

## Original Article

# Percutaneous closure of ventricular septal defects in children: key parameters affecting patient radiation exposure

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**Abstract:** Background: Ventricular septal defect (VSD) transcatheter closure is gaining worldwide popularity despite its complexity. Reports on key factors affecting radiation exposure in children are scarce. Aims: This clinical study is the first to comprehensively analyze the impact of all relevant parameters on children's radiation exposure during VSD interventional closures. Methods: Between March 2016 and August 2019, all pediatric VSD cases percutaneously treated at a reference center for interventional congenital cardiology and equipped with a single-plane Innova 2100 X-ray unit were retrospectively reviewed. Multiple linear regression was performed to investigate the impact of clinical, technical, and procedural parameters on patients' radiation exposure assessed using total air kerma area product (PKA,T). Results: A total of 85 patients were included in this study and 82.4% had perimembranous defects. Device implantation was successful in 96.5% of cases. The procedure lasted for a median of 60 min with a median  $P_{KA,T}$  of 19.6 Gy.cm<sup>2</sup> (range, 1.1 to 244.8 Gy.cm<sup>2</sup>). Patients' weight (B = 1.679, P = 0.01), number of operators (B = 1.561, P = 0.02), device positioning complexity (B = 2.381, P = 0.002), and procedural incidents (B = 2.096, P = 0.008) significantly increased  $P_{KA,T}$ . Patients' age (B = 1.053, P = 0.784), device design (B = -1.216, P = 0.780) and approach of delivery (B = -1.119, P = 0.511) did not significantly affect  $P_{KA,T}$ . Conclusions: Radiation exposure in children undergoing VSD percutaneous closure was highly variable. A higher patient's weight, numbers of operators, complexity in device positioning, and procedural incidents, were identified as key factors increasing patient dose for this kind of intervention.

**Keywords:** Ventricular septal defect, percutaneous closure, children, radiation

## Introduction

Ventricular septal defect (VSD) is one of the most common congenital heart defects with perimembranous VSD (pmVSD) being the most common subtype. While spontaneous closure rates are high, open-heart surgical repair may be indicated during early infancy in case of severe pulmonary hypertension or failure to thrive despite medical management. Later in life, children with small residual defects develop cardiac problems, becoming candidates for closure. With the advances in vascular occlusion technology and cardiac imaging, transcatheter closure of VSD became one of the

most emerging interventions in rising nations with several positive reports on its safety, efficiency, and promising outcomes [1-4]. However, pediatric interventional cardiologists still consider this procedure technically challenging and time-consuming. Additionally, it may involve high exposure levels owing to variable anatomical morphology, proximity to valves, and complex manipulation process [5-8]. Compared to adults, pediatric procedures are of special concern because children are more vulnerable to the detrimental effects of radiation [9-12]. Yet, analytic studies on children's exposure during VSD interventions are still scarce. This might be related to the fact that VSD closures, especially

for the perimembranous subtypes, remain controversial in many developed countries [13-15] and certainly to the paucity of dosimetric data for pediatric examinations [16]. Therefore, this pilot study aims to comprehensively understand the key factors involved in the variability of exposure levels during pediatric VSD closures.

### Materials and methods

#### *Study design and study population*

This retrospective observational study was conducted at our institution, a tertiary referral medical center that recruits the vast majority of pediatric interventional cardiology activity in the country [3, 4, 17]. The study protocol was reviewed and approved by the research ethics committee on human clinical research of the Saint Joseph University. Written informed consent was signed by the patients' legal guardians to perform the procedure after they were provided with a comprehensive explanation about the procedural details, advantages, and possible complications. Patients included in this clinical study were children (age 2 to 18 years) with hemodynamically significant (muscular or perimembranous) VSD who underwent attempted transcatheter device closure between March 2016 and August 2019. Excluded patients had one or more of the following criteria: (1) age > 18 years; (2) aborted procedures for technical, hemodynamic, or anatomic reasons before any attempt of device placement (no wasted device) and (3) procedures during which another therapeutic intervention for an associated congenital heart defect was performed additionally to VSD closure.

For the study, all parameters potentially associated with radiation exposure were collected from the Medical records and catheterization reports: patient demographics; VSD anatomical subtype; number of operators; occluder device characteristics (manufacturer origin, size category, design, geometry, and approach of delivery); complexity of device positioning (easy or difficult (> 2 deployment attempts or device valvular entrapment)) and presence of any procedural incidents as well as procedure outcomes. Procedural incidents included: reported difficulty to cross the defect especially when using different types of catheters/guidewires or to establish the arteriovenous guidewire circuit (AVGC) (associated rhythm or valv-

lar disturbances); hemodynamical instability or arrhythmias during the procedure requiring intervention; inadequate sheath length and sheath kinking; per-procedural device re-sizing and intraoperative device displacement requiring recapture [2]. The procedure was declared successful only when an occluder was placed and released into position without any major immediate complication.

#### *Interventional procedure*

All procedures were performed under the supervision of the same senior operator, in the catheterization laboratory, under general anesthesia, adjunctive transesophageal echocardiography (TEE), and fluoroscopic control. One femoral vein (FV) and one 5F contralateral arterial line were obtained and intravenous heparin and Cefazolin were given. Left ventricle (LV) angiography (55-60° left anterior oblique (LAO) and 20° cranial) using a marked pigtail catheter was performed to profile the defect and was combined with intraoperative TEE to accurately determine the VSD anatomical characteristics. The procedural steps of VSD transcatheter closure are well reported in the literature [3, 4, 18]. At our institution, three Amplatzer™ (Abbott, USA) occluders (Amplatzer Muscular VSD Occluder (AMO), Amplatzer Duct Occluder I (ADO I), and Amplatzer Duct Occluder II (ADO II)) were used for this intervention along with the Lifetech™ KONAR-MF VSD occluder (Lifetech, Shenzhen, China). All defects were crossed from the LV side, using a 4 or 5 F Judkins right coronary catheter along with a J tip Terumo guidewire. A prograde approach was used to implant ADO and AMO. Therefore, the Terumo wire was exchanged with a 300 cm noodle wire to be snared and exteriorized through the FV, establishing an AVGC over which the device was transvenously delivered. More recently, the retrograde approach was used to transarterially implant the ADO II and Lifetech devices obviating the need for AVGC. Final angiography was substituted with TEE to evaluate the final result after device release. All previously cited devices were used for pmVSDs while muscular defects were closed using either AMO or ADO II.

#### *Angiographic equipment*

All interventions were performed using a single-plane Innova 2100 X-ray unit (General Electric Healthcare) equipped with a flat panel detector installed in 2010. The tube has an inherent filtration of 3.5 mm Al at 70 kV. For fluoroscopy,

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**Table 1.** Dosimetric parameters

Dosimetric Parameters	Median (range)
Air kerma area product ( $P_{KA}$ ) (Gy.cm <sup>2</sup> )	19.6 (1.1-244.8)
Air kerma at patient entrance reference point ( $Ka,r$ ) (mGy)	257 (19-1878)
Fluoroscopy time (FT) (min)	14.3 (3.7-125.6)

an additional 0.6 mm copper filter is used, while 0.3 mm is used in cine acquisition. The normal and low modes were commonly used during fluoroscopy and cine acquisition. Pulsed fluoroscopy of 15 and 30 pulses per second and cine acquisitions of 30 frames per second were applied. Collimation of the beam to the region of interest was performed for all the cases especially when image magnification was deemed necessary. The grid was routinely removed for all patients < 10 kg unless a poor image quality was observed. The total air kerma area product ( $P_{KA,T}$ ), was recorded from the X-ray equipment console at the end of each procedure.

### Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences Statistics (SPSS), version 22 for Macintosh (IBM, Armonk, NY). Categorical variables were reported as frequency and percentage. Continuous variables are represented as mean with standard deviation or median with total range depending on normality of distribution. The normality of variables was assessed using skewness and kurtosis values and supported by the Shapiro-Wilk test. Statistical analysis for continuous variables was conducted using Mann-Whitney U or Kruskal-Wallis tests as appropriate to evaluate the distribution of  $P_{KA,T}$  according to study parameters. A  $p$ -value < 0.05 was considered statistically significant. A  $p$ -value < 0.02 was considered as a criterion for variable inclusion in the multiple linear regression model to increase model statistical significance. All reported  $p$  values are two-sided. Log transformation was used to address positively skewed  $P_{KA,T}$  with subsequent normal distribution allowing the correct use of the multiple linear regression model.

### Results

#### Clinical and procedural characteristics

A total of 85 patients were included in this study. At the time of the intervention, patients'

mean age was 5.2 ( $\pm$  3.7) years and the median body weight was 15 kg (range, 7.6 to 64 kg). The defects were perimembranous in 82.4% of patients and muscular in 15 patients. The

pmVSDs had a mean left ventricular diameter of 10.2 ( $\pm$  3.4) mm, a mean right ventricular diameter of 4.2 ( $\pm$  1.3) mm, and a mean depth of 7.4 ( $\pm$  1.7) mm. The sub-aortic rim was deficient (< 2 mm) in 26 cases. The muscular defects were classified high in 2 cases, mid-muscular in 6 cases, and apical in 7 cases. Their overall mean diameter was 8.1 ( $\pm$  3.4) (range, 3 to 15 mm). Device Implantation was successful in 96.5% of cases. The intervention was performed by a single senior operator in 41.2% of cases. The median fluoroscopy time (FT) was 14.3 min (range, 3.7 to 125.6 min), and the median  $P_{KA,T}$  was 19.6 Gy $\cdot$ cm<sup>2</sup> (range, 1.1 to 244.8 Gy $\cdot$ cm<sup>2</sup>). Dosimetric parameters are summarized in **Table 1**. An Amplatzer™ device was implanted in 74.1% of patients and retrograde delivery was the most frequent approach of closure. Device positioning was complex in 11 patients while procedural incidents were seen in 15.3% of cases.

#### Bivariate analysis

Distribution of  $P_{KA,T}$  values as a function of VSD anatomy, clinical, device, and procedure parameters are summarized in **Tables 2-5**. Our results showed that the delivered dose significantly increased with the patient's age, weight, and the number of operators performing the procedure. Patients with muscular defects received a higher  $P_{KA,T}$  (median = 38 Gy $\cdot$ cm<sup>2</sup>) when compared to patients with perimembranous subtypes (median = 17.4 Gy $\cdot$ cm<sup>2</sup>), but this difference was not statistically significant ( $P = 0.057$ ). Patients treated with ADO I received the highest  $P_{KA,T}$  (median = 66.4 Gy $\cdot$ cm<sup>2</sup>) while ADO II and Lifetech devices were delivered with the lowest  $P_{KA,T}$  ( $p = 0.02$ ). Based on the results of the study, single disk devices and venous approach were associated with a significant increase in patient exposure while device size and geometry were not. Additionally,  $P_{KA,T}$  tends to significantly increase with complex device deployment and procedural incidents but did not significantly vary with the procedural outcome. Finally, the results of the multiple linear

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**Table 2.** Distribution of total air kerma area product according to patient demographics

	N (%)	Median	Range	p-value
Gender				
Male	44 (51.8)	16.8	2.5-128.6	0.358 <sup>a</sup>
Female	41 (48.2)	25.7	1.1-224.8	
Age groups				
<1 year	3 (3.5)	6.2	4-39.5	
1 to <5 years	46 (54.1)	14.9	1.1-128.6	<b>0.017<sup>b</sup></b>
5 to <10 years	26 (30.6)	27.7	5.7-87.2	
10 to 15 years	10 (11.8)	52.9	11.3-244.8	
Weight groups				
5 to <15 kg	40 (47.1)	10.2	1.1-85.2	
15 to <30 kg	36 (42.4)	23.7	5.7-128.6	<b>0.001<sup>b</sup></b>
30 to <50 kg	6 (7.1)	45.1	17.1-81.8	
≥50 kg	3 (3.5)	159.1	73.3-244.8	

a: Mann-Whitney U test; b: Kruskal-Wallis test. Bold values are significant *p*-values.

**Table 3.** Distribution of total air kerma area product according to defect anatomical subtype and number of operators

	N (%)	Median	Range	p-value
VSD subtype				
Perimembranous	70 (82.4)	17.4	1.1-244.8	0.057 <sup>a</sup>
Muscular	15 (17.6)	38	5.4-128.6	
Number of operators				
One senior operator	35 (41.2)	11.3	1.1-80.8	<b>0.005<sup>a</sup></b>
One senior & one junior operator	50 (58.8)	29.5	2.2-244.8	

VSD: ventricular septal defect. a: Mann-Whitney U test. Bold values are significant *p*-values.

regression indicated that the overall model was a good fit for the data. It was a significant predictor of the delivered dose ( $F = 10.01$ ,  $P < 0.001$ ), and explained 50.4% (adjusted  $R^2$ ) of its variance. While patient's weight ( $B = 1.679$ ,  $P = 0.01$ ), number of operators ( $B = 1.561$ ,  $P = 0.02$ ), device positioning complexity ( $B = 2.381$ ,  $P = 0.002$ ), and procedural incidents ( $B = 2.096$ ,  $P = 0.008$ ) were significant predictors; age groups ( $B = 1.053$ ,  $P = 0.784$ ), device design ( $B = -1.216$ ,  $P = 0.780$ ) and approach of delivery ( $B = -1.119$ ,  $P = 0.511$ ) did not contribute significantly to the model.

### Discussion

Children and young adult patients with congenital heart disease have an increased risk of developing malignancies compared with healthy matched controls [19, 20]. Because of their

higher radiosensitivity, there is a need to assess the doses delivered to pediatric patients who undergo interventional cardiac procedures and especially complex ones [21]. Reports on radiation exposure during VSD closures are limited. The common occurrence of secondary complete heart block kept this intervention controversial in many developed countries [13-15] along with the general paucity of dosimetric data for patients in pediatric imaging [16]. Our study stands out as the first to critically analyze children's radiation exposure during VSD closures performed in a single specialized reference center that recruits the vast majority of the Lebanon activity for this kind of intervention.

An overall comparison of our numbers to other reports shows that our patients are treated with equivalent and sometimes less radiation exposure, indicating a good local practice and radiation optimization [22-24]. As expected, patients' weight was a significant predictor of the delivered dose ( $B = 1.679$ , 95% CI: 1.137-2.48) [6-10, 25]. This might be related to an increase of the X-ray output to maintain the same intensity at the detector level and an increase of the beam area to include the region of interest with larger patients. Patients' age was not a good predictor of the delivered dose ( $B = 1.053$ , 95% CI: -1.382-1.532) and this finding is in concordance with the publication 135 of ICRP recommending to substitute age with weight categories when analyzing radiation exposure [16].

The number of operators was found to be a significant predictor of the delivered dose ( $B = 1.561$ , 95% CI: 1.076-2.266) and this finding is in line with previous studies [26, 27]. The presence of a junior operator can increase the dose

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**Table 4.** Distribution of total air kerma area product according to device parameters

	N (%)	Median	Range	p-value
<b>Device Manufacturer</b>				
Amplatzer	63 (74.1)	21.8	1.1-244.8	0.269 <sup>a</sup>
Lifetech	22 (25.9)	16.7	2.5-85.2	
<b>Devices</b>				
Amplatzer VSD Muscular Occluder	19 (22.4)	36.8	5.4-128.6	<b>0.020<sup>b</sup></b>
Amplatzer Duct Occluder I (ADO I)	7 (8.2)	66.4	27.2-244.8	
Amplatzer Duct Occluder II (ADO II)	37 (43.5)	16.7	1.1-87.2	
Lifetech KONAR-MF VSD Occluder	22 (25.9)	16.7	2.5-85.2	
<b>Device size category</b>				
Small size	45 (52.9)	22	2.5-128.6	0.807 <sup>a</sup>
Big size	40 (47.1)	18.8	1.1-244.8	
<b>Device Design</b>				
Single disk	7 (8.2)	66.4	27.2-244.8	<b>0.015<sup>a</sup></b>
Double disk	78 (91.8)	17.7	1.1-128.6	
<b>Device geometry</b>				
Asymmetrical	29 (34.1)	21	2.5-244.8	0.966 <sup>a</sup>
Symmetrical	56 (65.9)	18	1.1-128.6	

a: Mann-Whitney U test; b: Kruskal-Wallis test. Bold values are significant p-values.

**Table 5.** Distribution of total air kerma area product according to procedure parameters

	N (%)	Median	Range	p-value
<b>Approach of delivery</b>				
Venous (prograde)	23 (27.1)	38.8	5.4-244.8	<b>0.007<sup>a</sup></b>
Arterial (retrograde)	62 (72.9)	16.7	1.1-128.6	
<b>Device positioning complexity</b>				
Easy	74 (87.1)	16.8	1.1-128.6	<b>&lt;0.001<sup>a</sup></b>
Difficult	11 (12.9)	57	13.2-244.8	
<b>Procedural incidents</b>				
Yes	13 (15.3)	37.7	16.8-87.2	<b>0.001<sup>a</sup></b>
No	72 (84.7)	16.1	1.1-244.8	
<b>Successful implantation</b>				
Yes	82 (96.5)	18.8	1.1-244.8	0.522 <sup>a</sup>
No	3 (3.5)	38.8	5.8-85.2	

a: Mann-Whitney U test. Bold values are significant p-values.

encountered during the procedure; a direct consequence of the learning curve. The mandatory presence of a second operator in complex procedures and particularly in those requiring the establishment of an AVGC may also legitimate this finding. We found out that single disk devices were delivered with significantly higher radiation exposure compared to double disk devices. The simple fact is that single disk design presumes the establishment of an AVGC

under cine acquisition sequences to be delivered transvenously [4]. El-Sisi et al. compared ADO II to ADO I and demonstrated that FT needed to occlude a perimembranous defect was significantly lower in the ADOII group of patients [28]. However, FT is not a good indicator of patient exposure, and  $P_{KA,T}$  should be used instead [16]. Unexpectedly, the multiple linear regression model showed that device design was not a significant predictor of patient dose ( $B = -1.216$ , 95% CI  $-2.819-2.185$ ) and this could be related to unbalanced group sizes in the study sample and collinearity with the approach of delivery.

The retrograde arterial approach significantly decreased patient dose when compared to the transvenous delivery (16.7 vs. 38.8 Gy $cm^2$ ,  $P = 0.007$ ). In fact, with the development of newer devices and low profile delivery systems, all ADO II and Lifetech devices were retrogradely delivered [3, 4]. This decrease in patient dose is believed to be in part related to the adoption of TEE

instead of final angiography for documenting the absence of shunting and valvular disturbances following device release. Similarly, Muthusamy reported the advantages of shifting from antegrade to retrograde approach in VSD closure to shorten procedural and fluoroscopy time and to simplify perimembranous VSD closure [29]. However, the approach of delivery was not found to be a significant predictor of the dose delivered in our multiple linear model

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( $B = -1.119$ , 95% CI:  $-1.922-1.389$ ) and this is probably related to inadequate study sample size and unbalanced group sizes.

The complexity of device positioning has been proved to be the most important predictor of patient dose ( $B = 2.381$ , 95% CI:  $1.367-4.119$ ). Continuous angiographic guidance using cine acquisitions mode with echocardiographic monitoring is continuously needed during device deployment and positioning to ensure surrounding valves' normal function and proper device position [30]. However, several Chinese pediatric cardiology interventionists demonstrated that percutaneous device closure of VSD can be successfully performed, in selected patients, under the sole guidance of ultrasound with outcomes similar to those achieved with fluoroscopy guidance [31-33]. For this, interventionists must rely on echocardiographic guidance whenever possible to limit unnecessary radiation exposure.

As expected, the presence of procedural incidents were also found to be a significant predictor of patient exposure ( $B = 2.096$ , 95% CI:  $1.223-3.594$ ). Similarly, many authors found that several technical challenges can be encountered during device closure of VSD, especially in small babies, such as passing the guidewire and catheter across the defect and creating the AVGC without resistance [30, 34]. Technical catheter manipulation challenges have also been reported by Butera et al. in young infants leading to longer catheterization and increased radiation dose [35].

Finally, our results showed that procedural failure was associated with an increase of radiation exposure but this association was not found to be statistically significant. We encountered two cases of accidental device embolization necessitating percutaneous snare recapture and retrieval during the same setting. The third failure was attributed to inappropriate device size selection. In this patient, the AMO device pulled through the defect multiple time, leading to the abortion of this prolonged procedure.

### *Study strengths and limitations*

With the increased need for updated and exhaustive dose estimates for complex and innovative interventional procedures, this study

fills the existing knowledge gap. Our study stands out as the first to comprehensively analyze the key factors behind the variability in pediatric patients' exposure levels during VSD interventional closure. The strict protocol of VSD closure in our institute made the collected data clear, comprehensive, and accurate. All procedures were performed by the same operators, offering a higher representation of the routine practice. However, the predictive model for radiation exposure is determined from the data of a single-center with a relevant workload when the aforementioned procedure is not performed regularly in most hospitals, they might not be generally applicable. The X-ray equipment setup and adopted protocol difference, experience, and radiation protection awareness of the operator might affect patients' exposure in the catheterization laboratory. Although all procedures were performed using a single-plane unit, our data can be generalized to centers with biplane systems as most VSD closure can be performed using mid-cranial, LAO projections while simultaneous orthogonal right anterior oblique projections might be needed only in posterior defects [36]. Finally, statistical tests did not identify a significant impact of VSD anatomical subtype, device geometry, and approach of device delivery and we believe that it's related to unbalanced group sizes and collinearity between some of the predictor variables.

### **Conclusions**

This study is the first to provide an overview of the complexity variables of pediatric VSD closure performed under the supervision of a single experienced operator at a specialized pediatric reference center. Radiation exposure in pediatric patients undergoing percutaneous VSD closure was highly variable. Patients' weight, numbers of operators, device positioning, and procedural incidents were found to be significant predictors of patient dose in this kind of intervention. We encourage interventionists to rely on echocardiographic guidance whenever possible to limit unnecessary angiographies to keep the radiation doses as low as possible for this radiation-sensitive population.

### **Disclosure of conflict of interest**

Z. Saliba is a proctor and consultant for Abbott Vascular and Lifetech. The other authors de-

clare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

### Author contributions

RH provided substantial contributions to the design of the study, double-checked collected data, designed and performed all statistical calculations, analyzed and critically interpreted the results. RH took the lead in writing the entire manuscript with input from CR. ZS was the main operator in all procedures and was assisted by RH. All authors discussed the results, read and approved the final manuscript.

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