Editor's Choice — Use of Disposable Radiation-absorbing Surgical Drapes Results in Significant Dose Reduction During EVAR Procedures

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WHAT THIS PAPER ADDS
Because of the increasing number of endovascular procedures with fluoroscopy, the corresponding high annual dose for interventionalists, and the European directive (ICRP 2011) requiring a lower annual radiation dose to the eye lens, additional dose-protecting measures are desirable for all operating staff during endovascular aneurysm repair (EVAR). The effect of disposable radiation-absorbing surgical drapes has never been studied before in a randomized controlled setting during endovascular procedures for AAA repair. This study evaluates the effect of these drapes on the annual dose to the interventionalist and supporting staff.

Objectives: Because of the increasing number of interventional endovascular procedures with fluoroscopy and the corresponding high annual dose for interventionalists, additional dose-protecting measures are desirable. The purpose of this study was to evaluate the effect of disposable radiation-absorbing surgical drapes in reducing scatter radiation exposure for interventionalists and supporting staff during an endovascular aneurysm repair (EVAR) procedure.

Materials: This was a randomized control trial in which 36 EVAR procedures were randomized between execution with and without disposable radiation-absorbing surgical drapes (Radpad: Worldwide Innovations & Technologies, Inc., Kansas City, US, type 5511A). Dosimetric measurements were performed on the interventionalist (hand and chest) and theatre nurse (chest) with and without the use of the drapes to obtain the dose reduction and effect on the annual dose caused by the drapes.

Results: Use of disposable radiation-absorbing surgical drapes resulted in dose reductions of 49%, 55%, and 48%, respectively, measured on the hand and chest of the interventionalist and the chest of the theatre nurse.

Conclusions: The use of disposable radiation-absorbing surgical drapes significantly reduces scatter radiation exposure for both the interventionalist and the supporting staff during EVAR procedures.

INTRODUCTION
In the last two decades endovascular aortic repair (EVAR) has become the preferred treatment of abdominal aortic aneurysm in patients suitable for EVAR.1 Despite precautions like a lead apron and thyroid shield, this increasing use of EVAR and other endovascular interventions results in considerable fluoroscopic exposure of the intervening physician.2 Low-energy scattered radiation scatters in all directions from the patient during fluoroscopy. This scatter radiation is the main source of exposure for medical staff during fluoroscopic procedures. Chronic exposure to low-dose radiation confers a small risk of stochastic effects, including malignant disease, skin damage, or eye problems.3–5 Recently the International Commission on Radiological Protection (ICRP) reported that the equivalent dose limit for the lens of the eye should be reduced from 150 to 20 mSv per year, averaged over a 5-year period, with no year’s dose exceeding 50 mSv.6 This reduction in eye dose limit and the applicable ALARA (as low as reasonably achievable) principle demands additional dose-protecting measures for operating staff performing EVAR procedures, especially in a non-dedicated endosuite, where no additional dose-protecting measures, like lead flaps or shields, are available.

In cardiac interventions, it is shown that the use of sterile disposable radiation-absorbing surgical drapes reduces the radiation exposure of the medical staff, from 23% to
The aim of this study is to evaluate the effect of these drapes in reducing scatter radiation exposure for endovascular surgeons and supporting medical staff during EVAR procedures.

MATERIALS AND METHODS

From June 2012 to October 2012, 36 consecutive EVAR procedures were randomly assigned to be performed with or without the use of radiation-absorbing surgical drapes (Radpad; Worldwide Innovations & Technologies Inc., Kansas City, MO; US type 5511A), henceforth referred to as “drape”. All patients with an indication for infrarenal endovascular aortic aneurysm repair with a bifurcated stent graft were included. The procedures were carried out by three vascular surgeons with extensive experience in performing EVAR procedures; no randomization of operators was performed. During the procedures, standard radiation protective measures were used for the interventionalist and supporting staff, including a lead apron and thyroid shield. The study was approved by the local ethics committee.

Positioning of the interventionalist and theatre nurse during the EVAR procedures was standardized: the primary operator (interventionist) stood on the right side of the patient near the pelvis, and the secondary operator stood on the opposite side of the operating table. The theatre nurse stood beside the secondary operator (Fig. 1). Both the interventionalist and the theatre nurse wore dosimeters for dosimetric measurements.

The drapes are the only commercially available, sterile, disposable, lead-free surgical drapes. They have a uniform thickness of a few millimeters and contain bismuth and barium. The dose-reducing function is comparable to 0.4–0.8 mm lead (Pb) depending on the kilovoltage used to make the image (90–60 kV). In the “drape” group two drapes were used. These sterile drapes were interposed between the patient and interventionalist, outside the radiation field, and positioned above the normal sterile surgical drape after the femoral operative site had been prepared. Positioning of the drapes is shown in Figs. 1 and 2.

All procedures were performed in a non-dedicated endosuite, where no additional dose-protecting measures, like lead flaps or shields, were available. A mobile angiographic C-arm was used (Axiom Artis U; Siemens, Munich, Germany) for fluoroscopic imaging. Both the milliAmpere (mA), which is the quantity of produced radiation, and the peak kilovoltage (kVp), which is a quantity of the beam penetrability, were kept in a range between 2.1–2.5 mA and 60–90 kVp for all procedures. The image intensifier was positioned above the abdomen of the patient. Scatter radiation was measured on the left chest of the interventionalist and theatre nurse using a calibrated electrical personal dosimeter (EPD, DoseAware system, Philips Medical Systems, Eindhoven, The Netherlands). Scatter radiation was measured on the base of the left ring finger of the primary operator with a calibrated ring dosimeter (Nuclear Research and consultancy Group, Arnhem, The Netherlands).

For each procedure the start and end time of the procedure, the total fluoroscopy time(s), the dose area product (DAP) (cGy cm²), and dose (μSv) were registered. Since start and end times of the procedures were registered, the dose could be determined after the procedure by selecting the time frame in which the procedure was performed using special software (DoseManager, Philips Medical Systems, Eindhoven, The Netherlands). Since the path length difference for the scattered radiation to chest and eye is just a few centimeters, it can be assumed that the measured dose on the chest is comparable to the dose on the eye lens. The ring dosimeter was sent monthly to the Nuclear Research and consultancy Group for evaluation.

By dividing the measured dose by the DAP value of each procedure, compensation for the inequalities due to different interventionalist, fluoroscopic times, and body
whether data were normally distributed. A Student percentages. A skewness test was performed to investigate the mean dose (Figure 3).

Fluoroscopy time (s) was performed to determine whether dosimetric measurements with the use of the drapes were significantly different from those without the drapes. A value of \( p \leq .05 \) was considered statistically significant. The analyses were performed using SPSS (Version 15.0, IBW Company, Chicago, IL, USA). The annual doses for both the interventionalist and the theatre nurse were calculated by multiplying the mean dose per procedure by the number of procedures performed annually per surgeon. It was assumed that each interventionalist and supporting staff members were present during 80 EVAR procedures annually. Since all medical staff wear a lead apron and thyroid shield during the procedure, the measured dose on the chest can be reduced fivefold to obtain the actual dose received.

**RESULTS**

All data were successfully collected during the 36 EVAR procedures. An overview of the procedural data is given in Table 1. Dosimetric data are normally distributed. The mean DAP was 9548 cGycm² and 8638 cGycm² in the control group and “drape” cohort respectively (\( p = .613 \)).

During a single EVAR procedure, the mean dose measured on the chest of the interventionalist was 167.7 μSv in the control group compared with 73.0 μSv (\( p = .008 \)) in the drape group. The mean dose measured on the hand of the interventionalist was reduced from 470.3 μSv to 236.8 μSv (\( p = .002 \)) with the use of a drape. A dose reduction due to the use of the drapes was found at the chest of theatre nurse as well (42.3 μSv to 21.4 μSv); however, this difference did not reach significance (\( p = .29 \)) (Table 1, Fig. 3).

This results in a decrease in the annual dose on the chest of the interventionalist from 13.4 mSv to 5.8 mSv (55%); the annual dose on the hand of the interventionalist from 37.6 mSv to 18.9 mSv (49%); and the annual dose on the chest of the theatre nurse from 3.4 to 1.7 mSv (48%). Since it can be assumed that the dose measured in front of the lead apron on the chest is representative for the dose on the eye lens, the eye lens dose of the interventionalist will reduce from 13.4 mSv to 5.8 mSv, which corresponds to a dose reduction of 55%.

**DISCUSSION**

This randomized trial in humans shows that the use of a sterile lead-free disposable drape is feasible during EVAR procedures and significantly reduces the radiation exposure of the intervening endovascular surgeons. The Radpad drape is simple to position and does not interfere with the EVAR procedure. There were no safety issues, prolonged fluoroscopy times or complications associated with the use of the drape. The protective lead-free drape we used in the study has been tested before in phantoms showing a radiation exposure reduction varying from 14% up to 94%, depending on the amount of radiation-absorbing material used in the drape, distance, and position of the measurements and additional protection measures.13–17

### Table 1. Procedural data.

<table>
<thead>
<tr>
<th>Operator</th>
<th>Control group</th>
<th>Drape cohort</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>9</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>7</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>2</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy time (s)</td>
<td>(208–1089)</td>
<td>(515–1385)</td>
<td>0.613</td>
</tr>
<tr>
<td>Dose per procedure in front of apron chest</td>
<td>167.7 ± 134.1</td>
<td>73.0 ± 50.9</td>
<td>0.008&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Dose/DAP per procedure chest operator (mSv/Gycm²)</td>
<td>0.023</td>
<td>0.011</td>
<td>0.023&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Dose per procedure on hand operator (μSv)</td>
<td>470.3 ± 222.4</td>
<td>236.8 ± 193.1</td>
<td>0.002&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Dose/DAP per procedure hand operator (mSv/Gycm²)</td>
<td>0.050</td>
<td>0.025</td>
<td>0.000&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Dose per procedure in front of apron chest theatre nurse (μSv)</td>
<td>41.9 ± 74.8</td>
<td>21.4 ± 33.3</td>
<td>0.29</td>
</tr>
<tr>
<td>Dose/DAP per procedure chest theatre nurse (mSv/Gycm²)</td>
<td>0.006</td>
<td>0.003</td>
<td>0.086</td>
</tr>
</tbody>
</table>

* Data are expressed as number or mean (range) and mean ± SD.

<sup>a</sup> Significant difference between control group and drape cohort.

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**Figure 3.** Overview mean dose (μSv) on chest and hand of the operator and chest of theatre nurse during an endovascular aneurysm procedure with (Drape group) and without (Control group) the use of the drapes.
device implantation, 11 electrophysiology procedures, 10 and cardiac resynchronization therapy 7 all showing a significant reduction in radiation exposure. The drape had not previously been tested during abdominal procedures like EVAR.

The risk of radiation-induced lens opacities among interventional cardiology and radiology workers is higher than suspected, and the lowest cataractogenic dose in humans seems to be substantially less than previously thought. 6,19–21 In 2011 the ICRP statement prescribed new restrictions, reducing the annual eye dose limit from 150 to 20 mSv. 7 The number of endovascular procedures performed by endovascular surgeons has increased significantly in recent years. As a result of this increase, the endovascular surgeon is cumulatively exposed to radiation and is in danger of exceeding the new limitations for eye lens dose. Our study showed that about 49% of cumulative operators involved. We think that the results are representative for many other centers performing EVAR procedures in a non-dedicated endosuite without additional radiation protection measures like a lead acrylic radiation protective shield in the ceiling or lower body protective lead panels mounted on the operating table. When EVAR procedures are performed in a dedicated endosuite, with the above-mentioned additional radiation protection, the dose reducing effect of the drapes is expected to be lower because of the stochastic effects of radiation. We also showed that the relative reduction in doses to the interventionalist depends strongly on the set up in the operating room, that is the position of the medical staff relative to the patient (and scatter radiation) and angulations of the C-arm. A drawback of the lead-free drapes is the fact that they are disposable, and therefore for each procedure additional costs are made (approximately 75 euros per drape).

Our study has certain limitations. First, operators were not blinded with respect to the presence of a protective drape since no sham drape was used in procedures in the control group. However, it is unlikely that this circumstance will influence the results of this study. Further, in this study, only patients with an infrarenal aortic repair were included. More complex and lengthier procedures like fenestrated/branched EVAR procedures were excluded. Since the position of the medical staff relative to the source of radiation is the same during standard and complex EVAR procedures, we can assume that the relative reduction in doses to the interventionalist and theatre nurse is approximately equal.

CONCLUSION
Endovascular interventionalists are more frequently exposed to radiation due to the increase in EVAR and other endovascular procedures which employ fluoroscopy. This study showed that the use of disposable, radiation-absorbing drapes significantly reduces scatter radiation exposure for the interventionalist, resulting in a lower risk of the stochastic effects of radiation. We also showed that staff during EVAR procedures are additionally protected by the use of these drapes. In adherence to the ALARA principle, we prefer the use of the scatter radiation protective drapes.

Each hospital has to weigh the amount of dose reduction with the costs of the drapes and consider other possible dose-protecting measures like lead glasses, lead panels, and lead shields. The dose-reducing effect of all these measures depends strongly on the set up in the operating room, that is the position of the medical staff relative to the patient (and scatter radiation) and angulations of the C-arm. A drawback of the lead-free drapes is the fact that they are disposable, and therefore for each procedure additional costs are made (approximately 75 euros per drape).

CONFLICT OF INTEREST
None.

FUNDING
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ACKNOWLEDGEMENT
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REFERENCES


4 ICRP 22. Implications of commission recommendations that doses be kept as low as readily achievable. Ottawa: ICRP; 1973.


