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Original Article

Protected and Unprotected Radiation Exposure to the Eye Lens during Endovascular Procedures in Hybrid Operating Rooms

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What this study adds to the current evidence

This study provides information about the exposed eye lens dose of operators working in a hybrid OR environment. It demonstrates, that the current annual dose limit for the eye lens of 20 mSv per year can be complied with if adhering to recent radiation protection measures including the use of low dose programs, image fusion and the wear of lead glasses.

Abstract

Objective:

Radiation cataract has been observed at lower doses than previously thought. Therefore, the annual limit for equivalent dose to the eye lens has been reduced from 150 to 20mSv. This study evaluates radiation exposure to the eye lens of operators working in a hybrid operating room before and after implementation of a dose reduction program.

Methods:

From April–October 2019, radiation exposure to the first operator was measured during all consecutive endovascular procedures performed in the hybrid operating room using BeOSL $H_p(3)$ eye lens dosimeters placed both outside and behind the lead glasses (0.75mm lead equivalent). Measured values were compared to data from a historic control group from the same hospital before implementation of a dose reduction program.

Results:

A total of 181 consecutive patients underwent an endovascular procedure in the hybrid operating room. The median unprotected eye lens dose (outside lead glasses) of the main operator was 0.049mSv for EVAR (n=30), 0.042mSv for TEVAR (n=23), 0.175mSv for

complex aortic endovascular procedures (F/BEVAR; n=15) and 0.042mSv for peripheral interventions (n=80).

Compared to the control period, EVAR had 75% lower, TEVAR 79% lower and F/BEVAR 55% lower radiation exposure to the unprotected eye lens of the first operator. The lead glasses led to a median reduction of the exposure to the eye lens by the factor 3.4.

Conclusion:

The implementation of a dose reduction program has led to a relevant reduction of radiation exposure to head and eye lens of the first operator in endovascular procedures. With optimum radiation protection measures including a ceiling-mounted shield and lead glasses, more than 440 EVARs, 280 TEVARs or 128 FEVARs could be performed per year until the dose limit for the eye lens of 20 mSv would be reached.

Introduction

In infrarenal and descending aortic pathologies, endovascular aortic repair (EVAR) and thoracic endovascular aortic repair (TEVAR) have become the standard of treatment in up to or even more than 70% of cases.[1,2] In juxtarenal and thoracoabdominal aortic pathologies, complex endovascular aortic procedures with fenestrated or branched endografts (F/BEVAR) have become more frequent and widely used in high volume centers .[3–6]

Therefore, endovascular surgeons are more and more exposed to ionizing radiation. X ray exposure can lead to radiation-induced lens injuries which typically manifest as cataracts.[7] In the past, the threshold for cataract formation was believed to be at 4 Gy for fractionated exposures, equivalent to an annual limit of 150mSv. After years, it became evident, that the threshold for cataract induction is substantially lower and is believed to be around 0.5 Gy.[8] Therefore, the International Commission on Radiological Protection (ICRP) recommended since 2011 an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv.[9] This is a relevant reduction and important measure in staff radiation protection. There are concerns, how vascular surgeons can comply with this new, lower limit in order to be relatively safe from the formation of radiation cataracts.[10] Attigah et al published in 2016 that the dose limit of 20mSv per year could be exceeded with an estimated continuous fluoroscopy time of 23h.[11] Low dose programs were meanwhile established from several imaging systems in order to reduce the dose area product (DAP). In addition, fusion imaging technology, increased awareness and radiation protection education were established.[12,13]

The aim of this study was to compare radiation exposure to eye lens with modern protection measures with results of the study conducted with unprotected eye lens doses.

Also, the radiation doses behind the lead glasses (protected eye lens dose) was measured to investigate if the new annual dose limit for the eye lens of 20mSv can be adhered to.

Materials and Methods

Between March and October 2019, a total of 181 endovascular procedures were performed in 181 patients in the Department of Vascular and Endovascular Surgery of the University of Heidelberg. All patients were treated in the same Hybrid-OR (Artis-Zeego and floating carbon table, Siemens, Forchheim, Germany). Baseline patient characteristics (age, height and weight), the procedure type, the operating time, the fluoroscopy time (FT), the digital subtraction angiography (DSA) time and the dose-area product (DAP, unit µGym^2) was recorded. The detector field of view had a diagonal of 48 cm. Basic protection measures including undertable lead aprons, a ceiling mounted lead acrylic overhead suspension shield (0.5mm lead equivalent) and lead glasses (0.75mm lead equivalent) were used by all operators in every procedure. The types of lead glasses were not standardized and depended on the desire of the different operators. However, lead equivalent was 0.75mm in all lead glasses and all lead glasses had lateral lead protection.

Historic control group. This group consisted of 171 consecutive patients between March 2012 and July 2013 from two centers (including the Department of Vascular and Endovascular Surgery of the University of Heidelberg).[11] The procedures were EVAR (n=65), TEVAR (n=32), BEVAR (n=17), FEVAR (n=25), IBD (n=8) and Peripheral (n=24). The hybrid OR was the same (Artis-Zeego). There was exactly the same setup present in both centers regarding distance of shielding and size of shielding with undertable lead aprons and a ceiling mounted lead acrylic overhead suspension shield (0.5mm lead equivalent) . However, a third of the personnel changed between 2012/2013 and 2019.

Dose reduction program. Between the historic control group and the present study, a dose reduction program was implemented. The summary of the bundle of dose reduction measures is presented in Figure 1. The goal was to lower DAP in endovascular procedure to reduce ration both to patients and the hybrid OR personnel. The first phase focused on education of the surgeons to use collimation and to reduce magnification and unnecessary DSA and fluoroscopy time. In addition, fusion imaging was implemented. If possible contrast fluoroscopy instead of DSA was used. In the second phase, dose reduction programs were implemented. Both the dose and the fluoroscopy / DSA frame rate were reduced. In the last phase a Hybrid OR technician was employed and the doses were even further reduced. No changes were made concerning shielding.

Eye lens dosimetry. Eye lens dosimetry was provided by a German official individual monitoring service (IMS) Mirion Technologies (AWST) GmbH. Eye lens dosimeters[14,15] (ELDs) based on BeOSL technology[16] were worn by the first operator in every procedure. One ELD was placed with headband adapters at the side of the head facing the radiation source (outside the lead glasses) and another was mounted on the same side inside the lateral 0.75mm lead equivalent protection of the lead glasses directly or by means of adhesive adapters (Fig 2).[14] In each procedure, a new set of ELDs was used. ELDs are calibrated in $H_p(3)$ using the secondary standards of the IMS[17–19]. To account for radiation background during storage and transport, the readings of dedicated transport dosemeters were used in each shipment to calculate net doses for the test ELDs. Measurement uncertainties and lower limits of detection (LODs) for the obtained net doses were provided by the IMS for each batch of dosemeters using uncertainty models[20] based on Guide to the Expression of Uncertainty in Measurement (GUM)[21]. The LOD was 0.042 mSv. The uncertainty models account for background subtraction, statistical measurement effects and various influence quantities such as angular and energy response of the $H_p(3)$ dosimeters.[20] Expanded relative uncertainties (k=2, 95% confidence) were approximately 23% at 0.2 mSv and 33% at 0.1 mSv.

This study was approved by the institutional ethics committee (Approval Number S-052/2019) and written informed consent was obtained from all participating vascular surgeons.

Statistical analysis

Prism 8 (Version 8.3.1. Graphpad Software, San Diego, CA) was used. Regarding descriptive statistics, the values were presented as mean values ± standard deviation or median with interquartile range. Head doses and DAP were compared with the control group using the t-test. Correlation between DAP and reported parameters were calculated using linear regression analysis. $P < 0.05$ was considered statistically significant.

Results

A total of 181 patients (152 male =84%, mean age 70 yrs.) and consecutive procedures were enrolled and conducted in the hybrid-OR. The mean body mass index BMI was 27.7 ± 5.5 kg/m^2. The performed endovascular operations were split into six treatment categories: standard endovascular aortic repair EVAR (n = 30), standard thoracic endovascular aortic repair TEVAR (n = 23), complex juxtarenal and thoracoabdminal aortic procedures F/BEVAR (fenestrated or branched endovascular aortic repair, chimney aortic repair, n = 15), interventions for peripheral artery occlusive disease (PAOD) (n = 80) and others (n = 33) not being enrolled in this study because of the heterogeneity of those procedures (e.g. embolization for endoleaks, carotid artery stenting, vascular plugs). There were six emergency procedures. Baseline characteristics of categories and radiation doses are reported in table 1.

There was a significant correlation in DAP between both the unprotected eye lens dose ($p < 0.0001$, $R^2 = 0.282$, Fig 3) and the protected eye lens dose ($p < 0.0001$, $R^2 = 0.512$, Fig 4). DAP significantly correlated with total operating time, total fluoroscopy time, total DSA time and the BMI of the patients (calculated for EVAR and TEVAR, details in table 2).

Comparing the unprotected eye lens dose of this study with the historic control group from 2012/2013, there was a 75% reduction in the dose to the head in EVAR ($p < 0.0001$), -79% in TEVAR ($p < 0.0001$), -55% in F/BEVAR ($p = 0.0358$) and -91% in PAOD Interventions ($p < 0.0001$), respectively (Table 3).

The DAP in the current study was significantly lower than the control group: reduction of - 74% for EVAR ($p = 0.0004$), -51% for TEVAR ($p < 0.0098$), -50% for F/BEVAR ($p = 0.0271$) and -94% for PAOD ($p = 0.0002$), respectively (Table 3).

The second ELD was placed inside the lead glasses. The measured absorbed radiation was low. For EVAR, the measured absorbed radiation was lower than the LOD (0.042 mSv) in 24 out of 30 cases, for TEVAR in 19/23 cases, for F/BEVAR in 5/15 cases and in PAOD interventions in 79/80 cases.

If the cases lower than the LOD were assumed to be just at the detection limit of 0.042 mSv, the dose would be 0.045 mSv for EVAR, 0.071 mSv for TEVAR and 0.156 mSv for F/BEVAR. Dividing those mean values from the current equivalent dose limit for the lens of the eye of 20 mSv, 442 EVAR, 280 TEVAR or 128 F/BrEVAR procedures could be done by a single surgeon, until the equivalent dose limit of 20 mSv would be exceeded.

Lead glasses. The median radiation reduction of the lead glasses was 3.4 (IQR 1.45-5.09; calculated from 22/148 cases where both values were above the lower LOD).

Discussion

This prospective single center study investigated the unprotected and the protected eye lens dose of first operators working in a hybrid operating room. The values of the head dose were compared to a historic control group from 2012-2013 published earlier by the group.[11] After 2014, a dose reduction program was implemented which resulted in a significant lower DAP of 50-94%, depending on the type of endovascular procedure, respectively. The median DAP for EVAR procedures was lower compared to the current literature (3'895 µGym2 compared to 9'300 – 11'600 µGym2)[22–24], whereas the DAP for TEVAR was in the range of the current literature (8'819 µGym2 compared to 6'200-19'000 µGym2)[22–24]. The DAP for F/BrEVAR was 21'006 µGym2 (compared to 17'200 – 69'600 µGym2 in the literature), but this strongly depends on number of target vessels, which wasn't assessed in this study.[22,23,25,26]

Compared to our initial study published by Attigah et al, a significant reduction of the unprotected eye lens dose of 55-91% was achieved by implementing dose reduction programs (Table 3). This reduction corresponds with the reduction in DAP since the unprotected eye lens dose significantly correlates with the DAP (Fig 3).

The DAP strongly depended on operation time, fluoroscopy and DSA time. Shielding and the hybrid OR did not change since the control study, therefore the dose reduction program with the goal of reducing DAP was the main reason for the lower unprotected eye lens dose. Increasing experience of the main operator is believed to play an important role, but a clear correlation couldn't be found. Compared to the historic control group , procedure time was longer in the present study for EVAR, shorter for TEVAR and the same for F/BEVAR and PAOD. Fluoroscopy time was as well longer for EVAR, shorter for TEVAR, slightly shorter for PAOD and F/BEVAR. That means that other than in EVAR, the lower fluoroscopy time could partially explain the lower DAP. But this was expected, since fluoroscopy times have been expected to be lower as a result of the dose reduction program, especially the "education" part.

Different and in addition to the control study in 2015, the "real" eye lens dose with a dosimeter placed behind the lead glasses was investigated. Due to a median dose reduction of the lead glasses of a factor of 3.4, the radiation doses behind the lead glasses were low.

In ideal static laboratory tests lead glasses with 0.75 Pb equivalent shielding have been shown to provide a dose reduction of 5-10 times , strongly depending on the median photon energy of the radiation field.[9] However, the same laboratory tests show that the dose reduction is highly influenced by geometric factors such as exact radiation incidence angles on the head and can be lower under certain angles. Therefore, the reduced value of the measured average dose reduction of 3.5 in this study is to be expected for the non-static situation in real applications, and agrees with other results[21].

For EVAR, a radiation dose above the lower limit of detection (0.042 mSv) was measured in only 6 out of 30 procedures. Extrapolating the results, 442 EVAR procedures, 280 TEVARs or 128 FEVARs could be performed in order to reach the annual organ dose limit of 20mSv for the eye lens. PAOD interventions are associated with low radiation eye exposure in compliance with recent standard radiation exposure measures. The unprotected eye lens doses in PAOD interventions were above the lower limit of detection in only 8 out of 80 interventions. Only 1 of 80 PAOD interventions behind the lead glasses (protected eye lens dose) were above the lower limit of detection. DAP for PAOD interventions is more than ten times lower than for TEVAR procedures

In summary, the annual dose limit for eye lenses of 20 mSv can be adhered to in clinical practice, even for operators with a high case load of endovascular aortic procedures.

Limitations. This study has several limitations. Due the low radiation values, many ELDs were lower than the lower limits of detection, mostly observed in PAOD interventions. Therefore, the exact eye lens doses in these interventions cannot be calculated. However, even if eye lens doses below LOD is replaced by the value of the LOD in a worst case scenario, it will not reach the annual dose limit of 20mSv. The measurement of the ELD is subjected to certain uncertainties following from the necessary subtraction of background radiation (transportation, storage) and various influence quantities such as angular and energy response of the Hp(3) dosemeters.[20]

Conclusion.

The use of dose reduction programs in endovascular procedures lead to a relevant reduction of radiation exposure to eye lenses of the first operator. With optimum radiation protection measures including undertable lead aprons, ceiling-mounted shields and lead-glasses, more than 440 EVARs, 280 TEVARs or 128 FEVARs could be performed per year for an individual operator, until the dose limit for the eye lens of 20 mSv would be reached. The lead glasses reduces absorbed radiation by the factor 3.5. Wearing lead glasses in a hybrid OR is mandatory in order to reduce the risk of radiation induced cataract.

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Conflict of Interest

The authors declare no conflict of interest.

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Tables

Table 1

Variable	**EVAR**	**TEVAR**	**F/BEVAR**	**PAOD**
No.	30	23	15	80
OR time [min]	119 (95-144)	85 (55 - 113)	267 (225 - 315)	75 (55 – 100)
Fluoroscopy time [min]	22 (16 - 28)	10 (6 - 15)	62 (50 - 71)	8 (5 - 14)
DSA time [min]	0.8 (0.7 - 1.0)	0.6 (0.4 - 1.2)	2.2 (1.4 - 2.8)	1.4 (0.9 - 2.3)
Dose-Area Product (DAP) [µGy/m2]	3'895 (2'714 - 7'609)	8'819 (4'212 - 18'036)	21'006 (8'066 - 26'695)	528 (257 - 1351)
Unprotected eye lens dose [mSv]	0.049 (0.042 - 0.083)	0.042 (0.042 - 0.098)	0.175 (0.071 - 0.47)	0.042 (0.042- 0.042)

Table 2

	EVAR (n=30)			**TEVAR (n=23)**		
Variable	Median (IQR)	R^2	p	Median (IQR)	R^2	p
Total operating time (minutes)	118.5 (94.5-144.3)	0.164	**0.0262**	85 (55-113)	0.321	**0.0049**
Total fluoroscopy time (minutes)	21.75 (15.95-27.88)	0.701	**<0.0001**	10 (6.4-14.5)	0.435	**0.0006**
Total DSA time (minutes)	0.83 (0.65-0.95)	0.14	**0.0455**	0.58 (0.42-1.2)	0.458	**0.0004**
BMI of patient (kg/m2)	27.3 (24.15-31.95)	0.527	**<0.0001**	30.4 (27.6-33.5)	0.568	**<0.0001**

Table 3:

Variable	EVAR	TEVAR	F/BEVAR	PAOD
Unprotected eye lens dose [mSv]	0.119 ± 0.154	0.118 ± 0.197	0.312 ± 0.320	0.046 ± 0.019
Unprotected eye lens dose [mSv] control group	0.47 ± 0.34	0.57 ± 0.41	0.70 ± 0.65	0.52 ± 0.38
Unprotected eye lens dose percent reduction	*75% (p=0.001)*	*79% (p<0.0001)*	*55% (p=0.0358)*	*91% (p<0.0001)*
Dose-Area Product (DAP) [µGy/m2]	5'965 ± 5'306	11'210 ± 7'808	20'860 ± 13'261	843 ± 1'476
DAP control group	23'000 ± 25'000	23'000 ± 20'000	42'000 ± 35'000	13'000 ± 23'000
DAP percent reduction	*74% (p=0.0004)*	*51% (p<0.0098)*	*50% (p=0.0271)*	*94% (p=0.0002)*

Figure and Table Legends

Figure 1

Summary of different steps in the dose reduction program. The left column provides the standard value of the angiography system. First, education was intensified, then, low dose protocol were implemented. The last column shows the last changes including the engagement of a hybrid OR technician.

Figure 2:

Eye lens dosemeters connected with headband for unprotected eye lens dose (left) and eye lens dosemeters mounted on different lead glasses for protected eye lens dose (right).

Figure 3:

Unprotected eye lens dose (head dose) as a function of DAP (dose-area product).

Figure 4:

Protected eye lens dose as a function of DAP (dose-area product).

Table 1

Procedural details of the 4 treatment categories. DAP, dose-area product; EVAR, endovascular aortic repair; F/BEVAR, fenestrated or branched endovascular aortic repair, chimney endovascular aortic repair; OR, operating room; PAOD, treatment for peripheral occlusive disease; TEVAR, thoracic endovascular aortic repair.

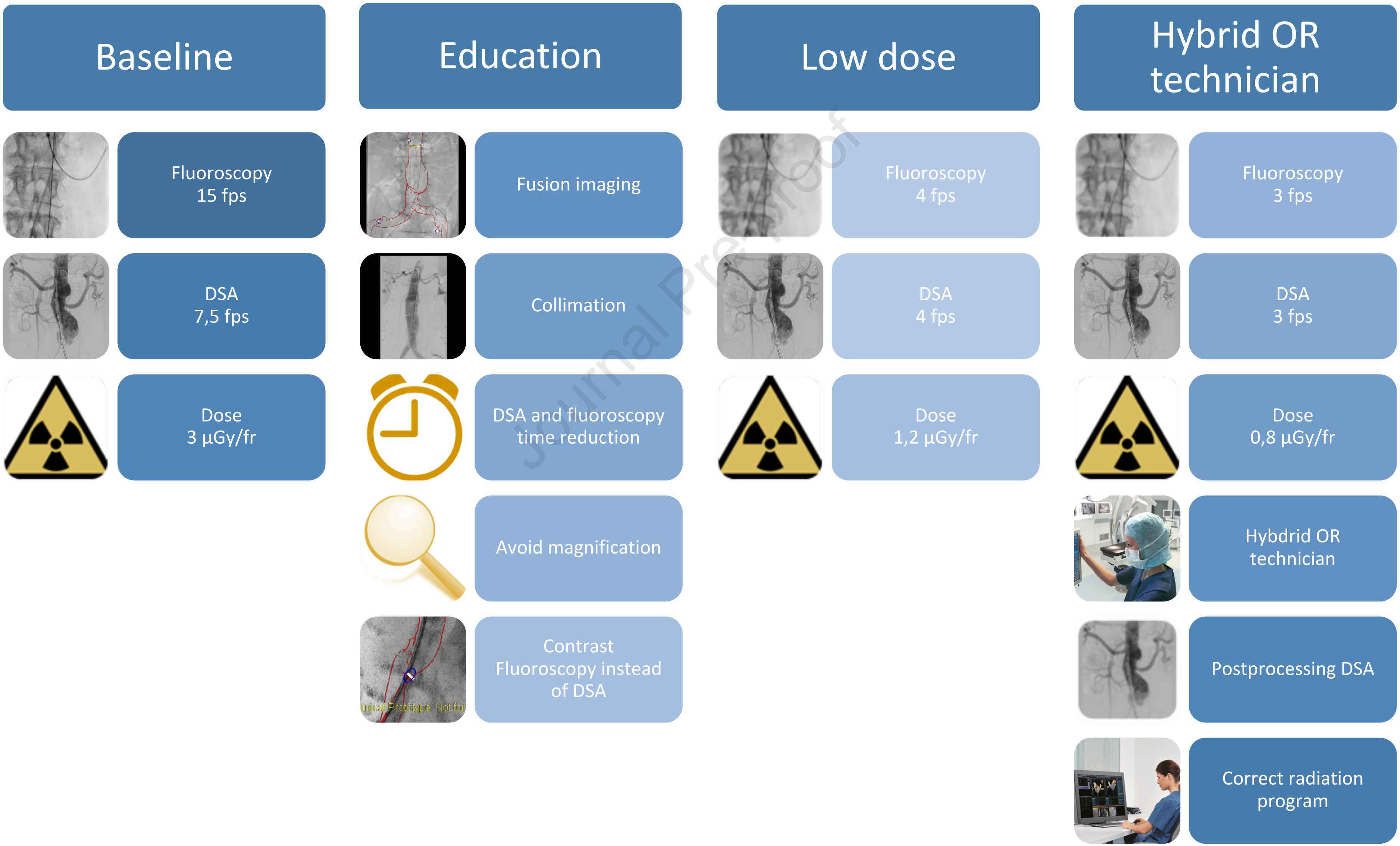
All values are presented as median (interquartile range).

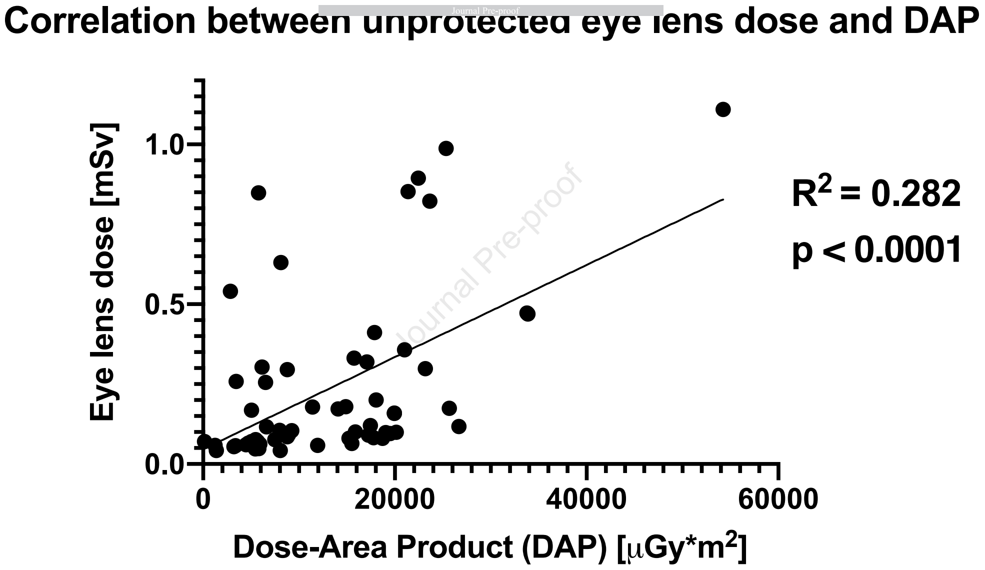
Table 2

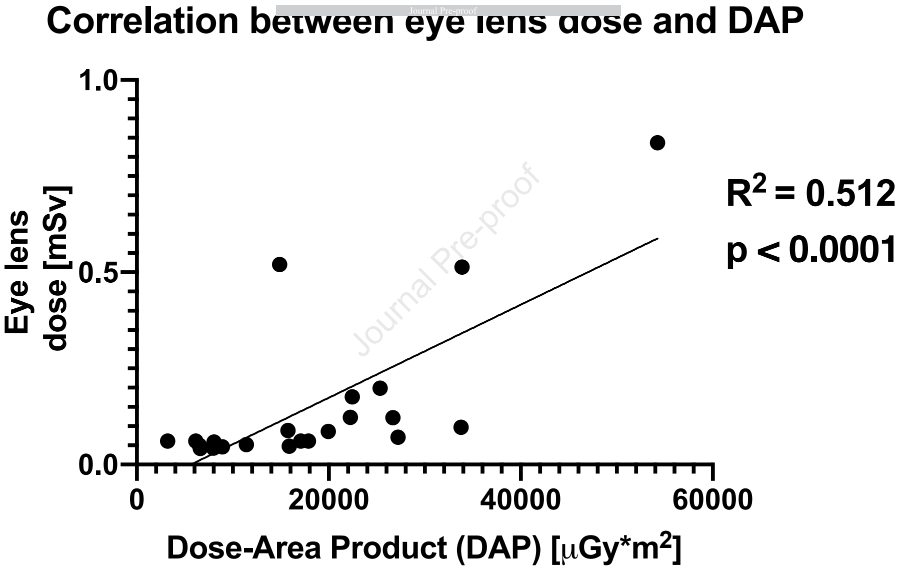
Results of univariate linear regression analysis for predicting DAP in EVAR and TEVAR. BMI = body mass index; DAP = dose-area product; DSA = digital subtraction angiography.

Table 3.

Comparison and percent reduction of unprotected eye lens dose and DAP compared to the historic control group (March 2012-Juli 2013). All values are presented as mean ± standard deviation.


Baseline
Education
Low dose
Hybrid OR technician
Fluoroscopy 15 fps
Fusion imaging
Fluoroscopy 4 fps
Fluoroscopy 3 fps
DSA 7,5 fps
Collimation
DSA 4 fps
DSA 3 fps
Dose 3 µGy/fr
DSA and fluoroscopy time reduction
Dose 1,2 µGy/fr
Dose 0,8 µGy/fr
Avoid magnification
Hybdrid OR technician
Contrast Fluoroscopy instead of DSA
Postprocessing DSA
Correct radiation program


Correlation between unprotected eye lens dose and DAP
Eye lens dose [mSv]
0.0
0.5
1.0
0
20000
40000
60000
Dose-Area Product (DAP) [μGy*m2]
R2 = 0.282
p < 0.0001



Correlation between eye lens dose and DAP
Eye lens dose [mSv]
1.0
0.5
0.0
0
20000
40000
60000
Dose-Area Product (DAP) [μGy*m²]
R² = 0.512
p < 0.0001
Journal Pre-proof