Characteristics of Patients with Ventricular Septal Defect that Had Been Closed with Transcatheter in Dr. Soetomo General Hospital from January 2019 to December 2021

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Abstract

VSD is the most common congenital heart disease in newborns. VSD can close spontaneously in the early years of life. However, VSD can not close spontaneously in a few patients and cause complications so that it is necessary to perform VSD closure earlier, one of all options is transcatheter. Transcatheter is a minimal invasive procedure with a high success rate and safety also the incidence of cardiorespiratory disturbances are less while using transcatheter devices making it an alternative intervention for VSD closure. This study aims to determine the outcome characteristics and complications of VSD closure with transcatheter intervention. This study was a descriptive observational study using a cross-sectional design with a retrospective approach, based on secondary data. Sampling was done by total sampling technique. A sample of 27 patients was obtained with a mean age of 4.48 ± 3,298 years, an average weight of 17.70 ± 10.5550 kg, and male sex dominated by 55.6%. The most common type of VSD that was closed with a transcatheter was the perimembranous type of 70.4% and the size of the VSD was dominated by the medium size of 85.2%. The transcatheter VSD closure was successful in 24 patients (88.9%) and failed in three (11.1%). Residual shunt developed in one of three patients who failed. The most common complication was arrhythmia with NSVT type of 62,96%. Other complications were PVC 7.4%, aortic valve regurgitation 3.7%, and hypotension 3.7%. Closure of VSD by transcatheterization has a high success rate, no death is found, and there are no major complications that require long-term or life-threatening therapy. All complications found only occurred during transcatheterization, i.e. arrhythmia, mild aortic valve regurgitation, and hypotension.

Keywords: VSD; Transcatheter; Characteristics; Outcome; Complication

1. Introduction

Ventricular septal defect (VSD) is one of the most common congenital heart diseases resulting in cardiac malformations .[1] VSD occurs due to the failure of the development of the interventricular septum during pregnancy, leaving a hole between the two ventricles.[2] VSD occurs in 2-6 per 1000 babies born and around 15-20% of all congenital heart disease.[3] The most common type is the perimembranous type with a prevalence of around 70% of the total cases of VSD. The Muscular type VSD is the second most common type with a prevalence of 5-20% of the total cases of VSD. Other types of VSD are outlet type which has more percentage in far eastern countries than western countries and inlet.[4]

Ventricular septal defects can close spontaneously in the early years of life.[5] Even though VSD can close spontaneously, VSD can cause several complications such as pulmonary hypertension in infants, aortic regurgitation, infective endocarditis, and also sub-valvular pulmonary stenosis, requiring immediate VSD closure intervention.[6] Although a small defect size is asymptomatic, a small VSD can cause long-term sequelae, such as left ventricular hypertrophy, aortic regurgitation, pulmonary hypertension, arrhythmias, right ventricular double-chamber, and endocarditis. Therefore, VSD patients must be routinely monitored for symptoms that appear because if significant hemodynamic disturbances occur, VSD closure interventions must be carried out immediately.[7]

VSD closure is performed routinely by open heart surgery (cardiac pulmonary bypass) or by percutaneous transcatheter

intervention.[8] Open heart surgery is the gold standard of intervention for VSD closure. However, open heart surgery has disadvantages and contraindications so that in certain cases an alternative intervention with a percutaneous transcatheter is performed. The disadvantages of open heart surgery are the increased length of stay in hospital, surgical scars, the need for reoperation, and cardiorespiratory disorders.[9] One of the other disadvantage of open heart surgery in Indonesian hospitals is the long queues to get the intervention, so patients who need to have their VSD closed immediately have to wait longer. In addition, open heart surgery requires more human resources and facilities to specifically monitor patients in the ICU, making it more inefficient and costly.[10] Open heart surgery is also contraindicated in patients who have severe pulmonary hypertension, have previously undergone thoracic surgery, and patients who have many comorbidities.[11]

Percutaneous transcatheter intervention for VSD closure has now been widely used because of its minimally invasive action so that for pediatric patients who have perimembranous and muscular type VSD, transcatheter intervention can be an alternative choice because of its high safety and fewer incidences of cardiorespiratory disorders as evidenced by the reduced duration of use ventilator compared to patients who underwent VSD closure with open-heart surgery.[12] In addition, transcatheter intervention can help overcome the problem of waiting for open heart surgery to close the VSD in the hospital because the time needed to perform the transcatheter procedure is faster. This study aims to determine the outcome characteristics and complications of VSD closure with transcatheter intervention.

2. Method

This was a descriptive observational study using a cross-sectional design with a retrospective approach. The data were in the form of secondary data obtained from the medical records of VSD patients in Dr. Soetomo General Hospital Surabaya from January 2019 to December 2021. The samples were collected by total sampling method, with the results of 27 patients. The samples were VSD patients aged 1-18 years who had been closed with transcatheter in Dr. Soetomo General Hospital Surabaya from January 2019 to December 2021. Patients who did not undergo transcatheter VSD closure were excluded from this study. This research had obtained permission from the Health Research Ethics Committee of Dr. Soetomo General Hospital with Letter of Exemption number 0774/LOE/301.4.2/I/2022. The data included patient characteristics such as age, gender, weight, VSD type, VSD size, outcomes which includes the success rate, the failure rate, and residual shunt, complication after transcatheterization. The data were collected using Microsoft Excel 2016 and then analyzed using the IBM SPSS Statistic version 26 application.

3. Results

A total of 27 patients met the inclusion and exclusion criteria and became study participants. The characteristics of the participants are shown in Table 1. The average age was 4.48 years. The percentage of male (55.6%) was higher than female (44.4%). The average weight was 17.7 kg.

Table 1. The VSD patients characteristics aged 1-18 years who had been closed with transcatheter in Dr. Soetomo General Hospital Surabaya from April 2020 to March 2021

Variables	Total (27)
Age	4,48 ± 3,298

Gender	
Male	15 (55,6%)
Female	12 (44,4%)
Weight	17,7 ± 10,5550
VSD types	
Perimembranous	19 (70,4%)
Subaortic	4 (14,8%)
SADC	4 (14,8%)
VSD sizes	
Small	2 (7,4%)
Medium	23 (85,2%)
Large	2 (7,4%)

The lowest patient's weight was 7.5 kg and the largest was 56 kg. The most common type of VSD that had been closed by transcatheterization was the perimembranous VSD (70.4%), then followed by the SADC and subaortic types with the same percentages for these 2 types (14.8%). There was one case of the perimembranous type that had underwent transcatheterization to close the residual defect after previous transcatheter VSD closure.

The most common defect size was medium size which occurred in 23 patients with a percentage of 85.2% followed by small and large sizes with the same percentages (7.4%).

Table 2. The outcomes after percutaneous transcatheterization in Dr. Soetomo General Hospital Surabaya from April 2020 to March 2021

Outcomes	Total (27)
Success	24 (88,9%)
Failed	3 (11,1%)
Residual Shunt	1 (3,7%)

Transcatheter occlusion for VSD closure has a relatively high success rate of 88.9%. Failure of transcatheter occlusion including residual shunt occurred in 3 patients or 11.1%.

Table 3. The complications after percutaneous transcatheterization in Dr. Soetomo General Hospital Surabaya from April 2020 to March 2021

Complication	Number of cases (n)
Arrhythmia	
NSVT*	17
PVC**	2
Aortic Valve Regurgitation	1
Thrombosis	0
Embolism	0
Bleeding Requiring Blood Transfusion	0
Hypotension*	1
Death	0

Notes: *one patient had NSVT and hypotension concurrently
**one patient had NSVT and PVC concurrently

Complications from closing the VSD with a transcatheterization occluder occur only during the transcatheterization procedure and disappear after the transcatheterization procedure. The most common complications were arrhythmias with the NSVT type of 62.96% of the total patients. One patient had NSVT and PVC concurrently. One patient had NSVT and hypotension concurrently. Aortic valve regurgitation occurred in 1 patient and hypotension was also found in 1 patient. There were no complications such as death, thrombosis, embolism, or bleeding requiring blood transfusion.

4. Discussion

In this study, the mean age of VSD patients was 4.48 ± 3.298 years. Another study with a sample age of 2-18 years showed that the average age of VSD patients who had transcatheter defect closure was 5.2 ± 3.7 years.[13] This can occur due to spontaneous closure of defects which generally occur early in life, usually in the first 2 years of life.[14] Thus, the incidence of VSD is less at older ages. Defect closure should be done at the maximum age of 2 years. However, several factors caused delays in closing the defect in the sample of this study. Factors that might cause the delays of patients age in closing defects are a slow referral system, delays in referring doctors, patients who delay closing, and symptoms of VSD that appear late. The sex that performed VSD closure with a transcatheter was dominated by the male sex. However, in the journal of Li et al., (2016), studies from many researchers did not mention that gender is a factor that determines the incidence of spontaneous VSD closure.[15] The average weight of patients who underwent VSD closure with transcatheter intervention was 17.7 kg with the lowest patient weight was 7.5 kg, while the patient's largest body weight was 56 kg. Another study with a sample age of 2-18 years showed that the median body weight of VSD patients who had transcatheter defect closure was 15 kg with a range of 7.6 kg to 64 kg.[13] In this study, four patients were found to be underweight for their normal age and the four patients had moderate size VSD. Thus, the underweight in these four patients might be an effect of medium size VSD. The ideal body weight for transcatheterization for VSD closure is 8-10 kg. Even so, other studies have shown that the patient's weight that can be done with a transcatheter defect closure is at least 7 kg and even 6 kg.[16,17] This is because body weight is one of the factors that contribute to the successful closure of defects with transcatheter occlusions because patients with low body weight have small vascular diameters so that the selection of the right device and vascular access becomes more difficult.[18]

The most common type of VSD that was closed with a transcatheter in this study was the perimembranous type, followed by the subaortic type and the SADC type. The subaortic and SADC types had the same number of patients in this study. Another study with a sample age of 2-18 years showed that most VSD patients who had transcatheter defect closure had the perimembranous VSD type.[13] This could happen because the perimembranous type is the most common type of VSD with a percentage of 70%, followed by 15-20% muscular type and 5% subarterial.[19] However, the prevalence of the subarterial type is higher in Asia, which is 30%.[20] In addition, the difference in the number of types of VSD that were performed the transcatheter VSD closure could be influenced by the prevalence of spontaneous closure of the defect which was different for each type of VSD. The spontaneous closure occur mostly in muscular type followed by perimembranous, whereas the subarterial type had a low prevalence of spontaneous closure.[14] The most common size VSD that was closed with a transcatheter occluder in this study was medium size and the small and large size VSD has the same amount of patients. This difference in the number of patients can be influenced by spontaneous closure of defects that differ in each size and

degree of severity of hemodynamic disturbances due to the size of the defect which is an indication for closure. The size of the defect affects the size of the shunt. The size of this shunt can cause hemodynamic disturbances ranging from heart failure to pulmonary arterial hypertension.[19] Although small defects are more likely to close spontaneously early in life than large defects, small defects can cause complications, such as heart failure in some patients, so that closure interventions are needed at once to prevent long-term complications, such as pulmonary arterial hypertension, arrhythmias, endocarditis, to pulmonary vascular obstructive disease or Eisenmenger syndrome.[19,21]

Indicators of successful transcatheter implantation for closure of VSD in this study were successful insertion of the occluder device, stable position, good occluder function as assessed using echocardiography and no residual shunts. This study shows that transcatheter intervention for closure of ventricular septal defects which has been performed on 27 people using various types of occluder devices has a high success rate of implantation (88.9%). The percentage of successful transcatheter implantation in this study corresponds to the success rates of transcatheterization for VSD closure in other literature, which are 87-100%.[22] Occluder failed to be implanted in 2 patients. It might be due to the defect was too large or the size of the occluder was too small, whereas one patient was said to have had an occluder unsuccessfully implanted because he had a residual central shunt. Residual shunts can occur because the occluder is unable to completely close the defect. Therefore, the type of occluder must be chosen appropriately according to the location of the defect, the size of the defect, and other specific conditions of the defect to be closed.[23]

There was no death and no major complications found in this study which life threatening and require long term medications. Complications that can occur after transcatheterization for VSD closure are heart rhythm disturbances with the most serious and frequent type being complete heart block of 3-20%. Other complications are aortic or tricuspid valve disorders with an incidence of 5-26%, embolization of 4%, residual shunt, up to death.[24] The most common complications found in this study were heart rhythm disturbances or arrhythmia in 17 patients. NSVT type in 17 patients and PVCs type were found in 2 patients. Arrhythmias that occur during cardiac catheterization can be caused by the catheter and wire being adjacent to the ventricular wall thereby stimulating the ventricular myocardial tissue and interfering with local electrical activity. It can also be caused by contrast toxicity. Isolated NSVT or PVC events often occur during right heart catheterization, that is, when the catheter tip enters the right atrium, right ventricle, pulmonary artery with a percentage of about 20%.[25] Other complication in this study was mild qualitative aortic valve regurgitation in 3.7% of the total 27 samples and no new case of tricuspid regurgitation was found from a total of 27 samples in this study shortly after the transcatheterization procesure. In a study conducted by Liu et al., (2013), it was found that the emergence of new cases of aortic valve regurgitation was 1.37% and tricuspid regurgitation was only around 0.57% of a total of 871 samples.[26] Aortic valve regurgitation after transcatheter intervention to close the VSD can occur due to occlusion of the occluder with the aortic valve, defects near the right coronary valve edge, and impact of the occluder on aortic valve closure. Meanwhile, regurgitation of the tricuspid valve occurs as a result of the occlusion of the occluder with the valve leaflets which disrupts the structure of the chordae tendinae.[26,27] Hypotension was found in 1 patient during the transcatheterization procedure. Hypotension during cardiac catheterization can occur due to vasovagal reflexes, bleeding, myocardial ischemia, allergic reactions, or bacteremia. However, hypotension during cardiac catheterization is most often caused by vasovagal reflexes.[28] A vasovagal reaction is a sudden decrease in blood pressure, heart rate, and cardiac output (CO) due to stimulation of the parasympathetic nervous system and causes activation of the vagus nerve. The vasovagal reflex is most often induced by pain.[29] Pain at the arterial and venous puncture site and fear of the patient during transcatheterization can induce a vasovagal reflex and cause the patient to be hypotensive.

Conclusion and Suggestion

This study figured out that percutaneous transcatheter is a minimally invasive alternative method to close VSD with high successful rate (88.9%) and safety with no major complications. In this study, there are several limitations including the data collection is only done one time and cannot follow research subjects prospectively in analyzing the effectiveness of transcatheter occlusion and VSD complications that appear in the long term. Researchers suggest further research to collect data in time series (e.g. 1, 3, 6, 12-month) and long duration to follow up the efficacy and complications of transcatheter VSD closure in long term and ensure the clinical improvement of patients. Moreover, it is also necessary to look for the effect of occluder size, occluder type, and distance between defect and valve on successful rate and complications.

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References

1. Spicer, D.E., Hsu, H.H., Co-Vu, J., Anderson, R.H., Fricker, F.J., 2014. 'Ventricular septal defect', Orphanet Journal of Rare Diseases [online], vol 9, no 1,[Viewed 30 June 2021].
2. Centers for Disease Control and Prevention, 2020. Facts about ventricular septal defect, Retrieved: May 30, 2021, from https://www.cdc.gov/ncbddd/heartdefects/ventricularseptaldefect.html.
3. Chaudhry T.A., Younas, M., Baig, A., 2011. 'Ventricular septal defect and associated complications', J Pak Med Assoc, vol 61, no 10, pp. 1001–1004. Irwanto, FH, Puspita, Y and Yuliansyah, R 2017, 'Penutupan defek septum ventrikel secara transtorakalis minimal invasif dengan panduan transesophageal echocardiography (TEE)', Jurnal Anestesi Perioperatif [online], vol 5, no 2, pp. 134-140, [Viewed 28 June 2021].
4. Park, M.K., 2014. Pediatric cardiology for practitioners, 6th ed, Mosby: Saunders Elsevier,pp. 208-211, 267-276.
5. Mavroudis, C. and Dearani, J. A., eds 2020, Atlas of adult congenital heart surgery, Cham,Springer International Publishing, pp. 91-115.
6. Rafiei A., Molaei A., Khosroshahi A.J., Samadi M., Ghaffari S., 2021. 'The comparison of the early outcomes of perimembranous ventricular septal defect closure by two different methods: transcatheter and open-heart surgery in the northwest of Iran', Crescent Journal of Medical and Biological Sciences [online], vol 8, no 3, pp. 1-5,[Viewed 29 June 2021], https://www.cjmb.org/uploads/pdf/pdf_CJMB_512.pdf.
7. Morray, B.H., 2019. 'Ventricular Septal Defect Closure Devices, Techniques, and Outcomes', Interventional Cardiology Clinics [online], vol 8, no 1, pp. 1–10,[Viewed 28 June 2021].
8. Irwanto, F.H., Puspita, Y., Yuliansyah, R., 2017. 'Penutupan defek septum ventrikel secara transtorakalis minimal invasif dengan panduan transesophageal echocardiography (TEE)', Jurnal Anestesi Perioperatif [online], vol 5, no 2, pp. 134-140, [Viewed 28 June 2021].
9. Zhou, Y., Liu, L.X., Zhao, F., Tang, S.H., Peng, H.L., Jiang, Y.H., 2017. 'Effects of transthoracic device closure on ventricular septal defects and reasons for conversion to open-heart surgery: a meta-analysis', Scientific Reports [online], vol 7, no 1, [Viewed 29 June 202.
10. Yosy, D.S., Djer, M.M., Putra, S.T., 2020. 'Comparison of complications between transcatheter and surgical ventricle septal defect closure: a single-center cohort study', Medical Journal of Indonesia [online], vol 29, no 3, pp. 268–274, [Viewed 28 June 2021].
11. Dakkak, W. and Oliver, T.I., 2020. Ventricular Septal Defect, Treasure Island (FL): StatPearls Publishing, pp. 1-14.
12. Liu, H., Lu, F., Zhou, J., Yan, F., Qian, S., Li, X., Zheng, S., Chen, J., Zhong, J., Feng, Q., Ding, T., Fan, J., Gu, H., Liu, X., 2018. 'Minimally invasive perventricular versus open surgical ventricular septal defect closure in infants and children: a randomised clinical trial', Heart [online], vol 104, no 24, pp. 2035–2043, [Viewed 28 June2021].
13. Haddad, R.N., Rizk, C., Saliba, Z., 2021. 'Percutaneous closure of ventricular septal defects in children: key parameters affecting patient radiation exposure', American journal of cardiovascular disease [online], vol 11, no 1, pp 65-72, [viewed 4 November 2022].
14. Xu, Y., Liu, J., Wang, J., Liu, M., Xu, H., Yang, S., 2015. 'Factors influencing the spontaneous closure of ventricular septal defect in infants', International Journal of Clinical and Experimental Pathology [online], vol 8, no 5, pp 5614–5623, [Viewed 11 Oct. 22],
15. Li, X., Song, G.-X., Wu, L.-J., Chen, Y.-M., Fan, Y., Wu, Y., Shen, Y.-H., Cao, L., Qian, L.-M., 2016. 'Prediction of spontaneous closure of isolated ventricular septal defects in utero and postnatal life', BMC Pediatrics [online], vol 16, no 1, [Viewed 10 Oct. 22].
16. Butera, G., Carminati, M., Chessa, M., Piazza, L., Micheletti, A., Negura, D.G., Abella, R., Giamberti, A., Frigiola, A., 2007. 'Transcatheter Closure of Perimembranous Ventricular Septal Defects', Journal of the American College of Cardiology [online], vol 50, no 12, pp.1189–1195, [Viewed 10 Oct. 22].
17. Kouakou, N.Y.N., Song, J., Huh, J., Kang, I.S., 2019. 'The experience of transcatheter closure of postoperative ventricular septal defect after total correction', Journal ofCardiothoracic Surgery [online], vol 14, no 1, [Viewed 30 June 2021].
18. Chen, T.-Y., Ju, Y.-T., Wei, Y.-J., Hsieh, M.-L., Wu, J.-M. and Wang, J.-N., 2021. 'Clinical Experience of Transcatheter Closure for Ventricular Septal Defects in Children Weighing under 15 kg', Acta Cardiologica Sinica, [online], vol 37, no 6, pp 618–624, [Viewed 10 Oct. 22].
19. Alizadeh, B., 2019. 'Transcatheter closure of congenital VSDs: tips and tricks', In: Angiography[online], IntechOpen, [Viewed 11 July 2021].
20. Duong, D.H. and Pham, Q.D., 2019. 'Closure of subarterial ventricular septal defect with minimally invasive surgical technique: A case report', International Journal of Surgery Case Reports [online], vol 58, pp 142–144, [Viewed 11 Oct. 22].
21. Turner, S.W., Hunter, S., Wyllie, J.P., 1999. 'The natural history of ventricular septal defects', Archives of Disease in Childhood [online], vol 81, no 5, pp 413–416, [Viewed 10 Oct. 22]

22. Carminati, M., Butera, G., Chessa, M., De Giovanni, J., Fisher, G., Gewillig, M., Peuster, M., Piechaud, J.F., Santoro, G., Sievert, H., Spadoni, I. and Walsh, K., 2007. 'Transcatheter closure of congenital ventricular septal defects: results of the European Registry', European Heart Journal [online], vol 28, issue 19, pp 2361–2368, [Viewed 10 Oct. 22].
23. Li, H., Shi, Y., Zhang, S., Ren, Y., Rong, X., Wang, Z., Xia, T., Wu, T., Xu, H., Yan, Y., Zhan, Y., Chu, M., Wu, R., 2019. 'Short- and medium-term follow-up of transcatheter closure of perimembranous ventricular septal defects', BMC Cardiovascular Disorders [online], vol 19, no 1, [Viewed 10 Oct. 22].
24. Yulianti, A.C., Murni, I.K., Noormanto, N., Nugroho, S., 2021. 'Predictors of transcatheter closure cancellation in children with ventricular septal defect', Paediatrica Indonesiana [online], vol 61, no 6, pp 311–6, [Viewed 11 Oct. 22].
25. Shaik, F.A., Slotwiner, D.J., Gustafson, G.M., Dai, X., 2020. 'Intra-procedural arrhythmia during cardiac catheterization: A systematic review of literature', World Journal of Cardiology [online], vol 12, no 6, pp 269-284.
26. Liu, J., Wang, Z., Gao, L., Tan, H.-L., Zheng, Q. and Zhang, M.-L., 2013. 'A Large Institutional Study on Outcomes and Com vbnjhplications after Transcatheter Closure of a Perimembranous-Type Ventricular Septal Defect in 890 Cases', Acta Cardiologica Sinica [online],vol 29, no 3, pp.271–276, [Viewed 14 Oktober 2022], https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4804839/#__ffn_sectitle.
27. Fu, Y.C., Bass, J., Amin, Z., Radtke, W., Cheatham, J.P., Hellenbrand, W.E., Balzer, D., Cao, Q.L., Hijazi, Z.M., 2006. 'Transcatheter closure of perimembranous ventricular septal defects using the new amplatzer membranous VSD occluder', Journal of the American College of Cardiology [online], vol 47, no 2, pp. 319–325, [Viewed29 June 2021].
28. Al-Sadawi, M, Garcia, AN, Ihsan, M, Cavusoglu, E and McFarlane, SI 2019, 'Bladder Distension: An Overlooked Cause Vagal-induced Hypotension during Coronary Angiography', American Journal of Medical Case Reports [online], vol 7, no 8, pp.180–183.
29. Kern, M.J., Sorajja, P. and Lim, MJ 2015. Cardiac catheterization handbook. Elsevier Health Sciences.