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Lightweight Lead Aprons: The Emperor's New Clothes in the Angiography Suite?

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WHAT THIS PAPER ADDS

The aim of this study was to test the performance and labelling of garments that are in contemporary use for radiation protection. A significant proportion of garments failed to comply with international labelling standards and did not provide the protection claimed by manufacturers. In addition, garments labelled at the same lead equivalence performed vastly differently in attenuation of scatter. These findings were demonstrated in the real world setting, by testing garments that are in current use across multiple centres. The study highlights current concerns regarding radiation protection standards and the need to identify composites that can consistently provide better protection than lead.

Objective: The aim was to determine whether lead containing and lead free composite garments in current use provide the level of radiation protection stated by manufacturers.

Methods: Fifteen garments, produced by five different manufacturers using eight different composites, were randomly selected for testing from four hospitals in South Australia. Labelling, material composition, design, and condition of the garments were assessed by direct garment examination, garment label, and product information. Garment attenuation was tested in a simulated angiography suite using a Siemens Ysio Max digital Xray machine. The front and back panels of each garment were tested under direct beam at 100 kVp. A Perspex phantom was used to simulate the density and scatter properties of the human abdomen. The front panels of each garment were tested under scattered radiation at Xray tube voltages of 50 and 70 kVp.

Results: Forty-seven per cent of front panels and 90% of back panels provided lower lead equivalence than claimed by the manufacturer. Twenty per cent of front panels and 62% of back panels tested did not meet the minimum International Electrotechnical Commission requirements for angiographic use. There was a 38 fold difference in front panel performance of garments to scatter radiation, which were all labelled 0.5 mm lead equivalence. 56% of garments had differences in scatter transmission of at least 49% when tested at 50 and 70 kVp.

Conclusion: The results show that lead containing and lead free composite garments probably provide less radiation protection than manufacturer stated lead equivalence. The demonstrated wide variations in attenuation of scatter radiation are greater than previously reported. It was found that most garments failed to comply with labelling standards. The study highlights challenges in radiation shielding and the need to identify composites that consistently provide better attenuation per unit weight than lead.

Keywords: Lead, Protective clothing, Radiation dosage, Radiation protection, Radiation scatter
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INTRODUCTION

The number and complexity of procedures performed using interventional radiology is increasing.[1] These procedures can be prolonged and require staff to be in close proximity to the patient. In the working environment, the interventionist should, under no circumstances, be subject to direct beam exposure. Provided basic radiation protection principles are followed, radiation exposure to staff is likely to be entirely due to the scattered beam. Adequate radiation protection for healthcare workers, especially those performing interventional radiology procedures, is critical. Lead has traditionally been used in protective garments and shields across the range of radiation energies typically found in diagnostic and interventional procedures.

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Lead is particularly suitable for radiation protection because of its high absorption and attenuation of Xray photons and its relatively cheap cost to manufacture. However, lead is a heavy material, and when worn can lead to chronic musculoskeletal disorders.[2] These musculoskeletal effects may reduce the quality of life and productivity of workers.

Given the problems associated with lead's weight, there is ongoing interest in developing lighter weight alternatives, including lead containing and lead free composites. Combinations of metals including antimony, bismuth, tin, aluminium, tungsten, titanium, and barium have been used. Lead only garments have largely been surpassed in favour of lighter weight alternatives that offer 25–40% weight reductions and are more flexible.[3,4] However, verifying manufacturer claims about how these garments compare to traditional lead garments regarding their protective properties can be challenging. In addition, the performance of composites has been mixed, with composites often underperforming relative to the stated lead equivalence.[3,5–9]

International standards and garment labelling

The level of protection provided by protective garments is described in terms of millimetres of lead equivalence (mm Pb LE), defined as the "thickness of lead, which would attenuate the same amount of radiation as the given material when exposed to radiation of the same type and quality".[3] The attenuation coefficient of a material determines how easily it can be penetrated by radiation, and is influenced by structural forces at atomic level, which, in turn, are highly dependent on the tube voltage that the material is tested at.[4]

Most national standards, including European standards, are based on the International Electrotechnical Commission (IEC) International Standard 61331–3:2014.[10] The standard states that the thickness of "light workload" garments should be at least 0.25 mm Pb LE over the entire area and for "heavy workload" garments it should be at least 0.35 mm Pb LE at the front. Heavy workload use refers to angiographic type work and light workload encompasses all other work.

The primary aim of this study was to determine whether composite garments in current use provide the level of protection stated by manufacturers.

MATERIALS AND METHODS

The study aim was addressed by assessing garment (i) labelling; (ii) material composition; (iii) design; (iv) condition; (v) direct beam attenuation; and (vi) scatter attenuation. Owing to the heterogenicity of the published data, a meaningful power calculation was not possible. Fifteen garments were chosen as the maximum number available for testing without disrupting the daily workflow of the departments from which they were sourced. These were randomly selected for testing from four public hospitals within Adelaide, South Australia. They were a representative sample of garments used in angiography suites at the four sites. They were all transported and tested at the same facility under the same conditions on one day.

Labelling

The labelling of garments was tested against IEC International Standard 61331–3:2014.[10] The standard states that garments should be labelled with (i) name/trademark of the manufacturer or supplier; (ii) area density; (iii) attenuation equivalent; (iv) Xray tube voltage (and filtration); (v) size of garment; (vi) reference to the standard; and (vii) workload (heavy or light).

Material composition

The garment manufacturer and the proportion of garments where the exact material was stated on the label was recorded. If the material of the gown was not stated, an attempt was made to identify it using the manufacture's product information.

Design

A description of each garment was made and morphometric assessment of garment design regarding efficacy of coverage of the body was performed.

Condition

Owing to the potential confounding effect of a garment's physical condition on the results, an assessment was made by three investigators regarding the overall condition based on subjective degree of "wear and tear": (i) heavy; (ii) medium; (iii) light; (iv) new.

Table 1 Provides a description of the garments examined.

Direct beam attenuation

Garment attenuation was tested in a simulated angiography suite using a Siemens Ysio Max (Siemens Healthcare, Erlangen, Germany) digital Xray machine with field area of 10 cm × 10 cm. Garments were placed 100 cm from the Xray machine and a Raysafe Xi solid state radiation detector (Unfors RaySafe AB, Billdal, Sweden) was placed behind the garment prior to exposure to the direct beam (Fig. 1). Prior to testing, repeated measures of each parameter were performed to confirm equipment performance. Consistency was excellent with negligible differences; coefficients of variation were 0.23% kVp, 0.06% exposure time, and 0.1% tube output.

The front and back panels of each garment were tested under direct beam at 100 kVp. The duration of each Xray was 100 ms and the resulting measurement was an average of three separate measurements. The lead equivalence of each garment was calculated from its attenuation with no apron present, and by repeating this with high purity lead foils, the lead equivalence could be determined using the Archer equation.[11] The use of broad beam geometry in the measurement incorporates the production of scatter within the material being investigated. In long garments, measurements were taken at the chest to measure dose to the radiosensitive organs of interest. In garments with an overlapping front section, measurements were taken at the

Table 1. Description of garments used in 15 investigated apron models, including composition of garment, compliance with International Electrotechnical Commission (IEC) Standards and lead equivalence values

Garment number	Material composition	Design	Condition	Labelling compliance	Lead equivalence: front panel (mm Pb)	Lead equivalence: back panel (mm Pb)
1	Composite	Open back apron	Heavy	Fail[a,b]	0.38	No back
2	Composite	Closed back apron	Medium	Fail[a,b]	0.87	0.25
3	Composite	Vest	Light	Fail[b]	Transmission undetectable	0.49
4	Composite	Skirt	Medium	Pass	0.47	0.23
5	Composite	Vest	New	Fail[b]	0.84	0.18
6	Composite	Vest	New	Pass	0.97	0.22
7	Lead free composite, including antimony	Skirt	Heavy	Fail[a,b]	0.30	0.22
8	Pb: 70—90%, Plastisol: 10—30%	Closed-back apron	Light	Fail[b]	0.30	0.31
9	Pb: 50—70%, Sb: 20—40%, Plastisol: 10—20%	Open-back apron	Medium	Fail[b]	0.66	No back
10	Composite	Vest	New	Pass	0.85	0.16
11	Composite	Poncho	Heavy	Fail[b]	0.34	0.33
12	Composite	Skirt	Medium	Fail[b]	0.48	0.24
13	Bismuth, antimony	Vest	New	Fail[a,b]	0.44	0.21
14	Composite	Closed back apron	Heavy	Fail[a,c,d]	0.60	0.33
15	Bismuth, antimony	Vest	New	Fail[b]	0.45	0.22

Pb = lead; Sb = antimony; Bi = bismuth.
[a] size of garment
[b] workload (heavy or light)
[c] attenuation equivalent
[d] x-ray tube voltage (and filtration)

overlap section as this is the part which the manufacturer stated lead equivalence refers to.

Scatter attenuation

A Perspex phantom (17.5 cm × 17.5 cm × 29 cm) was used to simulate the density and scatter properties of the human abdomen. Garments were placed below and 50 cm away from the phantom to simulate the position of an operator in relation to a patient on an angio table. A Raysafe XI radiation detector was placed inside the garment to measure the amount of scattered radiation reaching the operator (Fig. 1). In order to compare a homogenous group of garments, scattered radiation attenuation was tested by front panels only of the 9 garments labelled 0.5 mm Pb LE. Xray tube voltages of 50 kVp and 70 kVp were used, with a 200 ms exposure duration. Results were reported with a transmission coefficient, given as a percentage.

$$\text{Transmission coefficient } (\%) = \frac{\text{Dose with barrier } (\mu\text{Gy})}{\text{Dose without barrier } (\mu\text{Gy})} \times 100$$

RESULTS

Labelling

Compliance to IEC International Standard 61331—3:2014 labelling standard is detailed in Table 2. The majority (80%) of labels failed the standard. Eighty per cent failed to state whether the garment was intended for heavy or light use. The attenuation equivalence and Xray tube testing voltage were each missing in 7%. Thirty-three per cent did not have sizing labels.

Most vests and skirts have an area of overlap at the front where the material thickness is doubled. Many manufactures rely on this overlapping design to provide the required minimum thickness for the front panel.[12] Labels were unclear regarding whether the stated lead equivalence referred to the single layer or overlapping area. This apparently simple overlap design varied significantly among garments tested and was fundamental to whether the vest provided adequate coverage. If the overlap was large then the degree of protection was adequate; however, a narrow overlap led to a large area of the vest failing to provide adequate protection, despite purported front panel protection of 0.5 mm Pb (Fig. 2).

Material composition

The 15 garments were produced by five different manufacturers using eight different composites. These composites were identified by proprietary names and included lead containing and lead free composites. None of the labels provided information regarding material composition. Details from manufacturers pertaining to only three composites were found. Descriptions included containing “antimony and bismuth” and containing “70—90% lead and 10—30% plastisol”.

Design

The 15 garments consisted of five different designs: open back apron ($n = 2$), closed back apron ($n = 3$), poncho ($n = 1$), vest ($n = 6$), and skirt ($n = 3$).

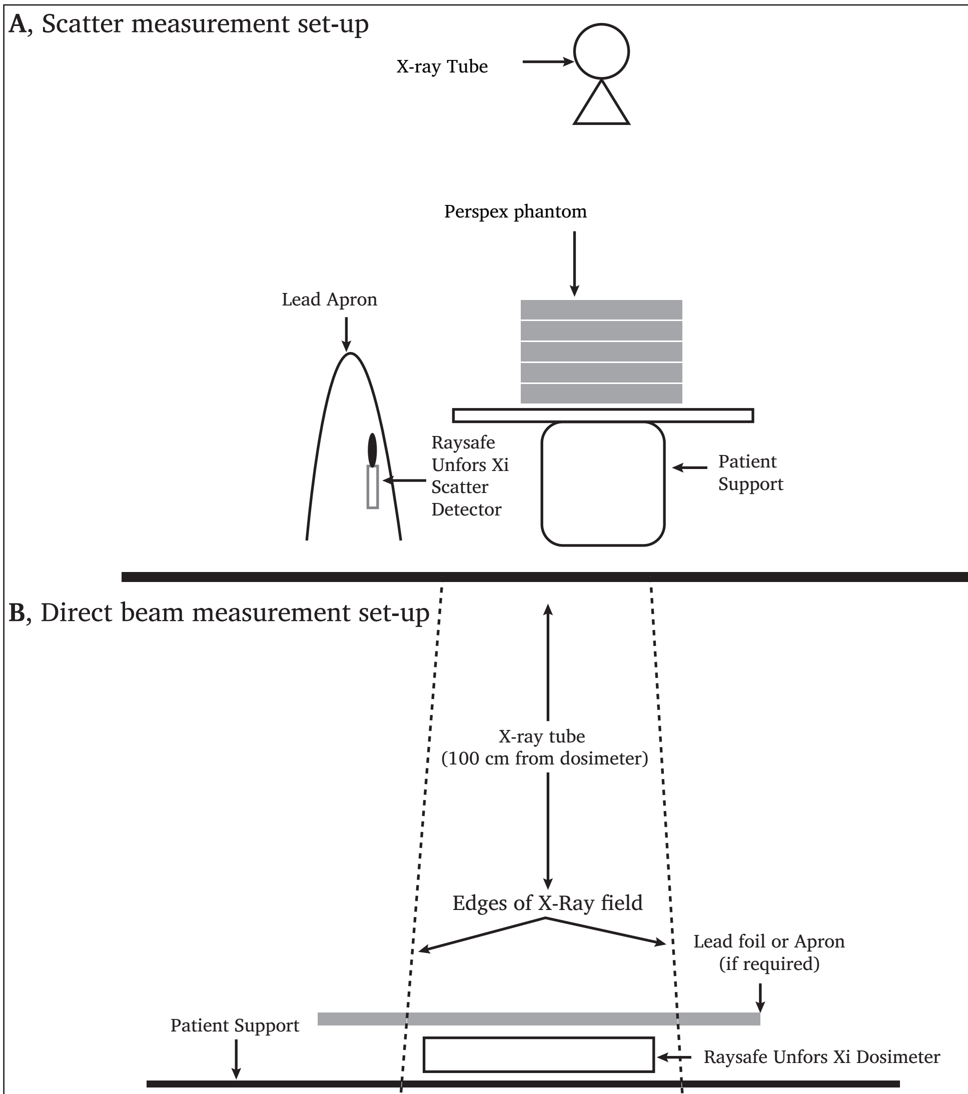

Figure 1. Set up for scatter attenuation measurement (A) and direct beam attenuation measurement (B).

Table 2. Compliance with International Electrotechnical Commission (IEC) International Standard 61331–3:2014 by labelling item

Labelling item	Number of compliant garments	Percentage of compliant garments
Name/trademark of manufacturer or supplier	15/15	100
Area density[a]	NA	NA
Attenuation equivalent	14/15	93
Xray tube voltage (and filtration)	14/15	93
Size of garment	10/15	67
Reference to the standard[a]	NA	NA
Workload (heavy or light)	3/15	20

NA = not applicable.
[a] Not recorded in study.

Direct beam attenuation

Front panel. All 15 garments had front panels and were tested. Seven garments (47%) provided lower than the stated attenuation equivalence (Fig. 3). Three (20%) garments provided $<$ 0.35 mm Pb LE protection and fell below the minimum IEC requirement for front panel angiography use.

Back panel. Two garments did not have a back panel and therefore were not tested. Three garments with a back panel did not display a stated lead equivalence and

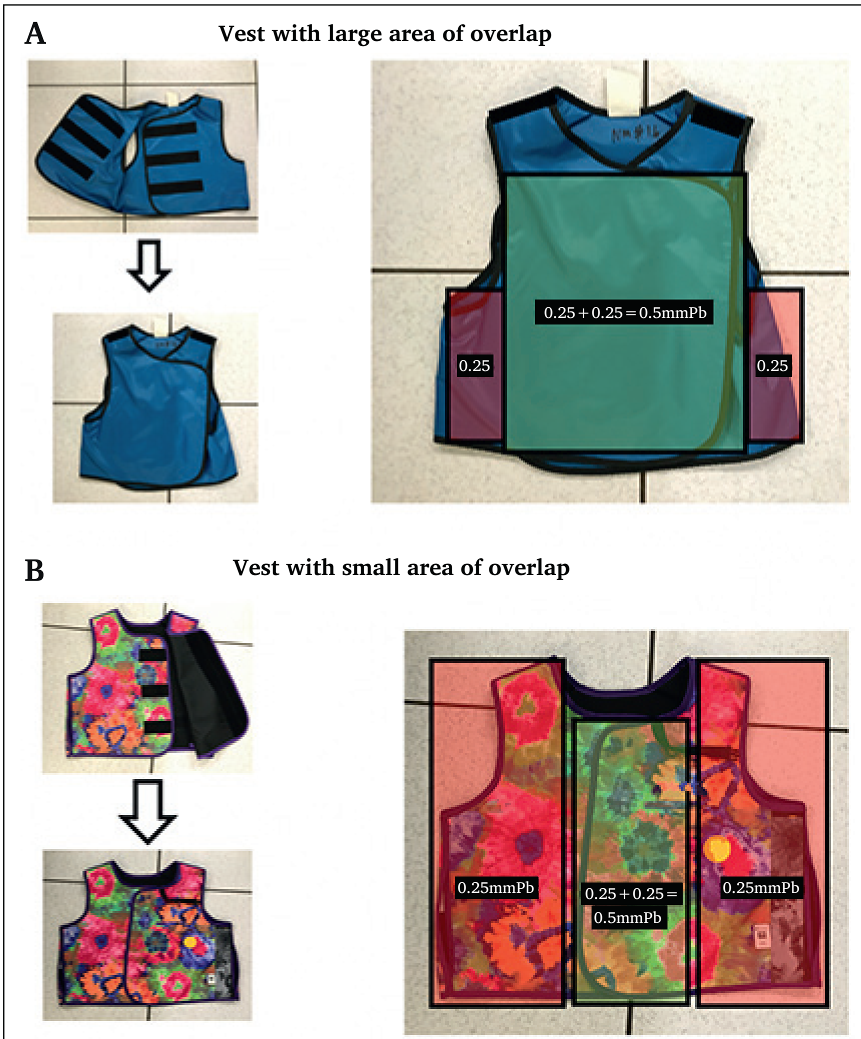

Figure 2. Vest with a large area of overlap resulting in minimal areas of reduced protection at the side (A) vs. vest with small area of overlap resulting in large areas of reduced protection at the side (B). Pb = lead.

therefore comparisons with the manufacturer's stated protection could not be made. When testing the remaining 10 garments with the manufacturer's stated back panel equivalence, nine (90%) provided lower than the stated attenuation equivalence (Fig. 4). Of the 13 garments with back panels, eight (62%) provided < 0.25 mm Pb protection and fell below the minimum IEC requirements for back panels.

Scatter attenuation

Attenuation of scattered radiation was highly variable among the nine garments tested (Fig. 5). Transmission varied up to 38 fold from 0.05% to 1.90% between garments with purported identical protection according to the manufacturer. Individual garments performed significantly differently and unpredictably when tested at the two different Xray tube voltages, 50 kVp and 70 kVp. Five of the nine garments (56.6%) had differences in transmission of at least 49% between these two energies. For example, garment no. 6 permitted a 52% increase in transmission at a lower testing energy (0.79% at 50 kVp vs. 0.52% at 70 kVp), whereas garment no. 7 permitted a 388% increase in transmission at the higher energy (0.49% transmission at 50 kVp vs. 1.90% transmission at 70 kVp).

Condition

The condition of the garments was well distributed between heavy ($n = 4$), medium ($n = 4$), light ($n = 2$), and new ($n = 5$) in appearance. All gowns are assigned a 10 year "lifespan" prior to decommission and all aprons had been purchased within this time period. Although there was a trend towards decreased attenuation in front panel with older garments ($p = .32$), the converse was true for the back panel ($p = .004$). Owing to the small numbers involved, additional statistical analysis was made comparing an older group ("heavy" and "medium") to a "newer" group ("light" and "new"). Applying the Mann—Whitney and Krukal—Wallis tests, there was no statistically significant difference in attenuation with subjective assessment of garment condition (Table 3).

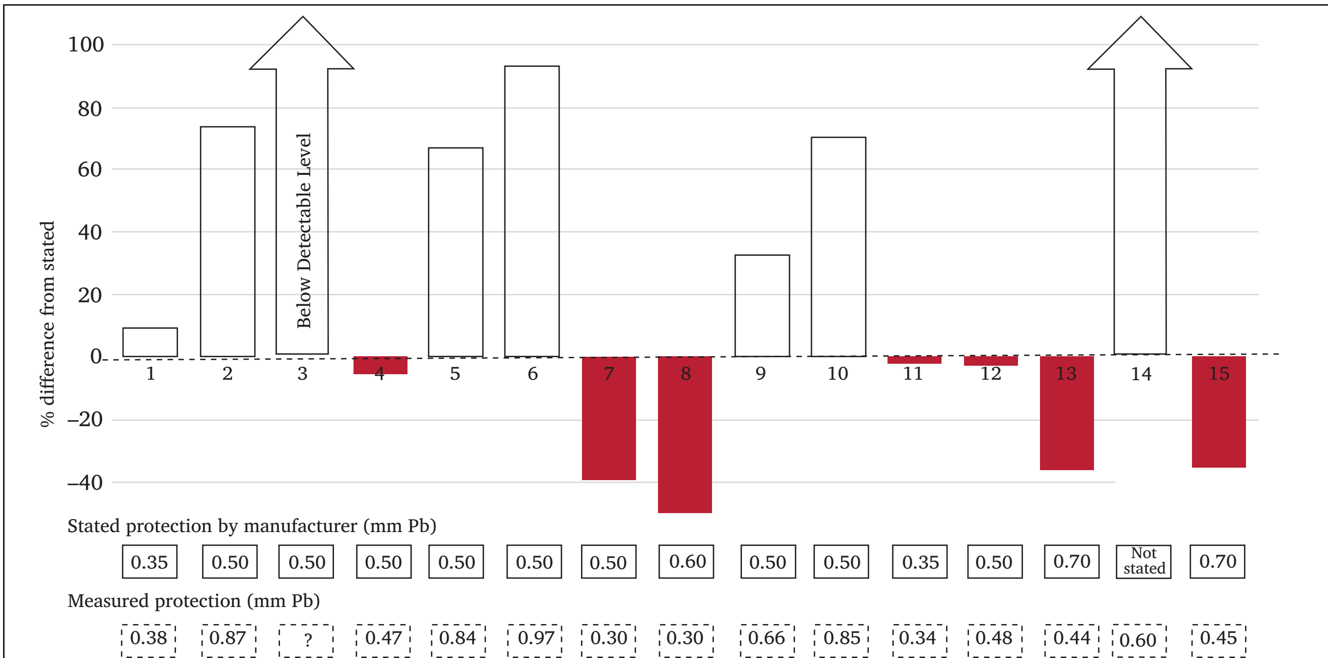

Figure 3. Front panel lead equivalence to direct beam. Each garment has been assigned an arbitrary identification number (1–15) on the *x* axis and the manufacturer's stated protection (mm Pb LE) is displayed at the bottom (solid box). The actual measured protection (mm Pb LE) is displayed directly beneath (dotted box). The bar graphs represent the percentage difference of the actual protection compared with the manufacture's stated. Garments that performed better than expected are depicted as a bar above the *x*-axis in white, and those that performed worse as a bar below the x axis in red. Garment no. 3 measured an unrecordable attenuation and therefore performed better than stated to an undetermined degree. Garment no.14 had no manufacture's stated protection making comparison impossible but performed well at a measured protection of 0.6 mm Pb LE. Pb = lead.

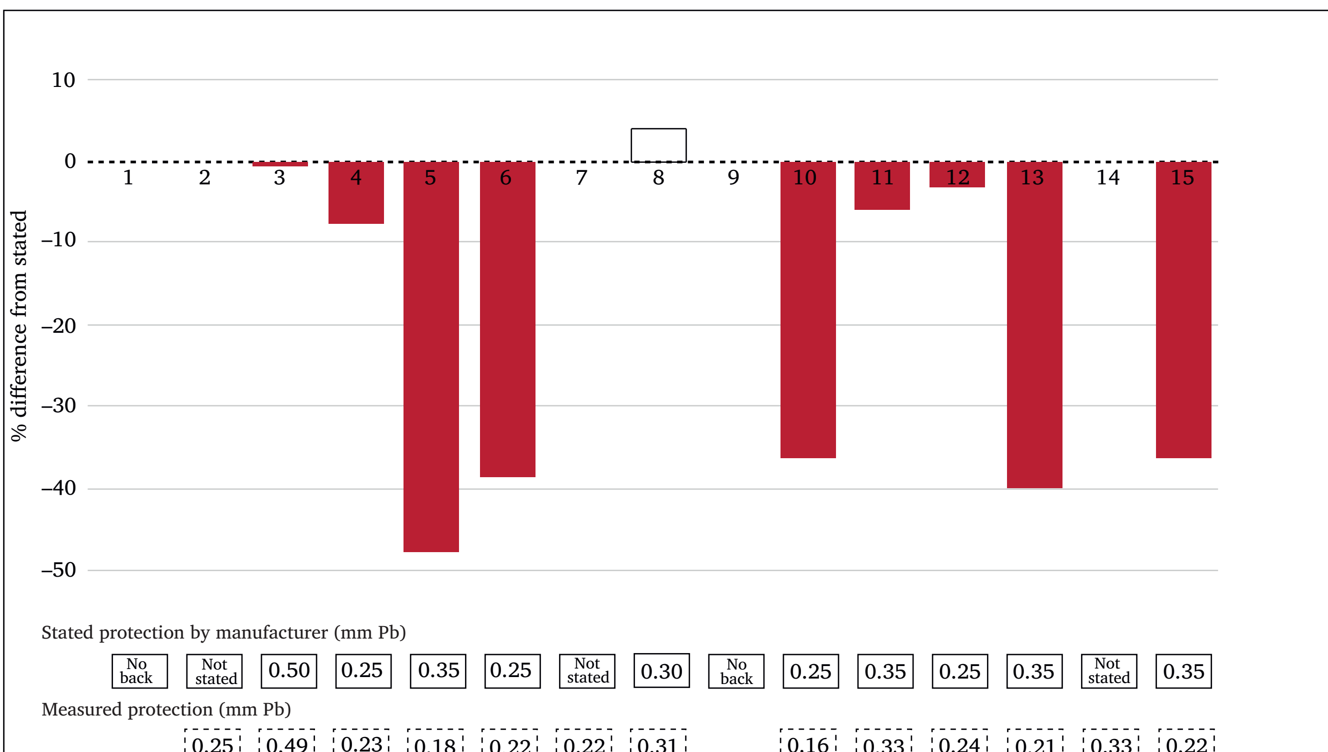

Figure 4. Back panel lead equivalence to direct beam. Each garment has been assigned an arbitrary identification number (1–15) on the *x* axis and the manufacturer's stated protection (LE, Pb mm) is displayed at the bottom (solid box). The actual measured protection (LE, Pb mm) is displayed directly beneath (dotted box). The bar graphs represent the percentage difference of the actual protection compared with the manufacturer's stated. Garments that performed better than expected are depicted as a bar above the *x* axis in white, and those that performed worse as a bar below the *x* axis in red. Garment nos: 1 and 9 had no back and were therefore not tested. Garment nos: 2, 7, and 14 did not display any stated manufacturer's protection for the back panel and therefore a comparison could not be made. Pb = lead.

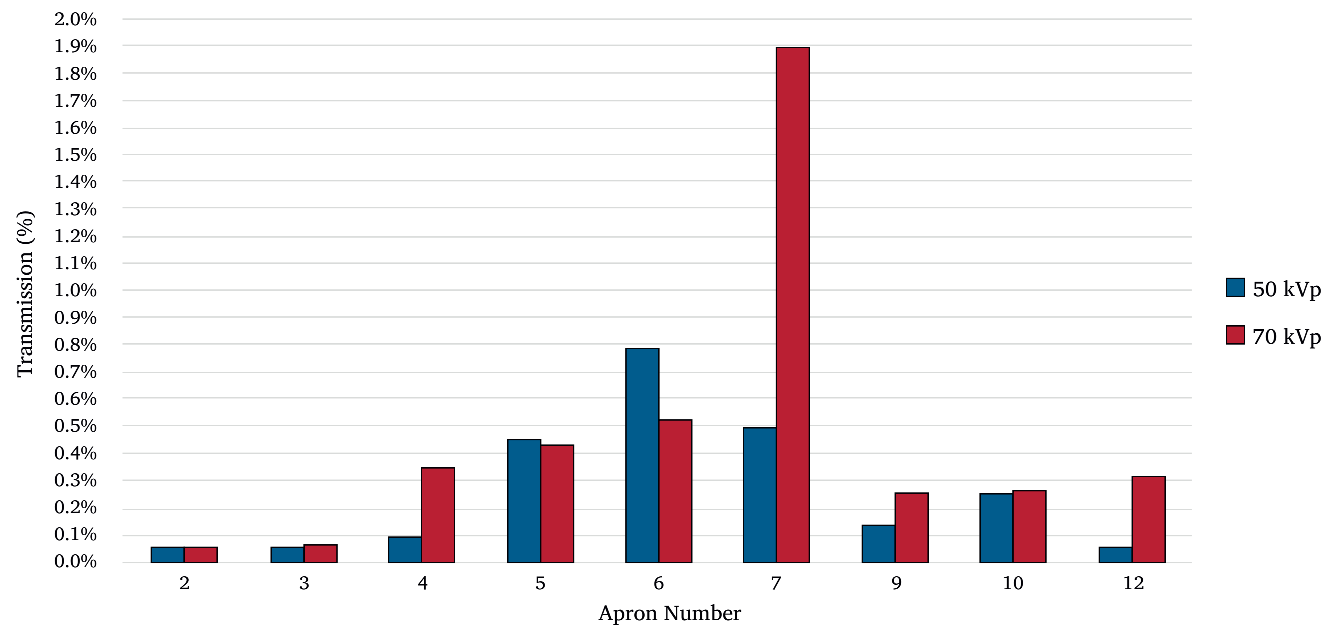

Figure 5. Transmission of scattered radiation at tube voltages 50 kVp and 70 kVp by front panels of 9 garments labelled 0.5 LE mmPb. Pb = lead.

DISCUSSION

Radiation physics and performance of composite garments

The attenuation coefficient is used to describe how strongly a material interacts with radiation. Generally, the attenuation coefficient decreases with lower density materials and with higher incident photon energy. The "K-edge" is the binding energy of the innermost electron shell of the atoms within the material being tested. At this energy level, there is an abrupt increase in attenuation coefficient such that the photons just above this energy level are much more easily absorbed than photons just below this energy level. This non-linear behaviour is depicted as "spikes" on attenuation coefficient figures. The K-edge is highly variable among different materials and this has a significant influence on the attenuation coefficient, especially when exposed to the range of photon energies used in medical radiology. Xray tube voltages, which determine the incident photon energy, typically range from 60 to 125 kVp for diagnostic radiology and up to 140 kVp for angiography.[13,14]

The attenuation coefficient of lead has a relatively linear relationship with incident photon energy levels within the range of tube voltages typically used, with little K-edge influence (Fig. 6). Other elements used in composites, such as antimony, do not have such a predictable and linear behaviour, and the K-edge of the material becomes highly influential. In order to compensate for this phenomenon, manufacturers use multiple materials with different attenuation coefficients to provide an "overlap" of protection to exploit the K-edge.

Performance of lead composites has been mixed, with composites often underperforming relative to the stated

Table 3. Effect of garment condition on transmission attenuation (measured in Pb LE)

	Overall older group		Overall newer group		p-value
	Heavy	Medium	Light	New	
Transmission Front Panel					
Number of garments	8		7		
	4	4	2	5	
Pb LE (mm)	0.48 (0.36-0.87)		0.84 (0.44-0.97)		.351[a]
	0.37 (0.31-0.55)	0.57 (0.47-0.82)	0.65 (0.3-1.0)	0.84 (0.45-0.91)	.316[b]
Transmission Back Panel					
Number of garments	7		7		
	3	4	2	5	
Pb LE (mm)	0.25 (0.23-0.33)		0.22 (0.18-0.31)		.152[a]
	0.33 (0.22-0.33)	0.25 (0.25-0.25)	0.4 (0.31-0.49)	0.21 (0.17-0.22)	.004[b]

Data are median (interquartile range). LE = lead equivalence; Pb = lead.
[a] Mann—Whitney test.
[b] Kruskal Wallis refers to 'one-way ANOVA on ranks'.

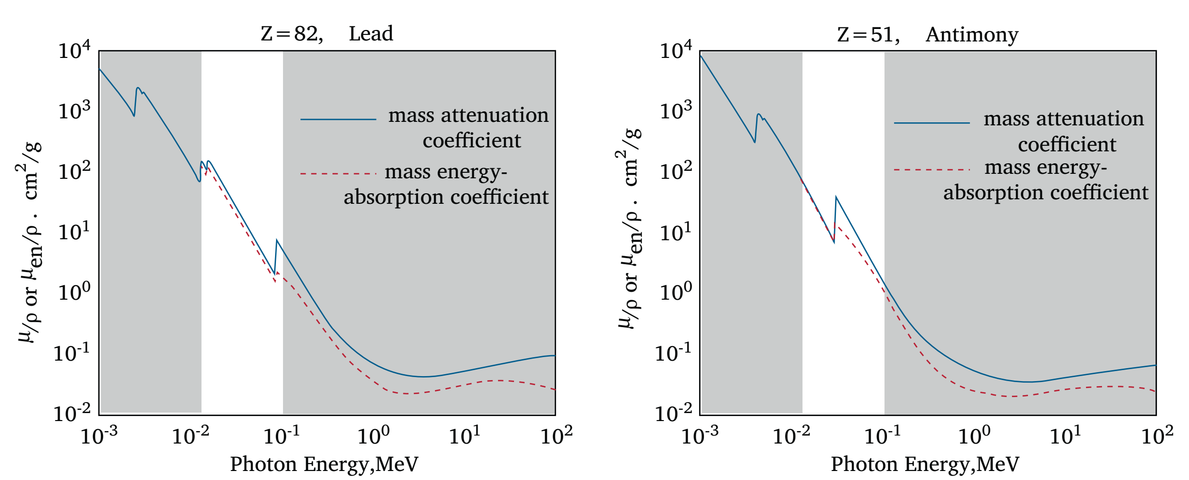

Figure 6. Relationship between attenuation coefficient (μ/ρ in cm^2/g) and photon energy (MeV) for lead (left) and antimony (right). The white area highlights the typical range of energy levels encountered in diagnostic radiology. Adapted from X-Ray Mass Attenuation Coefficients, National Institute of Standards and Technology[25].

lead equivalence.[3,5–9] Studies have reported composites transmitting as much as double the radiation of equivalent lead only aprons,[7] with non-lead composites failing to provide better attenuation per unit weight than lead only and lead containing composites.[15,16] Lichliter *et al.* found up to 12 fold transmission differences for composites labelled 0.5 mm Pb LE.[15] Although some studies have found that composites are equivalent or better than lead at certain tube voltages it must be stressed that for adequate protection garments need to provide protection across a wide range of Xray voltages.[17,18]

This study has demonstrated a wide variation in compliance to labelling standards and protection provided by radiation protection garments tested in a real world setting.

It was found that most garments failed to comply with labelling standards. Given labelling requirements in most countries, including Australia, are based on IEC standards, it is possible poor labelling compliance is present worldwide.

Overall, the tested garments generally performed poorly both in terms of achieving the lead equivalence claimed by manufacturers, as well as meeting the minimum IEC requirements. Front panels generally provided much better protection than back panels, with 53% outperforming manufacturer stated lead equivalence. However, 20% still did not meet the minimum IEC requirements for angiographic use. Back panels performed poorly, with 90% underperforming according to manufacturer's claims, and 62% not meeting the minimum IEC requirements for angiographic use.

One criticism of current garment testing protocols is the heavy reliance on narrow direct beam testing. What is of much more concern is exposure to the more unpredictable scattered radiation, which is rarely tested. This study highlighted the concerning finding of a 38 fold difference in performance of garments to scatter, which purportedly all provided the same level of protection. This wide discrepancy is much larger than previously documented.[19] Furthermore, protection against scattered radiation was shown to be highly variable and unpredictable at different energies. While it is impossible to determine the absolute health risk that these findings represent, simple calculations assuming the linear no threshold model of radiation biology would suggest that it is statistically possible a fatal cancer could be induced by the widespread use of substandard radiation protection apparel. Therefore, it is important to apply vigilantly ALARA radiation protection principles ("as low as reasonability achievable") in the workplace in conjunction with providing appropriate protective garments and other forms of shielding to staff. These include a reduction of fluoroscopy and angiography duration, avoiding steep angulation, increasing the distance between healthcare workers and the radiation source, reducing magnification and frame rate, and the use of collimation.

Limitations

This study tested garments currently used in hospitals in a "real world" setting, which inevitably led to several limitations. Although an attempt was made to choose a selection of different garment designs and manufacturers, the choice was inevitably random and subject to availability. However, a good selection of garments has been demonstrated, varying in condition from heavily worn to new. Although the exact age of the garments within their 10 year procurement could not be confirmed, subgroup analysis failed to show that condition significantly affected the results (Table 3). Although shielding integrity looking for cracks in the garments was not performed in this study, as part of accreditation requirements, the relevant national codes of practice dictate that aprons within each health organisation are screened for shielding integrity annually and faulty garments removed.[20]

The testing environment was a simulated angiography suite. A real angiography suite could not be used as the Xray beam energy is automatically set by the machine, preventing measurement consistency and comparison of results. Therefore general radiographic apparatus was used with manual control of beam filtration, tube current, and photon energies. Although the Xray source was above the phantom (opposite to a real laboratory), to compensate for this discrepancy the garment and detector were positioned below the phantom in the equivalent position that an operator would be standing. While the use of a simulated laboratory failed to test the performance of the gowns in daily practice, it allowed for control of the numerous confounding variables that influence radiation exposure, resulting in an experimental set up focused on performance of gowns based on composition, design, and condition only.

It was hoped that testing could be performed across the range of Xray energies typically used in interventional radiology (60—140 kVp). This was not possible owing to a significant range of radiation energy and intensity between primary beam, scattered radiation, and attenuated scattered radiation. Although the use of multiple dosimeters would allow measurements across all energy and intensity ranges, comparison would be difficult. Although devices with dose and energy response ranges of this magnitude exist, such as large volume ionisation chambers, they have limited utility in a hospital environment and a prohibitively high cost. Therefore, the study was limited to the ranges measured, although the large variations in protection afforded even with these limited energies, was adequately shown.

The impact of scatter can affect direct beam attenuation measurement. In order to minimise this, the experiment was set up so that the location of the measurement probe would be minimally impacted by scatter reaching it over or around the apron. In addition the use of broad beam geometry in the measurement, incorporated the production of scatter radiation within the material being investigated.[21]

Finally, the exact composition of all eight of the composites tested could not be determined, and the study only determined nebulous details of three. This uncertainty does not alter the overall findings, and, in fact, highlights the difficulty in determining exactly what the garments are made of and how much protection they actually provide.

CONCLUSIONS

Radiation exposure can be significantly reduced by wearing protective garments, utilising mounted shields,[22—24] and adhering to ALARA principals. Currently, however, the complex and ambiguous nature of "lead equivalence" as a descriptor of radiation protection may result in confusion when choosing protective garments. It is recommended that garment labels better reflect the level of protection provided, and should include lead equivalence and transmission values at a range of photon energies at which the garment is designed to be used, including overlap and nonoverlap segments. Until then it is possible that garments will continue to fail to provide the protection that users expect and deserve.

CONFLICT OF INTEREST

None.

FUNDING

None.

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COUP D'OEIL

External Iliac Artery Aneurysm Causing Severe Venous Obstruction

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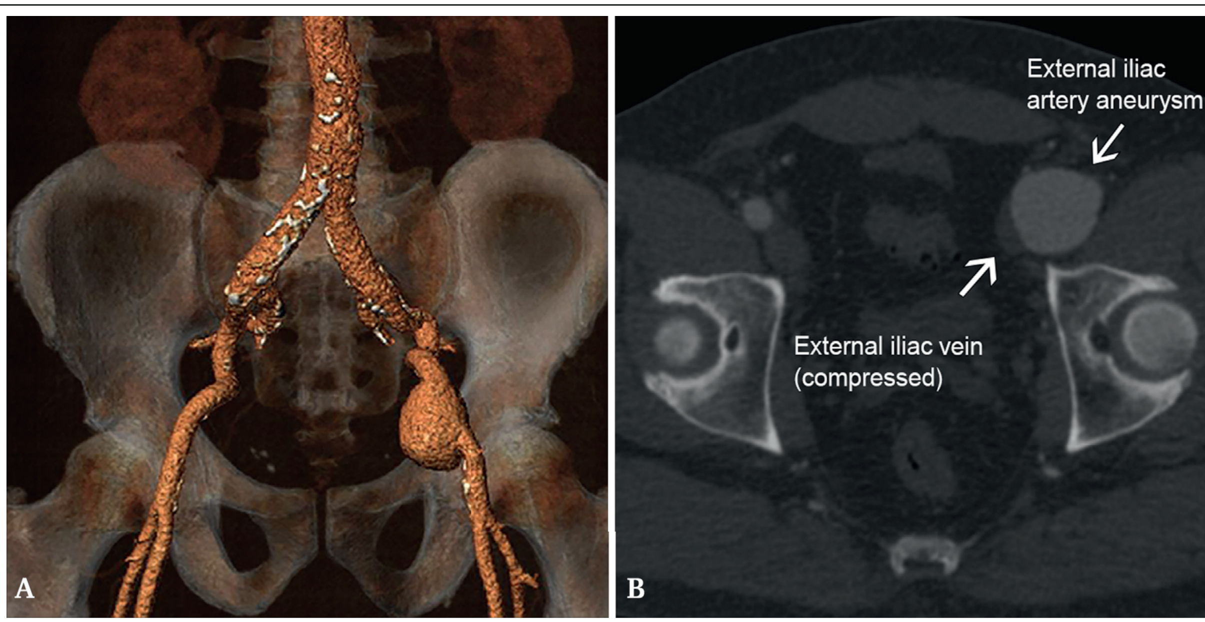

A 65 year old otherwise healthy man was admitted with a swollen left leg of three weeks' duration. Treatment by his general practitioner with antibiotics, diuretics, and steroids was unsuccessful. Imaging showed no signs of deep vein thrombosis (DVT), but revealed a 3.5 cm external iliac artery aneurysm with severe iliac venous obstruction (A, B). He was treated by aneurysm excision and tube graft replacement via a retroperitoneal approach. Recovery was uneventful and his oedema resolved completely within three weeks. True isolated external iliac artery aneurysm is extremely rare, with only a dozen cases described in the literature to date. Although rare, they may mimic DVT or May—Thurner syndrome.

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