N
o dose of radiation may be considered safe or harmless. 1 All medical exposure for radiodiagnostic purposes should be kept "as low as reasonably achievable," 1 and "shielding, attached to either the equipment or the operator, should be used as completely as possible without encumbering the examining physician or . . . jeopardising the welfare of the patient." 2 Nevertheless, practising interventional cardiologists are reported to receive an annual average x-ray dose of 1.7 mSv with the use of a thyroid shield, and 3.5 mSv without this protection (both figures include the use of a lead apron). 3 Their effective dose per procedure varies between 9–50 µSv. 4 Without lead protection, the operator’s eye receives a mean (SEM) entrance skin dose of 165 (97) µSv per coronary angiography session. 5, 6 The use of lead eyeglasses lowers this level to 37 (15) µSv. 6 The annual head dose sustained by cardiologists may reach 60 mSv a year, and may in some cases exceed the occupational limit of 150 mSv a year recommended for the lens of the eye. 7 There is current consideration of the risks of radiation induced cataracts 8, 9 and malignancy, particularly brain cancer. 10 Until now operators have not used personal protective garments to shield their forehead and brain. The goal of our study was to determine the effectiveness in invasive cardiology of lead equivalent caps 0.5 mm thick, and to compare this new type of protection with an improved 1.0 mm lead equivalent glass overcouch shield.

METHODS

Definitions

Patient’s entrance skin air kerma (ESAK) is the dose to the air in the entrance plane of the patient without backscatter. Entrance skin dose (ESD) includes backscatter and is appropriate for characterisation of deterministic risks for skin lesions. Both are measured in Grays (Gy = J/kg). Dose–area product (DAP) is the product of the area of the cross section of an x-ray beam and the air kerma averaged over that cross section. The unit is Gray square centimetre (Gy cm²).

S-ESAK-O is the scatter entrance skin air kerma to the operator position caused by stray radiation, which is defined as the sum of the following: primary scatter emitted from the patient in all directions, secondary scatter reflected from the walls, and the small fraction of tube housing leakage.

DAP was measured for 122 patients as well as at an anthropomorphic Alderson-Rando phantom. In a second step, we measured S-ESAK-O at this phantom, representing the patient, during fluoroscopy for all standard angulations and calculated S-ESAK-O per DAP.

Equipment

We employed a digital, single arm Advantx LC+- undercouch and overcouch image intensifier system (GE Medical Systems, Fairfield, Connecticut, USA) with the following installed in the x-ray beam: 0.1 mm copper filter, 2.9 mm aluminium filter, and—throughout all measurements—an antiscatter grid. Under conditions of focus image intensifier distance of 1 m, and for a copper absorber 2 mm thick, the image intensifier entrance dose rates during fluoroscopy were 0.21 µGy/s for the 23 cm image intensifier field and 0.30 µGy/s for the 17 cm field. During cine acquisition (12.5 frames/s), these values were 0.08 µGy/frame (23 cm field). The DAP was measured by an ionisation diamentor, calibrated in situ on the x-ray tube (reliability for repetition < 3%; total uncertainty for linearity (60–150 kV) < 5% (M4, PTW, Freiburg, Germany)).

The electrical charge generated in the ionisation chamber was equivalent to the DAP (Gy cm⁻²) and accordingly was directly proportional to the collimated radiation beam passing through.

Abbreviations: DAP, dose–area product; ESAK, entrance skin air kerma; ESD, entrance skin dose; LAO, left anterior oblique; PA, posterior-anterior; RAO, right anterior oblique; S-ESAK-O, scatter entrance skin air kerma to the operator position.
the cross sectional chamber area as well as the patient’s body surface area. The company’s product specifications declare that the attenuation of the carbonaceous table, including the table cover (Omega 4, type 2181400, GE, Buc cedex, France), is equivalent to 1.2 mm aluminium, and that the correction factors at 70–90 kV are 1.10 for direct lateral exposures and 0.97 for undercouch exposure perpendicular to the couch.

Complete radiation protection (as supplied by MAVIG, Munich, Germany) was achieved by an articulated ceiling screen ($60 \times 75$ cm), lengthened by a flap beside the table ($21 \times 80$ cm); a longitudinal table mounted lead drape ($60 \times 20$ cm); and a lead cover around the phantom’s (patient’s) thighs. Each shield showed 1.0 mm lead equivalence (fig 1). The operator used a cap (Burkhart Roentgen International, St Petersburg, Florida, USA), glasses, apron, and collar (MAVIG, Munich, Germany), all with 0.5 mm lead equivalence (fig 2). The lead cap weighs approx 1140 g and offers acceptable wearing comfort.

**Cardiac catheterisation procedures**

One interventionist performed 122 diagnostic catheterisations with femoral access. We documented total DAP, DAP from cinemography ($DAP_C$) and fluoroscopy ($DAP_F$), the number of cinegraphic frames, and the time adjusted cinegraphic dose area product per frame. The patients’ mean (SD) age was 65 (8) years, 56% were male and 44% female, and their body mass index was 28 (4) kg/m$^2$.

**Characterisation of the patients’ in vivo conditions using a Rando phantom**

The first methodological step was to validate the assessment of DAP obtained with the phantom with that received by a patient in an analysis of 122 coronary angiographic examinations. The mean patient DAP/frame (17 cm intensifier field) obtained with the phantom did not differ significantly from that measured in vivo: 21.6 (7.7) v 24.0 (7.6) Gy $\times$ cm$^2$ (p > 0.38), respectively. Using straight line regression, the correlation coefficient for all the various tube angulations was 0.91 (fig 1).

The second step was to correlate stray radiation to the operator with the DAPs measured on the phantom. The correlation coefficient was 0.99 between S-ESAK-O and DAP in 0°/0° posterior-anterior (PA) tube angulation at a table height of 95 cm, and with a dosimeter height of 100 cm at a distance of 100 cm from the isocentre. In agreement with other research, S-ESAK-O/DAP increased slightly with kV and field size (diameter 13–23 cm).

In order to diminish the investigator’s radiation exposure, we undertook further scatter radiation measurements in fluoroscopy mode.

**Data collection**

We conducted measurements of fluoroscopy scatter radiation ($\mu$Sv/h) at a male anthropomorphic Alderson-Rando phantom, using a Szintomat 6134 A system (Automess, Ladenburg, Germany). The system was calibrated for a dose intensity range of 100 nSv/h to 100 mSv/h. For an incident angle of 45°, the measured radiation exposure uncertainty was < 10%. At an operator’s position 100 cm from the isocentre (60 cm adjacent to and 80 cm caudally to the tube), we measured S-ESAK-O in 10 cm increments within a height range of 140–200 cm (seven positions), for all 10 standard tube angulations of coronary angiography (fig 1) and for all 11 angles of incidence to the operator (fig 3: $-120^\circ$, $-90^\circ$, $-60^\circ$, $-40^\circ$, and $-20^\circ$ to the left; 0°; and +20°, +40°, +60°, +90°, and +120° to the right of the operator’s front).
Measurements were done in four steps: without any radiation protection; with an articulated, ceiling mounted 1.0 mm lead glass screen lengthened by the lead flap; with a helmet of 0.5 mm lead equivalence; and with both protection devices together (fig 2). We accordingly undertook a total of 3080 (7 × 10 × 11 × 4) individual measurements.

With measurements based on DAP per second and applied to the phantom, we calculated the ratio of S-ESAK-O to DAP at all heights for each angulation and angle of incidence to the operator. We then took into account the partial DAP contributions of the respective tube angulation to the overall in vivo DAP (6.5 Gy × cm²) obtained for the patients during coronary angiography.27 On this basis, we finally computed the local scatter-ESAK to the operator (S-ESAK-O) per applied Gy × cm² during one coronary angiography session, in 10 cm increments within the height range of 140–200 cm. Under these conditions we analysed the efficacy of the ceiling mounted 1.0 mm lead glass screen lengthened by the lead flap, of a helmet of 0.5 mm lead equivalence, and of both protection devices together.

We used Student’s t test to verify differences in continuous variables and expressed the significance at a probability level of p = 0.05.

RESULTS
Fluoroscopic local scatter radiation exposure to the operator’s head
The primary scatter ESAK to the operator’s unprotected head (170 cm body height) under conditions of low level fluoroscopy (image intensifier entrance dose rate of 0.30 µ Gy/s for the 17 cm field) was highest for left anterior oblique (LAO) tube angulations (fig 4). Posterior-anterior (PA) angulations induced lower S-ESAK-O, and right anterior oblique (RAO) projections, the least. Cranial angulations (black symbols in the figures) apparently induced slightly, but not significantly, higher S-ESAK-O levels than caudal angulations (white symbols). Mean (SD) S-ESAK-O ratios were 23.1 (10.1) for LAO/PA, and 3.5 (1.2) for PA/RAO angulations. The greatest scatter ESAK to the operator’s position was in the form of irradiation from the tube direction of −40° to −60° on the operator’s left, but also from 0° and a direction slightly to the right. Scatter radiation from +60° to +120° on the right side, however, was much lower.

Benefit of 1.0 mm lead screen and 0.5 mm lead cap
Overall in vivo DAP to patients during coronary angiography (n = 112) is the sum of all partial DAPs applied to them for the various tube angulations.29 We multiplied these partial in vivo DAPs by the S-ESAK-O per Gy × cm², applied to the Rando phantom, for each respective tube angulation. The sum of these partial products represents the S-ESAK-O that reaches the operator from various angles of incidence during coronary angiography within a range of 140–200 cm body height. Dividing this value by the mean overall DAP of a coronary angiography, we obtained the mean S-ESAK to the operator per Gy × cm² applied to the patient during coronary angiography (figs 5 and 6). Scatter ESAK to the operator’s eyes without radiation protection was much higher at a line of vision of −120° to 0° to the operator’s left than was scatter ESAK coming from ≥ +60° to the right side. The operator will be exposed, over the range of 140–200 cm body height, to mean (SD) levels of 2.1 (0.5) nSv/Gy × cm² from the left, and to less than 240 (40) nSv/Gy × cm² from the right lines of vision ≥ +60°. As measurement points rose along the operator’s height, the mean (SD) local operator radiation exposure decreased by 10 (3)% per 10 cm (fig 5).

A 1.0 mm lead glass shield reduced mean (SD) S-ESAK-O/DAP from coronary angiography from 1089 (764) to 54 (29) nSv/Gy × cm², depending on angle of incidence and body height. A 0.5 mm lead cap was effective in lowering measured levels to 1.8 (1.1) nSv/Gy × cm². Both devices together achieved attenuation to 0.5 (0.1) nSv/Gy × cm² (fig 6).

Dependence of operator’s scatter radiation exposure on line of vision
To enable the patient to follow the interventional procedure, the monitors in many catheterisation laboratories are positioned in a line of vision of −40° to the operator’s left. Regardless of tube angulation and of the absence or quality of lead protection, this line of vision (fig 7, black symbols) occasions higher S-ESAK-O levels to the operator’s eyes and brain than does looking to the right at an angle of incidence of +60° (fig 7, white symbols). With application of the protective devices,
the ranking of radiation exposure according to tube angulation was no longer LAO > PA > RAO as demonstrated with no protection (black and white diamonds). Using both the glass shield and personal protection devices in the form of glasses and cap, scatter exposure to the operator's eyes and brain during fluoroscopy while looking to the right (+60°) will be reduced for all tube angulations to similar mean S-ESAK-O levels within 30–67 nSv/h (white circles). The lower parts of the operator's face unprotected by lead will be exposed to radiation levels of 800–4500 nSv/h with an overcouch lead glass shield (white triangles), and to 4500–110 000 nSv/h without this protection (white diamonds).

**DISCUSSION**

Primary scatter ESAK to the operator's unprotected head is highest for left anterior oblique (LAO) tube angulations. This configuration is typically employed in invasive cardiology to document left main stem bifurcation (caudal LAO 60/20 spider view), the left anterior descending coronary artery (LAO 90/0), the bifurcation of the left anterior descending artery, and the diagonal branch (cranial LAO 60/20), and the left ventricle (LAO 60/0). Right anterior oblique (RAO) projections occasion the least radiation exposure. Mean S-ESAK-O ratios of LAO/RAO angulations to the operator's brain were within 4.6 to 38.2, and ranged above reported ratios—that is, 2.6 to 12.4 with respect to total body height. Cardiologists should consequently limit fluoroscopic LAO projections and shorten cinegraphic LAO documentation whenever possible. The highest S-ESAK-O is of course emitted from the tube direction to the operator's left, whereas scatter radiation from > +60° to the right is much lower. In order to protect lenses of the eyes and the brain, operators should attempt to work with monitors positioned to the right (fig 3).

In this study we measured mean S-ESAK-O/DAP levels of 2.1 (0.5) µSv/Gy × cm² irradiating from the isocentre direction, with calculations based on all tube angulations used during coronary angiography. These results were significantly lower than the occupational doses of 8.4 µSv/Gy × cm² reported for a modern catheterisation system. However, several methodological differences explain this higher stray radiation/DAP measured by other researchers. The distance to the isocentre in other studies was < 75 cm (v > 100 cm in our catheterisation laboratory), dose measurements were done at 150 cm (170 cm in our laboratory), and operators did not consistently use low level modes as practised in the present study. For comparable circumstances with the operator's position at a distance of 1 m to the isocentre, for 150 cm above ground, and for LAO 90°/0° tube angulation, our determined stray radiation level of 4.7 µSv/Gy × cm², measured towards the isocentre, correlates well with published stray radiation levels of 4–8 µSv/Gy × cm² for this exposure intensive tube angulation.

Modern coronary angiography and percutaneous transluminal coronary angioplasty, as most recently reported, induce mean (SEM) DAPs of 62 (28) Gy × cm², and 85 (34) Gy × cm², respectively. The patient's DAPs and, in
Radiation exposure benefit of a lead cap

turn, the operator’s stray radiation vary greatly, depending on the x-ray system employed, the operator’s experience, the protocol, and the efficiency and placement of protection devices. Unfortunately, “many interventionists are not aware of the potential for injury from procedures, their occurrence, or simple methods for decreasing their incidence utilizing dose control strategies.” Staff doses can be considerably increased if inappropriate x-ray equipment or inadequate personal protection is used. Operators in a high volume catheterisation laboratory with a cumulative yearly workload of 1000 interventions, 40% of them typically being percutaneous transluminal coronary angioplasties, will subject their patients to a yearly cumulative radiation load of approximately 171 Gy x cm². Without lead protection, they will be exposed over the range of 140–200 cm² body height to mean (SD) levels of 146 (38) mSv from the left sided lines of vision, down to less than 17 (3) mSv from right sided angles of incidence of ≥+60°. Greater body height reduces the mean operator’s head exposure by approximately 1%/cm (fig 5). In good agreement with these calculations, the published mean entrance skin dose per coronary angiography to the lens of the operator’s eye under the same workload produces a mean (SEM) local annual radiation exposure of more than 665 (97) mSv. This level reflects the fact that coronary interventions typically include not only coronary angiography but also radiation intensive percutaneous transluminal coronary angioplasty. Such exposure levels exceed the recommended occupational limit of 150 mSv/year for the lens of the eye. This fact has prompted discussion in the literature of the relevance of these levels with respect to above normal frequencies of cataract development and brain cancer observed among interventionists. These data should motivate cardiologists to make every effort to reduce such high exposure to their eyes and brain by application of the means of protection examined in the present study—that is, the use of both a 1.0 mm lead screen and a 0.5 mm lead cap. This recommended solution achieved a reduction of mean S-ESAK-O levels to 1.2 (1.4) x 10⁻² of baseline. However, these results can vary according to the x-ray systems used, the catheterisation protocols, and the operator’s correct use of the individual radiation protection devices. Unexpectedly, a cap with only 0.5 mm lead equivalence was more protective than an overcouch shield with 1.0 mm lead equivalent (fig 6). This finding indicates that a significant amount of secondary scatter radiation, reflected from the laboratory walls, may reach the operator’s head, despite the presence of a ceiling mounted lead glass shield designed to protect the face and head from primary scatter radiation from the patient. Without any protection, or with 1.0 mm lead equivalent overcouch protection alone, the monitor position typically determines the operator’s predominant line of vision in invasive cardiology. Regardless of tube angulation, the lowest S-ESAK-O will typically occur in a line of vision toward the foot of the table (fig 7). The use of additional 0.5 mm lead equivalent caps and glasses reduces such dependence on the operator’s head, despite the presence of a ceiling mounted lead glass shield designed to protect the face and head from primary scatter radiation from the patient. At the same time, we did not take into account the S-ESAK-O fraction resulting from scattering around personal lead garments from the unprotected lower parts of the operators’ face, up to their brain and eyes. Anatomical and technical circumstances render these levels hardly measurable with the EASK acquisition systems currently in use. Even under conditions of optimised radiation protection of the head region as outlined in this study, looking toward the foot of the table (+60°) nevertheless exposes the lead-unprotected lower parts of the operator’s face to considerable mean radiation levels—that is, to 2300 (1050) nSv/h (white triangles) and 35 600 (37 100) nSv/h (white diamonds) in the presence and absence of an overcouch lead glass shield, respectively. We determined that looking towards the tube exposes the lower parts of the face to levels 4–10 times greater than does looking rightwards (fig 7). Optimal minimisation of this fraction would be possible through an improved lead helmet, including protection of nose and chin regions. The additional efficacy of a lead cap with respect to protection from stray radiation, as evidenced in this study, may encourage interventionists to use one, especially as this cap is hardly more uncomfortable to wear than the conventionally recommended lead apron and lead glasses.

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A 5 year old girl presented with mild cyanosis since birth. Systemic oxygen saturation was 80%. Chest radiography revealed a prominent round opacity at the upper right heart border. Transsthoracic echocardiography showed a dilated proximal right pulmonary artery. Echocadast introduced into a peripheral vein opacified the right heart, then passed rapidly to the left atrium. Positive pressure ventilation during cardiac catheterisation caused further systemic desaturation to 54%. Pulmonary artery angiography demonstrated a large fistula between the proximal right pulmonary artery and the left atrium. The communication tapered at its midpoint to a minimum diameter of 9.8 mm (below left). The fistula was crossed from the right heart with a long transseptal sheath and a 14 mm Amplatzer muscular ventricular septal defect occluder was deployed at its narrowest point (below centre). Oxygen saturation increased immediately to 100%. Repeat angiography demonstrated complete occlusion of the fistula. The device did not obstruct the right pulmonary artery and remained stable on release.

Direct communication between the right pulmonary artery and the left atrium is a rare congenital cardiac malformation. It may present in the neonatal period with intense cyanosis requiring urgent intervention. If desaturation is less severe, presentation may be delayed to later in childhood or even adult life. Early repair should be performed to avoid complications, particularly systemic emboli, cerebral abscess, and rupture of aneurysmal communications. Although surgical ligation or division is the accepted treatment, transcatheter coil occlusion has been described in one neonate and Amplatzer device occlusion offers an alternative for larger communications.

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Radiation exposure benefit of a lead cap in invasive cardiology

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