Lightweight Bilayer Barium Sulfate–Bismuth Oxide Composite Thyroid Collars for Superior Radiation Protection in Fluoroscopy-guided Interventions: A Prospective Randomized Controlled Trial

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Purpose: To test whether newer bilayer barium sulfate–bismuth oxide composite (XPF) thyroid collars (TCs) provide superior radiation protection and comfort during fluoroscopy-guided interventions compared with standard 0.5-mm lead-equivalent TCs.

Materials and Methods: Institutional review board approval and written informed consent were obtained for this HIPAA–compliant study, and 144 fluoroscopy-guided vascular interventions were included at one center between October 2011 and July 2012, with up to two operators randomly assigned to wear XPF (n = 135) or standard 0.5-mm lead-equivalent (n = 121) TCs. Radiation doses were measured by using dosimeters placed outside and underneath the TCs. Wearing comfort was assessed at the end of each procedure on a visual analog scale (0–100, with 100 indicating optimal comfort). Adjusted differences in comfort and radiation dose reductions were calculated by using a mixed logistic regression model and the common method of inverse variance weighting, respectively.

Results: Patient (height, weight, and body mass index) and procedure (type and duration of intervention, operator, fluoroscopy time, dose–area product, and air kerma) data did not differ between the XPF and standard groups. Comfort was assessed in all 256 measurements. On average, the XPF TCs were 47.6% lighter than the standard TCs (mean weight ± standard deviation, 133 g ± 44; P < .001) and had a significantly higher likelihood of a high level of comfort (visual analog scale >90; odds ratio, 7.6; 95% confidence interval: 3.0, 19.2; P < .001). Radiation dose reduction provided by the TCs was analyzed in 117 data sets (60 in the XPF group, 57 in the standard group). The mean radiation dose reductions (ie, radiation protection) provided by XPF and standard TCs were 90.7% and 72.4%, with an adjusted mean difference of 17.9% (95% confidence interval: 7.7%, 28.1%; P < .001) favoring XPF.

Conclusion: XPF TCs are a lightweight alternative to standard 0.5-mm lead-equivalent TCs and provide superior radiation protection during fluoroscopy-guided interventions.

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Introduction

Fluoroscopy-guided diagnostic and interventional procedures have increased substantially during the past decades (1). An increased incidence of cataracts, and possibly cancer and other diseases, has been associated with occupational radiation exposure (2,3). Although in recent years, several lighter leaded and lead-free materials have been approved by the Food and Drug Administration for radiation protection, apron weight–associated discomfort and fatigue during prolonged procedures, as well as chronic back problems, are well known among interventional operators (4,5). There is a clinical need for improvements in radiation attenuation capability, as well as comfort of personal radiations protection. Preliminary experimental data showed that a newer bilayer barium sulfate–bismuth oxide composite (XPF) provides better radiation attenuation per weight (in the range of 60–130 kVp) than do other commercially available 0.5-mm lead-equivalent materials (6). However, the attenuation measured in an experimental in vitro setting refers to primary beams only and does not include scatter radiation, which is a major portion of the occupational radiation exposure in clinical practice. Thus, the quality of radiation protection of a device is best measured in the specific clinical setting to account for patient and procedural factors that affect scatter radiation, as well as for the positioning, shape, and size of the shield. Because of a lack of power, a previous small clinical pilot study failed to meet the prespecified noninferiority limit for XPF compared with standard protection (7). However, the reported 95% confidence interval of the radiation protection difference between XPF and standard protection was wide (range, −5.9% to 21.6%) and indicated that XPF might provide up to 21.6% greater radiation protection. The purpose of this larger study was to test in a clinical setting whether newer XPF thyroid collars (TCs) provide superior radiation protection (primary objective) and comfort (secondary objective) during fluoroscopy-guided interventions compared with standard 0.5-mm lead-equivalent TCs.
Materials and Methods

This investigator-initiated, single-center, prospective, randomized controlled trial was performed in the interventional radiology suites of a tertiary care center. Institutional review board approval was obtained for this Health Insurance Portability and Accountability Act–compliant study, and all participating operators provided written informed consent. The study is registered at www.ClinicalTrials.gov (NCT01611454), and this article is written according to the reporting standards of the Consolidated Standards of Reporting Trials statement (8). The manufacturer of the XPF radiation protection devices (BloXR, Salt Lake City, Utah) provided the XPF TCs and radiation detectors used in this study. The study was designed, the data were collected and analyzed, and the manuscript was prepared exclusively by the study investigators, all of whom made the decision to submit the manuscript for publication and vouch for the accuracy and completeness of the data and analyses.

Procedures

On the basis of the sample size power analysis, measurements were performed in 144 vascular interventional radiology procedures requiring C-arm fluoroscopy between October 2011 and July 2012. Fourteen of 15 interventionalists agreed to participate in the study, and whenever a procedure was performed by two operators (n = 112), both were randomized, resulting in a total of 256 data sets. Patient (weight, height, and body mass index) and procedure (type and duration of intervention, operator, fluoroscopy time, dose–area product [DAP], and air kerma) data for each intervention were documented. As is customary, the system (Allura Xper FD20; Philips Medical Systems, Best, the Netherlands) had 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 89.5–119.5 cm. All tubes had DAP meters indicating the summed cumulative DAP (in centigray–square centimeters). DAP is used as a surrogate measurement for the total amount of radiation energy delivered to the patient and, hence, also serves as a relative indication of the scatter dose to the operator.

Protection Devices and Randomization

Immediately before each procedure, the operators were assigned to wear XPF TCs or standard 0.5-mm lead-equivalent TCs (Fig 1) by an independent member of the research department by using a random list of group assignment numbers (Research Randomizer, version 3.0; http://www.randomizer.org). When a procedure was performed by two operators, each was randomly assigned independently. The experimental shielding material, XPF, is approved as a personnel protective shield (Food and Drug Administration 510[k] number K110900). Two commercially available types of leaded and lead-free TCs (Ultra-Lite or Earth-Lite; Pulse Medical, Davie, Fla) were used as standard TCs in our institution. Fourteen XPF TCs and 14 standard TCs were weighed by using a scale with an accuracy of ±0.01 g according to the manufacturer (EL–2000S; Setra Weighing Systems, Boxborough, Mass).

Measurement of Radiation Exposure

Radiation doses in each procedure were measured with two optically stimulated luminescence dosimeters (Luxel+; Landauer, Glenwood, Ill) placed side by side—one outside the standard or XPF TC and one underneath the TC at a standardized position. Radiation dose (in millirems) was reported as a shallow dose equivalent, which applies to the external exposure of the skin or extremity at a tissue depth of 0.007 cm (7 mg/cm²) averaged over an area of 1 cm² and converted to microsieverts by multiplication with factor 10 (equivalent dose). The radiation protection (the predefined primary outcome) was calculated as specified later. The dosimeters were calibrated with x-ray beams identical to those used in clinical practice, and the sensitivity threshold for the dosimeters was approximately 10 µSv. After the procedure, the dosimeters were sent to Landauer, and radiation exposure readings were performed blinded with respect to the dosimeter study group allocation (standard vs XPF) and position (outside vs underneath).

Operator Comfort Assessment

After completing a procedure, the operators were asked to rate the comfort of wearing the TC on a scale from 0 (unbearably heavy, badly fitting) to 100 (very light, well fitting).

Statistical Analyses

The radiation protection (radiation dose reduction) expressed as a percentage was calculated by subtracting radiation measured underneath the TC from radiation measured outside the TC and then dividing this difference by the product of radiation measured outside the TC
multiplied by 100. The cumulative radiation doses were defined as the summation of all correspondent equivalent doses measured. Summary values were presented as mean ± standard deviation or median ± interquartile range (IQR). Normality was tested by using the Kolmogorov–Smirnov test. For normally distributed data, we used a two–sided unpaired Student t test, and for nonnormally distributed data, we used the nonparametric Mann–Whitney U test, Wilcoxon signed rank test, or χ² test, as appropriate. Because of the left skewed and slightly clustered distribution of radiation protection, the group means were compared by using a bootstrap method. To take the presence of more than one measurement per patient into account, we divided these analyses into three parts: (a) a comparison of measurements within patients with one value in the XPF and the other value in the standard group, (b) a comparison of group means in patients with just one measurement, and (c) a comparison of group means in patients with two measurements in the same group. For the latter comparison, the two values in each patient were first averaged. Each of these analyses provided an estimate of the difference in average radiation protection between the two groups. The overall estimate of this difference, its 95% confidence interval, and its P value were then obtained by means of the common method of inverse variance weighting.

For the analysis of comfort, the respective percentage was dichotomized into high comfort (ie, values >90%) or low to medium comfort (values ≤90%). A mixed logistic regression model with random effects for operators was then used to compare the likelihood of high comfort between both groups. A P value of less than .05 was considered to indicate a significant difference. All analyses were performed by using statistical software (R, version 2.15.2, Wirtschaftsuniversität Wien, Vienna, Austria; SPSS, version 20.0, IBM SPSS Statistics, Armonk, NY).

On the basis of previously reported dose reduction rates obtained during 60 procedures (total of 106 measurements, 78 analyzed dose measurements) (7), we estimated that approximately 25% of the outside radiation measurements would be below the detector threshold, so the sample size calculation indicated that a total of 256 measurements would be sufficient to demonstrate a 15% difference in radiation protection (effect size) between the groups with a statistical power of 80% and an α level of 5%. The null hypothesis was that the XPF TC would be equal to the standard 0.5-mm lead–equivalent TC with regard to radiation protection. The alternative hypothesis was that the XPF TC would be superior or inferior to the standard TC.

Results

Measurement Data

In 127 (49.6%) of 256 measurements, no radiation outside the TC was detectable. In 12 (4.7%) of 256 measurements, the radiation measured inside the TC was higher than that measured outside the TC, most likely because of an operator error, and these data were counted as a protocol violation. These measurements were excluded from further radiation protection analysis, resulting in 117 radiation protection measurements (60 in the XPF group and 57 in the standard group); however, an intention–to–treat analysis including these data sets showed the same findings as did the per–protocol analysis, which are reported later. All 256 data sets were included in the comfort analysis. Figure 2 displays the study and analysis flow. Table 1 displays and compares the procedure–specific data of the procedures with the XPF protection device (n = 60) with those of the procedures with the standard protection device (n = 57) included in the radiation protection analysis. No significant difference between the XPF and standard protection groups was detectable with regard to procedure and patient data as outlined in Table 1. No differences in fluoroscopy time, DAP, and air kerma were detectable between the groups. The cumulative radiation dose measured outside the TC was 34140 µSv, and the cumulative radiation dose inside the TC was 8670 µSv for an overall dose reduction of approximately 75%. The median radiation dose measured outside the TCs (140 µSv; IQR, 70–365 µSv) was significantly higher than the median radiation dose measured underneath the TCs (0 µSv; IQR, 0–50 µSv) (P < .001, Wilcoxon signed rank test).

Table 1

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<th>Procedure-specific Data</th>
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The radiation doses measured outside the TCs did not differ significantly between groups: radiation dose was 120 µSv (IQR, 60–320 µSv) in the XPF group and 190 µSv (IQR, 70–410 µSv) in the standard group (P = .233, Mann–Whitney U test). The XPF TCs provided significantly better radiation protection than did the standard 0.5-mm lead–equivalent TCs, as shown in Table 2, with an adjusted mean difference in radiation dose reduction between the XPF and standard TCs of 17.9% (95% confidence interval: 7.7%, 28.1%; P < .001) favoring XPF.
Operator Comfort Assessment

Mean XPF TC and standard TC weights were 133 g ± 14 and 254 g ± 44, respectively (P < .001, unpaired t test) (Fig 3). Thus, on average, the XPF TCs were 47.6% lighter than the standard TCs. The operator comfort rating on the visual analog scale (VAS) (score range, 0–100), with higher numbers indicating better comfort, was obtained in all cases and for all operators, resulting in a total of 135 XPF TC and 121 standard TC comfort ratings. The overall median comfort ratings were 90 minutes (IQR, 63–123 min): TCs were worn 87 minutes (IQR, 60–125 min) in the XPF group and 90 minutes (IQR, 66–121 min) in the standard group (P = .743, Mann–Whitney U test). The overall median comfort rating was 90 of 100 on the VAS (IQR, 90–100). Comfort ratings for the XPF TCs (VAS, 100; IQR, 90–100) were significantly better compared with the comfort ratings for the standard TCs (VAS, 90; IQR, 85–100; P = .001, Mann–Whitney U test). In the mixed logistic regression model with random effects for operators, the estimated conditional odds ratio of a high level of comfort (VAS >90) between the XPF and standard groups was 7.6 (95% confidence interval: 3.0, 19.2; P < .001) favoring XPF; the marginal proportions were 54.8% and 27.3%, respectively, with a marginal odds ratio of 3.2.

Discussion

The number, complexity, and length of fluoroscopy-guided interventions are increasing worldwide, resulting in increased and additive occupational radiation exposure to interventionalists. Personal protection devices, including aprons, goggles, and thyroid shields, play an important role in limiting radiation exposure; however, in daily practice, the weight of current shielding materials frequently leads to operator discomfort, fatigue, and orthopedic problems, such as chronic muscle hardening and chronic back or knee pain (5,9,10). Our randomized controlled trial results provide evidence that XPF has the potential to improve both radiation protection and comfort during fluoroscopy-guided interventions. When compared with the standard newest generation of 0.5-mm lead–equivalent TCs, XPF TCs were 48% lighter and simultaneously provided 18% better radiation protection.

Results from several studies indicate that long-term low doses of ionizing radiation can lead to significant somatic DNA damage in professionally exposed physicians (11–14), and our data demonstrate that interventional radiologists are exposed to a substantial cumulative radiation dose (34.1 mSv outside the TCs [unprotected body area] and 8.7 mSv at a protected body area [underneath the TCs]). Radiation awareness and use of equipment-mounted shielding seemed to be effective during our study, as indicated by a radiation exposure below the detector threshold in approximately 50% of the cases in our study. However, during the 256 cases monitored in our study, a procedure volume reached by many interventionalists within 1 year at high-volume centers, the cumulative radiation exposure at the thyroid level was greater than 34 mSv despite standard measures to limit radiation exposure (eg, by using ceiling–suspended transparent leaded plastic shields). Given the limitation of the detector threshold, the real overall cumulative radiation exposure was likely to be even higher than that observed and highlights the need for optimal personal radiation protection. As observed by others, leaded and lead–free standard protection devices provide suboptimal radiation protection (15), and the observation that the radiation protection is enhanced by 15%–20% by using XPF compared with standard leaded and lead–free material represents a potential important improvement in radiation safety. However, a major limitation of our study is that we did not compare the XPF thyroid shield with all commercially available thyroid shielding materials; thus, we cannot exclude the possibility that the XPF TC performs less favorably compared with protection shielding materials other than those used in our study.

The comfort of the XPF TC was rated significantly better in this study, but we cannot completely exclude bias in the interventionalists’ comfort rating because the operators could not be blinded with regard to the TC group assignment. A multicenter design and inclusion of more operators might have mitigated this limitation. However, the fact that the heavier standard TC was rated 100 (optimal) in 26% of the cases, likely reflecting the fact that the operators were already accustomed to their use, argues against a systematic operator bias toward the newer device. Although the difference in comfort was significant in our study, the comfort advantage of XPF TCs seems to be relatively small (VAS 100 vs VAS 90) and of questionable relevance. However, given the substantially lower weight of the XPF shielding, the improved comfort seems to be plausible, and the XPF weight advantage might be even more relevant in other applications (eg, aprons) in which the absolute weight difference as compared with standard protection is likely much greater. Particular strengths of the present study are its prospective
randomized design and the broad spectrum of diagnostic and interventional procedures ensuring that our results are applicable for most fluoroscopy-guided procedures.

In summary, our study results show that XPF TCs are a lightweight alternative to standard 0.5-mm lead-equivalent TCs and provide superior radiation protection during fluoroscopy-guided interventions. Protection devices made of XPF may have the potential to optimize radiation protection and operator comfort in the future; however, cost-effectiveness data are needed to facilitate more informed decision making.

**Advance in Knowledge**

- Bilayer barium sulfate–bismuth oxide composite (XPF) thyroid collars (TCs) are approximately 50% lighter than currently available standard 0.5-mm lead-equivalent TCs and simultaneously provide superior radiation protection during fluoroscopy-guided interventions.

**Implication for Patient Care**

- Protection devices made of XPF should reduce interventional operator radiation exposure and might have the potential to minimize discomfort, fatigue, and chronic back problems associated with wearing traditional protection material.

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**Footnotes**

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**Abbreviations:**

- DAP = dose-area product
- IQR = interquartile range
- TC = thyroid collar
- VAS = visual analog scale
- XPF = bilayer barium sulfate–bismuth oxide composite

**References**