The Egyptian Journal of Hospital Medicine (October 2022) Vol. 89 (2), Page 7429- 7434

Transcatheter Device Closure of Ventricular Septal Defect in Children: A Retrospective Study at Pediatric Cardiac Center, Children's Hospital, Ain Shams University

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Abstract
Background: Twenty percent of all isolated congenital cardiac abnormalities in children are due to ventricular septal defect (VSD). Congestive heart failure, failure to thrive, enlargement of the left atrium and left ventricle, or high pulmonary artery pressures are common indications for transcatheter closure of a moderately sized VSD (or both).
Objective: This study aimed to study the safety, efficacy, and outcome of transcatheter closure of VSDs in Paediatric Cardiac Catheter Unit in children's Hospital, Ain Shams University.
Subjects and Methods: This retrospective cohort study took place at Children's Hospital, Ain Shams University from January 2018 to January 2021 on 35 children with VSD. All VSD patients who underwent diagnostic or interventional cardiac catheterization in the last 3 years were recruited. Medical history, physical exam, pre-intervention investigation, or procedural data were collected from patient records.
Results: In 17 patients (48.6%), ADO II was employed, followed by muscle amplatzer VSD, PDA, and ADO I. (5.7 %). One patient (2.9%) experienced hemolysis and blood transfusion. The percentage of ADOI devices in complicated patients was statistically higher than in non-complicated patients (p = 0.001), but there was no difference in PDA, ADOII, or muscle amplatzer devices.
Conclusion: Transcatheter closure of congenital VSDs is successful. Transcatheter closure is a feasible and practical treatment for different VSD shapes.
Keywords: VSD, Transcatheter, Cardiac, Pediatrics.

INTRODUCTION

The most common congenital heart disease now affecting children is VSD, which makes up 20% of all isolated congenital heart conditions. Although VSDs can develop in any area of the interventricular septum, the perimembranous VSD and muscular VSD, which can occur anteriorly, posteriorly, inlet, or outlet, are the most frequent morphological forms. The supracristal variety is less prevalent [(1)].

Hemodynamic impairment may arise according to the size and flow of the VSD. Hemodynamically unstable patients particularly benefit from a successful closure. After conventional open surgery to treat VSDs, complications from cardiopulmonary bypass, are infection, postpericardiotomy syndrome, chylothorax, and a full atrioventricular block are still conceivable (e.g., myocardial, and pulmonary injury, electrolyte imbalance, coagulopathy, and acute renal failure). Furthermore, when compared to nonsurgical treatments, prolonged postoperative stays in the ICU or hospital are required [(2)].

The requirements for transcatheter intervention are determined by the size and type of VSD. Transcatheter closure of a moderate-sized VSD with congestive heart failure, failure to thrive, substantially enlarged left atrium and LV, or increased pulmonary artery pressures is frequently recommended (or both). A pulmonary-to-systemic flow ratio larger than 2:1 is also required. Large VSDs with RV and pulmonary artery systolic pressures close to the left ventricular and aortic systolic pressures should be closed. Since the first case was reported in 1988 and had satisfactory results, catheter-based therapies have demonstrated promising results in comparison to surgery [(3, 4)]. Our study aimed to evaluate the safety, efficacy, and outcomes of transcatheter closure of VSDs and to detect the predictors of success and risk factors of failure of transcatheter closure of VSDs among studied population in Pediatric Cardiac Catheter Unit in children's Hospital, Ain Shams University.

METHODS

This retrospective cohort study took place at the Pediatric Cardiac Catheterization Unit at Children's Hospital, Ain Shams University at the time between first of January 2018 to the end of January 2021 on a total of 35 patients with VSD. All VSD patients who undergone cardiac catheterization during the last 3 years for diagnostic or interventional procedure were enrolled in the study. Data were extracted from patient's medical records either medical history, physical examination, pre-intervention investigation or the procedural data. The research ethical committee and the institutional review board (IRB) of Ain Shams University's Faculty of Medicine gave their approval with number (FMASU-MS-280/2021). All procedures involving human participants were carried out in conformity with the principles outlined in the World Medical Association's Declaration of Helsinki on the Conduct of Medical Research Involving Human Subjects.

Ethics consent:

Both the Institutional Review Board and the Local Committee of Ethics approved the protocol of this

Received: 13/07/2022
Accepted: 16/09/2022

research in the Faculty of Medicine, Ain Shams University and was performed based on the Helsinki Declaration. A written consent of being informed was collected from all participants prior to their involvement within this study. The data supporting our study findings are provided by the corresponding author upon a reasonable request. All authors approved the final manuscript version. (FMASU-MS-280/2021).

Statistics analysis:

The data was analysed statistically using the Windows version of SPSS (Statistical Package for the Social Sciences). All statistical analyses were performed with a 95% level of confidence. Statistical significance was assumed when the P value was less than 0.05. SPSS's chart builder and Excel 2019 for Windows were used to create the charts. We used mean and standard deviation to describe quantitative variables, and frequency and percentage to describe qualitative ones. For comparing groups (between participants) using continuous data, both parametric and nonparametric tests (T and Mann Whitney, respectively) were employed on independent samples when there was no opportunity for further data collection. Crosstabs were utilised to compare groups of nominal data using the Fisher exact and Chi-square tests.

RESULTS

Table (1) revealed the demographic data of the studied groups. The median age was 5 years ranging from 1 y to 14 years. 18 cases (51.4%) of the study population were females and 17 cases (48.6%) of the study population were males. Follow up for echo parameters among the studied patients was showed in Table (2). The previous table showed that there was no statistically noticeable changes noticed in the level of fraction shortening or ejection fraction during the follow up of the studied patients with p-value = 0.303 and 0.171 respectively. Also, there was statistically valuable decline found in the level of LAD and aortic annulus diameter during the follow up of the studied patients (p-value = < 0.001 and 0.048 respectively). There was statistically significant decline in the level of LVEDD and LVSD during the study follow up (p-value < 0.001 and < 0.001 respectively. According to VSD types **(Figure 1)**, 19 cases (54.3%) were perimembranous, 12 cases (34.3 %) were muscular and 4 cases (11.4%) were basal muscular.

Table (3) cleared the type of the device used among the studied patients. The most frequent device used in the study was ADO II in 17 patients (48.6%), muscular amplatzer VSD device in 8 patients (22.9), PDA device in 8 patients (22.9%) and ADO I was attempted in 2 patients (5.7%). **Figure (2)** described the most frequent minor complications that were mild tricuspid regurge occurred in 5 patient (14.3%). Hemolysis and blood transfusion occurred in 1 patient (2.9%) and 1 patient (2.9%) respectively.

Table (4) and figure (4) showed that there was statistically substantial increase in the percentage of ADOI device in complicated than non-complicated patients (p-value = 0.001), while no statistically substantial difference was noticed between both groups regarding the percentage of PDA, ADOII and muscular amplatzer devices. Also, no statistically noticeable difference was noticed between complicated and non-complicated cases regarding fluoroscopy time and radiation dose.

TABLES

Table (1): Demographic data and characteristics of the studied patients

		No. = 35
Age (years)	Mean ± SD Range	5.3 ± 3.5 1 – 14
Gender	Males Females	17 (48.6%) 18 (51.4%)
Weight (kg)	Mean ± SD Range	19.8 ± 12.6 8 – 56
Height (cm)	Mean ± SD Range	105.1 ± 21.0 77 – 153
BMI (kg/m^2)	Mean ± SD Range	16.43 ± 3.78 9.57 – 27.08

Table (2): Follow up for echo parameters among the studied patients

		Pre	Post 1	Post 2	Post 3	Post 4	Test value	P-value*	Sig.
		No. = 35	No. = 35	No. = 35	No. = 35	No. = 35			
FS (%)	Mean± SD Range	36.30±3.30 31–45	36.60±3.20 33–49	36.90±3.10 33–49	36.90±3.10 33–49	36.40±3.20 31–49	1.214	0.303	NS
P-value		-	0.463	0.214	0.201	0.912			
EJ Fr (%)	Mean± SD Range	66.50±4.00 60–78	66.90±3.20 62–76	67.10±3.30 62–76	67.40±3.10 62–76	67.30±3.30 61–76	1.846	0.171	NS
P-value		-	0.478	0.266	0.095	0.155			
LVEDD (cm)	Mean± SD Range	3.44±0.59 2.8–5.3	3.31±0.61 2.7–5.2	3.30±0.59 2.7–5.2	3.28±0.61 2.6–5.2	3.27±0.58 2.6–5.2	32.806	<0.001	HS
P-value		-	<0.001	<0.001	<0.001	<0.001			
LVSD (cm)	Mean± SD Range	2.62±0.60 1.5–4.3	2.53±0.59 1.5–4.1	2.52±0.58 1.5–4.1	2.52±0.58 1.5–4.1	2.45±0.62 1.3–4.1	10.473	<0.001	HS
P-value			0.001	<0.001	<0.001	<0.001			
LAD (cm)	Mean± SD Range	2.21 ± 0.48 1.3 – 3.5	2.18±0.46 1.3–3.4	2.1 ±0.46 1.3–3.3	1.98±0.41 1.1–3.3	2.09±0.42 1.2–3.0	10.883	<0.001	S
P-value		-	0.070	<0.001	<0.001	<0.001			
Aortic annulus diameter (cm)	Mean±SD Range	1.68±0.35 1–2.5	1.63±0.37 1–2.5	1.62±0.34 1–2.3	1.62±0.34 1–2.3	1.60±0.33 1–2.3	3.468	0.048	S
P-value		-	0.004	<0.001	<0.001	0.046			

* Repeated measures ANOVA followed by post hoc analysis using Bonferoni.

Table (3): Procedural data of the studied patients

		No. = 35
Type of device	PDA device ADOII device Muscular amplatzer device ADOI device	8 (22.9%) 17 (48.6%) 8 (22.9%) 2 (5.7%)
Fluoroscopy time "Min"	Mean±SD Range	49.77 ± 20.57 11 – 91
Radiation dose "MGY"	Median (IQR) Range	132 (90 – 215) 42 – 1400
Total volume of contrast (ml)	Median (IQR) Range	60 (50 – 65) 20 – 190
Total volume of contrast (ml)	Median (IQR) Range	60 (50 – 65) 20 – 190

Table (4): Relation between occurrence of minor complications and procedural data of the studied patients

Procedural data		Non complicated No. = 29	Complicated No. = 6	Test value	P-value	Sig.
Type of device	PDA device	8 (27.6%)	0 (0.0%)	2.146*	0.142	NS
	ADOI device	0 (0.0%)	2 (33.3%)	10.253*	0.001	HS
	ADOII device	14 (48.3%)	3 (50.0%)	0.006*	0.938	NS
	Muscular amplatzer device	7 (24.1%)	1 (16.7%)	0.157*	0.691	NS
Fluoroscopy time (min)	Mean±SD	48.45 ± 20.44	56.17 ± 21.87	-0.833•	0.411	NS
	Range	11 – 91	25 – 90			
Radiation dose (MGY)	Median (IQR)	152 (99 – 290)	105 (88 – 132)	1.642‡	0.101	NS
	Range	47 – 1400	42 – 177			
Total volume of contrast	Median (IQR)	60 (50 – 65)	56 (45 – 61)	-0.483	0.629	NS
	Range	20 – 190	20 – 190			

P>0.05: Non significant (NS); P <0.05: Significant (S); P <0.01: Highly significant (HS) *: Chi-square test; •: Independent t-test; ‡: Mann-Whitney test

Figures:

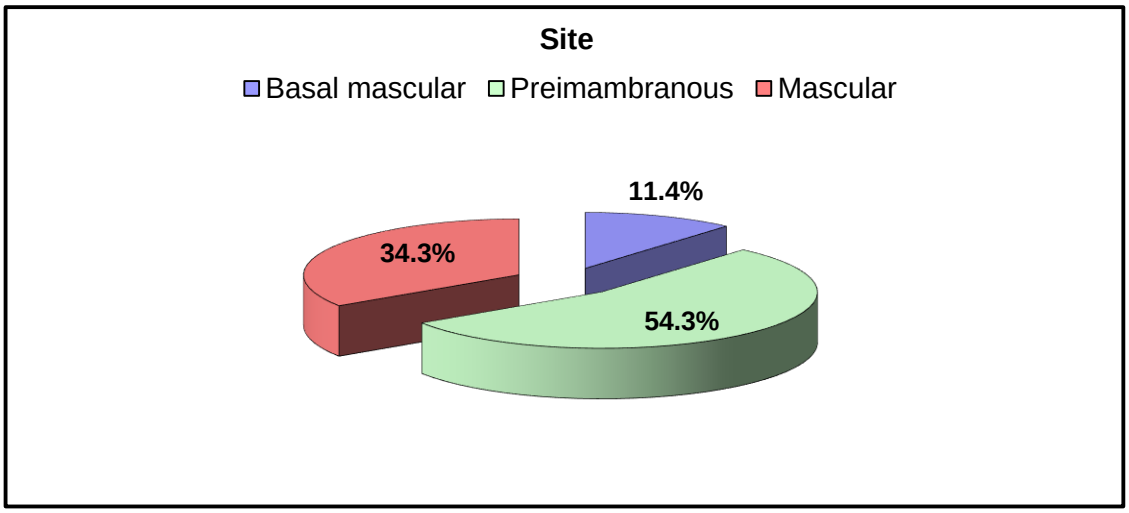

Figure (1): Site of VSD among the studied patients

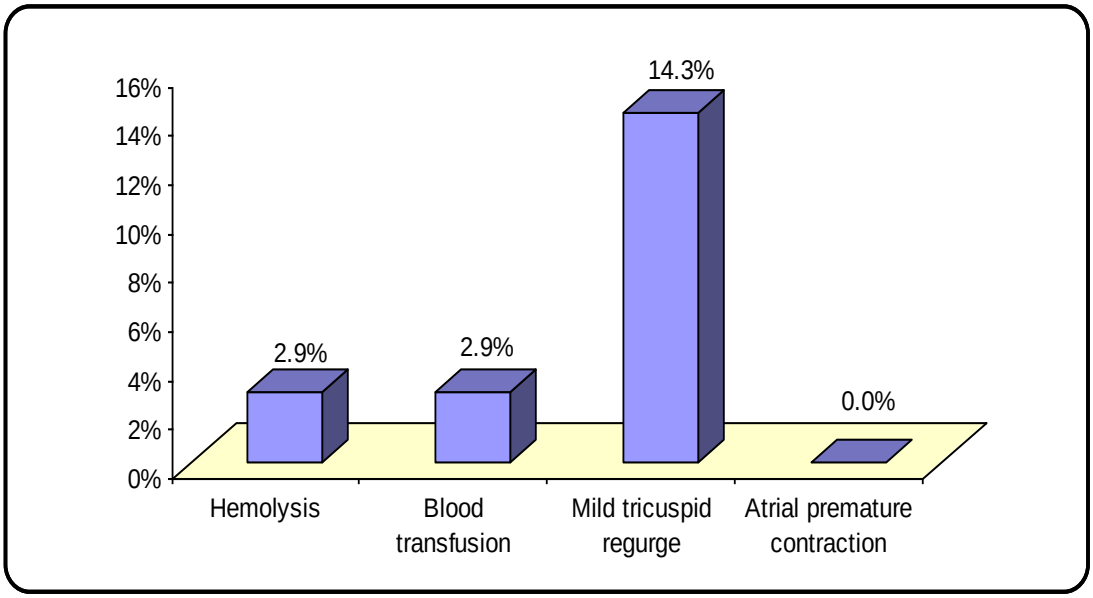

Figure (2): Frequency of minor complications among the studied patients

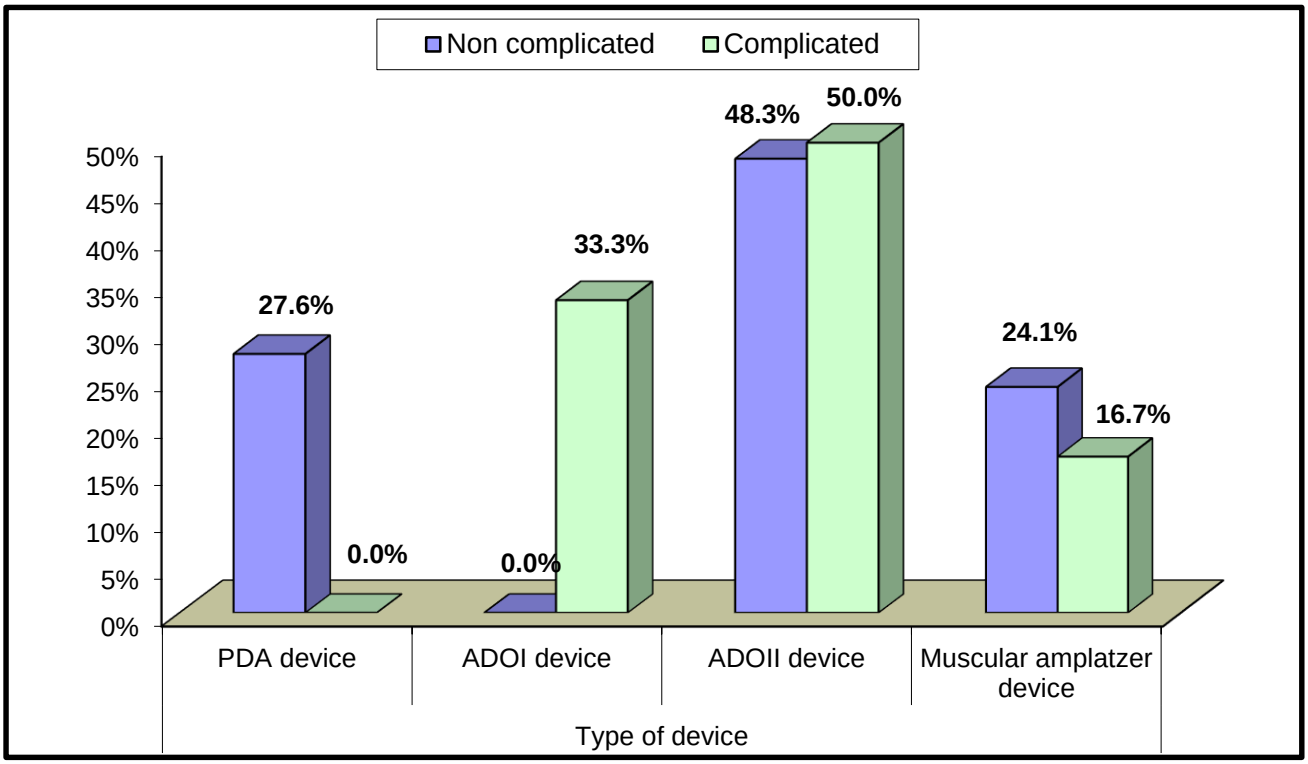

Figure (3): Relation between occurrence of minor complications and type of device.

DISCUSSION

The most prevalent congenital heart condition now affecting children is VSD (VSD), which is about 20% of all isolated congenital heart conditions. Any area of the interventricular septum is susceptible to VSDs. Perimembranous VSD is the most prevalent variant, followed by muscular VSD and the less frequent supracristal type [5, 6].

Transcatheter VSD closure was indicated for patients with congestive heart failure, failure to thrive, notably enlarged left atrium and left ventricle, high pulmonary artery pressure or both, and a pulmonary-to-systemic flow ratio greater than 2:1. In perimembranous VSD, a good aneurysmal tissue was required for best occluding device deployment away from the aortic valve, as well as a sub-aortic rim of at least 4 mm to prevent pressure on the aortic valve and other nearby structures [1,7].

This was a retrospective cohort study that was undertaken on 35 patients with VSDs who underwent interventional cardiac catheterization at the Cardiac Catheterization Unit during the last 3 years (From January 2018 to January 2021) at Children's Hospital, Ain Shams University. There was limited number of cases due to COVID era. It was designed to examine the safety, efficacy, and outcome of transcatheter closure of VSDs and to detect the predictors of success and risk factors of failure of transcatheter closure of VSDs among studied population.

In our study, the mean age was 5 years ranging from 1 y to 14 years. 18 cases (51.4%) of the study population were females and 17 cases (48.6%) of the study population were males. In **Adhikari *et al.*** [8] study, they reported that the mean age of the patient was 11.1 years. 29 (52.7%) were females and 26 (47.3%) were males. While in the study done by **Koshhal *et al.*** [1], the mean age of the patients was 10.2 years ranging from 2 to 18 years. Twenty-eight (40%) were males and 42 (60%) were females.

The present study showed that, according to VSD types, 19 cases (54.3%) were perimembranous, 12 cases (34.3 %) were muscular and 4 cases (11.4%) were basal muscular. This is in agreement with **Adhikari *et al.*** [8] who reported that there was perimembranous VSD in 49 cases (89%) and muscular VSD in 6 (11%) patients. While, in the study of **Khoshhal *et al.*** [1] they reported that 68.6% of the studied children had muscular VSD and 31.4% were diagnosed by perimembranous VSD.

In the current study, most frequent device used was amplatzer device occlude type II in 17 patients (48.6%), muscular amplatzer VSD device in 8 patients (22.9%), PDA device in 8 patients (22.9%) and amplatzer device occlude type I was attempted in 2 patients (5.7%). The most often used devices in literature are the amplatzer family of occluders, which are created for the closure of various types of VSDs or for other reasons [5]. **Khoshhal *et al.*** [1] reported that, most cases (91.4%) were closed by the amplatzer VSD occlude devices. This comes with **Elgindy *et al.*** [9] study, which reported that VSDs in determined patients may be closed percutaneously using an ADO II device. Regarding profile and trackability, ADO II appears to be the superior device for closing moderately sized defects (2-5 mm), particularly in newborns and younger children. While, in **Roy *et al.*** [10] study, they used ADO II when the right ventricular side defect measured 4-5 mm or less.

Amplatzer VSD occluder device was used for muscle defects as well as in perimembranous defect with aneurysmal tissue, but it cannot be used for defects larger than 5 mm due to availability of sizes.

In our study, hemolysis needed blood transfusion occurred in 1 case (2.9%), which didn't need surgical removal of device and successfully ended by device closure of the defect. Most frequent minor complications were mild tricuspid regurge occurred in 5 patient (14.3%). Adverse events including hemolysis and blood transfusion may occur shortly after device implantation (1 % of cases). Red blood cells may sustain mechanical damage leading to hemolysis if the device is closed with considerable residual shunts. It could be slight and self-limiting, or it might be severe enough that the device needs to be surgically removed [(11)]. This comes in agreement with **Khoshhal *et al.* [(1)]** who concluded that, only one case of hemolysis was documented, requiring a blood transfusion, device removal, and surgical defect closure. **Elgindy *et al.* [(9)]** reported that no substantial hemolysis with the need for retrieval of the device occurred and arrhythmic complications (minor) existed in two patients.

Since transesophageal echocardiography can more correctly show the location and morphological characteristics of the defect than TTE, it may make patients more uncomfortable and complicate the process, which could lengthen the procedure. They are convinced that substituting transesophageal echocardiography with TTE in VSD device closure in children will not raise the risk of problems due to the TTE monitoring technology's increasing level of maturity. Many studies are now evaluating the efficacy and safety of transcatheter occlusion for patients with aortic prolapse or intracranial VSD [(3, 12)].

CONCLUSION

Congenital VSDs can be transcatheterally closed, with good outcomes. With a low prevalence of unfavourable events, transcatheter closure is a safe and practical technique for VSDs with diverse morphologies. In terms of effectiveness (complete closure of the VSD) and safety (no major complications like Aortic regurge; Residual VSD; Arrhythmia or Heart block) during procedure, immediate and short to midterm follow-up, transcatheter closure of VSDs in children has a high success rate (100%).

Acknowledgement: The authors are grateful for the patients without whom this study would not have been done.

Funding: None.

Conflicts of interest: The authors affirm that they have no conflicts of interest.

REFERENCES

1. **Khoshhal S, Al-Mutairi M, Alnajjar A *et al.* (2020):** Transcatheter device closure of VSDs in children: a retrospective study at a single cardiac center. Annals of Saudi Medicine, 40 (5): 396-402.
2. **Saurav A, Kaushik M, Mahesh Alla V *et al.* (2015):** Comparison of percutaneous device closure versus surgical closure of peri-membranous VSDs: a systematic review and meta-analysis. Catheterization and Cardiovascular Interventions, 86 (6): 1048-1056.
3. **Shah J, Saraiya S, Nikam T *et al.* (2020):** Transcatheter device closure of perimembranous VSD in pediatric patients: long-term outcomes. Heart Views: The Official Journal of the Gulf Heart Association, 21 (1): 17.
4. **Khoshhal S, Al-Mutairi M, Alnajjar A *et al.* (2020):** Transcatheter device closure of ventricular septal defects in children: a retrospective study at a single cardiac center. Annals of Saudi Medicine, 40 (5): 396-402.
5. **El Shedoudy S, El-Doklah E (2019):** Mid-term results of transcatheter closure of VSD using Nit-Occlud Le VSD coil, single-center experience. Journal of the Saudi Heart Association, 31 (2): 78-87.
6. **Shehata B. M. (2011):** The Heart Color Atlas of Pediatric Pathology. https://books.google.com/books/about/Color_Atlas_of_Pediatric...
7. **Penny D, Vick G (2011):** Ventricular septal defect. https://pubmed.ncbi.nlm.nih.gov/21349577
8. **Adhikari C, Shrestha M, Shah S *et al.* (2019):** Device closure of VSD: Initial experience in Nepal. Asian Journal of Medical Sciences, 10 (4): 23-27.
9. **Elgindy R, Agha M, Hamza H *et al.* (2016):** Transcatheter closure of VSDs in infants and children. Al-Azhar Journal of Pediatrics, 19 (2): 1633-1649.
10. **Roy M, Gangopadhyay D, Goyal N *et al.* (2022):** Transcatheter closure of VSDs in children less than 10 kg: experience from a tertiary care referral hospital in Eastern India. Cardiology in the Young, 32 (1): 48-54.
11. **Mandal K, Su D, Pang Y. (2018):** Long-term outcome of transcatheter device closure of perimembranous VSDs. Frontiers in pediatrics, 6: 128-140.
12. **Zhang W, Wang C, Liu S *et al.* (2021):** Safety and efficacy of transcatheter occlusion of perimembranous ventricular septal defect with aortic valve prolapse: a six-year follow-up study. Journal of Interventional Cardiology, 5: 130-155.