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The Importance of Weight-Based Protocols and Reduction of Frame Rates in ASD Percutaneous Closure

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Abstract

Introduction: In the context of interventional and diagnostic cardiology procedures, there is a growing effort to minimize exposure to ionizing radiation. Most modern angiography machines allow selection of exposure parameters based on the patient's weight. Our experience has led us to question whether the use of weight-based protocols is the right approach for pediatric interventional cardiology exams.
Aim and Materials: The purpose of this research is to investigate the efficacy of techniques aimed at reducing radiation exposure during ASD percutaneous closure in pediatric patients. Since 2020, in all patients we used predefined acquisition parameters with a low exposure level (CARD <6Kg) and reduced pulsations to 4p/s. Therefore, from 2020 we used the lowest possible radiological pediatric protocol regardless of patient weight. We compared this group of patients (B) with an historical group of patients (A) with an ASD, in which a radiological protocol based only on patient's weight was applied.
Results: Group A included 92 patients with ostium secundum atrial septal defect. Group B included 114 patients with ostium secundum atrial septal defect. In this group, 22 patients received a Gore Cardioform ASD occluder device with the need of a biplane imaging. The two groups were comparable in terms of age (p=0.1) and weight (p=0.2). The absorbed dose in group A was significantly higher than in group B. Median total air kerma was 6.55 mGy(1.2-255,6 mGy) in group A and 5.25 mGy(0.4-140.5 mGy) in group B (p 0.001). Dose area product (DAP) was 130,2 μGym^2(24.25-5774 μGym^2) in group A and 67.1 μGym^2(8.6-3107 μGym^2) in group B(p 0.001).
Conclusion: Our strategy resulted in a significant reduction in radiation exposure to the patients while maintaining good radioscopic resolution. This significance was maintained despite the use of new devices in 2021 in addition to Amplatzer (GORE-Occlutech).

Keywords: Atrial Septal Defect; Dose Area Product; Radiation Exposure

Abbreviations: ASD: Atrial Septal Defect; ALARA: As Low As Reasonably Achievable; ALADA: As Low As Diagnostically Acceptable.

Introduction

Atrial septal defect is one of the most common congenital heart defects with an incidence of about 1.6 per 1000 live birth [1]. Large ASDs with a hemodynamic significance have to be closed. From 1980 most of the ASD can be closed percutaneously with optimal results. The percutaneous approach is, nowadays, the preferred method for ASD closure due to short recovery times, low complication rates and a high success rate [2]. Only disadvantage of the percutaneous procedure is radiation exposure. Given the expected longevity of children and the cumulative radiation doses patients, these children are at risk of subsequent immune dysfunction, cataract, malignancy and a congenital anomaly [3].

In recent years, significant efforts have been made to minimize the dose of ionizing radiation in pediatric catheterization procedures. These efforts have led to improvements in both technical equipment's and associated protocols, as well as increased awareness and responsibility among all the involved operators.

The purpose of our study is to investigate the efficacy of techniques aimed at reducing radiation exposure during ASD percutaneous closure. These techniques include reduction of frame rate but also the use of specific hardware weight-based protocols.

Methods and Materials

Study Design and Radiation Variables

We retrospectively reviewed data from all the children referred to our catheterization laboratory for ASD closure from 2018 to 2021. We divided the patients in two groups based on the radiological protocol used. Group A included patients undergoing Atrial Septal Defect closure between 2018 and 2019 and radiological protocols were based on the patient's body weight. Group B included patients undergoing percutaneous closure procedures during the period 2020-21 and we used the lowest possible pediatric protocol regardless of patient weight. All the procedures were performed in the same Siemens catheterization laboratory suite (Artis Qzen, Siemens Medical Solutions).Fluoroscopy's hardware has some protocols configurated on the basis of patient's weight. Large patients may require maximum output of the fluoroscopy, while small patients require different choices to manage dose. These protocols include these radiation adjustments:

- Select focal spot automatically based on patient's size.
- Keep pulse width < 5 ms in small children and < 10 ms in adolescents and adult patients.
- Use algorithms for small children to reduce tube current or pulse width to prevent reduction of voltage below 60 kV.
- Select voltage and added filter thickness automatically as a function of patient mass.
- Use AKIR α 1/(FOV)0.5 or constant based on pulse rate.

Using a fluoroscopy configured for adult patients on a child or infant can result in ionizing radiation doses that are orders of magnitude higher than needed. The protocol used in group B is CARD <6Kg. This protocol is usually used for pediatric patients weighing less than 6 kg and includes a fluoroscopy pulse rate form a maximum of 15 pulses per second to a minimum of 0.5 pulses per second, and a frame acquisition rate ranging from a minimum of 3 to a maximum of 30 frames per second for angiography exams. Moreover, in group B, we reduced the fluoroscopy rate to 4 pulses per second from 7.5 pulses per second in group A.

ASD Closure

Indication for ASD closure was the presence of an atrial septal defect with right ventricular enlargement. All the procedures were performed under general anesthesia with orotracheal intubation. All the children underwent a transesophageal echocardiography in order to better visualize the ASD and guide the procedure. As "complex" ASD was considered any defect with rim deficiency (< 5 mm) other than the antero-superior, mainly the posterior or inferior one, any relatively large defect (ASD diameter/patient weight ratio > 1.2, ASD diameter/patient BSA ratio > 20 mm/m2) or any multifenestrated atrial septum.

All the patients underwent balloon sizing and device dimension was selected on the basis of balloon sizing and stop flow technique. Most frequently used devices were Amplazter, Occlutech or, in the last period Gore that required the use of biplane projections. Invasive haemodynamics were performed only if non-invasive data were worrisome or discordant with the clinical evaluation.

Statistical Analysis

Patients will be described for demographical and clinical characteristics. Collected data will be presented as count and proportions (categorical data) or mean, median, standard deviation and interquartile range (continuous data). Comparisons between patients will be performed through Chi square test or Fisher exact test for categorical data; Student t test and ANOVA will be used for continuous data that follow a normal distribution, while Wilkoxon test and Kruskall Wallis test will be applied for data that are not normal distributed. Comparisons of measurements repeated in time, will be performed by using McNemar test for categorical data and paired T-test or the non-parametric Friedman test for continuous data.

Results

From 2018 to 2021, 206 patients were referred to our hospital for percutaneous ASD closure. Mean age and weight were 8.6 +/- 4.9 years and 31.2 +/-16 Kg, respectively. Patients treated from 2018 to 2019 were included in group A. Group A included 92 patients, with a mean age of 8.9 +/- 4.2 years and a mean weight of 33.5 +/- 17.4 kg. In this group, 59 patients underwent closure of the atrial septal defect through placement of an Amplatzer device (median size 15 mm), while 33 patients received an Occlutech device (median size 15 mm). No multiple devices were used. Complex ASDs were 24 (26%). In the 3 patients treated with an Occlutech device, biplane imaging was used due to positioning difficulties. Complications occurred in 1 (1%) patient, in which the device embolized and was retrieved percutaneously.

Patients treated from 2020 to 2021 were included in Group B. Group B consisted of 114 patients with a mean age of 8.5 +/- 5.7 years and a mean weight of 29 +/- 15.4 kg. In this group, 22 patients received a Gore Cardioform ASD Occluder device (median size 32 mm), 56 patients received an Occlutech device (median size 16.5 mm) and 36 patients were implanted with an Amplatzer device (median size 13 mm). The use of biplane imaging was required for closure of the ASD with the Gore device. In one patient two devices were implanted for a double ASD closure. Complex ASDs were registered in 33 patients (28%) and complications occurred in 2 patients: a device embolization and an AV block.

The two groups did not differ in terms of age (p=0.1), weight (p=0.2) and mean procedure duration (p=0.06) (Table 1). No differences were detected in terms of complex ASDs and complications. More patients in group B underwent ASD closure with a biplane image that could be responsible for a higher radiation exposure. Notwithstanding that, radiation exposure was significantly higher in group A compared to group B (Table 2). Median total air kerma was 6.55 mGy (1.2-255,6 mGy) in group A and 5.25 mGy (0.4-140.5 mGy) in group B (p 0.001). Dose area product (DAP) was 130,2 μGym² (24.25-5774 μGym²) in group A and 67.1 μGym² (8.6-3107 μGym²) in group B (p 0.001). Median DAP per body weight was 4.6 μGym². Kg (0.64-231.37 μGym². Kg) in group A and 2.8 μGym². Kg (0.51-46.37 μGym². Kg) in group B (p 0.001). Mean fluoroscopy time was similar between groups, 8.6+/-2.4 minutes in group A and 9.6+/-6.03 minutes in group B (p=0.2).

	Group A n 92	Group B n 114	p
Age (year)	8.9 ± 4.2	8.5 ± 5.7	ns
Weight (Kg)	33.5 ± 17.4	29 ± 15.4	ns
Device	Amplatzer 59	Amplatzer 36	
	Occlutech 33	Occlutech 56	
		Gore ASD 22	
Complex ASD	24 (26%)	33 (28%)	ns
Complications	1	2	ns

Table 1: Characterics of groups.

	Group A n 92	Group B n 114	p
Total air kerma (mGy)	6.55	5.25	0.001
Dose area product (DAP, μGym²)	130.2	67.1	0.001
DAP per body weight (DAP/p, μGym². Kg)	4.6	2.8	0.001
Mean fluoroscopic time (min)	8.6 ±2.4	9.6±6.03	ns

Table 2: Radiological characteristics of groups.

Discussion

Our study showed that the use of the lowest weight-based protocol of the fluoroscopy's hardware and decreasing the frame rate to 4p/s offered a significant reduction of patient's radiation dose during percutaneous ASD closure. Moreover, we demonstrated that this reduction does not affect procedural success since complication rate was similar in both groups. These results are even more significant considering that during the second study period (group B) we started to use the Gore Cardioform ASD occluder, that required more radiation exposure related to a natural learning curve and the use of a biplane fluoroscopy. ASD closure was specifically chosen for this study as it provides a cohort that Is fairly uniform with relatively standardized procedural and technical characteristics. This has allowed to better focus on the effect of a single specific modification among the various components of radiation exposure. Obviously, the results of this study allowed us to use the lowest weight-based protocol and a low frame rate protocol in all the procedures resulting in a real and important global dose reduction.

Other reports showed the advantages of reducing frame rate. Boudjemline Y [4] in his study about 144 patients undergoing percutaneous ASD closure, showed that during this procedure using fluoroscopy only at a frame rate of 4 frames per second reduces significantly the radiation exposure while maintaining excellent clinical results. The author concluded recommending this little change in every cath laboratory in order to achieve drastic reduction of radiation exposure not only to the patients but also to the personnel. In his work fluoroscopic time and radiation exposure doses were very low compared with those of our work. Main differences were that they did not use balloon sizing and that all the procedures were performed only by the same senior operator. In our center we always perform balloon sizing of the defects and since we work in a teaching hospital, the natural learning curve of the fellows has to be considered in the data analysis.

In another work published by Sitefane F, et al. [5] about radiation exposure during percutaneous ASD closure, factors independently related to radiation exposure reduction were age, balloon calibration, ASO size, complications and frame rate reduction. Also, Hiremath G, et al. [6] reported that reduction of frame rate to 4 frames per second had no impact in procedure, fluoroscopic and cine times, or in success and complication rates. However, they failed to demonstrate a statistically significant advantage of this strategy on radiation exposure reduction maybe for the low number of enrolled patients.

Use of lowest acceptable frame rate for fluoroscopy in an important tool for reducing radiation exposure. Obviously, there must be a balance between "a minimal radiation dose" and "adequate image quality for effective patient care" [7]. Ionizing radiation is a form of energy that can cause biological damage to human tissues. When pediatric patients are exposed to ionizing radiation, there are several harmful effects that can occur [8,9]. In particular children are more susceptible to the harmful effects of ionizing radiation since their tissues are more sensitive. Moreover, children live longer and have more time to manifest the deleterious effect of radiation [10].

Pediatric patients with congenital heart disease often undergo many diagnostic procedures during their life, further increasing the risk of long-term harmful effects. In general, it is important to carefully evaluate the balance between the potential benefits and risks of using diagnostic procedures that involve ionizing radiation in pediatric patients. The goal is to maximize benefits and minimize risks to ensure patient safety. For this reason, reducing radiation dose is an important quality improvement task in a Pediatric Cardiological center [11]. The principle of optimization, synthesized by the acronym ALARA (As Low As Reasonably Achievable), is one of the milestones of radiation exposure reduction. A few years ago, an adaptation to ALADA (As Low As Diagnostically Acceptable) was proposed in order to emphasize the importance of optimization, rather than simply reducing doses [12]. The expansion of the percutaneous procedures in last year's requires the definition of more effective and, above all, personalized optimization protocols.

In an interesting letter to the editor, recently published in the International Journal of Paediatric Dentistry, has been proposed a further advancing of the optimization principle, with the use of the new acronym ALADAIP [13]. The acronym stands for As Low As Diagnostically Acceptable. This principle has the advantages of being Indication-oriented and Patient-specific and it means: the lowest acceptable dose for diagnostic purposes, based on the clinical indication and specific to the patient. During a pediatric catheterization, many other manual adjustements can be used in order to reduce radiation exposure [14,15]. One example is the "air gap Technique" used in patients with a weight inferior to 20 Kg with the removal of the anti-scattered grid and a reduction of the Zoom. It is important to take in mind, that in older children the DAP tends to increase since their radiation exposed body area is larger compared to younger children. Additionally, the tissues of older children are less sensitive to radiation compared to younger children, so in order to obtain a good quality radiological image, the radiation dose must be increased with the objective to compensate this reduced sensitivity, further increasing the DAP.

Conclusion

Our results showed that the strategy of using predefined acquisition parameters with a low exposure level (CARD <6Kg) and reducing pulsations to 4p/s, resulted in a significant reduction in radiation exposure to the patient while maintaining good image resolution during percutaneous ASD closure. This significance was maintained despite the use of new devices in 2021, which required a better image definition and the use of Biplane. A perfect knowledgement of cath lab hardware and a great team-work between the different operators involved in the procedures are mandatory for a real and success radiation exposure reduction program.

Ethics Approval

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the institutional committee. The patients and their families gave their consent for publication of the cases.

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