistance; Qp:Qs = pulmonary to systemic flow ratio; VSD = ventricular septal defect; WU = Wood units.

<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

<sup>c</sup>LV enlargement with increased stroke volume.

<sup>d</sup>There are limited data available for a precise cut-off, but by clinical experience, this would be given by a fall of arterial oxygen saturation <90%.

and surgical VSD closure. The result of the study was no significant difference in residual VSD, but there were significant differences in the duration of ventilator, intensive care and total hospital length of stay, and blood transfusion in the transcatheter group.<sup>8</sup>

Study by Chen *et al.* evaluated 65 patients with VSD complicated by mild AR due to aortic valve prolapse (AVP), undergoing transcatheter VSD closure between 2008 and 2014. The procedure, guided by fluoroscopy and transthoracic echocardiography, achieved a high immediate success rate of 96.9% without any death or major complications, although two procedures were halted due to device-related AR worsening. After one year, no residual shunts or serious complications were

observed, with 61.9% of patients showing improvement in AR and 36.5% demonstrating reduced AVP severity. The study concluded that transcatheter closure is a feasible, safe, and effective alternative to surgery for selected patients with VSD, AVP, and mild AR. However, careful patient selection and further long-term studies were needed to confirm safety and efficacy.<sup>9</sup>

Another study by Zhang *et al.* evaluated long-term outcomes of transcatheter closure in 164 children with perimembranous ventricular septal defect (pVSD) and AVP, categorizing AVP severity as mild, moderate, or severe. The procedure showed high success rates for mild (93.7%) and moderate (89.9%) AVP with minimal complications and favorable five-year event-free

TABLE 2  
Indication for VSD Device Closure<sup>11</sup>

Age <18 years old	Mean ± SI (%)
PVRI <4 WU.m <sup>2</sup> , PVR/SVR ≤0.3 can undergo complete closure	PAP <40 mmHg without PVD or PVR <3 WU, recommended for closure regardless signs & symptoms.
PVRI 4-6 WU.m <sup>2</sup> , PVR/SVR ≤0.3 can undergo closure using perforated device/patch	VSD without significant L to R shunt with recurrent history of infective endocarditis, consideration for closure
PVRI 6-8 WU.m <sup>2</sup> , PVR/SVR 0.3-0.5 is given pulmonary vasodilator treatment for 1 year then re-evaluated	PVR 3-5 WU and Qp/Qs >1.5, consideration for closure.

survival, while severe AVP had a lower success rate (58.3%) and higher incidence of AR, suggesting surgical intervention may be preferable for severe cases. No serious complications occurred during follow-up, and transient arrhythmias and residual shunts were rare and manageable. The study emphasized the importance of accurate pre-procedural evaluation, device selection, and regular follow-up to monitor complications. They concluded that transcatheter closure is a safe, effective alternative to surgery for pVSD with mild to moderate AVP, though further large-scale studies are needed to optimize treatment strategies.<sup>10</sup>

Indications for VSD closure using device are perimembranous, subaortic, or subarterial doubly committed (SADC) VSD which fulfilled the criteria as showed in Table 2.<sup>11</sup>

However, there are absolute and relative contraindication for VSD device closure. Absolute contraindication is VSD with Eisenmenger syndrome, PVR ≥5 WU, or desaturation in cardiac exercise test. Relative contraindication is sepsis or uncorrected coagulation problem.<sup>11</sup>

The indication for VSD device closure in this patient was the RCC prolapse causing aortic insufficiency and to prevent further complication, such as worsening of the RCC prolapse, endocarditis, or pulmonary arterial hypertension.<sup>12</sup> There was no clinical sign of pulmonary vascular disease (PVD) and TTE showed left-to-right shunt VSD with 87 mmHg trans-VSD PG, so we decided to close the VSD without performing right heart catheterization.

Preparation for patient undergoing percutaneous transcatheter VSD closure starts with a thorough evaluation to determine the patient's eligibility for catheter-based closure. This assessment is primarily conducted using a TTE, which helps in measuring and locating the VSD, then followed by cardiac catheterization to detect pulmonary arterial hypertension. Additional preoperative procedures are chest X-rays, electrocardiograms (ECG), and laboratory tests to assess the patient's general condition and renal

function.<sup>13</sup>

Prior to the procedure, all patients scheduled for VSD closure should receive antiplatelet therapy, typically involving daily doses of both aspirin and clopidogrel. For patients requiring long-term antithrombotic treatment, warfarin may be used alongside low-molecular-weight heparin for bridging before and after the procedure. An intravenous dose of antibiotics, usually cefazolin or vancomycin (for those allergic to penicillin), should be administered one hour prior to the procedure. To prevent left atrial hypovolemia, patients should also receive intravenous normal saline before and during the intervention. Furthermore, all patients must be assessed by an anaesthesiologist before the procedure; generally, patients under 10 years old are given general anaesthesia, while conscious sedation is preferred for older patients.<sup>13</sup>

According to 2023 clinical pathway for VSD device closure without fluoroscopy in Harapan Kita National Cardiovascular Centre, the patient should be given injection of unfractionated heparin (UFH) 50-100 IU/kgBW IV (maximum dose 5000 IU) for antithrombotic therapy and cefazolin 50 mg/kgBW IV for endocarditis prophylaxis intra-procedural, and followed by acetylsalicylic acid therapy for 6 months.<sup>11</sup> This patient was given UFH 5500 IU intra-procedural for the antithrombotic therapy and Ampicillin 1375 mg for the endocarditis prophylaxis.

The European VSD registry studied complications related to transcatheter VSD closure in 430 patients with various types of VSDs. The procedure had a high success rate of 95.3%, using mainly Amplatzer devices tailored to the VSD type. Complications occurred in 12.7% of patients, including one death (0.2%), haemolysis, device embolization, vascular issues, infections, tachyarrhythmias, and complete atrioventricular (AV) blocks. Complete AV blocks were noted in 2.8% of patients, with half occurring during or immediately after the procedure and others developing within a week or months later, particularly in those with Amplatzer Perimembranous devices.<sup>14</sup>

Study by Holzer *et al.* on 100 subjects over 5 kg

undergoing perimembranous VSD closure with the Amplatzer device showed a 93% procedural success rate. Complications occurred in 29% of patients, with arrhythmia being the most common at 13%. New or worsening aortic valve regurgitation was noted in 9.2% of subjects, with some cases resolving or remaining mild during follow-up. Similarly, 9.2% experienced new or worsening tricuspid valve regurgitation, with partial resolution or mild severity in most cases. Only one patient experienced moderate or worsening valve regurgitation after a median follow-up of 182 days.<sup>15</sup>

Complications of device embolization can be avoided by choosing the correct size. Size of the device should be determined by the size of the defect, with an additional of 0.5 to 1 mm.<sup>14</sup> Another frequent complication that arises is total AV block, which seems to occur more often in younger patients. In contrast to surgical procedures, where total AV block typically manifests shortly after the operation, its onset in patients undergoing percutaneous closure is unpredictable and can occur much later.<sup>16</sup> Potential mechanisms for this include mechanical compression, tissue reactions, or inflammatory responses, which are generally resolved in the early stages. In some instances, patients have returned to sinus rhythm spontaneously or with the aid of temporary pacemakers, corticosteroids, salicylic acid therapy, or through device removal. The use of the Amplatzer Duct Occluder II may lower the risk of total AV block due to its flexibility and the straightforward implantation process.<sup>7</sup>

## CONCLUSION

The first zero fluoroscopy transcatheter device closure in Central Java has been successfully done in a 27-year-old female with subaortic VSD. Zero fluoroscopy transcatheter VSD device closure is feasible, safe, and effective procedure.

## Other Information

There is no conflict of interest to disclose.

The patient and her family were informed and agreed that her case as the first zero fluoroscopy VSD device closure in Central Java would be published in medical journal.

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