Patient radiation dose during percutaneous interventional closure of interatrial communications

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KEYWORDS
Foramen ovale; Atrial septal defect; Percutaneous closure; Radiation exposure; Fluoroscopy time

Summary
Objective: To determine fluoroscopy time (FT) and radiation dose (RD) applied in percutaneous closure of interatrial septal communications (IAC).
Background: Percutaneous closure of IAC, namely patent foramen ovale (PFO) and atrial septal defect (ASD) is increasingly performed. In this often young population in full reproductive age, radiation dosage should be an important issue, yet consistent data on applied radiation dose have not been available to date.
Methods: A single center observational cohort study in 50 consecutive patients undergoing closure of a PFO or ASD. RD and FT as recorded by the cardiac catheter laboratory were determined to be the main outcome measures. Secondary outcome measures were determined to be major adverse events.
Results: FT averaged 6.3 (±4, 1.4—21.1) min, whereas RD measured as dose area product averaged 325.5 (±271.1; 11.6—1103.4) dGray × cm². The latter is equivalent to an effective dose of 6.5 millisievert (0.24—22 mSv).
Conclusion: Whereas closure of IAC can be associated with a low radiation exposure of 0.24 mSv, sometimes appreciably higher doses are applied, mandating more careful consideration of radiation safety issues in this patient population, especially the subset younger than 45 years. Analogous to data and recommendations published for radiation dose in coronary angiography, there is a need for binding reference values which would serve as guidelines for closure of IAC.

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Introduction
Interest in fluoroscopy time (FT) and radiation dosage (RD) applied in diagnosis and percutaneous intervention in coronary artery disease (CAD) has been renewed recently, with ample data being published on the subject [1–3]. Less systematic
information is available concerning FT and RD applied during interventional closure of interatrial septal communications (IAC) namely patent foramen ovale (PFO) and atrial septal defect (ASD), but published data of FT by some large-volume centers are available [4,5]. Because closure of a PFO or ASD is increasingly performed in younger persons, the issue may be even more relevant than in patients with CAD. It may therefore be important to develop guidelines and reference values, especially for low-volume operators.

Methods

Patient group

This study includes all 50 consecutive patients (26 females) undergoing PFO or ASD closure by the authors. Mean age was 52.8 ± 15 (24—83) years; 16 patients (32%) were younger than 45 years of age. Four patients (8%) had an ASD, 2 of whom were asymptomatic with a left-right shunt calculated to be 30%. One patient had a shunt >50% and reported having dyspnea; echocardiography showed a significantly enlarged right atrium. One patient had recurrent atrial fibrillation and a shunt of about 40%. Patient body mass index (BMI) was 25.33 ± 4.23 (19—37.8). All patients with PFO were referred by a neurologist, primarily for a search for cardiogenic emboli and had either experienced a stroke, a transient ischemic attack, or had signs of vascular encephalopathy on magnetic resonance imaging or computed tomography scanning. The search for cardiogenic emboli included a thorough history and physical examination, a resting and stress electrocardiogram (ECG), a 24-h ECG recording, a transthoracic (TTE) and transesophageal (TEE) echocardiogram and routine clinical chemistry including cholesterol levels, a blood cell count, as well as a screening for coagulopathies including: activated protein C (APC) resistance, factor V Leiden mutation, prothrombin gene mutation, protein C and S, antithrombin III, and lupus anticoagulant.

PFO or ASD closure

Closure was performed simultaneously under fluoroscopy (Philips™ AD5, Philips Medical Systems, Eindhoven, the Netherlands) and echocardiography (Siemens Sequoia™, Siemens Medical Solutions, Erlangen, Germany); TEE was used during the procedure in 49 patients and intracardiac echocardiography (ICE) in 3 patients. 2 g Ceftriaxone was intravenously applied before and 6 h after implantation. Pre-interventional medication further included an antiemetic, atropine (to reduce salivation), and a benzodiazepine for sedation. Balloon sizing was only performed in the last 6 patients, all patients had pre-interventional TEE and defect sizing. Twenty-five Amplatzer™ (AGA Medical Corp., Plymouth, MN, USA), 8 Premere™ (St. Jude Medical, Maple Grove, MN, USA), 14 Figulla™ (Occlutech, Jena, Germany), and 5 Solysafe™ (Swissimplant, Solothurn, Switzerland) devices were used.

Follow-up evaluation

All patients were scheduled for TTE within 1 month and TEE within 6 months after implantation. One patient skipped the first follow-up. In a second patient, TTE quality was inadequate due to overweight.

Statistical analysis

Continuous variables are expressed as mean (S.D.) and were compared by a paired t-test. Significance was assumed at a p-value < 0.05. Regression analysis computed correlation coefficients. Categorical variables are reported as counts and percentages. All data were analyzed using the StatView® program, SAS systems™ (Cary, NC, USA).

Results

Short-term outcome

In all patients a device could be delivered, except in a 36-year-old patient with a residual shunt a few months after placement of an Amplatzer™ device. Although placement of the second device was straightforward, it was positioned vertically to the first one and protruding in the lumen of both atria. A better alignment could not be achieved, even with a larger device, so that it was decided to retrieve it. No patient experienced any complication or side effect during hospitalization. One patient returned 1 week after device placement because of a painful swelling at the puncture site, which showed to be a fistula between the femoral vein and a side branch of the femoral artery. The fistula was repaired surgically without interruption of platelet aggregation inhibitors and the patient was discharged the same day. He has since been seen for follow-up and was asymptomatic.

Mid-term outcome

Two patients (4%) showed residual shunts during 6 months of follow-up. The first, a 38-year-old
male, patient had a Premere\textsuperscript{TM} device implanted for a tunnelled PFO and showed a relevant residual shunt. It was closed successfully using a second similar device. The second patient (detailed above) was a saxophone player who had resumed playing shortly after Amplatzer\textsuperscript{TM} device implantation and omitted the 1-month TTE. After implantation of a second device was not successful, he was advised to undergo a third closure attempt with a different device or surgery; he chose to wait and continue on clopidogrel and aspirin. In 1 patient (2\%) device migration was documented and followed by its percutaneous retrieval [6].

Fluoroscopy and radiation dose (RD) data

FT and RD were automatically measured and printed at the end of each intervention. RD was measured as dose area product (DAP) in dGray × cm\textsuperscript{2}. FT averaged 6.3 (±4, range 1.4—21.1) min (Fig. 1). RD averaged 325.5 (±271.1, range 11.6—1103.4) dGray × cm\textsuperscript{2} (Fig. 2). Procedure time averaged 54.2 (±19.2, range 30—100) min (Fig. 1). As was to be expected, there was no correlation between FT and RD (Fig. 3), mainly because body mass is an important factor influencing RD.

Figure 1 Procedure and fluoroscopy time in minutes, \(n = 50\). The horizontal bars denote the 10th, 25th, 50th, 75th, and 90th percentile respectively. Dots denote single data sets below the 10th or above the 90th percentile.

Figure 2 Radiation dose in dGray × cm\textsuperscript{2}. The horizontal bars denote the 10th, 25th, 50th, 75th, and 90th percentile respectively. Dots denote single data sets below the 10th or above the 90th percentile.

Figure 3 Correlation between fluoroscopy time in minutes and radiation dose in dGray × cm\textsuperscript{2}, \(r^2 = 0.25\).
Table 1  List of patients (n=12; 24%) having received a radiation dose above the mean value of this series (326 dGray × cm²).

<table>
<thead>
<tr>
<th>Patient</th>
<th>RD (dGray × cm²)</th>
<th>Reason for increased RD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1103.42</td>
<td>Unnecessary long FT 12.4min, first patient with Premere™</td>
</tr>
<tr>
<td>2</td>
<td>471</td>
<td>None readily apparent, FT 7.6 min</td>
</tr>
<tr>
<td>3</td>
<td>431.7</td>
<td>Prior diagnostic CA during same procedure, FT 10.6 min</td>
</tr>
<tr>
<td>4</td>
<td>745.46</td>
<td>Prior diagnostic CA during same procedure, FT 11 min</td>
</tr>
<tr>
<td>5</td>
<td>366</td>
<td>None readily apparent, FT 5.6 min</td>
</tr>
<tr>
<td>6</td>
<td>558.3</td>
<td>None readily apparent, FT 8.4 min</td>
</tr>
<tr>
<td>7</td>
<td>393.3</td>
<td>None readily apparent, FT 6.5 min</td>
</tr>
<tr>
<td>8</td>
<td>544</td>
<td>None readily apparent, FT 8 min</td>
</tr>
<tr>
<td>9</td>
<td>953.8</td>
<td>ASD size underestimated by TEE alone, device had to be exchanged twice for right match after balloon sizing, large patient (98 kg, 165 cm)</td>
</tr>
<tr>
<td>10</td>
<td>868.5</td>
<td>Large patient, total FT 1.5 min</td>
</tr>
<tr>
<td>11</td>
<td>729.19</td>
<td>Attempt at closure of residual shunt, device exchanged twice</td>
</tr>
<tr>
<td>12</td>
<td>506</td>
<td>None readily apparent, FT 6.9 min</td>
</tr>
</tbody>
</table>

FT, fluoroscopy time; RD, radiation dose; CA, coronary angiography.

There was no difference between RD delivered to patients over and under 45 years of age respectively (362.1 ± 291; 19.4—1103.4 versus 219.9 ± 209.4; 11.6—729.2 dGray × cm²; p = 0.174). There was however a statistically significant difference in FT (7 ± 4.3; 1.5—21.1 min in patients aged over 45 years versus 4.8 ± 2.6; 1.4—11.3 min in those under 45 years; p = 0.0211). Data of all patients that received a RD above the mean of this series were examined to try to determine the cause of the delivered excess dosage or time needed (Table 1).

Twelve patients (24%) were exposed to more than the 50th percentile of the RD of 326 dGray × cm². In 2 patients, this was partly due to the coronary angiography (CA) performed prior to IAS closure. In 1 patient, the defect had been undersized by TEE. This was detected by inadequate positioning of the device before release, followed by retrieval, sizing balloon measurement, and placement of an adequate device. In 1 patient described above (Fig. 1), the prolonged FT resulted from an attempt of closure of a residual shunt with two devices. In 1 large patient (BMI 33.3), a large RD was applied, in spite of a FT of only 1.5 min. The maximal deviation in RD was 1103.4 dGray × cm², in whom the only explanation for the FT of 12.4 min was that it was the first time a Premere™ device was implanted. In the other 6 patients no obvious cause for prolonged FT was found. The longest FT of 21.1 min occurred in 1 of the patients in which CA was necessary, and which had very tortuous and kinked pelvic vessels, entailing insertion of a long arterial sheath and manipulation to get to the coronary ostia. In this series of 50 patients, CA was performed before IAC in 4 patients.

Procedure time ranged from 30 to 100 min, with a mean of 54.2 ± 19.2 min. Some of the longer procedure times resulted from, having to wait (sometimes for as long as 45 min) for the cardiologist performing TEE (MR), the latter not being dedicated to the cardiac catheterization laboratory, sometimes experiencing unexpected intraoperative and other delays.

Discussion

The fluoroscopy times in this series compare favorably with those reported by larger centers with means of 8.3 min [5] and 9.5 min for TEE and 6 min for ICE [4], although the latter institutions may now be able to report lower values with increasing experience. No data on RD are available, to the best of our knowledge.

Radiation is measured as DAP and not as effective dose (ED), the latter being the more relevant unit for assessing both the deterministic as well as the stochastic radiotoxicity risk. Although a conversion factor may be applied to compute the ED [2], the process remains approximative at best.

In certain cases, it is possible to reduce DAP to below 20 dGray × cm², amounting to an ED of 0.4 milliSievert (mSv). The mean DAP is 326 dGray × cm², yielding an average ED of 6.6 mSv, which is more or less equal to that needed for a diagnostic CA (including ventriculography and aortography) and less than that of an average coronary intervention [1—3]. Some patients received higher effective doses (Table 1), amounting to 22 mSv, which is obviously less desirable.
In the patient with the residual shunt treated by another Premere™ device, almost identical FT was needed. The first intervention was performed with the usual frame rate for CA of 15 frames/s, while for the second attempt, the frame rate was set at 3.75 frames/s. The reduction in DAP was drastic, from 558.8 to 197.4 dGray cm², whereas FT was unchanged 8.4 min versus 8.3 min. This finding underlines the fact that, while it is imperative to try to keep FT as low as possible, other factors may be equally important in reducing RD and have to be borne in mind.

Obviously this is an observational, single center study. But there is more to the findings than just the fact that a low-volume operator does not undercut a large-volume institution in terms of FT, procedure time, and RD.

Interventional cardiologists should be committed to the concept that minimizing RD in the younger patient population undergoing closure of an IAC has highest priority and precedes considerations of comfort (avoiding TEE) [7]. ICE is an attractive alternative, but its application is limited by its prohibitive price.

For us, sole echocardiography guidance without fluoroscopy [8] is no alternative for ASD and PFO closure. Most interventional cardiologists would use fluoroscopy anyway after venous puncture and while inserting the catheter and guide wire to the right atrium, as well as when pushing the sheath across the IAC. After realization that pre-interventional TEE may not always adequately assess defect size, sometimes grossly underestimating it, we returned to balloon sizing of every defect including PFOs, despite reports describing septum laceration during sizing [9].

Estimation of organ radiation dose applied during the procedure, especially the female breast and gonads, to our knowledge only be extrapolated from available CA data [10], the latter coming nearest to closure of IASD in terms of radiation type applied. Weighted organ equivalent doses, as documented for cardiac radionuclide and computed tomography studies [1] are yet to be provided. Although a linear extrapolation cannot be expected, an average of two- to three-fold breast, ovaries, and testicle dose compared to CA [10] may have to be expected, yielding 14—21 mSv for the breasts, 2.2—3.3 mSv for the ovaries, and 1—1.5 mSv for the testicles respectively.

To limit RD, we have lately begun to proceed as follows: if crossing the IAC under fluoroscopy is not successful within 90 s, further crossing attempts are continued only after the TEE is in place and the interatrial septum is visualized. Cine angiography frame rate will be set at the lowest possible minimum of 3.75 frames/s, compared to the default 15—30 frames/s. Frame rate is only increased if image quality is insufficient due to overweight or if CA is concomitantly needed. For fluoroscopy, parameters such as frame rate and delivered energy cannot be operator-modified in the angiography equipment used. These parameters are set by default once patient weight and height are entered. A gonadal protection is applied to all female patients of childbearing age and to all males under 50 years of age. We never perform closure of an IASD in a pregnant patient, even if the gestation is beyond the 4th month of conception.

It is certainly not up to a low-volume operator to recommend FT and RD figures for closure of IAC. The high-volume centers are invited to publish their data and work out binding reference values which should serve guidelines as for all interventional cardiologists involved.

Acknowledgments

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References
