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CLINICAL RESEARCH

Reduction of radiation exposure in transcatheter atrial septal defect closure: How low must we go?

Réduction de l'exposition aux rayonnements ionisants lors de la fermeture percutanée de communications inter-auriculaires : jusqu'à quel niveau doit-on aller ?

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KEYWORDS
Radiation exposure;
Atrial septal defect;
Transcatheter closure

Summary
Background. — Cardiac catheterization relies on X-ray imaging. Most procedures are now standardized. Interventionists must strive to minimize radiation exposure to reduce the risk of induced cancers.
Aims. — To describe the radiation level in our institution, and evaluate the components contributing to radiation exposure, during transcatheter atrial septal defect (ASD) closure.
Methods. — Radiation doses for ASD closure performed between January 2009 and November 2015 were reviewed retrospectively. Data on fluoroscopic time, dose area product (DAP), DAP/kg of body weight and total air kerma were collected.

Abbreviations: ASD, Atrial septal defect; ASO, Atrial septal occluder; DAP, Dose area product; f/s, Frames/second; QP/QS, Pulmonary flow/systemic flow.

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Results. — One hundred and seventy-four consecutive patients were included. Procedural success was 98.3%. Median procedural and fluoroscopic times were 15 minutes and 1.2 minutes, respectively. Median total air kerma, DAP and DAP/kg were 9.2 mGy, 88.3 μGy.m^2 and 3.2 μGy.m^2/kg, respectively. Risk factors associated with higher DAP were older age, larger ASD and device, need for balloon calibration, occurrence of complications and use of higher frame rate. Reduction of frame rate to 7.5 frames/second alone reduced by a factor of 2 the median DAP, DAP/kg and air kerma (99 vs 43 μGy.m^2, 3.5 vs 1.7 μGy.m^2/kg and 11 vs 4.8 mGy, respectively; $P < 0.001$).
Conclusions. — A low dose of radiation can be achieved for transcatheter ASD closure, even in complex ASDs, by following these recommendations: reduction of frame rate; avoidance of lateral view and cine acquisition; and limitation of fluoroscopic time by avoiding unnecessary manoeuvres and using echocardiographic guidance as much as possible.

MOTS CLÉS
Exposition aux rayons X ;
Communication inter-auriculaire ;
Fermeture par cathétérisme

Résumé
Contexte. — Le cathétérisme cardiaque repose sur l'imagerie aux rayons X. La plupart des procédures sont maintenant standardisées. Les cathétériseurs doivent travailler à réduire l'exposition des patients aux rayons X pour réduire le nombre de cancers radio-induits.
Objectifs. — Exposer les mesures implémentées pour réduire l'exposition aux rayons X et donner un référentiel de doses lors de la fermeture percutanée de communications inter-auriculaires (CIA).
Méthodes. — Nous avons rétrospectivement revu l'exposition aux rayons X de tous les enfants ayant eu une fermeture de CIA entre 1er janvier 2009 et 1er novembre 2015. Les données suivantes ont été collectées : temps de scopie, produit dose surface (PDS), produit dose surface par kilo de poids et la dose dans l'air (Air kerma).
Résultats. — Cent soixante-quinze patients ont été inclus. Les temps médian de procédure et de scopie étaient respectivement de 15 min et 1,2 min. Les doses médianes dans l'air, PDS et PDS/kg étaient respectivement de 9,2 mGy, 88,3 μGy.m^2 et 3,2 μGy.m^2/kg. Les facteurs de risques associés à un taux élevé de PDS étaient : un âge plus élevé à la fermeture, une CIA ou un dispositif de fermeture large, la calibration au ballonnet, la survenue de complications et l'utilisation d'une cadence-image élevée. La réduction de la cadence image à 7,5 images/seconde à elle seule a permis de réduire par facteur d'au moins 2 la médiane du DAP, DAP/kg et l'air Kerma (99 vs 43 μGy.m^2, 3,5 vs 1,7 μGy.m^2/kg and 11 vs 4,8 mGy, respectivement ; $p < 0,001$).
Conclusions. — Une irradiation faible est possible lors de la fermeture percutanée des communications inter-auriculaires, y compris pour les communications complexes sous réserve d'appliquer les recommandations suivantes : réduire de la cadence-image, éviter les projections de profil et l'acquisition en mode ciné, limiter le temps de scopie en utilisant au maximum le guidage échocardiographique.

Background

In recent years, it has been proved that cancer induced by radiation exists, and is related to the doses delivered and the stochastic effect [1—3]. This phenomenon is of particular importance in children, who will live longer, and are sometimes exposed to multiple sources of iatrogenic radiation, including multiple cardiac catheterizations, X-rays and computed tomography scans, in cases of complex congenital malformations [4]. This has led to the principle of reducing exposure to ionizing radiation (for both the patient and laboratory personnel) to ''as low as reasonably achievable'' — the so-called ALARA principle [5,6]. Minimizing radiation exposure has thus become a major topic in the field of interventional cardiology for patients with congenital heart diseases [6,7]. Some benchmarks for the most common procedures performed on children have been published recently. In these papers and a recent review, authors report the benchmarks, but also the ways in which radiation exposure can be reduced [8—11].

Length of exposure is not the only issue. The authors emphasize optimizing operator techniques by wise use of the equipment: reducing cineangiography; reducing zoom use; lowering the image intensifier; use of collimation; optimizing the use of equipment by reducing the frame rate; and, by close collaboration with the manufacturer, defining good settings that are a compromise between radiation dose and image quality [12].

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Percutaneous atrial septal defect (ASD) closure is of particular interest in this setting. This routine standardized procedure has been performed in most centres for many years, and is therefore perfect for reduction of radiation exposure [7]. In this paper, we review the radiation exposure of patients referred for ASD closure in our laboratory. We report the technical means of reducing radiation exposure, and seek to determine risk factors for higher irradiation. Finally, we report the effects that modification of practice and equipment have on radiation exposure.

Methods

Study design

We retrospectively reviewed data from all children referred to our catheterization laboratory for ASD closure between January 2009 and November 2015. Patients who were having additional interventional procedures were excluded from the analysis. Measures of radiation were obtained in each case from the Siemens system being used.

Radiation variables

The radiation measures recorded were fluoroscopy time (minutes); total air kerma (i.e. the total dose of energy extracted from the X-ray tube and delivered per unit of air, corresponding to total skin dose, measured in mGy); dose area product (DAP; the integral of air kerma emitted, representing the total amount of energy delivered to the child, measured in μGy.m^2 [also termed kerma area product]); and DAP/kg (μGy.m^2/kg). Units were those provided by the manufacturer. No calculations were made to avoid calculation errors.

During the survey, two different Siemens catheterization laboratory suites were used, with two different technologies (image intensifier and flat panel). Both catheterization laboratories (i.e. the biplane C-arm AXIOM Artis BC system, installed in 2003 [Siemens Medical Solutions, Forchheim, Germany] and the biplane C-arm Artis zee system, installed in March 2013 [Siemens Medical Solutions, Erlangen, Germany]) were inspected regularly for mechanical integrity and stability of delivered radiation doses, in accordance with *Agences régionales de santé* standards in France. Only the front plane was used for ASD closure.

Practice changed during the study. Until March 2013 (AXIOM Artis system), the frame rate was set at 15 frames/second (f/s). Short cineangiography (< 1 second) was performed with the device in place in all ASD closures (fluoroscopic image storage not available). With the installation of the Artis zee system, fluoroscopic images were stored, and cineangiography was avoided. From April 2015, the frame rate was reduced to 7.5 f/s. The machine setting for the Axiom Artis system, installed in 2013, is given in Table A.1.

ASD assessment

ASDs were assessed and closed, using standardized techniques, by a single operator (Y.B.). Briefly, detailed transthoracic echocardiography was performed before admission to the catheterization laboratory. The borders and size of the ASD (presence or absence, and softness) were carefully evaluated. Pulmonary flow/systemic flow (QP/QS) was evaluated, and pulmonary artery pressures were measured and calculated.

ASD closure

Procedures were done under general anaesthesia, with orotracheal intubation or deep sedation, and spontaneous breathing if transoesophageal echocardiography was not performed. In our centre, ASDs have been closed without ballooning sizing in most patients since 2008, after a 2-year period where device size was selected before and after balloon sizing (data not shown). Dimensions of the ASD were determined by echocardiography, and the ASD device size was chosen in accordance with those measurements. As a rule of thumb, 3—4 mm were added to the largest echocardiographic diameter in cases of normal rim, and 4—5 mm in cases of deficient aortic rim. In selected cases (discrepancy between transthoracic and transoesophageal echocardiography measurements, unusual anatomy, very floppy borders), balloon sizing was performed as previously described, using the ''stop-flow technique'' [13]. In this situation, the device size was chosen to be equal to the balloon diameter at stop-flow. Invasive haemodynamics were performed only if non-invasive data were worrisome or discordant with the clinical evaluation. Elsewhere, transthoracic echocardiography data was considered sufficient.

Recorded variables

Demographics, echocardiographic and procedural data were recorded and analysed. ASDs were characterized by several criteria, and were classified as simple or complex. Criteria for complexity were size (> 25 mm or > 15 mm/m^2), multiple defects and anatomy (deficient or floppy rim). The need for balloon calibration was evaluated. Complications, defined by others as any adverse event [14], and outcome were recorded. Procedural time was defined as time from puncture to unsheathing.

Measures to reduce irradiation exposure

A number of measures were undertaken to reduce irradiation in the catheterization laboratory. Firstly, the programme setting for dose delivery was defined with the manufacturer, the in-hospital radiophysician and the interventionist at the time of machine installation, and again in October 2015 to set, by default, a frame rate of 7.5 f/s for all procedures (the initial setting was 15 f/s). This variable can be changed any time by the operator (and was systematically changed by the operator from April 2015). Variables were set to have radiation as low as possible, while keeping image quality at an acceptable level. Additional measures not influencing image quality were employed, including setting the detector distance as short as possible, and use of collimation. Finally, operator-dependent variables were optimized, including use of single plane, use of fluoroscopy only, recording fluoroscopy instead of cineangiography loop, no use of lateral projections (for ASD closure), no use of cineangiography after 2013 (for ASD closure), reduction of frame rate, single trained operator performing the majority of procedures, and limiting unnecessary manoeuvres during ASD closure as eluded to previously (i.e. no QP/QS calculation, haemodynamic assessment only if pulmonary artery pressures found to be elevated on echocardiography, limited use of balloon calibration).

Statistical analysis

Analysis was performed using MedCalc (MedCalc Software, Ostend, Belgium). Descriptive statistics for categorical variables are reported as frequencies and percentages, and continuous variables are reported as means ± standard deviations or medians (ranges, and 25th—75th percentiles) and their 95% confidence intervals, as appropriate. The level of ionizing radiation exposure was evaluated by DAP. The association between DAP, as a continuous variable, and factors that might influence DAP (i.e. age, ASD size, atrial septal occluder [ASO] size, need for balloon calibration, occurrence of complications, frame rate, complexity of ASD, type of borders, multiple ASD and different catheterization laboratory suites) was evaluated by univariate and multivariable linear regression analysis. Significance was set at $P < 0.01$, and the Kolmogorov-Smirnov test for normality was performed to determine whether continuous variables were normally distributed, which was the case for each of these variables, to further account for multiple comparisons in the univariate analysis and for multivariable regression analysis. The multivariable regression model included variables with a significance level of $P < 0.2$ in the univariate analysis, after a backward selection of relevant variables, and excluding collinear variables from the model. For all analyses, a two-tailed P-value < 0.05 was used as the criterion for statistical significance.

Results

From January 2009 to November 2015, 188 children were referred for ASD closure. Fourteen patients were excluded because additional procedures were performed at the time of ASD closure. In total, 174 patients were ultimately included in the study.

Demographic data

The mean age and weight were 8.9 ± 3.9 years and 31.1 ± 15.3 kg, respectively. Mean body surface area was 1.04 ± 0.34 m^2. The sex ratio was 0.91 (male/female). The median ASD and indexed ASD sizes were 15 (range 6—29 mm; 25th and 75th percentiles 12—18 mm) and 15.9 (range 5.1—33.6 mm/m^2; 25th and 75th percentiles 10.9—19.7 mm/m^2), respectively. ASD was classified as complex based on one of three predefined criteria (indexed size, multiple ASD or deficient borders) in 130 patients (74.7%): 66 patients had one criterion; 54 had two criteria; and 10 had three criteria. Eighty-eight patients had an ASD > 25 mm or > 15 mm/m^2 (50.6% of the total). Seventy-nine patients had complex borders with aortic-deficient rims or floppy rims (45.4% of the total). Fifteen patients had multiple ASDs (8.6% of the total).

Procedural and radiation data

The procedural implantation rate was 98.3%. We failed to close the ASD in three of 174 patients (ASD too large, with deficient borders in three cases; one large device causing atrioventricular block retrieved). The median ASO size was 20.6 mm (range 10—36 mm; 25th—75th percentiles 16.5—24 mm). Only 15 of 174 patients (8.6%) had balloon calibration of their ASD. The complication rate was 3.5% (six of 174 patients), including five transient atrioventricular blocks (device successfully repositioned in four of five patients) and one device embolization with immediate retrieval (ASD successfully closed after balloon calibration with a larger device). Median procedural and fluoroscopic times were 15 minutes (range 5—80 minutes) and 1.2 minutes (range 0.5—21.4 minutes), respectively. The frame rate was set at 15 f/s in 131 patients and at 7.5 f/s in 43 patients. The median total air kerma, DAP and DAP/kg were 9.2 mGy (range 0.8—360 mGy), 88.2 $\mu Gy.m^2$ (range 12—2598 $\mu Gy.m^2$) and 3.16 $\mu Gy.m^2/kg$ (range 1.2—34.2 $\mu Gy.m^2/kg$), respectively.

Risk factors for higher radiation exposure

Figs. 1 and 2 show dose indicators according to time frame (Fig. 1), frame rate (Fig. 2A) and need for balloon calibration (Fig. 2B).

In the univariate analysis, risk factors associated with higher DAP were age, ASD size, ASO size, need for balloon calibration, occurrence of complications and frame rate. Complex ASD, type of borders, multiple ASD and different catheterization laboratory suites were not found to be risk factors (Table 1). Radiation variables are reported in detail in Tables 2 and 3, according to age and weight. Reduction of fluoroscopic frame rate to 7.5 f/s alone reduced the mean DAP and air kerma by almost a factor of 3 (210.7 vs 84.6 $\mu Gy.m^2$ [$P = 0.0006$] and 22.6 vs 7.2 mGy [$P = 0.0002$], respectively) and the median DAP, DAP/kg and air kerma by a factor of 2 (99 vs 43 $\mu Gy.m^2$, 3.5 vs 1.7 $\mu Gy.m^2/kg$ and 11 vs 4.8 mGy, respectively [$P < 0.001$]). In the multivariable analysis, age, balloon calibration, ASO size and complications were found to significantly reduce radiation exposure. Frame rate almost reached statistical significance (Table 4).

Discussion

Radiation exposure is a major concern in paediatric cardiac catheterization; it is linked with the occurrence of cancers [1—3]. Our practice should focus on reducing harmful exposure to ionizing radiation, and applying the ALARA principle — especially in procedures that are performed routinely, such as ASD closure [6,7]. There are few data on radiation exposure and how to reduce it in the paediatric population [8—11]. Variables available to express radiation exposition are limited and inaccurate, because the equipment provides indirect values rather than the effective and absorbed organ doses. These variables can only be derived from simulation using DAP (phantom or software) or from complicated physical measurements, which are not feasible in daily practice.

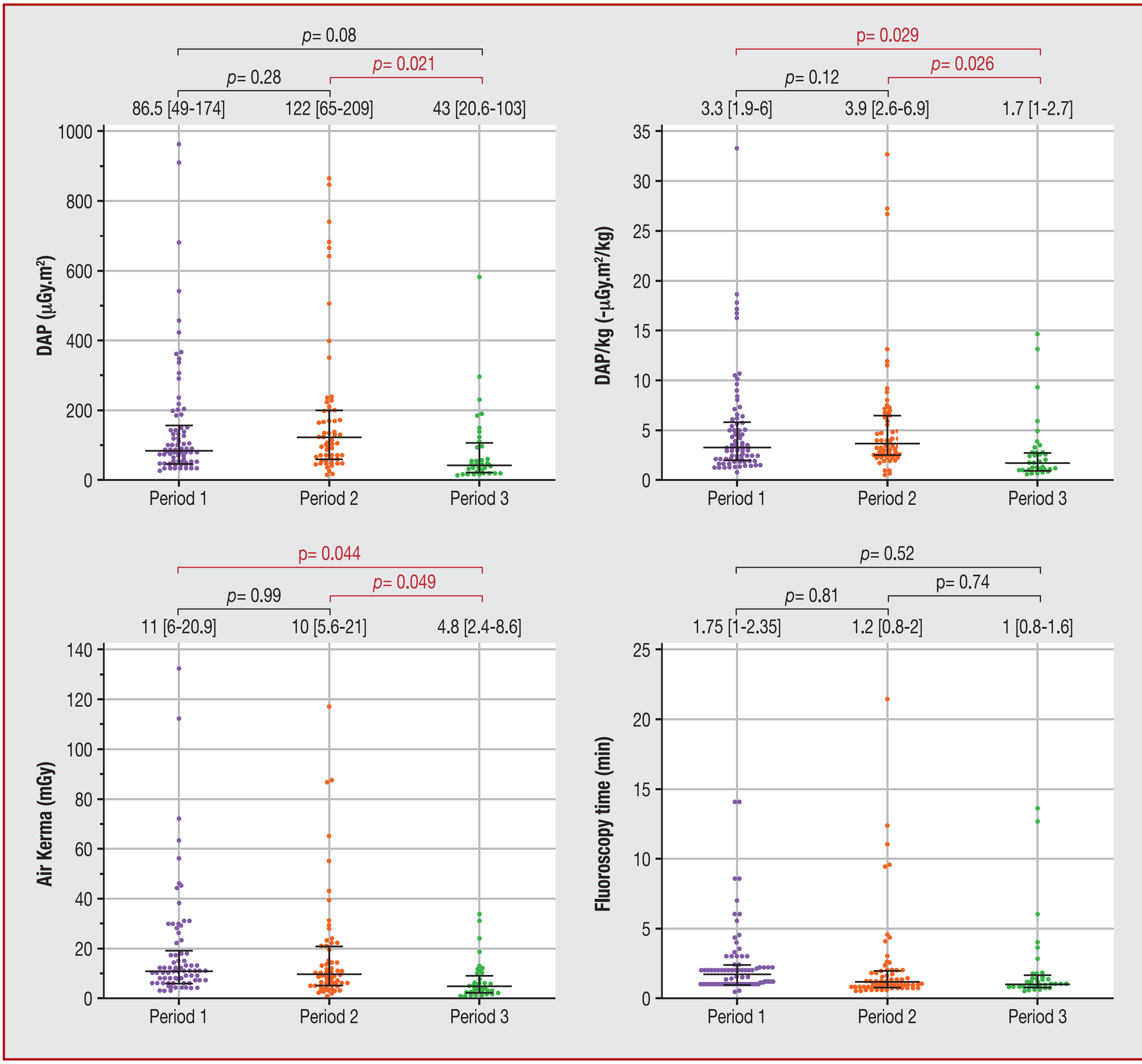

Figure 1. Radiation variables according to time frame. Period 1 from January 2009 to March 2013 ($n = 78$), period 2 from March 2013 to April 2015 ($n = 61$), period 3 from April 2015 to November 2015 ($n = 35$). DAP: dose area product.

As a result, DAP was the factor used to study ionizing radiation exposure.

Procedure length and radiation were very low in our population compared with those reported in multiple studies in a similar time frame (88 µGy.m^2 in our survey compared with 1038—2816 µGy.m^2 in other published surveys) (Table 5) [8—11]. Four potential explanations were given in a recent review to explain the great variability between centres [1].

First, the ages of the patients may vary between centres. We agree with this comment, as we and others have demonstrated an increase in DAP from the youngest/smallest to the oldest/largest populations (Tables 1—4). Studies should therefore by stratified by age and/or weight, for better comparison and understanding. This does not, however, explain our results, as we stratified the DAP and found lower DAP values than other studies in every age/weight group.

Second, variations in DAP may result from a mixture of procedure types, each having various complexities and degrees of irradiation. For this reason, we decided to focus on one specific procedure (ASD closure) rather than a collection of procedures. However, we anticipated that complex ASDs would require more skill, time and at last radiation exposure. Therefore, no patient selection was made for ASDs, and all patients undergoing this procedure as an intention-to-treat were included. This is reflected in the level of complexity, which exceeds 70% in our cohort, and is much higher than is usually seen. Papers on radiation do not report the level of complexity or related stratification, but it is highly improbable that this would explain the differences seen here.

A third potential explanation advanced by authors is incorrect recording or reporting of dose indicators. This

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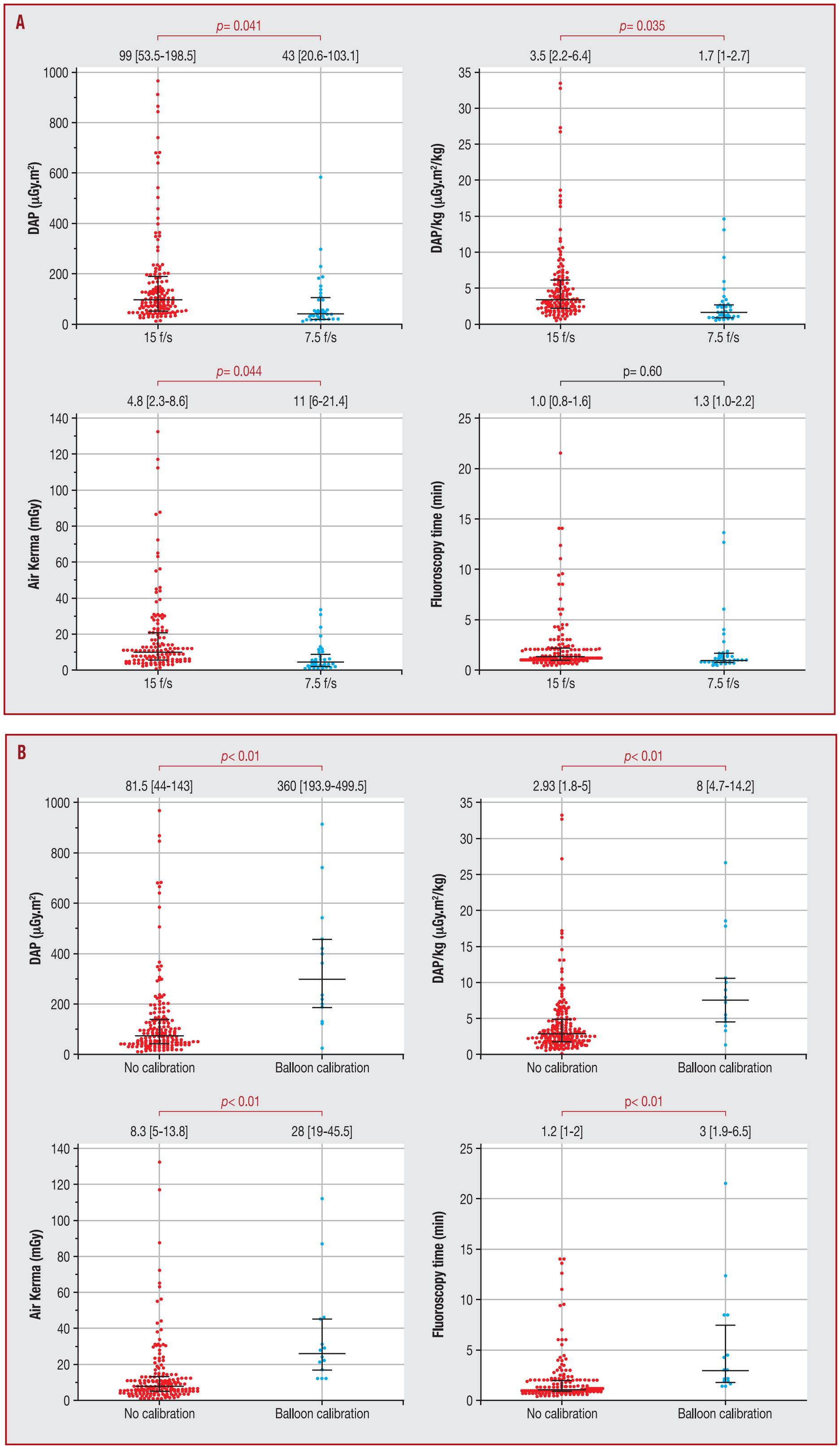

Figure 2. Radiation variables according to: (A) frame rate; and (B) use of balloon calibration. 15 frames/second (f/s) (n = 139), 7.5 f/s (n = 35). Balloon calibration (n = 15), no balloon calibration (n = 159). DAP: dose area product.

Table 1 Factors associated with dose area product; univariate analysis (linear regression).

	P	R^2
Age	0.0088	0.04
Body surface area	0.003	0.05
Atrial septal defect size	0.0059	0.04
Balloon calibration	0.0001	0.09
Complications	0.0011	0.06
Atrial septal occluder size	0.0001	0.08
Frame rate (15 f/s vs 7.5 f/s)	0.04	0.02
Catheterization laboratory (suite 1 versus suite 2)	0.9	0.0001

f/s: frames/second.

Table 4 Factors associated with dose area product; multivariable analysis.

	P	R^2
Age	0.04	0.025
ASD size	0.30	0.006
Balloon calibration	0.01	0.036
Complications	0.01	0.035
ASO size	0.03	0.027
Frame rate	0.18	0.011

ASD: atrial septal defect; ASO: atrial septal occluder.

is unlikely to explain the DAP variation reported in our study. Data were collected prospectively, and were recorded automatically on hardware (picture archiving and communication system [PACS] and CDs), the radiological database and the catheterization report. All sources match perfectly. Most recently, data were also recorded using dedicated software, recording all dose indicators from all sources (catheterization laboratory, X-ray, computed tomography scan and others). Moreover, data are presented in their original format, with no calculation to avoid mixing up units or conversion (e.g. μGy.m^2 to mGy.cm^2). Again, this does not explain the level of DAP that we have in this study.

The fourth explanation for DAP variation is related to the fluoroscopic equipment. There can be differences between manufacturers, and with the machine settings (frame rate, dose rate, use of filtration, antiscatter grid usage). This is well illustrated in our study, where two different machines were used in two time periods (before March 2013 and from March 2013). Despite more rigorous control of radiation in the second period, with flat-panel technology, no reduction

Table 2 Radiation variables, according to age.

	Air kerma (mGy)	*P*	DAP (μGy.m^2)	*P*	DAP/kg (μGy.m^2/kg)	*P*	FT (minutes)	*P*
Total population (*n* = 174)	9.2 (5–17.8)		88.2 (12–2598)		3.16 (1.9–5.8)		1.2 (1–2)	
1–5 years of age (*n* = 24)	8.5 (3.8–19.3)		73 (37.8–134.4)		4.2 (2.5–7.7)		1.3 (1–2.35)	
5–10 years of age (*n* = 92)	6.1 (4.4–12)	0.01	64.1 (39.8–123.3)	0.001	2.9 (1.7–5.2)	0.4	1.3 (1–2)	0.8
10–15 years of age (*n* = 42)	11.3 (8.7–25.5)		138 (78.9–215.5)		3.3 (2.2–4.7)		1.1 (1–2)	
15–18 years of age (*n* = 16)	13.8 (8–29.1)		160.4 (120.5–412.8)		3 (1.8–7.2)		1.1 (1–1.6)	

Data are expressed as median (25th–75th percentile). DAP: dose area product; FT: fluoroscopic time.

Table 3 Radiation variables, according to weight.

	Air kerma (mGy)	*P*	DAP (μGy.m^2)	*P*	DAP/kg (μGy.m^2/kg)	*P*	FT (minutes)	*P*
Total population (*n* = 174)	9.2 (5–17.8)		88.2 (12–2598)		3.16 (1.9–5.8)		1.2 (1–2)	
10–20 kg (*n* = 50)	6.6 (3.3–12)		53 (32.3–98.8)		3.2 (1.9–6.5)		1.3 (1–2.6)	
20–30 kg (*n* = 55)	6 (4.5–12)	0.02	68 (43.5–124.5)	0.01	2.9 (1.8–5.2)	0.6	1.3 (1–2)	0.7
30–50 kg (*n* = 41)	11 (6.3–26)		117 (70–209)		3.2 (1.9–4.9)		1.1 (1–2)	
≥ 50 kg (*n* = 28)	14 (8.5–29.5)		198.5 (131–350.5)		3.4 (2.1–5.8)		1.1 (0.8–1.6)	

Data are expressed as median (25th–75th percentile). DAP: dose area product; FT: fluoroscopic time.

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Table 5 Comparison of radiation exposure in our series and in the literature.

	Air kerma (mGy)	DAP (μGy.m^2)	DAP/kg (μGy.m^2/kg)	FT (minutes)
Our study				
Total population	9.2 (10.8—360)	88.3 (12—2598)	3.2 (0.5—81.2)	1.2 (0.4—21.4)
15 f/s	11 (0.8—360)	99 (12—2598)	3.5 (0.5—81.2)	1.3 (0.4—21.4)
7.5 f/s	4.8 (0.9—33.6)	43 (12.2—582)	1.7 (0.6—14.6)	1 (0.5—13.6)
Borik et al. [8][a]				
7.5 f/s	65 (5—2769)	504 (34—24496)	21 (2—367)	8 (2—95)
Hiremath et al. [12][a]				
7.5 f/s	Not provided	2895 (233—13955)	69.6 (8—201)	21.85 (8.3—59.4)
4 f/s	Not provided	1250 (186—24182)	47.8 (15.5—291)	19.3 (10.9—59.4)
Verghase et al. [11][a]				
1—4 years of age	540 (361—753)	2197 (1614—3048)	Not provided	30
5—9 years of age	522 (331—862)	2816 (1431—3978)	Not provided	31
10—15 years of age	1459 (814—2324)	7492 (4419—10582)	Not provided	34
15—18 years of age	1403 (983—2225)	9871 (6097—15341)	Not provided	28
Ghelani et al. [9][b]				
Total population	240	2100	Not provided	18
1—4 years of age	120 (101—134)	900 (800—1000)	Not provided	18 (16—20)
5—9 years of age	188 (156—211)	1400 (1100—1600)	Not provided	16 (15—18)
10—15 years of age	444 (310—550)	3900 (3100—5000)	Not provided	17 (15—19)
15—18 years of age	630 (550—954)	8900 (7100—11300)	Not provided	20 (18—24)

Data are expressed as median (range). DAP: dose area product; FT: f/s: frames/second; fluoroscopic time.
[a] Single-centre experience.
[b] Multicentre study

in DAP was seen at the same frame rate. In our practice, DAP is higher with flat-panel technology (in fact, the same when variables are optimized: reduction of image quality, no angiogram, storage of fluoroscopy) compared with image intensifier technology. The tremendous reduction in dose indicators seen in our study was related to frame rate reduction. By simply setting the frame rate to 7.5 f/s rather than 15 f/s, we were able to reduce the median DAP by a factor of 2.3. However, this is not the only reason for lower DAP compared with other studies. Hiremath et al. reported their experience of ASD closure with a frame rate of 4 f/s; even with this very low frame rate, their DAP value was at least 14 times higher than ours.

A fifth explanation must therefore be provided. Harbron et al. falsely assumed that practices are similar between centres. We think that radioprotection is a ''culture''. Physicians should be trained and conscious that radiation is deleterious to patients (and to themselves). A procedural goal should therefore be successful uncomplicated closure of ASD (short- and long-term), with minimal radiation exposure. The difference in practice is, in fact, the main explanation for variations in reported DAP. To support that assumption, one could compare the amount of fluoroscopic time. Even if this variable is not completely correlated with DAP, it is obvious to say that dose variables will be low if no radiation is emitted. By modifying our approach to ASD closure, we were able to reduce fluoroscopic time to a median of 1.2 minutes. This number, of course, includes all patients with complications or embolization or when multiple device openings were needed to close the defect.

We implemented multiple actions during ASD closure to minimize fluoroscopic time. First of all, the procedure was simplified, to avoid unnecessary measurements or manoeuvres. We relied on echocardiography for haemodynamic evaluation (pulmonary pressures, dilatation of the right ventricle to estimate the QP/QS) and anatomy of the ASD as transcatheter closure of ASDs does not start with the evaluation of the ASD based on X-ray imaging.

Secondly, the final decision regarding the size of the device to be implanted was made on the basis of echocardiographic measurements. Balloon calibration guided by angiography (and echocardiography) was avoided in most patients (91.4%), significantly reducing the radiation exposure of the cohort. In 9% of all cases, balloon calibration was necessary; it was used in patients with complex ASDs (i.e. multiple ASDs and/or when borders were very floppy). This contributed in part to an increase in radiation exposure in this population. A few studies have demonstrated the safety of ASD closure without balloon calibration [15,16]. The ASD was evaluated in three planes: four-chamber view, aortic valve short-axis view and bicaval view. The largest dimension was used, and 3—5 mm were added to that measure for ASO selection. Other authors have observed similar correlations between ASD and balloon calibration [17]. This rule is very reliable and reproducible. As it is not common practice in the field, one could ask or argue about the safety of such approach. We have been using this approach for more than 10 years now, with excellent results. Devices did appear flat on echocardiography and angiography, eliminating arguments about possible device oversizing. Results are excellent, with a high rate of success (procedural success > 98%; using a single device > 99%, data not shown) and a low rate of procedural complications (3.5%; all transient). We encountered five transient atrioventricular blocks related to manipulations during a difficult ASD closure; ASOs were immediately retrieved. In four patients, the same device was repositioned without any further complication, eliminating device oversizing as a potential cause of atrioventricular block. These patients were in permanent sinus rhythm at last follow-up. In the fifth case, the ASD was deemed too large for closure, and the device was retrieved without further attempt at closure. This patient was in sinus rhythm after device retrieval, and the ASD was closed surgically a few months later. One embolization occurred in a patient who had balloon calibration for a large ASD, deficient aortic rim and floppy rims. As expected, patients with complications had higher radiation exposure because of increased fluoroscopic time and manipulations. Balloon calibration statistically increases radiation and procedure length, and should, in our opinion, be used in selected cases only (i.e. a minority of patients).

Thirdly, most of the procedure was guided by echocardiography, limiting radiation exposure to positioning of the wire in the pulmonary vein, advancement of the delivery system and opening of the left disk.

Finally, other specific measures were used to reduce DAP: use of a single plane in frontal and 25° left anterior oblique projection, excluding lateral projection; use of minimal magnification; and setting the detector distance as low as possible. By applying these measures, we were able to decrease fluoroscopic time, DAP and DAP/kg by at least a factor of 8 compared with other studies (Table 4). ASD closure has been reported without the use of fluoroscopy, but this technique has failed to spread widely [18,19]; most operators still rely on fluoroscopy guidance. Between the two extremes (long and unnecessary fluoroscopy and no fluoroscopy), there is a place for a mixed approach, using fluoroscopy with parsimony and echocardiographic guidance.

Study limitations

This was an observational study that was not designed to provide recommendations on how to simplify the procedure in order to reduce radiation exposure. Such modifications need to be tested in a randomized trial. However, we identified the factors influencing radiation exposure, and showed how, in our institution, we are able to reduce it. Finally, our level of radiation exposure might serve as a reference for centres willing to compare their radiation exposure with ours.

Conclusions

Risk factors associated with higher DAP during transcatheter ASD closure were age, ASD size, ASO size, need for balloon calibration, occurrence of complications and frame rate. By simplifying the procedure and avoiding unnecessary manoeuvres, along with a reduced frame rate, we achieved a low ionizing radiation procedure with excellent procedural success and no increase in complication rate. This review suggests various ways to simplify the procedure in order to reduce its length and subsequent radiation exposure. Modification of practice is important to protect growing children from radiation exposure. Thanks to these results, we have modified our practice and reduced the fluoroscopy frame rate to 7.5 f/s for all cardiac catheterizations. Reduction of radiation exposure should be part of the final assessment of a named procedure, along with success rate and complication rate. As a result, a successful procedure is a procedure performed with as little harm as possible, including visible procedural complications and hidden side-effects induced by radiation exposure. However, reducing ionizing radiation alone by lowering the frame rate, leading to poor image quality and increases in procedural/fluoroscopic times and complication rates, should not be the goal.

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Table A.1. Machine setting for AXIOM Artis.

Necker hospital
Tube(s): CAT+ 3F
Detector: 30 × 40 high speed

	April 2015 to November 2015	March 2013 to April 2015
Exposure	Fluoro	Fluoro
kV	70	70
Pulse width	6.4	6.4
kV ms	125	125
Focus	S	S
Dose	32	45
kV Dose	109	109
EP reduction	2	2
Skin dose profile	Low	Normal
Minimum Cu filter	0.6	0.3
Maximum Cu filter	0.9	0.9
kV warning level	109	109
Image		
Image noise reduction	Smooth	Smooth
Image noise details	IA1-sm	IA1-sm
Edge enhancement NAT	15%	30%
EE kernel	3	3
DDO	35	35
DDO kernel	101	101
Window centre	1700	1700
Window width	2200	2200
Auto window setting	Normal	Normal
Auto centre correction	0	0
Auto width correction	1	1
Sigmoid window	Off	Off
Gamma correction	G6/3	G6/3
Gain correction	0	0
K-factor	KA4	KA4
EVE	EA2	EA2
Carto correction	No	No
Stripe compensation	Off	Off
Fluoro type		
Fluoro type	Pulsed	Pulsed
Pulse rate	7.5 frames/s	15 frames/s
Biplane pulse reduction	No	No
Gated phase centre	[−]0	[−]0
Gated phase width	[−]0	[−]0

Cu: copper; DDO: digital density optimization; EE: edge enhancement; EP: exposure; EVE: extended vessel enhancement.

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Disclosure of interest

Y.B.: proctor for the company St. Jude Medical.

The other authors declare that they have no competing interest.

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