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Transcatheter closure of doubly committed subarterial ventricular septal defect: Early to one-year outcome

Rahmat Budi Kuswiyanto [a,*], Sri Endah Rahayuningsih [a], Putria Rayani Apandi [a], Dany Hilmanto [a], Muhammad Hasan Bashari [b]

[a] Department of Pediatric and Child Health, Hasan Sadikin Hospital, Universitas Padjadjaran, Jalan Pasteur No. 38, 40161, Bandung, West Java, Indonesia
[b] Department of Pharmacology and Therapy Faculty of Medicine Universitas Padjadjaran, Jalan Professor Eyckman No.38, Bandung, 40161, Indonesia

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ABSTRACT

Background: The report of transcatheter doubly committed subarterial ventricular septal defect closure is limited. The objective was to evaluate the efficacy and outcome of transcatheter closure of doubly committed subarterial ventricular septal defect.

Methods: Clinical records, procedural and early to one-year follow-up data of doubly committed subarterial ventricular septal defect patient who underwent transcatheter closure between 2013 and 2018 in Hasan Sadikin Hospital Bandung Indonesia were retrospectively reviewed.

Results: There were 40 patients of doubly committed subarterial ventricular septal defect who underwent transcatheter closure, consisted of 18 female and 22 male. The median of age was 8.8 (range 2.7–48) years, weight 24 (range 10.3–70) kg, and defect size 3.1 (1.24–7.4) mm. Mean pulmonary arterial pressure 23.4 SD 5.4 mmHg and flow ratio 1.65 SD 0.28. Median of latest follow-up was 14 months. No serious complications or death. The median length-of-stay period was 3 days, without intensive care admission. Failure to attempt in 3 cases, resulted 92.5% of acute procedural success rate. The acute efficacy was 37.5%, and increased up to 92% on latest follow-up. Of 7 patients with pre-existing aortic regurgitation, three was improved, two persisted, and one progressed to moderate regurgitation. New onset mild aortic regurgitation occurred in 1 patient, which persisted in the same degree during follow-up.

Conclusion: Transcatheter closure of doubly committed subarterial ventricular septal defect is feasible, safe and effective as an alternative treatment to surgical closure in selected patient. The competence of the aortic valve remain the main concern and required further follow-up.

1. Introduction

Doubly committed subarterial VSD (DCSA-VSD), also known as infundibular VSD has higher prevalence in Asian [1], and has lower rate to close spontaneously but higher incidence of aortic valve prolapsed (AVP) and aortic regurgitation (AR) in untreated cases [1–6]. Therefore surgical closure is recommended as the standard treatment to close the defect and to prevent aortic insufficiency [5–9]. However, follow-up result of surgical closure of DCSA-VSD remains has problems, such as persistent and progression of AR [7,8,10], residual shunt, necessity for reoperation, and atrioventricular block (AVB) required pace maker [10]. Furthermore, the availability of intensive cares unit in certain area are limited, on the other side many patients are waiting in long queue for surgical closure such as in Indonesia.

Transcatheter closure of muscular and perimembranous VSD as alternative treatment has been done in many centers, showed encouraging result and excellent procedural success rate [11–13], without increased risk of significant valve regurgitation or AVB [14], and has the advantage in lower incidence of myocardial injury, less blood transfusion, faster recovery, shorter hospital stay, and lower medical expenses [15]. However supporting evidence, experience and report of transcatheter closure of DCSA-VSD is limited. Transcatheter closure of DCSA-VSD is challenging because the location of the defect close to the aortic and pulmonary valves. A few studies have reported with lower success rate [16,17], and higher rate of residual shunt and AR [17,18].

* Corresponding author. Department of Pediatric and Child Health, Hasan Sadikin Hospital, Universitas Padjadjaran, Jalan Pasteur No. 38, 40161, Bandung, West Java, Indonesia.
E-mail addresses: rahmat_budi_k@yahoo.co.id (R.B. Kuswiyanto), endah.perkani@gmail.com (S.E. Rahayuningsih), putrirayani@yahoo.com (P.R. Apandi), danyhilmanto@yahoo.com (D. Hilmanto), bashari@unpad.ac.id (M.H. Bashari).

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Abbreviation

ADO	Amplatzer ductal occluder
AR	aortic regurgitation
AVB	atrioventricular block
AVP	aortic valve prolapsed
DCSA-VSD	doubly committed subarterial ventricular septal defect
LAO	left anterior oblique
LV	left ventricle
mPAP	mean pulmonary arterial pressure
MFO	Konar multi functional occluder
RAO	right anterior oblique
RV	right ventricle
TTE	transthoracic echocardiography

The objectives of this study are to evaluate the efficacy and early and 1 year outcomes of transcatheter closure of DCSA-VSD in our institution.

2. Methods

2.1. Patient selection

We retrospectively reviewed clinical records of DCSA-VSD patients who underwent transcatheter closure of DCSA-VSD between January 2013 and December 2018 in Dr. Hasan Sadikin General Hospital Bandung Indonesia. The clinical criteria for intervention were age older than 2-year-old and body weight more than 10 kg. Echocardiography inclusion criteria were the defect size was less than 10 mm, well competence of aortic valve or less than mild AVP or AR, without septal malalignment or other cardiac anomalies requiring surgery. The exclusion criteria were pulmonary hypertension, thrombosis, bleeding disorder, active endocarditis or other active infections. Informed consent was obtained from all parents or patient prior to the procedure.

All patients underwent clinical assessment and chest x-ray, 12-lead electrocardiography. Complete standard transthoracic echocardiography (TTE) was performed to assess the defect, competency of aortic valve, and associated lesions. Criteria for DCSA-VSD was the defect seen in the standard parasternal long-axis view, with the plane of sound tilted to the left toward the pulmonary artery to angulate anteriorly and the defects located far to the left between the aortic and pulmonary valves at 12–13.30 o'clock on the short axis view at the level of the aortic valve. Size of defect were measured by two-dimensional and color Doppler echocardiography on TTE (Fig. 1 A, B, C).

The AVP and AR were assessed by two-dimensional and color Doppler echo in parasternal long-axis view. The severity of AVP and AR were graded according to previous study, which classified as follow: trivial, if the narrow jet reached just beneath the aortic valve; mild, when it was confined to the left ventricular outflow tract; moderate, if the regurgitation jet reached beyond the anterior cusp of the mitral valve but not reaching the left ventricular apex or the middle portion of the left ventricle, and severe, if regurgitated jet reached the left ventricular apex [3, 19].

2.2. Procedure of intervention

The procedure was modified procedure from studies by Hijazi and Fu et al. [12,13]. Briefly, the procedure performed under general anesthesia or local anesthesia and TTE guidance only. Access was obtained via the right femoral vein and right femoral artery. Intra-arterial heparin (75–100 IU/kg body weight) and intravenous cephazoline (50 mg/kg) was administered after obtaining these accesses. Routine right and left heart catheterization were performed to assess the degree of shunting and to evaluate the pulmonary vascular resistance. Left ventriculography on the right anterior oblique (40–50° RAO plus 20–25° caudal) and true lateral view was performed using a 4, 5 or 6 F pigtail catheter to profile the defect (Fig. 2 A, B). Aortogram was performed to assess the severity of aortic insufficiency and graded as previously described [20]. The defect was then crossed from the left ventricle (LV), using 0.035–260 cm J-angled tip Terumo exchanged guide wire® via a 4–5 F cutted pigtail catheter to establish arterial-venous loop. The exchange wire was snared in the pulmonary artery or superior vena cava, and then a delivery sheath

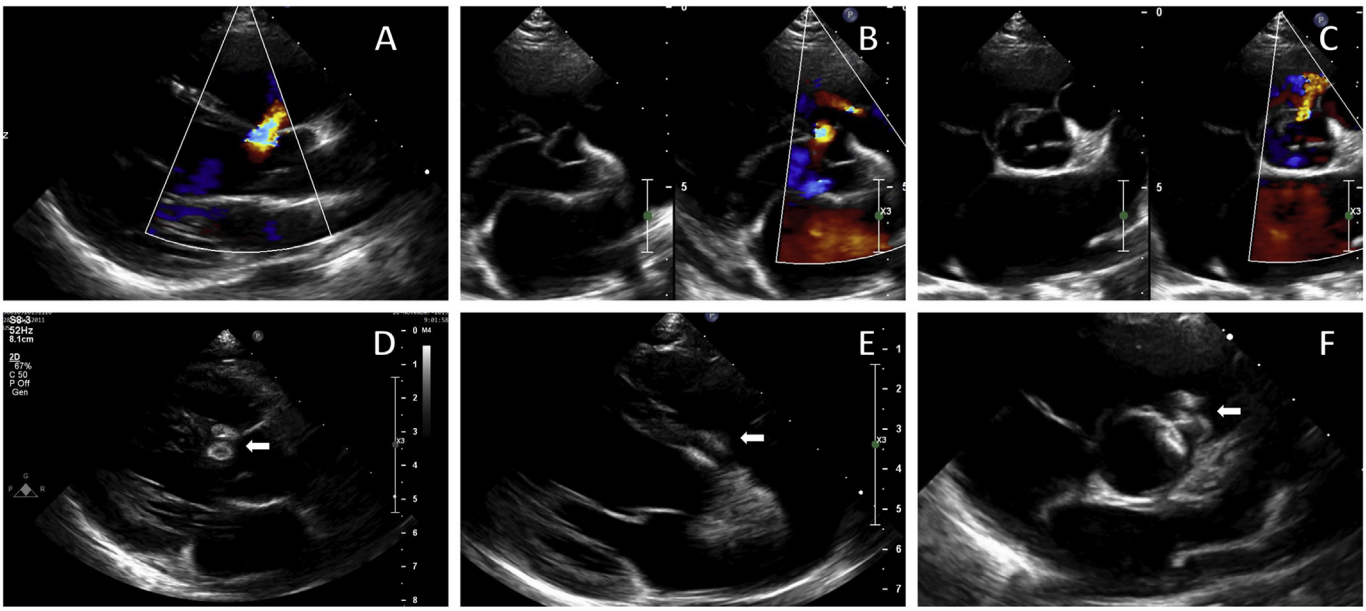

Fig. 1. Transthoracal Echocardiography of doubly committed subarterial ventricular septal defect.
A. Parasternal long axis view with color Doppler showing DCSA-VSD. B. Parasternal long axis view with anterior angulation showing DCSA-VSD with RCC prolapsed. C. Parasternal short axis view showing DCSA-VSD on 13 o' clock position. D. Parasternal long axis view showing device (ADO II) in good position. E. Parasternal long axis view with anterior angulation showed device (ADO II) in good position, with the left and right disc separated by septum (white arrow). F. Parasternal short axis view showed device (ADO II) in good position.

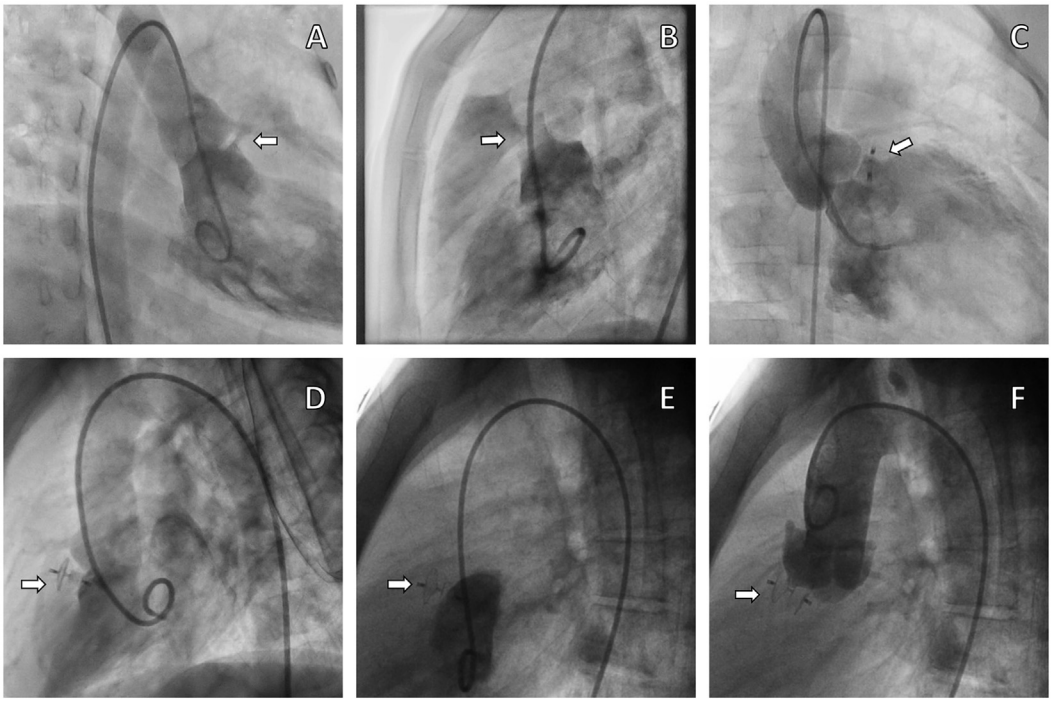

Fig. 2. Cine fluoroscopy image in DCSA-VSD.
A. Left ventricular angiogram in RAO view demonstrated defect (white arrow). B. Left ventricular angiogram in lateral view demonstrated the defect roofing by the leaflets of the aortic and pulmonary valve (white arrow). C. Left ventriculography showing good device (MFO) position. D & E. Lateral view showing good device (MFO) position. D. Aortogram showing device (MFO) sitting nicely just beneath the aortic valve, without causing regurgitation.

was advanced from the femoral vein with kissing technique to cross the defect, until it reached the descending aorta. A repeated angiogram in the same projection was then performed to reassess the defect size and to use as a landmark guide for device deployment. The LV disc was deployed in the ascending aorta on true lateral projection. Thereafter, delivery cable and delivery sheath was gently pulled back until across the aortic valve. Once the device in the left ventricular outflow tract, then all the delivery sheath and cable pulled back until the left side of the device perpendicular to the ventricular septum, then the connecting waist and RV disk were completely and simultaneously deployed, until the left disc toward the apex and raise the right disc in such a way. A repeated LV angiogram and echocardiography were performed to assess the position of the device, closure result, the competency of aortic and pulmonary valve and any obstruction of the right and left outflow tracts. If the result is satisfactory then the device will be released. Then echocardiography, left ventriculography and aortography were repeated to assess the final immediate results (Fig. 1 D, E, F and Fig. 2 C, D, E, F).

2.3. Device selection

Amplatzer duct occluder II® (ADO II, Abbot AGA Medical, Golden Valley, MN), Konar multifunctional occluder ®(MFO; Lifetech Scientific Corporation, Shenzhen, China) and Nit Occlud LêVSD Coil ®(Produkte fur die Medizin/PFM, Koln, Germany) were used because those have lower profile and more flexible property. The size of device was selected based on defect diameter measured by TTE combined with left ventriculography before and after delivery sheath crossed inside the defect. ADO II and MFO were selected by adding 1–2 mm to the narrowest part of defect. In AVP patient, the size of the ADO II and MFO was selected by add 2 mm if the shunt of the defect remain seen on repeated TTE and ventriculography with delivery sheath crossed inside the defect. The size of Le VSD coil was selected based on the distal diameter of the coil, which should be at least twice the diameter of VSD at right ventricular side and equal or 1–2 mm more than the diameter of VSD at left ventricular side. However the type of device was chose depending on the availability of the stock during the procedure.

2.4. Follow-up protocol and outcome measures

A follow-up protocol included detailed physical examination, electrocardiography, and TTE prior to hospital discharge, at 1-month, 6-month, and 12-month periods to assess the closure result, the presence of residual defect, competency of the aortic and pulmonary valves and any associated adverse events related to the procedure.

Acute procedural success rate is the proportion of patients who successfully implanted a device from the total number patients, which the device was attempted. Acute efficacy rate is the proportion of complete closure result in the total patients, which the device was attempted. Adverse event was documented during procedures and follow-up and residual shunt assessment was classified according to previous study [12]. Patients were started on aspirin 3–5 mg/kg body weight daily for 6 months and instructed to receive an infective endocarditis prophylaxis if needed until complete closure was documented.

2.5. Data analysis

Data collection was done after The Ethics Committee of the hospital approved the study. Continuous variables are presented as mean with standard deviation or median with range, depending on data distribution. Categorical variables are presented as frequencies and percentages. Data were analyzed by using SPSS Statistics for Windows, Version 23.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp).

3. Results

3.1. Baseline clinical characteristic

There were 40 complete clinical records of DCSA-VSD patients who underwent transcatheter closure during the study period from 2013 to 2018 in our institution, consisted of 22 male and 18 female. The median

of latest follow-up was 14 months (range 11–18 months). Prior to procedures, majority of the patients were asymptomatic, which malnourished condition in 20% patients. Additional cardiac anomaly was persistent left superior vena cava and mild coarctasio of the aorta, tiny patent ductus arteriosus, and mild pulmonary valve stenosis. Twelve patients (30%) showed pre-existing mild AVP, which three of them showed pre-existing trivial AR and four patients showed pre-existing mild AR, respectively. See Table 1.

3.2. Baseline procedural characteristic and outcome

Of the number of patients where the device was attempted, 37 implanted successfully, resulting 92.5% of total acute procedural success rate. Failure to attempt occurred in two patients with preexisting AVP and AR due to undersize of the defect and only ADO II was available on the stock during initial phase of the study and in one patient showed moderate significant residual shunt and worsened of AR after deployment of the MFO. The procedure was abandoned and the patient referred for surgery. Device size was changed and upsized in 4 patients successfully to eliminate residual significant shunt by the first device. The types of device were used respectively; ADO II in 19 (47.5%), MFO in 13 (32.5%), and Le VSD coil in 8 (20%).

Fifteen patients had complete closure of the defect at immediate result. Acute efficacy rate was increased from 37.5% to 60% at discharge next day after procedure. The rate of complete closure was increased in 30 patients (81%) at 1-month follow-up to 34 patients (92%) at latest follow-up. Two patients showed trivial residual shunt and one patient showed mild residual shunt on the latest follow-up. Of 7 patients with pre-existing AR, the regurgitation was improved after closure in 3 patients, persisted in 2 patients, and progressed to moderate regurgitation in 1 patient on further follow-up. New onset mild AR occurred in 1 patient, which persisted in the same degree until latest follow-up.

One patient experienced persistent severe hemolysis on the 10th day after discharge related to residual shunt through the coil and required multiple blood transfusions despite conservative treatment. Accordingly additional procedure was performed successfully to close the residual shunt with ADO II 6/4 mm, then hemolysis was subsided next day after procedure. However preexisting mild AR in this patient progressed to moderate degree at the latest follow-up. One patient aged 48 years old showed mild tricuspid regurgitation, mild pulmonary regurgitation, and mild pericardial effusion. Coronary angiography done prior to closure showed normal coronary artery. This patient required longer hospital stayed for observation and discharged well on 6th day. There were no other serious complications such as device embolization, infections, AVB or death during procedures or on follow-up. The median length-of-stay period was 3 days (range 3–6 days) and there were no subjects requiring admission to intensive care unit.

4. Discussion

4.1. Efficacy

Procedural success rate of transcatheter closure of DCSA-VSD in this study was 92.5%. The procedural success rate was higher compare previous study using asymmetric occluder [16]. Recent study reported failure to attempt in 1 of 20 patients using ADO I [17]. The studies using eccentric device to close intracristal VSD, a subgroup of infundibular VSDs which located in supraventricular crest and has muscular rim more than 2 mm from annulus pulmonary valve, reported failure to attempt in 6–34% of patients [21–23]. In this study failure to attempt rate was 7.5%, because of dislodgement, moderate significant residual shunt, and developing moderate AR. Dislodgement and developed new onset of AR also reported by other studies as a cause of failure procedure [21–23]. The size of defect was challenge to measure in DCSA-VSD especially if the aortic valve is prolapsing. Undersize of the defect may cause dislodgement and oversized may interfere aortic valve causing regurgitation. Our approach was combined TTE and ventriculography to measure the defect. Transoesophagal echocardiography was not use in this study and perhaps could delineate the defect better in pre-existing AVP patient. Left ventriculography with RAO angulation is better than LAO angulation to assess the defect and we routinely perform left ventriculography before and after delivery sheath crossing inside the defect to give more information in measuring the defect and determining the size of the device as well.

Table 1
Clinical and procedural baseline.

Patients characteristic	
Gender (n/%)	Male 22 (55%)
Age (year)	8.8 (2.7–48)[b]
Weight (kg)	24 (10.3–70)[b]
Defect size (mm)	3.1 (1.24–7.4)[b]
mPAP (mmHg)	23.4 SD 5.4[a]
Flow ratio	1.65 SD 0.28[a]
Fluoro time (minutes)	32.1 SD 13.9[a]
Procedures times (minutes)	91.5 (45–198)[b]

[a] Mean & standard deviation (SD).
[b] Median & range; mPAP = mean pulmonary arterial pressure.

The acute efficacy rate in this study was 37.5% and closure rate was increase to 92% on latest follow-up. This result was comparable with other studies. The proportion of residual shunt was higher immediate after DCSA-VSD closure using ADO I, but tend to reduce during follow-up [17]. The residual defect was small but had tendency to remain the same during follow-up in a study using Le VSD coil and membranous VSD occluder [18]. Studies from China reported closure rate on follow-up was 79–89% using asymmetric occluder and eccentric occluder [21,22]. These results suggested that the closure rate of transcatheter closure of DCSA-VSD was lower. The location of the defect that closed to the aortic and pulmonary valves and roofed by fibrous continuity between leaflets of the aortic and pulmonary valves and the device is moving following the valve may contribute in the slower endothelialization process. Other than that, the majority of patients in this study were closed using ADO II and small size MFO that does not contain membrane inside.

4.2. Aortic valve competency

The proportion of pre-existing AVP in this study was 30%, among them 12.5% showed pre-existing AR. This proportion may be lower since the patients with moderate or severe AVP and AR was excluded. The incidence of AVP and AR in DCSA-VSD in the literature is reported 43–73% [1,4,5] and 24–65%, respectively. The AVP and AR tend to progress during followed-up [1,4–9].

Of 7 patients with pre-existing AVP and AR, two patients were failure to implant and one patient with severe hemolysis was progressed to moderate regurgitation. Pre-existing AVP or AR, even in mild degree may indicate higher risk of procedure failure or worsening the degree of regurgitation and can be made as exclusion criteria for transcatheter closure. However, the incidence of AR post surgical closure was also higher, ranges between 28 and 63%. The degree of AR appeared persisted and similarly even after surgical closure of VSD was performed. Early closure of defect before development of aortic valve complication is recommended [5,9].

New-onset AR occurred only in one patient who has mild AVP before intervention. The degree of regurgitation of this patient was trivial to mild regurgitation and did not progress on further follow-up. The total proportion of pre existing and new onset of AR in this study was 11%. Previous studies reported new onset AR was higher and the most frequently complication. The frequency of new onset AR was found to be higher in the DCSA-VSD compared to perimembranous VSD, although the frequency of AR appeared did not change or worsened until 6 months follow-up [18]. A recent study reported 43% new-onset mild AR using ADO I in their subjects, and 33% unchanged during subsequent follow-up

period [17]. Eccentric occluder has advantage such as left disc does not have a superior margin avoiding to touch the aortic valve and support pre-existing AVP without interfering the valve. However the rate of new onset AR using eccentric device was remain higher [20–22]. The device might be touched and interfered the aortic valve, despite we used more flexible and lower profile device. Only one patient in our series developed new onset AR. This patient was closed with MFO. The left disc of MFO are stiffer compared to ADO II and coil, which may interfere the aortic valve resulting regurgitation. Based on the defect size; ADO II suitable for the defect up to 6 mm, VSD coil for the defect up to 8 mm and MFO for the defect up to 10 mm. Compared to MFO, the left disc of VSD occluder and ADO I are stiffer, which may increase risk of distortion, erosion, or rupture of the aortic sinus or valve resulting in aortic regurgitation, despite early result showed without new onset AR or were usually trivial and recoverable [17]. The disadvantage of eccentric device was the upper part of left disc may remain interfere the aortic valve as the upper edge of the defect, required more than 2 mm rim under the pulmonary valve [22], difficult to adjust the orientation and position of the device to keep the platinum marker on the left disk toward the apex [21], resulting in significant prolongation of procedure and fluoroscopic times [16,21]. Other factor may be related to oversize the defect that required larger device to close the defect, which may interfere to the aortic valve and lead to AR [22]. Currently there is no ideal device that satisfied to close VSD, especially DSCA-VSD. The incidence of new onset of AR after device closure was higher compared to surgical closure of DCSA VSD [7,8]. Further follow-up are required to assess the progression of new onset AR after device closure of DCSA-VSD.

4.3. Other complications

One patient experienced severe hemolysis related to residual shunt after closured using coil. It occurred because the position of coil was unstable and changed. The residual shunt was successfully closed using ADO II and the hemolysis was subsided afterward. Our study showed no patient experienced AVB during procedures and follow-up period, similar to the other report [16–18,21–23]. The incidence of AVB was lower in transcatheter DCSA-VSD closure, because this defect is located distant to the conduction tissue, thus the change to injure the conduction system is low.

Transcatheter closure of DCSA-VSD demonstrated comparable rates of adverse events and less invasiveness in terms of hospital and ICU stay, operating room and mechanical ventilation time, wound size, transfusion, and avoidance of cardiopulmonary bypass [16]. This present study showed the patients required shorter hospitalization and no patient admitted to intensive care unit. This advantage is important in center which many patients have waiting for surgical closure in long queue but the resources is limited.

4.4. Study limitations

This was retrospectively single center study involving small number of cases on relatively short period of follow-up time.

5. Conclusion

Transcatheter closure of doubly committed subarterial ventricular septal defects is feasible, safe and effective as an alternative treatment to surgical repair in selected patient. Further long-term evaluation studies are required to assess and confirm the efficacy and safety of this approach, particularly regarding the competency of the aortic valve.

CRediT authorship contribution statement

Rahmat Budi Kuswiyanto: conceptualization, methodology, investigation, data curation, writing-original draft preparation, formal analysis

Sri Endah Rahayuningsih: Methodology, investigation, validation, writing-reviewing.

Putria Rayani Apandi: Investigation, project administration.

Dany Hilmanto: Supervision, validation, visualization, writing-reviewing, and editing.

Muhammad Hasan Bashari: writing-reviewing and editing.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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