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ORIGINAL ARTICLE

Is it possible to reduce radiation exposure during transcatheter atrial septal defect closure in children?

Çocuklarda transkateter atriyal septal defekt kapatılması sırasında radyasyon maruziyetini azaltmak mümkün müdür?

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ABSTRACT

Objective: Cardiac catheterization continues to be a major source of radiation exposure for patients with congenital heart disease. As children are more prone to both deterministic and stochastic effects of radiation, every effort should be made to reduce radiation exposure. One way to reduce the radiation dose is to lower the pulse fluoroscopy rate. This study is an examination of the magnitude of radiation exposure with a 3.75 frames per second (fps) pulse fluoroscopy rate and a comparison with the previous 15 fps protocol used for transcatheter atrial septal defect (ASD) closure.

Methods: The radiation dose delivered during ASD device closure procedures performed between 2014 and 2016 (Group 1: 3.75 fps fluoroscopy rate) was compared with that recorded in procedures performed between 2011 and 2014 (Group 2: 15 fps fluoroscopy rate). The radiation dose was quantified as air kerma dose (milligray, mGy) and dose area product (DAP; mGy/m^2).

Results: There were 80 patients in each group. Baseline demographic characteristics and the body weight and height measurements were similar between groups. The mean fluoroscopy time was significantly longer in Group 2. Since the fluoroscopy time was significantly different between groups, the DAP and air kerma dose were indexed according to fluoroscopy time. In Group 1, the DAP and air kerma indexed to body weight values were statistically lower than those of Group 2 ($p<0.001$).

Conclusion: A significant reduction in the radiation dose was observed with the implementation of 3.75 fps pulse fluoroscopy, which is the lowest in use. Novel radiation dose reduction protocols can be easily applied without compromising safety or the effectiveness of transcatheter ASD closure and should be utilized for the safety of patients and healthcare staff.

ÖZET

Amaç: Kalp kateterizasyonu, doğuştan kalp hastalığı olan hastalarda radyasyona maruz kalmanın ana nedeni olmaya devam etmektedir. Çocuklar radyasyonun hem yıkıcı hem de zararlı etkisine daha yatkındırlar ve bu hastalarda maruziyeti azaltmak için her türlü çaba gösterilmelidir. Radyasyonun azaltılmasının bir yolu da düşük atım floroskopi hızı kullanmaktır. Bu çalışmanın amacı, transkateter atriyal septal defekt (ASD) kapatılması sırasında, 15 fps (saniyedeki resim atım hızı) protokolü ve 3.75 fps floroskopi protokolünün radyoasyon maruziyetini karşılaştırmaktadır.

Yöntemler: Aralık 2014 ile Eylül 2016 tarihleri arasında gerçekleştirilen transkatater ASD kapatma prosedürleri (Grup 1; 3.75 fps floroskopi oranı kullanılarak) ile Aralık 2011 ile Kasım 2014 (Grup 2; 15 fps floroskopi oranı kullanılarak) arasında gerçekleştirilen prosedürler radyasyon maruziyeti açısından karşılaştırıldı. Radyasyon dozu; hava kerma (mGy) ve doz alan çarpımı (DAP; mGy/m^2) olarak ölçüldü.

Bulgular: Her iki grupta 80 hasta vardı. Demografik özellikler, vücut ağırlığı ve boy açısından gruplar birbirine benzerdi. Ortalama floroskopi süresi Grup 2'de anlamlı olarak uzundu. Gruplar arasında floroskopi süresi farklı olduğundan, DAP ve hava kerma floroskopi süresine göre indekslendi. Grup 1'de indekslenmiş DAP ve hava kerma dozu ile vücut ağırlığına göre indekslenmiş DAP ve hava kerma Grup 2'de daha düşüktü ($p<0.001$).

Sonuç: Pratikte kullanılan en düşük hız olan 3.75 fps floroskopi protokolü ile radyasyon dozunda anlamlı bir azaltma olduğunu saptadık. Uygulanan yenilikçi radyasyon dozu azaltma protokolü, transkatater ASD kapatılması işleminin güvenirliliğini ve etkinliğini azaltmadan kolayca uygulanabilir. Bu yöntem hastaların ve sağlık personelinin güvenliği için de uygulanmalıdır.

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Atrial septal defect (ASD) is one of the most common congenital heart diseases. The incidence is reported at approximately 1.6 per 1000 live births.[1] Defects causing a hemodynamically significant left-to-right shunt should be closed. Until the 1980s, defect closure was performed surgically, but as a result of technological advances, today almost 70% of cases can be closed percutaneously with various devices.[2]

Despite the known negative effects, radiation is still the gold standard imaging technique used throughout the closure procedure to guide catheter manipulations; control guidewire position; measure the defect diameter, if a balloon-sizing method is used; and to deploy the device in the proper position.[3] Prolonged procedure time due to large defects with difficult anatomy, the effect of the learning curve in educational institutions, higher heart rates in children, and frequent use of magnification may result in increased radiation exposure. In addition, the radiation dose exposure may increase as a result of operative-dependent (the distance between patient and device) and independent (angiography device, image intensifier, procedure related) factors.[3–5]

Given the expected longevity of children and the cumulative radiation doses patients and laboratory workers are exposed to during fluoroscopy, both groups are at risk of subsequent immune dysfunction, cataract, malignancy, and a congenital anomaly.[6,7] Unfortunately, pediatric patients are more vulnerable to deterministic and stochastic effects of radiation. In order to minimize this risk, safe and effective new methods that reduce the fluoroscopy time and do not prolong procedure duration are needed.[8] The primary objective is to provide sufficient diagnostic and therapeutic benefit with the lowest possible radiation dose for patient and healthcare professionals. The second goal is to reduce the radiation dose without compromising the image quality. A limited number of studies involving the use of low-pulse-rate fluoroscopy to achieve both purposes have been reported.[9]

The present study compared the magnitude of reduction in radiation exposure with a 3.75 fps pulse fluoroscopy rate and the previous protocol of 15 fps used for transcatheter ASD closure.

METHODS

The cardiac catheterization data of transcatheter ASD closure in pediatric patients performed between December 1, 2011 and December 31, 2016 were evaluated. The study was approved by institutional ethics committee (2020/46). The data were retrospectively retrieved from the hospital pediatric cardiology department database records.

Abbreviations:

ASD	*Atrial septal defect*
BSA	*Body surface area*
DAP	*Dose area product*
Fps	*Frames per second*
mGy	*Milligray*

Data sheets were created including the age, weight, gender, echocardiographic diagnosis and measurements of ASD in different planes, ASD closure device size and type, fluoroscopy time, procedure time, and radiation dose used.

The University of Health Sciences Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital has been using a novel fluoroscopy technique (3.75 fps flour rate during fluoroscopy and a 15 fps fluoroscopy rate during cineangiography, with a normal fluoroscopy dose) since December 2014. Cineangiography is only used during deployment of the ASD device. Previously, the protocol applied had been a 15 fps flour with normal fluoroscopy dose rate both during cineangiography and fluoroscopy.

Transcatheter ASD closure procedures performed between December 1, 2014 and December 31, 2016 at 3.75 fps were defined as Group 1. The transcatheter ASD closure procedures in which the standard 15 fps method was used between December 1, 2011 and November 30, 2014 formed Group 2. Procedures where a contrast agent was used, multiple ASD devices were required, an ASD device was redeployed or embolized, or when the ASD could not be closed were excluded.

The same technique was used to close all of the ASDs analyzed for this study.[10] All of the procedures were performed under general anesthesia with transesophageal echocardiography guidance. The position, number, anatomy, and size of the defect in different echocardiographic planes were recorded. The pulmonary and systemic flow ratios (Qp/Qs) and pulmonary artery pressure were assessed using invasive measurement. Closure was performed with the appropriate device according to the diameter, anatomy, and number of defects, as described in the literature.[2]

The total procedure time was defined as the time interval between sheath insertion and removal. The total radiation time was defined as the total cineangiography time plus total fluoroscopy time. Measures of radiation usage were reported for each case using a Philips Allura Xper FD20/10® catheterization system (Philips Medical Systems International B.V., Best, Netherlands), and separated according to those acquired through fluoroscopy alone and those with digital acquisition. To monitor radiation exposure, the patient dose was indirectly recorded using standard techniques, including total fluoroscopy time (minutes), air kerma (milligray, mGy), and dose-area product (DAP; mGy/m^2).

The air kerma dose (mGy), namely, the dose measured in air at a fixed distance from the X-ray tube, is the best surrogate of the dose of radiation absorbed at the skin surface of the beam entrance site. This correlates with the risk of skin injury, with doses >2000 mGy at a single skin site known to increase the risk of acute skin injury. The DAP (mGy/m^2) is the instantaneous air kerma dose multiplied by the X-ray field area, and reflects the total dose given to the patient. For statistical analysis, the air kerma dose and DAP were normalized to body weight, body surface area (BSA) and total radiation time. The formula of square root of [height (cm) x weight (kg)/3600] was used to calculate the BSA.

Statistical analysis

SPSS for Windows, Version 15.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical analyses. Continuous variables were expressed as median (range) or mean±SD; categorical variables were expressed as percentages. The Student t-test was used to compare the mean values of the 2 groups, while a chi-squared and Fisher's exact test were used to compare the findings between groups. P values of <0.05 were considered statistically significant.

RESULTS

A total of 160 cases were included in the study. In 80 cases, a 3.75 fps/normal fluoroscopy dose was used for imaging during the ASD closure (Group 1) and in the remaining 80 patients, a 15 fps/normal fluoroscopy dose was used (Group 2).

In Group 1, 35% of the patients were male (n=28), the mean age was 9.9±4.2 years, and the mean weight was 33.5±14.4 kg. In Group 2, 48% were male (n=38), the mean age was 10.0±5.0 years, and the mean weight was 35.2±18.8kg. There was no statistically significant difference between groups in age, gender, or weight (p>0.05).

The mean Qp:Qs of the patients in Group 1 was 2.1±0.5 and the mean Qp:Qs of Group 2 patients was 2.0±0.4 (p>0.05). The mean length of procedure was similar in both groups (Group 1: 23.8 minutes vs Group 2: 27.4 minutes) (p>0.05). The mean fluoroscopy time in Group 1 was significantly shorter than that of Group 2 (5.2 minutes vs 9.2 minutes, respectively) (p<0.05). An Amplatzer septal occluder (St. Jude Medical, Inc., St. Paul, MN, USA) was the most frequently implanted device. Table 1 presents the basic demographic characteristics and procedural data for the study cohort.

Although there was no significant difference in terms of weight or BSA between the groups, to eliminate the effect of different fluoroscopy times, the DAP and total air kerma were compared after indexing total radiation doses to body weight, BSA, and fluoroscopy time. Both the total air kerma and DAP values, and the standardized form according to body weight, BSA, and fluoroscopy time of the patients in Group 1 were significantly lower (p<0.05). The radiation exposure characteristics of the patients are summarized in Table 2.

DISCUSSION

There are few published data about radiation exposure during interventional procedures and methods to reduce the dose in the pediatric population.[3,11,12] In this study, we reduced the fluoroscopy rate from 15 fps to the lowest possible rate of 3.75 fps with a simple and easily applicable angiography protocol for the transcatheter ASD closure and measured its effect on reducing radiation exposure. We believe that the radiation exposure of both patients and healthcare staff can be significantly reduced without compromising image quality or the success of the procedure. Our study is a contribution to the limited number of related studies reported in the literature.

Transcatheter ASD closure is a relatively simple procedure and is increasingly used as primary intervention. The amount of radiation exposure during the procedure varies depending on the proportions of fluoroscopy and cineangiography.[1,2] Fluoroscopy is frequently used to provide imaging for catheter manip-

Table 1. **Descriptive and procedural characteristics**

	3.75 fps - Group 1	15 fps - Group 2	*p*-value
Number of patients	80	80	
Gender (male/female)	28/52	39/41	0.11
Age (years)	9.9±4.2	10.0±5.0	0.88
Weight (kg)	33.5±14.4	35.2±18.8	0.52
Body surface area	1.11±0.3	1.13±0.4	0.79
ASD size (TEE)			
Aortic view, 2D	14.0±4.0	14.1±3.14	0.87
Four-chamber view, 2D	14.0±3.6	14.3±3.1	0.60
Bicaval view, 2D	14.6±3.6	14.4±3.8	0.86
Aortic view, color Doppler flow	14.9±4.1	15.3±3.2	0.52
Four-chamber view, color Doppler flow	15.0±3.7	15.6±3.3	0.28
Bicaval view, color Doppler flow	15.5±3.8	15.8±3.7	0.60
ASD device size	19.1±4.3	18.6±3.8	0.49
Qp:Qs	2.1±0.5	2.0±0.4	0.07
Number of ASDs			
Single	93%	93%	0.99
Multiple	7%	7%	
Procedure time (min)	23.8±8.7	27.4±11.0	0.32
Fluoroscopy time (min)	5.2±3.1	9.2±7.2	<0.001
Type of device			
Septal occluders	40%	44%	0.99
CeraFlex	55%	50%	
Multifenestrated or PFO device	5%	6%	

ASD: Atrial septal defect; PFO: Patent foramen ovale TEE: Transesophageal echocardiography.
Amplatzer septal occluder (St. Jude Medical, Inc., St. Paul, MN, USA), Cardio-O-fix septal occluder (Starway Medical Technology, Inc., Beijing, China), CeraFlex septal occluder (Lifetech Scientific, Co., Ltd., Shenzhen, Guangdong, China).

Table 2. **Radiation exposure characteristics of the patients**

	3.75 fps Group	15 fps Group	*p*-value
Total air kerma (mGy)	28.2±29.9	84.5±97.8	<0.001
Total air kerma/Fluoroscopy time	5.3±4.4	9.6±8.1	<0.001
Total air kerma/Weight	0.9±1.0	3.0±3.8	<0.001
Total air kerma/Body surface area	25.2±26	81.8±96.9	<0.001
Total air kerma/Weight/Fluoroscopy time	0.16±0.11	0.31±0.28	<0.001
Total air kerma/Body surface area/Fluoroscopy time	4.61±3.03	8.69±7.25	<0.001
Dose area product (mGy/m^2)	302±276	1088±1375	<0.001
Dose area product/Fluoroscopy time	58.2±42.7	126.7±133.2	<0.001
Dose area product/Weight	9.7±8.6	37±57	<0.001
Dose area product/Body surface area	271±232	1021±1423	<0.001
Dose area product/Weight/ Fluoroscopy time	1.8±1	4.1±6.5	<0.001
Dose area product/Body surface area/Fluoroscopy time	0.5±.0.3	1.2±1.6	<0.001

ulations, balloon sizing, or device deployment during the procedure. In most catheter angiography laboratories. the frame rate for fluoroscopy is typically set to 15 fps. Although many operators do not adjust them, the system settings can be modified according to patient's age, body weight, and image quality needs. The default frame rate for interventions is usually between 7.5 and 15 fps.[13] There have been a few recent reports describing the use of 4 fps during transcatheter ASD closure.[11,12] Radiation exposure during ASD closure in pediatric patients ranges from 1.038 to 2.816 mGy/m^2.[13,14]

The only variable in our study was reduction of the frame rate from 15 to 3.75 fps. We chose ASD patients as a cohort, since ASD closure is a relatively straightforward procedure with standard techniques and methods. This allowed us to better focus on the effect of a single, specific variable (fluoroscopy rate) among the many components of radiation exposure, as opposed to more complicated interventions with many more uncontrollable variables. The radiation dose at 15 fps is consistent with literature reports. At 3.75 fps, the exposed dose was much lower than that of the earlier procedures.

Many patients with congenital heart disease undergo multiple cardiac catheterization procedures and they are exposed to ionizing radiation, which can have both immediate and long-term effects. The negative consequences of ionizing radiation can also be categorized as either deterministic or stochastic effects. While deterministic effects, like cataract formation or skin injury, have a somewhat predictable dose-response relationship and the degree of injury directly correlates with absorbed radiation dose, stochastic effects, like cancer and genetic mutations, are unpredictable and without a threshold effect. Strides have been made, particularly in the past decade, to improve radiation safety profiles as well as public awareness. Initiatives such as the ALARA (as low as reasonably achievable) conference, conducted by the Society for Pediatric Radiology in 2006, concluded that fluoroscopy dose optimization and reduction were key areas of concern. Campaigns such as "Image Gently, Step Lightly," first launched in August 2009, incorporated a standard safety checklist to encourage proper preparation, technique, and strategies to lower radiation exposure. In particular, this checklist encouraged utilizing pulse fluoroscopy rather than continuous fluoroscopy when possible, as well as the using the lowest pulse rate possible.[4,5,8]

Amdani et al.[9] evaluated the effects of reducing the pulse rate of fluoroscopy on the efficacy and safety of cardiac catheterization in 943 cases of congenital heart disease. The patient demographics, procedural technique, closure devices, and fluoroscopy time were similar for 2 groups with different frame rates. There was a significant decrease in the total air kerma and DAP levels after reducing the frame rate. This decrease was more prominent in interventional procedures. This change had no negative impact on the safety and effectiveness of the procedure.

Covi et al.[5] compared 3 different fluoroscopy pulse rates, 15, 7.5, and 5 fps, in their study of 61 patients. In procedures with a similar procedural difficulty, duration, and complications, they found that the exposed radiation dose was significantly reduced at or below 7.5 fps without sacrificing image quality.

Boudjemline et al.[11] evaluated children of similar age and weight who had undergone transcatheter ASD closure in 2 groups of 7.5 fps (n=49) and 4 fps (n=85). They then evaluated the procedure duration, complication and success rates, and the exposed radiation dose. It was observed that there was a significant decrease in the total air kerma and DAP levels without significant changes in procedure success, duration, or complication rates in the 4 fps group.

Hiremath et al.[13] reported that the DAP, DAP normalized to body weight, total radiation time, and fluoroscopy time were lower in a 4 fps group, but not statistically significantly different than the values of a 7.5 fps group. Fluoroscopy at 4 fps can be safe and effective for ASD device closure in children and adults.

Although in this study we reduced the frame rate to a much lower value (3.75 fps) compared with most reports in the literature, there was no significant change in the procedure duration and efficacy. The decrease in radiation exposure measurements of total air kerma and DAP levels, however, was significant.

Limitations

This single-institution, retrospective study has several limitations. First, the air kerma and DAP doses reported here were directly reported from the X-ray system. It is important to understand that these measures reflect what is generated at the energy source and not necessarily what is actually absorbed by the patient. Another shortcoming is that the effective dose (millisieverts) reflecting both the absorbed dose of radiation and the susceptibility of the exposed organs to radiation-induced somatic or genetic effects could not be calculated. Exposed radiation doses were recorded in total after each procedure, but fluoroscopy and cineangiography doses were not calculated separately. Another point is that the experience gained by interventional cardiologists over 5 years and the closure of relatively moderate-sized defects may have contributed to reducing radiation exposure time and fps values.

In conclusion, our results indicate that the radiation dose can be reduced significantly without compromising the safety or effectiveness of transcatheter ASD closure by using the lowest fluoroscopy rate of 3.75 fps. Thus, the possible harmful effects of radiation can be minimized while increasing the safety of patients and healthcare staff.

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Ethical statement: This study was approved by the İstanbul University of Health Sciences İstanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital Ethics Committee (2020/46).

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Keywords: Atrial septal defect closure; catheterization; fluoroscopy rate; radiation exposure.

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