Evaluation of Novel Disposable, Light-Weight Radiation Protection Devices in an Interventional Radiology Setting: A Randomized Controlled Trial

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OBJECTIVE. Radiation exposure to interventionalists is increasing. The currently available standard radiation protection devices are heavy and do not protect the head of the operator. The aim of this study was to evaluate the effectiveness and comfort of caps and thyroid collars made of a disposable, light-weight, lead-free material (XPF) for occupational radiation protection in a clinical setting.

SUBJECTS AND METHODS. Up to two interventional operators were randomized to wear a XPF or standard 0.5-mm lead-equivalent thyroid collars in 60 consecutive endovascular procedures requiring fluoroscopy. Simultaneously a XPF cap was worn by all operators. Radiation doses were measured using dosimeters placed outside and underneath the caps and thyroid collars. Wearing comfort was assessed at the end of each procedure on a visual analog scale (0–100 [100 = optimal]).

RESULTS. Patient and procedure data did not differ between the XPF and standard protection groups. The cumulative radiation dose measured outside the cap was 15,700 µSv and outside the thyroid collars 21,240 µSv. Measured radiation attenuation provided by the XPF caps (n = 70), XPF thyroid collars (n = 40), and standard thyroid collars (n = 38) was 85.4% ± 25.6%, 79.7% ± 25.8% and 71.9% ± 34.2%, respectively (mean difference XPF vs standard thyroid collars, 7.8% [95% CI, –5.9% to 21.6%]; p = 0.258). The median XPF cap weight was 144 g (interquartile range, 128–170 g), and the XPF thyroid collars were 27% lighter than the standard thyroid collars (p < 0.0001). Operators rated the comfort of all devices as high (mean scores for XPF caps and XPF thyroid collars 85.4 ± 25.6%, respectively; mean scores for standard thyroid collars 89.6 ± 9.9) (p = 0.648).

CONCLUSION. Light-weight disposable caps and thyroid collars made of XPF were assessed as being comfortable to wear, and they provide radiation protection similar to that of standard 0.5-mm lead-equivalent thyroid collars.

Keywords: endovascular interventions, fluoroscopy, occupational radiation, radioprotection

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were randomized to wear thyroid collar composed of bilayer barium sulfate–bismuth oxide composite (XPF, Bloxr) in 58 cases and to wear standard thyroid collar in 48 cases.

No independent prospective randomized controlled trial, to our knowledge, has tested the radiation attenuation and comfort provided by XPF caps and XPF thyroid collars compared with standard 0.5-mm lead-equivalent protection devices.

The primary objective of our trial was to study the amount of radiation attenuation provided by XPF in absolute and relative terms. The second objective of our study was to measure and compare the amount of radiation that cardiovascular operators are exposed to per case in an interventional suite setting using an XPF thyroid collar or the standard 0.5-mm lead-equivalent thyroid collar. The third objective was to assess operator comfort wearing the XPF protection devices.

Subjects and Methods

This investigator-initiated, single-center, prospective, randomized controlled trial was performed in the endovascular interventional suites of a tertiary care center. This study protocol was approved by the institutional review board and the reporting standards of the Consolidated Standards of Reporting Trials statement [7]. This study is registered at ClinicalTrials.gov (NCT01450969).

All participating operators provided written informed consent.

Procedures

Measurements were performed in 60 consecutive endovascular procedures requiring C-arm fluoroscopy. The type, duration, and operator of each intervention were documented. The same x-ray system (Allura Xper FD 20, Philips Healthcare) was used for all procedures. As is customary, the system has automatic brightness control on each tube to generate an optimal x-ray beam. The image intensifiers were positioned as closely as possible to the patient with a source-to-image distance of between 89.5 and 119.5 cm. All tubes have dose-area product (DAP) meters that indicate the summed cumulative DAP in cGy cm². DAP is used as a surrogate measurement for the total amount of radiation energy delivered to the patient and, hence, serves as a relative indication of the scatter dose to the operator.

Protection Devices and Randomization

Immediately before each procedure the operators were randomized to wear a XPF thyroid collar or a standard 0.5-mm lead-equivalent thyroid collar using sealed envelopes containing a group assignment number generated with Research Randomizer (version 3.0. G. C. Urbaniak and S. Plous). When a procedure was performed by two operators, both were independently randomized to account for possible dropouts (e.g., invalid detector readings). All operators were asked to wear the XPF protection cap.

Figure 1 displays the study flow. The experimental shielding material, XPF, is a novel bilayer barium sulfate–bismuth oxide composite.

The XPF thyroid collar was found to be equivalent to 0.5-mm lead shielding averaged over 60, 90, and 130 kVp and was approved by the FDA. Small, medium, and large caps are available to properly fit the operators. Commercially available leaded (Ultra-Lite, Pulse Medical) and lead-free (Earth-Lite, Pulse Medical) thyroid collars are used as standard thyroid collars in our institution. Fifteen XPF caps of each size, 15 XPF thyroid collars, and 15 standard thyroid collars were weighed using a scale with an accuracy of ± 0.01 g according to the manufacturer (EL-2000S, Setra Weighing Systems).

Measurement of Radiation Exposure

Radiation doses in each procedure were measured with two thermoluminescent dosimeters (NanoDot, Landauer) or two optically stimulated luminescence dosimeters (Luxel+, Landauer) placed side-by-side, one outside of the protection device and one inside the protection device at a standardized position (Fig. 2). The detectors were calibrated with x-ray beams identical to those used in clinical practice and the sensitivity threshold for the detectors was approximately 10 µSv for the Luxel+ dosimeter and 50 µSv for the NanoDot dosimeter. After the procedure the detectors were sent to Landauer for blinded reading.

Fig. 1—Chart illustrates study flow: 46 of 60 consecutive endovascular procedures were performed by two operators, resulting in total of 106 measurements. Operators were randomized to wear thyroid collar composed of bilayer barium sulfate–bismuth oxide composite (XPF, Bloxr) in 58 cases and to wear standard thyroid collar in 48 cases.
**Operator Comfort Assessment**

After completing a procedure, the operators were asked to rate comfort wearing the cap and thyroid collar on a scale from 0 (unbearably heavy, malfunctioning) to 100 (very light, well-fitting).

**Statistical Analysis**

Summary values are presented as means ± SD or medians ± interquartile range (IQR). Data were compared using a two-sided unpaired Student t test, chi-square test, or nonparametric Mann Whitney U test as appropriate. Other than the assessment for noninferiority, all significance testing was two-sided, and p values of < 0.05 were considered to indicate statistical significance.

Our primary outcome measure was radiation attenuation in percentage and sample size calculation based on previously reported attenuation and transmission rates [8, 9]. Sample size calculation indicated that, if there is truly no difference between the standard and XPF thyroid collars, then 60 measurements would be required to be 95% sure that the lower limit of a one-sided 95% CI will be above the prespecified noninferiority limit of −0.7% attenuation difference rate.

The null hypothesis was that the XPF thyroid collar is inferior to the standard 0.5-mm lead-equivalent thyroid collar with regard to radiation attenuation. The alternative hypothesis was that the XPF thyroid collar is noninferior to the standard thyroid collar.

**Results**

Data were collected during 60 consecutive endovascular procedures performed between October and November 2011. Table 1 summarizes the procedure-specific data. Nine of 10 interventionalists agreed to participate in the study; whenever a procedure was performed by two operators (n = 46), both were randomized resulting in a total of 106 data sets. No significant difference between the XPF and standard protection groups was detectable with regard to procedure and patient data. No differences in fluoroscopy time and DAP were detectable between the groups.

The cumulative radiation dose measured outside the caps was 15,700 µSv and outside the thyroid shields 21,240 µSv. The cumulative radiation dose inside the caps and inside the thyroid collars were 3360 and 7660 µSv, an attenuation of the baseline radiation by a factor of 4.7 and 2.8, respectively. In 36 of 106 cases, no radiation outside the cap was detectable. Correspondingly, in 28 of 106 cases no radiation outside the thyroid collar was detectable. These cases were excluded from further radiation attenuation analysis, resulting in 70 analyzable cap measurements and 78 thyroid collar measurements: 40 in the XPF group and 38 in the standard group.

Comparing matched samples, the mean radiation dose measured outside the caps was significantly lower than the radiation dose measured outside the thyroid collars (232.8 ± 278.0 [SD] vs 314.9 ± 405.2 µSv, respectively; p = 0.004). The radiation dose measured outside the cap was significantly higher than the radiation dose measured inside the cap (224.1 ± 266.1 vs 48.1 ± 124.7 µSv; p < 0.001) and the mean radiation attenuation provided by the XPF cap was 85.4% ± 25.6%. Accordingly, the radiation dose measured outside the thyroid collars was significantly higher than the radiation dose measured under the thyroid collars (272.3 ± 373.3 vs 98.2 ± 203.1 µSv; p < 0.001), corresponding to a mean radiation attenuation of 75.7% ± 30.5%. The radiation doses measured outside the thyroid collars did not differ significantly (190.5 ± 364.5 µSv in the XPF group vs 212 ± 315.3 µSv in the standard group; p = 0.746). Comparing the radiation attenuation provided by the XPF thyroid collars versus the standard 0.5-mm lead-equivalent thyroid collars, no significant difference was detectable (79.7% ± 25.8% vs 71.9% ± 34.2%; p = 0.258). Figure 3 displays the mean attenuation percentages with corresponding 95% CIs. The mean difference in attenuation between the XPF and standard thyroid collar was 7.8%, favoring XPF with a 95% CI of −5.9% to 21.6% (Fig. 4). Given the higher-than-expected variation in attenuation and relatively high number of dropouts due to incapability to detect radiation doses at all, testing for noninferiority (one-sided) failed to prove the predefined noninferiority margin of −0.7% of attenuation difference. However, the lower margin of the one-sided 95% CI (−3.6%) indicates that the attenuation provided by the XPF thyroid collar is no more than 3.6% less effective than the standard 0.5-mm lead-equivalent thyroid collar. On the other extreme, the CI includes that the XPF thyroid collars may have provided a 19.3% more effective radiation protection compared with the standard thyroid collars.

**Operator Comfort Assessment**

The median weights of the XPF thyroid collar and standard thyroid collar were 138 g (IQR, 136–140 g) and 189 g (IQR, 178–232 g), respectively (p < 0.0001). The median weight of the XPF cap was 44 g (IQR, 128–170 g). The operators rated the comfort of the devices on a visual analog scale (VAS) from 0 to 100, with higher numbers indicating greater comfort. Ratings were obtained in all cases and from all operators, resulting in a total of 106 XPF cap, 58 XPF thyroid collar, and 48 standard thyroid collar comfort ratings.
Table 2 shows the median duration caps and thyroid shields were worn as well as the mean comfort ratings. It is noteworthy that there was no significant difference in the comfort ratings between the XPF and standard collars (mean ± SD, 88.5 ± 14.6 vs 89.6 ± 9.9, respectively; \( p = 0.648 \)) and, compared with the thyroid collar ratings, a similar high comfort rating for the XPF caps was observed (83.4 ± 12.7) (Fig. 5). In 94.3% of the data sets, the comfort of the caps was rated 70 or greater. The durations the cap or collars were used did not correlate with the corresponding comfort ratings (Spearman correlation coefficient: 0.005 [\( p = 0.960 \]) for caps and –0.164 [\( p = 0.093 \]) for thyroid collars). For example, in the 24 cases with a duration of more than 120 minutes, the comfort of the cap was rated 85.0 ± 8.8 compared with 83.3 ± 13.1 in the 24 cases with a duration of less than 60 minutes (\( p = 0.608 \)).

**Discussion**

The number, complexity, and duration of fluoroscopy-guided endovascular interventions have dramatically increased and occupational radiation exposure received by operators is a growing concern. To address these concerns, national and international established guidelines based on the ALARA principle [5, 10, 11]; undoubtedly, personal protection devices play a key role in radiation protection.

Our prospective randomized controlled study of caps and thyroid collars made of a disposable, light-weight, lead-free material (XPF) provides evidence for an effective way to optimize
radiation protection. Both the XPF cap and XPF thyroid collar reduced radiation exposure by more than 75% and provided good wearing comfort with an average VAS comfort rating of greater than 80. Previous innovations to reduce radiation exposure of the head, including conventional suspended shields [12, 13], a protection cabin [9], protection shields with a complex overhead motion system [14], and lead caps [15], have been reported. All devices were shown to provide a more complete protection but all have specific limitations preventing operators from using these devices during clinical work. Positioning for optimal protection during complex interventions requires frequent manipulations to account for tube angulations, motions of patient table, and changes in operator stance. Bulkiness and wall or ceiling fixation that impair the mobility of the operator limit the use of these devices. Furthermore, reduced access to the patient and vision limitations due to sterile covers on the devices decrease their usefulness in clinical practice.

Protective caps may represent an effective alternative and the use of a 0.5-mm lead-equivalent cap has been shown to be even more protective than an overcouch shield with 1.0-mm lead equivalence, indicating better protection against the significant amount of scatter radiation reflected by the laboratory walls that reach an operator’s head [15]. Unfortunately, the additional weight of the tested cap (≈1140 g) may induce discomfort and debilitating musculoskeletal disorders in the long term. The XPF cap represents a reasonable alternative given its average weight of less than 150 g. The high operator comfort ratings for the XPF caps observed in our study are therefore encouraging. As a major advantage, the disposability of XPF eliminates hygiene concerns and may facilitate implementation and acceptance of XPF caps among operators. As shown in our study, a significant cumulative radiation dose at the head was detectable (at least 15,700 µSv after 106 procedures), and given the detection limits of our detectors, the cumulative radiation dose was likely even higher. Every measure to optimize radiation protection of this body part is therefore recommended.

Our study has four major limitations. First, because of the detection limit of the detectors used, radiation exposure was not detectable in all cases. In combination with a higher variance in radiation attenuation than expected, we failed to show the prespecified noninferiority limit of −0.7% for XPF. However, the lower margin of the one-sided 95% CI indicates that the attenuation provided by XPF thyroid collar is no more than 3.6% less effective than the standard 0.5-mm lead-equivalent protection device. On the other extreme, the CI included that the XPF thyroid collars may have provided 19.3% more effective radiation protection than standard thyroid collars; thus, additional research is warranted to clarify this uncertainty.

**TABLE 2: Operator Comfort Assessment**

<table>
<thead>
<tr>
<th>Radiation Protection Device</th>
<th>Total (n = 106)</th>
<th>XPF (n = 58)</th>
<th>Standard (n = 48)</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td>Cap</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of wear (min)</td>
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<td></td>
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</tr>
<tr>
<td>Median</td>
<td>87</td>
<td>86*</td>
<td>90*</td>
<td>0.865</td>
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<tr>
<td>IQR</td>
<td>66–117</td>
<td>66–125*</td>
<td>61–110*</td>
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<tr>
<td>Comfort (VAS)</td>
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<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>83 ± 13</td>
<td>85 ± 13*</td>
<td>82 ± 13*</td>
<td>0.307</td>
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<tr>
<td>Thyroid collar</td>
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<td></td>
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<tr>
<td>Duration of wear (min)</td>
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<tr>
<td>Median</td>
<td>87</td>
<td>86</td>
<td>90</td>
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<td>IQR</td>
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<td>66–126</td>
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<tr>
<td>Comfort (VAS)</td>
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<tr>
<td>Mean ± SD</td>
<td>89 ± 13</td>
<td>89 ± 15</td>
<td>90 ± 10</td>
<td>0.717</td>
</tr>
</tbody>
</table>

Note—IQR = interquartile range, VAS = visual analog scale. *XPF caps were used in both groups.

Range of scores: 0–100, with 0 meaning unbearably heavy, mal-fitting; and 100, very light, well-fitting.
Second, we did not directly compare the XPF cap with a lead cap. The high weight of the lead cap (= 1140 g) was declared to be not acceptable in daily clinical practice by the operators. In fact, no standard head protection device exists and most operators worldwide do not use any specific head protection device at all. Nevertheless, the design of our study including the simultaneous randomized comparison of an XPF thyroid collar with a standard 0.5-mm lead-equivalent thyroid collar and the XPF cap enabled us to compare radiation attenuation across the groups.

Third, operators were not blinded with regard to the thyroid collar group assignment; thus, we cannot completely exclude bias in the operators’ comfort ratings. However, the heavier standard thyroid collar was rated 100 (optimal) in 31% of the cases, likely reflecting the fact that the operators were already accustomed to their use and arguing against a systematic operator bias toward the newer device. The XPF devices used were prototypes, and further optimization in design and materials (e.g., of the hook-and-loop fasteners [Velcro, Velcro Industries B.V.]) may improve wearing comfort of future XPF devices.

Fourth, radiation attenuation abilities of protection devices are not constant throughout all radiation energy levels; thus, the radiation attenuation may differ when other types of radiation sources or energy levels are used. However, the broad spectrum of diagnostic and interventional procedures in our study make our results applicable for most fluoroscopy-guided cardiovascular procedures with x-ray energies of 20–150 kV.

In summary, the results of the current study show that XPF caps and XPF thyroid collars provide radiation protection comparable to 0.5-mm lead-equivalent protection devices. The lighter weight and disposability make XPF an attractive option to optimize individuals’ radiation protection, both by covering a previously largely unprotected body area and by increasing compliance among operators and ancillary personnel.

Acknowledgments
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References